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A CROSS-SECTIONAL STUDY ON ASSESSING THE KNOWLEDGE, ATTITUDE AND BEHAVIOUR OF COMMUNITY PHARMACISTS TO ADVERSE DRUG REACTIONS RELATED ASPECTS

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Key words:

Community Pharmacists, adverse drug reaction, reporting skill

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ABSTRACT: The adverse drug reaction (ADR) programme in India, targeted all healthcare professionals to report the ADRs, however the response is very limited. The ADR reporting is much concentrated to hospital settings and the community pharmacies are unaware of this change. This study was conducted to assess the attitude, knowledge and behaviour of community pharmacists to ADR related aspects. A prospective study carried out over six months, self-prepared validated questionnaire was used. Awareness programme was conducted and a feedback questionnaire was provided. Improvement was seen after awareness programme. The response rate obtained was 93.7%. Pharmacist realizes the benefit a patient can obtain if an ADR is reported and some had noticed ADR. Few pharmacists knew about Central Drugs Standard Control Organisation (CDSCO) as a centre for reporting ADRs. Majority of pharmacists would direct the patients to the physician, in case of occurrences of ADR. According to 26.67% of the pharmacists in the study, busy schedule is considered as a vital factor for under-reporting an ADR.86.67% claimed that the application of information technology in pharmacies can indirectly improve patient health. In the current study, some pharmacists indicated that they did not have internet connection in their pharmacy; this may have partially contributed to the under-reporting of ADRs. Few pharmacists had recognised the importance of ADR reporting and the urgent need of making it mandatory, however the responsiveness was greater in abroad. Proper training need to be provided to the community pharmacist to get updated knowledge regarding the ADRs.

INTRODUCTION: The definition put forward by WHO for ADR is ‘‘any response to a drug that is noxious and unintended, and that occurs at doses used in man for prophylaxis, diagnosis, or treatment’’ [1]. Many serious reactions with respect to drugs are been encountered routinely.

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However, side effects can be related to the therapeutical effect produced by the specific drug, either desirable or undesirable [2]. 3-7% incidence of hospitalisation in USA has reported to be of ADR related [8].

Post marketing surveillance:

The Central Drugs Standard Control Organization (CDSCO) under the Ministry of health and family welfare furnished the Pharmacovigilance Programme with the objective of monitoring ADRs caused because of medical products in India [5]. Spontaneous reporting of ADR has been considered inexpensive and most effective method for the early detection so such occurrences [3]. Risk-Benefit

Ratio is assessed before a drug has been administered, such a practice would positively steepen the cure rate.

Studies in various countries have examined the level of pharmacist's attitude to ADR reporting which was govern by various factors. Some of them are as follows:

1. Pharmacist's uncertainty regarding the causative drug,

2. Lack of availability of reporting forms,

3. Lack of awareness in this area.

4. Anxiety concerning to legal formalities is another factor [14].

Direct reporting by patients is been encouraged in many countries also in India, such a trend can lead to specific reporting [4]. The physicians, pharmacists, nurses, paramedical staffs should be alert and should serve as a mainstay in reporting ADRs to the right authority. The forecasting of the specified ADR confining to the specific medicine should be made before proceeding with the treatment. Patient counselling, past medication history interview are some of the other techniques that can be employed in analysing the ADRs.

Improper utilisation of resources for the detention and prevention of ADR is prevailing in India and there is an urgent need of reconstruction. The ADR reporting is much concentrated to hospital settings and the community pharmacies are unaware of this change. Many studies were conducted to assess the medical practitioners and hospital pharmacists contribution in ADR reporting. The study aimed at assessing the community pharmacist's attitude, knowledge and behaviour on adverse drug reaction (ADR) related aspects.

METHODOLOGY:

Study Period: A prospective, nonrandomized, pre-post intervention study was carried out over a period of 6 months.

Study Site:

A cross sectional interventional study conducted in Perinthalmanna, which a municipality in Malappuram, Kerala and it consist of 64 pharmacies which is having a pharmacist in each.

