

Safe Drugs in Pregnancy



Drugs Safe in Pregnancy

Hypertension :- Labetalol, Methyldopa

Anti Coagulant :- Heparin

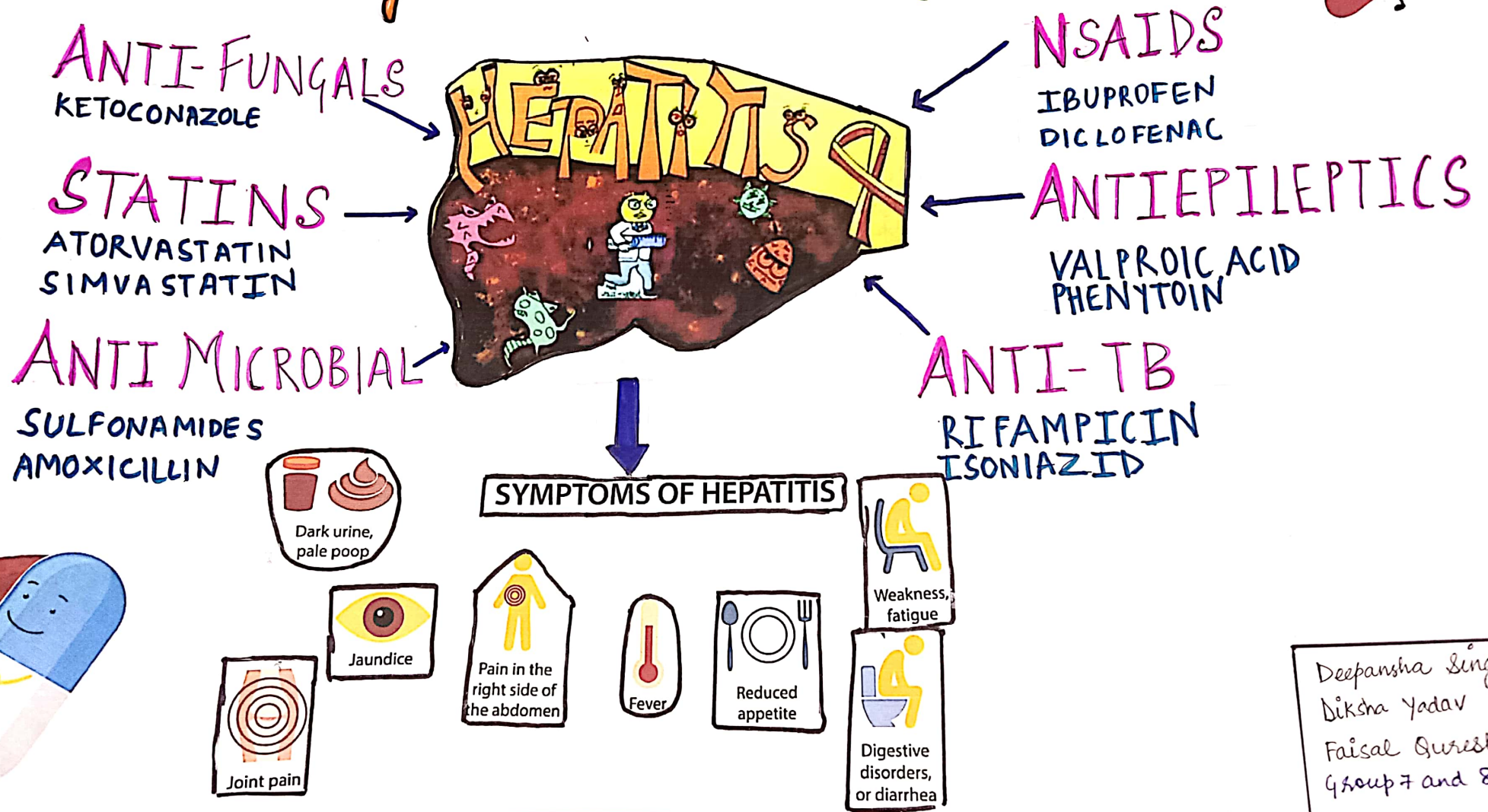
Anti microbial :- Penicillins, Cephalosporins

Analgesic :- Paracetamol

Protect your baby's first home - be medicine wise!

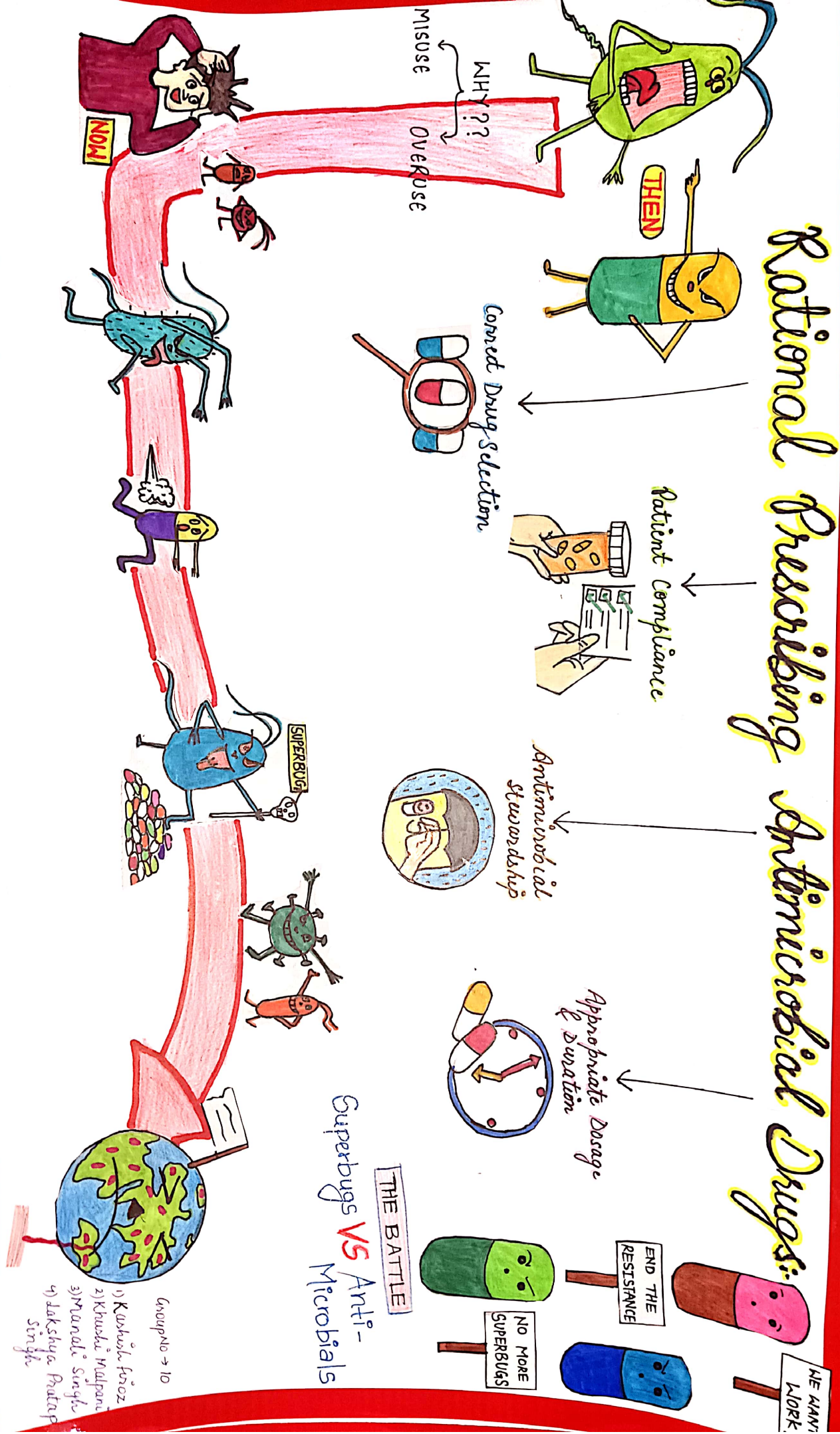
13-GROUP
MOHD. ASJAD.(68)
MOHD. SHABAN. PASHA(70)
MOHD. OVAISH (69)
MOHNEESH PANDEY(71)

Drugs CAUSING HEPATITIS



Deepansha Singh
Diksha Yadav
Faisal Qureshi
Group 7 and 8

Rational Prescribing Antimicrobial Drugs:



PHARMACOVIGILANCE
Pharmacovigilance is the science and monitoring of adverse drug reactions (ADRs) related to the detection, assessment, understanding and prevention of the adverse effect or any other drug-related problems.

