CERTIFIED

MAHILA KAVACH KENDRA

A comprehensive vaccination centre for women

FOGSI FOCUS PLUS ON

ADULT WOMEN VACCINATION

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MSD

POSTPARTUM WOMEN ARE AT AN INCREASED RISK OF HPV*,[1] INFECTION AND IT IS ONE OF THE OPPORTUNITIES FOR HPV VACCINATION†,[2]

Opportunity for HPV vaccination in young women after their first delivery[3]

Only **0.4% women aged 24-45 years** are infected with all 4 **HPV serotypes**[4]

>99% of women can still get full benefit from **HPV vaccination**[4]

YOUR STRONG RECOMMENDATION MAY HELP TO SAVE LAKHS OF WOMEN FROM HPV-RELATED CANCERS[5]

Image for representation purpose only

GARDASIL®
[Human Papillomavirus Quadrivalent (Types 6, 11, 16, 18) Recombinant Vaccine]

GARDASIL® 9
Human Papillomavirus 9-valent Vaccine, Recombinant

Why Wait?
Vaccinate Today!

*31% risk. †Quadrivalent HPV vaccine. HPV: Human papillomavirus

References: 1. Nobbenhuis MA, Helmerhorst TJ, van den Brule AJ, et al. High-risk human papillomavirus clearance in pregnant women: trends for lower clearance during pregnancy with a catch-up postpartum. Br J Cancer. 2002;87(1):75-80; 2. CY, Tseng CJ, Chang CC, et al. Postpartum HPV Vaccination Rate and Differences in Background Characteristics Between HPV Vaccinated and Unvaccinated Postpartum Women: Strict Monitoring and Follow-Up of Postpartum HPV Vaccination Program. Front Immunol. 2021;12:626582; 3. Rama CH, Villa LL, Pagliusi S, et al. Opportunity for catch-up HPV vaccination in young women after first delivery. J Epidemiol Community Health. 2010;64(7):610-5; 4. Velicer C, Zhu X, Vuocolo S, et al. Prevalence and incidence of HPV genital infection in women. Sex Transm Dis. 2009 Nov;36(11):696-703. 5. Seth S, Malhotra N, Malhotra J. HPV vaccination—An update. In: Sekaran SK, Patel M, Suman A, et al. (eds.) FOGSIs Update in Obstetrics and Gynaecology. Volume 2. Evangel Publishing, 2022, pp. 165-174.

SELECTED SAFETY INFORMATION

Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant
GARDASIL® (Suspension for intramuscular injection) **Contraindications:** Hypersensitivity to the active substances or to any of the excipients of the vaccine including severe allergic reactions to yeast (a vaccine component). **Warning and Precautions:** GARDASIL vaccine is not intended to be used for treatment of active external genital lesions; cervical, vulvar, or vaginal cancers; CIN, VIN, VaIN. This vaccine will not protect against diseases that are not caused by HPV. As with all injectable vaccines, appropriate medical treatment should always be readily available in case of rare anaphylactic reactions following the administration of the vaccine. The decision to administer or delay vaccination because of a current or recent febrile illness depends largely on the severity of the symptoms and their etiology. Individuals with impaired immune responsiveness, whether due to the use of immunosuppressive therapy, a genetic defect, Human Immunodeficiency Virus (HIV) infection, or other causes, may have reduced antibody response to active immunization. This vaccine should be given with caution to individuals with thrombocytopenia or any coagulation disorder because bleeding may occur following an intramuscular administration in these individuals. Syncope, sometimes associated with tonic clonic movements and other seizure-like activity, has been reported following vaccination with GARDASIL. **Use in special population:** Pregnancy: Pregnancy should be avoided during the vaccination regimen for GARDASIL. Nursing Mothers: GARDASIL may be administered in lactating women. It is not known whether vaccine antigens or antibodies induced by the vaccine are excreted in human milk. Pediatric Use: The safety and efficacy of GARDASIL have not been evaluated in children younger than 9 years. Elderly and HIV-infected individuals: The safety and efficacy of GARDASIL have not been evaluated in elderly and HIV-infected individuals. Drug Interactions: **Use with other Vaccines:** GARDASIL may be administered concomitantly (at a separate injection site) with H-B-VAX II™* [hepatitis B vaccine (recombinant)], Menactra [Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine], Adacel [Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (Tdap)], and Repevax [Diphtheria, Tetanus, Pertussis (acellular, component) and Poliomyelitis (inactivated) Vaccine, (adsorbed, reduced antigen(s) content)]. Use with Hormonal Contraceptives: Use of hormonal contraceptives did not appear to affect the immune responses to GARDASIL. Use with Steroids: Use with Steroids did not appear to affect the immune responses to GARDASIL. **Undesirable Effects:** The vaccine-related adverse experiences that were observed among recipients of GARDASIL at a frequency of at least 1%. Vaccine-Related Clinical Adverse Experiences in 9- Through 45-Year-Old Girls and Women are headache, dizziness, nausea, pain in extremity, pyrexia. Most of the adverse experiences seen with concomitant administration with other vaccines were reported as being mild to moderate in intensity. Undesirable effects as per Post-Marketing reports were cellulitis, idiopathic thrombocytopenic purpura, autoimmune hemolytic anemia, lymphadenopathy, pulmonary embolus, acute disseminated encephalomyelitis, dizziness, Guillain-Barre syndrome, headache, motor neuron disease, paralysis, seizures, syncope (including syncope associated with tonic-clonic movements and other seizure-like activity) sometimes resulting in falling with injury, transverse myelitis, deep venous thrombosis, nausea, pancreatitis, vomiting, arthralgia, myalgia, asthenia, chills, death, fatigue, malaise, Autoimmune diseases, hypersensitivity reactions including anaphylactic/anaphylactoid reactions, bronchospasm, and urticaria.
Before prescribing, please consult the full prescribing information.

Scan the QR code for Prescribing Information

HUMAN PAPILLOMAVIRUS 9-VALENT VACCINE, RECOMBINANT [Serotype 6 L1, 11 L1, 16 L1, 18 L1, 31 L1, 33 L1, 45 L1, 52 L1 & 58 L1]
GARDASIL® 9 (Suspension for intramuscular injection) **Contraindications:** GARDASIL 9 is contraindicated in patients with hypersensitivity to either GARDASIL 9 or any of the inactive ingredients in either vaccine.
Warning and Precautions: GARDASIL 9 vaccine is not intended to be used for treatment of active external genital lesions; cervical, vulvar, vaginal, or anal cancers; CIN, VIN, VaIN, or AIN. This vaccine will not protect against diseases that are not caused by HPV. As with all injectable vaccines, appropriate medical treatment should always be readily available in case of rare anaphylactic reactions following the administration of the vaccine. Syncope (fainting) may follow any vaccination, especially in adolescents and young adults. The decision to administer or delay vaccination because of a current or recent febrile illness depends largely on the severity of the symptoms and their etiology. Individuals with impaired immune responsiveness, whether due to the use of immunosuppressive therapy, a genetic defect, Human Immunodeficiency Virus (HIV) infection, or other causes, may have reduced antibody response to active immunization. This vaccine should be given with caution to individuals with thrombocytopenia or any coagulation disorder because bleeding may occur following an intramuscular administration in these individuals. **Use in special population:** Pregnancy: Pregnancy should be avoided during the vaccination regimen for GARDASIL 9. Nursing Mothers: GARDASIL 9 may be administered in lactating women. It is not known whether vaccine antigens or antibodies induced by the vaccine are excreted in human milk. Pediatric Use: The safety and efficacy of GARDASIL 9 have not been evaluated in children younger than 9 years. Immunocompromised Individuals: The immunologic response to GARDASIL 9 may be diminished in immunocompromised individuals. **Drug Interactions: Use with other Vaccines:** GARDASIL 9 may be administered concomitantly (at a separate injection site) with Menactra [Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine], Adacel [Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (Tdap)], and Repevax [Diphtheria, Tetanus, Pertussis (acellular, component) and Poliomyelitis (inactivated) Vaccine, (adsorbed, reduced antigen(s) content)] (dTap-IPV). Use with Hormonal Contraceptives: Use of hormonal contraceptives did not appear to affect the type specific immune responses to GARDASIL 9. Use with Steroids: Immunosuppressive therapies, including irradiation, antimetabolites, alkylating agents, cytotoxic drugs, and corticosteroids (used in greater than physiologic doses), may reduce the immune responses to vaccines. **Undesirable Effects:** The vaccine-related adverse experiences that were observed among recipients of either GARDASIL 9 or GARDASIL at a frequency of at least 1%. Few individuals (GARDASIL 9 = 0.1% vs. GARDASIL <0.1%) discontinued due to adverse experiences after receiving either vaccine. The safety profile was similar between GARDASIL 9 and GARDASIL in women and girls and boys. Solicited Systemic and Injection-Site Adverse Reactions: Temperature and injection-site pain, swelling, and erythema were solicited using VRC-aided surveillance for 5 days after each injection of GARDASIL 9 during the clinical studies. Undesirable effects as per post-Marketing reports were cellulitis, idiopathic thrombocytopenic purpura, lymphadenopathy, acute disseminated encephalomyelitis, dizziness, Guillain-Barré syndrome, headache, syncope sometimes accompanied by tonic-clonic movements, nausea, vomiting, arthralgia, myalgia, asthenia, chills, fatigue, malaise, hypersensitivity reactions including anaphylactic/anaphylactoid reactions, bronchospasm, and urticaria.
Before prescribing, please consult the full prescribing information.

