Post Marketing Surveillance

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HISTORY

- In the 1960 at least two serious drugs reactions were observed in many patients. thalidomide causes limb deformities(phocomelia).
- observed in Japan, was the optic nerve damage(subacute myelooptic –neuropathy) due to Clioquinol
- As a result, the joint commission on Prescription Drugs Use was established in 1976,funded largely by the drug industry, with the mandate to design a post-marketing surveillance system to detect, quantify, and describe the anticipated and unanticipated effects of marketed drugs.

SOURCES OF PMS INFORMATION

- The following may be considered as sources of information, some source are proactive and some are reactive.
  - Expert user groups.
  - Customer surveys.
  - Customer complaints and warranty claims.
  - Post CE-market clinical trials.
  - Literature reviews.
  - Device tracking/implant registries.
  - User reaction during training programmers.
  - The media.

Are there benefits to a PMS system

- Detection of manufacturing problems
  - Improvement of medical device quality
  - verification of risk analysis
  - intelligence of long-term performance
  - chronic complications
  - performance trends
  - performance in different user populations

Why do we need Post- Marketing Surveillance

- The primary objective of post-marketing surveillance is to develop information about drug effects under customary condition of drug use.
- Rare adverse events may not be detected in pre-licensure studies because in very large clinical trials have limitation.
- Access to more patient and given data
- Given diversity of data sources, innovative approaches to retrieval of key data may have great potential vs. single unified system.
- Better background rates, comparable “control” population.
- Increase in “non-medical” data sources

Post- Marketing Surveillance Opportunity

- Access to additional health system data.
- Access to global data: regulatory, inspectional, health system, international surveillance and pharmacovigilence.
- Better analytical tools and methods.

Practical Aspects of PMS

- PMS should be proactive.
- Manufacturer should document compliance.
- Manufacturer`s PMS procedure should discuss the information that will be collected and obtained as a part of system.

ABOUT PMS PROCEDURE

- It should assign departments or position a responsible for performing a particular function.
- Manufacturer may find it helpful to a have report at the end of year, as well as PMS tracking schedule and log.
- This information could constitute feedback received from user .

Methods of Surveillance

- Thus, four types of studies are generally used to identify drugs effects:
  1. Controlled clinical trials,
  2. Spontaneous or voluntary recording
  3. Cohort, studies and
  4. Case control studies

1. **Controlled clinical trials:**

- Controlled clinical trials match treatment and control groups as closely as possible, minimize bias through such methods as randomization and “double-blinding,” and directly monitor patients for the duration of the study.
- Controlled clinical trials are considered the most definitive method for evaluating a drug’s efficacy and safety.
- But they are often costly or impractical in specific situations, for example, when a drug’s effects are rare, or appear only after long-term use or a long latency period.

2. Spontaneous or voluntary reporting

- Voluntary reporting by physicians and other health providers, hospitals, and consumers may act to alert FDA and pharmaceutical firms to possible adverse effects of drugs, so that the inference of an association between a drug and an observed health condition may be further studied by cumulative, careful reporting, and confirmed or disconfirmed by more vigorous methods.
- Underreporting may be a serious deficiency of this method.
- A drug may also be erroneously associated with an adverse effect until the suspected association fails to show up in repeated, statistically validated studies

3. Cohort studies

- Cohort studies follow a defined group of patients (the cohort) for a period of time.
- In this method, patients are not randomly assigned to groups, and there is no blinding. Cohort studies are usually prospective and observe the cohort from the beginning of drug use.
- A group of patients taking the drug of interest is assembled and followed to see, for example, if adverse reactions occur. A second group of patients (the controls) with the same medical condition, who are not taking the drug and who may be receiving alternative treatment, but who are otherwise matched as closely as possible with the cohort, may also be studied in parallel.

- The control group is used to identify the frequency of occurrence of any condition observed in the drug-exposed group which is due to causes other than the drug (i. e., the “background incidence” of the condition).
- In this method, patients can be directly monitored to ensure they take the drug appropriately, and to observe the drug’s effects; or monitoring can be less controlled. With less control, a larger cohort can be followed, but bias is thus increased.

4.Case-control studies :

- Case-control studies identify patients with the adverse effects to be studied (the cases), and compare them with a sample (the controls), drawn from the same cohort that gave rise to the cases.
- Controls are matched as closely as possible with the cases, except with regard to the drug's suspected adverse effect, to examine whether exposure to the drug is the cause.