Original Article

Assessment of Awareness of Pharmacovigilance among Resident Doctors in a Tertiary Healthcare Centre of India: A Questionnaire-Based Study

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ABSTRACT

Introduction: To protect patients' safety, pharmacovigilance, a crucial branch of the drug sciences, looks for and reports ADR on its own initiative. Pharmacovigilance aims to enhance the safety and care of patients in the context of the use of medications and to contribute to the evaluation of the potential benefits, risks, and side effects of medications. Many studies have been conducted in the past to evaluate healthcare professionals' understanding and use of pharmacovigilance, but not many have evaluated resident doctors' understanding, which is crucial because residents are frequently the ones who care for patients first and for all time.

Aims/ objective: To evaluate the knowledge and practise of pharmacovigilance among resident doctors and evaluate the impact of sensitization on these outcomes.

Materials and Method: 15 questions about pharmacovigilance were included in a questionnaire on various domains of pharmacovigilance. Two trips were required to gather the data. During the initial visit, selected resident doctors had been approached and asked to complete questionnaires that were entered into an Excel spreadsheet. After first visit, awareness activities in the form of seminars, pamphlets, workshops, etc. were organised in period of 3 months. The same residents were revisited and asked to complete the same questions during a second visit that was conducted three months later. Each session lasted, on average, 30 to 40 minutes.

Results: There was statistically significant increase in mean score of resident doctors on all domain of pharmacovigilance after our awareness activities. There was nearly 18% decrease in residents having 0 score on domain "reporting of adverse drug reactions" of the questionnaire after awareness activities. There was nearly 7% increase in number of resident doctors having high score (4 or 3 out of 4) on domain "recommendation on improvement of pharmacovigilance system" after awareness activities.

***Conclusion*:** This study found that after providing sufficient sensitization, residents had increased knowledge and practise in various areas of pharmacovigilance. Therefore, for a better healthcare system, improved perception can eliminate the myths, challenges, and barriers to the practise of pharmacovigilance.

Keywords: Pharmacovigilance, Adverse Drug Reaction, Awareness, Questionnaire, Sensitization.

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INTRODUCTION

Drugs play a significant role in the treatment of all diseases and have a number of advantageous effects. Drugs, however, are like two-edged swords; while they can treat, control, or even detect diseases, they also carry the risk of injury in the form of adverse drug reactions (ADRs), which are among their main drawbacks.[1] The World Health Organisation (WHO) describes an adverse drug reaction (ADR) as "a response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function." [2] Regardless of the practise settings, a higher prevalence of ADRs is a global health issue that requires attention from every group involved.[3,4]

It has been noted that 10–20% of patients who are hospitalised experience adverse drug reactions (ADRs), which have a direct influence on health care costs. Drug-induced disorders account for 5% of the total number of hospitalisations.[5-8] In order to advance drug safety, WHO established the Programme for International Drug Monitoring in 1968. Subsequently, in 1978, it collaborated with the Uppsala Monitoring Centre (UMC) for International Drug Monitoring to advance pharmacovigilance programmes at the level of each nation. In India, the Central Drug Standard Control Organisation (CDSCO) created the Pharmacovigilance Programme of India (PvPI) in 2010 and designated the Indian Pharmacopoeia Commission (IPC) as the National Coordinating Centre (NCC) beneath the supervision of the ministry of health and family welfare.[9]

To protect patients' safety, pharmacovigilance, a crucial branch of the drug sciences, looks for and reports ADR on its own initiative. Pharmacovigilance aims to enhance the

safety and care of patients in the context of the use of medications and to contribute to the evaluation of the potential benefits, risks, and side effects of medications. Healthcare workers have a significant part in the pharmacovigilance programme.[10]

One of the pillars of the pharmacovigilance system, which incorporates reporters' active involvement in the identification and reporting of ADRs, is spontaneous reporting. A key flaw with this system is that, at the moment, ADR reporting does not seem to be something that healthcare providers perform on a regular basis.[11,12] Pharmacovigilance initiatives encounter a variety of difficulties in India, as they do in many other developing nations, including the underreporting of ADRs and maintaining the reporting culture. Healthcare providers who fail to record and disclose ADRs are causing avoidable drug-related morbidity and mortality to repeat.

