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A GLOBAL KEY TO MEDICATION SAFETY IN PHARMACOVIGILANCE

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Abstract:-

Pharmacovigilance definition given by WHO, it is “The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems.The volume of data handled has increased in tandem with the number of reported Adverse Drug Reactions (ADRs). Standardising the process of risk management and signal detection in the context of clinical trials and post-marketing pharmacovigilance is a difficult task. Nonetheless, there is a pressing need to comprehend and apply pharmacovigilance given the increased number of clinical trials and clinical research activities being carried out in India, as well as the phase of clinical trials and pharmaco epidemiologic studies.

Key words:-

Pharmaco epidemiologic studies, adverse drug reaction,clinical trials, post-marketing surveillance

Introduction:-

Pharmacovigilance

A crucial and essential component of clinical research is pharmacovigilance.[1] Throughout the course of a product's lifespan, both post-marketing pharmacovigilance and clinical trial safety are crucial. "The pharmacological science relating to the detection, assessment, understanding and prevention of adverse effects, particularly long- and short-term adverse effects of medicines," is the definition given to pharmacovigilance. In India, pharmacovigilance is still very new, and very little is known about the field. Not much has been accomplished in India in the area of pharmacovigilance, despite significant achievements in western nations. It is imperative to comprehend the significance of pharmacovigilance and its influence on the product's life cycle. This will make it possible to incorporate best practices in pharmacovigilance into the processes and procedures in order to improve post-marketing surveillance .(1)

It does this by:

1. Improving the prompt identification of hitherto unidentified adverse drug reactions (ADRs) and drug interactions.
2. Identifying the risk variables that lead to ADRs.
3. Evaluating the numerical components of the benefit/risk analysis.
4. Disseminating data to enhance medication prescription and regulation. (4) Pharmacovigilance starts in the clinical stage and continues the entire drug's life cycle. clinical trial safety while also assisting in ensuring regulatory compliance.

Pharmacovigilance begins from clinical phase and go on throughout the product life-cycle of the drug.[2]

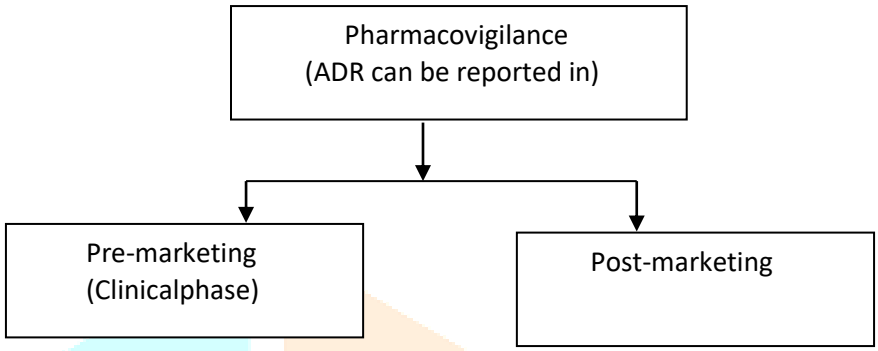

Table 1.Example of serious and unexpected adverse reactions[3]

Medicine	**Adverse drug reactions**
olanzepine	DRESS syndrome
Mefenamic acid	DRESS syndrome
Statins	Rhabdomyolysis
Chloramphenicol	Aplastic anaemia
Reserpine	Depression

Pharmacovigilance aims:-

• Identify and quantify adverse drug reactions (ADRs) that were previously unrecognized. • Determining patient subgroups that are specifically at risk for adverse drug reactions (ADRs) (the risk pertaining to dosage, age, gender, and underlying condition).

• The ongoing observation of a product's safety during its use in order make sure the advantages and hazards are still tolerable. This involves keeping an eye on safety in the wake of noteworthy recently approved indications.

• The relative profiles of adverse medication reactions among products belonging to the same therapeutic class.

• Finding and stopping the improper administration of prescription drugs.

• The additional clarification of a product's toxicological and pharmacological characteristics as well as the process by which it causes unfavorable medication responses.

• The identification of noteworthy drug-drug interactions between novel products and co-therapy with commercially available medications, which may only be discovered after extensive usage.[4]

Methods of pharmacovigilance:-

1. Active surveillance
2. Passive surveillance
3. Descriptive studies
4. Stimulated reporting
5. Targeted clinical investigations
6. Comparative observational studies[2]

Clinical Reasearch:-

Clinical research is a subfield of health science that evaluates the efficacy and safety of drugs, equipment, supplies, and treatment plans meant for human use.

New drug clinical trials are typically divided into four stages.Every stage of the medication approval procedure is handled like a different clinical trial. The drug will be approved for use in the general population by the national regulatory body if it successfully completes Phases I, II, and III. Post-approval studies are phase IV.[5]

Phase 1 clinical trial:-

Phase 1 aims to ascertain the safety of the treatment for humans and to ascertain the distribution of the treatment throughout the body. This test is typically conducted on a small number of well volunteers. The sponsor of the trial keeps an eye out for any potential "serious adverse events," which are defined as any toxic, undesired, or unwanted effect that results in death or poses a risk to health, such as a heart attack, birth defect, permanent damage, or other serious medical condition.

