# Knowledge, attitude, practices, and barriers regarding pharmacovigilance and adverse drug reaction reporting among medical and dental faculties of the teaching hospitals in Bhubaneswar City

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**Abstract:**

**AIM:** To assess the knowledge, attitude, practices (KAP), and barriers regarding pharmacovigilance and adverse drug reaction (ADR) reporting among medical and dental faculties of the teaching hospitals.

**METHODOLOGY:** This study was conducted for a period of 3 months among medical and dental faculties. A self-structured, 42-item closed-ended questionnaire based on pharmacovigilance and ADR reporting was used in this study. Data were analyzed using Statistical Package for the Social Sciences Version 21. All the items of the domains along with demographic variables were summarized as absolute and relative frequencies. Intergroup comparison was done using Kruskal–Wallis test and Mann–Whitney $U$-test. The correlation between the domains was assessed by Spearman correlation coefficient.

**RESULTS:** Among the study subjects, 272 (60.4%) were females and 178 (39.6%) were males. The number of medical and dental faculties was 360 (80%) and 90 (20%), respectively. The mean KAP scores for medical and dental faculties were 7.58 and 5.37, 8.78 and 6.01, and 6.91 and 6.32, respectively. The Spearman correlation coefficient ($\rho$) was found to be significant for knowledge–attitude and knowledge–practice domains. The values obtained between attitude with practice and barrier also were significantly correlated.

**CONCLUSION:** Our study findings advocate that although 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.

**Keywords:**
Adverse drug reaction, dental, medical, pharmacovigilance

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## Introduction

As said by Sir William Osler, "Medicine is a science of uncertainty and an art of probability." This statement well captures the complex nature of clinical medicine.

Since time immemorial, medicines have been proven to be effective in the prevention and treatment of diseases; however, on the other hand, they are also a threat as people may fall prey to deleterious drug reactions.

According to the World Health Organization, adverse drug reactions (ADRs) are noxious and unwanted effects produced by the drug when it is applied for the ailment of disease or diagnosis.[1]

The first international effort to address drug safety issues was initiated in 1961 after the disaster caused by thalidomide. At that time, thousands of congenitally deformed infants were born as a result of exposure in the uterus to an unsafe medicine promoted for use by the pregnant mothers.[2] The Sixteenth World Assembly (1963) adopted a resolution for early spreading out of information on ADRs, leading to the creation of the WHO Pilot Research Project for International Drug Monitoring in 1968. From this emerged "Pharmacovigilance" into the world of healthcare.

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other possible drug-related problems.[3,4] The most vulnerable population groups to ADRs are children, pregnant women, elderly, and the diseased. Hence, adequate information regarding drug safety should be conveyed through pharmacovigilance programs.[5]

The current global network of pharmacovigilance has been strengthened with the establishment of programs and centers for drug monitoring in most of the countries. Despite progress, the burden of ADRs on public health remains significant.[2]

Previous studies conducted on trends in emergency hospital admissions due to ADRs inferred that the total number of hospital admissions increased by 12.1%, i.e., 5,010,670 in 2008–2009 to 5,615,707 in 2014–2015.[6] Similarly, it was observed that among 529 prescriptions, ADRs were suspected in 287 patients in a study carried out in a tertiary care hospital in West Bengal.[7]

Medical and dental professionals play a significant role in the functioning of the healthcare delivery system. Hence, the risk of ADRs cannot be ignored in this field and their contribution in improving spontaneous reporting cannot be underestimated. The success of pharmacovigilance depends on cooperative and motivated prescribers. Under-reporting of ADRs by prescribers is a common problem.[8]

To boost spontaneous reporting by healthcare providers, ADR monitoring centers are being established across the country under the Pharmacovigilance Programme of India. However, under-reporting remains a major challenge, thereby delaying detection of serious drug reactions and causing danger to the public at large.[9] It is estimated that only 6%–10% of all ADRs are reported globally.[10]

Studies have been done previously on this topic among the medical professionals in India, but there is a dearth of information regarding the awareness of the pharmacovigilance program and the incidence of ADR reporting among the dental fraternity. Extensive research on drug safety and monitoring is the need of the hour of the healthcare system. The present study therefore proposed to evaluate the knowledge, attitude, and practice (KAP) of pharmacovigilance and ADRs and to explore the barriers preventing its reporting among the medical and dental faculties of the teaching hospitals in Bhubaneswar through a questionnaire survey.