According to earlier studies, the majority of ADRs that result in hospital admissions are brought on by routinely used drugs and are mostly avoidable.[13] Additionally, a study revealed that only 6–10% of ADR cases are reported.[14,15] By providing them with the necessary knowledge and skills, healthcare personnel can be made more sensitive, which could lead to a paradigm shift and the effective execution of a pharmacovigilance programme.[16,17]

Healthcare workers' engagement is crucial to the effectiveness of pharmacovigilance efforts since they diagnose, prescribe, and monitor patients on a daily basis. Their views and behaviours on ADRs are an essential part of pharmacovigilance since they help to compile the data on ADRs.[18] Regulatory agencies can make decisions on the use of pharmaceuticals that endanger patient safety based on the data gathered in this way.

Healthcare professionals have no obligations to report adverse drug reactions (ADRs), so under these circumstances awareness of ADR reporting should be evaluated. If it is not found to be at an appropriate level, then corrective action should be taken in the form of campaigns or training programmes for the same.[19]

Many studies have been conducted in the past to evaluate healthcare professionals' understanding and use of pharmacovigilance, but not many have evaluated resident doctors' understanding, which is crucial because residents are frequently the ones who care for patients first and for all time. There is a lack of information on how sensitization and awareness campaigns might improve the situation. This study was conducted to evaluate the knowledge and practise of pharmacovigilance among resident doctors and evaluate the impact of sensitization on these outcomes.

MATERIALS AND METHODS

This was an observational and prospective study conducted for a period of 6 months from February 2022 to July 2022. 15 questions about pharmacovigilance were included in a questionnaire on various domains of pharmacovigilance. In order to recruit resident doctors from our institute for this study, practical and purposeful sampling techniques were used. This made it possible to find individuals who were willing to talk about our hospital's pharmacovigilance procedures right away.

66 Residents in all were conveniently sampled, including 31 senior residents and 35 junior residents from various clinical areas. With the institution's previous approval, questionnaires were delivered to the junior and senior resident groups, respectively. After explaining the purpose of the study to the subjects, they were instructed to complete the questionnaire using their own knowledge. They were not permitted to ask the members of their group for their thoughts on any matter. The participants could only complete the questionnaire in one session and without any time restrictions. All of the completed survey forms were gathered, assembled, and examined.

Questionnaire:

1. Are you aware about the term Pharmacovigilance?
2. Are you aware about National Pharmacovigilance Programme?
3. Are you familiar with the relevance of the term Pharmacovigilance?
4. Do you know about the aims and objectives of Pharmacovigilance?
5. Do you have any knowledge about where you should report an adverse drug reaction?
6. Are you familiar with the different interventions that can be utilized in prevention of adverse drug reactions?
7. Are you having knowledge, skill and experience about how a doctor should proceed in case of occurrence of any adverse drug reaction or side effect of drugs?
8. After occurrence of an adverse drug reaction, have you done any intervention to manage it by using appropriate methods?
9. Do you believe that Pharmacovigilance activity will lead to improvement in knowledge of clinician about the drug?
10. Do you believe that Pharmacovigilance activity will lead to awareness and practice of the rational prescribing (right medicine for right indication in right patients)?
11. Do you believe that patient will have any benefit in through Pharmacovigilance activity?
12. Do you agree that there must be standardized system of pharmacovigilance in hospitals with the aim to ensure rational prescribing and management of ADRs?

13. Do you agree that there should be an integrated methodology towards education and training of medical students and public about the Pharmacovigilance?
14. Do you agree that we should have an independent department for reporting of adverse drug reactions in our institute?
15. Do you agree that there should be adequate recommendation in the areas of organization, legislation, regulation, and resources to improve rational and safe use of medicines?

Each of the questionnaire's questions had two possible outcomes: "Yes" or "No." The questionnaire's questions were then divided into four domains to assess knowledge of various pharmacovigilance concept fields.

Six questions, numbered 1, 3, 4, 6, 7, and 8, make up the first domain and are related to the basic understanding of pharmacovigilance and strategies therein. The second domain is made up of questions 2 and 5 that are concerned with reporting of ADRs. The questions in the third domain—numbers 9, 10, and 11—were about the potential benefits of pharmacovigilance. In a similar manner, the fourth domain was classified by creating a collection of questions, namely questions 12, 13, 14, and 15, relating to the ability to provide constructive opinions or ideas for improving the functioning of the framework for pharmacovigilance. Every "Yes" response received a score of one, while every "No" response received a score of zero. The average score for all of the question domains was then calculated.

