

PHARMACOVIGILANCE IN INDIA: CHALLENGES AND FUTURE PROSPECTS

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Article Received on
20 March, 2018,

Revised on 10 April, 2018,
Accepted on 30 April, 2018,

DOI: 10.20959/wjpr20189-12091

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ABSTRACT

In the scenario of ever increasing range and potency of medicines, safety of medicines is one of the key parameter along with therapeutic efficacy for success of any drug. Now India is a preferred clinical trial for lunch drug entities. By keeping in view of increasing standardization process, Pharmacovigilance play an key role in health care system and through assessment and discovery of interaction among drug and their effect. Pharmaceutical and biotechnology medicines are design to cure prevent and monitoring ADRs required for each medication throughout its life cycle. Especially in India adverse events reported by PV system potentially benefitted to the

community. PV helps to the patients to get well and manage optimally or ideally avoid illness is a collective responsibility of health care system the review summarized objective and methodology use in PV with critical overview of existing PV in India, challenges to overcome and future prospect to Indian context.

KEY WORD: Pharmacovigilance, Adverse drug reaction, Clinical trials, Biotechnology.

INTRODUCTION

Pharmacovigilance play a key role in the health care system through assessment, monitoring and discovery of interaction amongst drug and their effect. The amount of variety of safety relevant data gathered from different patient population in global clinical trials are enormous. The main aim of PV in india is that to monitor ADR in country population with creat awareness. Due to some lack of awareness and improper planning and method various challenges overcome day to day. which must needed a better planning and proper implication for future prospective.

PHARMACOVIGINANCE

The WHO defined as that, the science and activities relating to detection, assessment, understanding and prevention of adverse effect or any other medicines-related problem.

ADR monitoring-medicines safety-drug monitoring.



ADVERSE DRUG REACTION

Any harmful or seriously unpleasent effects occurring at doses intended for therapeutic effects and which requires reduction of dose or withdrawal of drug or forecasts hazards from future administration.

AIMS OF PHARMACOVIGINACE

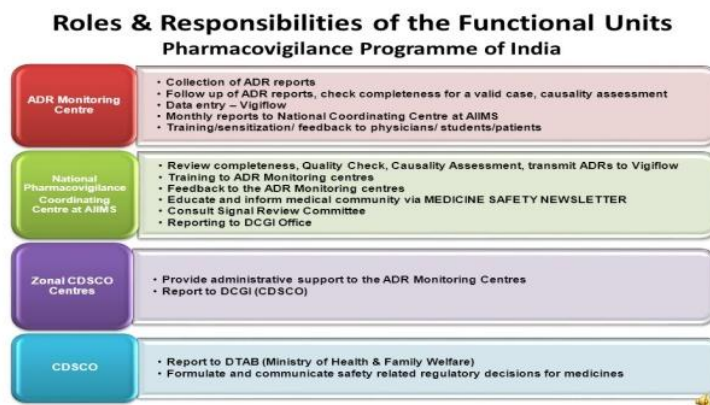
- Early detection of unknown safety problem
- Detection of increases in frequency
- Identification of risk
- Preventing patients from being affected



PHARMACOVIGILANCE IS IT NEEDED IN EVERY COUNTRIES ?

There are differences between countries in the occurrences of ADR due to differences in:

- Drug production
- Drug distribution and use
- Genetics, diet, traditions of the people
- Use of non-orthodox drug(e.g. traditional medicines)



PHARMACOVIGILANCE PROGRAMME OF INDIA

- To monitor ADRs in Indian populations
- To create awareness amongst health care professionals about the reporting in india
- To monitor benefits risk profile of medication
- Create a national centre of excellence at per which global drug safety monitoring standards.

PHARMACOVIGILANCE CHALLENGES AHEAD

1. India rates below 1% of PV while world 5% due to ignorance of subject and lack of training
2. The problems of large population that is predominately rural
3. Extensive use of traditional medicines
4. Poor spontaneous reporting
5. Inadequate post marketing surveillance



IMPROVING PHARMACOVIGILANCE

- Increase the awareness of health care professionals and public on the understanding of importance of pharamacovigilance
- Develop and promote an effective channel for ADR reporting
- Improve communication in the reporting of adverse event such as the regulator,the health care providers manufacturer for PV

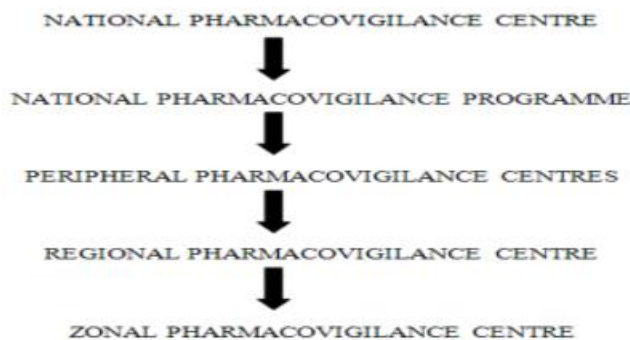
FUTURE STRATEGIES AND PROPOSALS

Training programs –medical students nursery and pharmacy graduates workers in rural area

A Uniform format for data collection and reporting needs to be designed

Active participation and enhancing drug safety

Building a network of pharmacovigilance and national data base in india



CONCLUSION

Pharmacovigilance is the system in which the pharmaceutical management of health care system is being quality assure. According to the growth of pharmaceutical sector the strong pharmacovigilance system must need to overcome for the current challenges to creat better healthy tomorrow.

AKNOWLEDGEMENT

I am grateful to Mr. Debdash panigrahi, lect., college of pharmaceutical sciences, puri for providing me knowledge and his guidance for presentation.

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