



# Indian Academy of Pediatrics (IAP) Advisory Committee on Vaccines and Immunization Practices (ACVIP): Recommended Immunization Schedule (2025) and Update on Immunization for Children Aged 0 Through 18 Years

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## Abstract

**Justification** Recent advancements in vaccinology and the introduction of new vaccines warrant a revision of the existing immunization guidelines.

**Objectives** To review and revise the IAP recommendations (2023) on immunization of children aged 0 to 18 years and issue recommendations on existing and new vaccines.

**Process** The Advisory Committee on Vaccines and Immunization Practices (ACVIP) of the Indian Academy of Pediatrics (IAP) discussed the updates and drafted evidence-based consensus recommendations after several rounds of meetings convened both in-person and virtually. The contents were finalized during the meeting held at the IAP Office, Navi Mumbai, on November 23, 2025.

**Recommendations** The major changes include recommendation of replacing the quadrivalent (A/H1N1, A/H3N2, B/Victoria, B/Yamagata) influenza vaccines with trivalent (A/H1N1, A/H3N2, B/Victoria) influenza vaccines. The use of nirsevimab for respiratory syncytial virus is recommended for high-risk cases, after consultation with the parents. Immunocompetent girls aged 9 to 15 years may receive a single dose of the human papilloma virus (HPV) vaccine. A 5-dose intramuscular rabies vaccination schedule administered on days 0, 3, 7, 14, and 28 is recommended for post-exposure prophylaxis (PEP), along with rabies immunoglobulin (RIG) or rabies monoclonal antibody (RMAb) based on the category of exposure.

**Keywords** Guidelines · HPV vaccine · Influenza vaccine · Rabies vaccine · RSV monoclonal antibodies

The Advisory Committee on Vaccines and Immunization Practices (ACVIP) of the Indian Academy of Pediatrics (IAP) convened through both in-person and virtual meetings to comprehensively review and update the previous IAP-ACVIP Guidelines (2023). During these deliberations, the recent and emerging scientific evidence and their practical implications for pediatric immunization practices in India were critically examined. Based on these discussions, the revised recommendations were formulated, culminating in the updated IAP Immunization Guidelines for 2025.

The aim was to equip that healthcare professionals with current, evidence-based recommendations to inform vaccination practices and optimize immunization strategies,

ultimately contributing to improved public health outcomes. The primary objective of these meetings was to integrate the latest scientific research and expert insights into pragmatic, contextually relevant immunization guidance.

This document presents the consensus recommendations developed after comprehensive literature review, structured debates, and detailed discussions conducted during both the in-person and virtual meetings.

## Process

The recommendations were developed following a comprehensive review of recently published literature, including vaccine clinical trials, as well as guidance

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from reputed international advisory bodies such as the Advisory Committee on Immunization Practices (ACIP), Centers for Disease Control and Prevention (CDC), American Academy of Pediatrics (AAP), and World Health Organization (WHO). Relevant unpublished data were also sought from researchers and vaccine manufacturers by personal communication to ensure that the emerging evidence was considered.

A systematic literature search was conducted using database-specific controlled vocabularies—Emtree (Embase), MeSH (PubMed), Scopus terms, CINAHL headings, and the Cochrane Library. Retrieved studies were critically appraised for scientific rigor and strength of evidence. Data from meta-analyses, systematic reviews, and randomized controlled trials were extracted to develop evidence-based statements. Particular emphasis was placed on studies conducted in India, and available indigenous data were accorded priority wherever applicable.

A series of physical and virtual meetings were convened to discuss the updates and formulate new recommendations. The physical meetings were held on March 16, 2024 (Kolkata), December 8, 2024 (Bhubaneswar), April 5, 2025 (Kolkata), and November 22–23, 2025 (Navi Mumbai). Multiple online meetings—facilitated through Editorial Manager® and ProduXion Manager® (Aries Systems Corporation)—were also conducted to enable detailed discussions and iterative revisions. Consensus among members of the IAP-ACVIP was achieved through structured deliberations. Representatives of various vaccine manufacturing companies presented their data in various meetings but none of them were involved in formulating the recommendations. The list of

members who attended the physical meetings is given in [Appendix](#). The recommendations were finalized during a physical meeting held at the IAP Office in Navi Mumbai on November 22–23, 2025.

## Recommendations

A summary of the key updates in the IAP-ACVIP 2025 recommendations is presented in [Table 1](#). The IAP-ACVIP 2025 recommendations for routine vaccines and newer vaccines are presented in [Tables 2 and 3](#), respectively. [Figure 1](#) depicts the routine immunization schedule for children aged 0–18 years.

## Influenza Vaccines

Influenza remains a major cause of illness, hospitalization, and death in children worldwide. Over the past two decades, there have been progressively expanded recommendations for pediatric influenza vaccination. The recent recommendation of the WHO and the AAP for the season 2025–2026 recommend a switch from the quadrivalent to trivalent influenza vaccines based on robust global surveillance evidence showing the apparent extinction of the B/Yamagata lineage globally from 2020 onwards [2]. Ongoing virologic and genetic surveillance through platforms such as the Global Initiative on Sharing All Influenza Data (GISAID) and WHO FluNet has not demonstrated sustained community transmission of influenza B/Yamagata lineage viruses in recent years

**Table 1** Changes in the IAP-ACVIP Immunization Guidelines 2025

### Influenza Vaccines

The quadrivalent (A/H1N1, A/H3N2, B/Victoria, B/Yamagata) Influenza vaccines are to be replaced with trivalent (A/H1N1, A/H3N2, B/Victoria) influenza vaccines

### Respiratory Syncytial Virus (RSV) Monoclonal Antibody-Nirsevimab

As of now, making recommendations for the universal use of Nirsevimab for all infants is not possible

