



# INDIAN CONSENSUS GUIDELINES ON ADULT IMMUNIZATION 2026 UPDATE



**Editors:**

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## A Collaborative Effort By

- Association of Physicians of India-Maharashtra State Chapter (API-MS)
- Cardiology Society of India (CSI)
- Clinical Infectious Diseases Society (CIDS)
- Chest Council of India (CCI)
- Federation of Obstetric & Gynaecological Societies of India (FOGSI)
- Geriatric Society of India (GSI)
- Heart Failure Association of India (HFAI)
- Indian Association of Preventive & Social Medicine (IAPSM)
- Indian Chest Society (ICS)
- Indian Rheumatology Association (IRA)
- Indian Medical Association-Mumbai West (IMA-Mumbai West)
- Indian Society of Nephrology (ISN)
- Indian Society of Oncology (ISO)
- Research Society for Study of Diabetes in India (RSSDI)
- National College of Chest Physicians (NCCP)
- Indian Menopause Society (IMS)
- Indian Academy of Geriatrics (IAG)
- Indian Society of Haematology and Blood Transfusion (ISHBT)
- Indian Society for Organ Transplantation (ISOT)
- Indian Society for Adult Immunization (ISAI)
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**This book is dedicated to the silent guardians of public health - who chose prevention over cure, and protection over applause.**

**May no deserving citizen ever be denied the protection of vaccination.**

# Preface

The release of the Indian Consensus Guidelines on Adult Immunization in 2024 marked an important milestone in the journey of preventive healthcare in our country. The document, unveiled at Bharat Mandapam by the Hon'ble Vice President of India, Shri Jagdeep Dhankhar ji, was the outcome of a rare and meaningful collaboration—thirteen leading professional medical associations coming together with a shared vision: to strengthen adult immunization practices in India through scientific clarity and collective responsibility.

Medicine, however, is a constantly evolving science. The introduction of newer vaccines—most notably the pneumococcal conjugate 20-valent vaccine—along with revised recommendations for several existing vaccines, and the imminent availability of promising candidates such as dengue and RSV vaccines awaiting DCGI approval, made it clear that an update of the guidelines was not only desirable but essential. Staying current is not a luxury in preventive medicine; it is an obligation we owe to our patients and to society.

What is truly heartening is that this updated edition has drawn even wider support. More professional bodies joined hands, reinforcing both the confidence in the concept and the credibility of the recommendations. Today, twenty-three national and regional associations stand united behind this document, endorsing uniform, evidence-based guidance for adult immunization in India.

This herculean task has been meticulously undertaken under the stewardship of the Indian Medical Association – Mumbai West, under the leadership of its President Dr Rashmi Mehta and Secretary Dr Madhubala Chinchalkar, and the Association of Physicians of India, Maharashtra State Chapter, guided by its Chairman Dr Nikhil Balankhe and Secretary General Dr Amit Saraf. Their leadership, commitment, and organizational strength have ensured that the updated guidelines are comprehensive, practical, and firmly rooted in real-world clinical practice.

For me personally, this document represents far more than an academic exercise. It reflects a journey of over twenty-five years—one that began as a small, sincere effort to sensitize clinicians about adult immunization and has gradually transformed into a national movement. This evolution reaffirms my belief that when intent is honest and collaboration is genuine, even modest initiatives can create meaningful change.

I would like to place on record my sincere gratitude to Dr O. P. Sharma, Dr Jayesh Lele, Dr Mangesh Tiwaskar, Dr Shashank Joshi, Dr Girish Mathur, and Dr Bijal Vora, all of whom played a pivotal role at different stages of my journey and strongly contributed to shaping my vision and commitment towards adult immunization.

I am equally thankful to the representatives of all twenty-three participating associations for their prompt support, generous time, thoughtful discussions, and countless constructive suggestions, which greatly enriched the scientific strength and practical relevance of this document. I would also like to acknowledge Mr Pranjit and the team at Proadwise for their valuable support in medical writing and for the clear, elegant design that has enhanced the overall presentation of these guidelines.

**I offer my heartfelt gratitude to my late father, Dr C. K. Vora, and my revered teacher, Professor Dr K. C. Mohanty, whose values, guidance, and grooming have shaped who I am today**

My sincere hope, wish, and prayer is that no deserving adult is deprived of the benefits of immunization because of our ignorance as healthcare providers. I trust that this document will empower each of you—not only to vaccinate your patients with confidence, but also to protect yourselves and your own family members. Preventive care begins with conviction, and conviction begins with knowledge.

If these guidelines help even one clinician practice adult immunization more effectively and even one patient live a healthier life, our collective effort will have been worthwhile.

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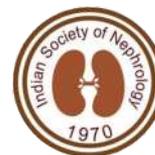
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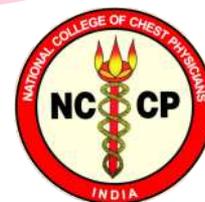
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# Contents

Introduction

Anthrax

BCG (Tuberculosis)

Chickenpox (Varicella)

Cholera

Corona Virus Disease (COVID-19)

Diphtheria, Pertussis and Tetanus

Haemophilus influenzae type b (Hib)

Hepatitis A

Hepatitis B

Hepatitis E

Human Papilloma Virus

Influenza

Japanese Encephalitis

Measles, Mumps and Rubella

Meningococcal Disease

Pneumococcal Disease

Poliomyelitis

Rabies

Typhoid

Shingles (Herpes Zoster)

Yellow Fever

Consensus Recommendations

Upcoming Vaccines

Conclusion

References

Appendix

## Need for the Consensus Update

This consensus represents a collaborative effort integrating vaccine recommendations from 21 medical societies across India, ensuring comprehensive and multidisciplinary expertise. The age grouping has been simplified to 18–49 years and 50 years and above, with the addition of an adolescent category (12–18 years) to enhance clarity and implementation. Specific at-risk and high risk/immunocompromised categories have been defined to enable targeted, disease specific vaccination strategies.

The update incorporates guidance on newer vaccines, including PCV20, and Dengue vaccines have been updated to reflect current immunization options. The comparative tables from the previous edition have been removed to maintain a uniform and simplified structure throughout the document. Booster dose recommendations and standardized formatting have been included for all vaccines to enhance consistency and usability. A unified Adult Immunization Card has been introduced to facilitate the systematic tracking of vaccine doses across various healthcare settings. (1)



# INTRODUCTION

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According to the latest data, India has made significant progress in paediatric vaccination coverage in 2024, while adult vaccination remains a major challenge with very low coverage rates.

## Paediatric Vaccination Coverage

India has achieved its highest-ever immunization coverage for children, according to 2024 data from the World Health Organization (WHO) and the United Nations Children's Fund (UNICEF) (2-3). India's DTP3 (third dose of diphtheria-tetanus-pertussis) vaccine coverage increased from 91% in 2023 to 94% in 2024, marking the country's best performance. This marks a strong recovery and surpasses pre-pandemic levels. Despite this national progress, a recent study published in *The Lancet Regional Health - Southeast Asia* highlighted that significant gaps remain at a local level (4). Over 50% of the variation in vaccination rates occurs in small local areas, meaning pockets of low coverage can be hidden within districts or states that perform well overall.

## Adolescent Vaccination and Catch-up Needs

The search results provide limited specific data on overall adolescent vaccination coverage. However, a key focus for this age group joining other South Asian countries like Bangladesh, Bhutan, and Nepal which have already made significant progress is the rollout of the national HPV vaccination program in India in 2025 (5-6). Also, the need for catch-up vaccination in adolescence is implied by the data on adult vaccination. With adult vaccine coverage extremely low, many adolescents and young adults have likely missed crucial booster doses (like Tdap) or vaccines not available in their childhood.

## Adult Vaccination Coverage and Updates

Adult vaccination in India is critically under prioritised with coverage rates described as "abysmally low" (7). Sample studies found adult vaccination coverage is in the single digits for major vaccines: Influenza: 1.5%, Pneumococcal: 0.6%, Hepatitis B: 1.9% (8-9).

# METHOD OF CONSENSUS DEVELOPMENT

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## Collaborative Framework

This guideline represents a historic harmonization effort involving multiple stakeholder organizations in India. Representatives from multiple medical societies collaborated in this project.

## Nominal Group Consensus Methodology

The guideline development process employed the Nominal Group Technique (NGT), a formal consensus development method that ensures inclusive decision making where the opinions of all stakeholders are heard without dominant viewpoints overshadowing minority perspectives. The NGT has been extensively validated and is widely used by health organizations worldwide for guideline development.

## Methodology

This consensus document was developed in accordance with a structured methodology to ensure scientific integrity and practical relevance:

- **Constitution of the Writing Committee:** A multi-disciplinary writing committee was formed, comprising experts from Internal Medicine, Infectious Diseases, Geriatrics, Family Medicine, and Public Health.
- **Integration with Global Standards:** This update aims to align Indian recommendations more closely with international guidelines from the Centres for Disease Control and Prevention Advisory Committee on Immunization Practices (CDC-ACIP), and World Health Organization (WHO), while maintaining applicability to the Indian context and healthcare infrastructure (10-12).

- **Adaptation for India:** International evidence was critically appraised and adapted to the Indian epidemiological landscape, disease burden patterns, and healthcare delivery structure.
- **Development of Recommendations:** Recommendations were formulated through a structured process of discussion and formal voting by the writing committee.
- **Peer Review:** The draft document underwent extensive peer review by an independent panel of national experts not involved in the writing process, whose feedback was incorporated into the final version.

## Method of Consensus Development

### Collaborative Framework

This guideline represents a historic harmonization effort involving multiple stakeholder organizations in India. Representatives from the following medical societies collaborated in this project: (4,17)

### Nominal Group Consensus Methodology

The guideline development process employed the Nominal Group Technique (NGT), a formal consensus development method that ensures inclusive decision making where the opinions of all stakeholders are heard without dominant viewpoints overshadowing minority perspectives (2,11). The NGT has been extensively validated and is widely used by the health organizations worldwide for guideline development (2,5,11).

### Process Steps

The consensus development followed these sequential phases:

### **Phase 1: Preparation and Planning**

- Definition of scope: Adult (>18 years) and adolescent (12-18 years) vaccination in India across all risk groups
- Identification and selection of vaccine topics based on CDSCO approval status and epidemiological relevance
- Formation of multi-disciplinary working group with representatives from various medical societies

### **Phase 2: Structured Discussion**

- Systematic discussion of each vaccine and recommendation followed
- Facilitators ensured structured interaction without allowing dominant personalities to control the dialogue
- Clinical evidence, implementation feasibility, and contextual factors were debated

### **Phase 3: Literature Review Integration**

- A thorough systematic literature review was conducted examining:
  - Global vaccination guidelines (CDC-ACIP, and WHO)
  - Indian epidemiological data
  - Vaccine efficacy and effectiveness studies
  - Safety and immunogenicity data
  - Cost-effectiveness analyses
  - Implementation research

### **Phase 4: Private Voting and Aggregation**

- Each expert independently recorded their judgment/vote on each recommendation
- Voting scales used:
  - R (Recommended): Vaccine should be routinely offered
  - BR (May be considered after benefit-risk evaluation): Conditional recommendation
  - NR (Not Recommended): Vaccine not recommended in this category
  - AR (With Additional Risk): Recommendation applies specifically to this risk group

### **Phase 5: Consensus Achievement**

- Individual judgments were aggregated statistically
- Consensus was defined as >70% agreement among experts
- Areas with <70% agreement underwent further discussion and re-voting
- Final recommendations reflect synthesized expert opinion adjusted for evidence quality

### **Phase 6: Documentation and Dissemination**

- Complete documentation of the process, including how and when consensus was reached
- Transparency regarding areas of strong consensus versus areas requiring further evaluation
- Recommendations were formatted for practical clinical use

### **Key Principles of This Consensus Process**

- 1. Inclusivity:** All stakeholder voices were heard, preventing single-specialty dominance
- 2. Transparency:** Clear documentation of the process and rationale for recommendations
- 3. Evidence-Based:** Integration of current best evidence with expert clinical judgment
- 4. Contextually Appropriate:** Consideration of India's unique healthcare infrastructure, disease epidemiology, and vaccine availability
- 5. Flexibility:** Mechanisms for rapid updates as new evidence emerges or epidemiological situations change

## Methods:

### 1. Formal, Structured Consensus Methodology:

The recommendations were developed using the Nominal Group Technique (NGT), a formal, validated method ensuring inclusive decision-making from a multi-disciplinary consortium of national medical societies and experts, preventing dominance by any single specialty.

### 2. Integration of New Evidence and Vaccines:

**COVID-19:** A comprehensive section has been updated, detailing all CDSCO-approved vaccines, their schedules, and strong consensus recommendations for all adult groups, including during pregnancy.

**Newer Vaccines:** Includes detailed guidance on vaccines that have gained prominence, such as Pneumococcal Polysaccharide Conjugate Vaccine 20-valent (PCV20), Hepatitis E, Recombinant Zoster Vaccine (Shingles) and Human Papillomavirus (HPV) vaccine for adults.

**Upcoming Vaccines:** A dedicated section covers vaccines on the horizon for India (e.g., Dengue, Chikungunya, Malaria, TB) and those approved internationally but not yet in India (e.g., Respiratory Syncytial Virus - RSV), keeping clinicians informed.

### 3. Enhanced Practicality and Clinical Utility:

**Structured Recommendation Tables:** For each vaccine, a standardized table provides clear, color-coded consensus recommendations (Recommended - R, Not Recommended - NR, etc.) across different age groups (18-49, ≥50 years) and risk categories (pregnancy, immunocompromised, lifestyle, etc.). Recommended - NR, etc.) across different age groups (18-49, ≥50 years) and risk categories (pregnancy, immunocompromised, lifestyle, etc.).

**At-Risk and High-Risk Group Focus:** Extensive, tailored recommendations are provided for specific patient populations, including those with:

- At-Risk individuals: Chronic Respiratory Disorders, Chronic Heart Disease, Chronic Liver Disease, DM
- High-risk/Immunocompromised conditions:

Chronic Kidney Disease, Nephrotic syndrome, Haemodialysis, HIV, Autoimmune inflammatory Rheumatic Disease, Malignancies (Solid and Haematological), Solid organ transplant, Functional or Anatomical Asplenia, SCD, Hodgkins Disease, Down Syndrome, CSF Leak, Cochlear Implant, complement deficiencies

- Lifestyle-related: Alcohol use disorder, smoking
- Special situations: HCPs, Travellers, Mass gatherings, occupational exposure

**4. Implementation:** Explicitly states its role as a scientific foundation for advocating the inclusion of adult vaccines in public health schemes and insurance coverage.

### 5. Refined and Updated Recommendations for Existing Vaccines:

- Recommendations for vaccines like **Pneumococcal, Tdap/Td, Hepatitis A & B, MMR, and Influenza** have been refined and contextualized for the Indian adult population, with clear guidance on booster doses and special situations.

This consensus document is more than an update; it is a transformative "call to action". It provides a definitive guide to empower healthcare providers and persuade policymakers in building a healthier, more resilient India through adult immunization.

