Print ISSN: 2319-2003 | Online ISSN: 2279-0780

IJBCP International Journal of Basic & Clinical Pharmacology

DOI: http://dx.doi.org/10.18203/2319-2003.ijbcp20180668

Original Research Article

Study of knowledge, attitude, and practices towards current updates of pharmacovigilance and adverse drug reaction reporting among doctors in a tertiary care teaching hospital of Western India

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Received: 01 January 2018
Accepted: 29 January 2018

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ABSTRACT

Background: In general, adverse drug reactions (ADRs) are global problems causing both morbidity and mortality. Spontaneous ADR reporting is important to monitor adverse effects of medicines but under reporting is still very prevalent so, there is a need of constant monitoring and rectification of system of Pharmacovigilance. The objective of this study was to evaluate the knowledge, attitude, and practices (KAP) of the healthcare professionals about Pharmacovigilance and to identify the reason for under reporting of ADRs.
Methods: A cross-sectional study was carried out using a pretested questionnaire among doctors with minimum qualification MBBS or B.D.S. including faculties, senior and junior residents. Subsequently, analysis of association between education and experience was done by chi square test at P-value <0.05.
Results: A pretested questionnaire was distributed among 403 doctors and 240 (59.16%) responded voluntarily. In general, 131(54.58%) participants noted lack of time to report ADR while 90 (37.50%) participants noted no benefit of reporting already known ADR. On the other hand, total 104 (43.33%) participants were aware about need to report a serious adverse event during "Clinical Trial" within 24 hours to the Ethics Committee. Only 87 (36.25%) participants noted a need of reporting of already known ADR.
Conclusions: Participants had good knowledge and attitude towards pharmacovigilance, but the actual practice of ADR reporting is still deficient among them that can be improved by sensitization training and involvement of grass root level health care workers.

Keywords: Adverse drug reactions, Attitude, Doctor, Knowledge, Pharmacovigilance, Practice, Questionnaire

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.

In the same manner in India, all healthcare professionals including doctors, nurses, and pharmacists can report an ADR by filling up updated current version of suspected ADR Form (Version 1.3) of the Central Drugs Standard Control Organization (CDSCO).[1]

For these reasons, it's important for healthcare professionals to know how to report and where to report an ADR. Hence, active participation of healthcare professionals in the Pharmacovigilance program can improve the ADR reporting.[2]

In spite of constant endeavor by the Pharmacovigilance Programme of India towards inculcating a culture of ADR monitoring; under reporting is very prevalent. Furthermore, as per current version of National Strategic Plan for scale up of Pharmacovigilance in India for 2018 - launched by National Coordination Centre-

Pharmacovigilance Programme of India (PvPI), Indian Pharmacopoeia Commission, Ghaziabad in technical collaboration with World Health Organization Country Office for India, there is a requirement for constant training and enactment of regulations for ADR reporting among healthcare professionals including PHC, CHC and Grass root level health care workers.[3] For instance, previous reported studies have noted that under reporting of ADR is related with shortcomings in the knowledge and attitude among healthcare professionals.[4,5]

Hence, this study was carried out with an objective to explore the knowledge, attitude, and practice (KAP) of doctors toward Pharmacovigilance in a tertiary care teaching hospital of Western India.

METHODS

Questionnaire development

In this study, questionnaire was framed as mentioned in Table 2. All questions were designed based on earlier meta-analysis and research on Pharmacovigilance.[6-8] Moreover, external and internal validation and corrections were done through voluntary participation of doctors by pilot study in group of 25 participants.

This study was approved by Institutional Ethics Committee for Human Research (EC Reg. No. IECHR/ECR/85/Inst/GJ/2013/26.05.2016). Moreover, prior permission of Chairperson of Adverse Drug Reaction Monitoring Centre (AMC) for Pharmacovigilance Programme of India (PvPI) was also taken before starting study. In general, study was explained by investigator and doctors who were ready to sign informed written consent voluntarily to participate in the study after reading the nature of the study explained by participant's information sheet.

Study design and sample size

A cross-sectional questionnaire-based study was carried out on participants consisting of the healthcare professionals including Consultant, Assistant Professor, Associate Professor, Professor and Resident Doctors.

On the whole, only those Doctors, who had given written consent to participate in the study voluntarily, were included by giving the questionnaire in presence of the investigator over a period of six months' study duration. Eventually, a hard copy of study questionnaire was filled by participants and given back to the investigator.

