


**Quick Reference:
Immunization Communication Tool
For Immunizers
HPV 2010**




**ImmunizeBC
BoosterEvents**

Are young girls being used as “guinea pigs” for an unproven vaccine?

Clinical Evidence	Client knowledge
<p>NO. In both clinical trials conducted for the testing of the vaccine prior to its approval, and in post-marketing surveillance, Gardasil™ has been shown to be safe. Sufficient numbers of doses have now been administered to identify the occurrence of even rare serious events.</p> <ul style="list-style-type: none">• Published results from pre-clinical studies in animals began in 1995. The earliest Phase II safety and efficacy studies in humans with the monovalent formulation (HPV 16) started in 1998 and the large Phase III trials started in 2002• The HPV vaccine has been thoroughly studied. In the combined analysis of studies with Gardasil™ vaccine - 20,583 women were enrolled in the studies and eligible for analysis. Of these, 10,291 were randomized to the vaccine group and 10,292 were randomized to the placebo group. These studies took place in North America, Europe, Latin America and the Asia Pacific Region• Almost 100% of the women developed protective antibodies for the four strains of HPV included in the vaccine• For those women, the vaccine prevented almost 100% of pre-cancer changes in the cervix for the four strains of HPV included in the vaccine• The HPV vaccine is safe and effective. Reporting rate for adverse events for Gardasil™ in Canada is 36.6 per 100,000 doses distributed, which is comparable to the rate of reported adverse events for all vaccines in Canada, which has varied between 16 to 40 per 100,000 doses over the period 1992 -2004 <p>Supporting References:</p> <ol style="list-style-type: none">1. Global Advisory Committee on vaccine safety. Weekly Epidemiological Rec 2007 82:252-259.2. Barr E & Tamms G. Quadrivalent human papillomavirus. Clinical Infectious Diseases 2007; 45:609–617.	<p>NO. Young women are benefiting from a safe and effective vaccine. Vaccines are licensed for use in Canada only if they meet very strict standards for safety and effectiveness.</p> <ul style="list-style-type: none">• The HPV vaccine has been scientifically studied in thousands of women in North America, Europe, Latin America, and the Asia Pacific Region• Assuring the safety of vaccines and medications does not stop with licensing. Across Canada there is a reporting network to Health Canada that keeps track of side effects from both vaccines and medications. Health Canada investigates any possible problems• Since 2006, Gardasil™ has been licensed/ approved in 112 countries and more than 45 million doses have been distributed worldwide in over 77 countries. As of July 2009 26 national authorities had recommended its use and it has been funded through public sector programs in 25 countries• The HPV vaccine is safe. Most side effects are minor and last only a day or two (fever; pain, redness and swelling at the site where the vaccine was given). These reactions are part of the body’s normal immune response and are common after most vaccines  <p>DID YOU KNOW? Vaccines are only licensed for use in Canada if they meet very strict standards for safety and effectiveness.</p>


