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Research

A Scoping Strategic survey of post-natal mothers on adverse events following immunization from the urbanized areas in the south Tamilnadu.

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Abstract

Adverse Events Following Immunization (AEFI) are a significant public health concern, particularly in pediatric immunization programs. This study aims to evaluate the occurrence and impact of AEFI among postnatal mothers in urbanized areas of South Tamil Nadu. A structured survey was conducted among 100 mothers to assess immunization-related adverse effects, awareness, and healthcare responses. The findings revealed a predominance of mild to moderate reactions, such as fever, swelling, and redness at the injection site, with no reports of severe complications. The study highlights the need for enhanced surveillance systems, proper vaccine administration training, and public awareness initiatives to improve vaccine safety and confidence. Future research should focus on personalized immunization approaches and novel vaccine formulations to mitigate AEFI risks effectively.

Keywords: Adverse Events Following Immunization (AEFI), Vaccine Safety, Pediatric Immunization, Immunization Surveillance, Vaccine-Related Reactions, Postnatal Mothers, Immunization Side Effects.

INTRODUCTION

Vaccine are one of the most reliable advancements in modern medicines, providing protection against disease by stimulating the Immune System [1]. Pediatric Immunization undoubtedly protects against severe

diseases; however, administering these vaccines to healthy children also carries the risk of adverse drug reactions, some of which can be serious. Adverse Events Following Immunization (AEFI) are a significant concern in the field of vaccine safety, particularly in children aged 0-10. Despite the importance of vaccination in preventing infectious diseases, AEFI can lead to serious health complications and even death. This article aims to provide a comprehensive overview of the current challenges and future directions in preventing and managing AEFI in children. Introduction to AEFI is crucial in understanding the scope of the problem. AEFI can range from mild reactions such as redness and swelling at the injection site to severe reactions such as anaphylaxis and neurological disorders [2-4]. The exact mechanisms of AEFI are not fully understood, but it is believed that a combination of genetic, environmental, and vaccine-related factors contribute to the development of adverse reactions.

The plan of work for preventing and managing AEFI involves a multi-faceted approach. Firstly, it is essential to improve vaccine safety through the development of safer vaccine formulations and delivery systems. Secondly, bhealthcare providers must be trained to recognize respond to AEFI promptly and effectively. Thirdly, parents and caregivers must be educated on the importance of vaccination and the potential risks and benefits associated with it. Finally, surveillance systems must be established to monitor and report AEFI, allowing for the identification of potential safety signals and the implementation of corrective actions, as recommended by the World Health Organization [5]. The current challenges in preventing and managing AEFI are numerous. One of the significant challenges is the lack of effective surveillance systems, which hinders the ability to detect and respond to AEFI in a timely manner. Another challenge is the limited understanding of the causes and risk factors of AEFI, which makes it difficult to develop targeted interventions. Additionally, there is need for more effective treatments and interventions for managing AEFI, particularly in severe cases. Future directions in preventing and managing AEFI involve the development of innovative technologies and strategies, which involve tailoring vaccine regimens to individual patients based on their genetic profiles and medical histories. Another area of research is the development of alternative vaccine formulations, such as mRNA-based vaccines, which have shown promise in reducing the risk of AEFI.

The Expanded Program on Immunization (EPI) was introduced in India in 1978 to combat and eradicate specific infectious diseases, and it was later renamed the Universal Immunization Program (UIP) in 1985. UIP targeted nine vaccine preventable diseases (UPDs), including tuberculosis, diphtheria, whooping cough (pertussis), tetanus, measles, polio, hepatitis – B, mumps and rubella. The National Population Policy (NPP) of 2000 emphasized the importance of vaccinating all children against six prevalent childhood illness. TB, pertussis, polio, measles, tetanus and diphtheria [6].

Bacillus Calmette – Guerin (BCG) Vaccine

The Bacillus Calmette Guerin (BCG) vaccine has been widely utilized since 1928 to stimulate specific immunity against tuberculosis and has been administered in India for nearly five decades [13]. It has been the main preventive measure against tuberculosis since 1921 [14]. It is a live attenuated vaccine delivered through intradermal infection, usually administered to the upper arm. Worldwide, the vaccine is given to nearly 100 million new born annually. A case control study revealed that BCG vaccination is highly effective in safeguarding children against advanced forms of primary tuberculosis, such as tuberculosis meningitis, bone tuberculosis, miliary tuberculosis, and scrofula. As part of the UIP, BCG vaccine is still advised for all children within 48-72 hours after birth, ideally before the mother leaves the hospital, to ensure optimal coverage. It is administered intradermally on the outer side of the left upper arm, near the insertion point of the deltoid muscle. Following intradermal infection, BCG replicates at the infection site and subsequently spreads to the nearly lymph nodes [7].