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FROM THE PRESIDENT'S DESK

DR. JAYDEEP TANK
PRESIDENT; FOGSI

With nearly 1.4 billion people, accounting for approximately 18% of the world's population, India is the second most populous country in the world. Of this the % of total female population in India was reported at 48.41 % in 2022, according to the World Bank collection of development indicators, compiled from officially recognized sources. It has also been estimated that up to 63 million people in India are pushed into poverty by health expenses each year.

Even with tremendous improvement in childhood vaccination coverage in India, adult vaccination coverage is still negligible, more so for women. FOGSI hence aims to create awareness about the importance of adolescent and adult immunization in women. Although the true burden of vaccine-preventable diseases (VPDs) among Indian adults is unknown, adults are particularly vulnerable during outbreaks, due to a lack of immunization, waning immunity, age-related factors (e.g., chronic conditions & immunosenescence), and epidemiological shift.

No national adult women immunization guidelines exist in India, and although several medical societies have published adult immunization guidelines, these vary, making it unclear who should receive which vaccines (based on age, underlying conditions, etc.). Other barriers to adult women's immunization include vaccine hesitancy, missed opportunities, and cost.

Steps to improve adult vaccination for women could include adoption of a single National Protocol on Adult Women Vaccination, education of healthcare providers and the public, and promotion of life-course immunization, led by both the gynecologists in the government hospitals as well as the private practitioners.

A practically possible way of improving vaccine coverage for adolescent and adult women is now being driven by the FOGSI members, by establishing the newly launched, FOGSI Certified "MAHILA KAVACH KENDRAs" in their own clinics and nursing homes. This could immensely help reduce the burden of vaccine-preventable diseases (VPD) significantly, particularly among adolescent girls, adults, and older women, well through their age window from "Menarche to Menopause and beyond", because of improved access to both in-clinic knowledge on vaccine preventable disease and the vaccines itself stocked by the gynecologists.

FROM THE FIGO TRUSTEE'S DESK

PROF. DR. HRISHIKESH PAI
MD, FRCOG (UK-HONS), MSc (USA), FICOG, FCPS,
TRUSTEE FIGO-ASIA-OCEANIA
IMMEDIATE PAST PRESIDENT-FOGSI-2023

Over 2/3 of Indian adults are not aware of adult vaccination & many still think that vaccines are only for children. Concerted efforts are therefore required to improve the awareness of public in general and Healthcare Practitioners (HCPs) in particular, regarding Vaccine-Preventable Diseases (VPDs) and the benefits of adult vaccination. Only then will we be improving over the current status of low vaccine coverage, across Vaccine-Preventable disease. A survey revealed that >80% of adults lacked awareness about "adult vaccination" & there is not much awareness in the aging population and both in patients and providers. Economic burden, lack of insurance coverage, vaccine delivery problems, and lack of adequate adult vaccination centers for ease of access, add to the many existing challenges. While low perception of risk for infections and trivialization of disease were other reasons that led to low uptake across some surveys, lack of information or insufficient information from healthcare professionals has been cited as a barrier in certain studies. It is therefore important to create awareness among HCPs and patients about the potential cost-saving benefits of vaccines. It is crucial hence to set up dedicated adult vaccination centers that cater to adults, the elderly, and the adolescents. An effective approach to bridge the gap between the expected and actual rates of adult vaccination is to use non-traditional vaccination delivery sites equipped with special walk-in service and extended hours that cater to adults, the elderly, and adolescents. Studies also have revealed that if the source of information on vaccine was from a healthcare worker (i.e., recommendation of a vaccine by a healthcare worker) and or a doctor, the probability of the counseled person receiving vaccination was multiplied by 14-fold. According to a World Economic Forum and McKinsey Health Institute report in 2024, despite living longer on average, women spend 25% more of their lives in poor health. We need to change this, and we hope through this effort to facilitate the ease of access to women's vaccination, by opening Mahila Kavach Kendras at every gynecologist's clinic, we can make preventive healthcare through vaccination, particularly HPV Vaccination preventing Cervical Cancer a priority and more acceptable for women in India." I appreciate the efforts of FOGSI in this direction and convey my best wishes to all FOGSI'ans working towards a "Cervical Cancer Mukt Bharat" by vaccinating more and more girls and women from 9 to 45 years across their clinics.

FROM THE SECRETARY GENERAL'S PAGE

DR. MADHURI PATEL
SECRETARY GENERAL, FOGSI

Age is an intrinsic host factor that merits extra attention because it is one of the few biologically-based factors that is associated with risk for acquiring HPV infection in addition to its association with downstream events in the oncogenesis pathway. Because of this, age might be considered by providers who are attempting to target HPV vaccination based on a woman's risk profile. In addition to the risk of HPV infection, age is also associated with risk of viral persistence. As age increases, so does the possibility that a given high-risk HPV infection will persist, based on important viral factors which include the specific type of HPV causing infection, whether coinfection with multiple HPVs occurs, and viral load.

Because of the societal, religious, and ethical issues associated with the vaccination of adolescent girls in India together with lack of awareness about of HPV and HPV vaccines, no successful HPV immunization program has yet been employed in India. Although, the Government of India is contemplating of its inclusion in the National Immunisation protocol for girls aged 9–14 years.

With the inclusion of the age group of 9–14 years in the NIP by the government of India, approximately 30% of the targeted population would be covered and the balance would constitute the age group between 15–45 years, who would be left behind without the protective "KAVACH" of HPV vaccination. The concern here, therefore,... lies in the fate of these adolescents and young adults from the age of 15–45 years who are out of the scope of the government-targeted population. It is, therefore, in this age group, that the role of us FOGSI'ans in private practice is of immense importance. It will have to be us, who will be helping the government achieve its goal of "Cervical Cancer Mukt Bharat", by propagating the advantages of HPV vaccination to our patients in this "left-behind age group" and vaccinating them in our in-clinic "FOGSI CERTIFIED MAHILA KAVACH KENDRAS".

Numerous studies have demonstrated an increased risk of HPV infection in younger ages—the highest prevalence of HPV occurs among adolescents and young adults between the ages of 15 and 25, and it is believed that more than 75% of new HPV infections occur in individuals of this age range. The content of this referral handbook has been curated with a lot of care and is going to help you immensely in helping your patients with the "KAVACH" of HPV vaccination.

FROM THE EDITOR'S DESK

DR. PRIYA GANESH KUMAR
CHAIRPERSON, FOGSI ONCOLOGY COMMITTEE

In India, every year approximately 120,000 women develop carcinoma of the uterine cervix that accounts for 15.2% of the total cervical cancer deaths in the world. Human papillomavirus (HPV) is the primary cause of cervical cancer and is also associated with the cancers of the oropharynx, vagina, vulva, and anus.

The data of a meta-analysis on HPV-related cancer incidence and treatment from 28 population-based and 96 hospital-based cancer registries under the NCRP network in India. Incidence of HPV-related cancers for 2025 was projected. Among all cancers, 7.5% were HPV-related cancers. Cervical cancer (87.6%) and oropharyngeal cancer (63.2%) were the most common HPV-related cancers in India among females and males, respectively.

The projected incidence of HPV-related cancers is expected to increase to 121,302 by 2025. Implementation of effective prevention and control strategies like HPV vaccination and scaling up of screening could reduce the burden of HPV-related cancers.

Among HPV-attributable cancers, 80% are cervical cancer, which are preventable through HPV vaccination along with other HPV-related cancers. But there are no designated VACCINE CENTERS in the private setup and are only available in designated government healthcare facilities and in the private clinics of pediatricians in India, more so nothing designated for adult women.

There are four main reasons why adults might be susceptible to outbreaks of Vaccine-Preventable diseases (VPDs): (1) lack of adult immunization common protocol; (2) waning immunity; (3) age-related factors (including immunosenescence); and (4) epidemiological shift.

Various reported barriers to adult vaccination including socioeconomic factors and religious and cultural beliefs, particularly in rural India along with poor disease surveillance amongst Indian adults, which results in under-recognition of outbreaks on the real burden of VPDs in India. Vaccination advice also depends on various, complex risk factors (e.g., chronic conditions, age, occupations, lifestyle, health status, etc.) and vaccination/disease history.

As a sequel to the HPV Vaccination project of training 10,000 FOGSI members in the science of HPV Vaccination and art of counseling, we are launching this FOGSI FOCUS PLUS ON ADULT VACCINATION as a ready reckoner for the gynecologists in India, driving "FOGSI Certified MAHILA KAVACH KENDRAS – An In-Clinic Comprehensive Vaccination Center for women", within their own clinics.

