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PHARMACOVIGILANCE AWARENESS ASSESSMENT AMONG HEALTHCARE PROFESSIONALS THROUGH KAP QUESTIONNAIRE STUDY IN A TERTIARY CARE HOSPITAL

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ABSTRACT

Under reporting of Adverse drug reactions (ADRs) is daunting challenge very commonly encountered in the practice of pharmacovigilance. Evaluating the reasons behind the under-reporting is a necessity which differ as per individual institutions. The present study was aimed at assessing awareness and perceptions about pharmacovigilance in a tertiary care teaching hospital along with the reasons for the underreporting of the ADRs. **Methods:** A pre-tested questionnaire was used with 20 questions from knowledge, attitude and practice (KAP) domains. Data was collected from clinicians, residents and interns. Analysis was done by using the Statistical Package for Social Sciences (SPSS) statistical software. **Results:** Out of 112 respondents 62 (55.4 %) had correct knowledge of definitions while 95 (84.8 %) responded wrongly about individuals authorized to report. Question about reporting of a serious adverse event was answered correctly by 59 (52.7%); however 95 (84.8%) responded about ADR reporting being a necessity. It was considered as a professional obligation by 73 (65.2%). Among the participants 61 (54.5%) experienced ADR in the practice but only 15 (13.4%) reported. Reasons stated for difficulty in reporting the ADRs were lack of adequate time for 35 respondents (31.3 %) while 34 (30.4 %) mentioned uncertainty about labelling incidence as ADR. **Conclusion:** Study showed considerable lack of precise knowledge and awareness about ADR reporting protocol. Factors which discourage the ADR reporting can be worked upon by stressing upon the awareness measures and necessity about ADR reporting as well as improving the simplicity and easy accessibility of the ADR reporting protocol.

KEYWORDS: ADRs, under- reporting, Pharmacovigilance, KAP.

INTRODUCTION

Despite comprehensive and stringent phases of clinical trials and surveillance efforts, unexpected and serious adverse drug reactions (ADRs) repeatedly occur after the drug is marketed. The burden of ADRs in global scenario is high and accounts for considerable morbidity, mortality, and extra-cost to the patients.[1] Median incidence of ADRs that lead to hospitalization and those occurred during hospital stay 2 .85 % and 6.34 % respectively.[2] This makes ADR reporting an important factor in patient safety and a vital parameter in medical management.

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem as defined by World Health Organization (WHO)[3] Pharmacovigilance is the arm of patient care and surveillance and a good pharmacovigilance identifies the risks within the shortest possible time after the medicine has been marketed and helps to establish or identify risk factors. However 21st century pharmacovigilance is not merely about uncovering, reporting, and addressing adverse events associated with already approved and marketed agents, but can be described as the systematic monitoring of the process of pre-market review and post-market surveillance, which includes the use of medicines in everyday practice.[4]

ADR reporting is an important aspect of an efficient and effective pharmacovigilance program.[1,5] When communicated effectively, this information allows intelligent, evidence-based prescribing and also has the potential for preventing many ADRs. Such information can ultimately help each patient to receive optimum therapy at a lower cost to the health system.

Country like India by virtue of its population can serve as a great tool with a large sample size to gather information about the ADRs which are not always known in the process of clinical trials and drug development. This mainly depends on the spontaneous reporting of ADRs as well sharing this information to WHO.

The spontaneous ADR reporting for marketed drugs in India is covered under the Pharmacovigilance Program of India (PvPI) which was initiated by the Central Drugs Standard Control Organisation (CDSCO), New Delhi, under the aegis of the Ministry of Health and Family Welfare, Government of India in July 2010. [6] The mission of PvPI is to safeguard the health of the Indian population by ensuring that the benefit of the use of medicine outweighs the risks associated with its use. The program aims to foster the culture of adverse drug event notification and generate broad-based ADR data on the Indian population and share the information with the global health-care community.[7]

Currently 250 teaching hospitals and corporate hospitals (Medical Council of India approved) have been identified as ADRs Monitoring Centres (AMCs) across the country. These centres are covered in four zonal offices of Central Drugs Standard Control Organization (CDSCO) for administrative and logistic purpose. These AMCs are connected with international networking (reporting through VigiFlow; WHO-Uppsala Monitoring Centre [UMC] software). These AMCs report ADRs to NCC through VigiFlow, the software owned by WHO-UMC, Sweden.[1] Sharing adequate information to WHO contributes to more safer drug prescriptions and reduced incidences of ADRs.