Data collection tools:

Two self-prepared validated questionnaires were used to obtain relevant data. They are as follows:-

Assessment questionnaire: Questionnaire was used to assess community pharmacist's attitude, knowledge and behaviour on adverse drug reactions. It is made as simple as possible
and was divided into four portions:

1) **About pharmacy**
2) **Attitude**
3) **Experience**
4) **Updating needed?**

First portion**,** **'**About Pharmacy' consist of the rudimentary particulars of the pharmacy. Name of the pharmacist, his/herage, total experience as a pharmacist, his/her qualification. Category of the community pharmacy whether it's an independent pharmacy, chain pharmacy or pharmacy at the clinic. Number of prescriptions dispensed per day and approximate contact time with a patient was included in this section.

Second portion is used for assessing the **'**Attitude' of pharmacist towards ADR reporting. It consist of 8 questions of which 7 are closed ended and an open ended one. The questions include the safety of the drugs available in the market and does the pharmacist feel that ADR need to report, has the pharmacist noticed an ADR in patients. The mentality of the pharmacist to discuss an ADR with his/her pharmacist colleagues. The need of physician to be assisted by pharmacist in ADR reporting. The beneficence of ADR monitoring and reporting. Whether he/she needs assistance in the field of ADR.

Third portion, the opinion of the pharmacist based on his/her 'Experience' in the pharmacy. It's also meant to assess his/her knowledge in the field. It consists of 11 questions of which 9 are closed

ended. The sources of ADR information available and his/ her satisfaction to it. Whether he/she know about the pharmacovigilance programme of India of CDSCO. The type of ADR that need to be reported and his/her knowledge on ADR form. An approximate range of ADRs the patient complaint and measures adopted by pharmacist to comfort the patient. He/she is worried of the legal problems while thinking about ADR reporting. The pharmacist awareness of drug that can harm the pregnant women. Last the confidentiality of the patient information that needs to be maintained while reporting an ADR. The two open ended questions are to list out five ADRs and the causative class of drugs.

Last and the fourth portion is to assess whether the pharmacist **'**Need any Updating?**'**It is meant to analyse his/her behaviour in ADR reporting. 6 closed ended and 2 open ended questions comprised in this section. The addressed questions were whether they are trained properly in ADR reporting procedure. Assessing their need to for providing information regarding ADR reporting to the physician. The cause of under reporting of ADR.

He/she feel that ADR reporting is a time consuming activity with no outcome. The suitability of information technology for improving ADR reporting. Opinion on making ADR reporting mandatory and necessity of feedback from ADR monitoring centres. Last any additional recommendations about improving pharmacovigilance in India.

Feedback Questionnaire:
Feedback questionnaire comprises of 12 total questions of which 11 are closed ended. This questionnaire is given to the pharmacist after the intervention has been done, it was used as a tool to analyse the success of the intervention made in the study. Questions in this phase includes, whether the patients require enquiry from the pharmacist after the succeeding visit to the pharmacy and should ADR be reported and documented, to whom ADR should be reported. If they not meant to be reported, then the reason. The interest of the pharmacist in disseminating their knowledge. The benefit for the patients if ADR is reported. The pharmacovigilance programme of India of CDSCO under Ministry of Health, Govt. of India. The type of ADR that need to be reported. Assess the assurance of the pharmacist in reporting an ADR by using ADR reporting forms. Is pharmacist the right person to assist physician in reducing ADR. The confidentiality that need to be maintained while reporting an ADR.

Direct Pharmacist Interview:
Each pharmacist is interviewed initially during pilot study to assess the peripheral response rate.

Inclusion Criteria:
Pharmacies which consist of at least one registered pharmacist in Perinthalmanna municipality.

Study Procedure:
The prospective study was conducted in the Perinthalmanna municipality, Malappuram district over a period of 6 months. Sample size determined and pharmacies which satisfied the inclusion and exclusion criteria were enrolled in the study. They were followed up for 6 months. The nature, type or intention of the study was explained to the pharmacist by direct patient interaction and informed consent letter was obtained from each pharmacist who was willing to participate in the study.

