GMR
The Original

KNOWLEDGE, ATTITUDE, AND AWARENESS OF DENTAL UNDERGRADUATE CLINICAL STUDENTS, INTERNS AND POSTGRADUATE STUDENTS TOWARDS PHARMACOVIGILANCE IN DENTISTRY AMONG VARIOUS DENTAL INSTITUTIONS ACROSS ANDHRA PRADESH AND TELANGANA STATES- A SURVEY

Dr. Jyothsna Dasari[1], Dr. M. Rohith Abhilash[2], Dr. B. Lakshmana Rao[3*], Dr. M. Vaishnavi Devi[4], Dr. K. Sridevi[5], Dr. M. Dinesh Lal[6]

[1]Assistant Professor, Dept of Oral Pathology, Panineeya Institute of Dental Sciences & Research Centre, Hyderabad, Telangana., Email; jyothsnaudaykumar@gmail.com
[2]Sr. Resident, Dept of Biochemistry, Govt Medical College, PiduguRala, Andhra Pradesh., Email: Abhilash-mallela.rohit16@gmail.com
[3*]Prof & HOD, Dept of Prosthodontics, Lenora Institute of Dental Sciences, Rajahmundry, Andhra Pradesh., Email: kushulubathala@gmail.com
[4]Professor, Dept of Oral and Maxillofacial Surgery, Lenora Institute of Dental Sciences, Rajahmundry, Andhra Pradesh., Email: vaishnavidevimajeti@gmail.com
[5]Prof & HOD, Dept of Oral Medicine and Radiology, Lenora Institute of Dental Sciences, Rajahmundry, Andhra Pradesh., Email: srigivi123@gmail.com
[6]Senior Lecturer, Dept of Oral Pathology and Microbiology, Lenora Institute of Dental Sciences, Rajahmundry, Andhra Pradesh. Email: drdineshlal@gmail.com
*Corresponding Author: Dr. B. LakshmanaRao, Email: kushulubathala@gmail.com

ABSTRACT

Objective: To assess the awareness, knowledge and attitude of Dental Undergraduate Clinical students, Interns and Post Graduate students towards Pharmacovigilance in Dentistry by using an electronic survey.

Methods: A questionnaire survey was conducted among Dental Undergraduate Clinical students, Interns, and Postgraduate students. The questionnaire was circulated via Google Forms, with the help of WhatsApp and email. Responses were examined using descriptive statistics. The chi-square test was applied to assess the association between awareness, knowledge, and attitude regarding Pharmacovigilance in Dentistry.

Results: A total of 437 responded. Both genders participated in equal percentages. From the designation point of view, Post Graduate students participated more than Interns, 4th BDS and 3rd BDS students.

Conclusion: There are clear evidence of underreporting and a lack of information regarding the reporting system, yet the responder has a general comprehension regarding ADR. An orientation session and increased knowledge of ADR reporting may lead to better patient care and more spontaneous reporting.

Keywords: Pharmacovigilance (PV), Pharmacovigilance in Dentistry, Adverse Drug Reaction (ADR), Adverse drug reaction underreporting, Materiovigilance.

INTRODUCTION

The drug discovery and development process needs scrupulous safety monitoring at all phases of any clinical study. What is even more important is to monitor the safety of drugs once they are licensed, in the real world. Vigilance is the word that means “watching carefully for any bad effects. It is mostly based on voluntary reporting by healthcare professionals and patients to health authorities and marketing authorization holders in the post-marketing situation. The study of unfavorable occurrences associated with the use of medical devices is called materiovigilance. It is about the strict monitoring of medical equipment after the post-marketing phase. The present study is aimed to analyze the knowledge, attitude, and practice of oral health practitioners regarding the pharmacovigilance and materiovigilance program of the Government of India. [1-3]

The World Health Organization (WHO) defines pharmacovigilance as “the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem. Pharmacovigilance was born from the thalidomide disaster of the 1960s and has since become a cornerstone of the world's drug regulation structure. [1,3]

The focus on pharmacovigilance in dentistry has been comparatively less. Local anesthetics, analgesics, antibiotics, antifungals, antiseptics, hemostatic, corticosteroids and sedatives are among the many pharmacological drugs used in dentistry that are at risk of adverse drug reactions (ADRs). The notion that dental drug prescriptions are low-risk and temporary may impair the need for monitoring and reporting of drug-related harms in the outpatient dentistry practice. ADRs are a huge global problem. Adverse medication responses are responsible for approximately 5-7% of hospital

admissions worldwide, and a large proportion of them are preventable. The ongoing systemic concerns in dentistry are overuse of analgesics, overprescription of antibiotics, and poor screening for medication interaction. [1,2]

In 2010, the Central Drugs Standard Control Organization (CDSCO) of India introduced the Pharmacovigilance Programme of India (PvPI) to improve reporting of ADRs in all areas of medicine. Dental participation in this program is modest at best, though. Poor institutional reporting infrastructure and lack of structured pharmacovigilance training in undergraduate dental curriculum maintains the absence. [4] Common Adverse Drug Reactions in Dentistry, covers Toxicity of Local Anaesthetics, Adverse Reactions Associated with Antibiotics, Non-Steroidal Anti-Inflammatory Drugs and Analgesic Concerns and some of the dental materials. Pharmacovigilance competency in dentistry needs curriculum and institutional change. Pharmacovigilance should be included into undergraduate clinical pharmacology education, including organized exercises in ADR causation evaluation using WHO-UMC causality categories and the Naranjo Adverse Drug Reaction Probability Scale. Pharmacovigilance is becoming more and more crucial in dentistry for patient safety. A broad spectrum of medications are used by dental practitioners with catastrophic consequences in susceptible patient groups, significant potential for drug interactions and well-documented systemic side effects. However, there is still a notable lack of reporting of such unfavorable effects in all resource situations. [5,6]

A compliant Pharmacovigilance (PV) System is a formal system run by marketing authorization holders (MAHs) and regulatory agencies to monitor the safety of pharmaceutical products and to analyze changes in the risk-benefit balance. A functioning PV system is defined by the International Council for Harmonisation (ICH), the European Medicines Agency (EMA) and the World Health Organization (WHO) as a set of fundamental, inter-connected components.

Main Components of a Pharmacovigilance System

1. Qualified Human Resources and Governance): A dedicated, highly trained professional who has the ultimate responsibility 24/7 for the set-up, maintenance and oversight of the complete PV system. Organizational Structure: A specified network of safety specialists, medical reviewers and local partners that gather data in regional marketplaces.
2. Standard Operating Procedures (SOPs) & Quality Management: Structural framework of thorough SOPs, routine employee training matrices, and internal compliance tracking. Audits and Inspections: Systematic internal audits and external regulatory inspections to ensure that all processes comply with the current regulatory frameworks (e.g. EMA GVP Module IV).
3. Adverse Event Case Management: Systems to capture raw information from spontaneous reporting (patients, healthcare professionals), clinical trials, and literature searches. Data Processing: Scientific confirmation of the four necessary elements of an individual case safety report (ICSR) An identifiable patient, an identifiable reporter A questionable substance an adverse event Medical Coding: Standardized language based on the MedDRA (Medical Dictionary for Regulatory Activities) hierarchy to standardize the conversion of clinical narrative notes.
4. Safety Database and Technological Infrastructure: A secure, computerized repository (e.g., Argus, ArisGlobal) for tracking, compilation and electronic transmission of large volumes of safety data. Electronic Reporting Gateways Infrastructure set up to transfer data electronically in compliance formats (e.g. ICH E2B) straight to multi-national regulatory gateways (e.g. EudraVigilance, FDA FAERS).
5. Signal Detection and Risk Management: continuous statistical and clinical assessment of the compiled data to detect new, evolving or unanticipated cause-effect correlations between a medicinal product and an adverse event (signal detection). Risk Management Plans (RMPs): Dynamic, regularly updated profiles recording a drug's known safety standards together with strategic activities assigned to mitigate detected safety problems. Risk Minimization Measures (RMMs): Tactical updates of product labels (SmPC), Dear Healthcare Professional Communications (DHPCs) and obligatory patient educational materials.
6. Periodic and Aggregate Safety Reporting: regular collection of safety data over defined periods to assess the overall risk/benefit balance. These are: DSUR (Development Safety Update Report) for experimental phase medications. Post-authorization follow-up PSUR / PBRER (Periodic Safety Update Report / Periodic Benefit-Risk Evaluation Report).
7. The Pharmacovigilance System Master File (PSMF): Full and formal collection of the absolute scope, safety databases, SOP registries, QPPV qualifications and overall quality controls of the operational PV system. [7-11]

Barriers to Adverse Drug Reaction Reporting in Dentistry

The following are major obstacles that cause underreporting:

Dental professionals' lack of awareness, Insufficient instruction in pharmacovigilance, Systemic problems with reporting systems, Fear of the repercussions of reporting and Insufficient knowledge of the significance of pharmacovigilance. Significant barriers prevent spontaneous reporting of ADRs in India, necessitating focused remedies. Current gaps for improvement have been highlighted by evaluating the quality of pharmacovigilance training at health professional training institutions. [12-14]

Pharmacovigilance Process in Dental Practice

The identification, assessment, and reporting of adverse drug reactions related to medications, local anesthetics, and biomaterials used in oral procedures constitute pharmacovigilance in dental practice. Dental ADRs are still woefully underreported globally, even though dentists frequently employ advanced materials and administer powerful systemic drugs (such as NSAIDs and antibiotics). [13,14]

Numerous studies have shown that dental professionals' understanding, attitudes, and practices surrounding ADR reporting are inadequate. One of the biggest challenges to efficient pharmacovigilance systems is underreporting, which restricts the early identification of uncommon and severe adverse events. As a result, there is an increasing need to raise dental professionals' understanding of and involvement in national and international pharmacovigilance programs.

