FOGSI - ICOG

Good Clinical Practice Recommendations

GCPR

VACCINATION IN WOMEN

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FOODS & DRUGS AND MEDICO SURGICAL EQUIPMENT COMMITTEE

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Fogsi Good Clinical Practice Recommendations

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Disclaimer: These recommendations for FOGSI GCPR on Vaccination in Women has been developed for the assistance of obstetricians, gynecologists, consulting physicians, and general practitioners providing guidance and recommendation on vaccination for women's health. The recommendation included here should not be viewed as being exclusive or other concepts or as covering all legitimate strategies. The suggestions made here are not meant to dictate how a particular patient should be treated because they neither set a standard of care nor do they guarantee a particular result. To improve the scope of vaccination in women and provide the best care possible while also taking the necessary safety precautions, clinicians must rely on their own experience and knowledge. The writers or contributors disclaim all responsibility for any harm and/or damage to people or property resulting from the use or operation of any techniques, goods, guidelines, or ideas presented in this content.

1. PURPOSE AND SCOPE

The guidelines are a reference of recommended care and are subject to evolution with advances in scientific knowledge and technology. As a ready reckoner, this good clinical practice recommendation (GCPR) has been formulated in a structured manner with easily understandable tables to give clear and precise tool to gynecologists working across the country, to perform evidence-based vaccination in day-to-day practice with the aim of reducing related morbidity and mortality in the women of all ages.

2. METHODOLOGY

The extensive literature search of randomized controlled trials (RCTs), meta-analyses, and systemic review studies has been done by the core team and the document has been reviewed by national and international expert group. This good clinical practice recommendation (GCPR), given by the Federation of Obstetric and Gynaecological Societies of India (FOGSI), followed all the key recommendations mentioned in the World Health Organization (WHO), Government of India (GOI), Indian Academy of Pediatrics (IAP), American College of Obstetricians and Gynecologists (ACOG), and Centers for Disease Control and Prevention (CDC) guidelines. The existing guidelines were reviewed by the core group and after the multiple rounds of discussions, recommendations relevant to the Indian scenario were framed. The guideline was peer reviewed by experts' multiple times and feedback was incorporated. The committee evaluated recommendation and evidence using the methodology of the United States Preventive Services Task Force (USPSTF), based on the strength of evidence and magnitude of net benefit **(Table 1)**.

Table 1 Levels of Evidence

Level of Evidence	*Recommendation*	*Type of Evidence*
Level 1	Strongly Recommended	Data derived from multiple randomized controlled trials (RCTs) or meta-analyses
Level 2	Suggested	Data derived from a single randomized trial or large non – randomized trail
Level 3	Unresolved	Consensus of experts or small studies, retrospective studies, or registries
Grade A	Strongly Recommended	Well-conducted RCT with 100 or more patients including meta-analysis
Grade B	Recommended	Poorly controlled RCT, well-conducted case control or observation study
Grade C	Suggested	Expert opinion
CPP	Clinical Practice Points	Evidence not sought. A practice point has been made by the guideline development group where important issues arose from discussion of evidence based or clinical consensus recommendations

3. INTRODUCTION

Immunization is a global health and development success story, saving millions of lives every year. Immunization currently prevents 3.5–5 million deaths every year from diseases such as diphtheria, tetanus, pertussis, influenza, and measles.

India is a country of high endemicity with 300,000 new hepatitis cases occurring each year and has an estimated number of 40 million hepatitis B surface antigen (HBsAg) carriers. Around 205,286 deaths related to chronic hepatitis are recorded annually.[1] About 25% of chronic hepatitis B infections progress to liver cancer, which is quite alarming. Similarly, congenital rubella syndrome (CRS) is a big public health problem of India. It has been observed that around 40–45% of

women in the childbearing age are susceptible to rubella and over 2 lakh babies are born with birth defects because of rubella infection during pregnancy in the Indian subcontinent.[1] The CRS accounts for 10–15% of pediatric cataract. About 10–50% of children with congenital anomalies have the laboratory evidence of CRS. Around 132,000 women in India each year are detected with cervical cancer and 74,000 of them die.[1] We now have vaccines to prevent more than 20 life-threatening diseases, helping the women of all ages live longer, healthier lives.[2]

4. PRE-IMMUNIZATION CHECKLIST

Women coming for vaccination are to be checked for contraindications and precautions before a vaccine is administered, even if the same vaccine was administered previously. A woman's health status or the recommendations for contraindications and precautions may have changed since the last dose was given. Screening helps prevent adverse reactions such as anaphylaxis.[4]

Key Points of Pre-immunization Checklist

- Any recent sickness, having a temperature over 38.5°C at present
- Have had a serious reaction to any vaccine or any component of the vaccine
- Have had a severe allergy to anything
- Have had a 'live' vaccine in the last month
- Have had recent immunoglobulin or blood transfusion treatment
- Having a disease or treatment that causes low immunity
- Are pregnant or intend to become pregnant.

