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Original Research Article

Assessment of Knowledge, Attitude and Perception of Healthcare Professionals towards Adverse Drug Reactions Reporting: A Questionnaire Based Survey

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Abstract: Adverse drug reactions are an important cause of morbidity and mortality and are responsible for a significant number of hospital admissions ranging from 0.3% to 11%. The ADR reporting rate in India is below 1% compared to worldwide rate of 5%. One of the reasons for low reporting rate in India may be a lack of knowledge and sensitization towards pharmacovigilance and ADR among health care professionals. The aim of the study is to investigate the knowledge, attitudes and perception of health care professionals towards adverse drug reaction reporting. A cross sectional study was carried out using a pretested questionnaire for a period of 6 months among 340 healthcare professionals. The questionnaire was designed to assess the KAP regarding pharmacovigilance. The healthcare professionals (doctors, nurses, dentists and pharmacists), trainee and internship students working in the NMCH and RC, Raichur, Karnataka during the study period were included. About 300 questionnaires where returned which were adequately filled, of which 37% were doctors, 33% dentists, 17% nurses and 13% pharmacists. Mean knowledge score of doctors, dentist, nurses and pharmacists where 5.29±1.73, 4.9±1.13, 5.41±1.34 and 7.08±1.36 respectively. Mean attitude score of doctors, dentist, nurses, pharmacists were 4.87±1.29, 4.78±1.107, 4.53±1.24 and 5.84±1.02 Mean perception score of doctors, dentist, nurses and pharmacists were found to be 4.87±1.29, 4.78±1.107, 4.53±1.24 and 5.84±1.20. It was observed that most of the professionals were aware of ADR. They were having sound knowledge and positive attitude towards ADR reporting. But unfortunately the practice of ADR reporting where deficient among the health care professionals.

Keywords: ADR Reporting, Attitude, Health care Professionals, Knowledge, Perception Questionnaires

INTRODUCTION

Adverse drug reaction (ADR) which is defined as ‘response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function’ is the major problem of global concern. Pharmacovigilance is the science and activities relating to detection, assessment, understanding and prevention of adverse effects or any other drug related problems. Pharmacovigilance should however not be limited to the reporting of classical adverse effects, it should also be concerned with identification of product defects, unexpected insufficient therapeutic effects, intoxications and misuse – abuse situation [1].

Adverse drug reactions are an important cause of morbidity and mortality and are responsible for a significant number of hospital admissions ranging from 0.3% to 11% . The ADR reporting rate in India is below 1% compared to the worldwide rate of 5%.One of the reasons for low reporting rate in India may be a lack of knowledge and sensitization towards pharmacovigilance and ADR among health care professional [2].

Proper monitoring of ADRs is a necessity. In India, all healthcare professionals including doctors, nurses, and pharmacists can report an ADR by filling an ADR form of the CDSCO.Although many studies in India have evaluated the KAP of pharmacovigilance among the healthcare professionals, it is imperative to conduct similar studies in teaching hospital of other parts of India to generalize findings of those studies [3].

Voluntary ADR reporting is fundamental to medical drug safety surveillance; however, substantial under- reporting is the main limitation of the system. It is estimated that only 6-10% of all ADRs are reported. Spontaneous reporting of adverse drug reactions is one of the basic methods for post-marketing surveillance and is a method to generate signals of unrecognized ADRs. The attitude and awareness towards Adverse Drug Reaction reporting shows great variation among

the health professionals and many factors influences the reporting of Adverse Drug Reaction [4-6].

Spontaneous reporting system still remains as the most common method to report adverse drug reaction even though under reporting is estimated higher than 90–95%. There are different factors which encourage healthcare professionals to report ADRs. Among all, healthcare professional's knowledge about and attitudes towards ADR and ADR reporting debate more frequently as an influential factors. Healthcare professionals are reluctant to report ADR when the ADR is common, but it is interesting that some healthcare professionals especially doctors report ADR because of their professional interest to inform others. Overall, knowledge about and attitudes towards ADR plays vital role in terms of ADR reporting [7].

The Pharmacovigilance Programme of India (PvPI) like most others around the world suffers from underreporting of ADRs by the healthcare professionals; this can delay the detection of important ADRs. However, the Indian national Pharmacovigilance programme lacks continuity due to lack of awareness and inadequate training about drug safety monitoring among healthcare professionals in India [8].

