

Sex, Lies, and Vaccination: HPV - the big facts

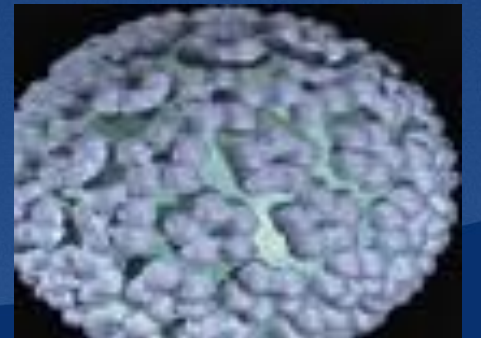
FRANCOISE BAYLIS
*Canada Research Chair
Bioethics and Philosophy*

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Halifax, Canada*



Human Papillomavirus (HPV)

- HPV is the most common sexually transmitted virus in the world today – most common in people in late teens and early 20s.
- Most sexually active people will get HPV at some time in their lives, but never know it. The viral infection usually clears up by itself (within 24 months) and causes no signs or symptoms.

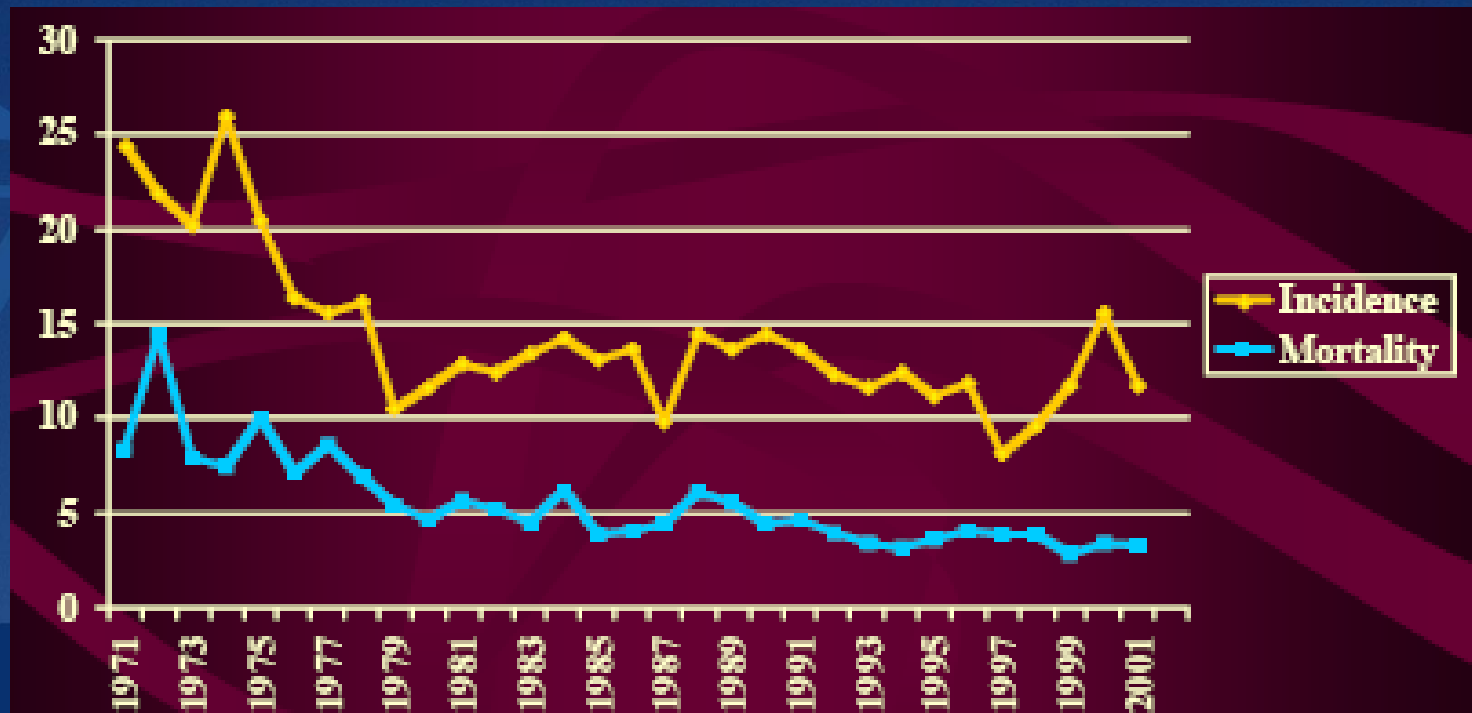


Human Papillomavirus (HPV)

