International Journal of Pharmacological Research
ISSN: 2277-3312
www.ssjournals.com
Journal DOI:10.7439/ijpr

Knowledge, Attitude and Practice of Adverse Drug Reactions Reporting Among Healthcare Professionals

Siddeshwara M.G.[1*], Jeevangi Santoshkumar[2], Vardhamane S.H.[3]

[1]*Post Graduate Student/Tutor, Department of Pharmacology, M.R. Medical College, Kalaburagi, India.*
[2] *Professor, Department of Pharmacology, M.R. Medical College, Kalaburagi, India.*
[3]*Professor and Head, Department of Pharmacology, M.R. Medical College, Kalaburagi, India.*

Corresponding author*

Dr. M G Siddeshwara
Post Graduate Student/ Tutor
Department of Pharmacology,
M.R. Medical College, Kalaburagi - 585105, Karnataka, India.
E-mail: siddeshwarmg@gmail.com

Abstract

Objectives: This study was conducted to evaluate knowledge, attitude and practice of Adverse Drug Reactions (ADR) reporting among Healthcare Professionals.

Methods: A cross-sectional study was done by survey using questionnaire. Questionnaire was distributed to 260 healthcare professionals working at M.R. Medical College and S Nijalingappa Institute of Dental Sciences, Kalaburagi, India.

Results: Out 260 people 221 provided the response, giving a response rate of 85%. Among respondents 69.68% were Doctors, 23.53% were Nurses and 6.78% were Pharmacists. 71% of the healthcare professionals knew what are ADRs, 62.4% knew what is pharmacovigilance, 35.7% were aware of Pharmacovigilance Programme of India (PvPI) and 21.7% knew nearest pharmacovigilance center. 50.2% had seen patients experiencing ADR out of which only 8.1% of them have reported ADR to the concerned unit. 72.4% feel that all the cases of ADR should be reported irrespective of seriousness. Concern that report may be wrong and fear of legal liability were the main factors discouraging them for reporting ADR. Local coordination, Financial Support, ADR reporting awareness programmes were the major expectations from respondents.

Conclusion: Healthcare professionals working at HKE Society's M.R. Medical College and S Nijalingappa Institute of Dental Sciences have positive attitudes towards ADR reporting. However knowledge regarding ADR reporting among Doctors is superior to that of Nurses and Pharmacists, awareness programmes can overcome this problem. But the practice of ADR reporting is poor among all Healthcare professionals.

Keywords: Adverse Drug Reaction (ADR), Attitude, Pharmacovigilance, PvPI.

1. Introduction

Adverse drug reactions (ADRs) are unwanted, unexpected and harmful reaction to a drug. ADRs are significant cause for morbidity and mortality worldwide [1]. ADRs occur approximately in 30% of hospitalized patients, and patients in the ICU are exposed to more danger than the others [2]. ADRs can be a threat for patient's safety and quality of their life and may impose a lot of costs on the health systems [3]. Unfortunately, in India, required attention is not given to ADR reporting. ADR reporting rate in India is below 1% compared to worldwide rate of 5% [4]. Voluntary ADR reporting, based on monitoring safety of medicine, must be a major responsibility for all the health care professionals [5].

Knowledge and awareness of health care professionals with respect to the effects, adverse effects and methods of administration of drug, could help to elevate the quality of pharmacotherapy in hospitals. It is not possible to prevent each and every ADR, but the knowledge among health care professionals is very effective to decrease the rate of occurrence of ADRs [6,7], it can also prevent occurrence of new medicine tragedies and increase patient safety.