**There's been a rush to use this vaccine.
Shouldn't we wait until we have more answers?**

Clinical Evidence	Client Knowledge
<p>NO. There was no rush. We know the vaccine is very effective and safe. Pre-licensure, HPV vaccine is one of the most extensively studied vaccines.</p> <ul style="list-style-type: none"> • We know the vaccine is very effective and safe. Pre-licensure, HPV vaccine is one of the most extensively studied vaccines • Published results from pre-clinical studies in animals began in 1995. The earliest Phase II safety and efficacy studies in humans with the monovalent formulation (HPV 16) started in 1998 and the large Phase III trials started in 2002 • HPV vaccine is now being approved for use in 112 countries around the world (for example, Australia, New Zealand, the US, UK, most European and Scandinavian countries) <p>Supporting references:</p> <ol style="list-style-type: none"> 1. Munoz N. et al. Safety, immunogenicity and efficacy of quadrivalent human papillomavirus (6, 11, 16, 18) recombinant vaccine in women aged 24-45 years: a randomized double blind trial. <i>Lancet</i> 2009; 373:1949-1957 2. Reisinger KS. Safety and persistent immunogenicity of a quadrivalent human papillomavirus types 6,11,16,18 L1 virus-like particle vaccine in preadolescents and adolescents. <i>Journal of Pediatric Infectious Diseases</i> 2007; 26:201-209 3. Barr E & Tamms B. Quadrivalent human papillomavirus. <i>Clinical Infectious Diseases</i> 2007; 45: 609-617. 	<p>NO. There was no rush. HPV vaccine has been very carefully studied. We know the vaccine works extremely well and is safe.</p> <ul style="list-style-type: none"> • Before HPV vaccine was licensed for use it was studied more than many other vaccines • Young girls can be protected now. It's always better to prevent disease than treat it • Cervical cancer is the second most common cause of cancer in women between the ages of 20 - 44 years • Planning in BC started in the fall of 2005 in consultation with BC Cancer Agency, Ministry of Health, BC Women's and Children's Hospital, and BCCDC <div data-bbox="816 1266 1175 1507" style="background-color: yellow; padding: 5px;"> <p>DID YOU KNOW? Before it was licensed, the HPV vaccine was studied for more than 10 years, more than many other vaccines.</p> </div> 


Hasn't it been confirmed the HPV vaccine caused serious side effects?

Clinical Evidence	Client Knowledge
<p>NO. While serious events have been reported following the receipt of HPV vaccine, none can be convincingly linked to the vaccine.</p> <ul style="list-style-type: none"> • During the HPV vaccine trials, the women who had the HPV vaccine were compared with women who received placebo (salt-water) injections. The rate of serious events was identical in both groups • In the vaccine trials, deaths were reported in both groups. Investigators have concluded that it is highly unlikely that the HPV vaccine caused the deaths. Deaths were caused by the usual reasons seen in the age groups studied (motor vehicle accidents, overdose and blood clots). Other causes were blood poisoning, pancreatic cancer, heart beat irregularities, and suffocation • There have been reports of Guillain Barre Syndrome (GBS), a nervous system disorder, in vaccinated people in the US. So far, the number of cases of GBS is below the number that is usually reported for the US population. It is thought that these cases occurred by coincidence following vaccination • 95% of reported HPV vaccine side effects are very minor and similar to those following other vaccines (i.e. fever and injection site reactions) • Health Canada monitors all adverse events following immunization (including HPV). All identified problems are investigated and acted upon as needed <p>Supporting References:</p> <ol style="list-style-type: none"> 1. Vaccine safety update: Summary of Findings for HPV post licensure safety monitoring. Report to the Advisory Committee on Immunization Practices, Oct 22-23, 2008 2. Block SL et al. Clinical trial and post licensure safety profile of a prophylactic human papillomavirus (types 6,11,16 and 18) L1 virus like particle vaccine. Pediatric Infectious Disease Journal 2010; 29:95-101. 	<p>NO. While serious events have been reported following the receipt of HPV vaccine, none can be convincingly linked to the vaccine.</p> <ul style="list-style-type: none"> • Most reporting systems for vaccine safety include reports of events that occur after receipt of the vaccine, regardless of the likelihood that the event is caused by the vaccine • Because many millions of doses of this vaccine have been given to young women it is not surprising that some have experienced serious health events • It is important to distinguish between an event caused by a vaccine, and an event that merely follows the receipt of a vaccine • During the HPV vaccine trials, the women who had the HPV vaccine were compared with women who received placebo (salt-water) injections. The rate of serious events was identical in both groups • In the vaccine trials, deaths were reported in both groups. Investigators have concluded that it is highly unlikely that the HPV vaccine caused the deaths. Deaths were caused by the usual reasons seen in the age groups studied (motor vehicle accidents, overdose and blood clots). Other causes were blood poisoning, pancreatic cancer, heart beat irregularities, and suffocation • In Canada there have been no reports of GBS in those vaccinated • 95% of reported HPV vaccine side effects are very minor and similar to those following other vaccines (i.e. fever and injection site reactions) <div data-bbox="857 1591 1490 1759" style="background-color: yellow; padding: 5px;"> <p>DID YOU KNOW? The most commonly reported events following HPV vaccination were minor and included redness, swelling and/or pain at the injection site.</p> </div>


My daughter isn't sexually active; does she need the HPV vaccine now?

