

To Study Adverse Drug Reaction and Its Method in Pharmacovigilance

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Date of Submission: 27-05-2023

Date of Acceptance: 08-06-2023

Abstract- Currently, patients experience various side effects during drug therapy. Drug side effects continue to be a challenge in modern medicine, especially given the increasing complexity of treatments, aging populations, and increasing comorbidities. Similar to the COVID-19 pandemic, a large number of people have been affected by COVID-19 and are suffering from many side effects and other diseases such as cancer, AIDS, viral infections and bacterial infections. is. Drug-related adverse events are also called adverse drug reactions. When you take drugs, there are consequent critical events. ADR can have a significant impact on a patient's quality of life and put a strain on the healthcare system. ADRs are a leading cause of morbidity and mortality worldwide and will continue to be a major public health concern as treatments for many diseases become more sophisticated in aging societies.

Keywords: Adverse drug reactions, Spontaneous reporting, Under reporting, Pharmacovigilance, Causality assessment.

I. Introduction

It is defined as a significant adverse or unpleasant reaction resulting from a drug use-related intervention that predicts the risk of future administration and justifies prophylaxis, specific treatment, change in dosing regimen, or discontinuation of the drug. will be ⁽¹⁾ Adverse drug reactions can be considered a form of toxicity. However, it is used for consequences such as overdose, elevated blood levels, and increased drug effects. The frequency and severity of adverse drug reactions depend on patient characteristics such as age, sex, and genetic factors, as well as drug factors such as drug type, route of administration, duration of treatment, dose, and bioavailability. Drug toxicity refers to the undesired effects of a drug resulting from an intentional or unintentional increase in dose or

plasma concentration above the therapeutic range. Substance abuse is the misuse of therapeutic agents that can lead to addiction or dependence, severe physiological damage, or death. Adverse drug reactions are adverse and unintended reactions to drugs that occur at doses normally used in humans for the prevention, diagnosis, or treatment of disease, or for alteration of physiological function. Post-market surveillance is therefore an important step to detect drug-related problems that could not be detected in the pre-market stage. ⁽²⁾ ADR is a major health concern and leading cause of death worldwide. ADR is among the top 10 causes of death in some countries. Globally, reported rates of fatal side effects in hospitalized patients range from 0.1% to 10%. Studies conducted in developed countries have shown that the rate of fatal ADR in patients hospitalized for ADR ranges from 0.05% to 3%.

Classification of ADRs ⁽³⁾

Drug side effects were originally classified into two subtypes. Type A ADRs are dose-dependent and predictable. This is an increase in the known pharmacological effect of the drug. B. Orthostatic hypotension with antihypertensive drugs. Type B ADRs are rare and unpredictable depending on the drug's known pharmacology. They are dose-independent and affect small populations, suggesting that individual patient host factors are important (Pirohamed 2003; Edwards 2000). Hypersensitivity (allergic) reactions to drugs are examples of type B ADR, with type A reactions later being called augmented reactions and type B reactions bizarre. Finally, he added two types of reactions. Chronic reactions (type C) and delayed reactions (type D) related to both dose and time. Subsequently, withdrawal symptoms became the fifth category (type E), and more recently, unexpected treatment failure became the sixth category (type F) (Rohilla 2013; Edwards 2000). Table 1-1 shows the capabilities and management options for each ADR classification. Approximately 80% of ADRs in hospital settings or hospital admissions are type A (Pirmohamed 1998). These ADRs can be avoidable and are often predictable. The most common drug classes that cause ADR in adults are corticosteroids, antibiotics, anticoagulants, antineoplastic and immunosuppressive drugs, cardiovascular drugs, nonsteroidal anti-inflammatory drugs, and opiates. In children, anti-infectives, respiratory drugs, and vaccines are the most common drug classes for ADR (Kongkaew 2008; Bond 2006).

