

Assessment of Knowledge, Attitude and Practice among the Health Care Professionals towards Adverse Drug Reactions Reporting

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Abstract:

Background: Healthcare professionals (HCPs) should have an updated knowledge on the drug safety concerns and their management to minimize the risks of ADRs. This survey was conducted to assess the knowledge, attitude and practice (KAP) of HCPs towards ADRs and Pharmacovigilance and to identify the reasons of under reporting.

Materials and Methods: A Cross-sectional questionnaire-based study was conducted for a period of 6 months at various hospitals in and around Kadapa using a self-designed questionnaire with 25 questions [knowledge (9), attitude (9), practice (7)].

Results: A total of 87 participants were included in the study, 27 (31%) were males and 60 (69%) were females. Among all the participants, 21 were Doctors, 13 were Clinical pharmacists, 31 were Interns, 17 were Nurses, and 5 were Hospital pharmacists. In this study, majority (87%) of the participants has defined the ADR correctly and same percentages of HCPs were known the National Pharmacovigilance system. A significantly high number of participants(85%) were known that all reactions need to be reported. The discouraging factors of ADR reporting found among the study HCPs were legal issues (7%), no encouragement (12.64%), and 48.27% have claimed multiple factors.

Conclusion: With this study we conclude that, the HCPs of the study site have a good KAP towards ADR reporting. But still there is a need to improve the KAP of Nurses as they have very poor practicing habits when compared to other HCPs and Doctors were found to be involved majorly in ADR reporting.

Key Words: Pharmacovigilance, Adverse drug reactions, Knowledge, Attitude, Practice, Health care professionals.

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I. Introduction

Adverse drug reactions (ADRs) encountered commonly in daily practice¹ and are identified as one of the major contributing factors for morbidity and mortality. ADR also causes an economic burden on the health-care system by reduction in the quality of life, increase hospitalization, lengthen hospital stay and increase mortality. Hence, their early detection and prevention is necessary.¹

The global epidemiological data show that 3–6% of hospital admissions are due to ADRs and the percentage of patients experiencing ADRs during hospitalization ranges from 1.5% to 35%.

Pharmacovigilance has constantly grown its importance in last 15 years, relating to the absolute amount of adverse drug reactions (ADRs) and to the fact of several hospital admissions are due to ADRs.² The success of a pharmacovigilance program depends upon the involvement of the healthcare professionals and reporting the ADRs. The main reasons for the failure of pharmacovigilance programs are due to the underreporting of ADRs.³ It is estimated that only 6–10% of all ADRs are reported.

Being the key HCP (healthcare professionals), the doctors, nurses and pharmacists have immense responsibility in reporting ADRs and strengthening the pharmacovigilance mechanisms that exists in their vicinity.

According to the studies from various settings, the inadequate knowledge and attitude of healthcare professionals about Pharmacovigilance are associated with a high degree of underreporting.⁴ An educational

interventional session can increase the knowledge about pharmacovigilance and better the attitude and practice of it among the healthcare professionals. Before establishing any intervention, it is necessary to evaluate their knowledge, attitude and practices regarding ADRs reporting. Therefore, the objective of this study is to determine the current status of Knowledge, Attitudes and Practice (KAP) towards ADRs reporting among healthcare professionals (HCPs).⁵

II. Material And Methods

The Study was commenced in various hospitals in and around Kadapa after getting approval from the Institutional Ethical Committee. A cross-sectional descriptive questionnaire-based survey was conducted on the HCPs and all interns of medical, nursing and pharmaceutical fields or academics for 6 months.

Eligibility criteria:

Inclusion Criteria:

All healthcare professionals including medical, nursing and pharmaceutical fields and academics.

Exclusion Criteria:

- Non interns
- Lab technicians as not directly involved in patient care
- Dispensing pharmacists
- Radiologists
- Incomplete questionnaires
- The healthcare professionals who were not willing to participate.