Note: As per the CDC recommendations, these all are good practice recommendations to avoid any kind of anaphylactic reaction and untoward effect on developing fetus following vaccination.

5. SUMMARY OF FOGSI RECOMMENDATIONS

Vaccination is recommended for all women, including pregnant women **(Flowchart 1)**.

5.1 Adolescent Girls

- For adolescent girls, human papilloma virus (HPV) and tetanus, diphtheria (Td)/tetanus, diphtheria, acellular pertussis (Tdap) are mandatory vaccines. (Grade A)
- During adolescence, certain vaccines are optional and should be administered only if they have not been given during childhood. These vaccines include measles, mumps, rubella (MMR), varicella, typhoid, hepatitis A and B. (Grade B)
- There are certain other vaccines given only under special circumstances. These vaccines include: rabies, Japanese encephalitis, meningococcal, and seasonal inactivated flu vaccine. (Grade A)

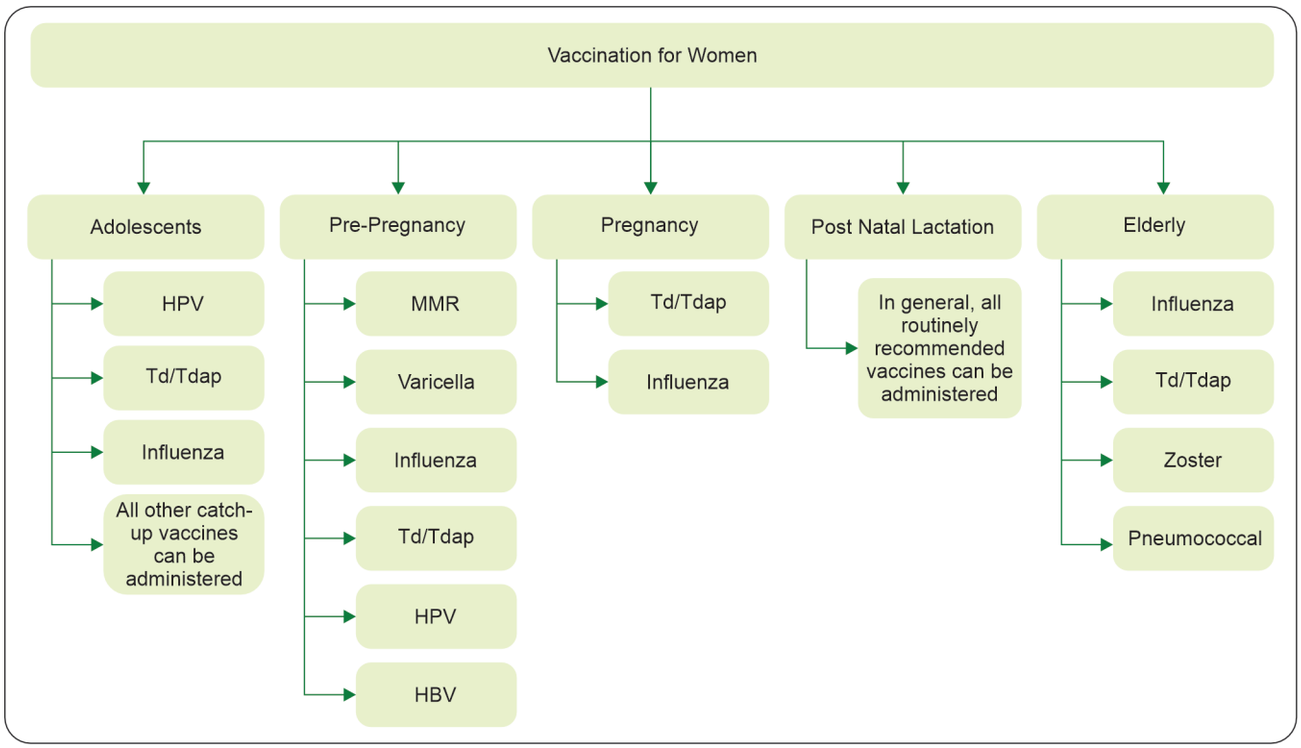
5.2 Preconception Period

- MMR vaccine should be administered to those women who have not received it earlier. Women should be advised not to get pregnant for at least 4 weeks after receiving MMR vaccine. (Grade A)
- Varicella vaccine should be administered to those who have neither been infected nor vaccinated before. Women should be advised not to get pregnant for at least 4 weeks after receiving varicella vaccine. (Grade B)
- Hepatitis B vaccine should be administered to all women who are planning pregnancy and are at risk of catching hepatitis B infection. (Grade A)
- Women who have started to receive their HPV vaccination, should complete the schedule before planning pregnancy. (Grade B)

