Original article

A Study on Knowledge, Attitude and Practices among Healthcare Professionals Regarding the Adverse Drug Reaction Monitoring and Reporting at a Tertiary Care Teaching Hospital

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Abstract

Objective*:** This study was aimed to assess the knowledge, attitude, and practices (KAP) of the healthcare professionalsin respect to pharmacovigilance and to compare the KAP of resident doctors with KAP of staff nurses. The secondary objective of this study was to further compare the results of various other studies done till dateacross India so as to assessthe major contributors responsible for under reporting. ***Materials and Methods:This is a cross-sectional, questionnaire-based study; carried out on 70 resident doctors and 71 staff nurses of Hakeem Abdul Hakeem Centenary Hospital, Jamia Hamdard, New Delhi. The questionnaire was designed to assess the KAP regarding pharmacovigilance among the healthcare professionals. Statistical analysis was done using student t- test and Pearson correlation. ***Results:***Our study showed a considerable gap between the adverse event experienced (82.26%) and adverse event reported (39.71%) by the healthcare professionals. From the result of the study it is clearly evident that the resident doctors have unquestionably more knowledge of pharmacovigilance (67.71%) when compared to the nurses (49.85%). How so ever, the nurses showed a better attitude towards the reporting of adverse events (80.12%) and significantly far better in practices (60.71%)regarding pharmacovigilance. It has also been seen there is a significant positive correlation betweenpharmacovigilance training and adverse event reporting.Also healthcare professionals believe that regular workshops and continuing medical education (CMEs) would definitelyimprovethe reporting culture of adverse event among them.***Conclusion:***From the present study, we concluded that there is a considerable gap between the adverse events experienced and adverse event reported; although our HCPs have fine knowledge and attitude regarding pharmacovigilance yet their practices are not upto the mark; good number of our HCPs are trained on pharmacovigilance yet their ADR reporting is low; there is a strong positive correlation between pharmacovigilance training and ADRs reporting.There is a need to develop a system for pharmacovigilanceand active measures,should be taken for making the HCP accountable for the ADRs, like remuneration, credit point system for each HCP reporting ADRs and appraisals of clinical departments reporting ADRs so as to inculcate the culture of ADRs reporting among healthcare professionals.

Keywords: Adverse event; adverse drug reactions; health care professionals;pharmacovigilance; questionnaire.

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Introduction

One of the significantetiologies of morbidity and mortality all over the world is adverse drug reactions or adverse events[1,2].Therefore, proper monitoring as well as adverse events reporting is very essential. In India, all the healthcare professionals counting doctors, nurses along with pharmacists can report an adverse drug event by filling a form i.e., adverse drug reaction (ADR) form which is issued by the Central Drugs Standard Control Organization (CDSCO)[3]. It is of utmost importance for the healthcare professionals to learn what to report, how to report and where to report an adverse drug event. The active taking part by the healthcare professionals in the pharmacovigilance program can enhance the monitoring of adverse drug event plusreporting[4].

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In country like India, apart from modern medicines there are many other systems of traditional medicines such as Ayurveda, Homeopathy, Unani and Siddha which has also been practiced by the significant rural population. Many efforts have been put forward by the Ministry of Health and Family Welfare to initiate thisPharmacovigilance program in their systems as well. Beside this, Pharmacovigilance has been incorporated in the pharmacology curriculum of the medical undergraduatesas well as postgraduates in India. Moreover, the Medical Council of India (MCI) has made it compulsory to have an operating unit ofPharmacovigilanceprogramme in each medical college to enhance the culture of adverse drug event monitoring as well as reporting. These efforts aimed toraise awareness among the coming uphealth care professionals which mayfinally translate into improved practices in terms of Pharmacovigilance. Taking all this into account, our medical college has also includedPharmacovigilance in thecurriculumof the medical students and also it has a registeredADR monitoring centre (AMC) under the Pharmacovigilance program of India (PvPI).