In India, the gross under-reporting of ADRs is a cause of concern, the reasons for which may be due to lack of trained staff and lack of awareness regarding detection, communication, and spontaneous monitoring of ADRs among the health-care professionals (physicians, nurses, pharmacist, and dentists). Previously reported study has found that underreporting of ADR is related with shortcomings in the knowledge and attitude among health-care professionals. It is important for health-care professionals to know how to report and where to report an ADR. The active participation of health-care professionals in the pharmacovigilance program can improve the ADR reporting [9].

The success of a pharmacovigilance program depends upon the involvement of the healthcare professionals and reporting the ADRs. Similarly, in order to improve an existing pharmacovigilance program, there is a need to improve healthcare professionals KAP. Prior to carrying out any intervention, it is necessary to evaluate the baseline KAP of the healthcare professionals regarding ADR monitoring and pharmacovigilance so that the intervention can be targeted, based on the specific findings [10].

In order to improve the participation of health professionals in spontaneous reporting, it might be necessary to design strategies that modify both the intrinsic (knowledge, attitude and practices) and extrinsic (relationship between health professionals and their patients, the health system and the regulators) factors. A knowledge, attitude, and practice (KAP) analysis may provide an insight into the intrinsic factors and help understand the reasons for under-reporting. Knowledge, attitude, and practice regarding ADR reporting has not been studied extensively in India. A few studies carried out in India and Nepal have shown poor knowledge, attitude, and deficient practices of ADR reporting among the prescribers and healthcare professionals [11].

Even though the literature reports a number of studies on knowledge, attitude, perception of healthcare professionals towards adverse drug reaction reporting, the data available on such studies in India is limited. Hence the present study was conducted to investigate the knowledge, attitude, perception of healthcare professionals towards adverse drug reaction reporting.

MATERIALS AND METHODS

The study was a cross-sectional, observational, questionnaire-based survey involving doctors, Nurses, Pharmacists and Dentists working in Navodaya Medical College Hospital and research center, Raichur for a period of 6 months from November 2015 to April 2016. The study was approved by Institutional ethical committee by issuing ethical clearance certificate. Convenient sampling method was used. A total of 340 questionnaires were distributed. The completion of the questionnaire by respondents was taken as their consent to participate in the study. Those who were not willing to participate or did not return the questionnaire within the given time were excluded from the study. Hence out of 340 questionnaires, only 300 were taken into consideration.

A KAP questionnaire containing 29 questions in which 9 questions assess Knowledge, 8 questions for attitude and 12 questions for perception were designed, to obtain the information regarding demographics of the respondents, knowledge regarding ADR reporting system, attitude and perception of ADR reporting. More than one answer was allowed in some questions. The information was recorded and analysed using MS excel spreadsheet and the statistical analysis was performed using SPSS 19.0 version IBM USA. The data was expressed as quantitative and qualitative

The quantitative data was expressed in mean ± standard deviation and the qualitative data was expressed in percentage. The mean comparison of score between 4 groups were done by one way ANOVA test. P value was taken to be <0.05 as significant and <0.001 as highly significant.

RESULTS

A total of 340 health professionals participated in the study. However, 40 participants did not return

and appropriately fill the questionnaire thus excluded from the analysis making the response rate 300(88.23%). The mean age of the respondents were 29.05 (± 9.31) with a range of 20 to 75 years **.**Out of the total 300 participants, 56.7% of the respondents were male and 43.3% were female. Most of the professional were having under graduate(46.7%) and post graduate(45.7%) qualification **.**Out of total 300 professionals 37.00% were physicians, 17.3% were nurses, 12.67 were pharmacists and 33.33% were dentists **.**Almost 76.3% oh healthcare professionals had experience less than 10 years, 13.6% with 10-20 years of experience, 6.3% with 20-30 years of experience and 3.6% were having more than 30 years of experience are depicted in table 1**.**

All the values and percentage of positive and negative responses for the KAP questionnaire comprising of 29 questions was evaluated and tabulated in table 2.

Majority of the ADR reported in the hospital were of the serious and unexpected ADRs (81.33%) followed by ADRs of old (66%) and new (65.33%) drugs as shown in Table 3.

The factors cited as discouraging ADR reporting where, cause of managing patient was more important than ADR reporting (68.67%),lack of assess to ADR reporting forms(40.33%),not knowing where to report(37%). Thirty five percentage of healthcare professionals opined that legal liability issues as discouraging factors are depicted in table 4.

As shown in table 5, 63.67% of healthcare professionals opined that seriousness of the ADR were major factor governing the decision to report ADRs followed by involvement of the new drug(14.00%) and unusualness of the reaction 13.67%.

