



ISSN Print: 2394-7500  
ISSN Online: 2394-5869  
Impact Factor: 5.2  
IJAR 2020; 6(9): 229-233  
[www.allresearchjournal.com](http://www.allresearchjournal.com)  
Received: 20-06-2020  
Accepted: 03-08-2020

**Kriti Garg**  
Department of Oral Medicine  
& Radiology, Rama  
University, Kanpur Uttar  
Pradesh, India

**Rohan Sachdev**  
Department of Public Health,  
UWA School of Population  
and Global Health, University  
of Western, Australia

**Samiksha Shwetam**  
Department of Oral Medicine  
& Radiology, Rama  
University, Kanpur, Uttar  
Pradesh, India

**Shubhra Saxena**  
Department of Oral Medicine  
& Radiology, Rama  
University, Kanpur, Uttar  
Pradesh, India

**Corresponding Author:**  
**Kriti Garg**  
Department of Oral Medicine  
& Radiology, Rama  
University, Kanpur Uttar  
Pradesh, India

## **Pharmacovigilance and adverse drug reaction: A study to evaluate how dental post graduate students and dental practitioners grasp the infrequent topic of dentistry in central Uttar Pradesh, India**

**Kriti Garg, Rohan Sachdev, Samiksha Shwetam and Shubhra Saxena**

DOI: <https://doi.org/10.22271/allresearch.2020.v6.i9d.7122>

### **Abstract**

Pharmacovigilance is a term of pharmacology which helps in the observation, evaluation, understanding, and prevention of adverse effects, mostly long-acting and short-acting adverse affect of various medicines. To assess the knowledge, attitude, and practices among dental students and professionals about pharmacovigilance and adverse drug reactions, a cross-sectional questionnaire study close-ended questioner based study among 190 dental postgraduate students and dental practitioners was performed. 47.8% postgraduates students and 37.1% dental practitioners knew pharmacovigilance while 85.5% postgraduates and 83.4% dental practitioners were unaware of adverse drug reactions. No postgraduate student and 96.6% dental practitioners were not trained to report adverse drug reactions. Insufficient knowledge about pharmacovigilance and poor application to use adverse drug reaction in clinical work was common and more academic exposure is required to increase awareness and safe use of drugs to save more lives of patients in a day to day practice.

**Keywords:** Adverse drug reactions, post graduate students, dental practitioners, pharmacovigilance

### **1. Introduction**

WHO describes pharmacovigilance (PV) as the science and activities related to the identification, assessment, awareness, and prevention of adverse effects or any other drug-related problem<sup>[1, 2]</sup>. WHO has described adverse drug reaction (ADR) as "a drug that is noxious and unintentional and occurs at doses usually used in humans for prophylaxis, treatment or therapy of a disease, or alteration of physiological function<sup>[3, 4, 5]</sup>."

Pharmacovigilance in India started in 1986, but India's National Pharmacovigilance Program (NPPV), sponsored by the World Bank and assisted by the WHO in 2005, became operational focusing mainly on adverse drug reactions<sup>[6, 7]</sup>. Any drug can be used according to safety and efficacy for a patient. Thus it has become important to identify and record adverse drug reaction results, and all health care workers should be encouraged to achieve this ability to ensure a healthier and effective use of the medication. Understanding how to report, and when to report an adverse drug reaction is critical for health care professionals<sup>[8]</sup>. Pharmacovigilance is known to medical professionals as jargon but to the dental community, it is somewhat new. This study examines the knowledge, behaviors, and activities of postgraduate dental students and dental practitioners about pharmacovigilance and adverse drug reactions.

