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## A REVIEW ON ROLE OF PHARMACIST ON ECONOMIC BURDEN OF ADVERSE DRUG REACTIONS

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#### **ABSTRACT**

Adverse drug reaction (ADR) defined as harmful or unpleasant reaction resulting from intervention due to the use of medicinal product which may produce hazard from future administration. The incidence of ADRs was being increased from 3.7% to 30%. The studies report that ADRs account for 5% of hospital admissions and seen in 10-20% of hospitalized patients. Incidence of serious ADRs was 6.7% and fatal ADRs were 0.32% respectively. ADRs account for 4.2-30% of hospital admissions in United States and Canada, 2.5-10.6% in Europe and 5.7-18.8% in Australia. The pharmacist must assist in monitoring the safe and effective use of medication and reduce the occurrence of ADRs. As the pharmacists have vast knowledge of therapeutics and pharmacology of medications they can detect and monitor the ADRs and other medication related problems. Pharmacists should work together with other health care professionals to increase reporting of ADRs in hospital and community settings.

**KEYWORDS**: Adverse drug reaction, economic burden, patients', pharmacist, medications.

#### INTRODUCTION

Adverse drug reaction (ADR) defined as harmful or unpleasant reaction resulting from intervention due to the use of medicinal product which may produce hazard from future administration. Even though ADRs are to be concerned by the medical professionals, pharmaceutical industry and regulatory authorities, they are not being reported. In India, under aegis of ministry of health and family welfare initiated Pharmacovigilance Programme of India and established adverse drug monitoring centers at different areas of the country to monitor ADRs. [2] The incidence of ADRs was being increased from 3.7% to 30%. Based on the incidence and severity of ADRs the cost per ADR ranges from 215- 459 United States (US) dollars and cost per in-house ADRs alone was 2 million US dollars in general medicine department. In India it has been estimated that the amount to treat ADRs was INR690/- (Indian Rupee). Underreporting of ADR is the most commonly reported problem for the incidence of ADRs. This increases the economic burden on the society and government and affects the healthcare system and patients in many ways such as complication of therapy, prolongation of hospital visits and in turn leads to increased economic costs for patients as well as government. In US the annual economic burden accounts 177.4 billion dollars. [4] The present review focus on

economic burden on patients and government due to ADRs and role of clinical pharmacist to compensate them with specific treatment or alteration of dosage regimen or withdrawal of product (drug).

## **EPIDEMIOLOGY**

A systematic review was done by considering 16 studies to find out the incidence of ADRs that lead to hospitalization and that developed during hospitalization. The risk factors for ADRs were age, gender and polypharmacy. Studies which include ADR that lead to hospitalization and developed during hospitalization were 10. Six studies included ADRs that lead to hospitalization and 5 studies included ADRs that developed during hospitalization. This study concluded that hospitalized patients had significant burden of ADRs. [1] The studies report that ADRs account for 5% of hospital admissions and seen in 10-20% of hospitalized patients. Incidence of serious ADRs was 6.7% and fatal ADRs were 0.32% respectively. [2] ADRs account for 4.2-30% of hospital admissions in United States and Canada, 2.5-10.6% in Europe and 5.7-18.8% in Australia. [5] Another study reported that in south India, among 3.7% hospital admissions suffering from ADR, 1.3% was fatal and 0.7% of admissions were due to ADRs. [10]

#### **Economic Burden In Various Parts of The World**

A review was conducted to identify the economic burden and revealed that US costs 30.1 billion dollars annually and costs may be due to increased hospitalization, length of stay and lab investigations. The cost to prevent the ADR was reported to be higher than non-preventable ADRs. The inpatient cost per ADR was found to be US\$ 2262 and in non-intensive care unit was US\$ 13,994 and in Intensive care unit (ICU) was US\$ 19,685. [8]

