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Comparative study of knowledge, attitude and practices of pharmacovigilance programme between clinicians and nurses in tertiary care teaching hospital of central India

Chetan S. Urade[1], Avinash V. Turankar[2], Vinay A. Bajaj[3], Vijay M. Motghare[4,*], Ganesh N. Dakhale[5]

[1]Assistant Professor, [2]Associate Professor, [3]PG Student, [4]Professor & HOD, [5]Professor, Dept. of Pharmacology, Govt. Medical College, Nagpur, Maharashtra

***Corresponding Author:**
Email: vm.motghare@gmail.com

Abstract

Introduction: Adverse drug reactions (ADRs) routinely occurs in clinical practice, raises the financial burden on both patients and hospitals. To monitor ADRs, vigilance programme commenced across the country since 2001. Also MCI made a compulsion to have ADR monitoring centre (AMC) in every medical colleges of India. As there is scarcity of comparative studies between clinicians and nurses, we planned study with objective of comparison between clinicians and nurses about KAP of pharmacovigilance programme.

Material and Method: A cross-sectional, questionnaire based study. Clinicians and nurses of tertiary care teaching hospital of central India voluntarily answered the 28 pretested questionnaires. The study commenced only after approval of IEC. The duration of study was 12 weeks.100 clinicians and 100 nurses enrolled as participants. The data was analysed by graph pad prism version 6.

Results: Statistically significant differences were seen between clinicians and nurses about awareness of national ADR reporting system, definition of ADR, definition of pharmacovigilance and knowledge of relation between serious adverse events &causality. 67% clinicians ticked "correct regulatory body", responsible for monitoring ADR in India ($p < 0.0001$). Preferred mode to report ADRs in clinicians and nurses is phone.

Conclusion: Clinicians had better knowledge and attitude about pharmacovigilance programme than nursing staff. So we recommend more focus on training of nurses in the form of CMEs and workshops with the emphasis on knowledge and attitude gaps, reducing the reporting anxiety and reducing the fear of legality associated with ADR reporting.

Keywords: Pharmacovigilance, Adverse drug reactions, Clinicians, Nurses

Introduction

According to WHO, adverse drug reaction (ADR) is "a response to a drug that is noxious and unintended and occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease, or for modification of physiological functions." Adverse drug reactions (ADRs) occurs commonly in routine practice. Though most of them are preventable, contributing to serious morbidity and mortality all over the world.[1,2]Although prevalence of hospital admission in India due to ADRs is comparatively less than USA and Canada i.e. 3.4%, they increased financial burden on both patients and hospitals.[3] Ramesh M et al study showed the average cost per patient to treat ADR was approximately INR 900/- (USD 15 $).[4] In India, national level vigilance programme would be functional from year 2001 to monitor drugs related ADRs and to reduce drugs related morbidity and mortality. That programme came forward with the name of "Pharmacovigilance Programme of India (PvPI)" which was fully geared up from 2003. According to WHO, pharmacovigilance is "a science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problems".[5]

Medical council of India (MCI) had mandate to have an ADR monitoring centre in every medical colleges of India. MCI had given additional responsibility to the health care professionals (doctors, dentists, nurses and pharmacists) as a part of their routine work for reporting suspected, unsuspected, serious, unusual ADRs under PvPI. ADR monitoring centres (AMCs) are being deeply rooted across the country in order to step up the spontaneous reporting by health care professionals.[3]

Our institute registered as an AMC in November 2013. Since then, we organized various continuing medical education (CMEs) / workshops in our institute to sensitize the health care professionals about PvPI.

Various studies from India, Iran& Sweden concluded about underreporting of ADRs.[1–3] This may be due to lack of knowledge, attitude and practicing methods among health care professionals. Some studies elaborated the reasons responsible for underreporting of ADRs.[1,4–8] Only one study from north India region showed comparative assessment of knowledge, attitude and practices of pharmacovigilance programme between nurses and resident doctors.[9] As there is scarcity of comparative studies between nurses and doctors about awareness of pharmacovigilance programme in central India region, this study is planned with the objective of comparison between clinicians and nurses about knowledge, attitude and practices of pharmacovigilance programme.

Materials and Method

This was across-sectional, questionnaire survey based study. 28 questions (12 – knowledge based, 7 – attitude based and 9 – practice based) was first pretested in 5 doctors to assess the validity of the questions. Once the validity was confirmed then clinicians and nurses of tertiary care teaching hospital of central India voluntarily answered the 28 pretested structured questionnaires containing both open & closed ended questions by direct face to face interview. The study commenced only after approval of Institutional Ethics Committee. All clinicians and nurses completed the questionnaire in the study who were enrolled by convenience sampling method with a mix of various departments. The departments were general medicine, respiratory medicine, paediatrics, gynaecology, surgery, ophthalmology, oto-rhino laryngology and dermatology. The included clinicians were from senior faculties, assistant professors, senior residents and junior residents.

