IAPSM's *Textbook of* Vaccinology

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Vaccination and Disease Control

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INTRODUCTION

From at least the 15th century, people in different parts of the world attempt to prevent illness by intentionally exposing healthy people. In the year 1796, Dr Edward Jenner created the world's first successful vaccine. The term Vaccine was coined which derives from the Latin word 'Vacca' for cow. Following this, the era of vaccination begins and researchers started targeting different disease which can be prevented by vaccines.

Vaccine-preventable diseases (VPDs) are significant public health issue in India. In India, the Universal Immunization Program (UIP) provides free immunization against around 12 vaccine-preventable diseases, including 11 nationally and 3 sub-nationally, aiming to reduce childhood mortality and morbidity.

Any adverse medical event after vaccination should be reported as an AEFI, regardless of whether it is directly caused by the vaccine.

This chapter outlines the current scenario of different VPDs and vaccine coverage, comprehensive strategies employed in India to eliminate VPDs, supported by evidence and best practices along with a brief on adverse medical event after vaccination.

CURRENT SCENARIO OF VACCINE-PREVENTABLE DISEASES AND VACCINE COVERAGE

Tuberculosis

Tuberculosis (TB), caused by bacteria *Mycobacterium tuberculosis*, is a major health issue in developing countries and is closely linked to poverty, making its control a matter of justice and human rights. TB control strategies are struggling, particularly where TB and human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS) intersect, and drug-resistant strains are worsening the crisis. The Bacillus Calmette–Guérin (BCG) vaccine protects against severe forms of TB in children but does not prevent primary infection or reactivation of latent infection. In 2023, around 87% of children had received the BCG vaccine in their first year of life.[1]

Diphtheria

The number of cases and deaths due to diphtheria has reduced significantly due to vaccination, but it remains a major health concern for children in countries with low routine immunization coverage. In diphtheria-endemic regions, cases usually appear sporadically. The disease is fatal in 5–10% of cases, especially among young children.[3]

As the diphtheria vaccine is a bacterial toxoid, it is an inactivated toxin from the bacteria but still capable of triggering immunity. It is usually administered in combination with other vaccines, such as tetanus, pertussis, Hib, and Hep-B. For adults and adolescents, a lower-concentration combination of diphtheria and tetanus toxoids (Td vaccine) is often used.

The **Figures 1 and 2** shows the prevalence of diphtheria globally and in India corresponding to the coverage of the diphtheria, tetanus, and pertussis (DPT) vaccine first dose and third dose. It has been observed that in the last 4 years, the number of diphtheria cases has increased globally.

Measles

Measles is a highly contagious viral disease which leads to high fever and rash and can result in complications such as encephalitis, blindness, or death. In the year 2023, around 83% of children had received at least one dose of a measles vaccine by 2 years of age, and around 74% had received at least two doses of the vaccine. Additionally, 190 member states had included two doses of the measles-containing vaccine in their national immunization schedules.

Measles anywhere is a threat everywhere. Measles poses a global threat, no matter where it occurs. Due to its highly contagious nature, measles can quickly spread

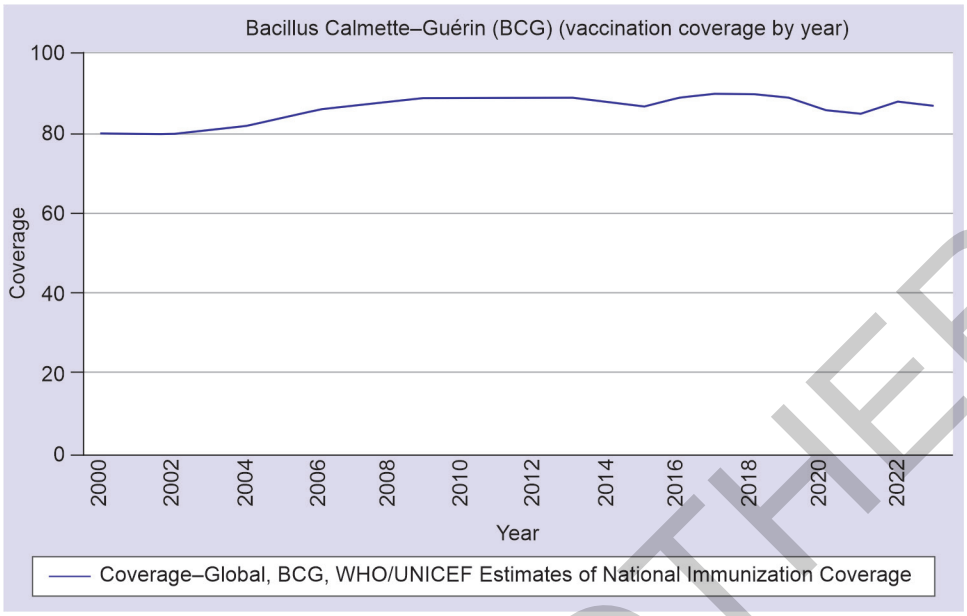

FIG. 1: Global coverage of BCG vaccine.[2]

