Clinical Perspectives in Adverse Drug Reactions: A Review

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Abstract - Adverse drug reactions are major problem globally. It increasesmorbidity, mortality as well as suffering of patients. Pharmacovigilance is a science aboutdiscovery, collection and reportage of ADRsfor drugs. During clinical trials, ADRs are not detected properly. Here, Pharmacovigilance plays vital role in forming the safety of promoted drugs. Pharmacists have poor basic knowledge of Pharmacovigilance, ADRs & their monitoring.

Keywords: Adverse drug reaction, Pharmacovigilance, ADRs monitoring, Pharmacist.

I. INTRODUCTION

ADRsare result of misuse,overdose, or abuse of medicine which may be injurious, unintended effect of drug, and which occurs at any dose. Pharmacovigilance is a broad concept, here concerned with ADR monitoring. During clinical trials, sometimes unpredictable types of ADRs are not detected in small groups of peoples. Pharmacovigilance is science which involve in detection, understanding, and prevention of ADRs of drugs. However, ADRs monitoring and its reporting are in their infancy in India. Studies have shown that the active involvement of pharmacists is critical for the success of the Pharmacovigilance system. Review is prepared with object to evaluate the knowledge of pharmacist about Pharmacovigilance and ADRs monitoring. ADRs mainly of two types predictable and unpredictable. In case of unpredictable ADRs are not identified unless it has been subjected to most widespread use. It includes idiosyncratic reaction, allergic reaction genetic determined effects. To detect ADRs different methods like cohort study, spontaneous report, statistical analysis, and case-control are used. [1]

Types of ADRs: ADRs mainly classified mainly as predictable and unpredictable.

1.Dose-related ADRs:Meansan embellishment of the drug's therapeutic effects.

2.Allergic ADRs: It requires prior exposure to drug, which is drug independent. Allergymeans body’s immune response to drug which consider as foreign material.

3.Idiosyncratic ADRs: Exact mechanism and this raction occurs still not known exactly.It comes under the category of un predictable reaction.

ADRs monitoring system

Pharmacovigilance concept based on-

-Collection of information from scientific resources.

-Classify and analyze the information.

-Circulate the content and any action taken in all health sectors.

Following are success factors of Pharmacovigilance

-Public awareness to report suspected ADRs.

-Trained health care workers.

-Government support and well-defined policies.

-Presence of national coordinators and an advisory committee. [2-4]

Methods of identifying ADRs

1. Review on case reports

2. Cohort chart record review

3. Electronic patient record

4. By screening patient record

Status of Pharmacovigilance in ADRs monitoring in country:

National Pharmacovigilance Advisory Committee (NPAC) monitors the regionals well as all peripheral centers. Central Drug standard control organization has started a Pharmacovigilance program under DGHS, family welfare. Presently after every 6 months for first 2 years of marketing drug and annually for the subsequent 2 years' reports shall be submitted. All generated data including reports form shall be preserved for 5 years at zonal regional centers. [5]

Recommendation and Suggestions:

-Involvement of all categories of health professionals.

-There should be feedback from reported cases timely.

-Publishing reported ADRs in journalswill help to keep peoples and health professionals informed.

-Conduction of regular workshops, training regarding Pharmacovigilance.

-Periodical meeting from experts.

-Easy availability of ADRs reporting form.

-Incorporation of Pharmacovigilance in the syllabus.

-Each hospital should have local Pharmacovigilance centers.

- Regulatory authorities should make compulsion regarding qualified person practice in pharmacy.

Issues of ADRs & Pharmacovigilance:

-Most drugs are developed in western countries so clinical data is not available on Asian peoples.

-No data is available on ADRs due to the interaction between traditional drugs. [6-7]

II. PHARMACIST AND ROLE IN ADRS

He should play important role in evaluation of ADRs. He should obtain approval for the evaluation of ADRs through appropriate committees like the pharmacy and therapeutics committee. Pharmacist involves in ADRs reporting directly.

Involment of Pharmacist in analysis of ADR

It is responsibility of pharmacist to identify the drugs and patients who are at higherrisk .He should develop the policies and procedures for the ADR-monitoring and reporting program. Pharmacist should engage in development, maintenance, and evaluation of ADR records within the organizationas well as reporting of ADRs to the FDA or directlymanufacturer. [8-11]

Benefits of ADRs monitoring:

1. It gives summarize data about the quality and safety of drugs.
2. It initiates risk-management plans about the drugs which are on higher risk.
3. It can prevent predictable type of adverse effects.
4. It instructs and aware the health care team, patients, pharmacists, and nurses about adverse drug effects. [12-13]

III. CONCLUSION

Education and training to health professionals to improve the ADRs monitoring system should be given. Involvement of Pharmacovigilance in the pharmacy curriculum. There is a need to involve all health professionals in the ADRs monitoring system and in the future attention on ADRs of traditional drugs should keep.

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