Clinical Evidence	Client Knowledge
<p>YES. We want to protect girls before they are sexually active.</p> <ul style="list-style-type: none">• The majority of females become infected with at least one type of HPV within 2 to 5 years of becoming sexually active• In BC, 3% of girls aged 12 or younger have already had sexual intercourse and over 30% are sexually active by age 16• A recent US study in college-aged women showed that infection with HPV happens very commonly with the first sexual partner• The vaccine should be given to girls before they are exposed to HPV through sexual activity. This includes any oral or genital contact-intercourse isn't necessary• This is the same approach taken with any vaccine: it needs to be given prior to exposure to the infectious agent• If a girl is already infected with one or more types of HPV prior to vaccination, the vaccine will not treat or get rid of those HPV types <p>Supporting References:</p> <ol style="list-style-type: none">1. McCreary Report: McCreary Center Society, Adolescent Health Survey 111, 20032. Collins S et al. High incidence of cervical human papillomavirus infection in women during their first sexual relationship. BJOG 2002; 109:96-83. Infectious Diseases and Immunization Committee, Adolescent Health Committee, Canadian Paediatric Society (CPS). Human papillomavirus vaccine for children and adolescents. Paediatrics & Child Health 2007;12(7):599-603.	<p>YES. It is important to protect girls before they are sexually active because exposure to HPV virus happens commonly with the first sexual partner.</p> <ul style="list-style-type: none">• HPV vaccine is cancer prevention.• In BC, over 30% of girls are sexually active by the time they are 16 years old• The majority of females become infected with at least one type of HPV within 2 to 5 years of becoming sexually active, so it is important to vaccinate them before they are sexually active. This includes any oral or genital contact-intercourse isn't necessary• The vaccine prevents infection with the types of HPV in the vaccine. Before vaccination, if a girl is already infected with one or more types of HPV, the vaccine will not treat or get rid of those HPV types  <p>DID YOU KNOW? It is always better to prevent disease than treat it. The HPV vaccine is most effective if given to girls before they are exposed to the HPV virus.</p>

Were there any studies done in the group of girls (aged 9 to 15 years) that public health wants to vaccinate?

Clinical Evidence	Client Knowledge
<p>YES. There were studies of the vaccine immune response in this age group. Health Canada reviewed the data and approved the use of the vaccine.</p> <ul style="list-style-type: none">• In the studies with older women (aged 16 – 26 years), researchers were able to do both blood tests and pelvic exams. Blood tests show antibody protection and pelvic exams detect pre-cancer changes in the cervix. As it is not ethical to do pelvic exams on girls so young (9 –15 years old), only blood tests were done• Two immunogenicity bridging studies were done. 2797 boys and 9-16 year old girls were enrolled for these safety and immunogenicity studies. Compared to females 16-23 years, geometric mean titers one month post dose 3 were 1.7 – 2.7 fold higher in girls and boys 9-15 years old <p>Supporting References:</p> <ol style="list-style-type: none">1. Block SL et al. Comparison of the immunogenicity and reactogenicity of a prophylactic quadrivalent human papillomavirus (Types 6,11,16,18) L1 virus-like particle vaccine in male and female adolescents and young adult women. <i>Pediatrics</i> 2006; 118:2135-2145.2. Reisinger KS. Safety and persistent immunogenicity of a quadrivalent human papillomavirus types 6,11,16,18 L1 virus-like particle vaccine in preadolescents and adolescents. <i>Journal of Pediatric Infectious Diseases</i> 2007; 25:201-209.	<p>YES. There were studies in this age group that showed the immune response was very good - the girls made high levels of antibodies against HPV.</p> <ul style="list-style-type: none">• In the studies with older women (aged 16-26 years), researchers were able to do both blood tests and pelvic exams. Blood tests show antibody protection and pelvic exams detect pre-cancer changes in the cervix. As it is not ethical to do pelvic exams on girls so young (9-15 years old), only blood tests were done• The studies showed that both age groups developed high antibody levels after vaccination. In fact, the younger girls developed higher antibody levels than the older females. In the older age group the vaccine prevented almost 100% of pre-cancer changes in the cervix. Therefore, the researchers concluded that the vaccine would also prevent pre-cancer cervical changes for the younger girls 