INTRODUCTION TO PHARMACOVIGILANCE AND TYPES OF ADVERSE DRUG REACTION (ADR)

NAME: Abroo Hasan
Roll No.: 05
NAME: Abuzar Hussain
Roll No.: 06
GROUP NO.: 01

TYPES OF ADVERSE DRUG REACTION (ADR)

TYPE A (Augmented)

- Characteristics :- Predictable, dose-dependent
- Example :- Hypoglycemia from insulin overdose

TYPE B (Bizarre)

- Characteristics :- Unpredictable not dose related
- Example :- Anaphylaxis from Penicillin

TYPE C

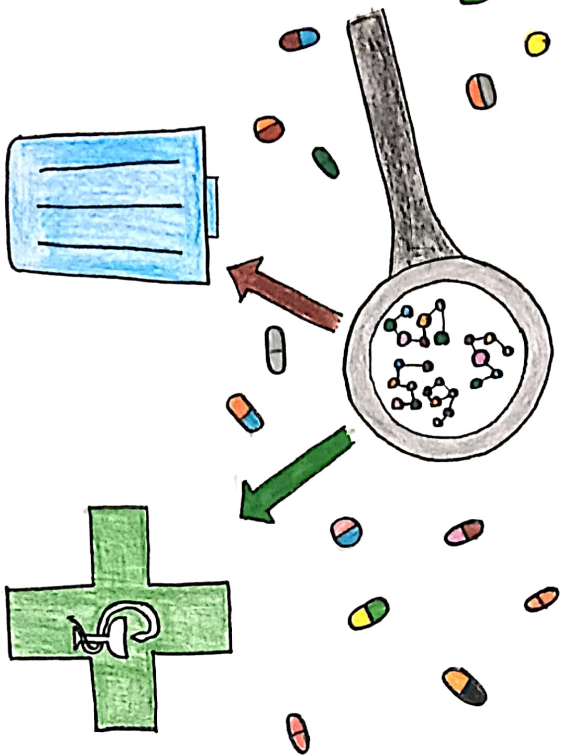
- Characteristics :- Occur due to long term use
- Example :- Adrenal suppression from Prolong Corticosteroid Therapy

TYPE D

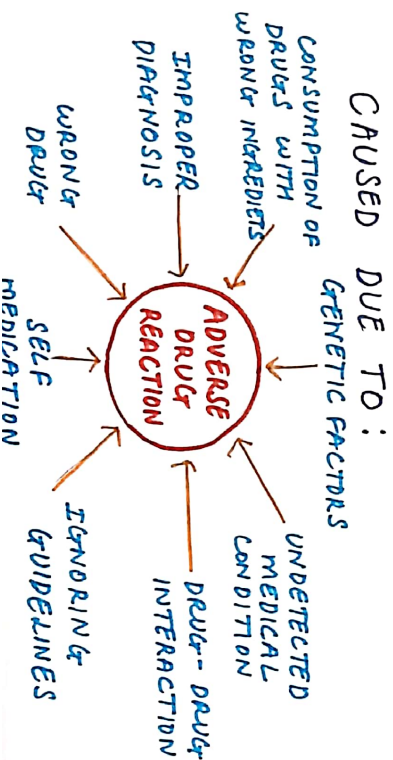
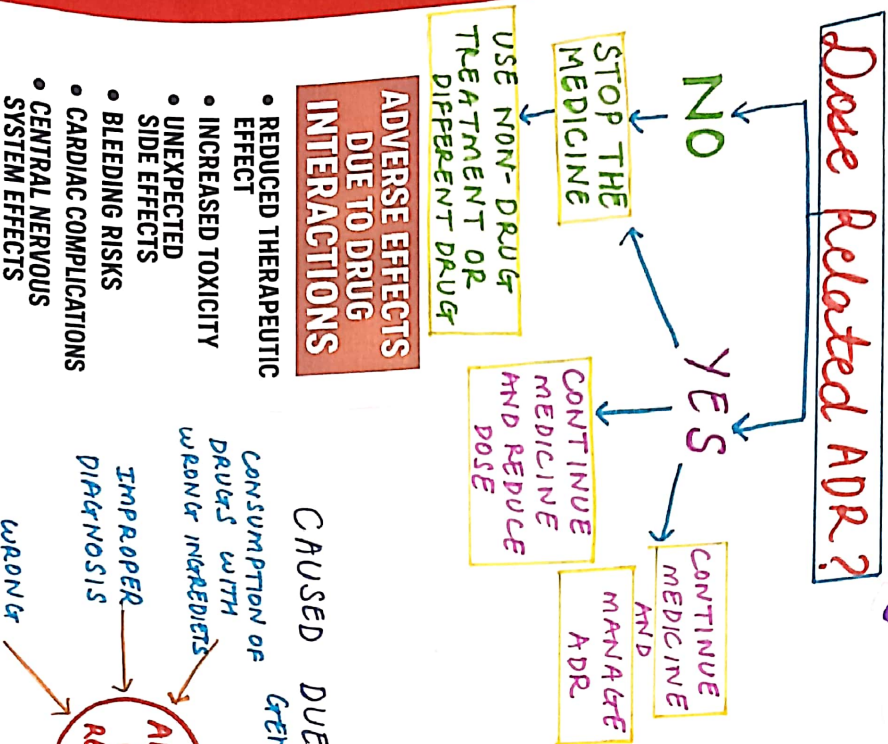
- Characteristics :- (Delayed) Become Apparent after some time
- Example :- Teratogenic effects from Thalidomide

Importance of Pharmacovigilance

- Early detection of unknown adverse drug Rxn
- Prevention of harm from Medication Errors and Misuse.
- Promotion of rational and safe use of Medicine.



Drug Interactions Causing ADRs



- Reduced ADR:-**
- 1) Taking medicine prescribed by qualified physician
 - 2) Accurate dose of the drug at the right time.

COMMON EXAMPLES OF DRUG INTERACTIONS LEADING TO ADRs :-

- 1) Warfarin + Antibiotics (ciprofloxacin, macrolides) → increased risk of bleeding
- 2) ACE inhibitors (enalapril)

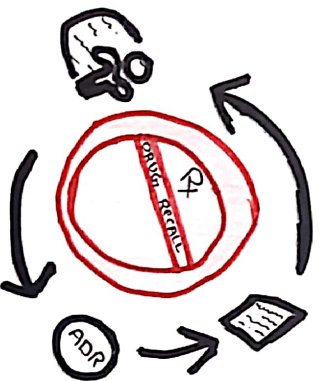
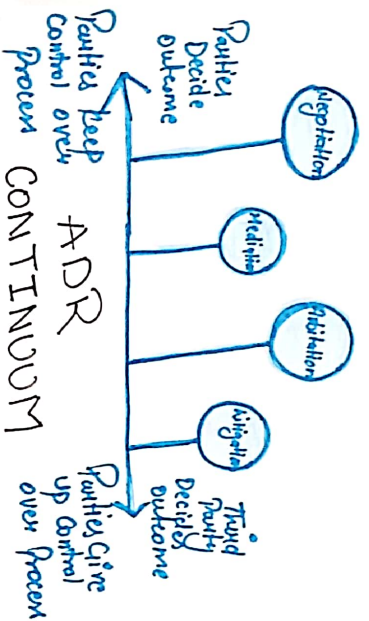
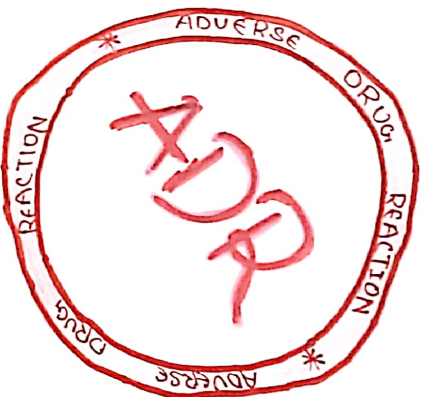
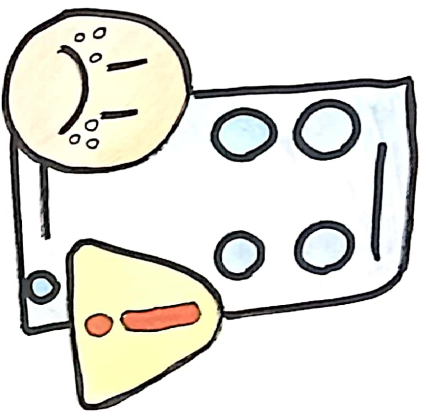
+ Potassium sparing diuretics (spironolactone) → **HYPERKALEMIA**

3) STATINS (simvastatin) + macrolide (erythromycin) → increased risk of myopathy

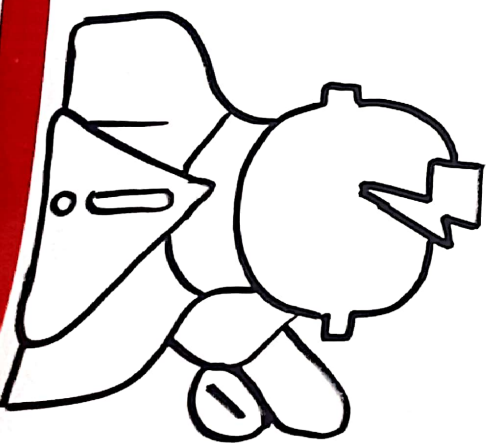
GROUP-15
RICHA JOSEPH - 83
PRIYANSHU KUMAR - 80



Adverse Adverse Drug Reaction.



