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Study on Assessment on Obstacles and Solution for Spontaneous Reporting of Adverse Drug Reaction among Hospital Pharmacists

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ABSTRACT

Background: The adequate knowledge, attitude, and practice (KAP) of ADRs reporting is crucial for hospital pharmacists.

Objective: This study aimed at assesas the obstacles and solution for spontaneous reporting of adverse drug reaction among hospital pharmacists.

Methodology: The study was a cross-sectional questionnaire-based study designed to assess the obstacles and solution for spontaneous reporting of adverse drug reaction among hospital pharmacists. To Assess the knowledge and detect level of ADR reporting. A validated self- administered (KAP) Knowledge, Attitude, Practice survey questionnaire was used in the study. The questionnaire included 13 questions of knowledge, 5 questions of attitude and 5 questions of knowledge. This prospective knowledge, attitude, practice (KAP) questionnaire study, of 4-month duration included a total of 70 participants.

Result: We approached 75 hospital pharmacists and we got response from 70 pharmacists. Majority of pharmacists are aware of ADR (84%) while 16% responded that they don't know about ADR. Most of the pharmacists had not reported any ADR in their career (85%). It was found that only 15% had reported ADR. Pharmacists have no knowledge about ADR reporting form (70%).50% of pharmacists responded that they don't have any role in the ADR reporting.63 % of pharmacists considered ADR reporting is not a professional obligation and as time consuming. 62 % of pharmacist responded that ADR monitoring is important. We identified several barriers to reporting ADEs in this study.

Conclusion: Detection of barriers to reporting ADRs by hospital pharmacists is necessary to design appropriate interventions. Our findings strongly suggest that under-reporting of ADR is a major limitation of spontaneous reporting. Lack of time, lack of team work etc. were also found as other barriers in reporting ADRs. There is a great need to create awareness about ADRs and also to promote the reporting of ADRs among Pharmacists

Keywords: Adverse-Drug reactions, knowledge attitude practice questionnaire, spontaneous reporting.

1. INTRODUCTION

1.1 PHARMACOVIGILAE

Pharmacovigilance is the science and practice involved in the identification, evaluation, comprehension, and mitigation of side effects and other drug-related issues. It focuses on examining and keeping track of adverse drug responses following the licensing of pharmaceuticals. The Government of India started the Pharmacovigilance Programme of India in July 2010 with AIIMS, New Delhi as the NCC for monitoring ADRs in the nation to protect public health by ensuring the safety of pharmaceuticals. On April 15, 2011, the NCC was moved from AIIMS, New Delhi, to IPC, Ghaziabad. (1)

The FDA started collecting reports of adverse reactions in 1960, the UK's Yellow Card Scheme launched in 1964, the WHO International System of Monitoring ADRs was established in 1967, the first edition of Meyler's Side Effects of Drugs was published in 1952, and an early instance of a systemic collection of adverse drug reactions was reported during a small pox vaccination campaign in the Netherlands at the beginning of the 19th century. The only truly effective means of ensuring the public's health is through appropriate and efficient ADR monitoring, or pharmacovigilance. The most popular way to submit ADRs is through the spontaneous reporting system (SRS). Due to the limited amount of safety-related data accessible, it is capable of early detection of new, rear, and significant ADRs. based on previously published. (2)

The most popular technique for data analysis to determine the relationship between a drug and an important adverse drug reaction is disproportionality analysis. ADRs are severely underreported; it is estimated that just 6% of ADRs are reported. The under reporting of ADRs is caused by a variety of reasons, including the people, professional, and reporting knowledge and attitudes of healthcare professionals. Health practitioners' knowledge and attitudes are closely tied to ADR reporting. An effective teaching intervention can considerably reduce the under-reporting of safety- related data. More

than 65 nations have their own pharmacovigilance divisions in 2002.The WHO Collaborating Centre for International Drug Monitoring oversees who joins the WHO Programmed for International Drug Monitoring. (3)

When a new drug is introduced into the market without any known long-term safety studies, it may not be able to make the claim that it is therapeutically safe and effective and may instead have negative or fatal effects on the general population. A few years ago, India relied on a practice that was erroneous and fell short of guaranteeing complete safety when evaluating a drug's safety based on chronic use. 17 In light of this, numerous businesses or CROs began looking into individual drug research and releasing innovative products on the market. New information that may be helpful or harmful and that may affect the risk-benefit profile of that pharmaceutical product tends to be generated after the development of a new product. Complete a safety and effectiveness research or evaluation of newly acquired data using information. The pharmaceutical company and regulatory agencies are rigorously focusing on the safety of drug in market, i.e., PV, as a result of previous high-profile drug removal. (4)