### **2. Materials and Methods**

The study was directed at a dental college and with dental specialists of Kanpur, Uttar Pradesh, India in December 2019. An aggregate of 190 members was enrolled for the study, comprised of 69 postgraduate dental students (PGs) of dental college and 121 dental specialists of the city. This was a cross-sectional questionnaire-based examination; all members were evaluated for their insight, mentality, and practice of pharmacovigilance and unfavorable medication response (ADR). Members who addressed the questionnaire review from the start contact were enrolled for the investigation. The survey was made to gather the socioeconomics of the members like age, sex, assignment, their insight into

pharmacovigilance and ADR detailing, mentalities towards revealing and their act of pharmacovigilance. Every single imaginable recommendation was incorporated to improve ADR announcing and pharmacovigilance.

### 2.1 Ethical clearance and data collection

Institutional Ethics Committee endorsement was taken for the examination. The verbal consent of the participants was taken before they were permitted to answer the questionnaire. In the initial step, as indicated by the Indian Dental Association Practitioners list (Kanpur branch), every single dental expert was reached through the phone and clarified in a nutshell about the examination. Dental experts who consented to partake just enrolled for the examination and reasonable time was taken from them to meet. All the postgraduate's students of the dental college were enrolled for the study with the authorization of the particular head of department.

In the subsequent advance, the questionnaire was given and all participants were mentioned to answer to the study inside a half-hour at a solitary gathering time. Versatile and web use while noting the questionnaire was confined. The appropriately filled questionnaire was gathered by and by from all participants by guaranteeing that privately will be kept up.

### 2.2 Statistical analysis

Information gathered was examined utilizing the Statistical Package for Social Sciences (SPSS) programming variant 17 utilizing a spellbinding recurrence technique. Results are mentioned as frequency and percentages

### 3. Results and Discussion

Pharmacovigilance includes distinguishing proof of the reactions related with drugs and limiting the damage brought about by the medication. Regularly utilized medications by dental specialist in treatment of different oral and maxillofacial infection may incorporate non steroidal calming drugs, opiod analgesics, anti-toxins, steroids, multivitamins, anti-oxidants, carbamazepine and injectable medications like lignocain with or without adrenaline for nearby anaesthesia<sup>[9, 10]</sup>. Not so upkeep of records, absence of information and poor mentality among dental brotherhood is being dependable as a significant reason which can prompt more patients being presented to the destructive impacts of medications while experiencing treatment<sup>[11]</sup>. Most of information, demeanor and practice concentrates on pharmacovigilance and unfavorable medication revealing are done among clinical wellbeing experts and not very many investigations among dental experts. Hence the current study was done to evaluate information, demeanor and practices of pharmacovigilance and ADR revealing among 190 postgraduate dental students and dental specialists in Kanpur city. [Table-1]

It is a typical conviction that dental specialist have poor information about pharmcovigilance programe and its motivation. In our study 47.8% and 37.1% post graduates students and dental experts knew about definition while just 44.9% understudies and 70.2% dental specialists had the information about motivation behind pharmcovigilance [Table-2] which was discovered like the examination by Sudhakar *et al.* where 51% dental specialist were had the information about pharmcovigilance<sup>[12]</sup>. While in the study done by Jhadav An *et al.* and Sarfaraz AK *et al.* in an

extremely low proportion 17.9% and 27.5% separately, dental specialist knew about this term and its motivation<sup>[9, 13]</sup>. In the current study 85.5% postgraduate students and 83.4% dental specialists were know about the distinction between unfavorable medication reaction (ADR) and antagonistic medication impact [Table-2] which was discovered comparable 84.9% to concentrate by Jhadhav An *et al.*<sup>[9]</sup> Currently, ADR revealing framework isn't totally settled as India. In the current study just 13% postgraduates and 20.6% dental specialists knew about Central Drugs Standard Control Organization (CDSCO), India administrative body answerable for checking of unfavorable medication response, it is like investigation done by Jhadhav An *et al.* it is just 10.3%<sup>[9]</sup>.

