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Review on Pharmacovigilance

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I. INTRODUCTION

Clinical Research

Definition and Phases of Clinical Trials

Clinical trials are studies that examine brand-new techniques for illness prevention, diagnosis, treatment, and screening is called clinical trials.

Clinical trial phases:

The following phases of clinical trials:

- One) PHASE I
- Two) PHASE I
- Three) PHASE III
- Fourth) PHASE IV

Clinical study phase 1:

- Healthy volunteers between the of 20 and 30 are chosen, and the medicine is delivered to them to see how it works and any potential side effects it may have on patients.
- Recognize a drug's side effects.
- Determine the pharmaceutical drug's safe dosage.
- Determine the Safety of the Drug

Clinical study phase 2:

- In this stage, between 100 and 300 workers are employed.
- This stage focuses more on the medication's efficacy.
- The objective is to gather information on whether the medicine is
- After getting approval from the FDA the drug is checked on diverse populations for safety and effectiveness
- Provide Additional Information After Approval including risk Benefits and Use
- The objective is to gather information on the drug's efficacy in diagnosing particular human illnesses.
- Even in this stage, the focus on safety is maintained, but it is mostly limited to investigating any potential negative effects that the medication may have on the patient.
- Test the medication's efficacy.

Clinical study phase 3:

- In this phase, there are typically between 1000 and 3000 subjects.
- The drug's usefulness and safety are still being studied, but this time with various populations and dosages.
- If the medicine receives FDA approval following successful trial outcomes from the relevant authorities or organisation.
- It then moves on to the last stage.
- Verify the effectiveness
- Keep an eye on any side effects

Functions of Drug Controller General of India (DCGI) and Central Drugs Standard Control Organization (CDSCO):-

- You would think the mandate of the Central Drugs Standard Control Organization (CDSCO) is to ensure that medicines on the Indian market are safe, effective, and necessary for public health.
- But the government thinks differently.
- According to a statement by the ministry to the Department Related Standing Committee on Health and Family Welfare (1), the CDSCO's mission as stated in the committee's report, is to "meet the aspirations…. Demands

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and requirements of the pharmaceutical industry".(1: 8).

- It is no wonder, then, that this industry can do just about anything it wants, at the cost of people's health.
- The internal workings of the office are for the first time made public in the 59th report of this committee on the operation of the CDSCO, together with documentary evidence of wrongdoing.
- The authors' criticism of the Drugs Controller General of India (DCGI) office is unvarnished, and their findings are backed up by a technique that is clearly stated and verifiable facts.
- The investigation verifies what everyone already knows: the approval process is a fraud and the regulatory body and a group of medical "experts" are beholden to industry.

Types of Regulatory Applications:

Investigational New Drug (IND):

- If their research involves the use of a pharmacological agent, clinical investigators must comply with a number of special regulatory restrictions.
- If a study satisfies specific regulatory exemption requirements, an IND may not be required.
- Studies using a drug that has not been approved by the Food and Drug Administration (FDA) or for indications not in the approved labelling may require filing an Investigational New Drug (IND) application with the FDA.
- Individual investigators may fall under the FDA's definition of a sponsor-investigator, in which case the application procedure is typically simpler than it is for commercial sponsors, and this review only deals with this situation.
- An IND may not be necessary if a study complies with specified regulatory exemption conditions. It may be necessary to submit an Investigational New Drug (IND) application to the Food and Drug Administration (FDA) for studies involving medications that have not received FDA approval or that are being used for indications outside of the approved labelling.
- Individual investigators may qualify as sponsors-investigators under the FDA's definition; in this instance, the application process is frequently simpler than it is for commercial sponsors, and this study only addresses this circumstance.
- Three sets of paperwork must be filled out in order to submit an IND: one describing the study.

