GMR
The Original

ASSESSMENT OF KNOWLEDGE, ATTITUDE, AND PRACTICE REGARDING ADVERSE DRUG REACTION REPORTING AMONG DENTAL PROFESSIONALS: A QUESTIONNAIRE-BASED SURVEY

Dr.Vijay Wadhwan[1], Dr. Sanjana Malhotra[2*], Dr. Preeti Sharma[3], Dr. Ekta Vishnoi[4], Dr. Aanchal Jain[5], Dr. Bhuvi Tandon[6]

[1]Professor and Head, Department of Oral and Maxillofacial Pathology and Oral Microbiology, Subharti Dental College and Hospital, Swami Vivekanand Subharti University, Meerut, India, Email: pathogen@rediffmail.com,ORCID ID: 0000-0002-6394-9067
[2*]Junior Resident, Department of Oral and Maxillofacial Pathology and Oral Microbiology, Subharti Dental College and Hospital, Swami Vivekanand Subharti University, Meerut, India, Email: msanjana964@gmail.com,ORCID ID: 0009-0008-9635-0705
[3]Professor, Department of Oral and Maxillofacial Pathology and Oral Microbiology, Subharti Dental College and Hospital, Swami Vivekanand Subharti University, Meerut, India, Email: sharmaneepreeti@gmail.com,ORCID ID: 0000-0001-8673-7131
[4]Assistant Professor, Department of Oral and Maxillofacial Pathology and Oral Microbiology, Subharti Dental College and Hospital, Swami Vivekanand Subharti University, Meerut, India, Email: dr.ekta23@gmail.com, ORCID ID – 0000-0003-3186-4939
[5]Intern, Subharti Dental College and Hospital, Swami Vivekanand Subharti University, Meerut, India, Email: aanchalj3@gmail.com, ORCID ID-0009000634950081
[6]Intern, Subharti Dental College and Hospital, Swami Vivekanand Subharti University, Meerut, India, Email: bhuvi17tandon@gmail.com, ORCID ID-0009000344296827

ABSTRACT:
Background:ADRs are major contributor to morbidity in clinical practice and pharmacovigilance plays vital role in their detection and prevention. A lot of medicines are routinely used in dentistry, including analgesics and antibiotics, and it is important that patients are aware of ADR and that reports are made to ensure patient safety.
Methods: The study was of the cross-sectional type in which questionnaire was used with 98 clinically exposed dental undergraduates and postgraduates. The knowledge, attitude and practice regarding ADR reporting and Pharmacovigilance was evaluated using structured 10 item questionnaire.
Results: The majority of the participants were undergraduates (61.2%) and females (79.6%). Of the individuals who were able to correctly identify ADRs, 55.1% said they did not know about reporting systems, which was described as the biggest barrier by 90.8% of people. Overall, 91.8% highlighted the need for collective involvement of health care professionals in pharmacovigilance.
Conclusion: The study suggests that there is a moderate awareness among dental students regarding reporting of ADR and their knowledge of ADR systems is lacking. Enhancing Pharmacovigilance education and training is crucial for enhancing ADR reporting and patient safety.

KEYWORDS: Adverse drug reaction, pharmacovigilance, dental students, questionnaire survey, ADR reporting, patient safety

INTRODUCTION

Diseases have been modified in their treatment and prevention through newer medicines Adverse effects are however common cause of morbidity and mortality despite all their advantages, with medicines. Pharmacovigilance (PV) is the sum of activities related to the detection, assessment, understanding, and prevention of adverse drug reaction (ADRs) caused by drugs.[1]
It was defined as “any response to a drug that is noxious and unintended and occurs at doses used in man for the prophylaxis, diagnosis, or therapy of disease or for modification of physiological function.” It excludes adverse reactions due to drug overdose (poisoning), drug abuse, and therapeutic errors.[2]
Adverse drug reactions was defined by WHO as a response of a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of a disease or for the modification of physiological function.[3]
The prevalence of ADRs in dental practice has been documented to range from 5% to 10% among patients receiving dental care, indicating a considerable impact on treatment outcomes.[4]
Pharmacovigilance is about identification, gathering, assessment, monitoring, and avoidance of unfavourable drug effects experienced when taking pharmaceutical preparations. All health-care professionals including doctors, nurses, and pharmacists in India can file an ADR to the NCC, Ghaziabad. Health-care professionals should be alerted to the procedure for reporting and the location for reporting an ADR. The vital participation of health-care professionals in the pharmacovigilance program can enhance ADR reporting.[5] In recent times, reporting of ADRs has been the principal cause of withdrawal of numerous drugs, namely rofecoxib, cisapride, and terfenadine.[2]
The profession of dentistry is an important part of health care delivery system of India and enjoys sovereignty. Pharmacotherapy is one of most wonderful resources that can be used to treat and manage oral diseases, such as dental

