Knowledge, Attitude, and Practices toward Adverse Drug Reaction Reporting among Healthcare Professionals in South India: A Hospital-based Cross-sectional Study

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Abstract

Background: Underreporting of Adverse Drug Reactions (ADRs) is a major obstacle to the successful implementation of the Pharmacovigilance Program of India (PvPI).

Methods: A cross-sectional survey was conducted at a tertiary care hospital located in Nellore, Andhra Pradesh, India to assess the knowledge, attitude, and practice (KAP) level toward ADR reporting among healthcare professionals (HCPs). A validated, self-administered questionnaire was used to obtain information on socio-demographics, Pharmacovigilance (PV) exposure, ADR reporting preferences, reasons for underreporting, and KAP towards ADR reporting. Aunivariate combined with multivariate logistic regression analysis was used to assess factors associated with KAP toward ADR reporting.

Results: Among 396 HCPs, the majority of them showed a positive attitude towards the ADR reporting (254; 64.14%), but very few had good knowledge (102; 25.76%) and rational practices (97; 24.49%). Pharmacists and academicians were positively associated with good knowledge (*AOR* 8.56; 95%*CI* 4.23-18.62), positive attitude (*OR* 2.84; 95%*CI* 1.12-12.35), and rational practice (*AOR*4.13 95%*CI* 1.94-10.32) towards ADR reporting compared with the doctor. Whereas, nurses (*AOR* 0.19; 95%*CI* 0.12-0.74), lab technicians (*AOR* 0.11; 95%*CI* 0.01-0.74), and interns (*AOR* 0.38; 95%*CI* 0.12-0.93) were negatively associated with the practice of ADR reporting compared with doctors. Advanced age, healthcare experience, PV training, and work in the PV were shown a significant association with KAP towards ADR reporting.

Conclusion: Although the majority of HCPs expressed a positive attitude towards ADR reporting, there was a gap in the adequacy of knowledge and practices toward ADR reporting. Nurses and practicing interns have shown a very low KAP toward ADR reporting. The study recommends that PV training programs targeting individual professional needs, and barriers to underreporting can improve the reporting of ADRs among HCPs.

Keywords: Adverse drug reaction; Barriers, Pharmacovigilance; Knowledge; Healthcare professional; Drug safety.

Introduction

What is known/What does it Contribute

What is known

Since ADRs are a major cause of morbidity, mortality, and increased healthcare costs, all healthcare professionals need to be alert towards unknown/suspected ADRs for old or new drugs used in routine clinical practice. In India, most of the existing evidence of KAP towards ADR reporting was conducted among healthcare students or interns.

What does it contribute

Whilst KAP studies are required among healthcare students, a gap exists among working healthcare professionals toward ADR reporting. The current study contributes to filling the gap and explores the factors associated with knowledge, attitude, and practices toward pharmacovigilance and ADR reporting among healthcare professionals. The study provides insights for providing educational interventions among healthcare professionals to improve ADR reporting practices.

According to World Health Organization (WHO), an Adverse Drug Reaction is defined as "any noxious or unintended effect produced by the drug when it is given in doses for prophylactic, therapeutic, diagnostic, and alteration of the physiological function.[1]

Pharmacovigilance is a branch of pharmaceutical science that relates to the collection, detection, assessment, monitoring, and prevention of adverse effects associated with the use of pharmaceutical products.[1]

Adverse drug reactions are a major global public health concern that declines patients‟ health and increase the riskof hospitalizations, readmission, prolonged hospital stay, morbidity, mortality, and economic burden.[2] According to the Centre for Drug Evaluation and Research, ADR is the 4th leading cause of death in the United States (US).[3]Globally, 5% of hospitalizations are triggered by ADRs, and 10-20% of hospitalized patients can experience at least one ADR.[4]The management of ADRs is complex, in the USA it costs 30.1 billion dollars annually.[5] Hence, monitoring and management of adverse drug reactions is critical to promote global healthcare.

Though clinical trials are conducted to authorize the safety and efficacy of drugs before launching in the market. These trials are not enough to capture the rare events, safety concerns in special populations (Pediatrics, Geriatrics, and Pregnant women), and long-term effects of the drugs.[6] Hence, it is essential to have a national and global ADR surveillance system throughout the life cycle of the drug. Due to variations in the drug effects among individuals, prescribing practices, regulatory aspects, and availability of drugs in the market, it has been recommended to every country establish its own pharmacovigilance system.