5.3 Pregnancy

- ***Td/Tdap:*** Tdap is the preferred vaccine during pregnancy and should be administered in early third trimester through 36 weeks for the benefit of baby during neonatal period. Td should be administered for routine indications. (Grade A)

Flowchart 1: Summary of FOGSI recommendation



Abbreviations: HBV, hepatitis B virus; HPV, human papilloma virus; MMR, measles, mumps, rubella; Td, tetanus, diphtheria; Tdap, tetanus, diphtheria, acellular pertussis

- Pregnant women should be administered a dose of Tdap during each pregnancy irrespective of the patient's prior history of receiving Tdap. (Grade A)
- Women who are or will be pregnant during influenza season should receive inactivated influenza vaccine (IIV) or recombinant influenza vaccine (RIV)**.** (Grade A)
- Pregnant women who are at risk of catching hepatitis B infection, should be administered with hepatitis B vaccine. (Grade B)

5.4 Postpartum

- Women who have not received MMR vaccine before, can be vaccinated during postpartum period before discharge from hospital. (Grade A)
- For women not previously vaccinated with Tdap, if Tdap is not administered during pregnancy, Tdap should be administered immediately postpartum. (Grade A)
- Women who skipped their HPV vaccine dose during pregnancy, should receive it during postpartum period as early as possible. (Grade B)

5.5 Elderly Women

- All elderly women of above 65 years age should be vaccinated with seasonal inactivated flu vaccine annually. (Grade A)
- Td booster vaccination should be continued for all elderly women. (Grade A)
- All elderly women of above 60 years age should be vaccinated with single dose of herpes zoster vaccine. (Grade A)
- All elderly women of above 65 years age should be vaccinated with a single dose of pneumococcal vaccine. (Grade A)

5.6 Special Situations

- These vaccines are administered under certain special situations only viz. women with chronic medical conditions, suppressed immunity, animal bites, living in or travelling to endemic areas.
- These vaccines are to be administered only after taking opinion from an expert.

Note: Newborns do not yet have fully developed immune systems, making them particularly vulnerable to infections. Because of this, anyone who is around these babies should be vaccinated with all routine vaccines including whooping cough vaccine (DTaP for children and Tdap for preteens, teens, and adults) and flu vaccine during flu season. (Grade A)

6. VACCINATION IN ADOLESCENT GIRLS

The percentage of adolescents (10–19 years) in India comprises of more than one-fifth of the total population. The immunization is one of the most important, most beneficial, and cost-effective disease prevention measures that can be provided for adolescents.

Discussion

- Under the Universal Immunization Program (UIP) and GOI guidelines, adolescents aged 10 years and 16 years are to be vaccinated with tetanus and adult diphtheria (Td) vaccine as per the national immunization schedule in India.
- Considering the highly effective preventive role of HPV vaccine in preventing carcinoma cervix, the WHO has recently recommended to include HPV vaccine among adolescent immunization schedule.
- Immunization against influenza infection (seasonal flu) has been included in all major guidelines as an important vaccine across all age groups.
- Adolescents need to be protected against many other diseases which may cause high morbidity if caught during adolescence (hepatitis A and varicella) and some diseases which per se tend to affect adolescents (mumps and meningococcal infection).
- In females, vaccination against MMR infection is very important to prevent its transmission to fetus in pregnancy.
- In India, there is no specific vaccination schedule which targets the needs of adolescents. However, the Indian Academy of Pediatrics (IAP) has recommended a separate adolescent immunization schedule.
- The CDC has come up with a detailed immunization schedule for adolescents in 2023 which talks about all important vaccines required to be administered to this age group.

Taking in account both, the specific needs of adolescent age group and the guidelines from all major agencies worldwide, this committee recommends the following vaccination schedule in adolescent females **(Table 2)**.

7. VACCINATION IN THE PRECONCEPTION PERIOD

- Many vaccine-preventable diseases can have serious consequences for both mother and fetus during pregnancy, which makes the immunization status of the women of reproductive age an important focal point for preconception care.
- Vaccination during preconception period depends upon the prior immunization status of the women; therefore, a thorough vaccination history should be taken from all women who are planning to conceive **(Table 3)**.