# Anthrax

**Vaccine Type:** Toxoid vaccine

**Route of administration:** Intramuscular (IM) for pre-exposure | Subcutaneous (SC) for post-exposure

**Storage:** 2 °C – 8 °C

**Dose schedule:** 0.5 ml

Pre-exposure prophylaxis (in adults with high risk for exposure) - 0, 1, and 6 months (3 doses) IM

Post-exposure prophylaxis (in adults with suspected or known exposure) - 0, 2, and 4 weeks (3 doses) SC

**Revaccination/Booster dose:**

- Pre-exposure prophylaxis - 6 and 12 months (2 doses) IM and at 12-month intervals thereafter if the risk persists (13-14)

**Consensus Recommendations**

≥50 years	18 - 49 years					
	Pregnancy	At-risk	High-risk/ Immunocompromised	Lifestyle-related	Special situations	12-17 years (Adolescents)
AR*	NR	BR	NR	BR	BR	NR

**R** = Recommended | **NR** = Not Recommended | **BR** = May be considered after benefit risk evaluation | **AR** = With additional Risk

**At-Risk individuals:** Chronic Respiratory Disorders, Chronic Heart Disease, Chronic Liver Disease, DM

**High-risk/Immunocompromised conditions:** Chronic Kidney Disease, Nephrotic syndrome, Haemodialysis, HIV, Autoimmune inflammatory Rheumatic Disease, Malignancies (Solid and Haematological), Solid organ transplant, Functional or Anatomical Asplenia, SCD, Hodgkins Disease, Down Syndrome, CSF Leak, Cochlear Implant, complement deficiencies

**Lifestyle-related:** Alcohol use disorder, smoking

**Special situations:** HCPs, Travellers, Mass gatherings, Occupational exposure

**Key considerations:**

- Not recommended for general use; should only be used in people at increased risk of exposure or in people who have been exposed
  - \*Livestock handlers in endemic areas
  - \*Laboratory workers at risk of exposure

## BCG (Tuberculosis)

**Vaccine Type:** Live attenuated

**Route of administration:** Intradermal injection

**Storage:** 2 °C – 8 °C. Do not expose to direct sunlight or heat

**Dose schedule:** 0.05 ml in infants aged < 1 month | 0.1 ml in infants aged >1 month

**Revaccination/Booster dose:** Re-vaccination in adults, particularly among vulnerable populations, could offer added protection against the disease

**Note:** BCG vaccination is generally not administered to individuals above the age of 16 years due to limited evidence supporting its efficacy in adults. However, certain occupational groups, including healthcare workers, veterinary staff, and abattoir workers, who fall within the age range of 16 to 35 years and are at risk of tuberculosis (TB) through their work, may receive the BCG vaccine. (15-17)

### Consensus Recommendations

≥50 years	18 - 49 years					
	Pregnancy	At-risk	High-risk/ Immunocompromised	Lifestyle-related	Special situations	12-18 years (Adolescents)
BR	NR	BR	NR	BR	BR	AR

R = Recommended | NR = Not Recommended | BR = May be considered after benefit risk evaluation | AR = With additional Risk

**At-Risk individuals:** Chronic Respiratory Disorders, Chronic Heart Disease, Chronic Liver Disease, DM

**High-risk/Immunocompromised conditions:** Chronic Kidney Disease, Nephrotic syndrome, Haemodialysis, HIV, Autoimmune inflammatory Rheumatic Disease, Malignancies (Solid and Haematological), Solid organ transplant, Functional or Anatomical Asplenia, SCD, Hodgkins Disease, Down Syndrome, CSF Leak, Cochlear Implant, complement deficiencies

**Lifestyle-related:** Alcohol use disorder, smoking

**Special situations:** HCPs, Travellers, Mass gatherings, Occupational exposure

## Chickenpox (Varicella)

**Vaccine Type:** Live attenuated vaccine

**Route of administration:** Subcutaneous injection (SC)

**Storage:** 2 °C – 8 °C

**Dose schedule:** 0.5 ml (2 doses, 4-8 weeks apart)

**Revaccination/Booster dose:**

Post-exposure: Recommended within 3-5 days of exposure

Pre-vaccinated: 1 dose, Not-Vaccinated: 2 doses (18)

**Consensus Recommendations**

≥50 years	18 - 49 years					
	Pregnancy	At-risk	High-risk/ Immunocompromised	Lifestyle-related	Special situations	12-18 years (Adolescents)
NR	NR	BR	NR	BR	*NR	AR

R = Recommended | NR = Not Recommended | \*BR = May be considered after benefit risk evaluation | AR = With additional Risk

**At-Risk individuals:** Chronic Respiratory Disorders, Chronic Heart Disease, Chronic Liver Disease, DM

**High-risk/Immunocompromised conditions:** Chronic Kidney Disease, Nephrotic syndrome, Haemodialysis, HIV, Autoimmune inflammatory Rheumatic Disease, Malignancies (Solid and Haematological), Solid organ transplant, Functional or Anatomical Asplenia, SCD, Hodgkins Disease, Down Syndrome, CSF Leak, Cochlear Implant, complement deficiencies

**Lifestyle-related:** Alcohol use disorder, smoking

**Special situations:** HCPs, Travellers, Mass gatherings, Occupational exposure

**Key considerations\*:**

- Routinely recommended in adults without evidence of immunity
- Potential risk of exposure: Individuals or students residing in a hostel
- Increased risk of exposure: HCPs and household contacts
- In special situations indicated for post occupational exposure in the susceptible

# Cholera

**Vaccine Type:** Killed Whole-Cell Monovalent (O1) Vaccine with a Recombinant Cholera Toxin B Subunit WC-rBS, Killed Whole-Cell Bivalent (O1 and O139) Vaccine without the Cholera Toxin B Subunit BivWC, Live Attenuated Vaccine CVD 103-HgR

**Route of administration:** Oral

**Storage:** 2 °C – 8 °C

**Dose schedule:**

- Killed Whole-Cell Monovalent (O1) Vaccine with a Recombinant Cholera Toxin B Subunit WC-rBS – 1.5 ml (2 doses; ≥1 week before potential exposure)
- Killed Whole-Cell Bivalent (O1 and O139) Vaccine without the Cholera Toxin B Subunit BivWC - 1.5 ml (2 doses at an interval of 2 weeks)
- Live Attenuated Vaccine CVD 103-HgR - 100 ml (single dose ≤ 10 days before potential exposure)

**Revaccination/Booster dose:**

During Endemic/Outbreak: booster dose after 2 years (19)

**Consensus Recommendations**

≥50 years	18 - 49 years					
	Pregnancy	At-risk	High-risk/ Immunocompromised	Lifestyle-related	Special situations	12-18 years (Adolescents)
NR	NR	BR	NR	NR	R	R

R = Recommended | NR = Not Recommended | BR = May be considered after benefit risk evaluation | AR = With additional Risk

**At-Risk individuals:** Chronic Respiratory Disorders, Chronic Heart Disease, Chronic Liver Disease, DM

**High-risk/Immunocompromised conditions:** Chronic Kidney Disease, Nephrotic syndrome, Haemodialysis, HIV, Autoimmune inflammatory Rheumatic Disease, Malignancies (Solid and Haematological), Solid organ transplant, Functional or Anatomical Asplenia, SCD, Hodgkins Disease, Down Syndrome, CSF Leak, Cochlear Implant, complement deficiencies

**Lifestyle-related:** Alcohol use disorder, smoking

**Special situations:** HCPs, Travellers, Mass gatherings, Occupational exposure

**Key considerations:**

- Routine administration is not recommended
- Travellers at high risk
- Potential exposure to cholera patients or contaminated water and food, particularly those staying in areas with limited access to health care facilities – 2 doses – at least 2 weeks apart
- During natural calamity: 2 doses – at least 2 weeks apart
- Live vaccine should be avoided in pregnancy

## Corona Virus Disease (COVID-19)

### List of COVID-19 Vaccines Approved by CDSCO in India (20-21)

Type of vaccine	Route of administration	Storage	Dosing schedule	Revaccination/ Booster dose
ChAdOx1 nCoV-19 Corona Virus vaccine Recombinant (COVISHIELD)	IM	2-8°C	2 doses, 4 to 6 weeks apart	Single dose in 12 months
Whole-Virion Inactivated SARS-CoV-2 Vaccine (COVAXIN)	IM	2-8°C	2 doses, Day 0 & 28	Single dose in 12 months
Gam COVID Vac (component I & II) (SPUTNIK-V)	IM	-18°C	2 doses, Day 0 (comp I) & Day 21 (comp II)	Single dose in 12 months
mRNA-1273 COVID-19 vaccine (Spikevax)	IM	-25°C to -15°C & 2-8°C	2 doses, Day 0 & 28	Single dose in 12 months
COVID-19 vaccine (Ad26.COV2-S) [recombinant] (Jcovden)	IM	-25°C to -15°C & 2-8°C	Single dose	Single dose in 12 months
Novel Corona Virus-2019-nCov vaccine (recombinant DNA) (ZyCoV-D)	Intradermal	2-8°C	3 doses (Day 0, 28 and 56)	Single dose in 12 months
SARS-CoV-2 vaccine containing Receptor Binding Domain (RBD) of SARS-CoV-2 gene (CORBEVAX)	IM	2-8°C	2 doses, Day 0 & 28	Single dose in 12 months
SARS-CoV-2 rS Protein (COVID-19) recombinant spike protein Nanoparticle Vaccine [COVOVAX]	IM	2-8°C	2 doses, Day 0 & 21	Single dose in 12 months
Recombinant adenoviral vector vaccine containing particles of S gene of the SARS-CoV-2 virus (SPUTNIK Light)	IM	-18°C	Single dose	Single dose in 12 months
Gemcovac-19	IM	2-8°C	2 doses, Day 0 & 28	Single dose in 12 months
Vaxzevria	IM	2-8°C	2 doses, Day 0 & 28	Single dose in 12 months

# Corona Virus Disease (COVID-19)

## Consensus Recommendations

≥50 years	18 -49 years					12-18 years (adolescents)
	Pregnancy	At-risk	High-risk/ Immunocompromised	Lifestyle related	Special situations	
R	R	R	R	R	R	R

R = Recommended | NR = Not Recommended | BR = May be considered after benefit risk evaluation | AR = With additional Risk

**At-Risk individuals:** Chronic Respiratory Disorders, Chronic Heart Disease, Chronic Liver Disease, DM  
**High-risk/Immunocompromised conditions:** Chronic Kidney Disease, Nephrotic syndrome, Haemodialysis, HIV, Autoimmune inflammatory Rheumatic Disease, Malignancies (Solid and Haematological), Solid organ transplant, Functional or Anatomical Asplenia, SCD, Hodgkins Disease, Down Syndrome, CSF Leak, Cochlear Implant, complement deficiencies

**Lifestyle-related:** Alcohol use disorder, smoking

**Special situations:** HCPs, Travellers, Mass gatherings, Occupational exposure

### Key considerations:

- \*Although new variant-specific vaccines are not yet available in India, existing boosters can still offer strong protection and these boosters can reduce the risk of symptomatic infection by 50% and severe disease by up to 80%
- At the time of pandemic or local epidemic situations: Routine administration is strongly recommended for all, even during pregnancy – 2 doses – at least 4 weeks apart
- Additional booster doses: for all older adults and adults with significant comorbidities or severe obesity (high priority-use group) – At least 12 months after the previous dose

### Note:

- The recommendations for use are limited to pandemic or local epidemic situations only. Please refer to the latest government recommendations for frequency of repeat/ booster doses.
- There are no head-to-head studies comparing the different vaccines available for the prevention of COVID-19. Please check local availability and most recent government notification for the selection of vaccine.

## Diphtheria, Pertussis and Tetanus

**Vaccine Type:** Tdap: Diphtheria and tetanus toxoids with acellular pertussis antigens;  
Td: Diphtheria (reduced dose) and tetanus toxoids

**Route of administration:** Intramuscular injection (IM)

**Storage:** 2 °C – 8 °C

**Dose schedule:** 0.5ml

Un-vaccinated: 3 doses (1st dose Tdap, 2nd dose Td or Tdap 4 weeks apart, 3rd dose Td or Tdap after 6–12 months)

**Revaccination/Booster dose:** Single dose every 10 years (Td or Tdap) (22)

### Consensus Recommendations

Vaccine	≥50 years	18 -49 years					12-18 years (adolescents)
		Pregnancy	At-risk	High-risk/ Immunocompromised	Lifestyle related	Special situations	
Td	R	R	R	R	R	R	R
Tdap	R	R	R	R	R	R	R

R = Recommended | NR = Not Recommended | BR = May be considered after benefit risk evaluation | AR = With additional Risk

**At-Risk individuals:** Chronic Respiratory Disorders, Chronic Heart Disease, Chronic Liver Disease, DM

**High-risk/Immunocompromised conditions:** Chronic Kidney Disease, Nephrotic syndrome, Haemodialysis, HIV, Autoimmune inflammatory Rheumatic Disease, Malignancies (Solid and Haematological), Solid organ transplant, Functional or Anatomical Asplenia, SCD, Hodgkins Disease, Down Syndrome, CSF Leak, Cochlear Implant, complement deficiencies

**Lifestyle-related:** Alcohol use disorder, smoking

**Special situations:** HCPs, Travellers, Mass gatherings, Occupational exposure

### Key considerations:

- During each pregnancy, it is recommended to receive one dose of Tdap, preferably between the gestational weeks of 27 and 36.
- Wound management: If a person has not been fully immunized, they should receive a primary series of three doses: one immediately, a second 4 to 8
- In the event of injuries with risk of tetanus after 5 years even in fully vaccinated persons, Tdap booster is recommended

## Haemophilus influenzae type b (Hib)

**Vaccine Type:** Lyophilised killed | Conjugate Vaccine (capsular polysaccharide bound to carrier protein) - pentavalent/bivalent combination or hexavalent injection

**Route of administration:** Intramuscular injection (IM)

**Storage:** 2 °C – 8 °C

**Dose schedule:** 0.5 ml (At risk - 1 or 3 doses) (23)

**Revaccination/Booster dose:** NA

### Consensus Recommendations

≥50 years	18 -49 years					
	Pregnancy	At-risk	High-risk/ Immunocompromised	Lifestyle related	Special situations	12-18 years (adolescents)
R	NR	R	R	R	NR	AR

R = Recommended | NR = Not Recommended | BR = May be considered after benefit risk evaluation | AR = With additional Risk

**At-Risk individuals:** Chronic Respiratory Disorders, Chronic Heart Disease, Chronic Liver Disease, DM

**High-risk/Immunocompromised conditions:** Chronic Kidney Disease, Nephrotic syndrome, Haemodialysis, HIV, Autoimmune inflammatory Rheumatic Disease, Malignancies (Solid and Haematological), Solid organ transplant, Functional or Anatomical Asplenia, SCD, Hodgkins Disease, Down Syndrome, CSF Leak, Cochlear Implant, complement deficiencies

**Lifestyle-related:** Alcohol use disorder, smoking

**Special situations:** HCPs, Travellers, Mass gatherings, Occupational exposure

### Key considerations:

- This vaccination is a part of primary immunization
- Adults at high risk, such as patients with immunocompromised state, CSF leak, trauma, diabetes, pregnancy, alcoholism, cancer, radiation, or chemotherapy: 1 dose
- Elective splenectomy. If unvaccinated: 1 dose (at least 14 days before splenectomy)
- Functional or anatomic asplenia. If unvaccinated: 1 dose
- Recipients of hematopoietic stem cell transplant: 3 doses at 4-week intervals; 6–12 months after transplant, regardless of Hib vaccine history