Until robust epidemiological data on RSV infection in infants and young children in India is available, the use of nirsevimab may only be restricted for high-risk cases, after consultation with the parents

### Human Papillomavirus Vaccine (HPV)

IAP-ACVIP recommends that immunocompetent girls of 9 up to 15 years can be given a single dose of HPV vaccine for sustained protection 9–up to 15 years of age (boys): Two-dose schedule (0.5 mL at 0 and 6 months). The interval between the 1st and 2nd dose should not be < 5 months

For children more than 15 years, and immunocompromised children of any age, three doses are to be given

The second dose should be administered at least 1 month after the first dose, and the third dose should be administered at least 3 months after the second dose

### Rabies Vaccine

IAP ACVIP recommends 5-dose IM schedule of rabies vaccine on days 0,3,7,14,28 for post-exposure prophylaxis along with Rabies Immunoglobulin/Rabies Monoclonal Antibodies as per category of bite



**Table 2** IAP-ACVIP Immunization Timetable 2025: Vaccines for Routine Use

Age	Vaccine	Comments
Birth	BCG, OPV, Hep B-1 (BD)	BCG: before discharge OPV: as soon as possible after birth Hepatitis B vaccine: administered within 24h of birth
6 weeks	DTwP/DTaP-1, IPV-1 Hib-1, Hep B-2, Rotavirus-1, PCV-1	DTwP or DTaP may be administered in primary immunization IPV: 6–10–14 weeks is the recommended schedule. If IPV, as part of a hexavalent combination vaccine, is unaffordable, the infant should be sent to a government facility for primary immunization as per universal immunization program
10 weeks	DTwP/DTaP-2, IPV-2, Hib-2, Hep B-3, Rotavirus-2, PCV-2	RV1: 2-dose schedule; all other rotavirus brands: 3-dose schedule
14 weeks	DTwP/DTaP-3, IPV-3, Hib-3, Hep B-4, Rotavirus-3 PCV-3	An additional 4th dose of Hep B vaccine is safe and is permitted as a component of a combination vaccine
6 months	Influenza (IIV)–1	Uniform dose of 0.5 ml $\geq$ 6 months
7 months	Influenza (IIV)–2	To be repeated every year, till 5 years of age
6–9 months	Typhoid Conjugate Vaccine	There is no recommendation for a booster dose
9 months	MMR-1	
12 months	Hepatitis A Vaccine	Single dose for live attenuated vaccine
15 months	MMR-2, Varicella-1, PCV-booster	
16–18 months	DTwP/DTaP-B1, Hib-B1, IPV-B1	
18–19 months	Hepatitis A-2, Varicella-2	Only for inactivated hepatitis A vaccine
4–6 years	DTwP/DTaP-B2, IPV-B2, MMR-3	
9-up to 15 years	HPV	Immunocompetent girls—single dose 9–up to 15 years of age (boys*): Two-dose schedule (0.5 mL at 0 and 6 months)
10 years	Tdap	Tdap is to be administered even if it has been inadvertently administered earlier (as DTP-B2)
15–18 years	HPV	15–26 years of age (females and males*) and immunocompromised: 3-dose (0.5 mL at 0, 2, and 6 months) schedule
16–18 years	Td/Tdap	

Age in completed weeks/months/years

\*Cervavac 4® (by SII) is approved for use in males from 9 to 26 years, Gardasil-9® (by MSD) is approved for use in boys from 9 to up to 15 years.

BCG Bacillus calmette-guérin, BD Birth dose, DTwP Diphtheria (full strength), Tetanus, and whole-cell pertussis, DTaP Diphtheria (full strength), Tetanus, and acellular Pertussis, IPV-Inactivated polio vaccine, Hep B Hepatitis B vaccine, Hib Hemophilus influenzae type b, OPV Oral polio vaccine, PCV Pneumococcal conjugate vaccine, RV Rotavirus vaccine, IIV Inactivated influenza vaccine, MMR Measles, Mumps, and Rubella, B Booster, HPV Human papillomavirus vaccine, Tdap Tetanus, diphtheria (reduced strength), and acellular pertussis, Td Tetanus, diphtheria (reduced strength)

[3]. Isolated reports have largely been linked to vaccine-related detections or laboratory artifacts.

As the B/Yamagata lineage has not demonstrated sustained circulation in recent years, its continued inclusion in seasonal formulations confers no additional protective advantage while adding to manufacturing complexity and potential costs. Excluding the B/Yamagata component also streamlines production and minimizes theoretical concerns related to vaccine-derived detections [4]. The trivalent vaccine—comprising two influenza A strains (H1N1 and H3N2) and one B/Victoria strain—provides protection that is appropriately matched to currently circulating viruses.

This epidemiological transition, supported by expert consensus, has prompted the World Health Organization and other leading public health authorities to recommend a return to trivalent influenza vaccines for improved programmatic efficiency and cost-effectiveness while maintaining optimal strain coverage [2, 5–7]. This update ensures that immunization strategies remain aligned with the prevailing viral landscape.

### IAP-ACVIP Recommendation

- The quadrivalent (A/H1N1, A/H3N2, B/Victoria, B/Yamagata) influenza vaccines can be replaced with trivalent (A/H1N1, A/H3N2, B/Victoria) influenza vaccines.