Pharmacovigilance is the science related to Detection, Assessment, Understanding and Prevention of adverse effects or any other drug related problems. The national pharmacovigilance programme (NPP) was launched by Ministry of Health and Family Welfare in July 2010. National pharmacovigilance center has been set up (in AIIMS, New Delhi) by Drug Controller General of India under Central Drugs Standard Control Organization (CDSCO). National pharmacovigilance center is linked downward with Zonal, Regional and peripheral pharmacovigilance centers. The generated data will then be forwarded to global pharmacovigilance database at the WHO-Upsala Monitoring Centre in Sweden [8]. Doctors, Nurses and pharmacists can report adverse drug reactions. The success of a Pharmacovigilance programme depends upon the active involvement of Healthcare Professionals such as Doctors, Nurses and Pharmacists [9, 10].

Therefore the present study was carried out to evaluate the knowledge, attitude and practice of ADR reporting among health care professionals working at M.R. Medical College and S Nijalingappa Institute of Dental Sciences, Kalaburagi.

2. Materials and Methods

It is an cross sectional study done by survey using a questionnaire, conducted in HKE Society's M R Medical College and S Nijalingappa Institute of Dental Sciences, Kalaburagi. Study was conducted over a period of five months (01-02-2015 to 31-06-2015) after approval of protocol from Institutional Ethics Committee. The study was conducted in accordance to the protocol after written informed consent from study subjects.

2.1 Procedure: Questionnaire was structured to obtain the demographics of healthcare professionals, expectations from pharmacovigilance programme and to evaluate their knowledge, attitude and practice of Adverse Drug Reactions (ADR) reporting. Questions were distributed as follows: 5 questions to assess the knowledge, 8 questions to assess the attitude, 2 questions to evaluate the practice. Questionnaire was designed to 4 level likert scale (1- strongly disagree and 4- strongly agree) and single choice. Questionnaire was attached with a covering letter, which had aimed to provide the information of the research to participants. The participant information sheet contained the objective of the research, the way to respond the questionnaire, their right to decide about whether or not to participate in the study and confidentiality of the response.

The questionnaire was tested for content validity by consensus of the expert panel comprising of Dr. Santoshkumar R Jeevangi (Professor, Department of Pharmacology, M R Medical College, Kalaburagi) and Dr. S. H. Vardhamane (Professor & Head, Department of Pharmacology, M R Medical college, Kalaburagi).

2.2 Data collection: Questionnaire was distributed to 260 health care professionals personally. Questionnaire was collected back after one hour of distribution.

2.3 Statistical analysis: The data was analyzed question-wise and their percentage value was calculated with the help of Microsoft Excel Spread sheet in MS office 2010.

3. Results

Out of 260 participants 221 provided the response with a response rate of 85%. There were 63 males, 152 females and 6 did not mention their gender. There were 152 doctors, 52 nurses and 15 pharmacists. Among respondents 55.20% were in the age group 26-30 and 23.9% had experience of 6-10 years. 93.21% completed their under-graduation in India and 5% abroad. Demographic details and characteristic features are shown in the Table 1.

Table 1: Demographic details and characteristic features of respondents

Category	Sub – Category	Number
Gender	Male	63(28.50%)
	Female	152(68.77%)
	Data missing	6(2.71%)
Age (Years)	20 – 25	46(20.81%)
	26 – 30	**122(55.20%)**
	31 – 35	24(10.86%)
	36 – 40	12(5.42%)
	41 – 45	2(0.90%)
	46 – 50	4((1.71%)
	> 50	1(0.45%)
	Data missing	10(4.53%)
Professional Qualification	Doctor	154(69.68%)
	Nurse	52(23.53%)
	Pharmacist	15(6.78%)
Work Experience(Years)	None	50(22.62%)
	< 1	38(17.19%)
	1 – 5	32(14.47%)
	6 – 10	**53(23.9%)**
	11 – 15	9(4%)
	16 – 20	Nil
	21 – 25	4(1.8%)
	>26	1(0.45%)
	Data missing	34(15.38%)
Doctor	MD/MS	39(25.32%)
	MBBS	**71(46.10%)**
	MDS	26(16.88%)
	BDS	18(11.68%)