New Drug Application (NDA):

- In medication development and regulatory assessment, quantitative thinking is becoming increasingly valued.
- Pharmaceutics analyses are frequently used to describe modelling and simulation of data related to pharmacokinetics, pharmacodynamics, and disease progression.
- The current report's goal is to evaluate how the US Food and Drug Administration (FDA) uses pharmaceutics to make decisions about which drugs to approve and how to label them.
- The New Drug Applications (NDAs) filed to the Cardio-renal, Oncology, and Neuropharmacology drug product divisions between 2000 and 2004 were examined.
- The clinical pharmacology scientists graded the influence on the regulatory decision for those NDA reviews that included a pharmaceutics consultation (s).
- 42 of the approximately 244 NDAs had a pharmaceutics section. Even when such analysis was not performed by the sponsor, FDA pharmaceuticals nevertheless conducted independent, quantitative examination of NDAs. In more than half of the 42 NDAs, pharmaceutics analyses played a crucial role in the regulatory decision-making process.
- Of the 14 reviews that were crucial to decisions relating to approval, five identified the need for more trials, while six lessened the burden of completing more trials.
- It was crucial for the impact to happen because the FDA's clinical pharmacology, medical, and statistical reviewers worked together and effectively communicated with the sponsors.
- The survey and case studies highlight the necessity for early interaction between the FDA and sponsors to better understand regulatory expectations and plan the development more effectively.

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Abbreviated New Drug Application (ANDA):

- A sponsor of an Abbreviated New Drug Application (ANDA) must have proof that the innovator product and the proposed generic product are therapeutically similar since they are both pharmaceutically and biochemically equivalent.
- Numerous medicinal substances are polymorphic in that they can take on different crystalline structures.
- The physicochemical properties of the active component may differ due to polymorphism, and changes to these qualities may cause a generic drug product to be bio inequivalent to the innovator brand.
- Because of this, the impact of polymorphism on the comparability of generic medicine products is carefully considered in ANDAs.
- This review explores how polymorphism affects the performance, quality, and manufacturability of pharmaceutical products.
- The analysis' conclusions show that pharmaceutical solid polymorphism is irrelevant for determining whether a drug substance is "identical" in ANDAs.
- To determine when and how polymorphs of pharmacological substances should be monitored and managed in ANDA submissions, three decision trees are offered for solid oral dosage forms or liquid suspensions.
- Case studies from ANDAs are offered to show how polymorphism has no bearing on the determination of a pharmacological substance's "sameness."

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Good Clinical Practice

Objectives and scope of "ICH-Good Clinical Practice" and "New Drugs and Clinical Trial Rules 2019":

Objectives:

- Describe the reasons why the ways in which the ICH's GCP guideline, which summarises GCP's guiding principles, influences clinical research practise.
- Describe the key roles in a clinical trial team, their responsibilities, and the interactions between them.
- Describe the obligations of a trial sponsor.
- Give an explanation of the duties of a clinical investigator.
- Describe the purpose and steps of the informed consent procedure, and talk about any practical problems that might occur.
- Give an explanation of the duties of a trial monitor.
- To promote the reciprocal recognition of clinical data by the authorities in the European Union (EU), Japan, and the United States by providing a common standard for these regions
- Encourage the exchange of clinical data amongst ICH GCP regions to prevent study duplication (saving time, money, resource)
- Technical specifications for pharmaceutical products containing novel ingredients. Facilitate international submissions by mutual acceptance of data.
- Safeguard the sufferer
- Promote mutual recognition of clinical data among ICH GCP regions
- Prevent conducting duplicate trials (saving time, money, resource)
- Facilitate international submissions through data sharing
- Technical specifications for pharmaceuticals comprising novel

Drugs and Clinical Trial Rules 2019:

- By establishing a predictable, transparent, and effective framework for clinical trials and by guaranteeing that innovative medications are made more quickly available to Indians, the new regulations seek to advance clinical research in India.
- New regulations have shortened the approval process, which now takes 30 days for pharmaceuticals made in India and 90 days for those developed outside of the nation.
- The application will be regarded as having been approved if the Drugs Controller General of India doesn't

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respond

- Drug Controller General of India shall make the decision on compensation in the event that a trial subject dies, becomes permanently disabled, or sustains another type of injury.
- If a new drug is licenced and marketed in any of the nations listed by the Drugs Controller General with the government's consent, the need for a local clinical study may be waived for approval.
- The ethics committee will oversee the proceedings and make decisions regarding the amount of compensation in the event of unfavourable outcomes.
- Medical management for the clinical trial participant must be provided in the event of harm, for as long as the investigator deems necessary.
- New drugs approved for use in select developed markets will be automatically allowed in India provided global trials includes Indian patients.
- This exception would also apply to medications that obtain these marketing authorizations even though an Indian trial is ongoing.
- In cases where medications have been approved and marketed for longer than two years in highly regulated foreign markets, new laws have eliminated restrictions on animal testing.

