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Research

Assessment of knowledge, attitude and practice of pharmacovigilance and ADR reporting in health care professionals

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Abstract

Background: Lack of awareness among healthcare professionals is cited as one of the main reasons along with under reporting of adverse drug reactions. Knowledge, attitude, and practice (KAP) studies can help to understand various issues and improve pharmacovigilance system.

Objectives: The present study was undertaken to assess the knowledge, attitude, and practices (KAP) regarding pharmacovigilance and ADR reporting among healthcare professionals at the various departments of hospitals in Northern Kerala to get an insight into the causes of under-reporting of ADRs.

Materials and Methods: The data was collected using a pre-designed questionnaire. A total of 25multiple choice questions related to knowledge, attitude and practice. There were 6 Knowledge based 7 Attitude and 12 Practice based questions. The participants were graded in three categories as good, fair and poor depending on the mean score. The data were interpreted by calculating the frequencies, one-way ANOVA test.

Results: A total of 300 healthcare professionals who completed the questionnaire were considered of which 110 were doctors, 98 were nurses and 92were pharmacist. Among them, doctors have relatively better score than nurses and pharmacists in knowledge and attitude. Most healthcare professionals have showed fair practice in pharmacovigilance and ADR reporting and the pharmacists being the best performers.

Conclusion: To facilitate the culture of reporting and creating awareness among health professionals, CME, workshops, conferences, post training reminders such as periodic E-mails and SMS alerts should be conducted. Pharmacovigilance is being taught to some degree in theory, but the knowledge on the practical method is lacking. The existing academic curriculum can be amended to incorporate the application of pharmacovigilance in the medical practice.

Keywords: Adverse drug reaction; Pharmacovigilance; Knowledge, attitude and practice; Healthcare professionals.

INTRODUCTION

Pharmacovigilance (PV) is defined by WHO as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems [1]. The word & quot;pharmacovigilance" is derived from pharmakon (Greek for drug) and vigilare (Latin for to keep watch). As such, pharmacovigilance heavily focuses on Adverse Drug Reactions(ADR), which are defined as any response to a drug which is noxious and unintended, including lack of efficacy (the condition that this definition only applies with the doses normally used for the prophylaxis, diagnosis or therapy of disease) [2,3] .

Improve patient care and safety in relation to the use of medicines and all medical and paramedical interventions. Contribute to the assessment of benefit, harm, effectiveness and risk of medicines, leading to the prevention of harm and maximization of benefit. Encourage the safe, rational and more effective (including cost-effective) use of medicines. Promote understanding, education and clinical training in pharmacovigilance and its effective communication to the public. Enhance public health programmes by collecting good information on the effects of medicines and develop early warning of problems which might affect the success of programmes [4,5].

Good pharmacovigilance practice needs to be developed to ensure that data are collected and used in the right way and for the right purpose. Pharmacovigilance, and more generally the study of the benefits and risk of drugs, plays a major role in pharmacotherapeutic decision-making, be it individual, regional, national or international. In addition, pharmacovigilance is becoming a scientific discipline in its own right [6,7].

In India, consideration for the surveillance of ADRs developed relatively late, as traditionally there was no concept of surveillance of medicines in the country. Even though PV is still in its infancy, it is not new to India [5] .It was not until 1986 when a few physicians, mainly from academic institutions, called for greater attention to be devoted to the potential adverse effects of prescription medicines and rational prescribing of medicines[8,9]. This led to the formation of the first ADR monitoring program consisting of 12 regional centers, each covering a population of 50 million, but was unsuccessful [10,11] . Nothing much happened until a decade later when India joined the WHO Adverse Drug Reaction Monitoring Programme based in Uppsala, Sweden in 1997.

The National Pharmacovigilance programmes (NPVP), established in January 2005, and was to be overseen by the National Pharmacovigilance Advisory Committee based at the Central Drugs Standard Control Organization (CDSCO). Two zonal centers, the South-West (SW) zonal center (located in the Department of Clinical Pharmacology, Seth GS Medical College and KEM Hospital, Mumbai) and the North-East (NE) zonal center (located in the Department of Pharmacology, AIIMS, New Delhi) were to collect the information from all over the country and send it to the committee as well as to the Uppsala Monitoring Center (UMC) in Sweden [12, 13].

