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Original Research Article

A cross-sectional, questionnaire-based study on knowledge, attitude, and practice of pharmacovigilance among post-graduates at a tertiary care teaching hospital, Telangana

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ABSTRACT

Background: Pharmacovigilance is the process of drug safety monitoring that improves patients' quality of life through the collection and analysis of Adverse Drug Reactions (ADRs). In our state, most of the ADRs are reported by a spontaneous reporting system of individual cases from health care professionals to Adverse Drug Reaction Monitoring Centre (AMC) under the Pharmacovigilance Programme of India (PvPI). Post-graduates (PGs) play a vital role in reporting ADRs as they are in personal evidence with all events after drug administration. The main objective of our study is to evaluate the Knowledge, Attitude, and Practice of Pharmacovigilance among post-graduates.
Methods: The present study was a cross-sectional questionnaire-based study on knowledge, attitude, and practice (KAP) of Pharmacovigilance among 150 post-graduates at a tertiary care teaching hospital, Telangana. The statistical analysis was done using Statistical Package for Social Sciences (SPSS) version 25 software.
Results: The results showed that there is relatively less knowledge among postgraduates. Attitude and practice-based questions evidenced a paradigm shift towards the construction of an organized Pharmacovigilance system. This study also highlights the under-reporting and the interventions needed to improve spontaneous reporting of ADRs.
Conclusions: The knowledge of Pharmacovigilance with a positive attitude and practice among post-graduates is essential for reporting ADRs and reducing under-reporting.

Keywords: Pharmacovigilance, Knowledge, Attitude, Practice, Post-graduates, Under-reporting

INTRODUCTION

Pharmacovigilance is defined as the science and activities relating to the detection, assessment, understanding, and prevention of Adverse Effects (AEs) or any other drug-related problems.[1] There is a limited value of animal studies and clinical trials as these are conducted in a highly sophisticated laboratory condition, with limited population size and for a short duration of time. Once the medicine is placed in the market, it leaves the protected scientific environment and is available for use outside the controlled environment of clinical trials.

The demand for post-authorization Pharmacovigilance (Pv) arises at this point when such medicines are required to be monitored for their effectiveness and safety under real-life conditions.[2] Pharmacovigilance is necessary for the safe use of medicines, early detection of Adverse Drug Reactions (ADRs), promoting the rational use of medicines, to reduce the cost of drug-related morbidity and mortality, to ensure public confidence and ethical

concern.[3] Pv helps to assess and communicate data on benefits or risks in the use of medicines and educate and inform the patients. Knowledge of the Pv system also limits the undetected use of ineffective, substandard, and counterfeit medicines thus minimizing the possibility of wastage of resources.[4]