Protocol Designing for Clinical Trial:

The ICH Good Clinical Practice recommendations state that the following areas should be covered in a protocol:

1. Title Page (General Information)
2. Background Information
3. Objectives/Purpose
4. Study Design
5. Selection and Exclusion of Subjects
6. Treatment of Subjects
7. Assessment of Efficacy
8. Assessment of Safety
9. Adverse Events
10. Discontinuation of the Study
11. Statistics
12. Quality Control and Assurance
13. Ethics
14. Data handling and Recordkeeping
15. Publication Policy
16. Project Timetable/Flowchart
17. References
18. Supplements/Appendices

Process of Clinical Trial Application (CTA):

1. **Initial Application** – A sponsor must file a first application when seeking approval for a fresh clinical study in the EU.
2. **Substantial Modification Application** –If any significant alterations to an approved clinical trial are necessary, this application must be submitted.
3. **On-substantial Modification Application** –If any minor adjustments to an approved clinical trial are needed, this application must be submitted.
4. **Additional MSC Application** –If an additional member state is included in a clinical trial that has already been approved, a new MSC application is necessary.

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II. CONCEPT OF PHARMACOVIGILANCE

Definition, objectives, types and components of pharmacovigilance:-

Definition:

It basic objective of pharmacovigilance has safe use of drugs, patient safety,ultimately, safeguarding public health.

Objectives of Pharmacovigilance:

- Improvements in patient care and safety with regard to the use of medications in conjunction with medical and paramedical interventions continue to be a key factor.
- Pharmacovigilance's primary goals include demonstrating the efficacy of medications by recording any severe side effects of medications and studying their adverse effect profiles over a long period of time from the lab to the pharmacy.
- Enhancing public health and safety in relation to the use of medications; promoting the safe, sane, and economical use of medications; fostering knowledge, education, and clinical training in pharmacovigilance; and effective public outreach.
- [14] In addition, developing strategies and procedures for gathering and analysing patient and clinician reports, educating consumers, practitioners, and regulators about the proper use of medications, andi

Types and of pharmacovigilance:

- Passive surveillance:
- Active surveillance :
- Cohort event monitoring :
- Targeted Clinical Investigations:

Passive Surveillance:-

- The use of spontaneous adverse event reports voluntarily reported to the marketing authorization holder or regulatory authority by healthcare professionals or patients is referred to as passive surveillance.
- Here, information on the negative effects is gathered and stored in a national or local database.
- The reporter's name is kept secret, but information about the patient, including country, age, gender, and co-morbidities that were present before, can be retrieved through the reporting forms.

Active Monitoring:

- This approach intends to track particular adverse drug events and ascertain the total number of adverse drug reactions using a pre-planned procedure.
- It is frequently referred to as safety monitoring or toxicity monitoring.

Cohort event monitoring :

- In this approach, the monitoring study is prepared before the drug therapy even starts.
- A group of individuals is exposed to a drug for a predetermined amount of time and is closely monitored throughout treatment.
- Adverse drug reactions or reactions to one or more medications used along with the target drug are kept track of.

Targeted Clinical Investigations:

- These studies are carried out to identify and define the negative effects of a medicine in particular populations, such as those with certain genetic abnormalities, pregnant women, and senior citizens.

Components of pharmacovigilance

Core Capabilities:

- Pharmaceutical businesses benefit from pharmacovigilance in four key ways:

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- Case management for adverse events, which includes faster reporting;
- Reporting in aggregate;
- Signal intelligence, as well as
- Risk Control.

