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KNOWLEDGE, ATTITUDE, AND PRACTICE TOWARDS ADVERSE DRUG REACTION REPORTING AMONG HEALTH CARE WORKERS: A HOSPITAL BASED CROSS-SECTIONAL STUDY

Kiran Kumar Chemudugunta*[1], Dr. Habib Habibuddin M[2]

[1]Research Scholar, Rayalaseema University, Kurnool, Andhra Pradesh, India

[2]Chairman, Managing Director, TAU Pharma Bio PVT. LTD, Hyderabad, Telangana, India)

*Corresponding author E-mail:kiranpharmaco@gmail.com

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ABSTRACT

Background: The success of Adverse Drug Reaction (ADR) reporting system is depends upon a collaborative work of all healthcare profession in Indian hospital settings. The study aims to assess the knowledge, attitude, and practices towards ADR reporting among healthcare professionals. **Materials and Method:** This is a prospective, cross-sectional study conducted in a tertiary care hospital, located in Hyderabad, Telangana, India. Healthcare workers knowledge, attitude, and practices (KAP) towards reporting of ADRs was assessed by using a suitably designed pre-validated questionnaire. Descriptive statistics like frequency, mean, proportion, and standard deviation were used to represent socio-demographic characteristics of the respondents. Chi-square test was used to associate demographic with KAP levels.**Results and Discussion:** total of 140 healthcare providers were recruited in the study. Most of the respondents were belongs to 31 to 40 years of age (62; 44.3%), female gender (80; 57.1%), graduates (79; 86.4%), married (110; 78.6%), Doctors (42; 30.0%) and average health care experience (7.5±5.3). Adequacy levels of knowledge, attitude, and practice findings were represented as, majority of the healthcare providers having poor knowledge (77; 55.0%) and no practice (102; 72.8%) of ADR reporting. More than half of the respondents shown positive attitude (96; 68.0%) to ADR reporting system. **Conclusion:** The study concludes that, majority of the healthcare professionals are having positive attitude to report ADR to the concerned regulatory authority. The existence of the paucity in knowledge and practice levels is the major concern for underreporting. Targeting educational program to physicians, pharmacists, and nurses on pharmacovigilance will drive up the ADR reporting system.

INTRODUCTION

Adverse Drug Reaction (ADR) is a global burden, and significantly affects the morbidity, mortality, healthcare costs, and quality of life of the patients. (1) According to World Health Organization (WHO) Adverse Drug Reaction means (ADR) “any noxious or unintended effect produced by the drug when it will be used in doses for prophylactic, Therapeutic, diagnostic and prevention of disease or alteration of physiological function”. (2) The study conducted in India reveals that, 6% of the hospital admissions are majorly due to the ADR, and 6 to 15% of the ADRs appears after patient admitted in the hospital. (3) The success of the ADR reporting system is

depends upon the collaborative work of all healthcare professionals and patient. ADR reporting is an important role of all healthcare providers (Physicians, Pharmacists, Nurses and other Paramedical staff). (4)In India, Pharmacovigilance Program of India (PvPI) was started in July 2010, in collaboration with Central Drug Standard Control Organization (CDSCO) and Ministry of Health and Family Welfare (MoHFW), Government of India. Nearly one decade for PvPI, still most of the healthcare providers are unaware about ADR reporting and its importance. This is the preliminary study that aims to explore the gaps among healthcare providers to understand the concept of ADR reporting system by the assessment of Knowledge, Attitude, and Practices towards ADR.

MATERIALS AND METHODS

This is a cross-sectional questionnaire based study conducted among healthcare workers in a tertiary care hospital located in Hyderabad, Telangana, India. The study was conducted over a period of one year from March 2018 to February 2019. Due permission was sought from the hospital authority before commencing study. The study was approved by ethical review board after review of complete protocol.

