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ROLE OF PHARMACIST IN PHARMACOVIGILANCE

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ABSTRACT

In the situation of increasing range and strength of medicines, safety of medicines is the key parameter along with therapeutic efficacy for favorable outcome of any drug. India is now a preferred clinical trials port of call for drug entities to be launched. By viewing the increasing incidences, dug related mortality rate, proper identification of ADR's, reporting, evaluation and understanding of adverse drug reaction leads to the development of pharmacovigilance. Pharmacovigilance is branch of pharmacological science censorious to effective clinical practices and public health with immense ability of growth. This article summarizes aims, objectives and methods of pharmacovigilance and characterization of ADR's.[1]

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INTRODUCTION

The world health organization (WHO) defines adverse drug reactions (ADRs) as the reaction which is noxious and unintended to occur at dose used in humans for prevention of disease, diagnosis or therapy of disease and for the modification of physiological features. Major cause of morbidity and mortality around the world are due to ADR's. To build up reliable information on safety of medicines systemic pharmacovigilance is required. Patient care and patient safety comes under pharmacovigilance. It ensures best use of medicines for better treatment and prevention of ADRs. Pharmacist plays a major role in medication safety by reporting the ADR's. ADR reporting and monitoring system started in developing countries mainly in period of the Thalidomide tragedy. Pharmacovigilance is most important as it is concerned with identifying, validating, quantifying, evaluating and minimizing the adverse effects of medicines and thereby increasing the safety of drugs, nevertheless, under reporting can delay an early detection of ADR's. Among other health care professionals pharmacist have a unique position in monitoring and reporting ADR's.[1] ADR's may cause some serious untoward medical condition which may result in Hospitalization, prolonged hospitalization and may cause death.

CATEGORIZATION OF ADR's

Type A (Augmented)

- These are increasingly common and easily predictable.
- Mostly, occurs in each person if enough dose is given.
- Toxicity or overdose (e.g.: high dose of paracetamol may lead to hepatic failure).
- Side Effects (e.g.: sedation with Antihistamines).
- Secondary effects (e.g.: development of diarrhea with antibiotic therapy).

Type B (Bizarre Effects)

- These are unpredictable for the individual.
  - Not dose related.
  - Caused in less number of people
  - Intolerance (e.g.: tinnitus with aspirin administration).
  - Hypersensitivity: (e.g.: anaphylaxis with penicillin inundate)
  - Pseudo allergic: (e.g.: radio contrast dye reaction)

Type C (Chronic)

- These are associated with long term exposure to drug.
- E.g. Analgesic neuropathy

Type D (Delayed)

- These reactions show delayed effect on onset following prolonged exposure.
- These show carcinogenic actions.

Type E (Ending of Use)

- This occurs when a drug is suddenly discontinued after long term use, then the patient is affected with withdrawal reaction (e.g.: adrenal steroid).

Type F (Failure of treatment)

- It is frequently dose related and results from ineffective treatment.

Type G (Genotoxicity)

- These produce heritable damage in humans.

Type H (Hypersensitivity reaction)

- These are side effects caused by allergy or hypersensitivity. They are likely to be most common adverse reaction after type A. These can't be predicted and are dose dependent. In such cases the drug must be stopped.

Type U (Unclassified)

- Some ADRs have a process that can't be understood and these must remain uncategorized until anything is known about them[2]

Pharmacovigilance

In 1960's term "Pharmacovigilance" first appeared. This system is used to collect information, which helps in surveillance of medicinal products with particular reference to human beings and to assess such information scientifically[3]. The history of Pharmacovigilance goes many years back. A chain of cluster of cases resulted due to the use of some drugs (Thalidomide disaster, Sulfonamides disaster etc). For morning sickness and nausea Thalidomide was prescribed in 1957 in pregnant women, which soon caused congenital abnormality, which caused birth defects in infants. Due to which in 1965, Thalidomide have had been removed from the pharmacies in almost all countries. Nevertheless, it continued to be in the market for the treatment of leprosy, and in later years, it's indications extended to much wider range of medical conditions. It's use is allowed only under supervision of prescriber. Despite these precautions, in between 1969 -1995, 34 cases of thalidomide embryopathy were investigated[4]

The aims of pharmacovigilance

Events like thalidomide tragedy highlight utmost significance of effective drug monitoring systems for all medicines.

