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A Review on Pharmacovigilance

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Abstract: *Pharmacovigilance, as defined by the World Health Organization (WHO), is the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems. It plays a crucial role in ensuring that patients receive safe medications. Our understanding of a drug's adverse reactions can be enhanced through various methods, including spontaneous reporting, intensive monitoring, and database studies. Both regulatory and scientific processes are continually being developed to strengthen pharmacovigilance efforts. At the regulatory level, transparency and increased patient involvement are key elements.*

Keywords: Drug regulation, drug safety, adverse effects, pharmacovigilance, spontaneous reporting

I. INTRODUCTION

Pharmacovigilance encompasses the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other drugrelated problems. Adverse drug reactions (ADRs) not only contribute to patient suffering but also increase morbidity, mortality, and impose a financial burden on society. The overall incidence of ADRs in hospitalized patients is estimated to be 6.7% (range: 1.2–24.1%), with fatal ADRs occurring in 0.32% (range: 0.1–0.85%). Data indicates that patients experiencing ADRs have a 19.18% higher mortality rate and an 8.25% longer hospital stay. Additionally, medical costs for patients with ADRs are, on average, 19.86% higher.

However, clinicians' inability to suspect or detect such adverse events may lead to inappropriate management, exposing patients to additional risks. To minimize patient suffering from ADRs, establishing a causal relationship between the drug and the even known as causality assessment—is essential. Causality assessment involves evaluating the likelihood that a particular treatment caused an observed adverse event, thereby assessing the relationship between drug treatment and the occurrence of an adverse event.

Clinical Research

Introduction

A clinical trial is a research study that evaluates a new medical treatment or a novel approach to using an existing treatment to determine if it can more effectively prevent, diagnose, or treat a disease. Before a new drug can enter clinical trials, it must undergo preclinical studies. Preclinical studies involve laboratory (in vitro) experiments and animal testing to assess the drug's preliminary effectiveness, toxicity, and pharmacokinetics. Pharmaceutical companies carry out extensive preclinical studies before initiating clinical trials on a drug.

Pre clinical Studies

Preclinical studies consist of in vitro (laboratory) experiments and trials conducted on animals. A wide range of drug dosages is administered to animal subjects or in vitro substrates to collect early data on the drug's efficacy, toxicity, and pharmacokinetics. These studies help pharmaceutical companies decide whether the drug should proceed to further testing.

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Phase 0

Phase 0 refers to the initial exploratory human trials, conducted according to the U.S. Food and Drug Administration's (FDA) 2006 guidelines on Exploratory Investigational New Drug (IND) Studies. These trials aim to accelerate the development of promising drugs or imaging agents by quickly determining if the drug behaves as expected in humans, based on preclinical data. Phase 0 trials involve administering a single, sub-therapeutic dose of the drug to a small group of 10 to 15 participants. The purpose is to gather early data on the drug's pharmacokinetics (how the body processes the drug) and pharmacodynamics (how the drug affects the body. Phase I

Phase I trials are the first stage of human testing, typically involving a small group of 20 to 80 healthy volunteers. These trials are designed to evaluate the drug's safety, tolerability, pharmacokinetics, and pharmacodynamics.

Phase I Trials

Phase I trials are often conducted in inpatient clinics, where subjects can be continuously monitored by full-time staff. Participants who receive the drug are typically observed until several half-lives of the drug have passed.

Phase II Trials

Once the initial safety of the drug is established in Phase I trials, Phase II trials are conducted with larger groups (20-300 subjects) to evaluate the drug's effectiveness. These trials also continue the safety assessments from Phase I, now with a broader group of volunteers and patients. If a drug fails in development, it often happens during Phase II when the drug is found to be ineffective or to have toxic effects.

Phase III Trials

Phase III trials are randomized, controlled, multicenter studies conducted with large patient groups (ranging from 300 to 3,000 or more, depending on the disease or condition). These trials are aimed at providing a definitive evaluation of the drug's effectiveness compared to the current "gold standard" treatment. Due to their size and duration, Phase III trials are the most expensive, time-consuming, and challenging to design, particularly for therapies treating chronic conditions.

Phase IV trials, also known as post-marketing surveillance trials, are conducted after the drug has been approved for sale. These trials focus on monitoring the drug's safety (pharmacovigilance) and providing ongoing technical support.

a) Registration of foreign manufacturers of drugs and medical devices whose products are to be imported into the country.

b) Grant of licenses to import drugs by Government hospitals or Medical Institutions for the use of their patients.