.....continued Table 1		
Nurse	M.Sc. Nursing	2(3.8%)
	B.Sc. Nursing	15(28.84%)
	GNM	**35(67.31%)**
	ANM	Nil
Pharmacist	B. Pharm	2(13.33%)
	D. Pharm	**13(86.66%)**
Country of Undergraduate study	India	206(93.21%)
	Others	5(2.26%)
	Data missing	10(4.52%)

Note*: *MD- Doctor of medicine, MS-Master of Surgery, MBBS-Bachelor of Medicine and Bachelor of Surgery, MDS-Master of Dental Surgery, BDS-Bachelor of Dental Surgery, M.Sc-Master of Science, B.Sc.-Bachelor of Science, GNM-General Nursing and Midwifery, ANM-Auxilary Nursing Midwifery, B.Pharm- Bachelor of Pharmacy, D.Pharm-Diploma in Pharmacy.*

Among respondents 71% knew what are ADRs, 35.7% were aware of Pharmacovigilance programme of India (PvPI) and 21.7% knew about nearest pharmacovigilance center. 72.4% of the respondents felt all cases of ADRs should be reported, 62.4% of them knew what is Pharmacovigilance. Details of knowledge assessment of respondents are shown in Table 2.

Respondent were also evaluated for their attitude towards ADR reporting by asking them factors discouraging for ADR reporting. Responses were recorded on likert scale of 4 (1-strongly disagree and 4-Strognly agree). Details of which are produced in Table 3.

50.2% of the respondents have seen patient experiencing ADR but unfortunately only 8.1% of them have reported ADR to pharmacovigilance center or concerned unit of their hospital. Complete results of which are produced in table 4.

Table 2: Evaluation of knowledge

Questions	Doctors		Nurses		Pharmacists		Total	
	Yes	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**
1. Do you know what are adverse drug reactions (ADR)	136 (88.31%)	2 (1.3%)	17 (32.69%)	35 (67.30%)	4 (26.66%)	11 (73.33%)	157 (71%)	48 (21.7%)
								Data missing: 16 (7.23%)
2. Are you aware of National Pharmacovigilance programme of India (PvPI)	79 (51.3%)	72 (46.8%)	Nil	45 (86.53%)	Nil	12(80%)	79 (35.7%)	129 (58.4%)
								Data missing: 13 (5.9%)
3. Do you know the nearest pharmacovigilance centre	**48 (31.16%)**	99 (64.3%)	Nil	45 (86.53%)	Nil	12(80%)	**48 (21.7)**	156 (70.6)
	Doctors		**Nurses**		**Pharmacists**		**Total**	
4. Pharmacovigilance deals with							*DM: 7(3.2%)	
a) Drug Manufacturing	1(0.55%)		30(57.69%)		9(60%)		40(18.1%)	
b) Drug Cost Monitoring	3(1.95%)		8(15.38%)		1(6.6%)		12((5.4%)	
c) Adverse Drug Reactions Reporting	**133(86.36%)**		4(7.69%)		1(6.6%)		**138(62.4%)**	
d) Drug Approval	17(11.03%)		3(5.77%)		4(26.6%)		24(10.9%)	
5. ADR should be reported only when							*DM: 3(1.3%)	
a) Serious and life threatening	1(0.65%)		34(65.38%)		14(93.3%)		49((22.2%)	
b) Severe and cause disability	2(1.3%)		3(5.77%)		Nil		5(2.2%)	
c) Mild and cause less inconvenience	4(2.59%)		Nil		Nil		4(1.8%)	
d) All cases of ADR	**144(93.5%)**		15(28.84%)		1(6.6%)		**160(72.4%)**	