Response "Yes" to questions on knowledge aspects was confirmed by asking some fundamental question on the concerned topic. Two trips were required to gather the data. During the initial visit, selected residents had been approached and asked to complete questionnaires that were entered into an Excel spreadsheet.

After first visit, awareness activities in the form of seminars, pamphlets, workshops, etc. were organised in period of 3 months. The same residents were revisited and asked to complete the same questions during a second visit that was conducted three months later. Each session lasted, on average, 30 to 40 minutes.

Statistical Analysis

Score obtained from each resident doctors were presented in tabular form using Microsoft Excel 365. Descriptive analysis was done to calculate percentage, mean, and standard deviation (SD) of data using Graph Pad Prism 8.4.3. Statistical significance of difference in scores obtained in different domains between two visit was tested using paired t-test. P-value of less than 0.05 was taken as measure of statistical significance.

OBSERVATIONS AND RESULTS

66 resident doctors submitted the response to the questionnaire at first visit and second visit after awareness activities. Mean age of resident doctor was 29.89 ± 4.31 years. There were 41 (62.12 %) male resident doctors and 25 (37.88 %) female resident doctors.

Table 1: Comparison of scores obtained (out of 6) by resident doctors on the domain "fundamental knowledge regarding pharmacovigilance" between two visits.

Score Obtained	Visit 1		Visit 2	
	Number of Residents	% of Residents	Number of Residents	% of Residents
6	13	19.70	14	21.21
5	8	12.12	12	18.18
4	17	25.76	18	27.27
3	9	13.64	6	9.09
2	6	9.09	7	10.61
1	9	13.64	7	10.61
0	4	6.06	2	3.03

There was decrease in number of residents having low score. Overall improvement was seen in scores obtained by residents after awareness activities.

Table 2: Comparison of scores obtained (out of 6) by resident doctors on the domain "reporting of adverse drug reactions" between two visits.

Score Obtained	Visit 1		Visit 2	
	Number of Residents	% of Residents	Number of Residents	% of Residents
2	20	30.30	22	33.33
1	18	27.27	28	42.42
0	28	42.42	16	24.24

There was nearly 18% decrease in residents having 0 score on domain "reporting of adverse drug reactions" of the questionnaire after awareness activities.

Table 3: Comparison of scores obtained (out of 6) by resident doctors on the domain "possible positive impact of pharmacovigilance" between two visits.

Score Obtained	Visit 1		Visit 2	
	Number of Residents	% of Residents	Number of Residents	% of Residents
3	19	28.79	19	28.79
2	18	27.27	23	34.85
1	14	21.21	17	25.76
0	15	22.73	7	10.61

There was nearly 12% decrease in residents having 0 score on domain "possible positive impact of pharmacovigilance" of the questionnaire after awareness activities.

Table 4: Comparison of scores obtained (out of 6) by resident doctors on the domain "recommendation on improvement of pharmacovigilance system" between two visits.

Score Obtained	Visit 1		Visit 2	
	Number of Residents	% of Residents	Number of Residents	% of Residents
4	18	27.27	20	30.30
3	18	27.27	21	31.82
2	10	15.15	10	15.15
1	7	10.61	8	12.12
0	13	19.70	7	10.61

There was nearly 7% increase in number of resident doctors having high score (4 or 3 out of 4) on domain "recommendation on improvement of pharmacovigilance system" after awareness activities.

Table 5: Comparison of mean score of resident doctors on different domain between two visits

Domain	Mean score in visit 1 ± SD	Mean score in visit 2 ± SD	P-Value (Paired t-test)
Fundamental knowledge regarding pharmacovigilance	3.55 ± 1.86	3.86 ± 1.74	<0.0001
Reporting of adverse drug reactions	0.88 ± 0.85	1.09 ± 0.76	<0.0001
Possible positive impact of pharmacovigilance	1.62 ± 1.13	1.82 ± 0.98	<0.0001
Recommendation on improvement of pharmacovigilance system	2.32 ± 1.48	2.59 ± 1.32	<0.0001

There was statistically significant increase in mean score of resident doctors on all domain of pharmacovigilance after our awareness activities.

