

Cervical cancer vaccine

Efficacy and safety of the
Human Papillomavirus vaccine

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Declaration

- One slide provided by CSL, distributors of Gardasil vaccine in Australia
- Background details on the HPV vaccine in Lebanon provided by Dr Ghassan Khoury of Merck Sharp and Dohme in Lebanon
- No funding received from the makers or distributors of Gardasil or any other HPV vaccine

American National Cancer Institute

- "Widespread vaccination has the potential to reduce cervical cancer deaths around the world by as much as two-thirds, if all women were to take the vaccine and if protection turns out to be long-term.
- "In addition, the vaccines can reduce the need for medical care, biopsies, and invasive procedures associated with the follow-up from abnormal Pap tests, thus helping to reduce health care costs and anxieties related to abnormal Pap tests and follow-up procedures."



Image: [CDC HPV Brochure](#)

HPV vaccine in Lebanon

- Two HPV vaccines are currently on the market worldwide: Gardasil and Cervarix
- Both available in Lebanon
- National recommendations are to be published soon under the auspices of
 - Lebanese Family Medicine Society
 - Lebanese Order of Physicians
 - Lebanese Ob/Gyn Society
 - Lebanese Pediatric Society

Cervical Cancer in Australia

- In Australia about 700 women each year are diagnosed with cervical cancer (an incidence of 7 per 100,000)
- In Australia 200 women die of cervical cancer each year
- By world standards these rates are low and are attributed to the national cervical screening program

- Worldwide incidence is 9 per 100,000
- In Lebanon the incidence of cervical cancer is variously reported as being between 6 and 14 per 100,000
- Cervical cancer is one of the common causes of death due to cancer among women in Lebanon

- Over 85% of women in Australia who develop cervical cancer have had inadequate PAP test screening
- In developing countries, where screening is largely unavailable, the incidence is well over 30 per 100,000
- In developing countries, there are 250,000 deaths each year from cervical cancer

- Virtually all cervical cancer is attributable to infection with the Human Papillomavirus (HPV)
- There are over 100 HPV subtypes
- High risk types of HPV are found in different proportions throughout the world

- Up to 70% of all sexually active women will become infected with at least one strain of HPV during their lifetime
- HPV16 and HPV18 cause 70% of all cancers and 50% of high grade cervical abnormalities
- HPV6 and HPV11 cause >90% of all cases of genital warts

- HPV infection only leads to cancer in a small percentage of cases but because of the prevalence of HPV, absolute numbers of women developing cancer is large
- The vaccine, Gardasil, provides protection against HPV types 6, 11, 16 and 18
- The vaccine, Cervarix, provides protection against HPV types 16 and 18
- These HPV types represent a significant burden to public health

- Infection causes about 25% of all cancers
 - Hepatitis B virus
 - Hepatitis C virus
 - Epstein Barr virus (EBV)
 - Helicobacter pylori
 - Human papillomavirus