Discussion

Special Considerations of MMR Vaccine

- MMR is preferred over MR or rubella vaccine alone for the purpose of routine preconceptional vaccination as it gives additional protection against mumps and measles. (Strength of recommendation: A; quality of evidence III)
- All women in the preconceptional period should be screened for MMR infection and vaccinated if nonimmune. (Strength of recommendation: A; quality of evidence III)
- Serological testing for MMR, however, is not absolutely essential before vaccinating all women. (Strength of recommendation: B; quality of evidence IV)
- As it is an attenuated live vaccine, women should be counseled not to become pregnant for at least 1 month after receiving the MMR vaccination. (Strength of recommendation: A; quality of evidence III)
- Accidental vaccination in pregnancy or if pregnancy occurs after within 4 weeks of vaccination, it does not pose a substantial risk to the fetus and should not be strictly considered as an indication for the termination of pregnancy.

Table 2 Vaccination in Adolescents[1,2]

Name of Vaccine	***9–14 years***	***15–18 years***	***Route & Schedule***
Essential			
Tdap*/Td	Depends upon the type used		IM, Td at 10 & 15 years f/b once in 10 years as GOI guidelines, Tdap
HPV#	Before 14 completed years, HPV vaccines are recommended as a 2-dose schedule, 6 month apart	From 15th year onwards and the immunocompromised subjects at all ages, HPV vaccines are recommended as a 3-dose schedule, 0–1–6 (HPV2) or 0–2–6 (HPV4)	IM, schedule as mentioned in column 3 & 4
Influenza	Once every year		IM, Age & season appropriate single dose
Conditional **			
Varicella	Any time earliest		IM, 2 doses at 4–8 weeks interval
MMR	Any time earliest		IM, 2 doses at minimum 4 weeks interval (one dose if previously vaccinated with one dose)
Typhoid	Any time earliest		IM, single dose
Hepatitis A	10–18 years		IM, 2 doses series at 6 months interval
Hepatitis B	10–18 years		IM, 3 doses series at 0, 1-2, 6 months
Special* ***See section on vaccination in Special Situations***			

*Depending upon affordability and availability
**These are catch up vaccines which may have been missed during childhood
***These vaccines are to be given in a special set of population or during special situations
#*For further details, refer to FOGSI GCPR on Cervical Cancer Prevention-2023*
Abbreviations: GOI, Government of India; HPV, human papilloma virus; IM, intramuscular; MMR, measles, mumps, rubella; Td, tetanus, diphtheria; Tdap, tetanus, diphtheria, acellular pertussis

Table 3 Vaccination during preconception period[3,4]

Vaccine	***Dosage***	***Special considerations***
Tdap*/Td	IM, Td/Tdap at 11 & 16 years f/b once in 10 years as GOI guidelines, (Strength of recommendation: A; quality of evidence III)	If Tdap is administered at a preconception visit, it should be administered again during pregnancy between 27 weeks and 36 weeks gestation
HPV	From 15th year onwards and immunocompromised subjects at all ages, HPV vaccines - recommended as a 3-dose schedule, 0–1–6 (HPV2) or 0–2–6 (HPV4)	To be given if not received earlier
MMR	S/C 2 doses at minimum 4 weeks interval	One dose - if previously vaccinated with one dose
Varicella	S/C 2 doses at 4–8 weeks interval	One dose - if previously vaccinated with one dose
HBV	IM, 3 doses at 0, 1, 6 months interval	If received earlier, antibody levels are to be checked

*Depending upon affordability and availability
Abbreviations: GOI, Government of India; HBV, hepatitis B virus; HPV, human papilloma virus; IM, intramuscular; MMR, measles, mumps, rubella; S/C, subcutaneous; Td, tetanus, diphtheria; Tdap, tetanus, diphtheria, acellular pertussis

2. Special Considerations for Varicella

- Women should be screened for varicella immunity in the preconception period by taking a history of past infection or previous vaccination or by serology. (Strength of recommendation: A; quality of evidence III)
- All the nonimmune women should be vaccinated and counseled to avoid pregnancy for a month. (Strength of recommendation: A; quality of evidence III)
- Two doses of the chickenpox vaccine are over 90% effective at preventing it. Several studies have shown that people vaccinated against varicella had antibodies for at least 10–20 years after vaccination.

- Sore arm from the injection, redness, or rash where the shot is given, or fever can happen after varicella vaccination. More serious reactions happen very rarely. These can include pneumonia, infection of the brain and spinal cord covering, or seizures that are often associated with fever.

8. VACCINATION IN PREGNANCY

- Pregnant women and their fetuses are among the vulnerable population that can be severely affected by communicable diseases.
- Immunization in pregnancy prevents both neonatal and maternal complications through the prevention of fulminant disease or by offering the passive transfer of maternal antibodies, thus narrowing the "window of vulnerability" to infections, and prolonging the period of protection from disease **(Table 4)**.

Discussion

- Vaccines such as the influenza and the Tdap (Tetanus toxoid, reduced diphtheria toxoid and acellular pertussis) are strongly recommended in each pregnancy.
- Other vaccines can be offered based on risk factors and only when the benefits of receiving them outweigh the risks.
- There is no evidence of adverse fetal effects from vaccinating pregnant women with inactivated virus, bacterial vaccines, or toxoids.