Some Drugs with Their Adverse Reaction

Some Drugs with Their Adverse Reaction

INDICATION AND USAGE

SCEMBLIX is a kinase inhibitor for the treatment of adult patients with chronic phase (CP) Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+CML) who have been previously treated with two or more tyrosine kinase inhibitors (TKIs). is. This indication is approved under accelerated approval under the Major Molecular Response (MMR). Further approval for this indication may depend on validation and characterization of clinical benefit in one or more confirmatory studies. ⁽⁴⁾

WARNING & PRECAUTION	ADVERSE REACTION
1) Myelosuppression- severe thrombocytopenia and neutropenia may occur	1) Skin & subcutaneous tissue disorder - rash
2) Pancreatic toxicity	2) Fatigue
3) Hypertension	3) Nausea
4) Cardiovascular toxicity	4) Diarrhea
5) Embryo-Fetal toxicity – Can cause fetal harm	5) Abdominal pain

Table: Warning & Precaution and ADR of SCIMBLIX

EXKIVITY™ (Mobocertinib) (Capsules, For oral use)

INDICATION AND USAGE

EXKIVITY for adults with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations detected by an FDA-approved test who have progressed on or after platinum therapy. It is a kinase inhibitor indicated for therapy. -Based chemotherapy. This indication is approved under accelerated approval based on overall response rate and duration of response. Further approval for this indication may depend on validation and characterization of clinical benefit in one or more confirmatory studies.

WARNING & PRECAUTIONS	ADVERSE REACTION
1) Cardiac toxicity- Monitor cardiac function, including left ventricular ejection fraction, at baseline & during treatment. Withhold, resume at reduce dose or discontinue	1) Eye disorder – Ocular toxicity
2) Diarrhea	2) Respiratory, Thoracic and mediastinal disorder – Dyspnea, Rhinorrhea, Cough
3) Embryo Fetal Toxicity	3) Nervous system disorder - Headache

Table: Warning & Precautions and ADR of EXKIVITY

TIVDAK™ (Tisotumab vedotin-tftv) (injection, for intravenous use)

INDICATION AND USAGE

TIVDAK is a tissue factor-targeted antibody-microtubule inhibitor conjugate intended for the treatment of adult patients with recurrent or metastatic cervical cancer during disease progression or after chemotherapy. This indication is adjuvant under an approved label based on tumor response rate and duration of response. Further approval for this indication may depend on validation and description of clinical benefit in confirmatory studies.

WARNING & PRECAUTIONS	ADVERSE REACTION
1) Peripheral Neuropathy – Monitor patients for new or worsening peripheral neuropathy. Withhold reduce the dose or discontinue.	1) General – Fatigue, Pyresia, Purities 2) Skin and subcutaneous tissue disorder – Alopecia Rash
2) Hemorrhage – Monitor patients for signs and symptoms of hemorrhage withhold, reduce the dose or discontinue	3) Eye disorder – Dry Eye, corneal adverse reaction

Table: Warning & Precaution and ADR of TIVDAK

Table: Some Drugs with their Warning & precaution and ADR

Selection of drug

Metformin

Metformin is the main first-line drug used to treat type 2 diabetes, especially in overweight people. Metformin has been shown to reduce diabetes mortality and complications by 30% compared to insulin, glibenclamide and chlorpropamide. ⁽⁹⁾

Synthesis of N,N-dimethylguanidine

Clinical data:

