

## Assessment of knowledge, attitude and practice of pharmacovigilance among healthcare professionals

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### Abstract

**Background:** All health-care professionals including doctors, dentists, nurses, and pharmacists and even consumers can voluntarily report an ADR. The present study was conducted to assess knowledge and attitude of pharmacovigilance among healthcare professionals. **Materials & Methods:** 120 healthcare professionals which comprised of doctors, nurses, and pharmacists of both genders were subjected to questionnaire comprised of 14 questions in 6 related to knowledge, 4 related to attitude, and 4 related to practice. **Results:** There were 21 male and 36 female doctors, 16 male and 18 female nurses and 13 male and 16 female pharmacists. What of Pharmacovigilance, in this 65% replied correct and 35% incorrect, what is role of pharmacovigilance, in this 79% replied correct and 21% incorrect, ADR reporting is professional obligation 75% replied correct and 25% incorrect, 70% correctly answered regarding which healthcare professional is responsible for ADR reporting, 78% had correct idea regarding pharmacovigilance programme and 45% replied correctly regarding which body is responsible for monitoring ADR. 91% replied correct regarding essentiality of ADR reporting, 86% replied correct that pharmacovigilance programme should be taught in detail, 90% had read about ADR and 70% had correct opinion about opening ADR monitoring centre. The difference was significant ( $P < 0.05$ ).

**Conclusion:** The actual practice of ADR reporting is deficient among health care professionals.

**Keywords:** Adverse drug reactions, Pharmacovigilance programme, health care professionals

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### Introduction

One of the major reasons of morbidity and mortality all over the world is adverse drug reactions (ADRs). Hence, proper monitoring of ADRs is a necessity[1]. In India, all healthcare professionals including doctors, nurses, and pharmacists can report an ADR by filling an ADR form of the Central Drugs Standard Control Organization. It is important for healthcare professionals to know how to report and where to report an ADR. The active participation of healthcare professionals in the pharmacovigilance program can improve the ADR reporting[2]. In India, all health-care professionals including doctors, dentists, nurses, and pharmacists and even consumers can voluntarily report an ADR by filling an ADR reporting form as devised by Central Drugs Standard Control Organization[3]. Notwithstanding the constant endeavor by the PvPI toward inculcating a healthy reporting culture, underreporting is still much prevalent and a barrier to smooth PV system. Constant training and enactment of regulations for ADR reporting among health-care professionals are thus required. Inculcating the ADR reporting culture during early days of medical training can help with this situation[4]. The pharmacovigilance programme of India towards inculcating a culture of ADR monitoring; underreporting is still very

prevalent. There is a requirement for constant training and enactment of regulations for ADR reporting among healthcare professionals. Previous reported study has found that underreporting of ADR is related with shortcomings in the knowledge and attitude among healthcare professionals[3]. The present study was conducted to assess knowledge and attitude of pharmacovigilance among healthcare professionals.

### Materials & Methods

The present study comprised of 120 healthcare professionals which comprised of doctors, nurses, and pharmacists of both genders. All were informed regarding the study and their informed consent was obtained. Data such as name, age, gender etc. was recorded. KAP questionnaire comprised of 19 questions in 6 related to knowledge, 4 related to attitude, and 8 related to practice. These questions were designed based on earlier studies for assessing KAP of ADR reporting. Results of the study was subjected to statistical analysis using Mann Whitney U test. P value  $< 0.05$  was considered significant.

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**Results**

**Table 1: Distribution of subjects**

Status	Male	Female	P value
Doctors	21	36	0.05
Nurses	16	18	0.91
Pharmacists	13	16	0.82

Table 1 shows that there were 21 male and 36 female doctors, 16 male and 18 females nurses and 13 male and 16 female pharmacists. The difference was significant (P< 0.05).

**Table 2: Assessment of knowledge**

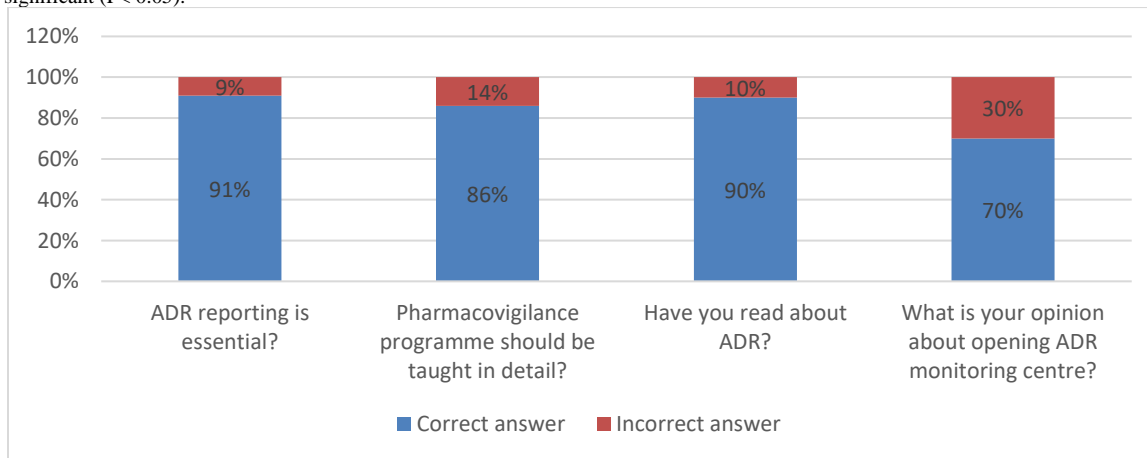
Questionnaire	Correct answer	Incorrect answer	P value
What of Pharmacovigilance?	65%	35%	0.01
What is role of Pharmacovigilance?	79%	21%	0.02
ADR reporting is professional obligation?	75%	25%	0.05
Which healthcare professional is responsible for ADR reporting?	70%	30%	0.01
Have you any idea regarding Pharmacovigilance programme?	78%	22%	0.01
Which body is responsible for monitoring ADR?	45%	55%	0.12

Table 2 shows that what of pharmacovigilance, in this 65% replied correct and 35% incorrect, what is role of pharmacovigilance, in this 79% replied correct and 21% incorrect, ADR reporting is professional obligation 75% replied correct and 25% incorrect, 70% correctly answered regarding which healthcare professional is responsible for ADR reporting, 78% had correct idea regarding pharmacovigilance programme and 45% replied correctly regarding which body is responsible for monitoring ADR. The difference was significant (P< 0.05).