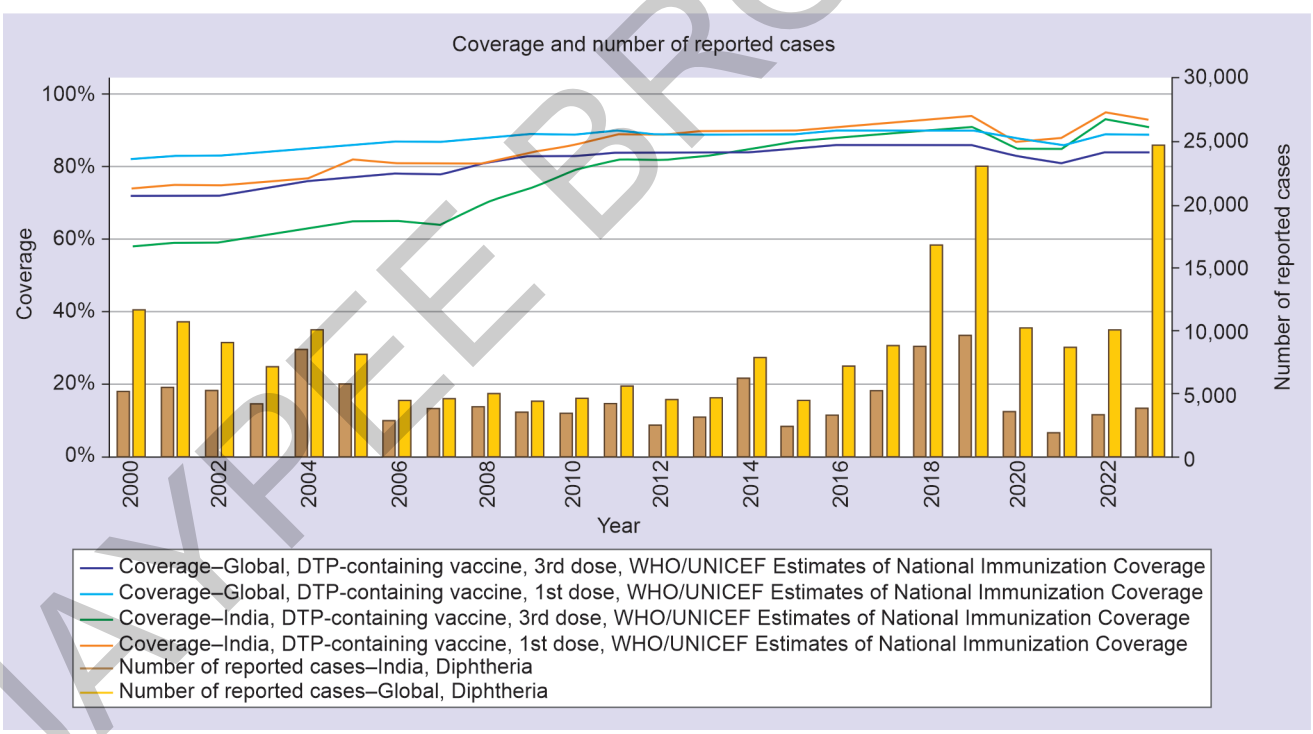

FIG. 2: Number of reported cases of diphtheria globally and in India with coverage of the diphtheria, tetanus, and pertussis (DPT) vaccine first dose and third dose.[2]

across borders. The graph illustrates the global and Indian prevalence of measles in relation to the coverage rates of both doses of the measles vaccine. It is been observed that global cases of measles have decreased as the coverage of vaccines increases. Unvaccinated individuals are at risk of contracting measles while traveling abroad and can easily transmit the virus to others upon their return.

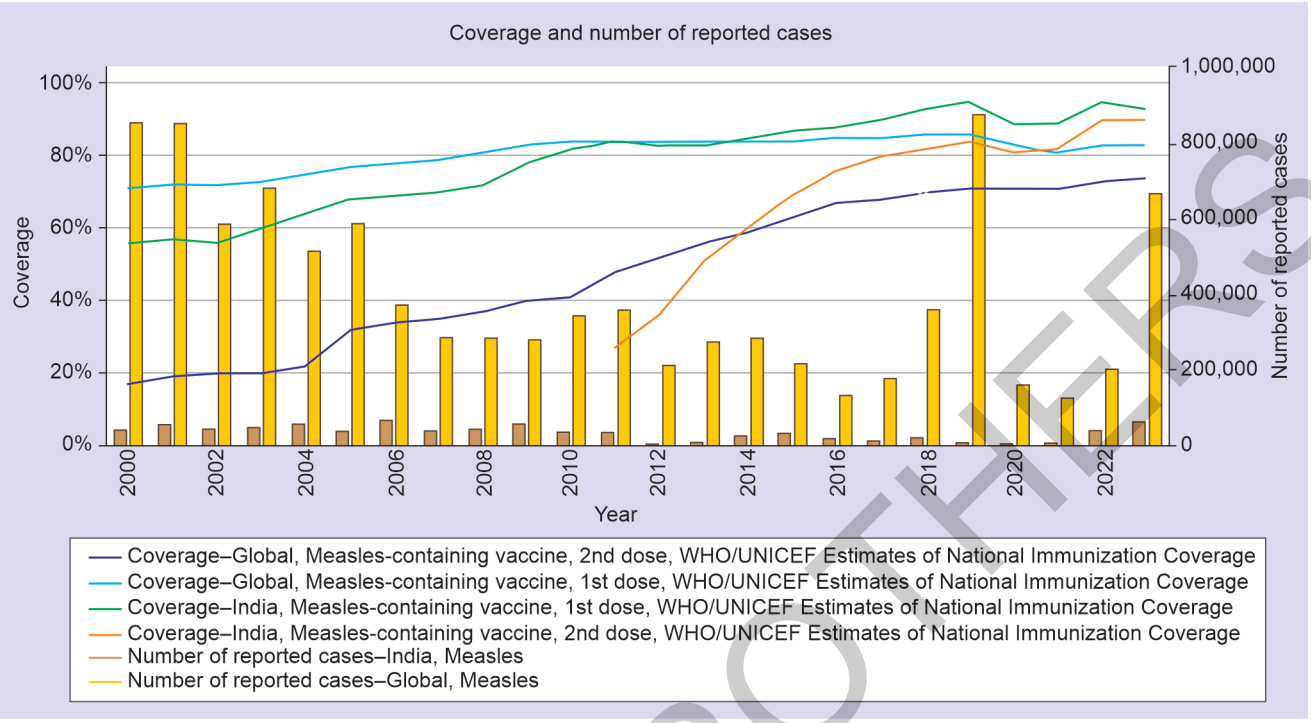

FIG. 3: Number of reported cases of measles globally and in India with coverage of the measles vaccine first dose and second dose.[2]

Figure 3 depicts that; between 2000 and 2022, vaccination efforts have averted an estimated 57 million deaths. In 2022 alone, the disease claimed over 1,36,000 lives.

Rubella

Rubella is a viral disease, mild in children, but infection in early pregnancy can lead to congenital rubella syndrome, causing defects in eyes, ears, heart, and brain. In the year 2023, the rubella vaccine has been introduced in 175 member states, with coverage estimated at 71%.

Congenital rubella syndrome is used as an indirect indicator of the disease burden of rubella in the community. India has introduced the rubella antigen in the national immunization schedule in the form of two doses of measles-rubella (MR) vaccine after a successful MR campaign in 2016–2017. The trend of congenital rubella syndrome increased in the last 5 years **(Fig. 4)**.

Haemophilus Influenza Type B

Haemophilus influenza type B (Hib) is causing meningitis and pneumonia in children. In the year 2023, the Hib vaccine is covered in 193 member states, with global coverage for three doses estimated at 77% **(Fig. 5)**. However, coverage varies significantly by region, the European Region achieving an estimated 94%, while the Western Pacific Region lags at just 33%.[4]

Hepatitis B

It is a viral infection that mainly affects the liver. In the year 2023, 190 member states had introduced the hepatitis B vaccine, achieving an estimated global coverage of 83% for three doses **(Fig. 6)**. This coverage peaks at 79% in Western Pacific Region, while the African Region has a much lower rate of just 17%.[4]

Polio

Polio, or poliomyelitis, is a highly infectious viral disease that is caused by the poliovirus. Most infections are asymptomatic or mild, with symptoms such as fever, fatigue, headache, and sore throat. In severe cases, it can cause permanent paralysis, typically in the legs. If the respiratory muscles are affected, it can be life-threatening. Globally, an estimated 83% of infants received three doses of the polio vaccine in the year 2023. Of the three strains of wild poliovirus, type 2 was eradicated in 1999, and type 3 was eradicated in 2020 **(Fig. 7)**. Despite significant progress, polio remains endemic in Afghanistan and Pakistan.[5] All countries having weak public health and immunization systems remain at risk of polio importation from these countries. Polio has been eliminated from most countries, including India and China, by maintaining a high level of coverage of the polio vaccine.