abscess, periodontal diseases, opportunistic infections in oral cancer patients and many more, and it is never too late. The scope of oral pharmaceutical paraphernalia is expanding with the use of traditional and modern pharmaceuticals, and mixing different pharmaceuticals, day by day. Dentists prescribe various antibiotics, analgesics and anti-inflammatory medications and other remedies such as application of local anaesthetic for numerous dental procedures. The CDSCO set up a national PvPI for monitoring the ADRs and to provide drug safety reports to Uppsala WHO-ADR monitoring center in 2004, in India. To co-ordinate ADR monitoring throughout India, the Drug Controller General of India (DCGI) and Indian Council of Medical Research (ICMR) have established many peripheral Pharmacovigilance centers in various hospitals located in major Indian cities.[1] The risk of ADR cannot be overlooked in dentistry and dentists can be a vital source in reporting ADRs as they are equally distributed as that of medical professionals in the health care sector in the Indian scenario.[5]

This research aims to find dentists' knowledge, attitude and behaviour towards ADRs and Pharmacovigilance, to enhance the safety & care of patients. The positive attitude of the dentists is indicator of Pharmacovigilance could be incorporated in curriculum and in general practice. Information about barriers to reporting of ADRs might help identify potential solutions to overcome the specific barriers.

MATERIALS AND METHODOLOGY

The number of samples and the sampling method used during the survey is described. A total of 98 undergraduate and postgraduate dental students who were clinically exposed were selected for participation in the study. Convenience sampling was employed to recruit participants based on their availability and accessibility. Data collection was carried out using a structured, self-administered questionnaire consisting of 10 close-ended questions. Prior to the commencement of the study, ethical approval was obtained and informed consent was taken from all participants. The selected sample provided adequate data for meaningful statistical analysis and interpretation.

Questionnaire

1.WHO defines ADR as?
A. Any intended effect of drug at normal dose
B. Any noxious, unintended effect of a drug at normal dose
C. Any toxic effect after overdose
D. Any side effects occurring only during long-term use

2.In which month is Pharmacovigilance Week celebrated?
A. August
B. September
C. October
D. November

3.Under-reporting of ADR is mainly due to?
A. Lack of awareness about reporting system
B. No financial incentives
C. Difficulty in accessibility
D. Fear of patient’s reaction

4.Which tools are available for ADR reporting in India?
A. ADR reporting forms
B. PvPI mobile app
C. Toll-free helpline (1800-180-3024)
D. All of the above

5.Is it necessary to be certain that a medicine caused the adverse effect before reporting?
A. Yes, absolute certainty is required
B. No, suspicion is enough to report
C. Only after laboratory confirmation
D. Only if reported by two professionals

6.ADRs should be reported by healthcare professionals:
A. Only for serious reactions
B. Whenever suspected, even if details are incomplete
C. Only after confirmation by pharmaceutical company
D. Only for new medicines

7.In India, ADR reporting to the regulatory body should be done within:
A. 24 hours
B. 7 days
C. 15 days
D. 30 days

8.Are patients allowed to report ADRs independently?
A. Yes, through various reporting systems
B. No, only through healthcare providers
C. Only by mail to regulatory authorities
D. Only through their treating physician

9.Patient counselling about potential ADRs should be done:

A. Only for high-risk medications
B. Only when patients ask
C. Always, for all medications
D. Only for hospitalized patients

10.The success of pharmacovigilance programs depends on:

A. Participation of all healthcare professionals
B. Advanced technology only
C. Government funding only
D. Pharmaceutical company initiatives only

RESULTS

A total of 98 responses were calculated, of which 61.2% were undergraduate students and 38.8% were postgraduate students. Female participants constituted the majority of the study population (79.6%), while male participants accounted for 20.4%.

Assessment of knowledge regarding adverse drug reactions (ADRs) revealed that 55.1% of the participants correctly identified ADRs as "any noxious and unintended effect of a drug at normal dose," whereas 37.8% considered them as "any intended effect of a drug at normal dose." A majority of the participants (72.4%) were aware that Pharmacovigilance Week is observed in September.

Regarding the causes of under-reporting of ADRs, 90.8% of the participants attributed it to a lack of awareness about reporting system. Awareness regarding available ADR reporting tools in India was also measured, and it was found that 86.7% respondents correctly identified all the available tools such as ADR reporting forms, PvPI mobile application and toll-free helpline no. 1800-180-3024. 5.1% of them knew about the reporting forms, 6.1% knew about the PvPI mobile application and 2% knew about the toll-free helpline.

When asked about the degree of certainty needed to report an ADR, 49% said it needed to be certain while 44.9% said only if they suspected it was an ADR. In regards to the timing of ADR reporting, 71.4% said that an ADR should be reported when suspected, even if full details of the event were not available, and 25.5% said they should only be reported after confirmation by the pharmaceutical company.