Although, there is continuous effortsmade by the Pharmacovigilance Programme of India towards improving the monitoring of adverse drug events but still underreporting is a major drawback.The prime reason for underreporting is lack of adverse event (AE) reporting practices among the healthcare professionals.On the conflicting end, in a study done by Tachéet *al*., it has been seen that the median preventable adverse drug reaction rate for ambulatory care-based studies was 16.5%, when compared to 52.9% for hospital-based studies[5]. It is obvious from this study thatthe healthcare professionals are greatly responsible for the detection, monitoring and reporting of the adverse event[6,7]. Thus, it is a professional necessity to organiseregular training programs to inculcate the adverse event reporting among the healthcare professionals.

Taking this into consideration, the present study has been designed with the primary objectiveto evaluate the knowledge, attitude, and practices (KAP) of the healthcare professionals regarding pharmacovigilance and adverse event reporting. Though, there are many studies which have evaluated the KAP of pharmacovigilance among the healthcare professionals[3,4,8-21] but those studies have beendone in the teaching hospitals of other parts of India to generalize the findings of the previous studies. The secondary objectiveof the present study was tocompare the KAP of resident doctors with those of staff nurses,to compare the findings of this study with the results of the earlier published studies from India and to analyse the cause ofthe underreporting of adverse events.

Materials and methods

This is a cross-sectional questionnaire-based study done onthe healthcare professionals ofHamdard Institute of Medical Sciences, New Delhi, a tertiary care teaching hospital. A total of 70 resident doctors and 71 staff nurses from differentmedical and surgical disciplines were enrolled in the study in the month of November, 2017.Only the healthcare professionals who has given the consent to participate were included in the study.

The KAP questionnaire was designed to determine the healthcare professionals for their knowledge, attitude and practices on pharmacovigilance and adverse event reporting. The questionnaire was designed based on earlier studies for assessing KAP of adverse event reporting[3,4,8,10,13,14,16,21]. The structured questionnaire consists of 10questions based on knowledge, 9questions on attitudeand 9questions that are practice based.At the end of the questionnaire there were some questions that has been put torevealgeneral information regarding the cause for under reporting and asking for suggestions to enhanceadverse event reporting. One question was also put down to assess the status of thetraining on pharmacovigilance among the healthcare professionals.A total of 151questionnaires [Appendix-II] were distributedandthe healthcare professionals were requested to fill and return themwithin 20 minutes.

Statistical analysis

All the information which we received from the returned questionnaire was coded and entered into Statistical Package for Social Sciences (SPSS) version 16 software. Comparison between KAP data obtained from resident doctorsand nurses was performed using student t-test with$P<0.05$ wasconsidered as significant. Pearson correlation was used to determine any relationship between training of pharmacovigilance and reporting adverse event.

Ethical Clearance: This research was approved by Hamdard institute of Medical Sciences and Research, Hamdard University, New Delhi.

Results

Table 1: Demographic details

Table 1 shows the demographic details of the healthcare professionals (n=141) The response rate was a high of 94%, with 141 completed questionnaires out of the 151 distributed.

Table 1: Demographic profile of healthcare professionals

	Doctors		Nurses	
	Frequency (n = 70)	%	Frequency (n = 71)	%
Gender				
Male	45	64.29	14	19.72
Female	25	35.71	57	80.28
Age (years)				
24-35	50	71.43	58	81.69
36-45	14	20.00	10	14.08
> 45	6	8.57	3	4.23
Mean age				

Table 2: Knowledge based questions

Table 2 shows the knowledge-based questions, it showed that 93.61% of healthcare workers gave correct response regarding the definition of an adverse drug reaction. 60.28% healthcare professional were aware that the most important purpose of pharmacovigilance is to identify safety of the drug; whereas, 57.44% of healthcare workers knew about the existence of a Pharmacovigilance Programme of India. However, only 20.56% were aware that rare ADRs can be identified during phase 4 clinical trial.

Table 2: Comparison of knowledge of resident doctors and nurses regarding pharmacovigilance.