# Hepatitis A

**Vaccine Type:** Inactivated vaccine, live attenuated vaccine

**Route of administration:** Inactivated - intramuscular (deltoid) Live - subcutaneous (deltoid)

**Storage:** 2 °C – 8 °C

**Dose schedule:** Inactivated- 1 ml HAV 2 doses, 6 months apart  
Live - 0.5 ml single dose

**Revaccination/Booster dose:** NA

## Consensus Recommendations

≥50 years	18 -49 years					
	Pregnancy	At-risk	High-risk/ Immunocompromised	Lifestyle related	Special situations	12-18 years (adolescents)
AR	NR	R	R (Only inactivated)	R	R	R

R = Recommended | NR = Not Recommended | BR = May be considered after benefit risk evaluation | AR = With additional Risk

**At-Risk individuals:** Chronic Respiratory Disorders, Chronic Heart Disease, Chronic Liver Disease, DM

**High-risk/Immunocompromised conditions:** Chronic Kidney Disease, Nephrotic syndrome, Haemodialysis, HIV, Autoimmune inflammatory Rheumatic Disease, Malignancies (Solid and Haematological), Solid organ transplant, Functional or Anatomical Asplenia, SCD, Hodgkins Disease, Down Syndrome, CSF Leak, Cochlear Implant, complement deficiencies (only inactivated vaccine)

**Lifestyle-related:** Alcohol use disorder, smoking

**Special situations:** HCPs, women of child bearing age, students, travellers traveling to endemic areas, occupational exposure to animals Mass gatherings, Occupational exposure

## Key considerations:

- Chronic liver disease (e.g., persons with hepatitis B, hepatitis C, cirrhosis, fatty liver disease, alcoholic liver disease, autoimmune hepatitis, alanine aminotransferase [ALT] or aspartate aminotransferase [AST] level greater than twice the upper limit of normal)
- \*Occupational exposure includes food and beverage handlers, care givers to high risk groups
- HIV infection
- Men who have sex with men
- Injection or non-injection drug use
- Persons experiencing homelessness
- Work with hepatitis A virus in research laboratory or with non-human primates with hepatitis A virus infection
- Travel in countries with high or intermediate endemic hepatitis A (HepA - HepB may be administered on an accelerated schedule of 3 doses at 0, 7, and 21–30 days, followed by a booster dose at 12 months.)
- Post-exposure vaccination is recommended for Men who have Sex with Men (MSM) and other high risk situations in adults

Note: Contraindicated during pregnancy

# Hepatitis B

**Vaccine Type:** Recombinant DNA or plasma derived inactivated subunit vaccine (Monovalent | HepA + HepB)

**Route of administration:** Deep Intramuscular injection (IM) in Deltoid region; avoid buttocks

**Storage:** 2 °C – 8 °C

**Dose schedule:** 0.5 ml (3 doses (0, 1, 6 months in high risk)

**Revaccination/Booster dose:** Booster doses need to be calculated based on titres (25)

## Consensus Recommendations

≥50 years	18 -49 years					
	Pregnancy	At-risk	High-risk/ Immunocompromised	Lifestyle related	Special situations	12-18 years (adolescents)
AR	R	R	R	R	R	R

R = Recommended | NR = Not Recommended | BR = May be considered after benefit risk evaluation | AR = With additional Risk

**At-Risk individuals:** Chronic Respiratory Disorders, Chronic Heart Disease, Chronic Liver Disease, DM

**High-risk/Immunocompromised conditions:** Chronic Kidney Disease, Nephrotic syndrome, Haemodialysis, HIV, Autoimmune inflammatory Rheumatic Disease, Malignancies (Solid and Haematological), Solid organ transplant, Functional or Anatomical Asplenia, SCD, Hodgkins Disease, Down Syndrome, CSF Leak, Cochlear Implant, complement deficiencies

**Lifestyle-related:** Alcohol use disorder, smoking

**Special situations:** HCPs, Travellers, Mass gatherings, Occupational exposure

### Key considerations:

- Chronic liver disease (e.g., persons with hepatitis C, cirrhosis, fatty liver disease, alcoholic liver disease, autoimmune hepatitis, alanine aminotransferase [ALT] or aspartate aminotransferase [AST] level greater than twice the upper limit of normal)
- HIV infection
- Men who have sex with men
- Injection or non-injection drug use
- Travel in countries with high or intermediate endemic hepatitis A (HepA + HepB may be administered on an accelerated schedule of 3 doses at 0, 7, and 21–30 days, followed by a booster dose at 12 months)
- Dose and schedule in CKD and dialysis patients is 40mcg ie., 1 ml at 0,2,6 and 12 months.

Note: Revaccination is recommended every 5 years for high-risk individuals (E.g., immunocompromised, healthcare professionals, individuals with chronic kidney disease on haemodialysis, etc.)

## Hepatitis E

**Vaccine Type:** Recombinant vaccine (E. Coli-based)

**Route of administration:** Intramuscular (IM) – deltoid

**Storage:** Stored between 2 °C and 8 °C

**Dose schedule:** 0.5 ml (3 doses (0, 1, 6 months in high risk) (78)

**Revaccination/Booster dose:** NA

### Consensus Recommendations

≥50 years	18-49 years					
	Pregnancy	At-risk	High-risk/ Immunocompromised	Lifestyle related	Special situations	12-18 years (adolescents)
R	NR	R	R	AR	R	NR

R = Recommended | NR = Not Recommended | BR = May be considered after benefit risk evaluation | AR = With additional Risk

**At-Risk individuals:** Chronic Liver disease, Chronic respiratory disease, Chronic Heart Disease, DM  
**High-risk/Immunocompromised conditions:** Chronic Kidney Disease, Nephrotic syndrome, Haemodialysis, HIV, Autoimmune inflammatory Rheumatic Disease, Malignancies (Solid and Haematological), Solid organ transplant, Functional or Anatomical Asplenia, SCD, Hodgkins Disease, Down Syndrome, CSF Leak, Cochlear Implant, complement deficiencies

**Lifestyle-related:** Alcohol use disorder, smoking

**Special situations:** HCPs, Travellers, Mass gatherings, Occupational exposure

### Key considerations:

- Recommendation in pregnancy and lactation should be based on shared clinical decision-making
- Special situations include women of child bearing age, Travellers to endemic areas, students, occupational exposure like animal husbandry/catering, Military personnel, outbreak situations.

# Human Papilloma Virus

**Vaccine Type:** Bivalent recombinant protein capsid liquid vaccine (HPV2) protects against HPV 16 and 18; Quadrivalent vaccine (HPV4) protects against HPV 6, 11, 16 and 18; Nonavalent vaccine (HPV9) protects against HPV 6, 11, 16, 18, 31, 33, 45, 52 and 58

**Route of administration:** Intramuscular injection (IM)

**Storage:** 2 °C – 8 °C

**Dose schedule:** 1 ml

Girls/Boys aged 9–14 years as a 2-dose schedule (atleast 5 months apart)

From age 15, a 3-dose schedule is indicated (at 0, 1–2 months and 5–8 months) (26)

**Revaccination/Booster dose:** NA

## Consensus Recommendations

≥50 years	18 -49 years					
	Pregnancy	At-risk	High-risk/ Immunocompromised	Lifestyle related	Special situations	12-18 years (adolescents)
NR	NR	R	R	R	NR	R

R = Recommended | NR = Not Recommended | BR = May be considered after benefit risk evaluation | AR = With additional Risk

**At-Risk individuals:** Chronic Respiratory Disorders, Chronic Heart Disease, Chronic Liver Disease, DM

**High-risk/Immunocompromised conditions:** Chronic Kidney Disease, Nephrotic syndrome, Haemodialysis, HIV, Autoimmune inflammatory Rheumatic Disease, Malignancies (Solid and Haematological), Solid organ transplant, Functional or Anatomical Asplenia, SCD, Hodgkins Disease, Down Syndrome, CSF Leak, Cochlear Implant, complement deficiencies

**Lifestyle-related:** Alcohol use disorder, smoking

**Special situations:** HCPs, Travellers, Mass gatherings, Occupational exposure

## Key considerations:

- Before the first sexual encounter
- HPV vaccination is advised for all people up to age 26: Depending on the age at the first immunisation or the condition, a 2- or 3-dose series:
  - Age 15 or older at the time of the initial vaccination: 3-dosage series given over the course of 0, 1, and 6 months. (minimum intervals: 4 weeks between doses 1 and 2, 12 weeks between doses 2 and 3, and 5 months. between doses 1 and 3; repeat dose if given too soon)
- Adults age 27–45 years: Based on shared clinical decision-making, complete a 2-dose series (if initiated age 9-14 years) or 3-dose series (if initiated ≥15 years)
- Immunocompromising diseases: Such as HIV infection: 3-dose series, even for those who start immunisation at age 9 to 14

Note: There is currently no recommendation for HPV use in pregnancy. Consider delaying HPV until after pregnancy

# Influenza

**Vaccine Type:** Tetra/ Quadrivalent influenza vaccine - contains inactivated (dead) viruses from four different strains: two type A strains (H1N1 and H3N2) and two type B strains (Victoria and Yamagata), Trivalent Influenza Vaccine (TIV) protecting against the three influenza strains: two type A strains (H1N1 and H3N2) and one type B strains (Victoria)

**Route of administration:** IM, intranasal

**Storage:** 2 °C – 8 °C

**Dose schedule:** IM: 0.5 ml single dose

**Revaccination/Booster dose:** annually (27,28)

## Consensus Recommendations

Vaccine	≥50 years	18 -49 years					
		Pregnancy	At-risk	High-risk/ Immunocompromised	Lifestyle related	Special situations	12-18 years (adolescents)
Tetra-valent vaccine	R	R	R	R	R	R	R

R = Recommended | NR = Not Recommended | BR = May be considered after benefit risk evaluation | AR = With additional Risk

**At-Risk individuals:** Chronic Respiratory Disorders, Chronic Heart Disease, Chronic Liver Disease, DM

**High-risk/Immunocompromised conditions:** Chronic Kidney Disease, Nephrotic syndrome, Haemodialysis, HIV, Autoimmune inflammatory Rheumatic Disease, Malignancies (Solid and Haematological), Solid organ transplant, Functional or Anatomical Asplenia, SCD, Hodgkins Disease, Down Syndrome, CSF Leak, Cochlear Implant, complement deficiencies

**Lifestyle-related:** Alcohol use disorder, smoking

**Special situations:** HCPs, Travellers, Mass gatherings, Occupational exposure

## Key considerations:

- Adults who have not received the vaccine should continue to receive it throughout the entire influenza season, especially during times when the virus is active in the neighbourhood e.g. before the monsoon season in South India or before the winter season in Northern India
- All adults, including pregnant women: 1 dose annually
- It is advisable to use the trivalent influenza vaccine comprising influenza A(H1N1)pdm09, A(H3N2), and B/Victoria strains as per WHO recommendations for the upcoming influenza season. However, in instances where the recently recommended trivalent formulation is unavailable, the use of the quadrivalent influenza vaccine is recommended.

Note: Close contacts and caregivers who care for severely immunocompromised persons (i.e., those who require care in a protective environment) should also receive a single dose of tetravalent vaccine

# Japanese Encephalitis

**Vaccine Type:** Live attenuated, Inactivated Vero cell-derived

**Route of administration:** subcutaneous injection (SC)

**Storage:** 2 °C – 8 °C

**Dose schedule:** Live attenuated vaccine: 0.5 ml (2 doses; 7-28 days apart)  
Inactivated Vero cell-derived vaccine: 0.5 ml (2 doses at Day 0 and Day 28)

**Revaccination/Booster dose:** Live attenuated vaccine: After 11 months in high risk  
Inactivated Vero cell-derived vaccine: After 1–2 years if ongoing exposure (29)

## Consensus Recommendations

≥50 years	18 -49 years					
	Pregnancy	At-risk	High-risk/ Immunocompromised	Lifestyle related	Special situations	12-18 years (adolescents)
BR	NR	BR	BR	BR	BR	BR

R = Recommended | NR = Not Recommended | BR = May be considered after benefit risk evaluation | AR = With additional Risk

**At-Risk individuals:** Chronic Respiratory Disorders, Chronic Heart Disease, Chronic Liver Disease, DM

**High-risk/Immunocompromised conditions:** Chronic Kidney Disease, Nephrotic syndrome, Haemodialysis, HIV, Autoimmune inflammatory Rheumatic Disease, Malignancies (Solid and Haematological), Solid organ transplant, Functional or Anatomical Asplenia, SCD, Hodgkins Disease, Down Syndrome, CSF Leak, Cochlear Implant, complement deficiencies

**Lifestyle-related:** Alcohol use disorder, smoking

**Special situations:** HCPs, Travellers, Mass gatherings, Occupational exposure

### Key considerations:

- Vaccination is recommended for travellers who plan to stay in endemic areas for a month or longer during the transmission season, even if they stay primarily in urban areas.
- For short-term travellers (less than a month), vaccination should be considered if they plan to spend long periods outdoors in rural or agricultural areas, engage in outdoor activities, or be in areas without adequate protection such as air conditioning, screens, etc. or mosquito nets.
- It should also be considered for travellers visiting areas with ongoing outbreaks or uncertain travel destinations, activities and travel duration.
- However, vaccination is not currently recommended for short-term travellers whose plans relate exclusively to urban areas.
- Can be administered during Kumbh Melas if stay is longer than 1 month.
- Patients with chronic illness or immunodeficiency who live in or move to endemic areas.
- Pregnant women traveling or staying in endemic areas always weigh the benefit-risk ratio before administration
- Inactivated Vero cell-derived vaccine is approved for ≥2 months; used for travelers and high-risk adults.

Note: Live vaccine should not be given during epidemic season

## Measles, Mumps and Rubella

**Vaccine Type:** live-attenuated combined vaccine (MR= Measles & Rubella | MMR= Measles, Mumps & Rubella | MMRV= Measles, Mumps, Rubella & Varicella)

**Route of administration:** subcutaneous injection (SC)

**Storage:** : 2 °C - 8 °C

**Dose schedule:** 0.5 ml (2 doses; 4 weeks apart) (30)

**Revaccination/Booster dose:** NA

### Consensus Recommendations

≥50 years	18 -49 years					
	Pregnancy	At-risk	High-risk/ Immunocompromised	Lifestyle related	Special situations	12-18 years (adolescents)
NR	NR	BR	BR	BR	NR	R

R = Recommended | NR = Not Recommended | BR = May be considered after benefit risk evaluation | AR = With additional Risk

**At-Risk individuals:** Chronic Respiratory Disorders, Chronic Heart Disease, Chronic Liver Disease, DM

**High-risk/Immunocompromised conditions:** Chronic Kidney Disease, Nephrotic syndrome, Haemodialysis, HIV, Autoimmune inflammatory Rheumatic Disease, Malignancies (Solid and Haematological), Solid organ transplant, Functional or Anatomical Asplenia, SCD, Hodgkins Disease, Down Syndrome, CSF Leak, Cochlear Implant, complement deficiencies

**Lifestyle-related:** Alcohol use disorder, smoking

**Special situations:** HCPs, Travellers, Mass gatherings, Occupational exposure

### Key considerations:

- If a woman of childbearing age is found to be rubella susceptible and is not pregnant, give 1 dose of MMR; if she is pregnant, the dose should be given postpartum
- MMR vaccine is not advised if the patient is pregnant because it is a live attenuated vaccine and could potentially harm the foetus. But in case a pregnant woman receives the MMR, the pregnancy should NOT be terminated on that basis since, there is no proof that the MMR or MMRV vaccines pose a teratogenic risk. Pregnant women may receive the MMR vaccine during measles or rubella outbreaks since the possible advantages of vaccination outweigh the dangers. Since the MMR vaccine is safe during breastfeeding, non-immunized patients should receive it after delivery.

