Adverse drug Reactions

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Outline

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- Statistics
- Common causes of ADR
- Classification
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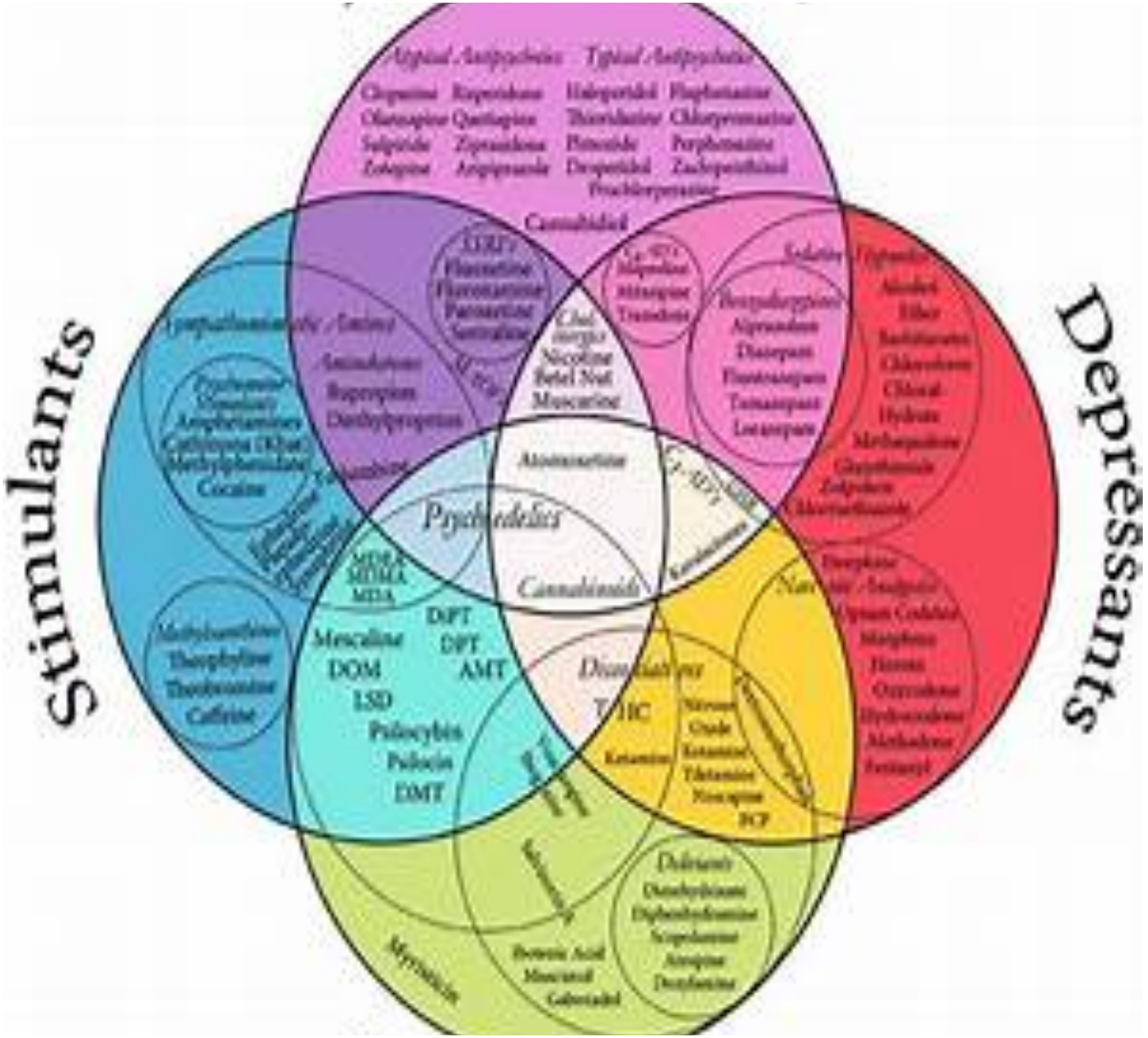
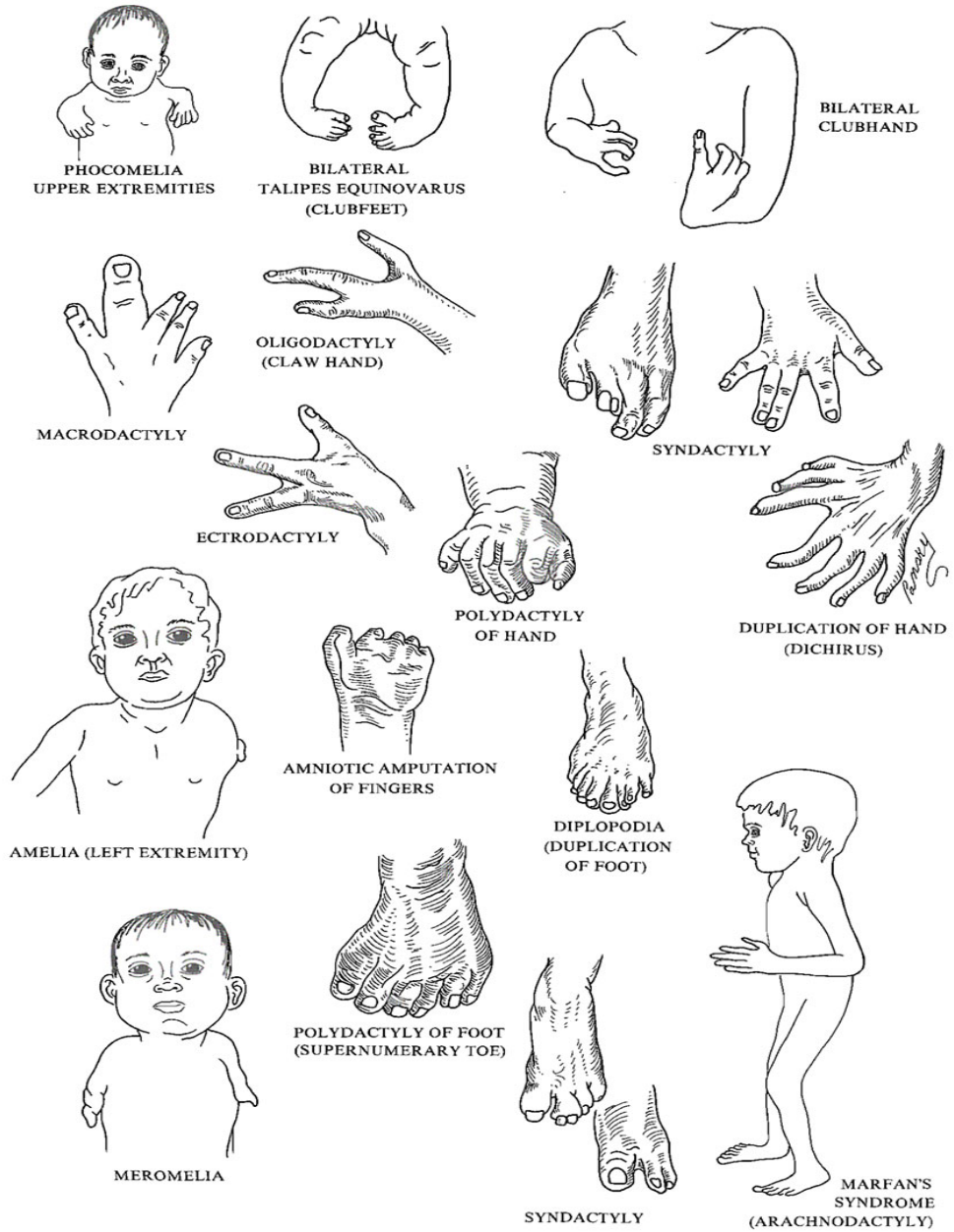
Definition