S.No.	Question	Doctors		Nurses	
		Frequency (n=70)	%	Frequency (n=71)	%
1	Do you know an adverse drug reaction (ADR) is defined as "a response to a medicine which is noxious and unintended, and which occurs at doses normally used in man"?				
	a) Yes	70	100	62	87.32
	b) No	0	0	9	12.68
2	The most important purpose of Pharmacovigilance (PhV) is:				
	a) Correct response	41	58.57	44	61.97
	b) Incorrect response	29	41.43	27	38.03
3	Do you know regarding the existence of a National Pharmacovigilance Programme in India?				
	a) Yes	41	58.57	40	56.34
	b) No	29	41.43	31	43.66
4	In India which regulatory body is responsible for monitoring ADRs?				
	a) Correct response	37	52.86	40	56.34
	b) Incorrect response	33	47.14	31	43.66
5	"Who can report?" The healthcare professionals responsible for reporting ADRs in a hospital is/are:				
	a) Correct response	62	88.57	44	61.97
	b) Incorrect response	8	11.43	27	38.03
6	ADR reporting to be done for:				
	a) Correct response	49	70	53	74.65
	b) Incorrect response	21	30	18	25.35
7	Did you know a serious adverse event (SAE) is "any event that is fatal, life-threatening, permanently/ significantly disabling, requires or prolongs hospitalization, causes a congenital anomaly or requires intervention to prevent permanent impairment or damage"?				
	a) Yes	66	94.29	31	43.66
	b) No	4	5.714	40	56.34
8	"What to report?"				
	a) Correct response	58	82.86	36	50.7
	b) Incorrect response	12	17.14	35	49.3

S.No.	Question	Doctors		Nurses	
		Frequency (n=70)	%	Frequency (n=71)	%
9	"Whom to report ADRs?"				
	a) Correct response	21	30	4	5.634
	b) Incorrect response	49	70	67	94.37
10	Rare ADRs can be identified in the following phase of a clinical trial:				
	a) Correct response	29	41.43	0	0
	b) Incorrect response	41	58.57	71	100
	TOTAL CORRECT RESPONSE	**474**	**67.71**	**354**	**49.85**
	TOTAL INCORRECT RESPONSE	**226**	**32.28**	**356**	**50.14**

Table 3: Attitude based questions

Table 3 shows attitude based questions, it implies that a total of 97.16% healthcare professionals agreed that reporting of adverse event is necessary; whereas, 69.50% of the participants had read articles on prevention of adverse events.In our study 97.16% of health care professionalsthought that pharmacovigilance should be taught to all health care providers. How so ever, only 70.21% participants knew about the status of the pharmacovigilance committee in their institute and 59.57% healthcare professionals believed that ADR reporting damages their professional image.

Table 3: Comparison of attitude of resident doctors and nurses towards ADR monitoring and reporting.

S.No	Question	Doctors		Nurses	
		Frequency (n=70)	%	Frequency (n=71)	%
1	Is ADR reporting necessary?				
	a) Yes	70	100	67	94.37
	b) No	0	0	4	5.63
2	Is there any Pharmacovigilance Committee in your Institute?				
	a) Correct response	41	58.57	58	81.69
	b) Incorrect response	29	41.43	13	18.31
3	Who benefits from ADR reporting?				
	a) Correct response	66	94.29	49	69.01
	b) Incorrect response	4	5.714	22	30.99
4	Does ADR reporting damage professional image?				
	a) Yes	66	94.29	18	25.35
	b) No	4	5.714	53	74.65
5	Is there need of information on drug causing ADRs and their risk management strategies?				
	a) Yes	70	100	71	100.00
	b) No	0	0	0	0.00
6	Do you think Pharmacovigilance should be taught in detail to healthcare professionals?				
	a) Yes	66	94.29	71	100.00
	b) No	4	5.714	0	0.00
7	Have you anytime read any article on prevention of adverse drug reactions?				
	a) Yes	40	57.14	58	81.69
	b) No	30	42.85	13	18.31
8	What is your opinion about establishing ADR monitoring centre in every hospital?				
	a) Should be in every hospital	45	64.29	67	94.37
	b) Not necessary	25	35.71	4	5.63
9	Do you think your institute is registered as an ADR monitoring centre (AMC)?				
	a) Correct response	29	41.43	53	74.65
	b) Incorrect response	41	58.57	18	25.35
	TOTAL CORRECT RESPONSE	**493**	**78.25**	**512**	**80.12**
	TOTAL INCORRECT RESPONSE	**137**	**21.74**	**127**	**19.87**

Table 4: Practice based questions

Table 4 shows 82.26% of healthcare professionals had experienced adverse events in their patientswheras only 35.46% had seen the ADR reporting form and 39.71% had ever reported an adverse event. It also shows that merely 11.34% healthcare professional are aware that a serious adverse event(SAE) should be reported to the regulatory authority within 14

calendar days.