Data collection

After getting prior permission of department head, a questionnaire was given to the healthcare professionals working in clinical departments during face to face meeting, before or after case presentation, seminar or journal club of individual department. Moreover, all forms were collected immediately after filling up the form by participants in presence of investigator. Consequently, data was coded and scored before transferring in to the excel sheet for analysis. Finally, completeness and accuracy of the data was checked before and after the data entry.

Statistical analysis

On the whole, Chi Square test was used to identify association between good knowledge /attitude and practice towards Pharmacovigilance to identify 1) Association between academic qualification, knowledge and practice of Pharmacovigilance 2) Association between years of experience, attitude and practice towards Pharmacovigilance.

Overall statistical analysis was done by using windows excel software and GraphPad InStat software. For P - Value <0.05, the null hypothesis was rejected, and the alternative hypothesis was accepted for association analysis.

RESULTS

Table 1: Demographic characteristic of participants.

Characteristic of Participant	Total participant (n= 240) (240/403=59.55%)
Highest academic qualification:	
M.B.B.S.	142 (59.16%)
M. D.	48 (20%)
M. S.	46 (19.16%)
B.D.S.	3 (1.25%)
M.D.S.	1 (0.41%)
Current designation:	
Resident (JR and SR)	146 (60.83%)
Tutors	6 (2.5%)
Assistant professor	42 (17.50%)
Associate professor	31 (12.92%)
Professor	11 (4.58%)
Gender:	
Male	183 (76.25%)
Female	57 (23.75%)
Professional experiences after graduation (M.B.B.S./ B.D.S.) (e.g. Internship = 0-year, first year resident = 1 year)	
<5 years	150 (62.50%)
5-10 Years	44 (18.33%)
10-15 years	34 (14.16%)
>15 years	12 (5%)

Finally, the sample of the study consisted of 403 doctors including Professors, Associate Professor, Assistant professor, Tutors, Senior Residents and Junior Residents. Overall, total 240 (59.16%) participants were finally included in study analysis. Academic qualification,

experience, and designation profile of participants are as mentioned in the Table 1.

As mentioned in Table 2, Table 3 and Table 4, a cross-sectional analysis was carried out using a pretested questionnaire among 240 (240/403= 59.16%) participants with minimum qualification MBBS or B.D.S. including faculties, senior and junior residents, in a government hospital for six months. Subsequently, statistical analysis was done by evaluation of association between level of education, experience versus knowledge, attitude and practice about Pharmacovigilance by Chi square test. Among participants, knowledge about who can do reporting of ADRs in a hospital is not independent from years of experience ($\chi2$ = 38.51; P - Value = 0.0001) or level of education ($\chi2$ = 41.88; P - Value <0.0001).

Moreover, total 145 (60.42%) participants had ever seen the voluntary ADR reporting form that's not independent from years of experience ($\chi2$ = 27.88; P - Value <0.0001), but among them only 68 (46.90%) participants were ever been trained on how to fill up ADR form that's not independent from years of experience ($\chi2$ = 32.12; P - Value <0.0001) or level of education ($\chi2$ = 6.45; P - Value = 0.17).

Table 2: Participants' questionnaire scores regarding their perceived knowledge, attitude and practice of Pharmacovigilance (N= 240).

