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Purple Book

IAP Guidebook on Immunization 2025

By Advisory Committee on Vaccines and
Immunization Practices (ACVIP)

5th Edition

Editors

**Digant D Shastri
Shashi Kant Dhir**

Forewords

**GV Basavaraja
Vasant Khalatkar
Neelam Mohan
Upendra Kinjawadekar
Yogesh N Parikh**



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CHAPTER

Immunization in India: Past, Present, and Future

Raman Gangakhedkar, M Indra Shekhar Rao

■ INTRODUCTION

Immunization is one of the most cost-effective public health interventions and is largely responsible for the reduction of the under-five mortality rate, and indeed, is one of the strong pillars of child survival. Of the estimated 1.2 million deaths that occur among children under five annually in India, over 400,000 could be attributed to vaccine-preventable diseases (VPDs) in 2017.

■ STORY SO FAR

India and China were two countries where “some form of inoculation” was practiced even before the 16th century. However, modern immunization developed in India in the 19th century, parallel to the Western world. The Compulsory Vaccination Act was passed in India in 1892 to ensure higher coverage with smallpox.

In 1904–1905, the Central Research Institute was set up in Kasauli, Himachal Pradesh, and then the Pasteur Institute in Coonoor in 1907. The Pasteur Institute of India produced the neural tissue antirabies vaccine in 1907, subsequently developed influenza vaccines, trivalent oral polio vaccines (OPVs), and first tissue culture, and then Vero cell-derived rabies vaccine. As early as 1955–1956, the bacillus Calmette–Guérin (BCG) vaccination mass campaign was initiated in India.

In 1958, World Health Assembly (WHA) passed a resolution to eradicate smallpox; India started National Smallpox Eradication Programme (NSEP) in 1962, and universal vaccination of entire population within 3 years was planned in two phases—attack phase with 80% coverage of population followed by maintenance phase to include all newborns, infants, and children.

The last case was reported in 1975 from West Bengal, but surveillance continued thereafter. The world was declared free from smallpox on May 8, 1980, by the World Health Assembly.

The Pasteur Institute of India developed an influenza vaccine in 1957, the beta-propiolactone (BPL) inactivated rabies vaccine, and trivalent OPV in 1970. There were nearly 19 vaccine-manufacturing units in the public sector and 12 in the private sector in 1971.

Universal Immunization Programme (UIP) is one of the largest public health programs. Routine immunization (RI) targets to vaccinate 29 million newborns each year, with all primary doses, nearly 100 million children of 1–5 years of age with booster doses of UIP vaccines, and 30 million pregnant mothers are targeted for tetanus toxoid (TT) vaccination each year. Recognizing the importance of vaccine-preventable illnesses on morbidity and mortality, the Government of India accorded high primacy to full vaccine coverage. In 2014, Mission Indradhanush was launched to reach the missed-out and dropped-out children and pregnant women across India with an objective of achieving overall coverage of 90% by 2022. The initial missions focused on high and medium-priority districts in India. According to the National Family Health Survey-5 (NFHS-5) (2019–21), the overall vaccination coverage was 76.6%, perhaps a reflection of the coronavirus disease 2019 (COVID-19) pandemic. The estimated number of zero-dose children before COVID was 1.3 million, and it increased to 2.7 million and 1.6 million in 2021 and 2022, respectively. Intensified Mission Indradhanush 5.0 among children under 5 was launched in all districts between August and October 2023 in response to the estimates. It has raised the overall full immunization coverage to 93.5% for FY 2023–24.

India has an annual birth cohort of about ~2.67 crores. Most of the immunization sessions are focused on rural areas. According to NFHS-4, about 90.7% of vaccinations in India are provided through the public sector, while the private sector contributed to only 7.2%. **(Table 1)**. However, the private sector played an important role in providing newer vaccines. The private sector's share in providing vaccines covered under UIP between 2012 and 15 based on data

TABLE 1: Vaccine milestones in India.