Pharmacovigilance is important for drug monitoring and surveillance, for easing human suffering, for reducing disease-related economic loss, for discovering new information about hazards associated with medicines, for proactive monitoring and reporting on the quality, safety, and efficacy of medicines, for evaluating the risks and benefits of commercially available medicines, for informing patients, healthcare professionals, and regulators about the proper use of medications; designing programs and procedures for gathering and analyzing patient and clinician reports; early detection of safety issues and increases in the frequency of adverse drug reactions (ADRs); identification of risk factors for ADRs; analysis and mitigation of risks; and, last but not least, the most crucial aspect, patient safety.(5)

1.2 Adverse drug reactions (ADRs)

Adverse Drug reaction are still a significant problem for public health. Since medication safety continues to be a significant source of morbidity and mortality, it is the duty of all healthcare system stakeholders. Unfavorable reactions are one of the top causes of death in various nations. "Response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease or for the modification of physiologic function" is the definition of an adverse drug reaction. There are six different categories of adverse drug reactions: dose-related (aggravated), non-dose-related (bizarre), dose-related and time-related (chronic), time-related (delayed), withdrawal (end of use), and failure of therapy (failure). (6)

The incorrect prescribing and misuse account for a substantial increase in adverse drug reactions (ADRs), which are the principal reasons for unplanned hospitalization, morbidity, fatality, and raised health-care expenses worldwide. Therefore, for assuring the patient’s well-being, this is a call of the hour to recognize ADRs and if practicable prevent them, at a sensible cost. (9) An important aspect of clinical practice is maintaining and monitoring pharmacological efficacy and safety. Thus, pharmacovigilance is an essential clinical discipline to ensure the appropriate use of medicines and patient safety, worldwide. (10)

Pharmacists are the healthcare professionals who patients can reach out to the most, so with the help of SR initiatives, patients could further be protected from medication-related harm. Appropriate counselling from pharmacists could also help patients deal with any negative outcomes they may have experienced. (11) With adequate knowledge and practices of pharmacovigilance and ADR reporting, there will be not only increasing reporting of ADR, but also reducing incidence rate as well as health care cost of patient and also banned harmful drug to the patient in actual clinical practices. (12)

Adverse drug reactions can be monitored through two ways:

1. Active surveillance system

2. Passive surveillance system

1.2.1 Spontaneous reporting

A spontaneous report is an unsolicited communication by healthcare professionals or consumers, pharmaceutical company to NCC or other organization (CDSCO, AMCs) that describes one or more suspected ADR in a patient given a medicinal product that does not drive from study or any organized data collection scheme. Presently PvPI is following spontaneous reporting system to collect data on drug safety. (14)

1.2.2 Suspected adverse drug reaction reporting form

The NCC has designed a Suspected Adverse Drug Reaction Form to record adverse reaction related to drugs. Separate forms are available to record adverse reactions associated with transfusion of blood and blood related products and Adverse Event Following Immunization (AEFI). A report that contains information describing a suspected ADRs related to administration of one or more medicinal products to an individual patient is termed as ICSR.[15]

Following are the points to be filled in an ADR form.

1. Patient information

2. Suspected adverse reaction

3. Suspected medications

4. Reporter details

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reactions by Healthcare Professionals

INDIAN PHARMACOPOEIA COMMISSION
(National Coordination Centre-Pharmacovigilance Programme of India)
Ministry of Health & Family Welfare, Government of India
Sector-23, Raj Nagar, Ghaziabad-201002
www.ipc.nic.in

FOR AMC/NCC USE ONLY

AMC Report No. :

Worldwide Unique No. :