## Methodology

A cross-sectional, questionnaire study was conducted among the medical and dental faculties working in the six teaching hospitals in Bhubaneswar city for a period of 3 months (April 2019–June 2019). Universal sampling technique was followed, and a total of 450 faculties had given the consent to participate. The study was approved by the institute ethics committee (KIMS/KIIT/IEC/605/2019).

A self-structured closed-ended questionnaire based on pharmacovigilance and ADR reporting was developed. The construct of the questions was checked by five subject experts. The content validity was tested by a panel of five experts, including two dentists, a medical professional, a biostatistician, and a professor from the Department of Pharmacology. Before data collection, a pilot study was conducted and questions that were reported to be difficult were re-framed. The reliability coefficient (Cronbach's alpha – α) was found to be 0.703, 0.837, 0.739, and 0.844 for KAP and barriers, respectively.

Sociodemographic data (age of the participant, gender, specialty, and years of experience) were obtained. A total of 15, 13, 9, and 5 items assessed participants' KAP and barriers toward pharmacovigilance and ADR reporting. Knowledge-domain questions had multiple options where each correct answer was given a score of 1 and wrong/not attempted was scored as 0. Attitude was assessed on a 5-point Likert scale (strongly agree, agree, don't know, disagree, strongly disagree) ranging from +2 to −2. Reverse coding was followed for negatively framed questions. Practice of ADR reporting among the participants was assessed through questions that had options as yes/no, except for question numbers 30 and 33 which had multiple options. Barriers preventing ADR reporting were also evaluated on a 5-point Likert scale (ranging from strongly agree to strongly disagree).

Training and calibration of the examiner and recording assistant was carried out in the department, prior to the study under the supervision of the guide. The questionnaire was manually distributed among the participants. The instructions to fill the questionnaire were given by the investigator and were collected back from each participant on the same day.

## Statistical analysis

Data were entered into Microsoft Excel and analyzed using Statistical Package for the Social Sciences (SPSS) version 21.0, IBM, USA. All the items of KAP and barrier domains along with demographic variables were summarized as absolute and relative frequencies. KAP and barrier scores were also summarized as mean and standard deviation. Intergroup comparison of the domains was done using Kruskal–Wallis test and Mann–Whitney *U*-test. The correlation between the domains was assessed by Spearman correlation coefficient, and the level for statistical significance was set at 0.05.

## Results

A total of 450 subjects participated in the study, out of which 272 (60.4%) were females and 178 (39.6%) were males; 360 (80%) were medical faculties and 90 (20%) dental faculties; 132 (29.3%) had a professional work experience of 0–5 years, 168 (37.3%) 5–10 years, and 150 (33.3%) more than 10 years. The mean age of the study participants was 42.29 years [Figure 1].

Table 1 shows the relationship between the demographic characteristic of the study participants and mean KAP and barriers regarding pharmacovigilance and ADR reporting. The mean attitude, practice, and barrier scores were significantly ($P < 0.0001$) higher among female respondents (9.58, 7.18, and 17.83). Among the two specialties, the mean knowledge score was significantly ($P < 0.0001$) higher among medical faculties as compared to dental faculties (7.58). Mean attitude score was significant ($P = 0.002$) and higher in medical faculties than in dental faculties. Among all the respondents,
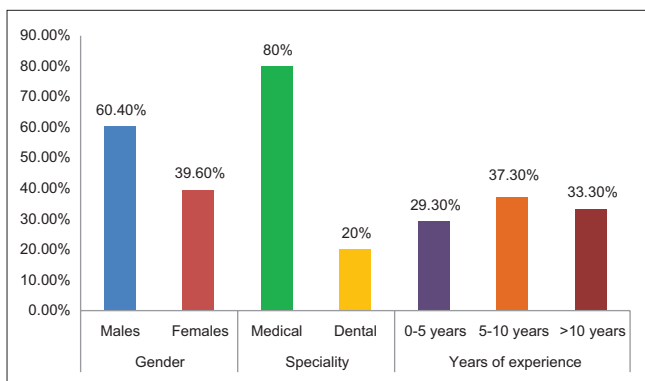
the mean knowledge score was significant ($P = 0.002$) and higher in those with 5–10 years of experience (7.46) whereas the mean attitude, practice, and barrier scores were significantly higher ($P < 0.0001$) in those who had an experience of >10 years (12.39, 7.43, and 18.25).