To promote PV in the country, notably, to collect and manage adverse drug reaction (ADR) reports, reports of medication errors and suspected counterfeit/substandard drugs; to collaborate and harmonize with existing ADR collection activities within the country[14,15]

MATERIALS AND METHODS

Study Setting

This was a cross-sectional, questionnaire-based study conducted in various departments of hospitals in Northern Kerala. Study was conducted for a period of 6 months, November 2021 to February 2022.

Study Design

It was a cross-sectional, non interventional, questionnaire-based study. The study participants consisted of all the practicing healthcare professionals (doctors, nurses and pharmacists) who were willing to participate in study. Those who were not willing to participate were excluded from the study.

Study questionnaire

The data was collected using a pre-designed questionnaire in printed and google format. The predesigned questionnaire had two domains. The first domain was included with socio-demographic data of the healthcare professionals. The second domain had 25 multiple choice questions related to Knowledge, attitude and practice . There were 6 Knowledge based 7 Attitude and 12 Practice based questions. The questionnaire was distributed in English. The responses that were given choice were 'Yes', 'No', 'May be', & can't say and for certain questions were provided with more optional answers. Scores of the question were determined in such a way that correct answers were given a score of one, wrong answers with score zero and indefinite. The respondents to knowledge, attitude and practice based questions were divided as 'Good', 'Fair' and 'Poor'.

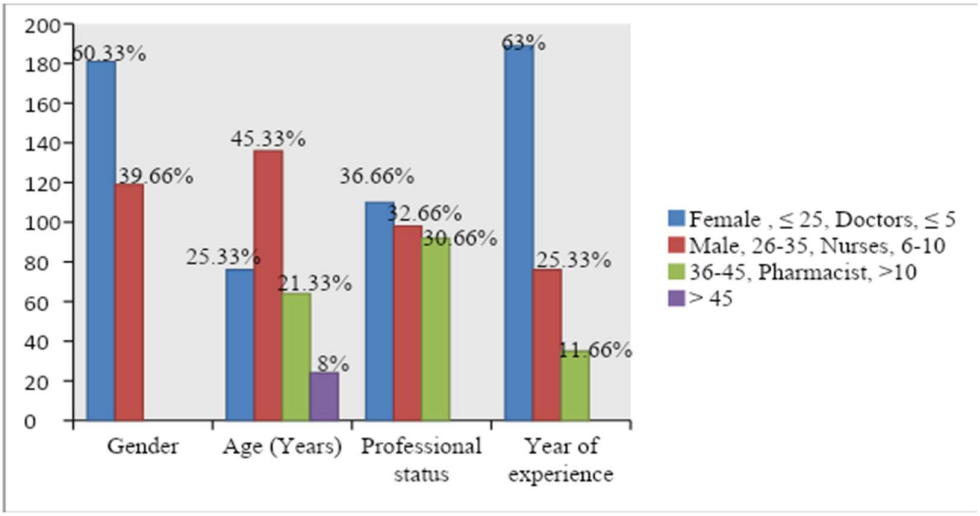
Statistical Analysis

Statistical significance was calculated by ANOVA one-way analysis of variance was used to test the difference between the group to evaluate whether the means were significantly different each other. P values below 0.05 were considered significant.

RESULTS AND DISCUSSION

SI. No.	Variables	Category	Frequency (n=300)	Percentage
1	Gender	Female	181	60.33%
		Male	119	39.66%
2	Age (Years)	≤ 25	76	25.33%
		26-35	136	45.33%
		36-45	64	21.33%
		> 45	24	8%
3	Professional status	Doctors	110	36.66%
		Nurses	98	32.66%
		Pharmacist	92	30.66%
4	Year of experience	≤ 5	189	63%
		6-10	76	25.33%
		>10	35	11.66%

The study was conducted in various departments of the hospitals among healthcare professionals in Northern Kerala. A total of 300 healthcare professionals who completed the questionnaire were considered of which 110 were doctors, 98 were nurses and 92 were pharmacist. The socio-demographic characteristics of participants are summarized below.