Study materials:

- KAP questionnaire (Annexure I)
- Likert scale, (Annexure II)
- Bloomsscale (Annexure III)
- Informed consent form (Annexure IV)
- Educational materials like pamphlets, posters, notification form, Drug Alerts (IPC/CDSCO) (Annexure V)
- IPC Suspected ADR Reporting Form (Annexure VI)

A self-designed and pre-validated questionnaire was circulated to the HCPs after getting their consent by explaining the purpose of the study. Then the filled questionnaires were screened for their completeness and the data was entered into the spreadsheets (Micro-Soft Excel) for the analysis. This questionnaire consists of 2 parts, first part includes participant's demographics, and the later part includes 3 subdivisions i.e. knowledge, attitude, and practice-related questions and options. A total of 25 multiple options and close-ended questions related to the Knowledge (9), Attitude (9), and Practice (7) of ADR reporting and the PV were included.

Knowledge was assessed by using the scoring system where each correct answer carries 2 marks and 0 marks for the wrong answer. The attitude related questions were scored based upon the participant's degree of agreement using Likert scale. The score is as following; "0"- strongly disagree, "1"- disagree, "2"- Neutral, "3"- agree and "4"-strongly agree. Practice refers to the ways in which they demonstrate their knowledge and attitude through their actions.

Educational strategies:

Educational strategies towards improving the KAP of the HCPs will be implemented through pamphlets, posters, notification form, Drug Alerts(IPC/CDSCO), different modes of reminders (regular visits to the HCPs and circulating ADR notification forms (Annexure-V)

Statistical analysis:

All data summaries and listings were generated using MS Excel, under the Micro-Soft XP operating system 2013.Descriptive statistics like percentage, mean, SD were used to analyse the data.

II. Results

All the study participants were categorized based on their qualification into nine groups. Among all, 25 (28.7%) were Pharm.D graduates and 22 (25.3%) were MBBS graduates.

Table no 1: Qualification of the participants

S. No	Qualification	Frequency	%
1.	MD	8	9.2%
2.	MBBS	22	25.3%
3.	Pharm.D	25	28.7%
4.	M.Pharmacy	3	3.4%

5.	B.Pharmacy	10	11.5%
6.	M.SC Nursing	1	1.1%
7.	B.SC Nursing	15	17.2%
8.	Dental	2	2.3%
9.	BPT	1	1.1%

Discouraging factors for reporting ADRs among participants

An analysis of the factors discouraging HCPs from reporting ADRs showed that the 48.27% of HCPs have expressed multiple discouraging factors for reporting ADRs.

Table no 2: Factors discouraging the HCPs from the reporting of ADRs.

S. No.	Factor	Number of respondents	Percentage of respondents
1	Lack of time	05	5.74%
2	Legal issues	06	7%
3	No encouragement and no remuneration	11	12.64%
4	Not aware	15	17.24%
5	One ADR may not affect	03	3.44%
6	Problem of confidentiality	03	3.44%
7	Treatment is important	02	2.3%
8	All the above	42	48.27%

Knowledge

We have assessed the participants’ knowledge about the ADR reporting and PV using Bloom’s cut-off scale and found that 26 % had Good knowledge and the detailed information was presented in Table 3.

Table no 3: Knowledge of the HCPs on the reporting of ADRs

Bloom’s cut-off percentage	No. of participants	Percentage
Good knowledge (80-100%)	23	26.43
Moderate knowledge (60-79%)	35	40.22
Poor knowledge (<60%)	29	33.33

We have compared the knowledge among HCPs and found that 57% of Doctors had Moderate knowledge, 60% of Hospital pharmacists had Moderate knowledge, 53% of Clinical pharmacists had Good knowledge, 47% of Nurses had Moderate, and 41% of Interns had Poor knowledge.

Table no 4: Responses to Knowledge related questions.

