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On-line resource centre

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HPV

HPV vaccine was added to the National Immunisation Schedule from 1 September 2008 for girls and young women.

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Causative Organism

Human papillomaviruses (HPV) cause cutaneous and genital warts and some strains are the causative organisms that lead to cervical cancer. HPV is present in the biopsies of more than 99% of cervical cancer specimens. Malignant progression is thought to be due to the direct action of two viral oncogenes E6 and E7, which inactivate two tumour suppressor genes. The oncogenes also cause genetic instability, which subsequently leads to dysplasia.

As well as cervical cancer, HPV can cause:

- Vulvar cancer (HPV 16 and 18) and vaginal cancer (HPV 16).
- Penile cancer (HPV 16, less often HPV 18).
- Cancer of the anus (HPV 16 and 18).
- Oropharyngeal (mouth and throat) cancer (HPV 16).
- Recurrent respiratory papillomatosis (RRP). RRP is caused by HPV infection of the respitory tract. It is a rare disease. It is usually benign but papillomas can sometimes block the respiratory tract, and in a few cases can become cancerous. The majority of cases occur in children, probably contracted from the mother during birth (this is called vertical transmission of the virus). RRP is most often caused by HPV types 6 and 11.

Signs, Symptoms and Complications

- **HPV infection** - Presentation can vary according to type, of which there are more than 100: Generally types 1 and 2 affect skin, types 5 and 8 Epidermodysplasia verruciformis (EV), types 6 and 11 result in genital warts. Around 40 types affect the genital region of which approximately 15-20 types are oncogenic and found in genital cancers, with types 16 and 18 being the most common.
- "Low-risk" types of HPV cause benign warts and verrucae.
- 98% of infections resolve with no problems. About 2%, however, are still present after 5 years.
- **Cancer** - Low-grade cervical dysplasias identified in Pap smears indicate productive HPV infection; most resolve spontaneously, probably the result of cell-mediated immune responses. A small percentage progress to cancer.
- Cervical intraepithelial neoplasia (CIN) is another method of

HPV Vaccine and Cervical Cancer - Fact Sheet for Parents and Caregivers IMAC 2008

HPV - Concerns Addressed

Responding to recent concerns about the safety, adverse events and effectiveness of the Gardasil vaccine. Click Here to read IMAC articles adressing these issues and more.

signifying atypical cellular findings on a Pap smear, which commonly is HPV caused.

- CIN is categorized into CIN 1, 2, or 3, depending on the severity of the abnormality and the thickness of the abnormal cell layer

Method of transmission

Whilst HPV is a sexually transmitted infection, wearing a condom may not be enough to prevent passing it on. This is because HPV can be contracted from parts of the genitals not protected by a condom (genital-genital contact). Indeed, penetrative sex is not necessary: hand-genital and oral-genital contact can also spread HPV. Occasionally, HPV is passed from a mother to her baby during birth (vertical transmission). HPV can also be caught from contaminated clothes and objects, but this route is uncommon.

Public health significance

HPV infection

- All sexually active people are susceptible to HPV infection.
- By 3 years post the onset of sexual activity, up to 2/3 women have been asymptomatically infected.
- Ongoing infection, usually over many years can lead to cancer, although shorter time periods are also seen.

Cervical Cancer

- Cervical cancer is the second or third leading cause of cancer deaths in women worldwide.
- Estimated 450,000 cases and 200,000 deaths annually.
- Most common among women in Latin America, India and Sub-Saharan Africa (where there are no cervical screening programmes), but common and widespread in all countries.
- Generally affects younger women in comparison to other cancers.

Risk factors for cancer include:

- Having a greater number of sexual partners, both lifetime and recent.
- Having sex with a new partner, particularly someone recently met; and the new partner's sexual history is also a high risk factor.
- Young age - most infections occur in girls aged 20-24 years. It is possible that the cervix is more susceptible to infection in young girls, and that biological changes occur as they get older that make them more resistant to infection.
- Young age at first sexual intercourse. Sexually active young girls are more likely to have multiple partners and to have had sex without adequate barrier protection.
- Immune suppression. This may affect the body's ability to clear infections.
- "High-risk" types, in particular, HPV types 16, 18, 31,33 and 45 are found in tumour tissues of about 90% of cervical cancers worldwide.
- Type 16 is associated with approximately 50% of cervical cancers and type 18 another 20%.
- The current method of prevention worldwide involves identification of pre-malignant lesions with significant health costs. (Pap smears).

New Zealand Epidemiology

- Both cervical cancer incidence and mortality have fallen dramatically in New Zealand (as in other developed countries) over the last decade, due to cervical screening however approx 160 New Zealand women are diagnosed with cervical cancer each year and on average 60 women die of the disease each year.
- New Zealand's National Cervical Screening Programme, administered by the National Screening Unit of the Ministry of Health, became operational in 1991 and now achieves

over 70 percent coverage of eligible women (ie, the 20–69 year age range).