The study was divided into 3 phases:

Phase 1- Providing and collecting of Assessment Questionnaire:
Pharmacist were provided with the Assessment questionnaire. The questionnaire was collected as soon as possible.

Phase 2- Intervention:
The pharmacist was provided with all the sufficient information regarding the ADR**.** A pharmacist awareness ADR leaflet was prepared and was delivered (**Fig.1**). The information included WHO definition of ADR, Pharmacovigilance programme of India and CDSCO, toll free number for reporting an ADR. The importance of reporting an ADR and the impact that can bring to the social health on continuation of reporting. ADR forms developed by CDSCO were introduced to the pharmacist, also

they were encouraged to use such forms. Who and to whom the ADR should be reported.

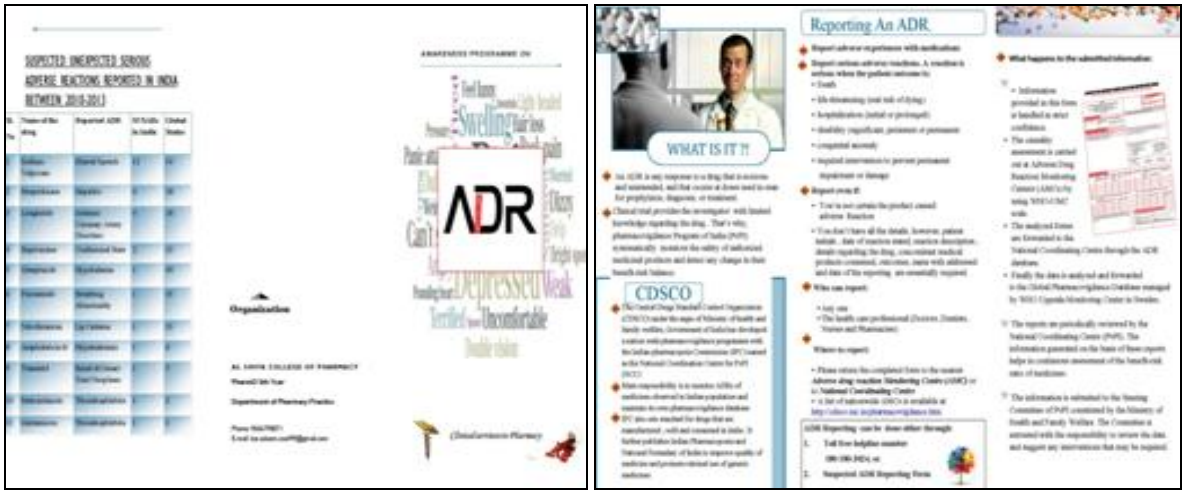

FIG.1: PHARMACIST AWARENESS ADR LEAFLET

An ADR Reporting Form for Community Pharmacy was developed (**Fig. 2**), the pharmacists were encouraged to accept and use it in their pharmacies.

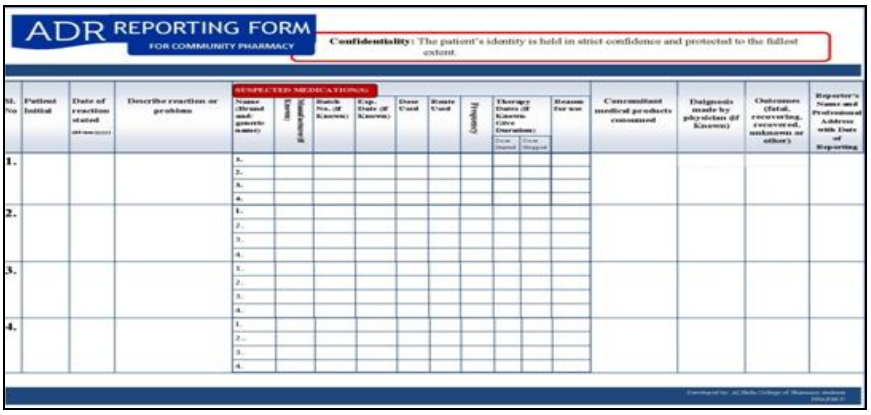

FIG. 2: ADR REPORTING FORM FOR COMMUNITY PHARMACY

Phase 3- Feedback Questionnaire Provided and collected: All the pharmacist who returned the Assessment Questionnaire was provided with the Feedback Questionnaire. Collected immediately.