In India – ADRs are resulting in hospital admission and promotes significant economic burden. Many studies included assessment of ADRs using different scales like Naranjo, World Health Organization (WHO) causality assessment scale, Hartwig siegel scale etc. A study included epidemiology and economic burden of ADRs and risk factors among ambulatory patients for a period of 6 months. The study included 400 prescriptions in which 138 identified with ADRs. The ADRs were assessed using Naranjo's algorithm and revealed that 48 ADRs were definite, 57 were probable and 33 were possible. Severity of ADRs was assessed using Hartwig siegel scale and Schumock Thornton scale was used to assess preventability of ADRs. Severe ADRs were 27 and preventable ADRs were 36. 28 ADRs were not preventable and accountable a mean hospital stay of 8 days. The average cost per patient suffered with ADR was INR 3,751/-. The reported risk factors were age (>60 years), gender (female), polypharmacy (>5 drugs), duration of treatment (>1 month). The study concluded the economic burden in ambulatory patients only and accounted for increased treatment costs for the ADR. [3]

**In South India** – A study was conducted in south Indian tertiary care teaching hospital for a period of 6 months. Patients in one female medical ward and 2 male medical wards were included in the study. Total number of male patients was 104 and female were 142. The age groups included from 16 years to 76 years and above. The ADRs were assessed using Naranjo scale and severity was assessed using Hartwig siegel scale and classification of ADRs into type A or type B was done according to Rawlins and Thompson classification. It was estimated that a total of 317 ADRs among 246 patients were identified. The total cost was found to be Rs. 1,567,397 (US \$ 36,451) and average cost per patient due to ADR was Rs. 4,945 (US\$ 115). The cost was calculated based on organ system classification and it revealed that cost per ADR was highest in Urinary system disorder (US\$ 1455). Hepatocellular damage was most commonly seen in patients and that accounted for a cost of US\$ 7520. The study included intensive monitoring method to detect the ADRs and the incidence rate was 32.7%. This study concludes the economic burden on patients due to ADR increases as per organ system classification. [4]

### In Eritrea (Africa)

A study was conducted in 17 Eritrean public hospitals and one private hospital to determine the economic burden of ADR related health problems for a period of 5

months. The prevalence of cost of treatment for ADR was assessed. A total of 5848 patients were admitted in 18 hospitals and of them 922 were identified with ADRs and 891 patients received management or treatment for ADR. The total expenditure for patients with ADR was US\$ 9,517. The cost of ADR per patient was US\$ 34.33. At zonal level hospitals, 287 patients were identified with ADRs and total expenditure was found to be US\$ 14,922.3. The total recurrent expenditure resulted in 35% of total expenditures on ADRs. The zonal referral hospitals accounted for high costs of total expenditure that includes consultation fee, bed charge, diagnostic and treatment expenditure. The next highly reported ADRs and economic burden was Orrora Pediatric National referral hospitals. The study revealed that the ADR related economic burden was found to be substantial.<sup>[5]</sup>

#### In Nigeria

A descriptive prospective study was conducted in Nigeria for serial entry of patients in internal medicine department of south-south Nigeria for a period of 9 months. The causality assessment was done using WHO rating scale and Naranjo algorithm. According to the WHO scale, the ADRs were classified as certain which were 10, probable cases were 17 and possible cases were 24. According to the Naranjo algorithm definite cases were 8, probable were 19 and possible were 23. The statistical analysis was done using CHI-square distribution and found that there is association between ADR and comorbidities, number of medications. The average cost for treatment of ADRs among the inpatients was US\$ 24.38. Total medicine cost for treatment of ADR was US\$ 1243.60. Insulin, analgesics used highest number of ADRs among the study patients. The study included only the medication costs excluding the costs for bed space, diagnostic tests, consultation fee and miscellaneous costs. The study concluded that ADRs were resulting in economic burden on the society. [6]

