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Design and Implementation of Adverse Drug Reaction Reporting System in Community Pharmacies

Raja Rakesh Chandra P, Adepu Ramesh*

Department of Pharmacy Practice, JSS College of Pharmacy, SS Nagara, Mysore -570 015
Address for correspondence: adepu63@rediffmail.com

Abstract

An open prospective study was conducted to implement ADR reporting system in Community pharmacies and analyze the pharmacists reported ADRs using the causality assessment scales. Structured training was offered to the selected Community Pharmacists (CPs) regarding definition, precipitating factors, how to identify & report an ADR was discussed during the training. A manual containing guidelines to report ADRs was given to the participants. The ADR reports submitted by the trained CPs were analyzed for causality. Strategies to improve reporting ADRs by Community pharmacists were also studied. After attending the ADR training session, ten community pharmacists (35.7%) submitted 42 ADR reports in three months period. The causality assessment of the submitted ADR reports suggest that antibiotics (42.85%) were the class of drugs that caused more ADRs and the dermatological system (45.23%) was the most affected organ system. Most of the reported ADRs were found to be mild (69.04%) in nature. Display of posters motivating the patients to report to their pharmacist whenever they experience an adverse event, thanks giving notes and reminder phone calls to pharmacists were the strategies planned to improve ADR reporting. The present study concluded that the structured training has created awareness among the trained community pharmacists regarding ADR reporting and motivated them towards reporting.

Key words: *Community Pharmacists, ADR reporting*

INTRODUCTION

Medicines are used to treat illnesses as they have the ability to modify the altered physiological processes in the body. But at the same time, due to various predisposing factors, drugs always pose certain amount of risk in the form of unwanted or unintended effects known as adverse drug reactions (ADRs).[1]

ADRs are identified as one of the leading causes of increased health care cost, morbidity and mortality.[2] It is estimated that approximately 3%-6% of the hospital admissions are due to ADRs.[3] The cost to treat a single adverse drug event (ADE) was found to be more than US$ 2500 and the total health care cost for treating ADRs was estimated as US $ 4 billion per year for drug-induced injuries in US.[4] An Indian study calculated the average cost incurred per patient in treating an ADR to be Rs.690.[5] Patients with one or more of the predisposing factors such as poly pharmacy, age, gender, race, genetics, multiple and inter current diseases are at higher risk for developing ADRs

The Uppsala Monitoring Centre (UMC) is an operational arm of World Health Organization (WHO) with its 86 member countries maintains the global ADR data base.[6] Most of the developed countries have developed their own ADR reporting schemes and encouraged all health care professionals to report ADRs. Systematic review of ADR reporting schemes of various countries shows that community pharmacists are playing vital role in reporting ADRs.[7] A study conducted in UK has mentioned the community pharmacists have adequate knowledge and ability to report ADRs.[8] A study conducted by Sarah Davis suggest that quality of ADR reporting by community pharmacists was comparable with reports submitted by General Practitioners in terms of causality and completeness of the reports.[9] In another study conducted in UK, the general practitioners have accepted the community pharmacists involvement in ADR reporting to overcome under reporting by GPs due to increased patient load, lack of ADR reporting knowledge and time, and non availability of reporting system.[10]

The Netherlands Pharmacovigilance center, Lareb receives almost 40% of ADR reports only from the community pharmacists.[11] Similar scenario is prevailing in Australia, Canada, USA and Spain.[6]

These studies have corroborated community pharmacists

Indian Journal of Pharmacy Practice
Received on 12/10/2008 Modified on 13/07/2009
Accepted on 28/07/2009

involvement in ADR reporting. Due to their advisory role while dispensing the medications to patients, community pharmacists are in a suitable position to detect and report ADRs.