Reasons for under reporting by healthcare professionals were difficult to pinpoint suspected drug(31.60%), busy schedule (29.00%), difficult to admit harm to patient(29.00%), don't know whom to report(28.30%). Among the participants 10.67% claimed that only safe drugs as shown in table 6.

As shown in table 6 &fig .1, reasons cited by healthcare professionals for reporting ADRs were to improve patient safety (60.6%), to identify relatively safe drugs (15.00%), to measure the incidence of ADR(11.00%), to identify and detect ADR (11.00%) and to share information with colleagues (2.3%).

Table 1: Demographic data of respondents(n=300)

Age in years	**No.of respondents(%)**
20-29	223 (74.33)
30-39	37(12.33)
40-49	16(5.33)
50-59	9(3.00)
>60	15(5.00)
S.M = 29.05 S.D = 9.31	
Gender	
Male	170(56.67)
Female	130(43.33)
Qualification	
Undergraduate	140(46.67)
Graduate	137(45.67)
Postgraduate	23(7.67)
Profession	
Doctors	111(37.00)
Pharmacists	38(12.67)
Dentists	99(33.00)
Nurses	52(17.33)
Experience in years	
<10	229(76.33)
10-20	41(13.67)
21-30	19(6.33)
>30	11(3.67)

Table 2: Knowledge, Attitude and Perception of healthcare professionals towards ADR Reporting (n=300)

Q.no	Questions	Yes(%)	No(%)	Don't know(%)
1	Do you believe all the drugs available in the market are safe?	40(13.33)	252(84.00)	8(2.67)
2	Have you experienced any ADR during your practice?	159(53.00)	128(46.00)	3(1.00)
3	Are you aware of any drug that has been banned due to ADR?	198(65.00)	77(25.67)	28(9.33)
4	Does your patients complain about ADR?	228(76.00)	71(23.67)	1(0.33)
5	Is it important to report ADRs	300(100)	-	1(0.33)
6	Should ADRs be reported by physicians?	279(93.00)	19(6.33)	2(0.67)
7	Do you think that pharmacist could be the right person to assist physician in ADR reporting?	225(75.00)	58(19.33)	17(5.67)
8	Is ADR reporting form available at your job?	99(33.00)	165(55.00)	36(12.00)
9	Have you ever reported an ADR?	98(32.67)	200(66.67)	2(0.67)
10	Do you think that some factors may govern in your decision to report an ADR?	300(100)	-	-
11	Do you think that ADR reporting & monitoring system would benefit the patient?	259(86.33)	30(10.00)	11(3.67)
12	Do you consider ADR information provided to you as satisfactory?	177(59.00)	106(35.33)	17(5.67)
13	Is there any special circumstances when ADR should be reported?	298(99.33)	2(0.67)	-
14	Are they any types of ADRs that are usually reported?	290(96.67)	10(3.33)	-
15	Do you think you are adequately trained in ADR reporting?	92(30.67)	198(66.00)	10(3.33)
16	Do you feel proper training should be provided to physician in ADR reporting?	245(81.67)	48(16.00)	7(2.33)
17	Do you feel patient confidentiality should be maintained while reporting ADRs?	240(80.00)	47(15.67)	13(4.33)
18	Do you worry about legal problems while you think of ADR reporting?	181(60.33)	102(34.00)	17(5.67)
19	Does any factor discourage you from reporting ADRs?	287(95.67)	13(4.33)	-
20	Do you think there is under-reporting of ADR?	292(97.33)	7(2.33)	1(0.33)
21	Do you feel ADR reporting is time consuming activity with no outcome?	83(27.67)	189(60.33)	36(12.00)
22	Is there any nearby ADR reporting and monitoring system or centre in your knowledge?	81(27.00)	133(44.33)	86(28.67)
23	Do you support "Direct ADR Reporting" by patients instead of physicians?	151(50.33)	135(45.00)	14(4.67)
24	Have you ever shared information about ADRs with anyone?	198(66.00)	101(33.67)	1(0.33)
25	Do you picture a role of information technology in ADR reporting in the country(internet, mobile service)?	219(73.00)	62(20.67)	19(6.33)
26	At present ADR reporting is voluntary; do you feel it should be made mandatory?	252(84.00)	37(12.30)	11(3.67)
27	Are you aware of "Pharmacovigilance Programme of India (PVPI)"of CDSCO, Ministry of health, Govt. of India?	176(58.67)	118(39.30)	6(2.00)
28	Has this system created an awareness of ADR reporting in you?	267(72.33)	68(22.67)	15(5.00)
29	Do you expect feedback from ADR monitoring centres?	262(87.33)	31(10.33)	7(2.33)