RESULT AND DISCUSSION:

1. Pharmacist's Attitude:

The survey questionnaires was designed and prepared by referring previous studies conducted in abroad [14] as well as in our country [13]. This is the first survey in Malappuram district, Kerala to evaluate attitude, knowledge and behaviour of community pharmacists towards ADR related aspects. 64 pharmacies are situated at Perinthalmanna municipality; response rate was around 93.75%, 63 consented to take part in the study. Unfortunately, 3 pharmacists even though they agreed to participate in the study, were less cooperative during the conduct. Similar studies conducted in India had a poor response rate i.e.53% from Hyderabad [16], 37.4% from Karnataka [13]. Although, healthier rate of response were observed from Riyadh (70.7%) [15], Oman (72.3%) [18], Makkah (77.27%) [19] and Republic of Moldova (61.7%) [17].

The pharmacists in Perinthalmanna were very enthusiastic in filling up the questionnaire. Majority of the participants in the study were males and those with a bachelor's degree qualification. More pharmacists who were young (age group of 21–30) and had greater years of experience (>6 years) participated in the study. Only just more than a quarter of the participants had received any sort of training in ADR reporting in the past.

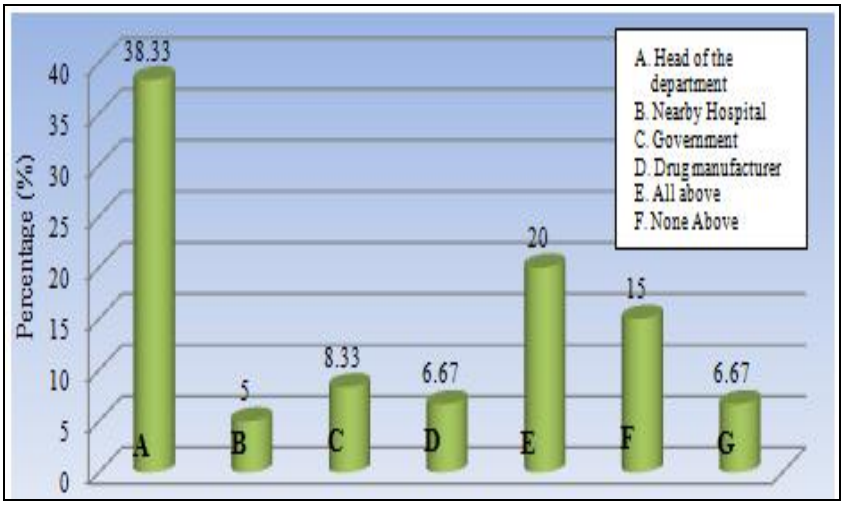

FIG.3: SIMPLE VERTICAL BAR DIAGRAM SHOWING 'TO WHOM SHOULD ADR BE REPORTED?

The ADR reporting rate was found to be nil in our study. Especially, none have reported to regional reporting centres but a greater percentage prefer reporting to the Head of their department and least to CDSCO (**Fig.3**). The reasons for this situation are trader attitude of the community pharmacists and non-legalization of professional services [20]. Our study showed that majority of pharmacist with M. pharm had knowledge on pharmacovigilance programme of India, followed by D pharm holders and least by those with B pharm. There was an association between pharmacist's perception in reporting ADR and category of pharmacy. From the result obtained, Chain pharmacies were more conscious of reporting ADR, which was followed by pharmacist at clinics and least by independent pharmacist. All medicines available in the market aren't safe and (**Table 1**) 29.41% of the pharmacist found it important to assess the drug safety [19]. Jimmy Jose et al exhibited, reporting of ADRs is a professional responsibility of the pharmacists according 90.6% [18, 16, 19], while a decreased percentage was obtain from Perinthalmanna i.e. 71.67%.85% pharmacists admit their need to reduce ADR by assisting the physician. The interaction between pharmacists and doctors varies and is dependent on the individuals involved. The concept that a team based approach to patient care is necessary for better patient outcomes, in general health care management [17].