The importance of drug safety and pharmacovigilance in dentistry, common drug-related issues that arise in dental practice, the responsibility of dentists in reporting adverse drug reactions (ADRs), present difficulties, and potential solutions for improving patient safety are all covered in this review.

MATERIALS AND METHODOLOGY

Study Design: Cross sectional descriptive study

Study Population: Dental Under Graduate Clinical students [III BDS & IV BDS], Interns and Post Graduate students among various Dental Institutions across Andhra Pradesh and Telangana States.

Selection Criteria:

The study used purposive sampling technique. The study instrument was a self-administered closed-ended, pre-tested and validated questionnaire, which was adapted from the existing recorded studies in the literature [Annexure-1]. This questionnaire was used in the study and disseminated through Google Forms. One of the best tools for gathering data online is "Google forms" which has several advantages such as the participants' identity is kept confidential, the forms evaluate and give the researcher instant statistics of the interpretation in order to understand the interpretation. The participants can fill out the form in privacy and comfort even with their smart phones, and the responses given by the participants will not be tracked on the questionnaire confirmation

1. The questionnaire was developed by trained and experienced person.
2. Face validity of the questionnaire was validated after discussion with other dental specialists.
3. A pilot study was conducted randomly among 30 participants before performing the study and necessary modifications were done as required.

An electronic survey was undertaken among III BDS, IV BDS, Interns and Post Graduate Students from March 2026 to May 2026. There were 26 questions out of which 4 questions were to collect demographic data and 7 questions were meticulously crafted to assess the Awareness, 9 questions on knowledge and 6 questions on the attitude of the participants on Pharmacovigilance. A Google link questionnaire was sent to the participants via WhatsApp group/ email. A total of 437 responses from participants were received for this cross-sectional online survey. [Appendix-I] Ethical consideration: Prior to the start of the study, institutional ethics committee approval was acquired for the study protocol (File No.04/IEC/LIDS/2026/Faculty, Dt: 13/02/2026).

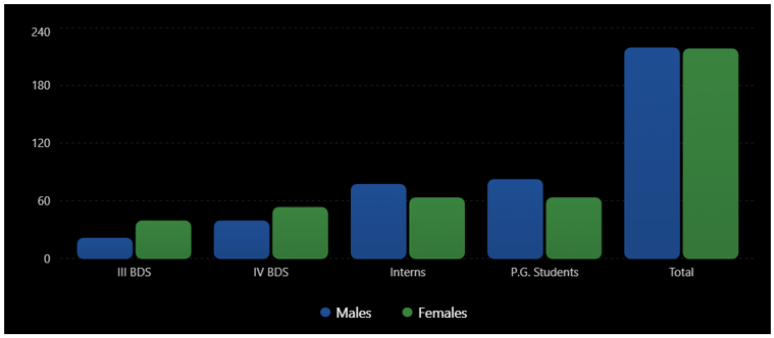
Statistical Analysis

The data obtained were loaded in Microsoft Excel sheet, and descriptive statistical analysis was done using Statistical Package for Social Sciences (SPSS) 26 (SPSS Inc., Chicago, IL, USA). Descriptive statistics were used to examine the frequency and proportion of the participants' responses. Categorical data were analyzed using the Chi-Square test (X2). The level of significance was established at $P < 0.05$. Any value less than or equal to 0.05 was considered statistically significant.

RESULTS

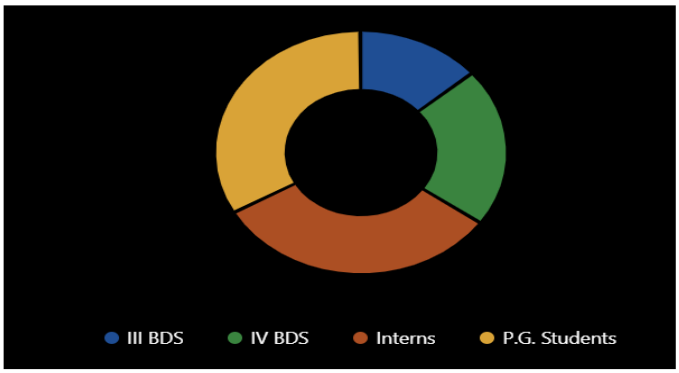
I. Demographic Details

A). Graph I: Presents the general distribution of participants by gender. The 437 participants included approximately equal numbers of males [219] and females [218]. Post graduate students [82] showed male domination and least from III BDS [21] while in females, domination was shared by Post graduate students [63] and Interns [63] and least again from III BDS [39].



Graph-1: Distribution of Subjects According to Gender

B). Pie Diagram: Describes how the participants were distributed by their academic level. The questionnaire was filled by 145 Post graduate students, 140 Interns, 92 IV BDS and 60 III BDS, thus totaling 437 participants.



Pie Chart 1: Distribution of Subjects According to Academic Level

Section II: Awareness of Pharmacovigilance Programs

Table 1: Shows the distribution of awareness on the phrase "any unintended and harmful response to a drug used at normal doses is an Adverse Drug Reaction (ADR)" among the individuals. Of the 437 participants, 380 (86.95%) properly answered "Yes" for awareness of the definition of ADR, whereas 57 (13.04%) answered "No."
III BDS students had the highest awareness with 100% (60/60) properly identifying the term of ADR. IV BDS students also had good awareness with 95.65% (88/92) right response and just 4.34% (4/92) incorrect response. Among P.G pupils 91.03% (132/145) knew the proper term and 8.96% (13/145) did not know the correct definition. Interns had the lowest level of awareness, with 71.42% (100/140) answering correctly, and 28.57% (40/140) answering incorrectly.
A very statistically significant correlation was found between the academic level and the awareness of the definition of ADR by the Chi-square test ($\chi 2 = 47.021$, $p < 0.0001$). This implies that there was a substantial difference in awareness between the different academic groups and that the variations observed were unlikely to be due to chance. In general, most of the participants had an acceptable grasp of the definition of an ADR. The p-value is extremely significant and implies that the academic level significantly affects the participants' knowledge of ADRs.

Table 1: Distribution of subjects Awareness according to any unintended or harmful response to a medicine used at normal doses is an Adverse Drug Reaction (ADR)

Designation	Response- Yes	No	Total
III BDS	60(100.0%%)	0(0.0%)	60(100.0%)
IV BDS	88(95.65%)	4 (4.34%)	92(100.0%)
Interns	100 (71.42%)	40 (28.57%)	140(100.0%)
P.G.Students	132 (91.03%)	13 (8.96%)	145 (100.0%)
Total	380 (86.95%)	57 (13.4%)	437 (100.0%)

X^2Value= 47.021, P= <0.0001) (Highly Significant)
Table 2: Presents the variation of participants' awareness about the assertion that commonly used in dentistry medications such as antibiotics, non-steroidal anti-inflammatory drugs (NSAIDs) and local anesthetics might cause adverse drug reactions (ADRs). Out of 437 participants, 387 (88.55%) answered "Yes" indicating their awareness that, these regularly prescribed dental drugs can cause ADRs and 50 (11.44%) answered "No" indicating their lack of understanding.
Among the academic groupings, P.G. students had the highest awareness, 93.79% (136/145) properly knowing that certain medications may cause ADRs and only 6.20% (9/145) ignorant. Also, the IV BDS students shown a high level of awareness, 86.95% (80/92) of them answered properly and 13.04% (12/92) answered negatively. Similarly, III BDS students had strong awareness with 85.0% (51/60) answering Yes and 15.0% (9/60) saying No. Among the interns, 85.71% (120/140) were aware of the possibility of ADRs with these drugs, while 14.29% (20/140) were not informed. There was no statistically significant association between academic level and awareness of the ADRs of antibiotics, NSAIDs and local anesthetics ($\chi 2 = 6.0218$, $p = 0.1106$). The variations identified in the awareness among the academic groups were not statistically significant since the p-value was > 0.05. This implies that knowledge of ADRs related with routinely used dental drugs was common and roughly similar across all levels of education.

Table 2: Distribution of subjects according to Awareness on Antibiotics, NSAIDs and Local Anethetics which are commonly used in dentistry may cause adverse drug reactions (ADR)

Designation	Response- Yes	No	Total
III BDS	51(85.0%%	9(15 .0%)	60 (100%)
IV BDS	80(86.95%)	12 (14.28%)	92 (100%)
Interns	120 (85.71%)	20 (28.57%)	140 (100%)

P.G.Students	136 (93.79%)	9 (6.20%)	147 (100%)
Total	387 (88.55%)	50 (11.44%)	437 (100%)

X^2 value = 6. 0218 P = 0.1106

Table 3: Denotes the relation between designation and awareness of the fact that different countries use distinct color cards for ADR reporting is substantial. P.G. students were the most aware, whereas III BDS and IV BDS students were not aware at all and interns had minimal understanding.

III BDS: 0/60 (0.0%) answered "Yes" and were unaware. Therefore, nobody knew: IV BDS: 0 of 92 (0.0%) answered "Yes". Interns: 8/140 (5.71%) responded "Yes" (extremely little awareness). Among the P.G. pupils, 58 out of 145 (40.0%) responded "Yes" exhibiting maximum awareness. The value of chi-square is 106.763 with $P < 0.0001$, which suggests that there is a highly significant difference in awareness across the groups. In practice, awareness is not equally distributed by designation, but grows significantly with level of training. The outcome indicates that post-graduate training is linked to greater awareness of ADR reporting systems including the usage of different color cards in different nations.

"Designation varied widely in awareness of the use of different color cards for ADR reporting systems. None of the III BDS and IV BDS students were aware of this. Only 5.71% of interns were aware whereas 40.0% of P.G. students were informed. The link was extremely statistically significant ($\chi 2 = 106.763$, $P < 0.0001$)."

Table 3: Distribution of subjects according to awareness on different countries use different color cards associated to ADR Reporting systems.