Table 3 : Types of ADR that are usually reported (n=300)

S.No.	Types of ADR	Number of Respondents	Percentage
1	Serious unexpected and suspected	244	81.33
2	ADR of old drug	198	66.00
3	ADR of new drug	196	65.33
4	Adverse event	186	62.00

Table 4: Response of healthcare professionals in relation to the factors discouraging from ADR reporting (n=300)

S.No	Discouraging Factors	Number of responses	Percentage
1	Don't know how to report	64	21.33
2	Don't know where to report	111	37.00
3	Don't think it's important	13	4.33
4	Managing patient was more important than ADR reporting	206	68.67
5	Lack to assess to ADR reporting forms	121	40.33
6	Patient confidentiality issues	97	32.33
7	Legal liability issues	105	35.00
8	Concerns about professional liability	57	19.00
9	Others(non serious ADRs and lack of manpower)	5	1.67

Table 5 : Factors governing decision to report an ADR by healthcare professionals (n=300)

S.No.	Types of ADR	Number of respondents	Percentage
1	Seriousness of the ADR	191	63.67
2	Unusualness of the reaction	41	13.67
3	Involvement of a new drug	42	14.00
4	Confidence in diagnosis of ADR	26	8.67

Table 6 : Causes of under reporting of ADR(n=300)

S.No.	Reasons	Number of Respondents	Percentage
1	Only safe drugs are available on market	32	10.67
2	Reporting does not influence the treatment scheme	42	14.00
3	Busy schedule	89	29.60
4	Lack of incentives	80	26.60
5	Physician should rather collect data and publish	36	12.00
6	Difficult to pinpoint suspected drug	95	31.60
7	ADR is known to physician	31	10.30
8	Don't know whom to report	85	28.30
9	Reporting could show ignorance	30	10.00
10	Difficult to admit harm to patient	87	29.00
11	Insufficient clinical knowledge	59	19.60
12	Thinking one report doesn't make difference	68	22.60
13	Others	4	1.30

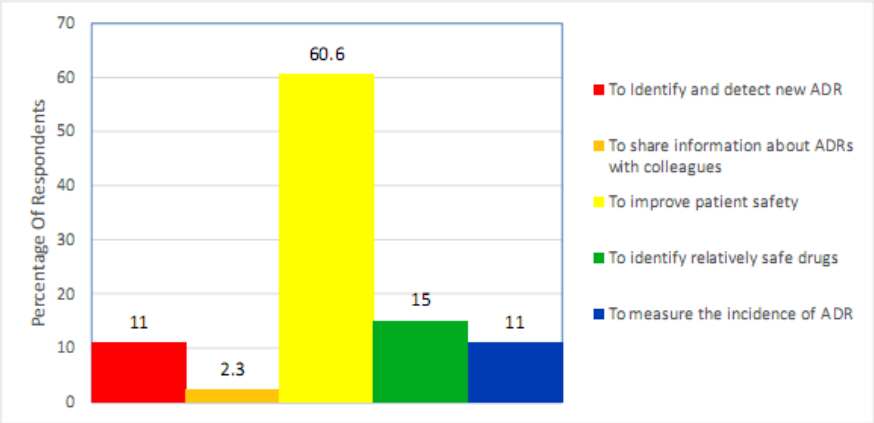

Fig-1: Reasons cited by healthcare professionals for reporting ADRs (n=300)

In our study **,**the questionnaire was divided into knowledge, attitude and perception with 9, 8 and 12 questions respectively. According to that scoring for knowledge, attitude and perception score was performed which were found to be 0-4.5(unsatisfactory) and 4.5-9(satisfactory), 0–4(unsatisfactory) and 4-8(unsatisfactory) and 0-6(unsatisfactory) and 6-12(satisfactory). The mean knowledge, attitude and perception score and standard deviation for each KAP item was calculated for each group.

The mean knowledge score of pharmacists was 7.08±1.36, followed by nurses 5.41±1.34, doctors 5.29±1.73 and dentists 4.9±1.13. When the mean score was compared, it was found statistically highly significant(P<0.001) .

Mean attitude score of pharmacists was 5.84±1.20, followed by, doctors 4.87±1.29, dentists 4.78±1.107 and nurses 4.53±1.24. When the mean score was compared, it was found statistically highly significant(P<0.001).