Product name: Glucophage, Glucophage XR

IUPAC name: N,N-dimethylimidocarbonimide diamide

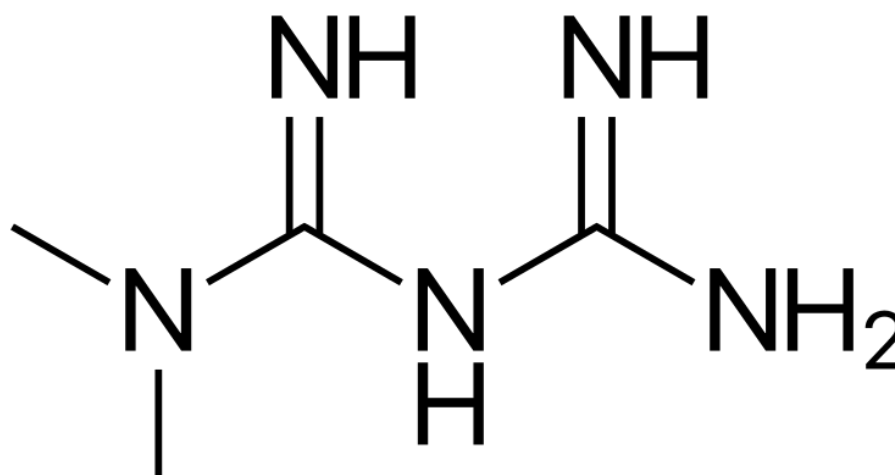
Route of administration: oral ⁽¹⁰⁾

Pharmacokinetic data:

Bioavailability: 40-60%

Elimination half-life: 4-8.7 hours

Structure of metformin:



Metformin

Sr. No.	DRUGS	WARNING & PRECAUTION	ADVERSE EFFECTS
1.	Atropine	Acute Glaucoma	Dryness of mouth
2.	Chlorambucil	Lymphopenia	Alopecia
3.	Chloramphenicol	Edema	Bone marrow syndrome
4.	Chloroquine, ciprofloxacin	Hepatic necrosis	Phototoxicity
5.	Clofazimine	Bowel obstruction	Pigmentation of skin, discoloration of urine
6.	Clozapine	Seizures	Agranulocytosis
7.	Ethambutol	Thrombocytopenia	Optic neuritis
8.	Hydrochlorothiazide	Impaired renal function	Hypokalemia
9.	Isoniazid	Pancreatitis	Peripheral neuritis
10.	Metronidazole	Anorexia	Disulfiram like reaction
11.	Minoxidil	Temporary edema	Hirsutism
12.	Morphine	Drowsiness	Constipation
13.	Gentamicin	Pulmonary fibrosis	Thrombophlebitis
14.	Nitroglycerin	Increased Angina	Palpitation
15.	Penicillin G	Anaphylaxis	Nausea

16.	Quinidine	Cinchonism	Diarrhoea
17.	Quinine sulphate	Convulsions	Unusual sweating, dizziness
18.	Rapaglinide	Arthralgia	Hyperglycemia
19.	Rosiglitazone	Yellowing of eyes	Anemia, Weigh gain



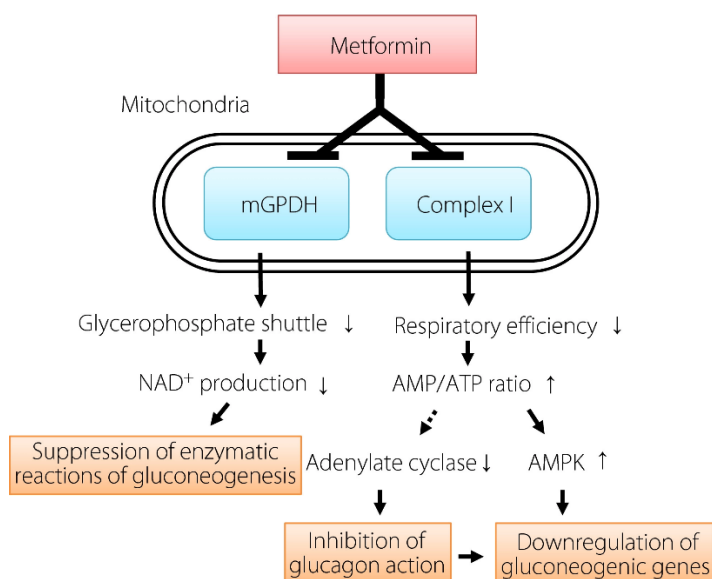
Metformin Hydrochloride

Mechanism of action:

