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Safety evaluation of immunization in infants and childrens

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ABSTRACT

comprehensive safety evaluation of immunization in infants and children in India, focusing on the immunization schedule, vaccine safety, adverse events, and strategies to address the Hesitancy of vaccines. The National Immunization Schedule (NIS) in India recommends a series of vaccines for infants and children to protect them against various diseases. All vaccines undergo rigorous testing and safety assessments before being introduced in the NIS. The well-being of vaccination far outweighs any possible risks. While immunization is generally safe, few children may see mild effects. Serious AEFIs are rare but can occur. The National AEFI Surveillance System in India monitors and investigates AEFIs to ensure the safety of vaccines. Hesitancy while immunization is a developing concern in India. Healthcare professionals play a crucial role in addressing concerns about immunization safety and promoting vaccine acceptance. This paper highlights the importance of immunization and the need for continued efforts to strengthen the immunization program, address vaccine hesitancy, and ensure impartial accessibility to vaccines for all children in India.

Objective: This study's aim is to evaluate the safety of immunization schedule in 0 Months to 12 years children.
Methods: In this study, we observed the ability to fight off infections in children aged 0 months - 12 years and followed a list of vaccinations given by the National Immunization Schedule. Data was collected from ANMs (Auxiliary Nurse Midwives or nurse hybrid) and from the immunization book provided to parents. A cohort of 500 children of age between 0 Months to 12 years are included in our study.
Results: This study evaluates the safety of immunization in children aged 0 months to 12 years, analyzing data from 500 participants. Fever and swelling were the most common adverse events following immunization (AEFI), with severe reactions being rare. Pentavalent and oral polio vaccines were identified as the primary sources of AEFI. The findings highlight that while mild to moderate reactions are common, vaccines remain safe and effective overall.

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INTRODUCTION

"Immunization is a highly effective public health intervention that has significantly reduced childhood mortality and morbidity globally. India's Universal Immunization Programme (UIP) provides free vaccines to protect children against preventable diseases.". However, concerns about vaccine safety can lead to vaccine hesitancy and affect immunization coverage. This article provides a comprehensive safety evaluation of immunization in infants and children in India, addressing the immunization schedule, vaccine safety, adverse events following immunization (AEFI), and strategies to address vaccine hesitancy.

Immunization Schedule in India

The National Immunization Schedule (NIS) in India recommends a series of vaccines for infants and children to protect them against various diseases. The schedule includes vaccines for tuberculosis BCG, Hepatitis-B, Polio(OPV), Diphtheria, Tetanus, Pertussis, Hib, rotavirus, pneumococcal disease (PCV), MMR, JE, and chickenpox. The NIS has been updated to include two doses of MMR vaccine at 9 months and 15 months of age and no standalone measles vaccine at 9 months. A single dose of the live attenuated H2 strain Hepatitis- A vaccine or two doses of the inactivated Hepatitis-A vaccine is also included. additionally, a new slot at 9-12 months for the typhoid conjugate vaccine has been added to the National immunization schedule. Two doses of the human papillomavirus vaccine, with a minimum interval of 6 months between doses, are recommended for Teenage girls.

National Immunization Schedule for Infants and children

Vaccine	When to given	Dose	Route	Site
BCG	At birth or as early as possible 1 year of age	0.1ml (0.05ml unit 1 month of age)	Intradermal	Left Upper Arm
Hepatitis B-Birth dose	At birth or as early as possible within 24 hours	0.5ml	Intramuscular	Anterolateral side of mid-thigh
OPV-0	At birth or as early as possible with in the first 15 days	2 drops	Oral	Oral
OPV-1,2&3	At 6weeks,10 weeks & 14 Weeks (OPV can be given till 5 years of age)	2 drops	Oral	Oral
Pentavalent 1,2&3	At 6 Weeks,10 weeks & 14 weeks (can be given till one year of age)	0.5ml	Intramuscular	Anterolateral side of mid-t high

Rota virus	At 6 Weeks , 10 Weeks & 14 Weeks (can be given till one year of age)	5 drops	Oral	Oral
IPV	Two fractional dose at 6 and 14 Weeks of age	0.1 ml	Intradermal two fractional dose	Intradermal Right upper arm
Measles/ MR1st Dose	9 Completed months (can be given till 5 years of age)	0.5ml	Subcutaneous	Right Upper arm
JE-1	9 completed months	0.5ml	Subcutaneous	Left upper arm
Vitamin A (1st dose)	At 9 completed months with measles and Rubella)	1ml	Oral	Oral
DPT +Polio	AT 16-24 months	0.5ml	Intramuscular	Anterio -lateral side of left mid thigh
MR 2dose	16-24 months	0.5 ml	Sub-cutaneous	Right upper arm
OPV booster	16-24 months	2drops	oral	Oral
JE-21	6-24 months	0.5 ml	Intra-muscular	Anterio -lateral side of left mid thigh
Vitamin-A	16-24 months with MR and remaining at an interval of 6months up to the age of 5 years	2ml	oral	Oral
DPT Booster	5-6 years	0.5 ml	Intra-Muscular	Upper-arm
Td	10 years &16years	0.5ml	Intra-Muscular	Upper-arm

It is important to note this schedule can be changed, and healthcare professionals should follow to the latest recommendations from the Ministry of Health and Family Welfare.

