Volume 8, Issue 4 July-Aug 2023, pp: 1317-1329 www.ijprajournal.com ISSN: 2249-7781

Assessment of Knowledge, Attitude and Practice of Community Pharmacists towards Pharmacovigilance

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Submitted: 20-07-2023 Accepted: 31-07-2023

ABSTRACT: This study aimed to assess the knowledge, attitude, and practice (KAP) of community pharmacists towards pharmacovigilance, which plays a critical role in identifying and preventing adverse drug reactions. The objectives were to evaluate the pharmacists' understanding of pharmacovigilance principles, their attitudes towards adverse drug reaction (ADR) reporting, and their current practices in pharmacovigilance activities. The study was conducted through a prospective cross-sectional design in Thiruvananthapuram District, Kerala, over four months. Data was collected using validated questionnaires, and ethical considerations were followed. The results showed that a majority of the participants were female and young pharmacists with a D Pharm qualification. While the knowledge and attitude of community pharmacists towards pharmacovigilance were good, their actual practice of ADR reporting was unsatisfactory. The study concluded that targeted education programs and awareness campaigns should be implemented to enhance the knowledge, attitude, and practice of community pharmacists, ultimately improving patient care safety and quality.

KEYWORDS: Adverse Drug Reaction, Knowledge, Attitude, Practice, Questionnaire, Community Pharmacists, Pharmacovigilance.

I. INTRODUCTION

Pharmacovigilance, defined as the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems, plays a vital role in ensuring the safe and effective use of medications. Community pharmacists, as accessible healthcare professionals, have a significant responsibility in pharmacovigilance by identifying, reporting, and managing adverse drug reactions (ADRs).

Traditionally, a community pharmacist's only responsibility has been to prepare and dispense the medications that a patient has been given. In recent years, the responsibilities of pharmacists have changed from being product-oriented to being patient-oriented. These responsibilities include tracking and reporting new ADRs [1]. The worldwide drug safety monitoring systems heavily depend on all healthcare professionals' spontaneous reporting of adverse drug reactions (ADRs). Community pharmacists, like other health care professionals, play a larger role in the formal reporting system and add to the pharmacovigilance system in most developed nations. They must have good knowledge, attitudes, and practices in reporting adverse drug reactions (ADRs) because they are the most approachable healthcare providers. With the goal of improving the accuracy of reporting ADRs, numerous studies have been carried out to examine pharmacists' knowledge and attitudes towards ADR reporting. These studies have also successfully identified the critical factors affecting their knowledge and attitudes [2, 3]. Poor understanding and practice compromise community pharmacists' ability to report ADRs in India, which needs to be resolved. Medication safety will be enhanced by community pharmacists fostering a culture of reporting adverse drug reactions (ADRs) and raising knowledge of medication safety [1]. With this background, the present study is being carried out to assess the level of knowledge, attitude and practice of community pharmacists towards pharmacovigilance.

Knowledge refers to the understanding and awareness of pharmacovigilance principles, including the identification, documentation, and reporting of ADRs. Attitude encompasses the perception, beliefs, and motivation of community pharmacists towards pharmacovigilance, including their willingness to report and contribute to the

Volume 8, Issue 4 July-Aug 2023, pp: 1317-1329 www.ijprajournal.com ISSN: 2249-7781

overall safety of drug therapy. Practice reflects the implementation of pharmacovigilance activities in daily routines, such as ADR monitoring, documentation, and reporting.

By conducting this assessment, we aim to identify potential gaps in knowledge, attitudes, and practices among community pharmacists. The findings will serve as a foundation for developing targeted interventions, training programs, and strategies to enhance pharmacovigilance activities in community pharmacy settings. Ultimately, improving the knowledge, attitude, and practice of community pharmacists towards pharmacovigilance will contribute to the overall safety and quality of patient care.