ADR is a lethal, unintentional & unwanted side effects of a drug which occurs due to dosages used in humans for prophylaxis, diagnosis or treatment of disease or for the alteration of physiological function.



History

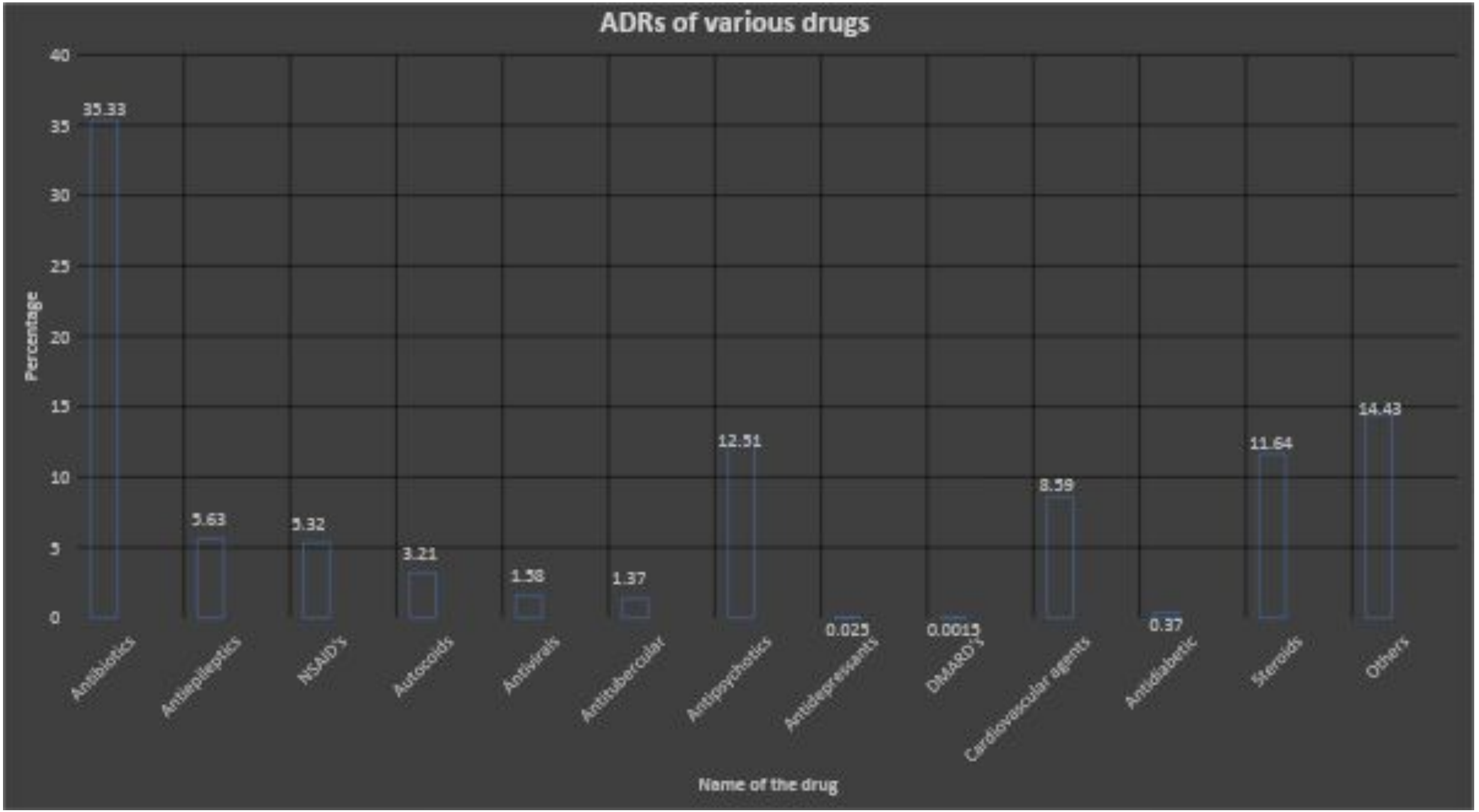
- 1922 : Jaundice associated with the use of Salvarsan , in the treatment of syphilis.
- 1937 : In USA 107 people died from taking an elixir of Sulphanilamide that contained the solvent diethylene glycol.
- 1958 : Thalidomide marketed in west Germany for morning sickness during pregnancy.
- 1959 – 1961 : reported outbreak of Phocomelia.



