Assessment of impact of educational intervention on knowledge, attitude and practice of Pharmacovigilance among interns

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Abstract
Background: Adverse drug reactions (ADRs) are described as ‘a response to a medicament which is noxious and unforeseen and which happens at dosages ordinarily utilized for the diagnosis, prophylaxis or treatment of a disease or for the alteration of physiological function’. The present study was conducted to assess impact of educational intervention on knowledge, attitude and practice of pharmacovigilance among interns.

Materials and methods: 280 dental interns of both genders were given a questionnaire related to knowledge, attitude towards pharmacovigilance. The questionnaire (pre-KAP) was administered and subjects were asked to submit the completed questionnaire. Results of each response were recorded.

Results: Out of 280 subjects, males were 110 and females were 170. Pre-KAP value was less as compared to post KAP value in each question. The difference was significant (P<0.05). There was significant difference in pre and post KAP attitude value (P<0.05).

Conclusion: Interns had insufficient knowledge, attitude and practice regarding pharmacovigilance and adverse drug reactions, however post KAP response found to be good.

Keywords: Adverse drug reactions, pharmacovigilance, interns

Introduction
Adverse drug reactions (ADRs) are described as ‘a response to a medicament which is noxious and unforeseen and which happens at dosages ordinarily utilized for the diagnosis, prophylaxis or treatment of a disease or for the alteration of physiological function’ [1]. ADRs inflict a considerable economic burden on the healthcare system and society, thereby posing a major impact on public health [2]. The World Health Organization (WHO) defined the term pharmacovigilance (PV) as ‘The pharmacological science and activities relating to the detection, assessment, understanding and prevention of the adverse effects or any other drug related problems’. In the recent past, its worries have been broadened to incorporate herbal, traditional and complementary medicines, blood products, medical devices and vaccines [3]. Health professionals played a very vital role in reporting of ADR around the world which has led to the detection of serious and unusual ADR that were previously undetectable and many drugs like “rofecoxib” were withdrawn in the past, therefore, enhancing the safety of patients. Reporting of ADR can result in detection of serious and unusual ADR which was remained undetected during a clinical trial. Rational use of medicines not only decreases morbidity and mortality but also increases the quality of life [4].

Studies conducted worldwide showed that ADRs produce a significant reduction in the quality of life, increase hospitalisation, lengthen hospital stay and increase mortality. The switching from prescription-only medicines to over the counter drugs has increased the risk of general public to ADRs, which are reported sporadically [5]. The present study was conducted to assess impact of educational intervention on knowledge, attitude and practice of pharmacovigilance among interns.

Materials and Methods
The present study was conducted among 280 dental interns of both genders. All enrolled subjects were made aware of the study and their consent was obtained. Data such as name, age, gender etc. was recorded. A questionnaire related to knowledge, attitude towards PV as interns were used.
The questionnaire (pre-KAP) was administered and subjects were asked to submit the completed questionnaire. Results of each response were recorded and subjected to statistical analysis. *P* value less than 0.05 was considered significant.

**Results**

Table 2 shows that out of 280 subjects, males were 110 and females were 170.

### Table 2: Knowledge of pharmacovigilance and adverse drug reactions reporting before and after educational intervention

| Questionnaire                           | Pre-KAP (%) | Post-KAP (%) | *P* value |
|-----------------------------------------|-------------|--------------|-----------|
| What is Pharmacovigilance?              | 42          | 94           | 0.04      |
| Main function of Pharmacovigilance?     | 28.4        | 90.4         | 0.01      |
| Who regulates Pharmacovigilance programme? | 37.2        | 92.6         | 0.01      |
| What is ADR reporting system?           | 38.2        | 90.1         | 0.02      |
| Where is ADR centre located?            | 32.5        | 85.2         | 0.01      |

Table 2 shows that pre-KAP value was less as compared to post KAP value in each question. The difference was significant (*P*<0.05).