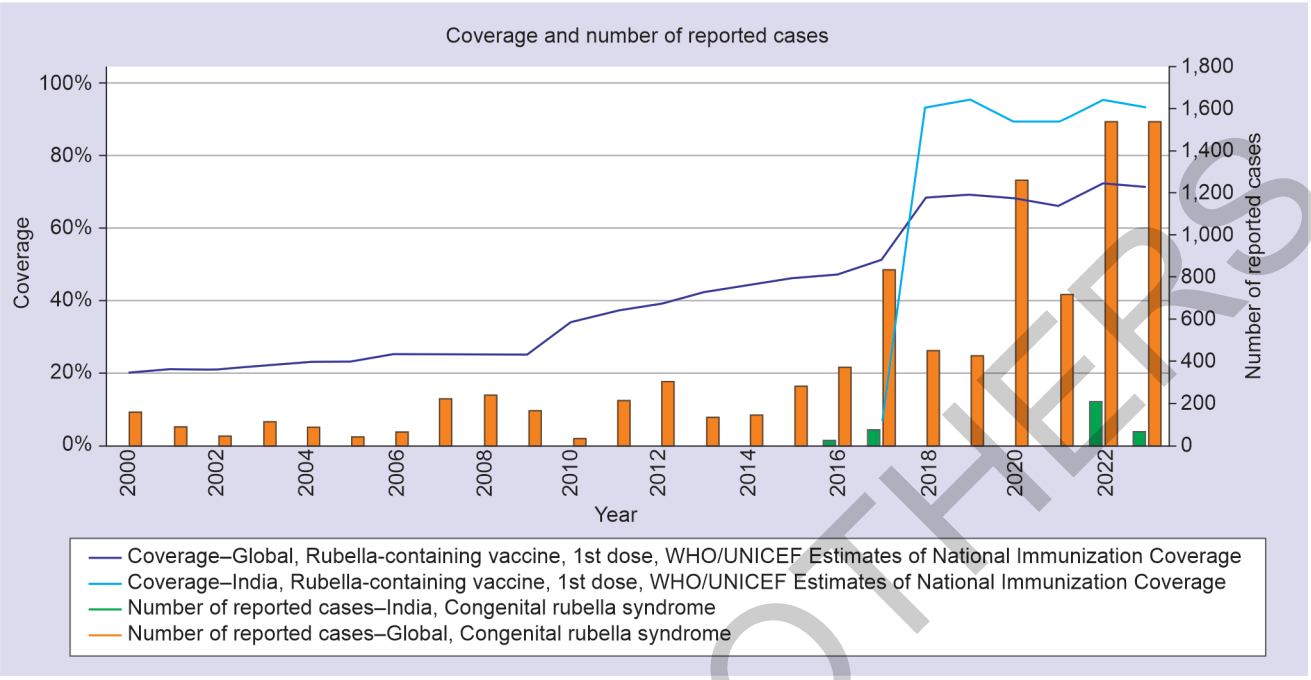

FIG. 4: Number of reported cases of congenital rubella syndrome globally and in India with coverage of the measles vaccine first dose and second dose.[2]

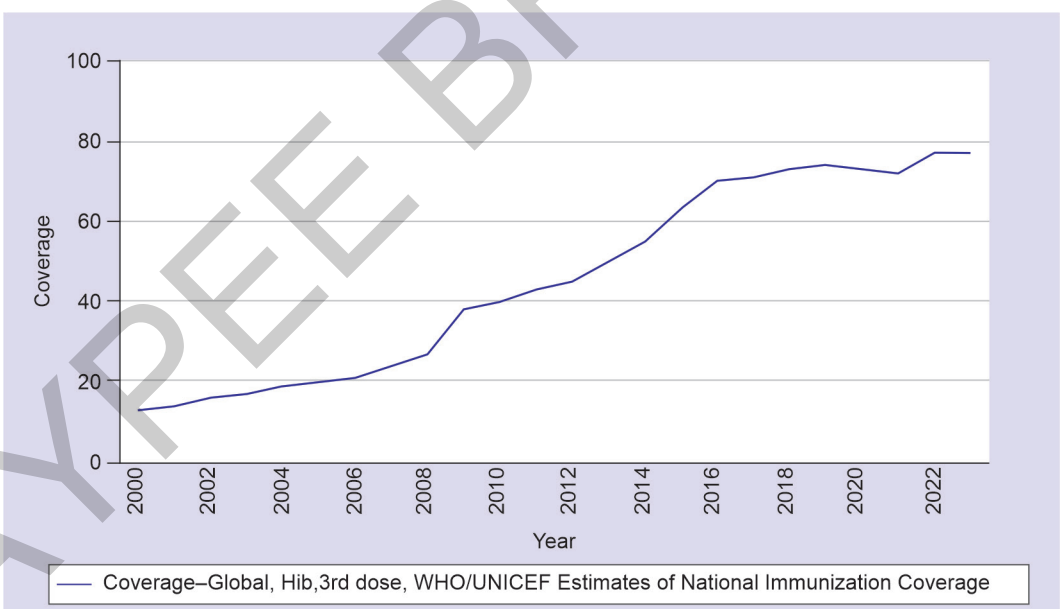

FIG. 5: Global coverage of *Haemophilus influenza* type B (Hib) vaccine third dose.[2]

Rotavirus

It is the leading cause of severe diarrheal disease in young children. **Figure 8** shows that; in the year 2023, the rotavirus vaccine is included in 123 countries, with global coverage of around at 55%.[6]

Tetanus

Tetanus is caused by *Clostridium tetani*, a bacterium that thrives in low-oxygen environments. The spores of this bacterium are ubiquitous and found in the environment regardless of location. Once in the body, *C. tetani* produces

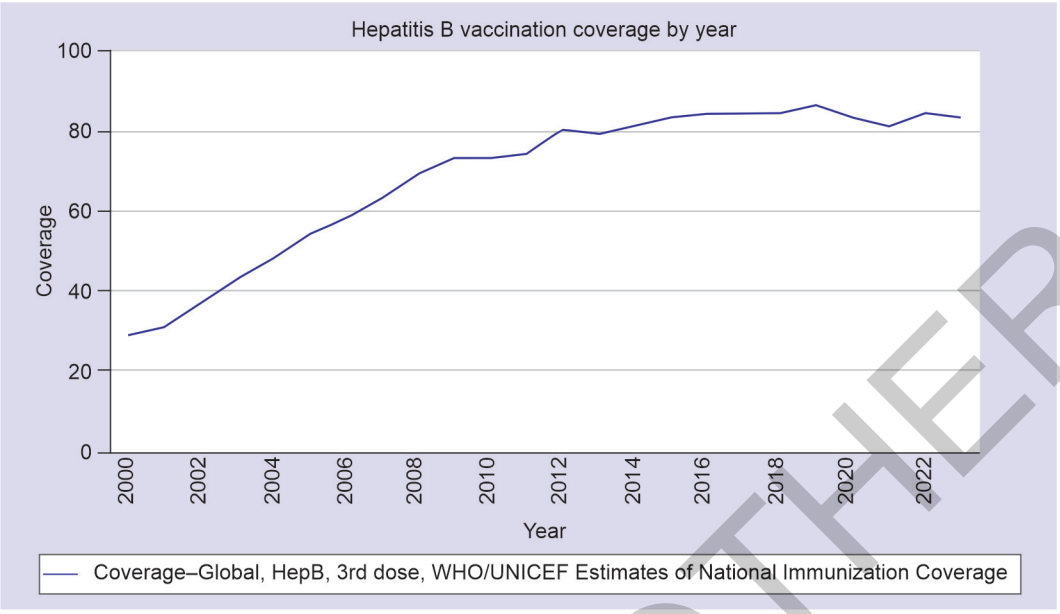

FIG. 6: Global coverage of hepatitis B (Hep B) vaccine third dose.[2]