Study questionnaire	Frequency (percentage) (n=240)
Knowledge	
Who can do reporting Adverse Drug Reactions in a hospital?	
(a) Doctor	148 (61.67%)
(b) Nurses	38 (16.25%)
(c) Pharmacist	46 (19.17%)
(d) All of the above	8 (3.33%)
In India which regulatory body is monitoring Adverse Drug Reactions (ADRs)?	
(a) Central Drugs Standard Control Organization (CDSCO)	118 (49.17%)
(b) Indian Council of Medical Research (ICMR)	43 (17.92%)
(c) Indian Pharmacopoeia Commission (IPC)	72 (30%)
(d) Medical Council of India (MCI)	7 (2.92%)
In India, a serious adverse event during "Clinical Trial" should be reported by the Principal Investigator to the Ethics Committee within...	
(a) One day (24 hours)	104 (43.33%)
(b) Seven calendar days	68 (28.33%)
(c) Fourteen calendar days	62 (25.83%)
(d) No idea	6 (2.50%)
Attitude	
Which of the following factor discourage you from reporting Adverse Drug Reactions (ADRs)?	
No remuneration (financial benefit) for reporting	11 (4.58%)
Lack of time to report ADR	131(54.58%)
Lack of information about how to fill up ADR reporting form	71 (29.58%)
No benefit of reporting already known ADR	90 (37.50%)
None of Above	34 (14.17%)
Other Reason_____	14 (5.83 %)
Do you think reporting of already known adverse drug reaction is necessary?	
(a) Yes	87 (36.25%)
(b) No	71 (29.58%)
(c) Can't say (I have no idea what they do after getting already known ADR)	47 (19.58%)
(d) May be (It may help to calculate incidence of reported ADR)	35 (14.58%)
Practice	
Have you ever seen the Adverse Drug Reaction -ADR reporting form?	
(a) Yes	145 (60.42%)
(b) No	95 (39.58%)
If yes, then have you ever been trained on how to fill up and report Adverse Drug Reaction (ADR)?	
(a) Yes	68 (46.90%)
(b) No	77 (53.10%)

Table 3: Analysis of association between level of education versus knowledge, attitude and practice of ADR reporting.

Questionnaire	Level of education (degree)						Chi Square test result
	M.B.B.S.	M. D.	M. S.	B.D.S.	M.D.S.	Total	Association analysis
Who can do reporting Adverse Drug Reactions in a hospital?							
(a) Doctor	107	16	23	2	0	148	$X^2 = 38.518$
(b) Nurses	12	13	12	0	1	38	df = 12
(c) Pharmacist	20	16	9	1	0	46	P - Value = 0.0001
(d) All of the above	3	3	2	0	0	8	
	142	48	46	3	1	240	
In India which regulatory body is monitoring Adverse Drug Reactions (ADRs)?							
(a) Central Drugs Standard Control Organization (CDSCO)	77	16	22	3	0	118	$X^2 = 20.159$
(b) Indian Council of Medical Research (ICMR)	17	15	11	0	0	43	df = 12
(c) Indian Pharmacopoeia Commission (IPC)	42	17	12	0	1	72	P - Value = 0.0641
(d) Medical Council of India (MCI)	6	0	1	0	0	7	
	142	48	46	3	1	240	
In India, a serious adverse event during “Clinical Trial” should be reported by the Principal Investigator to the Ethics Committee within...							
(a) One day (24 hours)	70	16	15	3	0	104	$X^2 = 16.179$
(b) Seven calendar days	33	18	16	0	1	68	df = 12
(c) Fourteen calendar days	34	13	15	0	0	62	P - Value = 0.1832
(d) No idea	5	0	1	0	0	6	
	142	47	47	3	1	240	
Which of the following factor discourage you from reporting Adverse Drug Reactions (ADRs)?							
(a) No remuneration (financial benefit) for reporting	6	3	2	0	0	11	$X^2 = 18.855$
(b) Lack of time to report ADR	80	25	24	1	1	131	df = 20
(c) Lack of information about how to fill up ADR reporting form	49	13	8	1	0	71	P - Value = 0.5313
(d) No benefit of reporting already known ADR	61	9	18	2	0	90	
(e) None of Above	14	9	11	0	0	34	
(f) Other Reason_____	7	3	4	0	0	14	
	217	62	67	4	1	351	
Do you think reporting of already known adverse drug reaction is necessary?							
(a) Yes	36	23	26	1	1	87	$X^2 = 30.660$
(b) No	51	6	13	1	0	71	df = 20
(c) Can't say (I have no idea what they do after getting already known ADR)	35	8	4	0	0	47	P - Value = 0.0022
(d) May be (It may help to calculate incidence of reported ADR)	20	11	3	1	0	35	
	142	48	46	3	1	240	
Have you ever seen the Adverse Drug Reaction -ADR reporting form?							
(a) Yes	94	24	25	1	1	145	$X^2 = 6.446$
(b) No	48	24	21	2	0	95	df = 4
	142	48	46	3	1	240	P - Value = 0.1682
If yes, then have you ever been trained on how to fill up and report Adverse Drug Reaction (ADR)?							
(a) Yes	34	15	17	1	1	68	$X^2 = 13.425$
(b) No	60	9	8	0	0	77	df = 4
	94	24	25	1	1	145	P - Value = 0.0094

