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ADVERSE DRUG REACTION MONITORING AND REPORTING BY COMMUNITY PHARMACISTS: A REVIEW

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ABSTRACT

Adverse drug reactions are one of the leading causes of morbidity, mortality and increased health related cost. Since the incidence of ADRs is more than 50% in community settings, community pharmacists in overseas are playing vital role in monitoring and reporting the ADRs to their respective national Pharmacovigilance program. Research studies have corroborated that community pharmacists in Canada (89%), Australia (41%), The Netherlands (40.2%), Spain (26%) and Portugal (24%) are reporting ADRs to their respective national Pharmacovigilance programs. However in India, due to trader attitude the community pharmacists have not yet started their contribution to Pharmacovigilance program of India (PvPI). This review article describes about the attitudes, behaviours and current practices of community towards ADR reporting and a brief discussion on barriers in reporting ADRs.

KEYWORDS: Adverse drug reactions, community Pharmacists, Attitudes and behaviors, Barriers.

INTRODUCTION

Drugs 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 they always pose unwanted or unintended effects known as adverse drug events. [1] Adverse Events (AEs) are defined as any unfavourable and unintended medical occurrence that in coincidence may present during treatment with a medicinal product but does not necessarily have a causal relationship with this treatment. It includes all adverse reactions or events due to medicinal products and any other incidents thought not to be reactions. Simply, not all AEs are due to

medicinal products as some may be resulted due to patient's illness or conditions, genetic or environmental factors, diet or any other causes. [2]

World Health Organisation (WHO) defines adverse drug reaction as "any response to a drug that is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of a physiological function". [3]

Factors Underlying For Occurrence of Adverse Drug Reactions

Factors which are underlying in the occurrence of ADRs have been identified and listed below.

1. Pharmacodynamic factors
- Receptor sensitivity variations

2. Pharmacokinetic factors
- Absorption
- Distribution
- Metabolism
- Excretion

3. Concurrent disease
- Impairment in renal function
- Impairment in hepatic function
- Heart failure

4. Drug-Drug interactions
5. Physiological condition
- Age
- Pregnancy
- Obesity
- Lifestyle factors
- Alcohol intake
- Smoking

6. Changeability in genetic factors
7. Adherence to prescribed therapy
8. Medication errors. [4]

Importance of the ADR Monitoring and Reporting

In clinical trials, drugs are generally studied in a controlled environment like small number of patients with a limited duration of time. The safety profile of the drug was not fully established with different co morbid conditions and special populations. While the approval process includes extensive safety testing, these trials sometimes exclude the elderly, the very young, and patients with co morbidities. Often patients on multiple drug therapy and patients with decreased renal and hepatic function are also excluded. In this patient population, any potential to ADRs will be missed in tracking the ADRs during research studies. It is extremely difficult to predict prescription pattern in the patients by the clinicians.[5]

Benefits of ADR reporting

Following are the benefits of ADR reporting

1. Provide information regarding risk profile of the drug.
2. Harmonizes the risk-management activities and efforts to minimize the drug related problems.
3. Assess the safety profile of drugs, especially recently approved drugs.
4. Quantify the ADR incidence rate.
5. Awareness development in health care professionals and patients about potential drug related problem and monitoring them to report ADRs.
6. Assessment of economic impact due to ADRs and strategies to minimize the same by assessing severity and preventability. [6]

Incidence of Adverse Drug Reactions incidence – Global Scenario

Adverse drug reactions are a significant cause of morbidity and mortality. They are adding huge healthcare cost to exchequer. The global scenario reflects that 3% to 6% of hospital admissions are due to ADRs while percentage of patients experience ADRs during hospitalization ranges from 1.5 to 35%. [7] A meta analysis suggest that ADRs were rated as between fourth and sixth commonest cause of death in the US and fatal adverse drug reactions being expected in approximately 0.32% of all hospitalized patients. [8] It is estimated that a hospital spends an average of Rs.481/- per day for the management of ADRs.[9] However in the incidence of ADRs in community settings are estimated to the tune of 57% and often go undetected due to under reporting by health care professionals. [10] Various countries follow their own method of reporting schemes to detect and report ADRs to their national Pharmacovigilance programs. Majority countries have permitted physicians,

pharmacists and nurses to take the active part in reporting ADRs. However in recent times consumers were also encouraged to report ADRs. All healthcare providers have specific roles to play in maintaining balance between benefits of medicines and their risks through identifying and reporting ADRs.

