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A STUDY ON ASSESSMENT OF KNOWLEDGE, ATTITUDE AND PRACTICE REGARDING PHARMACOVIGILANCE AMONG HEALTHCARE PROFESSIONALS IN A TERTIARY CARE HOSPITAL, ANDHRA PRADESH

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ABSTRACT: Objectives: The aim of this study was to assess knowledge, attitude and practice of the healthcare professionals about Pharmacovigilance in a tertiary care hospital, Rajahmundry, Andhra Pradesh. **Materials and Methods:** A cross-sectional questionnaire based study was carried out on healthcare professionals (Faculties, Postgraduates, Interns & Nurses) to assess the knowledge, attitude and practice regarding Pharmacovigilance. Those who gave their consent to participate were included in the study. The obtained data was analyzed using the Statistical Package for Social Sciences (SPSS) statistical software, version 21. Qualitative variables were expressed as percentages and Chi-square test was used to compare the difference in correct responses for each question. For all statistical analysis $p < 0.05$ was considered statistically significant. **Results:** 290 pretested questionnaires were distributed among the participants, out of whom 272 responded. The study results showed that more than 55% of the study participants had knowledge and attitude regarding Pharmacovigilance but in the matter of practice of Pharmacovigilance less percentage of participants had experience. A major difference was noted between ADR (Adverse drug reaction)-experienced (65.81 %) and ADR-reported (23.9 %) individuals. **Conclusion:** This study demonstrated that knowledge and attitude towards Pharmacovigilance is gradually improving among healthcare professionals, but unfortunately the actual practice of ADR reporting is still lacking among them. Hence, strengthening of such practice will help in the future success of Pharmacovigilance programmes.

INTRODUCTION: Pharmacological interventions are an integral part of the patient care system. The safety of the patients with regard to the cautious use of medicines is of highest priority in the modern day therapy. Adverse drug reactions (ADRs) are associated with significant morbidity and mortality in addition to imposing considerable economic burden on the society.¹⁻⁴

Effective generation of ADR related data helps in practicing evidence-based medicine and thus prevents many adverse drug reactions. Several countries have initiated Pharmacovigilance programmes to monitor the drugs causing ADRs.⁵ According to World Health Organization (WHO) definition, Pharmacovigilance is, "The science and the activities which relate to the detection, assessment, understanding and the prevention of adverse effects or any other drug-related problems".⁶

The Uppsala Monitoring Centre (UMC, WHO), Sweden, maintains the international database of the adverse drug reaction reports. It has been estimated that only 6-10% of all the ADRs are reported.⁷ Although, India is participating in the program, its

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contribution to the UMC database is 2% only⁸; still, further active participation is required to increase spontaneous reporting. Lack of awareness about Pharmacovigilance is one of the most important causes of such under-reporting. Spontaneous reporting system is considered the main mechanism of pharmacovigilance study for gathering information about ADRs.¹ Hence this study was undertaken to assess the knowledge, attitude and practice regarding Pharmacovigilance among healthcare professionals in a tertiary care hospital.

MATERIALS AND METHODS:

This study was conducted at a tertiary care hospital in Rajahmundry, Andhra Pradesh, India. The approval for conducting this study was obtained from the Institutional Ethics Committee. This was a cross sectional questionnaire-based study conducted on 272 study participants, who were selected using stratified random sampling method. The study participants consisted of healthcare professionals who gave their informed consent and who were working at the hospital during the study period. Faculties, post graduates, interns with minimum graduation degree (MBBS) and nurses with minimum graduation degree (B.Sc Nursing) were included in the study. Pharmacists and those who are not involved in hospital-based patient care services were excluded from the study. Those who were not willing to participate in the study were also excluded.

KAP (knowledge, attitude and practice) questionnaire was designed to assess the knowledge and attitude regarding

Pharmacovigilance, and their practice on ADR reporting. There were total 15 questions, five each related to knowledge, attitude, and practice regarding Pharmacovigilance respectively.