TABLE 1:

Sl. No.	Attitude Questions	Response		
		Yes	No	Don't know
1.	Do you believe all drugs available in the market are safe?	8	48	4
2.	Have you ever noticed /experienced of an ADR in patient?	21	39	-
3.	Should ADR be reported by pharmacist?	43	15	2
4.	Do you think pharmacist is the right person to assist physician in reducing ADR?	51	3	6
5.	Do you think proper ADR reporting and monitoring will benefit the patient?	55	4	1
6.	Do you support ADR reporting by patients instead of pharmacist?	38	15	7
7.	Do you feel that you need assistance in the area of ADR?	39	13	8

As previously discussed, ADR is an unwanted (unintended) reaction of drug, pharmacist (91.7%) identified the benefit a patient can obtain if an ADR is reported. The pharmacist attitude towards

ADR reporting by patients was satisfactory i.e. 38 of 6o agreed, while 15 disagreed. Avery AJ et al encouraged patient to participate in ADR reporting. According to him, descriptive detailing of the reaction specified by the patient can improve the health care professionals reporting [22]. However, contrasting result obtained from a study conducted in Bangalore city [23]. It was found that a greater proportion of pharmacist in South India, need aid in the field of ADR [13, 10].

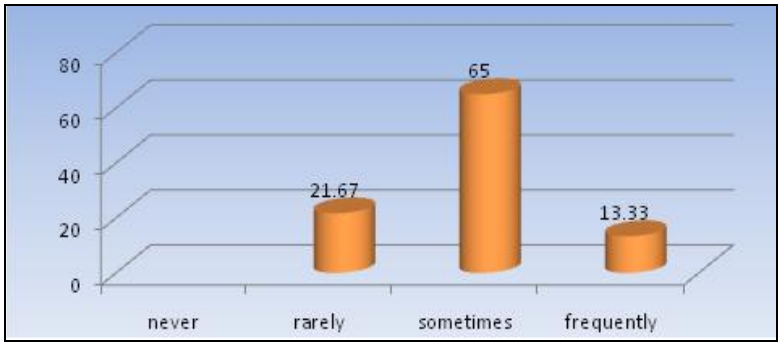

FIG.4: SIMPLE VERTICAL BAR DIAGRAM SHOWING PHARMACIST TENDENCY TO SHARE ADR KNOWLEDGE

The pharmacist tendency to disseminate the information regarding the ADR was observed. Majority of the pharmacists (65%) replied 'sometimes', 21.67% rarely and 13.33% frequently (**Fig.4**). A similar question was asked by Mansour et al and the response obtained was 13.5% rarely, 45.2% sometimes and 36.5% frequently[15].