Mohammad Jubayr [59]
Mohammad Abbas [62]
[group → 11]



DRUGS CAUSE ARRHYTHMIA



CARDIAC GLYCOSIDES

↳ Digoxin

ANTI PSYCHOTICS

↳ Haloperidol
↳ Risperidone

ANTIDEPRESSANT

↳ Amitriptyline
↳ Citalopram

ANTIEMETICS

↳ Domperidone
↳ Metoclopramide

DIGOXIN

MECHANISM OF ACTION

Cardiac Glycosides

Inhibit Na^+ pump in cardiac cell

Accumulation of intracellular Na^+

Reversent exclusion of Ca^{2+}

Increase entry of Ca^{2+} into cell

Increase intracellular Ca^{2+}

$\uparrow \text{Ca}^{2+}$ released during each contraction

Increased force & velocity of contraction

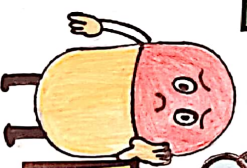
ADVERSE EFFECTS

1. Extracardiac

- iii- Psychosis
- iii- Disorientation
- iii- Restlessness
- iii- Headache
- iii- Vomiting
- iii- Abdominal pain
- iii- Xanthopsia / Yellow vision

दवा है सफ़ा , फ
साइड इफ़ेक्ट से रहे
हो छि गार

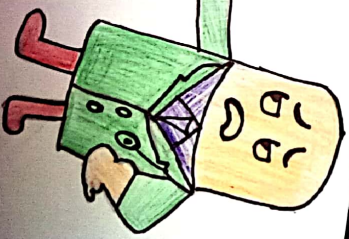
PHARMACOLOGICAL USES

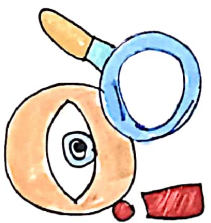


CCF [chronic congestive failure]
Atrial FIBRILATION
Atrial FLUTTER

GROUP-3

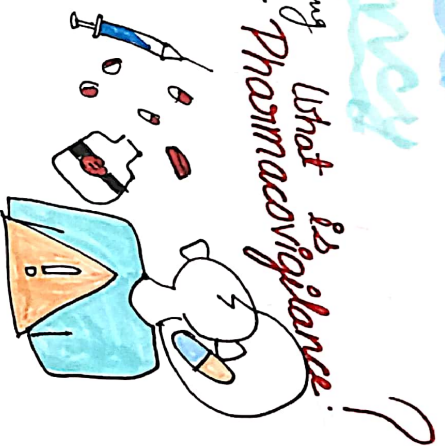
ALEENH AKIF [12]
ALEENA [15]
ALZIA [16]
AMANULLAH [16]





Pharmacovigilance in drug safety in pregnancy

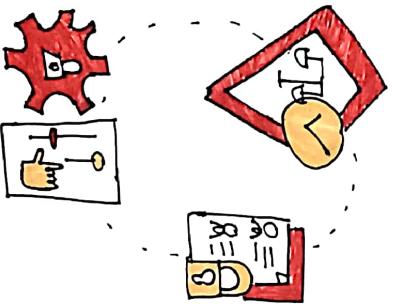
monitors and prevent adverse drug reaction. and other safety issue. ensures medicine post market. ensures medicine remain safety and effective population.



- ### Key functions
- Adverse Monitoring
 - Risk Management
 - Signal detection.
 - Communication

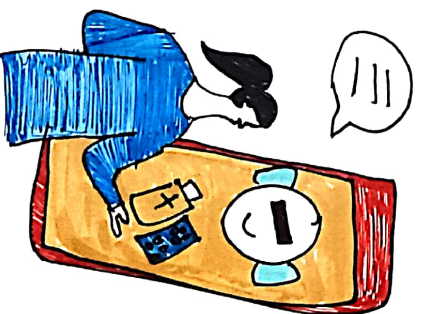
Global Collaboration

- An organization like WHO, FDA, EMA, CASUO ensures global safety standard.
- Reporting system (eg. medwatch, vigo) allow patients and professional to report.



Challenges

- Under reporting
- Data compliability
- Global variability.



Future Trends

- Wearable and apps for real time ADAR, reporting.
- AI driven insights for faster safety action.

In Pregnancy

Focus on monitoring the safety of medication used by pregnant women and assessing potential risk to both the mother and developing fetus.

Naman 73
Nashrah 74
Nazia 75
Paveez 79
Group No. 14

DRUGS CAUSING ARRHYTHIA & QT PROLONGATION



Anti-Arrhythmics
 Quinidine, disopyramide, quinidine.

Antibiotics
 macrolides, fluoroquinolones.

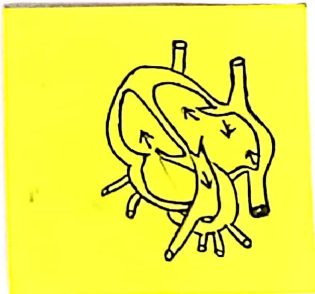
Antipsychotics
 amisulpride, chlorpromazine, thioridazine.

Anti-depressants
 SSRIs (citalopram), TCAs (amitriptyline).

Anti-emetics
 domperidone, ondansetron.

Anti-fungals
 azoles (fluconazole), posaconazole.

Risk factors
 * Bradycardia
 * Cardiac abnormalities
 * Electrolyte abnormalities
 [Hypokalaemia]
 * Genetic factors



Anti-arrhythmics

Anti-microbials

Anti-histamines

Anti-psychotics

Diuretics



Diuretics
 Thiazide, Furosemide.

Anti-psychotics
 Chlorpromazine, Thioridazine, Clozapine, pericyazine.

Anti-histamines
 Astemizole, Ebastine, Terfenadine, hydroxyzine.

Anti-microbials
 Erythromycin, Azithromycin, Clindamycin, Levofloxacin.

Anti-arrhythmics
 Quinidine, procainamide, Flecainide, Propafenone.

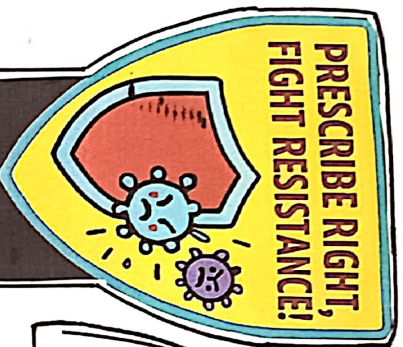
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20	Am
21	Am
24	Am

Gap +

RATIONAL PRESCRIBING

A POWERFUL WEAPON AGAINST

MICROBIAL RESISTANCE



WHAT IS RATIONAL PRESCRIBING?

- ✓ Right Drug
- ✓ Right Dose
- ✓ Right Duration
- ✓ Right Patient



Use antibiotics wisely to stop superbugs.

HOW IT REDUCES MICROBIAL RESISTANCE

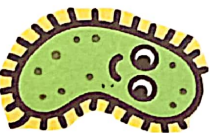
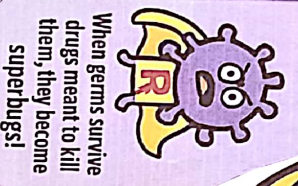
- Avoids unnecessary antibiotics
- Prevents resistant strains from emerging
- Improves patient outcome



WHY RATIONAL PRESCRIBING?



WHAT IS MICROBIAL RESISTANCE?



YOU CAN HELP!



GrKoup 9
Haidou (47)
Mina (48)
Tina (49)
Kouf (50)

BE WISE. PRESCRIBE RIGHT. SAVE LIVES.

Doctors + Pharmacists + Patients = Team Against Resistance.

PHARMACOVIGILANCE



WHAT IS PHARMACOVIGILANCE?

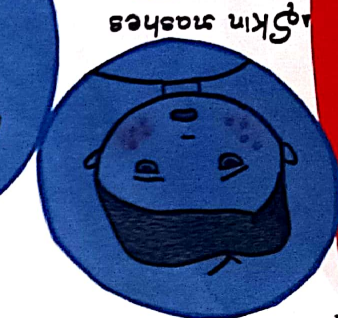
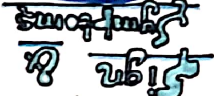
Monitors and prevents adverse drug reaction (ADRs) and other safety issue post-market. Ensures medicine remain safe and effective for diverse population.

KEY FUNCTIONS

- ADR Monitoring
- Risk Management
- Signal detection
- Communication

Global Challenges

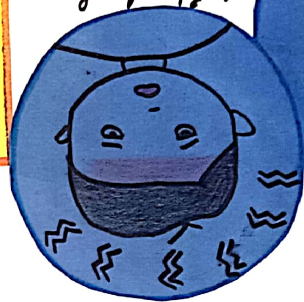
- Organization like WHO, FDA, EMA & CDSCO ensure global safety standards
- Reporting systems allow patients and professionals to report ADRs.



Gastric upset



VOMITING



Headache



Dizziness

PHARMACON - DRUG

VIGILANCE - TO KEEP WATCH

ADR REPORTING

WHAT IS AN ADR? An unwanted and harmful reaction to a medication which may occur at normal dose used for treatment that result in death.

WHY TO REPORT AN ADR?