**Table 3** IAP-ACVIP Recommendations on Newer Vaccines**Pentavalent Meningococcal Polysaccharide-Conjugate Vaccine**

Meningococcal conjugate vaccine is recommended for use only in special situations, as published earlier by ACVIP

**Hepatitis A Vaccines- Havisure**

This vaccine is recommended for the prevention of Hepatitis A in children  $\geq 12$  months of age in a 2-dose schedule of 0–6 months

**Respiratory Syncytial Virus Monoclonal Antibody-Nirsevimab**

As of now, making recommendations for the universal use of Nirsevimab for all infants is not possible

Until robust epidemiological data on RSV infection in infants and young children in India is available, the use of nirsevimab may only be restricted for high-risk cases, after consultation with the parents

**Rotavirus Vaccines**

Rotavac 5D can be used for active immunization of infants from the age of 6 weeks for the prevention of gastroenteritis due to rotavirus infection when administered as a 3-dose regimen

**Newer Pneumococcal Conjugate Vaccines (PCV)**

13-valent Pneumococcal Conjugate Vaccines Conjugated with Tetanus Toxoid (13v PCV-TT conjugate vaccine) can be used for the prevention of invasive pneumococcal disease caused by the serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9 V, 14, 18C, 19A, 19F, 23F. In a 6–10–14w administration schedule. This vaccine is presently not recommended for the booster dose

**14-valent Pneumococcal Conjugate Vaccine (manufactured by BE limited marketed by Abbott)**

This vaccine is recommended for the primary immunization, for the prevention of invasive pneumococcal disease caused by pneumococcal serotypes 1, 3, 4, 5, 6B, 7F, 9 V, 14, 18C, 19A, 19F, 22F, 23F and 33F, in a 6–10–14w schedule. This vaccine is presently not recommended for the booster dose

**20-valent Pneumococcal Vaccine**

When indicated, can be used in persons more than 18 years of age as a single IM dose

**Typhoid Conjugate Vaccine (TCV)****Single dose of TCV**

The IAP-ACVIP had recommended single dose of TCV vaccine, 0.5 mL, by intramuscular (IM) route, from 6 months onward, in its earlier guidelines [1]. A 7-year follow-up data in the 6–23 months cohort reported non-significant differences in the titers in the boosted and non-boosted groups at the end of 7 years [8]. Additionally, in view of the reported heterogeneity in the incidence of enteric fever in India and non-availability of robust evidence on significant waning of immunity after a single dose of TCV, the IAP-ACVIP recommends continuation of the single TCV dose strategy.

**IAP-ACVIP Recommendation**

- The IAP-ACVIP recommends continuation of single dose (0.5 mL, IM) of TCV vaccine from 6 months of age.

**Respiratory Syncytial Virus (RSV) Monoclonal Antibody (mAb)-Nirsevimab**

Respiratory syncytial virus (RSV) is one of the most common etiological agents of respiratory infections in infants and young children. Infection during infancy has been associated with long-term respiratory sequelae, including recurrent wheezing and asthma, underscoring the need for effective preventive strategies. To protect infants against RSV infection, both direct and indirect preventive approaches

have been implemented. These include maternal immunization with an RSV vaccine administered between 32 and 36 weeks of gestation and the use of monoclonal antibodies targeting RSV, administered prior to the onset of the RSV season [9, 10].

For many years, palivizumab has been used for prophylaxis in high-risk infants. However, its broader application has been limited by restrictive eligibility criteria, the need for monthly dosing during the RSV season, and logistical and cost-related challenges. To overcome the shortcoming of palivizumab, a long-acting molecule—nirsevimab—was introduced. In a phase 2b study among preterm infants, the efficacy of nirsevimab was 70.1% (95% CI 52.3, 81.2) against medically attended RSV lower respiratory tract infection (MA-RSV LRTI) and was 78.4% (95% CI 51.9, 90.3) against RSV LRTI hospitalization [11].

In another phase 3 trial (MELODY), 3,012 healthy term and late preterm (i.e., gestational age  $\geq 35$  weeks) infants were randomized to receive nirsevimab ( $n = 2,009$ ) or placebo ( $n = 1,003$ ) just before they entered the RSV season [12]. Nasopharyngeal swabs were obtained from infants presenting with LRTI and were tested for 22 respiratory pathogens using the BioFire® Respiratory Panel 2.1. The incidence of RSV-associated and non-RSV MA-LRTIs through day 511, along with disease severity, was evaluated. By day 511, 852 nasopharyngeal swabs had been collected from 561 participants (519 from 337 infants in the nirsevimab group; 333 from 224 infants in the placebo group). RSV was detected in 22.7% samples, while non-RSV pathogens were identified in 64.7% samples. RSV infection rates were lower among infants who received nirsevimab compared



Vaccine	Age in completed weeks/months/years															
	Birth	6w	10w	14w	6m	7m	9m	12m	13m	15m	16-18m	18-24m	2-3 Y	4-6 Y	9-<15 Y	15- 18 Y
BCG																
Hepatitis B	HB 1 <sup>a</sup>	HB 2	HB 3	HB 4 <sup>b</sup>												
Polio	OPV	IPV 1 <sup>c</sup>	IPV 2 <sup>c</sup>	IPV 3 <sup>c</sup>						IPV <sup>a</sup> B1				IPV <sup>a</sup> B2		
DTwP/DTaP		DPT 1	DPT 2	DPT 3						DPT B1				DPT B2		
Hib		Hib 1	Hib 2	Hib 3						Hib B1						
PCV		PCV 1	PCV 2	PCV 3					PCV B							
Rotavirus		RV 1	RV 2	RV 3 <sup>d</sup>												
Influenza					Dose 1 <sup>e</sup>	Dose 2	Dose 2									
MMR							Dose 1			Dose 2				Dose 3		
TCV																
Hepatitis A								Dose 1				Dose 2 <sup>f</sup>				
Varicella										Dose 1		Dose 2 <sup>g</sup>				
Tdap <sup>h</sup>																
Td																
HPV															Dose 1 <sup>i</sup>	1,2 & 3 <sup>h,j</sup>
Meningococcal <sup>k</sup>							Dose 1	Dose 2								
JE <sup>l</sup>								Dose 1	Dose 2							
Cholera								Dose 1	Dose 2							
PPSV 23								Dose 1	Dose 2							
Rabies <sup>m</sup>																
Yellow Fever																