Special Considerations for Tdap Vaccine

- Tdap vaccine is a combination vaccine that protects against three bacterial infections – Tetanus, Diphtheria and Pertussis with a single dose. This minimizes the morbidity and mortality associated with pertussis in neonates before their own pertussis primary vaccine series can be completed.
- The Advisory Committee on Immunization Practices (ACIP) and the ACOG recommend that pregnant patients receive Tdap vaccine in each pregnancy, regardless of their prior vaccination history.
- The optimal timing is between 27 weeks and 36 weeks of pregnancy to maximize the maternal antibody response and passive antibody transfer to the fetus.
- Even if a woman has taken 2 doses of tetanus toxoid (TT), she can be given Tdap vaccine between 27 weeks and 36 weeks of gestation. No reported increase in the severity of the duration of adverse events associated with the administration of an extra tetanus containing vaccine.
- If Tdap is not administered during pregnancy, it should be given immediately postpartum.
- It is also recommended that any person who is expected to be in close contact with an infant and has not received Tdap vaccination before gets a single dose of Tdap vaccination at least 2 weeks before they have any contact with the infant.
- Adverse effects reported with the use of the Tdap vaccine are limited to pain at the site of injection, erythema, and swelling. Most symptoms are mild and resolve within 72 hours.
- There is no association with clinically significant harmful effects on the fetus or the neonate.

Table 4 Vaccination during pregnancy[5-8]

Vaccine	*Type of Vaccine*	*Interval*	*Dose & Route*
Td1 */TT1	Tetanus, diphtheria toxoid	Early in pregnancy	Single, 0.5 mL IM
Td2*/Tdap	Tetanus, diphtheria toxoid and acellular pertussis	27–36 weeks	Single, 0.5 mL IM
Influenza (IIV)	Inactivated vaccine	26 weeks** onwards/Any time in pregnancy if risk of influenza is high	Single, 0.5 mL IM

*Available in Public Health System.
**Earlier in case of community outbreak:
- Td2/Tdap given 4 weeks after Td1/TT1
- If previously immunized for tetanus with 2 doses during last pregnancy within the past 3 years, then only dose Td2/Tdap in this pregnancy.

Special Considerations for Influenza Vaccine

- Influenza is an RNA virus with A and B serotypes that undergoes yearly antigenic shift and drift, causing both endemic and pandemic flu.
- Influenza A/H1N1 infection increased maternal mortality by 25–75%, and is associated with greater disease severity when compared to nonpregnant women.
- Maternal influenza infection also increased fetal mortality rate by 5.5–33%.
- The inactivated virus vaccine, containing either 3 (trivalent influenza vaccine) or 4 (tetravalent influenza vaccine) strains of the influenza virus, is recommended for administration during pregnancy.
- The third-generation tetravalent subunit vaccines have the highest safety profile by the absence of infectious viruses. They are associated with a lower frequency of local and systemic reactions than split vaccines.
- It can be administered at any time during pregnancy, before and during the influenza season.
- Influenza vaccination during pregnancy protects the mother against infection, due to the transplacental transfer of maternal antibodies before birth, it also protects the infant in the first few months of life.
- It takes about 2 weeks after vaccination for antibodies to develop in the body and provide protection against influenza infection, as such vaccination must be considered as early as possible.
- The live attenuated influenza vaccine, which is administered intranasally, is contraindicated during pregnancy because of the theoretical risk of the placental transmission of the virus to the fetus.

Special Considerations for Hepatitis B Vaccination during Pregnancy

The hepatitis B vaccine is recommended for pregnant people who are at risk for acquiring hepatitis B during pregnancy (e.g., due to living with someone infected with hepatitis B, health care workers, sex workers) and for people who started the vaccine series before getting pregnant as per the CDC and ACOG recommendations.

Special Considerations for Varicella Infection during Pregnancy

- Congenital varicella syndrome, maternal varicella zoster virus pneumonia and neonatal varicella infection are associated with serious fetomaternal morbidity and not infrequently with mortality.
- Vaccination against varicella zoster virus can prevent the disease and outbreak control limits the exposure of pregnant women to the infectious agent.
- Maternal varicella zoster immune globulin (VZIG) administration before rash development, with or without antivirals medications can modify the progression of the disease.

9. POSTPARTUM VACCINATION

Postnatal period is a good window of opportunity which should not be missed to protect the mother and her future progeny.

Recommended postnatal vaccinations to all nonimmunized postnatal mothers as an opportunity for catch-up vaccination are mentioned in **Tables 5 to 7**.