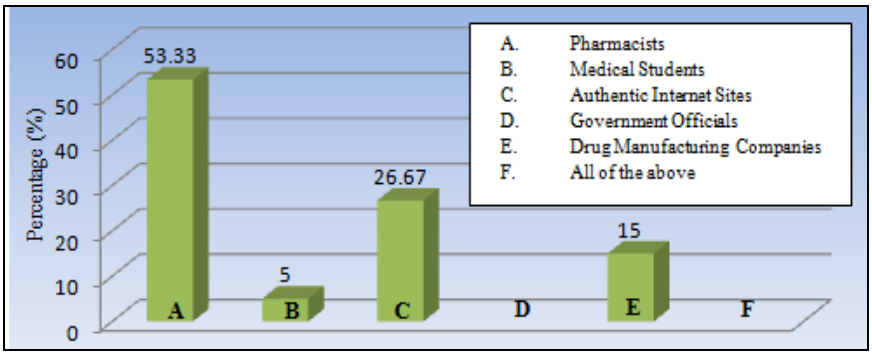

FIG.5: SIMPLE VERTICAL BAR DIAGRAM SHOWING SOURCE OF INFORMATION AVAILABLE TO THE PHARMACIST

In Perinthalmanna 53.33% relay on ADR information obtained from other pharmacists, authentic site act as sources of ADR information to 26.67% of the pharmacists (**Fig.5**). Internet / website and drug information sheets/ leaflets were the primary and secondary source of information reported obtained in the study conducted by Prakasam et al. 43.33% are aware of the pharmacovigilance programme of India of CDSCO while Hyderabad pharmacists were comparatively having less knowledge in it. Also, there was a high reporting rate to the medical representatives and physicians which may be indicative of an even lower level of pharmacovigilance awareness among the study population [16].

Majority of the pharmacies don't have ADR Reporting form, only few established the forms in their premise. In Bangalore, a study disclosed that greater number of pharmacist didn't even know where ADR Forms can be obtained [23, 13]. In Saudi Arabia, the most common approach perceived by community pharmacist to manage patients suffering from ADRs was to refer him/her to a physician [15] which was found to be similar in Perinthalmanna (**Table 2**).

There are lot of drug dispensary units which are been run not complying with the rule and regulations set up by the National Authority of India. Legal problems were considered as a constrain in ADR reporting for 53.33% of total pharmacist (**Table 3**).

The pharmacists (91.67%) are cautious while dispensing medicine to pregnant women. Pharmacist at Saudi Arabia asks female if she is pregnant when dispensing teratogenic/ abortive medication [15]. The physician usually consult his patients with maximum privacy, similarly ADR reporting process should be performed by upholding their dignity (as recommended by CDSCO).

TABLE 2:

Sl. No.	Knowledge Questions	Response		
		Yes	No	Don't know
1.	Are you aware of the Pharmacovigilance program of India of CDSCO under Ministry of Health, Govt. of India?	26	26	8
2.	Has the system created awareness in ADR in you?	27	11	22
3.	Do you think the information provided to you is satisfactory?	39	21	-
4.	Do you have an ADR reporting Form?	16	43	1

TABLE 3:

Sl. No.	Knowledge Questions	Response		
		Yes	No	Don't Know
1.	Do you worry about legal problems while thinking about ADR reporting?	32	28	-
2.	Are you conscious about the drug that can harm the pregnant women?	55	5	-
3.	Do you feel that patient confidentiality should be maintained while reporting an ADR?	40	10	10

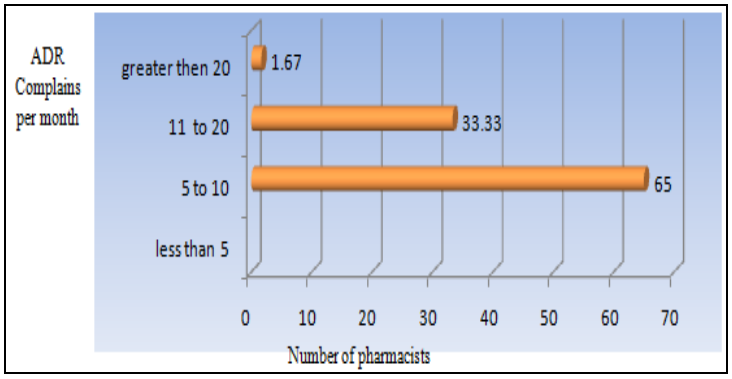

FIG.6: SIMPLE HORIZONTAL BAR DIAGRAM THE PERCENTAGE OF ADR COMPLAINT BY THE PATIENTS PER MONTH.

