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A REVIEW ON VACCINE SAFETY SURVEILLANCE IN PHARMACOVIGILANCE

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ABSTRACT
Vaccination is one of the most important achievements in public health. Vaccines help prevent diseases and reduce mortality worldwide. However, vaccine safety is a critical issue that ensures public confidence and effective immunization coverage. This review focuses on the principles of vaccine safety, why vaccine important to humans, the vaccine development process, and post-marketing surveillance systems. It also discusses various adverse events following immunization (AEFI), safety monitoring programs, and challenges in addressing misinformation. With advances in science and technology, vaccine safety evaluation has become more efficient, and also know how vaccine work in human body, ensuring that vaccines remain safe and effective for global.

KEYWORDS: However, vaccine safety is a critical issue that ensures public confidence and effective immunization coverage.

INTRODUCTION

Vaccination has been one of the most powerful and effective tools in modern medicine for preventing infectious diseases and reducing global morbidity and mortality. Since the discovery of the first vaccine by Edward Jenner in 1796 against smallpox, vaccines have revolutionized public health and saved millions of lives in critical stage. Through large-scale immunization programs, deadly diseases such as smallpox have been eradicated, and others like polio, diphtheria, and measles have been significantly controlled. Despite these remarkable achievements, the concept of vaccine safety has always remained a central concern. Vaccines are biological preparations that interact with the human immune system to stimulate protective immunity. Because they are administered to healthy individuals often infants, children, and pregnant women the safety standards for vaccines are extremely stringent. Even rare adverse reactions can raise significant public concern and potentially lead to vaccine hesitancy or refusal. Therefore, ensuring and maintaining vaccine safety is essential to preserve public confidence in immunization programs and to sustain their success. And now vaccination are most important part in our human life after birth.

Definition of Vaccine and Immunization

A vaccine is a biological substance designed to induce specific protection against a disease.

It typically contains one or more components of a pathogen, such as proteins, polysaccharides, or genetic material, that stimulate the immune system without causing the disease itself. The process of administering a vaccine to an individual to induce immunity is called immunization.

Vaccines can prevent disease by preparing the immune system to recognize and combat specific infectious agents. When a vaccinated person is later exposed to the real pathogen, their immune system can respond more quickly and effectively, preventing illness or reducing its severity.

Importance of Vaccines in Public Health

Vaccines have transformed global health by preventing millions of deaths every year. According to the World Health Organization (WHO), immunization currently prevents 4–5 million deaths annually from diseases like diphtheria, tetanus, influenza, and measles. The widespread use of vaccines has also led to a decline in healthcare costs and increased life expectancy. Beyond individual protection, vaccines contribute to herd immunity, a phenomenon in which a sufficient proportion of the population is immune to an infection,

thereby reducing the overall transmission of the disease and protecting unvaccinated individuals.

Need for Vaccine Safety

The development and use of vaccines are guided by the fundamental principle that **"the benefits must always outweigh the risks."** Although most vaccines are safe and well-tolerated, no medical intervention is completely risk-free. Some individuals may experience mild or transient side effects such as pain, swelling, or fever. In very rare cases, more serious adverse reactions may occur. Vaccine safety refers to the continuous process of ensuring that vaccines meet the highest standards of quality, safety, and efficacy through scientific evaluation, regulatory oversight, and post-marketing surveillance. Maintaining vaccine safety is not only a scientific requirement but also a social responsibility, as any breach of safety can result in loss of trust among the public.

CLASSIFICATION OF VACCINES

The classification helps in understanding how each vaccine works, its advantages, limitations, and safety considerations.

Broadly, vaccines are classified into the following categories.

Live Attenuated Vaccines

Definition: Live attenuated vaccines contain living microorganisms (bacteria or viruses) that have been weakened (attenuated) so that they cannot cause disease in healthy individuals but still trigger a strong immune **response.**

Mechanism: When administered, the attenuated organism replicates in the host body in a limited way, mimicking natural infection and stimulating both humoral (antibody-mediated) and cell-mediated immunity.