A. PATIENT INFORMATION

1. Patient Initials .....

2. Age at time of Event or Date of Birth _____

3. M ☐ F ☐ Other ☐

4. Weight_____Kgs

12. Relevant tests/ laboratory data with dates

B. SUSPECTED ADVERSE REACTION

5. Date of reaction started (dd/mm/yyyy)

6. Date of recovery (dd/mm/yyyy)

7. Describe reaction or problem

13. Relevant medical/ medication history (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/renal dysfunction etc.)

14. Seriousness of the reaction (Yes ☐ No ☐)
☐ Death (dd/mm/yyyy) ☐ Congenital-anomaly
☐ Life threatening ☐ Required intervention to Prevent permanent
☐ Hospitalization/Prolonged impairment/damage
☐ Disability ☐ Other (specify)

15. Outcomes
☐ Recovered ☐ Recovering ☐ Not recovered
☐ Fatal ☐ Recovered with sequelae ☐ Unknown

C. SUSPECTED MEDICATION(S)

S.No	8. Name (Brand/Generic)	Manufacturer (if known)	Batch No. / Lot No.	Exp. Date (if known)	Dose used	Route used	Frequency (OD, BD etc.)	Therapy dates		Indication
								Date started	Date stopped	
i										
ii										
iii										
iv										

S.No as per C	9. Action Taken						10. Reaction reappeared after reintroduction			
	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown	Yes	No	Effect unknown	Dose (if reintroduced)
i										
ii										
iii										
iv										

11. Concomitant medical product including self medication and herbal remedies with therapy dates (Exclude those used to treat reaction)

D. REPORTER DETAILS

16. Name and Professional Address:_____

_____

Pin:_____E-mail_____

Tel. No. (with STD code)_____

Occupation:_____ Signature:_____

17. Causality Assessment:

18. Date of this report (dd/mm/yyyy):

Additional Information:

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Programme staff is not expected to and will not disclose the reporter's identity in response to a request from the public. **Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction.**

Who can Report?

All healthcare professionals (clinicians, dentists, pharmacists, nurses etc.) and non-healthcare professionals including consumers can report suspected adverse drug reaction. Pharmaceutical companies can also send ICSRs specific for their product to NCC.

Why to Report?

As a healthcare professional, it is a moral responsibility to report adverse reactions associated with use of medicines and safeguard the health of public. The safety of more than 1.2 billion population is a concern and occurrence of ADR constitutes a significant economic burden on the patient and government. India has a vast genetic and ethnic variability with different disease prevalence. Use of multi-modal practices, poor patient compliance are the other factors requires ADR reporting. (16)

What to Report?

In order to foster the culture of reporting, PvPI encourages reporting of all types of suspected ADRs- irrespective of whether they are known or unknown, serious or non-serious, frequent or rare and regardless of an established causal relationship. Although pharmacovigilance is primarily concerned with pharmaceutical medicines and vaccines, adverse reactions associated with drugs used in traditional medicine (e.g., herbal remedies), medical devices, contrast media and other pharmaceutical will also be consider. Specific fields of interest are outcomes associated with the drug use in pregnancy, lactation, pediatric and geriatric. In addition, the reporting of ADRs due to lack of efficacy, overdose, antibiotic resistance and suspected pharmaceutical defects (spurious and adulterated drugs) is recommended. Reporting of ADRs encountered with abuse, off-label use, misuse or occupational exposure is not currently included in PvPI; however, physician judgement shall be final.

How and whom to report?

Use the 'Suspected Adverse Drug Reaction Reporting Form' which is available on the official website of IPC (www.ipc.gov.in) as well as CDSCO (www.cdsco.nic.in) to report any ADR. Reporters from AMCs after filling the above-mentioned Suspected ADR Reporting form can submit it to the coordinator or technical associate of the respective AMC. A reporter who is not a part of AMC can submit the filled ADR form to the nearest AMC or directly to the NCC. A reporter can also mail the form at pvpi.ipcindia@gmail.com.

2.MATERIALS AND METHODS

2.1 STUDY SETTING

This study was carried out among pharmacists working at private hospitals of Kasaragod district including teaching hospitals providing medical, dental, eye care and super-specialty services.

2.2 STUDY DURATION

The study duration was 4 months.

2.3 STUDY DESIGN

We adopted a qualitative approach to conduct the study. We adopted this design due to certain reasons as the design is flexible and it allows an in-depth understanding that further helps in understanding of participant's knowledge, attitude and practices. The methodological approach can identify the pharmacist's point of view.

2.4 STUDY SIZE

Approximately 70 pharmacists.