Metformin is mainly used to treat his type 2 diabetes, especially obese patients. 4 patients. Metformin has been shown to reduce diabetes mortality and complications by 30% compared to insulin, glibenclamide and chlorpropamide. ⁽⁹⁾

Metformin lowers serum glucose levels through multiple mechanisms, particularly non-pancreatic mechanisms, without increasing insulin secretion. Increases the effect of insulin. Therefore, it is called an "insulin sensitizer". ⁽¹⁰⁾ Metformin also suppresses endogenous hepatic glucose production,

mainly by slowing the rate of gluconeogenesis and marginally affecting glycogenolysis. In addition, metformin activates the enzyme adenosine monophosphate kinase (AMPK), inhibits key enzymes involved in gluconeogenesis and glycogen synthesis in the liver, and simultaneously stimulates insulin signaling and glucose transport in muscle. AMPK regulates cell and organ metabolism, and decreased liver energy leads to her AMPK activation. This study helped to some extent explain the mechanism of action of metformin on hepatic gluconeogenesis. ⁽¹¹⁾



Pharmacodynamics

Increased glucose uptake, increased insulin signaling, decreased fatty acid and triglyceride synthesis, increased beta-oxidation of fatty acids.

Pharmacokinetics:

Metformin has a bioavailability of 50-60% under faster conditions and is slowly absorbed. Maximum plasma concentrations are reached within 1-3 hours after administration of immediate-release metformin and 4-8 hours of sustained-release formulations.

Medical uses:

Metformin is used to treat high blood sugar levels caused by a type of diabetes mellitus called type 2 diabetes, or diabetes mellitus. It is used in combination with a good diet and exercise program and sometimes other medications to control high blood sugar levels. Used in people with type 2 diabetes. Controlling high blood sugar helps prevent kidney damage, blindness, nerve problems, limb loss, and sexual problems. Good management of diabetes can also reduce the risk of heart attack and stroke.

IMPORTANT WARNING:

Metformin can, in rare cases, cause a serious, life-threatening condition called lactic acidosis. Tell your doctor if you have kidney disease. Your doctor will probably advise you not to take metformin. Also, tell your doctor if you're over 65 and have had a heart attack, stroke; diabetic ketoacidosis (blood sugar levels so high that they cause serious symptoms and require urgent treatment), coma, or heart or liver disease. Taking certain other drugs with metformin may increase the risk of lactic acidosis.

What special precautions should follow?

Before taking Metformin

tell your doctor and pharmacist if you are allergic to metformin, any of the ingredients of metformin liquid or tablets, or any other medications. Ask your pharmacist or check the manufacturer's patient information for a list of the ingredients.

What side effects can this medication cause?

This medication may cause changes in your blood sugar. You should know the symptoms of low and high blood sugar and what to do if you have these symptoms.

Metformin may cause side effects. Tell your doctor if any of these symptoms are severe, do not go away, go away and come back, or do not begin for some time after you begin taking metformin:

- diarrhea
- bloating
- stomach pain
- gas

- indigestion
- constipation

In case of emergency/overdose:

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help>. If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

Symptoms of overdose may include:

- irregular heartbeat
- diarrhea
- vomiting
- headache
- ringing in the ears or loss of hearing
- vision changes (blurred vision or light sensitivity)

Contraindications

Metformin is contraindicated in patients with severe renal impairment defined as glomerular filtration rate (GFR) <30 mL/min/1.732. This limit also corresponds to a serum creatinine (SCr) of at least 1.5 in men and 1.4 in women, or an abnormal creatinine clearance (CrCl). Do not take drugs that can damage your kidneys at the same time. (21.23)

Metformin should also be stopped on the day of surgery. Other contraindications are hypersensitivity to metformin and metabolic acidosis.

