Reporting of Adverse Drug Reactions(ADRs)

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- WHO defines an ADR as "Any response to a drug which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function"

- Pharmacovigilance is defined as "the science and activities relating to the detection, assessment, understanding and prevention of adverse drug reaction or any other possible drug-related problems".

- Adverse drug reaction is an important arm of patient care.
- It aims at making the safe use of medicines for the treatment or prevention of disease.
- No one wants to harm patients, but unfortunately any medicine will sometimes do just this.
- Good pharmacovigilance program will identify the risks and the risk factors in the shortest possible time, so that harm can be avoided or minimized.

- When communicated effectively, this information allows for the intelligent, evidence-based use of medicines and has the potential of preventing many adverse reactions.

- Ultimately help each patient to receive optimum therapy, and will help to ensure the acceptance and effectiveness of health programmes

- Central Drugs Standard Control Organization (CDSCO), Ministry of Health and Family Welfare and Government of India launched the National Pharmacovigilance Programme.

- There is no clinical trial design or other evaluation method that is capable of eliminating the risk of serious ADRs occurring after marketing.
- Clinical trials are only suited to the validation of clinical effects but are of limited value for identifying rare ADRs.
- Knowledge of a drug's safety is incomplete when it first becomes available and it is monitored closely after marketing.

Aims of Pharmacovigilance studies

- Essential to identify and to measure ADRs in order to prevent further occurrences.
- To Identify early detection and early prevention of occurrence of ADRs.
- To improve drug safety monitoring.
- To ensure better patient care.

Pharmacovigilance centers

- Pharmacovigilance centers pursue four objectives:
- To detect ADRs
- To evaluate them
- To study them
- To inform prescribing physicians.

Pharmacovigilance centers

- The regional pharmacovigilance centers are in charge of recording, evaluating, and exploiting data on ADRs.
- An important task of the regional pharmacovigilance center is evaluation of causal relationships between unwanted events and drugs.
- Documented ADRs are recorded in the national pharmacovigilance database which communicates the data to the World Health Organization.

Classification of ADRs

Traditionall ADRs

- Type A (Augmented) reaction are usually the exacerbation of pharmacological effects of a drug, thus are dose-dependent, usually predictable due to the known pharmacology of a drug, preventable
- Eg Insulin induced hypoglycemia

- Type B (Bizarre) reaction are hypersensitivity reaction.
- Are not dose dependent.
- These reaction are often not predictable and preventable (unless the patient has known history of this type of reaction)
- Eg penicillin induced hypersensitivity reaction, Type B reaction is rare but often serious with high mortality rate.

Newer classification

- Type A (Augmented)
- Type B (Bizarre)
- Type C (Continuous)
- Type D (Delayed effects)

Wills and brown

- Type A (Augmented)
- Type B (Bizarre)
- Type C (Chemical)
- Type D (Delivery)
- Type E (Exit)
- Type F(Familial)
- Type G (Genotoxicity)
- Type H (Hypersensitivity)
- Type U (Un classified)

Mechanisms of Type A ADRs

- Pharmaceutical causes
- Pharmacokinetic causes
- Pharmacodynamic causes

Pharmaceutical causes

- Changes in the drug quantity present in a particular product.
- Changes in its drug release properties.
- Eg Rate- controlled preparation of "indomethacin"

  Induced gastrointestinal bleeding and hemorrhage certain doxycycline salts can cause corrosive effects on the esophagus.

Pharmacokinetic causes

- Alterations in the Absorption,Distribution, Metabolism and elimination of drugs may alter drug effects by changing the concentration of drug present at the site of action.

- The change in the drug effect due to alterations in Pharmacokinetics parameters may be experienced as either therapeutic failure, toxicity

Pharmacodynamic causes

- Increased sensitivity of target tissues or organs may predispose a person to adverse drug reaction

- These target tissue or organ sensitivity is influenced by the drug receptors themselves by homeostatic mechanisms and by diseases.

Mechanisms of Type B ADRs

- Decomposition of the active ingredient
- Effect of the non drug excipient

(Additives, preservaties, colouring,solubilising agent)

- Genetic factors.
- Eg 1) Death have been reported due to decomposition of paraldehyde to acetaldehyde and its subsequent oxidation to acetic acid.
- 2). Many additives like propylene glycol, CMC, may cause hypersensitivity reactions.

Detection of ADRs

- Pre- marketing studies
- Post marketing surveillance

Pre- marketing studies

- The safety of new medicines are tested in animal models.
- Risk information of newer drugs may be obtained from such tests
- Eg The level of acute toxicity, which organs will be affected, in case of toxicity and dose dose dependency of such tissues, injuries, specific animal tests for carcinogenicity, teratogenicity, mutagenicity are also seen.