Duration of the study: October 2016 to January 2017.

Sample size: 100 clinicians and 100 nurses from tertiary care teaching hospital of central India enrolled in this study.

Statistical analysis: The data was analysed by Graph pad prism version 6.0.

Results

In this study, the statistically significant difference were seen between clinicians and nurses about awareness of national ADR reporting system of India, definition of adverse drug reaction and definition of pharmacovigilance (Table 1). However, nearly 60% health professionals i.e. 63% clinicians and 60% nurses were wrongly stated the main purpose of pharmacovigilance programme (Table 1).70% clinicians and 56% nurses had knowledge about institutional pharmacovigilance committee (Table 1).The knowledge (reporting of ADRs is only for allopathic drugs) is not statistical significant between clinicians and nurses. 43% of clinicians and 19% of nurses had knowledge of relation between serious adverse events and causality ($p < 0.0004$). 67% clinicians compared to 27% nurses ticked "correct regulatory body" which is responsible for monitoring ADR in India ($p < 0.0001$).

In this study, 83% clinicians and 64% nurses said ADR reporting is necessary. 79% clinicians and 59% nurses mentioned pharmacovigilance programme in India plays an important role in drug safety. 61% clinicians vs. 27% nurses completed the training regarding reporting ADRs ($p <0.0001$). 40% nurses suggested six monthly frequency of pharmacovigilance training. However, 65% clinicians suggested training frequency once in a year. Feedback (48%) and publication (45%), the major responses of clinicians expect from reported ADR. However, 60% nurses expect responses in terms of feedback, 12% in terms of publication, 13% nurses expected legal action on reporter. 47% clinicians and 40% nurses claimed lack of time is responsible to discourage them from reporting ADR (Table 2).

The preferred mode to report ADRs in both clinicians (72%) and nurses (49%) is phone. If drop box is kept, the preferred location is at ward/OPD for both clinicians (68%) and nurses (70%). The preferred way to find adverse drug reaction are by asking directly to patients or relatives or by monitoring patients reports for both clinicians (72%) and nurses (65%). For suspected adverse drug reaction, 72% clinicians gave a call to pharmacovigilance person and 60% nurses report it to treating physicians. 75% clinicians and 67% nurses reported all mild, moderate and severe form of ADR. 26% clinicians always did routine discussion regarding adverse drug reactions at their work place. However, 16% clinicians and 20% nurses reframed from any discussion regarding adverse drug reactions. 54% clinicians and 38% nurses always wrote the details of ADR on patient's record(Table 3).

Table 1: Comparison of knowledge about pharmacovigilance programme of India between clinicians and nurse

S. No	Questions	Clinicians (n=100)		Nurses (n=100)		P value
		Correct	Wrong	Correct	Wrong	
1	Definition of adverse drug reaction (ADR).	90	10	52	48	< 0.0001
2	Are you aware about national ADR reporting system of India?	99	1	26	74	< 0.0001
3	Definition of pharmacovigilance.	82	18	31	69	< 0.0001
4	The main purpose of pharmacovigilance is to identify the previously unrecognized adverse drug reactions.	37	63	40	60	0.7714

5	Awareness about pharmacovigilance committee in institute.	70	30	56	44	0.06
6	Knowledge about ADR reporting is done for allopathy medicine.	53	47	50	50	0.7773
7	Knowledge about health care professionals responsible for reporting ADRs.	100	0	98	2	0.4975
8	Definition of serious adverse event (SAE).	81	19	67	33	0.0355
9	Knowledge about relation between SAE and causality.	43	57	19	81	0.0004
10	What to report? a. SAE b. Adverse events c. ADRs d. Side effect e. All of the above	76	24	55	45	0.0028
11	Whom to report ADRs?	28	72	28	72	1.0000
12	Which regulatory body is responsible for monitoring ADR in India?	67	33	27	73	< 0.0001

Fisher's exact test is applied.

Table 2: Comparison of attitude towards pharmacovigilance programme of India between clinicians and nurses

S. No.	Questions	Clinicians	Nurses
1	Is ADR reporting necessary?		
	a. Yes	83	64**
	b. No	6	3
	c. Can't say	3	9
	d. May be	8	24
2	Is it good to report adverse drug reactions as per as professional image is concerned?		
	a. Yes	84	62**
	b. No	2	5
	c. Don't know	6	10
	d. May be	8	23
3	Pharmacovigilance programme in India plays an important role in drugs safety		
	a. Yes	79	59**
	b. No	7	7
	c. Don't know	1	6
	d. May be	13	28
4	Have you ever been trained on how to report Adverse Drug Reaction?		
	a. Yes	61	27***
	b. No	39	73
5	What should be the frequency of pharmacovigilance training?		
	a. Once in a month	7	13
	b. Six monthly	14	40***
	c. Once in a year	65	36

	d. Once in 3 years	14	11
6	What kind of response do you expect from reported ADR?		
	a. Feedback	48	60
	b. Publication	45	12***
	c. Nothing	6	15
	d. Legal action on reporter	1	13
7	Which of the following factor discourage you from reporting ADRs?		
	a. No remuneration		
	b. Lack of time to report ADRs	10	16
	c. A single reported case may not affect ADR database	47 09	40 11
	d. Difficult to decide whether ADR has occurred or not	25	22
	e. Legal action on reporter	09	11