- **Low risk:** anogenital warts and mild cervical dysplasia
- **High risk:** severe cervical dysplasia and cervical cancer
 - 400 Canadian women die each year of cervical cancer
 - In 2007, an estimated 1,350 new cases of cervical cancer and 390 cervical cancer-related deaths.
(Canadian Cancer Society)



Cervical cancer in Nova Scotia



Prevention Strategies

- Sexual behaviour modification
 - Delayed sexual debut
 - Consistent condom use
 - Reduced number of sexual partners
- Pap Smear Screening
 - Detection, follow-up and treatment of precancerous abnormalities (20 year lag from infection to invasive cancer)
- Vaccination
 - Three doses (months 0,2, and 6)

**DID YOU
KNOW?**

HPV vaccination

- **Two prophylactic vaccines for HPV**
 - Gardasil (Merck Frosst)
 - Cervarix (GlaxoSmith Kline)
- **Gardasil protects against infection with:**
 - HPV-16 and HPV-18 that cause 70% of cervical cancers
 - HPV-6 and HPV-11 that cause 90% of anogenital warts

**DID YOU
KNOW?**

HPV vaccination

- **July 10 2006:** Health Canada approves Gardasil for girls aged 9-26
- **March 2007:** Government of Canada creates a HPV trust fund (\$300m)
- **September 2007:** Publicly-funded school immunization programs begin in four provinces (girls aged 9-13)
 - Nova Scotia, Newfoundland and Labrador, PEI, and Ontario

Decision-making and HPV

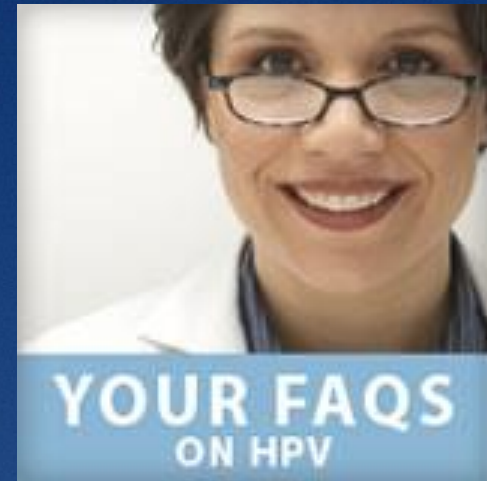
- Make informed decisions about your sexual health
- If you are a female or have young female children between 9 to 26 years of age, consider immunization with the HPV vaccine.
- For more information on HPV, cervical cancer screening or vaccination talk to your doctor or visit your local public health clinic.

Health Canada

<http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/diseases-maladies/hpv-vph-eng.php#is>

Elements of a valid choice

- Decisional capacity
- Disclosure
- Understanding
- Voluntariness



HPV Vaccine Myths

- 1: Young girls are being used as “guinea pigs” for an unproven vaccine.
- 2: There's been a rush to use this vaccine - we should wait until we have more answers.
- 3: My daughter does not need this vaccine now because she is not sexually active.
- 4: There weren't any studies done in the group of girls (aged 9 to 15 years) that public health wants to vaccinate.
- 5: We don't know how long the vaccine protection will last.



HPV Vaccine Myths

- 6: We don't need an HPV vaccine when Pap testing catches cervical cancer early and it can be treated.
- 7: Once you get the vaccine you won't need to get Pap tests anymore.
- 8: This vaccine is really expensive – it's not worth it.
- 9: This vaccine will promote earlier sexual activity.
- 10: There have been reports that the vaccine causes serious side effects.



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- 6: We don't need an HPV vaccine when Pap testing catches cervical cancer early and it can be treated.
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- 9: This vaccine will promote earlier sexual activity.
- 10: There have been reports that the vaccine causes serious side effects.