Designation	Response- Yes	No	Total
III BDS	0 (0.0%)	60 (100.0%)	60 (100.0%)
IV BDS	0 (0.0%)	92 (100.0%)	92(100.0%)
Interns	8(5.71%)	132(94.28%)	140(100.0%)
P.G.Students	58(40.0%)	87(60.0%)	145 (100.0%)
Total	66 (15.10%)	371 (52.6 %)	437 (100.0%)

X^2 value =106.763, P = <0.0001 (Highly Significant).

Table 4: Indicates that the awareness on drug-drug interactions can occur in dental practice was quite high throughout all categories from 58.33% in III BDS students to 75.17% in P.G. students. However, the difference among designation was not statistically significant ($\chi 2=5.37$, $P=0.146$).

III BDS: 35/60 (58.33%) said YES. IV BDS: 61/92 (66.30%) said YES. Interns: 99/140 (70.71%) answered "Yes". P.G. students: 109/145 (75.17%) answered "Yes". Awareness seems to increase gradually with clinical seniority, although the variance is not substantial enough to be statistically significant. This suggests that the differences we see may be due to chance rather than a meaningful link between designation and awareness.

The understanding about drug-drug interactions in dental practice was strong across all categories, with the highest awareness being among P.G. students (75.17%) and the lowest awareness being among III BDS students (58.33%). However, the correlation between designation and awareness was not statistically significant ($\chi 2=5.37$, $P=0.146$).

Table 4: Distribution of subjects awareness about 'Drug-drug interactions can occur in dental practice

Designation	Response- Yes	No	Total
III BDS	35(58.33%)	25(41.66%)	60(100.0%)
IV BDS	61(66.30%)	31(33.69%)	92(100.0%)
Interns	99(70.71%)	41(29.28%)	140(100.0%)
P.G.Students	109(75.17%)	36 (24.82%)	145 (100.0%)
Total	304 (69.56%)	133 (30.43%)	437(100.0%)

X^2 Value =5.37, P= 0.146 (Not Significant)

Table 5: Signify that overall awareness regarding the Pharmacovigilance Programme of India (PvPI) was found to be moderate with 67.6% of the individuals answering "Yes". There was a significant correlation between designation and awareness (χ 2=9.583, P=0.022) showing that awareness differed across academic levels.

III BDS: 30 (67.4%) were aware & 14 (32.6%) were not aware IV BDS: 61 out of 82 (74.7%) were aware, 21 out of 82 (25.3%) were unaware. Interns 75/130 (57.6%) were aware 55/130 (42.4%) were not. P.G. students: 105/145 (72.5%) were aware while 42/145 (27.5%) were unaware.

Maximum awareness was seen among IV BDS and P.G. students and minimum among interns. This pattern shows that exposure to pharmacovigilance information may not grow linearly with clinical progression and that interns may represent a population that needs more concentrated training.

Awareness of the Pharmacovigilance Programme of India (PvPI) was present in about 67.6% of the participants. Highest awareness was found among IV BDS Students (74.7%) and P.G. Students (72.5%) . Lowest awareness was seen among interns (57.6%). The correlation between designation and awareness was statistically significant ($\chi 2=9.583$, $P=0.022$).

Table 5: Distribution of subject's awareness about Pharmacovigilance Programme of India (PvPI)

Designation	Response- Yes	No	Total

III BDS	30(67.4%)	14(32.6%)	44(100.0%)
IV BDS	61(74.7%)	21(25.3%)	82(100.0%)
Interns	75(57.6%)	55(42.4%)	130(100.0%)
P.G.Students	105(72.5%)	42(27.5%)	145 (100.0%)
Total	271(67.6%)	132(32.4%)	401(100.0%)

X^2 value =9.583, P = 0.022 (Significant).

Table 6: Designates about the understanding that the prescriber dentist is responsible for reporting an ADR in the clinical environment was very low overall and only 3 of 401 participants (0.7%) answered "Yes". Association with designation was significant ($\chi 2$=11.798, P=0.008).
III BDS: 0/44 (0.0%) responded "Yes" IV BDS: 3/82 (3.6%) answered "Yes Interns 0/130 (0.0%) said "Yes." P.G. students 0/145 (0.0%) said "Yes."
This implies a relatively low awareness among all demographics of the role of the dentist in ADR reporting. The low proportion of accurate replies in IV BDS students indicates less understanding in the group but overall, the finding indicates a huge knowledge gap.
"Participants had very low awareness of the prescribing dentist's responsibility to report an ADR in the clinical setting, with only 0.7% responding 'Yes.'" Statistically significant connection was seen between designation and awareness ($\chi 2$=11.798, P=0.008).

Table 6: Distribution of subjects awareness about the prescribing dentist is responsible for reporting an ADR in the clinical setting

Designation	Response- Yes	No	Total
III BDS	0(0.0%)	44(100.0%)	44(100.0%)
IV BDS	3(3.6%)	79(96.4%)	82(100.0%)
Interns	0(0.0%)	132(100.0%)	130(100.0%)
P.G.Students	0(0.0%)	145(100.0%)	145 (100.0%)
Total	3(0.7%)	398(99.3%)	401(100.0%)

X^2 value =11.798, P = 0.008 (Significant).

Table 7: Represents the overall awareness of the fact that the dental practitioner in India directly reports an ADR to the National Pharmacovigilance Centre (PvPI) was fairly high with 69.56% of individuals replying "Yes." However, the difference across designation was not statistically significant (χ^2=5.37, P=0.146).
III BDS: 35/60 (58.33%) Yes IV BDS: 61/92 (66.30%) Yes. Interns: 99/140 (70.71%) answered "Yes." P.G. students: 109/145 (75.17%) answered "Yes."
There is probably a progressive increase in awareness as clinical seniority increases but the change is not large enough to reach statistical significance. This suggests that the variations found between designations might have happened by accident and not be necessarily an indication of a real link.
69.56% of the participants were aware that ADRs can be reported directly by dental practitioners to the National Pharmacovigilance Centre (PvPI), India. Maximum awareness was seen among P.G students (75.17%) followed by interns (70.71%), IV BDS students (66.30%) and III BDS students (58.33%). However, designation was not shown to be statistically significantly associated with awareness ($\chi 2$=5.37, P=0.146)".

Table 7: Distribution of subjects awareness In India, the dental practitioner reports an ADR directly to National Pharmacovigilance Centre (PvPI)

Designation	Response- Yes	No	Total
III BDS	35(58.33%)	25(41.66%)	60(100.0%)
IV BDS	61(66.30%)	31(33.69%)	92(100.0%)
Interns	99(70.71%)	41(29.28%)	140(100.0%)
P.G.Students	109(75.17%)	36 (24.82%)	145 (100.0%)
Total	304 (69.56%)	133 (30.43%)	437(100.0%)

X^2 Value =5.37, P= 0.146 (Not Significant)
Section III: Knowledge of Drug Safety and Pharmacovigilance

Table 8: Specify that knowledge on Drug Safety and Pharmacovigilance was exceptionally high in all classifications with a total right answer rate of 98.0%. The association between designation and knowledge was very strong ($\chi 2$=19.176, P<0.001).
III BDS: 42/44 (95.3%) responded "Yes" and 2/44 (4.7%) responded "No" IV BDS: 76/83 (92.8%) responded "Yes" and 6/83 (7.2%) responded "No" Interns: 130/130 (100%) answered "Yes". Post graduate students: 145/145 (100%) answered "Yes".
The knowledge was high in all the groups but it was significantly less in III BDS and IV BDS students when compared with interns and P.G. students. The statistical significance of the chi-square outcome implies that the discrepancies among designations are unlikely to have arisen by chance.

"Knowledge on Drug Safety and Pharmacovigilance was high across all designations with 98.0% participants answering correctly. Interns and P.G. students had complete awareness, but III BDS and IV BDS students showed slightly less correct responses. A very strong correlation was noted between designation and knowledge (χ^2=19.176, P<0.001)."

Table 8: Distribution of subjects according to their knowledge on Drug Safety and Pharmacovigilance

Designation	Response- Yes	No	Total
III BDS	42(95.3%)	2(4.7%)	44(100.0%)
IV BDS	76(92.8%)	6(7.2%)	83(100.0%)
Interns	130(100.0%)	0(0.0%)	130(100.0%)
P.G.Students	145(100.0%)	0 (0.0%)	145 (100.0%)
Total	393(98.0%)	8(2.0%)	401(100.0%)

X^2 Value= 19.176, P=0.000 (Highly Significant)

Table 9: Imply that pharmacovigilance is mostly associated with medication safety monitoring was practically universal. 99.3% of participants answered "Yes". It was significantly associated with designation (χ2=11.798, P=0.008). III BDS: 44/44 (100.0%) – "Yes" IV BDS: 79/82 (96.4%) – "Yes" Interns: 130/130 (100%) answered 'Yes'. P.G. students: 145/145 (100%) answered 'Yes'.

Knowledge was good in all groups but IV BDS students had somewhat lower percentage of accurate answers compared to the other classifications. The difference, though minor, was statistically significant, suggesting a meaningful difference in the distribution of knowledge between the groups.

Pharmacovigilance is mainly the monitoring of drug safety. Almost all participants (99.3%) knew this statement. IV BDS students had slightly lower correct responses, although III BDS students, interns and P.G. students were completely knowledgeable. There was a statistically significant connection between designation and knowledge (χ2=11.798, P=0.008).

Table 9: Distribution of subject's knowledge on Pharmacovigilance is primarily concerned with Drug safety monitoring?

Designation	Response- Yes	No	Total
III BDS	44(100.0%)	0(0.0%)	44(100.0%)
IV BDS	79(96.4%)	3(3.6%)	82(100.0%)
Interns	130(100.0%)	0(0.0%)	130(100.0%)
P.G.Students	145(100.0%)	0(0.0%)	145 (100.0%)
Total	398(99.3%)	3(0.7%)	401(100.0%)

X^2value=11.798, P = 0.008 (Significant)

Table 10: Convey that the knowledge of the primary purpose of pharmacovigilance was quite high overall, with 98.5% of participants answering "Yes." The connection with designation was statistically significant (χ2 = 15.786, P = 0.001). III BDS: 41 of 44 (93.0%) responded "Yes" and 3 of 44 (7.0%) responded "No" IV BDS: 79 of 82 (96.4%) responded "Yes" and 3 of 82 (3.6%) responded "No" Interns: 130/130 (100%) answered "Yes." P.G. students: 145/145 (100%) answered "Yes."