**p < 0.001, ***p < 0.0001. Chi-square test is applied.

Table 3: Comparison of practices about pharmacovigilance programme of India between clinicians and nurses

S. No.	Questions	Clinicians	Nurses
1	Preferred mode to report adverse drug reactions in your institute.		
	a. Phone	72	49
	b. Drop box	6	7
	c. Email	2	2
	d. Personal visit (on call by help)	20	42
2	If drop box is opted then preferred location		
	a. Ward/OPD	68	70
	b. ADR monitoring centre	17	15
	c. Nearby chemist	0	1
	d. Medical superintendent office	15	14
3	How would you find adverse drug reactions?		
	a. By directly asking patient	24	21
	b. By asking patients relatives	1	13
	c. By only monitoring patients report	3	1
	d. All of the above	72	65
4	What you do with suspected adverse drug reactions?		
	a. Report to AMC centre/treating physicians (In case of nurses)	26	60
	b. Do not inform to anybody as it is routine part of the treatment	2	8
	c. Phone to on call pharmacovigilance person	72	32
5	Which severity of ADR do you report?		
	a. Mild: no therapy required	3	1
	b. Moderate: required therapy	0	0
	c. Severe: life-threatening	21	24
	d. All of the above	75	67
	e. None of the above	1	8
6	Is there any routine discussion regarding adverse drug reactions at your work place?		
	a. Always	26	8
	b. Sometimes	45	43
	c. Occasionally	13	29

	d. Never	16	20
7	Do you mention the ADRs on the patient's record?		
	a. Always	54	38
	b. Sometimes	19	27
	c. Occasionally	11	15
	d. Never	16	20
8	What should be incentives for reporting adverse drug reactions?		
	a. Getting score that will be help in university examination	58	17
	b. Getting certificate/appreciation letter from Head of Institute	37	75
	c. Winner of reporting among different categories and prize on that	5	8
9	What are the reasons for non-reporting/underreporting of adverse drug reactions in your institute?		
	a. Lack of time	53	54
	b. Lack of knowledge	32	33
	c. Lack of proper administration	9	13
	d. Don't know	6	0

Discussion

In India, pharmacovigilance is emerging field with the shift of pharmaceutical activities (i.e. new drug development and clinical trials) from west to east. Hence it is important to build up a system to handle trial and patient care as per ICH GCP guidelines to ensure patient safety. There are number of studies which suggest that health care professional's attitude to report ADR is a significant determinant of the reporting rate.[10,11] In this study, results related to knowledge of the clinicians and nurses about pharmacovigilance programme was encouraging. Awareness of national ADR reporting system was significantly more among clinicians than nurses. However, knowledge of established pharmacovigilance committee in institute was inadequate in nurses than clinicians. These findings are in agreement with Belton K[11], Nichols V et al[12], Aziz Z et al[13], Fadare JO et al[14] studies. The encouraging finding from our study is that majority of clinicians and nurses felt that ADR reporting is necessary and ongoing pharmacovigilance programme in India plays very important role in drug safety issue(Table 2).

A previous study conducted by Pimphalkhute et al[15] on 2012 reported that KAP about ADRs of resident doctors from the same institute was inadequate and needed further improvement. Over the span of four years, this study shows improvements of KAP about ADRs among the clinicians. However, KAP of nurses about ADR reporting is found to be inadequate. The probable reason for such improvements among clinicians is that in last four years department of pharmacology organized various workshops, continued medical educations (CMEs) about awareness of pharmacovigilance programme for clinicians. We suggest to organize various workshops, CMEs and group discussions among nurses to increase the awareness about pharmacovigilance programme. Also we request all head of departments to circulate the newsletters of PvPI among nursing staff to improve the knowledge of ADR reporting.

In this study, knowledge of clinicians about "what to report" ADRs was better than nurses ($p < 0.0028$). The probable reason for better knowledge of "what to report" is that clinicians have better knowledge of medicines and diseases, which help to analyse the appearance of ADRs. In this study, there is statistically significant difference occurred between clinicians and nurses about training of "how to report ADR" ($p < 0.0001$). This lack of training may be the reason for less knowledge of nurses about "what to report".