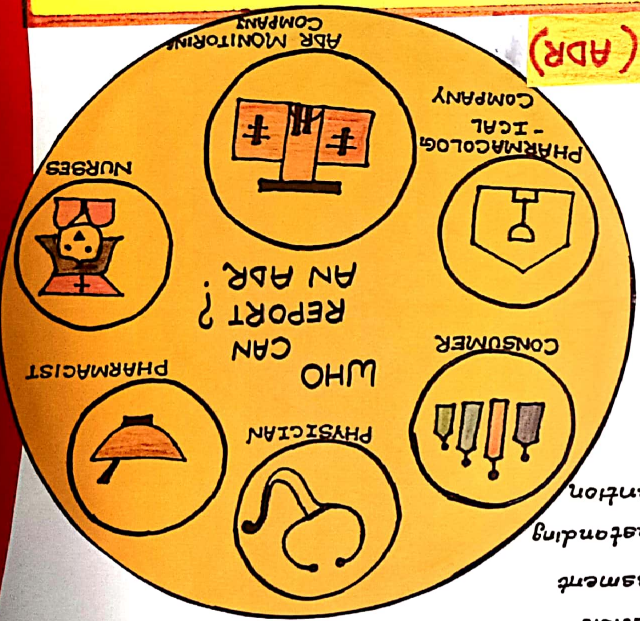
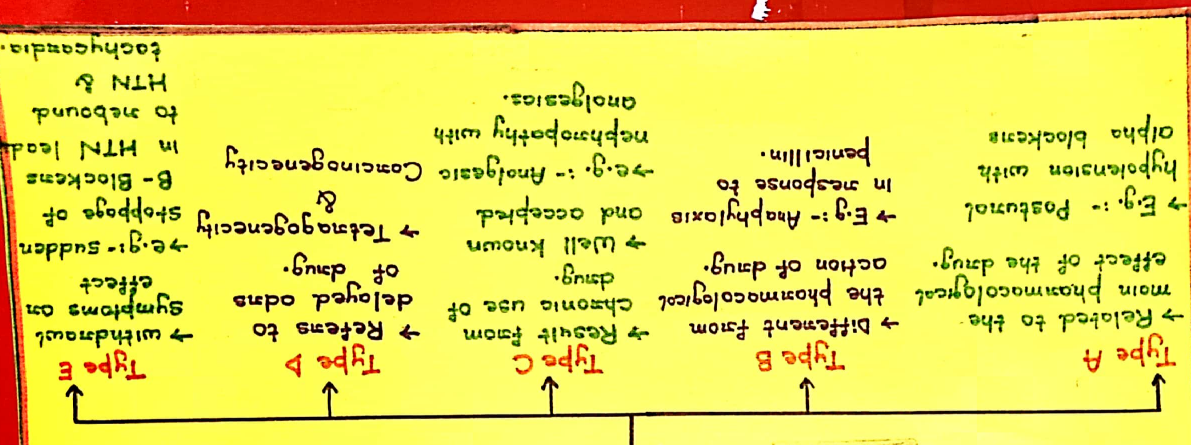
- PATIENT SAFETY
- ONGOING MONITORING
- IMPROVING DRUG SAFETY

ADVERSE

DRUG

REACTION (ADR)

ADR TYPES

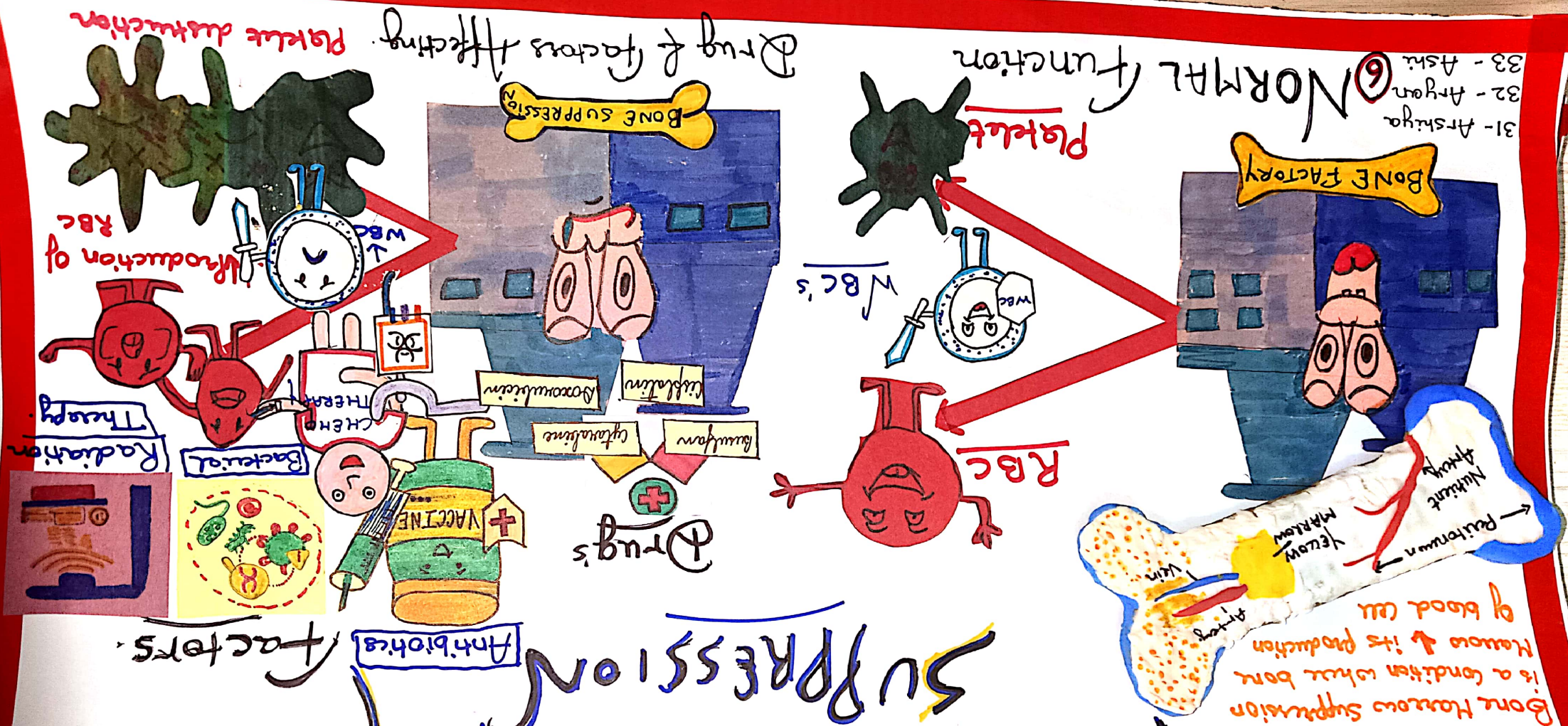


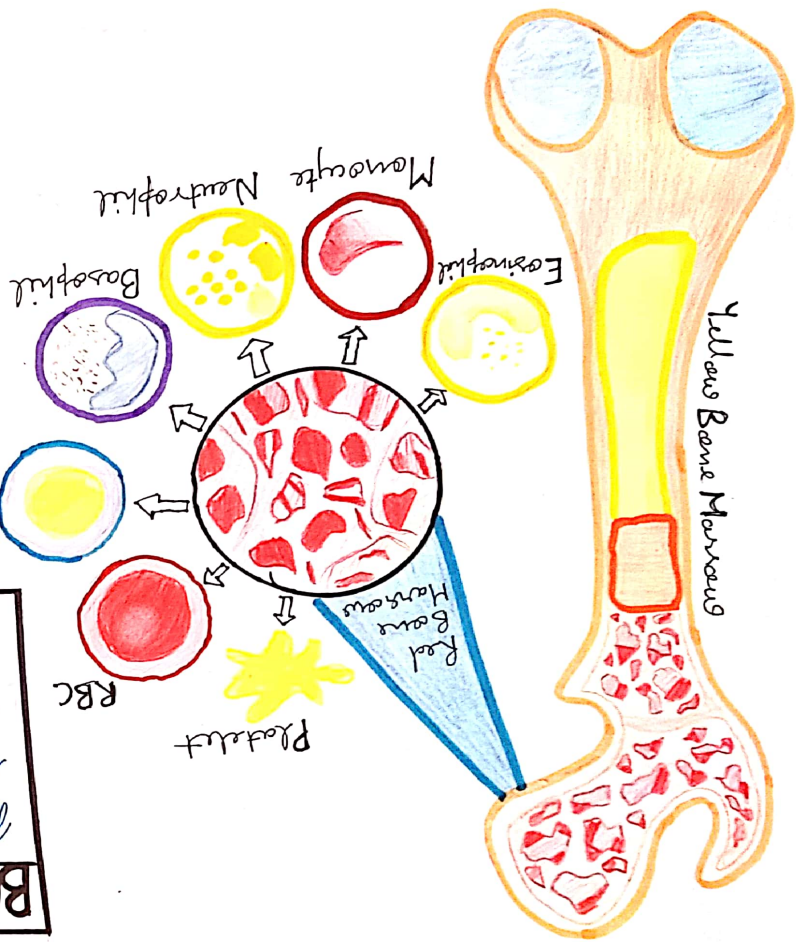
Group-1
Adiba (08)
Atiya (08)
Akilesh (11)

Drug Cause Bone Marrow Suppression

Antibiotics factors

Bone Marrow Suppression is a condition where bone marrow & its production of blood cells





BONE MARROW SUPPRESSION?