Won't the HPV vaccine promote earlier sexual activity?

Clinical Evidence	Client Knowledge
<p>NO. Being vaccinated does not promote earlier sexual activity.</p> <ul style="list-style-type: none">• There were similar concerns in 1992 when the hepatitis B vaccine was introduced and there has been no rise in earlier sexual activity since then• We want to immunize early as younger females are at increased risk of HPV infection, as:<ul style="list-style-type: none">○ Their reproductive tracts are still developing and immature cervical cells may be especially susceptible to HPV○ The transformational zone of the cervix of younger females is more anatomically vulnerable to infection○ There may be inadequate production of cervical mucus, which may act as a barrier against infection○ Increased susceptibility to minor trauma of the cervix during sexual intercourse <p>Supporting References:</p> <ol style="list-style-type: none">1. McCreary Report: McCreary Center Society, Adolescent Health Survey 2008.2. Tarkowski et al. Epidemiology of HPV infection and abnormal cytologic test results in an urban adolescent population. Journal of Infectious Diseases 2004; 189:46-50.	<p>NO. Immunization does not promote earlier sexual activity. Immunization should occur BEFORE sexual activity to be most effective.</p> <ul style="list-style-type: none">• There were similar concerns in 1992 when BC introduced the hepatitis B vaccine program for grade 6 students. There has been no rise in earlier sexual activity since then.• There is NO evidence that being vaccinated against HPV influences a young girl's decision regarding earlier sexual activity  <p>DID YOU KNOW? There are many factors that influence young people's decisions about early sexual activity including peer pressure, self-image, sex education and impact of the media.</p>

Should my daughter receive the HPV vaccine when we don't know how long the vaccine protection will last?

Clinical Evidence	Client Knowledge
<p>YES. There is mathematical modeling data that predicts HPV vaccine protection will last for at least 15 years, and probably lifelong.</p> <ul style="list-style-type: none"> • We know from the vaccine studies that there is good protection 5 years after the first dose of vaccine and that the antibody level is much higher after vaccination than after natural infection with HPV. This is good news as a high antibody level usually means longer protection • When any new vaccine is approved for use there are unanswered questions such as the length of protection and the need for a booster dose. An example is the grade 6 hepatitis B vaccine program that was started in BC in 1992. The length of protection from hepatitis B vaccine is still being studied all these years later • Clinical trials demonstrate high protection – antibodies highest at 8 months, waned and settled at 15 months and immunity has lasted 5 years • The HPV vaccine will protect girls now. It's far better to give the vaccine and then give a booster in the future, if needed, than not to give the vaccine at all <p>Supporting References:</p> <ol style="list-style-type: none"> 1. Olsson SE, et al. Induction of immune memory following administration of a prophylactic quadrivalent human papillomavirus (HPV) types 6/11/16/18 L1 virus-like particle (VLP) vaccine. <i>Vaccine</i> 2007; 25:4931-4939. 	<p>YES. Researchers predict that HPV vaccination will last for at least 15 years, and probably lifelong.</p> <ul style="list-style-type: none"> • Many successful vaccination programs have been introduced without knowing how long the vaccine protection will last (e.g. hepatitis B vaccine program in grade 6) • Researchers predict this because the HPV vaccine causes an immune response similar to that seen with other vaccines • We know from the vaccine studies that there is good protection 5 years after the first dose of vaccine and that the antibody level is much higher after vaccination than after natural infection with HPV. This is good news as a high antibody level usually means longer protection • Follow-up studies are being done to see if there will be a need for a booster dose in the future • The HPV vaccine will protect girls now. It's far better to give the vaccine and then give a booster in the future, if needed than not to give the vaccine at all <div data-bbox="927 1297 1435 1465" style="background-color: yellow; padding: 10px; margin-top: 20px;"> <p>DID YOU KNOW? It is best to be immunized now and if needed get a booster later, than not to be immunized at all.</p> </div>

Do we need an HPV vaccine program when Pap testing catches cervical cancer early and it can be treated?