Table 4: Comparison of practices of resident doctors and nurses of ADR monitoring and reporting.

S.No.	Question	Doctors		Nurses	
		Frequency (n=70)	%	Frequency (n=71)	%
1	To find ADRs:				
	a) Correct response	66	94.29	62	87.32
	b) Incorrect response	4	5.71	9	12.68
2	Do you enquire about occurrence of ADRs?				
	a) Yes	47	67.14	20	28.16
	b) No	23	32.85	51	71.83
3	Which severity of ADRs do you report?				
	a) Correct response	49	70	53	74.65
	b) Incorrect response	21	30	18	25.35
4	Have you ever experienced adverse drug reactions in your patient during your professional practice?				
	a) Yes	58	82.86	58	81.69
	b) No	12	17.14	13	18.31
5	Have you ever reported ADR to the Pharmacovigilance centre?				
	a) Yes	16	22.86	40	56.34
	b) No	54	77.14	31	43.66
6	Have you ever seen the ADR reporting form?				
	a) Yes	29	41.43	31	43.66
	b) No	41	58.57	40	56.34
7	Is there any routine discussion on ADRs at your work place?				
	a) Yes	29	41.43	58	81.69
	b) No	41	58.57	13	18.31
8	Do you mention the ADRs on the patient's record?				
	a) Correct response	49	70	62	87.32
	b) Incorrect response	21	30	9	12.68
9	A serious adverse event in India should be reported to the regulatory body within				
	a) Correct response	12	17.14	4	5.63
	b) Incorrect response	58	82.86	67	94.37
	TOTAL CORRECT RESPONSE	**355**	**56.34**	**388**	**60.71**
	TOTAL INCORRECT RESPONSE	**275**	**43.65**	**251**	**39.28**

Table 5: Reasons for under-reporting& suggestions to improve the adverse event reporting rate

Table 5 shows the reasons for under-reporting & suggestions to improve the adverse event reporting rate. The main explanation for under reportingof adverse events as given by our health care professionals aredifficulty in deciding whether an adverse drug reaction has actually occurred or not (36.17%), lack of remuneration (27.65%), lack of time to report adverse event (30.49%) and lastly the belief that a single unreported case may not affect adverse event

database (2.83%). However, both resident doctors, 77.14% as well as nurses, 81.69% documented that workshops, continuingmedical education (CMEs) and other academic activities wouldimprove the understanding of Pharmacovigilanceand adverse event reporting. In our study "email" (29.78%) followed by"drop box" and phone call (21.27%) were the preferred mode of reporting adverse events. Among those who suggested that the drop box as mode of reporting, many of them suggested nursing station in wards and OPDs (54.60%) as a suitable site for its location.

Table 5: Suggestions regarding improving the ADR monitoring and reporting

S.No.	Questions	Doctors		Nurses	
		Frequency (n=70)	%	Frequency (n=71)	%
1	What do you think is the reason for under reporting of Adverse Drug Reaction in India?				
	(a) Lack of remuneration.	12	17.14	27	38.03
	(b) Lack of time to report ADR	21	30.00	22	30.99
	(c) Belief that a single unreported case may not affect ADR database	0	0.00	4	5.63
	(d) Difficulty to decide whether ADR has actually occurred or not	33	47.14	18	25.35
2	Have you ever been trained on how to report Adverse Drug Reaction?				
	(a) Yes	37	52.86	51	71.83
	(b) No	33	47.14	20	28.17
3	Do conference/workshops on Pharmacovigilance improve reporting?				
	a) Yes	54	77.14	58	81.69
	b) No	16	22.86	13	18.31
4	If answer to Q3 is "Yes" then suggested frequency of ADR conference/ workshops:				
	a) Three monthly	21	30.00	58	81.69
	b) Six monthly	37	52.86	13	18.31
	c) Once in a year	12	17.14	0	0.00
	d) Once in 3 years	0	0.00	0	0.00
5	Preferred mode to report ADR:				
	a) Phone	12	17.14	18	25.35
	b) Drop box	25	35.71	5	7.04
	c) E-mail	29	41.43	13	18.31
	d) Personal visit	4	5.71	35	49.30
6	If opted "drop box" then the preferred location should be:				
	a) Ward/OPD	41	58.57	36	50.70
	b) ADR Monitoring Centre (AMC)	25	35.71	13	18.31
	c) Nearby chemist	4	5.71	9	12.68
	d) Office of medical officer	0	0.00	13	18.31