QUESTIONS	FREQUENCY OF CORRECT ANSWERS	
	n=87	%
1. The important purpose of pharmacovigilance is	17	19.54
2. Which of the following method is commonly employed by the pharmaceutical companies to monitor adverse drug reactions of new drugs in the market?	69	79.31
3. In India, which regulatory body is responsible for monitoring of ADRs?	76	87.35
4. Which of the following defines an ADR correctly?	76	87.35
5. Which ADRs should be reported?	74	85.05
6. Is Adverse Drug Event and ADR same?	58	66.66
7. Which one of the following is the “WHO online database” for ADRs?	44	50.57
8. Choose the correct order (or) sequence from the following.	55	63.21
9. What possible factors pre-dispose a patient to develop ADRs?	66	75.86

Attitude

More than fifty percent of participants have strongly agreed that the implementation of ADR reporting system and active discussion on the observed ADR during their practice will be useful for the improvement of the knowledge. Around 50% of the study HCPs has agreed that the establishment of the ADR monitoring centre in every hospital, regular training programs on Pharmacovigilance and close monitoring of the new drug therapy would be beneficial for both the HCPs and patients. And 62 % had felt that the reporting is compulsory. Table 5 explains the detailed attitude of the HCPs at the study center.

We have assessed the attitudes of HCPs towards ADR reporting. This section included 7 questions, responses to which were measured on a five-point Likert scale. A mean score ≥ 2 was considered to reflect a positive attitude, while a score < 2 was considered to indicate a negative attitude. Number of participants with positive and negative attitudes was presented in Table 6.

Table no 5: Responses to Attitude related questions.

QUESTIONS	FREQUENCY OF RESPONSES (%)				
	Strongly disagree	Disagree	Agree	Strongly agree	Neutral
1. Implementation of ADR reporting or making the habit of ADR reporting in your practice is useful or appreciable	7 (8.04)	2 (2.29)	26 (29.88)	45 (51.72)	7 (8.04)
2. Professional discussion on suspected ADR helps health care professionals in developing their knowledge of treatment outcomes and may improve the patient care.	4 (4.59)	1 (1.14)	34 (39.08)	45 (51.72)	3 (3.44)
3. Treatment of ADRs may pose the financial burden on the patients and the health system	5 (5.74)	25 (28.73)	24 (27.58)	23 (26.43)	10 (11.49)
4. Establishment of an ADR monitoring center in every hospital will improve the patient care and also reduces safety issues.	2 (2.29)	2 (2.29)	35 (40.22)	42 (48.27)	6 (6.89)
5. Do you agree that ADR reporting system would benefits both patients and doctors	2 (2.29)	1 (1.14)	36 (41.37)	41 (47.12)	7 (8.04)
6. Habit of monitoring new drugs & their outcomes can improve the patient care	1 (1.14)	5 (5.74)	36 (41.37)	42 (48.27)	3 (3.44)
7. Proper training should be provided to the health care professional to improve the habit of ADR reporting.	1 (1.14)	1 (1.14)	38 (43.67)	44 (50.57)	3 (3.44)
QUESTION	VOLUNTARY	COMPULSARY	REMUNERATED		
8.ADR reporting should be	23 (26.43)	54 (62.02)	10 (11.49)		

Table no 6: Assessing Attitude based on Likert Scale.

QUESTIONS	No. of participants with positive attitude	No. of participants with negative attitude
1. Implementation of ADR reporting or making the habit of ADR reporting in your practice is useful or appreciable	78	9
2. Professional discussion on suspected ADR helps health care professionals in developing their knowledge of treatment outcomes and may improve the patient care.	82	5
3. Treatment of ADRs may pose the financial burden on the patients and the health system	57	30
4. Establishment of an ADR monitoring center in every hospital will improve the patient care and also reduces safety issues.	83	4
5. Do you agree that ADR reporting system would benefits both patients and doctors	84	3
6. Habit of monitoring new drugs & their outcomes can improve the patient care	81	6
7. Proper training should be provided to the health care professional to improve the habit of ADR reporting.	85	2

Practice

We found that 57% of the study HCPs were identified the ADRs during their practicing and 32 % were reported at least one ADR. More than 80% of HCPs at the study site are collecting the patients’ drug allergic history before the prescription. And the detailed information on the study participants’ practice is presented in Table 7.