The mean perception score of pharmacists was 10.79±0.81, followed by dentists 9.17±1.32, doctors 9.16±1.91, and nurses 9.02±1.75. When the mean score was compared, it was found statistically highly significant (P<0.001) as shown in table 7**.**

Table 7: Comparison of mean score in different groups (n=300)

KAP items	Group	N	Mean	Std. Deviation	F	Df	P	Inference
Knowledge score	Doctors	111	5.92	1.73	23.101	3	0.0001 (<0.001)	Highly significant
	Pharmacists	38	7.08	1.36				
	Nurses	52	5.41	1.34				
	Dentists	99	4.90	1.13				
	Total	300	5.64	1.60				
Attitude score	Doctors	111	4.87	1.29	9.733	3	0.0001 (<0.001)	Highly significant
	Pharmacists	38	5.84	1.20				
	Nurses	52	4.53	1.24				
	Dentists	99	4.78	1.07				
	Total	300	4.91	1.26				
Perception score	Doctors	111	9.16	1.91	12.004	3	0.0001 (<0.001)	Highly significant
	Pharmacists	38	10.79	.81				
	Nurses	52	9.02	1.75				
	Dentists	99	9.17	1.32				
	Total	300	9.35	1.68				

When a comparative study was performed the percentage of doctors, nurses, dentists with satisfactory knowledge score were 56.7%, 46.1% and 31.3% respectively, whereas pharmacists (89.47%) had the highest satisfactory knowledge score than other health care professionals as shown in table 8 & fig 2.

Table 8: Distribution of study subjects according to knowledge of ADR reporting (n=300)

KAP item		Doctors	Pharmacists	Nurses	Dentists
		No.(%)	No.(%)	No.(%)	No.(%)
Knowledge	Unsatisfactory	48(43.2)	4(10.5)	28(53.8)	68(68.6)
	Satisfactory	63(56.7)	34(89.47)	24(46.1)	31(31.3)
	Total	111	38	52	99

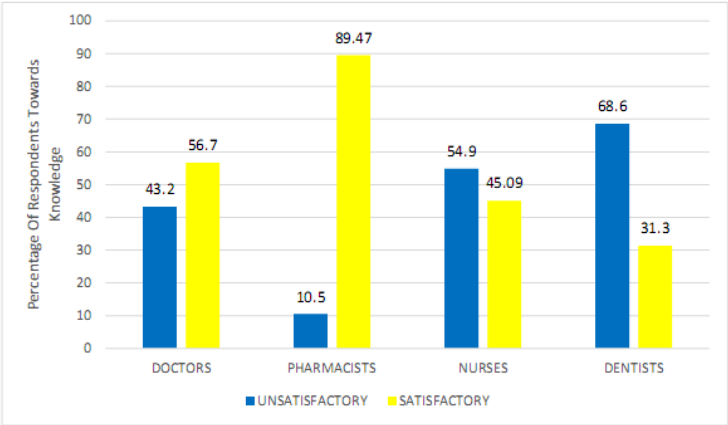

Fig-2: Distribution of study subjects according to knowledge of ADR reporting (n=300)

Data's were also analysed for the percentage of pharmacists, dentists, doctors and nurses with satisfactory attitude score and they were found to be 84.2% , 63.6%, 61.2%, and 48.00% respectively as shown in table 9 & fig. 3.

Table 9: Distribution of study subjects according to attitude towards ADR reporting (n=300)

KAP item		Doctors	Pharmacists	Nurses	Dentists
		No.(%)	No.(%)	No.(%)	No.(%)
Attitude	Unsatisfactory	43(38.7)	6(15.8)	27(52)	36(36.3)
	Satisfactory	68(61.2)	32(84.2)	25(48)	63(63.6)
	Total	111	38	52	99

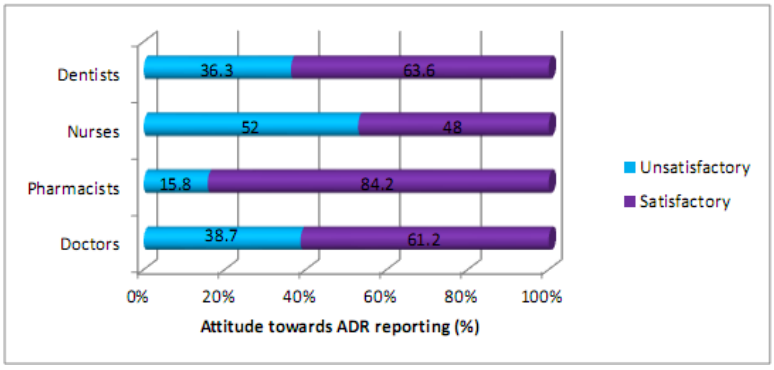

Fig-3: Distribution of study subjects according to attitude towards ADR reporting (n=300)

The percentage of dentists, doctors and nurses with satisfactory perception score were 99.8, 96.39 and 88.46, respectively. All the pharmacists had a satisfactory perception score as shown in table 10 & fig 4.