1. Young girls are being used as “guinea pigs”

Fact: *Young women are benefiting from a safe and effective vaccine*



- “A cautious approach may be warranted in light of important unanswered questions about overall vaccine effectiveness, duration of protection, and adverse effects that may emerge over time.” NEJM (2007) 356;19:1993
- “Despite a great beginning, there are many unanswered questions pertaining to long-term efficacy, optimal dosing, overall effectiveness against HPV in the real world and optimal delivery modalities in high-risk and impoverished populations.”

CMAJ (2007) 177;5: 433.

2. There's been a rush to use this vaccine

Fact: *HPV vaccine has been very carefully studied*



- “A careful review of the literature, including that submitted by the manufacturer with its application for approval of Gardasil, reveals a sufficient number of unanswered questions to lead us to conclude that a universal immunization program aimed at girls and women in Canada is, at this time, premature.”

CMAJ (2007) 177;5: 484

- “Although Gardasil and Cervarix have demonstrated favourable beginnings, there are still a number of *knowledge gaps*” CMAJ (2007) 177;5: 456

Knowledge gaps

- Will HPV vaccines affect cervical cancer incidence and mortality?
- Is the priming vaccine series sufficient or will a booster dose be required?
- Will exposure to wild-type HPV contribute to natural boosting?
- Will other HPV genotypes fill the niche previously filled by HPV types 16 and 18?
- How will the vaccination program affect current cytology screening programs?
- Will current cytology screening programs need to be adapted to identify vaccine failures?
- Are there rare but serious adverse effects of vaccination that have not yet been detected?

CMAJ (2007) 177;5: 456

3. My daughter does not need this vaccine

Fact: *We want to protect girls before they are sexually active*

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.

- Parents object that their daughters are not sexually active and are not at risk
NEJM (2008) 359;8: 863.
- When are girls sexually active?
- In BC, over 30% of girls are sexually active by the time they are 16 years old.
Immunize bc
- 20% of girls in grade 9 and 46% of those in grade 11 have had sexual intercourse
SOGC Canadian COnsensus guidelines 2007
- “half of Canada’s young women become sexually active by age 16”
CMAJ (2008) 179; 6: 503

Table 1

Number and percentage of 15- to 19-year-olds who had sexual intercourse at least once, by gender, age group and province, Canada excluding territories, 1996/1997, 2003 and 2005

	1996/1997		2003		2005	
	'000	%	'000	%	'000	%
Total	920	47*	862	45	868	43
Gender						
Males†	434	43	437	46	432	43
Females	486	51*‡	425	45	435	43
Age group						
15 to 17†	380	32	348	30	362	29
18 to 19	540	70‡	514	68‡	506	65‡
Province						
Newfoundland and Labrador	23	46	19	54‡	17	49
Prince Edward Island	4 ^E	37 ^E	5	52*	3	35
Nova Scotia	16 ^E	31*‡ ^E	29	49	29	49
New Brunswick	28 ^E	43 ^E	24	52*‡	19	43
Quebec	297	59‡	252	62‡	263	58‡
Ontario	269	41*‡	302	40‡	302	37‡
Manitoba	30	39‡	31	43	27	39
Saskatchewan	38 ^E	54	27	39‡	28	43
Alberta	82	44	80	39‡	77	39
British Columbia	133	47	93	37‡	103	40‡

Table 2

Number and percentage of 15- to 19-year-olds who had sexual intercourse before age 15 or at ages 15 and 16, by gender and age group, Canada excluding territories, 1996/1997, 2003 and 2005

Age when first had sexual intercourse	1996/1997		2003		2005	
	'000	%	'000	%	'000	%
Total						
Less than 15	230	12*	172	9	162	8
15 to 16	428	22	420	22	426	21
Gender						
Males						
Less than 15	104	11	87	9	80	8
15 to 16	194	20	206	22	215	22
Females						
Less than 15	126	13*	85	9	82	8
15 to 16	234	25	214	23	210	21