Study criteria: All healthcare workers (Doctors, Nurses, Pharmacists, Laboratory personnel, and Social workers) who are willing to participate and present on the period of the study were recruited in this study. Participants who are not ready to give oral or written consent form were excluded from the study.

Sample size: The required sample size was estimated as 138. The number was determined by using single population proportion formula, considering 10% of responds have adequate knowledge, 95% confidence interval, 5% margin of error, and 80% of power. The final sample size was 152 by 10% of non-response or dropout rate. (6)

Data collection: Healthcare workers knowledge, attitude, and practices (KAP) towards reporting of ADRs was assessed by using a suitably designed pre-validated questionnaire. The questionnaire was designed based on previously conducted KAP studies in the area of pharmacovigilance (PV). After designing of the questionnaire, it was subjected for face validity and reliability test. The scale level content validity index was; knowledge (0.8), attitude (0.85), practice (0.9) and cronbachs alpha value of the reliability test was 0.94. So the final prepared questionnaire will gives reliable results in Indian settings.

KAP Questionnaire: Knowledge domain comprise 7 questions regarding definition of pharmacovigilance (PV), importance of PV, existence of PV program in India, ADR reporting is a professional obligation, healthcare workers are responsible to report ADR, regulatory body responsible to monitor ADR reporting, and global center for ADR monitoring was located. Blooms cut-off criteria were used to grade adequacy of knowledge levels. If respondents answers 80-100% of questions, will be considered as good knowledge, 60-79% moderate knowledge, and <60% poor knowledge. (7)Attitude of respondents was assessed by 4 questions regarding necessity of ADR reporting, PV should taught to all healthcare providers, spending time to read ADR related article, and opinion about establishment of ADR monitoring center in every hospital. If respondents answers more than two questions would considered as positive attitude and answers only two or less questions considered as negative attitude. (8)Practice towards ADR reporting was assessed by 4 questions regarding experienced ADR among patients who were treated, previously reported ADR, seen ADR reporting form, and trained in ADR reporting. (9) If respondents answers more than two questions would considered as good practice and answers only two or less questions considered as no practice.

Statistical analysis: Descriptive statistics like frequency, mean, proportion, and standard deviation were used to represent socio-demographic characteristics of the respondents. Chi-square test was used to associate demographic with KAP levels. P value less than 0.05 will be considered as statistically significant result. Epi-info 7 statistical software which was given by center for disease control was used to analyze the data.

RESULTS

The current study revealed that most of the respondents were belongs to 31 to 40 years of age (62; 44.3%), female gender (80; 57.1%), graduates (79; 86.4%), married (110; 78.6%), Doctors (42; 30.0%) and average health care experience (7.5±5.3). Majority (110; 78.6%) of the healthcare providers were not trained or experienced in pharmacovigilance sector. The complete results were depicted in Table 1. The findings of this study explored that, less than half of the respondent's only answered about importance of PV (64; 45.7%), existence of PvPI (60; 42.8%), ADR reporting is a professional obligation (32; 22.8%), responsibility of reporting (25; 17.8%), regulatory body name (38; 27.1%), and global ADR monitoring center location (10; 7.1%). 55.7% of the healthcare workers know the definition of PV. The findings of the knowledge domain were represented in Table 2. The respondents given high percentages in attitude domain compared to practice domain. Healthcare provider's attitude and practice of ADR reporting system was shown in Table 3. The study results reveal that, majority of the healthcare providers having poor knowledge (77; 55.0%) and no practice (102; 72.8%) of ADR reporting. More than half of the respondents shown positive attitude (96; 68.0%) to ADR reporting system. Adequacy levels of knowledge, attitude, and practice findings were shown in Table 4.

