

Vaccine Safety Surveillance

Vaccine Safety Surveillance

Definition:

- Vaccine safety surveillance is the continuous, systematic collection, analysis, and interpretation of health data related to vaccine use.
- The purpose is to monitor the safety of vaccines after they are licensed and introduced into the general population.

Purpose:

- To detect adverse events (any undesirable medical occurrence after vaccination) early.
- To assess whether adverse events are causally linked to vaccination.
- To estimate the incidence (rate) of adverse events.
- To ensure public confidence in vaccination programs.
- To guide regulatory actions (e.g., warnings, vaccine withdrawal).

Types of Vaccine Safety Surveillance:



1. Passive Surveillance:

- **Definition:** Health professionals, vaccine recipients, or manufacturers voluntarily report adverse events.
- **Examples:**
 - VAERS (Vaccine Adverse Event Reporting System) in the U.S.
 - AEFI reporting systems in many countries.
- **Advantages:** Simple, inexpensive, covers large populations.
- **Disadvantages:** Underreporting, bias (serious events more likely to be reported).

2. Active Surveillance:

- **Definition:** Systematic solicitation or active follow-up with vaccine recipients to check for adverse events.
- **Examples:**
 - Follow-up phone calls, home visits.

- Sentinel site surveillance.
- **Advantages:** More complete and accurate data.
- **Disadvantages:** Costly, logistically complex.

3. Enhanced Surveillance:

- Focuses on a specific vaccine, adverse event, or period (e.g., after a new vaccine introduction).
- Example: Monitoring for myocarditis after COVID-19 mRNA vaccines.

Data Sources:

- Hospitals, clinics.
- Electronic health records.
- National vaccine registries.
- Specialized studies (e.g., case-control studies).

Data collected includes:

- Type of vaccine
- Lot number
- Patient demographics
- Time to onset of symptoms
- Clinical course and outcome

Real-World Scenario:

Case: Rotavirus Vaccine and Intussusception

- **Background:** The first rotavirus vaccine (RotaShield) was withdrawn in 1999 after reports of intussusception.
- **Learning:** Post-marketing surveillance revealed a rare but serious adverse effect not seen in clinical trials, prompting the withdrawal.

Outcome:

- Safety signal detection (early warning).
- Risk-benefit assessments.
- Informing public health policy.

Vaccine Pharmacovigilance

Definition:

- Vaccine pharmacovigilance is a subfield of pharmacovigilance focusing exclusively on vaccines.
- It involves all activities to monitor, detect, assess, understand, and prevent adverse effects following immunization (AEFIs).

Key Objective:

- **Detection:** Identify any unexpected or serious adverse events.
- **Assessment:** Determine causality between vaccine and adverse event.
- **Understanding:** Study mechanisms behind adverse events.
- **Prevention:** Modify vaccine use, update information leaflets, or improve vaccine formulations if needed.

Unique Challenges Compared to Drug Pharmacovigilance:

- Vaccines are preventive, given to healthy individuals, often children.
- The public's tolerance for vaccine side effects is much lower than for drugs used to treat illnesses.
- Many adverse events may not be directly caused by the vaccine (coincidental).
- Mass campaigns mean large populations are exposed in short times, requiring rapid response.

Phases where Vaccine Pharmacovigilance is involved:

1. **Pre-licensure:** (during clinical trials) Safety profiles are established.
2. **Post-licensure:** (after public release) Real-world safety data are collected and analyzed.

Common methods:

- Spontaneous reporting systems (e.g., WHO's VigiBase)
- Periodic Safety Update Reports (PSURs)
- Risk Management Plans (RMPs)
- Post-Authorization Safety Studies (PASS)

Important regulatory bodies:

- World Health Organization (WHO)
- US Food and Drug Administration (FDA)
- European Medicines Agency (EMA)

International Collaboration:

- WHO Global Vaccine Safety Initiative (GVSI).



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