The typical local response to intradermal BCG vaccination includes swelling and redness at the

injection site, appearing a few weeks post-vaccination. This progresses to a small ulcer, which heals over weeks to months, leaving a minor scar. Localized lymph node enlargement of less than 1cm is also a normal reaction. The BCG vaccine is generally regarded as safe, with severe Adverse Events Following Immunization being uncommon. Earlier research has indicated that factors such as vaccination technique, dosage and vaccine formulation significantly influence the risk of adverse reactions. AEFIs associated with intradermal BCG vaccination include localized abscesses, both suppurative and non suppurative lymphadenitis, osteitis, osteomyelitis and widespread BCG related diseases.

DTaP Vaccine

The reduced prevalence of disease in developed nations is primarily attributed to the effective rollout of immunization programs utilizing multivalent combination vaccines. For decades, vaccines combining diphtheria, tetanus and acellular pertussis (DTaP) has been a cornerstone of universal immunization program. Following three doses of the vaccine, long term immunity improved to 87% for tetanus and 97% for diphtheria. In 2014, Indian children made up 22% of the 18.7 million children globally who had not completed the three dose DPT vaccination series by age one. It is important to maintain immunization of children against diphtheria and pertussis, as any decrease in DTP vaccination coverage could have severe consequences. The Diphtheria epidemic resulted from declining DTaP immunization in children, caused by failing healthcare infrastructure, decreased public backing for vaccination programs, an altered primary schedule with fewer doses and lower antigenic potency and postponing the second childhood DPT booster to 9 years rather than the recommended 6 years [8]. Another notable scenario in India is the routine administration of tetanus toxoid infections to children by private general practitioners. Often, parents either forget the child s immunization status or fail to bring the immunization record card. As a result, children receive a tetanus toxoid infection after every injury. While tetanus toxoid is a safe vaccine, repeated revaccination can lead to hypersensitivity reactions.

Polio Vaccine

Since the inception of the Global Polio Eradication Initiative (GPEI) in 1988, the yearly global count of polio cases has been reduced by 99.99%, dropping from an estimated 3,50,000 cases across more than 125 countries to just 74 cases in 2015, confined to two endemic countries, Pakistan and Afghanistan. Until 2009, India accounted for the majority of global polio cases, but it was officially certified polio – free in 2014. The Global Polio Eradication Initiative (GPEI) has utilized the oral polio virus vaccine (OPV) to effectively eliminate the transmission of wild polio virus in the majority of countries worldwide. The GPEI has preferred OPV as its vaccine due to its simplicity in mass campaign administration, affordability, and capacity to generate strong intestinal mucosal immunity, effectively preventing poliovirus shedding and transmission [9]. In India, as a part of the Universal Immunization Program (UIP), OPV is administered to every child at 6, 10, and 14 weeks as part of primary immunization schedule.

Hepatitis Vaccine

Viral hepatitis is a global health concern, but vaccination against hepatitis A and B have significantly reduced illness and death, contributing to a decline in vaccine preventable diseases.

Measles Vaccine

Measles is a highly infectious viral disease, preventable through vaccination, caused by the Measles morbillivirus, which belongs to the para myxoviridae family. Immunization against measles at the community level has proven to be the most efficient method for preventing the disease. The WHO recommended the first measles vaccine dose at 9 months in high risk areas and at 12 15 months. Elsewhere, with a second dose at 15 18 months. The Universal Immunization Programme (UIP) began in 1985, delivering 160 million measles vaccine doses by 1995 while most vaccine batches met WHO Standards, severe reactions including 79 deaths from toxic shock syndrome (TSS) were linked to non sterile syringes, improper handling, and contaminated reconstituted vaccines. Symptoms included high fever, vomiting and diarrhea, leading to death within 24 hours. To prevent TSS, the government mandated using reconstituted vaccines within 4 hours, keeping them under 8^0C, and destroying unused vials, significantly reduced TSS cases [10].

Research confirms the high efficacy of the two – dose measles vaccine, with measles rarely occurring in fully vaccinated individuals (who received both doses) regardless of age. The National family health survey 5 (2019 2021) reported MCV1 coverage at 88.6% and MCV2 at 58.6% showing significant improvement from NFHS – 4 (2015 – 16) where MCV1, coverage was 81.1%. Live attenuated measles vaccines are available either as a single dose vaccine or as a combination measles containing vaccine (MCV) with rubella or mumps vaccine. The available measles vaccines are safe, effective and can be used interchangeably in vaccination programs.