In all countries, a spontaneous reporting system is a primary mode to report ADRs to the national coordinating centre (NCC) by healthcare professionals, manufacturers, and individuals. India acts as a member country in the WHO program for international drug monitoring managed Upsala Monitoring Centre (UMC), Sweden. In 2010, the Centre for Drugs Standard Control Organization (CDSCO), New Delhi under the aegis of the Ministry of Health and Family Welfare (MoHFW) initiated a nationwide pharmacovigilance program in July 2010, with the All-India Institute of Medical Sciences (AIIMS), New Delhi as NCC. Currently, a total of 250 ADR monitoring centers (AMCs) are existing nationwide to capture spontaneous reports submitted by healthcare professionals.[7]Though spontaneous ADR reports have the advantage of detecting a safety signal, they have major drawbacks like under-reporting, poor quality reports, and not possible to determine the incidence rate.[8]

The evidence shows that underreporting is one of the major obstacles faced by many Low- and Middle-Income Countries (LMICs), including India.[9]There are seven factors that are associated with underreporting of ADRs among healthcare professionals. These factors are referred to as „the seven deadly sins‟ of pharmacovigilance. These include the misconception that only serious ADRs must be reported, reluctance to report suspicious ADRs, perceiving that serious ADRs are already well documented, fear of litigation, guilt feeling for events observed in patients, lack of time, and lack of knowledge among healthcare professionals.[10]

The success of the pharmacovigilance system depends on the healthcare professionals‟ involvement in the promotion of drug safety by continuous and prompt reporting of ADRs. There is a need to identify the knowledge, attitude, and practice (KAP) gap existing among healthcare professionals about reporting ADRs and the promotion of drug safety. The current study aimed to assess the knowledge, attitude, and practices (KAP) of healthcare professionals toward ADR reporting and explore the factors associated with the KAP levels.

Methods

Study design and settings

A cross-sectional, self-administered, questionnaire-based survey was conducted at a tertiary care hospital located in Nellore, Andhra Pradesh, India to evaluate the KAP level and correlates associated with ADR reporting. The study was conducted for a period of one year from February 2020 to January 2021.

Stud population

A total of 950 healthcare staff comprising doctors, nurses, pharmacists, laboratory persons, interns, and academicians that are involved in direct patient care activities are our target population.

Study criteria

All healthcare professionals that are involved in direct patient care and willing to give consent to participate in the study are considered for inclusion. The healthcare professionals that are leave on the day of the survey and who are not willing to participate in the study are excluded.

Sample size and sampling technique

A single population proportion formula is used to determine the required sample size. Assuming 50% of the healthcare professionals have adequate knowledge about ADR, reporting, 95% confidence level, 5% margin of error, and 80% of power, the sample size was determined as 384. Considering the fact that there will be insufficient or incomplete responses, the sample size was increased by 10% to about 422.

A stratified random sampling technique was used to capture representation from all groups of healthcare professionals. The healthcare staff is divided into a stratum based on their profession which includes doctors, nurses, pharmacists, laboratory personnel, interns, and academicians. From each stratum, a simple random sampling technique was used to select the sample by using a random number table generator.

Ethical considerations

The study was protocol, data collection tool, and informed consent procedures were approved by Institutional

ethics committee (IEC/2019/0018). The study was conducted according to ICH-GCP guidelines. All the study subjects were explained about the study and its objectives, and informed consent was obtained.

Questionnaire and validation

A self-administered questionnaire was prepared based on the current literature available on knowledge, attitude, and practices toward ADR reporting. The questionnaire comprises four components: 1. Socio-demographics, Pharmacovigilance exposure, and Preferences of healthcare staff; 2. Knowledge about Pharmacovigilance system and ADR reporting; 3. Attitude towards ADR reporting 4. Practices toward ADR reporting

Socio-demographics, Pharmacovigilance Exposure, and Preferences of Healthcare Staff.

Socio-demographic characteristics like age, gender, profession, and healthcare experience are included in this section. The section also comprises previous exposure to pharmacovigilance areas like working in a department specialized in PV, undergoing any PV training program, studied PV courses in their graduation or postgraduation. In this section, respondents are given an option to their preferences for a better mode of communication of observed ADR, and reasons for underreporting of ADRs. Knowledge about the Pharmacovigilance system and ADR reporting

The knowledge domain comprises a total of 16 questions, that cover whether the respondent is aware of the Pharmacovigilance Program of India (PvPI) (K1), the definition of PV (K2) and ADR (K3), the difference between ADR and AE (K4), the difference between adverse effect and side effect (K5), recognizing ADR in the patient (K6), predisposing factors for ADR (K7), immediate measure to handle serious reaction (K8), the process of reporting ADR (K9, K11-K14), responsible healthcare staff to report (K10), and benefits from ADR reporting (K15, & K16). All correct answers are assigned a score of one and the wrong answer is zero. From each respondent, the maximum score expected was 16, and a minimum of zero. After scoring, the knowledge levels of the respondents are segregated into three domains based on Bloom‟s cut-off criteria. These include good (80-100% of maximum score), moderate (60-79% of maximum score), and poor knowledge (<60% of maximum score) levels. All knowledge questions are illustrated in Table 2.