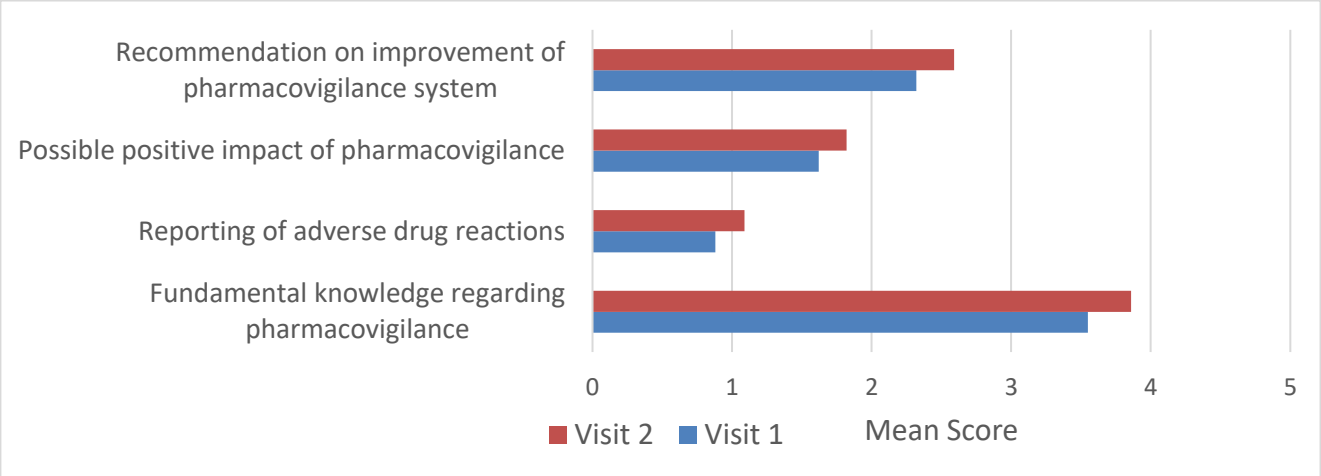

Figure 1: Comparison of Mean Score Obtained by Resident Doctors at visit 1 and visit 2

DISCUSSION

In order to gauge the level of pharmacovigilance knowledge and practise among healthcare professionals, a questionnaire-based survey with fifteen questions was used in this study on 66 resident doctors. This study demonstrated that although many residents were aware of pharmacovigilance, their rate of reporting was still low when considered in its context.[20,21] Resident doctors had slightly lower levels of PvPI awareness, which contributes to their constructivist approach to pharmacovigilance. This number was somewhat higher on the second visit, which is consistent with findings from another study.[22]

Almost all resident doctors appeared to be familiar with the idea of pharmacovigilance, however the majority of participants were unable to describe the term. The majority of the participants were able to describe adverse drug reactions (ADRs) and medication errors, as well as provide some details and examples of ADRs they had seen in their domains of practise. The majority of residents were unaware of the reporting processes and instruments. This was demonstrated by the stark discrepancy between their testimony regarding how frequently they encounter ADRs and the number of ADR reports gathered from the hospital during that time. Other observational studies and this one shared some similarities.[23,24]

Although spontaneous reporting is a crucial component of pharmacovigilance, our research found that knowledge and practise of it were on the low end of the spectrum. This can be explained by an intense workload, a shortage of time, a lack of understanding about the existing pharmacovigilance framework, a lack of criticism, and a lack of resources.[25] The majority of residents believed that avoidable adverse drug reactions (ADRs) were a critical clinical component that needed to be reported in order to avert tragedies in the future brought on by avoidable ADRs. However, they recognised that any extra work might not be very welcome given the substantial amount of work they already faced in their daily practise, but they still accepted to report. This was an encouraging reaction for potential future pharmacovigilance initiatives in the institution.

The purpose of this study was also to evaluate the resident doctors' level of knowledge and awareness of several pharmacovigilance domains. The study questionnaire included four different domains of questions to gauge participants' levels of knowledge about various topics. These four domains included the following: basic understanding of pharmacovigilance (questions nos. 1, 3, 4, 6, 7 and 8); drug safety reporting system (questions nos. 2 and 5); the potential advantages of pharmacovigilance (questions nos. 9, 10, and 11); and ability to provide constructive feedback or suggestions regarding the enhancement of pharmacovigilance framework (questions nos. 12, 13, 14, and 15).