Sarfaraz AK *et al.* in their research among dental experts found that absence of information and issues in disposition of dental specialists is available because of specific factors, for example, absence of mindfulness about antagonistic medication response announcing framework, deficient preparing to perceive unfavorable medication response, dread elements, dormancy and absence of expert obligations<sup>[13]</sup>. According to Sarfaraz *et al.* 65.5% of dental specialists discovered trouble to perceive whether ADR has happened or not and in Jhadav An *et al.* study this proportions was 60.4% while in Arjun *et al.* study it was 34.5%<sup>[9, 13, 14]</sup>. ADR acknowledgment discovered comparable in our examination 60.8% and 73.5% among postgraduates and dental professionals individually. [Table-3] While in study performed by Sudhakar *et al.* just 7% dental specialist have encountered ADRs, which is less in contrast with other studies<sup>[12]</sup>. In the investigations done by Gupta *et al.* 75.5%, Jhadhav An *et al.* 88.6%, Arjun *et al.* 72.3% and Sudhakar *et al.* 94% dental specialist concurred for the revealing of ADR in all cases<sup>[9, 12, 14, 15]</sup>. In this study 82.6% dental postgraduates and 78.5% dental experts were consented to report ADR in clinical practice which is like different examinations directed in different pieces of India.

The vast majority of the investigations set up that the fundamental explanation behind not detailing ADR are absence of information and preparing of announcing ADR. In the current investigation practically all members bolstered to incorporate pharmacovigilance and ADR programs in students study educational program to make more awareness<sup>[9]</sup>. All postgraduates and 96.6% dental specialists have never gotten any training about ADR detailing which is discovered like examination done by Jhadav An *et al.* 99.65 and Torawane *et al.* 100%, where no dental specialist has gotten any preparation for ADR<sup>[16]</sup>. In the current study just 3.3% dental professionals have gotten ADR revealing preparing which was discovered comparable 5.5% to contemplate directed by John *et al.*<sup>[17]</sup> Immense number of dental specialist is rehearsing in each city of India, still exceptionally less in number knows about ADR and its detailing framework. No dental postgraduate under study in our investigation announced ADR in their training, comparatively 98.3% dental experts of present examination never detailed, in spite of they have gone over the ADRs. [Table-4] Comparative outcomes were available in examines done by Sarfaraz *et al.* and Jhadhav An *et al.*<sup>[9, 13]</sup> 93.3% dental specialists of present examination have run over with ADR however they have never announced, like investigation done by Jadhav An *et al.* which was 65%<sup>[9]</sup>.

To give mindfulness among dental specialist different measures are available to improve the pharmacovigilance,

preceded with dental instruction (CDE) and preparing are most normally proposed. All members of the current investigation consented to go to different CDE and preparing programs while 94.2% dental postgraduates and 97.5% dental experts were consented to build the mindfulness educational program from ADR observing advisory group. [Table-5] Our examination results were like different investigations directed by Jhadhav *et al.*, Khan SA *et al.* and Hardeep *et al.* [9, 18, 19] In the present investigation 90.9% dental experts consented to put ADR master in emergency clinic/facilities while 78.5% consented to build up a different pharmacovigilance division in medical clinic/center. Further it has been reemphasized that there is a positive connection between's preparation of pharmacovigilance and ADR reporting [20]. The impediment of the current examination was being a limited report with less number of dental specialists and just dental

postgraduates were the members, we recommend a multi driven investigation that may give profound view about information, demeanor and practice of announcing ADR among dental specialists.

### 3.1 Tables

**Table 1:** Demographic distribution of all participants

Variation	Number (n) (190)	Percentage (%)
<b>Sex</b>		
Male	109	57.3%
Female	81	42.6%
<b>Education Status</b>		
Dental Post Graduates students	69	36.3%
Dental practitioners	121	63.6%