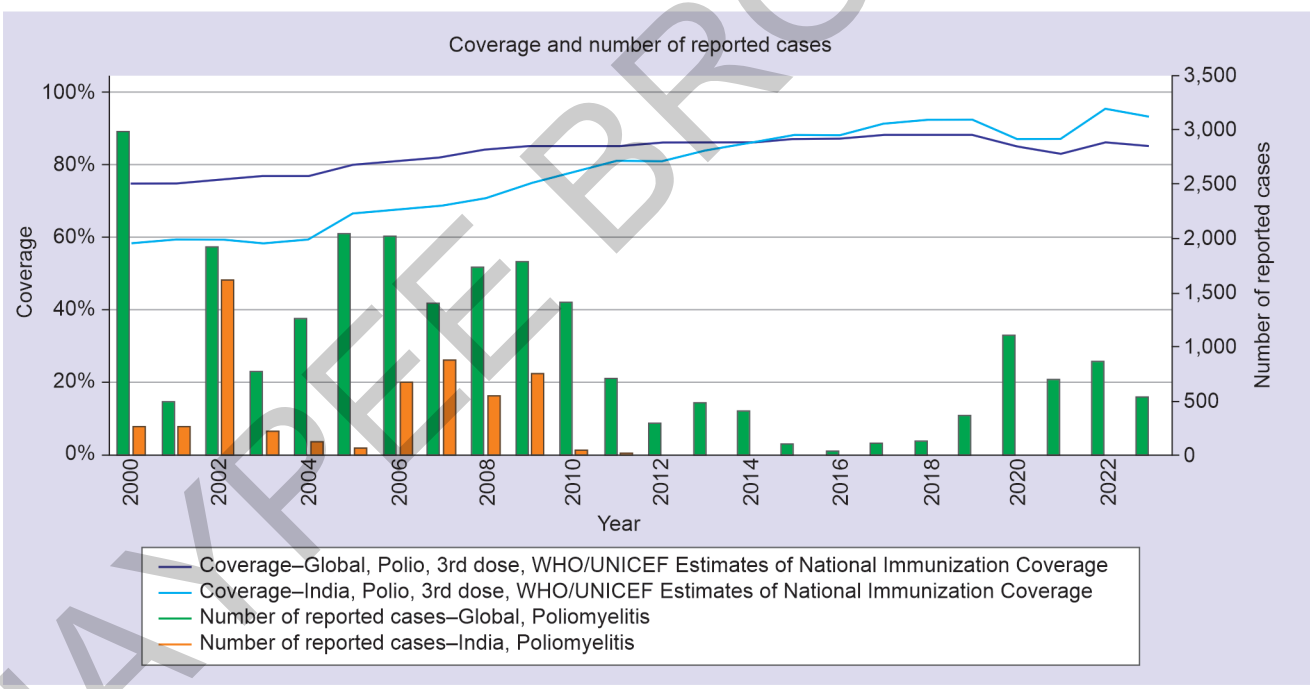

FIG. 7: Number of reported cases of polio globally and in India with coverage of the polio vaccine third dose.[2]

a toxin that can lead to severe disease or death. Neonatal tetanus remains a significant public health problem in around 10 countries, primarily in Africa and Asia.

Figure 9 shows the trend of the number of cases of neonatal tetanus and total tetanus globally and in India and coverage of tetanus vaccination. Globally, cases of tetanus have decreased with few peaks in between. In India, the number of neonatal tetanus and total tetanus both decreased drastically in the recent past.

Pneumococcal

Pneumococcal diseases encompass a range of illnesses, including pneumonia, febrile disease, meningitis, otitis media, and bronchitis. In the year 2023, pneumococcal

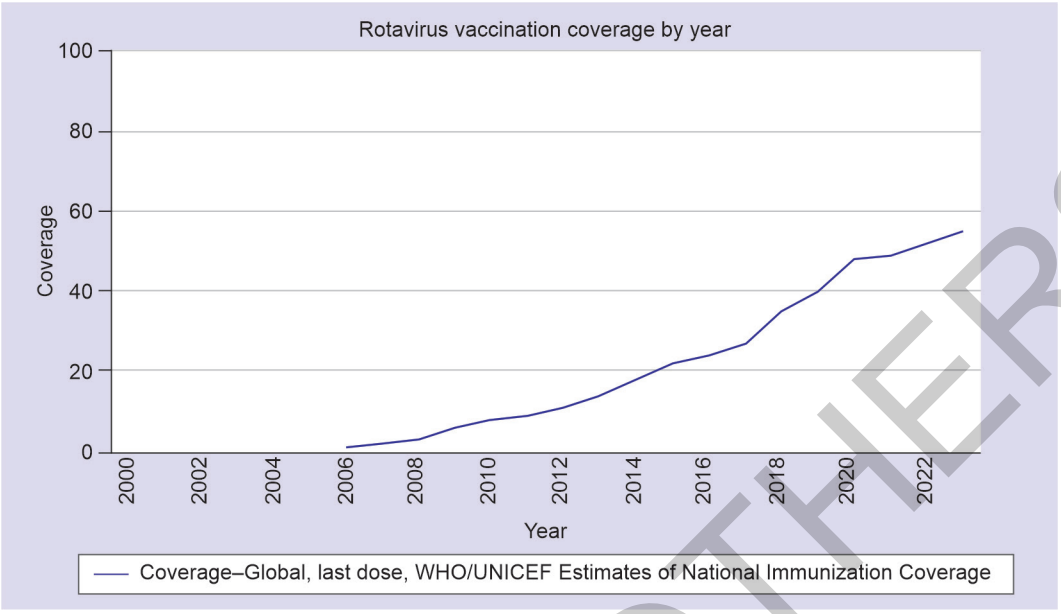

FIG. 8: Global coverage of rotavirus vaccine third dose.[2]