Example

BCG vaccine (for tuberculosis)
Measles, Mumps, Rubella (MMR) vaccine
Oral Polio Vaccine (OPV)
Varicella (chickenpox**) vaccine**

Advantages

Produces strong and long-lasting immunity.
Usually requires fewer doses or boosters.
Elicits both antibody and cellular immune responses.

Disadvantages

May cause mild infection in immunocompromised individuals.
Requires careful storage (cold chain maintenance).
Risk of reversion to a virulent form, though very rare

Inactivated (Killed) Vaccines
Definition

Inactivated vaccines contain microorganisms that have been killed by heat, radiation, or chemicals such as formalin. They cannot replicate but retain the ability to stimulate an immune response.

Mechanism

Since the pathogen is inactivated, the immune system recognizes its antigens and develops antibodies without risk of actual infection.

Examples

Inactivated Polio Vaccine
(IPV) Hepatitis A vaccine
Rabies vaccine
Influenza (inactivated) vaccine

Advantages

Safe for immunocompromised individuals and pregnant women.
Stable and easier to store compared to live vaccines.

Disadvantages / Safety Concerns

Usually require multiple doses and boosters.
Induce mainly humoral immunity; cell-mediated response is weaker.
May need adjuvants (e.g., aluminum salts) to enhance immunogenicity.

Toxoid Vaccines
Definition

Toxoid vaccines are made from inactivated toxic compounds produced by bacteria rather than the microorganism itself. These vaccines prevent diseases caused by bacterial toxins.

Mechanism

The inactivated toxin (toxoid) stimulates the immune system to produce antibodies that neutralize the toxin during future exposure.

Examples

Diphtheria toxoid vaccine
Tetanus toxoid **vaccine**

Advantages

Highly safe since no live organisms are used.
Induce effective antibody response.

Disadvantages / Safety Concerns

Require booster doses for long-term immunity.
Protect only against toxin-mediated diseases, not the infection itself.

mRNA Vaccines (Modern Vaccine Technology)
Definition

mRNA vaccines use a piece of messenger RNA (mRNA) that encodes a viral protein (antigen). Once inside the body's cells, the mRNA instructs cells to produce the antigen, which then triggers an immune response**.**

Examples
Pfizer-BioNTech COVID-19 vaccine
Moderna COVID-19 vaccine

Advantages
Rapid development and production.
Do not require live virus, hence safe.
Can be modified easily for emerging variants.

Disadvantages / Safety Concerns
Require very low-temperature storage (−70°C).
May cause short-term side effects such as fever or fatigue.
Limited long-term data since technology is new.

Vaccine Development and Pre-Licensure Safety Assessment
Before a vaccine is approved for public use, it undergoes a long, careful, and scientifically rigorous development process. The main goal is to ensure the vaccine is safe, effective, and of high quality. Pre-licensure (before approval) safety assessment is one of the most important phases of vaccine development.

Stages of Vaccine Development
Exploratory
Scientists identify antigens (proteins or parts of pathogens) that can trigger an immune response.
Lasts 2–4 years.

Pre-clinical Studies

Performed in cell cultures and animal models.
Helps determine.
1. Immune response
2. Safe doses
3. Potential toxicity

Only vaccines with promising results move to human trials.

Clinical Trials (Human Testing)
Before a vaccine is licensed, it passes through three phases of clinical trials, each designed to assess safety and effectiveness.

☐**Phase I (Safety & Dosage)**
Small group: 20–100 healthy volunteers.
Purpose
Check basic safety
Identify side effects
Find safe dose range

RESULT: Determines if vaccine is safe enough for Phase II.

☐ **Phase II (Safety & Immune Response)**
Larger group: several hundred volunteers.
Purpose
Confirm safety
Study optimal dose, schedule
Identify common short-term side effects
Measure immune response

Helps finalize dosage for Phase III.

☐ **Phase III (Large-Scale Safety & Efficacy)**
Thousands to tens of thousands of volunteers.

Purpose
Detect rare side effect
Measure real-world protection levels
Compare vaccinated group with placebo group

Provides the strongest evidence for approval.

Pre-Licensure Safety Assessment
This is the process of evaluating all safety data collected before a vaccine is approved.