Precautions

- It is very important that you carefully follow all instructions given by your medical team.
- Alcohol - Drinking alcohol can significantly lower your blood sugar. Discuss this with your medical team.
- Other Medications - Do not take any other medications unless consulted with your doctor. These include over-the-counter medications such as aspirin, and medications for anorexia, asthma, colds, coughs, hay fever, and sinusitis, among others.

FDA-approved metformin combination drugs include:

- ActoPlus Met (metformin and pioglitazone)
- Avandamet (metformin and rosiglitazone)
- Glucovance (metformin and glyburide)
- Invokamet (metformin and canagliflozin)
- Janumet (metformin and sitagliptin)
- Jentadueto (metformin and linagliptin)

- Kazano (metformin and alogliptin)
- Kombiglyze XR* (metformin and saxagliptin)
- Metaglip (metformin and glipizide)
- PrandiMet (metformin and repaglinide)
- Segluromet (metformin and ertugliflozin)
- Synjardy (metformin and empagliflozin)
- Xigduo XR (metformin and dapagliflozin)
- Trijardy XR (empagliflozin, linagliptin, and metformin)

Side effects of Actoplus Met (Metformin Pioglitazone)

- unusual muscle pain;
- feeling cold;
- trouble breathing;
- feeling dizzy, light-headed, tired, or very weak;

Contraindication-

Initiation of ActoPlus Met is contraindicated in patients with established New York Heart Association (NYHA) class III or IV heart failure. Additionally, ActoPlus Met is contraindicated in patients with:

1. Kidney disease or dysfunction (e.g., indicated by serum creatinine levels of 1.5 mg/dL [men], 1.4 mg/dL [women] or abnormal creatinine clearance), also due to heart or other disease, collapse (shock), can cause acute myocardial infarction, sepsis.
2. Known hypersensitivity to any component of pioglitazone, metformin, or ActoPlus Met
3. Acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma. Diabetic ketoacidosis should be treated with insulin.

Common Avandamet side effects may include:

- nausea, vomiting, upset stomach, diarrhea;
- headache, dizziness; or
- joint pain.

Avandamet is contraindicated in patients with known hypersensitivity to rosiglitazone maleate or metformin hydrochloride. Avandamet is contraindicated in patients with acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma. Diabetic ketoacidosis should be treated with insulin.

Test before giving drug:

1. Antibiotic susceptibility testing:

An antibiotic susceptibility test or antibiotic susceptibility test measures the susceptibility of bacteria to antibiotics. It is used because bacteria can become resistant to some antibiotics. Susceptibility testing, usually done in medical laboratories,

involves culture methods in which bacteria are exposed to antibiotics and genetic tests to see if the bacteria have genes that make them resistant.

lab supplies

Kirby Bauer:

culture 4 ml/tt

Staphylococcus aureus 1/table

E. coli 1/table

Bottle of 95% ethanol + tweezers 2/table

BHI plate 2/group Donor with antibiotic disc 1 of each type/table

Sterile cotton swabs 2/group

The Kirby-Bauer Disc Method

1. Obtain 2 plates and the cultures of E. coli and Staph. aureus.
2. Obtain a swab and dip it into the E. coli broth culture. Roll the swab against the inside of the tube to remove excess liquid. Microbiology BIOL 275 Dr. Eby Bassiri ebassiri@sas.upenn.edu 5
3. Streak one of the plates with the swab in even strokes to obtain a uniform growth pattern across the entire surface of the plate. Rotate the plate 90 degrees and using the same swab, streak the plate again. Rotate the plate 45 degrees and reswab. Replace the lid. Discard the swab. Label the plate.
4. Repeat the above procedure for Staph. aureus with a new plate.
5. Allow the plates to dry for 2-5 minutes.
6. Remove the forceps from the alcohol beaker and pass through the flame of a bunsen burner. When all the alcohol has burned off, use the sterile forceps to aseptically remove one of each antibiotic disc from the dispenser and place it on each plate. You can draw pie lines on the back to divide each plate into 6 sections. The antibiotic discs used are: gentamicin, tetracycline, penicillin G, chloramphenicol, ampicillin and erythromycin.
7. Repeat the alcohol-flame sterilization of the forceps and tap each disc gently onto the plate.
8. Replace the lid, and invert the plate. Complete the label at the bottom of plates and incubate at 37°C for 2 days.
9. Record the results by measuring the diameters of the zone of inhibition (ZOI). The data is recorded and interpreted using tables supplied at the introduction section of this lab exercise.