2.5 STUDY DEVELOPMENT

A KAP questionnaire approach was used in this study. questionnaires were developed by using the style and format of some of the questions used in previous research works. Since the journals we reviewed are developed questionnaires for physicians and community pharmacist, we expected the barriers reported by hospital pharmacists to be different from those reported by community pharmacists and physicians. The study questionnaire included specific questions to identify the barriers of ADR reporting among hospital pharmacists. The Content of questionnaire was validated by an expert committee consisting of pharmacist and general physician.

2.6 CONTENTS OF STUDY QUESTIONNAIRE

The study survey form has 5 sections in which the first section contains the consent form, the second section contain demographic information of respondents, third section contain 13 knowledge-based questions, fourth section contain 5 attitude-based questions, fifth section contain 5 practice-based questions. The questionnaire consists of 23 close ended questions. The knowledge-based question consists of multiple-choice questions, the attitude and practice-based question consist of objective type.

2.7 QUESTIONNAIRE DISTRIBUTION AND DATA COLLECTION

Questionnaire was prepared using word format and distributed directly among hospital

pharmacist. Prior to the participation in the study, the consent form was circulated among them, the objectives and the purpose of the study were explained to the pharmacists. Participant's personal information was collected by the self-administered questionnaire. The study was conducted under the proper guidance of a guide, and using form-based questionnaire for the convenience of pharmacists as it would be difficult for them to find time for the interview between their busy working hours. The questionnaire was distributed among pharmacists working at different places of Kasaragod. With the support we reach the target (n=70) within short period.

2.8 READABILITY TEST

Readability tests are indicators that measure how easily a questionnaire is to read and understand. Readability was assessed by using FRE and FKG test (**FRE**: Flesch Reading Ease, **FKG**: Flesch Kincaid Grade Level) and the readability scores were 54.0and 7.4 respectively. It indicates that questionnaire can read for college level students.

2.9 STUDY CRITERIA

Inclusion and exclusion criteria

Hospital pharmacists working private hospital as a full time, were selected for the study. Hospital pharmacist including qualification of D pharm, B pharm, M pharm and Pharm D also included. Pharmacists working in community pharmacies, pharmaceutical industries and non-pharmacist were excluded from this study. Participants who do not give their consent were excluded from the study.

2.10 STATISTICAL ANALYSIS

The collected data was entered into a spread sheet format using Microsoft Office Excel.

3.RESULTS

3.1 Demographics detail of the participants

A total of 70 pharmacists aged between 20 to 45 years filled in self-administered questionnaire. From them 51(72%) of them were female and 19(27%) were male.

were graduates [B-pharm], 7 (10%) of the participants from M pharm, 31(44%) had diploma in pharmacy [D-pharm] while 2(2%) participants belonged to pharm D.

DEMOGRAPHICS		NO. OF. RESPONDENTS	PERCENTAGE(%)
GENDER	MALE	19	27
	FEMALE	51	72
AGE	20-30	57	81
	31-40	11	15
	>40	2	2
QUALIFICATION	DPHARM	31	44
	BPHARM	30	42
	MPHARM	7	10
	PHARMD	2	2

TABLE 1 contains the data related to demographic distribution of the participants.

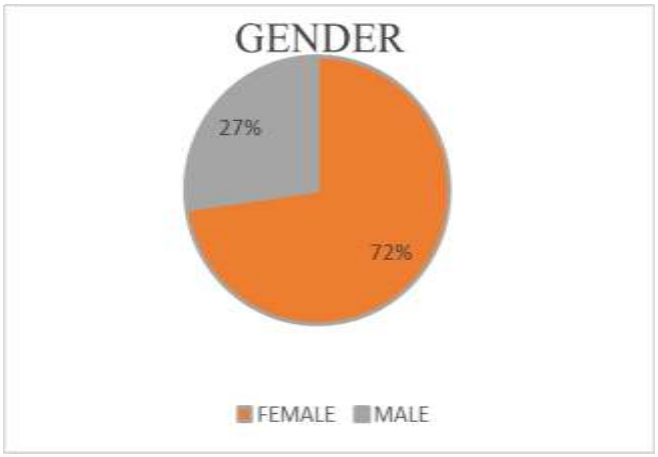

Figure.3Genderwisedistribution.