Vaccine Safety All vaccines available in India are rigorously tested and approved by the Drug Controller General of India (DCGI) before being included in the National Immunization Schedule (NIS). Regulatory bodies like the Central Drugs Standard Control Organization (CDSCO) and the Indian Council of Medical Research (ICMR) ensure strict quality and safety

standards. Both the government and private sector procure vaccines from approved manufacturers.

Vaccination provides essential protection against preventable illnesses, and its benefits far outweigh any potential risks. Vaccines strengthen a child's immune system, enabling them to fight off harmful pathogens and develop healthily.

While immunization is a proven and cost-effective preventive measure, many children, particularly in developing countries, still lack access. In India, recent data shows that only 61% of the 26 million infants targeted annually receive all the necessary vaccines. This highlights the need for increased immunization efforts.

It's also important to note that influenza vaccines have been proven safe and effective.

International Perspectives on Immunization Safety

Reputable international organizations like WHO and UNICEF emphasize the safety and effectiveness of immunization in infants and children. Vaccines undergo rigorous testing and monitoring to ensure they are safe and effective. The benefits of vaccination greatly outweigh any potential risks. Organizations like the WHO and UNICEF provide resources to address vaccine hesitancy and promote immunization.

Timely vaccination is crucial for protection against serious diseases. Immunization has successfully eradicated smallpox and nearly eliminated polio.

It's important to know that vaccines are not linked to conditions like diabetes, infertility, autism, or developmental delays. Measles-containing vaccines are also safe. Common side effects are mild, such as minor pain or swelling at the injection site. Serious reactions are extremely rare, and healthcare providers are trained to handle them.

Vaccines for children are generally tested using a step-down approach. This means clinical trials usually begin with adults first and then step down in age to teens, then children, then babies. Clinical trials for children normally focus on finding the right dosage that will give children of all ages the best protection with the fewest side effects. Once the clinical trials are over.

To ensure safety and effectiveness, medical experts rigorously evaluate vaccine data before public availability. Vaccines have dramatically reduced child mortality worldwide, saving countless lives. Due to widespread vaccination, many have grown up without witnessing the devastating effects of preventable diseases like measles and polio. Stringent safety testing, including clinical trials, is mandatory for all vaccines. Only those meeting high quality and safety standards are approved for distribution.

National Adverse Event Following Immunization Surveillance System

The National Adverse Event Following Immunization Surveillance System in India is passive and Depends on reporting by healthcare providers and the people. The system plays a vital role in monitoring vaccine safety in the post-licensure phase. The AEFI Secretariat, with the support of the National AEFI Technical Collaborating Centre and World Health Organization -India Country Office, develops and updates national AEFI guidelines. The system has been strengthened over the years, with the latest guidelines being released in 2015. The government has increased investment to improve the AEFI surveillance in the country. One of the strategies to improve the AEFI system is to establish a Quality Management System for the AEFI surveillance system. The AEFI Secretariat has achieved quality certification under the National Quality Assurance Standards (NQAS).

The reporting of serious or severe AEFI is done using by a Case Reporting Format. The CRF gives only basic details of the affected person, Immunization and discussed details, and status at the time of filling the format.

Adverse Events Following Immunization (AEFI)

While taking vaccines is safe, Few children may experience mild side effects such as fever, tenderness at the injection site, or fussiness. These side effects are usually mild and temporary. Serious AEFIs are rare but can occur. The National AEFI Surveillance System in India monitors and investigates AEFIs to ensure vaccine safety . Studies on AEFIs in India have shown that the incidence of serious AEFIs is low. A study in Uttarakhand found an AEFI incidence of 33 per 100 doses of vaccines administered, with fever (47.6%) and swelling (25.0%) being the most common AEFIs.

Contraindications and Precautions

Certain medical conditions may require precautions or contraindicate the administration of specific vaccines. Healthcare professionals should carefully assess the child's health status and medical history before administering any vaccine. Some common contraindications and precautions include

Table 2: World Health Organization (WHO) cause specific definition/ type of AEFIs

TYPE	DESCRIPTION	EXAMPLE
Vaccine product related reaction	An AEFI that is caused or precipitated by a vaccine due to one or more of the inherent properties of the vaccine product.	A common reaction is soreness or redness at the site where the vaccine was administered.
Vaccine quality defect related	An AEFI that is caused or precipitated by a vaccine that is due to one or more quality defects of the vaccine product including its administration device as provided by the manufacturer.	H1N1 flu vaccine by Novartis company; Some batches of the vaccine contained a higher than recommended concentration of the active ingredient (antigen).
Immunization error related reaction	An AEFI that is caused by Inappropriate vaccine handling, prescribing or administration.	Zoster (Shingles vaccine) in United States. The reaction was caused by incorrect administration of the vaccine, where healthcare

		providers mistakenly administered the zoster vaccine intramuscularly (IM) instead of the proper route of subcutaneous (SC) injection.
Immunization anxiety related reaction	An AEFI arising from anxiety about the immunization	Following the launch of COVID-19 vaccines (such as Pfizer-BioNTech, Moderna, and Johnson & Johnson), health authorities reported increased cases of people experiencing anxiety-related reactions such as fainting, dizziness, hyperventilation, and rapid heartbeat when receiving the vaccine.
Coincidental events	An AEFI that is caused by something other than the vaccine product, immunization error or immunization anxiety	The initial association between the MMR vaccine and autism was a coincidental event: some children were diagnosed with autism around the time they received the vaccine, but the two events were unrelated. This example highlights how the timing of an event (in this case, the MMR vaccine and the onset of autism) can sometimes create the appearance of a causal relationship, even though the events are unrelated.