Year	Vaccine	Milestone remarks
1985	BCG, DPT, OPV, and MCV	The Universal Immunization Programme (UIP) was launched with six antigens
2002	Hepatitis B—pilot	Hepatitis B vaccine launched as a pilot program in 33 districts and 14 metropolitan areas
2006–2010	JE	JE vaccine added to the UIP in selected endemic districts in a phased manner
2007–2011	Hepatitis B—scale up	Hepatitis B vaccination scaled up to cover 10 additional states in India
2010	MCV2 + rubella	MCV2 (in the form of measles-rubella vaccine) was added to the UIP in 21 states (in the remaining 14 states, a catch-up campaign was initiated for children aged 9 months to 9 years)
2011	Hib-83	Hib vaccine introduced as the pentavalent (DPT + Hib + HepB) vaccine in two states (Tamil Nadu and Kerala)
2016	Human papilloma-virus-84	Pilot program launched by state governments in Delhi and Punjab
2016–2018	Rotavirus-85	Introduced in two phases in nine states (Andhra Pradesh, Haryana, Himachal Pradesh, Odisha, Assam, Madhya Pradesh, Rajasthan, Tamil Nadu, and Tripura)
2017–2019	PCV-86	• PCV introduced in selected high-burden districts in six states (Bihar, Uttar Pradesh, Haryana, Himachal Pradesh, Rajasthan, and Madhya Pradesh) • 2024 HPV vaccinations start in Sikkim, Bihar, Tamil Nadu

(BCG: bacillus Calmette–Guérin; DPT: diphtheria, pertussis, and tetanus; HepB: hepatitis B; Hib: *Haemophilus influenzae* type b; JE: Japanese encephalitis; MCV: measles-containing vaccine; MCV2: measles-containing vaccine dose 2; OPV: oral polio vaccine; PCV: pneumococcal conjugate vaccine)

from IQVIA was as follows; BCG (19.2%), Hepatitis B (5.8%), OPV (5.5%), DPT (2.7%), Measles (2.2%), HiB pentavalent (11.1%) and for newer vaccines, such as pneumococcal conjugate vaccine (PCV), rotavirus, hepatitis A and typhoid it was 100%.

BACKGROUND NOTES AND PRESENT STATUS OF IMMUNIZATION

In 1978, after the Alma-Ata declaration aimed at immunizing all children, the Expanded Programme on Immunization (EPI) was launched in 1978. It was renamed as UIP in 1985, when its reach was expanded beyond urban areas. In 1992, it became part of the Child Survival and Safe Motherhood Programme, and in 1997, it was included in the ambit of the National Reproductive and Child Health Programme. Since the launch of the National Rural Health Mission in 2005, UIP has always been an integral part of it.

The UIP is one of the largest public health programs targeting close to 2.67 crore newborns and 2.9 crore pregnant women annually, with all primary doses, nearly 100 million children of 1–5 years of age with booster doses of UIP vaccines, and 30 million pregnant mothers are targeted for TT vaccination each year. The Universal Immunization Program (UIP) provides vaccines at no-cost to children against tuberculosis, diphtheria, tetanus, and pertussis (DTP), Polio, Hepatitis B, Pneumonia, and Meningitis due to *Haemophilus influenzae* type b (Hib), measles, rubella, Japanese encephalitis (JE), pneumococcal pneumonia, human papillomavirus (HPV) diseases, and rotavirus diarrhea. (Rubella, JE, and HPV vaccine in selective states and districts).

A child is said to be fully immunized if the child receives all due vaccines as per the national immunization schedule within the first year of age.

According to the World Health Organization (WHO), zero-dose children are those who have not received any RI services, with an operational definition as those who did not receive the first dose of the DPT vaccine of a child. The two major milestones of UIP have been the elimination of polio in 2014 and maternal and neonatal tetanus elimination in 2015.

The new vaccines introduced in recent years are:

- Inactivated polio vaccine (IPV), November 2015–April 2016.
- *Rotavirus vaccine (RVV)*: In March 2016, and expanded across the country in 2019–20.
- *Measles rubella (MR) vaccine*: Introduced in the country through a campaign mode in 2017, followed by two doses in RI at 9–12 months and 16–24 months.
- *PCV*: Launched in May 2017 and now expanded to the entire country
- *Tetanus and adult diphtheria (Td) vaccine*: Which replaced the TT vaccine in UIP to limit the waning immunity against diphtheria in older age groups. Td vaccine is to be administered to adolescents at 10 and 16 years of age and to pregnant women.
- *HPV vaccine*: Introduced in a phase-wise manner in selected states for girls between 9 and 14 years (two doses).