**Table 2:** The response of participant's knowledge toward pharmacovigilance and adverse drug reactions

Questions	Post graduates n=69(%)	Dental practitioners n=121(%)
<b>Definition of pharmacovigilance?</b>		
a) The science of ADR happening in a hospital	2(2.8%)	15(12.3%)
b) The process of improving the safety of drug	11(15.9%)	21(17.3%)
c) The detection, assessment, understanding and prevention of adverse effects.	23(33.3%)	40(33%)
d) The science reporting the type and incidence of ADR after drug is marketed.	33(47.8%)	45(37.1%)
<b>Purpose of pharmacovigilance is to evaluate?</b>		
a) Safety	31(44.9%)	85(70.2%)
b) Efficacy	20(28.9%)	25(20.6%)
c) Cost	12(17.3%)	9(7.4%)
d) None	6(8.6%)	2(1.6%)
<b>Pharmacovigilance includes</b>		
a) Drug related problems	29(42%)	86(70.4%)
b) Blood related problems	23(33.3%)	22(18.1%)
c) All of the above	11(15.9%)	10(8.2%)
d) None	6(8.6%)	3(2.4%)
<b>Is adverse drug reaction (ADR) and adverse drug effect is same?</b>		
a) Yes	10(14.4%)	20(16.5%)
b) No	59(85.5%)	101(83.4%)
<b>The commonly seen ADR such as headache, fever, vomiting has to be reported?</b>		
a) Yes	56(81.1%)	98(80.9%)
b) No	13(18.8%)	23(19%)
<b>In India regulatory body responsible for monitoring of adverse drug reaction?</b>		
a) Central Drugs Standard Control Organization(CDSCO)	9(13%)	25(20.6%)
b) Dental council of India	20(28.9%)	17(14%)
c) Pharmacy council of India	11(15.9%)	21(17.3%)
d) Food and Drug Administration	29(42%)	58(47.9%)

**Table 3:** The response of participant's attitude toward pharmacovigilance and adverse drug reactions

Questions	Post graduates n=69(%)	Dental practitioners n=121(%)
<b>The healthcare person responsible for reporting of ADR in hospital is/are?</b>		
a) Doctor	5(7.2%)	15(12.3%)
b) Pharmacist	11(15.9%)	20(16.5%)
c) Nurses	15(21.7%)	35(28.9%)
d) All of the above	38(55.0%)	51(42.1%)
<b>Which among the following factors discourage you from reporting and ADR??</b>		
a) Non remuneration for reporting	8(11.5%)	2(1.65%)
b) No time to report	12(17.3%)	25(20.6%)
c) A single unreported may not affect ADR database	7(10.1%)	5(4.13%)
d) Difficult to decide whether ADR has occurred or not	42(60.8%)	89(73.5%)
<b>Do you think reporting of ADR is necessary?</b>		
a) Yes	57(82.6%)	95(78.5%)
b) No	12(17.3%)	26(21.4%)
<b>Do you think pharmacovigilance should be taught in detail to all health professionals?</b>		
a) Yes	51(73.9%)	96(79.3%)

b)	No	18(26%)	25(20.6%)
<b>Financial help should be given to doctors for ADR reporting at hospitals/clinic</b>			
a)	Yes	69(100%)	102(84.2%)
b)	No	0	19(15.7%)
<b>Is there a need to include pharmacovigilance in undergraduate curriculum to create awareness among the new doctors?</b>			
a)	Yes	69(100%)	121(100%)
b)	No	0	0

A and D were most expected answer

**Table 4:** The response of participant's practice toward pharmacovigilance and adverse drug reactions

Questions		Post graduates n=69(%)	Dental practitioners n=121(%)
<b>Have you ever been trained on how to report ADR?</b>			
a)	Yes	0	4(3.3%)
b)	No	69(100%)	117(96.6%)
<b>Do you give ADR information to patients?</b>			
a)	Yes	9(13.0%)	11(9.0%)
b)	No	60(86.9%)	110(90.9%)
<b>Have you ever come across with an ADR?</b>			
a)	Yes	55(79.7%)	113(93.3%)
b)	No	14(20.2%)	8(6.6%)
<b>Have you reported ADR in any patient?</b>			
a)	Yes	0	2(1.6%)
b)	No	69(100%)	119(98.3%)
<b>Are you interested to learn ADR reporting?</b>			
a)	Yes	69(100%)	120(99.1%)
b)	No	0	1(0.8%)
<b>Have you visited any website for pharmacovigilance</b>			
a)	Yes	0	7(5.7%)
b)	No	69(100%)	114(94.2%)