In India, community pharmacy practice is predominantly confined to trade. Majority of registered pharmacists are with diploma in pharmacy qualification and their knowledge regarding professional services is also limited. Pharmacy Council of India and respective state pharmacy councils are providing educational motivation to change their trader attitude. In our health care system, more than 80% of the prescriptions are filled by the community pharmacists. This high number of prescriptions offer great opportunity for them to monitor and report ADRs. Availability of a reporting system and education may help them to report potential adverse events.

The present study was aimed at introducing ADR reporting scheme in community pharmacies and assesses the causality of the reports using the valid causality assessment scales and also design the strategies to improve ADR reporting

METHODOLOGY

The present study is an open labeled prospective study conducted over a period of nine months.

The list of community pharmacists (CPs) practicing in the city was collected from the Assistant Drugs Controller Office and identified the practicing qualified pharmacist (QP) owners.

A brief introductory letter about the importance of ADR reporting, along with the letter of participation for one-day ADR workshop was sent by post along with the reply paid envelope.

A training manual was prepared, consisting of information about ADR definition, classification, precipitating factors, incidences, consequences, how to detect and report an ADR, importance of ADR reporting and also about the National Pharmacovigilance Programme in India. The content of the manual was validated by senior clinical pharmacists.

A one-day workshop on ADRs was conducted to train and educate the CPs on ADR reporting. An ADR notification form was designed and printed in pink color (PINK FORM) and supplied to the participating CPs to report the suspected ADRs. *:*

The trained community pharmacists were followed up with regular phone calls and personal visits. A review meeting was also organized for the trained pharmacists to assess the barriers in reporting ADRs. Suitable strategies were discussed to improve ADR reporting and posters were prepared to create general public awareness regarding the side effects.

The information in the collected ADR notification form was analyzed and documented in a suitably designed ADR documentation form. Various standard causality assessment scales were used to assess the collected ADR reports. Approval for the study was taken from the institutional ethical committee.

RESULTS

A total of 219 practicing qualified pharmacist (QP) owners were identified and letters were sent to them regarding the workshop on ADR reporting. Fifty-two community pharmacists (23.74%) responded to participate in the ADR workshop. Among the responded pharmacists, only 28 Community pharmacists (53.84%) attended the ADR workshop.

Of the 28 trained Community Pharmacists (CPs), only 10 CPs (35.71%) submitted 42 ADR reports in a period of three months.

Antibiotics showed higher incidence 18 (42.85%) of causing ADRs followed by NSAIDs 7 (16.66%) and antihypertensives 7 (16.66%). The most common organ systems affected by the ADRs were dermatological, nervous, gastrointestinal system and the least affected organ system is cardiovascular system.

Upon causality assessment of the reported ADRs as per the WHO probability scale, majority of ADRs were rated as 'probable' 27 (64.28%) followed by 'possible' 15 (35.71%). Similarly, ADRs were also assessed with other causality scales like Naranjo, and Karch & Lasagna.

The level of severity of reported ADRs was also analyzed. Among the 42 ADR reports, 29 (69.04%) ADRs were mild in severity and 13 (30.95%) ADRs were moderate.

Of the total 42 reported ADRs, 40 (95.23%) reactions were predictable and 2 (4.76%) ADRs were unpredictable and the majority of the ADRs 36 (85.71%) was not preventable.

Of the 42 reported ADRs, in 26 (61.90%) cases, the suspected drug was withdrawn and symptomatic treatment was given in 24 (57.14%) cases.

The factors predisposing to reported ADRs were analyzed. Multiple drug therapy (36%) was found to be the major predisposing factor of the reported ADRs followed by age, gender and intercurrent disease. In 40% of the patients, there were no predisposing factors. The management of the reported ADRs suggests that 23 (55%) cases recovered and in 16 (38%) cases the outcome was unknown and 3 (7%) were recovering from the ADRs.