A correlation analysis was done using Spearman correlation coefficient, and it was found to be significant when knowledge was compared with attitude and practice domains ($P < 0.0001$). Significant results were also obtained when attitude was compared with practice, attitude with barrier, and practice with barrier, respectively ($P < 0.0001$) [Table 2].

## Discussion

Pharmacovigilance aims to improve patient care and safety and advancement in public health and contributes to the assessment of benefit, harm, and effectiveness of medicines. Within the last decade, there has been a growing awareness that the scope of pharmacovigilance should be extended beyond the strict confines of detecting new signals of safety concerns.[2,11] The present study was conducted with the objective of evaluating the KAP regarding pharmacovigilance and the barriers preventing ADR reporting among medical and dental professionals.

In the present study, 60.4% of the participants were females and 39.6% of them were males, out of which 80% were medical faculties and 20% were dental faculties. Similar findings were obtained in a study in which females comprised of 62.3% of the total study population.[12] Females are more in number in the healthcare sector as it is believed that they have more empathy towards patients. In a study done by Tsugawa *et al.*, it was seen that elderly hospitalized patients treated by female internists had lower mortality and readmissions compared with those cared for by male internists.[13]

It can be seen that the mean knowledge score was higher in medical faculties as compared to the dental faculties. Similar results were observed in the studies done by Kumar *et al.* and Torwane *et al.* This could be because of pharmacovigilance not being an integral part of the dental education curriculum.[14,15] The mean knowledge score for participants with the experience 0–5 years and 5–10 years was higher than the mean of those with an experience of >10 years. This might be due to the fact that those doctors who have recently graduated or started their clinical practice are well versed with the system of pharmacovigilance due to continuous changes and developments in the programs along with seminars and workshops being organized. On the contrary, in another study carried out by Kumar Damodar *et al.*, respondents



**Figure 1:** Demographic characteristics of the respondents

**Table 1: Demographics of respondents and relationship between the mean knowledge, attitude, and practices and barrier scores**

| Demographic variable | n | Mean knowledge score (SD) | P | Mean attitude score (SD) | P | Mean practice score (SD) | P | Mean barrier score (SD) | P |
|---|---|---|---|---|---|---|---|---|---|
| Gender | | | | | | | | | |
| Male | 272 | 7.01 (2.83) | 0.390 | 9.58 (9.85) | <0.0001** | 7.18 (2.62) | <0.0001** | 17.83 (4.91) | <0.0001** |
| Female | 178 | 7.33 (2.51) | | 6.17 (7.71) | | 6.20 (2.05) | | 14.89 (4.69) | |
| Specialty | | | | | | | | | |
| Medical | 360 | 7.58 (2.54) | <0.0001** | 8.79 (9.69) | 0.002* | 6.91 (2.54) | 0.073 | 16.82 (5.30) | 0.142 |
| Dental | 90 | 5.37 (2.64) | | 6.01 (6.54) | | 6.32 (2.04) | | 16.07 (3.73) | |
| Years of experience | | | | | | | | | |
| 0-5 | 132 | 7.40 (2.57) | 0.002* | 5.61 (7.29) | <0.0001** | 7.11 (2.13) | <0.0001** | 16.47 (4.98) | <0.0001** |
| 5-10 | 168 | 7.46 (2.76) | | 6.58 (8.47) | | 5.98 (2.27) | | 15.42 (5.02) | |
| >10 | 150 | 6.55 (2.69) | | 12.39 (10.09) | | 7.43 (2.69) | | 18.25 (4.68) | |

