



EVALUATION OF THE KNOWLEDGE, ATTITUDE AND PRACTICE AMONG HEALTH CARE PROFESSIONALS IN REPORTING OF ADVERSE DRUGS REACTIONS IN TELANGANA: A CROSS-SECTIONAL QUESTIONNAIRE SURVEY

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Abstract : Aim: The main objective of this study is to evaluate the knowledge, awareness, attitude, and practice related to adverse drug reaction reporting among the healthcare professionals working in Hyderabad, Telangana State.

Methods: The study was designed as a cross-sectional, observational, questionnaire-based survey. The questionnaire was designed to test the knowledge, attitude, and current practice of doctors about ADR reporting. The questionnaire was distributed to randomly selected healthcare professionals ($n = 200$) such as physicians, pharmacists, and hospitals' nurses.

Result: Out of the 200 questionnaires circulated, a total of 190 healthcare professionals responded, which comprised 87 doctors, 26 nurses, and 77 pharmacists. The percent of the respondents who accepted to enroll in the study was 95%. All HCPs had an excellent knowledge of Pharmacovigilance and ADRs terminology and showed a more positive attitude to report ADRs. Few healthcare professionals, that is, 23.12%, have ever reported ADR to Pharmacovigilance center. 93.6% of HCPs agree that Awareness about ADR, making the availability of the ADR's reports format, and Continuous Follow-up of patients were the three factors that encouraged ADR reporting.

Conclusion:

The results of our study indicate that most of the healthcare professionals had good knowledge and a positive attitude about pharmacovigilance. There was a considerable gap between the ADR experienced and ADR reported by the healthcare professionals, especially among doctors and nursing staff. It has been suggested that healthcare personnel, particularly doctors and nurses, be thoroughly trained on ADR reporting to improve the current situation in India's Pharmacovigilance program.

KEYWORDS: Pharmacovigilance, Adverse drug reactions, HCPs, pharmacovigilance program (PP).
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I. INTRODUCTION

Adverse drug reactions (ADRs) are a huge global problem. They have varying degrees of impact on both children and adults, resulting in morbidity and mortality. According to reports, adverse reactions account for 2.4 % to 6.5% of all hospital admissions, many preventable. The incidence of serious ADRs in India is around 6.7%.^[1]

Adverse Drug reaction is defined by the World Health Organization (WHO) as "a noxious, unintended effect of a drug that occurs in doses normally used in humans for the diagnosis, prophylaxis, and treatment of disease"^[2]

The World Health Organization defines pharmacovigilance as "science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other medicine-related problems."^[3]

The pharmacovigilance program (PP) has been instrumental in detecting ADRs and removing several drugs from the market. However, the under-reporting of ADRs is one of the main problems associated with PP^[4] Due to variation in drug response, individual prescribing habits, drug regulatory system, and availability of drugs, it has been recommended for every country to Line up their own PP.^[5]

The government of India has launched a pharmacovigilance program to strengthen pharmacovigilance in the country (PvPI). Furthermore, the Drug Controller General of India and the Indian Council of Medical Research have established ADR monitoring centers at various hospitals across India.^[6]

Despite these efforts, pharmacovigilance is still in its infancy in India. The principal reason behind this is the poor understanding of the healthcare professionals (HCPs) toward the Prevailing pharmacovigilance program.^[7] Various reasons for under-reporting ADRs by HCPs can be lack of knowledge and practice, too busy to report ADRs, feeling that a single case report may not be important, concern that reporting can generate additional work, and fear of legal implications. It is important for healthcare professionals to know how to report and where to report ADRs. Healthcare professionals' active participation in the pharmacovigilance program can help to enhance ADR reporting.^[8]

Thus, the present study was designed to assess the knowledge, attitude, and practices of the healthcare professionals regarding reporting of ADRs, to get an insight into the reasons for under-reporting, and also to suggest possible ways of improving spontaneous ADRs.

II. MATERIALS & METHODS

2.1 Study design

The study was designed as a **cross-sectional, observational, questionnaire-based survey**.

2.2 Study Setting

A Web-Based survey using Google forms as a platform to create questionnaires comprised of 29 questions to gather information from healthcare professionals (medical, nursing, and pharmacy professionals) about awareness related to reporting of adverse drug reactions. The survey link was disseminated through e-mail and various social media platforms. The participant's responses were secured using a "Cloud" database where the data was automatically sorted, organized, and analyzed.