ACKNOWLEDGMENTS

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CHAPTER 1

INTRODUCTION

Vaccines stand as one of the greatest achievements in the history of medicine and public health, contributing to an unparalleled increase in life expectancy and a significant reduction in morbidity and mortality from vaccine-preventable diseases.[1]

India's National Immunization Programme (NIP) stands as one of the largest immunization programs in the world, aiming to vaccinate nearly 2.7 crore newborns annually. Moreover, it targets nearly 3 crore pregnant mothers for tetanus toxoid vaccination each year.[2] Recently, the Government of India has also recommended the introduction of the HPV vaccine in the NIP for girls aged 9-14 years. While childhood vaccination coverage has significantly improved in India, adult vaccination coverage remains low.[3]

Proper vaccine storage and handling are key components of immunization programs. Errors in these processes can compromise vaccine potency, leading to insufficient immune response and inadequate protection against diseases.[4,5] Despite this, India lacks national adult immunization guidelines that provide clear protocols for vaccine storage, handling, and administration.[3]

FOGSI focus plus on adult vaccination outlines the principles of safely administering vaccination to adults. The purpose of this guidance is to ensure the smooth and efficient administration of vaccines while maintaining safety and quality standards. The document primarily focuses on clinical considerations for planning a vaccination clinic, encompassing vaccine storage, handling, administration, disposal, and documentation.

MAHILA KAVACH KENDRA
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CHAPTER 2

FOGSI Immunization Schedule for Adult Women

- Vaccination is a preventive measure that should be embraced wisely. Vaccination before, during, and after pregnancy protects women from infections, improving overall health.[6]
- Improving adult vaccination can help to reduce the burden of disease among those with chronic conditions by reducing hospital admissions, health costs, and mortality rates, and improving quality of life.[3]

Recommended Adult Women Immunization Schedule

Vaccine	Dosage schedule
Human papillomavirus (HPV)[7–14]	**Age 9–15 years:** 2-dose schedule (0 and 6 months); **15 years onwards:** 3-dose schedule (0, 2, and 6 months) **Remarks:** Quadrivalent vaccine (types 6, 11, 16 and 18) and Nonavalent vaccine (types 6, 11, 16, 18, 31, 33, 45, 52, 58) for females aged 9–45 years. The Government of India has also recommended the introduction of the HPV vaccine in the UIP.[$] **Disclaimer:** In reference to the single dose of HPV Vaccine recommended by WHO to facilitate mass vaccination of girls in the Age group of 9 to 14 years, please note that FOGSI will update this vaccination protocol once the same stands approved for India by DCGI
Inactivated influenza vaccine[6, 9, 10]	1 dose annually
Hepatitis B[9]	3 doses at 0, 1, and 6 months
PCV13[9]	1 dose
PPSV23[9]	2 doses 5 years apart
Varicella[9, 15]	2 doses at an interval of 4–8 weeks
Zoster recombinant[16]	2 doses given 2–6 months apart
COVID-19[17]	**Unvaccinated:** 1 or 2 doses depending on the vaccine **Previously vaccinated:** 1 dose administered at least 8 weeks after the previous dose
Tdap/Td[9, 15]	1 dose of Tdap followed by Td booster every 10 years **Remarks:** For adults who have not received prior vaccination, three doses of Td vaccine are indicated; two doses are administered at least 4 weeks apart, and the third dose is given 6–12 months after the second dose.
MMR[9,10,15]	2 doses 4 weeks apart for routine preconception/postnatal womren **Remarks:** Pregnancy should be avoided for at least 4 weeks after MMR vaccination.

Maternal Immunization Recommendations

Vaccine	Pregnancy	Postpartum
Human papillomavirus (HPV)[7–13, 18]	*	3-dose schedule at 0, 2, and 6 months[#] **Remarks:** Quadrivalent vaccine (types 6, 11, 16 and 18) and Nonavalent vaccine (types 6, 11, 16, 18, 31, 33, 45, 52, 58) for females aged 9-45 years. The Government of India has also recommended the introduction of the HPV vaccine in the UIP.[$]
COVID-19 Vaccine[17]	2 doses	**Unvaccinated:** 1 or 2 doses depending on the vaccine **Previously vaccinated:** 1 dose administered at least 8 weeks after the previous dose
Influenza vaccine[6, 9, 10, 18]	1 dose at any gestational age preferably between 27 and 36 weeks or during flu	1 dose annually
Pneumococcal vaccine[9, 10, 18]	1 dose if risk factor present	PCV13: 1 dose, PPSV23: 2 doses 5 years apart
TT or Td[6, 9, 10, 15]	2 doses of TT at least 28 days apart commencing from second trimester[6, 9]	Td booster every 10 years
Tdap[9, 18]	1 dose between 27 and 36 weeks	A single dose, if not vaccinated previously

*If found pregnant after initiating 3 dose series, remainder doses should be given after delivery If inadvertent vaccination during pregnancy, no need for the medical termination of pregnancy.[3, 11, 18]
[#]Only the remaining doses should be administered in case the series was initiated before pregnancy.[3, 18]
[$]Recommended in the adolescent girls aged 9–14 years.[14]

COVID-19: Coronavirus disease; FOGSI: The Federation of Obstetric and Gynecological Societies of India; PCV: Pneumococcal conjugate vaccine; PCV13: 13-valent Pneumococcal Conjugate Vaccine; PPSV23: 23-valent Pneumococcal Polysaccharide Vaccine; Td: Tetanus and diphtheria toxoid; Tdap: Tetanus, diphtheria, acellular pertussis vaccine; TT: Tetanus toxoid.

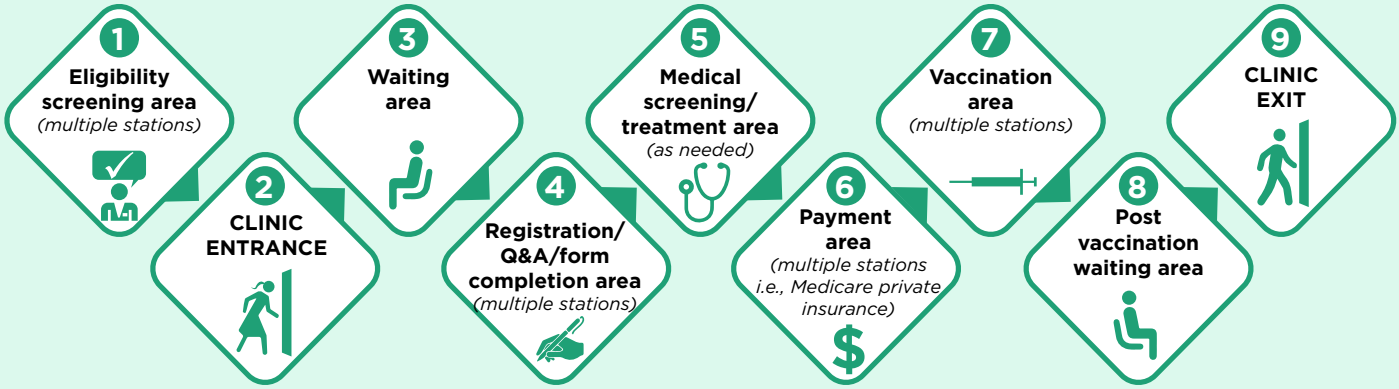
Contraindications Vaccines are not recommended in individuals with a severe allergic reaction after a previous dose or to a vaccine component.[9]

CHAPTER 3

VACCINATION CENTER **OVERVIEW**

The purpose of this chapter is to provide guidance for planning the workspace of an adult vaccination clinic.

Figure 1: Considerations for planning a vaccination clinic layout.[19]



*These activities can also be combined with activities, for example, they might be part of activity 1 or 3.

3.1. Other Key Factors to Consider Include[20, 21]

Adequate lighting and ventilation

Telephone/mobile access

Ensure adequate power supply

Adequate space for patients to sit or recline

Cabinets, shelves, and slots for:

- Storing needles, alcohol wipes, and other requirements
- Accommodating forms, informational materials, and record cards

Handwashing sink

Refrigerator space for maintaining cold storage of vaccines

Space for preparation of the vaccine

Adequate space to place sharps containers for used needles close to the vaccination administration area

Data entry tools such as computers, barcode scanners, etc.

CHAPTER 4

ROLES AND **RESPONSIBILITIES**

This chapter aims to outline the roles and responsibilities of the personnel within a vaccination center.

4.1. Roles and Responsibilities of a Vaccine Center Staff[4, 5, 20–23]

Role	Responsibilities
Doctor 	• The registered and trained healthcare professionals who are responsible for planning, preparing, and administering the vaccine
Nurse 	• Ordering and maintaining vaccines, syringes, and other supplies • Organizing vaccines within storage units • Assisting with the day-to-day responsibility of the vaccination clinic • Assisting vaccinators and vaccinees • Observe for post-vaccine reactions
Allied staff 	• Overseeing proper receipt and storage of vaccine deliveries • Following vaccine storage protocols, including temperature monitoring and recording • Maintaining all documentation, such as inventory and temperature logs • Overseeing emergency preparations, such as ensuring appropriate handling of vaccines during a disaster or power outage • Scheduling appointments for clients

4.2. Staff Training Protocol

All staff involved in vaccine handling or administration should receive training in

- **Vaccine fundamentals, including preparation and administration of vaccines[1,5]**
- **Proper vaccine storage and handling practices[5]**
- **Adverse event reporting[19]**

Additionally, a plan for medical management of adverse events should be in place, and clinical staff should understand their roles in implementing the plan, including:

- Recognition and management of severe allergic reactions
- Prevention and recognition of syncope

Documentation[21]

Staff should be trained in documenting administered vaccines, adverse events, standing orders, billing, etc.