1. Strategy:
The benefit-risk aspects of each product must be considered in business planning. When PV is used properly, it can create a stronger benefit-risk profile and more accurate identification of patients who are at risk, which can lead to competitive advantage.

2. Global Networks
The regulatory frameworks for PV must be varied, market-specific, and gain worldwide coverage. To preserve visibility and consistency while promoting local response, a network of centralised, regional, and local capabilities is necessary.

3. Governance:
Clear governance is necessary for the effective escalation and settlement of issues. A closed loop approach can reduce safety hazards while upholding compliance if it is closely tied to organization-wide crisis management procedures.

Constitution and objectives of Pharmacovigilance Program India (PVPI):-

- To keep track of adverse drug reactions (ADRs) among Indians
- To increase awareness of the value of ADR reporting among medical professionals in India
- To track the risk-benefit ratio of pharmaceuticals
- Produce recommendations on the safety of medicines that are independent and supported by evidence.
- Assist the CDSCO in making regulatory judgements on pharmaceutical safety.
- Share findings with all important stakeholders.
- Establish a national centre of excellence that complies with the highest criteria in the world for drug safety monitoring

The Pharmacovigilance Programmed of India will be administered and monitored by the following two committees.

1. Steering Committee
2. Strategic Advisory Committee

Technical support will be provided by the following committees:

1. Signal Review Panel
2. Core Training Pane
3. Quality Review Panel

List of National Adverse Drug Monitoring Centers (AMCs) and their functions:-
National Coordinating Centre (NCC):
Department of Pharmacology, All India Institute of Medical Sciences, New Delhi. **Coordinators** Dr. Y.K. Gupta National Coordinator

ADR Monitoring Centres (AMC):

- Department of Pharmacology, &nbs &nbsbsp Therapeutics & Toxicology, Govt. Medical College, Bashir Nagar, Jammu.
- Department of Pharmacology, PGIMER, Chandigarh
- Department of Pharmacology, R.G. Kar Medical College, Kolkatta

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- Department of Pharmacology, Lady Hardinge Medical College, New Delhi
- Department of Clinical Pharmacology, Seth GS Medical College & KEM Hospital, Parel, Mumbai

International Conference on Harmonization (ICH) E2e Guidelines
Elements of the non-clinical and clinical safety specification:
1. Non-Clinical:

- This section of the Specification should include non-clinical safety data that
- Clinical data have not effectively addressed, for instance:Toxicity (including damage from repeated doses, toxicity to the developing foetus,
- Genotoxicity, carcinogenicity, nephrotoxicity, and so forth);
- General pharmacology (including cardiovascular, nervous system, and QT interval prolongation);
- Adverse drug reactions
- Additional facts or information pertaining to toxicity. If a product is designed for use in a niche market, it is important to assess whether there are any particular non-clinical data requirements.

2. Clinical
a) Limitations of the Human Safety Database:-
Limitations of the safety database (such as those linked to the study population's size and inclusion/exclusion criteria) should be taken into account, and their effects on predicting a product's safety in the marketplace should be openly stated. Populations likely to be exposed during the intended or anticipated use of the product in medical practise should be specifically mentioned.
The world-wide experience briefly discussed, including:

- The scope of the global exposure;
- Any newly discovered or distinctive safety problems;
- Any safety-related regulatory actions.

b) Populations not Studied in the Pre-Approval Phase:-
Which populations have not been examined or have only been studied sparingly during the pre-approval period should be covered in the specification. It is important to discuss the ramifications of this in terms of forecasting the product's safety in the market (CTD 2.5.5). Populations that should be taken into account should include (but not be limited to):

- Youths; Senior citizens;
- Women who are expecting or nursing;
- People with pertinent co-morbidities, like hepatic or renal conditions;
- Patients whose disease is more severe than those observed in research trials;
- Subpopulations that exhibit recognised and pertinent genetic polymorphism;
- Patients from various racial or ethnic backgrounds.

c) Adverse Events (AEs) / Adverse Drug Reactions (ADRs):

- This section ought to include a list of the significant identified and prospective risks that need more characterization or assessment. To direct a reviewer to the locations where clinical safety data are presented, specific references should be included (e.g., pertinent portions of the CTD).
- A discussion of risk factors and probable explanations for the Aes/ADRs that have been identified. The CTD (clinical and non-clinical) and other pertinent information, such as other drug labels, scientific literature, and post-Marketing experience, should be consulted.