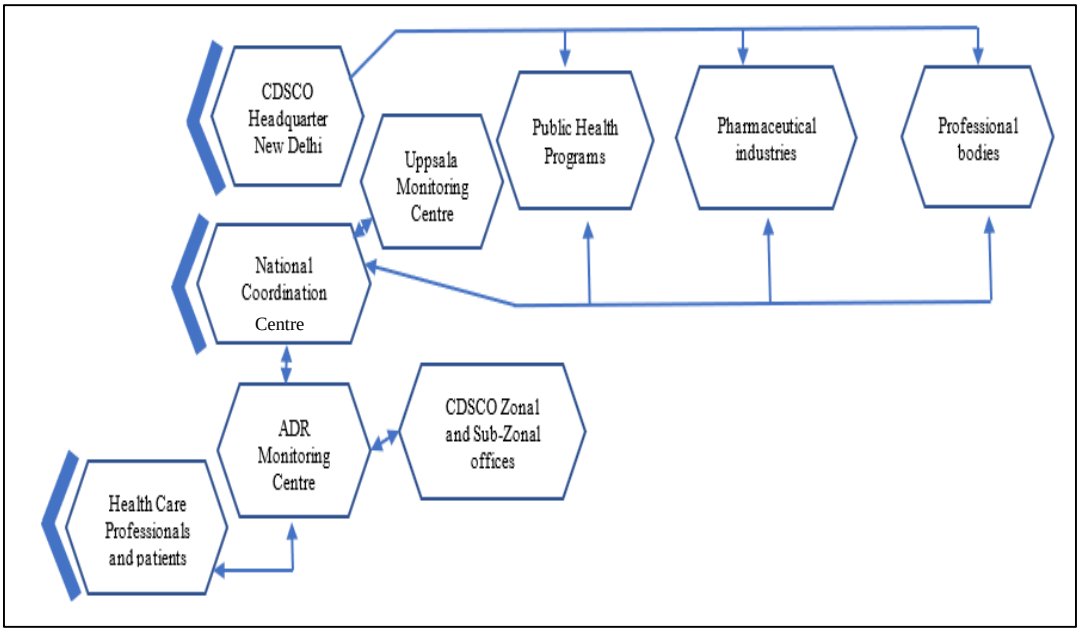

Figure 1: Communication system of PvPI.

Recognizing the need for ADR monitoring in India, the Pharmacovigilance Programme of India (PvPI) was initiated on 14th July 2010 with its National Coordination Centre located at the Indian Pharmacopeia Commission, Ghaziabad, Uttar Pradesh.[4] The primary objective of NCC-PvPI is to promote the safest use of medicines through appropriate education in Pharmacovigilance training activities across the country. At present, there are 444 Adverse Drug Reaction Monitoring Centres (AMCs) under PvPI.[5] The Uppsala Monitoring Centre (UMC) located in Sweden has an international database of ADR reports worldwide. Studies revealed that about 6.2% of hospital admissions are due to ADRs and about 3.2% of them occurred during the hospital stay.[6]

The eventuality of ADRs contributes a remarkable burden to the country's economy and also loss of quality of life.[7] There is a large divergence in the population in our country related to genetic and cultural traditions. All these issues vitalize the responsibility of post-graduates to report ADRs arising out of drugs promptly and efficiently.

Post-graduates can report ADRs through Standardized ADR reporting forms, Toll-Free number-18001803024, Mail to pvpi@ipcindia.net.or, and Mobile app to AMC or directly to NCC. Figure 1 explains the communication system of PvPI. Lack of this knowledge is responsible for the under-reporting of Adverse Drug Reactions.[8,9] There is a need to develop a positive attitude towards the various workflow of Pharmacovigilance to reduce Adverse Events and for smooth functioning of the Pharmacovigilance system. Therefore, my study is intended to assess the Knowledge, Attitude, and Practice (KAP) of Pharmacovigilance among post-graduates (PGs) of Osmania Medical College.

METHODS

Study design

This was a cross-sectional questionnaire-based study. The approval to conduct this study was obtained from the Institutional Ethics Committee of Osmania Medical College, before the study.

KAP Questionnaire was designed to assess their knowledge on Pharmacovigilance, attitude towards Pharmacovigilance, and their practice on ADR reporting. There were 20 questions in the questionnaire to assess the knowledge, attitude, and practice on ADR reporting. The study instrument was a self-administered KAP-based questionnaire designed by the Department of Pharmacology faculty based on previous studies.

Study setting

The study was conducted at Osmania Medical College and its hospital branches in Hyderabad, a tertiary care teaching hospital, Telangana. The study was conducted during the period from April 2021 to July 2021.

Study duration

The duration of the study was 4 months.

Study participants

The study participants included 200 Postgraduates.

Study data collection

Out of 200 post-graduates, a total of 150 post-graduates participated in this cross-sectional questionnaire-based study, one day was given for the participants to read, understand and answer the questions.

Inclusion and exclusion criteria

All postgraduates who gave their informed consent and who were studying in the college during the study period were included. The postgraduates who were not willing to participate in the study and those who were on leave were excluded.

Statistical analysis

Information from the returned questionnaire was entered and analyzed by Statistical Package for Social Sciences (SPSS) version 25 software.

RESULTS

Baseline demographic characteristics

Out of 200 questionnaire forms communicated among postgraduates, a total of 150 PGs gave consent to participate in this study and responded by answering the questionnaire. The demographic details of the postgraduates with baseline characteristics are summarized in Table 1.

Table 1: Baseline demographic characteristics of the study participants.