DISCUSSION

The Pharmacovigilance is the system of medical science where all the healthcare professionals must involve actively to report ADR to concerned regulatory authority. This information is helpful to establish the safety profile of the drug after marketing. Most of the developed countries like USA, Canada, Australia, and United Kingdom are developed consumer ADR reporting system. Still, India is facing to sensitize healthcare professional regarding ADRs reporting system. Even there are more studies in the area of KAP assessment among healthcare professionals; the KAP levels are showing wide variation among one study to other study.This study explores the deficiencies, gaps in the healthcare workers to report ADRs. Healthcare professionals revealed most common reasons for under reporting of ADRs are lack of time, no remuneration, reporting affects the practice, not trained, and no experience. The similar type of reasons is also expressed in the study conducted Gupta *et al* in South India. (4) The positive attitude of the respondents was high compared to the other studies conducted in India.The healthcare professional's knowledge and practice are slightly improved compared to previous studies, but still it is low. The ADR reporting among respondents is low, which is similar to the studies conducted in India from Nagpur,(10) Bangalore,(11) Jalandhar,(12) Ahmedabad,(13) and Indore.(14)The major factors influencing the poor knowledge, attitude, and practice are no training in PV and non-physicians. Providing appropriate training to the doctors, pharmacists, nurses, and other paramedical staff specific to their role in healthcare will bring the change.

Table 1: Socio-demographic characteristics of the healthcare workers (n=140)

Variable	Frequency (%)
Age in years (Mean ± SD)	35.7 ± 8.1
≤30	50 (35.7)
31-40	62 (44.3)
41-50	26 (18.6
>50	2 (1.4)
Gender	
Male	60 (42.8)
Female	80 (57.1)
Professional Category	
10th Grade and less	36 (25.7)
Pre University and Graduates	79 (86.4)
More than graduate	25 (17.8)
Marital status	
Yes	110 (78.6)
No	30 (21.4)
Health care experience (Mean ± SD)	7.5 ± 5.35
No experience	10 (7.1)
1 – 5	38 (27.1)
6 – 10	40 (28.6)
11 – 15	34 (24.3)
15 – 20	12 (8.6)
>20	06 (4.3)
Worked in Clinic/Hospital/Department specialized PV	
Yes	30 (21.4)
No	110 (78.6)
Professional category	
Doctor	42 (30.0)
Nurse	40 (28.6)
Paramedical staff	18 (12.8)
Support staff	08 (5.7)
Admin staff	08 (5.7)
Social workers and counsellors	10 (7.1)
Others	14 (10.0)

Table 2: Knowledge towards ADR reporting system among healthcare workers (n=140)

ADR=Adverse Drug Reaction

Knowledge variable	Correct answer	Wrong answer
Definition of pharmacovigilance	78 (55.7)	62 (44.3)
Importance of pharmacovigilance	64 (45.7)	76 (54.3)
Existence of pharmacovigilance program in India	60 (42.8)	80 (57.1)
ADR reporting is a professional obligation	32 (22.8)	108 (77.1)
All healthcare workers are responsible to report ADR	25 (17.8)	115 (82.1)
Regulatory body responsible to monitor ADR reporting	38 (27.1)	102 (72.8)
Global center for ADR monitoring was located	10 (7.1)	130 (92.8)

Table 3: Attitude and Practice towards ADR reporting system among healthcare workers (n=140)

Attitude variable	Correct answer	Wrong answer
Necessity of ADR reporting	62 (44.3)	78 (55.7)
PV should taught to all healthcare providers	72 (51.4)	68 (48.6)
Spending time to read ADR related article	38 (27.1)	102 (72.8)
Opinion about establishment of ADR monitoring center	90 (64.3)	50 (35.7)
Practice variable	Correct answer	Wrong answer
Experience ADR among patients who were treated	56 (40.0)	84 (60.0)
Previously reported any ADR	31 (22.1)	109 (77.8)
Seen ADR reporting form	28 (20.0)	112 (80.0)
Trained in ADR reporting	30 (21.4)	110 (78.6)

ADR=Adverse Drug Reaction

Table 4: Adequacy of Knowledge, Attitude, and Practice towards ADR reporting (n=140)ADR=Adverse Drug Reaction