# Meningococcal disease

**Vaccine Type:** Purified bacterial capsular polysaccharide (PBCP) | Conjugate Vaccine

**Route of administration:** PBCP Subcutaneous | Conjugate vaccine intramuscular injection (IM)

**Storage:** 2 °C – 8 °C

**Dose schedule:** 0.5 ml Single dose IM

Dosage schedule is different for high-risk adults (anatomical or functional asplenia (including sickle cell disease), HIV infection, persistent complement component deficiency, complement inhibitor (e.g., eculizumab, ravulizumab), travel to countries with hyperendemic or epidemic meningococcal disease, mass gatherings)

**Revaccination/Booster dose:** MenACWY – revaccinate every 5 years if risk remains

MenB – 1 booster dose a year after primary series and revaccinate every 2–3 years if risk remains (31,32)

## Consensus Recommendations

Vaccine	≥50 years	18 -49 years					
		Pregnancy	At-risk	High-risk/ Immunocompromised	Lifestyle related	Special situations	12-18 years (adolescents)
Men ACWY	AR	NR	R	AR	AR	R	R
MenB	AR	NR	R	AR	AR	AR	R

**R** = Recommended | **NR** = Not Recommended | **BR** = May be considered after benefit risk evaluation | **AR** = With additional Risk

**At-Risk individuals:** Chronic Respiratory Disorders, Chronic Heart Disease, Chronic Liver Disease, DM

**High-risk/Immunocompromised conditions:** Chronic Kidney Disease, Nephrotic syndrome, Haemodialysis, HIV, Autoimmune inflammatory Rheumatic Disease, Malignancies (Solid and Haematological), Solid organ transplant, Functional or Anatomical Asplenia, SCD, Hodgkins Disease, Down Syndrome, CSF Leak, Cochlear Implant, complement deficiencies

**Lifestyle-related:** Alcohol use disorder, smoking

**Special situations:** HCPs, Travellers, Mass gatherings, Occupational exposure

## Pneumococcal Disease

### Vaccine Type:

- **Pneumococcal Polysaccharide Conjugate Vaccine Adsorbed I.P. 20-valent (PCV20):** PCV20 provides protection against 20 serotypes of *S. pneumoniae* viz.; 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33F
- **Pneumococcal Polysaccharide Conjugate Vaccine Adsorbed I.P. 13-valent (PCV13):** PCV13 provides protection against 13 serotypes of *S. pneumoniae* viz.; 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F
- **Pneumococcal Polysaccharide Vaccine I.P. 23-valent (PPSV23):** It provides protection against 23 serotypes of *S. pneumoniae* serotypes viz.; 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19A, 19F, 20, 22F, 23F, and 33F

**Route of administration:** PCV20: Intramuscular | PCV13: Intramuscular | PPSV23: Intramuscular or Subcutaneous injection

**Storage:** 2 °C – 8 °C

**Dose schedule:** 0.5 ml: 1 Dose of PCV20 OR 1 dose of PCV13 followed by 1 dose of PPSV23 (8 weeks to 1 year later)

**Revaccination/Booster dose:** Revaccination/booster dose: - 1 Dose of PPSV23 - 5 years after the last dose of PPSV23 (18-21) (33-35)

### Consensus Recommendations

≥50 years	18 -49 years					
	Pregnancy	At-risk	High-risk/ Immunocompromised	Lifestyle related	Special situations	12-18 years (adolescents)
R	NR	R	R	R	R	AR

R = Recommended | NR = Not Recommended | BR = May be considered after benefit risk evaluation | AR = With additional Risk

**At-Risk individuals:** Chronic Respiratory Disorders, Chronic Heart Disease, Chronic Liver Disease, DM

**High-risk/Immunocompromised conditions:** Chronic Kidney Disease, Nephrotic syndrome, Haemodialysis, HIV, Autoimmune inflammatory Rheumatic Disease, Malignancies (Solid and Haematological), Solid organ transplant, Functional or Anatomical Asplenia, SCD, Hodgkins Disease, Down Syndrome, CSF Leak, Cochlear Implant, complement deficiencies

**Lifestyle-related:** Alcohol use disorder, smoking

**Special situations:** HCPs, Travellers, Mass gatherings, Occupational exposure

### Key considerations: for PCV20:

- 18-49 years with chronic medical conditions (At-risk, High-risk/Immunocompromised, Lifestyle or Special situations) OR all ≥ 50 years: single dose of PCV20
- Previously vaccinated with any pneumococcal vaccine- Single Dose of PCV20, One year later
- Vaccinated with PCV 13 + PPSV23 schedule - One dose of PCV20 - 5 years after the last dose of PPSV23

### Key considerations with PCV13 and PPSV23:

- Above 50 years: PCV 13 followed by PPSV23 1 year later
- 18-49 years with At-risk: PCV 13 followed by PPSV23 1 year later
- 18-49 years with High-risk: PCV 13 followed by PPSV23 8 weeks later

\* PCV20 can be administered in adolescents with additional risk after its regulatory approval in <18 years in India

# Poliomyelitis

**Vaccine Type:** Live Attenuated (OPV) | Inactivated Polio Vaccine (IPV)

**Route of administration:** OPV Oral | IPV intradermal (id)

**Storage:** 2 °C - 8 °C | OPV: Highly heat sensitive and should be kept frozen during storage (after thawing it can be kept between 2 °C - 8 °C for up to 6 months)

**Dose schedule:** IPV 0.1 ml | OPV: 2 drops

**Unvaccinated or incompletely vaccinated adults:** 3 doses (1st dose at any time, followed by 2nd dose at least 1 month later & 3rd dose 6-12 months after)

**Revaccination/Booster dose:** in previously vaccinated - 1 booster dose of IPV (36)

## Consensus Recommendations

≥50 years	18 -49 years					
	Pregnancy	At-risk	High-risk/ Immunocompromised	Lifestyle related	Special situations	12-18 years (adolescents)
R	NR	R	NR	NR	BR	R

R = Recommended | NR = Not Recommended | BR = May be considered after benefit risk evaluation | AR = With additional Risk

**At-Risk individuals:** Chronic Respiratory Disorders, Chronic Heart Disease, Chronic Liver Disease, DM

**High-risk/Immunocompromised conditions:** Chronic Kidney Disease, Nephrotic syndrome, Haemodialysis, HIV, Autoimmune inflammatory Rheumatic Disease, Malignancies (Solid and Haematological), Solid organ transplant, Functional or Anatomical Asplenia, SCD, Hodgkins Disease, Down Syndrome, CSF Leak, Cochlear Implant, complement deficiencies

**Lifestyle-related:** Alcohol use disorder, smoking

**Special situations:** HCPs, Travellers, Mass gatherings, Occupational exposure

### Key considerations:

- Previously vaccinated: one lifetime booster dose of IPV
- IPV vaccine not available in India as a single injection
- Travellers to countries with polio epidemic or is endemic
- Laboratory and healthcare workers who handle specimens that might contain polioviruses
- Healthcare workers or other caregivers who have close contact with a person who could be infected with poliovirus

# Rabies

## Categories of contact with suspect rabid animal

Category I - Touching or feeding animals, animal licks on intact skin (no exposure)

Category II - nibbling of uncovered skin, minor scratches or abrasions without bleeding (exposure)

Category III - single or multiple transdermal bites or scratches, contamination of mucous membrane or broken skin with saliva from animal licks, exposures due to direct contact with bats (severe exposure)

**Vaccine Type:** Human diploid cell vaccine (HDCV) | Purified chick embryo cell vaccine (PCEC) | Purified duck embryo cell vaccine (PDEC) | Purified Vero cell rabies vaccine (PVRV)

**Route of administration:** Intramuscular injection (IM)| Intradermal injection (for resource-limited setup e.g., government hospitals receiving several at-risk patients in a day)

**Storage:** 2 °C - 8 °C

**Dose schedule:** IM dose: 0.5ml PVRV | 1 ml HDCV or PCEC or PDEC

Pre-exposure - 3 doses at 0, 7 & 21 – 28 days

Post-exposure - 5 doses at day 0, 3, 7, 14 and 28

ID dose: Pre-exposure:- 0.1 ml, 3 dose as in im schedule

Post-exposure:- 0.1 ml, 4 doses at day 0,3,7 and 28

Re-exposure:- completed PreEP and Post EP: 2 doses,0 and 3 months with equal volume as in im(0.5 ml) & id(0.1ml)

**Revaccination/Booster dose:** 2 booster doses in case of new exposure in previously vaccinated individuals.

Dose 1: Given immediately on Day 0

Dose 2: Given on Day 3 (37)

## Consensus Recommendations: Post exposure

≥50 years	18 -49 years					
	Pregnancy	At-risk	High-risk/ Immunocompromised	Lifestyle related	Special situations	12-18 years (adolescents)
<b>R (5 doses)</b>	<b>NR</b>	<b>R</b>	<b>R</b>	<b>R</b>	<b>R</b>	<b>R</b>

**R** = Recommended | **NR** = Not Recommended | **BR** = May be considered after benefit risk evaluation | **AR** = With additional Risk

**At-Risk individuals:** Chronic Respiratory Disorders, Chronic Heart Disease, Chronic Liver Disease, DM

**High-risk/Immunocompromised conditions:** Chronic Kidney Disease, Nephrotic syndrome, Haemodialysis, HIV, Autoimmune inflammatory Rheumatic Disease, Malignancies (Solid and Haematological), Solid organ transplant, Functional or Anatomical Asplenia, SCD, Hodgkins Disease, Down Syndrome, CSF Leak, Cochlear Implant, complement deficiencies

**Lifestyle-related:** Alcohol use disorder, smoking

**Special situations:** HCPs, Travellers, Mass gatherings, Occupational exposure

## Key considerations:

- Pre-exposure high risk
  - Work as a veterinarian or animal handler
  - Are a veterinary student
  - Study or explore caves
  - Study the rabies virus
  - Are traveling to other countries where rabies is common
  - Joggers, walkers and pet owners should be encouraged

\*India follows the National Guidelines for Rabies Prophylaxis developed by the National Centre for Disease Control (NCDC), which are consistent with World Health Organization (WHO) recommendations - latest recommendations emphasize immediate wound care, timely vaccination, and the use of rabies immunoglobulin (RIG) for severe exposures.

# Typhoid

**Vaccine Type:** Inactivated typhoid vaccine I Vi Polysaccharides Vaccine (ViPS) I Typhoid conjugate vaccine (TCV) I Live typhoid vaccine

**Route of administration:** Inactivated typhoid vaccine I ViPS I TCV - IM I Live typhoid vaccine - Oral

**Storage:** 2 °C - 8 °C

**Dose schedule:** Inactivated typhoid vaccine I ViPS I TCV – 0.5 ml IM single dose of ViPS/TCV  
Live typhoid vaccine – 4 capsules (Day 1, 3, 5 and 7)

**Revaccination/Booster dose:** ViPS - Every 2 years if risk continues  
Live typhoid vaccine - Every 5 years, if risk continues (38)

## Consensus Recommendations:

≥50 years	18 -49 years					
	Pregnancy	At-risk	High-risk/ Immunocompromised	Lifestyle related	Special situations	12-18 years (adolescents)
R	NR	R	R	R	R	R

R = Recommended | NR = Not Recommended | BR = May be considered after benefit risk evaluation | AR = With additional Risk

**At-Risk individuals:** Chronic Respiratory Disorders, Chronic Heart Disease, Chronic Liver Disease, DM

**High-risk/Immunocompromised conditions:** Chronic Kidney Disease, Nephrotic syndrome, Haemodialysis, HIV, Autoimmune inflammatory Rheumatic Disease, Malignancies (Solid and Haematological), Solid organ transplant, Functional or Anatomical Asplenia, SCD, Hodgkins Disease, Down Syndrome, CSF Leak, Cochlear Implant, complement deficiencies

**Lifestyle-related:** Alcohol use disorder, smoking

**Special situations:** HCPs, Travellers, Mass gatherings, Occupational exposure

## Key considerations:

- Professional food handlers
- Unvaccinated Adults age 18 through 45yrs may be given TCV in endemic areas
- Travellers at risk of exposure
- During outbreaks
- Inactivated typhoid vaccine: One dose is recommended at least 2 weeks before travel.
- Live typhoid vaccine: The last dose should be taken at least 1 week before travel

**\*Do not use live vaccine if pregnant**

## Shingles (Herpes Zoster)

**Vaccine Type:** Recombinant zoster vaccine

**Route of administration:** Deltoid area IM

**Storage:** 2 °C - 8 °C. Do not expose to direct sunlight or heat

**Dose schedule:** 0.5 ml (2 doses – 2-6 months apart) (39)

**Revaccination/Booster dose:** NA

### Consensus Recommendations:

≥50 years	18 -49 years					
	Pregnancy	At-risk	High-risk/ Immunocompromised	Lifestyle related	Special situations	12-18 years (adolescents)
R	NR	BR	R	R	BR	NR

R = Recommended | NR = Not Recommended | BR = May be considered after benefit risk evaluation | AR = With additional Risk

**At-Risk individuals:** Chronic Respiratory Disorders, Chronic Heart Disease, Chronic Liver Disease, DM

**High-risk/Immunocompromised conditions:** Chronic Kidney Disease, Nephrotic syndrome, Haemodialysis, HIV, Autoimmune inflammatory Rheumatic Disease, Malignancies (Solid and Haematological), Solid organ transplant, Functional or Anatomical Asplenia, SCD, Hodgkins Disease, Down Syndrome, CSF Leak, Cochlear Implant, complement deficiencies

**Lifestyle-related:** Alcohol use disorder, smoking

**Special situations:** HCPs, Travellers, Mass gatherings, Occupational exposure

### Key considerations:

- Routinely recommended for all people above 50 years of age: 2-6 months apart (also to prevent recurrence of HZ)
- Recommended in patients with CVD e.g. MI, CHF, Stroke etc. (Bi-directional risk between HZ & CVD)

## Yellow fever

**Vaccine Type:** Live attenuated vaccine

**Route of administration:** Deltoid or anterolateral thigh area IM

**Storage:** 2 °C - 8 °C

**Dose schedule:** 0.5ml single dose

**Revaccination/Booster dose:** - (40)

### Consensus Recommendations:

≥50 years	18 -49 years					
	Pregnancy	At-risk	High-risk/ Immunocompromised	Lifestyle related	Special situations	12-18 years (adolescents)
NR	NR	NR	NR	NR	AR	NR

R = Recommended | NR = Not Recommended | BR = May be considered after benefit risk evaluation | AR = With additional Risk

**At-Risk individuals:** Chronic Respiratory Disorders, Chronic Heart Disease, Chronic Liver Disease, DM

**High-risk/Immunocompromised conditions:** Chronic Kidney Disease, Nephrotic syndrome, Haemodialysis, HIV, Autoimmune inflammatory Rheumatic Disease, Malignancies (Solid and Haematological), Solid organ transplant, Functional or Anatomical Asplenia, SCD, Hodgkins Disease, Down Syndrome, CSF Leak, Cochlear Implant, complement deficiencies