Attitude toward ADR reporting

Healthcare professionals‟ attitude towards ADR reporting was assessed by using nine statements that cover professional responsibility (A1), education to all healthcare professionals (A2), the establishment of AMC (A3), components covered in PV (A4-A6), type of ADRs need to be reported (A7), impact on patient safety (A8), and close monitoring of new drugs safety concerns (A9). Participants‟ response to each statement was graded on a 3-point scale agree 3, neutral 2, and disagree 1. Statements A5 and A7 were reversely coded to reduce the respondents intentional bias. The maximum expected from each respondent is 27 and a minimum of 9. The outcome of the attitude domain is dichotomized into positive attitude (≥ 14 score) and negative attitude (< 14 score) based on the respondent's total score. All attitude statements are represented in Table 3.

Practice ADR reporting

Healthcare professional's practice towards ADR reporting is assessed by seven questions that cover notification of ADR in clinical practice (P1), reporting of ADR to the concerned authority (P2), willingness to undergo training (P3), and implementation PV in practice (P4), patient counseling regarding ADRs associated with drugs (P5), updating knowledge in PV (P6) and causality assessment (P7). Each correct answer is weighted as 1 and the wrong answer as 0. The maximum expected score from each respondent is seven and a minimum of zero. The outcome of the practice questionnaire was also dichotomized into „practice present‟ (score ≥ 4) and „no practice‟ (score <4) based on the total score attained in the practice questionnaire. All practice questions regarding ADR reporting are represented in Table 4.

Validation of data collection tool

An appropriately designed self-administered questionnaire was prepared by including various components like socio-demographics, PV exposure, ADR reporting preferences of the participants, reasons for underreporting, and KAP towards PV and ADR reporting. The questionnaire is subjected to content validity and reliability tests.

The content present in the questionnaire was evaluated by a panel of experts comprising PV specialists working PvPI, coordinator of AMC, Physician, Pharmacist, Nursing superintendent, and academician having experience in the ADR reporting system. Expert opinion on the inclusion of question/statement/component in the data collection tool was graded on a four-point Likert scale (Strongly disagree=1, Disagree=2, Agree=3, Strongly agree=4). The scale level content validity indicators like S-CVI/average number, S-CVI/Utility agreement, and item level content validity (I-CVI) were evaluated and the content was adjusted to an acceptable margin (>0.8) for each indicator.

The reliability of questions/statements/components indicated in the questionnaire was examined. The results of the reliability test performed in a pilot sample (n=30) revealed a Cronbach‟s alpha coefficient of 0.82 for the knowledge domain, 0.78 for the attitude domain, and 0.80 for the practice domain which represents acceptable internal consistency.

Data collection

A total of 396healthcare professionals who met the eligibility criteria were recruited in the study after clearing the informed consent process. A pre-tested, validated, self-administered questionnaire was used to obtain the information from the healthcare professionals. From each participant, information on socio-demographics, PV exposure, ADR reporting preferences of the participants, reasons for underreporting, KAP towards the PV system, and ADR reporting were collected. The collected data were subjected to data analysis to estimate the KAP levels towards PV and ADR reporting and explore the factors associated with the optimal KAP levels.

Data analysis

IBM SPSS software for Windows Version 26 (IBM Corp., Armonk, NY, USA) is used to analyze the data collected from healthcare professionals. Descriptive statistics like mean, standard deviation, and frequency were used to represent the socio-demographics and adequacy of KAP level towards PV and ADR reporting. A Univariate logistic regression analysis was used to correlate socio-demographics, and PV exposure, with KAP toward ADR reporting. The significant variables in Univariate analysis were subjected to Multivariate logistic regression analysis to assess the impact of confounders on the KAP level. A P-value less than 0.05 is considered statistically significant.

Results

A total of 409 eligible healthcare professionals are recruited after the informed consent process is cleared. By removing 13 incomplete filled questionnaires, 396 healthcare professionals" responses were subjected to the data analysis. The findings of the study revealed that most of the respondents belonged to the age group of less than 30 years (174; 43.94%), males (240; 60.61%), interns (108; 27.27%), no experience (206; 52.02%), not works in PV specialized department (375; 94.70%), no PV training exposure (378; 95.45%), and not studied PV in their UG/PG curriculum (280; 70.71%). Most of the respondents preferred to report ADRs through the mobile application (234; 59.09%). The most common barriers mentioned by healthcare professionals toward ADR reporting are lack of incentive (115; 29.04%) and time (59; 14.9%). The distribution of the sociodemographic, PV exposure, and respondents" preferences toward ADR reporting were represented in Table 1.