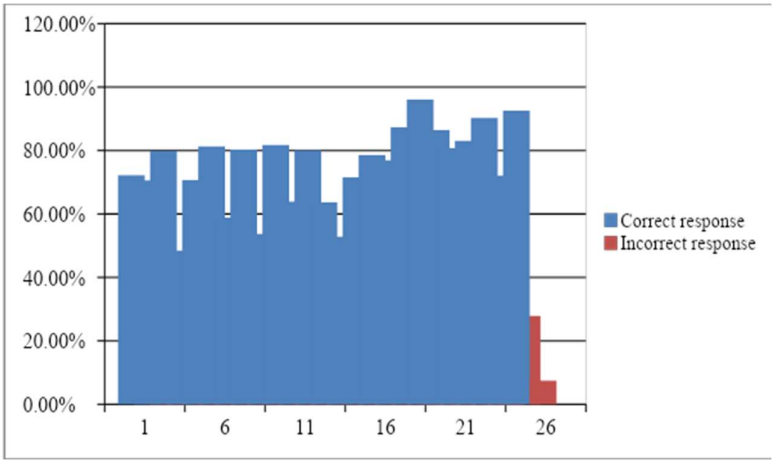


These results were conducted by Sandeep kumar gupta et.al., in which females (53.5%) were more compared to males (46.5%) and most of the participants were doctors (49.5%).

Knowledge, Attitude and Practices of Healthcare professionals

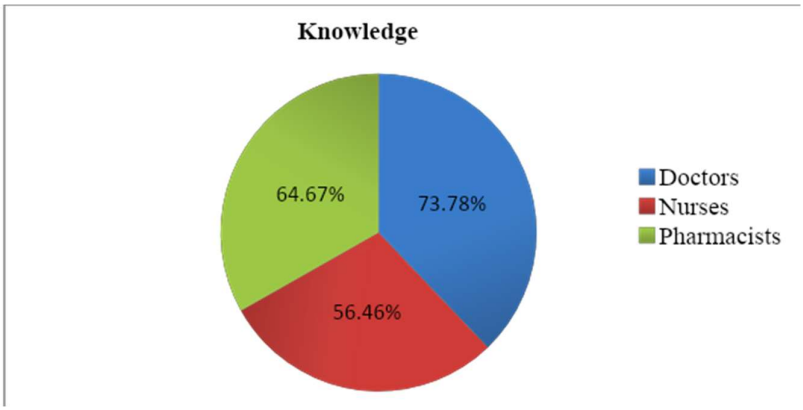
The healthcare professional's knowledge, attitude and practices was assessed and tabulated below.

Questions	Correct Response %	Incorrect response %
1. Define Pharmacovigilance?	72.2%	27.8%
2. The most important purpose of Pharmacovigilance is?	70.56%	29.44%
3. In India which regulatory body is responsible for Monitoring ADRs?	79.82%	20.18%
4. Where is the international center for adverse drug reaction Monitoring located?	48.42%	51.58%
5. Are you aware of any drug that has been banned due to the ADRs? If yes, name drugs and ADRs?	70.65%	29.35%
6. From which source do you gather information about ADRs to new drugs?	81.34%	18.65%
7. Have you ever seen the ADR reporting form?	58.86%	41.14%
8. In your view which ADRs should be reported?	80.29%	19.71%
9. Rare ADRs can be identified in the following phase of a Clinical trial?	53.66%	46.34%
10.Do you think reporting of adverse drug reactions is necessary?	81.76%	18.24%
11. Do you keep the records of ADR?	63.93%	36.07%
12.Do you think pharmacovigilance should be taught in detail to health care professionals?	80.06%	19.94%
13.What is your opinion about establishing ADR monitoring Centers in every hospital?	63.62%	36.38%
14. Have you ever played any role in reporting ADR from Your hospital?	52.79%	47.21%
15. List three common ADRs along with the medicine that Causes them?	71.58%	28.42%
16.Have you ever experienced adverse drug reactions in Your patient during your professional practice?	78.59%	21.41%
17.What factors do you think are important while deciding to report an ADR?	76.89%	23.11%
18. Which method would you prefer to send ADR Information to an ADR reporting center?	87.35%	12.65%
19. Have you ever shared information about ADRs with anyone?	96.06%	3.94%
20. Do you think reporting ADR will increase patient safety?	86.39%	13.69%
21. Would you like to be part of any future training sessions in pharmacovigilance?	80.69%	19.31%
22. Which of the following factors discourage you from reporting ADR ?	83.01%	16.99%
23. How often are you reporting the ADR?	90.31%	9.69%
24. Expedited reporting of serious and unexpected ADRs is required?	72.1%	27.9%
25. Are you willing to implement ADRs reporting in your practice ?	92.56%	7.44%