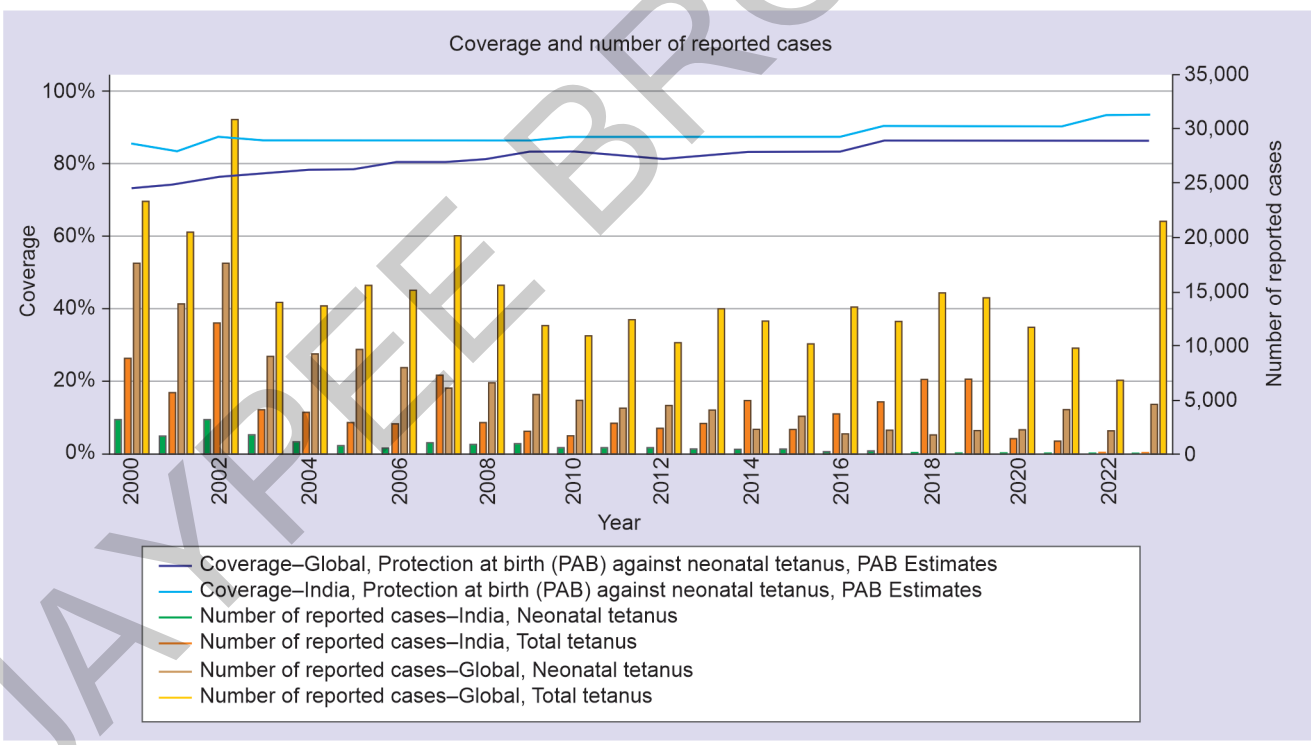

FIG. 9: Number of reported cases of tetanus globally and in India with coverage of the tetanus vaccine.[2]

vaccines are being used in 159 member states, with global coverage for the third dose estimated at 65% **(Fig. 10)**. However, coverage varies widely by region, with the WHO European Region achieving an estimated 86% coverage compared to just 26% in the Western Pacific Region.[6]

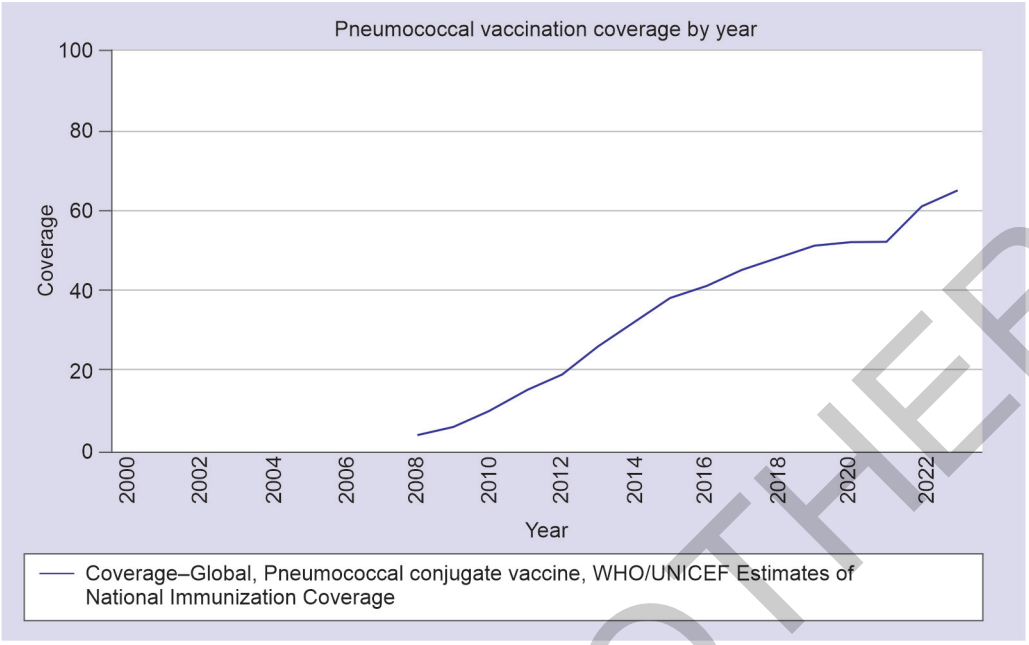

FIG. 10: Global coverage of pneumococcal conjugate vaccine.[2]