Characteristics	Frequency
Pre-clinical -pgs.	40
Para-clinical pgs.	60
Clinical-pgs.	100
Male pgs.	120
Female pgs.	80
1st-year pgs.	100
2nd-year pgs.	50
3rd-year pgs.	50

Assessment of knowledge among post-graduates regarding ADR reporting

Information about post-graduate knowledge in reporting ADRs was evaluated based on vital parameters represented in Table 2. Almost 100% of PGs answered correctly when simple knowledge-related questions were posed but we can assess that the levels of knowledge reduced when questions were asked in-depth. Table 3 shows that 12-20% of post-graduates knew Post Marketing Surveillance (PMS). As a result of the knowledge-based questionnaire, it is evident that almost 100% of post-graduates answered correctly initially when elementary questions were posed, but as we go in-depth of knowledge of Pv the percentage declined to 12%. Sensitization programme was conducted for PGs but due to COVID-19 pandemic, this resulted to be unsuccessful. Lack of knowledge about reporting ADRs is the main cause of under-reporting.

Assessment of attitude of postgraduates towards ADR reporting

From the questionnaire, it is clear that the attitude of post-graduates is raising positively, which can be an important string to improve the under-reporting of ADRs.

Assessment of post-graduate practice towards ADR reporting

80% of post-graduates know that ADR Monitoring Centre (AMC) is present in our institution. About 90% of post-graduates think that AMC should be present in every hospital. 100% of post-graduates agree that it is a collective responsibility of doctors, pharmacists, and nurses to report ADRs and they also agree that Pharmacovigilance should be taught in detail to the health care professionals.

Factors discouraging ADR reporting

The factors that were oppressing post-graduates from reporting ADRs include lack of complete knowledge of reporting ADRs (79%), difficulty to decide whether ADR has occurred or not (19%), a single unreported case may not affect the ADR database (1%), no remuneration for reporting ADRs (1%).

Table 2: Knowledge among post-graduates regarding ADR reporting.[10]

Knowledge related questions	Correct response N (%)	Incorrect response N (%)
1)What is meant by ADR? **a) Association for Democratic Reforms.** **b) Adverse Drug Reaction.** **c) Adverse Data Reporting.** **d) American Depositary Receipt**	150 (100)	0

Continued.

Knowledge related questions	Correct response N (%)	Incorrect response N (%)
Define Pharmacovigilance? a) The science of detecting the type and incidence of ADR after the drug is marketed. b) The science of monitoring ADR occurring in a hospital. c) The process of improving the safety of the drug. d) The detection, assessment, understanding, and prevention of adverse effects.	150 (100)	0
The important purpose of Pharmacovigilance is? a) To identify the safety of the drug. b) To calculate the incidence of ADR. c) To identify unrecognized ADRs. d) All of the above	150 (100)	0
What is an Adverse Event? a) Any untoward medical occurrence during treatment that may or may not be related to treatment. b) Any expected medical event after treatment. c) Any medical occurrence which is related to treatment. d) None.	105 (70)	45 (30)
What has to be reported in ADR reporting form? a) Patient details and significant medical history. b) Details of medicines, reporter details, Date and Place of reporting c) Both a and b. d) Nothing has to be reported.	78 (52)	72 (48)
In India which regulatory body is responsible for monitoring ADR? a) Central Drug Standard Control Organization. b) Indian Council of Medical Research. c)Indian Clinical Research Institute. d)Medical Council of India.	74 (49)	76 (51)

Table 3: Knowledge among post-graduates regarding post marketing surveillance.

Knowledge related questions	Yes N (%)	No N (%)
Are you aware of any drug that has been banned recently due to ADR?	30 (20)	120 (80)
Are you aware of the suspected ADR reporting system in India?	18 (12)	132 (88)

Table 4: Post-graduates' response towards attitude-related questions.[11]

Attitude related questions	Correct response N (%)	Incorrect response N (%)
Do you think that ADR monitoring centre is present in your institution? (Yes/No)	120 (80)	30 (20)
What is your opinion about establishing an ADR monitoring center in every hospital? a) Should be in every hospital. b) Not necessary in every hospital. c) One in a city is sufficient. d) Depend on the number of bed sizes in the hospital.	135 (90)	15 (10)
The health care professionals responsible for reporting an ADR in a hospital is/are? a) Doctor. b) Pharmacist. c) Nurses. d) All the above.	150 (100)	0
Do you think reporting an ADR is necessary? (Yes/No)	150 (100)	0
Do you think Pharmacovigilance should be taught in detail to health care professionals? (Yes/No)	150 (100)	0

Continued.