Knowledge was good in all the groups however III BDS, IV BDS students had significantly less correct responses than interns and P.G. students. A significant chi-square score implies that these disparities between designations are unlikely to have occurred by chance.

Knowledge about the primary purpose of pharmacovigilance, i.e. to detect, assess, understand and avoid harmful effects of drugs and communicate findings in a timely way was very high amongst all participants. Complete awareness was seen in interns and P.G. students whereas, somewhat less correct replies were seen in III BDS and IV BDS students. The link between designation and knowledge was statistically significant (χ2=15.786, P=0.001).

Table 10: Distribution of subjects according to knowledge on the primary objective of Pharmacovigilance is to detect, assess, understand and prevent adverse effects of medicines and communicate findings in a timely manner.

Designation	Response- Yes	No	Total
III BDS	41(93.0%)	3(7%)	44(100.0%)
IV BDS	79(96.4%)	3(3.6%)	82(100.0%)
Interns	130(100.0%)	0(0.0%)	130(100.0%)
P.G.Students	145(100.0%)	0(0.0%)	145 (100.0%)
Total	395(98.5%)	6(1.5%)	401(100.0%)

X^2 value =15.786, P = 0.001 (Significant)

Table 11: Insinuate that the distribution reveals very poor knowledge about the WHO PIDM concept of pharmacovigilance across all groups with only 3 out of 437 participants answering "Yes" and 434 answering "No". There was a statistically significant correlation between designation and response χ 2 =11.798, P=0.008. This means that academic level was significantly different in terms of knowledge. III BDS: 44 respondents, 0% said "Yes", 100% said "No".
IV BDS: 3.6% said "Yes" and 96.4% said "No" out of 82 Interns: 0% said "Yes" and 100% said "No" out of 130 PG students: 0% said "Yes" and 100% said "No" out of 145 Knowledge of the WHO PIDM definition of pharmacovigilance was relatively low across all designations. Only 0.7 % of the respondents gave the proper definition and 99.3% did not. "There was a statistically significant association between designation and response and there was variation in awareness across academic levels".

Table 11: Distribution of subjects knowledge on World Health Organization (WHO)'s Programme for International Drug Monitoring [PIDM] defines Pharmacovigilance as the science and activities related to the detection, assessment, understanding, and prevention of adverse effects

Designation	Response- Yes	No	Total
III BDS	0(0.0%)	44(100.0%)	44(100.0%)
IV BDS	3(3.6%)	79(96.4%)	82(100.0%)
Interns	0(0.0%)	130(100.0%)	130(100.0%)
P.G.Students	0(0.0%)	145(100.0%)	145 (100.0%)
Total	3(0.7%)	434 (99.3%)	437(100.0%)

X^2 value =11.798, P = 0.008 (Significant).

Table 12: Bespeak about the knowledge that Pharmacovigilance Programme of India (PvPI) is co-ordinated by CDSCO was moderate overall with 67.6% of participants responded "Yes". The link between designation and knowledge was significant (χ2=9.583, P=0.022).
III BDS 30/44 (67.4%) replied "Yes" 14/44 (32.6%) answered "No" IV BDS 61/82 (74.7%) answered "Yes" 21/82 (25.3%) answered "No" Interns 75/130 (57.6%) replied "Yes" 55/130 (42.4%) answered "No" P.G students 105/145 (72.5%) answered "Yes" 42/145 (27.5%) answered "No"
IV BDS and P.G. students were had more knowledge, whereas interns were least. This implies a lack of standard awareness of the administrative coordination of PvPI across designations and highlights a need for reinforcing this information, especially among interns.
67.6% of the participants knew about the statement that the Pharmacovigilance Programme of India (PvPI) is coordinated by the Central Drugs Standard Control Organisation (CDSCO). The greatest number of right replies was recorded in IV BDS students (74.7%) and P.G. students (72.5%) whereas the interns showed the least awareness (57.6%). There was a statistically significant connection between designation and knowledge (χ 2 =9.583, P=0.022)."

Table 12: Distribution of subjects according to their knowledge on The Pharmacovigilance Programme of India (PvPI) is co-ordinated by Central Drugs Standard Control Organisation (CDSCO) ☺

Designation	Response- Yes	No	Total
III BDS	30(67.4%)	14(32.6%)	44(100.0%)
IV BDS	61(74.7%)	21(25.3%)	82(100.0%)
Interns	75(57.6%)	55(42.4%)	130(100.0%)
P.G.Students	105(72.5%)	42(27.5%)	145 (100.0%)
Total	271(67.6%)	132(32.4%)	401(100.0%)

X^2 value =9.583, P = 0.022 (Significant).

Table 13: This table evince that knowledge that anaphylactic reaction is a major ADR was quite poor overall, with only 15.10% of individuals replying "Yes". Designation was highly significantly associated with knowledge (χ2=106.763, P<0.0001) with clear disparities between groups.
III BDS: 0/60 (0.0%) replied "Yes." IV BDS: 0/92 (0.0%) replied "Yes." Interns: 8/140 (5.71%) responded "Yes." P.G. students: 58/145 (40.0%) responded "Yes."
The knowledge was very poor among III BDS and IV BDS students and slightly higher among interns and greatest among P.G. students. The pattern observed indicates that detection of anaphylaxis as a major adverse medication reaction improves with increased training, although overall awareness remains poor.
The knowledge of anaphylactic reaction as a significant adverse medication reaction was quite poor in the subjects, just 15.10% answered correctly. P.G. pupils showed maximum awareness (40.0%) and no correct replies were obtained among III BDS & IV BDS students. The link between designation and knowledge was highly significant (χ2=106.763, P<0.0001).

Table 13: Distribution of subjects according to their knowledge on Anaphylaxis reaction is a serious ADR

Designation	Response- Yes	No	Total

III BDS	0 (0.0%)	60 (100.0%)	60 (100.0%)
IV BDS	0 (0.0%)	92 (100.0%)	92(100.0%)
Interns	8(5.71%)	132(94.28%)	140(100.0%)
P.G.Students	58(40.0%)	87(60.0%)	145 (100.0%)
Total	66 (15.10%)	371 (52.6 %)	437 (100.0%)

X^2 value =106.763, P = <0.0001 (Highly Significant).

Table 14: Notify the knowledge about the association of the red card/red form with the ADR reporting system in India was very strong with 93.9% of individuals replying "Yes." There was a strong correlation between designation and knowledge ($\chi 2$=19.416, P<0.001).
III BDS: 40/44 (90.7%) replied "Yes," and 4/44 (9.3%) answered "No." IV BDS: 79/82 (96.4%) answered "Yes," and 3/82 (3.6%) answered "No." Interns: 130/130 (100%) answered "Yes." P.G. students: 127/145 (87.9%) answered "Yes" and 18/145 (12.1%) said "No."
Knowledge was excellent in all groups with full knowledge among interns. However, the overall level was high, with P.G. students having a somewhat lower knowledge as compared to other groups. The chi-square result was statistically significant meaning that the distribution of correct replies differed by designation.
The knowledge of the participants regarding the association of the red card/red form with the ADR reporting system in India was great (93.9% responded correctly). Complete awareness was detected in interns whereas somewhat reduced correct replies were recorded in III BDS, IV BDS and P.G. students. The designation and expertise showed significantly significant connection ($\chi 2$=19.416, P<0.001)."

Table 14: Distribution of subjects according to their knowledge on Red card/Red form is associated with ADR Reporting system in India

Designation	Response- Yes	No	Total
III BDS	40(90.7%)	4(9.3%)	44(100.0%)
IV BDS	79(96.4%)	3(3.6%)	82(100.0%)
Interns	130(100.0%)	0(0.0%)	130(100.0%)
P.G.Students	127(87.9%)	18(12.1%)	145 (100.0%)
Total	376(93.9%)	25(6.1%)	401(100.0%)

X^2 value =19.416, P = 0.000 (Highly Significant).

Table 15: The table betoken about the knowledge that ADR reporting contributes to patient safety was moderate with 72.7% of the participants replying "Yes." The connection between designation and awareness was highly significant (χ 2 = 49.607, P<0.001).
III BDS: 38/44 (86.0%) responded "Yes" and 6/44 (14.0%) responded "No" IV BDS: 82/82 (100%) responded "Yes" Interns: 79/130 (61.4%) replied "Yes" and 51/130 (38.6%) replied "No". P.G. students: 91/145 (63.8%) replied "Yes" and 54/145 (36.2%) replied "No".
The statement indicated 100% agreeability with the highest knowledge among the IV BDS students. On the other hand, interns and P.G. students showed a much lower number of right answers, which means that the information was not evenly dispersed over the training levels. The very significant chi-square shows that these variations are unlikely to be attributable to chance.
72.7% of the participants had knowledge about the contribution of ADR reporting to patient safety. Maximum correct response was reported in IV BDS students (100%) followed by III BDS students (86.0%) however interns (61.4%) and P.G. students (63.8%) had less knowledge comparably. The connection of designation and awareness was highly significant ($\chi 2$=49.607, P<0.001).

Table 15: Distribution of subjects according to their knowledge on ADR reporting contributes to patient safety

Designation	Response- Yes	No	Total
III BDS	38(86.0%)	6(14.0%)	44(100.0%)
IV BDS	82(100.0%)	0(0.0%)	82(100.0%)
Interns	79(61.4%)	51(38.6%)	130(100.0%)
P.G.Students	91(63.8%)	54(36.2%)	145 (100.0%)
Total	290(72.7%)	111(27.3%)	401(100.0%)

X^2 value =49.607, P = 0.000 (Highly Significant).