Identified risks that require further evaluation
The most significant recognised Aes/ADRs, such as those that are severe or frequent and may have an effect on how well the product balances its advantages and risks, ought to be covered in greater detail. Evidence supporting a causal

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association, severity, seriousness, frequency, reversibility, and at-risk populations should be included in this knowledge, if it is accessible. It is important to talk about risk variables and probable mechanisms. As part of the Pharmacovigilance Plan, these Aes/ADRs should often necessitate additional evaluation (e.g., frequency in normal conditions of Use, severity, outcome, at-risk groups, etc.).

Potential risks that require further evaluation:-

In this section, significant potential concerns should be discussed. It is important to present the data that supported the judgement that a risk existed. It is anticipated that additional analysis will be done to define the Association for any significant potential risk.

D. Identified and Potential Interactions, Including Food-Drug and Drug:-

- It is important to identify drug interactions and discuss any possible pharmacokinetic and pharmacodynamic interactions.
- The evidence for each interaction and proposed mechanism should be outlined, as well as any potential health hazards associated with the various indications. And it should be discussed in the various populations.

e) Epidemiology:

- It is important to talk about the epidemiology of the indication(s). When possible, stratification by age, sex, and racial or ethnic origin should be taken into account in this debate, along with incidence, prevalence, mortality, and pertinent co-morbidity. Differences If this information is available, a discussion of the epidemiology in the various locations should be made because the epidemiology of the indication(s) may differ between regions.
- Additionally, it is helpful to assess the incidence rates of these occurrences among patients for whom the medicine is indicated for significant adverse events that may necessitate additional research (i.e., the background incidence rates). For instance, it is useful to assess the incidence of illness X if it is a significant adverse event in patients receiving medicine Y for sickness Z.

f) Pharmacological Class Effects

- The Safety Specification should list risks that are thought to be typical of the

2) Identification and evaluation of risks including drug-drug interactions and drug-food Interactions:-

Types of Drug interactions:-

- Drug-drug interactions
- drug-food Interaction

Drug-drug interactions

This occurs when the actions of one medicine can alter the actions of another. Many people picture this kind of connection when they hear the term "drug interaction."

1) Propranolol and asthma:

A beta blocker drug called propranolol is used to treat diseases including high blood pressure. Many medical professionals refrain from administering propranolol to patients who have asthma. Propranolol can cause tightening of the breathing muscles, which can lead to an asthma attack.

1. Diphenhydramine and glaucoma:

Diphenhydramine should not be taken if you have glaucoma (Benadryl). Diphenhydramine is an antihistamine that could exacerbate this problem by raising the pressure inside of your eye.

2. Pseudoephedrine and high blood pressure:

A nasal decongestant called pseudoephedrine (Sudafed) works by constricting the blood vessels in your nose and sinuses. However, it also has an impact on all of your body's blood vessels. This might raise your blood pressure. In general, if you have high blood pressure, it's advised to utilise allergy drugs without a decongestant.

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3. Furosemide and severe kidney disease:
Water pill or furosemide is a diuretic. It aids in the removal of surplus fluid from your body by the kidneys. However, furosemide might not function as effectively as it should in those with severe chronic renal disease. In this situation, you might require a greater dosage of furosemide to efficiently rid your body of additional fluid.

Food-Drug Interactions:-
This occurs when consuming a food or beverage may have an impact on how a drug functions.

Calcium and antibiotics:
Tetracycline, an antibiotic, is one that may interact with dairy products like milk, yoghurt, and cheese. The calcium level prevents the body from adequately absorbing the antibiotic as a result.