Awareness on timeline for reporting ADR to the regulatory authority in India revealed that 58.2% felt that it should be done within 24 hours, 20.4% felt 7 days, 16.3% felt 15 days, and only 4.1% felt 30 days. The majority of participants knew that patients could report adverse drug reactions through multiple reporting methods (86.7%) with a smaller proportion of participants stating that ADRs can only be reported by the patient to a healthcare provider (6.1%) and via mail to regulatory authorities (5.1%).

Most dental professionals (86.1%) indicated that counselling the patient about possible ADRs is should be done for all medications.

Furthermore, 91.8% of the respondents believed that success of pharmacovigilance programs is based on active participation of all healthcare professionals, while only 4.1% each attributed success solely to advanced technology or pharmaceutical company initiatives.

DISCUSSION

The present questionnaire-based study was conducted to evaluate awareness of ADRs among dental professionals, with particular emphasis on undergraduate and postgraduate students. Pharmacovigilance and ADR reporting constitute an essential component of patient safety and rational drug therapy, especially in dentistry where antibiotics, analgesics, local anesthetics, and other medications are routinely prescribed. Adequate knowledge regarding identification and reporting of ADRs is therefore crucial for minimizing drug-related complications and improving healthcare outcomes.

In the present study, a total of 10 questionnaire-based questions were administered to assess the awareness regarding ADRs among dental undergraduates and postgraduates. Among the participants, undergraduate students constituted the majority (61.2%), while postgraduate students accounted for 38.8% of the study population. The higher participation of undergraduate students may reflect their greater accessibility and willingness to participate in academic survey-based studies.

ADR was defined as "any response to a drug that is noxious and unintended and occurs at doses used in man for the prophylaxis, diagnosis, or therapy of disease or for modification of physiological function." Pharmacovigilance is the science of detecting, collecting, assessing, monitoring and preventing adverse effects experienced by subjects following administration of pharmaceutical preparations. In India, all health-care professionals including doctors, nurses, and pharmacists can report an ADR to the National Coordination Centre, Ghaziabad.[2]

Underreporting of ADR by dentists is attributed to various aspects of knowledge and attitude of doctors. Numerous studies had already been done on ADR and its reporting in India. Previous studies stated that knowledge of health care providers regarding ADR and its reporting is very low but surprisingly we noticed that 48.9% of dentists participated wereaware of ADR and 62.5% of dentists were aware of ADR reporting which is quite satisfactory compared to other studies conducted in various parts of India.[3]

According to sarfaraaz et al.6 18.9% of dental doctors were of ADR monitoring body whereas according to our study 46.8% of dentists were aware about central drug standard control association, as monitoring body for ADR in India.

According to the results obtained in the present study, the major reason for under-reporting of adverse drug reactions was found to be lack of awareness regarding the ADR reporting system, as reported by 90.8% of the participants. Osoro et al. in (2025)[7] reported that the major barrier for underreporting of adverse drug reactions was lack of understanding of the ADR reporting mechanism, which was observed among 52% of healthcare professionals. The authors also emphasized

that inadequate awareness regarding pharmacovigilance systems significantly affects ADR reporting practices and highlighted the need for continuous medical education and training programs to improve reporting behaviour.

A majority of the participants (71.4%) agreed that adverse drug reactions should be reported by healthcare professionals whenever suspected, even in cases where complete details regarding the reaction are unavailable. Matlala et al in (2023)[8] demonstrated that incomplete reporting remains a major limitation in pharmacovigilance systems. The authors reported that only 11.3% of ADR reports were considered well documented, while crucial information such as time-to-onset of reaction was missing in 52.82% of reports, significantly affecting the quality and causality assessment of ADR reporting.

According to findings of the present survey, 86.7% of the participants were aware that patients can independently report adverse drug reactions through various pharmacovigilance reporting systems. Shafei et al. in (2023)[9] patients and the public can report adverse drug reactions through multiple pharmacovigilance reporting systems, including national online reporting portals, mobile applications, telephone helplines, paper-based reporting forms, community pharmacies, and direct reporting to healthcare professionals or regulatory authorities. The authors emphasized that easy accessibility and awareness of these reporting systems enhance patient participation in ADR monitoring and strengthen overall drug safety surveillance.

The results of present study revealed that 91.8% of participants agreed that success of pharmacovigilance programs largely depends on active participation and collaborative involvement of all healthcare professionals in adverse drug reaction reporting. Alshammari et al. in (2023)[10] emphasized that active participation of all healthcare professionals is essential for an effective pharmacovigilance system and successful adverse drug reaction reporting. They noted that lack of involvement and insufficient knowledge of healthcare workers play a significant role in underreporting of ADRs, emphasizing the need for continuing training, awareness and a proactive approach to the entire team involved to enhance drug safety monitoring.