These questions were designed based on earlier studies.⁹⁻¹⁶ Questionnaire was designed and properly structured initially to capture relevant information pertaining to study objectives and then a pilot study was conducted. The pilot study concluded that there was no questionnaire fatigue and a good response rate provided the confidence to proceed with the study. The final questionnaire was modified based on the results of the pilot study. The questionnaire consisted of multiple choice and closed ended type questions. Each participant was allotted a time limit of 30 minutes to fill up the questionnaire. In response to each question, a positive response was considered as a correct answer and a negative or unattempted response was considered as an incorrect answer. In order to preclude any potential bias the disclosure of name of the responder was made optional. The completed questionnaires were collected and analyzed by using MS excel 2007 and SPSS software version 21. Qualitative variables were expressed by percentages and Chi-square test was used to compare the difference in correct responses for each question. For all statistical analysis $p < 0.05$ was considered statistically significant.

RESULTS: Out of 290 study participants 272 filled the given study questionnaire which means 93.79 % responded. Among the responders 23.6% were Faculties, 15% were Post graduates, 10.3% were Interns and 51.1% were Nurses respectively.

TABLE 1: RESPONSE REGARDING KNOWLEDGE OF PHARMACOVIGILANCE

Response to Questions	Faculties (n=64) n (%)	Post graduates (n=41) n (%)	Interns (n=28) n (%)	Nurses (n=139) n (%)	Total (n=272) n (%)	p Value
1. Knowledge about the term "Pharmacovigilance"						
Correct	45 (70.31)	28 (68.29)	17 (60.71)	78 (56.12)	168 (61.76)	p=0.20
Incorrect	19 (29.69)	13 (31.71)	11 (39.29)	61 (43.88)	104 (38.24)	
2. The healthcare professionals responsible for reporting ADRs in a hospital are						
Correct	43 (67.19)	26 (63.41)	17 (60.71)	76 (54.68)	162 (59.56)	p=0.36
Incorrect	21 (32.81)	15 (36.59)	11 (39.29)	63 (45.32)	110 (40.44)	
3. Is there any existing Pharmacovigilance Programme in India?						
Yes	44 (68.75)	26 (63.41)	16 (57.14)	74 (53.24)	160 (58.82)	p=0.18
No	20 (31.25)	15 (36.59)	12 (42.86)	65 (46.76)	112 (41.18)	
4. What adverse event should you report in ADR form?						
Correct	41 (64.06)	25 (60.98)	15 (53.57)	64 (46.04)	145 (53.31)	p=0.07
Incorrect	23 (35.94)	16 (39.02)	13 (46.43)	75 (53.86)	127 (46.69)	

5. Where is the National Pharmacovigilance Centre (NPC) located?						
Correct	38 (59.38)	23 (56.1)	13 (46.43)	54 (38.85)	128 (47.06)	<i>p</i> =0.02*
Incorrect	26 (40.62)	18 (43.9)	15 (53.57)	85 (61.15)	144 (52.94)	

**p*<0.05 is considered statistically significant.

Table 1 represents that 61.76 % healthcare professionals gave correct response regarding the term Pharmacovigilance. Regarding knowledge about those healthcare professionals who were responsible for reporting ADRs in a hospital, 59.56 % of participants responded correctly. 58.82% of

the study participants were aware of the existence of Pharmacovigilance programme in India. 53.31 % of all participants had correct knowledge on what adverse events were to be reported. Regarding the location of NPC (National Pharmacovigilance Centre), 47.06 % had correct knowledge.