The healthcare professionals" knowledge regarding ADR reporting findings revealed that more than 70% of the participants gave correct responses on awareness about PvPI (284; 71.72%), the difference between ADR and side effects (329; 83.08%), immediate measures for serious ADR encountered in the patient (308; 77.78%), healthcare professionals responsible to report ADR (296; 74.75), and the impact of ADR reporting on patient safety (312; 78.79%). Only half of the respondents are given correct answers for the remaining knowledge questions. The distribution of the healthcare professionals" responses to knowledge questions were represented in Table 2.

Only half of the HCPs perceived ADR reporting as a professional obligation (212; 53.53%), ADR reporting should be a mandatory activity (210; 53.03%),and close safety monitoring is required for new drugs (198; 50.00%). Most of the HCPs believe that PV should be taught to all HCP (324; 81.82%), need for the establishment of AMC at every district hospital level (291; 73.48%), medication errors are also a part of PV (328; 82.83%), and ADR monitoring would improve patient care (334; 84.34%). The distribution of HCP agreed attitude statements on ADR reporting were represented in Table 3.

Healthcare professionals" practices towards ADR reporting findings revealed that less than half of the respondents noticed ADRs during their routine clinical practice (171; 43.18%). Very few healthcare professionals are reporting ADRs (94; 2.74%), willing to implement ADR reporting in their routine clinical practice (145; 36.62%), have undergone PV training (18; 4.54%), counseling patients about possible ADRs (116; 29.29%), and reading articles relevant to ADR management and prevention (22; 5.55%). The distribution of HCP practices toward PV and ADR reporting is represented in Table 4.

The adequacy of knowledge, attitude, and practice levels revealed that most of the HCPs showed a positive attitude towards the ADR reporting system (254; 64.14%), but very few HCPs are having good knowledge (102; 25.76%) and practices (97; 24.49%). The distribution of the adequacy level KAP towards ADR reporting was represented in Table 5.

Findings of the univariate and multivariate logistic regression analysis show that pharmacists and academicians were positively significantly associated with good knowledge (*AOR* 8.56; 95% *CI* 4.23-18.62), positive attitude (*OR* 2.84; 95% *CI* 1.12-12.35), and rational practice (*AOR*4.13 95% *CI*1.94-10.32) towards ADR reporting compared with the doctor. Whereas, nurses (*AOR* 0.19; 95% *CI* 0.12-0.74), lab technicians (*AOR* 0.11; 95% *CI* 0.01-0.74), and interns (*AOR* 0.38; 95% *CI* 0.12-0.93) were significantly negatively associated with the practice of ADR reporting compared with doctors. Advanced age, healthcare experience of more than one year, underwent PV training, and work in the department specialized PV was shown a significant association with KAP towards PV and ADR reporting. The distribution of the correlates associated with good knowledge, positive attitude, and rational practice were represented in Table 6.

Table 1: Socio-demographics, Pharmacovigilance Exposure, and Preferences of healthcare staff (n=396)

Variable	Frequency (%)
Age in years (Mean ± SD)	
< 30	174 (43.94)
31 – 40	98 (24.75)
41 – 50	86 (21.72)
> 50	38 (9.59)
Gender	
Male	240 (60.61)
Female	156 (39.39)
Profession	
Doctor	78 (19.69)
Nurse	104 (26.26)
Pharmacist	38 (9.59)
Intern	108 (27.27)
Lab-technician	18 (4.54)
Academician	28 (7.07)
Others	22 (5.55)
Healthcare experience in Years (Mean ± SD)	
No experience	206 (52.02)
1 – 5	112 (28.28)
6 – 10	33 (8.33)
11 – 15	25 (6.31)
16 – 20	8 (2.02)
> 20	12 (3.03)
Works in a department specialized in Pharmacovigilance	
Yes	21(5.30)
No	375 (94.70)
Sources of information about pharmacovigilance	
From healthcare professionals	12 (3.03)
Colleagues	15 (3.79)
Through seminars and training	18 (4.54)
Medical/Nursing/Pharmacy resource material	73 (18.43)
Advertisement/Print media	26 (6.56)
Part of academics	168 (42.42)
Social networking sites like Facebook, WhatsApp, LinkedIn etc.	84 (21.21)
Healthcare staff underwent pharmacovigilance training	
Yes	18 (4.54)
No	378 (95.45)
Preference mode for the reporting of ADRs	
Email	14 (3.53)
Telephone	26 (6.56)
Tollfree number	98 (24.75)
Speed post	0 (0.0)
Mobile application	234 (59.09)
ADR monitoring centre	24 (6.06)
Studied Pharmacovigilance in UG/PG Curriculum	
Yes	116 (29.29)
No	280 (70.71)
Reasons for underreporting of ADRs	
No remuneration	115 (29.04)
Lack of time	59 (14.90)
Difficult to classify whether ADR or a clinical condition	11 (2.78)
Additional administrative burden	33 (8.33)
No ideas about what to report and how to report	76 (19.19)
Afraid of legal complications	19 (4.79)
How will my one report can help	8 (2.02)
Only safe medicines exist in the practice	10 (2.52)
Physicians can publish as case reports rather than reporting to AMC	4 (1.01)
Difficult to identify causative drug	17 (4.29)
Problem of confidentiality	26 (6.56)
No encouragement	18 (4.54)