Clinical Evidence	Client Knowledge
<p>YES. Both HPV vaccine and Pap tests are needed to prevent and detect cervical cancer.</p> <ul style="list-style-type: none"> • The HPV vaccine provides protection against the two HPV types (16 and 18) that cause 70% of all cervical cancer. There are at least 40 types of HPV that can infect the genital tract. There is still a need for Pap tests to screen for the cervical lesions caused by the remaining 30% of HPV types that contribute to cervical cancer • 30 % of women with cervical cancer in BC had adequate Pap screening; Pap testing simply identifies lesions that may progress to cervical cancer • Diagnostic accuracy of Pap screening is ~ 50% in routine clinical care • When abnormal lesions are found through Pap testing, women must have ongoing evaluation and treatment to prevent the progression to cancer; in BC more than 10,000 women are affected each year <p>Supporting References:</p> <ol style="list-style-type: none"> 1. BC Cancer Agency, Cancer Prevention Program. A population based HPV immunization program in British Columbia. January 17, 2006. 2. Statement on human papillomavirus vaccine. Canada Communicable Disease Report, 2007. National Advisory Committee on Immunization. Accessed March 11, 2010. 	<p>YES. Both HPV vaccine and Pap tests are needed to prevent and detect cervical cancer.</p> <ul style="list-style-type: none"> • The Pap test identifies changes in the tissues that may progress to cancer of the cervix. Further tests are needed to determine if it is cancer, and if so, then treatments are needed. These tests and treatments are uncomfortable and frightening • Over 30% of women with cervical cancer in BC have followed the provincial recommendations for Pap testing • The vaccine will prevent more than 60% of the infections that cause the changes to the cervix and will decrease the need for further tests and treatments. In BC each year, the vaccine will significantly reduce the number of women having to undergo procedures • Vaccinated women will need to continue with regular cervical cancer screening for three reasons: <ul style="list-style-type: none"> ○ The vaccine won't provide protection against all types of HPV that cause cervical cancer ○ Women may not receive full benefit of the vaccine if they do not complete the vaccine series. ○ Women may not receive full benefit of the vaccine if they receive the vaccine after they have acquired a vaccine HPV type <p>DID YOU KNOW? HPV vaccine can protect against cervical cancer whereas the Pap test simply identifies changes in tissues that may progress to cervical cancer.</p>

This vaccine is really expensive – is it worth it?

Clinical Evidence	Client Knowledge
<p>YES. An HPV vaccine program is worth the investment.</p> <ul style="list-style-type: none">• Several cost-effectiveness analyses have been available for several years, including a BC - specific study. These studies all estimate a “cost per quality life year saved” approach (which can be used to compare the costs and benefits of different kinds of health care interventions)• Based on these studies, an HPV vaccine program is as cost-effective as other recently implemented vaccine programs and is competitive with other widely accepted medical and surgical interventions <p>Supporting References:</p> <ol style="list-style-type: none">1. Kendall et al. The case for HPV vaccination. The Vancouver Sun 2007.	<p>YES. An HPV vaccine program is worth the investment.</p> <ul style="list-style-type: none">• Several HPV cost-effectiveness studies have been done. These studies show that the cost-effectiveness of an HPV vaccine program is similar to the cost of many other types of medical and surgical health care <div data-bbox="808 653 1118 915"><p>DID YOU KNOW? In the last 50 years, immunization has saved more lives in Canada than any other health intervention.</p></div> 