Good Clinical Practice (GCP)

I. Introduction

Good Clinical Practice (GCP) is an international standard that ensures clinical trials involving human participants are conducted ethically, scientifically, and with high quality. Trials conducted under GCP guidelines help guarantee the protection of participants' rights, safety, and well-being. They also ensure that the trial adheres to the principles outlined in the Declaration of Helsinki and that the trial results are reliable. "Trial conduct" in this context refers to the entire process, from planning to reporting, which includes activities such as planning, initiation, performance, recording, oversight, evaluation, analysis, and reporting, as applicable. The aim of the ICH GCP Guideline is to establish a unified standard that allows for mutual acceptance of clinical trial data by regulatory authorities in ICH member countries and regions.

II. Guideline Scope

This guideline applies to interventional clinical trials of investigational products that are intended to be submitted to regulatory authorities. It may also apply to other interventional clinical trials of investigational products that are not intended to support marketing authorization applications, in accordance with local requirements.

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III. Guideline Structure

The ICH GCP Guideline consists of core principles and annexes that elaborate on these principles, providing specific details for various types of clinical trials. The principles are designed to be broadly applicable across different types of clinical trials and settings, and they remain relevant as new technologies and methodologies evolve.

IV. Principles of ICH GCP

The principles of GCP are flexible and applicable to a wide range of clinical trials. This guideline, in conjunction with ICH E8(R1), encourages thoughtful planning and consideration of the unique aspects of each clinical trial. This includes evaluating various trial characteristics, such as the trial design and the investigational product being tested.

V. New Drug and Clinical Trial Rule 2019

The Ministry of Health and Family Welfare in India has introduced the Drugs and Clinical Trials Rules, 2019, aimed at promoting clinical research in the country.

• Objective: The primary objective is to revise the regulatory framework for the approval of new drugs and the conduct of clinical trials in India.

• Coverage: These rules apply to all new drugs, investigational new drugs for human use, clinical trials, bioequivalence studies, and Ethics Committees.

• Application Approval Time: The time for approving applications has been reduced to 30 days for drugs manufactured in India and 90 days for drugs developed outside the country. If the Drugs Controller General of India (DCGI) does not communicate within this timeframe, the application will be considered approved.

• Local Clinical Trials: The requirement for conducting a local clinical trial may be waived if a new drug has already been approved and marketed in countries specified by the Drugs Controller General, with government approval.

• Safety in Clinical Trials: The new rules ensure patient safety by requiring informed consent from participants. The Ethics Committee will oversee the trials and determine compensation in cases of adverse events.

VI. Features of the New Rules

a) The new rules are designed to promote clinical research in India by establishing a predictable, transparent, and effective regulatory system for clinical trials, while also ensuring faster access to new drugs for the Indian population.

b) The revised rules have shortened the application approval time to 30 days for drugs manufactured in India and 90 days for those developed outside the country.

c) If there is no communication from the Drugs Controller General of India (DCGI), the application will be considered automatically approved.

d) The Drugs Controller General of India will determine the compensation for cases involving death, permanent disability, or other injuries to trial participants.

e) The requirement for conducting a local clinical trial may be waived for a new drug if it has been approved and marketed in countries specified by the Drugs Controller General, with the government's approval.

f) The Ethics Committee will monitor the trials and determine the amount of compensation in cases of adverse events.

g) In case of injury to a clinical trial participant, medical management will be provided for as long as deemed necessary by the investigator.

h) New drugs approved for use in select developed markets will be automatically approved in India, provided that global trials include Indian patients.

i) This waiver will also apply to drugs that receive marketing approvals while a trial is still underway in India.

VII. Protocol Designing for Clinical Trials

Every clinical investigation begins with the development of a clinical protocol. The protocol is a document that outlines how a clinical trial will be conducted, including the objectives, design, methodology, statistical considerations, and organization of the trial. It also ensures the safety of trial participants and the integrity of the data collected.

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A research protocol provides a detailed description of the background, rationale, objectives, design, methodology, statistical considerations, and organization of the clinical research project. According to the ICH Good Clinical Practice (GCP) guidelines, a protocol should include the following sections:

a. Title Page (General Information)
b. Background Information
c. Objectives/Purpose
d. Study Design
e. Selection and Exclusion of Subjects
f. Treatment of Subjects
g. Assessment of Efficacy
h. Assessment of Safety
i. Adverse Events
j. Discontinuation of the Study
k. Statistics
l. Quality Control and Assurance
m. Ethics
n. Data Handling and Recordkeeping
o. Publication Policy
p. Project Timetable/Flowchartr. Supplements/Appendices
q. References