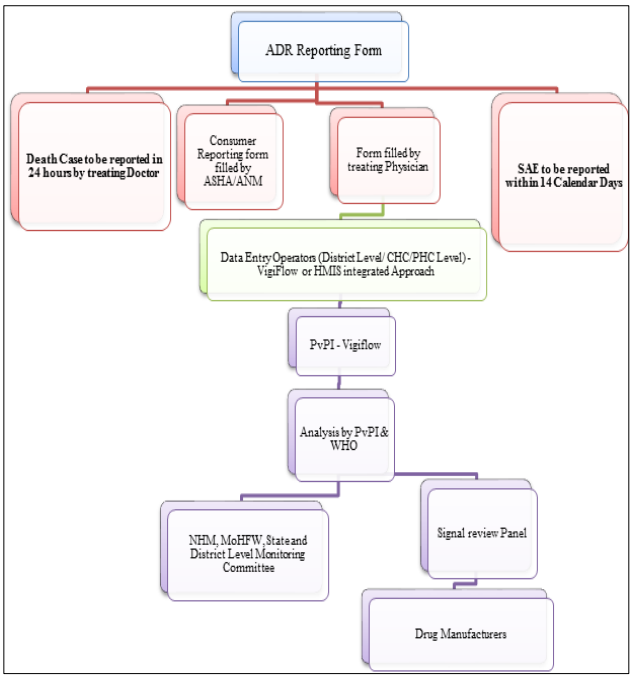
Table 4: Analysis of association between academic experience versus knowledge, attitude and practice of ADR reporting.

Questionnaire	Academic experience (years)				Chi Square test result
	<5	5-10	10-15	>15	Association analysis
Who can do reporting Adverse Drug Reactions in a hospital?					
(a) Doctor	107	27	9	5	$\chi^2 = 41.877$
(b) Nurses	17	5	12	4	df = 9
(c) Pharmacist	23	12	8	3	P - Value <0.0001
(d) All of the above	3	0	5	0	
In India which regulatory body is monitoring Adverse Drug Reactions (ADRs)?					
(a) Central Drugs Standard Control Organization	81	16	17	4	$\chi^2 = 13.703$
(b) Indian Council of Medical Research (ICMR)	20	9	10	4	df = 9
(c) Indian Pharmacopoeia Commission (IPC)	43	18	7	4	P - Value = 0.1333
(d) Medical Council of India (MCI)	6	1	0	0	
In India, a serious adverse event during "Clinical Trial" should be reported by the Principal Investigator to the Ethics Committee within...					
(a) One day (24 hours)	73	16	13	2	$\chi^2 = 11.265$
(b) Seven calendar days	35	17	10	6	df = 9
(c) Fourteen calendar days	37	10	11	4	P - Value = 0.2580
(d) No idea	5	1	0	0	
Which of the following factor discourage you from reporting Adverse Drug Reactions (ADRs)?					
(a) No remuneration (financial benefit) for reporting	7	3	0	1	$\chi^2 = 29.313$
(b) Lack of time to report ADR	82	25	22	2	df = 15
(c) Lack of information about how to fill up ADR reporting form	53	8	6	4	P - Value = 0.0147
(d) No benefit of reporting already known ADR	64	9	14	3	
(e) None of Above	15	6	8	5	
(f) Other Reason_____	7	3	4	0	
Do you think reporting of already known adverse drug reaction is necessary?					
(a) Yes	43	16	17	11	$\chi^2 = 36.037$
(b) No	51	7	13	0	df = 9
(c) Can't say (I have no idea what they do after getting already known ADR)	35	9	2	1	P - Value <0.0001
(d) May be (It may help to calculate incidence of reported ADR)	21	12	2	0	
Have you ever seen the Adverse Drug Reaction -ADR reporting form?					
(a) Yes	100	13	20	12	$\chi^2 = 27.883$
(b) No	50	31	14	0	df = 3
					P - value <0.0001
If yes, then have you ever been trained on how to fill up and report Adverse Drug Reaction (ADR)?					
(a) Yes	38	10	8	12	$\chi^2 = 32.117$
(b) No	112	35	25	0	df = 3
					P - value <0.0001

In general, 131 (54.58%) participants noted lack of time to report ADR while 90 (37.50%) participants noted no benefit of reporting already known ADR that's not independent from years of experience ($\chi2 = 16.18$; P - Value = 0.18) but independent from level of education ($\chi2 = 29.31$; P - Value = 0.01).