Additional training[19]

Ensure clinical staff are trained in:

- Cardiopulmonary resuscitation and basic life support
- Infection prevention and control practices

CHAPTER 5

INFORMATION **MATERIALS**

5.1. Vaccine Information Statement

Vaccination information statements (VIS) explain both the benefits and risks of a vaccine.[24] The VIS should be made available in both English and regional languages to reduce barriers to important vaccination information for individuals whose preferred language is not English.[25]

5.1.1. Responsibilities of the Healthcare Professional[25]

1. Verbally communicate information from the VIS.
2. Offer explanation.
3. Provide supplementary printed materials.

5.1.2. Important Elements of a VIS[6, 26, 27]

1. Why get vaccinated?

2. When to get vaccinated?

3. Talk to your healthcare provider.

4. Potential risks

5. Adverse events: How to deal with them?

6. Details of the recommending medical body, e.g., FOGSI: The Federation of Obstetric and Gynecological Societies of India & IAP: Indian Academy of Pediatrics

7. Learning sources

CHAPTER 6
CLIENT **REGISTRATION**

This chapter encompasses the entire client registration process, from initial outreach to the completion of vaccination.

6.1. Steps in Client Registration Process

Preparation[28]

1. Regularly review patient's immunization history during routine and acute-care visits for timely vaccination updates.
2. Utilize medical records, vaccination cards, and immunization information systems (IIS) to gather comprehensive vaccination data for each patient.

Enrollment[29]

1. Confirm client enrolment validation.

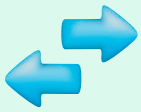
Assess patient needs[29]

1. Regularly evaluate the patient's immunization history during each visit to identify the need for routinely recommended vaccines.
2. Assess additional vaccines based on individual factors such as health status, occupation, and specific risk factors relevant to the patient.
3. If available, leverage IISs to determine real-time vaccine eligibility and ensure timely administration during the visit.

Online registration[30]

1. Can be done if applicable.

Contraindications and precautions[31]



1. Prioritize screening for contraindications and precautions in all patients before vaccine administration, regardless of previous doses, to account for potential changes in health status or guidelines.
2. Employ a standardized screening tool during each visit to ensure consistent and accurate assessment, mitigating the risk of adverse reactions like anaphylaxis.

Confirmation[30]

1. Confirm client registration.

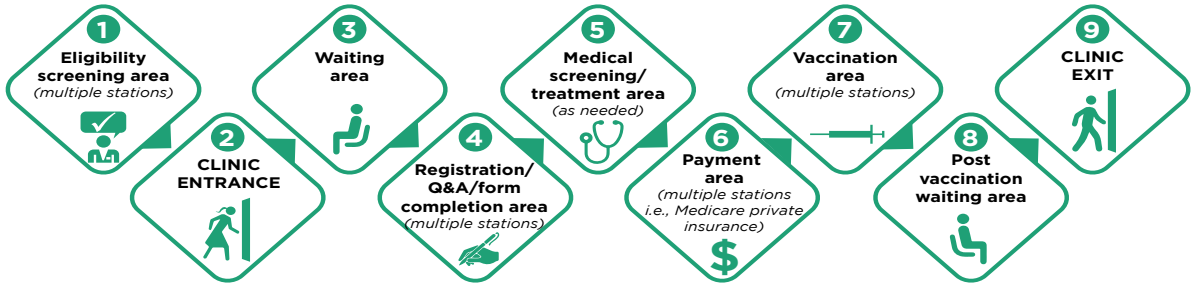
CHAPTER 7

VACCINE STORAGE AND **HANDLING**

7.1. Vaccine Cold Chain[32]

1. The cold chain is a temperature-controlled supply chain aimed at preserving the integrity of vaccines.
2. This chain initiates with the cold storage unit at the manufacturing plant and continues through vaccine transportation, delivery, and storage at the provider facility, concluding with the administration of the vaccine to the patient.
3. Manufacturers, distributors, public health staff, and healthcare providers all share responsibility for maintaining the vaccine cold chain.

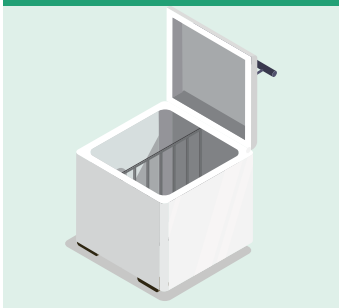
Figure 1: Vaccine cold chain system.[33]



*These activities can also be combined with activities, for example, they might be part of activity 1 or 3

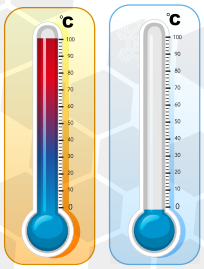
7.2. Vaccine Storage

Figure 2: Ice-lined refrigerator.



- Prefer purpose-built or pharmaceutical-grade ice-lined refrigerators for vaccine storage.[34]
- In the absence of purpose-built units, stand-alone household-grade refrigerators may be used, but only the refrigerator compartment should be utilized, avoiding the freezer compartment.[5]
- Ensure that the door seals are in good condition, seal tightly, and that the door closes properly automatically upon release.[4]
- Stabilize the refrigerator temperature before commencing vaccine storage.[4]

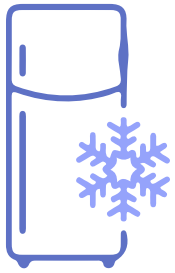
- Maintain the storage facility temperature between 2°C and 8°C.[5, 32]
- For frozen vaccines, the optimum temperature is at –15°C or lower.[5, 32]



- Monitor the temperature of every storage unit with specialized thermometers.[5, 34]
- Record the temperatures at least twice daily and chart them to indicate high/low excursions.[5, 34]

- Avoid storing food or beverages in vaccine storage units.[5, 34]

- Centrally store vaccines in the refrigerator or freezer, away from the walls of refrigerator, ensuring proper air circulation.[34]
- Never store any vaccine in the door of the refrigerator.[4]
- Maintain sufficient space between vaccine boxes or bins and shelving units.[34]
- Place a thermometer in the basket in between the vaccines.[33]
- Avoid overcrowding refrigerators, particularly during flu season.[34]



- Use non-frozen water bottles in the refrigerator to increase the cool mass and stabilize temperatures.[4]
- Store frozen water bottles in the freezer for emergency preparedness during transport and temperature stabilization.[34]

- Store vaccines in their original packaging with closed lids in separate containers until ready for administration.[32]
- Keep freeze-sensitive vaccines at the top of the ILR basket.[33]
- Keep heat-sensitive vaccines in the bottom of the ILR basket.[33]
- Arrange vaccines according to their expiry dates, placing those with earlier expiry dates above those with later ones.[33]
- Never store loose vials or prefilled syringes outside of their original packaging.[32]

- During transportation, the vaccines should be transported in a cold box with conditioned ice packs, and/or hard-frozen ice packs.[33]
- The temperature of the cold box should be maintained between +2°C to + 8°C.[4]

- Ensure that the power source is clearly marked to prevent the refrigerator from being accidentally unplugged or turned off.[4]

7.2.1. Verifying Vaccines for Proper Cold Chain Maintenance

Vaccines must undergo inspection for potential damage caused by excessive heat or freezing. Nevertheless, it is important to note that the physical appearance of a vaccine may not alter despite being damaged.[2]

Figure 3: Checking vaccines for heat damage.[2]