Knowledge among healthcare professionals

These findings were similar to the study of Asmatanzeem Bepari et.al., In which it was stated that doctors (3.39%) having more knowledge than (2.88%)pharmacist and (2.82%) nurses.

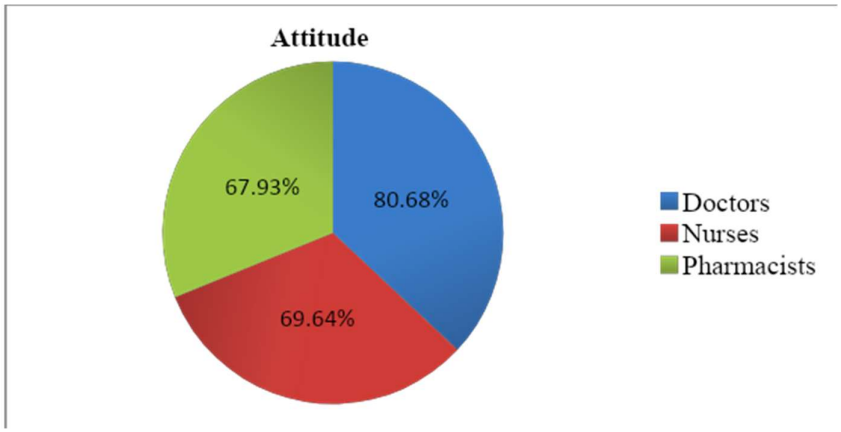


Knowledge	Doctors	Nurses	Pharmacist
Good (4-6)	56 (50.90%)	28 (28.57%)	40 (43.47%)
Fair (3)	36 (32.72%)	30 (30.61%)	35 (38.04%)
Poor (< 3)	20 (18.18%)	40 (40.81%)	17 (18.47%)

From this study, it was clear that nurses have inadequate knowledge about pharmacovigilance, which corroborates with the finding of Bikash Ranjan Meher et.al.,. The f-ratio value is 3.38726. The p-value is .035112. The result is significant at $p < .05$.

Attitude among healthcare professionals

The idea of teaching pharmacovigilance to healthcare professionals was more accepted by doctors 83 (75.45%) followed by nurses70 (71.42%) and pharmacists 68 (73.91%). To improve the spontaneity and the reporting rates, majority of doctors suggested the organization of training programmes and an uncomplicated reporting system with a quick feedback were the best measures. A similar study demonstrated that an educational intervention could increase the physician's awareness on ADRs and that the physicians would be able to incorporate the knowledge that they gained from their everyday clinical practice (Tabali *et al.,*). Considered the overall attitude of healthcare professionals to pharmacovigilance and ADR reporting most doctors (80.68%) considered ADR reporting as their professional responsibility, which is in contradiction to the results in Rabia Hussain, *et.al.,* where the majority of pharmacists (70.2%) considered ADR reporting as professional responsibility. This comparative study explored the attitudes of all HCPs towards pharmacovigilance activities and showed that overall, all HCPs had a positive attitude towards pharmacovigilance activities in general and ADRs reporting in particular.