2.3 Questionnaire Development

The questionnaire was designed to gather demographic data about the respondents (research participants), including their gender, field of study, specialty, type of practice, and experience. The rest of the questions were designed to test the knowledge, attitude, and current practice of doctors with regards to ADR reporting in the locality

The following are the specifics of the questionnaire:

1. Knowledge-related questions:

A total of six questions were designed to evaluate the participant's knowledge of pharmacovigilance

2. Attitude & practice-related questions

The assessment of participant's attitudes & practice toward pharmacovigilance included eight questions on experience of ADRs, report to pharmacovigilance center, ADR reporting form, training to report ADRs, reporting of a serious adverse event, identification of rare ADRs, methods to monitor ADRs of the new drug, presence of Pharmacovigilance Committee in Institute.

3. ADR's reporting to Pharmacovigilance Centres

Five questions were explicitly structured to understand how willing are the HCPs to take upon the responsibility of screening, diagnosing, and reporting ADRs

4. Factors that encourage ADR reporting questions

Four questions were asked to determine the factors that motivate ADR reporting

5. Factors that discourage ADR reporting questions

Six questions were asked to understand the factors, in their opinion, obstruct an efficient pharmacovigilance program.^[9]

2.4 Study population

The study participants were healthcare professionals (medical, nursing, and pharmacist professionals) working in reputed hospitals, clinics across Hyderabad, Telangana State.

2.5 Inclusion and Exclusion Criteria

The questionnaire was disseminated through e-mail to each of the randomly selected health care professionals with an HTML link to the web-based survey. A letter accompanied each of these e-mails with a note for their informed consent. It was up to the health care professional to decide whether or not to participate in the study. Those who did not want to take part in the study were advised not to respond to the e-mail that was sent. Those who had registered their response were deemed to have voluntarily participated in the study.

2.6 Sample size

The study included 190 participants, including 87 doctors, 26 nurses, and 77 pharmacists.

2.7 Data collection and analysis:

The questionnaire was distributed to all the subjects via e-mail, and they were asked to register their responses in their free time. The data obtained from filled questionnaires were sorted and analyzed with the help of a Microsoft Excel Spreadsheet. The data was reported as a percentage (%) of the total number of respondents. In case of unanswered questions, the participant was excluded from the study.^[10-11]

III. RESULTS

3.1 Demographic Data

The present study involved three different HCP's who participated in the survey. Details were categorized based on Gender, Professional qualifications, and Experience. The results of which are illustrated in Table1.

Table 1. Demographic details of respondents

Category	Sub – Category	Number/ Frequency %
Gender	Male	81
	Female	107
Age (Years)	20 – 25	104
	25-30	59
	30-40	22
	40-50	02
	41-45	01
	>50	02
	If Doctor: Specializations of respondents	General medicine
Cardiology		04
Dentistry		19
Surgery		02
Endocrinology		01
Neurologist		03
Obstetrics & Gynaecology		04
Orthopedics		01
Pediatrics		06
Psychiatry		03
Pulmonologist		01
Others		03
Professional Qualification	Doctor	87
	Nurse	26
	Pharmacist	77

Experience	<1 year	64
	1-5 years	75
	5-10 years	18
	>10 years	08

3.2 Adverse Drug Reaction Reporting – Evaluation of Knowledge

All the values and percentages of correct and incorrect responses for ADR reporting knowledge were examined and tabulated in Table 2.

Table 2. Respondent's knowledge on adverse drug reaction reporting

Knowledge related questions	Doctors		Nurses		Pharmacists		Total		Data Missing
	Yes	No	Yes	No	Yes	No	Yes	No	
Do you know what are adverse drug reactions (ADR)	85 (97.7%)	01 (1.1%)	26 (100%)	0	76 (98.7%)	0	187	01	02
Do you know the existence of a National Pharmacovigilance Program in India?	71 (86%)	08 (9.1%)	26 (100%)	0	72 (93.5%)	02 (2.5%)	169	10	11
	Doctors		Nurses		Pharmacists		Total		
	Correct response	Incorrect response	Correct response	Incorrect response	Correct response	Incorrect response	Correct responses	Incorrect responses	
In India, which regulatory body is responsible for monitoring ADRs?	68 (78.1%)	17 (19.5%)	25 (96.1%)	01 (3.8%)	71 (92.2%)	05 (6.4%)	164	23	03
Where is the international center for adverse drug reaction for monitoring located?	55 (63.2%)	26 (29.8%)	20 (76.9%)	06 (23.0%)	62 (80.5%)	11 (14.2%)	137	43	10
Pharmacovigilance deals with	78 (89.6%)	07 (8.0%)	26 (100%)	0	76 (98.7%)	01 (1.2%)	180	8	02
The most important purpose of pharmacovigilance is	55 (66.2%)	05 (51.7%)	23 (88.4%)	03 (11.5%)	67 (87%)	02 (2.5%)	145	10	35