The observations mentioned above indicate the critical role of including ADR reporting and pharmacovigilance education in the under-graduate training program of healthcare professionals. These topics could be integrated into pharmacovigilance education and training, with the necessary theoretical knowledge and practical exposure to this field can be enhanced by visiting nearby pharmacovigilance centers and training on ADR data handling and reporting procedures. Moreover, seminars, group discussions, workshops and continuing medical education (CME) programs can be an important element in raising awareness and motivating active reporting of ADR. The provision of educational programmes like this would enable future healthcare workers to appreciate that many ADRs can be avoided and that reporting in a timely fashion makes an important contribution to patient safety as well as enhancing the healthcare system and minimizing economic burden on patients by adopting suitable regulatory measures.

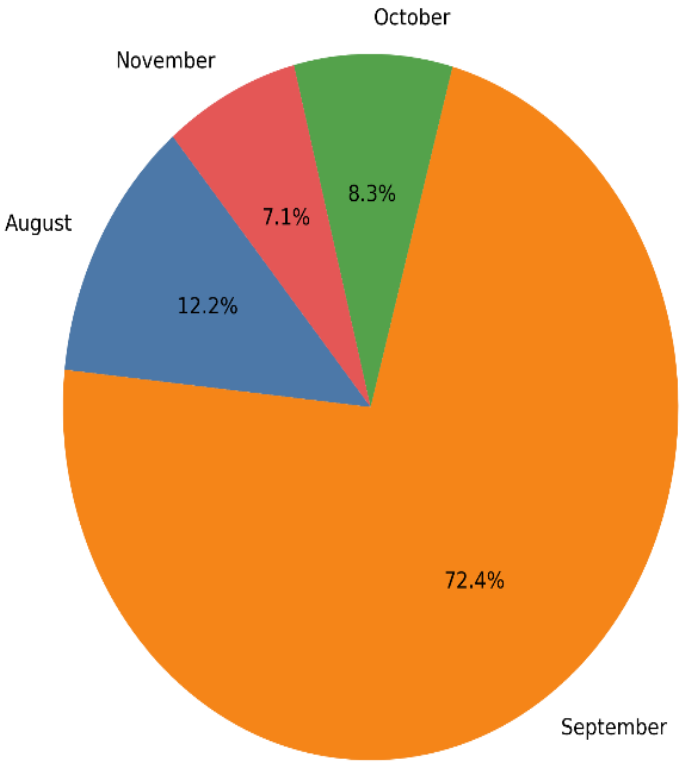

Figure 1: Month of Pharmacovigilance Week Celebration

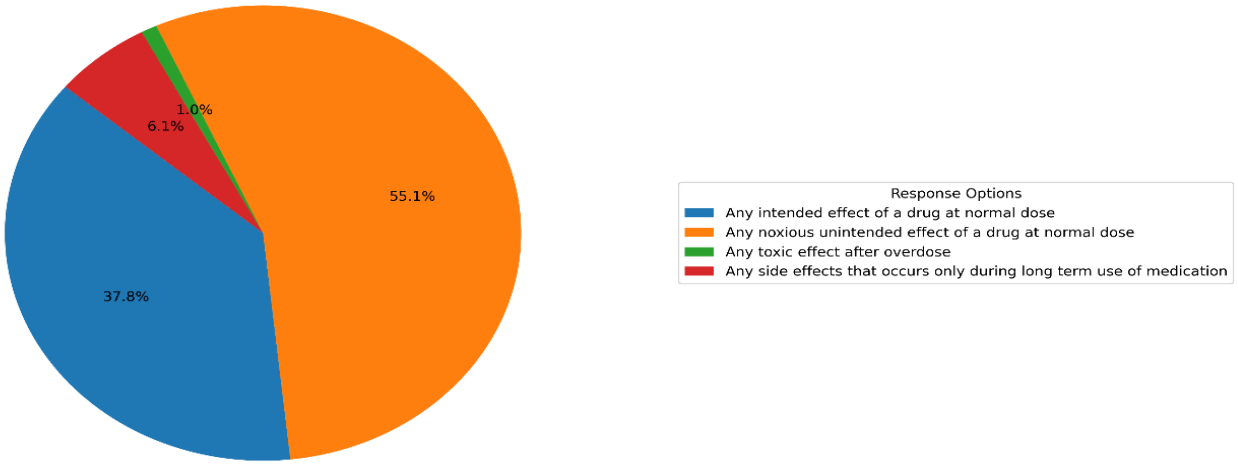