Nearly 70% of resident doctors in the first visit and nearly 75% in the second visit had average or above average fundamental knowledge of pharmacovigilance, while only 7% of resident doctors in the first visit and 3% in the second visit were completely ignorant of the concept. This result is somewhat consistent with the study by Sewal RK et al., where 83.6% of those surveyed had average or greater than average fundamental knowledge of pharmacovigilance and 6% were completely ignorant of the idea. [26]

In terms of knowledge of the drug safety reporting system, almost 55% of residents demonstrated average or above average knowledge during their first visit and 75% during their second visit, whereas nearly 45% during their first visit and 25% during their second visit were completely ignorant of any reporting method. It suggests that there is not enough of practise with regard to the drug safety reporting system, which is something that another study also noticed.[27] This startling figure necessitates enhancement in the drug safety reporting system through campaigns and educational programmes.

Underreporting is a severe problem, and its causes include a lack of interest in doing so as well as a lack of time brought on by the busy schedule of clinical tasks.[24] Underreporting can be reduced by streamlining documentation requirements, providing toll-free support, offering financial incentives, establishing additional ADR centres, and enhancing interactions between medical practitioners and pharmacovigilance facilities.[28,29]

Additionally, the difference between the mean scores obtained by residents in each of the four classes (A, B, C, and D) of distinct pharmacovigilance areas after the two visits was found to be highly significant.

We also discovered that regular orientation and sensitization enhanced the mean number of ADRs in three months following the conclusion of both visits. A different study also found a similar tendency.[30] Therefore, it is necessary to develop strategies to increase these professionals' familiarity with pharmacovigilance. To raise awareness regarding reporting ADRs, there is an opportunity for educational and training initiatives like CMEs.

The comparison of knowledge and practise before and after educational interventions is the study's main strength. This study also shown how regular training and sensitization can enhance knowledge and skills in a variety of pharmacovigilance-related areas. Our study is limited by the possibility that reporting bias affected the responses of participants. Additionally, the survey focused solely on the hospital's resident doctors under the presumption that the data collected would apply to all healthcare professionals working there, which adds another restriction.

CONCLUSION

This study found that after providing sufficient sensitization, residents had increased knowledge and practise in various areas of pharmacovigilance. Therefore, for a better healthcare system, improved perception can eliminate the myths, challenges, and barriers to the practise of pharmacovigilance. To better comprehend this system,

pharmacovigilance needs to be widely understood by all healthcare practitioners. Additionally, to reduce adverse drug events or other drug-related issues, future doctors must be made more aware of rational drug usage. This can be done by placing a special emphasis on pharmacovigilance in medical curriculum and incorporating it into medical internships.

REFERENCES

1. Ayalew MB, Megersa TN, Mengistu YT. Drug-related problems in medical wards of Tikur Anbessa specialized hospital, Ethiopia. J Res Pharm Pract. 2015;4(4):216-21.

2. The Importance of Pharmacovigilance Safety Monitoring of medicinal products [Internet]. United Kingdom: World Health Organization; 2002 [cited 3 April 2023]. Available from: https://apps.who.int/medicinedocs/pdf/s4893e/s4893e.pdf

3. Aronson JK. Adverse drug reactions- no farewell to harms. Br J Clin Pharmacol. 2007;63(2):131-5.

4. Pirmohammed M, James S, Meakin S, Green C, Park BK. Adverse drug reactions as a cause of admission to the hospital: prospective analysis of 18820 patients. Br Med J. 2004;329:15- 9.

5. Ratan JL, Mangala L, Sukirti D. A study on adverse drug reactions in a tertiary care hospital of northeast India. Alex J Med. 2017;53:151-6

6. Bouvy JC, De Bruin ML, Koopmanschap MA. Epidemiology of adverse drug reactions in Europe: a review of recent observational studies. Drug Saf. 2015;8:437-53.

7. Jayanthi CR, Renuka M, Panchaksharimath P. An observational Study to analyze the Adverse drug Reactions among the Elderly at A Tertiary Care Hospital. Biomed Pharmacol J. 201710(1):345-52.

8. Bates DW, Spell N, Cullen DJ, Burdick E, Laird N, Petersen LA. The costs of adverse drug events in hospitalized patients. Adverse Drug Events Prevention Study Group. JAMA. 1997;277:307–11

9. Pharmacovigilance Programme of India (PvPI) Updates: Performance Report 2018-19 [Internet]. Ghaziabad: Indian Pharmacopoeia Commission; 2019 [cited 2 February 2020]. Available from: https://ipc.gov.in/mandates/pvpi/pvpiupdates/8-category-en/646-annual-performance-report.