In spite of the implementation of this program nationwide through medical colleges, and although the reluctance in reporting is now changing.[1] still the reporting of ADRs is far from satisfactory.[7] Currently, the contribution of India to the WHO global Individual Case Safety Reports (ICSRs) database is 3%.[1] The underreporting of ADRs is mainly due to lack of knowledge about diagnosis of an ADR, ignorance on the part of clinicians, lack of time, etc. i.e. Attitude and also due to unawareness about their role in the program. As per published literature lack of awareness is the leading cause of underreporting of suspected ADRs.[8] This under-reporting as well as the poor quality of ADR reporting poses a challenge for the Pharmacovigilance program of India.[9] Thus, evaluation of reasons behind the under-reporting of ADRs is warranted. Also these reasons need to be worked upon in order to improve the spontaneous ADR reporting.

This questionnaire based study was an attempt to explore the awareness about ADR reporting and pharmacovigilance at a tertiary care teaching hospital; among clinicians, residents, as well as the interns being the budding doctors. The objectives of this study were to assess the level of awareness about knowledge, attitude, practice of pharmacovigilance among clinicians, residents and interns and also to evaluate reasons for underreporting of ADRs.

MATERIALS AND METHODS

The institutional ethics committee approval was taken before the conduct of the study. Cross sectional questionnaire based study which was completed over the period of three months in Dr. D. Y. Patil Hospital, Nerul, Navi Mumbai; A tertiary care teaching hospital.

Eligibility criteria: Clinicians, residents and interns those who were employed and working in the hospital and those who are willing to give informed consent. There were three groups as per their designation namely; Clinicians involving the assistant professors, associate professors, professors working in various departments of the hospital. Residents group consisted of the post graduate residents studying in all the years of the MD/ MS or Diploma courses in various clinical and paraclinical departments and the interns group had the interns posted in different clinical departments during the course of their internship. The sample size was decided to be 120 with 40 participants in each group.

Material-- The questionnaire

The Questionnaire used for this study was a pretested Questionnaire that was designed to assess the Knowledge, Attitude and Practices (KAP) regarding pharmacovigilance.[10]

Permission to use questionnaire was taken from the author of the original article **[10]** at the start of the study. Pretesting of questionnaire was done by the author on 20 randomly selected health professionals of author's institute. The questionnaire was finalized after ambiguous and unsuitable questions were modified based on the result of pre-test.

The questionnaire (refer annexure) had 20 questions in total from knowledge (10 questions), attitude (4 questions) and practice (5 questions) domains while one question was designed to assess the reasons discouraging the reporting of an ADR. The questionnaire was slightly updated by addition of the consent question and demographic data questions assessing the qualification and years of experience in clinical practice of the participant.

Data collection: The questionnaire forms were given to all 120 participants and their informed consent was noted in the form of a question at the start of the questionnaire along with the demographic data. The anonymity was maintained and such anonymously filled forms were collected after participant had marked all the questions. The data from 112 respondents was collected and analysed.

Data analysis: Data from the returned questionnaire forms was coded and entered in Microsoft Excel (MS Office version 2010) and tabulated analysis was done by using Windows based software "SPSS" version 21 (IBM corp.) with the help of a statistician.

The data was presented as numbers with percentages. The "p value" less than 0.05 is taken as significant.

RESULTS

Total 120 questionnaires were distributed to the sample of healthcare professionals among the population of prescribers and 112 responded. The response rate was 93.33%. Out of the respondents 36 were clinicians, 35 were residents while 26 were from interns group.

Table 1: Showing the gender bifurcations of the study sample size.

	N (112)	Percentage %
Males	50	44.6
Females	62	55.4

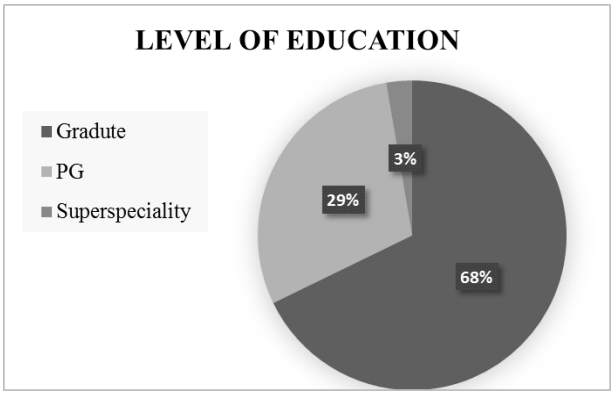

Figure 1: Showing the level of education among the participants.