Table 10: Distribution of study subjects according to perception of ADR reporting (n=300)

KAP item		Doctors	Pharmacists	Nurses	Dentists
		No.(%)	No.(%)	No.(%)	No.(%)
Perception	Unsatisfactory	4(3.60)	0	5(9.61)	2(0.2)
	Satisfactory	107(96.39)	38(100)	46(88.46)	97(99.8)
	Total	111	38	52	99

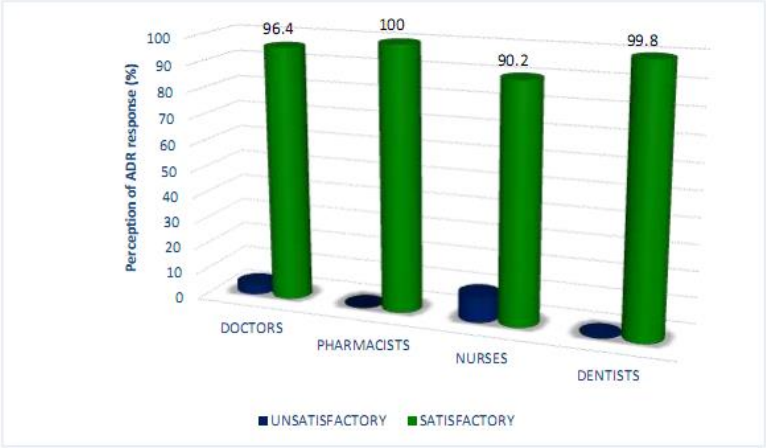

Fig-4: Distribution of study subjects according to perception of ADR reporting (n=300)

DISCUSSION

A smaller proportion of respondents 98(32.6%) had ever reported ADR they encountered during their professional practice. Of those health professionals who reported ADR, 67 (22.3%) reported to concerned pharmaceutical company and evaluating ADR. This study indicated that low reporting is a major problem among health professionals. The fact that majority of health professionals did not have basic knowledge on the reporting system might contribute to the low reporting practice. Poor feedback and limited options for reporting could also have additional impact on the reporting.

One of the important findings of this study is that even though 159(53%) of respondents had the experience of noting the ADR they encountered on their clinical materials, only less proportion of them (32.6%) actually reported one or more ADR in their clinical practice. The findings from the qualitative part of this study also showed that health professionals encountered a number of ADRs during their clinical activities but only few were reported to the responsible organizations. This implied that if those health professionals who noted ADR they encountered on their clinical records are encouraged and supplied with the necessary forms, it would positively affect the reporting. The larger proportion of respondents (93%) felt that reporting is the duty of physicians. This is the same as a study in Sweden where the majority (75%) of the healthcare professionals were in opinion that ADR reporting is the duty of doctors, nurses and pharmacists. This implied that health professionals have correctly understood that ADR reporting as part of their professional obligation.

In order to generalise our findings, it is imperative that similar studies be done on national basis in all the teaching hospitals of the country. Though the response rates was fairly good, with a higher response rates it would have been possible to draw more certain conclusions.

The comparisons with the results of the published and study from India demonstrated that knowledge and attitude towards pharmacovigilance is gradually improving among healthcare professionals but unfortunately the actual practise of ADR reporting is still deficient among them.

CONCLUSION

Our study gives pertinent information regarding knowledge, attitude and perception of health professionals towards adverse drug reaction reporting and factors associated with reporting. This study revealed that even though majority of health professionals have positive attitude towards ADR reporting, reporting among health professionals is low. This could be due to low level of knowledge and awareness among health professionals towards ADR reporting. Awareness raising program on the ADR reporting system need to be designed for health professionals by relevant bodies and ADR reporting system need to be introduced and given an emphasis at higher institution training. On top of this, establishing strong feedback and increasing options of reporting would improve the reporting system.

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