3.3 Adverse Drug Reaction Reporting – Attitude and Practice

Attitude and practice-based questions were evaluated amongst HCP's and reported in Table-3

Table 3. Respondent's attitude and practice on adverse drug reaction reporting

Attitude & Practice related questions	Doctors		Nurses		Pharmacists		Total		Data Missing
	Yes	No	Yes	No	Yes	No	Yes	No	
Are you aware of the process of ADR reporting?	52 (59.7%)	28 (32.1%)	16 (61.5%)	09 (34.6%)	50 (64.9%)	25 (32.4%)	118	62	10
Have you ever seen the ADR reporting form?	35 (40.2%)	46 (52.8%)	17 (65.3%)	07 (26.9%)	46 (59.7%)	27 (35%)	98	80	12
Have you ever experienced ADR from the patient during your professional practice?	31 (35.6%)	51 (58.6%)	07 (26.9%)	17 (65.3%)	37 (48%)	38 (49.3%)	75	106	09
Have you ever reported an ADR?	16 (18.3%)	67 (77%)	08 (30.7%)	17 (65.3%)	20 (25.9%)	54 (70.1%)	44	138	08
Have you anytime read an article on the prevention of ADRs?	45 (51.7%)	20 (22.9%)	13 (50%)	06 (23%)	44 (47.1%)	17 (22%)	102	43	45
Is there any acknowledgment for reporting an ADR in your hospital?	43 (49.4%)	39 (44.8%)	12 (46.1%)	14 (53.8%)	31 (40.2%)	34 (44.1%)	86	87	17
Does there a need for information on drug-causing ADRs and their risk management strategies?	83 (95.4%)	02 (2.2%)	23 (88.4%)	03 (11.5%)	74 (96.1%)	03 (3.8%)	180	8	02
Have you ever been trained on how to report ADR?	16 (18.3%)	70 (80.4%)	09 (34.6%)	17 (65.3%)	62 (80.5%)	15 (19.4%)	87	102	01

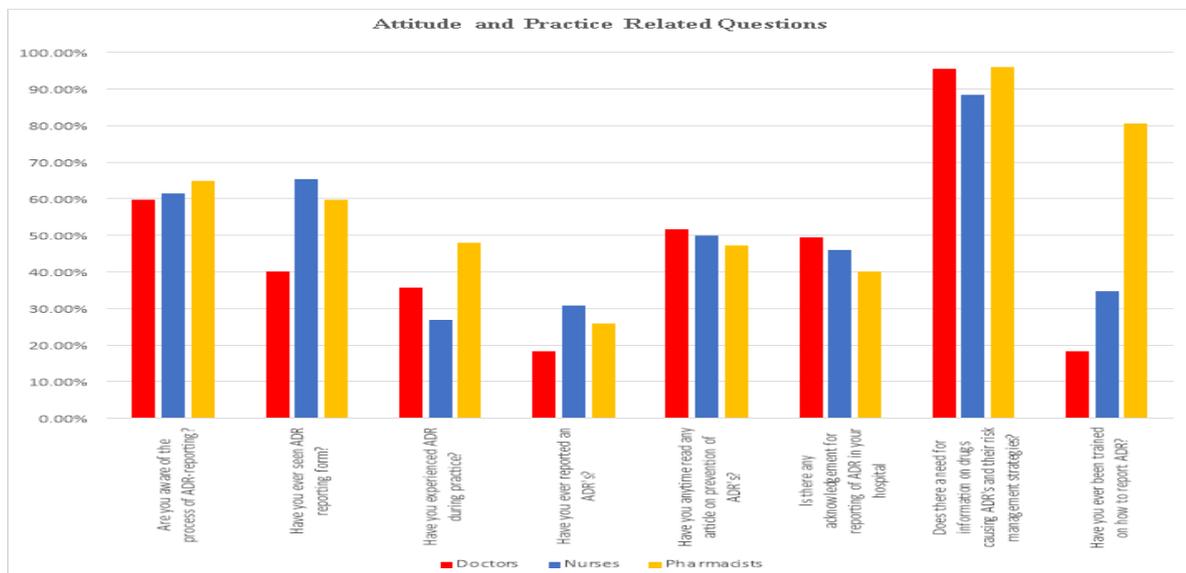


Fig 1. Evaluation of attitude and perception of ADR reporting among healthcare professionals
3.4 Types of ADRs Generally Reported to Pharmacovigilance Centers