Immunization Coverage in India

The immunization coverage in India is described in **Table 2**.

TABLE 2: The immunization coverage in India.

<i>Antigens/vaccines</i>	<i>Coverage (%)</i>			
	<i>2000</i>	<i>2010</i>	<i>2020</i>	<i>2023</i>
BCG	58	79	85	89
DTP3	—	38	85	91
HepB3	56	82	85	91
MCV1	—	—	89	93
MCV2	85	87	81	90
PAB	85	76	90	93
Pol3	—	—	85	91
Rotavirus	—	—	82	90
Hib3	—	—	85	91

(BCG: bacillus Calmette–Guérin; DTP: diphtheria, tetanus, and pertussis; HepB: hepatitis B; MCV: meningococcal vaccine; PAB: protection-at birth; Pol: polio; Hib: *Haemophilus influenzae* type B)

■ THE ROAD AHEAD AND THE FUTURE

Political and Bureaucratic Will

Such an elaborate National program obviously needs political and bureaucratic support at all levels. “Inter Agency Coordination Committee (ICC)” needs to increase its focus on RI. A public-private partnership (PPP) between government of India (GoI), National Technical Advisory Group on Immunization (NTAGI), Indian Academy of Pediatrics (IAP), Indian Medical Association (IMA), development partners, Integrated Child Development Services, Ministries of Railways, Education and Defense, and key nongovernmental organizations (NGOs) involved with immunization and State representation should be strengthened and monitored funds.

Program Monitoring

Vaccination is an essential preventive medical intervention; the vaccination program is not simply a medical modality—it is a management-dominant modality. The managerial, administrative, and governance-related aspects have been prioritized for high vaccine coverage rates across India.

Effective Surveillance Systems

Universal Immunization Programme is an opportunity to establish a surveillance system for all important childhood infectious diseases, as has been demonstrated by the experience of acute flaccid paralysis (AFP) and neonatal tetanus surveillance network in India. Additionally, efficient surveillance systems have also been established and ably supported through identified laboratory support against polio (10 laboratories), measles and rubella (28 laboratories), and pertussis (20 laboratories).

■ PROCESS ADOPTED TO INCLUDE NEW VACCINES INTO PROGRAM

The NTAGI is the highest body of independent experts that reviews data on the national disease burden, efficacy, and cost-effectiveness of newer vaccines available globally and locally for introduction into

the program. NTAGI is supported by the NTAGI secretariat through the Immunization Technical Support Unit (ITSU) located in the National Institute of Health & Family Welfare (NIHFW), New Delhi. NTAGI recommends a new vaccine to be introduced in the UIP based on the evidence to the Ministry of Health & Family Welfare, Government of India.

ADVERSE EFFECTS, DETECTION, REPORTING, CAUSALITY ASSESSMENT, AND REDRESSAL SYSTEM

Having a functional real-time reporting adverse events following immunization (AEFI) and postmarketing surveillance system helps in generating national data, identify a new unsolicited adverse event and may be useful to allow compensation claims for vaccination-related injuries and serious adverse events should the need arise. This will also provide sound basis for decisions to modify or abandon certain vaccine preparations based on reactogenicity profile. The AEFI mechanism has been in place since 1988 in India. These guidelines were revised in 2005, 2010, 2015, and 2024. Once an AEFI is reported, the assessments for severity—common minor, severe, and serious AEFI, and cause-specific type of AEFI are made. There are five cause-specific types of AEFI reactions, namely, (1) vaccine product-related, (2) vaccine quality defect-related, (3) immunization error-related, (4) immunization anxiety-related, and (5) coincidental events. The Medical Officer reports serious/severe AEFI in a Case Reporting Format to the District Immunization Officer, who in turn passes it to the State and Central Authorities. This AEFI data is accessed by the Pharmacovigilance Program of India (PvPI) for detecting signals of any new adverse event or its frequency to inform the government, regulators, and put it in product inserts for people. Vaccine providers in the private sector are also expected to inform of such events.

