Methods in Pharmacovigilance

DR. SATISH SHARMA
DEAN, SCHOOL OF PHARMACY, GLOCAL UNIVERSITY
Pharmaco-vigilance Methods

Active

Observational

Clinical studies

Passive
Types of surveillance/methods

- Passive surveillance
- Active surveillance
- Comparative observational studies
- Clinical studies
Some Common Terminologies In Pharmacovigilance

Pharmacovigilance
It is the science which deals with the study of the collection, detection, assessment, monitoring, and prevention of treatment adverse event and any other drug-related problem.

1. Adverse event
2. Adverse drug reaction
3. Seriousness and severity
4. Causality Assessment
5. Labeling
Passive surveillance

- Spontaneous reporting
- Stimulated reporting
- Intensified reporting
- Targeted spontaneous reporting
Spontaneous reporting

- A functional ADR system to monitor the safety of all medicines
- Reports are submitted voluntarily by health care professionals, pharmaceutical companies or patients to the pharmacovigilance centre
- Reporting systems are based on suspected ADRs
- Data are collected in a central or regional data base
- Reporting form contains: reporter details, patient details, suspected product details and the description of suspected reaction
- This reporting is based on suspected adverse drug reactions
- Cases are not collected systematically
### Spontaneous reporting

<table>
<thead>
<tr>
<th><strong>Pros</strong></th>
<th><strong>Cons</strong></th>
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<tbody>
<tr>
<td>Covers the whole population</td>
<td>Inherent under reporting</td>
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<tr>
<td>Includes all medicines</td>
<td>Captures only suspected ADRs</td>
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<tr>
<td>Continuous monitoring through-out the life cycle of a medicine</td>
<td>Reporting bias- seriousness, severity, publicity of specific ADRs</td>
</tr>
<tr>
<td>Signals of new, rare and serious ADRs can be obtained</td>
<td>Difficult to detect-delayed ADRs</td>
</tr>
<tr>
<td>Most commonly used pharmacovigilance method</td>
<td>Difficult to calculate reliable rate and measure risk factors</td>
</tr>
<tr>
<td>Easiest method to establish</td>
<td>Deaths are poorly reported</td>
</tr>
<tr>
<td>Relatively Inexpensive</td>
<td>Limitations in special areas-pregnancy, paediatrics</td>
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Intensified ADR reporting

- This is an extension of spontaneous reporting program
- It aims to enhance ADR reporting of specific medicines in early post marketing phase
- The procedure is usually followed for new drugs, biological medicines and for medicines that require additional studies
- Example: Antiretroviral medicines under a separate program
Targeted spontaneous reporting

- This method is used to learn more about ADR profile of a specific medicine in the population
- To estimate the incidences of a known ADR for a specific medicine in a population
- Example: Monitoring renal toxicities related to the use of tenofovir based regimen in antiretroviral therapy
Active surveillance

- Sentinel sites: It involves the collection of AE data from only part of the total population to learn something about the larger population. Example: to study the trends in a disease.

- Drug event monitoring: The patients are identified from electronic prescription data or automated health insurance claims. Patients will fill the survey form. Follow up questionnaire is then sent to prescribing physician.

- Registries: A registry is a list of patients with the same characteristics. This charate. The registries may be disease specific (disease registry) or drug specific (drug registry) or type of exposure during a specific life event (pregnancy exposure registry). The information is collected using standardized questionnaires.
Comparative observational studies

- Cross sectional study: The data collected from a population of patients can be attributed at a single point of time/time interval regardless of exposure or disease status.

- Case control study: Cases/patients of AEs are identified from an existing data base or using data collected specifically for the purpose of the study.

- Cohort studies
Cohort means a group of people who share a common characteristic such as exposure to a drug within a defined time period.

It is a prospective observational cohort study of adverse events associated with one or more medicines.

The study is planned prior to beginning of the treatment with the medication.

Every patient is followed up for adverse events since the time of treatment.

All adverse events are recorded.

Example: ADR monitoring of anti-retroviral drugs.
## Cohort event monitoring

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<tr>
<td>Effective in early detection of signals of unsuspected ADRs</td>
<td>Method is more laborious than spontaneous reporting method</td>
</tr>
<tr>
<td>Availability of denominator information allows calculation of incidence rates of ADRs</td>
<td>More expensive method than spontaneous reporting</td>
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<tr>
<td>Ability to produce a near complete profile of adverse events or ADRs for the medicines of interest</td>
<td>Training is necessary</td>
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<tr>
<td>Ability to identify and assess risk/risk factors</td>
<td>Long term follow up needs to be actively managed</td>
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<tr>
<td>Ability to make accurate comparisons between medicines</td>
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