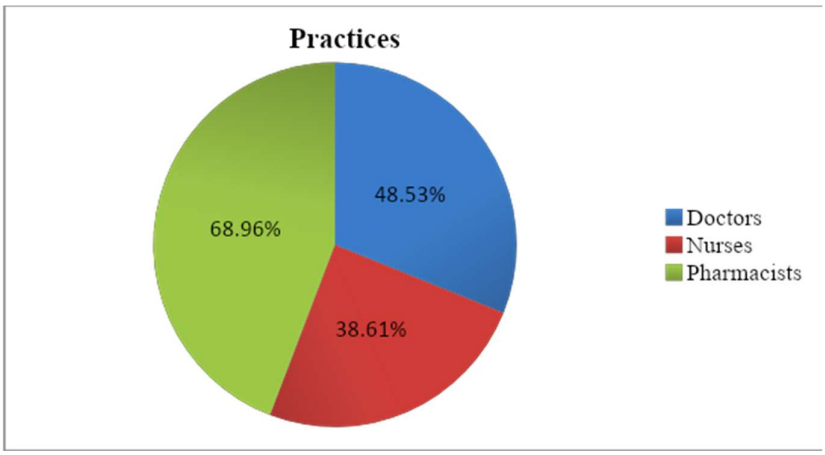


Attitude	Doctors	Nurses	Pharmacist
Good (4)	50 (45.45%)	40 (40.81%)	35 (38.04%)
Fair (3)	32 (29.09%)	38 (38.77%)	42 (45.65%)
Poor (<2)	28 (25.45%)	20 (20.40%)	15 (16.30%)

In our study nearly one-third of the pharmacist shows poor attitude towards pharmacovigilance which in contradiction to the results showed in studies conducted by Akram Ahamad, et.al., in which pharmacist shows good attitude towards pharmacovigilance. The f-ratio value is 2.52869. The p-value is .081479. The result is not significant at $p < .05$.

Practice among healthcare professionals

Majority of the ADR reporting form was handled by 87(79.09%) doctors when compared to 59 (64.13%) pharmacist. Large number of ADR reporting forms are recorded and kept by 90 (81.81%) doctors, and least recording of ADR reporting was done by 62 (63.26%) nurses. These results differ from the study found in Rabia Hussain et.al., in which it was stated that about 94 (83.9%) physicians, 23 (62.2%) pharmacists and 137 (69.5%) nurses never kept records of ADR. However, they kept the records of an ADR and few of them ever sent any ADR report to drug manufacturer. The practice of not keeping an ADR reporting documented the poor practice among these HCPs, which ultimately could lead to events of drug safety problems. Majority of doctors, pharmacists and nurses have experienced adverse drug reactions in patients during their professional practices. In which it was stated that pharmacist (68.96%) having more experience than doctors (48.53%) and nurses(38.61%).The similar findings were observed in the study of Asmatanzeem Bepari et.al., The mean practice score of the nurses (2.73%)was lower than pharmacists (2.91%) and the majority of healthcare workers showed least practice score.



Practices	Doctors	Nurses	Pharmacist
Good (10 - 13)	39 (35.45%)	30 (30.61%)	50 (54.34%)
Fair (5 - 9)	45 (40.90%)	48 (48.97%)	31 (33.69%)
Poor (1 - 4)	26 (23.56%)	20 (20.40%)	11 (11.95%)

Most healthcare professionals have showed fair practice in pharmacovigilance and ADR reporting of which the ones with highest percentage of professionals with adequate answers, with the pharmacists being the ones with best performance. These results similar from the results found in José Romério Rabelo Melo et.al., which pointed out that pharmacists, were with adequate pharmacovigilance practices. The f-ratio value is 12.10023. The p-value is < .00001. The result is significant at $p < .05$.

CONCLUSION

This study showed that majority of the healthcare professionals had good knowledge and attitude about pharmacovigilance and ADR reporting and understand the need for reporting. In spite of that the reporting rate of ADR by them is very low. Hence there was huge gap between the ADR experienced and ADR reported by healthcare professionals. Overall this study shows that doctors and nurses in Northern Kerala had good knowledge and positive attitude toward pharmacovigilance and ADRs reporting. However, the majority of them

have never reported ADRs. Among all healthcare professionals, pharmacists had better practice about ADR reporting and pharmacovigilance. A greater number of healthcare professionals referred to scientific journals as a source of information about ADR of new drugs. The discrepancies were observed in the practices related to ADR reporting, whereas most of the participants including physicians and nurses did not report any ADR. The above observations indicated that serious measures have to be taken to implement the regular reporting of ADRs among doctors, nurses, and pharmacists. To facilitate the culture of reporting and creating awareness among health professionals, CME, workshops, conferences, post training reminders such as periodic E-mails and SMS alerts should be conducted. This will reduce the ignorance of ADR reporting, as the perception that only serious ADRs are to be reported is one of cause for under-reporting of ADRs. Other measures would be providing active workers for busy clinicians and incentives to promote the reports on ADRs. As “lack of financial incentives” and lack of time are also the reasons for under-reporting of ADRs.