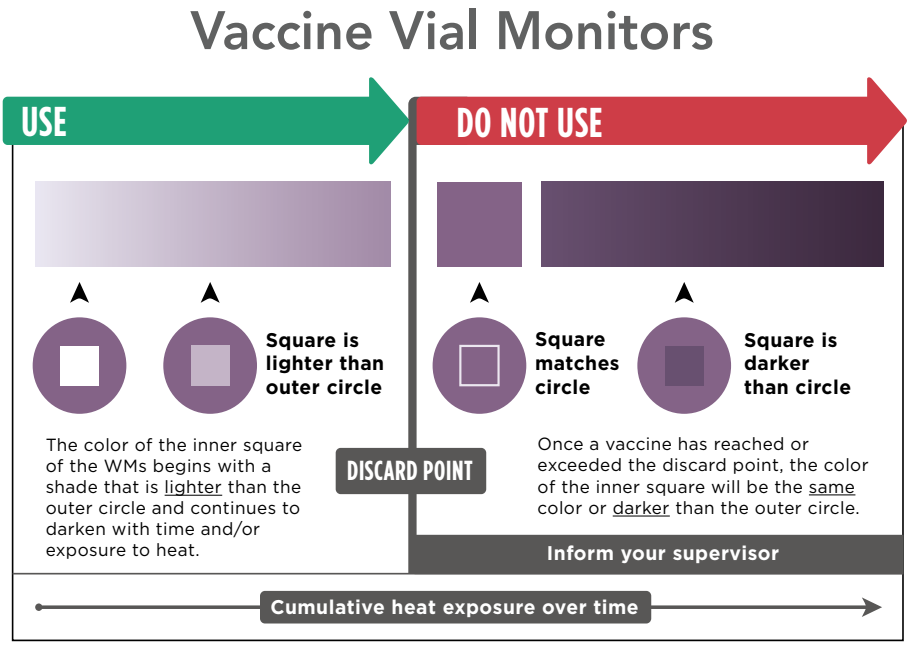
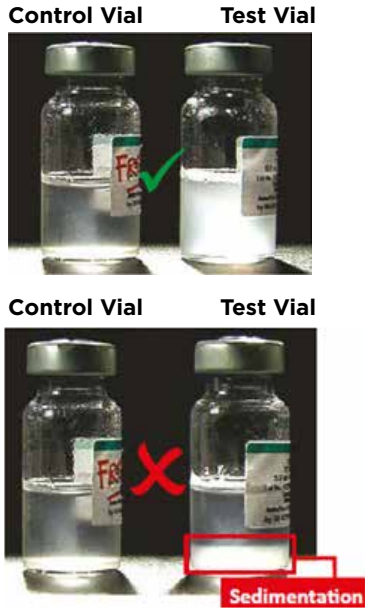


Figure 4: Checking vaccines for cold damage (freezing).[2]



7.2.2. Storage Labels

1. Label the vaccine storage area to prevent confusion among staff due to the variety of brands and formulations.[35]
2. Utilize strategies like color coding and additional information to facilitate quick and accurate vaccine selection, thereby reducing the risk of administration errors.[35]

7.2.3. Rotation and Disposal of Inventory

1. Regularly rotate and inspect vaccine stock for expired doses.[32]
2. Promptly remove any expired vaccines and diluents to prevent accidental administration.[32]
3. Ensure timely disposal of expired doses to maintain vaccine efficacy.[32]

7.3. Staff Training

1. Train all staff in vaccine storage and handling.[32]
2. Emphasize the importance of cold chain and individual responsibilities.[32]
3. Promptly report any storage deviations to the vaccine coordinator.[32]

7.4. Vaccinator's Logistics Diary

1. The vaccinator is responsible for maintaining the logistics diary and ensuring its availability at the session site.[33]
2. This diary should be used to record the inventory of received and returned vaccines, syringes, and diluents at the session site.[33]
3. Details for unopened vials and syringes and open vaccine vials must be recorded separately under the respective headings provided in the diary.[33]

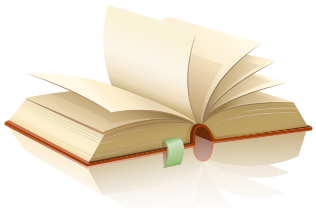


Figure 5: Sample format of a logistics diary.[33]

At the time of Receiving Vaccines/Diluents/Syringes and Other Logistics

Vaccinator's Logistics Diary

Name of Vaccinator: ..... Name of Health Facility: .....
Session Site: ..... Date of Session: .....

Unopened Vials & Syringes											
Item		Received (In Doses)					Returned (In Doses)				
Sl. No.	Name of the Items	Quantity	Manufacturer	Batch No.	Exp. Date	VVM	Quantity	Manufacturer	Batch No.	Exp. Date	VVM
1	DTP/DTaP										
2	Hep-A										
3	Hep-B										
4	HPV										
5	Influenza										
6	Pneumococcal vaccine										
7	Varicella										
8	JE										
9	COVID-19										
10	Zoster recombinant										

Other Logistics (in pieces)								
Items	Received	Returned	Items	Received	Returned	Items	Received	Returned
0.1 mL			0.5 mL			5 mL		
OPV Dropper			Black Bag			Red Bag		

CHAPTER 8

VACCINATION **PROCESS**

8.1. Guide to Vaccination Process

Administer the vaccine properly

- Use the proper needle gauge and length[21]
- Administer injections via the correct route[21]
- Safely dispose of the needle and syringe[21]
- Prevent vaccine administration errors[21]

Post-vaccination procedures

- Record keeping[4]
- Prepare and watch for anaphylaxis, any other adverse events, and syncope[21]

Post-vaccination counseling and follow-up

- Communicate about appointments for subsequent doses.[21]
- The vaccinee should also be counseled about possible side effects, their management, and danger signs before they are sent home.[4]

Always refer to the package insert included with each biologic for complete vaccine administration information.[36]

8.1.1. Use the Proper Needle Gauge and Length[4, 21, 36]

	Intramuscular injection	Subcutaneous injection
Needle gauge	22–25	22–25
Needle length	<60 kg: 1 inch >60 kg: 1.5 inch	5/8 inch

8.1.2. Before You Start Preparing Any Type of Vaccine[4, 21]

1. Wash your hands with soap and water. Alternatively, alcohol-based waterless antiseptic hand rubs may be used. (Refer to Chapter 12)

2. Gather alcohol pads, the appropriate needle, and a syringe, as needed.

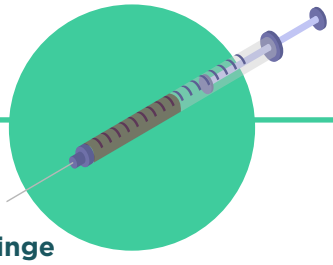
3. Obtain the vial or syringe of vaccine. Always double-check the vial label to ensure you have the correct vaccine for administration.

4. Check that today's date is earlier than the vaccine's expiration date.

8.1.3. Vaccination Preparation[21]

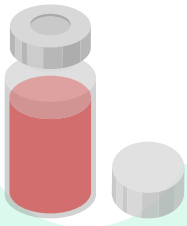
Single-dose vial

1. Remove the plastic cap and shake the vial.
2. Cleanse the stopper with an alcohol pad and let it dry.
3. Assemble the needle and syringe.
4. Uncap the needle.
5. Hold the vial steady on the counter.
6. Insert the needle straight into the center of the vial stopper. Invert (turn upside-down) the vial and pull the needle back so the tip is in the liquid. Pull back on the plunger and draw up the entire contents of the vial.
7. Withdraw the needle. Tap the syringe and push out any air.



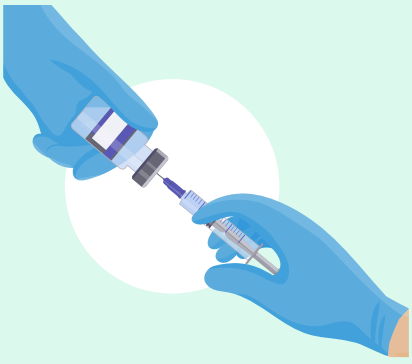
Prefilled syringe

1. Shake the syringe thoroughly.
2. Remove the syringe tip cover.
3. Attach the needle to the syringe.



Reconstituted vaccine

1. Remove the plastic caps, cleanse the stoppers with an alcohol pad, and let them dry.
2. Assemble the needle and syringe.
3. Hold the diluent vial steadily on the counter.
4. Insert the needle straight into the center of the vial stopper. Invert (turn upside-down) the vial and pull the needle back so the tip is in the liquid.
5. Draw up all the diluent into the syringe and then withdraw the needle.
6. Hold the vaccine vial steady on the counter. Insert the needle into the center of the stopper and inject the diluent.
7. Holding the vial and syringe together, shake to mix.



8.1.4. Do's and Don'ts for Safe Vaccination

Do's

- Needles used for injections must be sterile and preferably disposable.[4]
- Separate needles and syringes should be used for each injection.[4]
- Always pierce the rubber cap of the vial with a sterile needle.[2]
- Always have patients sitting or lying down during vaccine administration.[4]
- Administer all needed vaccines at the same visit.[21]
- Cut the used syringe at the hub immediately after use (Refer to Figure 1).[9]
- Immediately discard the used needle and syringe into a labeled, puncture-proof sharps container.[4, 21]
- All vaccine materials must be discarded through proper medical waste disposal procedures (Refer to chapter 11).[4]

Don'ts

- Changing the needles between drawing the vaccine from a vial and injecting it into a recipient is not necessary.[4]
- Different vaccines should never be mixed in the same syringe unless specifically licensed for such use.[4]
- Vaccine doses should not be drawn into a syringe until immediately before administration.[4]
- Needles should not be recapped before being discarded.[4, 21]

Figure 1: Correct use of a hub cutter.[9]

Adapted from: Indian Medical Association. Guidebook on life course immunization: Pediatric to geriatric vaccines.