Findings of various research studies suggest that pharmacists in overseas are playing vital role in ADR reporting. Community Pharmacists in countries like Canada (89%), Australia (41%), The Netherlands (40.2%), Spain and Portugal 26%, 24% respectively report ADRs to their respective National Pharmacovigilance Programs. [11]

Indian Scenario

Pharmacovigilance in India is a highly essential because of increasing trend of outsourced clinical trials and on going clinical research. Considering 1.21 billion population of India, estimated rate of spontaneous reports by WHO are around 200 per 1000000 population every year. However on an average only 23,310 cases were reported per year during last 3 years.[13]
In India, ADR reporting by healthcare professionals is not happening to the expected extent. The reasons identified for under reporting of ADRs are heavy patient load on doctors and lack of awareness about ADR reporting among pharmacists and nurses. Lack of training and motivation to healthcare professionals to report and monitor the suspected ADRs is also another important reason. In recent years clinical pharmacists are taking the responsibility to monitor and report adverse drug reactions. [14]

In India, community pharmacist's awareness towards ADR monitoring and reporting activity is in infancy. The reasons for this situation are trader attitude of the community pharmacists and non legalization of professional services. Community pharmacy is considered as last point of contact in health care system for patients where they procure their medicines on their prescriptions and have the opportunity to get medication usage information. Adequate sensitization of patients may motivate them to come back to their pharmacies to report any unpleasant event associated with their drug use. Thus, community pharmacists can play an important role in detection and reporting of suspected ADRs.

Community Pharmacists Knowledge, Attitudes and Practices towards Adr Reporting: International Scenario

In Sultanate of Oman a cross sectional pilot study was carried out in 2012 by Jimmy Jose *et al* to assess the knowledge, attitude and behaviour of community pharmacists towards

adverse drug reaction related aspects. They designed the questionnaires based on parameters evaluated as part of the study and by referring to previous literatures. Questionnaire consists of mainly three sections totally comprising of 21 questions. Section one comprises 9 questions to assess the knowledge of pharmacists on drug safety, Section two was having questions to assess the knowledge and attitudes of community pharmacists towards ADR reporting and their behaviour towards ADR related aspects. Finally section three was to capture demographics and professional details of the respondents. A total of 148 questionnaires were distributed to the pharmacists. Among them, 107 Pharmacists have participated in the study with a response rate of 72.3%. In section one, majority of respondents gave correct response to most of the questions. Consequently, the total median score for the questions in section one was 5 out of 9, which was a poor score. In section two, 89% of the respondents were aware of the national pharmacovigilance programme in Oman and 90.6% of the participants considered reporting of ADRs as their professional responsibility. The study findings conclude that pharmacists had an acceptable knowledge, attitude and behaviour towards ADR reporting and related aspects. This study suggests that the pharmacists require continuous educational programs about how to report ADR and motivate them suitably for an active participation in the ADR reporting programme. [15]

An another study was conducted by Mahmoud MA *et al* to assess the community pharmacists' knowledge, behaviors and experiences about adverse drug reaction reporting during 2013 in Saudi Arabia. Convenience sample of 147 community pharmacists, working in Riyadh were selected and questionnaires was distributed. About 104 pharmacists (70.7%) have responded to the survey. The study findings suggests that only 22% of the respondents were familiar with the ADR reporting process and only 20% knew that pharmacists can submit ADR reports through online and however majority of the participants (91%) had never reported ADRs. Reasons for not reporting of ADRs were lack of awareness about the method of reporting, misconception that reporting ADRs is the duty of physician and hospital pharmacists and ADRs in community pharmacies are simple and should not be reported. This study concluded that majority of community pharmacists in Riyadh have poor knowledge about the ADR reporting process and they need education and training programs to improve the knowledge and awareness of pharmacists regarding the ADR reporting. [16] Toklu *et al* conducted a study to know about the knowledge and attitude of the Turkish community pharmacists toward pharmacovigilance in the Kadikoy district of Istanbul during December 2005 and June 2006. A spontaneous survey was conducted in persons using a questionnaire;

the questionnaire consisted questions about the sociodemographic characteristics of the pharmacists, their knowledge of pharmacovigilance and their attitudes towards ADR reporting. Among 411 pharmacists requested to participate in the study, only 219 community pharmacists consented to participate in the study. The study findings suggests that 17.2% of the pharmacists had knowledge about pharmacovigilance, 65% of the pharmacists stated that, ADRs are reported by patients and 21% of pharmacists reported to the concerned organization. About 89% of the pharmacists believed that the role of the pharmacists in ADR reporting was essential. Finally the study concludes that the Turkish community pharmacists have poor knowledge about pharmacovigilance and a need for educational programs to train them about pharmacovigilance and ADR reporting. [17]

