

**Evaluation of Knowledge, Attitude and Practice of Health Care Providers towards Adverse Drug Reaction Reporting in a Tertiary Care Hospital**Ashraf Ali H<sup>1</sup>, T Siyamala Devi<sup>2</sup>, T Meenakshi<sup>3</sup><sup>1</sup>MBBS, Third Professional Year Part 2 Student, Chengalpattu Medical College, Tamil Nadu<sup>2</sup>Associate Professor, Department of Pharmacology, Government Chengalpattu Medical College, Tamil Nadu<sup>3</sup>Associate Professor, Department of Pharmacology, Government Medical College, Omanduram, Government Estate, Chennai-02, Tamil Nadu

Received: 28-05-2023 / Revised: 29-06-2023 / Accepted: 25-07-2023

Corresponding author: Dr T Siyamala Devi

Conflict of interest: Nil

**Abstract:****Background & Rationale:** Pharmacovigilance plays an essential role in the prevention of ADRs. Under-reporting of adverse drug reactions (ADRs) by Health care providers is a common problem. The study was undertaken to evaluate the knowledge, attitude, and practices (KAP) regarding ADR reporting among different healthcare providers.**Objectives:**

- To assess the knowledge, attitude and practice of health care providers in pharmacovigilance and adverse drug reactions reporting.
- To identify the reasons for underreporting of ADR.

**Materials & Methods:** A Cross sectional study was conducted in a tertiary care centre by circulating a standardized e questionnaire among healthcare professionals.**Results:** Among the total 444 Health Care providers, 90% of the health Care providers were aware of the existence of ADR reporting system in India. 94% have no idea about Causality assessment and 90% don't know about WHO online database for ADR reporting. 78% agreed that ADR reporting is necessary and 46% agreed that reporting ADR is a professional obligation. 92% have seen an ADR reporting form and 61% were trained in ADR reporting. 23% of responses attributed to Lack of time to report ADR as the most important reason for underreporting. 18% think that single report may not affect ADR database. Fear of legal liability (11%) and unavailability of easy access to ADR forms (11%) were also quoted as reasons for under-reporting. 34% think that making ADR reporting mandatory is the way to improve ADR reporting.**Conclusion:** This study concluded that the health care providers have broader knowledge towards ADR reporting. The attitude towards ADR reporting showed positive trend towards ADR reporting. Further training and motivating them will improve ADR reporting.**Keywords:** Pharmacovigilance, ADR reporting, Knowledge, Attitude, Practices.

This is an Open Access article that uses a funding model which does not charge readers or their institutions for access and distributed under the terms of the Creative Commons Attribution License (<http://creativecommons.org/licenses/by/4.0>) and the Budapest Open Access Initiative (<http://www.budapestopenaccessinitiative.org/read>), which permit unrestricted use, distribution, and reproduction in any medium, provided original work is properly credited.

**Introduction**

Adverse drug reaction (ADR)[3] is defined as one which is noxious and unintended, and which occurs in doses normally used in humans for prophylaxis, diagnosis or therapy of disease, or for the modification of physiological functions[17]. ADRs are an important public health problem in terms of mortality, morbidity, socio-economic consequences and also its management [7,19,20]. Pharmacovigilance [6] is the important entity that plays an essential role in the reduction of ADRs and prevention of unwanted effects of drugs in consumers and communities[18,21].

Studying various adverse drug reactions is an important step of patient care. It's main goal is to

ensure the safe use of medicines for the treatment or prevention of disease [6]. Since under-reporting is the common problem to improve the data including greater involvement of doctors, nurses, pharmacists [15,16] as well as consumers in the reporting of ADRs [3], making the process simpler and faster through electronic means, introducing educational interventions [24] and training programs for health care providers and spreading awareness about the reporting system amongst caregivers and receivers can be done.[1,2,7,25]

A healthy reporting process is a challenge but with proper planning, applicable solutions and well-focussed efforts can help bring about the change

ensuring patient safety. Spontaneous reporting is a heart piece tool in pharmacovigilance[3]. Thus the sole success of the program depends on cooperative and motivated providers. Even though there is an established system in India, Pharmacovigilance Program Of India the robust reporting of ADRs is yet to be achieved. The present study is undertaken to evaluate the knowledge, attitude, and practices (KAP) regarding ADR reporting among different healthcare providers, consultants, postgraduates, interns, nurses in a tertiary care centre to get an insight into the current scenario and find out the causes of under-reporting of ADRs.

