A simple question?

- If there was a vaccine that could prevent over 30,000 cases of cancer per year*, which would be your biggest worry?
  - How do we make and stock enough vaccine for the overwhelming demand that would arise for a product that can prevent cancer?

  or

  - How do we convince people that the vaccine is safe and effective so that coverage rates are greater than 43% after 11 years of availability?

*in the US; ~600,000 annual cases globally

Addressing HPV Vaccine Hesitancy and Myths

Robert A. Bednarczyk, PhD

May 17, 2018

New Jersey Immunization Conference

Disclosures

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- Portions of this presentation have been previously presented at Emory University, the American Society for Colposcopy and Cervical Pathology, the University of Calgary Pediatric Infectious Disease Conference, Georgia and Florida chapters of the AAP, Columbus GA Midtown Medical Center, the Texas Immunization Conference, and the Finger Lakes and Western NY Immunization Conferences.

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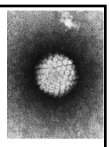
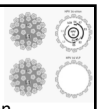
Brief Review:
HPV, HPV Vaccines, and Vaccine Uptake

Human Papillomavirus (HPV)



- Ubiquitous virus with specific tropism for epithelial cells
- Most commonly spread through sexual contact
- Cause of anogenital cancers (~27,000 new cases/year) and genital warts (~350,000 new cases/year)

HPV Vaccines



- Virus-like particle (VLP) vaccine
- Currently available as 9-valent vaccine, offering protection against HPV types responsible for 90% of cervical cancer and 90% of genital warts
- Recommended for 11-12 year old adolescents
  - If vaccinated <15 years of age, 2 doses – 6 months apart
  - If vaccinated >=15 years of age, 3 doses

The New York Times nytimes.com

June 30, 2006

Panel Unanimously Recommends Cervical Cancer Vaccine for Girls 11 and Up

← 2006

'Unacceptably Low' Numbers of Adolescents Getting HPV Vaccine, CDC Reports

2008 →

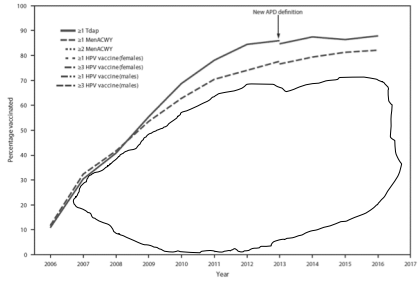
← 2014

HPV Vaccine Has Reached Quarter Of Teenage Girls In US

Beth Greenfield
Senior Writer
Jul 24, 2014
Follow

http://www.medicalnewstoday.com/articles/125013.php
http://www.nytimes.com/2006/06/30/health/30vaccine.html?_r=0
https://www.yahoo.com/health/unacceptably-low-numbers-of-adolescents-getting-hpv-92746576792.html

HPV vaccine uptake and acceptability



Walker et al.
MMWR 2017

Why is HPV vaccine coverage so low?

http://www.realclearscience.com/blog/2014/09/how_to_spread_misinformation.html

If you know yourself but not the enemy, for every victory gained you will also suffer a defeat.

Sun Tzu, The Art of War

MYTH 1: HPV VACCINES ARE NOT EFFECTIVE

HPV vaccines are not effective?

New Evidence Demolishes Claims of Safety and Effectiveness of HPV Vaccine

October 16, 2012 | 303,202 views | Disponible en Español

13.4K SHARES

Oncology Dietitian Exposes Fraud in CDC's HPV Vaccine Effectiveness Study

July 16, 2013 | 940,644 views | Disponible en Español

57.3K SHARES

http://articles.mercola.com/sites/articles/archive/2013/07/16/hpv-vaccine-effectiveness.aspx
http://articles.mercola.com/sites/articles/archive/2012/10/16/unproven-hpv-vaccine-safety.aspx

HPV vaccines are effective!

- Vaccine type HPV (6,11,16,18) prevalence
  - Among 14-19 year olds in US:
    - 2003 – 2006: 11.5% (95% CI: 9.2-14.4%)
    - 2007 – 2010: 5.1% (95% CI: 3.8-6.6%)
  - Among sexually active 14-19 year olds in US:
    - 2003 – 2006: 19.4% (95% CI: 15.7-23.8%)
    - 2007 – 2010: 9.0% (95% CI: 6.5-12.2%)
      - Prevalence in vaccinated females: 3.5% (95% CI: 1.4-6.6%)

Markowitz et al. J Infect Dis 2013;208(3):385-93.

HPV vaccines are effective!