AGE

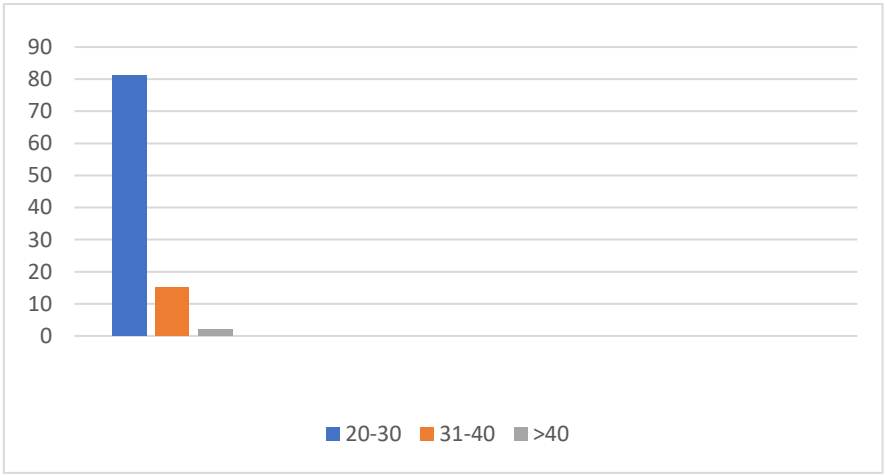

Figure.4Agewisedistribution.

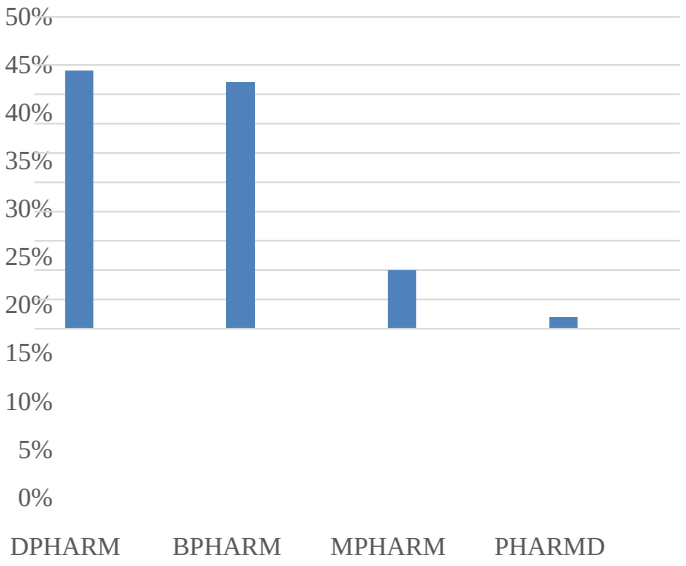

Figure.5Qualificationwisedistribution.

3.2 Pharmacist knowledge towards ADR reporting.

The questionnaire contained 13 closed-ended questions to assess pharmacists' knowledge regarding ADR reporting. The results of the present study firstly demonstrated that the majority of pharmacists have insufficient knowledge and lack of awareness about ADR reporting system. Majority of pharmacists are aware of ADR (84%) while 16% responded that they don't know about ADR.

Only 30% of the pharmacists know where they could get the ADR forms and where to report, 70% of pharmacists admitted that they don't know from where they could get the ADRs reporting forms.61% of the respondents considered that confirmation of drug before reporting is important and they know the definition and types of ADR.75% pharmacist believe that they have role in the ADR reporting system and remaining 25% admitted that they don't have any role in ADR reporting process .62% of pharmacists know the which are the medication is frequently implicated in causing ADRs. The hospital pharmacists were also asked about the commonly adopted method for reporting ADRs and only 54% of pharmacists corrected the answer,46% of pharmacist don't know what are the symptoms and causes of ADRs.

More than half of the pharmacists participated in the study were unaware about how to minimize ADRs.68% of pharmacist said that under reporting is the major limitation of spontaneous reporting of adverse drug reactions. Half of them responded that non-adherence is the predictable cause of ADRs.

From this section we strictly find that little percentage of pharmacist are not aware of ADRs.The is a great problem of unaware of ADR among hospital pharmacists, pharmacist should aware of ADR and hospital management should provide support for the ADR reporting process.