### Objectives

**Primary Objective:** To assess the knowledge, attitude and practice of health care providers in pharmacovigilance and adverse drug reactions reporting in a tertiary care centre.

**Secondary Objective:** To identify the reasons for under-reporting of ADR.

### Materials and Methods:

**Study design:** Cross sectional study(22).

**Study centre:** Government Chengalpattu Medical College & Hospital, Tamil Nadu.

**Assessment Method:** e-questionnaire - Google form.

**Study Population:** Faculties, postgraduates, CRRIs, Nurses.

**Study Period:** December 2022.

The Questionnaire regarding Knowledge Attitude Practice towards ADR reporting was developed by a multi-step(4) process by the pharmacologist involved in ADR monitoring centre after reviewing

the reporting system. It contains totally 30 questions.

The questions are mainly dichotomous, and some of the questions have multiple options. Content validation of the item was done by the experts in the field of pharmacovigilance.

The Questionnaire was pretested among 10 randomly selected healthcare professionals. The feedback regarding the clarity, wordings and difficulty in filling the questionnaire were collected. The corresponding amendments were made to keep the questions simple and specific. The total time taken to complete the questionnaire was measured which is around 20 minutes.

The final questionnaire was developed based on the analysis results and experts consensus with 4 main sections: General information, knowledge, attitudes and practices related to ADR reporting and its significance [4,5,23].

The study was conducted after obtaining Institutional ethics committee approval. Digital questionnaires (Google forms) is circulated in official WhatsApp groups and mail ids of healthcare providers, consultants, postgraduates, interns, nurses.

Personal identifiable information was not collected to protect privacy and to promote the participants to give genuine opinions.

The participants were instructed to complete the questionnaire without accessing any external knowledge sources. Answering the questionnaire itself is considered as they consented for the study.

### Results

**Table 1: Demographic profile**

Health Care Providers	Numbers	Percentage
post graduates	160	36.03 %
Interns	98	22.07 %
Assistant Professors	101	22.75 %
Associate Professors/professors	25	5.63 %
Nurses	60	13.51 %
Total	444	100 %

**Table 2a: Knowledge questions**

Q. No.	Knowledge Questions	yes	yes %	no	no %
1	Do you know what is pharmacovigilance	355	79.95	89	20.05
2	Do you know there is a difference between adverse drug reaction and adverse event?	133	29.95	311	70.05
3	Do you know what serious and non-serious ADRs are?	266	59.91	178	40.09
4	Do you know adverse reactions due to blood products, vaccines, Medical devices, cosmetics also be reported?	186	41.89	258	58.1q
5	Do you know the different forms available for each?	135	30.41	309	69.59
6	Do you know how to fill an ADR reporting form?	315	70.95	129	29.05
7	Are you aware of Presence of the ADR monitoring Centre in your institute ?	266	59.91	178	40.09

8	Do you know how Causality Assessment of ADR is done?	25	5.63	419	94.37
9	Do you know the ADR reporting system existing in India?	400	90.09	44	9.91
10	Do you know there is a WHO online database for reporting an ADR by the member countries?	43	9.68	401	90.32

**Table 2b: Knowledge questions**

Q.No	Questions	Options (Number Of Responses And Percentage)									
		Doctors	%	Nurses	%	Patients	%	General Population	%	All	%
11	Who Can Report An Adr?	266	59.91	22	4.95	4	0.9	4	0.90	148	33.33
12	What Type Of Adr Is Necessary To Report?	Untreatable Adrs	%	Serious Adrs	%	New Adrs	%	Known Adrs	%	All Adrs	%
		22	4.95	198	44.59	84	18.92	5	1.13	135	30.41

**Table 3: Attitude Questions**

Q. No	Questions	strongly Agree	%	Agree	%	Neutral	%	Disagree	%	strongly Disagree	%
		13	Adverse drug reaction reporting is necessary in every institute	98	22.07	256	57.66	57	12.84	23	5.18
14	Reporting adverse drug reaction is a professional obligation	18	4.05	187	42.12	207	46.62	18	4.05	14	3.15
15	Reporting adverse drug should be made compulsory	34	7.66	198	44.59	90	20.27	76	17.12	46	10.36
16	It is necessary to confirm that an ADR is related to a particular drug before reporting it.	57	12.84	123	27.70	34	7.66	157	35.36	73	16.44
17	It is necessary to report only serious and unexpected reactions	98	22.07	176	39.64	56	12.61	58	13.06	56	12.61
18	Pharmacovigilance should be taught to all health care students during their curriculum.	177	39.86	198	44.59	54	12.16	13	2.93	2	0.45
19	Your workplace encourages you to report an ADR	84	18.92	223	50.23	84	18.92	36	8.11	17	3.83
20	ADR database helps to select a safe drug and improves patient safety ?	111	25	189	42.57	89	20.04	34	7.66	21	4.73

