

# **UNIT-II**

## **INFORMATION RESOURCES IN PHARMACOVIGILANCE**



**CENTURION**  
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*Shaping Lives...  
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- **Basic drug information resources**
- **Specialized resources for ADRs**

## Information resources in pharmacovigilance

- **DEFINITION:-**The branch of science who's activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug related problem.
  
- **ORIGIN OF PHARMACOVIGILANCE:-**
  - The Thalidomide disaster in 1956 - Thalidomide launched in market and in 1956-61 report of foetal abnormalities (20000 cases) maximum in Germany.
  - In 1962 USA revised law requiring proving the safety and efficacy before issuing marketing authorization.
  - In 1963 British committee on safety of drug monitoring.
  - In 1964 UK starts the "YELLOW CARDS" system.
  - In 1964-65 National ADR reporting system UK, Australia, New Zealand, Canada, West Germany, Sweden .

➤ **OBJECTIVE:**

- 1- To know what are the various sources of drug information.
- 2- To select the appropriate source depending on the information.

➤ **BASIC DRUG INFORMATION RESOURCES-** Drug information is current, critically examined, relevant data about drugs and drug use in a given patient or situation.

- Current information uses the most recent, up-to-date sources possible.
- Critically examined information.
- Relevant information must be presented in a manner that applies directly to the circumstances under consideration (e.g. patient parameters, therapeutic objectives, alternative approaches).

➤ **TYPES OF RESOURCES:-**

- (I) Primary resources
- (II) Secondary resources
- (III) Tertiary resources





## (I) PRIMARY RESOURCES-

- Researcher's and manufacturer's information.
- Patents containing original information regarding the discovery of drug.
- Reports containing scientific data before product can be sold, supplied or represented.
- Scientific Journals
- Provide original studies or reports

### ➤ ADVANTAGES

- Most current evidences.
- Provide data on new drugs.
- Original document that was created at the time of the actual events.

### ➤ DISADVANTAGES

- Data can be controversial.
- Every study has limitation
- Complicated
- Time consuming.

## (II) SECONDARY RESOURCES-

- Abstract or index which summarizes the information arising in primary resource.
- Indexing and abstracting services are valuable tools for quick and selective screening of the primary literature for specific information, data, citation, and article.
- Bibliographic database that provide abstract or full-text of studies.

### ➤ ADVANTAGES-

- Find specific information at high granularity.
- Pick out key point.
- Quick to read.

### ➤ DISADVANTAGES-

- Detail missing.
- Two different authors can interpret the same piece of original material in two widely different ways.
- May be inaccurate.

### (III) TERTIARY RESOURCES-

- Compilation of knowledge in the field. e.g. Textbooks, handbook, online drug compendia.

#### ➤ ADVANTAGES-

- Provide comprehensive information.
- Information reflects views of multiple experts in field.
- Fast, easy to use, and may be good for patients.

#### ➤ DISADVANTAGES-

- Information may be dated due to gap between when resources is written and published.
- Chances of distorting a topic.



## ➤ OTHER SOURCES-

- Libraries
- Research association
- Government bodies
- Information center in industries

## ADVERSE DRUG REACTION

Any noxious change which is suspected to be due to drug, occur at doses normally used in man, require treatment or decrease in dose or indicates caution in future use of the same drug.

### CLASSIFICATION:-

1. **Type A effect:-** Augmented pharmacologic effects – dose dependent and predictable are those which are due to pharmacologic effects.
2. **Type B effect:-** Bizarre effects(idiosyncratic)- dose independent and unpredictable .
3. **Type C effect:-** Chronic effect refer to situation where the use of a medicine, often for unknown reasons, increase the frequency of a “spontaneous” disease.
4. **Type D effect:-** Delayed effects.
5. **Type E effect:-** End-of-treatment effect.
6. **Type F effect:-** Failure of therapy.

➤ **SPECIALISED RESOURCE OF ADR**

- Individual reporting
- Comprehensive Monitoring
- Population Monitoring
- Individual case safety report (ICSR)
- Spontaneous Reporting

## ➤ **INDIVIDUAL REPORTING**

- In individual reporting Doctor are the major source of report.
- The physician, during an outpatient or inpatient examination, may decide that the patient has a recognizable syndrome of signs, symptoms and/or laboratory finding and that this syndrome may be associated with a previously administered drug.
- Since most severe reaction are seen in hospitals, physicians who are Hospital-based are often able to ascertain previous drug administration, link it to the reaction, and submit a report.

## ➤ **COMPREHENSIVE MONITORING:-**

- Comprehensive monitoring is typically performed in a hospital setting and the input of abstract of patient identification, drug administration, and patient reaction.
- Specialised method are used to ensure that this information is complete, and case report or tabulated summary data can be supplied to the national centre.

➤ **POPULATION MONITORING:-**

- In population monitoring the record of hospital or clinic patients, or of the entire population of a district, may be employed.
- Such monitoring could be effective when a large stable population is surveyed in an organized medical care system.

➤ **INDIVIDUAL CASE SAFETY REPORT (ICSR):-**

- Individual Case Safety Report is a report which contains information describing suspected adverse drug reaction related to administration of one or more medicinal product.
- A document providing the most complete information related to an individual case at a certain point of time.



## ➤ SPONTANEOUS REPORTING:-

- Spontaneous reporting is a system whereby case report of adverse drug event are volunteer submitted by health professionals, pharmaceuticals companies or consumers to the national pharmacovigilance centre.
- It is basically the reporting of a suspected adverse reaction on the initiative of the health professional who became aware of the problem, or the patient initiative. These report can be communicated by any means, but in countries with a well developed pharmacovigilance system they are most often reported on the country- specific reporting card.
- Such reporting is sometime referred to as intensified spontaneous reporting, or ideally, prospective