Management of Adverse Drug Reaction

Treatment strategies used for ADR fall into the categories of drug discontinuation, dose

reduction, additional treatment for ADR, and no change in treatment plan without additional treatment. In addition, ADR outcomes are categorized in terms of responses after unchallenge and re-challenge, and final outcome of the event (Jimmy et al., 2006). For dose-dependent ADR,

modifying the dose or removing or reducing the provoking factor may be sufficient. Improving drug elimination rates is rarely necessary. For allergic and idiosyncratic ADRs, the drug should usually be discontinued and not tried again.

Methodology of reporting an ADR –

What to report?	When to report?	Who can report?	How to report?	Where to report?
1) Life threatening or death 2) Hospitalization 3) Medically significant 4) Lack of efficacy 5) All serious/nonserious reactions	1) Non serious cases within 30 days 2) All serious or death event as soon as possible and within 7 days	1) Medical specialists 2) Pharmacist 3) Dentists 4) Midwives	1) ADR reporting form 2) Toll free no. 1801803024 3) Email pvpi@ipcindia.net 4) ADR PvPI Android Application	1) Nearest AMC 2) Various zonal offices: i) East Kolkata ii) West Mumbai iii) North Gaziabad iv) South Chennai CDSCO WHO

Table: Criteria for ADR and its reporting to regulatory authority

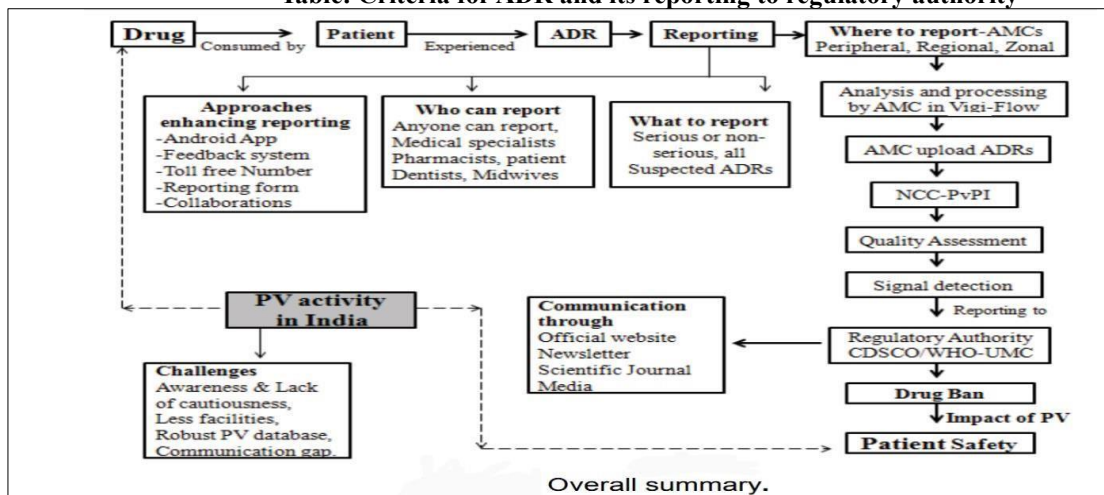



Figure: Overall Summary

Version-1.2



SUSPECTED ADVERSE DRUG REACTION REPORTING FORM
 For VOLUNTARY reporting of Adverse Drug Reactions by Healthcare Professionals