Categories of ADR's which Doctors, Nurses, and Pharmacists would report was included in Table 4

Table 4. Types of ADR's reported to Pharmacovigilance centres

Questions	Type of HCPs	Definitely would report	Might report	Definitely would not report	Data Missing
Serious ADR's and life-threatening reactions (risk of death)	Doctor	81 (93.1%)	04 (4.5%)	0	01
	Nurse	24 (92.3%)	02 (7.6%)	0	0
	Pharmacists	76 (98.7%)	01 (1.2%)	0	0
Severe and can cause disability (significant, persistent, or permanent)	Doctor	74 (85%)	10 (11.4%)	01 (1.1%)	01
	Nurse	21 (80.7%)	05 (19.2%)	0	0
	Pharmacists	75 (97.4%)	02 (2.5%)	0	01
Mild ADR's and cause less inconvenience	Doctor	26 (29.8%)	55 (63.2%)	04 (4.5%)	01
	Nurse	12 (46.1%)	14 (53.8%)	0	0
	Pharmacists	38 (49.3%)	37 (48%)	01 (1.2%)	01
All cases of ADR's	Doctor	39 (44.8%)	43 (49.4%)	03 (3.4%)	01
	Nurse	13 (50%)	13 (50%)	0	0
	Pharmacists	40 (51.9%)	36 (46.7%)	0	01
All suspected reactions to a new product	Doctor	65 (74.7%)	19 (21.8%)	01 (1.1%)	01
	Nurse	17	09	0	0

		(65.3%)	(34.6%)		
	Pharmacists	65 (84.4%)	11 (14.2%)	0	01
Total	Doctor	285	131	9	05
	Nurse	87	43	0	0
	Pharmacists	294	87	1	04

3.5 Factors that Encourage ADR Reporting

Factors that would encourage every healthcare professional to report ADRs are tabulated in Table 5.

Table 5. Factors that encourage ADR reporting

Questions	Type of HCPs	Agree	Disagree	Data Missing
Awareness creation on what, when, how, & to whom to report and increasing awareness at all levels of education	Doctor	82 (94.2%)	03 (3.4%)	01
	Nurse	26 (100%)	0	0
	Pharmacists	75 (97.4%)	01 (1.2%)	01
Announcing ADR report as it is a professional obligation of HCPs	Doctor	78 (89.6%)	07 (8%)	01
	Nurse	22 (84.6%)	04 (15.3%)	0
	Pharmacists	68 (88.3%)	08 (10.3%)	01
Make availability of the ADR's reports format	Doctor	81 (93.1%)	04 (4.5%)	01
	Nurse	26 (100%)	0	0
	Pharmacists	75 (97.4%)	02 (2.5%)	01
Continuous Follow-up of patients	Doctor	81 (93.1%)	03 (3.4%)	02
	Nurse	22 (84.6%)	04 (15.3%)	0
	Pharmacists	76 (98.7%)	01 (1.2%)	0
Total	Doctor	322	17	05
	Nurse	96	08	0
	Pharmacists	294	12	03