National Scenario

Prakasam *et al* conducted a cross sectional questionnaire based survey to assess the knowledge, perception and practice of pharmacovigilance among community pharmacists in various parts of Hyderabad during August 2011 to April 2012. The questionnaire encloses five sections, comprising of demographic data, questions on knowledge, perception and practice of pharmacovigilance. In this study, they approached to 650 community pharmacists, and 347 pharmacists completely filled the questionnaire. The study findings show that 28% of respondents have good knowledge about the ADR, 10% had fair knowledge and 62% had poor knowledge about Pharmacovigilance. Majority of pharmacists (64.3%) felt that the adverse event is very simple and non-serious, hence did not need to report. The study concludes that, if adequate training is given to the pharmacists, they can certainly take the responsibility of identifying and reporting ADRs. [18]

A pilot study was conducted by R Adepu *et al* in Mysore district. Pharmacists were offered a structured training. After the training 10 pharmacists have reported 45 valid reports in 3 months period of time and majority of the reported ADRs were possible in nature. This study suggests that, if adequate training is given to pharmacists, they can certainly take the responsibility of identifying and reporting ADRs. [19]

Barriers in Reporting the Adrs by the Community Pharmacists

In India, community pharmacists' awareness towards ADR monitoring and reporting activity is in infancy. The important reason for this is community pharmacies are more often managed by less qualified and untrained persons. In the pharmacies manned and managed by registered pharmacists are also having inadequate knowledge about adverse drug reactions and these

registered pharmacists did not know how to report ADRs. The curriculum that is being offered also not discuss about Pharmacovigilance activities. In addition, pharmacist's services are not legalized in India and they do not have any responsibility in drug therapy management. Thus pharmacists' do not show much interest in Pharmacovigilance activities. Although community pharmacy is the last point of contact for patients where they procure their medicines and share their problems regarding drug therapy. Majority times, pharmacists are not available physically to respond patients' queries. Thus patients do not show any interest to report any unpleasant event to the pharmacist. [19]

In the study conducted by Toklu HZ in Istanbul reported that the reasons for not reporting the ADRs were lack of time, different care priorities, uncertainty about the drug causing ADR, difficulty in accessing forms, lack of awareness of requirements for reporting and lack of understanding the spontaneous reporting systems. [17] In a study conducted by Mahendra kumar BJ et al, the authors have described the reasons for not reporting the ADRs. As pharmacists did not know how to report ADRs, pharmacists did not felt that ADR reporting was beneficial and did not know how to get the reporting forms and did not know that pharmacists can report ADRs and lack of time were identified as the barriers in reporting. In the study conducted by R Adepu et al, lack of remuneration was also identified as one of the reasons for not reporting ADRs.

In assessing the barriers to report ADRs, questionnaire survey regarding the knowledge of the Dutch ADR reporting system was conducted among a stratified random sample of 200 community pharmacists. The number of self reported ADR reports was compared with those actually received by their respective National Pharmacovigilance centre. Community pharmacists have considered reporting of ADR as an integral part of their professional's responsibilities. Comparison of self reported ADR reports and actually received reports indicated that pharmacists have overestimated the number of reports they have reported. Community pharmacists in Netherlands are knowledgeable about reporting ADRs and highly motivated to do so. This positive attitude towards adverse drug events is based on the established tradition of pharmacist reporting in the Netherlands. However Van Groothest AC et al had measured the barriers in reporting the ADRs by Dutch pharmacists as follows.