Rotavirus Vaccine

The rotavirus vaccine is a vaccine used to protect against rotavirus infections, which are the leading cause of severe diarrhea among young children. The vaccines prevent 15-34% of severe diarrhea in the developing world and 37-96% of the risk of death among young children due to severe diarrhea. Immunizing babies decreases rates of disease among older people and those who have not been immunized. The World Health Organization recommends that rotavirus vaccine be included in all national immunization schedules because the risk of intussusception following rotavirus vaccination reminds very low compared with the benefits of preventing the impact of severer and deadly diarrhea. A 2021 cochrane systematic review concluded that rotavac, rotateq, and rotaix vaccines are safe and are effective at preventing diarrhea that is relate to a rotavirus infection [11].

Pneumococcal Conjugate Vaccine

Pneumococcal vaccine made with the conjugate vaccine method and used to protect Infants, young children and adults against disease caused by the bacterium streptococcus pneumoniae (Pneumococcus). It contains purified capsular polysaccharide of pneumococcal serotypes conjugated to a carrier protein to improve antibody response compared to the pneumococcal polysaccharide vaccine.The world Health Organization (WHO) recommends the use of the conjugate vaccine in routine immunization given to children [12].

Revised National Immunization Schedule

1. Immunization Schedule by Age Group

Age	Vaccines Administered
At Birth	BCG, OPV-0, Hepatitis B (Birth Dose)
6 Weeks	OPV-1, Pentavalent-1, RVV-1, fIPV-1, PCV-1*
10 Weeks	OPV-2, Pentavalent-2, RVV-2
14 Weeks	OPV-3, Pentavalent-3, fIPV-2, RVV-3, PCV-2*
9 12 Months	MR-1, JE-1**, PCV Booster*
16 24 months	MR-2, JE-2**, DPT Booster-1, OPV Booster
5 6 Years	DPT Booster-2
10 Years	Td
16 Years	Td
Pregnant Women	Td-1, Td-2, or Td Booster***

Notes:

1. *PCV is administered in selected states/districts: Bihar, Himachal Pradesh, Madhya Pradesh, Uttar Pradesh (selected districts), Rajasthan, and Haryana (state initiative).
2. **JE vaccine is given in endemic districts only.
3. ***Td Booster is given if a woman has received 2 TT/Td doses during a pregnancy within the last 3 years.

2. Immunization Schedule by Vaccine Type

Notes:1.Vitamin A supplementation continues every 6 months until the age of 5 years.

Vaccine	Recommended Age	Dosage	Route	Injection Site
BCG	At birth (up to 1 year)	0.1 ml (0.25 ml for infants <1 month)	Intradermal	Left upper arm
Hepatitis B (Birth dose)	At birth (within 24 hours)	0.5 ml	Intramuscular	Mid thigh
Oral Polio Vaccine	Birth, 6, 10, 14 weeks, Booster at 16 24 months	2 drops	Oral	Oral
Penta Valent (DPT, Hepatitis B, Hib)	6, 10, 14 weeks	0.5 ml	Intramuscular	Mid thigh
Rota Virus Vaccine (RVV)	6, 10, 14 weeks	5 drops (liquid) / 2.5 ml (lyophilized)	Oral	Oral
Inactivated Polio Vaccine (fIPV)	6, 14 weeks	0.1 ml (2 doses)	Intradermal	Right upper arm

Measles – Rubella (MR)	9 12 months, 16 24 months	0.5 ml	Subcutaneous	Right upper arm
Japanese Encephalitis (JE)	9 12 months, 16 24 months	0.5 ml	Subcutaneous (live) / Intramuscular (killed)	Left upper arm (live) / Mid – thigh (Killed)
PCV (Pneumococcal Conjugate Vaccine)	6, 14 weeks, booster at 9 12 months	0.5 ml	Intramuscular	Mid thigh
DPT Booster	16 24 months, 5 – 6 years	0.5 ml	Intramuscular	Mid – thigh / Upper arm
Tetanus and Adult Diphtheria (Td)	10 and 16 years, Pregnant Women	0.5 ml	Intramuscular	Upper arm
Vitamin A Supplementation	9 months, then every 6 months until five years	1 ml (first dose) / 2 ml (subsequent doses)	Oral	Oral

Vaccine Counseling

Vaccine counseling is essential in ensuring vaccine acceptance, adherence, and safety. It involves educating parents and caregivers about vaccine benefits, risks, schedules, and adverse events following immunization (AEFI). Proper counseling enhances trust, addresses concerns, and minimizes misinformation.