- Over the past 10 years cervical screening has led to a 40 percent reduction in the incidence of invasive cervical cancer. However, incidence remains approximately twice as high among Mäori than among non Mäori women. Over the same period, mortality from cervical cancer has fallen about 60 percent. Again, ethnic inequalities remain, with mortality among Mäori still approximately 4 times that of non Mäori.
- In 2004 there were 3822 new diagnoses of genital warts in males and females in sexual health clinics; population rates cannot be calculated.
- The age group most affected by genital warts is young adults aged 15−24 years. The number of new cases seen has increased over time, although some of the increase may represent changes in presentation at clinics rather than a change in incidence. An Auckland study of 513 cervical swabs, mainly from women attending colposcopy clinics, found that 221 specimens (43 percent) were positive for HPV. Twenty-two different types of HPV were detected, and 141 were oncogenic types, representing 14 of the 18 known oncogenic types. Types 16, 18, and 31 were the most common detected, representing 39 percent, 10 and 10 percent of the oncogenic types found, respectively. The other 11 oncogenic HPV types ranged in prevalence from 7.4 to 0.6 percent.
- In considering options for timing an HPV vaccine for the immunisation schedule in New Zealand, it is useful to consider the results of the 2001 Youth Health Survey, which provides information on sexual behaviours. Among secondary school students in years 9 to 13, 17 percent of students aged 13 years reported they had had sexual intercourse, 33 percent of those aged 15 years, and 49 percent of students aged 17 years.

From the New Zealand 2006 Immunisation Handbook

Prevention

Non immunisation related preventions

- Primary prevention method - Use of condoms
- Secondary prevention methods:
  - Identification of pre-malignant lesions by regular Papanicolaou (Pap) screening.
  - Surgical management of high-grade lesions.

Vaccination

- Primary vaccination against HPV prior to infection is now possible.
- HPV vaccination was added to the NZ immunisation schedule in September 2008

Vaccine

- Gardasil® (MSD) is the only HPV vaccine currently available in New Zealand.
- It is funded and recommended for 12 year old girls (School year 8).
- A catch-up programme is also offering the vaccine for girls and young women from 11 to 18 years of age starting with those born in 1990 and 1991 from Sept 2008.

Gardasil® (MSD), Quadrivalent vaccine: HPV-6, 11, 16, 18 VLP

- Gardasil® (MSD) is a recombinant vaccine. It contains non infections virus like particles (VLP) of HPV types 16 and 18, which are responsible for approximately 70% of high grade CIN and cervical cancer. It also contains types 6 and 11 which are responsible for 90% of genital warts.
- The VLPs are produced in Saccharomyces cerevisiae (yeast)

- 225µg Aluminium Hydroxyphosphate Sulphate as adjuvant.

Efficacy and effectiveness

Clinical trials in over 20,000 participants demonstrated 95-100% efficacy of Gardasil® against pre-cancerous lesions.

Gardasil® prevented 95-100% of HPV 16/18/6/11 —related CIN, AIS or EGL in women not yet infected with either HPV 16,18, 6, or 11 at baseline.

NB Per protocol populations
CIN = cervical intraepithelial neoplasis; AIS = adenocarcinoma in situ; EGL = external genital lesions; VIN/ VaIN = Vulvar/ Vaginal intraepithelial neoplasia.

Gardasil® Quadrivalent vaccine: HPV-6, 11, 16, 18 VLP

- Efficacy was assessed in 4 placebo-controlled, double blind, randomised phase II trials and III clinical studies conducted with more than 20,000 people from more than 20 countries, including a range of ethnic groups
- 100% efficacy in preventing HPV 16 & 18 high-grade cervical pre-cancers, non-invasive cervical cancers (CIN 2/3) and adenocarcinoma in situ (AIS).
- 95% efficay in preventing HPV 6, 11, 16 & 18 CIN 1,2,3 or AIS
- 98.9% efficacy in preventing HPV 6,11,16 & 18 related genital warts
- Overall efficacy against persistent infection by all four HPV types estimated at 89% at 36 months.
- Antibody levels have been shown to persist at sustained, high levels for at least 5 years post immunisation.
- Trials with adolescent males and females aged 10-15 years indicate immunogenicity and safety in this age group.
- Gardasil® is not a therapeutic vaccine, vaccinating prior to HPV exposure results in greatest benefit

Availability

Gardasil® has been registered for use in NZ from 20th July 2006

Those who are not eligible for funded vaccine may consider the benefits sufficent to wish to purchase the vaccine. Gardasil is available for purchase from HealthCare Logistics. The cost to providers is $128.50 + GST per dose. Service and delivery charges are additional.

Dosage and Administration

- 0.5ml Intramuscular injection
- 3 doses at 0, 2 & 6 months

Indications and Recommendations

- Funded and recommended for 12 year old girls (School year 8).
- A catch-up programme is also offering the vaccine for girls and young women from 12 to 19 years of age starting in 2009 & 2010. (see National Implimentaion Strategy and local DHBs for dates of catch-ups)

Non-funded considerations Gardasil® is licensed for:

- Girls and young women from 9 to 26 years of age. (NB. Only routinely funded for girls age 11 - 18 years)
- Males from 9 to 15 years of age on the basis that males may be protected from ano-genital cancers and warts and be less likely to transmit HPV to their partners. (NB. not funded for boys)

Contraindications

- Anaphylactic sensitivity to any of the vaccine ingredients.
- Pregnancy

Adverse Events

- Local reactions are common, in particular pain.
- Mild systemic reactions also reported such as headache.
- Most reactions are mild and of short duration
- Anaphylactic reaction (3.2 per million doses)
- No other serious events reported

Risks vs Benefits

Risk from HPV infection	Risks from disease	Risks from Vaccine
• Infection of partner • Risk of development of persistent infection (2%) • Risk of cervical cancer • Risk of other anogenital and pharyngeal cancers (rare) • Genital warts • Recurrent respiratory papillomatosis (rare)	• Invasive treatment for pre-cancerous lesions • Some treatments increase risk of premature birth in subsequent pregnancies • Cervical cancer	• Mild-moderate local pain and inflamation at injection site (most vaccinees) • Severe pain and inflamation at injection site (<3%) • Mild-moderate fever (<1%) • Anaphylaxis - estimated at 3.2 per million

For more information for girls and young women - see AUT website www.oneforthegirls.org.nz

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