QUESTIONS	OPTIONS	NO.OF RESPONDENTS	PERCENTAGE(%)
1 Are you aware ofADR?	a. Yes	59	84%
	b. No	11	15.7%
2 Do you know where to obtain the ADR form?	a. Yes	21	30%
	b. No	49	70%
3 Confirmations of drug before reporting ADR isimportant?	a. Yes	43	61%
	b. No	27	38.5%
4 What is ADR indrugsafety?	a. Harmful reaction to medicine that occur at doses normally used for treatment	43	61%
	b. Harmful reaction that occurs due to disease	15	21.4%
	c. a and b	12	17.1%
5 What are the Common types of ADR?	a. Augmented and Bizarre	22	31.4%
	b. Chronic and delayed	5	7.1%
	c. End of use and failure	4	5.7%
	d. All the above	39	55%
6 Who can report ADR?	a. Doctor	10	14.2%
	b. Pharmacist	0	0%
	c. Nurses	7	10%
	d. Alltheabove	53	75%
7 Which of the following classes of medication is frequently implicated in causing ADR?	a. Vaccine	7	10%
	b. Anticoagulants	43	62%
	c. Antiemetics	0	0%
	d. a andb	20	28%
	a. Skinrash	5	7.1%

8 Which of the following symptoms may indicate the occurrence of an ADR?	b. Nauseaandvomiting	20	28%
	c. Renalfailure	4	5.7%
	d. Alloftheabove	41	58%
9 The most commonly adopted method for reporting of ADRis?	a. Expeditedreporting	10	14%
	b. Longitudinal electronicpatient records	2	2.8%
	c. Spontaneousreporting	38	54%
	d. Suspectedreporting	20	28%
10 A known limitation of spontaneous ADR reportingis?	a. Underreporting	48	68%
	b. Falsereporting	15	21.4%
	c. Excessreporting	5	7.1%
	d. SRhasnolimitations	2	2.8%
11 Incidence of ADR highest in	a. Children	25	35%
	b. Women	0	0%
	c. Elderly	39	54%
	d. Men	6	8.5%
12 Which of the	a. Nonadherence	39	54%
Following is apredictable cause of ADR?	b. Allergicreactions	25	35%
	c. Dosageform	6	8.5%
	d. Idiosyncraticcauses	0	0%
13 How can we minimize ADR?	a.Avoid and be vigilant of high-riskdrugs	20	28%
	b.Discontinue unnecessarydrugs	5	7.1%
	c. Avoiddrug-drug interaction & adjust dosing based on age	1	1.4%
	d. All of the above	44	62%

Table no 2 :Data related to the knowledge of participated pharmacists regarding ADR Reporting system and process.

The following graph gives idea about the knowledge of the pharmacists about reporting ADR