ADRs : Statistical Analysis

6th leading cause of death worldwide
4th leading cause of death in US and Canada

- Hospital in-patients : 10-20%
- Deaths in hospitals : 0.3-3%
- Hospital admissions : 0.3-5%


ADRs of various drugs
Percentage
40
35
30
25
20
15
10
5
0
35.33
5.63
5.32
3.21
1.58
1.37
12.51
0.025
0.0015
8.59
0.37
11.64
14.43
Antibiotics
Antiepileptics
NSAID's
Autacoids
Antivirals
Antitubercular
Antipsychotics
Antidepressants
DMARD's
Cardiovascular agents
Antidiabetic
Steroids
Others
Name of the drug

Common Causes of ADR

- Age
- Sex
- Concurrent Disease
- Polypharmacy
- Pharmacogenetics
- Drug interaction
- Previous ADR
- Miscellaneous (Diet, Smoking, Environmental exposure)

Classification

- Type A (Augumented): Dose related
- Type B (Bizzare): (“Patient Reactions”)
- Type C adverse effects (Statistical effects): Dose & time related
- Type D (Teratogenic, Carcinogenic): Time related
- Type E (End of dose effects): Withdrawal
- Type F (Failure of Therapy): Unexpected failure of therapy

Severity of ADR

- **MINOR** : No need of therapy
- **MODERATE** : requires drug change, specific treatment,hospitalization
- **SEVERE** : Potentially life threatening, permanent damage, prolonged hospitalization
- **LETHAL** : Directly or indirectly lead to death

List Of Drugs Withdrawn From Market

Name of the drug	Adverse reaction	Outcome
Temafloxacin	Serious allergic reactions	Withdrawn
Co-trimoxazole	Serious allergic reactions	Uses restricted
Terfenadine	Interacts with grapefruit juice	Withdrawn from OTC sale
Sotalol	Cardiac arrhythmias	Uses restricted
Astemizole	Interactions	Withdrawn
Cisapride	Cardiac arrhythmias	Withdrawn
Cerivastatin	Rhabdomylosis	Withdrawn