TABLE 2: RESPONSE REGARDING ATTITUDE OF PHARMACOVIGILANCE

Response to Questions	Faculties (n=64)	Post graduates (n=41)	Interns (n=28)	Nurses (n=139)	Total (n=272)	<i>p</i> Value
	n (%)	n (%)	n (%)	n (%)	n (%)	
1. Do you think ADR reporting is a professional obligation to you?						
Yes	48 (75)	29 (70.73)	19 (67.85)	80 (57.55)	176 (64.71)	<i>p</i> =0.07
No	16 (25)	12 (29.27)	9 (32.15)	59 (42.45)	96 (35.29)	
2. Instructions should be given regarding ADR to patient /patient’s party when prescribing medicines?						
Yes	45 (70.31)	27 (65.85)	17 (60.71)	77 (55.4)	166 (61.03)	<i>p</i> =0.20
No	19 (29.69)	14 (34.15)	11 (39.29)	62 (44.6)	106 (38.97)	
3. What is your opinion about establishing ADR monitoring centre in every hospital?						
Correct	42 (65.63)	25 (60.98)	15 (53.71)	72 (51.8)	154 (56.62)	<i>p</i> =0.27
Incorrect	22 (34.37)	16 (39.02)	13 (46.29)	67 (48.2)	118 (43.38)	
4. Are you willing to report an ADR?						
Yes	43 (67.19)	26 (63.41)	17 (60.71)	78 (56.12)	164 (60.29)	<i>p</i> =0.48
No	21 (32.81)	15 (36.59)	11 (39.29)	61 (43.88)	108 (39.71)	
5. Do you think Pharmacovigilance should be taught in details to health care professionals?						
Yes	43 (67.19)	25 (60.98)	16 (57.14)	72 (51.8)	156 (57.35)	<i>p</i> =0.21
No	21 (32.81)	16 (39.02)	12 (42.86)	67 (48.2)	116 (42.65)	

**p*<0.05 is considered statistically significant.

Table 2 represents that 64.71 % of the healthcare professionals opined that ADR reporting was required. 61.03% of the participants showed positive attitude towards giving instructions about ADR. 56.62 % agreed that ADR monitoring centre

should be established in every hospital. 60.29 % showed interest in reporting an ADR. With respect to teaching Pharmacovigilance in details to health care professionals, 57.35 % agreed to it.

TABLE 3: RESPONSE REGARDING PRACTICE OF PHARMACOVIGILANCE

Response to Questions	Faculties (n=64)	Post graduates (n=41)	Interns (n=28)	Nurses (n=139)	Total (n=272)	<i>p</i> Value
	n (%)	n (%)	n (%)	n (%)	n (%)	
1. Have you ever come across an ADR?						
Yes	50 (78.13)	29 (70.73)	19 (67.86)	81 (58.27)	179 (65.81)	<i>p</i> =0.03*
No	14 (21.87)	12 (29.27)	9 (32.14)	58 (41.73)	93 (34.19)	
2. Have you ever been trained on how to report ADR?						
Yes	42 (65.63)	25 (60.98)	15 (53.57)	57 (41)	139 (51.1)	<i>p</i> =0.005*
No	22 (34.37)	16 (39.02)	13 (46.43)	82 (59)	133 (48.9)	
3. Have you ever played any role in reporting ADR from your institution?						
Yes	25 (39.06)	11 (26.83)	6 (21.43)	23 (16.55)	65 (23.9)	<i>p</i> =0.005*
No	39 (60.94)	30 (73.17)	22 (78.57)	116 (83.45)	207 (76.1)	
4. To measure “Causality” which of the following is most commonly used scale?						
Correct	41 (64.06)	24 (58.54)	15 (53.57)	64 (46.04)	144 (52.94)	<i>p</i> =0.09
Incorrect	23 (35.94)	17 (41.46)	13 (46.43)	75 (53.96)	128 (47.06)	
5. Communication of ADR report to National Pharmacovigilance Centre (NPC) can be done by						

Correct	45 (70.31)	26 (63.41)	17 (60.71)	70 (50.36)	158 (58.09)	$p=0.04^*$
Incorrect	19 (29.69)	15 (36.59)	11 (39.29)	69 (49.64)	114 (41.91)	

* $p < 0.05$ is considered statistically significant.

Table 3 represents that among the health care professionals 65.81 % faced an ADR. 51.1 % of the study participants were trained on ADR reporting. Regarding practice of ADR reporting only 23.9 % played a role. 52.94 % of study participants knew about the most commonly used scale for measuring "Causality". 58.09 % of health-care professionals were aware regarding the mode of communication of ADR reporting to National Pharmacovigilance Centre (NPC).