Table 2: Knowledge towards pharmacovigilance system and ADR reporting (n=396)

Knowledge variable	Correct (%)
K1. Are you aware ofthe Pharmacovigilance Programme of India?	284 (71.72)
K2. Which of the following best defines Pharmacovigilance?	254 (64.14)
K3. Which of the following best defines adverse drug reaction?	234 (59.09)
K4. Are the adverse drug reaction and adverse events being same?	268 (67.68)
K5. Is the adverse drug reaction and side effect being same?	329 (83.08)
K6. How to recognize ADR in the patient?	221 (55.81)
K7. What are the pre-disposing factors for the occurrence of ADR	235 (59.34)
K8. What is the immediate measure need to be taken to manage serious ADR	308 (77.78)
K9. Do you know how to report adverse drug reactions?	218 (55.05)

K10. Who among the following can report adverse drug reactions?	296 (74.75)
K11. Are you aware of the existence of an adverse drug reaction reporting form to report Adverse Events associated with the use of drugs?	216 (54.54)
K12. Where do you get ADR reporting form?	204 (51.51)
K13. What is the mandatory information need to be filled in the ADR form?	189 (47.73)
K14. Where to report an adverse drug reaction related to the use of Drugs?	192 (48.48)
K15. Do you think reporting of adverse drug reactions will improve patients‟ safety?	312 (78.79)
K16. Ultimately, who benefits from the ADR reporting?	320 (80.81)

Table 3: Attitude toward Pharmacovigilance system and ADR reporting (n=396)

Attitude variable	Agree (%)	Neutral (%)	Disagree (%)
A1. Adverse drug reaction reporting is a professional obligation.	212 (53.53)	10 (2.52)	174 (43.94)
A2. Do you think Pharmacovigilance should be taught to all healthcare professionals?	324 (81.82)	6 (1.51)	66 (16.67)
A3. An ADR monitoring centre is needed at every district hospital level.	291 (73.48)	31 (7.83)	74 (18.69)
A4. Do you think quality defects, lack of efficacy of drugs, medication errors, prescription errors, and dispensing errors are part of Pharmacovigilance?	328 (82.83)	14 (3.53)	54 (13.64)
A5. Adverse drug reactions are due to the errors made by the healthcare staff	116 (29.29)	38 (9.59)	242 (61.11)
A6. Do you think reporting adverse drug reactions should be mandatory for physicians, pharmacists, and Nursing staff?	210 (53.03)	42 (10.61)	144 (36.36)
A7. Only serious reactions associated with drugs need to be reported.	165 (41.67)	26 (6.56)	205 (51.77)
A8. ADR reporting and monitoring would improve the patient care	334 (84.34)	8 (2.02)	54 (13.64)
A9. Close monitoring is required in case of new drugs	198 (50.00)	35 (8.84)	163 (41.16)

Table 4: Practice toward Pharmacovigilance system and ADR reporting (n=396)

Practices	Yes (%)
P1. Have you ever noticed adverse drug reactions during your routine clinical practice?	171 (43.18)
P2. Have you ever reported Adverse Drug Reactions?	94 (23.74)
P3. Are you willing to implement adverse drug reaction reporting in your daily practice?	145 (36.62)
P4. Have you ever been trained for reporting adverse drug reactions or pharmacovigilance	18 (4.54)
P5. Patient counseling about possible ADRs associated with drugs	116 (29.29)
P6. Reading article in relation to prevention of ADR	22 (5.55)
P7. Assessment of causality	10 (2.52)

Table 5: Adequacy of Knowledge, Attitude, and Practice towards ADR reporting (n=396)

Variable	Frequency (%)
Knowledge	
Good knowledge	102 (25.76)
Moderate knowledge	135 (34.09)
Poor knowledge	159 (40.15)
Attitude	
Positive attitude	254 (64.14)
Negative attitude	142 (35.86)
Practice	
Good practice	97 (24.49)
No practice	299 (75.50)

ADR=Adverse Drug Reaction

Table 6: Correlation of socio-demographics with KAP towards Pharmacovigilance among healthcare staff