**Table 4a: Practice Questions**

S.No.	Questions	Yes	%	No	%
21	Are you including ADR in your differential diagnosis?	150	39.06	234	60.94
22	Are you documenting ADR on patients medical records ?	204	53.13	180	46.88
23	Have you ever seen ADR reporting form?	411	92.57	33	7.43
24	Have you been trained in how to report ADR?	270	61.71	174	39.29
25	Have you ever reported ADR to pharmacovigilance centre?	198	44.59	246	55.41
26	Have you ever presented an ADR during case presentation	186	48.44	198	51.56

**Table 4b: Practice Questions**

Q.No	Questions	Responses (Numbers & percentage)							
		0	%	1	%	1 TO 3	%	> 3	%
27	Number of ADR cases reported during professional career	198	44.59	221	49.77	22	4.95	3	0.67
28	What is the preferred mode to report ADR ?	Phone apps	%	Drop box	%	e mail	%	collect personally	%
		124	27.93	55	12.39	51	11.49	214	48.19

**Table 4c: Practice Questions**

Q No 29	Options	No. of responses	Percentage
Most important three factors which discourage you from reporting ADR ?	I don't know that I need to report	22	2.56
	Non remuneration for reporting	40	4.66
	Lack of time to report ADR & It increases workload	205	23.86
	A single reported case may not affect ADR database	157	18.28
	Difficult to decide whether ADR has occurred or not	50	5.82
	Fear of legal liability	100	11.64
	ADR reporting form is not easily available	100	11.64
	Don't know whom to report	25	2.91
	Have not been trained adequately to fill ADR form	75	8.73
	Management of patients was more important than reporting	50	5.82
	Fear of breach of confidentiality with patient's data	35	4.07

**Table 4d: Practice Questions**

Q.No 30	Options	No. of responses	Percentage
Select 3 most important Suggestions you think that can improve the ADR reporting	Make it easier to submit reports and easy availability of forms	32	4.43
	Provide financial compensation to submit reports	10	1.39
	Education/increase awareness of reporting system among health care providers	125	17.31
	Make reporting mandatory	250	34.63
	Provide toll free number	120	16.62
	Make public more aware of reporting	150	20.78
	Ensure confidentiality of reports	35	4.85

Table 1 shows the distribution of healthcare providers among the total 444 Health Care providers who participated in the study, Postgraduates were of majority (36%).

Table 2a & 2b shows the results of knowledge based questions. Most of the health Care providers are aware of the existence of ADR reporting system in India (90%). Many participants know what is Pharmacovigilance (80%) and know about the existence of ADR reporting system in India (90%). Many (69%) don't know about various forms available to report the various types of ADR due to blood products, vaccines, Medical devices. Lots of participants have no idea about Causality

assessment (90%) and WHO online database for ADR reporting (90%). 59% of participants have the opinion that only Doctors can report ADRs and 45% of Health care providers think that only Serious ADRs have to be reported.

Attitude based questions are presented in Table 3. Most of the participants agree that ADR reporting is necessary in every Institute (79%) and reporting ADR is a professional obligation (46%). 52% of the participants opined that ADR reporting should be made compulsory. About 50% of the healthcare professionals agree that their Workplace encourages them in ADR reporting. 40% of the participants think that they should confirm that the

ADR is due to particular drug. 60% of healthcare professionals think only serious ADR should be reported. 44% of the participants think that pharmacovigilance should be taught in curriculum, 42% of the participants think that ADR reporting will improve patient safety.

Table 4a, 4b & 4C shows almost 92% of the participants have seen an ADR reporting form and 76% were trained in ADR reporting. 39% doctors said that they include ADR in differential diagnosis only 53% of the doctors document the ADR in patient records. 48% of professionals said that they have presented an ADR during Case presentation. Still, only 45% have ever reported an ADR to Pharmacovigilance Centre. 55% of the participants feel that they prefer mobile apps for reporting and 27% of the participants prefer the ADR forms to be collected from them. 11% voted for email mode.