II. AIMS AND OBJECTIVES

- To develop, validate and test the reliability of knowledge, attitude and practice questionnaires pharmacovigilance for community pharmacists.
- To assess the knowledge, attitude and practice pharmacists community towards pharmacovigilance.
- To assess the level of knowledge among community pharmacists pharmacovigilance principles, including the identification, documentation, and reporting of adverse drug reactions (ADRs).
- To evaluate the attitudes and beliefs of community pharmacists towards pharmacovigilance, including their perception of the importance of ADR reporting and their willingness to participate in pharmacovigilance activities.
- To examine the current practices of community pharmacists in relation to pharmacovigilance, including ADR monitoring, documentation, and reporting.
- To identify any gaps or deficiencies in knowledge, attitudes, and practices of community pharmacists towards pharmacovigilance.
- To explore the challenges faced by community pharmacists in implementing pharmacovigilance activities and reporting ADRs.
- To gather insights and recommendations from community pharmacists on strategies to improve their engagement pharmacovigilance activities and enhance patient safety.
- To provide recommendations for training programs, interventions, and policy measures

- that can improve the knowledge, attitude, and practice of community pharmacists towards pharmacovigilance.
- To contribute to the overall improvement of patient safety and the quality of healthcare services provided by community pharmacists through increased pharmacovigilance awareness and engagement.
- By achieving these objectives, the project aims to generate valuable data that can inform the development of targeted interventions, training programs, and policies to pharmacovigilance practices among community pharmacists. Ultimately, the project seeks to improve patient safety, promote adverse event reporting, and strengthen the role of community pharmacists in safeguarding the appropriate use of medications in the community setting.

III. MATERIALS AND METHODS MATERIALS REQUIRED

- Data collection form
- Informed consent form
- Validated KAP Ouestionnaire

DATA SOURCES

All the relevant and necessary data were collected by Interviewing community pharmacists

METHODOLOGY

Study Design: Prospective cross-sectional study Study site: Various community pharmacies of Thiruvananthapuram District, Kerala

Duration of Study: Four months (March 2023- June 2023)

Subjects: Registered pharmacists presently employed community pharmacists as Thiruvananthapuram District, Kerala

Sample size: A study was conducted by Alam K et al; observed the standard deviation of the knowledge domain among community pharmacists as 1.79. Taking this reference, at 5% level of significance and marginal error of 20 % of S.D is 0.358. The minimum sample size is estimated using the formula

$$n = \frac{\left[\left(z\frac{\alpha}{2}\right)^2 \times \sigma^2\right]}{E^2}$$

Where, σ is S.D

 $\left(z\frac{\alpha}{2}\right)$ is a constant i.e., 1.96 E is Marginal error

So, the minimum sample size estimated is 96 Further assuming 10% non-response rate, sample size required is 96+10% of 96≈106



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SAFETY CONSIDERATIONS

Ethical considerations: The study purpose was explained to all the participants, and they were enrolled only after obtaining informed consentsigned. The privacy and confidentiality of all participants will be protected. Data collection will be initiated only after obtaining permission from the concerned authority.

Inclusion Criteria: Subjects of both gender, who at least have a D. Pharm qualification and are registered under the State Pharmacy Council, presently working as community pharmacists in the district of Thiruvananthapuram, Kerala.

Exclusion Criteria: Registered Community pharmacists who are not willing to take part in the study.

OPERATIONAL MODALITY

Development, validation and reliability of the KAP Questionnaire: The KAP Questionnaire on Pharmacovigilance for community pharmacists was prepared by consulting various primary, secondary and tertiary resources of information. After preparation, it was validated by an expert committee of members, consisting of academic pharmacists and clinical pharmacists. Test-retest reliability was carried out by administering the prepared questionnaire to a random sample of 20 community pharmacists two times, 7 days apart. A Cronbach alpha value of greater than 0.70 is considered acceptable.

Data collection: A well-designed data collection form was prepared as per the need of the study. Data including gender, age, domiciliary status, work experience (in years), and educational qualification were collected. The previously validated KAP Questionnaire was administered to the subjects to get their responses recorded in it.

Statistical Analysis: Qualitative data were presented as frequency and percentage. And Quantitative data as mean and standard deviation. Statistical Package for the Social Sciences software was used to analyse the collected data.

IV. RESULT AND DISCUSSION RELIABILITY OF THE KAP QUESTIONNAIRE: Test-retest reliability was

carried out by administering the validated KAP questionnaire to a random sample of 20 community pharmacists two times, 7 days apart. On analysis, the Cronbach alpha value of the Knowledge, Attitude and Practice domain was found to be above 0.70. The details are summarised in Table 1.