In addition to that total 104 (43.33%) participants were aware about need to report a serious adverse event during "Clinical Trial" within 24 hours by the Principal Investigator to the Ethics Committee and they are independent from level of education ($\chi2 = 16.18$; P - Value = 0.17) or experience ($\chi2 = 11.26$; P - Value = 0.26).

At last, total 118 (49.17%) participants gave correct response telling regulatory body monitoring Adverse Drug Reactions (ADRs) but they are independent from level of education ($\chi2 = 20.16$; P - Value = 0.06) or experience ($\chi2 = 13.70$; P - Value = 0.13).



ADR - Adverse Drug Reaction, ANM - Auxiliary Nurse Midwife, ASHA - Accredited Social Health Activist, CHC - Community Health Centre, HMIS - Health Management Information System, NHM - National Health Mission, MoHFW - Ministry of Health and Family Welfare, PHC - Primary Health Centre, PvPI -Pharmacovigilance Programme of India, SAE-Serious Adverse Event.[3]

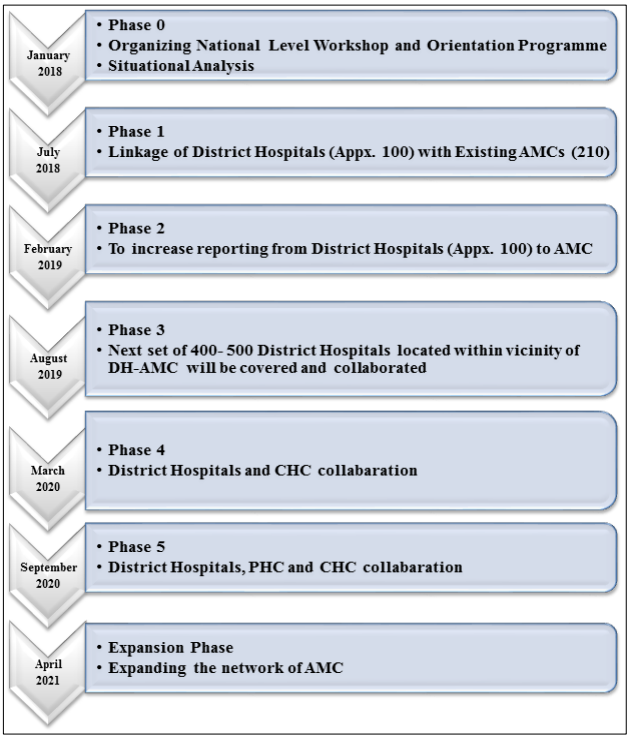
Figure 1: Timeline for adverse drug reaction notification and serious adverse event reporting.

DISCUSSION

In the past 20 years, many low- and middle-income countries have formed national pharmacovigilance (PV) systems and joined the WHO's global PV set-up. However, very few of them have fully functional systems. ADRs account for 4.2-30% of hospital admissions in USA and Canada, 5.7-18.8% in Australia, and 2.5-10.6% in Europe.[9] On the other side, a study in India reported overall incidence of 9.8% ADRs including 3.4% of total hospital admissions and 3.7% ADRs developed during hospital stay.[10]

In India, epidemiological data, scientific evidence on the local burden of medicine-related harm and their preventability are still missing. For this reason, legislation and regulatory framework as well as economic support to build sustainable PV systems are needed. Hence, signal analysis should focus on high-burden avoidable adverse drug problems. Similarly, increased contribution of healthcare professionals from public and private sectors, pharmaceutical companies, academic institutions and the public at large is necessary to assure a safe drug therapy.[6]

Overall, there is a need of frequent training and sensitization to improve total reporting of ADR at tertiary care teaching hospitals. Moreover, large scale awareness of pharmacovigilance is required among medical students, interns and residents for better understanding of ADR and its reporting. Furthermore, special emphasis of pharmacovigilance is needed in postgraduate curriculum and its incorporation in medical internship.[11]



AMC Adverse Drug Reaction Monitoring Centre, CHC - Community Health Centre, DH- District Hospital, PHC - Primary Health Centre, PvPI -Pharmacovigilance Programme of India.[3]

Figure 2: Year wise National strategic plan for scale up of pharmacovigilance in India.