Table 5: Post-graduates' response towards practice-related questions.[12]

Practice related questions	Yes N (%)	No N (%)
Have you ever reported ADRs to your AMC? (Yes, No)	120 (20)	30 (80)
Do you keep records of ADR? (Yes, No)	30 (20)	120 (80)
Have you ever been trained on how to report ADR? (Yes, No)	62 (41)	88 (59)
Have you ever come across an ADR? (Yes, No)	90 (60)	60 (40)
Have you ever seen the ADR reporting form (Yes, No)	111 (74)	39 (26)
Are you willing for ADR reporting? (Yes, No)	150 (100)	0

Table 6: Factors discouraging ADR reporting.[13]

Which among the following discourage you from reporting ADRs	Non-remuneration for reporting N (%)	Lack of complete knowledge of reporting ADRs N (%)	A single unreported case may not affect the ADR database N (%)	Difficult to decide whether ADR has occurred or not N (%)
Percentage (%)	2 (1)	118 (79)	2 (1)	28 (19)

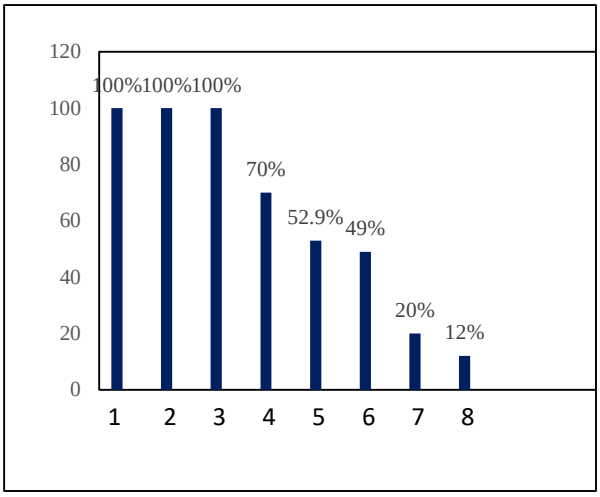

Figure 2: Knowledge based questionnaire.

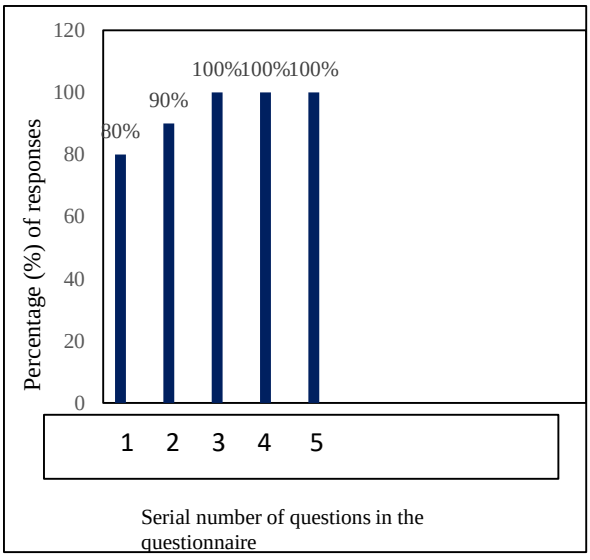

Figure 3: Attitude based questionnaire.

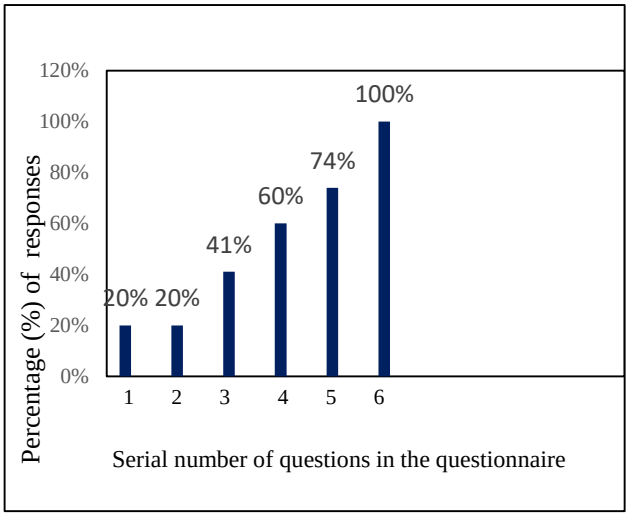

Figure 4: Shows progress in practices of PGs that reduce the under-reporting of ADRs.