Vaccine Hesitancy in India

Hesitancy of vaccines defined as the delay in receiving or rejection of vaccines despite the availability of immunization services, is a concern in India. Several parameters contribute to the hesitancy of vaccines, like misinformation, not having awareness, and concerns about side effects. Studies have shown that vaccine hesitancy can significantly impact immunization coverage. A study published in MDPI found that % increase in hesitancy can lead to a decreased in vaccination coverage by 30 percent. Fear of adverse effects is the primary driver of vaccine hesitancy.

A meta-analysis of 46 studies covering 65,551 respondents found that the estimated pooled COVID-19 vaccine hesitancy was 31%

In 2019, the World Health Organization declared vaccine hesitancy as one of the top 10 threats to global health. Vaccine hesitancy is a major challenge for immunization programs across the globe.

Vaccine hesitancy is likely to prolong the pandemic, leading to greater damage to the economy and threatening countries' abilities to recover from the current shocks.

The COVID-19 pandemic has interrupted India's immunization progress, disproportionately impacting less-resourced, vulnerable populations.

Despite improvements in vaccination coverage, inequity continues among vulnerable populations in India.

Addressing Vaccine Hesitancy

Healthcare professionals are crucial in addressing concerns about immunization safety and promoting vaccine acceptance. Recommendations from healthcare professionals in India include

- Providing evidence-based information about the safety of vaccines and effectiveness.
- To know individual problems and misunderstandings about vaccines.
- Building trust and rapport with parents and caregivers.

Engaging with communities and addressing cultural beliefs and practices. The concerns leading to hesitancy of vaccines among infants to children who are 0-12 years safety, science, efficacy, side effects, availability, and a belief that they have sufficient immunity to fight.

Methodology

Accurate immunization data is needed to assess coverage of vaccines, safety, and efficacy. We have collected the immunization data of the children aged 0 Months-12 Years and the comparison between partial and total percentage of vaccination in the children of 0 Months-12 Years age as per National immunization schedule estimates about the proportion of children fully vaccinated. We have also collected information from ANMs to estimate the vaccine coverage.

Study Site: Children's hospitals in Narasaraopeta.

Study type: Cross-sectional study.

Study period: 2.5 years

Sample Size: 500 cases.

Inclusion Criteria:

1. Those aged 0- 12 years who are scheduled to receive routine vaccinations at participating healthcare facilities.
2. The study population may be either male or female.
3. List of vaccines that are given to infants as per the National Immunization Schedule.

Exclusion Criteria:

1. Pregnant women are also excluded.
2. People who are uninterested in participating in the study are also excluded.

Results and Discussion

GENDER WISE DISTRIBUTION

The data for Gender wise distribution was summarized in Table 3. In 500 numbers of infant and children, 253 numbers are male and 247 are female. The same was presented as Figure 1.

Gender	Number
Males	253
Females	247

Table 3: Gender-wise Distribution

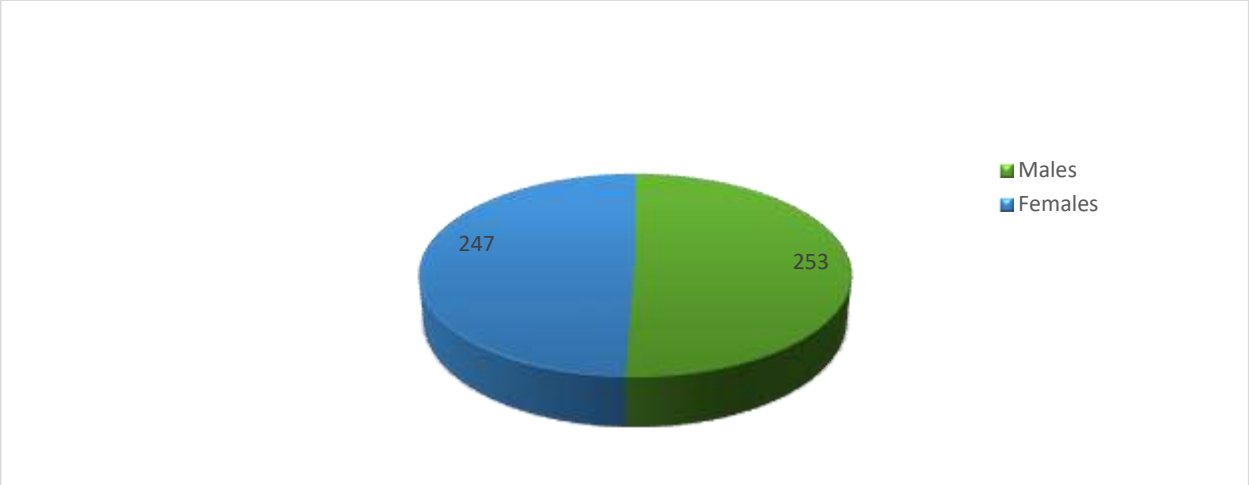

Figure-1 : Gender wise Distribution Chart

AGE WISE DISTRIBUTION

Age wise Distribution is based on the vaccines are given frequently to 0 Months to -12 years of different age groups. Data was presented in Table 4 and Figure 2.