Key Aspects of Vaccine Counseling

1. *Vaccine Schedule & Administration:*

Explain the recommended immunization schedule, including the number of doses, intervals, and booster requirements.

Inform caregivers about the disease each vaccine prevents and the expected immune response.

Encourage adherence to the schedule for maximum protectionDisease Risk & Vaccine Efficacy:

Discuss the risks of vaccine-preventable diseases, using local epidemiological data when available.

Explain that vaccines significantly reduce disease severity and transmission but may not provide absolute immunity.

2. *Vaccine Safety & Possible Adverse Effects:*

Assure caregivers that vaccines are generally safe, with benefits outweighing risks.

Discuss common side effects (e.g., fever, pain, redness at the injection site) and rare but serious AEFIs.

Advise on post-vaccination care, such as using acetaminophen for fever.

3. *Consent & Pre-Vaccination Assessment:*

Obtain informed consent after explaining potential side effects.

Screen for contraindications (e.g., allergies, immunocompromised status). Ensure proper vaccine storage, handling, and administration techniques.

4. *Injection Safety & Pain Management:*

Follow strict aseptic techniques and use auto-disable syringes. Avoid the gluteal region for intramuscular injections in infants to prevent sciatic nerve injury. Maintain a minimum distance of 1 inch between multiple injections. Observe the child for 15 20 minutes post-vaccination to detect immediate allergic reactions.

ADR Rare But Occur: Vaccinations are essential for preventing serious diseases in children under 10 years of age. While most vaccine related adverse reactions are mild and temporary, such as soreness at the injection site, fever, or fatigue, serious adverse events are rare but can occur.

Guidelines for Investigation and Causality Assessment

The WHO s Causality Assessment of an Adverse Event Following Immunization guidelines provide a structured approach to determine the cause of AEFI. Key steps include:

1. Comprehensive documentation of the event.
2. Reviewing the patient s medical history.
3. Evaluating vaccine quality and administration processes.
4. Using algorithms to determine causality based on evidence and expert judgement.

Step 1: Identification and Reporting (Within 24 hours)

1. Identify any adverse event following immunization.
2. Complete a standardized reporting form.
3. Report the event to the relevant authorities (e.g., national vaccine safety surveillance system).

Step 2: Initial Assessment (Within 24-48 hours)
1. Conduct an initial assessment of the reported event.
2. Determine the severity and seriousness of the event.
3. Decide whether further investigation is needed.

Step 3: Investigation (Within 7-14 days)
1. Conduct a thorough investigation of the reported event.
2. Collect relevant information (e.g., medical history, vaccine details).
3. Assess the causality of the event using established criteria.

Step 4: Causality Assessment (Within 14-30 days)
1. Assess the causality of the event using established criteria (e.g., WHO causality assessment criteria).
2. Determine whether the event is likely related to the vaccine.

Step 5: Classification and Coding (Within 30 days)
1. Classify the event as serious or non-serious.
2. Assign a coding category (e.g., MedDRA).

Step 6: Follow-up and Closure (Within 30-60 days)
1. Conduct follow-up evaluations to monitor the outcome of the event.
2. Close the case once the outcome is known.

Step 7: Reporting to National and International Authorities
1. Report the event to national and international authorities (e.g., WHO, CDC).
2. Provide regular updates on the investigation and outcome.

Challenges in Vaccine Safety Monitoring
1. Late Occurring AEFIs: Delayed reactions, often missed by current systems, require innovative monitoring solutions.
2. Complex Vaccines: New combination vaccines complicate the identification of AEFI causality.
3. Global Disparities: Variations in healthcare systems, socio economic factors, and vaccine policies affect surveillance quality.

Aim

The aim of this study is to assess the Adverse Effects Following Immunization (AEFI) among 100 children in Uthangudi, Othakadai, Thirumohur, Narasingam, and Omachikulam through random sampling in villages of South Tamil Nadu.

Objectives
1. To evaluate the occurrence of any adverse effects following immunization among children in the selected regions.
2. To assess parental awareness and concerns regarding immunization-related side effects.
3. To document the types and frequency of reported minor side effects post-immunization.
4. To analyze any potential correlation between immunization history and reported adverse effects.
5. To provide recommendations for improving community awareness regarding immunization safety.

METHODOLOGY

Procedure for Conducting the Survey:

This survey was conducted by five students who systematically collected data from the public in Uthangudi, Othakadai, Thirumogur, Narasingam, and Omachikulam. The methodology followed a structured approach to ensure accuracy and reliability.

Survey Design

Prior to data collection, a structured questionnaire was designed based on existing literature on AEFI.