Note: *DM - Data missing

Table 3: Factors Discouraging for ADR Reporting

Questions	Strongly Disagree	Disagree	Agree	Strongly Agree	Data missing
1. Belief that only safe drugs are marketed	24(10.9%)	80(36.2%)	73(33%)	36(16.3%)	8(3.6%)
2. Lack of time to actively look for an ADR and fill in a report	58(26.2%)	86(38.9%)	11(4.9%)	58(26.2%)	8(3.6%)
3. Concern that reporting may generate extra work	34(15.4%)	110(49.77%)	30(13.57%)	37(16.7%)	10(4.5%)
4. Concern that report may be wrong	27(12.2%)	53(23.9%)	**92(41.6%)**	**40(18.1%)**	9(4.1%)
5. Think that you may cause harm to the patient	29(13.1%)	82(37.1%)	62(28.1%)	39(17.6%)	9(4.1%)
6. Fear of legal liability for reporting ADR	9(4.1%)	45(20.4%)	104(47.1%)	**50(22.6%)**	13(5.9%)
7. Ambition to publish Case reports personally	24(10.9%)	98(44.3%)	39(17.6%)	12(5.4%)	48(21.7%)
8. Other colleagues are not reporting	41(18.6%)	89(40.3%)	65(29.4%)	13(5.9%)	13(5.9%)

Table 4: Evaluation of practice

Questions	Doctors		Nurses		Pharmacists		Total	
	Yes	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**
Have you seen any patient experiencing ADR	**92 (59.8%)**	58 (37.6%	17 (32.7%)	35 (67.3%)	2 (13.3%)	13 (86.6%)	**111 (50.2%)**	106 (47.9%)
Data missing: 4 (1.8%)								
Have you ever reported any ADR to your pharmacovigilance centre/Concerned unit of your hospital	16 (10.3%	**128 (83.1%)**	2 (3.8%)	50 (96.2%)	Nil	4 (26.6%)	18 (8.1%)	**182 (82.4%)**
Data missing: 21(9.5%)								

Table 5: Respondents expectations from pharmacovigilance programme

Expectations	Percentage of the respondents
1. Local Coordination	79.2%
2. Make ADR reporting compulsory	64.3%
3. Education or interest awareness of reporting system	79.2%
4. Provide toll free number	68.3%
5. Financial support	79.6%

4. Discussion

This study evaluated the knowledge, attitude and practice of ADR reporting among healthcare professionals. Response rate was 85% which is acceptable and comparable to previous studies. Higher percentage of females may be due to number female nursing staff and postgraduates working at both the hospitals. While looking at the age and working experience of the respondents, mostly young healthcare professionals were participated in this study. In India Doctors, Nurses and Pharmacists can report ADR. However Nurses and Pharmacists are not encouraged enough to report.

Different studies reported that all the ADRs encountered by healthcare professionals during their work are never reported [11-14]. This study also showed the similar results. This is confirmed by the huge gap between the percentages of the people those who have seen the patients experiencing ADR and those who have reported. 50.2% of the respondents had seen patients experiencing ADR but only 8.1% of them have reported.

This study showed positive attitudes towards ADR reporting among healthcare professionals as lack of time to actively look for an ADR and fill in a report (30.9%), concern that reporting may generate extra work (30.27%), other colleagues are not reporting (35.3%) and ambition to publish Case reports personally (23%) were not major factors discouraging them to report ADR. This shows that proper awareness and encouragement can improve ADR reporting immensely.

Knowledge of ADR reporting among Nurses and Pharmacists was very low as compared to that of Doctors. This is may be because of less awareness and education among Nurses and Pharmacists. Respondents were also asked about their expectations from Pharmacovigilance programme. Financial support and education or interest awareness programmes were major expectations.

Awareness programmes among healthcare professionals, collaboration among healthcare professionals, training and making ADR reporting compulsory are the highly suggested ways to improve ADR reporting.

5. Study Limitations

This study had few limitations,

- Interns and private practitioners were not included in the study
- Respondents were not personally monitored which may have resulted in respondents taking the help of colleagues or relevant books/Publications.

6. Recommendation

This study was conducted only in one city, a study including multiple cities covering different zones of India is required to clearly establish Knowledge, Attitude and Practice of ADR reporting among healthcare professionals.