Recommended age

Catch up age range

Vaccination in special situations

**Fig. 1** IAP-ACVIP Recommendations 2025. **(a)** To be given within 24h after birth. When this is missed, it can be administered at first contact with health facility. All stable preterms and LBW babies should be administered a birth dose and 3 more doses with pentavalent/hexavalent combination vaccines. **(b)** An extra dose of Hepatitis B vaccine is permitted as part of a combination vaccine when use of this combination vaccine is necessary. **(c)** IPV can be given as part of a combination vaccine. **(d)** 3rd dose of Rota vaccine is not necessary for RV1. **(e)** Influenza vaccine should be started after 6 months, 2 doses 4 weeks apart, usually in the pre-monsoon period. At other times of the year, the most recent available strain should be used. Annual influenza vaccination should be continued, for all, till 5 years of age. For those at high risk of Influenza related complications, annual vaccination should be continued till 18 years and beyond. **(f)** Single dose is to be given for the live attenuated Hepatitis A vaccine. The inactivated vaccine needs two doses. **(g)** 2nd dose of Varicella vaccine should be given 3–6 month after dose 1. In catchup schedule, in those > 12 years of age, the 2nd dose is to be given after 4 weeks. **(h)** Tdap should not be administered as the second booster of DPT at 4–6 y. For delayed 2nd booster, Tdap can be given after 7 y of age. A dose of Tdap is necessary at 10–12 y, irrespective of previous Tdap administration. If Tdap is unavailable/unaffordable, it can be substituted with Td. **(i)** HPV9-Gardasil9 is approved for boys between 9 and 14 years of age and females between 9 and 26 years of age. HPV4-SII is recommended for females and males between 9 and 26 years of age. Gardasil 4 is licensed till 45 years of age. **(j)** From 15th year onward and in immunocompromised subjects at all ages, HPV vaccines are recommended as a 3-dose schedule, 0–2–6 months. **(k)** Menactra is approved in a 2-dose schedule between 2 and 23 months. For individuals between 2 years and 55 years of the two meningococcal conjugate vaccines; Menactra and Menveo either can be used as single-dose schedule. For those with ongoing exposure to meningococci, boosters are recommended every 5 years. **(l)** In endemic areas. **(m)** Rabies vaccines can be given in any age



with those who received placebo; 70% of the isolated RSV infections were classified as mild. Hospitalization was required in 26.2% of isolated RSV infections and 24.5% of RSV coinfections.

Another multi-country study included 8058 infants in France, Germany and UK who were randomly assigned to receive nirsevimab ( $n = 4037$ ) or standard care ( $n = 4021$ ). Eleven infants (0.3%) in the nirsevimab group and 60 (1.5%) in the standard-care group were hospitalized for RSV-associated LRTI; nirsevimab efficacy of 83.2% (95% CI, 67.8, 92.0;  $P < 0.001$ ). Very severe RSV-associated LRTI occurred in 5 infants (0.1%) in the nirsevimab group and in 19 (0.5%) in the standard-care group; nirsevimab efficacy of 75.7% (95% CI, 32.8, 92.9;  $P = 0.004$ ). Treatment-related adverse events occurred in 86 infants (2.1%) in the nirsevimab group [13].

A meta-analysis of five studies involving 7,347 preterm infants demonstrated that nirsevimab significantly reduced MA-RSV LRTIs (OR 0.25;  $P < 0.001$ ) and RSV-related hospitalizations (OR 0.27;  $P < 0.001$ ) [14].

Nirsevimab has been widely used in more than 18 countries and has received approval from many regulatory bodies including European Medicines Agency (EMA) in October 2022 [15] and US Food and Drug Administration (US FDA) in July 2023 [16]. In June 2024, nirsevimab was approved by Drugs Controller General of India (DCGI) for use in children in India [17].

At present, the maternal RSV vaccine is not licensed in India. Considering the operational and cost-related constraints of using palivizumab, nirsevimab appears to be a promising option for RSV prevention in selected infant populations in India. However, in view of the absence of uniform nationwide RSV seasonality, limited robust epidemiological data on RSV burden in the country, the large annual birth cohort with the majority of deliveries occurring in the public healthcare sector, and the high cost of nirsevimab, the IAP-ACVIP does not currently recommend its universal use for all infants.

Until comprehensive epidemiological data on RSV infection among Indian infants and young children become available, the use of nirsevimab should be restricted to high-risk infants, following appropriate counseling and shared decision-making with parents.

The recommendations for nirsevimab are outlined in Table 4. Recommendation of the use of Nirsevimab in children less than 1.6 kg and in corrected gestation of less than 32 weeks is based on extrapolation of data.

#### IAP-ACVIP Recommendations

- The IAP-ACVIP currently does not recommend the universal use of nirsevimab for all infants.
- Until robust epidemiological data on RSV infection in infants and young children in India is available, the use

**Table 4** Nirsevimab: Dosage and Indications

Formulation/content	50 mg/0.5 mL and 100 mg/0.5 mL in a single-dose pre-filled syringe
Nature	Sterile liquid solution
Storage	2 °C to 8 °C; can be kept at 20 °C–25 °C for up to 8h. It should be stored in original carton to protect from light until time of use
Indication	Premature infants born before 32 weeks gestation Having risk of bronchopulmonary dysplasia Children below 24 months and having significant congenital heart disease Children below 24 months and having severely immunocompromised status, undergoing chemotherapy, those with HIV, or those who have had solid organ or stem cell transplants Children below 24 months and having severe neuromuscular disorders
Timing	Neonates and infants born during or entering their first RSV season and in children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season
Route	Intramuscular
Site	Anterolateral aspect of thigh
Dosage	50 mg if body weight < 5 kg; 100 mg if body weight ≥ 5 kg Children who are to be administered mAB in their second RSV season the recommended dose is a single dose of 200 mg, given as two intramuscular injections (2 × 100 mg)
Adverse effects	In the clinical trials, the most common adverse reactions were rash (0.9%) and injection site reactions (0.3%). The safety and efficacy data of nirsevimab in infants with body weight below 1.6 kg and less than 32 weeks corrected gestational age is limited and usage is based on extrapolatory data
Contraindications	History of serious hypersensitivity reactions, including anaphylaxis, to nirsevimab or to any of the excipients are the contraindications The safety and effectiveness of Beyfortus® in children older than 24 months of age have not been established.
Manufacturer	Beyfortus® by AstraZeneca and Sanofi Healthcare Ltd and marketed in India by Dr. Reddy's Laboratories Ltd.)



of nirsevimab may only be restricted for high-risk cases, after consultation with the parents.