Discussion

Vaccination Safety in Lactating Mothers

- According to the ACIP's General Best Practice Guidelines for Immunization in Special Situations, except for smallpox and yellow fever vaccines, neither inactivated nor live-virus vaccines administered to a lactating woman affect the safety of breastfeeding for women or their infants.
- Inactivated, recombinant, subunit, polysaccharide, and conjugate vaccines, as well as toxoids, pose no risk for mothers who are breastfeeding or for their infants.
- Breastfeeding is a contraindication for the smallpox vaccination of the mother because of the theoretical risk for contact transmission from the mother to infant.
- Yellow fever vaccine should be avoided in breastfeeding women. However, when the travel of nursing mothers to a yellow fever endemic area cannot be avoided or postponed, these women should be vaccinated.

Table 5 Vaccine in postpartum[7,8]

Vaccine	*Interval*	*Dose & Route*
HPV	0, 1, 6 months	3 doses, 0.5 ml, IM
Hepatitis B	0, 1, 6 months	3 doses,1 ml, IM
MMR *	0, 4 weeks	2 doses, 0.5 ml, SC
Influenza	–	1 dose, 0.5 ml, IM
Varicella	0, 4 weeks	2 doses, 0.5 ml, SC

*Available in Public Health System

Table 6 Vaccines safe for use in lactation

Inactivated	• Anthrax • Hepatitis A • Human papilloma virus (HPV) • Influenza • Japanese encephalitis • Polio (IPV) • Rabies
Live attenuated	• Influenza • Measles, mumps, rubella (MMR) • Chickenpox (VZV) • Typhoid (Ty21a)
Recombinant	• Hepatitis B • Meningococcal meningitis (MenB)
Conjugate	• Haemophilus influenzae type B (HiB) • Meningococcal meningitis (MPSV4, MenACWY) • Pneumococcal (PCV13)
Polysaccharide	• Pneumococcal (PPSV23) • Typhoid (ViCPS)
Toxoid	• Tetanus, diphtheria, acellular pertussis/tetanus, diphtheria (Tdap/Td)

Table 7 Vaccines contraindicated during lactation

Live attenuated	• Monkeypox/Smallpox (ACAM2000) • Yellow fever

10. VACCINATION OF ELDERLY WOMEN (TABLE 10)

Immunosenescence describes the decline in systemic immunity associated with aging involving both innate and adaptive immune responses. Older adults are, therefore, typically more susceptible to vaccine-preventable diseases and disease can be more severe than in younger people.

11. VACCINE IN SPECIAL SITUATIONS

11.1 Routine Vaccination Schedules

Routine vaccination schedules are administered to healthy individuals who can develop immunity after receiving these vaccines. One of the strategic objectives of the 2011–2020 Global Vaccine Action Plan is for the benefits of immunization to be equitably extended to all people. This approach encompasses special groups at an increased risk of vaccine-preventable diseases, such as preterm infants and pregnant women, as well as those with chronic and immune-compromising medical conditions or at an increased risk of disease due to immunosenescence **(Table 9)**.

Table 8 Vaccination of elderly women[9,10]

Vaccine	*Special considerations*
Seasonal inactivated influenza	*≥65 years of age:* One dose annually (WHO, ACIP)
Tdap/Td	*≥65 years of age:* Substitute one-time dose of Tdap for Td booster, then boost with Td every 10 years (ACIP)
Herpes zoster	*≥60 years of age:* One dose (ACIP)
Pneumococcal	*≥65 years of age:* One dose of PCV and/or pneumococcal polysaccharide vaccine, depending on vaccination history (ACIP)

Abbreviations: ACIP, Advisory Committee on Immunization Practices; PCV, pneumococcal conjugate vaccine; Td, tetanus, diphtheria; Tdap, tetanus, diphtheria, acellular pertussis; WHO, World Health Organization

Table 9 Vaccination in special situations[11]