Table 4: Age-Wise Distribution

Age wise distribution	Distribution in number
0-6 Months	80
6-12 Months	156
1-3 Years	76
4-6 Years	146
7-12 Years	42

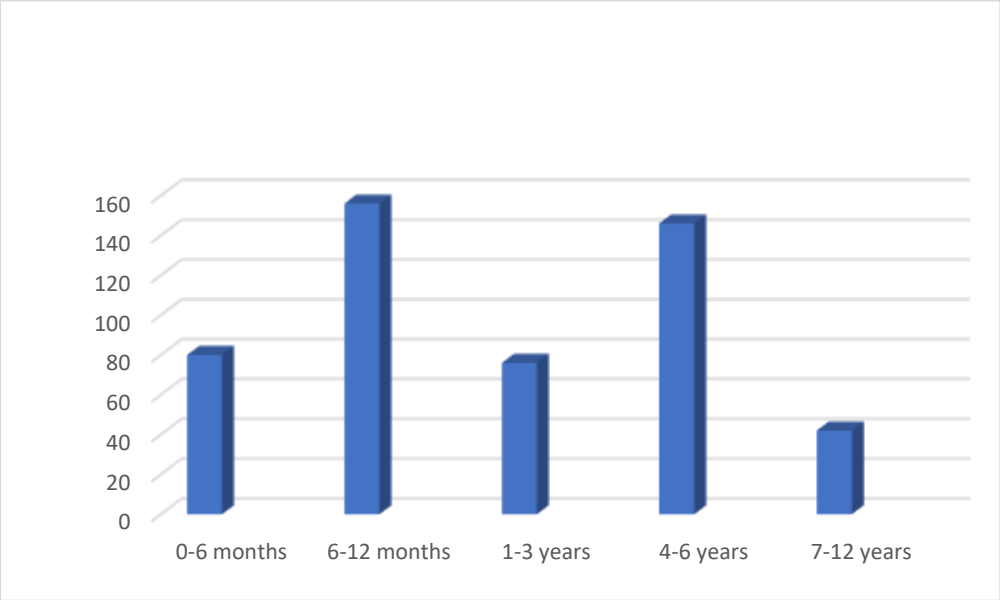

Figure 2: Age-wise distribution

SAFETY EVALUATION FOR IMMUNIZATION IN CHILDREN

Any vaccine can have adverse reactions but they are not that much harmful, they can be treated. Data for intensity of adverse reactions was presented in Table 4 and Figure 3.

Adverse event	No.of cases (n=500)	Percentage (%)
Fever	150	30%
Redness\Swelling at injection site	120	24%
Rash\Hives	40	8%
Vomiting	25	5%
Difficulty breathing	5	1%
Loss of consciousness	2	0.4%
Others	10	2%
No adverse events	188	37.6%
Total	500	100%