Table 16: This table manifest the overall, understanding of the ADRMS portal or the ADR PvPI 2.0 mobile application as an online tool for reporting ADRs in India was moderate, with 67.6% of the participants answering "Yes." The designation was significantly associated with knowledge ($\chi 2$=9.583, P=0.022).
III BDS 30/44 (67.4%) replied "Yes" 14/44 (32.6%) answered "No" IV BDS 61/82 (74.7%) answered "Yes" 21/82 (25.3%) answered "No" Interns: 75/130 (57.6%) replied "Yes" and 55/130 (42.4%) answered "No". P.G. students: 105/145 (72.5%) answered "Yes" and 42/145 (27.5%) answered "No".

Highest was among IV BDS and P.G students and lowest among interns. This indicates that knowledge of digital ADR reporting methods is not uniform across training levels and may need to be strengthened especially among interns. The large chi-square value means that the discrepancy between designations is not likely to be attributable to chance.
67.6% of participants were knew about ADRMS portal or ADR PvPI 2.0 mobile app as an online tool for filing ADRs in India under PvPI. IV BDS students and P.G. students had the highest percentage of accurate answers (74.7% and 72.5% respectively), while the least was by interns (57.6%). The link between designation and knowledge was statistically significant ($\chi 2$=9.583, P=0.022).

Table 16: Distribution of subjects according to their knowledge on ADRMS (Adverse Drug Monitoring System) portal or the ADR PvPI 2.0 mobile app, is an online tool used for reporting ADRs in India under the PvPI

Designation	Response- Yes	No	Total
III BDS	30(67.4%)	14(32.6%)	44(100.0%)
IV BDS	61(74.7%)	21(25.3%)	82(100.0%)
Interns	75(57.6%)	55(42.4%)	130(100.0%)
P.G.Students	105(72.5%)	42(27.5%)	145 (100.0%)
Total	271(67.6%)	132(32.4%)	401(100.0%)

X^2 value =9.583, P = 0.022 (Significant).

Section IV: Attitude Toward Pharmacovigilance

Table 17: The data designate that an overall agreement of 93.9% among the participants for the inclusion of pharmacovigilance in the dental curriculum, which signifies a positive attitude. The relationship between designation and attitude was highly significant ($\chi 2$=19.416, P<0.001).
III BDS: 40/44 (90.7%) agreed and 4/44 (9.3%) disagreed. IV BDS 79/82 (96.4%) Agree 3/82 (3.6%) Disagree. Interns: 130/130 (100%) agreed. P.G. students: 127/145 (87.9%) agreed while 18/145 (12.1%) disagreed.
Pharmacovigilance received good support from all the groups with the greatest support from the interns. P.G. students had the highest percentage of disagreement among the categories, although the overall response was definitely positive. The substantial result of chi-square implies that attitude varies with designation and this variation is not by coincidence.
There was a good attitude towards include pharmacovigilance in the dentistry curriculum with 93.9 % of participants agreeing with the statement. The interns showed total agreement, whereas the III BDS, IV BDS and P.G. students showed a little lower agreement. There was a significantly significant correlation between designation and attitude ($\chi 2$=19.416, P<0.001).

Table 17: Distribution of subjects according to their attitude on the statement Pharmacovigilance should be included in the dental curriculum.

Designation	Response- Agree	Disagree	Total
III BDS	40(90.7%)	4(9.3%)	44(100.0%)
IV BDS	79(96.4%)	3(3.6%)	82(100.0%)
Interns	130(100.0%)	0(0.0%)	130(100.0%)
P.G.Students	127(87.9%)	18(12.1%)	145 (100.0%)
Total	376(93.9%)	25(6.1%)	401(100.0%)

X^2 value =19.416, P = 0.000 (Highly Significant).

Table 18: The table presents a varied but generally positive opinion towards the assertion that ADR reporting is a professional responsibility of dentists, with 72.7% of participants agreeing overall. The correlation between designation and attitude was statistically significant (χ 2 =49.607, P<0.001).
III BDS: 38/44 (86.0%) agreed and 6/44 (14.0%) disagreed. IV BDS: 82/82 (100%) concurred. Interns: 79/130 (61.4%) agreed, 51/130 (38.6%) disagreed. P.G. students: 91/145 (63.8%) agreed, 54/145 (36.2%) disagreed.
The highest agreement was observed among IV BDS students who completely agreed that the professional role of a dentist was ADR reporting. Interns and P.G. students showed less agreement, indicating some ambiguity or different perspectives among these more senior groups. The chi-square result being highly significant shows that there is a considerable difference in attitude between designations.
72.7% of participants had a good attitude towards reporting of ADR as a professional responsibility of dentists. There was full agreement among IV BDS students while reduced agreement was seen among interns and P.G. The designation and attitude relationship was highly significant ($\chi 2$=49.607, P<0.001).

Table 18: Distribution of subjects according to their attitude on the statement ADR reporting is a professional responsibility of dentists.

Designation	Response- Agree	Disagree	Total
III BDS	38(86.0%)	6(14.0%)	44(100.0%)

IV BDS	82(100.0%)	0(0.0%)	82(100.0%)
Interns	79(61.4%)	51(38.6%)	130(100.0%)
P.G.Students	91(63.8%)	54(36.2%)	145 (100.0%)
Total	290(72.7%)	111(27.3%)	401(100.0%)

X^2 value =49.607, P = 0.000 (Highly Significant).

Table 19: This table explains that there is a very strong favorable attitude towards the assertion that reporting ADRs can improve patient safety, with 98.5% of participants agreeing in total, as seen in the table. There was a substantial correlation between designation and attitude ($\chi 2$ =15.786, P=0.001).
III BDS: 41/44 (93.0%) agreed while 3/44 (7.0%) disagreed. IV BDS: 79/82 (96.4%) agreed, 3/82 (3.6%) disagreed. Interns: 130/130 (100%) agree. P.G. students: 145 out of 145 (100%) agreed.
Attitude was quite favorable in all categories, with total agreement by interns and P.G. students. The view of III BDS and IV BDS students is still very positive with little less agreement. The significant chi-square result indicates that the distribution of responses was different by designation.
Attitude toward the assertion that reporting ADRs can improve patient safety was largely positive, 98.5% of participants agreed. III BDS and IV BDS students showed slightly less agreement, however, interns and P.G. students agreed completely. The relationship between designation and attitude ($\chi 2$=15.786, P=0.001).

Table 19: Distribution of subjects according to their attitude on the statement Reporting ADRs can improve patient safety.

Designation	Response- Agree	Disagree	Total
III BDS	41(93.0%)	3(7%)	44(100.0%)
IV BDS	79(96.4%)	3(3.6%)	82(100.0%)
Interns	130(100.0%)	0(0.0%)	130(100.0%)
P.G.Students	145(100.0%)	0(0.0%)	145 (100.0%)
Total	395(98.5%)	6(1.5%)	401(100.0%)

X^2 value =15.786, P = 0.001 (Significant).

Table 20: Reveals, there is a fairly positive attitude towards formal training in ADR reporting for dentistry students, with 72.7% replying 'Yes'. Designation was significantly associated with attitude (χ^2=49.607, P<0.001).
III BDS: 38/44 (86.0%) said "Yes" 6/44 (14.0%) stated "No". IV BDS: 82/82 (100%) responded "Yes". Interns: 79/130 (61.4%) answered "Yes" and 51/130 (38.6%) answered "No." P.G. students: 91/145 (63.8%) answered "Yes" and 54/145 (36.2%) answered "No."
The IV BDS students were unanimous in their agreement that proper training on ADR reporting is a must. Interns and P.G. students exhibited substantially less support indicating that the more advanced trainees may be more critical or may feel that they already had some exposure. The chi-square score is extremely significant indicating that attitude differs significantly among categories.
A positive attitude towards the requirement for formal training in ADR reporting was found in 72.7% of the dentistry students. IV BDS students showed complete agreement whereas interns and P.G. students showed less agreement. There was a very substantial correlation between designation and attitude ($\chi 2$=49.607, P<0.001).

Table 20: Distribution of subjects according to their attitude on the statement Dental students should receive formal training in ADR reporting.

Designation	Response- Yes	No	Total
III BDS	38(86.0%)	6(14.0%)	44(100.0%)
IV BDS	82(100.0%)	0(0.0%)	82(100.0%)
Interns	79(61.4%)	51(38.6%)	130(100.0%)
P.G.Students	91(63.8%)	54(36.2%)	145 (100.0%)
Total	290(72.7%)	111(27.3%)	401(100.0%)

X^2 value =49.607, P = 0.000 (Highly Significant).

Table 21: This table signal almost no consensus that pharmacovigilance should be included in standard dentistry practice with only 0.7% of participants responding "Agree." The connection with designation was significant (χ^2=11.798, P=0.008).
III BDS: 0/44 (0.0%) agreed, 44/44 (100.0%) disagreed. IV BDS: agree 3/82 (3.6%), disagree 79/82 (96.4%) Interns: 0/130 (0.0%) agreed, whereas 132/130 is likely a data input error and should read 130/130 disagreed. P.G. students: 0 (0.0%) of 145 agreed, and 145 (100.0%) of 145 disagreed.
The findings revealed an extremely negative attitude to the integration of pharmacovigilance into ordinary dentistry practice. The IV BDS students exhibited little agreement but the pattern of responses generally suggests that the notion was not well received. The substantial chi-square result demonstrates that there was a difference in replies between designations, while the table likely has an inconsistency in the intern count.

"Attitude towards integration of pharmacovigilance into ordinary dentistry practice was largely unfavorable with only 0.7% of individuals agreeing. All other groups completely disagreed and a small fraction of IV BDS students agreed. “The association between designation and attitude was statistically significant ($\chi 2$=11.798, P=0.008).