*Significant, **Highly significant. SD=Standard deviation

**Table 2: Spearman correlation coefficient between knowledge, attitude, practices, and barriers**

| ρ and P | Knowledge and attitude | Knowledge and practice | Knowledge and barrier | Attitude and practice | Attitude and barrier | Practice and barrier |
|---|---|---|---|---|---|---|
| Spearman correlation coefficient | 0.203 | 0.392 | 0.056 | 0.428 | 0.535 | 0.465 |
| P | <0.0001** | <0.0001** | 0.233 | <0.0001** | <0.0001** | <0.0001** |

*Significant, **Highly significant

who had more than 10 years' experience were more knowledgeable as compared to those with 5–10 years' and below 5 years' experience, with the results being statistically significant (*P* < 0.05).[16]

The mean attitude scores for medical faculties was higher than the dental faculties (*P* = 0.002). However, a mean score of 6.01 among the dental participants implies that if proper training is imparted to them, there would be an improvement in ADR reporting. Similar findings were seen in a study done by Khan *et al*. on dental doctors in which it was suggested that there is a need for education and training of dentists about ADRs from identifying the cases to reporting them.[17]

It was observed that the mean scores for attitude between males and females were 9.58 and 6.17 (*P* < 0.0001). The findings were analogous to a study done among healthcare professionals in Tamil Nadu, where male respondents were more aware about ADR reporting (18.4%) as compared to female respondents (13.8%).[16] When compared on the basis of years of experience, it was seen that the mean attitude score was higher among subjects with an experience of >10 years (12.39). Similarly, in a study conducted among doctors in a tertiary care teaching hospital in Western India, significant result was obtained on analyzing the association between years of academic experience and attitude toward ADR reporting (*P* = 0.0147).[18]

The barriers preventing ADR reporting found in the present study are concerns that the report might turn out to be wrong (34.9%), limited knowledge of the

participants (43.8%), limited literature available on the subject (42.2%), lack of confidence to discuss the cases encountered (44%), and fear of the report having a negative impact on the company (28.5%). In another study carried out by Al Rabayah *et al*., it was observed that not knowing the reporting rules (37.58%), lack of training (37.58%), and lack of time (30.71%) were the most common barriers.[19] These barriers could be removed by updating the knowledge of healthcare professionals regarding ADR reporting and that such reactions are part of the natural course of treatment, and they will not be held responsible for any such incidences.

From the current study, it was noticed that there is a significant positive correlation when knowledge was compared with attitude, which implies that the participants with adequate knowledge regarding pharmacovigilance have a positive attitude toward ADR reporting. The correlation between knowledge and practice was also statistically significant (*P* < 0.0001), indicating that a professional with good knowledge would devote for a better clinical practice. Similar results were seen in another study carried out to assess KAP among the healthcare professionals; there was a significant positive correlation between training of pharmacovigilance and reporting of an ADR (*r* = 0.327, *n* = 101, *P* < 0.0001).[20] The correlation coefficient was also found to be significant when attitude was compared with practice and barrier domains. This points toward the fact that medical and dental practitioners with a positive attitude and sound clinical practice are not being able to report, due to the barriers preventing the system of ADR reporting.

Our study findings advocate that although medical faculties have better knowledge about pharmacovigilance and ADR reporting, dentists also 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 curriculum as a part of their study. Healthcare professionals should be encouraged to report all suspected ADRs, and regular trainings should be conducted to raise the awareness of the pharmacovigilance programs through communications and advertisements.

## Limitations

Although this was a multicenter study, the ratio of medical and dental faculties was not proportionate as there are a less number of registered dentists working in the teaching hospitals in Bhubaneswar city.

Since this was a cross-sectional, questionnaire study, there is a possibility of bias associated with closed-ended questions and Likert scales as the participants might prefer marking the positive response.

## Conclusion

This study concluded that the medical faculties had better knowledge and attitude about pharmacovigilance and understood the need for reporting as compared to the dental faculties. Lack of confidence to discuss the cases and limited knowledge regarding the topics are the major barriers preventing ADR reporting among the medical and dental faculties. These factors should be considered while designing workshops and seminars related to pharmacovigilance. Continuing medical and dental education programs should be conducted to make them aware of the drug monitoring process and encourage them to report all suspected ADRs encountered in their practice.

**Conflicts of interest**
There are no conflicts of interest.

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