Table 5: Safety evaluation for immunization in children

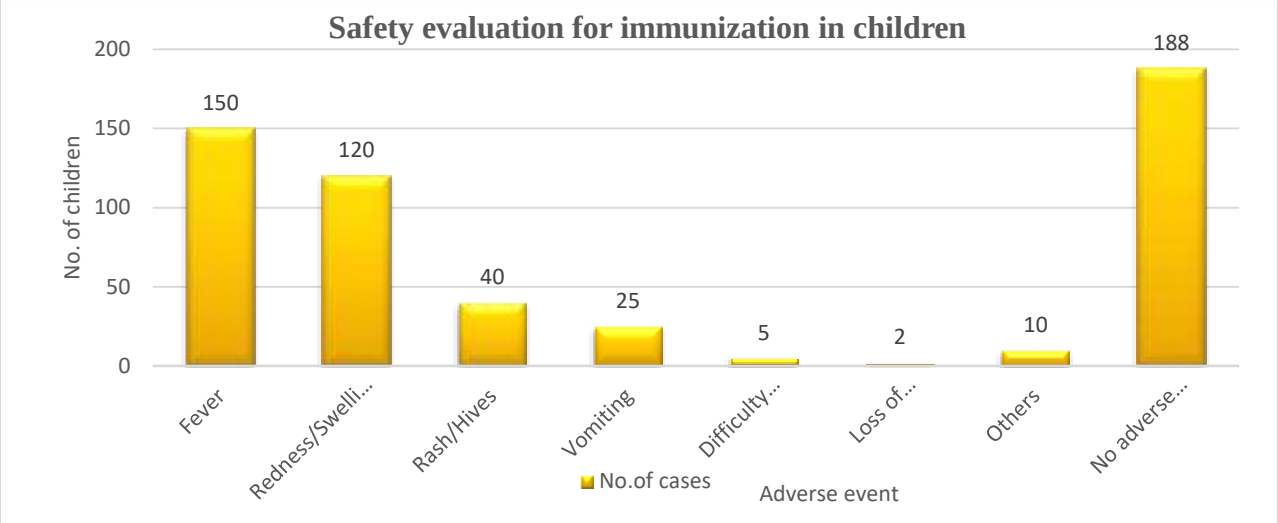

Figure 3: Safety evaluation for immunization in children

INTENSITY OF ADVERSE REACTIONS OF VACCINE

The intensity of adverse reactions to various vaccines administered to children. Most vaccines, such as BCG, Hepatitis-B, and Rotavirus, showed a majority of children with no adverse reactions, with mild reactions being the most common. Pentavalent and MR (1st Dose) vaccines had some reports of severe reactions (10 and 8 cases, respectively), while refusal rates were noted only for BCG and Pentavalent vaccines. Overall, severe reactions were rare, indicating the vaccines are generally safe with mild to moderate adverse reactions being manageable.

Vaccines	Intensity of Adverse Reactions				
	No AD	Mild	Moderate	Severe	Refusal
BCG	383	76	36	0	5
Hepatitis-B	476	16	8	0	0
OPV	316	113	71	0	0
Pentavalent	376	66	30	10	18
Rotavirus	433	50	17	0	0
IPV	416	56	28	0	0
MR 1st Dose	303	123	66	8	0
JE-1st Dose	333	93	64	0	0
Vitamin-A	466	23	11	0	0

Table 6: Intensity of Adverse Reactions of Vaccines

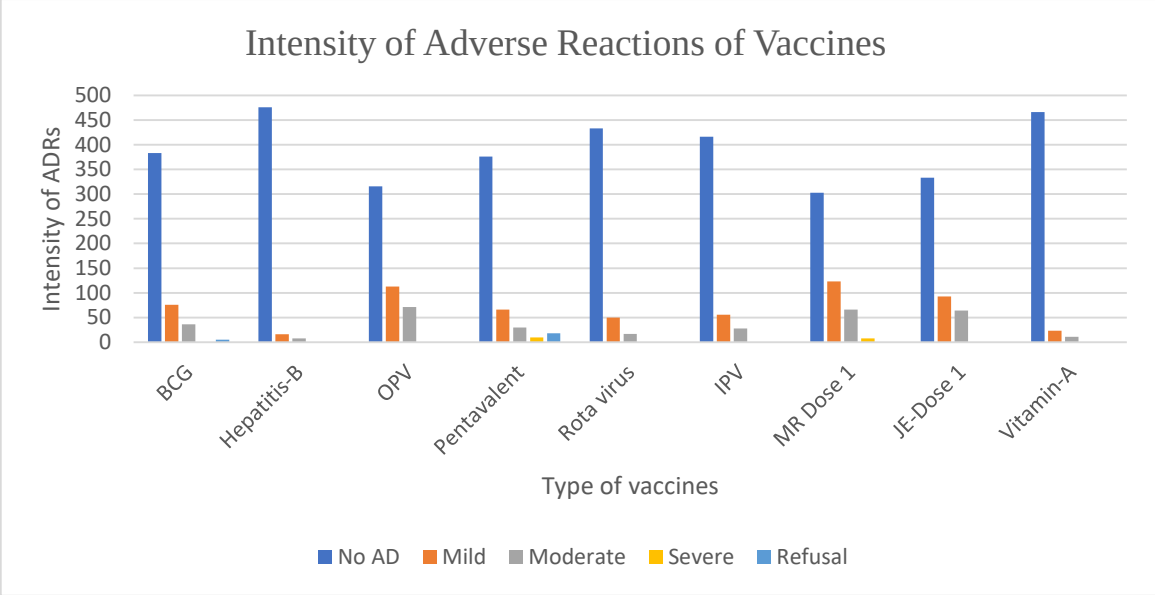

Figure 4: Intensity of Adverse Reactions of Vaccines

VACCINE EFFICACY IN CHILDREN

Vaccine efficacy in 500 children divided into fully immunized (n=300) and partially immunized (n=200) groups across different age ranges. Most children in the 1–3 years age group were fully immunized (90), while the 6–12 months group had a high number of partially immunized children (50). The total number of vaccinated children decreases with increasing age, with the 7–12 years group showing the lowest figures (50 in total). This data highlights a decline in immunization rates in older age groups, emphasizing the need for sustained vaccination efforts.