REFERENCES

1. Ganesan S, Sandhiya S, Reddy KC, Subrahmanyam DK, Adithan C. The impact of the educational intervention on knowledge, attitude, and practice of pharmacovigilance toward adverse drug reactions reporting among health-care professionals in a tertiary care hospital in South India. J Nat Sci Biol Med. 2017 Jul;8(2):203. doi: 10.4103/0976-9668.210014.
2. Wangge G, Akbar W. Knowledge, attitudes and practice of pharmacovigilance among health care professionals in Indonesia. Health Sci J Indones. 2016;7(1):59-63. doi: 10.22435/hsji.v7i1.5285.59-63.
3. Fornasier G, Francescon S, Leone R, Baldo P. An historical overview over pharmacovigilance. Int J Clin Pharm. 2018 Aug;40(4):744-7. doi: 10.1007/s11096-018-0657-1.
4. Routledge P. 150 years of pharmacovigilance. Lancet. 1998 Apr 18;351(9110):1200-1. doi: 10.1016/S0140-6736(98)03148-1.
5. Levy M. The epidemiological evaluation of major upper gastrointestinal bleeding in relation to aspirin use. In: Epidemiological concepts in clinical pharmacology. Berlin, Heidelberg: Springer Berlin Heidelberg; 1987. p. 100-4.
6. Jeetu G, Anusha G. Pharmacovigilance: a worldwide master key for drug safety monitoring. J Young Pharm. 2010 Jul;2(3):315-20. doi: 10.4103/0975-1483.66802.
7. Kulkarni RD. Reporting systems for rare side effects of nonnarcotic analgesics in India. Problems and opportunities. Med Toxicol. 1986;1;Suppl 1:110-3. PMID 3821424.
8. Moride Y, Haramburu F, Requejo AA, Bégaud B. Under-reporting of adverse drug reactions in general practice. Br J Clin Pharmacol. 1997 Feb;43(2):177-81. doi: 10.1046/j.1365-2125.1997.05417.x.
9. Adithan C. National pharmacovigilance programme. Indian J Pharmacol. 2005 Nov 1;37(6):347. doi: 10.4103/0253-7613.19069.
10. Nissen T, Wynn R. The clinical case report: a review of its merits and limitations. BMC Res Notes. 2014 Dec;7(1):1-7.
11. Sahu RK, Yadav R, Prasad P, Roy A, Chandrakar S. Adverse drug reactions monitoring: prospects and impending challenges for pharmacovigilance. Springerplus. 2014 Dec;3(1):1-9.
12. Aggarwal V, Gupta SK, Sharma DK, Arya S, Singh S. Adverse drug reaction policy in a tertiary care hospital. Int J Res Found Hosp Healthc Admin. 2015;3(1):41-7. doi: 10.5005/jp-journals-10035-1035.
13. Bepari A, Niazi SK, Rahman I, Dervesh AM. The comparative evaluation of knowledge, attitude, and practice of different health-care professionals about the pharmacovigilance system of India. J Adv Pharm Technol Res. 2019 Apr;10(2):68. doi: 10.4103/japtr.JAPTR_4_19.
14. Ahmad A, Patel I, Balkrishnan R, Mohanta GP, Manna PK. An evaluation of knowledge, attitude and practice of Indian pharmacists towards adverse drug reaction reporting: A pilot study. Perspect Clin Res. 2013 Oct;4(4):204. doi: 10.4103/2229-3485.120168.
15. Alsaleh FM, Alzaid SW, Abahussain EA, Bayoud T, Lemay J. Knowledge, attitude and practices of pharmacovigilance and adverse drug reaction reporting among pharmacists working in secondary and tertiary governmental hospitals in Kuwait. Saudi Pharm J. 2017 Sep 1;25(6):830-7. doi: 10.1016/j.jsps.2016.12.004.