The Current Perspective of Community Pharmacists towards Pharmacovigilance

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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. Proper training need to be provided to the community pharmacist to get updated knowledge regarding the ADRs.

Keywords: Assessment questionnaire; Application of interventions; Feedback questionnaire

Introduction

The World Health Organization (WHO) endorses an ADR definition that many health care practitioners have also adopted: “any response to a drug that is noxious and unintended, and that occurs at doses used in man for prophylaxis, diagnosis, or treatment” [1]. Moreover, it has been regarded as an appreciable harmful reaction which results from an intervention related to the use of medical products. An adverse effect, which occurs as overstate of the desired therapeutic effect, forms a part of ADR, whereas, side effects are generally related to the therapeutic activities of a drug which may be beneficial as well as harmful [2]. In US, 3-7% of all hospitalization are due to ADRs incidence and severity of ADRs vary by patient characteristics (e.g., age, sex, coexisting disorders, etc.) and by drug factors (i.e. type of drug, administration route, treatment duration, dosage and bioavailability) [3].

Post Marketing Surveillance

The Central Drugs Standard Control Organization (CDSCO) under the aegis of Ministry of Health and family welfare, Government of India has developed a nationwide pharmacovigilance programme with the Indian Pharmacopeia Commission (IPC) named as the National Coordination Centre for Pharmacovigilance Programme of India (NCC). Its main responsibility is to monitor ADRs of medicines observed in Indian population and maintain its own pharmacovigilance database [4].

The most sensitive, powerful and cost effective system for the identification of unknown drug related risk is spontaneous adverse reaction reporting [5]. Spontaneous adverse drug reactions (ADR) reporting is considered the cornerstone of any pharmacovigilance system. Post-marketing surveillance, especially for ADR, is therefore a critical part of the process that decides whether the benefits of a drug outweigh its risks. Most developed countries, have therefore, established formal spontaneous reporting programs to detect serious ADR as efficiently and inexpensively as possible [5].

Spontaneous adverse drug reaction (ADR) reporting is the mainstay of national and international drug safety evaluation in the post-approval phase. A major criticism of the method has been a high, but essentially unquantifiable and level of under-reporting by doctors. In most countries, the spontaneous ADR reporting program mainly targets physicians as the major source for reporting. However, in an attempt to increase reporting many countries allowed hospital pharmacists, community pharmacists, nurses and even patients to report ADR. Studies in various countries have examined the level of pharmacist’s attitude to ADR reporting and have found that a number of factors affect attitude. Factors cited by the surveyed pharmacists as deterrents for reporting ADR include, pharmacists were unsure that the drug caused the reaction; unavailability of reporting forms, pharmacists did not know how to report an ADR. When the ADR is expected, pharmacists did not think of reporting the ADR and fear of legal liability [6]. Patients reporting ADRs to the concerned authority would bring greater results in this area, according to studies. The national ADR registers in USA and Germany accepts report directly from patients [7].

In hospital set up, healthcare professionals should be very vigilant in detecting ADRs. The possibility of an ADR should always be considered during differential diagnosis. Patient counselling, medication history interview and communicating with other healthcare professionals may provide additional clues, which may be useful in the detection of ADRs. To assist the detection of ADRs, healthcare professionals should closely monitor patients who are at high risk. These include:

- Patients with renal or hepatic impairment.
- Patient taking drugs which have the potential to cause ADRs.

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The ADR program 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. Many studies were conducted to know about medical practitioners and hospital pharmacist’s contribution in ADR reporting. This study was conducted to assess the attitude, knowledge and behaviour of community pharmacists on 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/her age, 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 consists 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 an 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 was 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 (Picture 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. An ADR Reporting Form for Community Pharmacy was developed (Picture 2), the pharmacists were encouraged to accept and use it in their pharmacies.

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

Results and Discussion

The survey questionnaires was designed and prepared by referring previous studies conducted in abroad [8] as well as in our country [9]. 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 [10], 37.4% from Karnataka [9]. Although, healthier rate of response were observed from Riyadh (70.7%) [11], Oman (72.3%) [12], Makkah (77.27%) [9] and Republic of Moldova (61.7%) [13].

Pharmacist’s attitude

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.

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 (Figure 1). The reasons for this situation are trader attitude of the community pharmacists and non-legalization of professional services [14]. 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 [15]. Jimmy Jose et al exhibited, reporting of ADRs is a professional responsibility of the pharmacists according 90.6% [3,15,16], 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].

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
from other pharmacists, authentic site act as sources of ADR information to 26.67% of the pharmacists (Figure 3). 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].

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 [20]. The physician usually consults his patients with maximum privacy, similarly ADR reporting process should be performed by upholding their dignity (as recommended by CDSCO).

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 [12,19]. It was found that a greater proportion of pharmacist in South India, need aid in the field of ADR [11,12].

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 (Figure 2). A similar question was asked by Mansour et al and the response obtained was 13.5% rarely, 45.2% sometimes and 36.5% frequently [20].