Table 2: Showing the years of Clinical experience among the participants.

Years of Clinical experience	N (112)	Percentage (%)
0 - 5 yrs.	79	70.5
5- 10 yrs.	7	6.3
>10 yrs.	26	23.2

Figure 1 depicts that majority of the participants belonged to graduates group constituting 68% while super-speciality education category constituted only 3% of the total participants. Table 2 data results suggest maximum percentage of participants (70.5%) had clinical experience of less than 5 years. The numerical values from data suggest increased level of awareness with increase with the level of education and years of clinical experience.

Table 3: Showing the results of the questions from Knowledge domain.

Questions	Overall correct response N (%)	Correct response in Clinicians N(%)	Correct response in Residents N(%)	Correct response in Interns N (%)
1. Definition of pharmacovigilance	62 (55.4)	73 (66.7)	63 (56.8)	48 (43.6)
2. Purpose of pharmacovigilance	58 (51.8)	73 (66.7)	48 (43.2)	51 (46.2)
3. Who can report ADRs	8 (7.1)	6 (5.6)	9 (8.1)	9 (7.7)
4. Awareness about NPPI *	48 (42.9)	72 (63.9)	60 (54.1)	14 (12.8)
5. Awareness about Indian regulatory body *	61 (54.5)	86 (77.8)	87 (78.4)	11 (10.3)
6. International regulatory body	40 (35.7)	43 (38.9)	45 (40.5)	31 (28.2)
7. Reporting of Serious adverse event	59 (52.7)	65 (58.3)	60 (54.1)	51 (46.2)
8. Detection of Rare ADRs	38 (33.9)	40 (36.1)	48 (43.2)	25 (23.1)
9. Method of reporting *	38 (33.9)	59 (52.8)	36 (32.4)	20 (17.9)
10. Pharmacovigilance committee of institute *	39 (34.8)	73 (66.7)	30 (27)	14 (12.8)

*: indicates the significant p value (>0.05) for the responses for those questions

Table 4: Showing the results of the questions from Attitude domain.

Questions	Overall correct response N (%)	Correct response in Clinicians N (%)	Correct response in Residents N (%)	Correct response in Interns N (%)
Professional Obligation*	73 (65.2)	96 (86.1)	63 (56.8)	60 (53.8)
Reporting Necessary*	95 **(84.8)**	112 (100)	105 (94.6)	68 (61.5)
Teaching Pharmacovigilance in Curriculum*	82 (73.2)	90 (80.6)	99 (89.2)	57 (51.3)
What is your opinion about establishing ADR monitoring centre in every hospital? *	70 (62.5)	90 (80.6)	69 (62.2)	51 (46.2)

*: indicates the significant p value (>0.05) for the responses for those question

Table 5: Showing the results of the questions from the Practice domain.

Questions	Overall correct response N (%)	Correct response in Clinicians N (%)	Correct response in Residents N (%)	Correct response in Interns N (%)
Have you read an article about prevention of ADRs?	41 (36.6)	52 (47.2)	54 (48.6)	17 (15.4)
Have you experienced ADR in clinical practice?	61 (54.5)	87 (77.8)	60 (54.1)	37 (33.3)
Have you reported ADRs?	15 (13.4)	24 (22.2)	9 (8.1)	11 (10.3)
Have you received training on ADR reporting?	11 (9.8)	13 (11.1)	12 (10.8)	8 (7.7)