Following Phase 1, data are gathered, examined, and submitted to the FDA for approval to move forward with Phase 2 Clinical Trials. On the other hand, should the findings indicate that the medication was linked to one or more severe side effects, the FDA might not provide. However, the FDA might not approve moving forward to Phase 2 if the results indicate that the treatment was linked to one or more serious adverse events. Usually, the treatment's testing is stopped or it "drops out" of the running to be commercialised. The FDA authorises the treatment to move forward to Phase 2 Clinical Trial(s) if the trial achieves the primary outcome(s), as specified in the original study design.

Occasionally, a medication that may be used to treat one illness has already received approval to treat another (a cancer medication may be tested for treatment of Alzheimer's or macular degeneration, for example). This is known as "repurposing" a medication, and depending on the circumstances, it may allow for the acceleration of Phase 2 clinical trials or reduce the length of the Phase 1 clinical trial by testing the Phase 1 safety profile first.

Phase 2 clinical trial:-

A Phase 2 Clinical Trial's goal is to ascertain the ideal dosage and course of action for treating a specific illness. Typically, a greater number of volunteers with the disease participate in this testing. Trial sponsors can carry out their studies in a variety of ways, but the general strategy is to divide participants into treatment groups and give the treatment to each group at varying doses or delivery methods. Typically, a "control group" is assigned to either the current standard of care (if an alternative treatment is already marketed for that illness) or a "placebo" treatment (such as a sugar pill or innocuous injection that is devoid of the medication).

Comparison is made between the health of the patient group(s) receiving the various forms of treatment and the control groups. The FDA, however, might not approve moving on to Phase 3 if the results indicate that the treatment did not outperform the current standard of care, accelerated the disease, or resulted in other unanticipated, serious adverse events. Usually, the treatment's testing is stopped or it "drops out" of the running to be commercialised.

Phase 3 clinical trial:-

A much larger group of volunteers participate in a Phase 3 Clinical Trial, which is primarily focused on evaluating whether the treatment* would be safe and effective for a broad range of individuals. Assigning participants to treatment or control groups is a standard aspect of the plan. Multiple treatment groups may exist, particularly when the treatment entails the use of various drugs or components. Once more, there is a control group that is given a placebo or the current standard of care regimen.

The health of the patients who received the various forms of treatment is compared to the control groups following the conclusion of Phase 3 Clinical Trials. The FDA may refuse to approve the application for a New Drug Application (NDA) if the results indicate that the treatment did not work any better than the current standard of care, or even accelerated the disease or resulted in other unanticipated serious adverse events. This unique NDA, which is submitted to the FDA for review in order to authorise the treatment's commercialization, includes all of the findings from every phase of the process, from basic research and drug discovery to the outcomes of the Phase 3 clinical trials.

Phase 4 clinical trial:-

Following FDA approval and large-scale drug manufacturing by the sponsor, the process moves into what is known as Phase 4 Clinical Trial/Post-Market Surveillance/Report Adverse Events. The FDA keeps an eye out for potentially dangerous side effects and public safety issues for at least the duration that a treatment* is available on the market. Specifically, the FDA offers a service called MedWatch through which medical professionals, sponsors, or members of the public can report a serious adverse event they think is connected to a specific medication or treatment. Furthermore, Phase 4 Post-Marketing Clinical Trials may be required or voluntary in order to test the product in specific patient populations or to learn more about the risks, benefits, and long-term effects. The FDA offers a wealth of information regarding every medication that is presently available for purchase in the United States.[(6)]

Adverse drug reaction:-

The definition of an adverse drug reaction is defined as a "reaction to a drug which is noxious and unintended and which occurs at doses normally used in man for the modification of physiologic function or for prophylaxis, diagnosis, or therapy of disease." Be aware that a medication and an unfavorable drug response are causally related.

What distinguishes an ADR from an allergy or a side effect?
An allergic reaction is a negative drug reaction that is mediated by the immune system (rash, hives, etc.). An expected and recognised drug side effect is one that is not the drug's intended therapeutic outcome. The phrase "side effect" has a tendency to normalise the idea of drug-related harm. It is generally advised to steer clear of this term in favour of adverse drug reactions.[(7)]

Types of adverse drug reaction:-

Type A:

increased and predictable dose-dependent pharmacological effects About 80% of adverse drug reactions are type A reactions, which are predictable because they typically result from the drug's primary pharmacological effect (such as bleeding when using the anticoagulant warfarin) or from a low therapeutic index drug (such as nausea from digoxin). Although they are typically mild and dose-related, they can occasionally be dangerous or even fatal (e.g., intracranial bleeding from warfarin). Inappropriate dosage is typically to blame for these reactions, particularly in cases where drug elimination is compromised. Minor type A reactions can be referred to as side effects.

Type B:-

Type B reactions can be referred to as idiosyncratic since they are not dose-dependent and unpredictable. Certain aspects of the individual or the surroundings may be the cause of these reactions.[8]

Conclusion:-

Pharmacovigilance is still essential for addressing the problems brought about by the ever-widening variety and potency of medications, all of which have an unavoidable and occasionally unpredictable risk of side effects. When harmful effects and toxicity do occur, particularly when they were not known beforehand, it is crucial that they be documented, examined, and their importance clearly conveyed to the audience who is qualified to understand the information. There is always a trade-off between the possible advantages and risks of medications. The harm can be reduced by making sure that medications are used sensibly and that patient expectations and concerns are taken into consideration when making therapeutic decisions. Good quality, safe, and effective medications should also be used.

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