Questionnaire Development

A structured questionnaire was designed based on existing literature on AEFI and in consultation

with healthcare professionals. The questionnaire aimed to capture:

1. Basic demographic details of the child and mother
2. Vaccination history within the past six months
3. Any minor side effects observed post-immunization
4. Parental awareness and concerns regarding vaccination

Selection of Participants

Inclusion Criteria

1. Mothers of children who had received vaccination within the past six months
2. Residents of Uthangudi, Othakadai, Thirumogur, Thiruvathavur, and Omachikulam
3. Willingness to participate

Exclusion Criteria

1. Mothers unwilling to participate
2. Children with underlying health conditions unrelated to immunization
3. A total of 100 respondents were selected through a random sampling technique to ensure unbiased representation.

Data Collection Process

1. Student Training: Five students were trained on survey techniques, communication skills, and ethical considerations.
2. Household Visits: Each student covered specific areas within the selected regions to ensure even distribution of data collection.
3. Structured Interviews: The questionnaire was administered through face-to-face interviews, where mothers were asked about any post-immunization side effects observed in their children.
4. Data Recording: Responses were documented systematically, ensuring confidentiality and accuracy.
5. Quality Check: After data collection, responses were reviewed to identify inconsistencies or missing information.

Data Analysis

Following data collection, responses were categorized and analyzed. Since no minor side effects were reported, the findings indicated a high level of immunization safety in the surveyed population.

Current and Upcoming Solution for AEFI

1. Smart Vaccine Delivery Systems

Micro-Needle Patches with Real-Time Monitoring

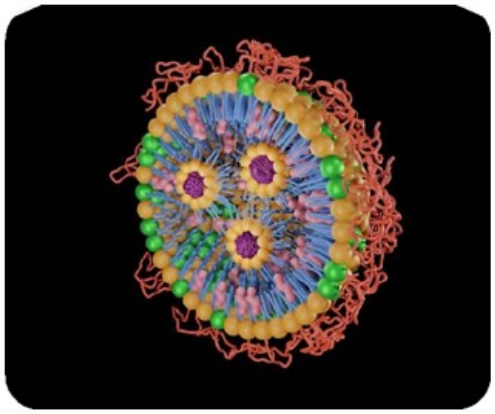
A dissolvable micro-needle patch embedded with biosensors that monitor local immune response and inflammation in real time. The data is transmitted to a smartphone app to track potential adverse reactions.Micro-needle patches have revolutionized vaccine administration by offering a pain-free, self-administrable, and highly efficient alternative to traditional injections. These patches consist of micron-scale needles that penetrate the epidermis, delivering vaccines directly to antigen-presenting cells in the dermis, ensuring a robust immune response. Recent advancements integrate real-time monitoring into micro-needle patches, enhancing their functionality. For example, iontophoresis-driven micro-needle patches facilitate active and controlled vaccine macromolecule delivery while tracking drug diffusion kinetics, ensuring optimal dosing and efficacy. Another breakthrough involves dissolvable micro-needle patches, which encapsulate vaccines within biodegradable micro-needles. These dissolve upon application, releasing vaccines without medical waste and improving stability, safety, and immunogenicity. [13]

A recent breakthrough in micro-needle technology involves the integration of biosensors that can dynamically monitor immune responses. These micro-needles, embedded with electrochemical or fluorescence-based biosensors, can detect cytokines and inflammatory markers in real time, providing immediate feedback on vaccine efficacy. This could transform vaccine surveillance, allowing healthcare professionals to personalize immunization based on real-time patient data. We would like to integrate wireless micro-needle patch with AI-powered biosensors for real-time immune response monitoring post-vaccination. It detects cytokine levels, predicts adverse reactions, and transmits data via 5G-enabled AI analytics. This patentable solution enhances vaccine safety, enabling personalized monitoring, early intervention, and smarter immunization strategies for improved global healthcare.

Controlled-Release Nanoparticle Carriers

Nanoparticles designed to deliver antigens in a controlled manner, minimizing immune system overstimulation and reducing the likelihood of side effects. Controlled-release nanoparticle carriers have

emerged as a transformative technology in vaccine delivery, ensuring sustained antigen release, enhanced stability, and optimized immune responses. Recent advancements highlight polymeric nanoparticles, which offer biodegradability and controlled antigen delivery. Lipid nanoparticles (LNPs), particularly in mRNA vaccines, protect payloads and facilitate efficient cellular uptake. Oral nanocarrier-based vaccines improve mucosal immunity and patient compliance, while nanoparticle-adjuvant combinations enhance immune activation. We would like to propose a smart nanoparticle system that integrates controlled- release mechanisms with biosensors for real-time immune monitoring. This innovation would adjust antigen release rates dynamically, ensuring personalized vaccination and optimized immunity, making it a patentable breakthrough.[14]