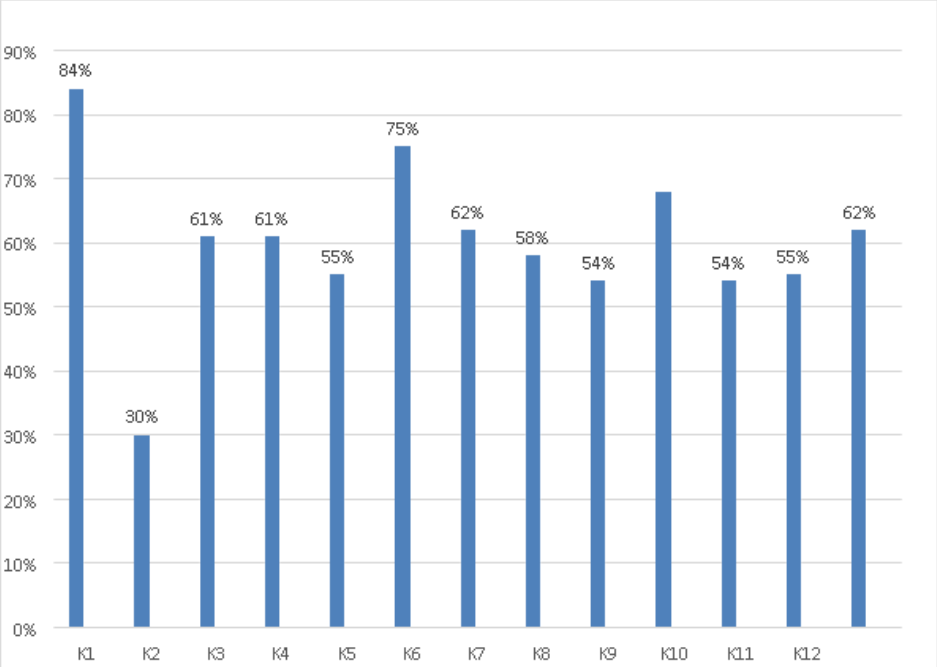

Figure. 6 Knowledge response

3.3 Pharmacist attitude toward ADRs reporting

QUESTIONS	RESPONSE	NO OF RESPONDENTS	PERCENTAGE
1)It is necessary to report ADR?	a) Yes	47	67%
	b)No	23	32.8%
2)Do you think reporting of ADR is an obligation to you?	a) Yes	12	17%
	b)No	58	82%
3)Do you think reporting of ADR is a time consuming?	a) Yes	26	37%
	b)No	44	62.8%
4)Should be there is an ADR monitoring Centre in every hospital?	a) Yes	48	68%
	b)No	22	31.4%
5)Reporting of ADR is important for patient care?	a) Yes	44	62%
	b)No	26	37.1%

TABLE 3 contains data related to the attitude of participated pharmacists regarding Reporting system and process.

The following graph gives idea about the attitude of the pharmacists about reporting ADR.

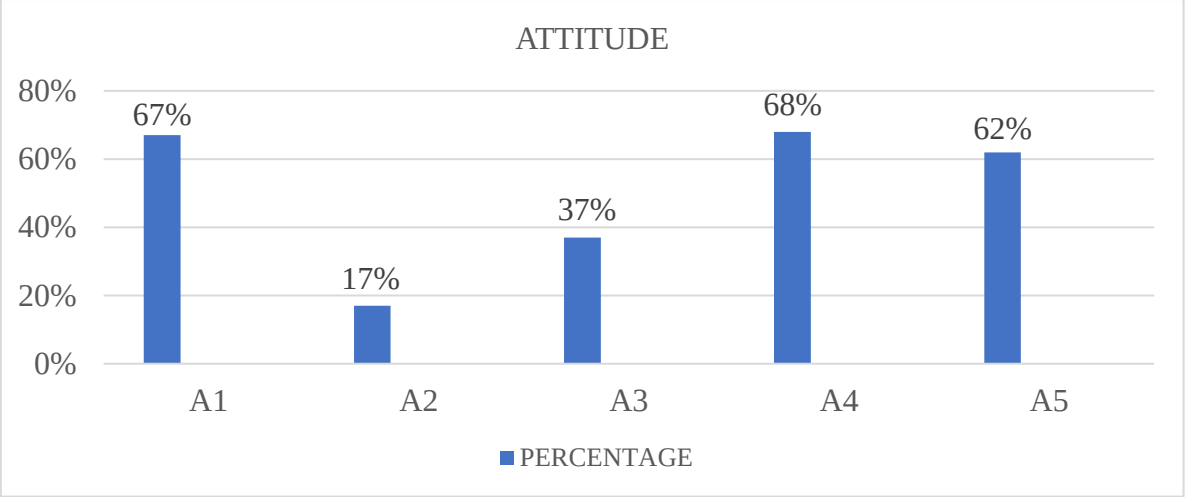

Figure.7 Attitude response

3.4 Pharmacist practice toward ADR reporting

QUESTIONS	RESPONSE	NO OF RESPONDENTS	PERCENTAGE
1.Have you ever reported ADR in your hospital?	a. Yes	11	15%
	b. No	59	84%
2. Have you ever been trained on how to report ADR?	a. Yes	26	37%
	b. No	44	62%
3.Do you find difficulties in reporting ADR?	a. Yes	49	70%
	b. No	21	30%
4.Have you maintained any records of ADR in your hospital?	a. Yes	16	22%
	b. No	54	77%
5. Have you ever seen an ADR reporting form?	a. Yes	29	41%
	b. No	41	58

TABLE 4 contains data related to the practice of participated pharmacists regarding ADR Reporting system and process The following graph gives idea about the practice of the pharmacists about reporting ADR.