## Human Papilloma Virus (HPV) Vaccine

Cervical cancer, driven predominantly by persistent infection with oncogenic human papillomavirus (HPV) types—particularly HPV16 and HPV18—remains a major global health burden. It is the fourth most common cancer among women worldwide, with a disproportionately high incidence and mortality in low- and middle-income countries. As of 2022, an estimated 660,000 new cases and approximately 350,000 deaths were reported globally.

Prophylactic HPV vaccination has demonstrated high effectiveness in reducing HPV infections and associated cervical precancerous lesions. Traditional vaccination schedules involve two or three doses, which, although effective, present challenges in resource-limited settings due to cost, logistical constraints, and adherence issues. The WHO has emphasized the need to achieve 90% vaccination coverage among girls by 15 years of age as a key pillar of the global strategy to eliminate cervical cancer as a public health problem by 2030 [18].

Emerging evidence indicates that a single-dose HPV vaccination schedule may provide protection comparable to multi-dose regimens, with the potential to overcome implementation barriers and expand vaccine coverage. In this context, the IAP-ACVIP team conducted a systematic review synthesizing data from randomized controlled trials and observational studies to evaluate the efficacy, durability of protection, safety, and public health implications of a single-dose HPV vaccination schedule (unpublished data). A comprehensive literature search was performed across multiple databases (PubMed, Embase, Cochrane CENTRAL, Web of Science, ClinicalTrials.gov, WHO IRIS) covering studies from inception up to September 2025. The search focused on terms related to “HPV vaccine”, “single dose”, “one dose”, including specific vaccine products. Out of 2835 studies identified, 158 were assessed for eligibility and 6 randomized controlled trials and high-quality observational studies were included. Data synthesis was narrative due to heterogeneity, emphasizing efficacy results in vaccine trials and long-term observational data on durability and safety. Risk of bias in RCTs and observational studies was assessed using RoB 2 tools and ROBINS-1 tools.

## Efficacy and Immunogenicity from Randomized Trials

- **KEN SHE Trial (Kenya):** This double-blind randomized controlled trial included 2,275 HIV-negative girls and young women aged 15–20 years. A single dose of either the bivalent or nonavalent HPV vaccine demonstrated 97% efficacy against persistent HPV16/18 infection at 18 months and 95% efficacy at 36 months, with comparable protection observed across both vaccine types [19, 20].
- **DoRIS Trial (Tanzania):** This study evaluated immunobridging in girls aged 9–14 years and demonstrated that single-dose recipients achieved non-inferior seroconversion rates and sustained antibody concentrations compared with two- or three-dose recipients up to 36 months of follow-up. Efficacy against persistent HPV16/18 infection remained high (approximately 97.5%), with a reassuring safety profile [21].
- **Costa Rica Vaccine Trial (CVT):** A large cohort of women aged 18–25 years vaccinated with one dose of bivalent vaccine displayed durable antibody presence and stable protection against HPV16/18 infection sustained for 10–16 years [22].
- **India IARC Cohort Study:** This study demonstrated vaccine efficacy of 92–95% against persistent HPV16/18 infection with a single-dose regimen compared to multi-dose schedules over 12 years of follow-up. Notably, no HPV16/18-related high-grade precancerous lesions were observed among vaccinated participants [23].

## Long-term Seroprotection

Long-term follow-up of women who inadvertently received a single dose in clinical trials demonstrated 99% seropositivity for HPV16/18 at 16 years, with reductions in persistent infection rates comparable to those observed in multi-dose recipients. Available data suggest that protection is likely to persist for at least 20 years [23, 24]. Population-level evidence from countries such as Kenya [20], Costa Rica [25], and Scotland [26] further supports the effectiveness of a single-dose schedule. However, direct evidence for prevention of invasive cervical cancer remains limited, given the long natural history of the disease. Additionally, a systematic review has reported sustained antibody persistence and continued immunoprotection for up to 11 years following a single dose [27].

## Safety

The single-dose schedule has an excellent safety profile, comparable to multi-dose vaccines, with no increase in



serious adverse events reported [21]. Antibody levels after one dose are lower than with multiple doses but remain durable and protective over extended follow-up periods [24, 27].

### Research Gaps

Evidence in immunocompromised populations, particularly among people living with HIV, remains limited; therefore, multi-dose HPV vaccination regimens continue to be recommended for these groups. Long-term follow-up is required to determine the durability of protection beyond 10–16 years and to establish the direct impact of single-dose schedules on cervical cancer prevention. Additionally, further evaluation is needed regarding the effectiveness of different HPV vaccine types and their performance in older age groups. Direct data on the prevention of cervical cancer endpoints with strictly single-dose schedules remain sparse given the natural latency of disease progression.