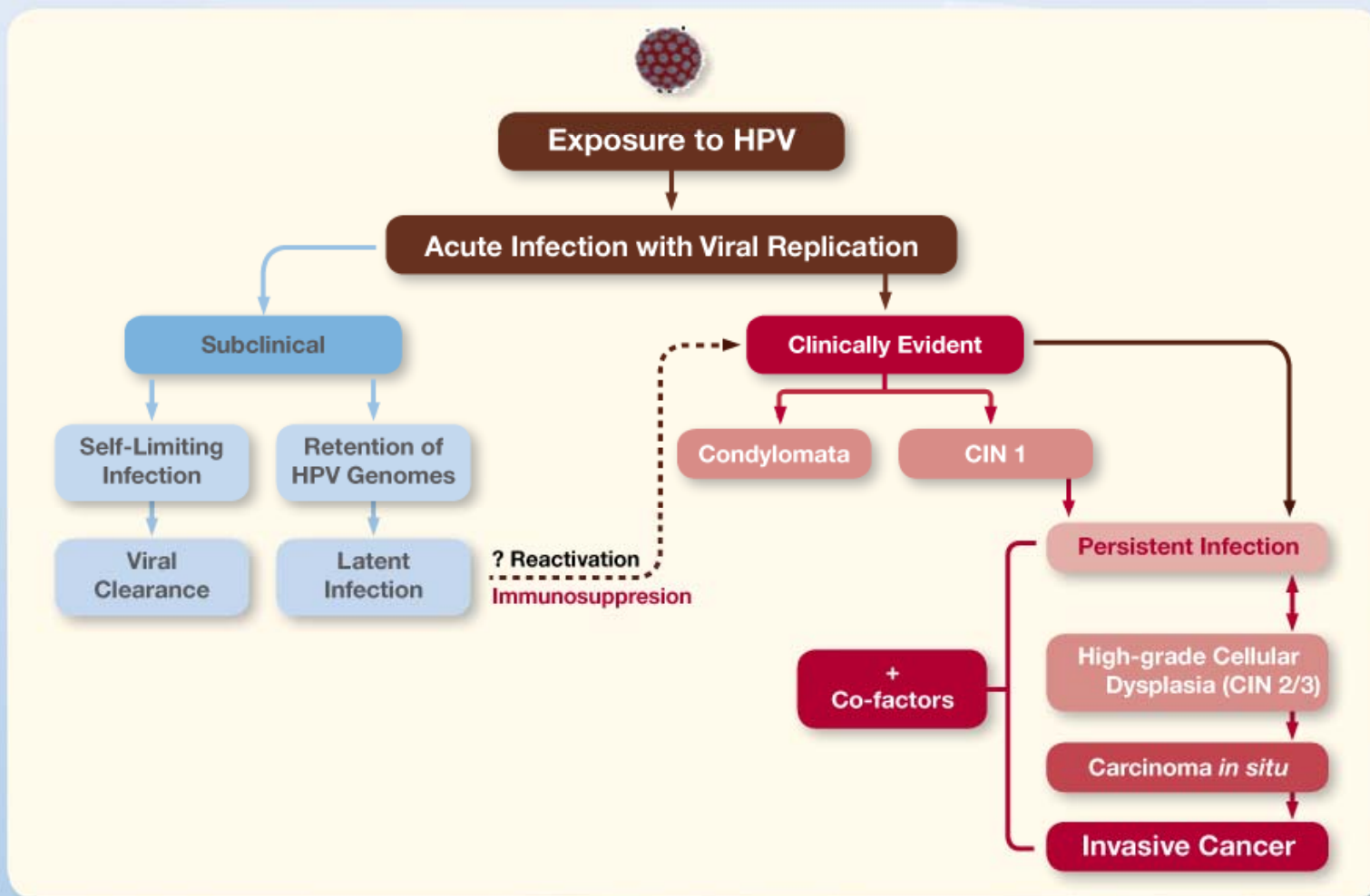
Natural history

- HPV is highly infectious with transmission rates over 50% following exposure to a person with productive anogenital HPV infection
- Highest prevalence of HPV has been identified in sexually active women aged 25 years and younger
- Up to 80% of sexually active women and men will be exposed to at least one strain of HPV during their lifetime.

Natural history

- Infection occurs through any type of genital contact
- Condoms can reduce, but not entirely prevent, transmission of HPV
- Most women who contract HPV infection clear it spontaneously within 8-14 months with persistence of a high risk HPV type only occurring in 3-10% of women

Natural history of HPV infection



CDC Guidelines

- The HPV vaccine is recommended for 11 and 12 year-old girls.
- It is also recommended for girls and women age 13 through 26 years of age who have not yet been vaccinated or completed the vaccine series.
- Note: The vaccine can also be given to girls 9 or 10 years of age.

Australian Government

- The quadrivalent HPV vaccine (Gardasil) is indicated for females aged 9 to 26 years, and males aged 9 to 15 years.
- It should ideally be administered before the onset of sexual activity
- However sexually active patients will also benefit as the vaccine can prevent disease due to the other HPV types

- In Australia the government has agreed to fund HPV vaccine for all young women
- Vaccine is delivered through schools
- Girls need to be vaccinated at a young age
- Vaccine is most effective if given before exposure to HPV
- Best antibody response occurs in the 12 years and under age group

- The Australian Government is also funding a catch up program for girls aged between 13 and 18 years in schools, and women aged between 18 and 26 to be delivered via their family doctor
- Schedule is 3 doses administered over 6 months (0, 2, 6 months)

Can pregnant women receive the vaccine?