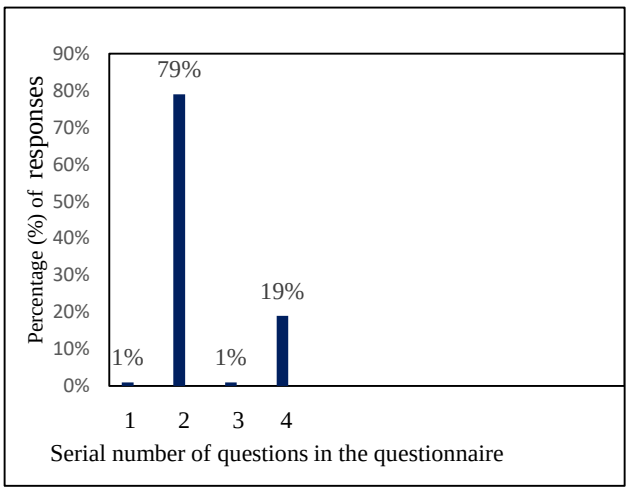

Figure 5: Explains the percentage of factors discouraging PGs from reporting ADRs.

DISCUSSION

This study deals with the assessment of Knowledge, attitude, and practice of Pharmacovigilance among post-graduates and the reasons for under-reporting of ADRs. A spontaneous reporting system is the main source of drug safety surveillance in India. Various studies are done to assess the KAP of Pharmacovigilance among health care professionals (HCPs) but there are comparatively fewer studies among postgraduates.[14] As postgraduates are in personal evidence with all events that occur after the administration of drugs knowledge of pharmacovigilance among them is very essential.

Almost 100% of postgraduates were aware of the existence of the Pv branch, ADR, and their importance. 70% of respondents knew the exact meaning of an adverse event. About 52% of post-graduates were vigilant regarding what has to be reported in the ADR reporting form. 49% of respondents were known about the presence of a regulatory body for monitoring ADRs. Only 12-20% of post-graduates knew about post marketing surveillance There is a relative decline in knowledge of Pharmacovigilance than expected among post-graduates.

Attitude revealed a positive behaviour of respondents as 100% of PGs think that Reporting ADRs is essential to curtail the burden of ADRs on society due to various reasons. Figure 3 shows that there is progress in practices of PGs that reduce the under-reporting of ADRs. The practice of Pharmacovigilance activities is hindered among post-graduates chiefly due to paucity of complete knowledge of ADR reporting followed by difficulty to decide whether ADR has occurred or not.

The main causes of under-reporting are the lack of knowledge and indifference to reporting.[15] Lack of time and remuneration contributes to the minor causes of under-reporting. Under-reporting can be overcome by providing easy access to registration forms, simplifying documents, toll-free number assistance, establishing more AMCs, facilitating communication between registrars and pharmacovigilance centers, and financial incentives.[16,17] All these activities would improve the notification rates of problems related to medication. There is a need for training and educational activities for increasing awareness about reporting ADRs. Obstacles to under-reporting can be reduced by conducting periodic educational, interventional programs, and sensitization programs for the health care professionals working in a tertiary care hospital.[18-21]

Limitations

The study was conducted during the COVID-19 pandemic because of which the sensitization programs were not successful as expected. This may be one of the reasons for less knowledge among postgraduates. Few of the postgraduates did not respond appropriately to the questionnaire. These were the major limitations faced during the study.

CONCLUSION

This study concludes that all the post-graduates who responded have relatively less knowledge than expected but they have shown a positive attitude towards improving knowledge and practices that reduce under-reporting of ADRs. The practice of Pharmacovigilance activities is hindered among post-graduates due to lack of complete knowledge of reporting ADRs, fear of the negative effect of reporting, and legal liability issues. Moreover, reassurance among doctors that ADR reporting has no legal implications and making reporting mandatory can prevent under-reporting. Finally, most of the post-graduates have a positive attitude towards Pharmacovigilance but in practice, there is a need to control the under-reporting of ADRs by imbibing knowledge

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Ethical approval: The study was approved by the Institutional Ethics Committee