The focus of pharmacovigilance programmes are-

- To upgrade patient care or safety in relation to the use of medicines.
- To enhance public well-being or safety in relation to the use of medicines.
- To contribute in the assessment of benefit, harm, effectiveness, risk of medicines, encouraging their safe; rational and more effective (including cost-effective) use
- To stimulate the understanding, education and clinical training of pharmacovigilance.[5]

Pharmacovigilance in national drug policy

Establishment of national pharmacovigilance systems in reporting of adverse events, including national and also if suitable regional pharmacovigilance centers.

- Develop the legislation/regulation for medicine monitoring.
- To develop national policy, this includes cost, budget and finance.
- To continue educating healthcare providers on safe and effective pharmacotherapy.
- Provision of the latest information got on adverse drug reactions to professionals and consumers.
- Monitor the action of pharmacovigilance through process indicators and outcome.[6]

Pharmacovigilance Methods

According to International Conference on Harmonization Efficacy Guidelines 2 (ICHE2E) guidelines, the pharmacovigilance methods can be classified as-

Passive surveillance

Spontaneous reporting system (SRS)
Case series Stimulated reporting

Active surveillance

Sentinel sites
Drug event monitoring
Registries

Comparatives observational studies

Cross sectional study
Case control study
Cohort study

Targeted clinical investigations Descriptive studies

Natural history of disease
Drug utilization study
Pharmacovigilance methods can be also characterized as hypothesis generation methods and hypothesis testing method as follows:

Hypothesis generating methods

Spontaneous ADR reporting
Prescription event monitoring

Hypothesis testing methods

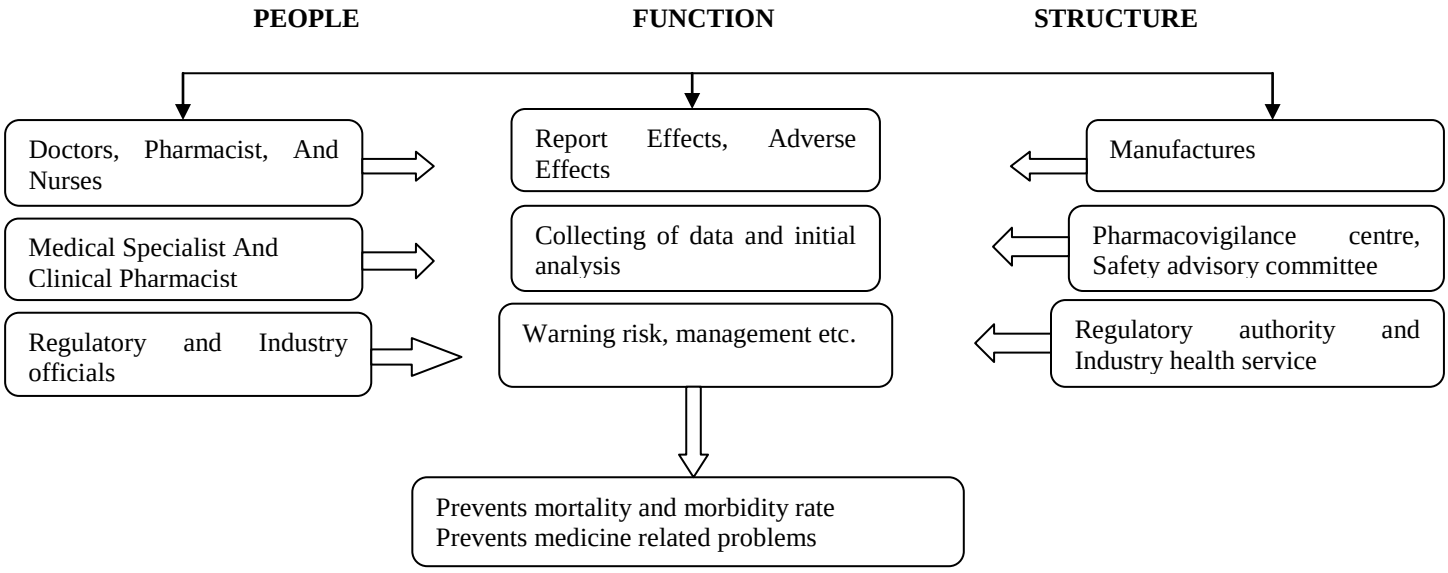
Case control
Cohort studies
Randomized controlled trials[7]