Table no7: Assessment of the practice

QUESTIONS	FREQUENCY OF RESPONSES (%)	
	YES	NO
1. Have you ever identified the adverse drug reaction/s in your patient during your professional practice?	50 (57.47)	37 (42.52)
2. Have you ever been attended on how to report Adverse Drug Reaction (ADR)?	46 (52.87)	41 (47.12)
3. Have you ever reported the adverse drug reaction/s (ADR) to the Pharmacovigilance center?	30 (34.48)	57 (65.51)
4. Are you collecting drug allergic history in your practice before the prescription?	71 (81.60)	16 (18.39)

5. Are you spending time in knowing the regulatory actions on the marketed drug?		50 (57.47)	37 (42.52)
6. Have you ever visited the ADR monitoring center in your hospital?	Don't know whether it is established or not	24 (27.58)	43 (49.42)
		20 (22.98)	

IV. DISCUSSION

The present study is a questionnaire-based study to assess the knowledge, attitude and practice of Pharmacovigilance among health care professionals in a tertiary care teaching hospital. Majority of the study participants were females (69%) and Interns (36%) of Pharm D, Medical PGs and MBBS.

Majority (36%) of the study participants are having 1-5 years of experience in the healthcare practice. The majority of the study participants had the considerable level of knowledge regarding the Pharmacovigilance i.e. 67% of study participants have answered correctly for more than 65% of the knowledge related questions, which is a good sign that at the study site can handle the drug safety issues. In the present study, the knowledge of HCPs on ADR reporting was low with only 29% of the HCPs having adequate knowledge.

In this study, majority (87%) of the participants have defined the ADR correctly and same percentage of HCPs were known the National Pharmacovigilance system. A significantly high number of participants (85%) were known that all reactions need to be reported irrespective of their seriousness, severity, frequency, and novelty.

When compared to all HCPs Clinical pharmacists have Good knowledge i.e, 53.84%, Hospital pharmacists have Moderate knowledge i.e, 60% and Nurses have poor knowledge i.e, 47%.

Overall, more than half of the health workers demonstrate positive attitude towards ADR reporting. Even though, healthcare providers play a significant role in ensuring a robust Pharmacovigilance system, the rate of spontaneous reporting of ADRs by healthcare professionals in many countries is extremely low (6–10%). By using Likert scale we have assessed Attitude of study participants. 97.70 % of health care professionals showed positive attitude towards proper training should be provided to the HCPs to improve the habit of ADR reporting. 96.55% HCPs thought ADR reporting benefits both patients and doctors. Only 65.51% thought treatment of ADRs may pose financial burden on the patients. 62.02% of the respondents felt that ADR reporting is compulsory.

Suggestions for improving ADR reporting

1. Each hospital should establish a local “Pharmacovigilance Unit” for reporting ADRs and collecting related data.
2. Pharmacovigilance workshops should be conducted to provide guidance to physicians, pharmacists and nurses for recognizing and reporting ADRs.
3. ADR reporting by patients should also be encouraged along with reporting by healthcare professionals.
4. Representatives from NPP should co-ordinate with healthcare professionals at their work place.
5. A separate column should be provided for ADR reporting in patient medication chart.
6. Incentives should be provided to pharmacists reporting ADRs not associated with human errors.
7. Periodic meetings of experts from NPP with pharmacists should be arranged to boost reporting.

V. Conclusion

With this study we conclude that on overall, the HCPs of the study site have a good KAP towards ADR reporting. But still there is a need to improve the KAP of Nurses as they have very poor practicing habits when compared to other HCPs and Doctors were found to be involved majorly in ADR reporting. We also conclude that there is need to remove the negative perceptions and discouraging factors of ADR reporting among HCPs. With this study we found there is a need for conducting an awareness program for Nurses and Interns to improve their KAP, which in turn improves the patient care.

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