JETIR.ORG ISSN: 2349-5162 | ESTD Year : 2014 | Monthly Issue
JOURNAL OF EMERGING TECHNOLOGIES AND INNOVATIVE RESEARCH (JETIR)
An International Scholarly Open Access, Peer-reviewed, Refereed Journal

VACCINE SAFETY SURVEILLANCE IN PHARMACOVIGILANCE - A REVIEW

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Abstract: Vaccines play a critical role in mitigating the impact of infectious disease outbreaks, including COVID-19 and monkeypox, representing a landmark achievement in global scientific collaboration and rapid development. For both diseases, vaccines have undergone accelerated regulatory review processes by national regulatory authorities to facilitate timely approval and deployment. Equitable distribution of these vaccines remains a global priority, ensuring access across diverse populations. Simultaneously, robust safety surveillance systems must be urgently established within countries to comprehensively monitor vaccine safety. Such systems are essential for identifying and investigating adverse events of special interest (AESIs) and adverse events following immunization (AEFIs), enabling the assessment of any potential changes in the benefit-risk profiles of the vaccines for both COVID-19 and monkeypox. Additionally, these systems should anticipate and differentiate coincidental events that may be mistakenly linked to vaccination. Effective safety monitoring is vital to maintain public trust, inform regulatory decisions, and ensure the sustained success of global vaccination efforts against both pandemics and emerging threats such as monkeypox.

IndexTerms - Adverse Events of Special Interest, Adverse Events Following Immunization, COVID-19, Monkeypox

I. INTRODUCTION

At present, there are no established population-based systems in the United States designed to rapidly detect adverse events associated with newly introduced vaccines. To explore the feasibility of developing such systems, a study was conducted using five years of data from four health maintenance organizations (HMOs) participating in the Centers for Disease Control and Prevention (CDC) Vaccine Safety Datalink (VSD) project. This effort aims to improve vaccine safety monitoring and establish mechanisms for timely detection of potential vaccine-related risks [1,2].

The monitoring of vaccine safety, known as vaccine pharmacovigilance, is defined by the Council for International Organizations of Medical Sciences (CIOMS) and the World Health Organization (WHO) as the scientific and operational activities involved in detecting, assessing, understanding, and communicating adverse events following immunization (AEFIs). This also includes addressing issues related to immunization safety and taking steps to prevent adverse effects caused by vaccines or immunization programs [1,2].

Vaccine pharmacovigilance often involves passive surveillance systems that rely on unsolicited reports of adverse events submitted to a centralized database or health authority. In the United States, such reports are collected and entered into the Vaccine Adverse Event Reporting System (VAERS), which is co-managed by the Food and Drug Administration (FDA) and the CDC. VAERS serves as a critical component of the nation's vaccine safety infrastructure, helping to identify potential safety concerns and guide further investigation and regulatory action [1,2].

Efforts to strengthen vaccine safety surveillance systems, such as the CDC's Vaccine Safety Datalink and VAERS, are essential to building public trust in immunization programs and ensuring that vaccines continue to provide significant public health benefits while minimizing risks [1,2].

Safety surveillance encompasses the scientific and operational activities involved in detecting, assessing, understanding, and preventing adverse effects or any other issues associated with drugs, including vaccines. It serves as a fundamental component of public health strategies to ensure the safe and effective use of vaccines and other pharmaceutical products [1,2].

The importance of maintaining robust vaccine safety measures cannot be overstated. With the successful reduction of disease risks due to widespread immunization efforts, public focus has shifted toward concerns about the safety of vaccines themselves. Confidence in the safety of vaccines is critical to maintaining high vaccination rates and preventing disease outbreaks. Society's tolerance for risks associated with vaccines is relatively low, as vaccines are administered to generally healthy individuals to prevent diseases rather than treat them. Consequently, the public and regulatory authorities demand a higher standard of safety for vaccines compared to other medical interventions. This has led to the necessity of monitoring for even rare adverse reactions to ensure vaccine safety and sustain public trust [1,2].