Variable	Frequency (%)
Knowledge	
Good knowledge	28 (20.0)
Moderate knowledge	35 (25.0)
Poor knowledge	77 (55.0)
Attitude	
Positive attitude	96 (68.6)
Negative attitude	44 (31.4)
Practice	
Good practice	38 (27.1)
No practice	102 (72.8)

Strengths and weakness:

The study will give insights for planning of educational program for healthcare professionals in pharmacovigilance sector. The results in this study may not suitable to other system based hospital because this is NGO hospital were healthcare policy is different with other hospital. The sample size is less compared to the other studies.

CONCLUSION

The study concludes that, majority of the healthcare professionals are having positive attitude to report ADR to the concerned regulatory authority. The existence of the paucity in knowledge and practice levels is the major concern for underreporting. Targeting educational program to physicians, pharmacists, and nurses on pharmacovigilance will drive up the ADR reporting system.

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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 Mar;6(1):29–34.
2. Meher B, Joshua N, Asha B, Mukherji D. A questionnaire based study to assess knowledge, attitude and practice of pharmacovigilance among undergraduate medical students in a Tertiary Care Teaching Hospital of South India. Perspectives in Clinical Research. 2015;6(4):217
3. Agarwal M, Ahmed J, Roy V. Knowledge, Attitude, and Practice

About Pharmacovigilance Among Healthcare Providers of a Tertiary Care Teaching Hospital in New Delhi (India). MAMC Journal of Medical Sciences. 2017;3(3):146

4. 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 Mar;6(1):45–52.

5. V S, D S, D M. Knowledge, Attitude and Practice of Pharmacovigilance among the Healthcare Professionals in a Tertiary Care Hospital – A Questionnaire Study. Biomedical and Pharmacology Journal. 2017 Sep 28;10(3):1441–7

6. Narayana G, Suchitra MJ, Sunanda G, Ramaiah JD, Kumar BP, Veerabhadrappa KV. Knowledge, attitude, and practice toward cervical cancer among women attending Obstetrics and Gynecology Department: A cross-sectional, hospital-based survey in South India. Indian J Cancer. 2017 Jun;54(2):481–7

7. Susheela F, Goruntla N, Bhupalam PK, Veerabhadrappa KV, Sahithi B, Ishrar SMG. Assessment of knowledge, attitude, and practice toward responsible self-medication among students of pharmacy colleges located in Anantapur district, Andhra Pradesh, India. J Educ Health Promot. 2018;7:96.

8. Goel D. Impact of educational intervention on knowledge, attitude, and practice of pharmacovigilance among nurses. Archives of Medicine and Health Sciences. 2018;6(1):32.

9. Ganesan S, Sandhiya S, Reddy K, 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. Journal of Natural Science, Biology and Medicine. 2017;8(2):203.

10. Pimpalkhute S, Jaiswal K, Bajait C, Gaikwad A, Sontakke S. Evaluation of awareness about pharmacovigilance and adverse drug reaction monitoring in resident doctors of a tertiary care teaching hospital. Indian Journal of Medical Sciences. 2012;66(3):55.

11. Kumar CU, Rao GH, Vasavi G. A questionnaire based study on the knowledge, attitude and the practices of pharmacovigilance among the postgraduate students at a tertiary care hospital in south India. International Journal of Basic & Clinical Pharmacology. 2019 Feb 23;8(3):457

12. Bajaj JK, 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. JOURNAL OF CLINICAL AND DIAGNOSTIC RESEARCH [Internet]. 2013 [cited 2019 Aug 13]

13. 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.

14. Khan S, Goyal C, Chandel N, Rafi M. Knowledge, attitudes, and practice of doctors to adverse drug reaction reporting in a teaching hospital in India: An observational study. Journal of Natural Science, Biology and Medicine. 2013;4(1):191