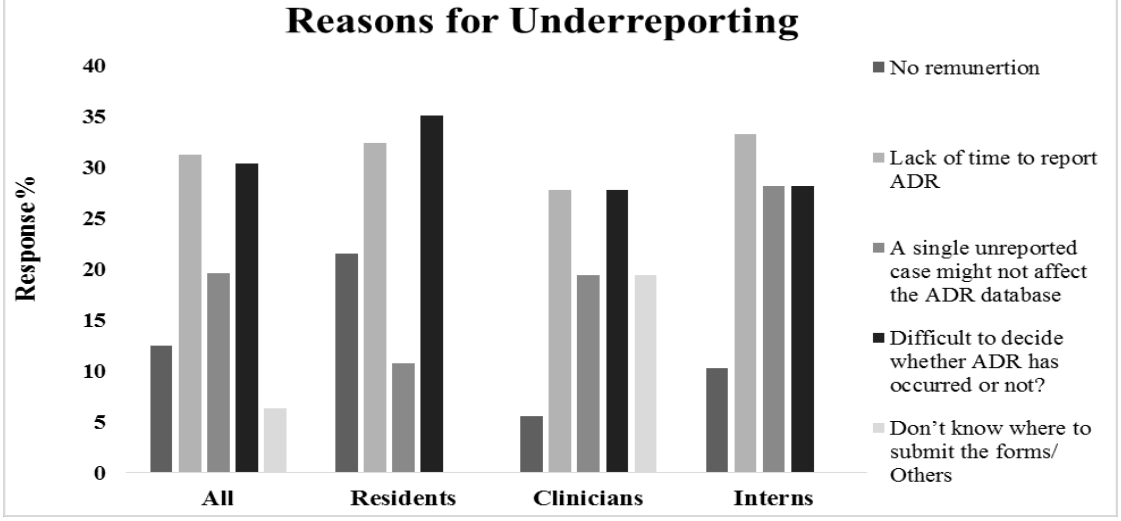

Figure 2: Showing the results for the reasons discouraging the ADR reporting.

DISCUSSION

Although most of the participants responded ADR reporting as a necessity; among those who have experienced ADRs in their clinical practice; very few had reported the ADRs to the pharmacovigilance centre. The major finding of this study can be this obvious considerable gap.

Results were evident for the serious lack of knowledge among the respondents. However it is evident from the results from the attitude domain that participants agreed upon the inclusion of the pharmacovigilance related protocols in the curriculum. The residents group stressed upon the inclusion more than the other two groups. The interns group showed the least awareness about practice of ADR reporting very well reflected in their response rate as well. They can be educated about and trained in the protocols for ADR reporting during their internship orientation programme. Overall very few participants responded about having received the training of ADR reporting protocol suggesting the need for efficient training programme.

We compared the results from present study with the results of other similar Indian studies previously conducted in the same state (Maharashtra) and in Tamilnadu. (Table 6). The comparison highlighted poor awareness about pharmacovigilance.

Table 6: Showing the comparison of results between the studies.

Questions	Current study (Navi Mumbai; Maharashtra)	Tertiary care Hospital study;[13] (Nagpur; Maharashtra)	Other study[10] (Tamil Nadu)
Pharmacovigilance definition	55.4 %	64.2 %	62.4 %
Pharmacovigilance purpose?	51.8 %	NA	66.3 %
Who can report ADRs?	7.1%	NA	80.2 %
Awareness about National PPI	42.9 %	52.38 %	75.2 %
Professional obligation?	65.2 %	35.72 %	69.3 %
ADR reporting necessity?	84.8 %	NA	97 %
ADR Experienced in practice?	54.5 %	NA	64.4 %
ADR reported in practice?	13.4 %	NA	22.8 %
Received training on reporting?	9.8 %	50.5 %	53.5 %

.Present study also evaluated the reasons of ADR underreporting which then were compared with similar studies done in the past assessing the factors discouraging the health professionals from ADR reporting. Desai CK et al.; 2011 study [14] done in Ahmedabad stated lack of awareness about where to and how to report ADRs as the most common reason for underreporting along with some other reasons like lack of accessibility of ADR forms, lack of time as treating the patient being the main priority as well as concerns about legal and professional liability, patient confidentiality issues. Some of these factors were taken care of over the years as; lack of clarity about ADR forms and insufficient training about identifying the ADRs remained the common reasons for difficulty in reporting as per the 2013 studies done by Khan SA et al. and Hardeep et al [15] ; Northern India study. However, there is major overlapping in the factors for underreporting of ADRs with those mentioned in previously done studies.[16,17,18] in last five years such as lack of time, medical management being the critical priority emphasizing the need for an update regarding better accessibility and simplicity in ADR reporting protocols. These comparisons have highlighted, dire need to improve awareness about significance of ADR reporting as majority of the healthcare professionals stated lack of remuneration as well as beliefs about the ADR database being not affected by a single unreported case.

The recommendation of addition of the pharmacovigilance to the undergraduate curriculum by present study respondents emphasizes that respondents have started understanding its importance. The intervention to boost the awareness among health care professionals can be implemented preferably under the National programme to ensure the uniformity all over the country. Other recommendations [16] in order to increase the ADR reporting are perseverance of pharmacovigilance centre and even the promotion of patient self-reporting. Electronic and social media can be utilized for the same purpose in the form of regular e-mails update on the safety of the drugs. Establishing a network of doctors through WhatsApp application for ADR reporting or electronic submission of spontaneous reporting of ADRs can be of great acceptance as a solution over the lack of time to report factor of underreporting. Small economic inducement could also be one of the measures taken in order to improve ADR under-reporting.