Tyramine and MAO inhibitors:
Foods that have been pickled, cured, or fermented contain tyramine. It can cause dangerously high blood pressure when taken along with MAO inhibitors.

Vitamin K and warfarin:
Green leafy vegetables including spinach, kale, and broccoli contain vitamin K. Patients must be advised to limit their intake of these vitamin K-rich foods since warfarin inhibits the effects of vitamin K.

Alcohol and stimulants:
All medicines should be avoided when combined with alcohol, although some substances respond differently. Inability to remember how much alcohol one has consumed and unstable and risky behaviour might result from combining alcohol and amphetamine.

Grapefruit juice and statins:
Grapefruit juice includes furanocoumarin chemicals that boost the efficacy of statins like atorvastatin, hence it is not advisable to take them together. Rhabdomyolysis, a disorder, could result from this.

Risk ratings:
Risk rating A:-

- Neither pharmacodynamic nor pharmacokinetic interactions between the listed drugs have been shown by data.
- Case with no interactions.

Risk rating B:-

- Data show that the particular drugs may interact with one another, however there is little to no proof that their concurrent use is clinically concerning.
- Case with no interactions.

Risk rating C:-

- Data show that the particular agents may interact with one another in a clinically meaningful way. In most cases, the advantages of taking these two drugs concurrently exceed the risks.
- Monitoring therapy is necessary.

Risk rating D:-

- To ascertain if the advantages of concurrent therapy outweigh the hazards, a patient-specific evaluation must be done.
- Monitoring therapy is necessary.

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Risk rating X:-

- The dangers of using certain drugs concurrently typically outweigh the advantages.
- Steer clear of combining.

3) Design and conduct of observational studies:

When conducting an observational study, researchers examine the effects of a particular intervention, risk, diagnostic test, or treatment without trying to control who is exposed to it.

The 3 types of Observational Studies:

Case Control Observational Study:

- In case control studies, researchers select individuals who already have a health problem or disease, or "cases," along with a comparable group of people who don't have it, or "controls." The results and predictors of these two groups are then compared.
- This kind of research is useful for developing a hypothesis that can later be investigated.

Cohort Observational Study:

- To better understand cause and effect, observational studies of this kind are frequently performed. A cohort observational study examines factors including causation, incidence, and prognosis. A cohort is a collection of people who are connected in some way. For instance, a birth cohort would consist of people who were born within a certain time frame.
- Scientists could compare what happens to cohort members exposed to a certain variable versus what happens to cohort members not exposed to the variable.

Cross Sectional Observational Study:

A cross sectional observational study, in contrast to a cohort observational study, examines prevalence rather than cause and effect.

In this case, you would examine data from a certain group at a very particular point in time.

Without changing any factors or making any interventions, researchers would merely observe and note information about something that was present in the population.

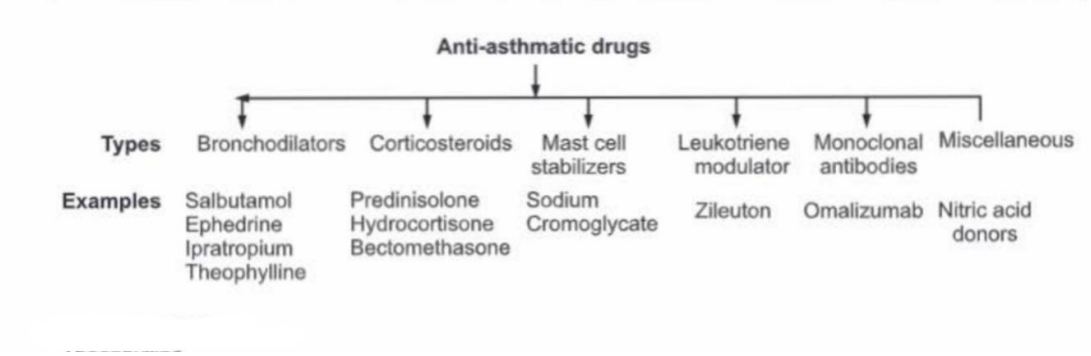
These studies are frequently employed in the fields of psychology, education, and social science.