Bone marrow suppression is a condition where the bone marrow activity is decreased, leading to reduced production of blood cells:

- ANEMIA (represented by a red circle)
- LEUKOPENIA (represented by a blue circle)
- PLATELET (represented by a yellow star)

SYMPTOMS

- Fatigue and weakness
- Pale skin
- Shortness of breath
- Frequent infections

TREATMENT OPTION

- Stopping or adjusting causative drugs
- Blood transfusions
- Antibiotics for infections
- Bone marrow transplant in severe cases

PREVENTION & MANAGEMENT

Regular monitoring during cancer treatment

DIAGNOSIS

- Complete blood count (CBC)
- Bone marrow biopsy
- Medical history

CAUSES

- Chemotherapy & Radiation therapy
- Autoimmune disease
- Bone marrow cancer
- Toxic exposure (Benzene, Pesticides)

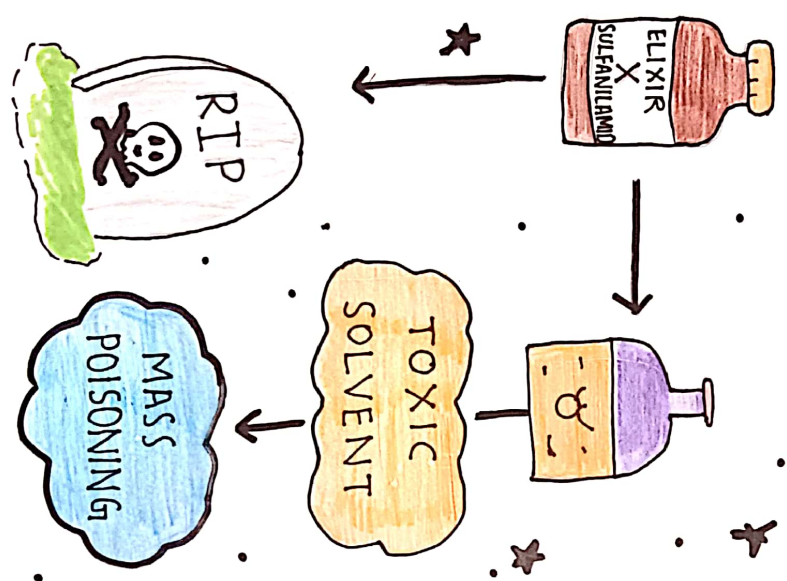
⑤

25 - Aged
27 - Aruba
28 - Aruba
29 - Arpa
30 - Aruba

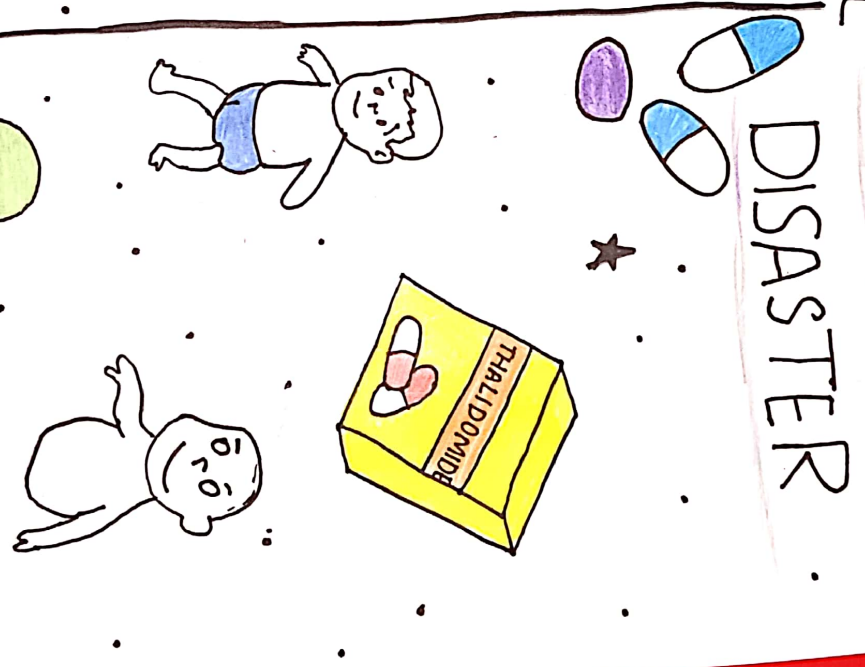
LANDMARK ADVERSE DRUG REACTIONS

DISASTERS

SULFANILAMIDE THALIDOMIDE
DISASTER . DISASTER



SULFANILAMIDE DISASTER		
POISONINGS	100	
DEATHS	70	



Name - मोनिका मुजुमदार (60) 9811111111
 UMR AZAM (60) 9811111111

TERATOGEN

TERATOGENIC DRUGS

Drugs Risk ALTERNATIVE

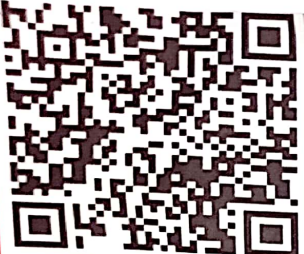
Isofluthin	Waglan	Tetracycline	Valproic Acid	Phenytoin	Thalidomide	Lithium	ACE inhibitors
Cleft palate	Fetal bleeding	Tooth discoloration	Neural tube defects	Fetal hydantoin Syndrome	Limb deformities	Caudal defects	Skull abnormalities
Topical Retinoids	Hepatic	Penicillin	Lamotrigine	Levofloxacine	Averse or Pregnancy	Lamotrigine	Methyldopa

BWARE



- GROUP-22**
- ① 119 - Shrinkala
 - ② 121 - Shuka abala
 - ③ 122 - Shunya Singh

SCAN for WHO guidelines



No No No! I was wrong friends, not kids!



"PROTECT the WOMB AVOID the DOOM"

PHARMACOVIGILANCE



INTRODUCTION

Pharmacovigilance is the science - and activities related to detecting - related to detecting - assessing - understanding, and preventing adverse effects or other drug-related problems.

ENSURING

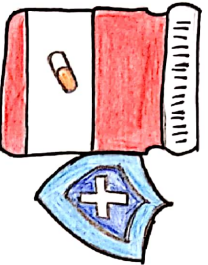
DRUG

SAFETY

IMPORTANCE OF

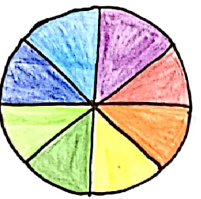
PHARMACOVIGILANCE

- Prevent harm to patients
- Reduce healthcare costs
- Build trust in medicines
- Ensuring regulatory compliance



To ensure the safe and effective use of medicines

IMPORTANCE



Doctors
Pharmacists
Patients
Clinical trials
Literature

Pharma companies

WORKFLOW

Drug Exposure (patient takes a medication)

ADR OCCURS

Any unwanted effect or suspected harm

ADR Reporting

By healthcare professionals
Phone, email, email

WORKFLOW

DRUG OCCURS
(Any unwanted effect or suspected harm)

ADR REPORTING

By healthcare professionals
patients of pharmaceuticals
→ Yellow card, e-reporting, Phone, email.

DATA COLLECTION & ENTRY
into safety databases
(like Vigibase)

SIGNAL DETECTION
identifying patterns, or repeated ADRs
use statistical methods

COMMUNICATION OF RISK

To healthcare surveillance
(Post-marketing surveillance)

RECENT CASE EXAMPLE

Thalidomide tragedy

Drug caused birth defects in 1950-1960s
led to stricter regulating and monitoring.

GROUP-17
SHARAH → (92)
SADAF → (93)
SAAD INITIAZ ALI (90)

NEPHROTOXIC DRUGS

TRACYCLINE

Mitochondrial dysfunction by binding to ribosome of the renal tubules. Blocks attachment of tRNA to mRNA.

AMINOGLYCOSIDES

Renal tubule accumulation causes mitochondrial damage and hence toxicity.

STATIN

Binds to ergosterol, when increased dose of systemic use, it causes toxicity.

CISPLASTIN

Renal tubular cell accumulation, which generates inflammation and reactive oxygen species, causing toxicity.

INDINAVIR

It crystallises in renal tubules that causes inflammation and hence toxicity.

VANCOMYCIN

Dose dependent, when increased causes renal tubule accumulation and hence toxicity.

AMPHOTERICIN-B

Binds to ergosterol forming pores causing ion leaks. This leads to renal vasoconstriction, damage the tubules hence toxicity.

CYCLOSPORINE

Inhibits calcineurin which causes vasoconstriction and induces tubular injury, thus toxicity.

Grp-24
130- TANISHKA
132- TANU KR
133- TANU TANISHK
134- TANVEER AHMED
136- TANVA BHARDWAJ

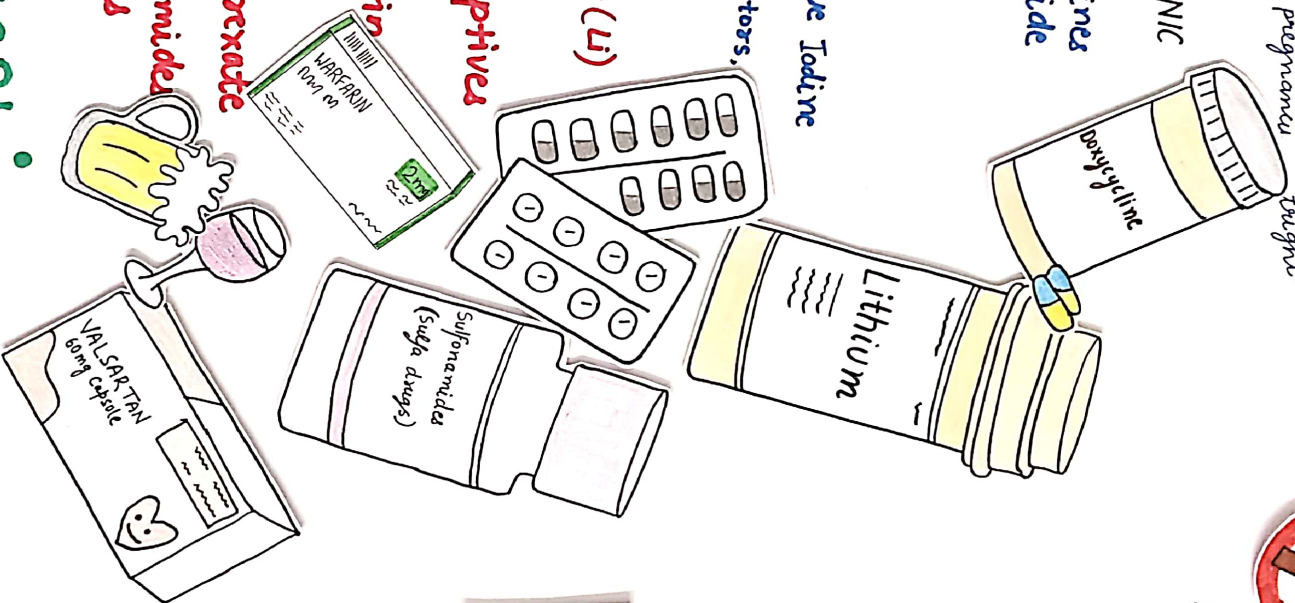
AT THE FIRST GLANCE DRUGS SEEMS COLORFUL BUT IT'S NOT