DISTRIBUTION OF SUBJECTS BASED ON THEIR SOCIO-DEMOGRAPHIC CHARACTERISTICS:

a. Distribution of subjects based on their Gender

Out of 106 subjects, 37 (34.9%) were Males and 69 (65.1%) were females. The details are summarised in the table2 and figure1

b. Distribution of subjects based on their Age groups

The mean age of the subjects enrolled was found to be 29.77 ± 6.48 SD. Out of the total subjects enrolled,71 (67.0%) was found to be within the age group of \leq 30 years whereas 35 (33.0%) were of \geq 31 years of age. The details are summarised in Table 3 and figure2.

c. Distribution of subjects based on their Domiciliary status

Out of total subjects,38 (35.8%) was found to be within the domiciliary status of rural and the rest of the 68 (64.2) were of urban status. The details are summarised in table4 and figure3.

d. Distribution of subjects based on their Educational qualification

Out of 106 subjects, 90 (84.9%) were found to be in Diploma in Pharmacy qualified and the remaining 16 (15.1) were found to be Bachelor of Pharmacy qualified. The details are summarised in Table5 and figure4

e. Distribution of subjects based on their Work experience groups

Out of the total subjects enrolled, 88 (83.0%) were found to be within the work experience group of \leq 10 years whereas 18 (17.0%) were of \geq 11 years of work experience. The details are summarised in Table 6 and figure5.

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Table 1: Reliability of the KAP Questionnaire

Domain	Day1 Score (Mean ± SD)	Day7 Score (Mean ± SD)	Cronbach's Alpha value
Knowledg e	3.25±1.4	3.30±1.45	0.994
Attitude	3.45±1.14	3.45±1.14	1
Practice	1.25±1.55	1.30±1.55	0.995

Table2: Distribution of subjects based on their Gender

Gender	Frequency (n)	Percentage (%)
Male	37	34.9
Female	69	65.1
Total	106	100

Figure1: Distribution of subjects based on their Gender

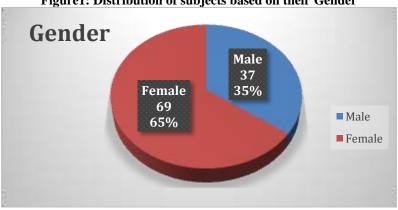


Table3: Distribution of Subjects based on their Age group

Age group	Frequency (n)	Percentage (%)
≤30 years	71	67.0
≥31 years	35	33.0
Total	106	100.0

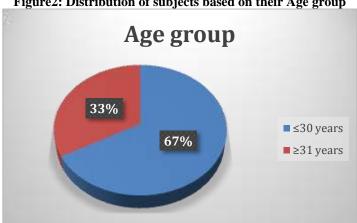


Figure 2: Distribution of subjects based on their Age group

Table4: Distribution of subjects based on their Domiciliary status

Domiciliary Status	Frequency (n)	Percentage (%)
Rural	38	35.8
Urban	68	64.2
Total	106	100.0

Figure 3: Distribution of subjects based on their Domiciliary status

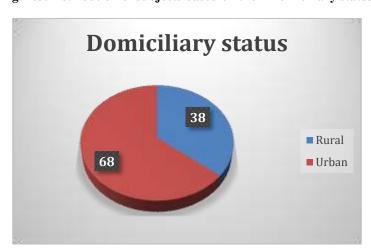


Table5: Distribution of subjects based on their Educational qualification

Educational Qualification	Frequency (n)	Percentage (%)
D Pharm	90	84.9
B Pharm	16	15.1
Total	106	100.0

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Figure 4: Distribution of subjects based on their Educational qualification

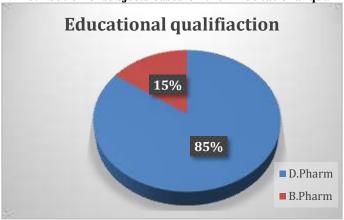


Table6: Distribution of subjects based on their Work experience group

Work Group	Experience	Frequency (n)	Percentage (%)
≤10 years		88	83.0
≥11 years		18	17.0
Total		106	100.0