8.2. Post-Vaccination Procedures

8.2.1 Record Keeping

The vaccine administrator must record the following details in the patient's file immunization record.[4]

- ✓ The type of vaccine
- ✓ Batch number
- ✓ Brand name
- ✓ Date of vaccine administration

8.2.2 Post-Vaccination Observation

- After administering any vaccine, the recipient must be observed for any allergic effects for at least 15 minutes after vaccination, and all resuscitative equipment must be kept on standby for possible anaphylaxis.[4]
- Instruct the patient to immediately report any itching, redness (with or without hives reaction), difficulty in breathing, or abdominal pain that occurs following the injection.[21]
- Prepare and watch for syncope (fainting), which is most common among young adults.[21]
- Caregivers and the recipients should also be counseled about possible side effects, their management, and danger signs before the vaccinee is sent home.[4]

CHAPTER 9
ADVERSE EVENT **REPORTING**

Similar to other medications, vaccines can also lead to adverse events. An adverse event following immunization (AEFI) is any untoward medical occurrence that occurs after immunization and may not necessarily be caused by the vaccine itself or the vaccination process.[4] To reduce the risk of an adverse reaction, it is important to screen patients for vaccine contraindications and take precautions before vaccination.[37]

9.1. Monitoring of Adverse Events

- Vaccine recipients must be monitored for any allergic effects, other adverse events, and syncope for at least 15 minutes after vaccination.[4, 21]
- Staff should be trained in suspecting, detecting, and reporting of AEFIs.[33]

9.2. Maintaining Records of AEFIs

- The details of all serious, severe, and minor AEFIs are to be recorded in an AEFI register.[2]

Figure 1: Format for block AEFI register.[2]

Week No.	Name of SC	Name of vaccinee	Father's name	Age	Date of vaccination	Name of vaccines given	AEFI noted (symptoms)	Category (serious/ severe/minor)	Case seen by MOIC (Yes/No)	Entered in case reporting form (Yes/No)

9.3. Reporting AEFIs

- Inform about all severe AEFIs telephonically or in person immediately.[2]
- Duly filled in Suspected Adverse Drug Reaction Reporting Form can be sent to the nearest Adverse Drug Reaction Monitoring Center or directly to the National Coordination Center.[38]

Figure 2: Suspected adverse drug reaction reporting form.[38]

A. PATIENT INFORMATION

1. Patient Initials _____	2. Age at the time of Event or Date of Birth _____	3. M ☐ F ☐ Other ☐
		4. Weight Kgs

Reg. No. /IPD No. /OPD No. /CR No.:

AMC Report No.:

Worldwide Unique No.:

B. SUSPECTED ADVERSE REACTION

5. Event/Reaction start date (dd/mm/yyyy)

6. Event/Reaction stop date (dd/mm/yyyy)

6 (A). Onset Lag Time

7. Describe Event/Reaction with treatment details, if any

12. Relevant tests/laboratory data with dates

13. Relevant medical/medication history (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/renal dysfunction, past surgery etc.)

14. Seriousness of the reaction: No ☐ if Yes ☐ (please tick anyone)

☐ Death (dd/mm/yyyy) ☐ Congenital-anomaly

☐ Life-threatening ☐ Disability

☐ Hospitalization/Prolonged ☐ Other Medically important

15. Outcomes

☐ Recovered ☐ Recovering ☐ Not recovered

☐ Fatal ☐ Recovered with sequelae ☐ Unknown

C. SUSPECTED MEDICATION(S)

S.No.	8. Name (Brand/ Generic)	Manufacturer (if known)	Batch No./ Lot No.	Exp. Date (if known)	Dose used	Route used	Frequency (OD, BD etc.)	Therapy dates		Indication	Causality Assessment
								Date started	Date stopped		
i											
ii											
iii											
iv*											

S.No. as per C	9. Action Taken (please tick)						10. Reaction reappeared after reintroduction (please tick)			
	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown	Yes	No	Effect unknown	Dose (if reintroduced)
i										
ii										
iii										
iv										

11. Concomitant medical product including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction)

S.No.	Name (Brand/Generic)	Dose used	Route used	Frequency (OD, BD, etc.)	Therapy dates		Indication
					Date started	Date stopped	
i							
ii							
iii*							

Additional Information:

D. REPORTER DETAILS

16. Name and Professional Address: _____

_____

Pin: _____ E-mail: _____

Tel. No. (with STD code) _____

Occupation: _____ Signature:_____

17. Date of this report (dd/mm/yyyy):

Sig. and Name of Receiver-

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction. Submission of an ADR report does not have any legal implication on the reporter.

*Use a separate page for more information

Alternatively, the healthcare professionals can report the adverse reactions directly on the manufacturer's portal.[39]

Report Adverse Events

You can report one or more Adverse Events/Product Quality Complaint(s) for each submission. Please ensure that your total attachments do not exceed 35 MB.

Business Partner/Vendor/Investigator/Other's Name*

Business Partner/Vendor/Investigator/Other's Email Address*

Comma separated for multiple emails

Country of Incidence*

Iraq

Description about the Adverse Event/Product Quality Complaint

Business Partner/Vendor/Investigator/Other's Case ID#

(optional field for you to enter your 'company's internal case reference ID, if available)

Attachment(s)

Choose files No file chosen

CHAPTER 10

EMERGENCY **SUPPORT**

All personnel and facilities providing vaccinations have procedures in place for the management of emergency situations.[4]

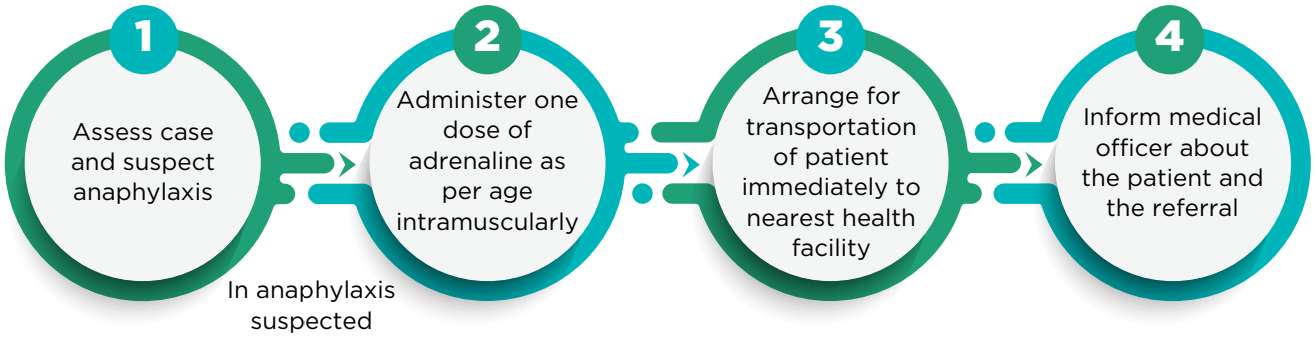
Steps to handle a medical emergency, if any

1. Ensure the availability of emergency drugs and medical equipment to deal with an AEFI (refer to Figure 1).[33]
2. Never leave the suspected case alone, and take necessary steps to stabilize the patient (refer to Figure 2).[2]
3. Arrangements should be made for immediate transfer to an emergency facility for additional evaluation and treatment.[4] Keep the contact numbers of the ambulance and the closest hospital accessible to all staff members for emergency situations. Keep contact details of an alternate vehicle owner/driver in case an ambulance is not available or is delayed.[2]

Figure 1: Contents of an emergency kit for managing an AEFI.[4, 33, 37]

1. Injectable adrenaline (1:1000) solution–2 ampules
2. Injection hydrocortisone (100 mg)–1 vial
3. Disposable syringe–Tuberculin syringes (1 mL) or insulin syringe (without the fixed needle of 40 units)–3 numbers
4. Disposable syringe (5 mL) and 24/25G IM needle–2 sets
5. Scalp vein set–2 numbers
6. Tablet paracetamol (500 mg)–10 tablets
7. Oral antihistaminics
8. IV fluids (Ringer lactate/normal saline)–1 unit in the plastic bottle
9. IV fluids (5% dextrose)–1 unit in plastic bottle
10. IV drip set–1 set
11. Cotton wool, adhesive tape–1 each
12. Alcohol wipes
13. Stethoscope
14. Blood pressure measuring device (with a variety of cuff sizes as needed)
15. AEFI case reporting form
16. Oxygen support and airway intubation facility should be available in hospital settings
17. Ambu bags with mask, endotracheal tube, laryngoscope with spare batteries

Figure 2: Initial management in case of emergency.[2]



CHAPTER 11
WASTE MANAGEMENT

All vaccine materials should be disposed of using medical waste disposal procedures.[4]

Standards for segregation and storage of waste.[40–42]