TERATOGENIC DRUGS

Teratogen: Any agent that can disturb the development of an embryo or fetus.
 Teratogens may cause a birth defect in the child or may halt the pregnancy **twight**.

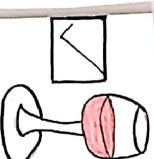
💡
MNEMONIC

- T** Tetracyclines
Thalidomide
- E** Epileptic drugs
- R** Retinoids
Radioactive Iodine
- A** ACE Inhibitors,
ARBs
- T** Third
element (Li)
- O** Oral
contraceptives
- W** Warfarin
- A** Alcohol,
methotrexate
- S** Sulfonamides
Statins

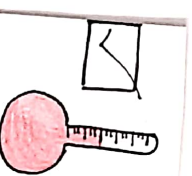


POP-QUIZ -

Alcohol



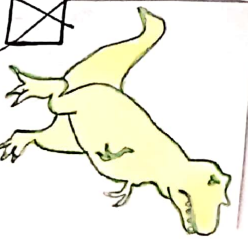
MERCURY



GERMAN
MEASLES



T-REX



CLINICAL:

• Thalidomide cause **Phocomelia**

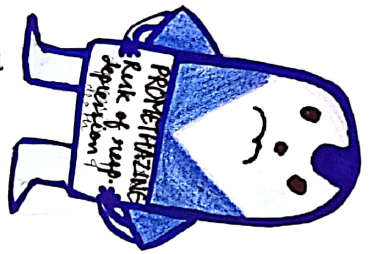
Phocomelia is a condition that involves malformation of arms and legs.

- Anticancer drugs cause -
- Cleft palate
- Hydrocephalus
- Multiple defects

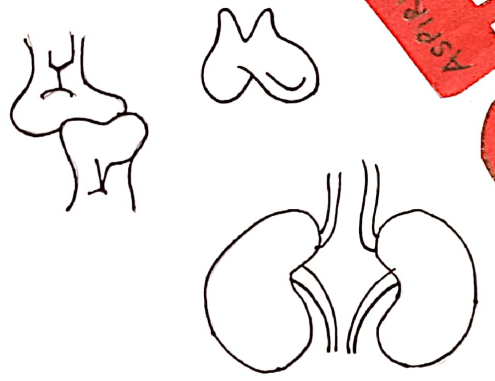
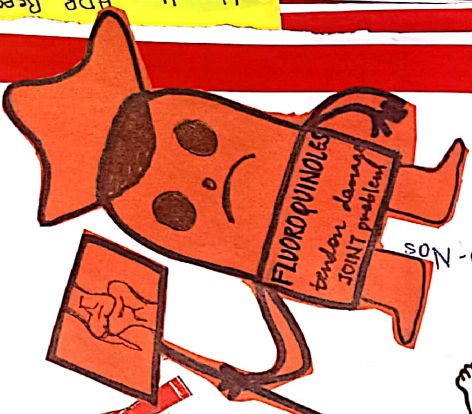
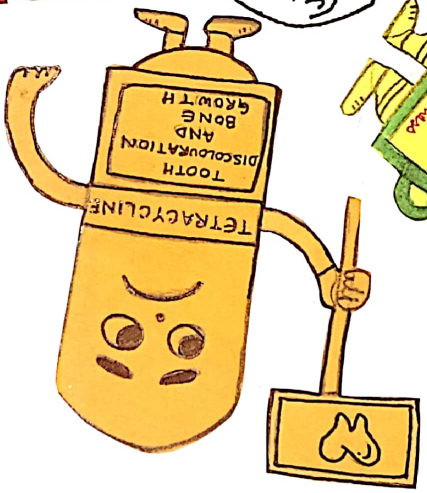
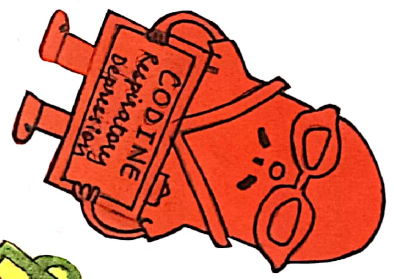


- 114 Shazia Habib
- 115 Sheeraz
- 116 Shezy
- 117 Shiksha

DRUGS CONTRAINDICATED IN CHILDREN



"Tiny Humans, Big No-Nos" Drugs NOT for kids!



- 143 - VINITA YADAV
- 144 - YASH PRATAP
- 145 - YASIR AHMED
- 146 - YESH TYAGI
- 147 - ZAKAR AHMED

Pharmacovigilance

Collection
Detection
Assess ment
Monitoring
Prevention

of Adverse effects
of drugs

Data Collection

Sources

- Healthcare professionals
- Patients
- Clinical trials etc

Reports

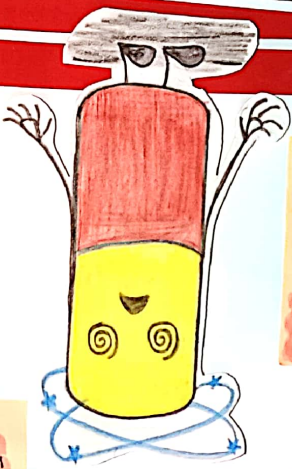
- Adverse medication errors
- Lack of efficacy

Case Range

Identifying and categorizing incoming adverse events report based on their seriousness and regulatory timeline.

Data Verification

- Medical Review
- Casualty Assessment
- Coding



CASE PROCESSING &

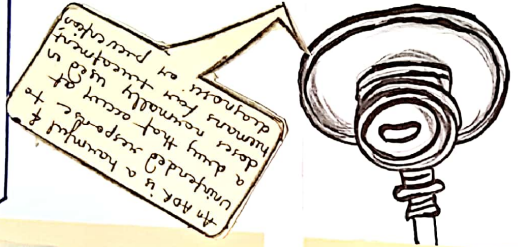
- Quality checks - to ensure accuracy and completeness
- Regulatory submission - To national / international authorities

SIGNAL DETECTION

- Identifying patterns in reported data that may indicate new risks
- Signal validation
- Risk assessment

RISK MANAGEMENT

- Minimization Measures
- Label changes
- Block box
- warnings
- Management Plans



WHERE TO REPORT ADRs IN INDIA

- National Coordination Centre - Pharmacovigilance Programme of India
- Use the ADR Reporting Form
- Toll free No. - 1800-180-3034

ADR TYPES

- Type A** - Related to main pharmacological effect of the drug
- Type B** - Diff. from Type A
- Type C** - Chronic use of drugs
- Type D** - Result from withdrawal symptoms/effects
- Type E** - eg - Sudden collapse of B-blockers in HTN leads to rebound of HTN.

WHO CAN REPORT ADRs?

- Patients, Caregivers
- Doctors, Nurses, Pharmacists

WHAT IS AN ADR?

- An Unwanted & Harmful reaction do a medication which may occur at Normal dose used for treatment that may result in death.