VIII. Document Requirements

The Clinical Trial Application (CTA) must include the following information as a minimum:

a. Full Protocol Title
b. DAIDS Protocol Number
c. DAIDS Protocol Version/Date
d. Accurate Identification of the Study Sponsor
e. Identification of the site(s) for which the application is relevant (when applicable
— see Submission Requirements below for further details)

Concept of Pharmacovigilance:

Definition:

Pharmacovigilance, as defined by the World Health Organization (WHO), is "the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems." Pharmacovigilance focuses on detecting, assessing, understanding, and preventing adverse drug reactions (ADRs) and other drug-related issues. ADRs not only contribute to the suffering of patients but also increase morbidity and mortality rates, along with imposing a financial burden on society.

Types of Pharmacovigilance:

1. Case-Control Study (Retrospective Study)
2. Prospective Study (Cohort Study)
3. Population Statistics
4. Intensive Event Report Objectives of Pharmacovigilance:

a. Identification and quantification of previously unrecognized adverse drug reactions (ADRs).
b. Identification of subgroups of patients who are at particular risk for ADRs, considering factors such as dose, age, gender, and underlying conditions.
c. Ongoing monitoring of product safety throughout its use to ensure that the benefits and risks remain acceptable. This includes monitoring safety after significant newly approved indications.

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d. Comparing the ADR profiles of products within the same therapeutic class.
e. Detecting inappropriate prescription and administration practices.In summary, the goal of pharmacovigilance is to enhance patient care and safety, improve public health, assess the benefits, harms, effectiveness, and risks of medicines, and promote understanding, education, and clinical training.

Pharmacovigilance in Acts & Rules:

a) Pharmacy Council of India: Pharmacovigilance is included as one of the subjects in the undergraduate Pharmacy curriculum.
b) Drugs & Cosmetics Act & Its Rules, 1945: The establishment of a Pharmacovigilance cell within the pharmaceutical industry is mandatory.
c) National Health Policy: Pharmacovigilance encompasses prescription audits, including the usage of antibiotics, as outlined by the Ministry of Health & Family Welfare, Government of India.
d) Pharmacovigilance aims to ensure that the benefit-risk ratio of a medicine remains favorable throughout its life cycle, from the time it is authorized for use until it is either withdrawn from the market or its production is discontinued.
International Conference on Harmonization (ICH) E2e Guidelines
Introduction:
This guideline is designed to assist in planning pharmacovigilance activities, particularly in preparation for the early post-marketing phase of a new drug. In this context, the term "drug" includes chemical entities, biotechnology-derived products, and vaccines. The primary focus of this guideline is on creating a Safety Specification and Pharmacovigilance Plan, which may be submitted at the time of the license application. Sponsors can use this guideline to develop a standalone document for regions that prefer this approach or to provide guidance on integrating elements of the Safety Specification and Pharmacovigilance Plan into the Common Technical Document (CTD).
Elements of the Specification:
Sponsors are encouraged to follow the structure provided below when compiling the Safety Specification. The listed elements are meant to serve as a guide.
Depending on the nature of the product and its development program, additional elements may be included. For products already on the market with emerging safety concerns, only a subset of these elements may be relevant. The main focus of the Safety Specification should be on identified risks, important potential risks, and significant missing information. The following elements should be considered for inclusion:
Within the Specification, this section should highlight non-clinical safety findings that have not been adequately addressed by clinical data, such as:
a) Toxicity (including repeat-dose toxicity, reproductive/developmental toxicity, nephrotoxicity, hepatotoxicity, genotoxicity, carcinogenicity, etc.)
b) interval prolongation, nervous system effects, etc.)
c) Drug interactions
d) Other toxicity-related information or data
If the product is intended for use in special populations, consideration should be given to whether specific non-clinical data are needed for these groups.
Limitations of the Human Safety Database
The limitations of the safety database, such as those related to the study population size and study inclusion/exclusion criteria, should be acknowledged. The implications of these limitations with respect to predicting the safety of the product in the marketplace should be explicitly discussed. The worldwide experience should be briefly reviewed, including:
a. The extent of global exposure
b. Any new or different safety issues identified
c. Any regulatory actions related to safety
d. Patients of various racial and/or ethnic backgrounds
Adverse Events (AEs) / Adverse Drug Reactions (ADRs)

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This section should list the important identified and potential risks that require further characterization or evaluation. Specific references should direct the reviewer to the relevant clinical safety data (e.g., relevant sections of the Common Technical Document (CTD) 2.5.5 and 2.7.4). The discussion should include risk factors and potential mechanisms associated with identified AEs/ADRs. This information should be drawn from all relevant parts of the CTD (non-clinical and clinical), along with other sources like drug labels, scientific literature, and postmarketing experience.
Identified and Potential Interactions, Including Food-Drug and Drug-Drug Interactions
Identified and potential pharmacokinetic and pharmacodynamic interactions should be discussed. For each interaction, the evidence supporting it and its possible mechanism should be summarized. The potential health risks posed by these interactions in various indications and populations should also be considered.

