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Scope of Pharmacovigilance

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Commentary

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INTRODUCTION

Pharmacovigilance is the pharmacological field which deals with the Detection, Assessment, Understanding and Prevention of unintended effects, adverse drug reactions or any other possible Medication errors, caused by Pharmaceutical product ^[1]. Pharmacovigilance aims to identifying new information about hazards as related to medication ^[2-3].

Pharmacovigilance promotes the systematic, rational use and assures the confidence for the safety of drugs. It improves Patient care and safety, Public health and safety ^[4-5]. The related fields to promote or encourage the Pharmacovigilance studies are Pharmaceutical industry, Paramedics, Pharmacists, and Practicing Clinicians etc ^[6-8].

Dying from a disease is sometimes unavoidable; dying from a medicine is unacceptable ^[9]. Pharmacovigilance concentrate on only drug monitoring and its process includes

- Collect and record of AEs/ADRs
- Causality assessment and analysis of ADRs
- Collate and code in database
- Compute risk-benefit and suggest regulatory action ^[10]
- Communicate for safe use of drugs among stakeholders

Adverse effects are manifold and numerous. Pharmacovigilance and signal detection are the activities to try and do for a drug (both pre and post marketing) to see adverse events & to suggest a new potentially causal association ^[11]. Anything which is new is considered as signal, it should be validated by taking into consideration of alternative relevant sources of Knowledge ^[12].

AE/ADR REPORTS: SOURCES

- Reporting Systems: From Health care Professionals (voluntary)-high incidence of under reporting
- Published scientific literature: From Pubmed, Scopus etc.
- Periodic Safety Update Reports (PSUR) ^[13]

The field of Pharmacovigilance has fully grown tremendously in recent years. This was caused by implementing advanced methods at pharmaceutical firms and at biotechnology companies through the addition of new products and in pioneering fields

^[14]. The most compelling source of growth within the Pharmacovigilance field has been through FDA needs related to the reporting of adverse events and other unexpected outcomes ^[15].

WIDENING SCOPE IN PHARMACOVIGILANCE

Pharmacovigilance conducting advanced drug monitoring study based Adverse drug reactions ^[16-19] adverse events report of new drugs include:

1. Medication errors and irrational use of medicines
2. Herbal, traditional and complimentary medicines
3. Substandard medicines and counterfeit medicines
4. Blood products, biologicals, medical devices and vaccines ADR

Pharmacovigilance main aim is to give clear information regarding drug safety and its Risk or benefits of drugs to the patients.

Patients are main end users of medicine. Patient information leaflet relating to medicine to be provided to the patient to increase the advantages of the medication and to reduce the risk associated with them ^[20-23]. It is essential for Risk Minimization by making an early detection and preventing the progression of the adverse effects.

IMPORTANCE OF PHARMACOVIGILANCE

Complete information of unintended and severe adverse events could be finding through the Pharmacovigilance. It could not be done through clinical trials which are conducted in an In vivo method ^[24].

CONCLUSION

It is expected that 50-75% of medical errors area unit preventable ^[25] therefore we'd like to suppose less concerning drug safety and additional concerning Patient safety.

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