Vaccine pharmacovigilance is defined as the science and activities related to the detection, assessment, understanding, prevention, and communication of adverse events following immunization (AEFIs) or any other vaccine- or immunization-related issues. This specialized field is essential for identifying and managing potential safety concerns associated with vaccines, enabling the prompt resolution of issues to maintain public confidence in immunization programs [1,2].

II. STEPS IN VACCINE PHARMACOVIGILANCE

The process of vaccine pharmacovigilance involves a series of systematic steps:

1. Signal Detection: Identifying signals that suggest an adverse event following immunization (AEFI) may be related to a specific vaccine. This involves analyzing data from surveillance systems and reports.

2. Hypothesis Development: Formulating hypotheses about potential causal associations between an identified AEFI and the vaccine in question, based on the observed patterns and available evidence.

3. Hypothesis Testing: Testing these hypotheses using appropriate epidemiological methods, such as case-control studies or cohort studies, to establish or rule out a causal relationship [3].

III. PHARMACOVIGILANCE

Pharmacovigilance refers to an active and systematic process designed to proactively identify, assess, and address potential risks associated with adverse events related to drugs and vaccines. It plays a crucial role in ensuring public safety and has become an essential component of the regulatory framework for monitoring the safety of pharmaceuticals and immunizations.

This comprehensive approach involves the timely detection and investigation of adverse events, ensuring that any reported incidents are thoroughly followed up and addressed in an appropriate manner. By continuously evaluating safety data, pharmacovigilance supports the identification of previously unknown risks, confirms the benefit-risk balance of products, and contributes to the ongoing improvement of safety measures. As a cornerstone of public health, pharmacovigilance not only helps protect individuals but also fosters public trust in medical interventions by demonstrating a commitment to safety and transparency [3].

Vaccine provide by government of India Government of India is providing vaccination to prevent vaccine preventable disease (VPDs) namely,

a. DIPHTHERIA
b. PERTUSSIS
c. TETANUS
d. POLIO
e. MEASLES
f. HEPATITIS B
g. BCG
h. JE VACCINATION
i. HIB (given as penta valent containing Hib+DPT+HEP)

Other Vaccines

i) Pneumococcal vaccine
ii) Rotavirus vaccine
iii) Hepatitis A
iv) MMR
v) Influenza
vi) Meningococcal
vii) Cholera

viii) HPV
ix) Varicella
x) Typhoid

IV. SOURCE OF 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

V. ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFIs):

1. AEFI

Defination: An adverse event following immunization (AEFI) is defined as any unintended or unfavorable medical occurrence that follows vaccination. Importantly, the occurrence of an AEFI does not necessarily imply a causal relationship with the vaccine.

2. Reporting and Classification

AEFIs That Should Be Reported Certain types of adverse events following immunization (AEFIs) must be reported to ensure proper monitoring and safety assessment.
These include:

3. Serious AEFIs: Any severe adverse event that may result in hospitalization, significant disability, or death.

4. Signals and Events Linked to Newly Introduced Vaccines: Adverse events associated with vaccines recently introduced into immunization programs.

5. AEFIs Potentially Caused by Immunization Errors: Adverse events that may have resulted from errors during vaccine preparation, handling, or administration.

6. Unexplained Significant Events: Events of unknown origin that occur within 30 days after vaccination and may be of concern.

7. Community or Parental Concern: Events causing anxiety or concern among parents or the community, irrespective of their severity.

8. Injection Site Reactions: Swelling, redness, or soreness at the injection site that persists for more than three days or extends beyond the nearest joint.

VI. CLASSIFICATION OF AEFI's

AEFIs can present as abnormal laboratory findings, symptoms, diseases, or other unintended signs. They are classified into the following categories:

1. Vaccine Product-Related Reaction

This type of AEFI is directly caused by a vaccine due to defects in the vaccine product or its administration device as provided by the manufacturer.

Example: Failure by a manufacturer to fully inactivate a batch of inactivated polio vaccine, leading to cases of paralytic polio.

2. Immunization Error-Related Reaction

These AEFIs occur as a result of errors in the immunization process, including vaccine preparation, handling, or administration. They are not caused by the vaccine itself but by improper practices.