**Lifestyle-related:** Alcohol use disorder, smoking

**Special situations:** HCPs, Travellers, Mass gatherings, Occupational exposure

### Key considerations:

- Not routinely recommended
- Travel to certain high-risk countries: 1 dose
- \*Key African countries (Angola, Benin, Burkina Faso, Burundi, Cameroon, Central African Republic, Chad, Congo, Cote d'Ivoire, Democratic Republic of Congo, Equatorial Guinea, Ghana, Nigeria, and Sierra Leone), key South/Central American countries [countries in the Amazon basin (e.g., Brazil, Colombia, Peru) and Panama]
- Proof of Vaccination: Required for entry into many African and South American nations, especially if arriving from a country with risk of yellow fever transmission.
- The vaccine should be administered at least 10 days before travel.
- Usually not recommended during pregnancy, and should try to postpone travel, however if travel cannot be avoided 1 dose can be administered after a through benefit vs. risk evaluation
- For most people, a single dose of yellow fever vaccine provides long-lasting protection and a booster dose of the vaccine is not needed, however booster dose (1 dose) is recommended if;
  - Vaccinated before 9 month of age
  - Immunosuppressive therapy
  - HIV/AIDS
  - Laboratory workers who handle wild-type yellow fever virus

Note: \*\*Before giving the vaccine, make sure to check the updated list of recognised centres by Government of India for Yellow Fever Vaccine23\*\*

## Consensus recommendations

### Recommendations for chronic disease patients

Diabetes Mellitus		
Influenza (inactivated)	1	Annually
HPV	Female: 2 or 3 doses ≤26 years Males: 2 or 4 doses ≤21 years	–
Tdap/Td	1	Every 10 years
Hepatitis A	Inactivated: 2 doses 1 ml (6 months apart) Live attenuated: 1 dose 0.5ml	–
Hepatitis B	2 or 3 doses (based on vaccine dose)	–
Pneumococcal	1 dose of PCV 20 Or PCV13 followed by PPSV23 1 year later	NA PPSV23 booster dose after 5 years (maximum 2 doses, one before 65 years and the other after 65 years)
COVID-19	1	Annually
MMR	1 or 2 doses depending on the condition	–
Varicella	2 doses 4 – 8 weeks apart	–
Shingles (Herpes Zoster)	2 doses 2 – 6 months apart	–
Chronic Liver Disease		
Hepatitis A	2 doses (6 months apart)	–
Hep E	3 doses (0, 1, 6 months in high risk)	–
Influenza (inactivated)	1	Annually
HPV	Female: 2 or 3 doses ≤26 years Males: 2 or 4 doses ≤21 years	–
Tdap/Td	1	Every 10 years
Pneumococcal	1 dose of PCV 20 Or PCV13 followed by PPSV23 1 year later	NA PPSV23 booster dose after 5 years (maximum 2 doses, one before 65 years and the other after 65 years)
COVID-19	1	Annually
MMR	1 dose	–
Varicella	1 or 2 doses depending on the indication	–
Shingles (Herpes Zoster)	2 doses 2-6 months apart	–
Chronic Heart Disease   Chronic Lung Disease		
Influenza (inactivated)	1	Annually
Hepatitis A	Inactivated: 2 doses 1 ml (6 months apart) Live attenuated: 1 dose 0.5ml	–
HPV	Female: 2 or 3 doses ≤26 years Males: 2 or 4 doses ≤21 years	–
Tdap/Td	1	Every 10 years
Pneumococcal	1 dose of PCV 20 Or PCV13 followed by PPSV23 1 year later	NA PPSV23 booster dose after 5 years (maximum 2 doses, one before 65 years and the other after 65 years)
COVID-19	1	Annually
MMR	1 or 2 doses depending on the condition	–
Varicella	1 or 2 doses depending on the indication	–
Shingles (Herpes Zoster)	2 doses 2 – 6 months apart	–
Meningococcal	2 doses 4 weeks apart (age >50 years)	–

### Chronic Kidney Disease | Haemodialysis | Nephrotic Syndrome

Influenza (inactivated)	1	Annually
Hepatitis A	Inactivated: 2 doses 1 ml (6 months apart) Live attenuated: 1 dose 0.5ml	-
Hepatitis B	2 or 3 doses (based on vaccine dose)	-
HPV	Female: 2 or 3 doses ≤26 years Males: 2 or 4 doses ≤21 years	-
Tdap/Td	1	Every 10 years
Pneumococcal	1 dose of PCV 20 Or PCV13 followed by PPSV23, 8 weeks later	NA  PPSV23 booster dose after 5 years (maximum 2 doses, one before 65 years and the other after 65 years)
COVID-19	1	Annually
MMR	1 dose	-
Varicella	2 doses 4 – 8 weeks apart	-
Shingles (Herpes Zoster)	2 doses 2 – 6 months apart	-

### Individuals with Cancer

As per ASCO 2024 guidelines “Vaccination should ideally precede any planned cancer treatment by 2-4 weeks. However, non-live vaccines can be administered during or after chemotherapy or immunotherapy, hormonal treatment, radiation, or surgery “ (41)

#### Before chemotherapy

Influenza (inactivated)	1	-
Pneumococcal (at-least 2 weeks before chemotherapy)	1 dose of PCV 20 Or PCV13 followed by PPSV23 after 8 weeks	-
Tdap/Td	1 dose	-
Hib	1 dose	-
Hepatitis A	Inactivated: 2 doses 1 ml (6 months apart) Live attenuated: 1 dose 0.5ml	-
Hepatitis B	2 or 3 doses (based on vaccine dose)	-
Hepatitis E	3 doses (0, 1, 6 months in high risk)	-
COVID-19	1 dose	-

#### After therapy

Influenza (inactivated)	1	Annually
Tdap	1 minimum 3 mo. after chemotherapy	Td every 10 years
Hib	1 at least 3 mo. after chemotherapy	
Pneumococcal (minimum 3 months after chemotherapy)	1 dose of PCV 20 Or PCV13 followed by PPSV23 8 weeks later	NA  PPSV23 booster dose after 5 years (maximum 2 doses, one before 65 years and the other after 65 years)
COVID-19	-1	Annually
MMR	2 doses 4 -8 weeks apart	-
Varicella	2 doses 4 -8 weeks apart	-
Shingles (Herpes Zoster)	2 doses 2 – 6 months apart	-

### Recommendation for Immunocompromised patients

- In general, most inactivated vaccines are safe for immunocompromised individuals, and these individuals should receive all age-appropriate vaccines. (42)

### Recipients of Hematopoietic Stem Cell Transplant

- Several factors, including the donor's immune status, the type of transplant, the time elapsed since the transplant, ongoing immunosuppressive treatment, and the presence of Graft versus Host disease, can influence the immunization process for individuals.

Vaccine	Dose	Schedule
TD/TdaP	3	6 – 12 mo. after transplant
Hepatitis A	2 + 1	Inactivated: 2 doses 1 ml (6 months apart) Live attenuated: 1 dose 0.5ml
Hepatitis B	3	6 mo. after transplant
Hepatitis E	3	0, 1, 6 months in high risk
Hib	2	6 – 12 mo. after transplant followed by booster dose 2 – 6 mo. Later
HPV	3	6 mo. after transplant
Influenza	1	4 – 6 mo. after transplant
IPV	3	6 – 12 mo. after transplant
Meningococcal conjugate	2	6 mo. after transplant.
MMR	2	4 – 8 weeks apart
Pneumococcal	3 + 1	Either PCV20 or PCV13: Three doses, with the first dose given at 3 to 6 months after HSCT and with an interval of at least 1 month between doses. A fourth (booster) dose is recommended 6 months after the third dose. PPSV23 may be administered 8 weeks after the booster dose
Varicella	2	4 – 8 weeks apart
Shingles (Herpes Zoster)	2 doses, 2-6 months apart (3-12 months after transplantation)	-

## Recipients of Solid organ transplant

An accelerated immunization schedule is recommended in donor and recipient. Below is the recommended schedule for patients and donors undergoing solid organ transplant: <sup>24,79,80,81,82</sup>

Vaccine	Recipient & Donor		Comments
<b>Inactivated vaccines</b>			
Pneumococcal	1 dose of PCV 20 Or PCV13 followed by PPSV23 8 weeks later		PCV20 alone OR PCV15 + PPSV23. If PCV20 is given, PPSV23 is not required; revaccination depends on prior product sequence.
Meningococcal	2 doses, 8 weeks apart in those at risk		Should be given before splenectomy, before Eculizumab. Booster every 5 years if risk persists (high-risk groups such as asplenia/complement deficiency/complement inhibitor therapy).
Hib	Complete schedule	As in normal individuals	
Influenza	1 dose annually		1 – 3 mo. after transplant, later results in better protection
Hepatitis A	2 doses, 6 mo. apart		If travelling to South Asia
Hepatitis B	3-4 doses before transplant		Booster dose if antibody titre <10mU/ml   Serology testing 4-weeks after complete dose
Hepatitis E	3 doses (0, 1, 6 months in high risk)		
IPV	Complete Schedule		Complete schedule if not vaccinated; booster IPV may be given/considered.
Tdap	1 dose – 2 weeks before Transplant		Booster every 10 years
HPV	3 doses at 0, 2, 6 mo.		Age 9–26 years (3-dose schedule).
Shingles (Herpes Zoster)	2 doses 2-6 months apart	Not recommended	Recombinant zoster vaccine (RZV/Shingrix), 2 doses 2–6 months apart; can be given after transplant (live zoster not recommended post-transplant).
Typhoid	Polysaccharide - 1 dose (Booster after 3 years)		Required: Before travel
	Conjugated - 1 dose (No booster required)		
COVID-19	2 doses 4 weeks apart (or as per individual vaccine recommendation)		Booster as required
<b>Live Vaccines</b>			
MMR	Should be complete before transplant		Contraindicated after transplant
Hepatitis A	1 dose 0.5 ml		
Varicella	Pretransplant 2 doses 1 month apart		Contraindicated after transplant
Yellow Fever	Contraindicated		Avoid travelling to Africa and South America if not vaccinated; if travel is necessary, must travel with yellow card with stamp and reason not vaccinated

## HIV infection or other immunocompromising conditions

HIV positive and other immunocompromised states		
Vaccines	Dose	Booster
Influenza (inactivated)	1	Annually
Tdap/Td	1	Td every 10 years
Hepatitis A	2 doses, 6 mo. apart	-
Hepatitis B	3 doses (0,1 and 6 months)	-
Hepatitis E	3 doses (0, 1, 6 months in high risk)	-
Pneumococcal	1 dose PCV20 or 1 dose PCV13 followed by PPSV23 8 weeks later	NA PPSV23 booster dose after 5 years (maximum 2 doses, one before 65 years and the other after 65 years)
COVID-19	1	Annually
HPV	3 doses	For individuals ≤26 years of age ay 0, 6 and 12 mo.
Shingles (Herpes Zoster)	2 doses 2-6 months apart	NA

### Recommendation for pregnant females

Vaccines recommended during pregnancy, play a crucial role in safeguarding their health and that of their unborn children. Some of the key vaccines recommended for pregnant women and females of childbearing age include: <sup>(43)</sup>

Vaccine	Pregnant females	Dose
Influenza	Recommended	1
Tdap	At least one dose of Tdap vaccine is recommended during each pregnancy, preferably between 27 and 36 weeks of gestation	1
COVID-19	Recommended	1
Hepatitis B	Recommended. Can also be given during pregnancy.	3

## Recommendations for Health Care Personnels

Vaccine	Dose	Frequency
Influenza	1	Annually
Typhoid	1	3-7 years in endemic setup
Tdap	1	Every 10 years
Hepatitis A	Inactivated: 2 doses 1 ml (6 months apart) Live attenuated: 1 dose 0.5ml	-
Hepatitis B	3 doses (0,1 and 6 mo.)	Every 5 years
Hepatitis E	3 doses (0, 1, 6 months in high risk)	-
MMR	2 doses to non-immunized (at least 28 days apart)	-
COVID-19	1	Annually
Varicella	2 doses	-
Pneumococcal	1 dose of PCV 20 Or PCV13 followed by PPSV23 1 year later	NA  PPSV23 booster dose after 5 years (maximum 2 doses, one before 65 years and the other after 65 years)

## Recommendation for travellers

Vaccines are recommended for India travel to protect against diseases prevalent in the region and to prevent potential health risks. Routine vaccines ensure basic immunization, while others target specific infections, such as Hepatitis A, Typhoid, and Japanese Encephalitis, commonly found in India. Hepatitis B and Rabies vaccines are advised based on potential exposure risks. Cholera vaccine may be recommended for travellers to outbreak-prone areas.

### List of recommended vaccines

**Routine:** MMR, DTaP, Varicella (chickenpox), Polio, Covid-19, Pneumococcal and Influenza vaccine status is up to date  
**Hepatitis A:** Risk of contracting hepatitis A through contaminated food or water is high  
**Typhoid:** Recommended for travellers at risk of exposure  
**Hepatitis B** (if needed): If one might have intimate contact with locals or require medical treatment during your stay  
**Hepatitis E** - Risk of contracting hepatitis E through contaminated food or water is high  
**Japanese Encephalitis:** If one plans to spend an extended period (>1 month) in rural or agricultural areas, especially during the monsoon season  
**Rabies:** Plan or risk of animal exposure, pre-exposure vaccine may be given (3 doses at 0,7 and 28 days)  
**Cholera** Plan to visit or stay in outbreak prone areas  
**Polio:** OPV is mandatory for people coming from these countries Afghanistan, Ethiopia, Israel, Kenya, Nigeria, Pakistan and Somalia at least 6 weeks before planned travel to India and is valid for 1 year  
**Meningococcal Meningitis:** 1 dose is recommended 10-14 days before planned travel date  
**Yellow Fever:** It is mandatory for travellers coming from Africa and South America. 1 dose in a life time is sufficient.

## Recommendation for students travelling from India to an International destination

The vaccines recommended for international travellers may vary depending on factors such as the traveller's age, destination, duration of stay, travel itinerary, and any underlying health conditions. It is recommended to visit an individual country's immunisation recommendations well in advance before travel to check for the latest recommendations. However, some of the common vaccines recommended for international travellers include:

**Routine Vaccines as per UIP India  
(for infants, children and pregnant women)**

Polio, Diphtheria, tetanus and pertussis Japanese Encephalitis, Rotavirus, Pneumococcal, Tuberculosis, Hepatitis B, Haemophilus influenzae type b, Influenza (seasonal), Measles, mumps and rubella (MMR).

**MMR:** Evidence of protective antibodies or MMR vaccination is mandatory for adolescents

**Hepatitis A:** Recommended for travellers to areas with poor sanitation and limited access to clean water and food safety. Even after serology negative, 30-40% can still be seropositive.

**Typhoid:** Recommended for travellers visiting regions with an increased risk of typhoid fever

**Yellow Fever:** Mandatory for travellers visiting certain countries with yellow fever transmission and require an International Certificate of Vaccination or Prophylaxis (ICVP) for entry

**Rabies:** Considered for travellers with potential exposure to animals or remote areas with limited access to medical care (Pre-exposure 3 dose schedule should be followed at 0,7 and 28 days)

**Japanese Encephalitis:** Recommended for travellers to areas with Japanese Encephalitis transmission, especially during the transmission season

**Meningococcal Meningitis:** Recommended for travellers visiting regions with a risk of meningococcal disease, especially during mass gatherings or outbreaks.

**Polio (Inactivated Polio Vaccine - IPV):** Recommended for travellers to areas with ongoing polio transmission

**Cholera:** oral cholera vaccine may be considered for travellers visiting areas with active cholera outbreaks

**COVID-19 Vaccine:** COVID-19 vaccination is essential for international travel and may be required by most countries

**Disclaimer:** Please refer to the destination country's vaccine recommendations as per CDC and WHO

**Recommendation for Religious Pilgrims**

**Mandatory vaccine:** Yellow fever/ Meningococcus and Influenza for Hajj and OPV for Indian travellers traveling to specific countries.