3. My daughter does not need this vaccine

Fact: *We want to protect girls before they are sexually active*

- Immunization programs vary across provinces (from age 9-14)
- **Grade 4** (age 8-9) and secondary 3rd of high school *Quebec*
- **Grade 5** (9-10) and **Grade 9** (13-14) *Alberta*
- **Grade 6** (age 10-11) *PEI*
- **Grade 7** (age 11-12) *Nova Scotia*
- **Grade 8** (age 12-13) *Ontario*
- **Grade 9** (age 13-14) *Newfoundland*

Access to the vaccine

- Lower rate of HPV vaccinations among several provinces that have the highest incidence of cervical cancer.
 - Nova Scotia, PEI and Alberta have the highest rates of cervical cancer in Canada, yet only 55% of females eligible for the vaccine are included in those provinces' vaccination programs
 - Quebec offers the most comprehensive immunization program against HPV, with 100 per cent of eligible females included, yet has the lowest cervical cancer rates in the country
 - Manitoba, only 32 % the target population of is getting the vaccine

3. My daughter does not need this vaccine

Fact: *We want to protect girls before they are sexually active*

- Immunization programs vary around the world
Other countries have not gone as low as 9
- *UK:* vaccine recommended 12-13 (Year 8). As well, one-off program to offer HPV vaccine to all girls born between 1st September 1990 and 31st August 1995 inclusive (girls aged 13-18)
- *US:* vaccine approved 9-26; recommended 11-12. National Advisory Committee on Immunizations Practices (also CDC)

4. There weren't any studies done in the group of girls (9-15)

- **Fact:** *There were studies in this age group that showed the immune response was very good - the girls made high levels of antibodies against HPV.*

- **What evidence is there that the HPV vaccine is effective in young girls in view of the fact that the vaccine has not been thoroughly studied in nine-to-15 year olds?**
- In clinical trials, pelvic examinations were conducted on women aged 15 -26 and clinical specimens were taken in order to assess the effectiveness of the vaccine.
- However, efficacy studies are not conducted in girls aged 9-13 because most are not sexually active so will not have acquired HPV and pelvic examination is not done in this age group

Public Health Agency of Canada 2009-01-06

4. There weren't any studies done in the group of girls (9-15)

- **Fact:** *There were studies in this age group that showed the immune response was very good - the girls made high levels of antibodies against HPV.*

- “Gardasil was approved based on four randomized double blind, placebo-controlled studies in 21 000 women aged 16-26.”
- “Relatively few girls (about 1200 aged 9-15 years) were enrolled in the clinical trials of Gardasil, the youngest of whom were followed for only 18 months...” CMAJ (2007) 177;5: 484.
- “although trials may enrol several thousand participants, this is often too few to detect rare serious adverse effects. This raises legitimate safety concerns among parents and potential recipients.” CMAJ (2008) 179;6: 503

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- **Fact:** *There were studies in this age group that showed the immune response was very good - the girls made high levels of antibodies against HPV.*

- “the only trials conducted in this cohort [preadolescents] have been on the immune response. The studies with clinical end points (i.e., CIN 2/3) involved 16- to 24-year-old women.” NEJM (2008) 359;8: 861-862.
- “Girls as young as nine were included in the safety and immunogenicity studies but not in the efficacy studies.” JLME (2008): 384-395
- Effectiveness: protects against HPV infection no proven protection against cervical cancer

5. We don't know how long the vaccine protection will last

- **Fact:** *Researchers predict that HPV vaccine protection will last for a least 15 years, and probably lifelong.*

- “Protection from HPV vaccine is expected to be long-lasting.”