Question numbers 29 and 30 asked to find out the causes for not reporting ADR. Top 3 reasons of not reporting ADR was asked. 23% said that the lack of time to report ADR was the most important reason for underreporting as they felt it increased their workload. 18% of the participant think single case report may not affect the ADR database Other than that, fear of legal liability (11%) and unavailability of easy access to ADR forms (11%) were also quoted as reasons for under-reporting. Not being trained in filling up the forms was said to be a reason in 9% of responses.

### Discussion

We could see from the results that many health care providers are aware about Pharmacovigilance, Almost 90% of the participants were aware of the existence of ADR reporting system in this study. This is higher than the results from the study conducted by Ahmad, et al 10 where it was only 57.5%. This probably because of the pharmacovigilance week celebrated every year and documents related to pharmacovigilance and drug alerts by pharmacovigilance program of India are circulated widely and healthcare providers have been constantly educated about the ADR reporting. There is a knowledge gap in Causality assessment and the types of ADRs to be reported. WHO online database was not known to many. This indicates the need to conduct orientation programs on a regular basis to fill the knowledge gap. As many have an idea that only doctors are stakeholders in ADR reporting, the training programs should include all the health care providers including Staff nurses and Pharmacists. This knowledge gap is probably due to shifting population in spite of the measures to educate the health care providers or could be due to inadequacy of training sessions.

Most of the healthcare providers have a positive attitude towards ADR reporting. They think that reporting ADR is their professional obligation. This

finding correlates with the results of the study conducted by Adisa and Omitogun[9] which showed that Seventy-nine (98.8%) of the health workers expressed willingness to report all the ADRs encountered, 74 (92.5%) believed that ADR reporting is part of their professional responsibilities as a healthcare professional. They also feel that Pharmacovigilance should be a part of the curriculum. The positive attitude towards ADR reporting can be utilised to improve the ADR reporting by conducting orientation and training programs and constantly motivating the health care providers on Pharmacovigilance on regular basis.

In Spite of knowing the importance of ADR reporting, the reluctance seems to be due to lack of time, increases the workload, fear of legal liability. ADR forms are not readily available. The study conducted by Srinivasan et al.[8] also showed that lack of time was the reason for under reporting in 35.2% of participants. Some have preferred Apps for reporting. So Training programs need to include demonstration of downloading App and reporting through it. Availability of ADR forms can be increased by circulating ADR forms through WhatsApp groups and mail ids and the distribution of hard copy of forms to drug dispensaries and to various departments. Boxes can be installed to collect the ADR forms at specified places to increase the ease of reporting.

### Limitations

Since this study is conducted in one tertiary centre, it can't be generalized. This study reflects the knowledge, attitude and practice of healthcare providers of a particular location. Similar studies to be conducted in many healthcare centres and Measures to be taken to address the lacunae identified from individual studies and the pooled data can be compared to make policy decision.

### Conclusion

This study concludes that health care professionals have a broader knowledge towards ADR reporting. The study also showed positive attitude of healthcare providers towards ADR reporting which may reflect positive trend in improving ADR reporting and safeguarding the wellbeing of the patients [11,14]. Reporting practices can be improved by conducting periodic sensitization and training programs for the healthcare professionals. [8,12,13]and make the ADR reporting easy.

### References

1. AMA Sharma R, Kellarai A. Pharmacovigilance and adverse drug reaction reporting perspectives among interns and postgraduates of a teaching hospital. J Pharmacol Pharmacother. 2014;5(4):248-250.
2. Kopeciuch D, Zaprutko T, Paczkowska A, Ratajczak P, Zielińska-Tomeczak Ł, Kus K,