Figure 2: WHO Defines ADR as

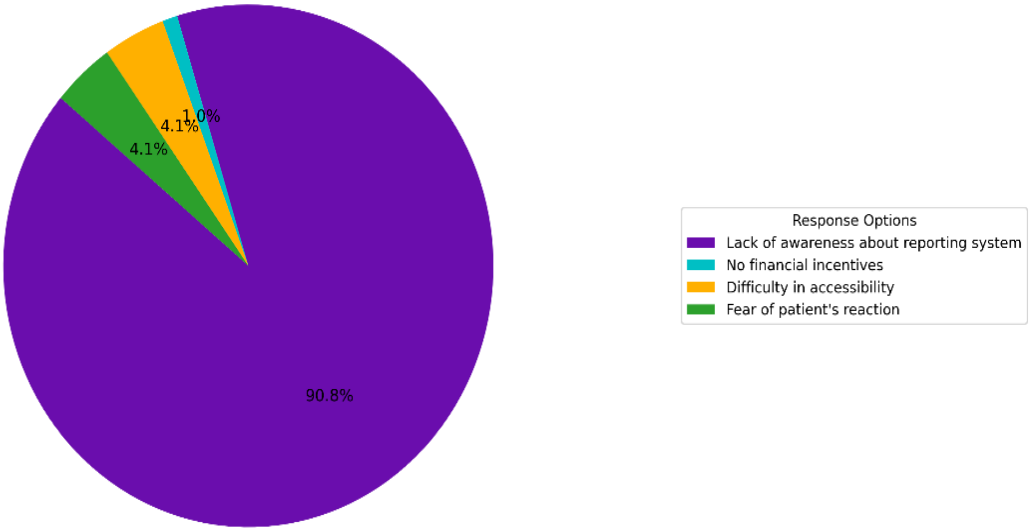

Figure 3: Under Reporting of ADR is Mainly Due To

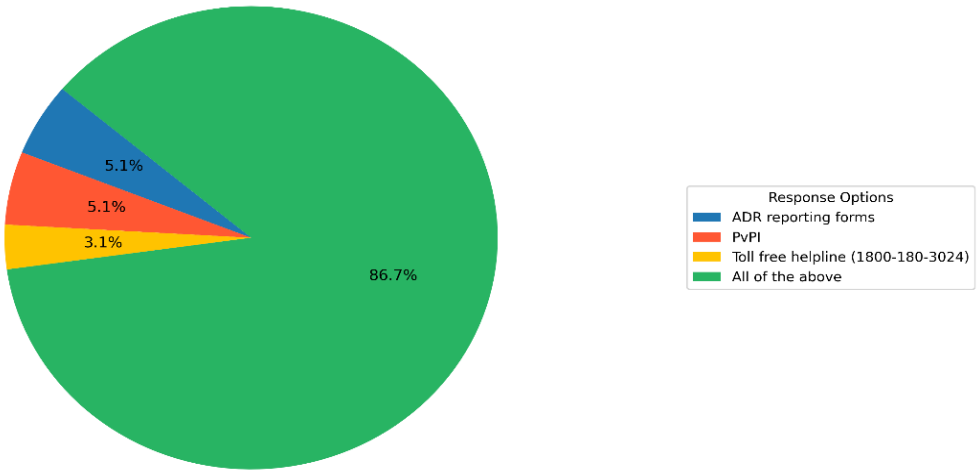

Figure 4: Tools Available for ADR Reporting in India

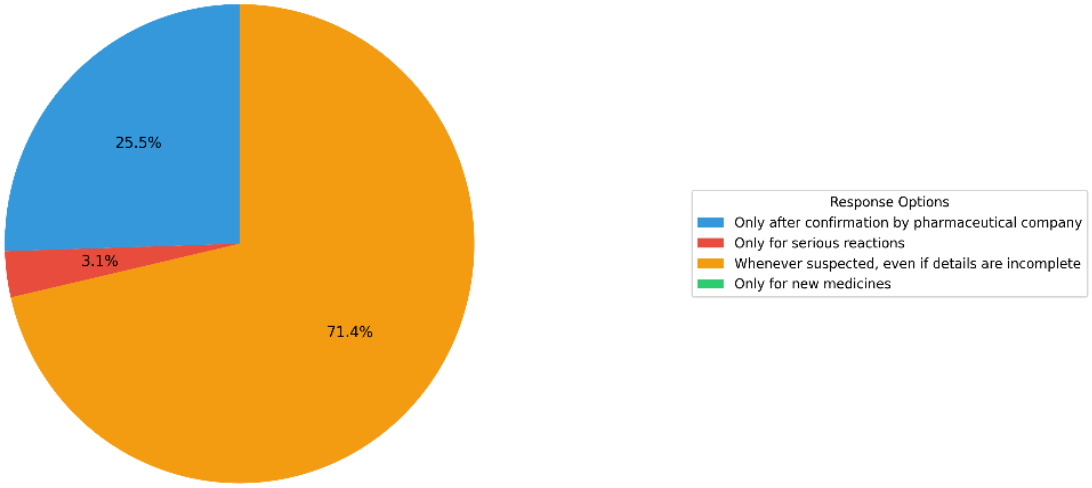

Figure 5: ADR Should Be Reported by Health Care Professionals

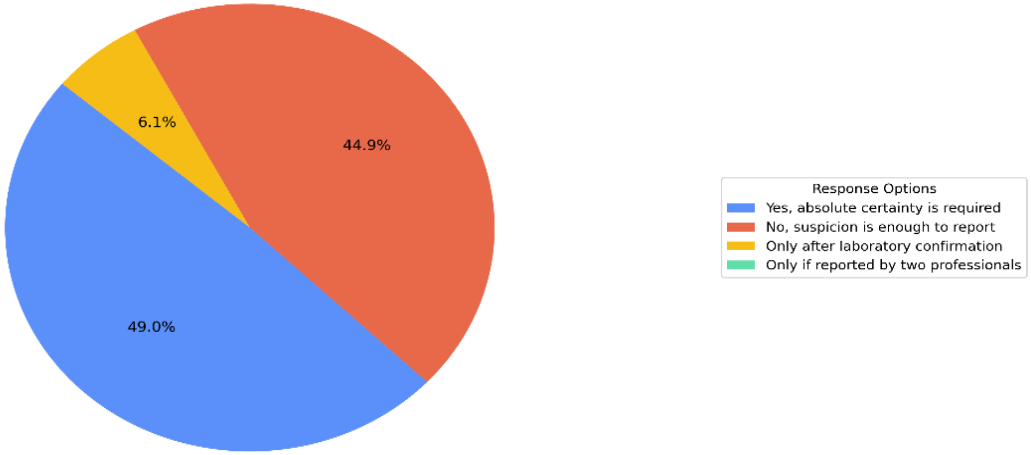

Figure 6: Necessity of Certainty Before ADR Reporting

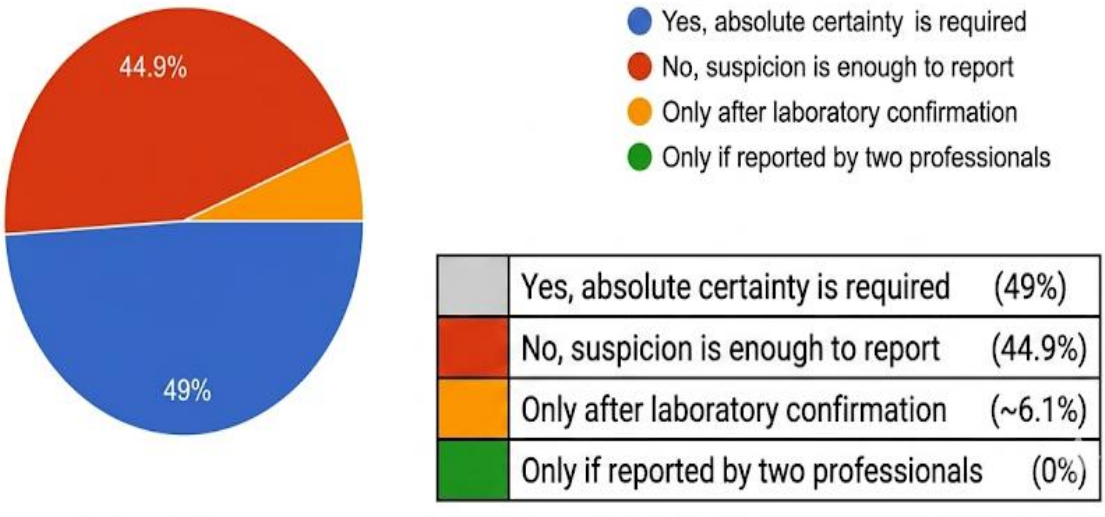

Figure 7: Is it necessary to be certain that a medicine caused the adverse effect before reporting?