### Table 3: Attitude of pharmacovigilance and adverse drug reactions

| Questionnaire                           | Pre-KAP (%) | Post-KAP (%) | *P* value |
|-----------------------------------------|-------------|--------------|-----------|
| ADR reporting is necessary?             | 45.3        | 84.9         | 0.05      |
| ADR should be mandatory?                | 29.4        | 85.4         | 0.02      |
| Which health care professional is responsible? | 37.8        | 88.6         | 0.05      |
| Pharmacovigilance should be taught in detail? | 40.6        | 84.5         | 0.02      |

Table 3 shows that there was significant difference in pre- and post KAP attitude value (*P*<0.05).

### Table 4: Practice of pharmacovigilance and adverse drug reactions

| Questionnaire                           | Pre-KAP (%) |
|-----------------------------------------|-------------|
| Have you reported ADR?                  | No-0        |
| Come across ADR?                        | Yes-35%     |
| Have you ever been trained how to report ADR? | No-95%  |

Table 4 shows that nobody had reported ADR, 35% came across ADR and 95% has not been ever trained how to report ADR.

### Discussion

Introduction of newer medicines has changed the way in which diseases are treated. However, it is not without risks. Adverse drug reactions (ADRs) are encountered commonly in daily practice, many of which are preventable [6]. Monitoring of ADRs is carried out by various methods, of which voluntary or spontaneous reporting is commonly practiced [7]. This system offers many advantages. It is inexpensive and easy to operate. It encompasses all drugs and patient populations, including special groups. However, under-reporting and an inability to calculate the incidence of ADRs are the inherent disadvantages of this method [8]. In order to improve the participation of health professionals in spontaneous reporting, it might be necessary to design strategies that modify both the intrinsic (knowledge, attitude and practices) and extrinsic (relationship between health professionals and their patients, the health system and the regulators) factors [9]. A knowledge, attitude, and practice (KAP) analysis may provide an insight into the intrinsic factors and help understand the reasons for under-reporting ADRs.

The present study was conducted to assess impact of educational intervention on knowledge, attitude and practice of pharmacovigilance among interns. In present study, out of 280 subjects, males were 110 and females were 170. We found that pre-KAP value was less as compared to post KAP value in each question. Goel et al. [11] planned to assess the level of knowledge awareness and practice of PV among interns and subsequent change in these after PV training session. A cross-sectional descriptive questionnaire-based study was conducted among interns of a tertiary health care and teaching institute. Participants were given descriptive questionnaire; they completed the questionnaire before and after the educational intervention. Educational program on PV was found to increase knowledge and positive attitudes towards various aspects of PV. Training program on PV may help increase the knowledge as well as awareness about principles and techniques of PV, which will increase the credibility of health care in the country.

We found that there was significant difference in pre and post KAP attitude value (*P*<0.05). Nobody had reported ADR, 35% came across ADR and 95% has not been ever trained how to report ADR. Desai et al. [12] evaluated the knowledge, attitude, and practices (KAP) regarding ADR reporting among prescribers. A pretested KAP questionnaire comprising of 15 questions (knowledge 6, attitude 5, and practice 4) was administered to 436 prescribers. The questionnaires were assessed for their completeness (maximum score 20) and the type of responses regarding ADR reporting. A total of 260 (61%) prescribers completed the questionnaire (mean score of completion 18.04). The response rate of resident doctors (70.7%) was better than consultants (34.5%). ADR reporting was considered important by 97.3% of the respondents; primarily for improving patient safety (28.8%) and identifying new ADRs (24.6%). A majority of the respondents opined that they would like to report serious ADRs (56%). However, only 15% of the prescribers had reported ADRs previously. The reasons cited for this were lack of information on where (70%) and how (68%) to report and the lack of access to reporting forms (49.2%). Preferred methods for reporting were e-mail (56%) and personal communication (42%).

### Conclusion

Interns had insufficient knowledge, attitude and practice..
regarding pharmacovigilance and adverse drug reactions, however post KAP response found to be good.

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