**Mandatory vaccines for mass gathering within India (e.g., Kumbh mela)**

For everyone	Prolonged Stay
Typhoid Hepatitis A Hepatitis E Influenza Pneumococcal	Hepatitis B Japanese Encephalitis
Mandatory vaccines for mass gathering outside India (e.g., Hajj or Umrah)	
For everyone	
Quadrivalent Meningococcal Vaccine, Influenza, Polio	

# Age-wise vaccination recommendation according to risk

	≥ 50 years	18 - 49 years					12- 18 years (Adolescents)
		Pregnancy	At-risk	High-risk/ Immunocompromised	Lifestyle - related	Special situations	
Anthrax	AR	R	BR	R	BR	BR	R
BCG (Tuberculosis)	BR	R	BR	R	BR	BR	AR
Chickenpox (Varicella)	R	R	BR	R	BR	R	AR
Cholera	R	R	BR	R	R	R	R
COVID - 19	R	R	R	R	R	R	R
Td	R	R	R	R	R	R	R
Tdap	R	R	R	R	R	R	R
Hib	R	R	R	R	R	R	AR
HepA	AR	R	R	R	R	R	R
HepB	AR	R	R	R	R	R	R
HepE	R	R	R	R	AR	R	R
HPV	R	R	R	R	R	R	R
Tetavalent influenza vaccine	R	R	R	R	R	R	R
Japanese Encephalitis	BR	R	BR	BR	BR	BR	BR
MMR	R	R	BR	BR	BR	R	R
MenACWY	AR	R	R	AR	AR	R	R
MenB	AR	R	R	AR	AR	AR	R
Pneumococcal	R	R	R	R	R	R	AR
Polio	R	R	AR	R	R	BR	R
Rabies	5 doses	R	R	R	R	R	R
Typhoid	R	R	R	R	R	R	R
Shingles (Herpes Zoster)	R	R	BR	R	R	BR	R
Yellow Fever	R	R	R	R	R	AR	R

### Legend to read the table

**R** = Recommended | **NR** = Not Recommended | **BR** = May be considered after benefit risk evaluation | **AR** = With additional Risk

**At-Risk individuals:** Chronic Respiratory Disorders, Chronic Heart Disease, Chronic Liver Disease, DM

**High-risk/Immunocompromised conditions:** Chronic Kidney Disease, Nephrotic syndrome, Haemodialysis, HIV, Autoimmune inflammatory Rheumatic Disease, Malignancies (Solid and Haematological), Solid organ transplant, Functional or Anatomical Asplenia, SCD, Hodgkins Disease, Down Syndrome, CSF Leak, Cochlear Implant, complement deficiencies,

**Lifestyle-related:** Alcohol use disorder, smoking

**Special situations:** HCPs, Travellers, Mass gatherings, Occupational exposure

# UPCOMING VACCINES IN INDIA

Vaccines that are currently in different phases of clinical trial or approved internationally but not yet approved in India for clinical use.

## Chikungunya <sup>(44-46)</sup>

USFDA approved a single-dose, live-attenuated vaccine, for individuals 18 years of age and older who are at increased risk of exposure to chikungunya virus in 2023. **Not yet approved for clinical use in India.**

### Vaccine Details:

Vaccine Type	Live attenuated vaccine
Dose	0.5 ml single dose
Route of administration	Intramuscular injection (IM)
Storage	Should be stored between 2°C and 8°C

### Clinical Data:

- **Efficacy:** Demonstrated 98.9% Seroresponse rate at 28 days post-vaccination in clinical trials
- **Duration of Protection:** Protective antibodies persist for at least 6 months
- **Safety Profile:** Generally well-tolerated; common side effects include injection site pain, headache, fatigue, myalgia, and arthralgia

### Important Safety Update:

On August 22, 2025, the FDA suspended the biologics license due to safety concerns regarding serious adverse events, including Guillain-Barré syndrome. Healthcare providers should stay updated on regulatory decisions.

### Contraindications:

- History of allergic reaction to any component of the vaccine
- Immunodeficient or immunosuppressed due to disease or medical therapy (e.g., hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, long-term immunosuppressive therapy)
- Patients with HIV infection who are severely immunocompromised
- Pregnancy and lactation

## Dengue <sup>(47-50)</sup>

Two dengue vaccines are WHO-approved and licensed globally, with additional vaccines in late stage development in India.

**1. TAK-003** - Live attenuated tetravalent dengue vaccine.

**WHO-prequalified vaccine** approved in multiple countries worldwide from 4 years of age.

### Vaccine Specifications:

- **Vaccine Type:** Live attenuated tetravalent vaccine designed to protect against all four dengue serotypes (DENV-1, DENV-2, DENV-3, and DENV-4)
- **Dose and Administration:** Two-dose series administered three months apart subcutaneous injection
- **Storage:** 2°C - 8°C

### Efficacy:

- Overall efficacy of 64.2% in individuals with prior dengue exposure
- 53.5% in those without prior exposure
- 84.1% efficacy against hospitalized dengue cases
- 75% efficacy in preventing symptomatic dengue (4.5-year follow-up data)
- Demonstrated protection against all four dengue serotypes

### Approval Status:

- **WHO Prequalification:** Added to WHO prequalified vaccines list (May 9, 2024)
- **Global Approvals:** Approved in European Union, UK, Brazil, Argentina, Indonesia, Thailand, and 20+ other countries
- **India Status:**
  - Regulatory application under review by Central Drugs Standard Control Organisation (CDSCO)
  - Partnership with Biological E. Limited for India launch
  - Expected launch: 2026
- **Target Population:** Children and adolescents 4-16 years (some countries approve up to 60 years)

## 2. Panacea Biotec & ICMR Indigenous Vaccine

**India's first indigenous dengue vaccine** currently undergoing Phase 3 clinical trial.

### Vaccine Specifications

- **Vaccine Type:** Tetravalent live attenuated vaccine
- **Developer:** Panacea Biotec in collaboration with Indian Council of Medical Research (ICMR)

### Trial Status:

- Phase 3 Trial: First-ever Phase 3 clinical trial for dengue vaccine in India
- Trial Sites: Conducted across 19 sites in 18 states and union territories
- Participants: Over 10,335 adult participants enrolled
- Follow-up Period: Participants being followed up for two years
- Expected Timeline: Results anticipated 2025-2026

## 3. Serum Institute of India (SII) & ICMR

**Indigenous tetravalent dengue vaccine** in advanced clinical development.

### Vaccine Specifications:

- **Vaccine Type:** Live attenuated tetravalent vaccine
- **Developer:** Serum Institute of India in partnership with ICMR

### Development Status:

- **Completed Phases:** Phase 1 and Phase 2 trials completed in both adults and children

### Phase 3 Trial:

- Expected to begin by end of 2025
- Will cover approximately 10,000 children aged 2 to 18 years
- Multiple sites across India

**Production Advantage:** Leverages SII's massive manufacturing capacity for affordable domestic supply

## 4. Sanofi Pasteur - live attenuated tetravalent dengue vaccine.

**Licensed in over 20 countries** - considered for trials in India.

### Vaccine Specifications:

- Type of Vaccine: Tetravalent live attenuated vaccine (CYD-TDV)
- Dosing: Three doses at 0, 6, and 12 months

### Important Safety Considerations:

- **FDA/WHO Restriction (2017):** Label updated to restrict use to individuals with laboratory-confirmed prior dengue virus infection.
- **Rationale:** Data showed that people who receive the vaccine without prior dengue infection may be at risk of developing severe dengue if they get infected after vaccination
- **WHO Recommendation:** Only for persons with laboratory-confirmed prior dengue virus infection
- **US Approval:** Approved for children aged 9-16 years with confirmed previous dengue infection living in endemic areas

### India Status:

- **Approval Status:** Trials are being considered for Phase II and III in India
- **Implementation Considerations:** Requirement for serological testing before vaccination may limit feasibility in India

### Global Context:

Dengue is endemic in over 100 countries, with India bearing a significant burden. The WHO estimates 390 million dengue infections annually worldwide. Multiple vaccine options will be crucial for comprehensive dengue control strategies.

## Respiratory Syncytial Virus (RSV) <sup>(51-60)</sup>

**Three RSV vaccines are FDA-approved for adults in the United States. Not yet approved for clinical use in India.**

### Approved Vaccines:

#### 1. GSK -recombinant subunit prefusion RSV F glycoprotein antigen (RSVPreF3) combined with AS01E adjuvant

The world's first RSV vaccine for older adults (May 2023).

### Vaccine Specifications:

- **Dose:** 0.5 ml
- **Route:** Intramuscular injection (IM)
- **Storage:** 2°C - 8°C
- **Type:** Adjuvanted recombinant protein vaccine (RSVPreF3 with AS01E adjuvant)

### Approvals:

- **May 2023:** Adults ≥60 years
- **June 2024 Expansion:** Adults 50-59 years at increased risk
- **Jan 2026 expansion:** approved by EU for everyone >18 years old
- **Unique Feature:** Contains an adjuvant (AS01E) to enhance immune response, potential to benefit older adults especially with comorbidities

## 2. Pfizer - Bivalent Vaccine (Contains two prefusion F proteins (preF) from RSV A and B

### Vaccine Specifications:

- **Dose:** 0.5 ml
- **Route:** Intramuscular injection (IM)
- **Storage:** 2°C - 8°C
- **Type:** Bivalent recombinant protein vaccine (non-adjuvanted)

### Approvals:

- **May 2023:** Adults ≥60 years
- **October 2024:** Adults 18-59 years at increased risk of RSV disease
- **August 2023:** Maternal immunization (administered 32-36 weeks of pregnancy to protect infants)
- **Unique Feature:** Only RSV vaccine approved for maternal immunization

## 3. Moderna - a modified nucleoside mRNA encoding F glycoprotein from RSV subtype A stabilized in pre-F protein

### Vaccine Specifications:

Age Group	Recommendation	Effective Date
Adults ≥75 years	Routine vaccination	2024
Adults 60-74 years at increased risk	Shared clinical decision-making	2024

Age Group	Recommendation	Effective Date
Adults 50-59 years at increased risk	Risk-based recommendation	June 2025

- **Dose:** 0.5 ml
- **Route:** Intramuscular injection (IM)
- **Storage:** 2°C - 8°C
- **Type:** mRNA-based vaccine

### Approvals:

- **May 2024:** Adults ≥60 years
- **2025 Expansion:** Adults 18-59 years at increased risk

### CDC/ACIP Recommendations (2024-2025):

#### Increased Risk Factors Include:

- Chronic heart disease (e.g., heart failure, coronary artery disease)
- Chronic lung disease (e.g., COPD, asthma)
- Chronic kidney disease
- Chronic liver disease
- Diabetes mellitus
- Neurologic conditions that impair airway clearance
- Weakened immune system (immunocompromising conditions)
- Morbid obesity (BMI ≥40)

#### Clinical Efficacy:

- **GSK - recombinant subunit prefusion RSV F glycoprotein antigen (RSVPreF3) combined with AS01E adjuvant:** 82.6% efficacy against RSV-associated lower respiratory tract disease
- **Pfizer - Bivalent Vaccine (Contains two prefusion F proteins (preF) from RSV A and B):** 66.7% efficacy against RSV-associated lower respiratory tract disease with ≥2 respiratory infection symptoms including cough, wheezing, mucous, shortening of breath and tachypnea 85.7% against ≥3 symptoms
- **Duration:** Protection demonstrated for at least 2 RSV seasons

#### Contraindications:

- History of severe allergic reaction to any component of the vaccine
- History of Guillain-Barré syndrome within 6 weeks of a previous dose (precaution)

- Pregnancy and lactation (except Abrysvo which is approved for maternal immunization)
- Moderate to severe acute illness (defer vaccination)

#### Important Notes:

- **Single Lifetime Dose:** Current data supports a single-dose regimen for adults; need for booster doses under evaluation
- **Not Interchangeable:** Different RSV vaccines are not interchangeable; complete series with the same product
- **Coadministration:** Can be given simultaneously with other vaccines (e.g., influenza, COVID-19) at different injection sites

## Leprosy <sup>(61-65)</sup>

National Leprosy Eradication Program (NLEP) initiated the implementation of the **Mycobacterium Indicus Pranii (MIP)**, also known as **Mw vaccine**, in India.

#### Vaccine Details:

- **Potential new tuberculosis (TB) vaccine (active agent):** Mycobacterium indicus pranii or MIP)
- **Developer:** National Institute of Immunology, New Delhi, in collaboration with ICMR
- **Type:** Heat-killed Mycobacterium indicus pranii (formerly Mycobacterium w)
- **Approval Status:** Approved in India as an immunomodulator and immunotherapeutic agent

#### Vaccine Specifications:

- **Dose:** 0.1 ml
- **Route of Administration:** Intradermal injection
- **Storage:** 2°C - 8°C
- **Schedule:** Single dose for leprosy prevention; may require additional doses for therapeutic use

#### Clinical Evidence

##### Large-scale Field Trial (1991-1993):

- **Study Size:** Approximately 24,000 household contacts of leprosy patients across south India
- **Design:** Randomized controlled trial with BCG + Mw vs. BCG alone

#### Efficacy Results:

- **4-years protection:** 68.6% efficacy

- **7-9 years protection:** 60% efficacy (some decline over time)
- **Duration of Protection:** Provides significant protection for 8-10 years
- **Population Benefit:** Particularly effective in household contacts of multibacillary leprosy patients

#### Implementation Status:

##### NLEP Pilot Programs:

- **2016:** Pilot implementation announced in Bihar and Gujarat
- **Target Population:** Household contacts of leprosy patients  
Individuals in high-endemic areas  
Healthcare workers with high exposure risk
- **Current Status:** Used in selected pilot programs; not yet integrated into standard NLEP protocol for routine nationwide use

#### Mechanism of Action:

The MIP vaccine works through multiple immunological mechanisms:

- **Th1 Response:** Activates cell-mediated immunity crucial for controlling intracellular Mycobacterium leprae
- **Th17 Response:** Enhances antimicrobial defense
- **Dendritic Cell Activation:** Improves antigen presentation and T-cell priming<sup>56</sup>
- **TLR-Dependent Pathway:** Toll-like receptor-mediated immune activation<sup>58</sup>
- **Macrophage Activation:** Enhanced phagocytic and killing activity

#### Additional Applications:

The MIP vaccine has also been studied for:

- **Tuberculosis:** As adjunct therapy in Category II pulmonary tuberculosis (MDR-TB)
- **Immunotherapy:** For various mycobacterial infections
- **Cancer Immunotherapy:** Under investigation for bladder cancer

#### Current Challenges:

- **Limited Awareness:** Low awareness among healthcare providers and community
- **Implementation Gaps:** Not yet part of routine immunization schedule
- **Supply Chain:** Limited availability outside pilot

program areas

- **Cost Considerations:** Pricing and reimbursement frameworks still being developed

#### Future Directions:

- Ongoing evaluation for integration into routine NLEP vaccination strategy
- Studies on optimal dosing schedules and booster requirements
- Cost-effectiveness analysis for nationwide
- Combination strategies with other preventive measures

**Note:** While the MIP vaccine shows significant promise based on trial data and has been approved as an immunomodulator, it has not yet been integrated into the standard treatment regimen under India's National Leprosy Eradication Programme (NLEP) for routine nationwide use. Its use remains largely confined to pilot programs and specific high-risk populations.