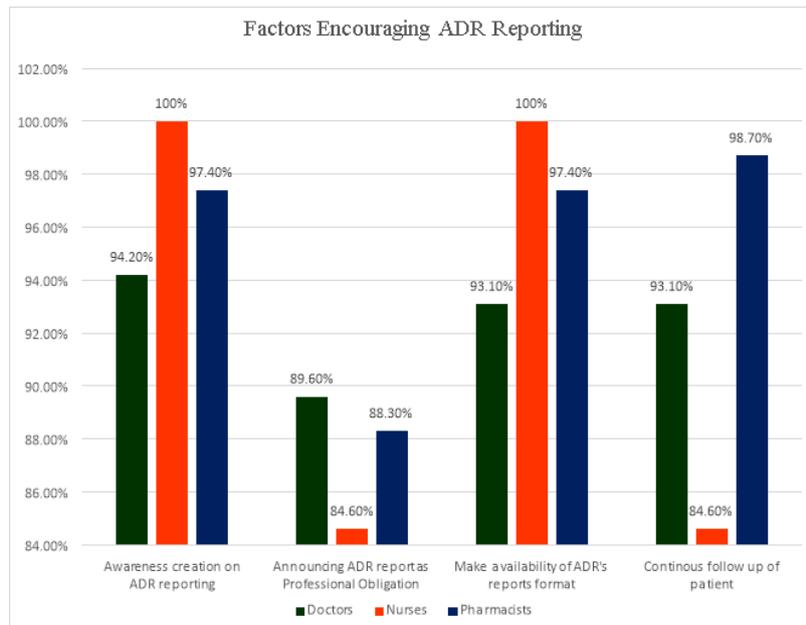


Fig 2. Factors that encourage ADR reporting

3.5 Factors that Discourage ADRs Reporting

The Possible Causes of not reporting ADRs Are Reported in Table 6

Table 6. Factors that discourage ADR reporting

Questions	Type of HCPs	Agree	Strongly Agree	Disagree	Strongly Disagree	Data Missing
Lack of awareness and Knowledge on what, when, and to whom to report	Doctors	60 (68.9%)	23 (26.4%)	01 (1.1%)	01 (1.1%)	01
	Nurse	22 (84.6%)	4 (15.3%)	0	0	0
	Pharmacists	62 (80.5%)	13 (16.8%)	02 (2.5%)	0	0
Belief that only safe drugs are marketed	Doctors	39 (44.8%)	35 (40.2%)	09 (10.3%)	01 (1.1%)	02
	Nurse	06 (23%)	19 (73%)	01 (3.8%)	0	0
	Pharmacists	24 (31.1%)	45 (58.4%)	06 (7.7%)	01 (1.2%)	01
Fear of legal liability for reporting ADR	Doctors	64 (73.5%)	08 (9.1%)	07 (8%)	05 (5.7%)	02
	Nurse	21 (80.7%)	01 (3.8%)	03 (11.5%)	01 (3.8%)	0
	Pharmacists	68 (88.3%)	02 (2.5%)	05 (6.4%)	0	02
Lack of time to actively look for an ADR and fill in a report	Doctors	56 (64.3%)	15 (17.2%)	14 (16%)	0	01
	Nurse	15 (57.6%)	07 (26.9%)	03 (11.5%)	01 (3.8%)	0
	Pharmacists	49 (63.6%)	16 (20.7%)	12 (15.5%)	0	0
Lack of Knowledge about the process of ADR's reporting	Doctors	75 (86.2%)	06 (6.8%)	03 (3.4%)	01 (1.1%)	01
	Nurse	18 (69.2%)	07 (26.9%)	01 (3.8%)	0	0

	Pharmacists	59 (76.6%)	12 (15.5%)	05 (6.4%)	0	01
Think that you may cause harm to the patient	Doctors	34 (39%)	04 (4.5%)	33 (37.9%)	14 (16%)	01
	Nurse	14 (53.8%)	0	07 (26.9%)	05 (19.2%)	0
	Pharmacists	42 (54.5%)	01 (1.2%)	28 (36.3%)	05 (6.4%)	01
Total	Doctor	328	91	67	22	08
	Nurse	96	38	15	07	0
	Pharmacists	304	89	58	06	05