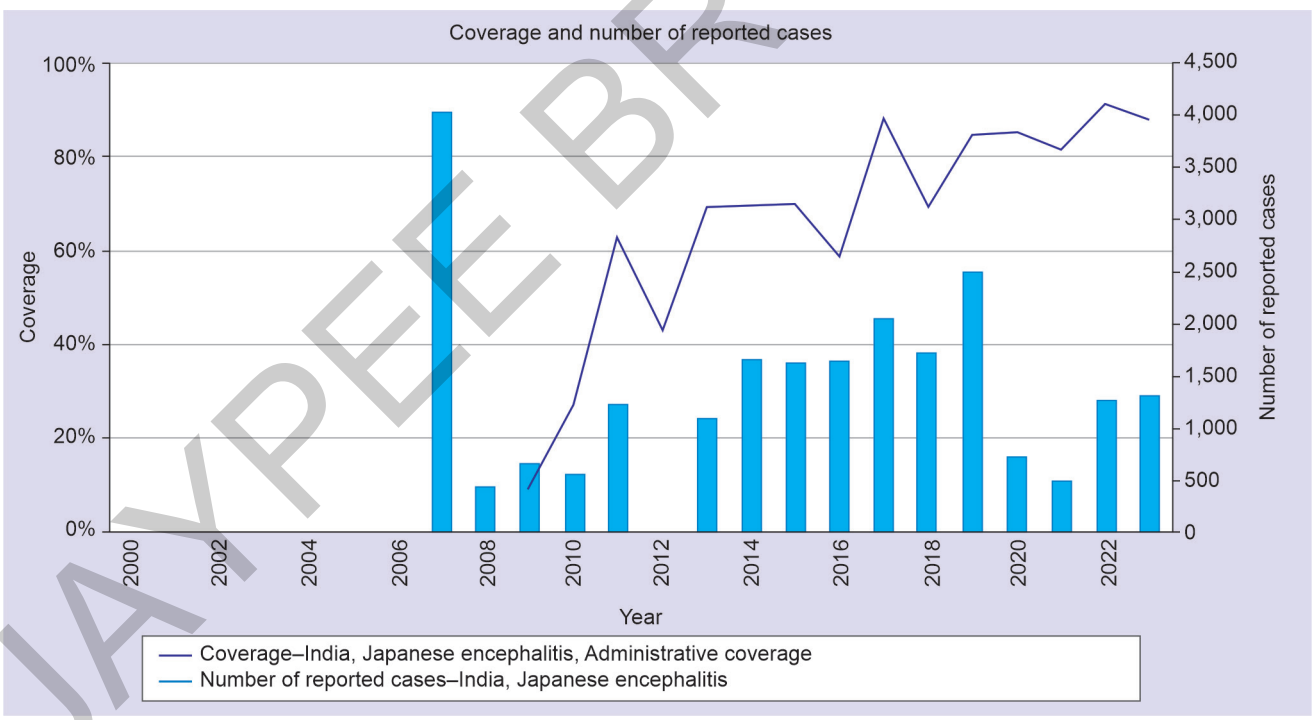

FIG. 11: Number of reported cases of Japanese encephalitis in India with coverage of the Japanese encephalitis vaccine.[2]

Japanese Encephalitis

It is a viral zoonotic disease transmitted by vectors and one of the leading causes of viral encephalitis. It affects nearly all countries across Asia, regardless of climate, and has spread into new regions via the movement of infected vectors. Presently, around 3 billion people in the South-East Asia and Western Pacific Regions are at risk of Japanese encephalitis (JE) **(Fig. 11)**.

ELIMINATION STRATEGIES FOR VACCINE-PREVENTABLE DISEASES IN INDIA

Reduction in prevalence of different vaccine preventable diseases (VPDs) are mainly due to the efforts of the team of health workers in India. Different strategies adopted for the elimination of these VPDs which includes, strengthening routine immunization, intensified immunization campaigns, disease surveillance and monitoring, efforts for public awareness and community engagement, well drafted National Immunization Policy and others.

Strengthening Routine Immunization

Universal Immunization Program

The Universal Immunization Program (UIP) is one of the largest health interventions. It is designed to provide life-saving vaccines to millions of children and pregnant women annually, significantly reducing the burden of VPDs. The program targets an estimated 26 million infants and 30 million pregnant women every year. Under UIP, vaccines are provided free of cost to protect against 12 VPDs.[6]

Cold Chain Management

Effective cold chain management is essential to ensure vaccines remain potent and effective from manufacture to administration. In India, the cold chain infrastructure has been significantly enhanced through various initiatives. One such initiative is Electronic Vaccine Intelligence Network (eVIN). It provides the availability of different vaccines and storage temperatures in real time, ensuring the quality of vaccines. This system helps in preventing vaccine wastage and ensures timely replenishment of stocks, thereby maintaining the integrity of vaccines.[7]

Microplanning

Microplanning is a critical component of the UIP, aiming to ensure comprehensive immunization coverage. It involves creating detailed operational plans to reach every child and pregnant woman with immunization services. This process includes mapping households, identifying high-risk areas, and organizing outreach sessions in hard-to-reach regions. Tools such as the Health Management Information System (HMIS) play a vital role in tracking immunization coverage. These systems help in identifying gaps in coverage and facilitate targeted interventions to improve immunization rates. By leveraging these technologies, health authorities can ensure that immunization services are effectively delivered to the most vulnerable populations.[8]

Community Engagement and Awareness

Community engagement and awareness campaigns are integral to the success of the UIP. Educating communities about the importance of vaccines and addressing vaccine hesitancy are crucial steps in ensuring high immunization rates. Various strategies, including mass media campaigns, community meetings, and involvement of local leaders, are employed to raise awareness and encourage participation.

Monitoring and Evaluation

Proper monitoring and evaluation are necessary to assess the quality and effectiveness of the UIP and identify the scope of improvement. Regular data collection, analysis, and feedback mechanisms help in understanding the program's impact and making evidence-based decisions. This iterative process ensures that the UIP remains responsive to emerging challenges and evolves to meet the healthcare needs of the population.

Intensified Immunization Campaigns

Supplementary Immunization Activities

These are critical public health interventions designed to increase the coverage of immunization programs, particularly targeting children who have missed routine vaccination sessions. These activities are crucial for enhancing community immunity, especially during outbreaks of VPDs. Supplementary immunization activities (SIAs) are implemented to address gaps in routine immunization and ensure that all children, including those who missed vaccinations due to various reasons, receive necessary immunizations.

In India, SIAs have been employed with significant success to control diseases such as measles and rubella. The introduction of the MR vaccination campaign, a notable example of SIAs, has been pivotal in reducing the incidence of these diseases nationwide. The WHO highlights the effectiveness of such campaigns in rapidly increasing vaccination coverage and achieving high levels of community immunity, which is essential for controlling and eventually the elimination and the eradication of these diseases.[9]

National Immunization Days

These are large-scale, mass immunization campaigns that aim to eliminate specific diseases by administering vaccines to a large segment of the population within a defined period. These campaigns are particularly effective for diseases where high vaccination coverage

is needed to interrupt transmission. In India, national immunization days (NIDs) have been a cornerstone of the polio eradication efforts. Multiple rounds of NIDs have been conducted as part of the comprehensive strategy to eliminate poliomyelitis, which culminated in India achieving polio-free status in 2014. The success of these campaigns underscores their role in achieving significant public health milestones, such as the eradication of polio.[10]

Disease Surveillance and Monitoring

Surveillance Systems

Robust disease surveillance systems are fundamental for the early detection of disease outbreaks and the effective management of VPDs. The Integrated Disease Surveillance Programme (IDSP) in India represents a decentralized, state-based approach that plays a vital role in monitoring and reporting on epidemic-prone diseases. This program allows for timely identification and response to disease outbreaks, which is essential for controlling the spread of VPDs. The IDSP's structure enables it to provide real-time data and support rapid response efforts, thereby enhancing the overall effectiveness of disease control measures.[11]

Vaccine-preventable Disease Surveillance

Continuous surveillance of diseases is crucial for assessing the impact of immunization programs and identifying areas with insufficient coverage or ongoing outbreaks. Surveillance networks, such as the Measles-Rubella Surveillance Network, are essential for collecting data on VPDs. This data is invaluable for informing targeted interventions and improving vaccination strategies. By monitoring trends and outbreaks, these networks help public health officials to focus efforts where they are most needed, thus enhancing the overall effectiveness of vaccination programs.[12]

Real-time Data Monitoring

The integration of digital tools and platforms, such as eVIN, has significantly advanced the management of immunization programs. eVIN enables real-time monitoring of vaccine stocks, storage temperatures, and immunization coverage, which is important for maintaining the quality and effectiveness of vaccination efforts. By providing timely and accurate data, eVIN supports informed decision-making and efficient resource allocation, thereby enhancing the overall management of immunization programs and ensuring that vaccines are distributed and stored properly.[13]

Public Awareness and Community Engagement

Health Education Campaigns

Public awareness campaigns are essential for educating communities about the importance of vaccination and countering vaccine-related myths and misconceptions. Initiatives such as Mission Indradhanush and its intensified version, Intensified Mission Indradhanush, have been instrumental in raising public awareness and demand for vaccines. These campaigns aim to reach out to underserved populations and ensure that all eligible children receive their vaccinations. The success of these campaigns highlights the necessity of comprehensive health education efforts in increasing immunization coverage and fostering community support for vaccination programs.