Key Components
Toxicity Studies
Dose Ranging & Adjuvant Safety
Monitoring Adverse Events
Quality Control Tests
Regulatory Review

Manufacturing Standards (GMP)
Vaccines must be produced under Good Manufacturing Practices (GMP):
Controlled environment
Strict hygiene
Standardized procedures
Prevention of contamination
This ensures every batch is safe and consistent**.**

Final Approval (Licensure)
If all safety, quality, and efficacy requirements are met, the regulatory authority grants licensure (approval) for public use. Even after approval, vaccines continue to be monitored through post-marketing surveillance (Phase IV studies).

Common and Serious AEFIs – Examples & Case Summaries.

Introduction to AEFIs
An AEFI (Adverse Event Following Immunization) is any medical occurrence after vaccination, which may or may not be related to the vaccine.

AEFIs can be classified into
Vaccine product–related reaction
Vaccine quality defect–related reactions
Immunization error–related reactions (programmatic errors)
Immunization anxiety–related reactions
Coincidental events
Common AEFIs
T reactions are usually mild, self-limiting, and resolve without treatment.

Common AEFI Examples

Type	Examples	Description
Local reactions	Pain, swelling, redness at injection site	Lasts 1–3 days
Systemic reactions	Fever, malaise, irritability, body ache	Due to immune response
Mild allergic reactions	Itching, mild rash, urticaria	Non-serious
Injection anxiety–related	Fainting, dizziness, hyperventilation	Seen in adolescents
Gastrointestinal	Nausea, vomiting (especially oral vaccines)	Self-limiting

Case Summaries – Common AEFIs

Case 1: Local Reaction After DPT Vaccine

Patient: 2-year-old

Event: Pain and swelling at injection site 12 hours after DPT

Assessment: Expected vaccine reaction

Outcome: Resolved within 48 hours with cold compress

Classification: Vaccine product–related reaction (common, non-serious)

Case 2: Fever After Measles Vaccine

Patient: 10-month-old

Event: Fever (102°F) 6 days after vaccination

Assessment: Normal post-measles vaccine reaction due to immune response

Outcome: Recovered with paracetamol

Classification: Vaccine product–related systemic reaction

Case 3: Fainting After HPV Vaccine

Patient: 15-year-old girl

Event: Brief loss of consciousness immediately after injection

Assessment: Vasovagal syncope due to anxiety

Outcome: Full recovery in minutes

Classification: Immunization anxiety–related reaction

Serious AEFIs

These events are **rare**, require medical attention, or can be life-threatening.

Serious AEFI Examples

Serious AEFI	Description
	Severe allergic reaction (within minutes to hours)
Seizures	Febrile or afebrile seizures post-vaccination
Encephalopathy	Extremely rare neurological complication
Bacterial abscess	Due to non-sterile injection technique
Toxic shock syndrome (TSS)	Life-threatening, due to programmatic error
Acute Flaccid Paralysis (AFP)	Rarely associated with OPV (vaccine-associated paralytic polio)
Thrombosis with thrombocytopenia (rare)	Observed with some COVID-19 vaccines

Case Summaries – Serious AEFIs

Case 4: Anaphylaxis After Hepatitis B Vaccine

Patient: 1-month-old infant

Event: Difficulty breathing, wheezing, generalized rash within 20 minutes

Management: Immediate epinephrine + emergency care

Outcome: Recovered within 24 hours

Classification: Vaccine product–related serious allergic reaction Comments: Extremely rare but medically emergency; reported to national AEFI surveillance.

Case 5: Seizure After MMR Vaccine

Patient: 14-month-old

Event: Fever (103°F) followed by a febrile seizure 9 days post-MMR

Assessment: Known rare adverse event; linked to fever spike

Outcome: Full recovery, no neurological deficit

Classification: Vaccine product–related serious AEFI

Case 6: Injection Site Abscess (Programmatic Error)

Patient: 3-year-old

Event: Painful swelling with pus 5 days after DPT injection

Assessment: Likely improper aseptic technique

Outcome: Required antibiotic + incision & drainage

Classification: Immunization error–related serious AEFI

Lesson: Highlights importance of proper injection technique.