Table 21: Distribution of subjects according to their attitude on the statement Pharmacovigilance should be integrated into routine dental practice

Designation	Response- Agree	Disagree	Total
III BDS	0(0.0%)	44(100.0%)	44(100.0%)
IV BDS	3(3.6%)	79(96.4%)	82(100.0%)
Interns	0(0.0%)	132(100.0%)	130(100.0%)
P.G.Students	0(0.0%)	145(100.0%)	145 (100.0%)
Total	3(0.7%)	398(99.3%)	401(100.0%)

X^2 value =11.798, P = 0.008 (Significant).

Table 22: The attitude towards the statement that awareness of drug interactions is necessary for safe prescribing was moderate-to-high favorable with an overall agreement of 67.6% among the participants (table). There was a significant correlation between designation and attitude ($\chi 2$=9.583, P=0.022).
III BDS: 30/44 (67.4%) agreed, 14/44 (32.6%) disagreed. IV BDS: 61 out of 82 (74.7%) agreed, 21 out of 82 (25.3%) disagreed. Interns: 75/130 (57.6%) agreed, 55/130 (42.4%) disagreed. P.G. students: 105/145 (72.5%) agreed, 42/145 (27.5%) disagreed.
Maximum agreement was seen among IV BDS and P.G students whereas interns had minimum agreement. This implies that although most respondents appreciated the necessity of understanding of drug interactions for safe prescribing, the attitude was not consistent across training levels. The large chi-square score suggests that the disparities across designations are unlikely to be random.
67.6% of participants had a favorable opinion on the statement "Knowledge of drug interactions is essential for safe prescribing". Maximum agreement was found in IV BDS students and P.G. students and minimum agreement was found in interns. The correlation between designation and attitude was statistically significant ($\chi 2$=9.583, P=0.022).

Table 22: Distribution of subjects according to their attitude on the statement Knowledge of drug interactions is essential for safe prescribing

Designation	Response- Agree	Disagree	Total
III BDS	30(67.4%)	14(32.6%)	44(100.0%)
IV BDS	61(74.7%)	21(25.3%)	82(100.0%)
Interns	75(57.6%)	55(42.4%)	130(100.0%)
P.G. Students	105(72.5%)	42(27.5%)	145 (100.0%)
Total	271(67.6%)	132(32.4%)	401(100.0%)

X^2 value =9.583, P = 0.022 (Significant).

DISCUSSION

The Detailed Dental Pharmacovigilance (PV) Procedure

1. Clinical Identification and Detection [15,16]

When a dentist notices or a patient reports an unexpected clinical change, the process starts at the chairside. These safety issues in dentistry usually fall into one of three categories:
a. Local drugs, b). Systemic Drugs and C). Dental Materials allergy.
Antiplatelet medications present a risk of bleeding, broad-spectrum antibiotics (such as amoxicillin and clindamycin) can induce severe gastrointestinal distress, and lidocaine or epinephrine can trigger local hypersensitivity reactions. Recognize secondary oral issues linked to systemic medications administered by other physicians, such as xerostomia (dry mouth) or drug-induced gingival overgrowth (calcium channel blockers like amlodipine).
Materiovigilance-Identifying local tissue reactions, mucositis, or edema related to dental biomaterials such as endodontic sealers, resin composites, or nickel-chromium crowns.

2. Documentation and Office Triage [17]

The practitioner must meticulously record any questionable reactions in the patient's electronic health record (EHR). The office must save four fundamental pieces of information in order to produce a valid Individual Case Safety Report (ICSR): The suspected medicinal agent or material (including brand name and batch/lot numbers if an anesthetic or material is suspected), the identifying reporter (the practicing dentist), the identifiable patient (age, sex, initials), and a detailed description of the adverse event (time of beginning, symptoms, necessary actions).

3. Evaluation of Causality [18]

The clinician evaluates the possibility that the drug or item caused the observed reaction before submitting. This is typically accomplished by using tried-and-true clinical techniques like the Naranjo Algorithm or the WHO Causality Assessment Scale, which take into account factors like the interval between the administration of a medication and the occurrence of an event. Status of the patient following drug cessation (dechallenge). symptoms that reappear after taking the drug again (rechallenge).

4. Notifying Regulatory Gateways [19]

National safety monitoring organizations (such as the FDA's MedWatch/FAERS in the US, the UK's Yellow Card program, or PvPI in India) are then notified of the confirmed case.Note: Clinical pharmacists are tasked with checking dental prescriptions, counseling patients, and administratively entering ADR data into national databases in many contemporary clinics that employ interprofessional collaboration.

5. Clinical Follow-Up and Risk Mitigation

Localized risk management is the final stage. To prevent future inadvertent exposure, the dentist modifies the patient's treatment plan (e.g., by switching to a dubious antibiotic or a different kind of local anesthetic) and clearly notes the allergy on the patient's chart. A strong national platform for tracking the safety of pharmaceuticals, analyzing adverse drug reactions (ADRs), and protecting public health in India is the Pharmacovigilance Programme of India (PvPI). Since its official inception in July 2010 by the Indian government's Ministry of Health and Family Welfare, the program has developed significantly to create drug safety networks throughout the nation, transforming India from a data-dependent nation to a global leader in the production of safety data. [20,21]

Organizational Structure and Governance

PvPI must have a dual-tier structure from regional medical facilities to federal regulatory oversight in order to be operationally successful. Under the Drugs Controller General of India (DCGI), the Central Drugs Standard Control Organization (CDSCO) is the highest executive body. CDSCO handles policy changes, legal obligations resulting from safety discoveries, and regulatory enforcement. Indian Pharmacopoeia Commission (IPC), Ghaziabad, Uttar Pradesh. The NCC-IPC is in charge of leading research, compiling clinical reporting data, and conducting quality evaluations. Since 1998, NCC has been an official member of the WHO Programme for International Drug Monitoring, contributing Indian demographic data to the global VigiBase database and sending validated clinical data directly to the Uppsala Monitoring Centre (UMC) in Sweden. [22-25]

Roopa Arun Korde et al., [26] from their study concluded that both medical and dental 3rd & 4th year students UG students, demonstrated basic knowledge and positive attitude toward pharmacovigilance; however, ADR reporting practices were low comparatively among dental students. Present study results also on par with their study results. These findings underscore the need for structured pharmacovigilance training programs to improve ADR reporting practices and enhance patient safety.

Dr. Naresh Budhe and colleagues [27], did a study on 2nd BDS students and concluded that, all the students showed a positive attitude toward pharmacovigilance, but their knowledge and practice of pharmacovigilance were limited. This finding suggests to incorporate structured training of the pharmacovigilance to promote patient safety. Whereas the current study covered 3rd and 4th BDS students, who expressed a positive attitude towards pharmacovigilance with good knowledge towards practice of pharmacovigilance.

Gopal Gudsurkar et al., [28] who did a study on Post Graduate students of both Dentistry and Physiotherapy and concluded that, there is a big need to inculcate awareness among them towards the improvement of reporting of ADRs. In our present study results on awareness of Dental Post Graduates needs to improve on this area. According to Rashmi Venkatesh and co-workers, [29] MDS faculty and practicing dentists are under reporting ADRs and they felt that, improper knowledge of faculty could be the reason. They suggested that, the awareness and knowledge on ADR reporting by all the dental personnel should be addressed immediately.

Jnaneswar A et al., [30] also did study by involving both medical and dental faculties. According to their study, medical faculties have better knowledge about pharmacovigilance and ADR reporting, dentists have a positive attitude, thereby suggesting a huge scope of progress if more emphasis is given on the need for continuous educational initiatives and including the topic in their academic curriculum. Present study participants were also under impression that, academic curriculum insists on the ADR reporting. Kumar G Chhabra and co-authors [31] did a study on BDS 3rd, 4th and Interns, and stated that, the participants had a comparatively favorable attitude toward Pharmacovigilance, but their knowledge and practice need considerable improvements. They suggested that, there is a need for appropriate dental curriculum changes and further multicentric studies to shed more light on important issues of Pharmacovigilance among dentists in India. The present study results are in favor of the above study reports.

Venkatesan Gayathri et al., [32] concluded from their study on 2nd BDS students' knowledge and attitude towards Pharmacovigilance and ADR reporting were satisfactory. Though the present study did not include the BDS students, the results were against to the above study reports. Gottipati Naga Haritha et al., [33] involved Medical and Dental P.G. Students in their study and they concluded that the ADR reporting is crucial for all healthcare providers. They felt that every healthcare professional should have proper knowledge and awareness for ADRs reporting. The present study authors also drawn the similar conclusions from the study. [33] Vaishnavi V and co-researchers [34] from their cross-sectional pilot study among dental teaching faculty, MDS and BDS students concluded that, robust grasp of pharmacovigilance fundamentals among participants. While knowledge is intense, there are opportunities for enhancing specific details and promoting wider awareness in the field. In our present study, only BDS Clinical students and MDS students were involved, but the results were concurring with the above study.

Lucky Yadav et al., [35] did a study among the undergraduates, graduated practitioner, and specialist practitioner, concluded that Oral health practitioners have a general understanding of ADR; however, there is substantial evidence of underreporting and a lack of reporting system information. They suggested that organizing an orientation program and raising awareness about ADR reporting could help improve spontaneous reporting and better patient care. Present study results on ADRs reporting are also in favor of Lucky Yadav et al., study.