REFERENCES

1. WHO Pharmacovigilance Indicators: A Practical Manual for the Assessment of Pharmacovigilance Systems. 2015.
2. Verma S, Gulati Y. Fundamentals of Pharmacovigilance, Need for Pharmacovigilance. 1st edition. 2017;9-12.
3. WHO. Safety of medicines in Public Health Programmes: Pharmacovigilance an essential tool. WHO. 2006.
4. Sarkar S, Srivastava V, Mohanty M. Textbook of Post-Graduate Pharmacology, Pharmacovigilance. 1st edition. 2020;84-9.
5. PvPI official website. Available at: https://www.ipc.gov.in/PvPI/pv_home.html. Accessed on 20 February 2021.
6. Giardina C, Paola M, Cutroneo, Mocciaro E, Giuseppina T et al. Adverse Drug Reactions in Hospitalized Patients: Results of the FORWARD (Facilitation of Reporting in Hospital Ward) Study, Pharmaceutical Medicine and Outcomes Research. 2018;9(350):1-12.
7. Srinivasan V, Sheela D, Mridula D. Knowledge, Attitude, and Practice of Pharmacovigilance among the Healthcare Professionals in a Tertiary Care Hospital – A Questionnaire Study, Biomedical and Pharmacology Journal. 2017;10(3):1441-7.
8. Pharmacovigilance Programme of India. Available at: https://www.ipc.gov.in/PvPI/faq.html. Accessed on 27 February 2021.

9. Rehan HS, Sah RK, Chopra D. Comparison of knowledge, attitude and practices of resident doctors and nurses on adverse drug reaction monitoring and reporting in a tertiary care hospital, Indian Journal of Pharmacology. 2012;44(6):699-703.
10. Kumar D, Muthu MS, Pandey BL. Pharmacovigilance program in India: Current status and its perspectives, Journal of Pharmacology and Toxicological Studies. 2015;3(4):20-4.
11. Dhananjay K, Himasri E. A study of assessing knowledge, attitude, and practice of pharmacovigilance among medical students of a South Indian teaching hospital. IJBCP. 2017;6(1):43-47.
12. Khan, SA Goyal C, Chandel N, Rafi M. Knowledge, attitudes, 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(1):191-6.
13. Smita S, Prasad SD, Prabin S, Pragati P. Knowledge, Attitude, and Practices of Pharmacovigilance among Doctors at a Tertiary Care Teaching Hospital Birgunj, Nepal. JNMC. 2021;6(1):14-8.
14. Gupta D, 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. 2015;6(1):45-52.
15. Avery AJ, Anderson C, Bond CM, Fortnum H, Gifford A, Hannaford PC et al. Evaluation of patient reporting of adverse drug reactions to the UK, Yellow Card Scheme: Literature review, descriptive and qualitative analyses, and questionnaire surveys. Health Technol Assess. 2011;15(20):1-234.
16. Nichols V, Thériault-Dubé I, Touzin J, Delisle JF, Lebel D, Bussières JF et al. Risk perception and reasons for noncompliance in pharmacovigilance: a qualitative study conducted in Canadá. Drug Saf. 2009;32(7):579-90.
17. Gavaza P, Brown CM, Khoza S. Texas pharmacists‟ opinions on reporting serious adverse drug events to the Food and Drug Administration: a qualitative study. Pharm World Sci. 2010;32(5):651-7.
18. Ganeshan S, Sandhiya S, Reddy KC, Adithan C. The impact of educational intervention on knowledge, attitudes, and practice of pharmacovigilance towards adverse drug reaction reporting among health care professionals in a tertiary care hospital in South India. Journal of natural science, biology and Medicine. 2017;8(2):203-9.
19. Alsbou M, Abdeen G Batereh A, Bawaresh N, Jaber J, Qawasmi G. Analysis of National Pharmacovigilance database in Jordan. Biomedical and Pharmacology Journal. 2017;10(1):319-28.
20. Kalaiselvan V, Prasad T, Bisht A, Singh S, Singh GN. Adverse drug reaction reporting culture in Pharmacovigilance program of India. Indian Journal of Medical Research. 2014;140(4):563-4.
21. Tandon VR, Mahajan V, Khajuria V, Gillani Z. Under-reporting of Adverse Drug Reactions: A challenge for Pharmacovigilance in India. Indian Journal of Pharmacology. 2015;47(1):65-71.

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