Age group	Fully immunized (n=300)	Partially immunized (n=200)	Total (n=500)
0-6 Months	50	30	80
6-12 Months	70	50	120
1-3 Years	90	60	150
4-6 Years	60	40	100
7-12 Years	30	20	50
Total	300	200	500

Table 7: Vaccine efficacy in children

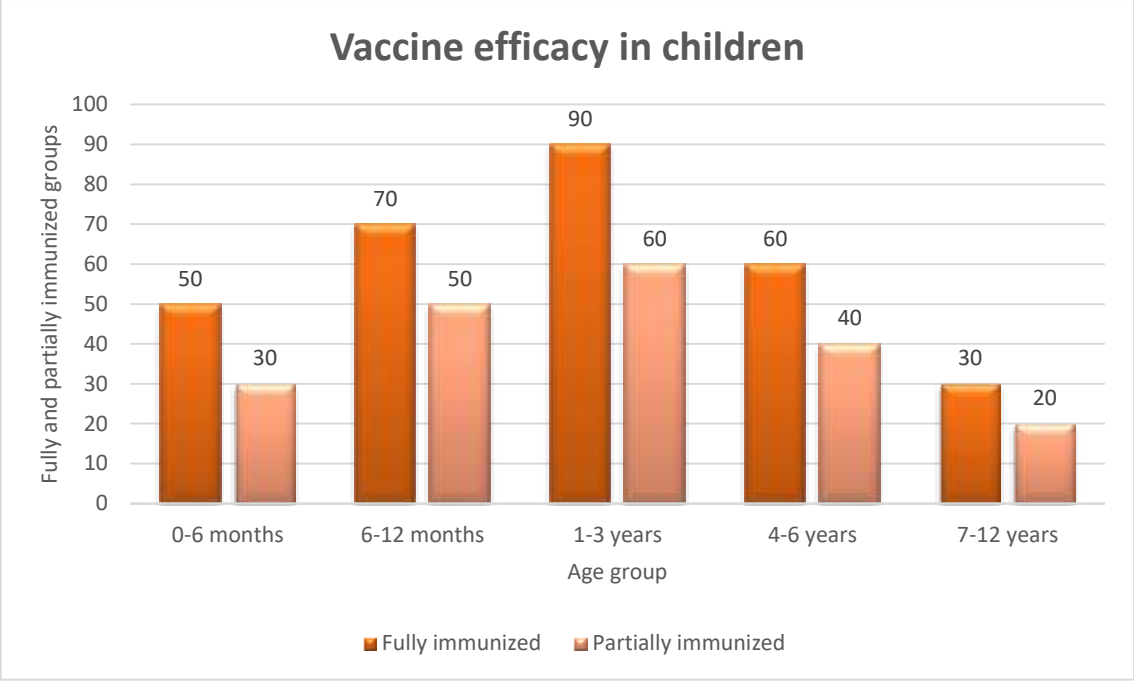

Figure 5: Vaccine efficacy in children

DOSE RESPONSE RELATIONSHIP IN COMBINED VACCINE

The table 6 represents infants aged 0–0.5 years had the highest alteration rate at 10% (15 out of 150 children), possibly due to their developing immune systems. Children aged 0.5–2 years and 2–5 years showed alteration rates of 8% and 10%, respectively, indicating variability in immune responses during early childhood. 6–12 years age group had the lowest alteration rate at 4% (6 out of 150 children), suggesting increased immune system maturity and stability in vaccine response.

Age group	Total children	Children with altered dose response
0-0.5 years	150	15
0.5-2 years	100	8
2-5 years	100	10
6-12 years	150	6