Adverse Drug Reactions (ADRs) are identified by the World Health Organization (WHO) and international regulatory authorities using spontaneous color-coded reporting systems. "Yellow Card" is frequently linked to reporting Adverse Drug Reactions (ADRs) in the context of pharmacovigilance in Yellow Cards. The Yellow Card Scheme, which was introduced by the UK's MHRA in 1964, is widely acknowledged and enables the public and medical professionals to report side effects. Similar yellow-branded schemes have been inspired by it in a number of other nations. Many nations utilize the Yellow Card Scheme to gather data on potential adverse drug reactions (ADRs) to medications, vaccines, herbal products, and medical equipment. Healthcare providers, patients, and even pharmaceutical firms are required to inculcate this system to report any adverse events they witness or encounter. [36,37]
Blue Cards: Used historically by health authorities like the FDA (MedWatch) for specific non-mandatory reports, as well as in nations like Australia and some Canadian or European hospital networks. Blue forms are frequently customized for unique pharmacovigilance tracking or particular categories of adverse event reporting. [38]
Red Cards and Red Forms: Many national centers utilize red forms to indicate adverse reactions that are urgent, serious, or fatal and that need to be evaluated by regulatory authorities right once. [39] Green cards are typically used to identify particular public health surveillance projects or to track and highlight adverse responses associated with a particular class of medications or vaccines.
White System: Used for digital workflows (like VigiFlow) in areas where hard-copy paper versions are not depended upon, as well as for a number of international web portals, such as the FDA MedWatch system in the USA.[39]
Adverse drug reactions (ADRs) can be directly reported to the Pharmacovigilance Programme of India (PvPI) by dentists, who are essential to patient safety. Dentists can simply submit reports by calling the toll-free helpline or using the official ADR PvPI Mobile App. [20,40]

Future Trends in Dental Pharmacovigilance
Dental pharmacovigilance (PV) is changing from manual and disorganized reporting methods to proactive, data-driven frameworks in the wake of the digital transformation of global healthcare models. By utilizing artificial intelligence, standardizing electronic data, and emphasizing patient-centered care, the industry is evolving to solve its historically low response rates. [12,25,41-44]

Important Upcoming Developments in Dental Pharmacovigilance
1. **Including Low-Threshold, Intelligent Electronic Medical Records (EMRs):** The dentist was previously disconnected from hospital reporting channels. In future clinical contexts, cloud-based Dental Electronic Health Record software will incorporate automated PV reporting plugins. In order to alert the doctor to the likelihood of Medication-Related Osteonecrosis of the Jaw (MRONJ), systems will automatically detect possible safety concerns, such as comparing a patient's long-term antiresorptive medications with a scheduled tooth extraction. To minimize administrative friction, required Individual Case Safety Report (ICSR) fields will be automatically filled up from chart data using drop-down triggers.

2. **Artificial Intelligence and Natural Language Processing (NLP):** The frameworks of the Council for International Organizations of Medical Sciences (CIOMS) highlight how AI and machine learning are revolutionizing post-marketing drug safety. A dentist's narrative progress notes, such as "Patient returned with severely swollen lip and ulcerative stomatitis 24 hours after filling placement," can be instantly read by Large Language Models (LLMs) and Natural Language Processing (NLP) and automatically translated into standardized MedDRA clinical terminology for regulatory submission. Early Identification of Signals In order to find minute patterns, such as whether a new composite resin or local anesthetic formula is the cause of an odd cluster of allergic contact mucositis, AI algorithms may search through massive regional and global multi-source health data.

3. **Digital health (mHealth) with patient-generated health data (PGHD):** In contemporary pharmacovigilance, it is widely recognized that patients are frequently the first to notice an adverse event, particularly after leaving a private dental office. In the future, patient-focused smartphone applications will be used to enable people to immediately report localized rashes, severe pain that doesn't go away with medication, or post-operative swelling. To find patient complaints about localized responses to common treatments like cosmetic dermal fillers or tooth-whitening gels, advanced PV systems currently use digital scraping algorithms to search public healthcare discussion forums and social media channels.

4. **Convergence of Materiovigilance and Pharmacovigilance:** Drug tracking and device tracking often result in data loss due to dentistry's unique reliance on intricate structural biomaterials. Systemic therapies and materiovigilance (monitoring dental implants, endodontic fillers, bone transplants, and metal crowns) will be monitored by unified regulatory approaches in the next years. Long-term monitoring is crucial to detect delayed-onset foreign body granulomas or persistent tissue hyper-reactivity linked to cosmetic materials like hyaluronic acid lip augmentation, which may manifest as late as 24–57 months following the procedure, according to recent systematic reviews.

5. Education reform and interprofessional cooperation Dental-Pharmacy Collaborations: Including active clinical pharmacists in dental school staff or larger clinical groups is a developing trend to close the data collection gap. Pharmacists assist dentists by handling reporting procedures, monitoring polypharmacy profiles, and conducting causality assessments. Dental schools are providing specialized modules on pharmaceutical safety and PV compliance at the start of clinical practice training, moving away from passive, procedure-based learning. [12,25,41-44]

CONCLUSION

Pharmacovigilance and drug safety are essential elements of contemporary dentistry. Many drugs that can result in adverse reactions, drug interactions, and medication-related issues are prescribed by dentists. Early detection, recording, and reporting of adverse drug reactions (ADRs) can greatly enhance patient safety, lower medication-related morbidity, and support national and international drug monitoring programs. Every dentist should view pharmacovigilance as a professional duty as dentistry becomes more and more intertwined with systemic healthcare.

Pharmacovigilance and drug safety are becoming essential parts of modern dental care. Dentists are in a unique position to recognize, treat, and record adverse medication reactions due to the frequent use of antibiotics, analgesics, local anesthetics, and other therapeutic medicines. Underreporting of adverse drug reactions (ADRs) among dental professionals is still a significant problem, despite growing knowledge of pharmacovigilance. Patient safety can be greatly improved by bolstering pharmacovigilance education, increasing interprofessional collaboration, integrating digital surveillance technologies, and fostering an ADR reporting culture. Every dentist has a professional and ethical obligation to actively participate in pharmacovigilance as dentistry becomes more integrated with larger healthcare systems.

REFERENCES

1. World Health Organization. The Importance of Pharmacovigilance: Safety Monitoring of Medicinal Products. Geneva: WHO; 2002. Available from: https://www.who.int/publications/i/item/10665-42493. Last accessed on 13 th June 2026.
2. Joshi A, Bhargava M, Joshi L, Bhargava N. Pharmacovigilance in dentistry – current scenario and future prospects. J Indian Assoc Public Health Dent. 2016;14(1):3–8.
3. Dr. B. LakshmanaRao, Dr. Vikas Punia and Dr. Rajeev Srivastava. "'Pharmacovigilance in Dentistry': An Emerging Need for Safer Dental Practice.". Int J Pharma Sci Health Care(IJPHC) 2026; 16 (3): 27/1-27/9. DOI: https://dx.doi.org/10.5281/zenodo.20628887]
4. Bhansali S, Bhansali A, Shah N. Pharmacovigilance in dental colleges: an unexplored territory. J Pharmacol Pharmacother. 2015;6(1):17–20.
5. Hersh EV, Moore PA. Adverse drug interactions in dentistry. Periodontol 2000. 2008;46:109–42.
6. Kanjanarat P, Winterstein AG, Johns TE, Hatton RC, Gonzalez-Rothi R, Segal R. Nature of preventable adverse drug events in hospitals. Am J Health Syst Pharm. 2003;60(17):1750–9.
7. World Health Organization. The global smart pharmacovigilance strategy. Geneva: World Health Organization; 2025 . Available from: https://www.who.int/publications/i/item/9789240101530. Last accessed on 24th June 2026.
8. European Medicines Agency. Guideline on good pharmacovigilance practices (GVP): Annex I - Definitions (Rev 5) [Internet]. Amsterdam: European Medicines Agency; 2024.Report No.: EMA/876333/2011. Available from: https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-good-pharmacovigilance-practices-gvp-annex-i-definitions-rev-5_en.pdf. Last accessed on 24th June 2026.
9. International Council for Harmonisation. ICH E2C(R2) Periodic benefit-risk evaluation report (PBRER) - Scientific guideline [Internet]. Geneva: ICH; 2012. Available from: https://www.ich.org/page/efficacy-guidelines. Last accessed on 24th June 2026.
10. Central Drugs Standard Control Organization (CDSCO). Guidance document for Marketing Authorization Holders (MAHs) of pharmaceutical products [Internet]. New Delhi: National Coordination Centre - Pharmacovigilance Programme of India (PvPI), Indian Pharmacopoeia Commission; 2021. Available from: https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/PSUR_PV_AEFI/Guidance-Document-for-Marketing-Authorization-Holders.pdf. Last accessed on 25 th June 2026.
11. Al-Shahi R, Al-Raisi S, Al-Harthi S. Pharmacovigilance: Basic concepts and an overview of the system in Oman. Oman Med J. 2021;36(3):e272.
12. Matar MS, Elatta LSHA, Basheir WAS, Khalid KM, Babiker DH, Yousef BA. Pharmacovigilance in Dental Practice: Opportunities for Pharmacy-Dentistry Collaboration. Ann Med Med Sci. 2025;1283-90.
13. Shivamurthi T, Dixit DC, Ramachandra MS. Review; Pharmacovigilance and Drug Safety: A Global Perspective. Asian J Pharm Res Dev. 2025;13(1):152-60. https://doi.org/10.22270/ajprd.v13i1.1519
14. Carnelio S, Khan SA, Rodrigues G. Pharmacovigilance in clinical dentistry: overlooked or axiomatic? Gen Dent. 2011 Jan-Feb;59(1):24-8; quiz 29-30, 80. PMID: 21613036
15. World Health Organization. The importance of pharmacovigilance: safety monitoring of medicinal products [Internet]. Geneva: World Health Organization; 2002 [cited 2026 Jun 25]. Available from: https://apps.who.int/iris/handle/10665/42493.
16. Malamed SF. Handbook of local anesthesia. 7th ed. St. Louis: Elsevier; 2020.
17. Hoste A, Bondon-Guitton E, Atzenhoffer M, Gaboriau L, Durrieu G, Montastruc JL, et al. Adverse drug reactions in dental practice: an analysis of reports submitted by dentists to the French Pharmacovigilance Database. Br J Clin Pharmacol. 2023;89(4):1412-9.
18. Kumar PR, Kadali RP, Chaitanya Y. Evaluation of knowledge, attitude, and practice of pharmacovigilance and materiovigilance among oral health practitioners. J Indian Assoc Public Health Dent 2024 ;22(1):45-51.
19. Vivekanandan K, Prakash J, Singh GN. Pharmacovigilance programme of India. Arch Pharm Pract. 2012;3(3):229-32.
20. Kalaiselvan V, Srivastava S, Singh A, Gupta S. Pharmacovigilance in India: Present scenario and future challenges. Drug Safety. 2019;42(3):339-46.
21. Lihite R, Lahkar M. An update on the Pharmacovigilance Programme of India. Front Pharmacol. 2015;6:1-3.