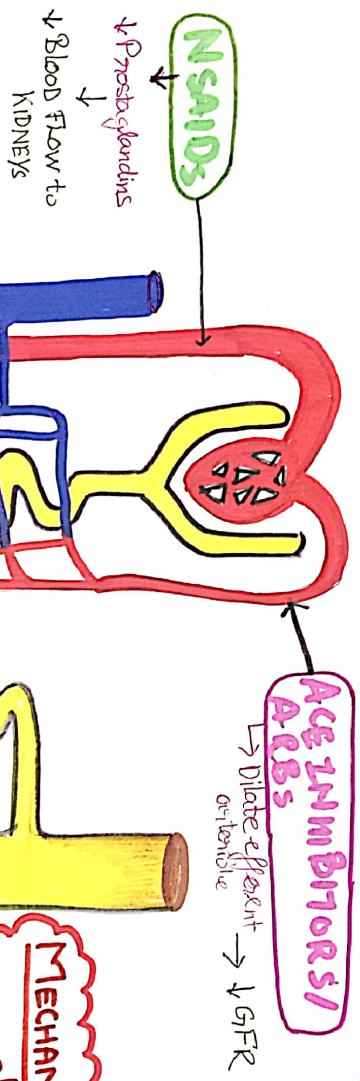
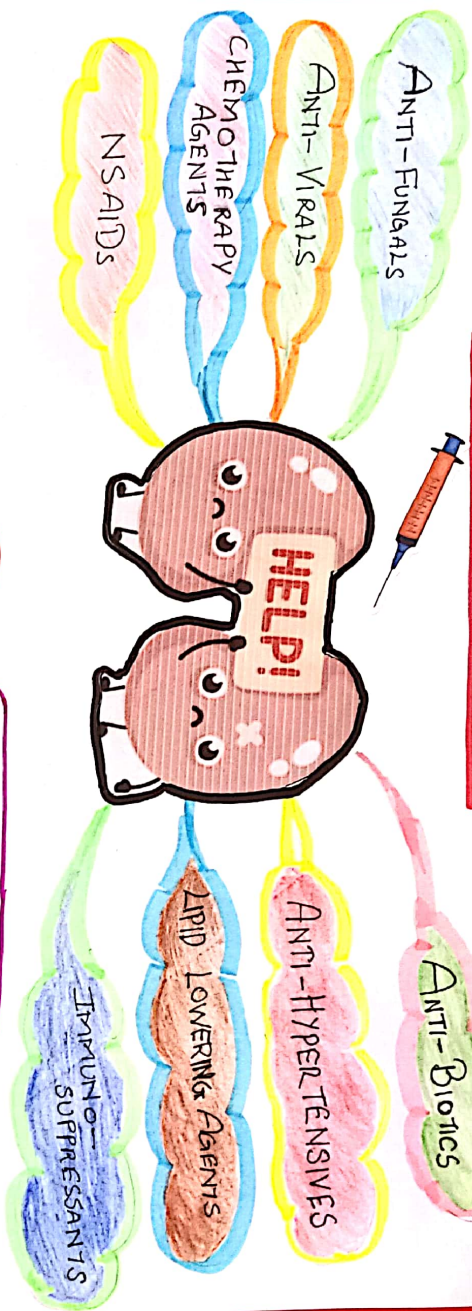
Made by -

- 98 - SAKSHAM JAIN
- 99 - SALMAN
- 101 - SAMIDHA
- 102 - SANAT CHAVHAN
- 103 - SANDEEP

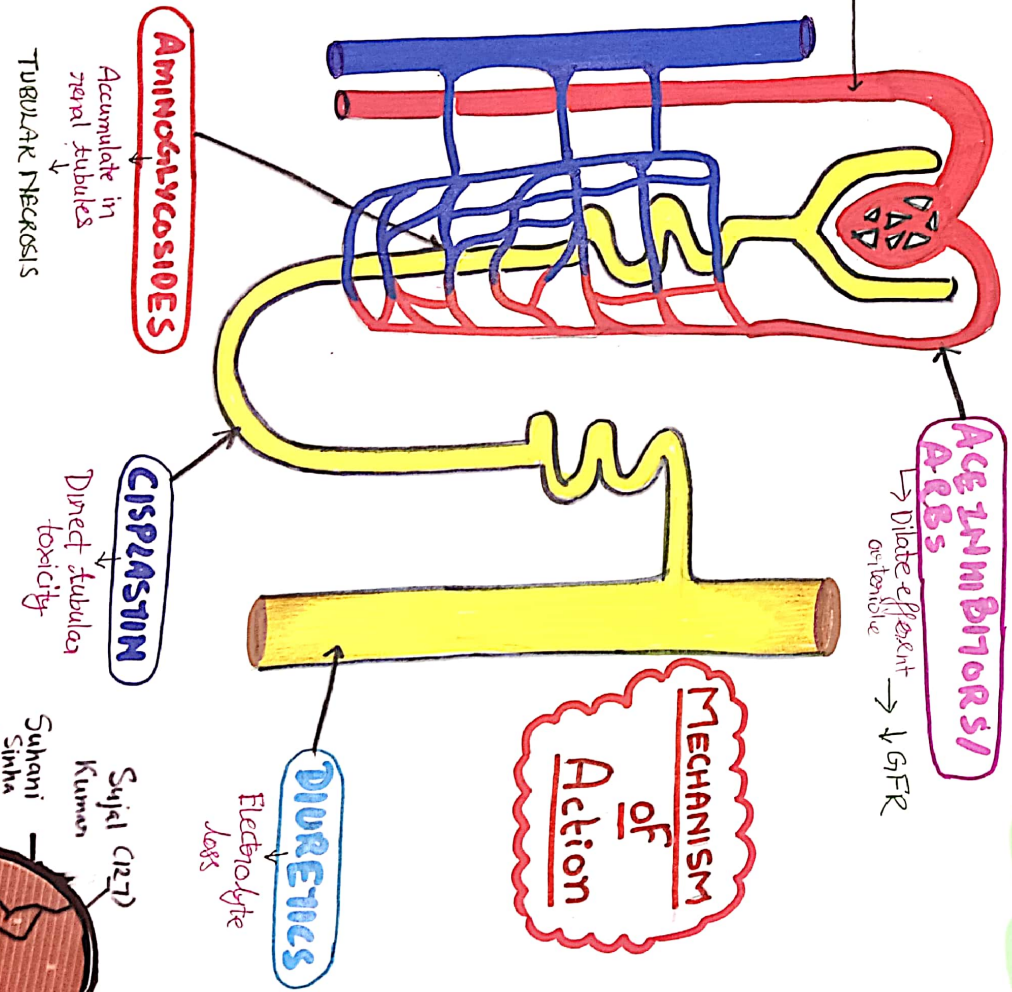
NEPHRO TOXIC DRUGS



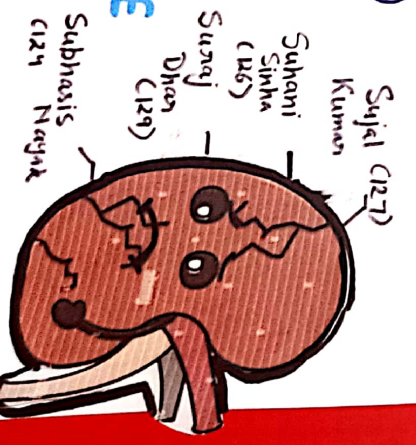
CLASSIFICATION.



MECHANISM of Action

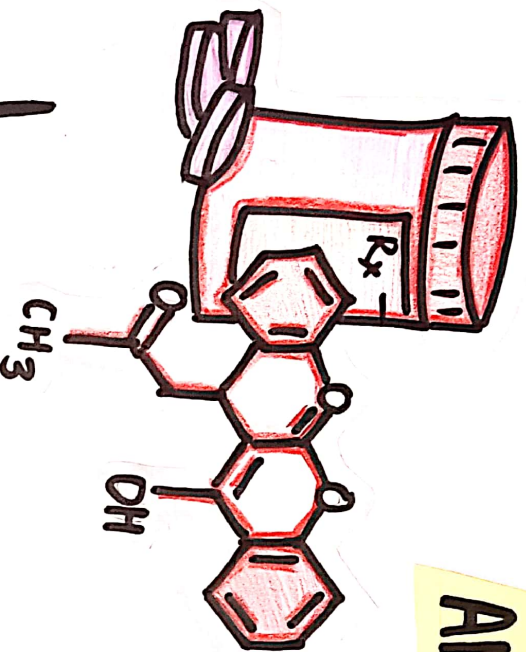


HEALTHY KIDNEY = Healthy Life



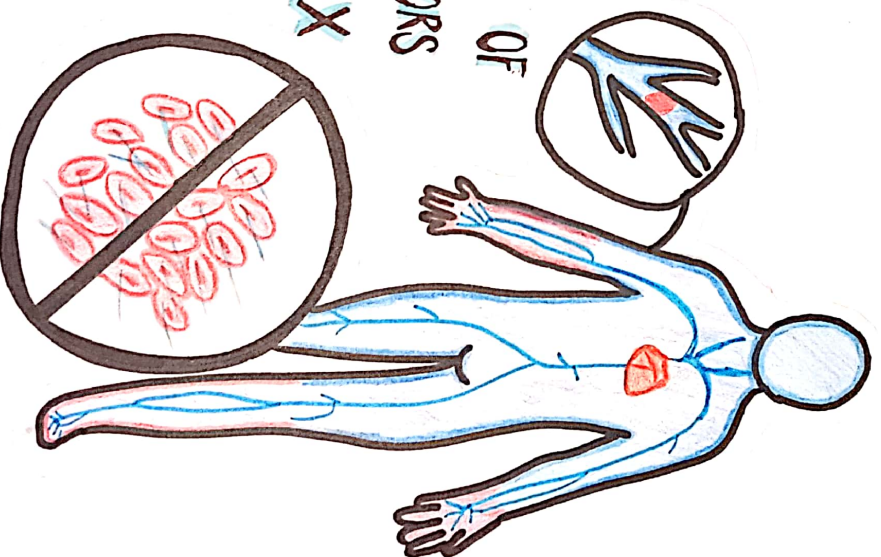
DRUG INTERACTIONS CAUSING ADRs

ANTICOAGULANT WARFARIN



BLOCKS SYNTHESIS OF
COAGULATION FACTORS

II, VII, IX and X



GROUP-16
RIYA - 87
ROSHIT - 88
RUSHDA - 89

WHAT IS A SIDE EFFECT?

side effect is an unwanted or unintended effect of a medication that occurs at normal doses. side effects can be

Mild Moderate Severe



Side effect

- Mild and temporary
- More severe
- Unintended harm
- May require medical attention
- Reversible when dose stopped

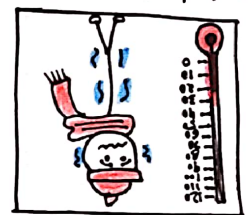
Adverse effect

WHAT IS TOXICITY?