Characteristics	Total (%)	Good knowledge (102)	COR (95% CI), *P-value*	AOR (95% CI), *P-value*	Positive attitude (254)	OR (95% CI), *P-value*	AOR (95% CI), *P-value*	Rational practice (97)	OR (95% CI), *P-value*	AOR (95% CI), *P-value*
Age (Years)										
≤ 30	174 (43.94)	38 (21.84)	1.00	1.00	88 (50.57)	1.00	1.00	25 (14.37)	1.00	1.00
31-40	98 (24.75)	23 (23.47)	1.09 (0.60-1.98)	-	64 (65.31)	1.83 (1.10-3.08) *	1.74 (1.62-2.68) *	21 (21.43)	1.62 (0.84-3.09)	-
41-50	86 (21.72)	29 (33.72)	1.81 (1.02-3.23) *	0.92 (0.89-1.62)	72 (83.72)	4.99 (2.66-9.81) ***	3.94 (2.12-7.87) **	28 (32.56)	2.86 (1.54-5.36) ***	2.21 (1.65-6.83) **
> 50	38 (9.59)	12 (31.58)	1.64 (0.74-3.55)	-	30 (78.95)	3.64 (1.62-8.91) **	2.76 (1.68-7.54) **	23 (60.53)	9.00 (4.16-19.99) ***	8.54 (5.24-14.62) **
Gender										
Male	240 (60.61)	58 (24.17)	1.00	1.00	150 (62.50)	1.00	1.00	61 (25.42)	1.00	1.00
Female	156 (39.39)	44 (28.20)	1.23 (0.78-1.95)	-	104 (66.67)	1.19 (0.79-1.84)	-	36 (23.08)	0.88 (0.54-1.41)	-
Profession										
Doctor	88 (22.22)	20 (22.73)	1.00	1.00	60 (68.18)	1.00	1.00	26 (29.54)	1.00	1.00
Nurse	104 (26.26)	14 (13.46)	0.53 (0.24-1.13)	-	62 (59.61)	0.69 (0.38-1.25)	-	11 (10.58)	0.28 (0.13-0.61) ***	0.19 (0.12-0.74) ***
Pharmacist	50 (12.63)	26 (52.00)	3.64 (1.73-7.81) ***	2.45 (1.64-6.68) **	35 (70.00)	1.09 (0.51-2.35)	-	24 (48.00)	2.19 (1.06-4.54) *	2.01 (1.03-3.94) *
Intern	108 (27.27)	19 (17.59)	0.72 (0.36-1.48)	-	69 (63.89)	0.83 (0.45-1.50)	-	16 (14.81)	0.41 (0.20-0.84) *	0.38 (0.12-0.93) *
Lab-technician	18 (4.54)	01 (5.56)	0.20 (0.01-1.23)	-	3 (16.67)	0.09 (0.02-0.33) ***	0.04 (0.01-0.26) **	1 (5.56)	0.14 (0.01-0.85) *	0.11 (0.01-0.74) *
Academician	28 (7.07)	21 (75.00)	9.94 (3.78-27.45) ***	8.56 (4.23-18.62) ***	25 (89.28)	3.85 (1.15-17.24) *	2.84 (1.12-12.35) *	19 (67.86)	4.95 (2.00-12.92) ***	4.13 (1.94-10.32) **
Healthcare experience (Y)										
No experience	206 (52.02)	27 (13.11)	1.00	1.00	121 (58.74)	1.00	1.00	32 (15.53)	1.00	1.00
1 – 5	112	44 (39.28)	4.26	3.92	72	1.26	-	34	2.36	2.24

	(28.28)		(2.46-7.50) ***	(2.39-8.02) ***	(64.28)	(0.78-2.04)		(30.36)	(1.36-4.12) **	(1.23-3.14) *
6 – 10	33 (8.33)	13 (39.39)	4.27 (1.87-9.63) ***	5.38 (2.91-9.32) **	24 (72.73)	1.86 (0.84-4.43)	-	12 (36.36)	3.09 (1.35-6.90) **	3.26 (1.48-7.39) *
11 – 15	25 (6.31)	11 (44.00)	5.15 (2.07-12.67) ***	6.13 (3.12-11.56) **	21 (84.00)	3.67 (1.29-12.89) *	3.12 (1.20-11.34) *	10 (40.00)	3.59 (1.44-8.76) **	4.28 (1.08-7.94) *
> 15	20 (5.05)	7 (35.00)	3.54 (1.22-9.67) **	4.26 (2.68-9.32) *	16 (80.00)	2.79 (0.94-10.05)	-	9 (45.00)	4.41 (1.64-11.68) **	4.02 (1.72-10.34) **
PV training										
Yes	18 (4.54)	13 (72.22)	8.38 (2.98-26.84) ***	8.02 (2.36-20.35) **	17 (94.44)	10.08 (1.79-214.9) **	9.62 (2.01-112.2) **	16 (88.89)	29.96 (7.71-196.2) ***	28.26 (6.54-112.2) **
No	378 (95.45)	89 (23.54)	1.00	1.00	237 (62.69)	1.00	1.00	79 (20.90)	1.00	1.00
Works in PV										
Yes	21 (5.30)	18 (85.71)	20.59 (6.43-89.55) ***	20.01 (5.38-7.64) **	18 (85.71)	3.52 (1.11-15.25) *	3.01 (1.96-13.22) *	16 (76.19)	11.52 (4.23-36.11) ***	10.64 (3.92-29.01) **
No	375 (94.70)	84 (22.40)	1.00	1.00	236 (62.93)	1.00	1.00	81 (21.60)	1.00	1.00