2. Personalized Vaccination Platforms[15]

AI-Driven Risk Assessment Tools

An AI-based system that analyzes an individual s genetic, medical, and immunological data to predict potential AEFI and recommend personalized vaccine formulations. Topol (2019) highlighted AI s transformative role in precision medicine, demonstrating how deep learning models analyze immunological risks and predict adverse reactions. Similarly, Wang et al. (2023) developed an AI-based prediction system using real-world immunization data, identifying high-risk individuals and reducing AEFI incidence through personalized vaccine recommendations. We would like to integrate A3PS which employs deep learning models to assess AEFI risk using electronic health records, genetic analysis, and wearable health data. It provides real-time monitoring and personalized vaccination schedules, ensuring safer immunization.

Genomic-Based Adjuvant Selection

Adverse events following immunization (AEFI) are often influenced by genetic variations affecting immune responses. Understanding these genetic predispositions enables personalized adjuvant selection, improving vaccine safety and efficacy. Genetic polymorphisms, particularly in human leukocyte antigen (HLA) genes, influence vaccine-induced immune responses. Certain HLA alleles have been linked to hypersensitivity reactions to vaccines, making genomic screening a valuable tool before immunization. Additionally, variations in Toll-like receptor (TLR) genes have been associated with differential responses to adjuvanted vaccines, further supporting the role of genomics in vaccine optimization. Using genetic screening, individuals at higher risk of AEFI can be identified, allowing for the selection of appropriate adjuvants that enhance immune responses while minimizing adverse reactions. Advanced AI models can analyze genomic data to predict the safest and most effective adjuvant formulations for each child. We would like to focus AI-driven platform that utilizes machine learning (ML) and genomic data analysis to predict the safest and most effective adjuvant composition for each child based on their genetic profile. Unlike existing patents that focus on predefined multi-adjuvant combinations, this system dynamically selects adjuvants tailored to indivual genetic markers, ensuring optimal immune response while minimizing AEFI.

By integrating whole-genome sequencing (WGS) with immune response biomarkers to determine individual child s likelihood of experiencing AEFI. It maps HLA variations, Toll-like receptor (TLR) polymorphisms, cytokine profiles, and epigenetic markers which is linked to immune reactivity. By using deep learning models, best adjuvant combination for a given child can be predicted. A cloud based adjuvant library categorize adjuvants based on their molecular actions (eg., TLR agonists, saponins, cytokine mimetics). This type of system generate personalized vaccine formulations. For data security and regulatory compliance, all genomic and immunization data is stored using blockchain encryption, prevents unauthorized access and ensuring privacy.

3. Next-Generation Vaccine Formulations[16]

Allergen-Free Vaccines

Traditional vaccines may contain allergens like egg proteins, gelatin, or formaldehyde, triggering hypersensitivity reactions in some individuals. To address this, novel allergen-free vaccine technologies are being developed.

Recombinant DNA Technology Uses yeast or insect cells for antigen production, eliminating egg-based allergens.

Synthetic Peptide Vaccines – Precisely designed to avoid allergenic proteins while maintaining immunogenicity.

Virus-Like Particles (VLPs) Mimic viruses without allergens, ensuring safety and efficacy.

A liposome-based vaccine can encapsulate synthetic peptides, ensuring targeted delivery without allergens. The liposomes are modified with mannose residues for enhanced immune activation, creating a safer and more effective immunization strategy.

We would like to propose a next generation, plant-based vaccine platform that eliminates common allergens found in traditional vaccine formulations to produce viral or bacterial antigens. Unlike conventional methods, this system leverages genetically engineering plant cells to produce synthetic, allergen-free antigens, ensuring a safety and more effective immunization strategy. By using AI-driven bioinformatics system, highly stable and immunogenic antigens can be designed by analyzing genetic sequences and optimizing codon usage for plant expression.

The plant derived antigens are encapsulated in biodegradable nanoparticles (eg., chitosan or lipid-based carriers) to enhance stability, controlled release, and immune targeting. This ensures efficient antigen uptake without the need for traditional adjuvants, reducing adjuvant-associated allergic reactions. Plant based vaccine can be formulated as oral or sublingual vaccine, eliminating the need for injections and stabilizing the vaccine at room temperature, reducing refrigeration dependency.

Self-Neutralizing Vaccines

Self-neutralizing vaccines represent an advanced immunization strategy where the vaccine itself generates neutralizing agents, reducing pathogen replication without external boosters or repeated doses.