Table 8: Dose response relationship in combined vaccine

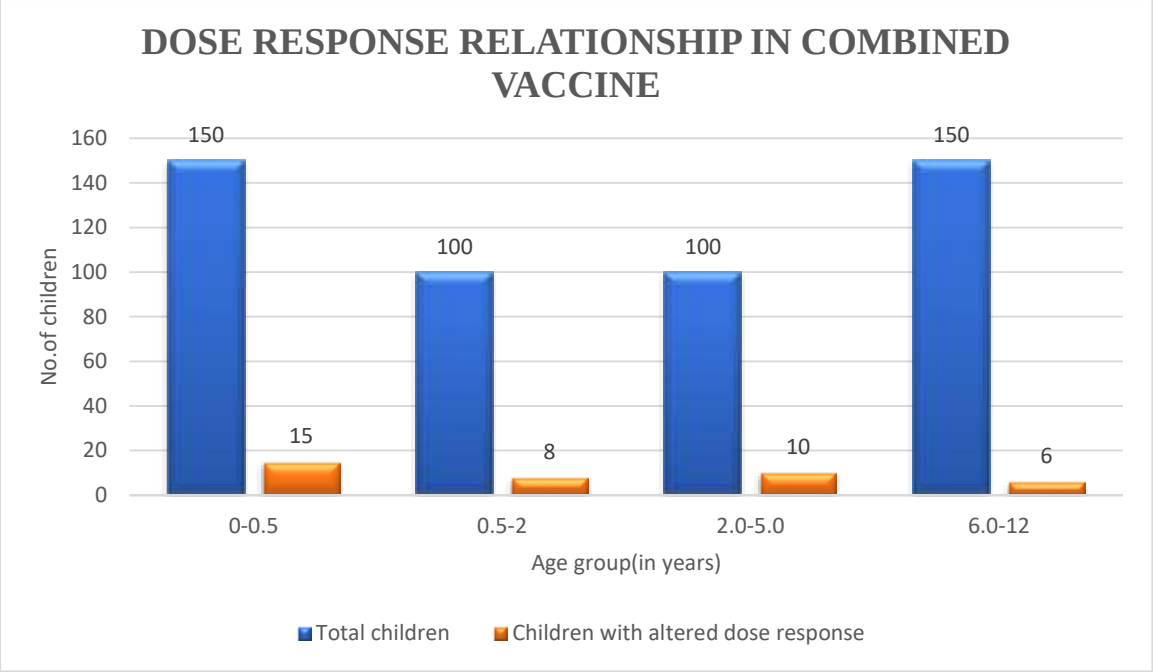

Figure 6: Dose-response relationship in combined vaccine

COMBINATION VACCINES

The table presents the number of children with altered dose response to various combination vaccines. The Hexavalent vaccine (DTaP-HepB-IPV-Hib) shows 15 children with altered responses, while the Pentavalent (DTaP-IPV-Hib) has 8 children affected. The MMRV vaccine (Measles, Mumps, Rubella, Varicella) has 10 children with altered responses, and the Tdap-IPV vaccine (Tetanus, Diphtheria, Pertussis, Polio) has 6 children. These numbers reflect the variability in vaccine effectiveness or reactions in children receiving these combination vaccines.

Table 9: Combination vaccines

Combination vaccine administered	Children with altered dose response
Hexavalent	15
Pentavalent	8
MMRV	10
Tdap-IPV	6

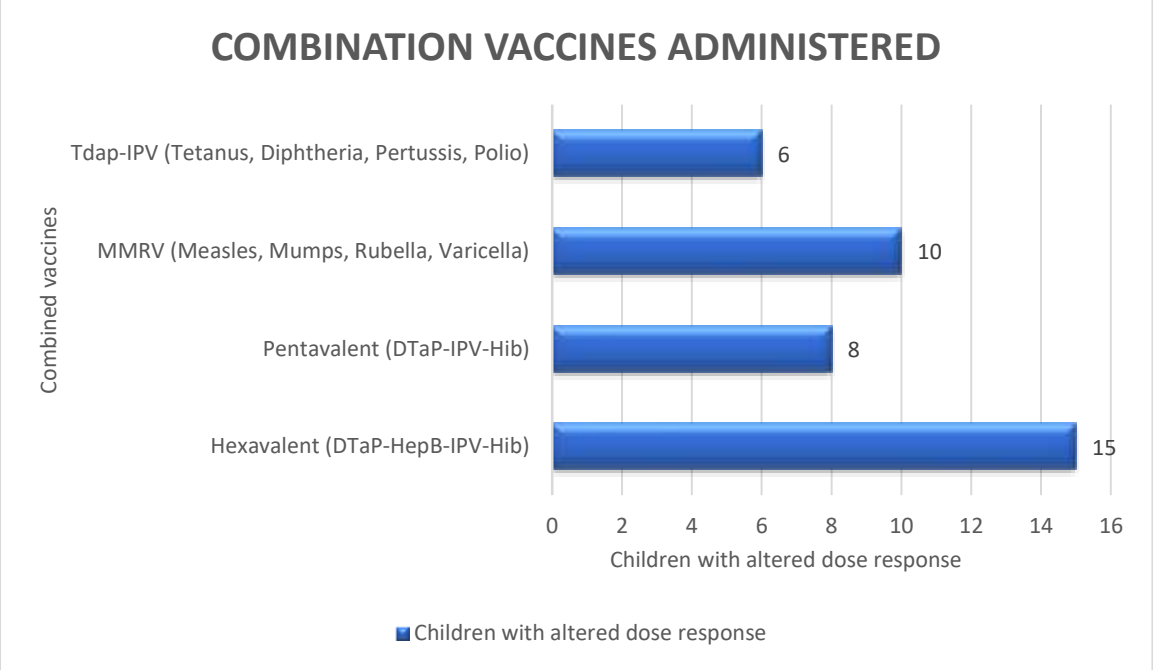

Figure 7: Combination vaccines administered

CO-ADMINISTRATION WITH ROUTINE VACCINE & IT'S ALTERED EFFICACY

The table represents among 500 children, the Hexavalent vaccine had the highest alterations, affecting 45 out of 150 children (30%). The Pentavalent vaccine (DTaP-IPV-Hib) and MMRV vaccine affected 24 (20%) and 20 (20%) children, respectively. The Tdap-IPV vaccine showed alterations in 26 out of 130 children (20%).

Table 10: Co-administered vaccine & altered efficacy

CO-ADMINISTERED VACCINE	CHILDREN ADMINISTERED	ALTERED EFFICACY
Hexavalent (DTaP-HepB-IPV-Hib)	150	45
Pentavalent (DTaP-IPV-Hib)	120	24
MMRV	100	20
Tdap-IPV (Diphtheria, Tetanus, pertussis, Polio)	130	26