- The vaccine is not recommended for pregnant women.
- There has been limited research looking at vaccine safety for pregnant women and their unborn babies.
- So far, studies suggest that the vaccine does not cause health problems for pregnant women or their developing child.
- But more research is still needed.

Can pregnant women receive the vaccine?

- For now, pregnant women should wait until their pregnancy is over before getting the vaccine. If a woman finds out she is pregnant after she has started getting the vaccine series, she should wait until her pregnancy is over before finishing the three-dose series

What about vaccinating boys and men?

- CDC reports that we do not yet know if the vaccine is effective in boys or men.
- It is possible that vaccinating males will have health benefits for them by preventing genital warts and rare cancers, such as penile and anal cancer.
- It is also possible that vaccinating boys/men will have indirect health benefits for girls/women.

What about vaccinating boys and men?

- Studies are now being done to find out if the vaccine works to prevent HPV infection and disease in males. When more information is available, this vaccine may be licensed and recommended for boys/men as well.
- It is already indicated for use in boys in Australia, based on research findings.

Questions still to be answered

- Duration of protection – possibly 10 years
- Cost and access issues for developing nations
- Broader spectrum vaccines

Why is the HPV vaccine only recommended for girls/women through age 26?

- The vaccine has been widely tested in girls/women 9 through 26 years of age.
- New research is being done on the vaccine's safety and efficacy in women older than 26 years of age.
- The FDA will consider licensing the vaccine for these women when there is enough research to show that it is safe and effective for them.

Side effects of vaccine

- Local symptoms – pain, swelling, erythema at the site of injection
- Fever (do not vaccinate during a febrile illness)
- Do not electively vaccinate if the patient is pregnant
- No contraindication at the moment to vaccination during lactation
- Ask about hypersensitivity to yeast or other vaccine components

Safety of the HPV vaccine

- This vaccine has been licensed by the FDA and approved by CDC as safe and effective.
- It was studied in thousands of females (ages 9 through 26 years) around the world and its safety continues to be monitored by CDC and the FDA.
- Studies have found no serious side effects.
- The most common side effect is soreness in the arm (where the shot is given).

- There have recently been some reports of fainting in teens after they got the vaccine.
- For this reason, it is recommended that patients wait in their doctor's office for 15 minutes after getting the vaccine.

Cervical cancer

- Early cervical cancer may be asymptomatic with diagnosis suggested by abnormal cytology and subsequent colposcopy and biopsy
- Invasive cervical cancer will have significant symptoms such as abnormal vaginal bleeding and/or discharge
- Postcoital bleeding may occur in sexually active women
- Beware of postmenopausal bleeding

Cervical cancer

- In Australia over 85% of women diagnosed with invasive squamous cervical cancer have not had regular Pap smear testing
- Recommend Pap smears every two years for all sexually active women to age 70 years, or longer if the patient requests
- Abnormal appearance of the cervix or contact bleeding during Pap smear is reason for referral for colposcopy

Recent case seen in a primary care clinic in a village in rural South Africa

- 65 year old woman with postmenopausal bleeding
- “Started having her periods again”
- Village nurse commenced the patient on oral contraceptive pill to regulate her periods
- Happy patient
- Referred to doctor for assessment after six months as bleeding was continuing

Postmenopausal bleeding

- Must always be investigated as 10% of patients will have endometrial cancer and others will have cervical cancer
- Commonest cause of PMB is atrophic vaginitis
- Tissue pathology assessment of endometrium is essential, even in the presence of obvious atrophic vaginitis or a cervical polyp

The HPV vaccine has led to a paradigm shift

- Vaccination and cervical screening offers women the best chance of protection against cervical cancer and cervical abnormalities
- Best time to vaccinate? The sooner the better – ideally before onset of sexual activity
- Pap tests are still essential
- Continue Pap smears as not all high risk types of HPV are covered by the vaccine