Example: A vasovagal syncope (fainting) episode in an adolescent due to anxiety related to vaccination.

3. Coincidental Event

Coincidental events are those that are not caused by the vaccine, immunization error, or immunization-related anxiety. They occur due to other unrelated factors that happen to coincide with the timing of vaccination.

Example: A fever occurring after vaccination due to a temporal association, later identified as being caused by a malarial infection detected in the bloodstream [4].

VII. TYPES OF VACCINE REACTIONS

Vaccine reactions can be broadly categorized into two types: minor reactions and severe reactions. These reactions are a part of the body's response to vaccination and vary in severity and duration.

1. Minor Reactions

Minor reactions are relatively mild and commonly occur within a few hours after the administration of a vaccine. These reactions are typically short-lived, resolving on their own without medical intervention, and pose minimal risk to the individual.

2. Local Reactions: These occur at the injection site and may include symptoms such as pain, swelling, or redness. These localized effects are generally mild and temporary.

3. Systemic Reactions: These involve broader symptoms affecting the whole body, such as mild fever, general discomfort (malaise), muscle aches, headaches, or a temporary loss of appetite. These systemic symptoms are also transient and usually resolve within a few days.

Minor reactions are considered a normal and expected part of the immunization process as they indicate the immune system's response to the vaccine. Proper communication about these common side effects helps manage expectations and build public confidence in vaccination programs.

Severe reactions to vaccines, while rare, can occasionally occur. These reactions typically do not lead to long-term health issues but can cause temporary discomfort or disability. In very rare cases, they may pose a serious risk to life. Examples of such severe reactions include seizures or allergic responses triggered by the body's sensitivity to specific components of a vaccine [4].

VIII. VACCINE EVALUATION PROCESS

1. Pre-Licensing Phase:

This phase involves conducting randomized, blinded, and controlled clinical trials to rigorously evaluate the vaccine's safety and efficacy before it is approved for use. These trials are designed to provide unbiased and high-quality data regarding the vaccine's performance under controlled experimental conditions.

2. Vaccine Efficacy:

Efficacy refers to the vaccine's ability to provide protection under ideal and highly controlled conditions, such as those in clinical trials. Randomized controlled trials (RCTs) serve as the foundation for assessing vaccine efficacy due to their straightforward design and clear interpretation of results.

3. Post-Licensing Phase:

After a vaccine is licensed and introduced to the public, observational studies are carried out to monitor its real-world performance. These studies help identify any issues or patterns that may not have been evident during the controlled clinical trial phase.

4. Vaccine Effectiveness:

Effectiveness measures how well the vaccine works under typical conditions within public health programs. Unlike efficacy, which is assessed in ideal settings, effectiveness reflects real-world conditions where external factors and biases can influence the outcomes. Interpreting vaccine effectiveness data is often more complex due to these variables [4].

IX. PRECAUTIONS AND SAFETY SURVEILLANCE IN VACCINATION

A precaution refers to a condition in a vaccine recipient that may increase the likelihood or severity of an adverse reaction or reduce the vaccine's ability to generate a protective immune response. Ensuring the safety of vaccines through vigilant monitoring systems is critical, particularly in the context of emerging diseases like COVID-19 and monkeypox. Monitoring vaccine safety helps maintain public health and fosters trust in immunization programs.

Vaccines are widely regarded as one of the greatest public health achievements in modern medicine. Before being approved for public use, they undergo extensive trials to meet stringent efficacy and safety benchmarks. However, safety monitoring does not end with approval; post-marketing surveillance plays an essential role in identifying rare or severe adverse events, especially given the large-scale exposure during mass immunization campaigns [4,5].

X. TOOLS FOR VACCINE SAFETY MONITORING

One of the key systems for monitoring vaccine safety is the Vaccine Adverse Event Reporting System (VAERS), jointly operated by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). This system relies on voluntary reports of potential vaccine-related adverse events. While VAERS provides valuable data, it has limitations, such as underreporting and challenges in establishing direct causal links between reported events and the vaccine. For instance, VAERS sensitivity for detecting anaphylaxis ranges from 13% to 76%, while for Guillain-Barré Syndrome, it ranges from 12% to 64%. Additionally, VAERS lacks a control group, making it difficult to assess whether observed adverse events exceed baseline population risks.