- Nowakowska E. Safety of medicines-Pharmacists' knowledge, practice, and attitudes toward pharmacovigilance and adverse drug reactions reporting process. *Pharmacoepidemiol Drug Saf.* 2019 Dec; 28(12): 1543-1551.
3. Desai CK, Iyer G, Panchal J, Shah S, Dikshit RK. An evaluation of knowledge, attitude, and practice of adverse drug reaction reporting among prescribers at a tertiary care hospital. *Perspect Clin Res.* 2011 Oct;2(4):129-36.
  4. K, Lohit & R, Vidya & Narasimhaiah, Manjunath. Development and Validation of Questionnaire to Assess The Knowledge, Attitude and Practice towards Adverse Drug Reactions Reporting among Healthcare Professionals. *Journal of International Medicine and Dentistry.* 2016;3: 63-72.
  5. Kharkar M, Bowalekar S. Knowledge, attitude and perception/practices (KAP) of medical practitioners in India towards adverse drug reaction (ADR) reporting. *Perspect Clin Res.* 2012 Jul;3(3):90-4.
  6. Rashmi Sharma. Evaluation of knowledge, attitude and practice of adverse drug reaction reporting among registrars and consultants in a tertiary care hospital. *Med Pulse International Journal of Pharmacology.* June 2018; 6(3): 15-19.
  7. Singh H, Dulhani N, Kumar B, Singh P, Tewari P, Nayak K. A pharmacovigilance study in medicine department of tertiary care hospital in Chhattisgarh (Jagdalpur), India. *J Young Pharm.* 2010;2(1):95-100.
  8. Srinivasan et al., *Biomed. & Pharmacol. J.*, 2017; 10(3): 1441-1447.
  9. Rasaq Adisa & Tomilayo I. Omitogun. Awareness, knowledge, attitude and practice of adverse drug reaction reporting among health workers and patients in selected primary healthcare centres in Ibadan, southwestern Nigeria, *BMC Health Services Research.* 2019; 19:926
  10. Ahmad, et al.: KAP analysis of ADR reporting in India Perspectives in Clinical Research. October-December 2013; 4(4).
  11. Gaude and De Sa KAP regarding pharmacovigilance among final year medical students. *National Journal of Physiology, Pharmacy and Pharmacology.* 2018;8(12).
  12. Kalaiselvan V, Prasad T, Bisht A, Singh S, Singh GN. Adverse drug reactions reporting culture in Pharmacovigilance Programme of India. *Indian J Med Res.*2014; 140:563-4.
  13. Tandon VR, Mahajan V, Khajuria V, Gillani Z. Under-reporting of adverse drug reactions: A challenge for pharmacovigilance in India. *Indian journal of pharmacology;* 2015; 47(1): 65.
  14. Alsbou M, Abdeen G, Batarseh A, Bawaresh N, Jaber J, Qawasmi G. Analysis of the National Pharmacovigilance Database in Jordan (2010-2014). *Biomedical and Pharmacology Journal.*; 2017;10(1):319-28.
  15. Generali JA, Danish MA, Rosenbaum SE. Knowledge of and attitudes about adverse drug reaction reporting among Rhode Island pharmacists. *Ann Pharmacother.* 1995; 29: 365-369.
  16. Valente S, Murray L, Fisher D. Nurses improve medication safety with medication allergy and adverse drug reports. *J Nurs Care Qual.* 2007; 22: 322-327.
  17. Who.int. 2018. Available from: [http://www.who.int/medicines/areas/quality\\_safety/safety\\_efficacy/trainingcourses/definitions.pdf](http://www.who.int/medicines/areas/quality_safety/safety_efficacy/trainingcourses/definitions.pdf). [Last cited on 2018 Mar 25].
  18. Oshikoya K, Awobusuyi J. Perceptions of doctors to adverse drug reaction reporting in a teaching hospital in Lagos, Nigeria. *BMC Clin Pharm* 2009;9:14.
  19. Pirmohamed M, James S, Meakin S, et al. Adverse drug reactions as cause of admission to hospital: prospective analysis of 18,820 patients. *BMJ.* 2004;329(7456):15-19.
  20. Bouvy JC, De Bruin ML, Koopmanschap MA. Epidemiology of adverse drug reactions in Europe: a review of recent observational studies. *Drug Safety.* 2015;38(5):437-453.
  21. Chatterjee, S., Lyle, N., and 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.
  22. Elfil M, Negida A. Sampling methods in clinical research: an educational review. *Emerg (Tehran).* 2017;5:e52.
  23. Paudyal V. Behavioral aspects of pharmacovigilance: research methods considerations. Social and administrative aspects of pharmacy in low-and middle-income countries. Elsevier; 2018; 163-75.
  24. Shrestha S, Sharma S, Bhasima R, Kunwor P, Adhikari B, Sapkota B. Impact of an educational intervention on pharmacovigilance knowledge and attitudes among health professionals in a Nepal cancer hospital. *BMC Med Educ.* 2020;20:1-10.
  25. Ashraf Tadv N, Alromaih AA, Aldahash AA, Almuhseny AA, Alotaibi SH, Alduhayshi IS, Alrukimi AS, Sami W. Knowledge, attitude and practice of pharmacovigilance in healthcare professionals and medical students in Majmaah, Saudi Arabia Care Centre. *Int J Med Res Heal Sci,* 2018; 7:101-7.