



Pharmacovigilance and its Methods: An Recent Review

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ABSTRACT:

Pharmacovigilance is a scientific branch that plays a vital role in ensuring drug safety and effectiveness. It focuses on detecting adverse reactions to drugs, particularly those not identified during clinical trials but observed in marketed drugs. The World Health Organization defines pharmacovigilance as "the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems." Various methods, including passive surveillance, active surveillance, and stimulated reporting, are employed to identify adverse drug reactions.

Keywords: Surveillance, consolidation, Pharmacovigilance, Investigation.

Introduction:

Pharmacovigilance is a study of safety and effectiveness of a drug and different health related products. Pharmacovigilance play an important role in detection, assignment, understanding and prevention of drug related problems^[1,2,3]. Identification of adverse drug reaction (ADR) is important for the safety of patient who take a drug. Monitoring drug usage thoroughly, including pharmacovigilance inspections, ADR reporting, periodic safety report collection, and post-authorization safety studies, is essential. Information technology plays a crucial role in advancing the healthcare industry, significantly enhancing clinical safety practices. Therefore, ensuring the safety, efficacy, and cost-effectiveness of drugs remains highly significant at present. ^[4]. An important and integral part of clinical research is pharmacovigilance^[5].

Objectives:

- 1) Enhancing patient care and safety in connection with the utilization of medicines and all medical and paramedical interventions.
- 2) Enhancing public health and safety related to the utilization of medicines.
- 3) Identifying complications linked to the use of medicines and communicating them appropriately.
- 4) Assessing the benefits, efficacy, and risks of medicines while advocating for their safe, rational, and more effective (including cost-effective) use.
- 5) Promoting education, comprehension, and clinical training in pharmacovigilance, coupled with its effective communication to healthcare professionals and the general public.

Scope:

1. Enhance patient care and safety concerning the utilization of medications, as well as all medical and paramedical interventions.
2. Enhance public health and safety regarding the usage of medicines.
3. Play a role in evaluating the benefits, risks, effectiveness, and overall safety of medications, fostering their secure, logical, and optimized (including cost-effectiveness) application.
4. Foster comprehension, education, and clinical training in pharmacovigilance, ensuring effective communication to the public^[6].

b. Drug event monitoring :

In active pharmacovigilance surveillance, drug event monitoring involves identifying patients through electronic prescription data or automated health insurance claims.

c. Registries:

Registries, whether focused on a disease or a specific exposure like drugs, compile lists of patients sharing common characteristics. These registries, such as those for blood dyscrasias, severe cutaneous reactions, or congenital malformations, gather a comprehensive set of information through standardized questionnaires in a prospective manner.[4].

4. COMPARATIVE OBSERVATIONAL STUDIES:**a. Cross-sectional Study:**

A cross-sectional study, mainly used for surveys or ecological analyses, involves collecting data on inhabitants of patients during a specified interval of time, irrespective of exposure or disease status..

b. Case-Control Study:

In a case-control study, individuals with the disease or event of interest (cases) are matched with controls who do not have the condition. Both cases and controls are selected from the source population that gave rise to the cases. The selection of controls ensures that their exposure prevalence mirrors that of the source population.

C. Cohort Study:

A population at risk for the disease (or event) is observed over time to record the

Occurrence of the disease (or event) in a cohort study. Exposure status

Information is available during the follow-up period for each patient. A patient Might be exposed to a medicine at one time during follow-up, but not exposed at Another time. Meanwhile the population exposure during follow-up is Acknowledged, incidence rates can be calculated Concerning medicine exposure, Appraisal cohorts of interest are selected on the basis of medicine use and Monitored over time in many cohort studies.[6].

5. TARGETED CLINICAL INVSESTIGATION :

When risks appear in preapproval trials, more studies may be needed to understand adverse reactions. Researchers might conduct pharmacodynamic and pharmacokinetic studies to assess dosing instructions' impact on patient risk.[10,11,12].

Conclusion:

Pharmacovigilance is a crucial aspect of drug safety and effectiveness. It reduces the risks associated with drugs and offers benefits to patients. Pharmacovigilance detects adverse reactions of marketed drugs that may not have been identified during clinical trials, helping to overcome them. Various methods, such as active surveillance and passive approaches, are employed to identify adverse drug reactions

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