To address these gaps, systems like the Vaccine Safety Datalink (VSD) have been established to collect detailed data from large and diverse populations. This allows for more robust analysis and the identification of clinically significant adverse events [4,5].

1. COVID-19 Vaccine Safety

In the United States, over 342 million doses of COVID-19 vaccines have been administered, primarily mRNA vaccines from Pfizer-BioNTech and Moderna. Research has shown these vaccines to be generally safe. However, a slight increased risk of myocarditis and pericarditis was identified in individuals aged 12 to 39 years. Cases of anaphylaxis following mRNA vaccination were found to be extremely rare. Ongoing monitoring through programs like the VSD ensures continued evaluation of adverse events, particularly after booster doses.

2. Monkeypox Vaccine Safety

As monkeypox cases emerged globally, vaccination efforts were rapidly deployed to control the outbreak. The primary vaccines used against monkeypox are the JYNNEOS vaccine (a modified vaccinia Ankara vaccine) and the ACAM2000 vaccine. The JYNNEOS vaccine, approved for preventing monkeypox and smallpox, has been shown to have a favorable safety profile, particularly for individuals with weakened immune systems or skin conditions such as eczema.

However, the ACAM2000 vaccine, derived from live vaccinia virus, carries a higher risk of adverse events, including myocarditis, pericarditis, and severe localized reactions at the injection site. Due to these risks, its use is limited to individuals with no contraindications. Monitoring systems such as VAERS and VSD have been instrumental in tracking and evaluating the safety of these vaccines during the monkeypox outbreak. [5].

3. Importance of Collaborative Safety Monitoring

Collaborative safety efforts, including the use of systems like VAERS and VSD, are vital for evaluating vaccine safety in diverse populations. Such efforts provide transparent data to inform public health strategies, build trust, and combat vaccine hesitancy. This is particularly crucial during global health emergencies like COVID-19 and monkeypox, where rapid vaccination campaigns expose millions to new vaccines.

By continually assessing vaccine safety and addressing potential risks, these programs contribute to public confidence in immunization efforts, ensuring the success of large-scale vaccination campaigns. This approach not only protects individuals but also supports broader efforts to control and prevent infectious diseases on a global scale [6].

XII. PLANNING FOR COVID-19 AND MONKEYPOX VACCINE SAFETY SURVEILLANCE

The development and deployment of vaccines are essential tools in combating pandemics such as COVID-19 and monkeypox. Effective vaccine safety surveillance systems are vital to ensure public trust, detect adverse events, and maintain a favorable benefit-risk profile. For COVID-19, global collaboration and accelerated development timelines have led to the creation of highly effective vaccines. Similarly, monkeypox vaccines have played a critical role in addressing the recent outbreaks. This document explores the planning and processes involved in vaccine safety surveillance for both diseases [5,6].

1. COVID-19 Vaccine Safety and Development

A. Unprecedented Vaccine Development

COVID-19 vaccine development has occurred at an extraordinary pace due to global collaborations, such as the Coalition for Epidemic Preparedness Innovations (CEPI), which facilitates partnerships among private, public, and philanthropic organizations. Established in 2017, CEPI aims to expedite vaccine production during epidemics, reducing the time from antigen identification to clinical trial readiness to just 16 weeks.

CEPI supports several rapid-response vaccine platforms, which involve adapting established systems with new protein or genetic sequences to target specific pathogens. This approach led to nine COVID-19 vaccine programs, incorporating technologies such as DNA vaccines, molecular-clamp vaccines, recombinant protein nanoparticle vaccines, and mRNA vaccines. By June 2020, 21 vaccine candidates were in clinical trials, with an estimated 182 candidates in preclinical development.

Most COVID-19 vaccines target the SARS-CoV-2 spike (S) protein, a crucial component that enables the virus to bind to and enter human cells. The S1 subunit contains the receptor-binding domain (RBD), which interacts with the ACE2 receptor on human cells. Vaccine designs have focused on inducing immune responses against this protein to prevent infection [6].