Table 6: Correlation between pharmacovigilance training and adverse event reporting practice

Table 6 shows correlation between pharmacovigilance training and adverse event reporting practice. Our study showed that 62.41% of our healthcare professionals have been trained on Pharmacovigilance (Table 5). In our study the correlation between the training on pharmacovigilance and adverse event reporting practice was analyzed by using Pearson's correlation coefficient. The results are shown inTable 6, suggest ed that there is a medium, positive correlation (at 0.01 level) between the training of pharmacovigilance and reporting of adverse event by healthcare professionals.

Table 6: Association of ADR reporting with training on Pharmacovigilance

	Doctors		Nurses	
	Frequency (%) (n=70)		Frequency (%) (n=71)	
	YES	NO	YES	NO
Ever reported an ADR	16 (22.86)	54 (77.14)	40 (56.34)	31 (43.66)
Trained on pharmacovigilance	37 (52.86)	33 (47.14)	51 (71.83)	20 (28.17)

Correlations			
		Ever reported an ADR	**Trained on pharmacovigilance**
Ever reported an ADR	Pearson Correlation	1	.628**
	Sig. (2-tailed)		**.000**
	N	140	140
Trained on pharmacovigilance	Pearson Correlation	.628**	1
	Sig. (2-tailed)	**.000**	
	N	140	140
**. Correlation is significant at the 0.01 level (2-tailed).			

Table 7: Comparison of various studies across India on pharmacovigilance. (Percentage of positive results)

Table 7 shows the comparison of various studies across India on pharmacovigilance.

	Our Study	New Delhi-LH	Tamil Nadu	Nagpur	Manipal	Jalendhar	Indore	Trivandarum	Ahmedabad	Bangalore
Knowledge Related Questions										
1. Definitions of Pharmacovigilance.	94	31	62	64	55	77	-	-	-	72
2. ADR reporting a professional obligation	96	100	69	36	89	-	66	80	-	-
3. Existence of pharmacovigilance program of India	57	72	75	52	-	59	69	67	-	-
Attitude Related Questions										
1. ADR reporting is necessary	97	100	97	-	92	-	96	89	97	66
2. Pharmacovigilance should be taught to healthcare professionals	97	88	92	-	94	-	-	76	-	58

	Our Study	New Delhi-LH	Tamil Nadu	Nagpur	Manipal	Jalendhar	Indore	Trivandarum	Ahmedabad	Bangalore
3. ADR monitoring centre should be established in every hospital	79	31	74	-	71	90	-	-	-	-
Practice Related Questions										
1. Experienced an ADR in a patient	82	-	64	68	-	-	-	82	85	60
2. Ever reported an ADR	40	60.5	23	25	-	23	19	17	15	12
3.Trained on pharmacovigilance	62	-	53.5	-	50.5	-	25	22	-	-

Comparison of KAP between resident doctors and staff nurses

The approximate results of our study showed that the resident doctors had considerably better knowledge on "what to report" (82.86%; $P<0.05$), "who can report" (88.57%; $P<0.05$) and "whom to report" (30%; $P<0.05$) an adverse event (Table 2). The resident doctors (94.29%) greatly believed thatreporting of the adverse events will harm their professional image among the colleagues as well as among the patients (Table 3) as compared to the nurses (25.35%). Consideratenumber of nurses (74.65%; $P<0.001$) were well informed regarding the status of AMC of the institute (Table 3). Surprisingly in our study, 81.69% nurses documented that adverse events were routinely discussed during the rounds, whereas only 41.43% resident doctors reported such discussions (Table 4). However, in comparison to the nurses (28.16%), the resident doctors (67.14%) frequently ($P<0.05$) enquired about the occurrence of any untoward outcome of the prescribed pharmacotherapy (Table 4). In reasons for under reporting, lack of remuneration was the major reason for nurses (38.03%) while difficulty in decision making was the major reason for doctors (47.14)