INDIAN PHARMACOPOEIA COMMISSION (National Coordination Centre-Pharmacovigilance Programme of India) Ministry of Health & Family Welfare, Government of India Sector-23, Raj Nagar, Ghaziabad-201002							FOR AMC/NCC USE ONLY				
Report Type <input type="checkbox"/> Initial <input type="checkbox"/> Follow up							AMC Report No. _____				
A. PATIENT INFORMATION							Worldwide Unique No. _____				
1. Patient Initials _____		2. Age at time of Event or Date of Birth _____		3. M <input type="checkbox"/> F <input type="checkbox"/> Other <input type="checkbox"/>			12. Relevant tests/ laboratory data with dates				
				4. Weight _____ Kgs							
B. SUSPECTED ADVERSE REACTION							13. Relevant medical/ medication history (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/renal dysfunction etc.)				
5. Date of reaction started (dd/mm/yyyy)											
6. Date of recovery (dd/mm/yyyy)											
7. Describe reaction or problem							14. Seriousness of the reaction: No <input type="checkbox"/> if Yes <input type="checkbox"/> (please tick anyone)				
							<input type="checkbox"/> Death (dd/mm/yyyy) <input type="checkbox"/> Congenital-anomaly <input type="checkbox"/> Life threatening <input type="checkbox"/> Required intervention to Prevent permanent impairment/damage <input type="checkbox"/> Hospitalization/Prolonged <input type="checkbox"/> Disability <input type="checkbox"/> Other (specify)				
							15. Outcomes				
							<input type="checkbox"/> Recovered <input type="checkbox"/> Recovering <input type="checkbox"/> Not recovered <input type="checkbox"/> Fatal <input type="checkbox"/> Recovered with sequelae <input type="checkbox"/> Unknown				
C. SUSPECTED MEDICATION(S)											
S.No	8. Name (Brand/Generic)	Manufacturer (if known)	Batch No. / Lot No.	Exp. Date (if known)	Dose used	Route used	Frequency (OD, BD etc.)	Therapy dates		Indication	Causality Assessment
								Date started	Date stopped		
i											
ii											
iii											
iv											
S.No as per C	9. Action Taken (please tick)						10. Reaction reappeared after reintroduction (please tick)				
	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unkn own	Yes	No	Effect unknown	Dose (if reintroduced)	
i											
ii											
iii											
iv											
11. Concomitant medical product including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction)											
S.No	Name (Brand/Generic)	Dose used	Route used	Frequency (OD, BD, etc.)	Therapy dates		Indication				
					Date started	Date stopped					
i											
ii											
iii											
Additional Information:							D. REPORTER DETAILS				
							16. Name and Professional Address: _____				
							Pin: _____ E-mail _____				
							Tel. No. (with STD code) _____				
							Occupation: _____ Signature: _____				
							17. Date of this report (dd/mm/yyyy): _____				
Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Programme staff is not expected to and will not disclose the reporter's identity in response to a request from the public. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction.											

Figure: ADR reporting form of India

ARGUS ORACLE METHOD OF ADR REPORTING.

This is ADR monitoring software used primarily by US pharmaceutical companies. It is a comprehensive pharmacovigilance platform that enables manufacturers to make faster and better safety decisions and better manage risk.

- It is therefore required for clinical and post-market surveillance.
- Software Capabilities – Single Global Database
- Case processing updates
- E2B Compliance (ICH)
- Regular declaration
- Advanced query and reporting data model for single detection



Figure: Argus Workflow

CAUSALITY ASSESSMENT-

Definition: Causality assessment is the assessment of the relationship between drug treatment and the occurrence of adverse events. ADR causality assessment can be performed by clinicians, researchers, the pharmaceutical industry, regulatory agencies, and in a variety of settings, including clinical trials. It is also used to assess and verify whether a particular treatment is responsible for the observed adverse events. This is an important part of the ADR report and an important task performed by each country's National Drug Surveillance Program.