B. Types of COVID-19 Vaccines

1. Pfizer-BioNTech:

Ages recommended: 5+ years
Primary series: Two doses, 21 days apart
Booster dose: Available for ages 16+ six months after the second dose
Fully vaccinated: Two weeks after the second dose

2. Moderna:

Ages recommended: 18+ years
Primary series: Two doses, 28 days apart
Booster dose: Available for ages 18+ six months after the second dose
Fully vaccinated: Two weeks after the second dose

3. Johnson & Johnson (Janssen):

Ages recommended: 18+ years
Primary series: Single dose
Booster dose: Available two months after the first dose
Fully vaccinated: Two weeks after the dose

The U.S. Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) closely monitor these vaccines for safety and effectiveness. Individuals with severe allergic reactions to a particular vaccine may be eligible for alternative vaccines.

i. Safety Monitoring for COVID-19 Vaccines

COVID-19 vaccines underwent rigorous clinical trials to evaluate their safety and efficacy before approval or emergency use authorization (EUA). Post-approval, the FDA and CDC continue to monitor these vaccines through various systems:

Vaccine Adverse Event Reporting System (VAERS): Tracks self-reported adverse events.

Vaccine Safety Datalink (VSD): Collects detailed data from large populations to assess real-world vaccine performance.

Clinical Trials: Assess effectiveness in subpopulations and monitor protection against severe outcomes and new variants.

C. Monkeypox Vaccine Safety and Development

Monkeypox, a zoonotic disease caused by the monkeypox virus, emerged as a significant public health concern. Vaccines like JYNNEOS and ACAM2000 have been instrumental in controlling outbreaks.

Monkeypox Vaccine Options

1. JYNNEOS:

Uses modified vaccinia Ankara (MVA) technology.

Safer for immunocompromised individuals and those with skin conditions.

Approved for preventing both monkeypox and smallpox.

2. ACAM2000:

A live, replicating vaccinia virus-based vaccine.

Effective but associated with higher risks of adverse events such as myocarditis and localized reactions.

Reserved for individuals without contraindications.

D. Safety Surveillance for Monkeypox Vaccines

Given the smaller target population compared to COVID-19 vaccines, safety surveillance systems for monkeypox vaccines leverage lessons from the COVID-19 pandemic. Programs like VAERS and VSD track adverse events, ensuring robust data collection and analysis.

Pharmacovigilance and Ongoing Monitoring

Pharmacovigilance involves systematic efforts to monitor vaccine safety and address adverse drug reactions (ADRs) [6].

XIII. OBJECTIVES:

- Establishing functional reporting systems.
- Assessing the safety profiles of new vaccines during early post-marketing phases.
- Estimating the incidence of known ADRs in specific populations.
- Utilizing electronic health records to support safety assessments.

XIV. Conclusion

The accelerated development of COVID-19 vaccines and the strategic deployment of monkeypox vaccines showcase the global capability to combat pandemics effectively. Ensuring safety through rigorous monitoring systems like VAERS, VSD, and clinical trials is critical to maintaining public trust and achieving vaccination goals. Collaborative efforts in vaccine surveillance not only protect individuals but also strengthen public health systems to respond to future pandemics [4,5,6].

XV. METHODS OF PHARMACOVIGILANCE AND SAFETY SURVEILLANCE

Pharmacovigilance involves various methods to monitor and assess drug and vaccine safety. These approaches include both passive and active surveillance systems, along with observational and descriptive studies. Below is a concise elaboration of these methods:

A. Passive Surveillance

1. Spontaneous Reports: Healthcare providers and patients voluntarily report adverse events. While cost-effective, it may suffer from underreporting and lack of causality determination.

2. Case Series: Aggregates multiple case reports to identify patterns and generate hypotheses regarding safety issues

B. Stimulating Reporting

Efforts to increase voluntary reporting by raising awareness among healthcare providers and the public.

C. Active Surveillance

1. Sentinel Sites: Pre-selected healthcare institutions collect systematic data on adverse events.

2. Drug Event Monitoring: Actively follows patients using specific drugs to identify and evaluate adverse effects.

3. Registries: Specialized databases track patients exposed to certain drugs or vaccines, particularly during long-term treatments or new interventions.