Functions of pharmacovigilance

a. Finding and analysis of new adverse drug reaction (ADR)
b. Exchange of information.
c. Periodical newsletter publication
d. Provision of WHO database as a reference source for signal strengthening
e. Supply of tools that helps in management of clinical information
f. Provision of training and consultancy support to national centers.
g. Designing of computer software for case report management.[8]

Pharmacovigilance – Reporting and functioning

Typical setup of pharmacovigilance studies, persons involved on various levels, organizational units and their functions are given below[9-10]



CONCLUSION

Despite 40-year history of pharmacovigilance it remains a dynamic clinical and scientific discipline. It plays a crucial role in meeting the challenges that come by the increasing range and vigor of medicines. Influence of pharmacovigilance is increasing in pharmaceutical industries and the examination of adverse drug reaction is increasing patient assent and safety.

Pharmacovigilance system is need of the hour in our country to protect the population from the potential harm and adverse effect due to some of the new drug molecules. It is the role of pharmacist to report ADR's.[11]

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Conflict of interest

The author declared no conflict of interest.

Abbreviations used

WHO - World Health Organization,
ADR'S - Adverse Drug Reaction,
SRS - Spontaneous Reporting System,
ICHE2E - International Conference on Harmonization Efficacy Guidelines 2

SUMMARY

Pharmacovigilance is an essential part of clinical research. It is "defined as the pharmacological science relating to the detection, assessment, understanding and prevention of adverse effects, for both long and short term adverse effects of drug. It's main aim is to contribute for the protection of public health in the terms of safety, quality and efficacy of medicines for human beings. This ensures the health care professionals and patients, to have access to information about the safe and defective use of medicine[12].

REFERENCES

1. Kaur M, Kosey S, Mehra N, Kumar R. KNOWLEDGE AND AWARENESS OF ADVERSE DRUG REACTIONS. International Journal of Pharmaceutical Sciences and Research. 2015 Nov 1;6(11):4601.
2. Härmark L, Van Grootheest AC. Pharmacovigilance: methods, recent developments and future perspectives. European journal of clinical pharmacology. 2008 Aug 1;64(8):743-52.
3. Parthasarathi G, Nyfort-Hansen K, Nahata MC, editors. A Text Book of Clinical Pharmacy Practice: Essential Concepts and Skills. Orient Blackswan; 2004
4. Kumar S, Baldi A. Pharmacovigilance in India: perspectives and prospects. Journal of Drug Delivery and Therapeutics. 2013 Nov 8;3(4):237-46.
5. Karelia BN, Piparava KG. Knowledge, attitude and practice of pharmacovigilance among private healthcare professionals of Rajkot city. International Journal of Basic & Clinical Pharmacology. 2017 Jan 23; 3 (1):50-3.
6. Meyboom RH, Lindquist M, Egberts AC. An ABC of drug-related problems. Drug safety. 2000 Jun 1; 22(6):415-23.
7. Jaiswal P. A Review on Adverse Drug Events to Create Awareness. Journal of Pharmacovigilance. 2014 Jun 6.
8. Abubakar AR, Simbak NB, Haque M. A systematic review of knowledge, attitude and practice on adverse drug reactions and pharmacovigilance among doctors. J Appl Pharm Sci. 2014 Oct 30; 4(11):117-27.
9. Desai CK, Iyer G, Panchal J, Shah S, Dikshit RK. An evaluation of knowledge, attitude, and practice of adverse drug reaction reporting among prescribers at a tertiary care hospital. Perspectives in Clinical research. 2011 Oct;2(4):129
10. Al-Hazmi NN, Naylor IL. A study of community pharmacists' awareness and contributions to adverse drug reactions (ADRs) reporting systems in the Makkah, Kingdom of Saudi Arabia (KSA). Journal of Clinical Trials. 2013;3(127):2167-0870.
11. Meyboom RH, Lindquist M, Egberts AC. An ABC of drug-related problems. Drug safety. 2000 Jun 1;22 (6):415-23
12. Pandurangan DK, Jithendra R, Sowjanya B, Perumal VK. Pharmacovigilance an Overview. International Journal of Research in Pharmaceutical Sciences. 2016 Dec 31;2(2):301-14.

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