Self-Assembling Nanoparticle Vaccines These mimic virus-like structures to enhance neutralizing antibody production, ensuring long term protection.

mRNA-Based Self-Amplifying Vaccines Engineered to continuously express neutralizing antibodies, reducing the need for booster doses.

Synthetic B-Cell Programming Directly modifies immune cells to autonomously detect and neutralize infections.

A novel mRNA vaccine platform that integrates:

1. AI-driven antigen selection for optimized neutralizing response.
2. Self-replicating RNA circuits to produce long-lasting neutralizing antibodies.
3. Lipid nanoparticle encapsulation for targeted immune activation.

A self-neutralizing mRNA vaccine that programs immune cells in vivo to continuously produce adaptive neutralizing antibodies, eliminating the need for boosters. AI-optimized mRNA encodes broadly neutralizing antibodies (bNABs) for real time pathogen adaptation. Self-replicating RNA circuit ensures controlled, long-term antibody production. Dual delivery (LNP + exosome) enhances targeted immune response. Self-limiting mechanism prevents overactivation, ensuring safety.

4. Enhanced Vaccine Packaging and Delivery[17]

Biodegradable Smart Syringes

Biodegradable smart syringes integrate eco-friendly materials with advanced delivery technologies, ensuring safe, precise, and sustainable vaccination.

Innovative approaches includes

Biodegradable Mini-Implants: known as Bioneedles, these small, biodegradable implants can be pre-filled with vaccines. Upon administration, they dissolve rapidly, releasing the vaccine without generating traditional medical waste.

Seaweed-Based Syringes: Utilizing seaweed-derived materials, these syringes are designed to be biodegradable, reducing plastic waste associated with conventional syringes.

Smart Syringe Platforms: Incorporating digital features, these syringes enhance dose accuracy and enable data collection for improved patient care.

A biodegradable smart syringe made from seaweed-derived polymers integrated with AI-Controlled microfluidic technology for precise, automated vaccine dosing, eliminating wastage and ensuring environmentally sustainable delivery.

AI-Guided Microfluidic Control to prevent over- or under-dosing.

Self-Degrading Biopolymer Body – made from seaweed-derived biopolymers, the syringe biodegrades in 48 hours, eliminating plastic waste and the need for medical waste disposal.

By integrating NFC (Near Field Communication) chip ensures tamper-proof tracking and real-time digital verification of administered doses, reducing counterfeit vaccines.

Pre-Vaccine Skin Preparation Kits

Ensuring proper skin preparation before vaccination is vital to minimize adverse events following immunization (AEFI). A pre-vaccination skin preparation kit can enhance vaccine safety and delivery.

Innovative approaches include:

Alcohol-Based Antiseptic Application

Utilizing alcohol swabs to cleanse the injection site can reduce the risk of bacterial infections. A study highlighted the importance of skin antisepsis in preventing post-injection infections.

Adhesive Bandage Application

Applying an adhesive bandage post-vaccination can protect the injection site from contamination. Guidelines recommend this practice to prevent minor bleeding and potential infections.

Monitoring for Immediate Reactions

Observing patients for immediate adverse reactions, such as anaphylaxis, ensuring prompt management. Health authorities emphasize the need for monitoring and readiness to manage such events.

pH-Sensitive Antiseptic Wipes

Color-changing alcohol wipes detect residual contamination and confirm adequate skin disinfection before injection.

Antimicrobial Smart Bandage – Coated with biodegradable nanomaterials (e.g., silver nanoparticles or chitosan) to provide extended antimicrobial protection and reduce post-vaccine site infections.

RESULTS AND DISCUSSIONS

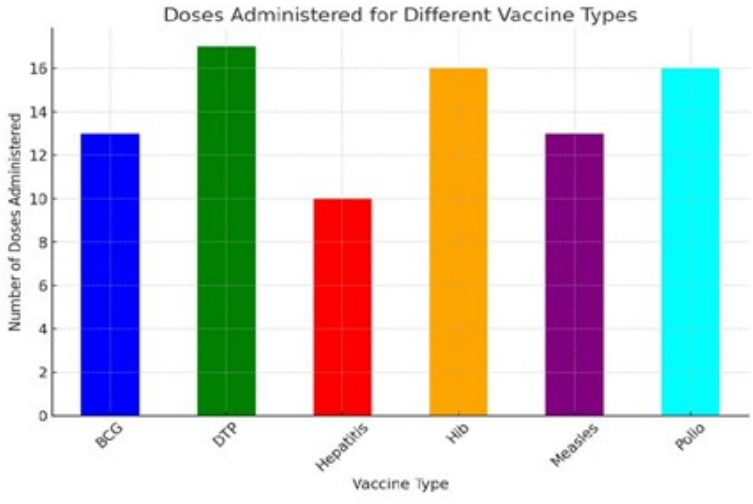
Vaccination Coverage

The survey included multiple childhood vaccines, with the following distribution:

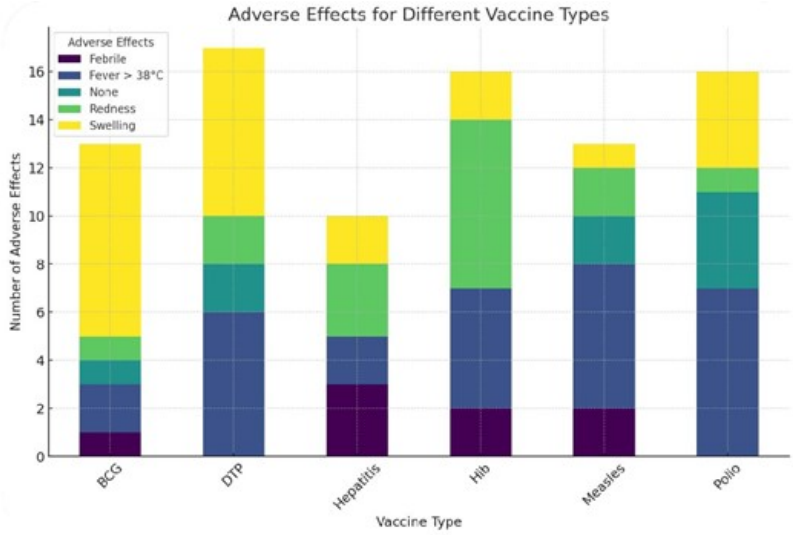
BCG: Administered to 16% of the participants.

DTP: Received by 22% of children.

Polio: Given to 19% of the surveyed children. Hepatitis: Administered to 13% of the participants. Measles: Received by 18% of the children.
Hib (Haemophilus influenzae type B): Given to 12% of the surveyed group.
These figures indicate strong adherence to routine childhood immunization schedules, with DTP and polio being among the most frequently administered vaccines.



Adverse Effects Following Immunization (AEFI)
The most commonly reported adverse effects included:
Fever (>38°C): 26% of vaccinated children experienced fever post-vaccination.
Redness at the injection site: Observed in 14% of cases.
Swelling: Reported in 17% of children.
Febrile reactions: Seen in 10% of cases.
No adverse effects: Notably, 33% of the children did not experience any post-vaccination reactions.



The high percentage of mild AEFI, such as fever and swelling, is consistent with global vaccine safety studies. These reactions are expected immune responses and do not indicate serious health risks.

The survey results confirm the overall safety and effectiveness of childhood vaccines. The absence of severe AEFI supports the importance of routine immunization while addressing vaccine hesitancy. The DTP vaccine had the highest rate of localized reactions (redness and swelling), which aligns with prior research indicating that combination vaccines can cause transient site reactions. Interestingly, the measles and polio vaccines showed the lowest incidence of adverse reactions, reinforcing their safety profile. The BCG vaccine was linked to a moderate occurrence of swelling and redness, which is an expected response due to its intradermal administration.[19] While the absence of reported AEFI is encouraging, it may also indicate

potential limitations, such as underreporting or regional reporting behaviours. Future studies should expand sample sizes and incorporate active surveillance methods to ensure comprehensive vaccine safety monitoring. Overall, the results reinforce the importance of ongoing immunization programs and the need for continuous efforts in communication education and healthcare following sustain high vaccine acceptance.[20]

CONCLUSION

Our study on Adverse Events Following Immunization (AEFI) in Southern Tamil Nadu provides valuable insights into vaccine safety and efficacy, emphasizing the need for continuous surveillance and innovation in immunization strategies. While vaccines remain one of the most effective public health interventions, the occurrence of adverse effects highlights the necessity for next-generation advancements in vaccine technology. To address these challenges, we propose transformative solutions such as smart vaccine delivery systems with real-time AI-driven monitoring, personalized vaccine platforms tailored to individual immune profiles, and genomic- based adjuvant selection for optimized immune responses. Furthermore, next-generation vaccine formulations leveraging nanotechnology and mRNA advancements, coupled with enhanced packaging and delivery innovations like microneedle patches and self-administering vaccines, will significantly improve safety, accessibility, and compliance. By integrating these cutting-edge approaches, our research lays the foundation for a future-ready immunization system that is safer, more efficient, and tailored to individual needs, ultimately driving a paradigm shift in global vaccine administration.

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