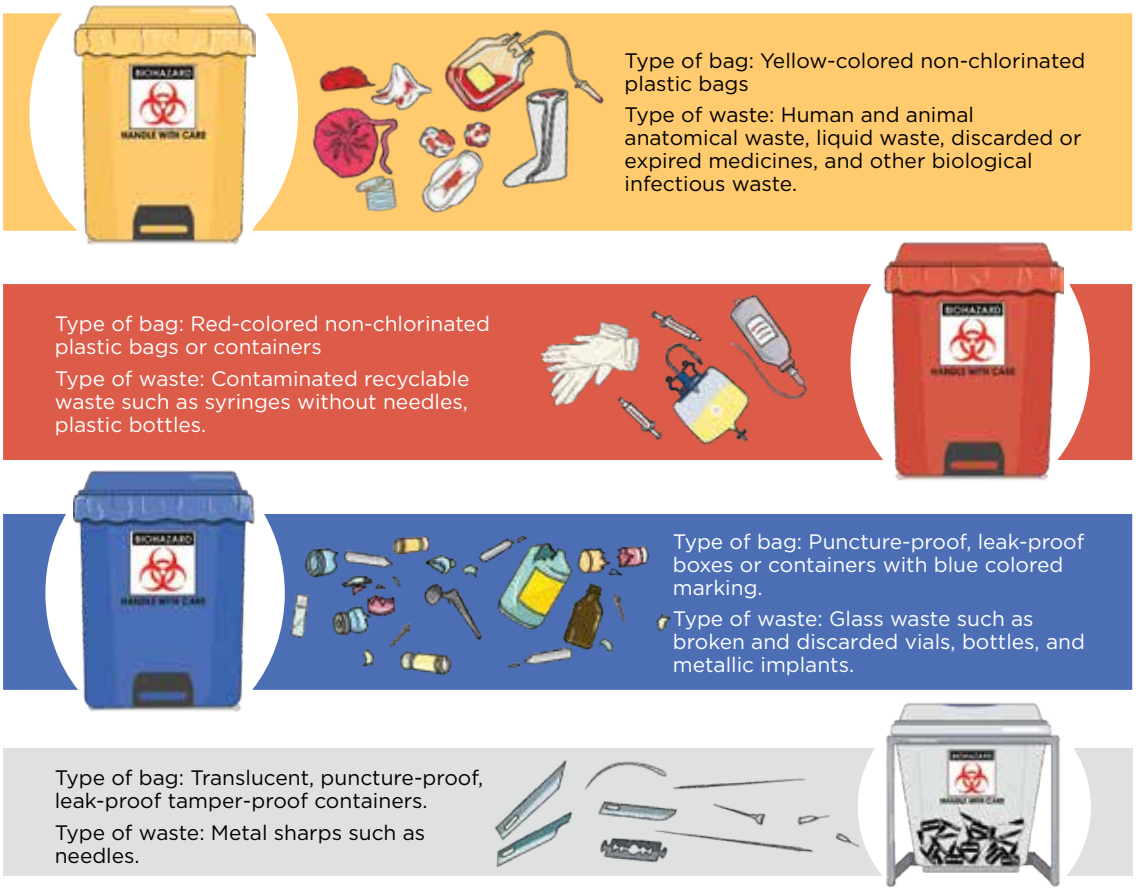


Figure 1: Segregation and safe disposal of immunization waste.[2]

Figure 2: Disinfection and disposal of sharps waste from immunization session.[2]

Disinfection corner

Instructions at disinfection corner

Bleach solution

Sharps in Hub Cutter

Disinfection using double bucket method

At the sharps pit

Disposing disinfected sharps into sharps pit

Securing sharps pit with lock

CHAPTER 12

INFECTION **PREVENTION**

The main aim of this chapter is to establish and maintain a standardized procedure for infection control during vaccination to minimize the risk of transmission of infections.

Infection Control and Sterile Procedures

Vaccine administration requires precautions to minimize disease exposure and spread.[43]

Cleanse hands with an alcohol-based waterless antiseptic hand rub or soap and water before preparing vaccines and between each patient contact.[43]

Wearing gloves is not mandatory unless administrators have open lesions or may come into contact with patient body fluids.[43]

Needles utilized for injections should be sterile and, preferably, for single-use.[4]

a. Use auto-disposable syringes whenever possible.

b. Always use a separate needle and syringe for each injection.

Prepare vaccines in a designated, clean medication area away from the patient and potential contaminants.[44]

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NOTES

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GARDASIL®

[Human Papillomavirus Quadrivalent (Types 6, 11, 16, 18) Recombinant Vaccine]

GARDASIL® 9

Human Papillomavirus 9-valent Vaccine, Recombinant

Available in 85 countries as part of NIP*,1

Available in 67 countries as part of NIP*,1

HPV vaccine administration prior to 15 years of age can result in **HPV antibody titers ~2-fold higher** than when given later[2,3]

Most HPV infections will clear on their own. However, persistent infections can cause cervical cancer & certain other HPV-related cancers.[4]

Images used for representation purpose only.

*As on December 2023

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SELECTED SAFETY INFORMATION

Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant

GARDASIL® (Suspension for intramuscular injection) **Contraindications:** Hypersensitivity to the active substances or to any of the excipients of the vaccine including severe allergic reactions to yeast (a vaccine component). **Warning and Precautions:** GARDASIL® vaccine is not intended to be used for treatment of active external genital lesions; cervical, vulvar, or vaginal cancers; CIN, VIN, VaIN. This vaccine will not protect against diseases that are not caused by HPV. As with all injectable vaccines, appropriate medical treatment should always be readily available in case of rare anaphylactic reactions following the administration of the vaccine. The decision to administer or delay vaccination because of a current or recent febrile illness depends largely on the severity of the symptoms and their etiology. Individuals with impaired immune responsiveness, whether due to the use of immunosuppressive therapy, a genetic defect, Human Immunodeficiency Virus (HIV) infection, or other causes, may have reduced antibody response to active immunization. This vaccine should be given with caution to individuals with thrombocytopenia or any coagulation disorder because bleeding may occur following an intramuscular administration in these individuals. Syncope, sometimes associated with tonic clonic movements and other seizure-like activity, has been reported following vaccination with GARDASIL®. **Use in special population:** Pregnancy: Pregnancy should be avoided during the vaccination regimen for GARDASIL®. Nursing Mothers: GARDASIL® may be administered in lactating women. It is not known whether vaccine antigens or antibodies induced by the vaccine are excreted in human milk. Pediatric Use: The safety and efficacy of GARDASIL® have not been evaluated in children younger than 9 years. Elderly and HIV-infected individuals: The safety and efficacy of GARDASIL® have not been evaluated in elderly and HIV-infected individuals. Drug Interactions: **Use with other Vaccines:** GARDASIL® may be administered concomitantly (at a separate injection site) with H-B-VAX II™ (hepatitis B vaccine (recombinant)); Menactra [Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine], Adacel [Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (Tdap)], and Repevax [Diphtheria, Tetanus, Pertussis (acellular, component) and Poliomyelitis (inactivated) Vaccine, (adsorbed, reduced antigen(s) content)]. Use with Hormonal Contraceptives: Use of hormonal contraceptives did not appear to affect the immune responses to GARDASIL®. Use with Steroids: Use with Steroids did not appear to affect the immune responses to GARDASIL®. **Undesirable Effects:** The vaccine-related adverse experiences that were observed among recipients of GARDASIL® at a frequency of at least 1%. Vaccine-Related Clinical Adverse Experiences in 9- Through 45-Year-Old Girls and Women are headache, dizziness, nausea, pain in extremity, pyrexia. Most of the adverse experiences seen with concomitant administration with other vaccines were reported as being mild to moderate in intensity. Undesirable effects as per Post-Marketing reports were cellulitis, idiopathic thrombocytopenic purpura, autoimmune hemolytic anemia, lymphadenopathy, pulmonary embolus, acute disseminated encephalomyelitis, dizziness, Guillain-Barre syndrome, headache, motor neuron disease, paralysis, seizures, syncope (including syncope associated with tonic-clonic movements and other seizure-like activity) sometimes resulting in falling with injury, transverse myelitis, deep venous thrombosis, nausea, pancreatitis, vomiting, arthralgia, myalgia, asthenia, chills, death, fatigue, malaise, Autoimmune diseases, hypersensitivity reactions including anaphylactic/anaphylactoid reactions, bronchospasm, and urticaria.

Before prescribing, please consult the full prescribing information.