### Implications for Policy

A single-dose HPV vaccination schedule offers potentially transformative benefits for global vaccine rollout, particularly in low- and middle-income countries (LMICs), where delivery is often constrained by cost, logistics, and adherence challenges. Achieving broader coverage with reduced financial and programmatic burden could significantly accelerate progress toward the WHO's cervical cancer elimination targets. WHO recommendations have evolved to endorse a single-dose schedule for immunocompetent girls and young women aged 9–20 years. The CDC, in its most recent guidance, has also supported a single-dose HPV vaccination schedule for girls aged 9–14 years [28]. While direct evidence for cancer prevention with single-dose vaccination is still emerging, existing data and programmatic reports suggest substantial reductions in precancerous cervical lesions and likely longer-term cancer risk. Continued surveillance and further research are essential to monitor real-world effectiveness, breakthrough infections, durability of protection, and long-term trends in cervical cancer incidence following single-dose vaccination. To maximize public health impact, only single-dose HPV vaccination could be implemented alongside continued research into durability beyond 10 years.

### IAP-ACVIP Recommendations

- IAP ACVIP recommends that immunocompetent girls of 9-up to 15 years can be given a single IM dose of HPV vaccine for sustained protection.
- 9-up to 15 years of age (boys): Two-dose schedule (0.5 mL, IM at 0 and 6 months). The interval between the 1st and 2nd dose should not be < 5 months.

- For children more than 15 years, and immunocompromised children of any age, three doses are to be given.

### Rabies Vaccine

Rabies is a universally fatal viral disease requiring urgent post-exposure prophylaxis (PEP). Effective and timely administration of PEP is critical to preventing mortality. Multiple international and national bodies, including WHO, National Centre for Disease Control (NCDC), and ACVIP, have published guidelines for PEP administration [29–31].

#### WHO-Recommended Post-Exposure Prophylaxis (PEP) Schedules

1. Two-site intradermal (ID) regimen (IPC regimen; 2–2–0–0): Administered on days 0, 3, and 7 at two sites per visit; completed within 7 days.
2. Intramuscular (IM) regimen (Essen regimen; 1–1–1–1–0): Administered on days 0, 3, 7, and 14 (with an optional day 28 dose in certain circumstances); total duration 14–28 days.
3. Intramuscular regimen (Zagreb regimen; 2–0–1–0–1): Two doses on day 0 (one in each deltoid), followed by single doses on days 7 and 21; completed in 21 days.

#### NCDC-Recommended Rabies Post-Exposure Prophylaxis (India)

- IM regimen–Thai Red Cross regimen: Administered one dose in deltoid on days 0, 3, 7, 14, and 28.
- ID regimen–Updated Thai Red Cross regimen: Administered on days 0, 3, 7, and 28 (two-site ID injections in each deltoid per visit).

#### IAP-ACVIP Position

The IAP-ACVIP recommendation to follow the NCDC 5-dose IM schedule reflects a safety-first approach. Considering the universally fatal nature of rabies, an additional dose on day 28 reduces uncertainty arising from variable clinical practices, patient factors, and limited evidence regarding the equivalence of lower-dose schedules. The alignment of ACVIP and NCDC guidelines also prevents confusion among clinicians in India, which is an important factor for improving adherence to standardized PEP practices. Consistent implementation across healthcare settings is expected to improve outcomes and reduce fatality risk.

Although available evidence suggests that current PEP schedules can be reduced in duration, and in some cases also in number of doses administered while maintaining immunogenicity and effectiveness of PEP. Further research



is needed on the potential for reducing dose and duration of IM schedules from India. Till NCDC reduces the number of doses in its IM PEP schedules, it is prudent to follow the 5-dose regimen. Besides, studies suggest lower titers in malnourished children and extremes of ages [32].

### IAP-ACVIP Recommendation

- A five-dose intramuscular (IM) rabies vaccination schedule is to be administered on days 0, 3, 7, 14, and 28 for post-exposure prophylaxis (PEP), along with rabies immunoglobulin (RIG) or rabies monoclonal antibody (RMAb) according to the category of exposure.

## New Vaccines

### Pentavalent Meningococcal Polysaccharide-Conjugate Vaccine-MenFive® by Serum Institute of India

The MenFive® is a pentavalent meningococcal polysaccharide conjugate vaccine for active immunization of individuals aged 18–85 years against invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, Y, W, and X.

### Content

Each dose (0.5 mL) contains 5 µg each of meningococcal A, C, Y, W, and X polysaccharide individually conjugated to a carrier protein, and serogroup A and X polysaccharides are conjugated to 10–20 µg of purified tetanus toxoid (TT) and the serogroup C, W, and Y polysaccharides conjugated to 15–20 µg of recombinant CRM197 protein.

### Nature/Diluent

Freeze-dried Lyophilized powder vaccine available in two presentations viz. 5-dose vial and single-dose vial, which is to be reconstituted with 0.9% sodium chloride prior to the administration by intramuscular route.

### Storage

The vaccine should be stored at +2° C to +8° C and is to protect from light. Once opened, multi-dose vials should be used as soon as practically possible and within 6 hours when kept between +2° C to +8° C. Once opened, multi-dose vials should be discarded at the end of the immunization session or within six hours, whichever comes first.

### Dose, Route, Site

Single dose of 0.5 mL is to be given by IM route in age group of 18–85 years in India.

### Adverse effects and Contraindications

Mild local and systemic reactions are the most commonly reported adverse events following immunization (AEFIs). The safety and immunogenicity of co-administration of MenFive® with other vaccines, as well as its use in pregnant and lactating women, have not yet been adequately evaluated [33]. Hypersensitivity to TT or CRM197 is a contraindication.