Table 1. Demographic details of the trained pharmacists

Gender n=28		Qualification		Professional Experience			
Male	**Female**	**D. Pharm**	**B. Pharm**	**<1 Yr**	**1-3 Yrs**	**3-5 Yrs**	**> 5 Yrs**
26(93%)	2(7%)	26(93%)	2(7%)	--	--	8	20

Table 2. Demographic characteristics of patients who experienced ADRs

Demographic Characteristics	Number of Patients n = 28	Percentage of Patients
	Sex	
Male	17	60.71
Female	11	39.28
	Age groups (in years)	
0-15	02	7.14
16-30	07	25.0
31-45	09	32.14
46-60	08	28.57
>61	02	7.14

Table 3. Drug Classes commonly implicated in reported ADRs

Drug class	No. of ADRs (N=42)	% of ADRs
Antibiotics	18	42.85
NSAIDs/ Analgesics	7	16.66
Antihypertensives	7	16.66
Muscle Relaxants	3	7.14
Antihyperlipidemic drugs	2	4.76
Antihistamines	1	2.38
Hypnotics/ Sedatives	1	2.38
Hypoglycemic agents	1	2.38
Immunosuppressants	1	2.38
Proton Pump Inhibitors	1	2.38

Table 4. Systems associated with reported ADRs

System affected	No. of ADRs (n= 42)	% of ADRs
Dermatological	19	45.23
CNS	10	23.80
Gastrointestinal	8	19.04
Respiratory	3	7.14
Cardiovascular	2	4.76

Table 5. Causality assessment of reported ADRs

Causality assessment scale	Number (%) (n= 42)			
	Certain/Definite	Probable	Possible	Conditional
WHO probability scale	00	27(64.28)	15(35.71)	00
Naranjo's algorithm	00	12(28.57)	30(71.42)	00
Karch & Lasagna	00	18(42.85)	4(9.52)	20(47.61)

Table 6. Level of severity of reported ADRs

Severity	No. of ADRs (n= 42)	% of ADRs
	Mild	
Level 1	14	33.33
Level 2	15	35.71
	Moderate	
Level 3	13	30.95
Level 4a	00	00
Level 4b	00	00
	Severe	
Level 5	00	00
Level 6	00	00
Level 7	00	00

Table 7. Predictability and Preventability of reported ADRs

Parameters	No. of ADRs (n= 42)	% of ADRs
	Predictability	
Predictable	40	95.23
Not Predictable	2	4.76
	Preventability	
Definitely Preventable	00	00
Probably Preventable	6	14.28
Not Preventable	36	85.71

Table 8. Management of reported ADRs

Management	No. of ADRs (n= 42)	% of ADRs
	Fate of suspected drug	
Drug withdrawn	26	61.90
Dose altered	00	00
No change with suspected drug	16	38.09
	Treatment for suspected reactions	
Specific treatment given	00	00
Symptomatic treatment given	24	57.14
No treatment given	18	42.85

DISCUSSION

Medicines are used to treat diseases as they have ability to modify the pathological changes in the body and often carry certain amount of risk in the form of unwanted effects known as adverse drug reactions (ADRs). No drug is absolutely safe, even when prescribed in therapeutic doses. As per a published report every year, 1, 06, 000 die in USA due to ADRs.[12]

Worldwide ADR reporting is considered as an essential part in the post marketing surveillance and drug safety. Thus many developed countries have introduced their own national pharmacovigilance program or ADR reporting schemes. Majority of these reporting systems are voluntary and encourages all health care professionals to report ADRs. In the beginning, only doctors were encouraged to report ADRS but later, pharmacists were also included in the reporting system as pharmacists are in a suitable position to enquire the patient about the usefulness of medication and any untoward incidents due to drug usage. Even some controlled trials have confirmed the useful role of pharmacists in detecting the ADRs during the clinical care.

