Recommendations for
Vaccination against Human Papilloma Virus (HPV) Infection
For the prevention of Cervical Cancer

Chairpersons : Dr.C.N.Purandare
Dr.Usha B.Saraiya

Committee Members : Dr.Duru Shah
Dr.Sanjay Gupte
Dr.P.K.Shah
Dr.Alka Kriplani
Dr.Hemant Tongaonkar
Dr.P.Usha Rani
Dr.Basu Partha Sarathi
Dr.Rajendra Kerkar
Dr.Ava D.Desai
Dr.Umadevi
Dr.Rekha Kurian
Dr.Neerja Bhatla
Dr.Harshad Parasnis
Dr.Hema Diwakar
Dr.Urvashi Jha

Discussed on : 11th October 2008

Core Committee Meeting : 14th March 2009

Website :

Reviewed on : 20th August 2010

Reviewed in presence of : Dr. C.N. Purandare
Dr. P.K.Shah
Dr. Sanjay Gupte
Dr. Suchitra Pandit
Dr. Amit Patki
Dr. Madhuri Patel
Dr. Girija Wagh
Dr. Tushar Kar
Dr. Uday Nagarsekar

Published in the FOGSI Journal on :

Recommendations for
Vaccination against Human Papilloma Virus (HPV) Infection
For the prevention of Cervical Cancer

Preamble

- Human papillomavirus (HPV) vaccines are now widely available for the purpose of cervical cancer prevention. The Quadrivalent vaccine (Gardasil) and bivalent vaccine (Cervarix) have been approved for this purpose.

- The objective of these Recommendations is to provide information on the use of HPV vaccine for the purpose of cervical cancer prevention and the need to continue with the current cervical screening programs.

General

- The Human Papilloma Virus (high-risk genotypes) is a necessary causal factor of cervical cancers.

- The HPV vaccine is a prophylactic vaccine. Both the bivalent and quadrivalent vaccine protects against infection of HPV genotypes (HPV-16 and HPV-18) that account for about 70% of HPV-related cervical cancers. The quadrivalent vaccine also protects against HPV types 6 and 11 that are responsible for about 90% of the genital warts.

- The HPV vaccine is not therapeutic. It does not treat existing HPV infection or cervical intraepithelial neoplasia (cervical pre-cancers).

Cervical Cancer Screening

- Women who have been vaccinated with the HPV vaccine should continue with the cervical cancer screening as per the recommendations in FOGSI Recommendations for Good Clinical Practice Guidelines.

Vaccination Target Group

- The bivalent vaccine has been approved for use in females aged 10 to 45 years, whereas the quadrivalent vaccine has been approved for use in females aged 9 to 45 years.
- The vaccine should target females at the most convenient and optimal age (12-16 years old) for vaccination before their first sexual exposure.
- Routine HPV vaccination is recommended for females aged 10 to 12 years.
- HPV vaccination may be offered to all upto 45 years), regardless of sexual activity, but offers less benefit if already sexually active. The decision is based on the informed discussion between the woman and her health care provider regarding risk of previous HPV exposure and potential benefit from vaccination.
- Vaccination is not recommended in males, at present. More data is awaited on this issue.

Dosage Schedule

- For the quadrivalent vaccine three doses at 0, 2 and 6 months are recommended intramuscularly (Minimum Intervals between doses are 4 weeks between 1st & 2nd dose and 12 weeks between 2nd and 3rd dose).
- For bivalent vaccine three doses at 0,1 and 6 months are recommended intramuscularly.
- At present there are no data to support the use of boosters.

Counseling before vaccination

- A full explanation of the role, action and usefulness of the vaccine should be provided to the woman or her parent/guardian where applicable, before vaccination.

- The explanation should typically include: the role of HPV in cervical carcinogenesis (in particular HPV-16 and HPV-18); trial results and expectations; immunological responses; safety and efficacy; as well as answer queries on issues, as highlighted in this document.

HPV Testing before Vaccination

- Testing for HPV is not recommended before vaccination.

Vaccination of Sexually Active Women

- Sexually active women and women with previous abnormal cervical cytology can receive the HPV vaccine. But the benefits may be limited to the protection against infection of HPV genotypes with which they have not been infected.

- Women who have been infected with vaccine HPV-type (serologically positive) and have cleared the cervical infection (DNA negative) appear to have similar protective effects as those who are naïve to the same vaccine HPV-type. Further scientific evidence is awaited on this issue.

Special Situations

Women with Previous Cervical Intraepithelial Neoplasia (CIN)

- The vaccine can be given to patients with previous CIN, but the benefits may be limited to the protection against infection of HPV genotypes (and related CIN) with which they have not been infected.

- It must be emphasized that cervical screening and corresponding management must continue.

Pregnancy and Lactating Women

- The use of the vaccine in pregnancy is not recommended, although no teratogenic effect caused by the vaccine has been reported.

- There is no evidence to show that the HPV vaccine adversely affects fertility, pregnancy or infant outcome.

- Women who are planning to conceive are advised to defer vaccination until after delivery.

- Women who become pregnant before completion of vaccination are advised to postpone the remaining dose until after the pregnancy.

- Termination of pregnancy is not indicated for women who become inadvertently pregnant during the course of vaccination.

- Lactating women can receive the HPV vaccine and still continue breastfeeding because it is a vaccine without live viral DNA.

Immunosuppressed Patients

- Immunosuppression is not a contraindication to vaccination. However, the immune response to the HPV vaccine may be less competent in these women compared with a healthy individual.

Contraindications and Precautions

- The HPV vaccine is contraindicated for people with a history of hypersensitivity to any vaccine component.
- Vaccine should be administered in lying down position and the vaccine should be observed for 15 minutes for possible dizziness/fainting attack
- Vaccination of people with moderate or severe acute illnesses should be deferred until after the illness improves.
- When the vaccine is administered concomitantly with any other vaccine, it should be at a separate site, with a separate syringe.

The FOGSI Recommendations have been drafted by the FOGSI Oncology Committee
At a Meeting held on 11th October 2008 at Mumbai.

The above statement has been reviewed by the GCPR committee after the meeting at Ambani Hospital, Mumbai in 20th August 2010.