Scan the QR code for Prescribing Information

HUMAN PAPILLOMAVIRUS 9-VALENT VACCINE, RECOMBINANT [Serotype 6 L1, 11 L1, 16 L1, 18 L1, 31 L1, 33 L1, 45 L1, 52 L1 & 58 L1]

GARDASIL® 9 (Suspension for intramuscular injection) **Contraindications:** GARDASIL® 9 is contraindicated in patients with hypersensitivity to either GARDASIL® 9 or any of the inactive ingredients in either vaccine. **Warning and Precautions:** GARDASIL® 9 vaccine is not intended to be used for treatment of active external genital lesions; cervical, vulvar, vaginal, or anal cancers; CIN, VIN, VaIN, or AIN. This vaccine will not protect against diseases that are not caused by HPV. As with all injectable vaccines, appropriate medical treatment should always be readily available in case of rare anaphylactic reactions following the administration of the vaccine. Syncope (fainting) may follow any vaccination, especially in adolescents and young adults. The decision to administer or delay vaccination because of a current or recent febrile illness depends largely on the severity of the symptoms and their etiology. Individuals with impaired immune responsiveness, whether due to the use of immunosuppressive therapy, a genetic defect, Human Immunodeficiency Virus (HIV) infection, or other causes, may have reduced antibody response to active immunization. This vaccine should be given with caution to individuals with thrombocytopenia or any coagulation disorder because bleeding may occur following an intramuscular administration in these individuals. **Use in special population:** Pregnancy: Pregnancy should be avoided during the vaccination regimen for GARDASIL® 9. Nursing Mothers: GARDASIL® 9 may be administered in lactating women. It is not known whether vaccine antigens or antibodies induced by the vaccine are excreted in human milk. Pediatric Use: The safety and efficacy of GARDASIL® 9 have not been evaluated in children younger than 9 years. Immunocompromised Individuals: The immunologic response to GARDASIL® 9 may be diminished in immunocompromised individuals. **Drug interactions: Use with other Vaccines:** GARDASIL® 9 may be administered concomitantly (at a separate injection site) with Menactra [Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine], Adacel [Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (Tdap)], and Repevax [Diphtheria, Tetanus, Pertussis (acellular, component) and Poliomyelitis (inactivated) Vaccine, (adsorbed, reduced antigen(s) content)] (dTap-IPV). Use with Hormonal Contraceptives: Use of hormonal contraceptives did not appear to affect the type specific immune responses to GARDASIL® 9. Use with Steroids: Immunosuppressive therapies, including irradiation, antimetabolites, alkylating agents, cytotoxic drugs, and corticosteroids (used in greater than physiologic doses), may reduce the immune responses to vaccines. **Undesirable Effects:** The vaccine-related adverse experiences that were observed among recipients of either GARDASIL® 9 or GARDASIL® at a frequency of at least 1%, Few individuals (GARDASIL® 9 = 0.1% vs. GARDASIL® <0.1%) discontinued due to adverse experiences after receiving either vaccine. The safety profile was similar between GARDASIL® 9 and GARDASIL® in women and girls and boys. Solicited Systemic and Injection-Site Adverse Reactions: Temperature and injection-site pain, swelling, and erythema were solicited using VRC-aided surveillance for 5 days after each injection of GARDASIL® 9 during the clinical studies. Undesirable effects as per post-Marketing reports were cellulitis, idiopathic thrombocytopenic purpura, lymphadenopathy, acute disseminated encephalomyelitis, dizziness, Guillain-Barré syndrome, headache, syncope sometimes accompanied by tonic-clonic movements, nausea, vomiting, arthralgia, myalgia, asthenia, chills, fatigue, malaise, hypersensitivity reactions including anaphylactic/anaphylactoid reactions, bronchospasm, and urticaria.

Before prescribing, please consult the full prescribing information.

Scan the QR code for Prescribing Information

HPV: Human papillomavirus; NIP - National Immunization Program

AE Reporting

To report Adverse Events (AEs) related to our products, please contact :

Mode of reporting the adverse event	Details
PV Dedicated Fax	91-124-4647339
PV Toll Free Number	18001032642
E-mail	dpoc_india@merck.com
Postal Address	International Pharmacovigilance Department, MSD Pharmaceuticals Pvt. Ltd., 6th Floor, Vatika Towers-B, Sector-54, Gurgaon-122002.

For the use of a registered medical practitioner or a hospital or a laboratory only.

Adverse Event (AE): Per the International Conference on Harmonization (ICH), an adverse event (AE) is defined as any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have to have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to this product. Privacy note: Any personal data provided by you will be treated by MSD with full respect of your privacy. Please read more about MSD's privacy commitment at https://www.msdprivacy.com/in/en/. In case you want to delete or edit Personal Health Information (PHI) already collected by MSD India please request at by MSD Pharmacovigilance.india@merck.com or call at 1244652637" International Pharmacovigilance, MSD Pharmaceuticals Pvt. Ltd.

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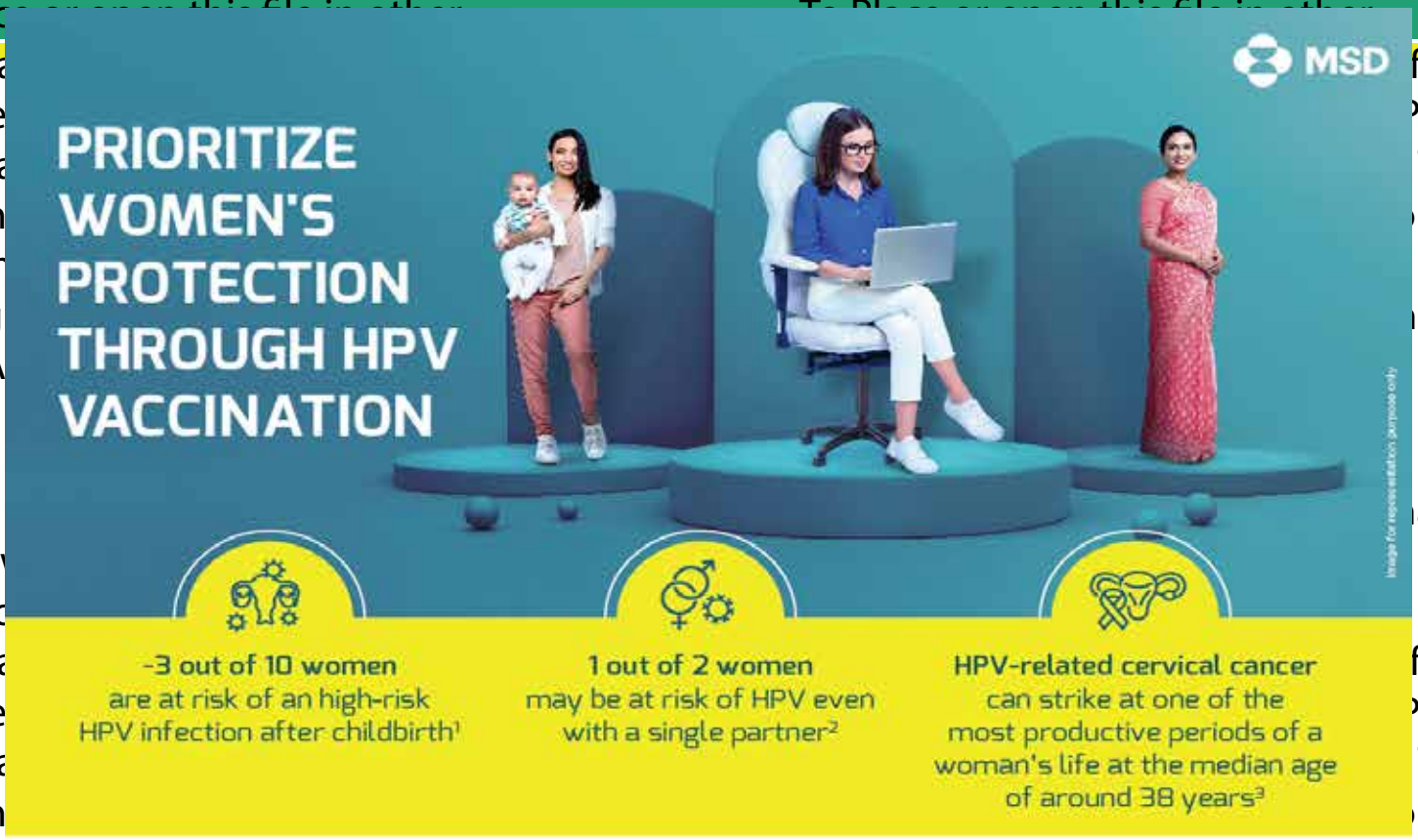

HPV vaccination helps offer ~98% effectiveness* against cervical cancer[4,5]

GARDASIL (Human Papillomavirus Quadrivalent Types 6, 11, 16, 18) Recombinant Vaccine

GARDASIL 9 Human Papillomavirus 9-valent Vaccine, Recombinant

Why Wait?
Vaccinate Today!

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SELECTED SAFETY INFORMATION

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Before prescribing, please consult the full prescribing information.

Scan the QR code for Prescribing Information

HUMAN PAPILLOMAVIRUS 9-VALENT VACCINE, RECOMBINANT [Serotypes 6 (L1), 11 (L1), 16 (L1), 18 (L1), 31 (L1), 33 (L1), 45 (L1), 52 (L1) & 58 (L1)]

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Before prescribing, please consult the full prescribing information.

Scan the QR code for Prescribing Information

HPV: Human papillomavirus; AIR: Anal intraepithelial neoplasia

AE Reporting

To report Adverse Events (AEs) related to our products, please contact:

Modes of reporting the adverse event	Details
PV Dedicated Fax	91-124-4047338
PV Toll Free Number	18001020642
E-mail	msd_india@merck.com
Postal Address	International Pharmacovigilance Department, MSD Pharmaceuticals Pvt. Ltd., 9th Floor, Vatika Towers B, Sector 54, Gurgaon-122002

Adverse Event (AE): Per the International Conference on Harmonisation (ICH), an adverse event (AE) is defined as any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have to have a causal relationship with this treatment. An AE can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to this product.

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