**Table-5:** Measures suggested for improving the Pharmacovigilance and ADR reporting in dental field

Questions		Post graduates n=69(%)	Dental practitioners n=121(%)
<b>Workshops and training should be there</b>			
a)	Yes	69(100%)	121(100%)
b)	No	0	0
<b>Encouraging the feedback between patients, doctors and pharmacist of the drugs</b>			
a)	Yes	60(86.9%)	117(96.6%)
b)	No	9(13.0%)	4(3.30%)
<b>Increased awareness curriculum from ADR monitoring committee</b>			
a)	Yes	65(94.2%)	118(97.5%)
b)	No	4(5.7%)	3(2.5%)
<b>Encouragement from monitoring committee and heads of respective departments/clinics</b>			
a)	Yes	67(97.1%)	115(95.0%)
b)	No	2(2.8%)	6(4.9%)
<b>Encouraging online and/or telephone reporting</b>			
a)	Yes	69(100%)	121(100%)
b)	No	0	0
<b>More publicity of the reporting scheme</b>			
a)	Yes	67(97.1%)	121(100%)
b)	No	2(2.8%)	0
<b>Ask patients to report ADRs</b>			
a)	Yes	69(100%)	121(100%)
b)	No	0	0
<b>Having an ADR specialist in hospital/clinic</b>			
a)	Yes	69(100%)	110(90.9%)
b)	No	0	11(9.09%)
<b>Establishing a separate pharmacovigilance department in hospital/clinic</b>			
a)	Yes	61(88.4%)	95(78.5%)
b)	No	8(11.5%)	26(21.4%)

#### 4. Conclusion

It is important to disclose ADRs, and their significance is successfully conveyed to the society on whom dental skilled expertise and attitude have a significant impact. The lack of awareness and negative attitudes about pharmacovigilance

and ADR coverage will result in under-reporting by ADR. Dental postgraduates and dental practitioners in the present study were not adequately informed of pharmacovigilance and harmful drug monitoring processes and their role in the wellbeing of patients. The plurality of participants

demonstrated a constructive attitude to educating themselves on the monitoring framework for ADRs through continued education and training programs. So we proposed the Indian Dental Association introducing Continuing Dental Education (CDE) based pharmacovigilance services for private dental practitioners and students at the local, city, and dental college level.