Community Mobilization

Engaging community leaders, religious figures, and other influential individuals is a critical strategy for promoting vaccine acceptance and overcoming vaccine hesitancy. Community mobilization efforts in states such as Uttar Pradesh and Bihar have demonstrated significant improvements in immunization coverage. By involving local leaders and influencers, these efforts help to build trust and address concerns about vaccines, leading to higher vaccination rates and better public health outcomes.

Behavioral Change Communication

They are employed to address vaccine hesitancy and misinformation through a variety of communication channels. Behavioral change communication (BCC) involves using mass media, social media, and interpersonal communication to disseminate accurate and compelling information about vaccines. These strategies aim to correct misconceptions, provide clear information about the benefits of vaccination, and encourage positive vaccination behaviors. Effective BCC is crucial for ensuring that the public receives reliable information and feels confident in the safety of vaccines.

Policy and Governance

National Immunization Policy

Formulating and continuously updating national immunization policies, grounded in robust evidence and recommendations from the WHO, are imperative for the successful implementation of vaccination programs. In India, the National Technical Advisory Group on

Immunization (NTAGI) plays an instrumental role in this process. NTAGI provides expert guidance on vaccine schedules, new vaccine introductions, and policy adjustments based on epidemiological data and global health trends.[14] Regular updates ensure that vaccination policies remain aligned with emerging health threats and advancements in vaccine technology.

Multisectoral Collaboration

Effective immunization efforts benefit greatly from multisectoral collaboration. Engaging various sectors such as education, transportation, and local governance can enhance vaccination coverage and program effectiveness. For instance, the School Health Program exemplifies how integrating immunization services with school health initiatives can improve vaccine uptake among school-aged children. By leveraging existing school infrastructure and networks, this approach ensures that children receive all vaccines in a proper manner.[15] Such collaborations also facilitate the development of community-based strategies that address local barriers to vaccination.

Regulatory Framework

A robust regulatory framework is important for ensuring the safety, efficacy, and quality of vaccines. In India, the Central Drugs Standard Control Organization (CDSCO) is responsible for the regulation and approval of vaccines. The CDSCO's mandate includes evaluating vaccine safety and efficacy through rigorous clinical trials, monitoring postmarketing surveillance, and ensuring compliance with quality standards. Strengthening these regulatory processes is essential for maintaining public trust and safeguarding health. Enhanced regulatory mechanisms also support the timely introduction of new vaccines.

Research and Innovation

Vaccine Development

Investment in research is critical for advancing vaccine technology and addressing emerging infectious diseases. The Indian Council of Medical Research (ICMR) are at the forefront of vaccine research in India, contributing to the development of newer vaccines. This research is crucial for responding to evolving public health threats and improving immunization coverage.[16] Collaborative efforts between research institutions and pharmaceutical companies can accelerate the development of innovative vaccines and expand their accessibility.

Operational Research

Operational research plays a key role in optimizing immunization programs by identifying best practices and innovative strategies. Research on vaccine delivery mechanisms, cold chain management, and community engagement provides valuable insights for improving program efficiency and coverage. For example, studies on cold chain logistics can inform strategies to enhance vaccine storage and distribution, thereby reducing vaccine wastage and ensuring that vaccines remain effective throughout the supply chain.[16] Operational research also supports evidence-based decision-making and the implementation of effective vaccination strategies.

Monitoring Vaccine Efficacy

Postmarketing surveillance is crucial for monitoring the long-term efficacy and safety of vaccines. The AEFI surveillance is a key component of this monitoring process, tracking and investigating adverse events to ensure public confidence in vaccination programs. By systematically collecting and analyzing data on vaccine-related adverse events, health authorities can identify potential safety concerns and make informed decisions about vaccine use.[17] Effective surveillance also contributes to the continuous improvement of vaccine safety and efficacy.

Human Resource Development

Capacity Building and Training

Ongoing training and capacity building are vital for maintaining high standards in immunization practices. Regular training programs for healthcare workers focus on vaccine administration techniques, cold chain management, and accurate data entry. These programs ensure that the knowledge and skills of healthcare improve, protocols are maintained, and high-quality services are delivered. Capacity-building initiatives also support the development of leadership skills and the ability to manage immunization programs effectively.

Supportive Supervision

Supportive supervision is an essential component of maintaining high standards in immunization practices. Supervisors provide on-the-job training, monitor performance, and offer constructive feedback to healthcare workers. This approach helps identify and address challenges in real time, promotes adherence to best practices, and supports continuous quality improvement. By fostering a supportive environment, supervisory practices contribute to the overall effectiveness and efficiency of immunization programs.

Capacity Enhancement

Enhancing capacity at all levels, from grassroots health workers to policymakers, strengthens the overall

immunization program. Initiatives such as training programs offered by the National Institute of Health and Family Welfare (NIHFW) are instrumental in building the skills and knowledge of health professionals. These programs focus on various aspects of immunization, including program management, data analysis, and community engagement. Strengthening capacity across all levels ensures that immunization programs are well-managed and responsive to emerging challenges.

Financial Sustainability

Government Funding

Adequate government funding is essential for the sustainability of immunization programs. The Government of India allocates substantial resources to the UIP through mechanisms such as the National Health Mission (NHM). This funding supports various aspects of the immunization program, including vaccine procurement, distribution, and program implementation. Ensuring financial sustainability is essential for maintaining program continuity and expanding vaccine coverage.

International Aid

International aid and partnerships play a significant role in supporting immunization efforts. Organizations such as GAVI, the Vaccine Alliance, and WHO provide financial and technical assistance to strengthen immunization programs in India. These partnerships facilitate access to funding, technical expertise, and resources that enhance the effectiveness of vaccination programs. Leveraging international support helps address resource gaps and ensures the successful implementation of immunization initiatives.

Public-private Partnerships

Public-private partnerships (PPPs) can enhance resource mobilization and the delivery of vaccination services. Collaborations with pharmaceutical companies, nongovernmental organizations (NGOs), and private healthcare providers expand the reach and impact of immunization programs. PPPs facilitate the sharing of resources, expertise, and technology, leading to more effective and efficient vaccination services.[18] Encouraging such partnerships supports the achievement of immunization goals and improves program outcomes.