Centers for Disease Control and Protection

- “...vaccinated people maintain high levels of protection for at least six years, and it is expected to last many years. ... If a booster dose of the vaccine is necessary later in life your daughter will be informed about this.” NHS *Beating cervical cancer Q&A*

5. We don't know how long the vaccine protection will last

- **Fact:** *Researchers predict that HPV vaccine protection will last for a least 15 years, and probably lifelong.*

- “The vaccine offers protection for at least 5.5 years, and studies are being performed to determine whether a booster dose will be required.” CMAJ (2007) 177;5: 462.
- How long does the immunity last? We do not know for sure. Research has tracked vaccinated girls for five years
SOGC
- Recent studies indicate good protection against HPV types in the vaccine for five years of follow-up. Studies are ongoing to determine if further immunization is needed for vaccinated women to have continued protection. Health Canada

8. This vaccine is really expensive – it's not worth it

Fact: *An HPV vaccine program is worth the investment.*

- In Canada the vaccine costs between \$400 and \$500 for the 3 required doses (\$135 per dose plus pharmacy fees)
- The real impact of HPV vaccination on cervical cancer will not be observable for decades NEJM (2008) 359;8821-832.
- “If protection of the vaccine wanes after 10 years, vaccination is much less cost-effective and screening is more effective than catch-up programs.” NEJM (2008) 359;8:861-862

8. This vaccine is really expensive – it's not worth it

Fact: *An HPV vaccine program is worth the investment.*



- The biggest problem in cervical cancer prevention is the failure of women to have regular cervical screening
- “Dr. Andrew Lynk, a pediatrician in Sydney, said about half of the women who get cervical cancer in Nova Scotia have never had a Pap smear or haven't had one recently, so he wonders if a vaccine is the best route.”
- “‘Maybe a better way to do this is to spend that \$2.8 million and hire 40 nurses and go looking for those people and track them down who aren't getting their Pap smears,’ said Lynk.”

10. The vaccine causes serious side effects.

- **Fact:** *While serious events have been reported following the receipt of HPV vaccine, there is no conclusive evidence linking them to the vaccine.*



SOURCE	MERCK FROST
Pain at injection site	•
Swelling at injection site	•
Itching at injection site	•
Redness at injection site	•
Fever	•
Nausea	•
Dizziness	•
Headache	•
Vomiting	•
Fainting	•
Minor allergic reaction	•
Bronchospasm	•
Swollen glands	•
Guillain-Barre syndrome	•
Anaphylactic reaction	•
Puritus	•
Diarrhea	•
Erythema	•
Gastroenteritis	•

SOURCE	MERCK FROST	NACI
Pain at injection site	●	●
Swelling at injection site	●	●
Itching at injection site	●	
Redness at injection site	●	●
Fever	●	●
Nausea	●	●
Dizziness	●	●
Headache	●	●
Vomiting	●	
Fainting	●	
Minor allergic reaction	●	*
Bronchospasm	●	●
Swollen glands	●	
Guillain-Barre syndrome	●	
Anaphylactic reaction	●	*
Puritus	●	●
Diarrhea	●	●
Erythema	●	●
Gastroenteritis	●	●
Hypertension		●
Vaginal hemorrhage		●
Injection site movement impairment		●

*Denotes a risk of which the source denies there is supporting evidence.

SOURCE	MERCK FROST	NACI	B.C.
Pain at injection site	●	●	●
Swelling at injection site	●	●	●
Itching at injection site	●		
Redness at injection site	●	●	●
Fever	●	●	●
Nausea	●	●	
Dizziness	●	●	
Headache	●	●	●
Vomiting	●		
Fainting	●		
Minor allergic reaction	●	*	
Bronchospasm	●	●	
Swollen glands	●		
Guillain-Barre syndrome	●		
Anaphylactic reaction	●	*	
Puritus	●	●	
Diarrhea	●	●	
Erythema	●	●	
Gastroenteritis	●	●	
Hypertension		●	
Vaginal hemorrhage		●	
Injection site movement impairment		●	
Anaphylaxis			●

* Denotes a risk of which the source denies there is supporting evidence.

SOURCE	MERCK FROST	NACI	B.C.	NOVA SCOTIA
Pain at injection site	•	•	•	•
Swelling at injection site	•	•	•	•
Itching at injection site	•			
Redness at injection site	•	•	•	•
Fever	•	•	•	•
Nausea	•	•		
Dizziness	•	•		
Headache	•	•	•	•
Vomiting	•			
Fainting	•			•
Minor allergic reaction	•	*		
Bronchospasm	•	•		
Swollen glands	•			
Guillain-Barre syndrome	•			•
Anaphylactic reaction	•	*		
Puritus	•	•		
Diarrhea	•	•		•
Erythema	•	•		
Gastroenteritis	•	•		
Hypertension		•		
Vaginal hemorrhage		•		
Injection site movement impairment		•		
Anaphylaxis			•	
Serious allergic reaction				•
Chills				•
Body aches				•
Sore joints				•
Swollen joints				•
Lightheadedness				•
Decreased energy				•

* Denotes a risk of which the source denies there is supporting evidence.