Name of special situation	*Name of vaccine*	*Special considerations*
Preterm infants		
	Hepatitis B	Birth doses given to infants <2 kg should not be counted towards the primary vaccination series because of the possibility of poor response (WHO, ACIP)
	Pneumococcal conjugate vaccine (PCV)	Booster dose in the second year of life if received 3 primary doses before 12 months of age (WHO)
Adolescents with chronic medical conditions		
	HPV	As for general population (WHO/ACIP) except: Extended duration of catch-up vaccination for immunocompromised males (ACIP) Increased dosing requirements for immunocompromised females
	Td/Tdap	As for general population (WHO/ACIP) except: Consider shorter dosing interval for Tdap for adolescents with high-risk conditions (ACIP)
	Meningococcal conjugate vaccine	As for general population (WHO/ACIP) except: For high-risk conditions (asplenia, complement component deficiency, HIV), 2 primary doses and (if asplenia or complement component deficiency) booster dose every 5 years (ACIP)
	Seasonal inactivated influenza	One dose annually (WHO, ACIP)
	Pneumococcal catch-up with PCV	If high-risk condition, e.g., CSF leak, cochlear implant, asplenia, immunocompromised (ACIP) One dose of pneumococcal polysaccharide vaccine if high-risk condition and additional dose after 5 years if asplenia or immunocompromised (ACIP)
Living in areas with specific endemic infections in India		
	Japanese encephalitis	Two dose series at 28 days interval
	Dengue	3 doses series administered at 0, 6, and 12 months
Traveling abroad to endemic areas		
	Yellow fever	Given to infants at age 9–12 months at the same time as the measles vaccine
	Japanese encephalitis	As mentioned above (to be taken at least 7 days before the traveling date)
Animal bite (Rabies)*- WHO recommendations[3,5]		
Category I	Category II	Category III (consultation with expert is must)
Touching or feeding animals, licks on intact skin, contact of intact skin with secretions if rabid animals or persons	Nibbling of uncovered skin, minor scratches, abrasions without bleeding	Single or multiple transdermal bites or scratches, licks on broken skin, contamination of mucous membrane with saliva from licks and exposure to bats

Contd...

Contd...

Animal bite (Rabies)*- WHO recommendations[2]		
Not regarded as exposure, no PEP** required	Vaccine should be injected as soon as possible	Vaccine and immunoglobulins (Ig) should be injected as soon as possible at distant sites, Ig can be administered up to 7 days after first dose of vaccine
Schedule[10]	4 doses on day 0-3-7-14 to 28 days (IM), on day 0, first dose of the vaccine is administered***	

*Pregnancy and infancy are not contraindications
**Postexposure prophylaxis
***For those who have received the full schedule of PEP, anytime in the past and if the exposure has occurred more than 3 months after the completion of the schedule, 2 doses on days 0–3 is recommended.
Abbreviations: ACIP, Advisory Committee on Immunization Practices; CSF, cerebrospinal fluid; PCV, pneumococcal conjugate vaccine; PEP, postexposure prophylaxis; Td, tetanus, diphtheria; Tdap, tetanus, diphtheria, acellular pertussis; WHO, World Health Organization

11.2 Vaccination of Immunocompromised Individuals

Immunocompromised individuals include those with primary (hereditary or genetic) immunodeficiency or secondary immunodeficiencies that are generally acquired and occur due to a disease process or immunosuppressive therapy. This set of population requires certain additional vaccines which may be different from routine vaccine preparations; therefore, an expert should always be consulted before advising these vaccines. We do not have any standard uniform Indian guideline on this group; however, Infectious Diseases Society of America (IDSA) has recommended a detailed vaccination program of these individual depending on their specific condition **(Table 10)**.

11.3 COVID-19 Vaccination

Since the entry of coronavirus disease 2019 (COVID-19) infection in 2019, the WHO has been releasing guidelines on COVID-19 vaccination from time to time. Our national COVID-19 vaccination program has been adopted from the WHO and best global practices (49-50). COVID-19 vaccination in our country commenced in January 2021 with the vaccination of health care workers. The program was expanded further to include the vaccination of frontline workers, citizens of >60 years age, citizens of >45 years of age, citizens >18years age, and eventually children between 12 years and 18 years of age. In India, vaccination for COVID-19 is voluntary now, however, it is advisable to receive the complete schedule of COVID-19 vaccine until the WHO declares not to receive it any further. For persons who have recovered from COVID-19 are advised to receive complete schedule of COVID-19 vaccine irrespective of the history of infection with COVID-19.[2]

Dose and Schedule

Currently, Bharat Biotech's CoVaxine, Serum institute's CoviShield, and Russia-made Sputnik V are available for use in India. For children between 12 years and 18 years of age another vaccine CorBeVax has been introduced.

- *CoVaxine:* It is administered in two doses of 1 mL each at 4–6 weeks apart through IM route.
- *CoviShield:* It is administered in two doses of 1 mL each at 12–16 weeks interval through IM route.
- *Booster Dose:* Preferable interval from the second dose to booster dose is recommended to be 6 months.
- *CorBeVax:* It is administered in 0.5 mL dose with dose schedule of day 0 and day 28 through IM route.

12. FUTURE RESEARCH IN VACCINATION

Diseases, such as human immunodeficiency virus (HIV), malaria, tuberculosis (TB), and Ebola virus, which have not been controlled till now by conventional vaccines, innovative strategies are being deployed to develop robust vaccines against them. Profound scientific advances in the next-generation sequencing has paved the way to better understanding of both epidemiology and immunology of these diseases leading to the development of innovative platforms such as nucleic acid vector vaccine.