Case 7: Toxic Shock Syndrome After Immunization Error

Patient: 2-month-old infant

Event: High fever, vomiting, shock within 12 hours

Cause: Contaminated multi-dose vial (reused improperly)

Outcome: Emergency ICU management needed

Classification: Programmatic error–related serious AEFI

Pharmacovigilance for Special Populations in Vaccine Safety

Special populations are groups who may respond differently to vaccines due to age, immunity, pregnancy status, or underlying medical conditions.

Pharmacovigilance for these groups is essential to detect.

Unusual AEFIs
Altered immune responses
Risk–benefit differences
Need for dose adjustment or specific precautions

These populations are usually under-represented in clinical trials, so post-licensure surveillance becomes very important.

Special Populations Requiring Enhanced Vaccine Safety Monitoring

Infants and Young Children

Why special?

Immature immune system
Multiple vaccines given in early life
Higher risk of fever, febrile seizures
Caregivers may misinterpret normal vaccine reactions

Key Pharmacovigilance Points

Monitor for local reactions, fever, irritability
Track febrile seizures after MMR, DPT
Ensure correct dose and injection technique
Detect programmatic errors (cold chain, reconstitution mistakes)

Pregnant Women

Why special?

Vaccines affect both mother and fetus
Safety must be established for fetal outcomes

Key Pharmacovigilance Points

Monitor for maternal events: fever, allergic reactions
Follow fetal outcomes: congenital anomalies, preterm birth
Vaccines commonly monitored: Tdap, Influenza, COVID-19
Use pregnancy registries to collect long-term safety data

Elderly Population (≥ 60 years)

Why special?

Weakened immune system (immunosenescence)
Higher comorbidities (diabetes, hypertension, COPD)
Polypharmacy → higher risk of drug–vaccine interactions

Key Pharmacovigilance Points

Monitor for exaggerated systemic reactions
Track syncope, fall risk post-vaccination
Collect data on reduced effectiveness (waning immunity)
COVID-19 & Influenza vaccines need close monitoring

Immunocompromised Individuals

Includes:
HIV/AIDS
Cancer patients on chemotherapy
Post-transplant patients
Chronic steroid use

Why special?

Live vaccines (MMR, Varicella, OPV) may be contraindicated
Reduced immunity → weaker vaccine response
Higher risk of severe AEFIs

Key Pharmacovigilance Points

Avoid live vaccines when contraindicated
Monitor for opportunistic infections
Evaluate antibody response (immunogenicity studies)
Close follow-up after vaccination

Patients with Chronic Diseases

Includes diabetes, hypertension, kidney disease, heart disease, asthma.

Why special?

Higher vulnerability to infections
Comorbidities may mimic vaccine reactions

Key Pharmacovigilance Points

Monitor for systemic reactions (fever → dehydration in kidney patients)
Observe for disease worsening (e.g., asthma flare-up)
Track interactions with chronic medications

Adolescent Population

Why special?

Common anxiety-related reactions (syncope, dizziness)
School-based vaccination programs → cluster AEFIs

Key Pharmacovigilance Points

Monitor for vasovagal episodes
Educate adolescents on relaxation techniques
HPV vaccine safety monitoring is especially important

CONCLUSION

Vaccine safety is a critical component of public health and an essential pillar of national immunization programs. Ensuring that vaccines remain safe, effective, and trustworthy requires a comprehensive and well-structured system that includes surveillance, reporting, causality assessment, regulatory oversight, risk communication, and community engagement. Continuous monitoring through both passive and active surveillance helps detect potential adverse events early, while epidemiologic investigations and standardized WHO causality assessment methods ensure scientific evaluation of AEFIs. A strong vaccine safety system also depends on trained healthcare workers, transparent communication, timely regulatory action, and effective management of misinformation. Special populations—

such as infants, pregnant women, elderly individuals, and immunocompromised patients—require additional attention due to their unique vulnerabilities. By strengthening infrastructure, improving cold chain management, supporting research, and enhancing coordination between national and international agencies, countries can build a robust and responsive vaccine safety framework. Overall, maintaining vaccine safety is an ongoing process. It not only protects individuals and communities from preventable diseases but also sustains public confidence in vaccination. A reliable and transparent safety system ensures that the benefits of vaccines continue to far outweigh the risks, supporting healthier populations and effective disease control worldwide.

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