List of drugs with possible Adverse Drug Reactions

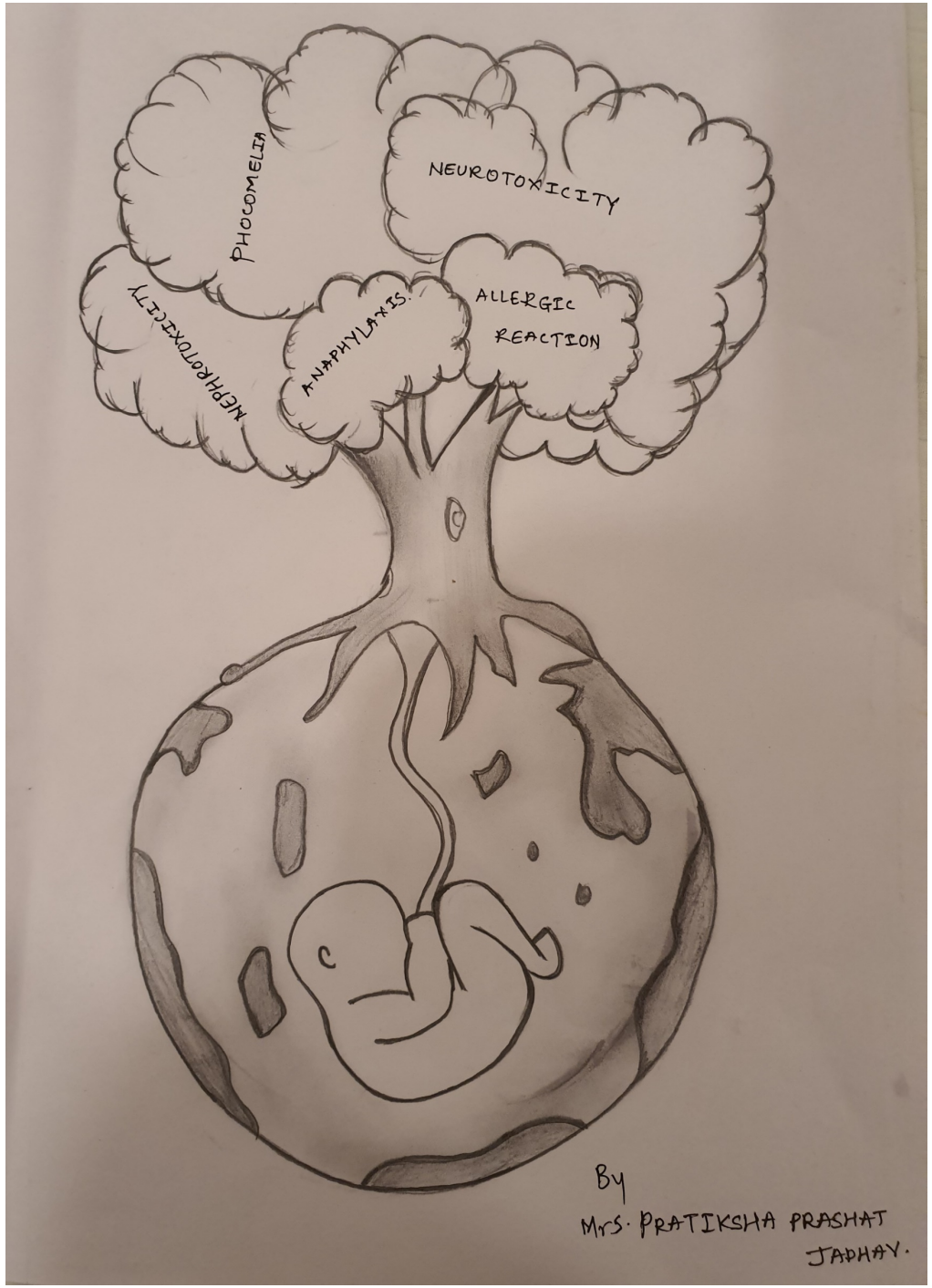
Sr. No	Name of the Drug	Possible adverse drug reactions
1	Ampicillin	Hepatitis
2	Formoterol+ Fenoterol	Acute atrial fibrillation.
3	Prednisone	Arterial hypertension.
4	Fentanyl, Hydrochlorothiazide	Postural Hypotension
5	Fluconazole	Cholestasis
6	Furosemide	Pancreatitis, Hypotension
7	Oxacillin	Tremor.
8	Codeine	Hallucinations & mental confusion.
9	Imipenam	Convulsions.
10	Vancomycin, Losartan, Furosemide, Captopril	Renal failure
11	Ceftriaxone	Angioedema + hives.

Pharmacovigilance

- Pharmacovigilance is the science, activities relating to detection, assessment, understanding & prevention of Adverse drug reaction or any other drug related problems.
- Pharmacovigilance programme of India (PVPI) are established in 1968.
- Has collaboration with Central Drug Standard Control Organization(CDSCO)
- India was 7^{th} in position among top 10 countries contributing to global drug safety database.

Conclusion

- New-borns, infants, and children are prescribed medications in an off-label fashion, which can increase the risk of ADRs.
- Drug evaluation studies are seldom done in this patient population because of practical difficulties and ethical concerns.
- In addition, the paediatric population often represents a small percentage of the pharmaceutical market, so clinical trials do not yield large profit expectations for drug companies.
- Consequently, many medicinal products that have no paediatric marketing authorization are prescribed outside the licensed indications for age, dosage, route of administration, and therapeutic indication.
- This leads to a potentially dangerous scenario for an ADR to occur.


PHOCOMELIA
NEUROTOXICITY
NEPHROTOXICITY
ANAPHYLAXIS
ALLERGIC
REACTION
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THANK YOU