Overall, there is a need of frequent training and sensitization to improve total reporting of ADR at tertiary care teaching hospitals. Moreover, large scale awareness of pharmacovigilance is required among medical students, interns and residents for better understanding of ADR and its reporting. Furthermore, special emphasis of pharmacovigilance is needed in postgraduate curriculum and its incorporation in medical internship.[11]

In one study conducted at Aurangabad, multispecialty faculties participated in the study. Their findings strongly suggested that healthcare professionals were having a positive attitude towards Pharmacovigilance but there was a great need to create awareness and to promote the reporting of ADR amongst prescribers of Government Medical College and Hospital, Aurangabad.[12,13]

In another study conducted on 147 doctors and 83 nurses at Saveetha Medical College Hospital, Thandalam, a multispecialty tertiary care hospital in Chennai, similar findings were observed. Overall, total 75.2% participants had ever seen the ADR reporting form and among them 64.3% participants were ever been trained on how to report Adverse Drug Reaction (ADR). On analysing reasons for

under reporting, Non remuneration for reporting, Lack of time to report ADR, A single unreported case may not affect ADR database, Difficult to decide whether ADR has occurred or not types of reasons were noted in 13.9%, 33.4%, 17.3% and 35.2% participant respectively.[14]

Presently, as shown in Figure 1 and Figure 2, National Strategic Plan for scale up of Pharmacovigilance in India for 2018 has been launched by National Coordination Centre-Pharmacovigilance Programme of India (PvPI), Indian Pharmacopoeia Commission, Ghaziabad in technical collaboration with World Health Organization Country Office for India.[3] Furthermore, newer ADR reporting forms in vernacular languages are already introduced by PvPI, and additional ADR monitoring forms form identification of ADR of Bedaquiline, and ADR of treatment of Kala Azar are under implementation phase.[15] In the end, communication of information about ADR including PvPI website, e-mails, Short Message Service and a dedicated toll-free helpline are possible by patients and health care workers at PHC, CHC and ANM level.[3] Presently, National Accreditation Board for Hospitals and Healthcare Providers (NABH) is also providing training for implementation of Pharmacovigilance Programme in Indian Hospitals.[16]

Challenges to adverse drug reaction reporting in pharmacovigilance reported by participants

Initiating a stable ADR reporting process involves many challenges as suggested by practicing doctors as a feedback.

- Doctors may be unwilling or uncomfortable reporting ADRs in presence of patient taking treatment due to fear of repeated violence due to false perceptions of professional error or fault.
- Practicing doctors are often few and they are having many patients to treat, with academic and administrative activities that spares little time to fill a form and report a suspected ADR.
- Information about need of consent before reporting Adverse Drug Reaction from patient's treatment record is not clear.
- In a busy OPD with serious patient load in the whole hospital, each patient requires attention, chain of investigation, procedure and queues to obtain medicine. Morally, it's difficult to retain patient for filling up so many information as demanded by new version of suspected ADR reporting form that may delay their investigation, report or medicines to next day.
- Clarity of maintaining source documents related to ADR is not provided as they are routinely needed in clinical trials.
- In case of incomplete information available with patients as needed in suspected ADR reporting form, their submission will become difficult.
- Lack of feedback about further advantage, regulatory consequences and updates about newer ADR of medicines.

Lastly, addressing above challenges of Doctors is dire need of actual functioning of Program with good quality reporting. Ultimately, help and participation of specialist from community medicine, medicine and paediatrics can facilitate in improvement in reporting of Adverse Drug Reactions.

Limitations of this study was only clinicians of Govt. Hospitals were included so it cannot be generalized due to non involvement of private practitioners.

CONCLUSION

In spite of having good knowledge and positive attitude towards Pharmacovigilance, practice of ADR reporting remains relatively poor due to lack of sufficient time due to workload of patients and academic activities being a tertiary care teaching hospital. Finally, the reporting rate of ADR can be improved with training about Pharmacovigilance to junior doctors.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee for Human Research (IECHR/ECR/85/Inst/GJ/2013/26.05.2016)

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Cite this article as: Mistry CB, Shah SM, Modi VA, Mistry SD. Study of knowledge, attitude, and practices towards current updates of pharmacovigilance and adverse drug reaction reporting among doctors in a tertiary care teaching hospital of Western India. Int J Basic Clin Pharmacol 2018;7:524-31.