10. Kalaiselvan V, Prakash J, Singh GN. Pharmacovigilance programme of India. Arch Pharm Pract. 2012;3:229-32.

11. Vallano A, Cereza G, Pedros C, Agustí A, Danés I, Aguilera C, et al. Obstacles and solutions for spontaneous reporting of adverse drug reactions in the hospital. Br J Clin Pharmacol. 2005;60(6):653-8.

12. A Framework for Assessing the Economic Value of Pharmacovigilance in Low- and Middle-Income Countries - Springer. [cited 2020 Jan 22]; Available from: http://link.springer.com/article/10.1007/s40264-014-0143- 1/fulltext.html

13. Hussain MM, Girhepunje K, Pal R, Siddiqua SS. Incidence of Adverse Drug Reactions in a Tertiary Care Hospital: A Systematic Review and Meta-Analysis of Prospective Studies. Scholars Res Library. 2010;2(3):358-67.

14. Khan FA, Nizamuddin S, Najmul H, Mishra H. A prospective study on prevalence of adverse drug reactions due to antibiotics usage in otolaryngology department of a tertiary care hospital in North India. Int J Basic Clin Pharmacol. 2013;2:548–53

15. Ramesh M, Pandit J, Parthasarathi G. Adverse drug reactions in a south Indian hospital – Their severity and cost involved. Pharmacoepidemiol Drug Saf. 2003;12:687-92.

16. 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.

17. Alan S, Ozturk M, Gokyildiz S, Avcibay B, Karatas Y. An evaluation of knowledge of pharmacovigilance among nurses and midwives in Turkey. Indian J Pharmacol. 2013;45(6):616- 8.

18. Arias E, Schauman WS, Eschbach K, Sorlie PD, Backlund E. The validity of race and Hispanic origin reporting on death certificates in the United States. Vital Health Stat. 2 2008;148:1-23.

19. Kalaiselvan V, Gakhar S, Prasad T, Gupta SK, Singh GN. Spontaneous reporting of adverse drug reactions in geriatric patients in India. Natl J Physiol Pharm Pharmacol. 2014;3:225-8.

20. Herdeiro MT, Figueiras A, Polónia J, Gestal-Otero JJ. Physicians' Attitudes and Adverse Drug Reaction Reporting. Drug Saf. 2005;28(9):825-33.

21. Carbonin P, Bernabei R, Sgadari A. Is age an Independent risk factor of adverse drug reactions in hospitalized medical patients?. J Am Geriatr Soc. 1991;39(11):1093-9.

22. Gupta P, Udupa A. Adverse drug reporting and pharmacovigilance: Knowledge, attitude and perception among resident doctors. J Pharm Sci Res. 2011;3:1064-6.

23. Ganesan S, Vikneswaran G, Reddy KC, Subrahmanyam DK, Adithan C. A survey on knowledge, attitude and practice of pharmacovigilance towards adverse drug reactions reporting among doctors and nurses in a tertiary Care Hospital in South India. J Young Pharm. 2016;8(4):471-6.

24. Agarwal R, Daher AM, Ismail MN. Knowledge, practices and attitudes towards adverse drug reaction reporting by private practitioners from Klang valley in Malaysia. Malays J Med Sci. 2013;20(2):52-61.

25. Vallano A, Castañeda PF, Quijada Manuitt MA, Simon PC, Pedrós C, et al. Hospital Doctors' Views and Concerns about Pharmacovigilance. J Pharmacovigilance. 2015;3:160.

26. Saini VK, Sewal RK, Ahmad Y, Medhi B. Prospective observational study of adverse drug reactions of anticancer drugs used in cancer treatment in a tertiary care hospital. Indian J Pharm Sci. 2015;77:687-93.

27. Grootheest V, others. Attitudinal survey of voluntary reporting of adverse drug reactions. Br J Clin Pharmacol. 1999;48(4):623-7.

28. Kharkar M, Bowalekar S. Knowledge, attitude and perception/practices (KAP) of medical practitioners in India towards adverse drug reaction (ADR) reporting. Perspect Clin Res. 2012;3;3:90-4.

29. 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.

30. Fabbri S, Sichetti D, Di Giulio P. Efficacy of an education on adverse drug reaction reporting by nurses in nursing homes: A pre-post study. J Hosp Clin Pharm. 2016;2(3):6-13.

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