5) Selection of a drug class

1) Selection of a drug class for pharmacovigilance study using different criteria :-

Anti-asthmatic drugs:

Any medication used to treat asthma symptoms is an antiasthmatic.



Salbutamol

Moa-

- acts as a B2-agonist.

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- They stimulate the B-receptors found on the smooth muscle of the airways.
- And improve camp release by turning on the adenylyl cyclase enzyme.
- Relaxing the smooth muscle of the airways.
- Preventing broncho-constricting chemical release, preventing microvascular leakage, and
- Mediators derived from mast cells.

Adverse effects-

- Shaking, especially in the hands
- A feeling of tension
- Chronic headaches
- Heartbeats that are noticeable all of a sudden (palpitations)
- Drug interactions and precautions for muscle cramps:

6) Selection of Drug

Top 10 most purchased drug:

- Hydrocodone (combined with acetaminophen) – 131.2 million prescriptions
- Generic Zocor (simvastatin), a cholesterol-lowering statin drug – 94.1 million prescriptions
- Lisinopril (brand names include Prinivil and Zestril), a blood pressure drug – 87.4 million prescriptions
- Generic Synthroid (levothyroxine sodium), synthetic thyroid hormone – 70.5 million prescriptions
- Generic Norvasc (amlodipine besylate), an angina/blood pressure drug – 57.2 million prescriptions
- Generic Prilosec (omeprazole), an antacid drug – 53.4 million prescriptions (does not include over-the-counter sales)Azithromycin (brand names include Z-Pak and Zithromax), an antibiotic – 52.6 million prescriptions
- Amoxicillin (various brand names), an antibiotic – 52.3 million prescriptions
- Generic Glucophage (metformin), a diabetes drug – 48.3 million prescriptions
- Hydrochlorothiazide (various brand names), a water pill used to lower blood pressure – 47.8 million prescriptions.

7) Identification of Adverse Effects of a Selected Drug

Adverse Effects:

Salbutamol

An allergic response Itchy rash, feeling faint and lightheaded (because to low blood pressure), collapsing, and swelling of the face, lips, mouth, tongue, or neck are some symptoms.

Predinisolone

fast weight gain, shortness of breath, swelling intense happiness or sadness, severe depression, personality or behaviour changes, and convulsions; tarry or bloody stools, bloody cough, Pancreatitis (severe discomfort in your upper stomach spreading to your back, nausea and vomiting, rapid heart rate) (severe pain in your upper stomach spreading to your back, nausea and vomiting, fast heart rate).

Cromoglycate

Swallowing difficulties, hives, increased wheezing or breathing difficulties, skin itchiness, low blood pressure, shortness of breath, swelling of the cheeks, lips, or eyelids, and chest tightness.

Zileuton

Headache, heartburn, diarrhoea, pain in the muscles, soreness in the throat and nose, and swelling or pain in the face.

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Omalizumab:
Additional symptoms include hives, anxiety, fear of fainting, flushing (warmth, redness, or tingling sensation), tightness in the chest, coughing, a sense of difficulty breathing, rapid or slow heartbeats, or swelling of the face, lips, tongue, or neck.

Nitric acid:
When rapidly rising from a laying or sitting posture, you may have loss of vision, confusion, dizziness, faintness, or lightheadedness as well as sweating, unusual fatigue, or weakness.

8) Adverse Drug Reaction (ADR) Monitoring Form
Methods for Identifying ADRs:

1. Case Record Review
2. Drug Chart Review
3. Laboratory Data
4. Computerized ADR Reporting System
5. Attendance at Ward Rounds
6. Interviewing Patients

Components of ADRs Monitoring:

1. Information about the patient
2. Description of ADRs
3. Suspected drug(s)
4. Reporter

Objectives of ADRs Monitoring

1. To identify the types and rates of ADRs
2. To aid in the reduction of ADRs by the Drug Regulatory Authority, Public Health Programs, Scientists, and Consumer Society.
3. Giving health care professionals the most recent drug safety information.
4. To modernise the package insert, create appropriate information for it, and plan information dissemination for marketing.
5. Information dissemination by creating suitable consumer education programmes
6. To find risk factors that could be a factor in the occurrence, severity, or development of ADRs.