Pharmacist’s knowledge

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 (Figure 3). 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].

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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 [16]. Naif pointed out both education and infrastructure should be given to pharmacist [17] to stop the drug suspected of the ADR [10], which was the second dominating option preferred in Perinthalmanna (Figure 5).

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]. Naif N Al-Hazmi et al. depicted, half of pharmacists in the study had the opinion that ADR is reported to find safe drugs [15] 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 [12]. Training programmes in ADR need to be organised for 71.67% of the pharmacists of awareness on how to report was the main reason [12]. Training programmes in ADR need to be organised for 71.67% of the pharmacists

Table 1: Attitude questions.

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<thead>
<tr>
<th>Sl. No.</th>
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<th>RESPONSE</th>
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<th>Don’t know</th>
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<tbody>
<tr>
<td>1</td>
<td>Do you believe all drugs available in the market are safe?</td>
<td></td>
<td>8</td>
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<tr>
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<td>Have you ever noticed/experienced of an ADR in patient?</td>
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<td>39</td>
<td>-</td>
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<td>Should ADR be reported by pharmacists?</td>
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<td>Do you think pharmacist is the right person to assist physician in reducing ADR?</td>
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<td>5</td>
<td>Do you think proper ADR reporting and monitoring will benefit the patient?</td>
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<td>4</td>
<td>1</td>
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<td>6</td>
<td>Do you support ADR reporting by patients instead of pharmacist?</td>
<td></td>
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<td>15</td>
<td>7</td>
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<td>7</td>
<td>Do you feel that you need assistance in the area of ADR?</td>
<td></td>
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Table 2: To manage patients suffering from ADRs was to refer him/her to a physician which was found to be similar in Perinthalmanna.

Table 3: Legal problems were considered as a constrain in ADR reporting for 53.33% of total pharmacist.

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Figure 4: Simple horizontal bar diagram the percentage of ADR complaint by the patients per month.

Figure 5: Simple vertical bar diagram the type of ADR that need to be reported.
the importance of ADR reporting and the urgent need of making it mandatory; however the responsiveness was greater in abroad [15]. Feedback from the ADR monitoring centres is needed for further continuation of the reporting process (Table 5). 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 between pharmacist’s knowledge on pharmacovigilance program and educational qualification: The pharmacist with diploma in pharmacy (48.14%), 26.08% of the B. Pharm holder and 70% of M. Pharm were aware about pharmacovigilance programme of India under CDSCO.

Association between 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, were aware about pharmacovigilance programme of India under CDSCO.

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 6) 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

IF A PATIENT COMES TO THE PHARMACY COMPLAINING OF SIDE EFFECT/ADR, THE PHARMACISTS WOULD PREFER TO- 

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<th>RESPONSE</th>
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<tbody>
<tr>
<td>1.</td>
<td>1. Do you feel that ADR reporting is a time consuming activity with no outcome?</td>
<td>18 (25%)</td>
</tr>
<tr>
<td>2.</td>
<td>2. Do you feel that ADR reporting is voluntary; do you feel that it should be made mandatory?</td>
<td>18 (29%)</td>
</tr>
<tr>
<td>3.</td>
<td>3. Do you expect feedback from ADR reporting centres?</td>
<td>40 (12%)</td>
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</table>

Table 4: The most common approach perceived by community pharmacist to manage patients suffering from ADR was to refer him/her to a physician.

Reasons for under reporting

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<th>Sl. No.</th>
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</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>1. Do you feel that you are adequately trained in ADR reporting procedure?</td>
<td>13 (40%)</td>
</tr>
<tr>
<td>2.</td>
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</tr>
<tr>
<td>3.</td>
<td>3. Do you feel proper training need to be provided to the physician for ADR reporting?</td>
<td>40 (12%)</td>
</tr>
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Table 5: Pharmacist’s behaviour.

Reasons for under reporting

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

Table 6: Reasons for under reporting.

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 [22]. 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 after providing awareness. Inhibitory effect persisted, however, greater than half of the pharmacists were confident enough to report an 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.

Conclusion

Pharmacists have little knowledge on pharmacovigilance. Periodic trainings should be held by pharmacy authorities to update reporting knowledge like ADR reporting form availability, reporting centres, modes and benefits of reporting etc. Moreover, authorities must create awareness among all the community pharmacists about National pharmacovigilance Program (NPP) in India. More peripheral pharmacovigilance centres should be set up to increase the convenience of reporting. Continuing educational programs would stimulate pharmacist’s active participation in the ADR reporting program.
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. The pharmacists must be encouraged and constantly motivated for ADR reporting and he/she should conceive it as his/her responsibility. Incentives and other encouraging perks should be given to reporting pharmacists to keep them motivated and focused. 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. Detection and prevention of ADRs at the earliest can not only reduce morbidity and mortality but also bring down the cost of their management which can otherwise burden the economic status of the developing countries like India. Well-trained pharmacists in the area of ADR detection, reporting and monitoring will prove to be an asset in providing better patient care.

**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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