### Supporting evidence

In a phase 3, randomized, non-inferiority trial conducted in Mali and The Gambia, 1,800 healthy participants aged 2–29 years were assigned in a 2:1 ratio to receive a single intramuscular dose of the meningococcal ACWYX conjugate vaccine (NmCV-5) or the comparator quadrivalent vaccine (MenACWY-D). At 28 days post-vaccination, seroresponse rates in the NmCV-5 group ranged from 70.5% (95% CI, 67.8, 73.2) for serogroup A to 98.5% (95% CI, 97.6, 99.2) for serogroup W. The seroresponse for serogroup X was 97.2% (95% CI, 96.0, 98.1). For the four serogroups shared with the comparator vaccine (A, C, W, and Y), the overall difference in seroresponse between the two vaccines ranged from 1.2 percentage points (95% CI, – 0.3, 3.1) for serogroup W to 20.5 percentage points (95% CI, 15.4, 25.6) for serogroup A. The geometric mean titer (GMT) ratios for the shared serogroups ranged from 1.7 (98.98% CI, 1.5, 1.9) for serogroup A to 2.8 (98.98% CI, 2.3, 3.5) for serogroup C. The serogroup X component of NmCV-5 achieved seroresponse rates and GMTs that met prespecified non-inferiority criteria. The incidence of systemic adverse events was comparable between groups (11.1% in the NmCV-5 group vs. 9.2% in the MenACWY-D group) [34].

The vaccine was licensed in India in 2022 for use in individuals between 18 and 85 years [35]. In July 2023, the WHO prequalified MenFive® [36]. This vaccine is especially important for countries where multiple serogroups are prevalent.

### IAP-ACVIP Recommendation

- Meningococcal conjugate vaccine is recommended for use only in special situations, as published earlier by ACVIP and Fig. 1 [30].



## Respiratory Syncytial Virus (RSV) Monoclonal Antibody (mAb)-Nirsevimab-Beyfortus<sup>®</sup> Manufactured by AstraZeneca and Marketed by Sanofi Healthcare India Private Limited

Beyfortus<sup>®</sup> an RSV long-acting mAb Nirsevimab is an F protein-directed fusion inhibitor indicated for the prevention of RSV-related lower respiratory tract disease in neonates and infants [37]. The details of this product are described in Table 4.

## Inactivated Hepatitis A Vaccines: Havisure<sup>®</sup> by (Human Biological Institute, a division of Indian Immunologicals Ltd)

Havisure<sup>®</sup> is India's first indigenous inactivated hepatitis A vaccine developed from HM175 strain

### Content

Each 0.5 mL dose contains not less than 25 IU/ml of inactivated hepatitis A antigen, adsorbed on aluminum hydroxide, Tween 20 ( $\leq 0.006\%$  w/v) and phosphate buffer saline.

### Nature/Diluent

Liquid inactivated vaccines

### Storage

The vaccine is stored at 2 °C–8 °C and is not to be frozen.

### Dose, Route, Site

Adult dose is 1 ml IM and the pediatric dose is 0.5 ml IM on the anterolateral thigh or deltoid as per age.

### Schedule

A two-dose schedule starting after 12 months of age up to 49 years of age, 6–12 months apart [38].

### Adverse effects and contraindications

Low-grade fever and local pain are common AEFI, the contraindications are known hypersensitivity to any of the vaccine components.

## Supporting evidence

In a head-to-head trial comparing the vaccine with Havrix<sup>®</sup>, Havisure<sup>®</sup> was demonstrated to be non-inferior, achieving 100% seroconversion and seroprotection among participants aged 12 months to 49 years [39].

## IAP-ACVIP Recommendation

- Havisure<sup>®</sup> is recommended for the prevention of hepatitis A in children  $\geq 12$  months of age in a 2-dose IM schedule of 0–6 months.

## Rotavirus vaccine-Rotavac 5D<sup>®</sup> by Bharat Biotech International Limited

Rotavac 5D<sup>®</sup> is a liquid oral rotavirus vaccine for the prevention of severe diarrhea and gastroenteritis caused by rotavirus infection in infants.

### Content

Each 0.5 mL dose contains not less than (NLT)  $10^5$  focus-forming units (FFU) of live attenuated rotavirus 116E strain. Excipients include sucrose (0.25 g), trehalose (2.5 mg), lactalbumin hydrolysate (2.5 mg), human albumin.

### Nature/Diluent

Liquid vaccine.

### Storage

Unlike the original Rotavac<sup>®</sup>, which needed storage at  $-20$  °C and demonstrated limited stability at 2 °C–8 °C, Rotavac 5D<sup>®</sup> is stable for its complete shelf life at 2 °C–8 °C, making it suitable for standard cold chains [40]. The use of protective sugars ensures vaccine potency during storage and transport. Importantly, the virus strains remain unchanged from the earlier formulation, ensuring consistent immunogenicity and efficacy in public health programs.

### Dose, Route, Site

Three oral doses are to be given with each dose of 0.5 mL; the first dose at 6–14 weeks, with minimum interval of 4 weeks between the doses and final dose before 32 weeks.

## Adverse Effects and Contraindications

Vomiting and irritability are among the commonly reported AEFIs. Intussusception has been reported rarely. Contraindications include severe combined immunodeficiency (SCID), a prior history of intussusception, and hypersensitivity to any component of the vaccine.

## Supporting Evidence

Phase III trials evaluating the Rotavac 5D® liquid formulation assessed its immunogenicity, safety, and lot-to-lot consistency in healthy infants. The vaccine demonstrated non-inferiority to the licensed frozen ROTAVAC formulation, supporting its reliability and effectiveness as an oral rotavirus vaccine [41, 42].

## IAP-ACVIP Recommendation

- Rotavac 5D® can be used for active immunization of infants from the age of 6 weeks for the prevention of gastroenteritis due to rotavirus infection when administered as a 3-dose regimen

## Newer Pneumococcal Conjugate Vaccines (PCV)

### a. 13-Valent PCV Conjugated with Tetanus Toxoid (TT)

These 13-valent PCVs, developed in China, are procured by GC Chemie Pharmie Ltd and remarketed by Dr. Reddy's Laboratories under the brand names Vaximune-13 and Pneumoguard 13. They are indicated for primary immunization to prevent invasive pneumococcal disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 6A, 6B, 7F, 9V, 18C, 19A, 19F, and 23F.