Limitations of the study

Small sample size can be stated as the first limitation. In this cross sectional study although the participants responded anonymously there was no blinding done. Also the convenience sampling method was used for this study.

CONCLUSION

Majority of healthcare professionals had good attitude towards and seconded the necessity for ADR reporting in-spite of the low ADR reporting rate. However, serious lack of awareness in terms of knowledge and practice of the ADR reporting protocols along with daunting reasons for underreporting stipulate more aggressive measures to create the necessary awareness. The percentage of the health professionals who received the training about ADR reporting protocols was low which in turn warrants stringent implementation of training programme containing training for the diagnosis of the ADRs as well as for the protocols of ADR reporting.

REFERENCES

1. Kalaiselvan et al.; "Pharmacovigilance programme in India: Recent developments and Future perspectives" Indian J Pharmacol., 2016 Nov-Dec; 48(6): 624-628.
2. Patel TK et al.; "incidence of Adverse Drug reactions in Indian Hospitals: systematic review" Curr Drug Saf., 2016; 11(2): 128-36
3. www.who.int/medicines/areas/quality_safety/safety_efficacy/pharmvigi/ (accessed January 2012).
4. PJ Pitts et al.; "21st century pharmacovigilance: efforts, roles, and responsibilities." The Lancet Oncology, e486–e492, November 2016; 17(11).
5. Singh and Bhatt; "Comparative evaluation of adverse drug reaction reporting forms for introduction of a spontaneous generic ADR form" J Pharmacol Pharmacother. 2012 Jul-Sep; 3(3): 228–232.
6. Pharmacovigilance Programme of India (PvPI) [Last updated on 2014 June 13]. Available from: http://www.ipc.gov.in/PvPI/pv.
7. Tripathi RK et al.; "Implementation of a module to promote competency in adverse drug reaction reporting in undergraduate medical students" Indian J Pharmacol, 2016 Oct; 48(1): S69-S73.
8. Bhagavathula AS et al.; "Health professionals KAP about Pharmacovigillance in India A systematic review" PLoSONE, 2016 March; 11(3).
9. Rishi et al.; "Under Reporting of ADRs by Medical Practitioners in India -Results of Pilot Study" Adv Pharmacoepidem Drug Safety, 2012; 1: 112. doi:10.4172/2167-1052.1000112.
10. Gupta, et al.; "A questionnaire study on the knowledge, attitude, and practices of pharmacovigilance." Perspectives in Clinical Research | January-March, 2015; 6(1): 45-52.
11. Reddy V Lokesh et al.; "Assessment of Knowledge, Attitude and Perception of Pharmacovigilance and Adverse Drug Reaction (ADR) Reporting among the Pharmacy Students in South India." Journal of Pharmacy and Biological Sciences, Mar-Apr. 2014; 9(2): (VersionIII), 34-43.
12. Pathak AK et al.; "A Retrospective Analysis of Reporting of Adverse Drug Reactions in a Tertiary Care Teaching Hospital: One Year Survey." J Clin Diagn Res., 2016 Aug; 10(8): FC01 - FC04.

13. Pimpalkhute SA et al., "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.
14. Desai C, Panchal J, Dikshit R, Iyer G, Shah S. An evaluation of knowledge, attitude, and practice of adverse drug reaction reporting among prescribers at a tertiary care hospital. Perspectives in Clinical Research, 2011; 2(4): 129.
15. Bajaj J, Rakesh K. A survey on the knowledge, attitude and the practice of pharmacovigilance among the health care professionals in a teaching hospital in northern India. [Internet]. PubMed Central (PMC). 2018. [cited 31 December 2018]. Available from: http://europepmc.org/articles/PMC3576761.
16. Patil AD. "Adverse drug reaction (ADR) reporting in India: a long way to go" Int J Basic Clin Pharmacol, 2013 Dec; 2(6): 846-848.
17. Kalaiselvan et al.; "Adverse drug reactions reporting culture in Pharmacovigilance program in India" Indian J Med Res, 2014 Oct; 140(4): 563-64.
18. Kharkar M and Bowalekar S. Knowledge, attitude and perception/practices (KAP) of medical practitioners in India towards adverse drug reaction (ADR) reporting. Perspect Clin Res., 2012 Jul-Sep; 3(3): 90–94.