DISCUSSION: The present study revealed that more than 55% of the study participants had knowledge and attitude regarding Pharmacovigilance. Regarding practice of Pharmacovigilance less than 30 % had experience. A study done by Gupta SK *et al*¹⁷ reported that 62.4 % of study participants had knowledge about Pharmacovigilance. Observations in the current study showed that 61.76 % of the study participants gave correct response to the definition of Pharmacovigilance. Regarding knowledge on the existing Pharmacovigilance programme in India, 58.82 % responded correctly.

This was in concordance with the study conducted by Hardeep *et al*¹² which reported that 59% of study participants had such knowledge. As far as the necessity of ADR reporting was concerned, 64.71 % of the participants agreed; such finding was in line with the study observation (66.2%) of Khan *et al*¹¹ which showed a positive attitude of the healthcare professionals towards ADR reporting. 57.35 % of the participants in the present study supported the fact that the healthcare professionals should be sensitised about Pharmacovigilance. Murararaih *et al*¹⁸ also similarly found that 58% of the participants were in favour of improving awareness about pharmacovigilance by educational programmes.

In matter of experiencing ADRs, majority of the participants (65.81 %) in the present study had come across an ADR which was similar to other studies.^{16,17} 23.9 % of the study participants in this study played a role in ADR reporting which was similar to other studies.^{12,17} Regarding the training

aspect on how to report ADRs, the current study showed that 51.1 % of respondents had received training which was in line with the findings (50.5%) of Rajesh R *et al*.¹⁵ In our study, there was notable gap between those who had knowledge and attitude (>55%) on Pharmacovigilance and those who had practised it (<30 %). Another interesting finding in the present study was that there was a major difference between ADR-experienced (65.81 %) and ADR-reported participants (23.9 %). Such a gap in practice might be due to time limitation in reporting ADR, false belief that the ADR database might be unaffected by a single unreported case, confusion in recognising ADR, lack of proper training, incomplete awareness on rules and procedures of ADR reporting.

Inappropriate knowledge on drug interactions, food and drug interactions may mislead the healthcare professionals in recognising and hence reporting an ADR, which ultimately may lead to poor practice of Pharmacovigilance. Pharmacovigilance programmes were meant for creating awareness among the healthcare professionals such as physicians, nurses and other healthcare providers actively involved.

After the thalidomide tragedy in 1961, the WHO established the International Drug Monitoring Programme in Geneva in 1968; it was later shifted to Uppsala, Sweden in 1978. This centre is now known as the Uppsala Monitoring Centre (UMC). One hundred and thirty four member countries report to UMC through their National Pharmacovigilance Centres.^{19,20}

Pharmacovigilance was introduced in India before the beginning of 21st Century. In January 2005 with sponsorship from the WHO and World Bank funding the National Pharmacovigilance Programme was established. But still it was not so successful. Among the major reasons for such failure were lack of proper ADR monitoring systems, communication gap among healthcare professionals and insufficient financial support by the government. Considering its earlier mistakes and pitfalls, serious attempts were made to formulate the framework of the subsequent

Pharmacovigilance programme. In July 2010, the Central Drugs Standard Control Organisation (CDSCO), New Delhi, under the control of Ministry of Health & Family Welfare, Government of India, started the Pharmacovigilance Programme of India (PvPI).

The National Co-ordination Centre for monitoring ADRs was set up at All India Institute of Medical Sciences (AIIMS), New Delhi, in 2010 and later shifted to the Indian Pharmacopoeia Commission, Ghaziabad in 2011.²⁰⁻²³

The present study revealed that majority of the health-care professionals had knowledge and attitude about Pharmacovigilance but they lack in practice. Hence in order to improve practice of Pharmacovigilance we would like to recommend the consideration of the following steps for effective implementation of Pharmacovigilance: Regular training programmes on Pharmacovigilance, mandatory provision of ADR reporting forms in every inherent clinical departments by the institutions, regular electronic communication updates on the safety of drugs to all health care professionals, timely financial funding for such programmes in institutions, promotion of patient self-reporting, filling the communication gaps regarding Pharmacovigilance among healthcare professionals.

CONCLUSION: For the success of Pharmacovigilance programmes only knowledge and attitude regarding Pharmacovigilance is not enough as is evident from our study. Success of Pharmacovigilance programmes depend also upon the effective practice of Pharmacovigilance by healthcare professionals.

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