In this study, nearly fifty percent of clinicians have always mentioned the ADR in patient's case paper. However, percentages of nurses of regular mentioning the ADR in patient's case paper is quiet low (38%) (Table 3). It may be possible that ADRs are being recorded by the nurses in the treatment books but they are unable to transfer them to the patient's case paper due to excessive work load. So to record the ADRs in patient's case paper, we would like to propose the hospital authorities that add statement stating "Did you encounter any ADR?" in front page of the patient's case paper which must be mandatory to mark "Yes/No" by clinicians and/or nurses before submitting it to medical record section. This may encourage the discussion regarding ADRs during clinical rounds. The front page of the patient case paper could be stand with information of AMC of the institute.

In this study, 58% clinicians suggested us for getting score which will help in the university examination in term of incentives to report ADRs. The probable reason

may be due to enrolment of postgraduate students in our study. However, 75% nurses and 37% clinicians wanted certificate/appreciation letter from head of institution as a part of incentives to report ADRs. So, we would recommend such a mechanism to appreciate the reporters of ADR. This step will definitely enhance the ADR reporting rate. Overall the results suggest underreporting by nurses and clinicians of ADR is because of lack of time due to excess workload. A creative idea of ADR reporting mobile application with simple feature could be thought of.

Limitation of the study

Inclusion of pharmacist in the study would have enhanced the value of the study as they are important element in drug related care system to the patient.

Conclusion

We concluded that clinicians had better knowledge and attitude about pharmacovigilance programme than nursing staff. So we recommend more focus on training of nurses in the form of CMEs and workshops with emphasis on knowledge and attitude gaps, reducing reporting anxiety and reducing the fear of legality associated with ADR reporting. This step will definitely improve the knowledge of nurses about ADR reporting.

References

1. Upadhyaya HB, Vora MB, Nagar JG, Patel PB. Knowledge, attitude and practices toward pharmacovigilance and adverse drug reactions in postgraduate students of Tertiary Care Hospital in Gujarat. J Adv Pharm Technol Res. 2015;6(1):29–34.
2. Hajebi G, Mortazavi SA, Salamzadeh J, Zian A. A Survey of Knowledge, Attitude and Practice of Nurses towards Pharamacovigilance in Taleqani Hospital. Iran J Pharm Res. 2010;9(2):199–206.
3. Ekman E, Petersson G, Tågerud S, Bäckström M. Awareness among nurses about reporting of adverse drug reactions in Sweden. Drug Healthc Patient Saf. 2012;4:61–6.
4. Desai C, Iyer G, Panchal J, Shah S, Dikshit R. An evaluation of knowledge , attitude , and practice of adverse drug reaction reporting among prescribers at a tertiary care hospital. Perspect Clin Res. 2011;2(4):129–36.
5. Gupta SK, Nayak RP, Shivaranjani R, Vidyarthi SK. A questionnaire study on the knowledge , attitude , and the practice of pharmacovigilance among the healthcare professionals in a teaching hospital in South India. Perspect Clin Res. 2015;6(1):45–52.
6. Khan SA, Goyal C, Tonpay SD. A study of knowledge , attitudes , and practice of dental doctors about adverse drug reaction reporting in a teaching hospital in India. Perspect Clin Res. 2015;6(3):144–9.
7. Hardeep, Bajaj JK, Rakesh Kumar. 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 Diagnostic Res. 2013;7(11):97–9.
8. Sharma PK, Singh S, Dhamija P. Awareness among tertiary care doctors about Pharmacovigilance Programme of India : Do endocrinologists differ from others ? Indian J Endocrinol Metab. 2016;20(3):343–7.
9. 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(6):699–703.
10. Li Q, Zhang S, Chen H, Fang S, Yu X, Lui D. A wareness and attitudes of health care professionals in Wuhan, China to the reporting of adverse drug reactions. China Med J (Engl). 2004;117:856–61.
11. Belton K. Attitude survey of adverse drug reaction reporting by health care professionals across the European Union. Eur J Clin Pharmacol. 1997;52:423–7.
12. Nichols V, Thériault Dubé I, Touzin J, Del isle J, Lebel D, Bussières J. Risk perception and reasons for noncompliance in pharmacovigilance: A qualitative study conducted in Canada. Drug Saf. 2009;32:579–90.
13. Aziz Z, Siang T, Badarudin N. Reporting of adverse drug reactions: Predictors of under reporting in Malaysia. Pharmacoepidemiol Drug Saf. 2007;16:223–8.
14. Fadare J, Enwere O, Afolabi A, Chedi B, Musa A. Knowledge, attitude and practice of adverse drug reaction reporting among healthcare workers in a tertiary centre in Nort hern Nigeria. 2011; 10: 235–42. Trop J Pharm Res. 2011;10:235–42.
15. Pimpalkhute S, Jaiswal K, Sontakke S, Bajait C, 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.