ADR Monitoring Systems:

1. Gathering fresh data from credible scientific sources
2. Sorting and evaluating the aforementioned data.
3. Notifying all health sectors of its contents and any actions taken regarding a particular drug.

9) Hospital Visit
10) Patient Interview

- Interaction with physicians and nurses:-
- Salbutamol :

An allergic response Itchy rash, feeling faint and lightheaded (because to low blood pressure), collapsing, and swelling of the face, lips, mouth, tongue, or neck are some symptoms.

Predinisolone :
Fast weight gain, shortness of breath, swelling intense happiness or sadness, severe depression, personality or behaviour changes, and convulsions; tarry or bloody stools, bloody cough, Pancreatitis (severe discomfort in your upper stomach

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spreading to your back, nausea and vomiting, rapid heart rate) (severe pain in your upper stomach spreading to your back, nausea and vomiting, fast heart rate).

Cromoglycate:
Swallowing difficulties, hives, increased wheezing or breathing difficulties, skin itchiness, low blood pressure, shortness of breath, swelling of the cheeks, lips, or eyelids, and chest tightness.

Zileuton:
Headache, heartburn, diarrhoea, pain in the muscles, soreness in the throat and nose, and swelling or pain in the face.

Omalizumab:
Additional symptoms include hives, anxiety, fear of fainting, flushing (warmth, redness, or tingling sensation), tightness in the chest, coughing, a sense of difficulty breathing, rapid or slow heartbeats, or swelling of the face, lips, tongue, or neck.

Nitric acid:
When rapidly rising from a laying or sitting posture, you may have loss of vision, confusion, dizziness, faintness, or lightheadedness as well as sweating, unusual fatigue, or weakness.

11) Assessment of ADR

Assessment of ADR by Naranjo Scale

Naranjo Scale:-

Method for determining if a medicine is the cause of a clinical occurrence that has been identified as being unpleasant by employing a straightforward probability questionnaire

Naranjo Adverse Drug Reaction Probability Scale

Question	Yes	No	Do Not Know	Score
1. Are there previous *conclusive* reports on this reaction?	+1	0	0	
2. Did the adverse event appear after the suspected drug was administered?	+2	-1	0	
3. Did the adverse reaction improve when the drug was discontinued or a *specific* antagonist was administered?	+1	0	0	
4. Did the adverse event reappear when the drug was re-administered?	+2	-1	0	
5. Are there alternative causes (other than the drug) that could on their own have caused the reaction?	-1	+2	0	
6. Did the reaction reappear when a placebo was given?	-1	+1	0	
7. Was the drug detected in blood (or other fluids) in concentrations known to be toxic?	+1	0	0	
8. Was the reaction more severe when the dose was increased or less severe when the dose was decreased?	+1	0	0	
9. Did the patient have a similar reaction to the same or similar drugs in *any* previous exposure?	+1	0	0	
10. Was the adverse event confirmed by any objective evidence?	+1	0	0	
			TOTAL SCORE:	

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III. COLLECTION AND COMPILATION OF DATA

To collect and compile the Data

Introduction

Adverse event (AE) detection, processing, and reporting requirements must be anticipated by registries that gather data on particular medications and medical devices. The identification, processing, and reporting of AEs discovered in circumstances where a registry has contact with specific patients are covered in this chapter. As a result of this document's lack of formal regulatory or legal status, any information or recommendations made here do not supersede, replace, or in any other way interpret any Federal guidance materials that address these topics. When preparing a registry, registry sponsors are urged to talk with local health authorities about their ideas for AE data collecting and processing

13. Report Writing

Preparation of a report on practice school

- Inside the Practice School employing various search engines to identify the negative effects of a chosen medicine.
- Pharmacovigilance research employing several medication criteria.
- Recognizing and assessing risks, especially those posed by drug interactions.
- ADR monitoring form in accordance with AMCs' instructions.
- Clinical and non-clinical safety requirements.

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