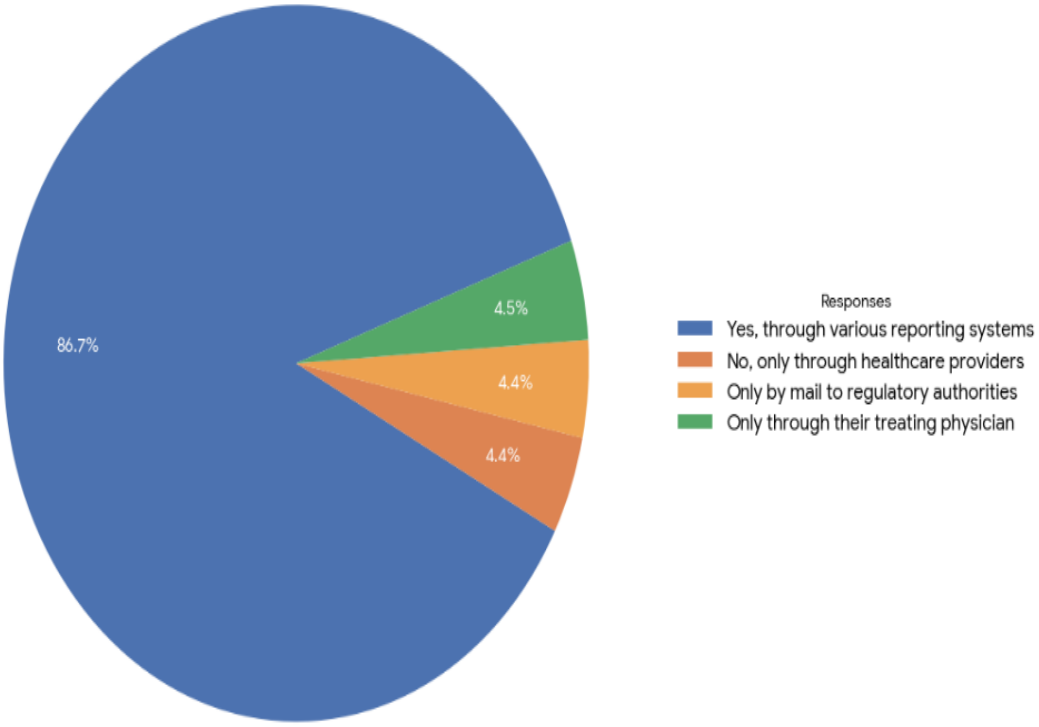

Figure 8: Are patients allowed to report ADRs independently? (n=98 responses)

