Hospital and Clinical Pharmacy Chapter 11

Pharmacovigilance (Overview)

Definition

Pharmacovigilance is made up of Two words one Greek word " Pharmcon " = Drug or medical substance , and second Latin word " Vigilare "= To keep watch

according to WHO Pharmacovigilance is defined as " the science and activities relating to the detection, assessment, understanding, and prevention of adverse effect or any other drug related problem".

Aims

- to make the treatment of a patient effective.
- To improve the patient care and safety related with the use of medicine and all medical and Paramedical intervention (The activities done by a non fully qualified doctor to support medical treatment like ultrasound CBC) .
- To improve the public health and safety related to use of medicine.
- For early detection of adverse drug reaction.
- For Identification of risk factors.

Aim

- To improve patient care and safety in relation to the use of medicines, and all medical and paramedical interventions
- To improve public health and safety in relation to the use of medicines
- To contribute to the assessment of benefit, harm, effectiveness and risk of medicines, encouraging their safe, rational and more effective (including cost-effective) use
- To promote understanding, education and clinical training in pharmacovigilance and its effective communication to health professionals and the public.
- To promote rational and safe use of medicines.

❖ Goals

The ultimate goals of pharmacovigilance are:

- The rational and safe use of medical drugs.
- The assessment and communication of the risks and benefits of drugs on the market.

❖ Why do we need pharmacovigilance ?

1. **Humanitarian concern**

   -animal toxicology is often not a good predictor for human effects.

   -evidence of safety from clinical trials is insufficient due to some limitations

   - limitations (phase 1-3): limited size ,
   - narrow population (age &sex specific),
   - narrow indications (only specific disease),
   - Short duration

2. **Safe use of medicines**
   - Medicines are supposed to save lives. Dying from a disease is sometimes unavoidable; dying from a medicine is unacceptable.
   - It has been find that ADRs may cause 5700 deaths per year in UK.
   - ADRs were 4th-6th commonest cause of death in the US in 1994.

3. ADRs are expensive
    - 6.5% of admissions are due to ADR
    - Cost £446 million per annum in US
4. promoting rational use of medicines
5. ensuring public confidence
6. to protect patients from unnecessary harm
7. ethical concern -to know of something that is harmful to another person who does not know, and not telling, is unethical.

❖ **Adverse drug reactions**

- Adverse Event (AE): Any untoward medical occurrence that may present during treatment with a pharmaceutical product but which does not necessarily have a causal relationship with this treatment.
- Adverse Drug Reaction (ADR): Any noxious change which is suspected to be due to a drug, occurs at doses normally used in man, requires treatment or decrease in dose or indicates caution in future use of the same drug.

Scope Of Pharmacovigilance

- Patient Monitoring: the person has knowledge of pharmacovigilance can provide his services in hospital for monitoring the patients
- Immunization(vaccination): pharmacovigilance plays an important role in vaccination because there are some certain vaccines which show serious adverse reaction so a person has knowledge of pharmacovigilance , required to monitor and control the adverse reactions
- Herbal Medicine : safety and efficacy of herbal medicine is necessary so pharmacovigilance required in herbal medicine practice

- Disease Control Public Health Program :The person has knowledge of pharmacovigilance can take a part in disease control programs to aware the public about safety and proper use of medicine to prevent adverse drug reaction
- Academy: a person has pharmacovigilance knowledge can go in academic field.

Pharmacovigilance

Pharmacovigilance:- Pharmakon = Drug, Vigilare = keep watching

Definition (WHO) – "Science and activity relating to the – ① Detection ② Assesment ③ Understanding ④ Prevention of Adverse effect

Aim/objective:- ↓ Drug related harm to patient

Activities:- ① Post marketing Study – Report by doctors or other health professionals

Formate
- Drug Name – Brand
- Manufactured by
- Batch/Lot No.
- Exp Date
- Dose used
- Route
- Frequency
- Reason for prescription
- Therapy date.

② Prescription event monitoring.

③ computerized medical record linkage.

④ Dissemination of ADR data through – 'Drug alert', Medical letters. Advisory sent to physician by regulatory agencies.

⑤ Change in the labelling of medicines - warning, precautions.

Causality Assesment –
① Relationship with time of drug administration.
② Previous knowledge about drug.
③ Dechallenge – Event subsided on stoping drug
④ Rechallenge –

Result:-
① Definite = proved.
② probable = Likely to cause event
③ possible = Drug + other cause
④ Doubtful = Unlikely to the cause, but can't ruled out

History of Pharmacovigilance

Major Historical Events Led to Pharmacovigilance:

- In 1922, there was an enquiry into the jaundice associated with the use of Salvarsan, an organic arsenical used in the treatment of syphillis.

- **Thalidomide Tragedy:** Thalidomide was a widely used drug in the late 1950s and early 1960s for the treatment of nausea in pregnant women. It became apparent in the 1960s that **thalidomide treatment resulted in severe birth defects in thousands of children**

- **Pharmacovigilance in current status:**
  WHO drug monitoring was laid in 1971 during the 20th world health assembly, established national pharmacovigilance center with WHO collaboration. WHO collaboration center for international drug monitoring is Uppsala in Sweden, its supports and co-ordinates the WHO international drug monitoring program

Pharmacovigilance in India

- In India pharmacovigilance was introduced in 1986 with the formal introduction of adverse drug reaction monitoring system , under the guidance of drug controller
- At that time there was only 12 main centre and district and primary Health care hospitals were affiliated to these main centres.
- In 1997 India become a part of who program for international drug monitoring
- On first January 2005 WHO sponsored and World Bank funded and National Pharmacovigilance Program of India, was started .

Pharmacovigilance in India

- Pharmacovigilance in India was initiated in 1986 with a formal adverse drug reaction (ADR) monitoring system, under supervision of the drug controller of India.
- India joined the World Health Organization (WHO) Programme for International Drug Monitoring controlled by Uppsala Monitoring centre(UMC), Sweden in 1997 but was not successful.
- Later, the National Programme of Pharmacovigilance was launched in 2005, and was renamed as the Pharmacovigilance Programme of India (PvPI) in 2010. The Central Drugs Standard Control Organisation (CDSCO) initiated a nation-wide