

UNIT-III

VACCINE SAFETY SURVEILLANCE



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Empowering Communities!*

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Vaccine Pharmacovigilance

Definition- According to the CIOMS/WHO working group on vaccine pharmacovigilance,

Vaccine pharmacovigilance is defined as “the science and activities relating to the”

- **Detection,**
- **Assessment,**
- **Understanding and**
- **Communication**

of adverse events following immunization and other vaccine or immunization-related issues, and to the prevention of untoward effect of the vaccine or immunization.

Importance of vaccine safety

- Decreases in disease risk and increased attention on vaccine risks
- Public confidence in vaccine safety is critical
- Low tolerance for vaccine risks
 - Higher standard of safety is expected
 - Vaccinees generally healthy
 - Lower risk tolerance = need to search for rare reaction

Steps of vaccine pharmacovigilance

Detect signal suggesting AEFI is related to vaccine.



Develop hypothesis about causal association between an AEFI and vaccination



Test hypothesis through appropriate epidemiological method

Vaccine provide by Govt. of India

Govt. of India is providing vaccination to prevent 7-vaccine preventable disease (VPDs) namely,

- ✓ Diphtheria,
- ✓ Pertussis,
- ✓ Tetanus,
- ✓ Polio,
- ✓ Measles,

Other vaccines.....

- Pneumococcal vaccine
- Rotavirus vaccine
- Hepatitis A
- MMR
- Influenza
- Meningococcal
- Cholera
- JE
- HPV
- Varicella
- Typhoid

Source for vaccine safety

- Local health workers
- Health education campaigns
- Visiting experts
- Online resources and communication network
- Religious and/or community leader
- Parents, guardians and vaccine
- Radio and television
- printed material
- Video or DVD

Which AEFIs should be reported?

- **Serious AEFI**
- Signal and events associated with newly introduced vaccine
- AEFI that may have been caused by an immunization error
- Significant events of unexplained cause occurring within 30 days after a vaccination
- Event causing significant parental or community concern
- Swelling, redness, soreness at the injection site IF it lasts for more than 3 days or swelling extended beyond nearest joint

Adverse event following immunization (AEFI)

Definition-

An AEFI is any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptoms or disease.

Classification of AEFIs

- **Vaccine product-related reaction** – An AEFI that is caused or precipitated by a vaccine due to one or more of the inherent properties of the vaccine product. Extensive limb e.g. swelling following DTP vaccination.
- **Vaccine quality defect-related reaction** – An AEFI that is caused or precipitated by a vaccine that is due to one or more quality defects of the vaccine product inducing its administration device as provide by the manufacturer.

Ex. Failure by the manufacturer to completely inactivate a lot of inactivated polio vaccine leads to cases of paralytic polio.

- **Immunization error-related reaction** – An AEFI that is caused by inappropriate vaccine handling, prescribing or administration.

Ex. Transmission of infection by contaminated multidose vial.

- **Immunization anxiety-related reaction** – An AEFI from anxiety about the immunization.

e.g. Vasovagal syncope in an adolescent following vaccination.

- **Coincidental event**- An AEFI that is caused by something other than the vaccine product, immunization error or immunization anxiety.

e.g. A fever after vaccination (temporal association) and malarial parasite isolated from blood

Two type of vaccine reaction-

- Minor reaction
- Severe reaction

Minor reaction

- Usually occur within a few hours of injection.
- Resolve after short period of time and pose little danger.
- Local (includes pain, swelling or redness at the site of injection).
- Systemic (includes fever, malaise, muscle pain, headache or loss of appetite).



Severe reaction

- Usually do not result in long-term problems.
- Can be disabling.