- Reporting ADR was too time consuming
- No reporting forms available

- Reporting address unknown
- Reporting form is too complicated
- Too time consuming
- All ADRS are known
- Fear of liability
- Insufficient Clinical Knowledge
- Do not know how to report
- Uncertainty of Causality. [21]

Elkalmi et al study reveal the reasons include attitudes and perceptions of community pharmacists towards ADR reporting as well as other logistic barriers such as unavailability of ADR reporting forms, lack of knowledge of how and where to report the ADRs, lack of time, uncertainty about the drugs causing the ADRs, poor awareness about the purpose of spontaneous reporting systems. [22] In a case-control study done in Portugal to assess the influence of pharmacists' attitudes on adverse drug reaction reporting, it was found that under-reporting was strongly associated with certain attitudes, possibly indicating that under-reporting could be minimized through educational interventions targeted at changing such attitudes. [23]

Impact of Educational Interventional Programs

A cross sectional study was conducted in 42 community pharmacies in the state of Penang, Malaysia. A pharmacist was approached through mail to participate in a half day educational seminar on Pharmacovigilance and ADRs reporting process. Among the 210 community pharmacists approached only 42 community pharmacists (20%) had agreed to participate in the educational program. The aim of training program to pharmacists was to gain knowledge and take initiative in the Pharmacovigilance activities and ADR reporting process. The knowledge of Pharmacovigilance and ADRs reporting among community pharmacists was assessed by asking 10 true/false questions. A score 1 was given for each correct answer and 0 score for each wrong answer. The community pharmacists overall pre-test and post-test scores were compared based on the number of questions answered correctly. The pre assessments and post assessments were completed by all of the 42 community pharmacists. The mean ± SD total knowledge score of Pharmacovigilance and ADRs reporting after the educational intervention significantly increased from 4.6 ±1.9 to 8.3 ± 1.4. This study concluded interventional program has a positive change in the knowledge and perception towards Pharmacovigilance activities compared with the baseline results. [25]

Reporting of Adrs by Community Pharmacists

Reporting the ADRs by community pharmacists can generate useful data regarding the safety profile of drugs. This information will help in developing strategies to minimize the occurrence of ADRs in the community. [24]

Strategies to Improve Adr Reporting By Community Pharmacists

Considering the high incidence of ADRs in community setting, to improve the ADR reporting in community pharmacies, following strategies may help in improving the reporting rate.

1. Improving the awareness about importance of Pharmacovigilance and role of pharmacists in strengthening the same through organising workshops on adverse drug reaction reporting and monitoring
2. Awareness on adverse drug reactions to consumers or general population.
3. Set up of the ADR drop boxes at the community pharmacy.
4. ADR Reporting should be made mandatory for community pharmacist.
5. Providing incentives to the community pharmacists for quality reports.
6. Creating consumers awareness in reporting ADRs.
7. Periodic meetings between community pharmacists and nearest ADR monitoring centre coordinator to improve the quality of reports.
8. Implement the data base system in community pharmacy setting which includes patient characteristics with respective treatment and physician details.
9. Awareness on important ADRs to the community.

CONCLUSION

Community pharmacists are in better position to know the patient needs, their suffering with medicines and professionally qualified to report adverse events to the Pharmacovigilance programs. Many research findings suggest that, lack of awareness regarding reporting, such as where to report and how to report and other personal barriers in reporting can be overcome through continuous education and motivation.

REFERENCES

1. Parthasarathi G and Olsson. S. Adverse Drug Reactions. A textbook of clinical Pharmacy Practice by Parthasarathi G, Karin Nyfort-Hansen & Nahata MC. Orient Longman, 2004; 8:84-86.