* <0.05, **<0.01, ***<0.001, AOR=Adjusted Odds Ratio, COR=Crude Odds Ratio

Discussion

Since ADRs are a major cause of morbidity, mortality, and increased healthcare costs, all healthcare professionals need to be alert towards unknown/suspected ADRs for old or new drugs used in routine clinical practice. In India, most of the existing evidence on KAP towards ADR reporting was conducted among healthcare students or interns. Whilst KAP studies are required among healthcare students, there is a gap existing among working healthcare professionals toward ADR reporting. The current study addresses this gap and explores the factors associated with KAPs towards PV and ADR reporting among healthcare professionals.

The study findings revealed that the adequate knowledge levels on ADR reporting among healthcare professionals were very low 25.76%. These findings were nearly similar to the findings of the studies conducted in Northeast Ethiopia (24.56%), and South Africa (23.2).[11,12] However, the knowledge level reported in this study is low compared to the studies conducted in Nepal (39.4%), Saudi Arabia (39.6%), Gondar Town-Ethiopia (53%), and Jordan (50%).[11,13–15]A study conducted in Nigeria revealed that only 15% of HCP have adequate knowledge of ADR reporting which is lower than the current study.[16]Healthcare professionals' wide variation in knowledge levels is due to changes in clinical practice, implementation of nationwide pharmacovigilance programs, exposure to training programs, availability of medication safety resources, and time points of the survey analysis. The difference in HCP knowledge is not only found among different nations but even it was reflected in various studies conducted in India. This difference may be due to the availability of the ADR monitoring center (AMC) in the hospital or nearby hospital. The low HCP knowledge level observed in our study may be due to a lack of AMC in the hospital.

Whilst the majority (71.72%) of the HCPs are aware of the Pharmacovigilance Program of India, the knowledge regarding the definition of PV (64.14%) and ADR (59.09%) is low. Our study findings on definitions were low compared to a study conducted among pediatricians in Odisha (73.3%), and pharmacists in China (88%).[17,18] The prime reason for variation in understanding the definitions might be due to the inclusion of pediatricians or pharmacists alone in elsewhere studies. Whereas, awareness about definitions is high in the current study compared to a study conducted in Ethiopia (8%).[11]The findings reveal that 83.08% of HCPs can differentiate the adverse effect and side effects, but only 67.68% of them distinguish the

difference between adverse effects and adverse events. The knowledge findings of HCPsshow that only half of the respondents were aware of how to recognize ADR among patients, predisposing factors for ADR, the form used in reporting, mandatory information that needs to be filled in the ADR form, and where to report the ADRs. This indicates that there is a need to sensitize all healthcare professionals regarding the process of the ADR reporting system. Though the majority of healthcare professionals are aware of PvPI, the deficit levels of knowledge regarding the process of the ADR reporting system may act as a hurdle for practical implementation. The current study findings revealed that 53.53% of healthcare professionals felt that ADR reporting is a professional obligation. Still, nearly half the respondents were unaware of the ADR reporting as a healthcare professional responsibility. There is a need to have personal discussions, awareness programs, and drug safety policy changes in the hospital settings to resolve misconceptions about ADR reporting existing among the healthcare fraternity and drive positive attitudes towards ADR reporting.[19]Despite adequate knowledge and practices ADR reporting is low among HCPs, the majority (64.14%) of HCPs show a positive attitude towards ADR reporting. The positive attitude among HCPs to report ADRs is very high compared to the study conducted in Malaysia (26.9%), and West Ethiopia (42.1%).[20,21] But the current finding is lower compared to the studies conducted in Nepal (66.3%), Gondar town, North Ethiopia (86%), and other parts of India (90%).[11,13,22] The positive attitude of HCPs present in this study will favor transforming their perception into real practice by providing systematic hands-on training programs on reporting ADRs.