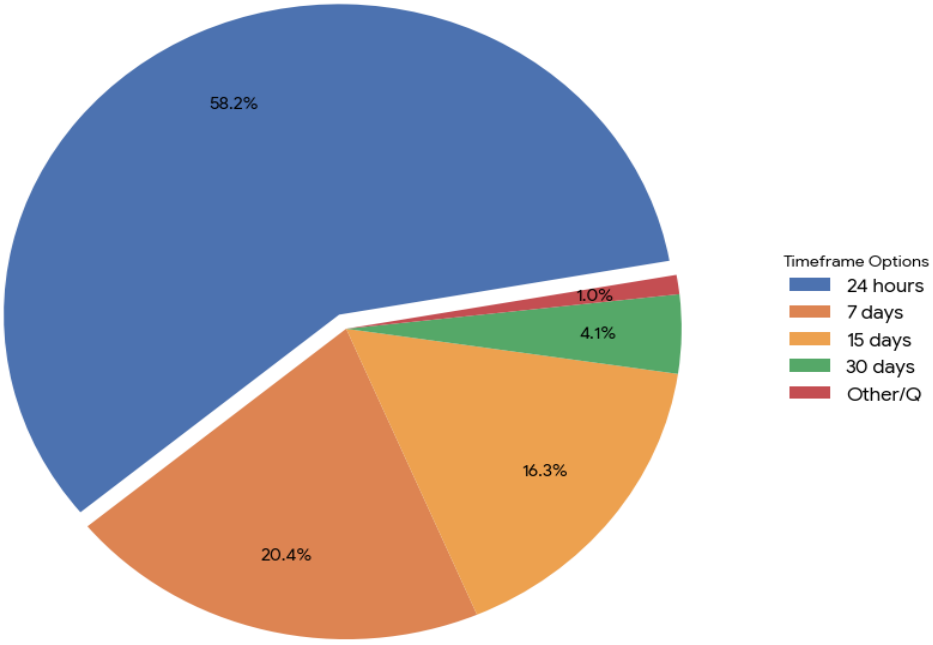

Figure 9: In India, ADR reporting to regulatory body should be done within

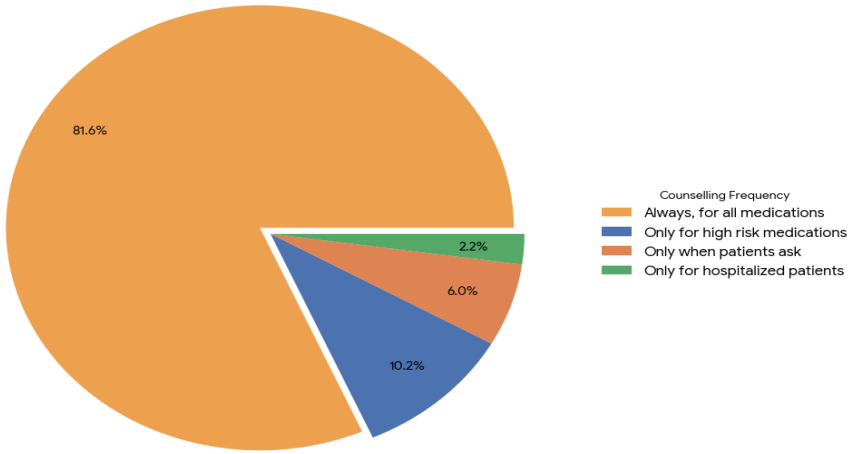

Figure 10: Patient counselling about potential ADRs should be done

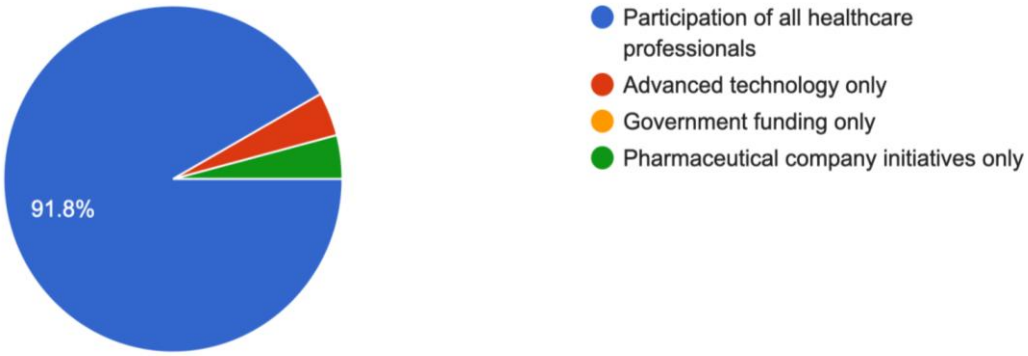

Figure 11: The success of pharmacovigilance programmes depends on

CONCLUSION

The present study revealed moderate awareness level regarding reporting of ADR among dental students and underreporting was mainly due to lack of knowledge of reporting systems and inadequate hands-on experience. The participants were found to be positive towards reporting of ADR, however there is lack of knowledge to translate the knowledge into practice as evidenced in this study, which calls for more robust pharmacovigilance education in undergraduate curriculum. A combination of structured theoretical training and hands-on training and ongoing professional development initiatives will substantially help to improve reporting behaviour and improve patient safety.

These findings are corroborated by published literature, which highlights that poor knowledge of the reporting procedures for ADR and documentation practices are still a major problem in pharmacovigilance. It has been also found that enhancing the accessibility of reporting tools, strengthening educational interventions and enabling all healthcare practitioners to participate actively in reporting culture are key to the enhancement of reporting culture in ADR. All the above findings suggest that good pharmacovigilance is not only a matter of awareness but also of organized training, streamlined reporting systems and active involvement of all stakeholders in the healthcare system.

DECLARATIONS

- **Ethical statement:** SMC/UECM/2026/1567
- **Consent for Publication:** Not applicable
- **Conflict of interest:** The authors declare no Conflict of interest
- **Funding statement:** No funding was received
- **AI statement:** No AI was used for manuscript writing.

Acknowledgements

None.

REFERENCES

1. Srinivas M, Sharma SN, Holla R. Knowledge, attitude and practice of medical professionals towards adverse drug reaction reporting and pharmacovigilance in a tertiary care hospital: a cross sectional study. Int J Basic Clin Pharmacol. 2018;7(5):970-975.

2. Pokala N, Sayeli V, Rayam S. A cross-sectional study to assess the knowledge attitude practice of pharmacovigilance among the dentists in an Indian tertiary care teaching dental hospital in South India. Asian J Pharm Clin Res. 2023;16(12):198-202.
3. Menga LSS, Laxmi V. Evaluation of knowledge regarding adverse drug reaction and its reporting among dentists in GDC, Hyderabad: a KAP study. Int J Sci Res. 2020;9(1):690-692.
4. Halling F, Lutz R, Meisgeier A. Trends in adverse drug reaction reporting by dentists: a 15-year analysis of German pharmacovigilance data. Clin Oral Investig. 2026;30:204.
5. Chhabra KG, Sharma A, Chhabra C, Reddy JJ, Deolia SG, Mittal Y. 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 Contemp Dent Pract. 2017;18(10):964-969.
6. Sarfaraz A, Chhaya G, 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.
7. Osoro IN, Suhaib KP, Rani JR, Rajanandh MG. Barriers to and facilitators of healthcare professionals in ADR reporting in a tertiary care hospital in India. BMC Health Serv Res. 2025;25(1):166.
8. Matlala MF, Lubbe MS, Steyn H. The completeness of adverse drug reaction reports in South Africa: an analysis in VigiBase®. Afr J Prim Health Care Fam Med. 2023;15(1):3659.
9. Shafei L, Khalili H, Dashti-Khavidaki S. Factors that influence patient and public adverse drug reaction reporting: a systematic review using the theoretical domains framework. Health Expect. 2023;45(4):801-813.
10. Alshammari TM, Almodaimegh HS, Alhawassi TM, et al. Evaluation of health care professionals' knowledge, attitudes, practices and barriers to pharmacovigilance and adverse drug reaction reporting: a cross-sectional multicentral study. PLoS One. 2023;18(5):e0285811.