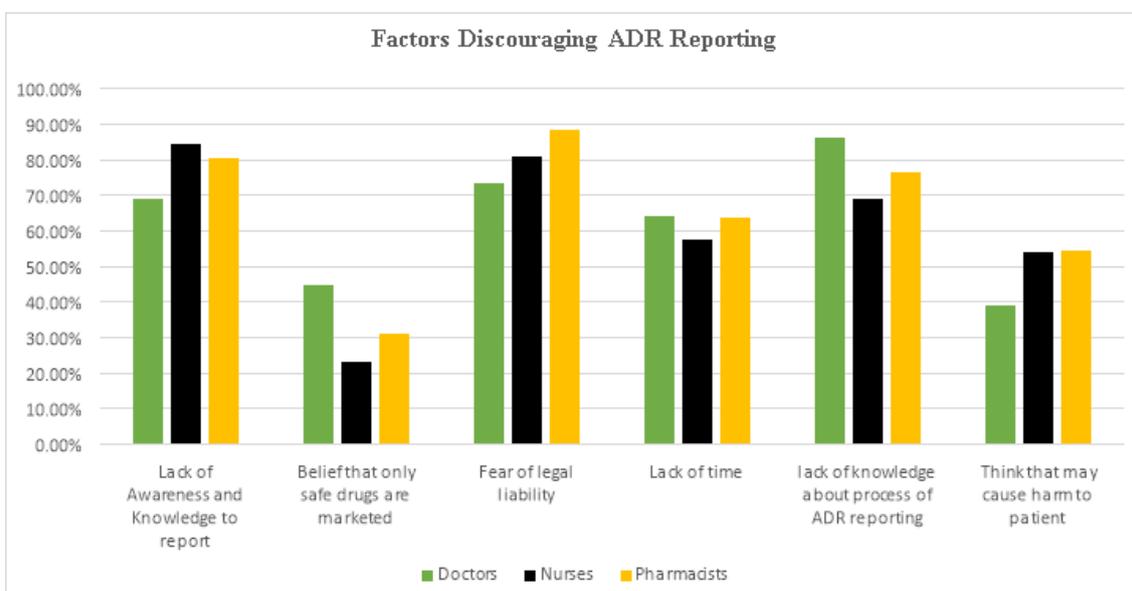


Figure 3. Factors that discourage ADR reporting

IV. DISCUSSION

The present study is survey-based which includes public and private hospitals of the Telangana region. This study was carried out to assess the knowledge, attitude, and practice of ADR reporting among healthcare professionals in these hospitals. The interesting findings show that 87 doctors, 26 nurses, and 77 pharmacists participated in the study

Most of the healthcare professionals were females (107) compared to males (81). The mean age (20-25) of study participants was 104.

Adverse Drug Reaction reporting - Knowledge

When it comes to reporting ADR, having a good Knowledge of ADR is crucial. It is very important for healthcare professionals to possess great Knowledge of ADR and the procedure of reporting ADR. The results showed that almost all healthcare professionals had completed knowledge about what are adverse drug reactions and also knew the existence of a National Pharmacovigilance Program in India.

The study also revealed 78.1% of doctors, 96.1% nurses, and 92.2% of pharmacists gave correct responses regarding the regulatory body responsible for monitoring ADR. Similarly, 63.2% of doctors, 76.9% nurses, and 80.5% pharmacists were aware of the location of the international center for an adverse drug reaction. About 89.6% of doctors, 100% nurses, and 98.7% pharmacists gave correct responses regarding the most important purpose of pharmacovigilance.

ADR reporting - Attitude and practice

It was evident from the survey that most healthcare professionals had positive attitudes and practiced towards ADR reporting.

About 59.7% of doctors, 61.5% nurses, 64.9% pharmacists were aware of the process of ADR reporting; Only 18.3% doctors, 30.7% nurses, 25.9% Pharmacist had reported an ADR's; 35.6% doctors, 26.9% nurses, 98% Pharmacist had experienced ADR from the patient during their professional practice and 18.3% doctors, 34.6% nurses, and 80.5% Pharmacist are trained on ADR reporting.

Types of ADRs generally reported by subjects

When asked if they would report serious ADRs and life-threatening reactions, almost all HCPs said they would definitely report such reactions. Similarly, when asked if they report Severe ADRs and which can cause disability, 85% of doctors, 80.7% of nurses, 97.4% of pharmacists said they would definitely report such reactions. With regards to reporting all suspected reactions to new products, 74.7% of doctors, 65.3% nurses, and 84.4% of Pharmacists said they would definitely report such reactions.

Factors that encourage ADR reporting

Awareness creation on what, when, how, & to whom to report and increasing awareness at all levels of education, making the availability of the ADR's reports format, and Continuous Follow-up of patients were the three factors that encouraged ADR reporting as per the results. On the other hand, announcing ADR report as it is a professional obligation was not a major factor that influenced ADR reporting

Factors that discourage ADR reporting

As far as factors discouraging the reporting of ADRs are concerned, most of the respondents felt that lack of knowledge and awareness about the reporting process, fear of legal liability was the main reason followed by lack of information and lack of time.

V. CONCLUSION

The findings of this study show that health care professionals have improved their Knowledge of ADR reporting and have a commendable attitude toward a uniformly structured system of ADR reporting. The under-reporting issues can be corrected by conducting periodic educational interventional programs and sensitizing programs for the health care professionals working in the hospital, and timely feedback is a crucial strategy to enhance spontaneous ADRs reporting.

CONFLICT OF INTEREST:

The authors have no conflicts of interest regarding this investigation.

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