Figure5: Distribution of subjects based on their Work experience group





International Journal of Pharmaceutical Research and Applications Volume 8, Issue 4 July-Aug 2023, pp: 1317-1329 www.ijprajournal.com ISSN: 2249-7781

DISTRIBUTION OF SUBJECTS BASED ON THEIR RESPONSES

Distribution of subjects based on their responses through Knowledge domain questions

Table7: Distribution of sub	iects based on their respons	ses through Knowledge (domain questions

	wledge Domain	*	Frequency	Percentage
	_		(n)	(%)
Q1	Which among the following is the best definition of Pharmacovigilance?	The science and activities relating to the detection, assessment, understanding and prevention of adverse effects	98	92.5
		The science of ADR monitoring in hospitals by doctors	6	5.7
		The science of identifying the class of ADR	1	0.9
		None of the above	1	0.9
Q2	What does ADR stand for?	Adverse Drug Reaction	100	94.3
		Adverse Disease Reaction	5	4.7
		Active Drug Reaction	1	0.9
		None of the above	0	0
Q3	Which among the following ADRs need to	Serious life- threatening	16	15.1
	be reported	ADRs to newer drugs	5	4.7
		ADRs to vaccines	2	1.9
		All of the above	83	78.3
Q4	Who among the following	Pharmacists	24	22.6
	is qualified to report ADRs?	Doctors	12	11.3
	ADINS:	Nurses	0	0
		All of the above	70	66
Q5	Which among the	CDSCO	70	66.6
	following is the regulatory body for ADR monitoring	FDA	7	6.6
	and reporting in India?	TGA	6	5.7
		AIIMS	23	21.7



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Distribution of subjects based on their responses Attitude domain questions

Table8: Distribution of subjects based on their responses through Attitude domain questions

Atti	tude Domain		Frequency (n)	Percentage (%)
Q1	Do you think it is necessary	Yes	105	99.1
	to report ADRs?	No	0	0
		Don't know	1	0.9
Q2	Do you think reporting ADR	Yes	102	96.2
	will benefit the patient?	No	2	1.9
		Don't know	2	1.9
Q3	Do you think only healthcare	Yes	57	53.8
	professionals can report ADRs?	No	46	43.4
	ADKs:	Don't know	3	2.8
Q4	Are you willing to report an	Yes	101	95.3
	ADR if it's identified during your professional practice?	No	5	4.7
Q5	Do you think that	Yes	93	87.7
	surveillance of drug safety is	No	1	0.9
	important?	Don't know	12	11.3

Distribution of subjects based on their responses Practice domain questions

Table9: Distribution of subjects based on their responses through Practice domain questions

Prac	ctice Domain	•	Frequency (n)	Percentage (%)
Q1	Have you ever identified an ADR among patients presenting to your	Yes No	74 32	69.8 30.2
Q2	pharmacy? Have you seen an ADR reporting	Yes	15	14.2
	form by CDSCO?	No	91	85.8
Q3	- 1		9	8.5
	ADR to a reporting centre?	No	97	91.5
Q4	Have you ever participated in any	Yes	19	17.9
awareness program on pharmacovigilance?		No	87	82.1
Q5	Do you have a habit of reading	Yes	44	41.5
	scientific literatures on pharmacovigilance for gaining upto-date information?	No	62	58.5

Table 7,8 and 9 summarises the details of responses provided by the subjects to the questions under the domains of Knowledge, Attitude and Practice.