7. Conclusion

This study showed that healthcare professionals working at HKE Society's M.R. Medical College and S Nijalingappa Institute of Dental Sciences have positive attitudes towards ADR reporting. However knowledge regarding

ADR reporting among Doctors is superior to that of Nurses and Pharmacists, awareness programs can overcome this problem. But the practice of ADR reporting is poor among all Healthcare professionals. Making ADR reporting compulsory, collaboration among healthcare professionals and proper training are highly suggested ways to improve ADR reporting.

Sources of Support: Nil

Conflicts of Interest: The authors declare that they have no conflict of interest.

Acknowledgement

The Authors wish to extend their gratitude to Dr. Manjunath H (Postgraduate, Department of Pharmacology, J. J. M. Medical College, Davangere, India) for helping in the preparation of this manuscript and our sincere thanks to postgraduate students of M R Medical college (Dr. Ashraffunnissa Fatima, Dr. Sharanabasappa, Dr. Ketan Patil, Dr. Basavaraj Bidarimath) for their help in proof reading.

References

[1] Lazarou J, Pomeranz BH, Corey PN. Incidence of adverse drug reactions in hospitalized patients: A meta-analysis of prospective studies. *JAMA*. 1998; 279:1200-5.

[2] Kaneg S, Rea RS, Verrico MM and Weber RJ. Adverse-drug-event rates for high-cost and high-use drugs in the intensive care unit. *Am. J. Health Syst. Pharm*. 2006; 63: 1876-81.

[3] Wasser Fallen JB, Livio F, Buclin T, Tillet L and Yersin B. Rate, type, and cost of adverse drug reactions in emergency department admissions. *Eur. J. Intern. Med*. 2001; 12: 442-7.

[4] Upadhyaya BH, Vora MB, Nagar JG, Patel PB. Knowledge, attitude and practices towards pharmacovigilance and adverse drug reactions in postgraduate students of Tertiary Care Hospital, Gujarat. *J Adv Pharm Technol Res.* 2015 Jan-Mar; 6(1): 29-34.

[5] Morrison-Griffiths S and Pirmohamed M. Specialist nurse reporting of adverse drug reactions. *Prof. Nurse* 2000; 15: 300-4.

[6] Pribisko RN. Preventing preoperative adverse drug reactions. *AORN J.* 2003; 77: 104-6, 109-14, 116-7, quiz 118-20.

[7] Ulfvarson J, Mejyr S and Begman U. Nurses are increasingly involved in pharmacovigilance in Sweden. Pharmacoepidemiol. *Drug Saf.* 2007; 16: 532-7.

[8] Singh A, Bhatt P. comparative evaluation of adverse drug reaction reporting forms for introduction of a spontaneous generic ADR form. *Journal of Pharmacology & Pharmacotherapeutics* 2012; 3(3):228-232.

[9] Ahmad SR. Adverse drug event monitoring at the Food and Drug administration. *J Gen Intern Med.* 2003; 18:57-60.

[10] Wysowski DK, Swartz L. Adverse drug event surveillance and drug withdrawals in United States, 1969-2002: The importance of reporting suspected reactions. *Arch Intern Med.* 2005; 165:1363-9

[11] Oshikoya KA, Awobusuyi JO: Perceptions of doctors to adverse drug reaction reporting in a teaching hospital in Lagos, Nigeria. *BMC Clin Pharmacol* 2009; 9:14.

[12] Chatterjee S, Lyle N, Ghosh S: A survey of the knowledge, attitude and practice of adverse drug reaction reporting by clinicians in eastern India. *Drug Saf* 2006, 29:641–642.

[13] Ekman E, Backstrom M: Attitudes among hospital physicians to the reporting of adverse drug reactions in Sweden. *Eur J Clin Pharmacol* 2009; 65:43–46.

[14] Li Q, Zhang SM, Chen HT, Fang SP, Yu X, Liu D, et al: Awareness and attitudes of healthcare professionals in Wuhan, China to the reporting of adverse drug reactions. *Chin Med J (Engl)* 2004; 117:856–861.