## Malaria (66-74)

### Currently Available Vaccines (WHO-Approved)

Two malaria vaccines have received WHO recommendation and are being deployed in Africa. A third vaccine is under development in India.

**The world's first malaria vaccine**, WHO-approved in October 2021.

#### Vaccine Specifications:

- **Manufacturer:** GlaxoSmithKline (GSK); production transferred to Bharat Biotech for long-term supply
- **Type:** Recombinant protein vaccine targeting Plasmodium falciparum circumsporozoite protein
- **Target Pathogen:** Plasmodium falciparum (most deadly malaria parasite)
- **Dosing:** 4 doses at 5, 6, 7, and 18-24 months of age
- **Storage:** 2°C - 8°C

#### Regulatory Status:

- **WHO Recommendation:** October 6, 2021 - for broad use in children in areas with moderate to high malaria transmission
- **WHO Prequalification:** July 2022
- **EMA Approval:** July 2015 (under Article 58)

#### Efficacy:

- **Standalone:** 30-40% efficacy against clinical malaria over 4 years
- **With Seasonal Malaria Chemoprevention (SMC):** ~75% efficacy
- **Severe Malaria:** 30% reduction in cases requiring hospitalization
- **Mortality:** 13% reduction in all-cause mortality in pilot implementation sites
- **Duration:** Protection wanes over time; booster dose at 18-24 months maintains efficacy

#### Implementation Status

- **Pilot Programs (2019-2023):** Ghana, Kenya, Malawi  
Over 2 million children vaccinated  
Confirmed safety and feasibility in real-world settings
- **2024 Scale-up:** Expanded to 24+ countries in sub-Saharan Africa
- **2024 Vaccinations:** Over 1.7 million children received at least one dose

#### Supply:

- **Current Production:** 15 million doses annually
- **Limitation:** Supply constraints limit immediate global scale-up
- **Solution:** Bharat Biotech licensed for long-term production to increase supply

## 2. R21/Matrix-M - University of Oxford & Serum Institute of India

**The second WHO-approved malaria vaccine** with superior efficacy and production capacity.

#### Vaccine Specifications:

- **Developers:** University of Oxford + Serum Institute of India
- **Adjuvant:** Novavax's Matrix-M™ saponin-based adjuvant
- **Type:** Virus-like particle (VLP) vaccine targeting P. falciparum circumsporozoite protein
- **Target Pathogen:** Plasmodium falciparum
- **Dosing:** 4 doses (3 primary doses at 5-6-7 months + booster at 12-18 months OR seasonal schedule)
- **Storage:** 2°C - 8°C

#### Regulatory Status:

- **WHO Recommendation:** October 2, 2023
- **WHO Prequalification:** December 21, 2023

- **First Country Approval:** Ghana (April 2023)
- **Additional Approvals:** Nigeria, Burkina Faso, Central African Republic, Kenya

#### Efficacy:

- **Phase 3 Trial:** 72% efficacy in 4,800 children across Burkina Faso, Kenya, Mali, Tanzania
- **Seasonal Transmission Areas:** 75% efficacy
- **Perennial Transmission Areas:** 68% efficacy
- **High-Dose Regimen:** 78% efficacy demonstrated in Phase 2b trials
- **Exceeds WHO Target:** First malaria vaccine to exceed WHO's 75% efficacy goal
- **Duration:** Protection maintained through at least 2 malaria seasons

#### Production & Access:

- **Manufacturing:** Serum Institute of India, Pune
- **Production Capacity:** 100-200 million doses annually (10-13x more than RTS,S)
- **Cost:** \$2-4 per dose (significantly more affordable than RTS,S at ~\$10 per dose)
- **First Deployment:** Côte d'Ivoire (July 15, 2024)
- **Scale-up Plan:** Multiple African countries implementing in 2024-2025

#### Advantages over RTS,S:

- **Higher Efficacy:** 68-75% vs. 30-40%
- **Lower Cost:** \$2-4 vs. ~\$10 per dose
- **Greater Supply:** 100-200M vs. 15M doses annually
- **Flexible Dosing:** Can adapt to seasonal or year-round transmission patterns
- **Easier Storage:** Standard cold chain requirements

#### India's Indigenous Vaccine Development

### 3. ICMR - developing India's first indigenous multi-stage malaria vaccine

#### Vaccine Specifications:

- **Developer:** Indian Council of Medical Research (ICMR), Regional Medical Research Centre, Bhubaneswar
- **Type:** Multi-stage vaccine with dual targeting approach
- **Innovation:** Targets BOTH pre-erythrocytic

(infection) AND sexual stages (transmission)

- **Target Pathogen:** Plasmodium falciparum
- **Technology:** Adenovirus-vectored vaccine platform

#### Unique Features:

- **Dual Protection Strategy:**
  1. **Pre-erythrocytic stage:** Prevents initial liver infection
  2. **Sexual stage:** Blocks transmission to mosquitoes (transmission-blocking vaccine component)
- **Population Benefit:** Can reduce community transmission by preventing parasite spread
- **First Indian Indigenous Malaria Vaccine:** Completely developed in India

#### Development Status:

- **Current Phase:** Preclinical to early clinical development
- **Technology Transfer (2025):** Licensed to 5 Indian pharmaceutical companies:
  1. Indian Immunologicals Limited
  2. Techinvention Lifecare Pvt. Ltd.
  3. Panacea Biotec Ltd.
  4. Biological E. Limited
  5. Zydus Lifesciences Limited
- **Expected Timeline:**
  - Clinical trials anticipated: 2026-2027
  - Potential market availability: 2028-2030 (if trials successful)

#### Strategic Importance:

- **National Priority:** Supports India's malaria elimination goal by 2030
- **Affordable Access:** Expected to be priced for domestic affordability
- **Self-Reliance:** Reduces dependence on imported vaccines
- **Regional Impact:** Could benefit entire South Asian region

#### India's Malaria Burden:

- **2023 Data:** India contributed 66% of malaria cases in WHO South-East Asia Region
- **Cases:** ~2 million cases annually (declining trend)

- **High-Burden States:** Odisha, Chhattisgarh, Jharkhand, Madhya Pradesh, Maharashtra
- **Elimination Target:** Zero indigenous malaria cases by 2030

### Global Context & Impact

#### Disease Burden:

- **Global Cases:** 249 million cases in 2022
- **Deaths:** 608,000 deaths (mostly children under 5 in Africa)
- **At-Risk Population:** 3.2 billion people in 84 endemic countries
- **Economic Impact:** \$12 billion in lost GDP annually in Africa

#### Vaccine Strategy:

- **Target Population:** Children 5-17 months in moderate-to-high transmission areas
- **Implementation:** Part of comprehensive malaria control (alongside bed nets, spraying, treatment)
- **Expected Impact:** Could prevent 500,000 child deaths by 2035 if scaled up effectively

#### Deployment Status (2024-2025):

- **Countries Rolling Out:** 15+ African nations
- **Children Targeted:** 6.6 million children in 2024-2025
- **Vaccine Choice:** Countries can choose RTS,S or R21 based on supply availability, cost, and program needs
- **Complementary Use:** Both vaccines address supply constraints together

#### Important Considerations:

- **Supplementary Tool:** Malaria vaccines are not standalone solutions. They must be used alongside:
  - Insecticide-treated bed nets (ITNs)
  - Indoor residual spraying (IRS)
  - Seasonal malaria chemoprevention (SMC)
  - Prompt diagnosis and treatment
  - Vector control measures

**Target Population:** Currently approved vaccines target **children in endemic areas**. Adult vaccines are

not yet available but may be developed.

**Not for Travelers:** Current vaccines are not approved for travelers from non-endemic countries. Travelers should continue using antimalarial prophylaxis.

**India-Specific Note:** While RTS,S and R21 are approved and used in Africa, they are **not currently available in India**. India is focusing on indigenous vaccine development (AdFalcivax) while maintaining malaria elimination efforts through existing control measures.

## Tuberculosis <sup>(75-77)</sup>

Two promising TB vaccine candidates are in clinical development in India, potentially offering improved protection beyond BCG.

### 1. MTBVAC

**The first live attenuated tuberculosis vaccine derived from a human Mycobacterium tuberculosis strain.**

#### Vaccine Specifications:

- **Developers:** Biofabri (Spain) in partnership with Bharat Biotech International Limited (India)
- **Type:** Live attenuated vaccine from human M. tuberculosis strain
- **Innovation:** First TB vaccine derived from human (not bovine) M. tuberculosis source
- **Target:** Both pulmonary and extrapulmonary tuberculosis

#### Development Rationale:

- **BCG Limitations:** BCG (derived from M. bovis) provides limited protection against pulmonary TB in adults
- **Human-Derived Advantage:** Contains antigens present in human M. tuberculosis but absent in BCG
- **Broader Protection:** Expected to provide superior protection across all age groups
- **Two deleted genes:** phoP and fadD26 genes deleted for safety while maintaining immunogenicity

#### Clinical Trial Status:

- **Phase 1/2a (Newborns):** Completed in South Africa - demonstrated safety and immunogenicity
- **Phase 3 (Newborns):**
  - Ongoing in South Africa, Madagascar, Senegal
  - 8,000+ newborns enrolled

- Comparing MTBVAC vs. BCG
- Expected completion: 2025-2026

### Phase 3 (Adults) in India:

- **Launch Date:** March 24, 2024<sup>68,69^</sup>
- **Trial Name:** MTBVAC-HIV-001
- **Sites:** Multiple centers across India
- **Target Population:** Adults (including HIV-positive individuals)
- **Primary Objective:** Evaluate safety, immunogenicity, and efficacy in preventing TB infection and disease
- **Expected Duration:** 3-4 years

### Key Advantages:

- **Better Antigenic Coverage:** Contains RD1 region antigens absent in BCG
- **Adolescent/Adult Protection:** Expected to protect age groups where BCG fails
- **HIV-Positive Individuals:** Being evaluated in immunocompromised populations
- **Boosting Potential:** May serve as booster for BCG-vaccinated individuals

## 2. VPM1002

A recombinant BCG vaccine with enhanced immunogenicity.

### Vaccine Specifications:

- **Developer:** Serum Institute of India (SIPL) in collaboration with Max Planck Institute, Germany
- **Type:** Recombinant BCG vaccine (genetically modified BCG)
- **Modification:** BCG with addition of listeriolysin gene and deletion of urease C gene
- **Target:** Primarily pulmonary tuberculosis

### Mechanism of Enhanced Protection:

- **Listeriolysin Gene (hly):** Allows vaccine antigens to escape from phagosomes into cytoplasm
- **Improved CD8+ Response:** Enhanced cytotoxic T-cell responses
- **Urease C Deletion:** Prevents pH neutralization in phagosomes, improving antigen processing
- **Better Immunogenicity:** Superior immune response compared to conventional BCG

### Clinical Trial Status:

- **Phase 2/3 Trials:** Ongoing in India
- **Target Population:**
  - Newborns (as BCG replacement)
  - Adults with latent TB
  - HIV-infected individuals
- **Previous Trials:** Completed safety studies in Germany, South Africa

### Key Advantages:

- **Enhanced Efficacy:** Preclinical studies show superior protection vs. BCG
- **Safer for HIV:** No urease C reduces risk in immunocompromised
- **Dual Use:** Can replace BCG at birth and serve as booster in adults

## 3. Other TB Vaccine Candidates in Development

### H4:IC31 (Subunit Vaccine)

- **Type:** Protein subunit vaccine with IC31 adjuvant
- **Status:** Phase 2 trials
- **Target:** Adolescents and adults with latent TB infection
- **Efficacy:** Shown to prevent infection in BCG-vaccinated adults

### M72/AS01E (Subunit Vaccine)

- **Type:** Protein subunit vaccine with AS01E adjuvant (GSK)
- **Status:** Phase 2b completed - showed 50% efficacy in preventing pulmonary TB
- **Target:** Adults with latent TB infection
- **Innovation:** First vaccine to demonstrate significant protection against progression to active TB disease
- **Future:** Phase 3 trials being planned

### ID93 + GLA-SE (Subunit Vaccine)

- **Type:** Fusion protein vaccine with GLA-SE adjuvant
- **Status:** Phase 2a trials in South Africa
- **Target:** BCG-vaccinated adults

### BCG Revaccination Strategies

- **Rationale:** Boosting waning BCG immunity in adolescents/adults
- **Studies:** Ongoing trials evaluating BCG revaccination efficacy
- **Considerations:** May provide short-term prote-

ction; needs evaluation of long-term benefit

### India's TB Burden & Vaccine Need:

#### Epidemiological Context:

- **Global Ranking:** India has the highest TB burden globally
- **Annual Cases:** ~2.6 million new TB cases (26% of global burden)
- **Deaths:** ~450,000 TB deaths annually
- **MDR-TB:** ~130,000 multi-drug-resistant TB cases per year
- **Economic Impact:** Significant loss in productivity and healthcare costs

#### National TB Elimination Programme (NTEP):

- **Target:** TB-free India by 2025 (5 years ahead of SDG target)
- **Strategies:** Active case finding, universal drug susceptibility testing, improved treatment
- **Vaccine Need:** New effective TB vaccine crucial to achieving elimination goal

#### Expected Impact of New TB Vaccines:

##### Population Benefits:

- **Adolescents/Adults:** Protection for age groups where BCG provides minimal benefit
- **HIV-Positive Individuals:** Safer and more effective vaccines for immunocompromised
- **Healthcare Workers:** Protection for high-risk occupational exposure
- **Household Contacts:** Preventing transmission in high-exposure settings
- **MDR-TB Reduction:** Preventing primary infection reduces resistance development

##### Implementation Timeline:

- **2025-2026:** Phase 3 results expected for MTBVAC
- **2026-2027:** Potential regulatory review and approval
- **2027-2028:** Phased introduction if approved
- **2030:** Potential nationwide rollout as BCG replacement or booster

#### Challenges & Considerations:

##### Clinical Development:

- Long follow-up periods required (TB development takes years)

- Large sample sizes needed for adequate power
- Need to demonstrate superiority over existing BCG

##### Regulatory Pathway:

- Approval by CDSCO in India
- WHO prequalification for global use
- Safety monitoring in diverse populations

##### Implementation:

- Integration into existing immunization programs
- Cold chain logistics for live vaccines
- Healthcare worker training
- Public awareness and acceptance

##### Cost-Effectiveness:

- Pricing for low- and middle-income countries
- Cost-benefit analysis vs. current BCG
- Funding mechanisms for procurement

##### Future Directions:

- **Multi-Stage Vaccines:** Combining prevention of infection and reactivation of latent TB
- **Therapeutic Vaccines:** For treating active or latent TB infection (in development)
- **Booster Strategies:** Optimal timing and dosing for BCG-primed populations
- **Combination Approaches:** Vaccines combined with shorter treatment regimens
- **Personalized Vaccination:** Based on genetic susceptibility and risk factors

**Note:** While these vaccines show great promise, they are still in clinical trials. BCG remains the standard TB vaccine for newborns. The timeline for new vaccine availability depends on successful completion of Phase 3 trials and regulatory approvals. India's participation in MTBVAC Phase 3 trials represents a significant step toward improving TB prevention strategies.

# Conclusion

In conclusion, adult vaccination plays a vital role in safeguarding individual and public health. The consensus statement highlights the vaccines essential in adults along with their dosage schedules in various populations. By ensuring high vaccination rates among adults, we can effectively prevent and control infectious diseases, protect vulnerable populations, and reduce the burden of illness within communities.