Addressing Equity and Accessibility

Targeting Vulnerable Populations

Ensuring equitable immunization coverage requires special attention to marginalized and hard-to-reach populations. Approaches such as mobile vaccination units and frequent outreach sessions in remote areas address geographical barriers and ensure that underserved populations receive necessary vaccines. Targeting vulnerable groups helps reduce health disparities and improve overall vaccination coverage.[19] Tailored approaches that address specific needs and barriers are essential for achieving equity in immunization.

Mobile Vaccination Units

Mobile vaccination units play an important role in providing immunization services in remote and underserved areas. These units are equipped with cold chain facilities and trained staff to administer vaccines safely and effectively. By overcoming logistical challenges and reaching communities with limited access to healthcare services, mobile vaccination units contribute to improving vaccination coverage and ensuring that no one is left behind.

Inclusive Policies

Formulating inclusive policies that address barriers faced by different socioeconomic groups is essential for achieving equitable immunization coverage. Policies should consider factors such as gender, socioeconomic status, and geographic location to ensure that all individuals have access to vaccination services. Inclusive policies help address systemic inequalities and promote health equity by targeting the needs of diverse populations.

Emergency Preparedness and Response

Outbreak Response Plans

Planning of comprehensive outbreak response is critical for managing VPD outbreaks. These may include strategies for rapid assessment, vaccination campaigns, and community engagement. Effective outbreak response plans ensure timely and coordinated action to control and contain disease outbreaks.[19] Preparedness and response activities are essential for minimizing the impact of outbreaks on public health.

Rapid Response Teams

Establishing rapid response teams is essential for swift action during outbreaks. These teams are trained to conduct rapid assessments, implement vaccination campaigns, and provide technical support to local health authorities. By mobilizing expertise and resources quickly, rapid response teams contribute to effective outbreak management and help mitigate the spread of disease.[19]

Stockpile Vaccines

Maintaining a strategic stockpile of vaccines for emergency use during outbreaks is crucial for timely response. The Government of India, in collaboration with international

partners, maintains reserves of vaccines for diseases such as measles and cholera. These stockpiles ensure that vaccines are available when needed and support rapid response efforts during emergencies.[19] Strategic vaccine reserves are a key component of preparedness and response planning.

ADVERSE EVENT FOLLOWING IMMUNIZATION

It is any untoward medical occurrence following immunization. It does not necessarily have a causal relationship with the usage of the vaccine. These events can include any unfavorable or unintended symptom, sign, or abnormal lab result.

Adverse events following immunization (AEFIs) can either be directly related to the vaccine or the vaccination process, or they might be coincidental, happening around the same time as the vaccination but not caused by it.

A vaccine reaction is a person's specific response to the vaccine's properties, which can occur even when the vaccine has been correctly administered, correctly prepared, and properly handled. A list of adverse events known to be associated with vaccines are provided in **Table 1**.

Any adverse medical event after vaccination should be reported as an AEFI, regardless of whether it is directly caused by the vaccine.

Adverse events following immunization may be broadly grouped as under:

- *Adverse events following immunization by the severity of the event:*
  - Minor reactions (common)
  - Serious and severe vaccine reactions (rare)
- *Cause-specific AEFIs:*
  - Vaccine product-related reactions
  - Immunization error-related reactions
  - Vaccine quality defect-related reactions
  - Immunization-triggered stress response (ITSR)

Severe Reactions

The term "severe" reaction is broader and not typically used for regulatory purposes. It encompasses reactions that are more intense than minor reactions but do not necessarily require hospitalization. Severe reactions may cause temporary disability and do not lead to long-term complications.

Severe AEFI:

- Can be disabling
- Most do not lead to long-term complications
- Must also be reported
- *Examples*: Prolonged crying, convulsion, hypotonic hyporesponsive episodes (HHEs), and thrombocytopenia

TABLE 1: List of adverse events known to be associated with vaccines.[7]

Vaccine	Reaction
BCG	• *Local*: Local abscess, keloid, lymphadenitis, and cutaneous lesions • *Systemic*: Osteitis, osteomyelitis, disseminated BCG disease, and immune reconstitution syndrome (HIV patients)
OPV	Vaccine-associated paralytic poliomyelitis (VAPP)
DTwP/pentavalent (DTwP + HiB + HBV)	• Fever > 38°C, irritability, and drowsiness • Prolonged inconsolable crying (>1 hour) • High fever >40.5°C • Acute encephalopathy/encephalitis, HHE, seizure, anaphylaxis/shock
Hepatitis B	Anaphylaxis
Measles/MR	• Fever >39.4°C, rash, and febrile seizure • Thrombocytopenia, anaphylaxis, encephalopathy/encephalitis/encephalomyelitis
Rubella	Arthralgia/arthritis/arthropathy
Mumps	Aseptic meningitis
MMR vaccine	Febrile seizure
Tetanus/Td	Brachial neuritis and anaphylaxis
Rotavirus	Intussusception
Japanese encephalitis	• Serious allergic reactions, seizures, encephalopathy, neuropathy, and encephalitis • Myelitis and aseptic meningitis

(BCG: Bacillus Calmette–Guérin; DTwP: diphtheria, tetanus, and pertussis; HBV: hepatitis B virus; HHE: hypotonic hyporesponsive episode; HiB: *Haemophilus influenzae* type b; MMR: measles-mumps-rubella; MR: measles-rubella; OPV: oral polio vaccine)

Serious Reactions

An AEFI is classified as "serious" if it meets any of the following criteria: It poses a life-threatening risk, requires hospitalization, leads to persistent or significant disability, causes a congenital anomaly, requires intervention to prevent permanent impairment, or may result in death.

Serious AEFI:

- Hospitalization
- Clusters
- Disability
- Congenital anomaly/birth defect
- Death
- Media reports/community or parental concern

Cause-specific Categorization of Adverse Event Following Immunization

- *Vaccine product-related reaction:* An event that is caused due to the inherent properties of the vaccine product.
- *Immunization triggered stress response (previously known as immunization anxiety-related reaction):* An event arising from anxiety regarding injections or vaccination.
- *Vaccine quality defect-related reaction:* A cause by quality defects of the vaccine product, including its administration device.
- *Immunization error-related reaction (previously known as "program error"):* An event that is caused by inappropriate vaccine handling or administration.
- *Coincidental event:* An event that is caused by something other than above all.

Each and every training of health works should encompass this AEFIs also. To minimize these events, focused efforts on training, raising awareness, and ensuring the commitment of health workers are crucial.

CONCLUSION

As one of the world's leading vaccine manufacturers, India continues to expand its National Immunization Schedule by introducing new vaccines and enhancing coverage of existing ones through various strategic approaches. While increasing immunization coverage through the dedicated efforts of health workers, it is equally important to recognize and address Adverse Events Following Immunization (AEFIs). Efforts should focus on minimizing AEFIs through comprehensive training, awareness, and the unwavering commitment of healthcare professionals.

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