Assessment of knowledge, Attitude and Practice of the subjects

Byassigning a score of '1' for every correct/positive response of Knowledge, Attitude

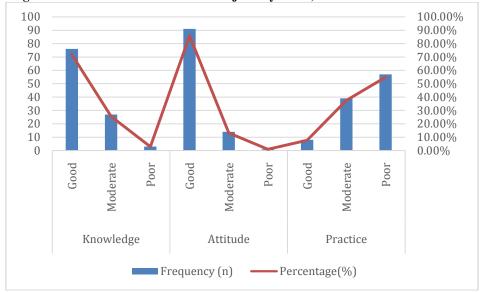


and Practice Questionnaire and assessed the subjects by grouping into Good, Moderate and Poor level. Out of 106 subjects, 76(71.70%) has good Knowledge, 91 (85.85%) have good Attitude and only 8 (7.69%) have good Practice towards pharmacovigilance. The details are summarised in table 10

Table 10: Assessment of KAP of the subjects by Good, Moderate and Poor level

Domain	Level Frequency (n) Percentage (%)		
Domain	Level	Frequency (II)	refeeltage (76)
Knowledge	Good	76	71.70%
	Moderate	27	25.47%
	Poor	3	2.83%
Attitude	Good	91	85.85%
	Moderate	14	13.21%
	Poor	1	0.94%
Practice	Good	8	7.69%
	Moderate	39	37.50%
	Poor	57	54.81%

Figure6: Assessment of KAP of the subjects by Good, Moderate and Poor in level



The mean Knowledge, Attitude and Practice scores of the total subjects enrolled in the study were found to be 3.95 ± 1.07 , 4.20 ± 0.81 and 1.53 ± 1.16 respectively. The details are summarised in table 11.

Table11: Assessment of KAP of the subjects

Domain	Mean±SD
Knowledge	3.95±1.07
Attitude	4.20±0.81
Practice	1.53±1.16



Volume 8, Issue 4 July-Aug 2023, pp: 1317-1329 www.ijprajournal.com ISSN: 2249-7781

V. SUMMARY AND CONCLUSION

This project work conducted a prospective, cross-sectional survey using questionnaires to evaluate the knowledge, attitude, and practice of community pharmacists regarding adverse drug reaction (ADR) reporting. The study aimed to assess the current status of ADR reporting among community pharmacists. The survey included a higher percentage of female participants, reflecting the increased representation of female pharmacists in community pharmacies. The respondents primarily consisted of young pharmacists, based on their age and working experience. Additionally, a significant portion of the pharmacists held a D Pharm qualification. The findings of this study provide insights into the ADR reporting practices of community pharmacists, highlighting areas that may require further attention and improvement.

In conclusion, the project work highlights the need for significant improvements in the practice of adverse drug reaction (ADR) reporting among community pharmacists. Although they possess good knowledge and a positive attitude towards pharmacovigilance, the actual reporting of ADRs remains unsatisfactory due to various factors, including a lack of proper training, guidance, and reporting systems.

To address these challenges and enhance ADR reporting, targeted education programs and awareness campaigns should be developed specifically for community pharmacists. Adopt continuous educational programme to enhance the current practices of community Pharmacists regarding pharmacovigilance and ADR reporting. Especially training and education about the types of ADRs to be reported can help to improve the reporting of ADRs.

Additionally, the implementation of efficient reporting mechanisms, such as user-friendly online platforms or dedicated reporting tools, can significantly boost ADR reporting rates. Simplifying the reporting process and providing clear guidelines will encourage community pharmacists to participate more actively in reporting ADRs, thereby enhancing drug safety monitoring.

Fostering a culture of open communication and collaboration between community pharmacists and healthcare professionals is also crucial. Creating a supportive environment where pharmacists feel comfortable reporting ADRs and where reporting is considered a professional responsibility will lead to increased reporting rates.

By addressing the lack of proper reporting systems and promoting a collaborative culture,

along with the education and awareness initiatives, the overall practice of ADR reporting among community pharmacists can be significantly improved. These efforts will contribute to better pharmacovigilance activities and, ultimately, enhance the safety and quality of patient care.

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ANNEXURE

INFORMED CONSENT FORM

Study Title: ASSESSMENT OF KNOWLEDGE, ATTITUDE AND PRACTICE OF COMMUNITY PHARMACISTS TOWARDS PHARMACOVIGILANCE

Investigators: Akhilesh A.B, Reshmi R & Swathy Raj V.R (8th semester B. Pharm Students)

We are doing a project entitled "ASSESSMENT OF KNOWLEDGE, ATTITUDE AND PRACTICE OF COMMUNITY PHARMACISTS TOWARDS PHARMACOVIGILANCE"

The study procedure involves no foreseeable risk or harm to you. In the study procedure, your participation is voluntary; you are under no obligation to participate. You have the right to withdraw at any time.