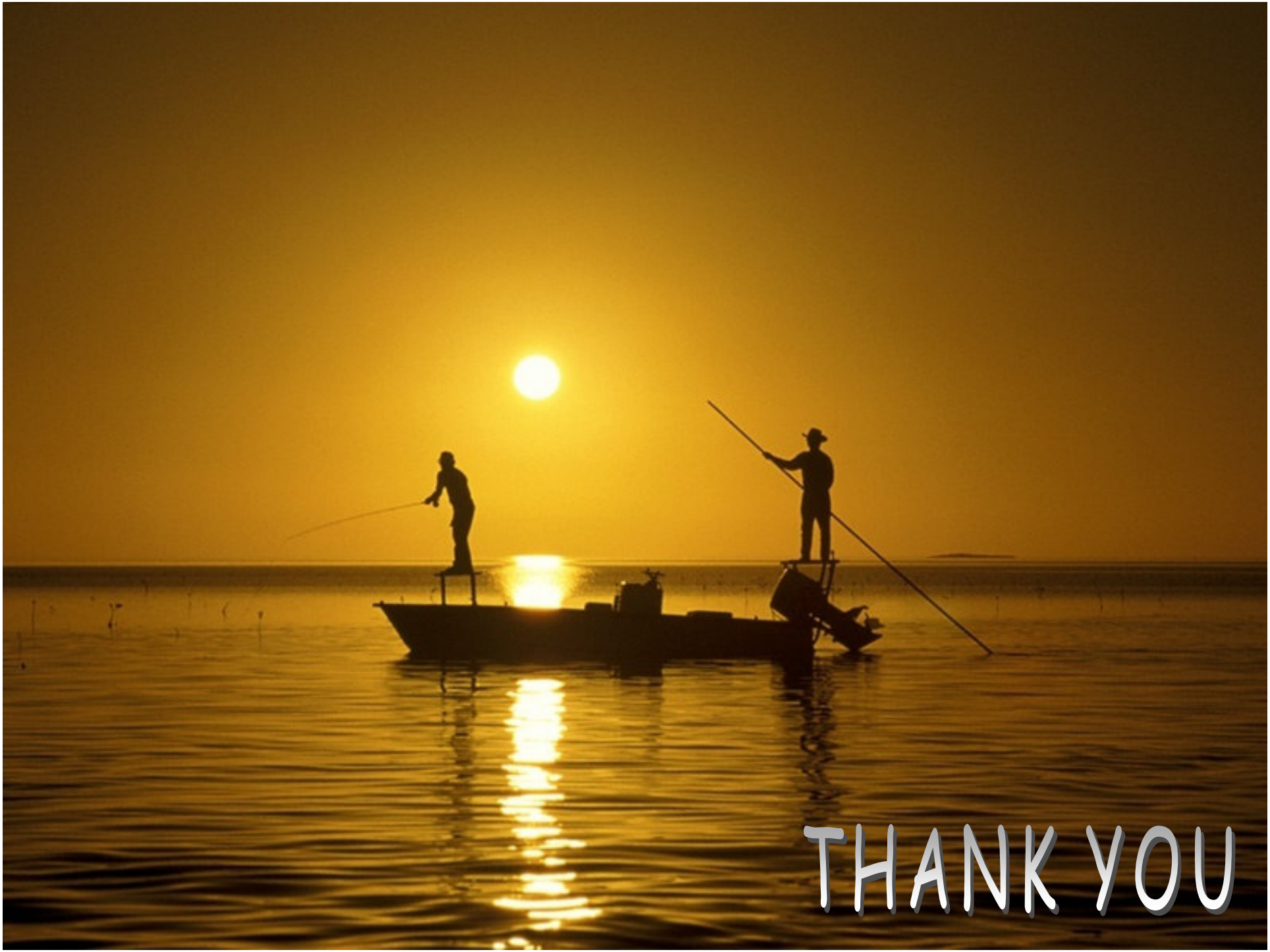
Post marketing surveillance

- Spontaneous adverse reaction reporting: every health care practitioner should report for any suspicious drug unexpectedly causing a risk situation for a patient.
- To assist the detection of ADRs, health care professionals should closely monitor patients who are at high risk.
- Renal or hepatic impairment
- Drugs which have potential to cause ADRs
- Previous allergic reactions
- Multiple drugs.

Data collection

- Patients demographic data
- Presenting complaints
- Past medication history
- Drug therapy detais including over OTC drugs
- Current medications
- Medication on admission
- Lab data.

- Detail of suspected adverse drug reaction, nature, severity,frequency, time of administration duration of treatment, plasma concentration of drug)
- Previous report on reported reaction, risk factors.
- Patients case notes, treatment chart, patient interview.
- Communication with health care dept.


THANK YOU