## 5. References

1. [https://www.who.int/medicines/areas/quality\\_safety/safety\\_efficacy/pharmvigi/en/](https://www.who.int/medicines/areas/quality_safety/safety_efficacy/pharmvigi/en/)
2. Uma B, Shruti J, Radha Y, Gouri G. A Pharmacovigilance Study of Anti- Asthmatic Agents in Patients of Bronchial Asthma at a Tertiary Care Hospital. JCER. 2013; 1:26-30. [https://www.researchgate.net/publication/271126560\\_A\\_pharmacovigilance\\_study\\_of\\_antiasthmatic\\_agents\\_in\\_patients\\_of\\_bronchial\\_asthma\\_at\\_a\\_tertiary\\_care\\_hospital](https://www.researchgate.net/publication/271126560_A_pharmacovigilance_study_of_antiasthmatic_agents_in_patients_of_bronchial_asthma_at_a_tertiary_care_hospital)
3. Sharma S, Phadnis P, Gajbhiye S. Pharmacovigilance: Its Awareness and Impact Care Teaching Medical College in Central India Impact- Study in a Tertiary care Teaching Medical College in Central India. IJPRBS. 2013; 2:234-247.
4. Shuka SS, Gidwani B, Pandey R, Rao SP, Singh V, Vyas A *et al.* Importance of Pharmacovigilance in Indian Pharmaceutical Industry. AJP Sci. 2012; 2:04-08.
5. Soni R, Kesari B. A Review on Pharmacovigilance. Int. J. Pharm. Sci. Rev. Res. 2014; 26(2):237-241.
6. Jadhav S, Chakraborty G. Pharmacovigilance in India: Need of Hour. JAPHR. 2011; 1:01-03.
7. Amarnath S, Jaikumar S, Basalingappa S, Thulasimani M, Ramaswamy S. Pharmacovigilance for Health Care Professional Students. RJPBCS. 2013; 4:1204-1217.
8. Remesh A. Identifying the reasons for underreporting of ADR: A cross sectional survey. Res J Pharm Biol Chem sci. 2012; 3:1379-386. [https://www.rjpbcs.com/pdf/2012\\_3\(4\)/\[154\].pdf](https://www.rjpbcs.com/pdf/2012_3(4)/[154].pdf)
9. Jadhav A, Chandrikapure A, Tarte P. 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. MedPulse – International Journal of Dentistry 2017; 2(2):14-18. [https://www.medpulse.in/Dentistry/Article/Volume2Issue2/Dentistry\\_2\\_2\\_1.pdf](https://www.medpulse.in/Dentistry/Article/Volume2Issue2/Dentistry_2_2_1.pdf)
10. Kulkarni MD, Baig MS, Chandaliya KC, Doifode SM, Razvi SU, Sidhu NS *et al.* Knowledge, attitude and practice of pharmacovigilance among prescribers of government medical college and hospital, Aurangabad (Maharashtra). Int J Pharm Ther. 2013; 3(3):10-18.
11. Rakesh RCP, Adepu R. Design and implementation of adverse drug reaction reporting system in community pharmacies. Indian J Pharm. 2009; 2(2):32-7.
12. Sudhakar S, Madhavan A, Balasubramani S. Attitude of dentists toward pharmacovigilance and reporting adverse drug reactions: A cross-sectional study. JCRI. 2015; 2:242-247.
13. Sarfaraz AK, Goyal C, Tonpay SD. A study of knowledge, attitudes, and practice of dental doctors about adverse drug reaction reporting in a teaching hospital in India. Perspect Clin Res. 2015; 6(3):144–149.
14. Arjun TN, Sudhir H, Gouraha A, Jain S, Chavan K, Dayma A *et al.* Assessment of knowledge, attitude and practice related to pharmacovigilance among the healthcare professionals in a teaching hospital in central India: A questionnaire study. World J Pharm Pharm Sci. 2015; 4:785-799.
15. Gupta P, Udupa A. Adverse drug reaction reporting and pharmacovigilance: knowledge, attitudes and perspective amongst residence doctors. J. Pharm. Sci. Res. 2011; 3:1064-1069.
16. Torwane N, Hongal S, Abhishek G, Shubham J. Assessment of knowledge, attitude and practice related to pharmacovigilance among the healthcare professionals in teaching a teaching hospital in central India: a questionnaire study. WJPR. 2015; 4(04):785-799.
17. John LJ, Arifullah M, Cherriathu J, Sreedharan J. Reporting of adverse drug reactions: a study among clinicians. Journal of applied Pharmaceutical Sci, 2012; 2(6):135-139.
18. Khan SA, Goyal C, Chandel N, Rafi M. Knowledge, attitude and practice of doctors to adverse drug reaction reporting in a teaching hospital in India: an observational study. J Nat Sci Biol Med. 2013; 4:191-196.
19. Hardeep, Bajaj JK, Kumar R. A survey on the knowledge, attitude and practice of pharmacovigilance among the health care professionals in a teaching hospital in northern India. J Clin Diagn Res. 2013; 7:97-99.
20. Gupta SK, Nayak RP, Shivaranjani R, Vidyarthi SK. A questionnaire study on the knowledge, attitude, and the practice of pharmacovigilance among the healthcare professionals in a teaching hospital in south India. Perspect Clin Res. 2015; 6:45-52. [http://www.picronline.org/temp/PerspectClinRes6145-4583857\\_124358.pdf](http://www.picronline.org/temp/PerspectClinRes6145-4583857_124358.pdf)