The study data will be coded. So, your identity will not be revealed while the study is being conducted or when the study is reported or published. All study data will be collected by us Akhilesh A.B, Reshmi R & Swathy Raj V.R and will be stored in a secure place and will not be shared with any other person without your permission.

I have explained this study to the above subject and have sought his/her understanding for informed consent.

.....

Investigators' Signature/Date

Declaration by the volunteer/patient/guardian

I have read this consent form and give voluntary consent to participate my participation in this study.



Volume 8, Issue 4 July-Aug 2023, pp: 1317-1329 www.ijprajournal.com ISSN: 2249-7781

DEPARTMENT OF PHARMACY PRACTICE

MAR DIOSCORUS COLLEGE OF PHARMACY

ASSESSMENT OF KNOWLEDGE, ATTITUDE AND PRACTICE OF COMMUNITY PHARMACISTS TOWARDS PHARMACOVIGILANCE

DATA COLLECTION FORM		
	Sl. No.: Date:	
1. 2. 3. 4.	Subject Initials:Age:years Gender: Male Female Domiciliary Status:	
5. 6.	Educational Qualification: Work experience (in years):	
	ESTIONNAIRE FOR ASSESSMENT OF KNOWLEDGE, ATTITUDE AND PRACTICE OF MMUNITY PHARMACISTS TOWARDS PHARMACOVIGILANCE	
1. effee	Which among the following is the best definition of Pharmacovigilance? The science and activities relating to the detection, assessment, understanding and prevention of adverse cts The science of ADR monitoring in hospitals by doctors The science of identifying the class of ADR The science of identifying and prevention of adverse The science of ADR monitoring in hospitals by doctors The science of ADR	
4.	Who among the following is qualified to report ADRs? Charmacists Coctors Nurses All of the above Which among the following is the regulatory body for ADR monitoring and reporting in India? CDSCO CDA CGA AIIMS	



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	UDE
1.	Do you think it is necessary to report ADRs?
☐ Yes	
□ No	
□ Don'	t know
2.	Do you think reporting ADR will benefit the patient?
☐ Yes	
□ No	
□ Don'	t know
3.	Do you think only healthcare professionals can report ADRs?
☐ Yes	bo you tillik only heardicate professionals can report Tibros.
□ No	
□ Don'	t know
4.	Are you willing to report an ADR if it's identified during your professional practice?
□ Yes	Are you willing to report all ADK if it's identified during your professional practice?
□ No	
	Dance think that annually and down after in insurants
5.	Do you think that surveillance of drug safety is important?
□Yes	
□No	
□ Don'	t know
DD A CIT	
PRACT	
1.	TICE Have you ever identified an ADR among patients presenting to your pharmacy?
1. □ Yes	
1. □ Yes □ No	Have you ever identified an ADR among patients presenting to your pharmacy?
1. ☐ Yes ☐ No 2.	
1. ☐ Yes ☐ No 2. ☐ Yes	Have you ever identified an ADR among patients presenting to your pharmacy?
1. ☐ Yes ☐ No 2. ☐ Yes ☐ No	Have you ever identified an ADR among patients presenting to your pharmacy? Have you seen an ADR reporting form by CDSCO?
1. ☐ Yes ☐ No 2. ☐ Yes ☐ No 3.	Have you ever identified an ADR among patients presenting to your pharmacy?
1.	Have you ever identified an ADR among patients presenting to your pharmacy? Have you seen an ADR reporting form by CDSCO?
1. ☐ Yes ☐ No 2. ☐ Yes ☐ No 3.	Have you ever identified an ADR among patients presenting to your pharmacy? Have you seen an ADR reporting form by CDSCO? Are you trained on how to report an ADR to a reporting centre?
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1.	Have you ever identified an ADR among patients presenting to your pharmacy? Have you seen an ADR reporting form by CDSCO? Are you trained on how to report an ADR to a reporting centre? Have you ever participated in any awareness program on pharmacovigilance? Do you have a habit of reading scientific literatures on pharmacovigilance for gaining up-to-date