Toxicity refers to the harmful or poisonous effects of a substance including medications, on the body.



SYMPTOMS



Low body temperature & skills

Adverse effect

ZARA RASHEED 148 gp.no
ZAINAB TARIQ 149 gp.no

WHAT IS AN ADVERSE EFFECT?

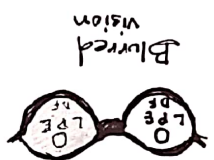
An adverse effect, also known as an unwanted or harmful effect of a medication that can be serious, debilitating or even life threatening.



Skin rashes



Abdominal pain

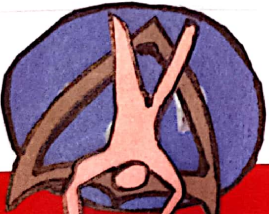


Blurred vision

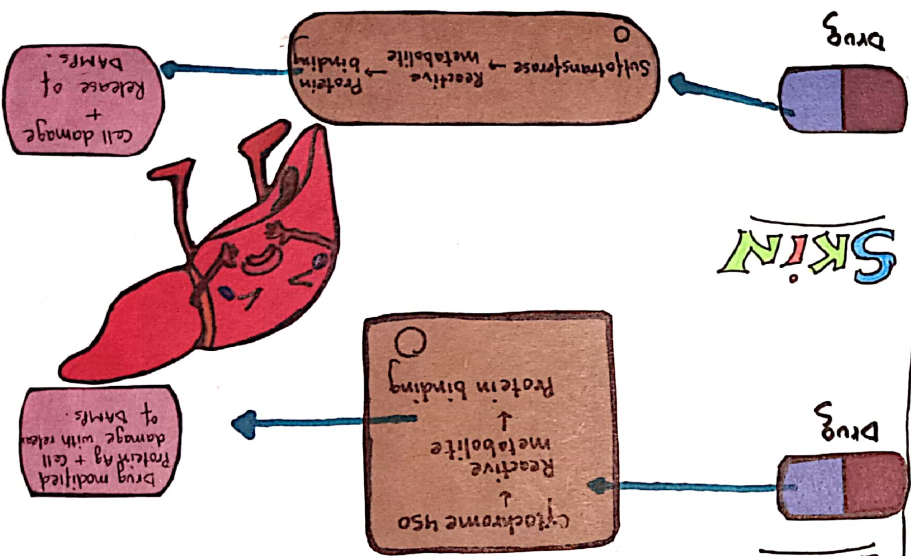
SYMPTOMS

WHAT IS IDIOSYNCRASY?

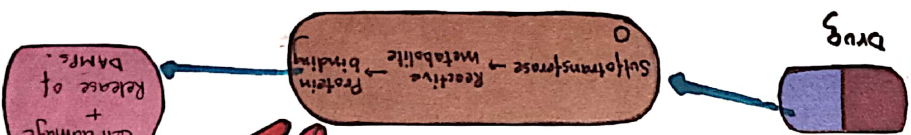
Idiosyncrasy refers to an abnormal or unusual response to a medication that is unique to an individual and cannot be explained by known pharmacology of the drug. Reactions are not related to dose or duration of treatment.



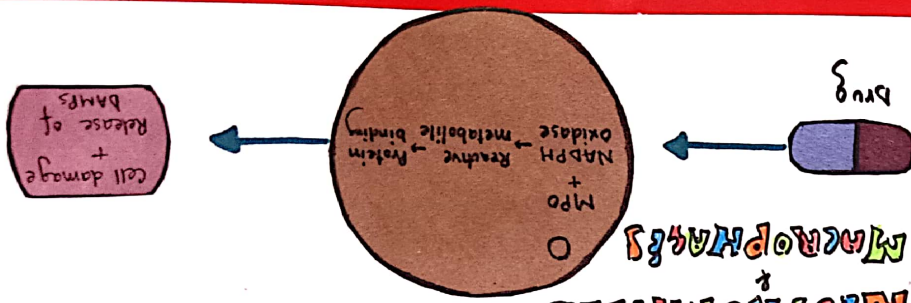
LIVER



SKIN



NEUTROPHILS & MACROPHAGES



Phases of Clinical Trials

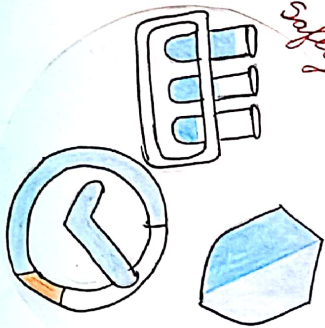
Presented by:

- 104 - Sania Chauhan
- 105 - Sania Nain
- 106 - Sania Chandra
- 107 - Sania Pawan
- 108 - Sania Shaikh

Phase-0

Participants - 10-15 healthy human
 Purpose - Microdosing study
 Duration - Short period

copy and MTD



Short Duration

Phase-1

Participants - 10-100 Volunteers
 Purpose - Safety & Max tolerated dose
 Duration - Several months

* No blinding



10-100 Volunteers

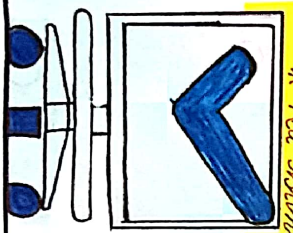


Several Months

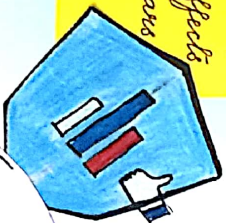


Phase-2

Participants - 50-500 (3-4 center)
 Purpose - Efficacy & Side effects
 Duration - Months to 2 years
 * No blinding



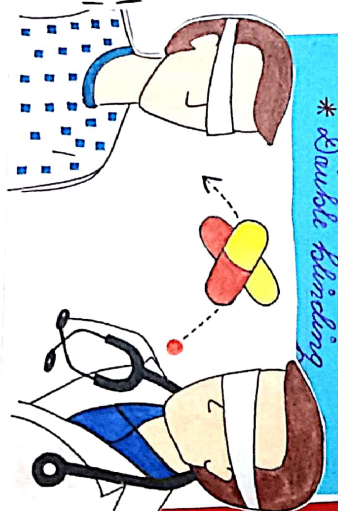
Efficacy & Side Effects



10-100 Volunteers

Phase-3

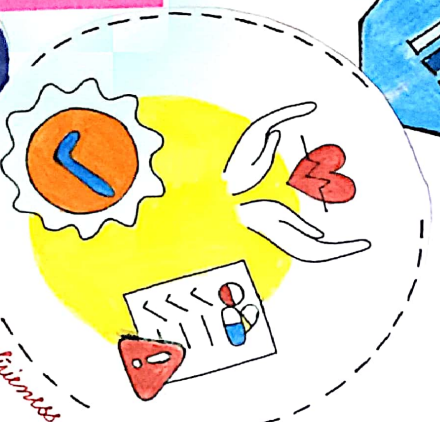
Participants - 500-5000
 Purpose - Long term effectiveness & S/E
 Duration - years
 * Double blinding



Double Blinding

Phase-4

Participants - Max no of patients
 Purpose - Surveillance on S/E, new adverse effect, effectiveness
 Duration - 2-4 yrs.



Long term effectiveness



Surveillance on S/E

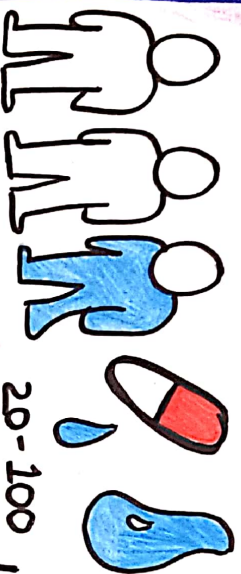
Summary

- Phase 1: Safety ▶ MTD ▶ PK
- Phase 2: Toxicity efficacy ▶ Safety
- Phase 3: Long term efficacy ▶ Safety

PHASES OF CLINICAL TRIALS

PHASE 1

Is it Safe?

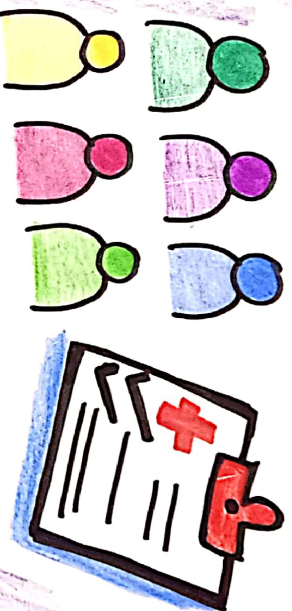


20-100

Aim: Safety and dosage

PHASE 2

Does it work?



100-300 participants

Aim: Side Effects

PHASE 3

Is it better than standard Treatment
1000-3000 participants



Aim: confirmation & monitoring

PHASE 4

Long-term effectiveness?



Aim: post-marketing Surveillance

DRUGS CONTRAINDICATED IN CHILDREN