#### In New Jersey

A total of 196 patients were included in the study and of them 131 were matched with 1338 patients who have not experienced any ADR. The organ systems affected most were gastrointestinal, dermatologic and immune systems. The total hospitalization cost was US\$ 22,775. The ADRs were observed mostly in geriatrics when compared with other age groups. The hospitalization cost per patient was US\$ 23,638 for > 65 years of age and US\$ 18,385 for < 65 years of age. The ADRs reported were nausea, itching, rash, thrombocytopenia, vomiting, hyperglycemia and diarrhea. Length of stay and hospitalization cost were higher for patients with ADR than those patients who had not experienced ADRs. Changes in ADR reporting and strengthening of ADR reporting are needed to improve patient outcomes and can decrease the economic burden by reducing the occurrence of ADRs.<sup>[7]</sup>

#### In Canada

A retrospective cohort design study was conducted to find the incidence and costs of ADRs in emergency department in Ontorio hospitals. 0.75% of total amount of annual emergency department visits found to be ADR related and among those patients 21.6% were hospitalized. The total costs was increased from 1965075 US\$ to 2408325 US\$ during 2003 to 2007. [9]

#### Role of Pharmacist In Management of Adr

The ADR monitoring and management is a part of Pharmacovigilance. Pharmacists prevent, identify. document and report the ADRs. The role of pharmacist varies from country to country but the professional responsibilities remain the same. The pharmacist must assist in monitoring the safe and effective use of medication and reduce the occurrence of ADRs. Pharmacist should involve in data collection from the patient and promote pharmacoepidemiological studies. Pharmacist should explain about the errors due to the medication, problems with non adherence to medications and counsel the patient to improve safety and quality of life of patients. These activities can be done in inpatient settings during the ward rounds, medication management and prescription handling. pharmacists have vast knowledge of therapeutics and pharmacology of medications they can detect and monitor the ADRs and other medication related problems. Group discussions, lectures, training programs to health care professionals about the importance of seriousness, preventability and necessity of reporting ADRs can improve the relation between pharmacists and other health care professionals and improve the quality of life of patient. Pharmacists who work in community can have a great advantage of detection, monitoring and reporting of ADRs to authorities. Clinical pharmacists should work together with other health care professionals to increase reporting of ADRs in hospital and community settings.[12]

## DISCUSSION

In India, epidemiological studies for incidence, prevalence, risk factors, outcome ADRs are limited. Most of the Indian studies were single centered with small sample and limited duration. Systemic reviews are required to identify the incidence of ADRs and factors associated with it. [1] The studies were least conducted in medicine department where a number of cases can be identified and reported. Previous studies commonly report the dermatological, pulmonology, cardiovascular ADRs etc., but not in medicine department. A study reported that the documentation of ADRs were unintentionally done and may be because of work stress, poor knowledge of reporting ADRs, etc. [2] The awareness of risk factors of ADRs could help the physicians to detect patients who are at risk and might benefit from monitoring and reporting of ADRs. The clinical pharmacist should play an important role in detecting and monitoring of ADRs. [3] The economic burden due to ADRs is increasing due to under reporting and lack of management of ADRs. A study included that the average cost for a patient with an ADR was approximately found to be Rs. 4945/- in India. [4]

#### CONCLUSION

The ADRs can be fatal if untreated and reported. Many studies are being published to reduce the under reporting and promote the health and quality of life of patients, The economic burden on patients increases with increase in severity of ADRs. Many countries have reported the economic burden of ADRs on patients and also the government. Different studies found that ADRs account for 30% if hospital admissions in US and 5.7-18.8% in Australia, 2.5-10.6% in Europe and in developing countries like Africa and India the incidence is 12.6%. [5] Annually the cost for drug related morbidity and mortality was estimated to be in between \$30-\$130 billion dollars.<sup>[7]</sup> The research in Pharmacovigilance can promote the role of pharmacist and educational trainings and programs can help pharmacist to interact with health care professionals. [11] Therefore to decrease the economic burden and incidence of ADRs the pharmacist should play a vital role in reporting of ADRs to authorities. Pharmacists must work together with physicians and other health care professionals to aid the reporting of ADRs in hospital setting and community setting. [12]

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#### CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

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