### Content

Each 0.5 mL dose contains the following pneumococcal polysaccharides:

- 2.5 µg each of serotypes 3, 5, 6A, and 9V
- 2.6 µg each of serotypes 1 and 19A
- 2.75 µg each of serotypes 14 and 19F
- 2.85 µg of serotype 7F
- 3.0 µg each of serotypes 4 and 23F
- 3.25 µg of serotype 18C
- 6.0 µg of serotype 6B

The carrier protein is TT, and the adjuvant (adsorbent) is aluminum phosphate.

## Storage

The vaccine should not be frozen but stored at 2–8° C. If any vaccine is frozen, it must be discarded [43].

## Dose, Route, Site

The vaccine is given as 0.5 mL IM in anterolateral thigh or deltoid as per age.

## Schedule

This vaccine is currently recommended in the 6–10–14 weeks schedule and is currently not recommended for use as a booster in the second year of life.

## Supporting Evidence

A phase 3 randomized, double-blind multi-center study conducted in 344 Indian subjects of age 6–8 weeks showed that after three doses of vaccination, antibody levels increased for all 13 serotypes and were similar between the PCV-13 TT and PCV-13 CRM groups (Unpublished data). The vaccine's effectiveness was comparable to the control group, Prevnar 13 [43].

## IAP-ACVIP Recommendation

- 13-valent Pneumococcal conjugate vaccines conjugated with tetanus toxoid (13v PCV-TT conjugate vaccine) can be used for the prevention of invasive pneumococcal disease caused by the serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9 V, 14, 18C, 19A, 19F, 23F. In a 6–10–14w administration schedule. This vaccine is presently not recommended for the booster dose

### b. 14-Valent Pneumococcal Conjugate Vaccines

Pneumoshield-14® (Biological E Limited), remarketed by Abbott Laboratories, is a 14-valent pneumococcal conjugate vaccine (PCV14) developed for the prevention of invasive pneumococcal disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6B, 7F, 9 V, 14, 18C, 19A, 19F, 22F, 23F, and 33F.

It is currently approved for administration in a 6–10–14-week primary immunization schedule only. Booster dose trials have been completed, and the report was



submitted to the CDSCO Vaccines Subject Expert Committee (SEC) in October 2025, as communicated to ACVIP by the manufacturer. Approval from the Drug Controller General of India (DCGI) is awaited.

### IAP-ACVIP Recommendation

- At present, this vaccine is not recommended for use as a booster dose in children.

### c. 20-Valent Pneumococcal Vaccine

Prevnar 20®, manufactured by Wyeth Pharmaceuticals and Marketed by Pfizer, is a vaccine indicated for active immunization for the prevention of pneumonia and invasive disease caused by *S. pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 8, 9 V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33F in adults 18 years of age and older. For > 19 years age, it has been indicated for patients with certain chronic conditions. It is preferred as a single 0.5 mL IM dose for those > 65 years of age [44]. Since June 2025, the PCV 20 vaccine has been licensed by DCGI, for use in those > 18 years of age as a single IM dose. For 18–49 years age, it is indicated for those who are at risk whereas in persons > 50 years, one dose of PCV 20 is recommended to all [45].

### IAP-ACVIP Recommendation

- When indicated, can be used in persons more than 18 years of age as a single IM dose

## Appendix

The list of members who attended various physical meetings are as follows:

*March 16, 2024 at Kolkata:* Digant D Shastri (Convenor of IAP-ACVIP), Shashi Kant Dhir (Member IAP-ACVIP), B Rajsekhar (Member IAP-ACVIP), Sumitha Nayak (Member IAP-ACVIP), Chandra Mohan Kumar (Member IAP-ACVIP), Anurag Agarwal (Member IAP-ACVIP), Swapan Kumar Ray (Member IAP-ACVIP), Krishna Mohan R (Member IAP-ACVIP), Bhadrash R Vyas (Member IAP-ACVIP), Rajeshwar Dayal (Member IAP-ACVIP), Vijay Bade (Member IAP-ACVIP), GV Basavaraja (President IAP, 2024), Vasant Khalatkar (President IAP 2025), Yogesh N Parikh (Secretary General, IAP 2025–26), Atanu Bhadra (Treasurer 2025–26).

*December 8, 2024 at Bhubaneshwar:* Digant D Shastri, Shashi Kant Dhir, B Rajsekhar, Sumitha Nayak, Chandra

Mohan Kumar, Swapan Kumar Ray, Krishna Mohan R, Bhadrash R Vyas, Rajeshwar Dayal, Vijay Bade, GV Basavaraja, Vasant Khalatkar, Yogesh N Parikh, Atanu Bhadra.

*April 5, 2025 at Kolkata:* Digant D Shastri, Shashi Kant Dhir, B Rajsekhar, Sumitha Nayak, Chandra Mohan Kumar, Anurag Agarwal, Swapan Kumar Ray, Krishna Mohan R, Bhadrash R Vyas, Rajeshwar Dayal, Joseph L Mathew (Advisor, IAP-ACVIP), Vijay Bade, GV Basavaraja (Past-President, IAP 2025), Vasant Khalatkar (President, IAP 2025), Yogesh N Parikh, Atanu Bhadra, Neelam Mohan (President-Elect, IAP 2025).

*November 22–23, 2025 at Navi Mumbai:* Digant D Shastri, Shashi Kant Dhir, B Rajsekhar, Chandra Mohan Kumar, Anurag Agarwal, Swapan Kumar Ray, Krishna Mohan R, Bhadrash R Vyas, Raman Gangakhedkar (Advisor, IAP-ACVIP), Rajeshwar Dayal, Vijay Bade, Yogesh N Parikh, Neelam Mohan (President-Elect IAP 2025).

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**Conflict of interest** None.

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