Discussion

KAP studies are an essential tool for data collection and interpretation for all healthcare related issues[22]. Pharmacovigilance is very quickly expanding with thegrowing of many pharmaceutical activities forthe development of new drug and clinical trials in India. Therefore, it is becoming obligatory to establish a well organisedPharmacovigilance system which will handle the AEs throughout the phases of clinical trialsas per the ICH-GCP guidelines[23]to ensure the safety of thepatients.It is important to put emphasis on understanding and knowledge of certain significant norms of medical practices among healthcare professionals. Stressing upon the ethical aspects of reporting an adverse event, medical professionals are capable dealing with the ethical codes while practicing[24]. All health care professionals play a very crucial role in the reporting of an adverse drug event. There are various reasons for the adverse event to occursuch as underreporting, medication errors, etc.[25,26,27]. The study data fromthe present studyshowed a significant gap between the adverse event experienced (82.26%) and adverse event reported (39.71%) by the healthcare workers. The prime contributingfactors behind underreporting of adverse events in our study are; difficulty to decide whether adverse drug reaction has actually occurred or not (36.17%), lack of time to report adverse event (30.49%), lack of remuneration (27.65%) and lastly the belief that a single unreported case may not affect adverse event database (2.83%). Further reasons for under reporting are unawareness (57.44%) and lack of training regarding the ADR reporting (37.58%). Moreover, the definiteconclusion from our study is thatthe most of the healthcare professionals acknowledge that it is necessary to report an adverse event (97.16%) and alsofrequent CME programs and training workshops should be organised to incorporate the AE reporting culture among the healthcare professionals (79.43%).

There are many studieswhich has been conducted among the healthcare professionals from nine European Union member states[28], Canada[29], Malaysia[30]and Nigeria[31]. They showed that the most of healthcare professionals had incomplete knowledge regarding theadverse events and Pharmacovigilance programme. Nevertheless, our study showed that the knowledge of the resident doctors about"what to report", "who can report" and "whom to report" was quite better ($P<0.05$) than the nurses. Doctorsgenerally

have betterunderstanding of the disease and its related drugsthat will help them in identifying and analysing the presentation ofadverse drug reactions (ADRs). A good medical practitionershould always look for thepossibleADRs as one of his differential diagnosis. Since nursesremain in close contact with the patients and they also have the responsibility of maintaining the patient treatment chart on daily basis. Thus, this could be a possible source of documentation of adverse events.It is evident from our study that there is a major difference in the KAP behaviour of the doctors when compared to nurses. After reviewing the data and corelating withthe correct responses for the KAP related questions it can be put forward that the resident doctors had unquestionablybetter knowledge regardingpharmacovigilance (67.71%; P<0.001). Nevertheless,nurses had better attitude (80.12%) andsignificantly better practices(60.71%; P<0.001) towards ADR monitoring and reporting of adverse events when compared to the doctors.

Although, in our study it has been seen that significant number of respondents specified that theywere used to record the adverse events in the case record file of the patients which is not in conformity with their data showing less reporting rate of adverse event. Taking these circumstances in mind, we support the recommendations made in a study done byRehan et al., 2012 at Lady Harding Hospital, New Delhi[32]that the governing authorities at the hospitalshould include a box which is supposed to be on the front page of the case sheet specifying "Adverse Event encountered: Yes/No",to assure that recording of all the adverse events are there in the case sheets. Also,it should be made compulsory to fill the boxby the concerneddoctor and/or nurses before it submitted to the MRD. Though it seems to be a very simplemeasure but in the long run this practice will boost or stimulate the discussion of adverse eventsamong the healthcare professionals during their clinical rounds and thus will definitely enhance the reporting ofadverse events.