Selection of Drug Class:
The selection of a drug class is crucial for monitoring the adverse effects of specific drugs that may have harmful impacts on the human body. Antibiotics are medications used to treat bacterial infections in both people and animals. They work by either killing the bacteria or inhibiting their growth and multiplication. Antibiotics are effective only against certain bacterial infections, such as strep throat, urinary tract infections, and E. coli. However, they do not work against viral infections. For example, antibiotics should not be used to treat:
• Colds and runny noses (even if the mucus is thick, yellow, or green)
• Most sore throats (except strep throat)
• The flu
• Most cases of bronchitis
The side effects of antibiotics can range from minor to severe. Some common side effects include:
• Rash
• Nausea
• Diarrhea
• Yeast infections

Antibiotics:
Antibiotics are a class of drugs that either kill bacteria or prevent their growth. There are two main types of antibiotics:
a. Bacteriostatic: These agents inhibit the growth of bacteria.
b. Bactericidal: These agents kill the bacteria.

Mechanism of Action:
Antibiotics work through various mechanisms to produce their effects. A significant number of antibiotics function by inhibiting bacterial cell wall synthesis. These agents are generally known as β-lactam antibiotics. The process of bacterial cell wall production involves the partial assembly of wall components inside the bacterial cell, followed by the transport of these structures through the cell membrane to the growing wall. Once there, they are assembled into the wall, and finally, the strands of wall material are cross-linked. Antibiotics that inhibit the synthesis of the cell wall affect specific phases of this process. The result is a disrupted cell wall and a change in the shape of the organism, ultimately leading to the bacterium's death.

Antibiotic Resistance:
The widespread use of antimicrobial agents in clinical practice, as well as in industries like livestock farming, has contributed to the development of bacterial resistance to these agents. In response, bacteria have evolved mechanisms to survive against the effects of antibiotics.
The Minimum Inhibitory Concentration (MIC) of a bacterial isolate is a measure of its susceptibility to specific antibiotics. A high MIC, which exceeds the susceptibility threshold for a particular antibiotic, indicates that the infection is resistant to that antibiotic. Bacteria can develop resistance to antimicrobial agents through either intrinsic or acquired mechanisms.

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• Intrinsic Resistance occurs when bacteria inherently lack the target for a specific antibiotic. For example, vancomycin, which targets gram-positive bacteria, cannot penetrate the cell wall of gram-negative bacteria. Similarly, beta-lactam antibiotics, which require a cell wall for effectiveness, are not active against bacteria like Mycoplasma species, which lack a cell wall.

• Acquired Resistance occurs when bacteria gain resistance through the acquisition of resistance genes from other bacteria or through mutations that reduce or eliminate the antibiotic's efficacy.

Bacteria can exhibit multiple forms of resistance simultaneously. The following are common mechanisms of antibiotic resistance:

Mechanisms of Resistance and Examples:

1. Reducing Intracellular Antibiotic Concentrations
2. Increased Efflux: The active expulsion of antibiotics from bacterial cells.
3. Decreased Influx: A reduction in the entry of antibiotics into bacterial cells.
4. Antibiotic Inactivation: Bacteria can produce enzymes that deactivate antibiotics.
5. Enzymatic Modification: Modification of the antibiotic by bacterial enzymes, rendering it ineffective.
6. Chemical Degradation: Chemical breakdown of the antibiotic molecule.
7. Target Site Alteration: Bacteria may alter the structure of the antibiotic's target site, preventing the antibiotic from binding.
8. Mutation of the Target Site: Changes to the antibiotic's binding site within the bacterial cell that reduce its effectiveness.
9. Antibiotic Modification: Direct modification of the antibiotic molecule itself, diminishing its activity.
10. Target Site Protection: Mechanisms that protect the bacterial target site from the antibiotic's effects.
11. Elimination of the Target Site: Bacteria may lose or alter the specific target site that the antibiotic is designed to attack.