Systematic review of literature on the incidence of ADRs in hospitalized patients has shown that 3.5 -7.3% of the hospitalized patients may experience an ADR[13]. In India, a study conducted by M. Ramesh et al in their seven months study involving 3,717 patients observed that 3.7% of the inpatients have experienced an ADR.[5] The prevalence and incidence rate of ADRs may be high in primary care settings. A recent cohort study has shown that 25% of the patients receiving the primary care prescriptions developed an ADR of which 7.1% of the ADRs required hospitalization.[14]

In India, majority of the prescriptions are dispensed in the community set up and ADRs often go unnoticed in community setup because of lack of awareness, poor reporting by general practitioners, and lack of reporting system. In 2004, National Pharmacovigilance Program (NPP) was started and encouraged all the health care professionals including pharmacists to report the ADRs.[15]

In the present study, although the invitation letters were sent to 219 qualified practicing pharmacists, 52 pharmacists have shown interest but ultimately only 28 pharmacists participated in the workshop. This poor response might be due to lack of interest, lack of time or other personal priorities. After the training, 10 community pharmacists have submitted 42 ADR reports in a period of three months. In such short span, 42 reports can be considered as an encouraging number. In a study conducted in Wales, over 17 month period, 49 reports were submitted by 21 pharmacists. Comparing to this number of reports, the number of reports received in our study can be considered as encouraging. The quality of ADR reporting by the study pharmacists was also examined. All the fields in the reporting form were appropriately filled by the trained pharmacists. This shows training has improved their understanding about identification of an event and appropriate filling of the fields to assess the causality.

The causality assessment of the reported ADRs in our study suggests that the drug class commonly implicated with ADRs was antibiotics (42.85%) followed by NSAIDs (16.66%) and cardiovascular. The findings are concurrent with the studies carried out by Swapna Varghese et al,[16] and Mathews George et al,[17] in the hospital setup where the drug class commonly implicated with ADRs was Antibiotics (16%), followed by NSAIDs (12.26%). and the most common organ system associated with ADRs was the dermatological system (45.23%) followed by nervous system (23.80%). Most of the reported ADRs were found to be mild (69.04%) in nature.

A review meeting was organized with the trained pharmacists to strengthen the ADR reporting. Their opinions, thoughts and problems experienced in ADR reporting were collected. The problems expressed by the pharmacists for poor reporting were unawareness of ADR reporting system by the patients, inadequate communication skills of the pharmacists, lack of motivation. To overcome these problems, few strategies were planned such as displaying suitably designed poster on ADRs in local language to motivate the patients to report the side effects experienced by them to the pharmacist. Regular telephone reminders, personal visits to the pharmacies, assisting the pharmacists in identifying an ADR, thanks giving notes to pharmacists whenever they reported an ADR helped us to get increased number of ADR reports. Even in developed countries, under reporting is common with doctors and pharmacists due to lack of reporting system, inadequate training, and may have a feeling that one report make hardly any difference. In Netherlands, where community pharmacists report maximum ADRs, the pharmacists have expressed that a small amount as an incentive may motivate them to report ADRs. Though ADR reporting is voluntary, the pharmacist has to spend his or her business time and energy to collect the information. In view of establishing the drug safety, pharmaceutical companies

offering a small amount for a valid report may also increase the number of ADR reports. The other most important opinion expressed by the respondent pharmacists is continuous training. These opinions were found similar with that of overseas pharmacists who have also expressed that regular training boosts their confidence in detection and reporting of an ADR.[18] An additional information and hands on training regarding how to collect information, how to fill the fields in the reporting form, strategies to manage the ADRs will further strengthen the confidence of the pharmacists and they can easily report an ADR. Further investigations on studying the attitudes of the community pharmacists towards ADR reporting may help in strengthen the reporting practices.

CONCLUSION

This study reveals that training has shown a positive influence in the knowledge, and attitude of practicing community pharmacists towards ADR reporting. Continuous motivation through phone calls, thanks giving notes and personal visits increased the number of ADR reports. The most common class of drugs causing more number of ADRs is Antibiotics and the organ system affected is dermatological

ACKNOWLEDGEMENTS

Authors thank Principal, JSS College of Pharmacy, Dr. G.Parthasarathi, Professor and Head, Dr. M.Ramesh, Professor for their valuable support in preparation of the manual and conduct of the training session.

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