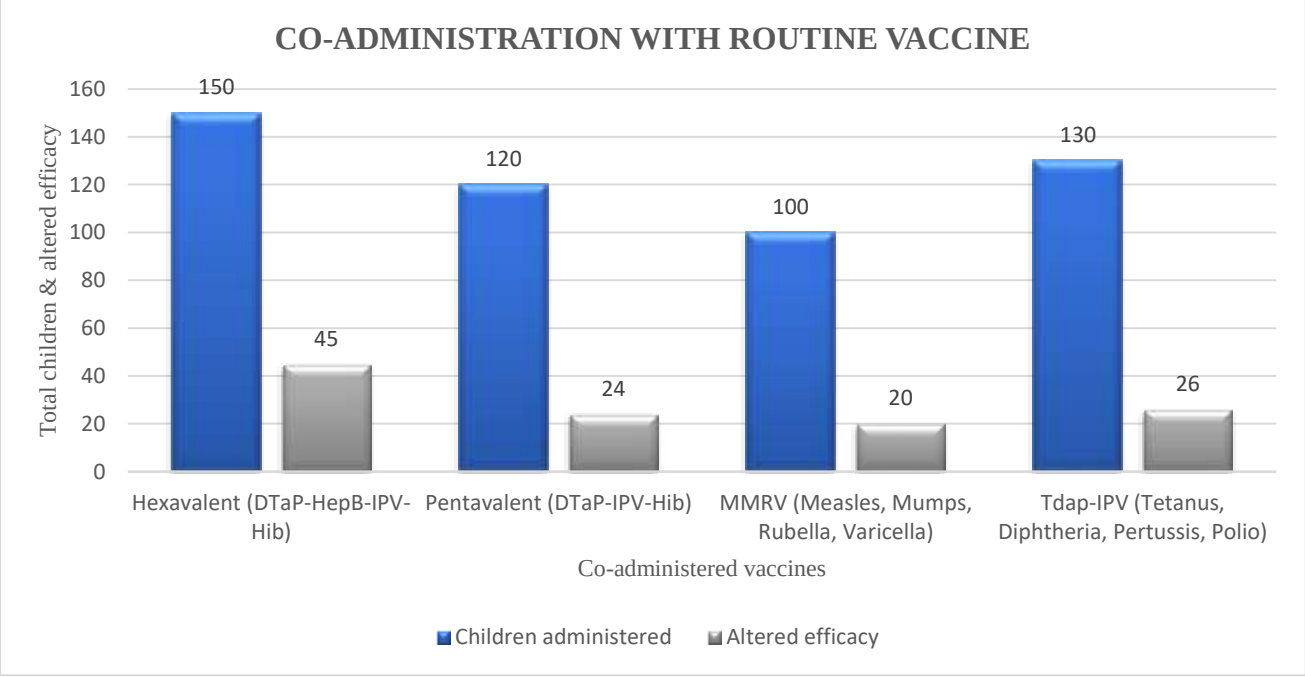

Figure 8: Co-administered vaccine& altered efficacy

Discussion

The study "Safety Evaluation of Immunization in Infants and Children" presents a comprehensive investigation into the safety and efficacy of vaccinations administered to 0 - 12-year-olds. study evaluates AEFI, coverage of immunization, and dose-response relationships. The study, based on data from 500 children, highlights mild to moderate adverse reactions, such as fever and swelling, as the most common outcomes, with severe reactions being rare. The findings emphasize the general safety of vaccines while acknowledging factors

such as socio-economic conditions, parental education, and healthcare accessibility that influence immunization practices and outcomes.

This discussion focuses on two significant aspects of the study. First, the research underlines the importance of continuous AEFI monitoring, not only to assure public trust in immunization programs but also to guide healthcare providers in addressing parental concerns. Second, the study reveals gaps in vaccination coverage, particularly in older age groups, suggesting the need for sustained education and outreach programs to promote vaccine acceptance. The results provide a valuable foundation for policymakers to enhance vaccine safety protocols and improve immunization strategies within diverse communities.

This study included 500 infants and children, consisting of 253 males and 247 females. Among them, 430 were delivered vaginally, and 70 were delivered via cesarean section. Some parents had completed their primary education and were well-informed about immunization and its importance, ensuring that their children received vaccinations on time. However, other parents, who had not received an education, were initially hesitant due to fears of side effects and delayed the vaccination process. The study found that mild to moderate adverse reactions, such as fever, inflammation at the injection site, & rashes were observed after most vaccinations and were treated accordingly. Severe reactions, including febrile seizures, were noted after the pentavalent vaccine and the first dose of the MMR vaccine. These cases required consultation with a specialist at an immunization clinic or a neurologist for treatment.

Conclusion

Immunization is a critical public health intervention that has significantly improved child health in India. While immunization has to do with the safety of vaccines are understandable, the evidence supports the safety and efficacy of vaccines. The National Immunization Schedule in India provides a comprehensive framework for protecting children against preventable diseases. The government is committed to seeing vaccine safety, as demonstrated by increased investment in the AEFI system. The System monitors vaccine safety and investigates all the potential adverse events. The AEFI Secretariat has achieved a high level of quality, as evidenced by its quality certification under the National Quality Assurance Standards (NQAS). Healthcare professionals play a decisive role in promoting vaccine confidence and addressing vaccine hesitancy. They can provide evidence-based information, address individual concerns, and engage with communities to ensure that all children in India receive full benefits of immunization. Despite the challenges posed by vaccine hesitancy and inequities in access, India has made significant progress in increasing immunization coverage and reducing child mortality. Continued efforts to strengthen the immunization program, address hesitancy of vaccines, and ensure equitable access to vaccines are essential to protect all children in India from preventable diseases.

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