METHODS (Classified under three broad categories)

Expert judgement / Global introspection:

The WHO-UMC causality assessment system

The WHO-UMC system has been developed in consultation with the National Centres participating in the Programme for International Drug Monitoring and is meant as a practical tool for the assessment of case reports. Since pharmacovigilance is particularly concerned with the detection of unknown and unexpected adverse reactions, other criteria such as previous knowledge and statistical chance play a less prominent role in the system. System is used to detect unknown and unexpected adverse drug reaction. Assessment is based on following four criteria –

a) Time relationships between the drug use and the adverse event.	c) Response to drug withdrawal or dose reduction (de-challenge).
b) Absence of other competing causes (medications, disease process itself).	d) Response to drug readministration (re-challenge).

The level of casual association is grouped into four categories are based on number of the above criteria being met

Causality terms	Assessment criteria
Certain	Event or laboratory test abnormality, with plausible time relationship to drug intake <ul style="list-style-type: none"> • Cannot be explained by disease or other drugs • Response to withdrawal plausible (pharmacologically, pathologically) • Event definitive pharmacologically or phenomenologically (i.e. an objective and specific medical disorder or a recognised pharmacological phenomenon) • Rechallenge satisfactory, if necessary
Probable / Likely	<ul style="list-style-type: none"> • Event or laboratory test abnormality, with reasonable time relationship to drug intake • Unlikely to be attributed to disease or other drugs • Response to withdrawal clinically reasonable • Rechallenge not required
Possible	<ul style="list-style-type: none"> • Event or laboratory test abnormality, with reasonable time relationship to drug intake • Could also be explained by disease or other drugs • Information on drug withdrawal may be lacking or unclear
Unlikely	<ul style="list-style-type: none"> • Event or laboratory test abnormality, with a time to drug intake that makes a relationship improbable (but not impossible) • Disease or other drugs provide plausible explanations
Conditional / Unclassified	<ul style="list-style-type: none"> • Event or laboratory test abnormality • More data for proper assessment needed, or • Additional data under examination
Unassessable/ Unclassifiable	<ul style="list-style-type: none"> • Report suggesting an adverse reaction • Cannot be judged because information is insufficient or contradictory • Data cannot be supplemented or verified
Adapted with permission from: World Health Organization (WHO). The Use of the WHO-UMC System for Standardised Case Causality Assessment. Geneva: WHO, 2014	

Table : WHO UMC causality categories

ADR DETECTION TEST

1) Sensitivity/susceptibility testing:

This test is done using broad-spectrum antibiotics such as penicillin and streptomycin. A rash on the skin when a needle is inserted into a vein

(2) ANA test (antinuclear/antibody):

The ANA test checks for antinuclear antibodies in the blood if antinuclear antibodies are detected in the blood. If this test detects antinuclear antibodies in your blood, you may have an autoimmune disorder.

Autoimmune diseases cause the immune system to mistakenly attack its own cells and tissues.

(3) ESR skin test (erythrocyte sedimentation rate):

A very high ESR value reduces the likelihood of developing other diseases, including autoimmune diseases and allergies. Example: For tuberculosis disease, drugs such as streptomycin are administered by the patient. so I did a skin test.

II. Result and discussion

Some patients experienced unpleasant drug reactions during post-discharge interviews. Few and most patients did not experience adverse pharmacological reactions in hospital. However, compared with other patients, those taking four or more medications were found to develop ADR. This includes antibiotics, antimalarial drugs, anticancer drugs, and over-the-counter drugs. Many people take over-the-counter medications from their local pharmacy, which can also cause dangerous drug reactions that can be avoided by talking to your doctor. Drugs used to treat cancer, COVID-19, steroids, and immunomodulators are highly associated with ADR. However, the main proportions are still underreported and therefore do not represent the true proportion of adverse effects by these groups. Improving the use of preventive measures can reduce the frequency and severity of side effects.

Most drugs are well tolerated and belong to the category of non-life-threatening drugs.

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