22. Sharma M, Baghel R, Thakur S, Adwal Sandeep. Surveillance of adverse drug reactions at an adverse drug reaction monitoring centre in Central India: a 7-year surveillance study. BMJ Open. 2021;11(10):e052737.
23. Lalthanpuii K, Kaur J, Saini S, Bhatti K, Nain P. Strengthen the Monitoring and Reporting of Adverse Drug Reaction at a Tertiary Teaching Hospital. Arch Pharm Pract. 2022;13(1):61-77..
24. Rimal J, Shrestha A, Maharjan IK. Knowledge, attitude, and practice of pharmacovigilance among dental professionals in a tertiary dental hospital. J Nepal Dent Assoc. 2021;21(2):45-51.
25. Inácio P, Cavaco A, Airaksinen M. Characterizing adverse drug reaction reports submitted by dental practitioners: a systematic review. Drug Saf. 2017;40(5):371-84.
26. Rupa Arun Korde, Priya Shodan. Knowledge, Attitude, and Practice of Pharmacovigilance among Undergraduate Medical and Dental students in a Tertiary Care Teaching Hospital. Int J Med Pharm Res 2026; 7 (1): 990-995.
27. Dr. Naresh Budhe, Dr. Sairam Vasanthakumari Nagarajan, Dr. Punam Gosavi, Dr. Mrunalini Kalikar, Dr. Sukant Pandit, Mr. Piyush Nama. Knowledge, Attitude & Practice about Pharmacovigilance among 2nd year BDS students in a tertiary care teaching hospital. Int J Med Pharm Res 2025; 6 (5): 1048-1053.
28. Gopal Gudsurkar, Vikalp Tiwari, Pooja Solanki Mishra. Assessment of knowledge, attitudes and practice among the post graduate students of dentistry and physiotherapy towards adverse drug reactions reporting and pharmacovigilance at a tertiary care centre at Indore, India. Int J Basic Clin Pharmacol 2018;7:626-30.
29. Rashmi Venkatesh, K. S. Poonacha, Vishnavee Vassandacoumara, C. G. Ajithkrishnan. Knowledge, attitude, and practice study of pharmacovigilance in a dental teaching institute in Western India. SRM J Res Dent Sci 2024;15:157-62.
30. Jnaneswar A, Hazarika SJ, Jha K, Vinay S, Kumar G. Knowledge, attitude, practices, and barriers regarding pharmacovigilance and adverse drug reaction reporting among medical and dental faculties of the teaching hospitals in Bhubaneswar City. J Edu Health Promot 2020;9:282.
31. Kumar G Chhabra, Ashish Sharma, Chaya Chhabra, J Jyothirmai Reddy, Shravani G Deolia, Yogesh Mittal. Knowledge, Attitude, and Practices regarding Pharmacovigilance and Adverse Drug Reaction reporting among Dental Students in a Teaching Hospital, Jodhpur, India: A Cross-sectional Study. J Contem Dent Pract 2017;18(10):964-969.
32. Venkatesan Gayathri, Subbiah Vijayalakshmi, TAR Raja. Knowledge and attitude towards pharmacovigilance among the dental undergraduates in a private dental college and hospital. Journal of Student's Research 2022;10(3):92–95 93.
33. Gottipati Naga Haritha, Annamalai Rama, Anup Naha, Usha Rani. Evaluation of knowledge, attitude, and practice of medical and dental postgraduates toward reporting of adverse drug reactions in a teaching hospital, South India. Journal of Applied Pharmaceutical Science 2022; 12(09): 025-033.
34. Vaishnavi V, Vinita Mary A, Kesavan R, Sree Swaroopa L, Kaveya N, Hasina Begum N. Assessing Knowledge and Attitude of Dental Students and Staffs Towards Pharmacovigilance: A Cross-Sectional Pilot Study. Int J Pharma Sci Rev Res 2024; 84(1): 56-61.
35. Lucky Yadav, Pravesh Mehra, Diwakar Vasisth, Navraj Mattu, Krishna Biswas, Neelam Yadav. Assessment of Knowledge, Attitude, and Practice of Pharmacovigilance and Materiovigilance among Oral Health Practitioners in India. J Pharm Bioallied Sci. 2024 Feb 29;16(Suppl 1):S202–S205. doi: 10.4103/jpbs.jpbs_456_23.
36. Samira Rafieian Kopaei. Yellow card Report. Available from : https://www.linkedin.com/posts/samira-rafieian-kopaei_the-term-yellow-card-is-often-associated-activity-7157061594709995520-5WPT. Last accessed on 24th June 2026.
37. What is the Yellow Card in Pharmacovigilance?. Available from: https://www.ddregpharma.com/what-is-the-yellow-card-in-pharmacovigilance. Last accessed on 24th June 2026.
38. Blue Card Scheme in Pharmacovigilance. Available from: https://www.scribd.com/document/795876143/bits. Last accessed on 24th June 2026.
39. Vikas Maharshi, Pravesh Nagar. Comparison of online reporting systems and their compatibility check with respective adverse drug reaction reporting forms. Indian J Pharmacol. 2017 Sep-Oct;49(5):374–382. doi: 10.4103/ijp.IJP_733_16 .
40. Pharmacovigilance Programme of India. Indian Pharmacopenia Commission.PvPI Toolkit. Available from: https://ipc.gov.in/PvPI/toolkit.html. Last accessed on 25th June 2026.
41. Lavertu A, Vora B, Giacomini K, Rensi S. A new era in pharmacovigilance: Toward real-world data and digital monitoring. Clin Pharmacol Ther [Internet]. 2021;109(5):1197-202.
42. Council for International Organizations of Medical Sciences. CIOMS Working Group XIV: Artificial intelligence in pharmacovigilance [Internet]. Geneva: CIOMS; 2025.Available from: https://cioms.ch/publications/product/artificial-intelligence-in-pharmacovigilance/. Last accessed on 25 th June 2026.
43. Sarangi SS. Artificial intelligence in pharmacovigilance: emerging trends and future perspectives. Int J Sci Res Technol [Internet]. 2024 [cited 2026 Jun 25];5(2):45-53.
44. Mancini L, Troiano G, Guida A. Aesthetic lip filler augmentation is not free of adverse reactions: lack of evidence-based practice from a systematic review. Front Oral Health [Internet]. 2024;5:1495012.

Appendix-1

Questionnaire

Section I: Demographic Information

1.Name…….[Optional]

2. Age: □ <20 years □ 20–22 years □ 23–25 years □ >25 years

3. Gender: □ Male □ Female

4. Academic Level: □ Third BDS □ Final BDS □ Intern □ Postgraduate Student

Section II: Awareness of Pharmacovigilance Programs

5. Are you aware that any unintended or harmful response to a medicine used at normal doses is an Adverse Drug Reaction (ADR)?

□ Yes □ No

6. Are you aware that Antibiotics, NSAIDs and Local Anethetics which are commonly used in dentistry may cause adverse drug reactions (ADR)?

□ Yes □ No

7. Are you aware that different countries use different colour cards associated to ADR Reporting systems, such as yellow cards, blue cards, red cards/Red forms and Green cards?

□ Yes □ No

8. Are you aware that 'Drug-drug interactions can occur in dental practice?

□ Yes □ No

9. Are you aware of the Pharmacovigilance Programme of India (PvPI)?

□ Yes □ No

10. Are you aware that the prescribing dentist is responsible for reporting an ADR in the clinical setting?

□ Yes □ No

11. Are you aware that In India, the dental practitioner reports an ADR directly to National Pharmacovigilance Centre (PvPI)

□ Yes □ No

Section III: Knowledge of Drug Safety and Pharmacovigilance

12. Have you heard the term "Pharmacovigilance"?

□ Yes □ No

13. Do you know that Pharmacovigilance is primarily concerned with Drug safety monitoring?

□ Yes □ No

14. Do you know that the primary objective of Pharmacovigilance is to detect, assess, understand and prevent adverse effects of medicines and communicate findings in a timely manner.

□ Yes □ No

15. Do you know that World Health Organization (WHO)'s Programme for International Drug Monitoring [PIDM] defines Pharmacovigilance as the science and activities related to the detection, assessment, understanding, and prevention of adverse effects?

□ Yes □ No

16. The Pharmacovigilance Programme of India (PvPI) is co-ordinated by Central Drugs Standard Control Organisation (CDSCO) ?

□ Yes □ No

17. Do you think Anaphylaxis reaction is a serious ADR?

□ Yes □ No

18. Do you know that Red card/Red form is associated with ADR Reporting system in India

□ Yes □ No

19. Do you think ADR reporting contributes to patient safety?

□ Yes □ No

20. Do you know that ADRMS (Adverse Drug Monitoring System) portal or the ADR PvPI 2.0 mobile app, is an online tool used for reporting ADRs in India under the PvPI?

□ Yes □ No

Section IV: Attitude Toward Pharmacovigilance

Statement	Agree	Disagree
21. Pharmacovigilance should be included in the dental curriculum.	□	□
22. ADR reporting is a professional responsibility of dentists.	□	□
23. Reporting ADRs can improve patient safety.	□	□
24. Dental students should receive formal training in ADR reporting.	□	□
25. Pharmacovigilance should be integrated into routine dental practice.	□	□
26. Knowledge of drug interactions is essential for safe prescribing.	□	□