The pharmacists had few situations were patient complain the reaction caused by the drug being dispensed, coincided with the report published by study conducted at Makkah depicted approximately 45% pharmacist noticed ADRs [19] (**Fig.6**)

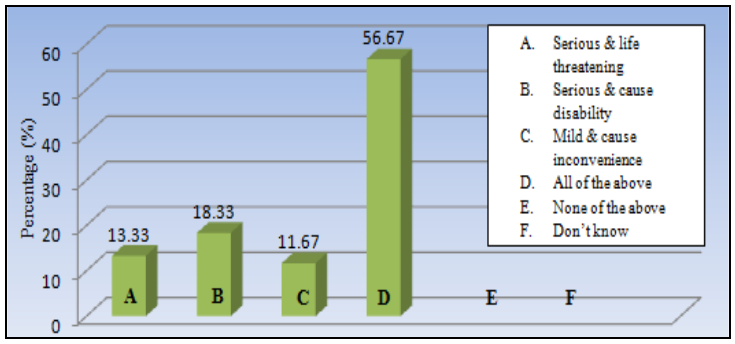

FIG.7: SIMPLE VERTICAL BAR DIAGRAM THE TYPE OF ADR THAT NEED TO BE REPORTED.

The most common approach perceived by community pharmacist to manage patients suffering from ADRs was to refer him/her to a physician (**Table 4**). Predominant pharmacist in Saudi Arabia disagree with the practice to provide medicine for the ADR and recommending to stop the drug suspected of the ADR[15], which was the second dominating option preferred in Perinthalmanna (**Fig.7**)

TABLE 4:

If A Patient Comes to the Pharmacy Complaining of Side Effect/ADR, The Pharmacists Would Prefer To-	Percentage (%)
1. Give him/her a medicine to treat his condition.	10
2. Refer him/her to a physician.	45
3. Just ask him/her to stop taking the medicine.	20
4.Give him/her medicine to treat the suspected ADR and ask him/her to stop the medication that has the likelihood to cause the ADR.	25

Pharmacist's Behaviour:

Majority of the pharmacist need training for ADR reporting. This was supported by the statements made by Maria Cordina et al, who pointed out both education and infrastructure should be given to pharmacists to take on increased responsibility in this area [17].

TABLE 5:

Sl. No.	Behaviour questions	Response		
		Yes	No	Don't know
1.	Do you feel that you are adequately trained in ADR reporting procedure?	13	40	7
2.	Do you feel that ADR reporting is a time consuming activity with no outcome?	18	29	13
3.	Do you feel proper training need to be provided to the physician for ADR reporting?	40	12	8

TABLE 6:

Reasons for Under Reporting	Percentage (%)
1. Only safe drugs are available in the market	5
2. Reporting doesn't influence the treatment scheme	8.33
3. Busy schedule	26.67
4. Physician should rather collect data and publish himself/herself	10
5. Difficult to pinpoint suspected drug	5
6. ADR is known to physician	23.33
7. Lack of incentives	3.33
8. Don't know how to report	6.67
9. Reporting could show ignorance	0
10. Insufficient clinical knowledge	10
11.Thinking one report doesn't bring the change	1.67

Naif N Al-Hazmi et al depicted, half of pharmacists in the study had the opinion that ADR is reported to find safe drugs [19] for better patient care which superimposes with those obtained from ours. According to 26.67% of the pharmacists in the study, busy schedule is consider an vital factor for under-reporting an ADR, whereas in Karnataka lack of awareness on how to report was the main reason [13]. Training programmes in ADR need to be organised for 71.67% of the pharmacists as they preferred to report ADRs to the authority [16].

TABLE 7:

Sl. No.	Behaviour Questions	Response		
		Yes	No	Don't know
1.	Do you think that information technology can improve ADR reporting and patient health?	52	5	3
2.	At present ADR reporting is voluntary; do you feel that it should be made mandatory?	18	29	13
3.	Do you expect feedback from ADR monitoring Centers?	40	12	8

86.67% claimed that the application of information technology in pharmacies can indirectly improve patient health. In the current study, some pharmacists indicated that they did not have internet connection in their pharmacy; this may have partially contributed to the under-reporting of ADRs [16]. Few pharmacists had recognised the importance of ADR reporting and the urgent need of making it mandatory; however the responsiveness was greater in abroad [19]. Feedback from the ADR monitoring centres is needed for further continuation of the reporting process (**Table**

7). Granas et al [21] has shown that an educational program can significantly modify pharmacist reporting related attitudes and influence the ADR reporting behaviour into a positive manner.