A similar study was conducted by SK Gupta et al.,[33]. From our study after evaluating the data we determined that there is a definite correlation (at 0.01 level; 2 tailed) between the pharmacovigilance training and adverse events reporting by the healthcare professionals. Continuous training programme on pharmacovigilance would be helpful in dealing with the factors like difficulty to decide whether the adverse drug reaction has actually occurred and unawareness about the adverse event reporting form[4]. Thus, it is essential to have an academic interference which will have angreatinfluence overadverse event monitoring and reporting.

The comparative analysis of the results of earlier published studies in India,as given in Table 7, showed that knowledge and attitude towards pharmacovigilance is constantlydeveloping among healthcare professionals but sadly the real or definite practice of adverse event reporting is still inadequate. It is importantto note that the gap between the adverse event experienced and adverse event reported by healthcare professional in our study was also apparent in previously conducted studies in Trivandrum[23], Nagpur[21], Bangalore[9],Ahmedabad[14] and Tamil Nadu[33].

Conclusion

From our study results we concluded that there is a huge gap between the adverse events experienced and adverse event reported; our HCPs have good knowledge and attitude on pharmacovigilance yet their practices are poor; good number of our HCPs are trained on pharmacovigilance yet their ADR reporting is low; there is a strong positive correlation between training on pharmacovigilance and reporting of ADRs. It is time to devise a system and propose active measures for making the HCP accountable for the ADRs, like remuneration, credit point system for each HCP reporting ADRs and appraisals of clinical departments reporting ADRs.

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Authors's contribution:

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References

1. Lazarou J, Pomeranz BH, Corey PN. Incidence of adverse drug reactionsin hospitalized patients: *A meta-analysis of prospective studies*. JAMA1998;279:1200-5.
2. Classen DC, Pestotnik SL, Evans RS, Lloyd JF, Burke JP. Adverse drug events inhospitalized patients.Excess length of stay, extra costs, and attributable mortality. *JAMA* 1997;**277**:301-6.
3. Upadhyaya P, Seth V, Moghe VV, Sharma M, Ahmed M. Knowledge of adverse drug reaction reporting in first year postgraduate doctors in a medical college. *Ther Clin Risk Manage*. 2012;**8**:307–12.
4. Remesh A. Identifying the reasons for under reporting of ADVERSE EVENT: A cross sectional survey. *Res J Pharm BiolChem Sci*. 2012;**3**:1379–86.
5. Taché SV, Sönnichsen A, Ashcroft DM. Prevalence of adverse drug events inambulatory care: A systematic review. *Ann Pharmacother* 2011;**45**:977-89.
6. Edwards I, Olsson S. WHO: global monitoring. In: Mann RD, Andrew E, editors.Pharmacovigilance. Chichester: John Wiley & Sons; 2002. p. 169-82.
7. Ahmad SR. Adverse drug event monitoring at the Food and Drug Administration. *J Gen Intern Med* 2003;**18**:57-60.
8. Khan SA, Goyal C, Chandel N, Rafi M. Knowledge, attitude 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**:191–6.
9. Muraraiah S, Rajarathna K, Sreedhar D, Basavalingu D, Jayanthi CR. A questionnaire study to assess the knowledge, attitude and practice of Pharmacovigilance in a paediatric tertiary care centre. *J Chem Pharm Res*. 2011;**3**:416–22.
10. Hardeep, Bajaj JK, Kumar R. A survey on the knowledge, attitude and the practice of pharmacovigilance among the health care professionals in a teaching hospital in northern India. *J Clin Diagn Res*. 2013;**7**:97–9.
11. Rehan HS, Chopra D, Sah RK, Mishra R. Adverse drug reactions: Trends in a tertiary care hospital. *Curr Drug Saf*. 2012;**7**:384–8.
12. 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 J Pharmacol*. 2012;**44**:699–703.
13. Gupta P, Udupa A. Adverse drug reaction reporting and pharmacovigilance: Knowledge, attitudes and perceptions among the resident doctors. *J Pharm Sci Res*. 2011;**3**:1064–9.
14. Desai CK, Iyer G, Panchal J, Shah S, Dikshit RK. An evaluation of knowledge, attitude, and practice of adverse drug reaction reporting among prescribers at a tertiary care hospital. *Perspect Clin Res*. 2011;**2**:129–36.
15. Ramesh M, Parthasarathi G. Adverse drug reaction reporting: Attitudes and perceptions of medical practitioners. *Asian J Pharm Clin Res*. 2009;**2**:10–4.
16. Rajesh R, Vidyasagar S, Varma DM. An educational intervention to assess knowledge attitude practice of pharmacovigilance among health care professionals in an Indian tertiary care teaching hospital. *Int J Pharm Tech Res*. 2011;**3**:678–92.
17. Sharma S, Phadnis P, Gajbhiye S. Pharmacovigilance: Its awareness and impact care teaching medical college in central india impact-study in a tertiary care teaching medical college in central India. *IJPRBS*. 2013;**2**:234–247.
18. Arbind KC, Nivedhitha S, Manicvasagam S, Tirumalikolundu SP. Awareness and perception experiences on adverse drug reaction among doctors, nurses and pharmacists of a tertiary care rural teaching hospital. *Indian J Drugs Dis*. 2013;**2**:248–58.
19. Chopra D, Wardhan N, Rehan HS. Knowledge, attitude and practices associated with adverse drug reaction reporting amongst doctors in a teaching hospital. *Int J Risk Saf Med*. 2011;**23**:227–32.
20. 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**:90–4.
21. Pimpalkhute SA, Jaiswal KM, Sontakke SD, Bajait CS, Gaikwad A. Evaluation of awareness about pharmacovigilance and adverse drug reaction monitoring in resident doctors of a tertiary care teaching hospital. *Indian J Med Sci*. 2012;**66**:55–61.
22. Ashiq, K., Ashiq, S., Bajwa, M., Tanveer, S., & Qayyum, M. (). Knowledge, attitude and practices among the inhabitants of Lahore, Pakistan towards the COVID-19 pandemic: an immediate online based cross-sectional survey while people are under the lockdown. *Bangladesh Journal of Medical Science*, 2020;**19**: S 69-S 76.
23. ICH (International Conference on Harmonisation). Guideline for good clinicalpractice, 1996. Available from: http://www.ich.org. Last assessed 17.10.2011.
24. Mohammad M, Ahmad F, Rahman SZ, Gupta V, Salman T. Knowledge, Attitude, Practice among doctors in a tertiary care government teaching hospital in India. *J. Clinic Res Bioeth* 2011;**2**:118. Doi:10.4172/2155-9627.1000118.
25. Anwer A, Rahman SZ, Singh PP, Usmani MA. Prescription auditing of patients admitted at Psychiatry ward of a test care hospital of western U.P. *Int. Arch*