REGULATORY AND ETHICAL ISSUES

The existing National Regulatory Authority (NRA) of the country is reliable and fully functional. Currently, the Indian NRA, i.e., the Central Drug Standards Controller Organisation (CDSCO), PvPI, and

Immunization division in the Ministry of Health & Family Welfare, and AEFI Secretariat review these data for taking appropriate action. India does not have a vaccine-specific NRA to oversee different issues related to vaccines, such as licensing, postmarketing surveillance, including AEFI surveillance, batch release process, laboratory support for vaccine testing, regulatory inspections of Good Manufacturing Practices (GMPs), authorization and approval of clinical trials, etc.

SUPPORT TO INDIGENOUS VACCINE INDUSTRY, RESEARCH AND DEVELOPMENT

Most low-cost traditional vaccines are now produced by vaccine manufacturers in India. Currently, about 43% of the global UIP vaccines come from India, and the Serum Institute is the world's leading producer of the UIP vaccines. Investment in research and development is bound to pay rich dividends. A large number of vaccine products are currently in the pipeline and are expected to become available in the near future. According to recent unpublished data, >80 candidate vaccines are in the late stages of clinical testing. About 30 of these candidate vaccines aim to protect against major diseases for which no licensed vaccines exist, such as malaria and dengue. Vaccines manufactured in India include COVID vaccines, RSVs, PCV, Japanese encephalitis vaccines, and the 4HPV vaccine by the Serum Institute of India, which recently received market authorization. Dengue vaccines are also in various phases of development in India.

The current national vaccine policy is supportive of the Indian vaccine industry with liberal support from government-owned institutions such as the Department of Biotechnology (DBT), the Indian Council of Medical Research, and the Department of Science and Technology (DST).

INTEGRATED DELIVERY OF HEALTH INTERVENTIONS

Strengthening of immunization systems so that they support and integrate with other preventive health services, such as providing vitamin A supplementation, deworming, growth monitoring, and

distribution of insecticide-treated bed nets, offers the opportunity to create synergies and facilitate the delivery of services to bolster comprehensive disease prevention and control. Incorporating immunization into integrated primary healthcare programs may also facilitate social mobilization efforts, help to generate community demand for services, and address equity issues. The strategy of child health days, led by the United Nations International Children's Emergency Fund (UNICEF), has also helped to promote RI.

■ FUTURE DIRECTIONS

The COVID-19 pandemic and rapid vaccine development against it by Indian vaccine manufacturers with the support of the Government have demonstrated our capacity to develop and manufacture vaccines to supply not only Indians but to other less developed countries. As a component of pandemic preparedness, India has managed to develop newer vaccine technology platforms such as mRNA, DNA, protein subunit, and vector-based vaccines. It has established a clinical trial network for undertaking various phases of vaccine trials across India at short notice. Currently, various dengue vaccines are undergoing trials in India. India is poised to introduce the HPV vaccine in the country.

■ CONCLUSION

India is on a strong path when it comes to promoting the health, economic, and social well-being of its citizens. The Indian government will do well to dedicate itself to continuing to expand its coverage, expand the number of vaccines in UIP, and expand its manufacturing industries. This must be done to ensure sustainable gains in the reduction of morbidity and mortality due to VPD and lifespan. For a further comprehensive understanding of this topic the readers are advised to go through the standard resources.¹⁻⁸

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IAP Guidebook on Immunization 2025

Salient Features

- An updated and revised guidebook with detailed information on various aspects of immunization.
- Practical guidelines on vaccine administration, storage, and handling (including cold chain equipment)
- Latest National Immunization Schedule and Indian Academy of Pediatrics (IAP) Immunization Time Table 2025
- New section on; “Newer Kids on the Block”, details of vaccines which are already licensed and used globally and likely to be in the Indian market in the near future.
- User- friendly format
- “Ideal Immunization Clinic”, Vaccine preparedness for the pandemic, revised AEFI form have also been added.

ACVIP Vaccine Helpline for all

- Advisory Committee on Vaccines and Immunization Practices (ACVIP) vaccine helpline is now fully functional and anyone may post their vaccination related queries at the ACVIP website.
- Please log on to <https://acvip.org/professional/contact-us/index>.
- Enter the details requested, Type the Question and Send
- The response to your query will be given by members of the ACVIP, based on national and international recommendations via email at earliest.

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