2. Adverse Drug Events, Adverse Drug Reactions and Medication Errors, *Frequently Asked Questions*, VA Center for Medication Safety And VHA Pharmacy Benefits Management Strategic Healthcare Group and the Medical Advisory Panel November 2006).
3. WHO Collaborating canter for international drug monitoring, the Uppsala monitoring centre. Adverse reactions and adverse reactions monitoring training course. Available from: http://www.who-umc.og/DynPage.aspid = 13140andmn = 1514#6.
4. Farcas A, Bojita B. Adverse Drug Reactions in Clinical Practice: a Causality Assessment of a Case of Drug-Induced Pancreatitis, J Gastrointestin Liver Dis. 2009.
5. Zolezzi M, Parsotam N. Adverse drug reaction reporting in Neazealand:implications for pharmacists, Therapeutics and clinical risk management, 2005; 1(3):181-188.
6. American Society of Health-System Pharmacists. ASHP guidelines on adverse drug reaction monitoring and reporting. *Am J Health-Syst Pharm.* 1995; 52:417–9.
7. Adhikarya J, Bhandare B, Adarsh E. A study to assess knowledge, attitude, and practice of Adverse drug reaction reporting among physicians in a tertiary care hospital, Journal of Evolution of Medical and Dental Scinces March 4, 2013; 2(9):1027-34.
8. Lazarou J, Pomeranz B, Corey PN. Incidence of adverse drug reactions in hospitalized patients. A meta-analysis of prospective studies. JAMA 1998; 279: 1200-1205.
9. Arulmani R, Rajendra SD, Sueash B. Adverse drug reaction monitoring in a secondary care hospital in South Indian. Br J Clin Pharmacol. 2008; 65; 210-6.
10. Mandavi, Cruz SD, Sachdev A. Adverse drug reactions & thier risk factors among Indian ambulatory elderly patients. Indian J Med Res September, 2012; (136):404-410.
11. Van Groothest K, Olsson S, Couper M. Pharmacists' role in reporting adverse drug reactions in an international perspective. Pharmacoepdemiology and Drug Safety July 2003; interscience (www.interscience .wiley.com).DOI;10.1002/pds.897.
12. Khalili H, Mohebbi N, Hendoiee N, Keshtkar Aa, Dashti-khavidaki S. Improvement of knowledge, attitude and perception of healthcare workers about ADR, a pre- and post-clinical pharmacists' interventional study. BMJ open accessible medical research 2012; (000367):1-5.
13. Kalaiselvan V, Gupta SK, Thota P. Pharmacovigilance programme of India. 2013 Dec Date; 02.
14. Adepu R, Nagavi BG. General practitioners perceptions about the extended roles of community pharmacists in the state of Karnataka: a study. Indian J Pharm Sci. 2006; 68(1):36-40.

15. Jimmy Jose, Beena Jimmy, Hamed AS. A cross sectional pilot study on assessing the knowledge, attitude and behavior of community pharmacists to adverse drug reaction related aspects in the Sultanate of Oman. Saudi Pharmaceutical Journal July 2013.
16. Mahmoud M.A. *et al*, community pharmacist's knowledge, behaviors and experiences about adverse drug reactions reporting in Saudi Arabia. Saudi pharmaceutical journal 2013; http:/dx.doi.org/10.1016/j.jsps.2013.07.005.
17. Toklu HZ, Uysal MK. The knowledge and attitude of the Turkish community pharmacists toward pharmacovigilance in the Kadikoy district of Istanbul. Pharm World Sci. 2008; 30(5):556-562.
18. Prakasam A, Nidamanuri A, Kumar S. Knowledge, perception and practice of pharmacovigilance among community pharmacists in south India. www.pharmacypractice.org. available. from;//http://scielo.isciii.es/pdf/pharmacin/v10n4/original16.pdf.
19. Raj Rakesha CP, Adepu R. Design and Implementation of Adverse Drug Reaction Reporting System in Community Pharmacies. Indian J. Pharm. 2009; 2(2):32-37.
20. Mahendra Kumar BJ, Sandeep A, Soumya M. A Survey on Assessing the Knowledge, Attitude and Behavior of Community Pharmacists to Adverse Drug Reaction Related Aspects. Indian Journal of Pharmacy Practice. 2012; 5(4):51-55.
21. Van Groothest AC, Mes K, De Jong-van Berg LT. Attitudes of community pharmacists in the Netherlands towards adverse drug reaction reporting. The International Journal of Pharmacy Practice December. 2002; 10:267-272.
22. Elkalmi RM, Hassali MA, Ibrahim MI. A qualitative study exploring barriers and facilitators for reporting of adverse drug reactions (ADRs) among community pharmacists in Malaysia. Journal of Pharmaceutical Health Services Research 2011; 2(2):71-78.
23. Herdeiro, Maria T1 2; Figueiras, Adolfo1; Polónia, Jorge3; Gestal-Otero, J J1 4. Influence of Pharmacists' Attitudes on Adverse Drug Reaction Reporting: A Case-Control Study in Portugal Drug Safety, 2006; 29(4): 331-340.
24. Palani S, Mishra P, Izham M, Celena A. Community pharmacovigilance in Nepal: a guide for community pharmacists. A publication of the regional pharmacovigilance centre 2008. Manipal teaching hospital, Pokhara, Nepal. Available from: URL:http://www.haiap.org.
25. Elkalmi RM, Hassali MA, Ibrahim MI. Impact of educational intervention for improving Pharmacists knowledge in adverse drug reaction reporting: Experience from Malaysia, The open Drug Safety J. 2011; 2: 47-53.