BiomedClini Res, 2015;**1**(2):20-23.

26. Bhat S, Rahman SZ. Prescription auditing of patients admitted at a ward of tertiary care hospital of western U.P. *Journal of Pharmacovigilance and Drug Safety* 2015;**12**(1):6-40.
27. A, Misha'lAly. Drug Prescribing to the Elderly Patients. *International Journal of Human and Health Sciences (IJHHS)* 2018;**1**(2):p. 65-69, jan..
28. Belton KJ. Attitude survey of adverse drug-reaction reporting by health careprofessionals across the European Union. The European Pharmacovigilance Research Group. *Eur J ClinPharmacol* 1997;**52**:423-7.
29. 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 Canada. *Drug Saf* 2009;**32**:579-90.
30. Aziz Z, Siang TC, Badarudin NS. Reporting of adverse drug reactions: Predictorsof under-reporting in Malaysia. Pharmacoepidemiol *Drug Saf* 2007;**16**:223-8.
31. Fadare JO, Enwere OO, Afolabi AO, Chedi BA, Musa A. Knowledge, attitude andpractice of adverse drug reaction reporting among healthcare workers in a tertiarycentre in Northern Nigeria. *Trop J Pharm Res* 2011;**10**:235-42.
32. 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 J Pharmacol* 2012;**44**:699-703.
33. Sandeep Kumar, Gupta Roopa P, Nayak, R. Shivaranjani, Surendra Kumar Vidyarthi. A questionnaire study on the knowledge, attitude, and the practice of pharmacovigilance among the healthcare professionals in a teaching hospital in South India. *PerspectClin Res*. 2015 Jan-Mar; **6**(1): 45–52.