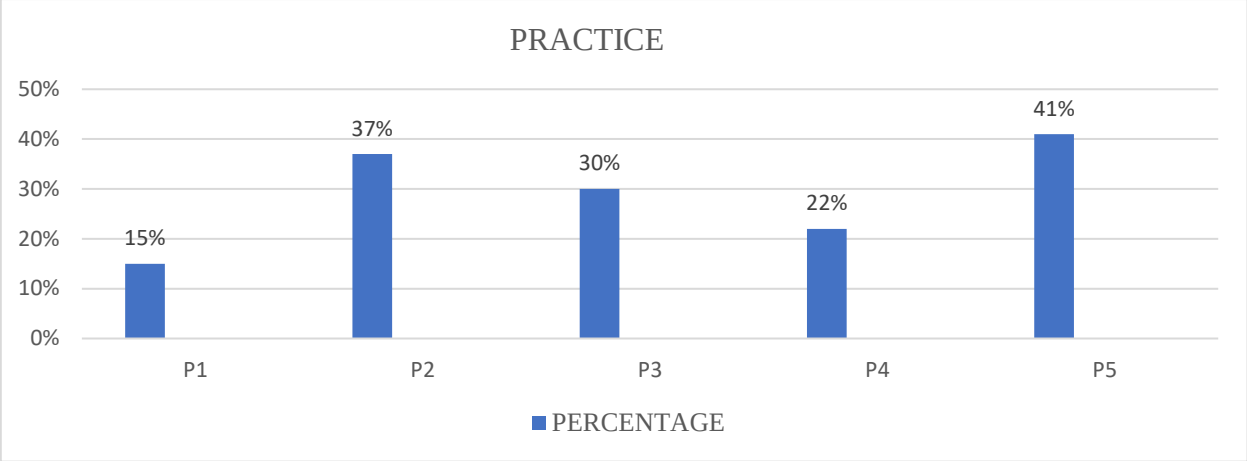

Figure .8 Practice correct response

3.5 Overall, Knowledge, Attitude, Practice Response Towards ADR Reporting Process

From the data collection we considering the overall percentage of knowledge, attitude, practice (KAP) questionnaire, from this we got 70 pharmacists from them they have 60% of knowledge about ADR reporting process and it implies that they have average knowledge.48% of correct attitude towards ADR reporting process and 29% of correct practice during their profession.

CATEGORY	**PERCENTAGE**
KNOWLEDGE	60%
ATTITUDE	48%
PRACTICE	29%

Table 5:shows data related to overall knowledge, attitude, practice-based response.

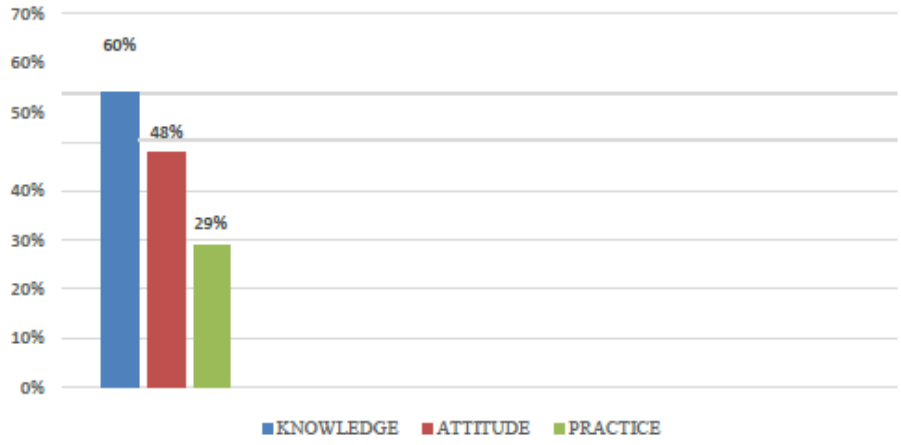

Figure .9 Overall KAP response

4. CONCLUSION

The study aimed to assess the understanding of hospital pharmacists about ADRs, their level of reporting and challenges to spontaneous reporting of ADR. Detection of barriers to reporting ADRs by hospital pharmacists is necessary to design appropriate interventions. Our findings strongly suggest that under-reporting of ADR is a major limitation of spontaneous reporting. Lack of time, lack of team work etc. were also found as other barriers in reporting ADRs. There is a great need to create awareness about ADRs and also to promote the reporting of ADRs among Pharmacists. Although the majority of hospital have no ADR monitoring system, the participants were ready to report ADRs and have interest in learning about the subject.

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