Similarly, another major area of research is the development of specific monoclonal antibodies or T-cell therapies, used in the management of spread of certain cancers. To combat the challenge of ever-evolving viruses, research is going on to develop broadly neutralizing antibodies.

Table 10 Vaccine for immunocompromised individuals[10]

Patient population/ condition	*Recommended vaccines*	*Contraindicated vaccines*
HIV infected	As for general population except for contraindicated vaccines	Live attenuated influenza vaccine Live MMR or VAR for children with CD4 T-cell percentage <15 or adults/adolescents with CD4 T-cell count <200 cells/mm^3 Live MMRV vaccine Live HZ vaccine
Cancer	Inactivated influenza vaccine annually except those receiving anti-B-cell antibodies or intensive chemotherapy Other inactivated vaccines for immunocompetent children receiving maintenance chemotherapy PCV followed by PPSV Three months after chemotherapy or at least 6 months after receiving anti-B-cell antibodies, can administer inactivated vaccines and live VAR, MMR, MMRV vaccines as for general population	Live viral vaccines during chemotherapy
Hematopoietic stem cell transplant	*Pretransplant:* As for general population if not immunosuppressed and if interval to start of conditioning regimen is P4 weeks for live vaccines and P2 weeks for inactivated vaccines. VAR for nonimmune transplant candidates if interval to start of conditioning regimen is P4 weeks *Starting 6 months after transplant:* Inactivated influenza vaccine, Td-containing vaccine *Starting 3–6 months after transplant:* PCV/PPSV Starting 6–12 months after transplant: Hib, meningococcal conjugate, hepatitis B, IPV, HPV vaccines *Starting 24 months after transplant:* MMR if measles-seronegative and VAR if varicella-seronegative and no graft vs host disease or ongoing immunosuppression	Live vaccines if <4 weeks inactivated vaccines if <2 weeks before start of conditioning regimen *After transplant:* Live vaccines to patients with active graft vs host disease or ongoing immunosuppression
Solid organ transplant	*Pretransplant:* As for general population, PCV/PPSV, hepatitis B, hepatitis A, HPV (age 11–26 years) vaccines. MMR and VAR (age 6–11 months) if not receiving immunosuppression and >4 weeks to transplant. HZ (age 50–59 years) if not severely immunocompromised and >4 weeks to transplant *Starting P1 month after transplant:* Inactivated influenza vaccine if disease outbreak *Starting 2–6 months after transplant:* As for general population. If not administered before transplant, PCV with timing based on the degree of immunosuppression *2–6 months after liver transplant:* Hepatitis B vaccine	No vaccines in first 2-month period post- transplant, apart from influenza vaccine if necessary MMR, VAR should generally not be administered to transplant recipients, except VAR in non immune children who are renal or liver transplant recipients and receiving minimal or no immunosuppression
Chronic inflammatory diseases on immunosuppressive medications	*As for general population:* Inactivated vaccines, PCV/PPSVVAR if nonimmune and P4 weeks to immunosuppression initiation or if low-level, long-term immunosuppression HZ (age P60 years or 50–59 years and varicella-seropositive) if before immunosuppression initiation or low-dose immunosuppression	Live vaccines LAIV, MMR, MMRV

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Patient population/ condition	***Recommended vaccines***	***Contraindicated vaccines***
Asplenia or sickle cell disease	As for general population aged <2 years, including PCV If aged P2 years, PCV/PPSV If aged P5 years, Hib vaccine If aged P2 months, meningococcal vaccine but not quadrivalent conjugate vaccine in patients aged <2 years because of reduced antibody response to PCV when coadministered. If aged P55 years, revaccination with quadrivalent vaccine every 5 years	LAIV
Anatomic barrier defects at risk of vaccine-preventable infection	*As for general population:* Adults and children with profound deafness scheduled to receive cochlear implant, congenital dysplasias of the inner ear or persistent CSF communication with oropharynx or nasopharynx Patients with or P2 weeks before cochlear implant or with persistent CSF communication with oropharynx or nasopharynx: PCV/PPSV	None

Abbreviations: CSF, cerebrospinal fluid; Hib, *Haemophilus influenzae* type b vaccine; HIV, human immunodeficiency virus; HPV, human papillomavirus vaccine; HZ, herpes zoster vaccine; Ig, immunoglobulin; IPV, inactivated poliovirus vaccine; LAIV, live attenuated influenza vaccine; MMR, measles, mumps and rubella vaccine; MMRV, MMR- varicella vaccine; OPV, oral poliovirus vaccine; PCV, pneumococcal conjugate vaccine; PPSV, pneumococcal polysaccharide vaccine; Td, tetanus toxoid, reduced diphtheria toxoid; VAR, varicella vaccine

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