SOURCE	MERCK FROST	NACI	B.C.	NOVA SCOTIA	MacLEAN'S
Pain at injection site	•	•	•	•	
Swelling at injection site	•	•	•	•	
Itching at injection site	•				
Redness at injection site	•	•	•	•	
Fever	•	•	•	•	•
Nausea	•	•			
Dizziness	•	•			
Headache	•	•	•	•	•
Vomiting	•				
Fainting	•			•	•
Minor allergic reaction	•	*			
Bronchospasm	•	•			
Swollen glands	•				
Guillain-Barre syndrome	•			•	•
Anaphylactic reaction	•	*			
Puritus	•	•			
Diarrhea	•	•		•	
Erythema	•	•			
Gastroenteritis	•	•			
Hypertension		•			
Vaginal hemorrhage		•			
Injection site movement impairment		•			
Anaphylaxis			•		
Serious allergic reaction				•	
Chills				•	
Body aches				•	
Sore joints				•	
Swollen joints				•	
Lightheadedness				•	
Decreased energy				•	
Neck ache					•
Back pain					•
Mobility impairment					•
Seizures					•
Mild paralysis					•
Death (blood clot)					•
Unknown potential risks					•

*Denotes a risk of which the source denies there is supporting evidence.

10. The vaccine causes serious side effects.

- **Fact:** *While serious events have been reported following the receipt of HPV vaccine, there is no conclusive evidence linking them to the vaccine.*

- HPV vaccine does not appear to cause any serious side effects. However, a vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. The risk of **any** vaccine causing serious harm, or death, is extremely small.

- Life-threatening allergic reactions from vaccines are very rare. If they do occur, it would be within a few minutes to a few hours after the vaccination. Like all vaccines, HPV vaccine will continue to be monitored for unusual or severe problems.

Centers for Disease Control and Prevention

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- Very rarely, some people have an allergic reaction soon after immunisation. This reaction may be a rash or itching affecting part or all of the body. NHS Beating cervical cancer Q&A
- Even more rarely, people can have a severe reaction, within a few minutes of the injection with breathing difficulties and collapse. NHS Beating cervical cancer Q&A

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- Researchers compared the occurrence of severe allergic reactions among 114,000 young women who had received Gardasil in 2007 with the rate among women of similar age who had received other vaccines.
- “Based on the number of confirmed cases, the estimated rate of anaphylaxis ... was significantly higher than identified in comparable school-based delivery of other vaccines.”
- “anaphylaxis due to vaccination is rare, with an estimated incidence of 0.1–1 per 100 000 doses.”
- With Gardasil “2.6 cases of anaphylaxis per 100 000 doses. ... no cases of anaphylactic shock. All of the girls recovered completely, usually rapidly after receiving epinephrine.”

CMAJ (2008) 179;6: 525-533

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- **Fact:** *While serious events have been reported following the receipt of HPV vaccine, there is no conclusive evidence linking them to the vaccine.*

- Ten hospitalizations following HPV immunization have been reported to date in Canada. One incident was found to be clearly linked the administration of the vaccine; in this case, the person fainted after receiving the vaccine and hit her head.
- One adverse event was found to be possibly related to the vaccine, and another two are pending scientific review.
- There has been a single report of Guillain-Barré Syndrome (GBS) following HPV immunization in Canada, resulting in a hospitalization.

Public Health Agency of Canada 2009-01-06

Lessons learned

- Need to be able to trust health information provided
- Information needs to be:
 - Accurate, respectful, and complete
 - Acknowledge complexity, gaps
 - Current (with a commitment to update information as it becomes available)
 - Attentive to sociodemographic disparities
- Coordinated pan-Canadian approach
 - harmonised policies and practices