D. Targeted Clinical Investigations

Studies designed to investigate specific safety concerns identified during clinical trials or post-marketing surveillance.

E. Comparative Observational Studies

1. Cross-Sectional Studies: Examine data at a single point in time to identify prevalence and associations.

2. Case-Control Studies: Compare individuals with adverse events (cases) to those without (controls) to identify risk factors.

3. Cohort Studies: Follow a group of individuals over time to assess the relationship between exposure to a drug/vaccine and the occurrence of adverse events.

F. Descriptive Studies

1. Natural History of Disease: Investigates the progression of a condition without intervention to understand baseline risks.

2. Drug Utilization Studies: Assess patterns of drug use to ensure rational prescription practices and identify potential safety concerns [7,8].

XVII. PHARMACOVIGILANCE TECHNIQUES FOR MONITORING ADVERSE DRUG REACTIONS (ADRS)

Pharmacovigilance employs various methods to detect, assess, and understand adverse drug reactions. The following are detailed descriptions of key methodologies:

1. Spontaneous Reporting

Spontaneous reporting involves healthcare professionals or consumers notifying pharmaceutical companies or regulatory authorities about adverse drug reactions (ADRs) experienced by patients after consuming a medication. This system plays a pivotal role in identifying safety signals once a drug is introduced into the market. It alerts stakeholders to rare adverse events (AEs) that might not have been identified during clinical trials or pre-marketing evaluations. By bringing previously undetected risks to light, spontaneous reporting facilitates timely action to ensure public safety.

2. Case Series

A case series compiles multiple case reports to examine potential relationships between drug use and adverse events. These compilations are particularly valuable for generating hypotheses about possible associations between a drug and specific outcomes. However, they are typically insufficient for confirming causal links. Case series are most effective for investigating rare but severe ADRs, such as anaphylaxis, aplastic anemia, or Stevens-Johnson syndrome. Such adverse events often necessitate detailed follow-up for a more comprehensive understanding of the risks.

3. Stimulated Reporting

Stimulated reporting aims to encourage and simplify the process of reporting adverse events, especially for newly launched products or for limited-time studies. This can be achieved through digital platforms for adverse event reporting or systematic outreach to healthcare professionals. Despite its utility, stimulated reporting has certain limitations, including incomplete data submission. Additionally, it is often ineffective for determining precise incidence rates of adverse events.

4. Active Surveillance

Active surveillance involves systematically and proactively identifying adverse events through a pre-established monitoring process. Unlike passive systems, active surveillance ensures a complete and continuous assessment of the number and nature of adverse events. It is particularly useful for gathering detailed and comprehensive data on individual ADRs associated with a specific drug. For instance, patients undergoing treatment with a specific medication can be closely monitored to capture detailed information about their experiences.

5. Sentinel Sites

Active surveillance often takes place at designated sentinel sites, such as hospitals, nursing homes, and specialized medical institutions. These sites focus on specific patient subgroups or contexts, such as tracking drug misuse or identifying ADRs in vulnerable populations. Data from sentinel sites provide invaluable insights for pharmacovigilance activities.

6. Drug Event Monitoring

Drug event monitoring is a proactive method that utilizes electronic prescription data or health insurance claims to identify patients exposed to specific medications. Follow-up questionnaires are distributed to physicians or patients at regular intervals to collect relevant information. These questionnaires may include details about patient demographics, reasons for prescribing the drug, treatment duration, dosage levels, clinical outcomes, and reasons for discontinuing therapy. This structured approach ensures a thorough understanding of the drug's safety profile in real-world settings [4,6,7,12].

XVIII. PRINCIPLES OF EFFECTIVE PHARMACOVIGILANCE COMMUNICATION

Effective communication is a cornerstone of successful pharmacovigilance practices. To ensure the safety and confidence of the public, healthcare professionals and authorities should adhere to the following principles when conveying pharmacovigilance messages.