In the current study, only half of the respondents believe that close safety monitoring is required for new drugs. Close monitoring of new medications is required for the development of ADRs since clinical trials frequently miss safety issues in vulnerable populations (Pediatrics, geriatrics, pregnant and lactating women, and critically ill patients), long-term effects, and uncommon adverse drug reactions. Thus, HCPs must closely monitor the development of ADRs for new drugs in patients by using active surveillance or a spontaneous reporting system. About 41.67% of healthcare professionals are wrongly perceived that only serious ADRs need to be reported to the concerned authorities. Irrespective of the seriousness of ADR, monitoring all types of ADRs is a critical standpoint for the successful implementation of PV in hospital care settings.

Though 43.18% of the HCPs noticed ADRs among patients during their routine clinical practice, the practice of reporting ADRs is very low among healthcare professionals. Only 23.74% of healthcare professionals are practicing reporting of the ADRs. This estimate is in contrast with the findings of the studies conducted in Gondar (55.9%), Addis Ababa (38%), South Western Nigeria (37.5%), Pakistan (60%), and Nepal (38%).[11,13,16,19,23]In the current study, the most common reasons for the underreporting were no remuneration, lack of time, not clear about ADR diagnosis, no idea about reporting procedure, the problem of confidentiality, legal concerns, HCPs‟belief that safe medicines only existed in practice, and difficult to identify a causative drug. Similar reasons for not reporting ADRs by HCPs are also observed in elsewhere studies. [11–14,19,20,23] The practices of healthcare providers may be improved by implementing educational and training modules based on the causes of underreporting of ADRs that were discovered in this study. The findings of practice towards ADR reporting reveal that very few HCPs are trained in PV (4.54%), read articles on ADR prevention (5.55%), and can assess causality (2.52%) of ADR by using standard scales.

Evidence shows that there are several regulatory interventions have proven to improve the practice of ADR reporting among HCPs including discussing rational medicine use in national medical congresses, make availability of public ADR reporting services, hanging posters about ADR reporting on the walls of hospitals, and providing contact information on the labels of medicines.[24–27] The current study suggests that incorporating mobile applications in the reporting of ADRs for HCPs and the public, organizing continuous educational programs highlighting the significance of ADR reporting, and rewarding good quality ADR reports may increase the reporting rate among HCPs.

In the current study pharmacists and academicians were positively significantly associated with good knowledge (*AOR* 8.56; 95% *CI* 4.23-18.62), positive attitude (*OR* 2.84; 95% *CI* 1.12-12.35), and rational practice (*AOR*4.13 95% *CI* 1.94-10.32) towards ADR reporting in relation to the doctor. Whereas, nurses (*AOR* 0.19; 95% *CI* 0.12-0.74), lab technicians (*AOR* 0.11; 95% *CI* 0.01-0.74), and interns (*AOR* 0.38; 95% *CI* 0.12-0.93) were significantly negatively associated with the practice of ADR reporting in relation to doctors. Similar to the findings of the current study, a study conducted in a public hospital in North East Ethiopia also showed nurses and interns had inadequate knowledge compared with pharmacists.[11] Nurses contribute a vital role in medication administration in hospitalized patients. So, all nurses need to be well-trained in the recognition and reporting of ADRs to promote medication safety in hospitalized patients. Advanced age, healthcare experience of more than one year, underwent PV training, and work in the department specialized PV was shown a significant positive association with KAP towards PV and ADR reporting. The correlates of ADR reporting suggest that formal training and work experience in PV are vital to acquire adequate knowledge, positive attitude, and rational practice toward

ADR reporting among healthcare professionals. So, organizing educational programs that inculcate PV in routine clinical practice may improve the HCP‟s practices towards ADR reporting.

Strengths and limitations

The primary strength of this study is diverse healthcare professionals that are responsible to promote medication safety have participated in the current study. The study provides insights for providing educational interventions among healthcare professionals to improve ADR reporting practices. As the study was conducted by using a self-administered questionnaire, there is a chance of response bias from the respondents. Though we had maintained the anonymity of the identifiers of the respondents, there will be a risk of hospital administrator influence over the findings of the study. In addition to the current research, qualitative research and in-depth analysis are required to understand individual healthcare professional requirements and barriers to ADR reporting.

Conclusion

In conclusion, majority of HCPs expressed a positive attitude towards ADR reporting, there was a gap in the adequacy of knowledge and practices toward ADR reporting. Nurses and practicing interns have shown a very low KAP toward ADR reporting. The study recommends that the implementation of structured hands-on training programs targeting individual medical professional needs, barriers to underreporting, and promoting the availability of mobile application facilities can improve the reporting of ADRs among healthcare professionals.

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