Side Effects of Antibiotics:

Antibiotics undergo multiple checks before being approved for clinical use. However, despite these precautions, some antibiotics can still cause adverse side effects. These side effects can vary based on the type of antibiotic, the specific microbes being targeted, and individual patient factors. While most side effects are not severe, they can still be bothersome. Common side effects include nausea, soft stools, and diarrhea.

Here are some possible side effects of antibiotics:

1. Anorexia (loss of appetite)
2. Increased Appetite
3. EKG Changes (alterations in heart rhythm)
4. Epistaxis (nosebleeds)
5. Gout
6. Hepatotoxicity (liver damage)
7. Hiccups
8. Hyperkalemia (high potassium levels)
9. Joint Pain (arthralgia)
10. Kidney Stones (nephrolithiasis)
11. Decreased Libido
12. Increased Libido
13. Myalgia (muscle pain)
14. Nasal Congestion 15. Selection of Drug:
16. A recent study conducted by The Lancet Regional Health – Southeast Asia found that Azithromycin 500 mg tablet was the most consumed antibiotic formulation in India, accounting for 7.6% of the market share, followed by Cefixime 200 mg tablet at 6.5%. This research highlights that widespread use of antibiotics is a significant driver of antibiotic

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resistance in India. Despite India being one of the largest consumers of antibiotics in absolute volume, the country lacks a formal system of antibiotic use surveillance. This absence hampers the development of an antimicrobial stewardship program, such as those seen in the US and Europe.

17. Various national commissions and reports from India have emphasized the importance of the NLEM as a crucial tool for achieving health equity.

Identification of Adverse Effects of Azithromycin:

Azithromycin, like many medications, may cause side effects. These are common side effects that occur in more than 1 in 100 people. If you experience any of these, there are strategies to help cope with them:

1. Feeling sick (nausea):Take the medication with food to reduce the feeling of nausea.
2. Diarrhoea:Stay hydrated and consider eating a bland diet to help manage the symptoms.
3. Being sick (vomiting):If vomiting persists, contact a healthcare provider as it may interfere with the effectiveness of the medication.
4. Losing your appetite:Eating smaller, more frequent meals can help manage loss of appetite.
5. Headaches:Stay hydrated and consider over-the-counter pain relief if recommended by a doctor.
6. Feeling dizzy or tired:Avoid sudden movements and rest if needed. Do not drive or operate heavy machinery if dizziness persists.
7. Changes to your sense of taste, stomach upset, and abdominal pain:These side effects may improve with time. If they are severe, speak with your healthcare provider.

If any of these side effects persist or worsen, it's important to consult with a healthcare professional for guidance. In rare cases, azithromycin may cause serious side effects, so monitoring your condition and seeking timely medical advice is crucial.

Assessment of Adverse Drug Reactions (ADR):

Among the 85 patients analyzed, the most frequently prescribed antibiotic was Azithromycin, accounting for 36.47% of the patients. This was followed by Penicillins at 31.76%.

The major adverse drug reactions (ADR) observed were:

1. Nausea – Affecting 52.95% of the patients.
2. Anaphylaxis reactions – Seen in 10.59% of the patients. Based on the Naranjo scale, the ADR was considered:

• Possible in 80% of the cases.
• Probable in 18.82% of the cases.

Among the antibiotics, Azithromycin was the most common drug responsible for the ADRs, with rash being the most commonly reported ADR associated with its use .

II. CONCLUSION

Pharmacovigilance plays a crucial role in ensuring the safety of drugs throughout their life cycle. It is essential as clinical trials have limitations in detecting rare and very rare Adverse Drug Reactions (ADRs). The knowledge and information available about a drug's safety are pivotal in making informed decisions and guiding drug regulators to safeguard public health. However, a significant challenge remains in the form of underreporting of ADRs globally.

Healthcare professionals are the key players in reporting ADRs, yet this continues to be a major challenge. Despite these limitations, the spontaneous reporting system remains the most widely used method for ADR reporting, and it can generate signals for even rare ADRs. If all healthcare professionals view ADR reporting as an ethical obligation and a key responsibility, we can work toward a safer world. Each ADR report, especially for serious and unlabelled reactions, holds immense value.

Since the concept of pharmacovigilance has emerged, it has become increasingly vital to improving drug safety monitoring. We are progressively moving closer to an ideal pharmacovigilance system, but it is our collective responsibility to ensure its proper functioning. ADR reporting should not be seen as an additional burden for healthcare professionals, but rather as a fundamental duty to guarantee safer drug usage worldwide.

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Ultimately, effective pharmacovigilance is essential for advancing public health and ensuring that drug safety is maintained throughout a product's market life. Every report matters and contributes to achieving safer medicines for all.

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