Healthcare professionals have a crucial role in promoting adult vaccination and leading by example. By prioritizing their own immunizations, they not only protect themselves but also serve as advocates for patients and the broader population.

Furthermore, adult vaccination goes beyond individual protection, fostering herd immunity and preventing the transmission of diseases to those who are more susceptible, such as the elderly, infants, and individuals with compromised immune systems. This collective effort is essential for minimizing the impact of vaccine-preventable diseases on public health.

In light of these considerations, it is crucial for healthcare providers, policymakers, and the public to recognize the significance of adult vaccination and work together to overcome barriers to immunization. Efforts should be made to increase awareness, improve access to vaccines, and address vaccine hesitancy through education and evidence-based communication.

By embracing the consensus statement on adult vaccines and implementing its recommendations, we can achieve a healthier and more resilient society, where preventable diseases are kept at bay, and individuals can enjoy a higher quality of life. Investing in adult vaccination is an investment in the well-being and future of our communities.





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# Appendix

## Screening Checklist for Contraindications to Vaccines for Adults

**Patient Information:** The following questions will help us determine which vaccines you may be given today. If you answer “yes” to any question, it does not necessarily mean you should not be vaccinated. It just means we need to ask you more questions. If a question is not clear, please ask your healthcare provider to explain it.

Question	Yes	No	Don't know
1. Are you sick today?			
2. Do you have allergies to medications, food, a vaccine ingredient, or latex?			
3. Have you ever had a serious reaction after receiving a vaccine?			
4. Do you have a long-term health problem with heart, lung, kidney, or metabolic disease (e.g., diabetes), asthma, a blood clotting disorder, no spleen, complement component deficiency, a cochlear implant, or a spinal fluid leak? Are you on long-term aspirin therapy?			
5. Do you have cancer, leukaemia, HIV/AIDS, or any other immune system problem?			
6. Do you have a parent, brother, or sister with an immune system problem?			
7. In the past 3 mo., have you taken medicines that affect your immune system, such as prednisone, other steroids, or anticancer drugs; drugs for the treatment of rheumatoid arthritis, Crohn's disease, or psoriasis; or have you had radiation treatments?			
8. Have you had a seizure or a brain or other nervous system problem?			
9. During the past year, have you received a transfusion of blood or blood products, or been given immune (gamma) globulin or an antiviral drug?			
10. Are you pregnant or is there a chance you could become pregnant during the next month?			
11. Have you received any vaccinations in the past 1 month (4 weeks)?			
12. Are you travelling internationally in foreseeable future?			

## Information for Healthcare Professionals about the Screening Checklist for Contraindications to Vaccines for Adults

Are you interested in knowing why we included a certain question on the screening checklist? If so, read the information below. If you want to find out even more, refer to individual vaccine section.

### Are you sick today? [all vaccines]

There is no evidence that acute illness reduces vaccine efficacy or increases vaccine adverse events. However, as a precaution with moderate or severe acute illness, all vaccines should be delayed until the illness has improved. Mild illnesses (e.g., upper respiratory infections, diarrhoea) are NOT contraindications to vaccination. Do not withhold vaccination if a person is taking antibiotics.

### Do you have allergies to medications, food, a vaccine ingredient, or latex? [all vaccines]

An anaphylactic reaction to latex is a contraindication

to vaccines that contain latex as a component or as part of the packaging (e.g., vial stoppers, prefilled syringe plungers, prefilled syringe caps). If a person has anaphylaxis after eating gelatin, do not administer vaccines containing gelatin. A local reaction to a prior vaccine dose or vaccine component, including latex, is not a contraindication to a subsequent dose or vaccine containing that component. For information on vaccines supplied in vials or syringes containing latex, see [www.cdc.gov/vaccinespubs/pinkbook/downloads/appendices/B/latex-table.pdf](http://www.cdc.gov/vaccinespubs/pinkbook/downloads/appendices/B/latex-table.pdf); for an extensive list of vaccine components, see [www.cdc.gov/](http://www.cdc.gov/)

vaccines/pubs /pinkbook/downloads/ appendices/ B/excipient-table-2.pdf. People with egg allergy of any severity can receive any IIV, RIV, or LAIV that is otherwise appropriate for the patient's age and health status; ccliV and RIV do not contain egg antigen. When administering an influenza vaccine other than ccliV or RIV to a person with a history of severe allergic reaction to egg, or who required emergency medical intervention (e.g., epinephrine), vaccination should occur in a clinic, health department, or physician office; vaccine administration should be supervised by a healthcare provider who is able to recognize and manage severe allergic conditions.

**Have you ever had a serious reaction after receiving a vaccine? [all vaccines]**

History of anaphylactic reaction (see question 2) to a previous dose of vaccine or vaccine component is a contraindication for subsequent doses. Under normal circumstances, vaccines are deferred when a precaution is present. However, situations may arise when the benefit outweighs the risk (e.g., during a community pertussis outbreak).

**Do you have a long-term health problem with heart, lung, kidney, or metabolic disease (e.g., diabetes), asthma, a blood clotting disorder, no spleen, complement component deficiency, a cochlear implant, or a spinal fluid leak?**

Are you on long term aspirin therapy? [MMR, VAR, LAIV] A history of thrombocytopenia or thrombocytopenic

**In the past 3 mo., have you taken medicines that affect your immune system, such as cortisone, prednisone, other steroids, or anticancer drugs; drugs for the treatment of rheumatoid arthritis, Crohn's disease, or psoriasis; or have you had radiation treatments? [LAIV, MMR, VAR]**

Live virus vaccines (e.g., LAIV, MMR, VAR) should be postponed until after chemotherapy or long-term high-dose steroid therapy has ended. For details and length of time to postpone, see references in Notes above. Some immune mediator and immune modulator drugs (especially the anti-tumour necrosis factor agent's adalimumab, infliximab, etanercept, golimumab, and certolizumab pegol)

may be immunosuppressive. A comprehensive list of immunosuppressive immune modulators is available in CDC Health Information for International Travel (the "Yellow Book") available at [wwwnc.cdc.gov/travel/yellowbook/2020/travelers-with-additional-considerations/immunocompromised-travelers](http://wwwnc.cdc.gov/travel/yellowbook/2020/travelers-with-additional-considerations/immunocompromised-travelers). The use of live virus vaccines should be avoided in persons taking these drugs. To find specific vaccination schedules for stem cell transplant (bone marrow transplant) patients.

**Have you had a seizure or a brain or other nervous system problem? [influenza, Td/Tdap]**

Tdap is contraindicated in people who have a history of encephalopathy within 7 days following DTP/DTaP. An unstable progressive neurologic problem is a precaution to the use of Tdap. For people with stable neurologic disorders (including seizures) unrelated to vaccination, or for people with a family history of seizure, vaccinate as usual. A history of Guillain-Barré syndrome (GBS) is a consideration with the following: 1) Td/Tdap: if GBS has occurred within 6 weeks of a tetanus toxoid vaccine and decision is made to continue vaccination, give Tdap instead of Td if no history of prior Tdap; 2) Influenza vaccine (IIV/LAIV): if GBS has occurred within 6 weeks of a prior influenza vaccine, vaccination should generally be avoided unless the benefits outweigh the risks (for those at higher risk for complications from influenza).

**During the past year, have you received a transfusion of blood or blood products, or been given immune (gamma) globulin or an antiviral drug? [MMR, VAR]**

Certain live virus vaccines (e.g., MMR, LAIV, VAR) may need to be deferred, depending on several variables. Consult General Best Practice Guidelines for Immunization (referenced in Notes above) for current information on intervals between antiviral drugs, immune globulin or blood product administration and live virus vaccines.

**Are you pregnant or is there a chance you could become pregnant during the next month? [HPV, HepB, IPV, LAIV, MenB, MMR, VAR]**

Live virus vaccines (e.g., MMR, VAR, LAIV) are contraindicated one month before and during



pregnancy because of the theoretical risk of virus transmission to the foetus. Sexually active women in their childbearing years who receive live purpura is a precaution to MMR vaccine. LAIV is not recommended for people with anatomic or functional asplenia, complement component deficiency, a cochlear implant, or CSF leak. Underlying health conditions of the heart, lung, kidney, or metabolic disease (e.g., diabetes) and asthma are considered precautions for the use of LAIV. Aspirin use is a precaution to VAR.

**Do you have cancer, leukaemia, HIV/AIDS, or any other immune system problem? [LAIV, MMR, VAR]**

Live virus vaccines (e.g., LAIV, MMR, VAR) are usually contraindicated in immunocompromised people. However, there are exceptions. For example, MMR vaccine is recommended and VAR vaccine may be considered for adults with CD4+ T-lymphocyte counts of greater than or equal to 200 cells/ $\mu$ L. Immuno-suppressed people should not receive LAIV.

**Do you have a parent, brother, or sister with an immune system problem? [MMR, VAR]**

MMR or VAR vaccines should not be administered to persons who have a family history of congenital or

hereditary immunodeficiency in first-degree relatives (i.e., parents and siblings), unless the immune competence of the potential vaccine recipient has been substantiated clinically or verified by a laboratory.

virus vaccines should be instructed to avoid pregnancy for one month following receipt of the vaccine. IPV and MenB vaccination should be limited to those with an elevated risk of exposure during pregnancy. IIV and Tdap are both recommended during pregnancy. Two brands of hepatitis B vaccine (Heplisav-B and PreHevbrio) are not recommended during pregnancy due to a lack of safety data in this population; pregnant people needing hepatitis B vaccination should receive Engerix-B or Recombivax-HB, which are known to be safe and effective during pregnancy. HPV vaccine is not recommended during pregnancy.

**Have you received any vaccinations in the past 4 weeks? [LAIV, MMR, VAR, yellow fever]**

People who were given either LAIV or an injectable live virus vaccine (e.g., MMR, VAR, yellow fever) should wait 28 days before receiving another live virus vaccination (30 days for yellow fever). Inactivated vaccines may be given at any spacing interval if they are not administered simultaneously.

**Abbreviations:** LAIV = Live attenuated influenza vaccine | HPV = Human papillomavirus vaccine | IIV = Inactivated influenza vaccine | cIIV = Cell culture inactivated influenza vaccine | IPV = Inactivated poliovirus vaccine | MMR = Measles, mumps, and rubella vaccine | RIV = Recombinant influenza vaccine | Td/Tdap = Tetanus, diphtheria, (acellular pertussis) vaccine | VAR = Varicella vaccine

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## Frequently Asked Questions on Adult Vaccination

### 1. Why are vaccinations important for adults?

Vaccinations are essential for adults to protect themselves from preventable diseases and to help reduce the spread of infections to vulnerable populations. Vaccines can also provide immunity to certain illnesses, which is especially important as we age and our immune systems may weaken.

### 2. Which vaccines are recommended for adults?

The specific vaccines recommended for adults can vary based on factors such as age, health status, and lifestyle. However, some common vaccines

recommended for adults include influenza (flu) vaccine, Tdap (tetanus, diphtheria, and pertussis) vaccine, pneumococcal vaccine, Shingles (Herpes Zoster) vaccine, and HPV (human papillomavirus) vaccine for certain age groups.

### 3. How often do adults need to be vaccinated?

The vaccination schedule for adults can vary depending on the type of vaccine and individual risk factors. In general, some vaccines require periodic boosters, while others may be given once

or twice in a lifetime. It's essential to consult with a healthcare provider to determine the appropriate vaccination schedule for each person.

#### **4. Are there any side effects of adult vaccinations?**

Most people experience minimal side effects from vaccinations, such as soreness at the injection site or mild flu-like symptoms. Serious side effects are rare. It's crucial to discuss any concerns about potential side effects with a healthcare provider before receiving a vaccine.

#### **5. Can adults get vaccinated if they have certain medical conditions?**

In many cases, adults with certain medical conditions can and should get vaccinated. However, the suitability of specific vaccines may depend on the individual's health status and medical history. Those with severe allergies to vaccine components or a history of adverse reactions to vaccines may need to avoid certain vaccinations.

#### **6. Can pregnant women receive vaccines?**

Some vaccines are safe and recommended during pregnancy, such as the influenza vaccine and the Tdap vaccine. However, other live vaccines, like the MMR (measles, mumps, and rubella) vaccine, are typically not given during pregnancy. Pregnant women should consult their healthcare provider to determine which vaccines are appropriate for them.

#### **7. Are there any vaccines recommended for travellers?**

Yes, some vaccines are recommended for travellers, especially if they are visiting areas with specific infectious disease risks. These may include vaccines for diseases such as yellow fever, typhoid, hepatitis A, and others. Travellers should consult a healthcare provider well in advance of their trip to discuss recommended vaccinations.

#### **8. Are vaccines covered by insurance?**

Many health insurance plans cover recommended vaccinations for adults. However, coverage may vary depending on the specific insurance policy. It's best to check with the insurance provider to determine coverage details.

#### **9. Do vaccines have damaging and long-term side-effects that are yet unknown. can vaccination be fatal?**

The 1998 study which raised concerns about a possible link between measles-mumps-rubella

(MMR) vaccine and autism was later found to be seriously flawed, and the paper has been retracted by the journal that published it. Vaccines are very safe. Most vaccine reactions are usually minor and temporary, such as a sore arm or mild fever. Very serious health events are extremely rare and are carefully monitored and investigated. One is far more likely to be seriously injured by a vaccine-preventable disease than by a vaccine. For example, in the case of polio, the disease can cause paralysis, measles can cause encephalitis and blindness, and some vaccine-preventable diseases can even result in death. While any serious injury or death caused by vaccines is one too many, the benefits of vaccination greatly outweigh the risk, and many, many more injuries and deaths would occur without vaccines.

#### **10. Vaccine-preventable diseases are almost eradicated in our country, so there is no reason to be vaccinated?**

Although vaccine preventable diseases have become uncommon in many countries, the infectious agents that cause them continue to circulate in some parts of the world. In a highly inter-connected world, these agents can cross geographical borders and infect anyone who is not protected. In western Europe, for example, measles outbreaks have occurred in unvaccinated populations in Austria, Belgium, Denmark, France, Germany, Italy, Spain, Switzerland and the United Kingdom since 2005. So, two key reasons to continue vaccinating are to protect ourselves and to protect those around us. Successful vaccination programmes, like successful societies, depend on the cooperation of every individual to ensure the good of all. We should not rely on people around us to stop the spread of disease; we, too, must do what we can.

#### **11. Giving more than one vaccine at a time can increase the risk of harmful side-effects, which can overload an individual's immune system.**

Scientific evidence shows that giving several vaccines at the same time has no adverse effect on immune system. People are exposed to several hundred foreign substances that trigger an immune response every day. The simple act of eating food introduces new antigens into the body, and numerous bacteria live in the mouth and nose. One is exposed to far more antigens from a common cold or sore throat than they are from vaccines. Key



advantages of having several vaccines at once is fewer clinic visits, which saves time and money, and individuals are more likely to complete the recommended vaccinations on schedule. Also, when it is possible to have a combined vaccination, e.g. for measles, mumps and rubella, that means fewer injections.

**12. Is it better to be immunized through disease than through vaccines.**

Vaccines interact with the immune system to produce an immune response similar to that produced by the natural infection, but they do not cause the disease or put the immunized person at risk of its potential complications. In contrast, the price paid for getting immunity through natural infection might be mental retardation from *Haemophilus influenzae* type b (Hib), birth defects from rubella, liver cancer from hepatitis B virus, or death from measles.