Association: Pharmacist's Knowledge on Pharmacovigilance Program and Educational:
The pharmacist with diploma in pharmacy (48.14%), 26.08% of the B. pharm holder and 70% of M. pharms, were aware about pharmacovigilance programme of India under CDSCO.

Association: Pharmacist's Perception in ADR Reporting and Category of Pharmacy:
It was found that 55.88% of the pharmacist in independent pharmacies would prefer to report ADRs. 95.23% of the pharmacist at the clinics considered ADR reporting while, entire chain pharmacies would like to report.

Impact of Intervention:
In the 3rd Phase of the study, assessment of ADR Awareness Programme has been done and following results were obtained. The feedback questionnaire (**Table 8**) revealed that, the awareness programme was useful. 95% of the pharmacist had the opinion of reporting and documentation of ADR. An enquiry of the medicine should be made to the patient during the succeeding pharmacy visit- 55% agreed, 5% disagreed and 40% didn't know. 98.3% were willing to participate in reporting procedures recognising the association between ADR with health.

In a study, only 11%, of the pharmacists asked the person who the prescription was for, the age and other patient details before dispensing the medications to the person.

This result showed that the majority of the pharmacists dispensed the medication without knowing the patient's medical details, as it increases the chance of having a drug related problem due to inappropriate dose [24]. Developing a routine of enquiry on the drug related aspect of drugs with the patients not only will improve the pharmacist – patient relationship but also would decrease the chance for occurrence of ADR. Majority were willing to participate in reporting procedures, after providing awareness. Inhibitory effect persisted, however, greater than half of the pharmacists were confident enough to report an ADR to the concern authority. 85% of pharmacists had the perception that he/she is the actual person to assist physician in reducing ADR, an 8% up-gradation has been found after providing awareness. Educating the pharmacist lead to a 33% of development from previous observation regarding the confidentiality of the patient.

TABLE 8:

Assessment questions	Yes	No	Don't Know
1. Do you find the information provided about ADR was useful?	60 (100%)	0 (00%)	0 (00%)
2. Do you feel that ADR should be reported and documented?	57 (95%)	0 (00%)	3 (05%)
3. Do you feel that an enquiry of the medicine should be made to the patient during the succeeding pharmacy visit?	33 (55%)	3 (05%)	24 (40%)
4. Should ADR be reported by pharmacist?	59 (98.3%)	3 (05%)	1 (1.7%)
5. Do you think proper ADR reporting and monitoring will benefit the patients?	59 (98.3%)	3 (05%)	1 (1.7%)
6. Are you confident enough to report an ADR to the concern authority?	33 (55%)	0 (00%)	27 (45%)
7. Do you think pharmacist is the right person to assist physician in reducing ADR?	56 (93.3%)	0 (00%)	4 (6.7%)
8. Do you feel that patient confidentiality should be maintained while reporting an ADR?	60 (100%)	0 (00%)	0 (00%)

CONCLUSIONS: Pharmacist's knowledge on pharmacovigilance was poor. Continuing education programme should be held by pharmacy authorities for augmenting their reporting skills. Development and proper funding system to the peripheral centres should be considered. Increasing rate in population and large scale dumping of medicines into the market suggest that there is an urgent need for making ADR reporting mandatory. Bonuses on reporting ADR can be proclaimed for motivating

the pharmacist. Training programme on ADR shouldn't be restricted to health care professionals rather it should be extended to all people. This study reveals that creating awareness about ADRs among the community pharmacists, made a very huge impact on level of understanding, attitude towards reporting of ADRs. The ultimate aim of healthcare professionals is to provide better patient care; early detection can not only reduce the mortality and morbidity, but also the economic burden on the patient.

Future Plan: Periodical analyse of the ADR form given to the pharmacist, obtain response produced and their reasons. Provide awareness programme to common people, for improvement of their knowledge regarding drugs and encourage patients to report ADR.

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