**Table 3: Assessment of attitude**

Questionnaire	Correct answer	Incorrect answer	P value
ADR reporting is essential?	91%	9%	0.01
Pharmacovigilance programme should be taught in detail?	86%	14%	0.02
Have you read about ADR?	90%	10%	0.05
What is your opinion about opening ADR monitoring centre?	70%	30%	0.01

Table 3, Fig 1 shows that 91% replied correct regarding essentiality of ADR reporting, 86% replied correct that pharmacovigilance programme should be taught in detail, 90% had read about ADR and 70% had correct opinion about opening ADR monitoring centre. The difference was significant (P< 0.05).



**Fig 1: Assessment of attitude**

**Table 4: Assessment of practice**

Questionnaire	Correct answer	Incorrect answer	P value
Have you ever experienced ADR?	62%	38%	0.02
Have you reported ADRs to monitoring centre?	25%	75%	0.01
Have you ever seen ADR form?	56%	44%	0.09
Have you ever trained how to report ADR?	53%	47%	0.07

Table 4 shows that 62% have experienced ADR, 25% have reported ADRs to monitoring centre, 56% have ever seen ADR form and 53% have ever trained how to report ADR. The difference was significant (P< 0.05).

### Discussion

There has arisen a need for pharmacovigilance as a branch of pharmacological science, critical to effective clinical practices and public health with immense possibility for growth[6]. The WHO defines it as, "the pharmacological science relating to the collection, detection, assessment, monitoring, and prevention of adverse effects with pharmaceutical products[7]. It has been noted that not only has the number of drugs available in the market increased, but so have the adverse drug reactions (ADR). This calls for a need of a system which will keep check on the increasing number of ADRs. One of the major reasons why pharmacovigilance programs have failed to achieve their motive is due to under reporting of the ADRs.<sup>8</sup> The lack of awareness and knowledge on how to report ADRs have led to poor reporting in the past. ADRs are global problems of major concern. They affect both children and adults with varying magnitudes; causing both morbidity and mortality in varying degrees.<sup>9</sup> The present study was conducted to assess knowledge and attitude of pharmacovigilance among healthcare professionals.

In present study, there were 21 male and 36 female doctors, 16 male and 18 female nurses and 13 male and 16 female pharmacists. Vohra et al[10] conducted a cross-sectional survey on 215 health care personnel working in a medical college in Jaipur. They were subjected to KAP questionnaire consisted of knowledge, attitude and practice-based questions, designed specifically to assess the awareness about pharmacovigilance. The mean KAP scores of physicians were found to be 5.75, 4.44 and 1.75 respectively. The KAP score of postgraduate students was 5.5, 4.25 and 1.5 respectively. The KAP score of final year MBBS students was 5, 3.4, and 1.4 respectively, and that of interns was 4, 4.2 and 1.4 respectively. The KAP score of pharmacists was 3.5, 2 and 1 respectively, and that of nurses was 2.75, 2.25 and 0.8 respectively. It was found that mean score of physicians and postgraduate students was higher than interns and final year MBBS and much higher than nurses and pharmacists. Still, they all fall under the poor score range to unsatisfactory score range which suggest that there is an urgent need for ongoing educational programs to train health care professionals about pharmacovigilance. We found that 65% replied correct that what of Pharmacovigilance, 79% replied correct about the role of pharmacovigilance, ADR reporting is professional obligation 75% replied correct, 70% correctly answered regarding which healthcare professional is responsible for ADR reporting, 78% had correct idea regarding pharmacovigilance programme and 45% replied correctly regarding which body is responsible for monitoring ADR. 62% have experienced ADR, 25% have reported ADRs to monitoring centre, 56% have ever seen ADR form and 53% have ever trained how to report ADR. Gupta et al[11] in their study on 150, pretested questionnaires were distributed among the healthcare professionals and 101 responded. 62.4% healthcare workers gave correct response regarding the definition of pharmacovigilance. 75.2% of healthcare workers were aware regarding the existence of a National Pharmacovigilance Program of India. 69.3% healthcare professional agreed that ADR reporting is a professional obligation for them. Among the participants, 64.4% have experienced ADRs in patients, but only 22.8% have ever reported ADR to pharmacovigilance center. Unfortunately, only 53.5% healthcare workers have been trained for reporting adverse reactions. But, 97% healthcare professionals agreed that reporting of ADR is necessary and 92.1% were of the view that

pharmacovigilance should be taught in detail to healthcare professional. Era et al[12] in their study a total of 247 questionnaires were assessed. Improved responses were observed in final year students as compared to the second and prefinal years. However, awareness pertaining to ADR reporting system in India and scales involved in causality was less among students. Awareness regarding necessity of ADR reporting was lacking in 50% of respondents. The practice of PV and reporting ADRs was assessed, which revealed though many came across ADRs, very few reported the same as majority did not know how to report ADRs to the national program.

### Conclusion

Authors found that the actual practice of ADR reporting is deficient among health care professionals.

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