1. Understand the Audience's Perspective

Tailor messages to align with the audience's existing knowledge, beliefs, and concerns. Effective communication begins with empathy and understanding of the audience's viewpoint.

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2. Avoid Trivializing Comparisons

Avoid making comparisons that could downplay the seriousness of a concern. The intent should be to address the issue constructively rather than diminish its importance.

3. Provide Comprehensive Information

Ensure that the communication is thorough and includes all necessary details. Transparency builds trust and helps the audience make informed decisions.

4. Maintain Balance, Honesty, and Empathy

Messages should strike a balance between addressing concerns and providing reassurance. Being truthful and empathetic fosters credibility and relatability.

5. Focus on the Core Issue

Center the communication on the specific concern that needs to be addressed without diverting to unrelated topics. Clear and concise messaging avoids confusion.

6. Acknowledge the Audience's Knowledge

Recognize and incorporate what the audience already understands about the topic. This helps in building upon existing knowledge and avoids redundancy.

7. Respect the Audience's Concerns

Validate people's right to be concerned about their health and well-being. Respectful communication fosters trust and cooperation.

8. Admit Scientific Limitations

Be transparent about the boundaries of current scientific knowledge. Acknowledging what is not yet known demonstrates honesty and builds credibility.

9. Address Uncertainty Openly

Where uncertainties exist, acknowledge them clearly. Providing context around unknowns helps manage expectations and reduces misconceptions.

10. Evaluate the Impact of Communication

Assess how the message is received and whether it achieves its intended purpose. Continuous improvement ensures that communication remains effective and relevant. [9,10,12].

XIX. CONCLUSION

The introduction of new and underutilized vaccines, such as those for Haemophilus influenzae type b (Hib), rotavirus, pneumococcal disease, meningococcal infections, and human papillomavirus (HPV), presents a significant opportunity to enhance public health. These vaccines have the potential to prevent numerous cases of illness and death, delivering considerable health benefits to people of all ages.

Vaccination against COVID-19, for instance, reduces the risk of contracting and transmitting the virus. Moreover, COVID-19 vaccines help prevent severe illness, hospitalization, and death. Rigorous testing and evaluation ensure that vaccines are both safe and effective for individuals aged five years and older.

Advanced real-time surveillance systems play a critical role in ensuring vaccine safety post-implementation. By integrating dynamic data files, aggregating relevant information, and employing sequential analysis methods, these systems enable the early detection of adverse events following the rollout of new vaccines. Such proactive monitoring contributes to maintaining public trust and maximizing the health benefits of immunization programs.

REFERENCES

1. Department of pharmacy, Indira Gandhi National Tribal University, Amarkanta (MP), India
2. Arlett, P. Safety monitoring of COVID-19 Vaccines, European medicines agency, 2021; 1-10.
3. FDA, Covid-19 Vaccine Safety Surveillance. Safety & Availability (Biologics), 2021; Accessed on July 12, 2021.
4. Joshi, J., Das, M. K., Polpakara, D., Aneja, S., Agarwal, M., & Arora, N. K. Vaccine Safety and Surveillance for Adverse Events Following Immunization (AEFI) in India. Indian journal of pediatrics, 2018; 85(2): 139–148.
5. Salman O, Topf K, Chandler R, Conklin L. Progress in Immunization Safety Monitoring — Worldwide, 2010–2019. MMWR Morb Mortal Wkly Rep, 2021; 70: 547–551. Retrieved from
6. Https://www.cdc.gov/vaccinesafety/ensuringsafety/monito ring/index.html TGA. Covid-19 Vaccine Safety monitoring plan. Australian Government, 2021; 1: 1-13.
7. Vaccine Centre, London School of Hygiene & Tropical Medicine, Retrieved from https://vaclshtm.shinyapps.io/ncov_vaccine_landscape.
8. https://spj.sciencemag.org>hds
9. http://www.who.int>sage>EURO
10. http://www.fda.gov>covid-19-vac.
11. https://www.cdc.gov>2019-nCoV
12. CEPI creating a world in which epidemics are no longer a threat to humanity. Accessed on mar 19, 2020, at https://cepi.net/about/why we exist.