TABLE 4. Per-protocol efficacy for prevention of human papillomavirus vaccine-type disease outcomes among females in trials of the bivalent and quadrivalent human papillomavirus vaccines, end-of-study analyses

	Vaccine		Control		Vaccine efficacy	
Vaccine/Endpoint related type	No.	Cases	No.	Cases	%	(95% CI)
Quadrivalent vaccine*						
CIN2/3 or AIS†						
HPV 6, 11, 16, 18	7,864	2	7,865	110	98.2	(93.3–99.8)
HPV 16	6,647	2	6,455	81	97.6	(91.1–99.7)
HPV 18	7,382	0	7,316	29	100.0	(86.6–100.0)
VIN/VaIN2/3†						
HPV 6, 11, 16, 18	7,900	0	7,902	23	100.0	(82.6–100.0)
HPV 16	6,654	0	6,467	17	100.0	(76.5–100.0)
HPV 18	7,414	0	7,343	2	100.0	(<0–100.0)
Genital warts§						
HPV 6 and/or 11	6,718	2	6,647	186	98.9	(96.1–99.9)
Bivalent vaccine¶						
CIN2/3 or AIS						
HPV 16 and/or 18	7,338	5	7,305	97	94.9	(87.7–98.4)
HPV 16	6,296	2	6,160	81	97.6	(91.0–99.7)
HPV 18	6,789	3	6,739	23	87.1	(57.2–97.5)

Markowitz LE, et al. MMWR Morbid Mortal Wkly Rep 2014;63(RR-5):1-36.

HPV vaccines are effective!

TABLE 5. Per-protocol efficacy of quadrivalent human papillomavirus vaccine for prevention of HPV 6-, 11-, 16-, and 18-related disease among males aged 16–26 years*

	Vaccine		Control		Vaccine efficacy	
Endpoint	No.	Cases	No.	Cases	%	(95% CI)
Genital warts†	1,397	3	1,408	28	89.4	(65.5–97.9)
PIN†	1,397	0	1,408	3	100.0	(-141.2–100.0)
AIN 1/2/3§	194	5	208	24	77.5	(39.6–93.3)
AIN2/3§	194	3	208	13	74.9	(8.8–95.4)

Markowitz LE, et al. MMWR Morbid Mortal Wkly Rep 2014;63(RR-5):1-36.

HPV vaccines are effective!

- Genital warts are a good model for early effectiveness
- HPV4 coverage in 12-13 year old Australians:
  - Dose 1: 83%
  - Dose 2: 80%
  - Dose 3: 73%

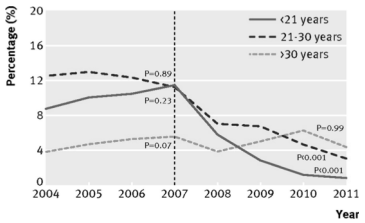


Fig 1 Proportion of Australian born women diagnosed as having genital warts at first visit, by age group, 2004-11

Ali H, et al. BMJ 2013;346:f2032.

HPV vaccines are effective (at herd immunity)!

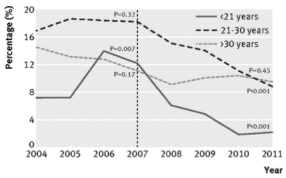


Fig 3 Proportion of Australian born heterosexual *men diagnosed as having genital warts* at first visit, by age group, 2004-11

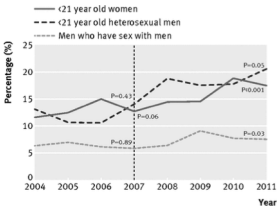
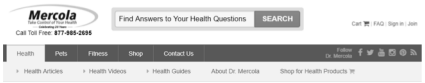


Fig 5 Proportion of Australian born women aged under 21 years, heterosexual men aged under 21 years, and men who have sex with men who tested positive for *chlamydia* at first visit, 2004-11

Ali H, et al. BMJ 2013;346:f2032.

MYTH 2: THERE'S NO EVIDENCE THAT HPV VACCINE PREVENTS CANCER…AND WE HAVE PAP SMEARS THAT DO…



Don't Give HPV Vaccine to Your Daughter – Despite What Your Doctor Says

- "Gardasil is NOT a cancer vaccine. It is simply a vaccine for two strains of human papillomaviruses (HPVs) that in some instances can lead to cancer in some women (Gardasil's other two HPV strains are for genital warts, which don't cause cancer)."
- "According to Merck's package insert on Gardasil, the end-point in its clinical trials for the vaccine's efficacy, or effectiveness, was NOT cancer, but instead was the presence, or non-presence, of vaccine-relevant pre-cancerous lesions (CIN 2/3). There is **absolutely no proof, and no clinical trials** that show Gardasil protects against cancer in the long-term."

https://articles.mercola.com/sites/articles/archive/2010/11/05/gardasil-vaccine-is-a-flop-for-good-reasons.aspx

Thursday, September 26, 2013

Another Doctor Testifies: 'HPV Vaccine Does Not Protect Against Cancer'

Melissa Melton
Activist Post

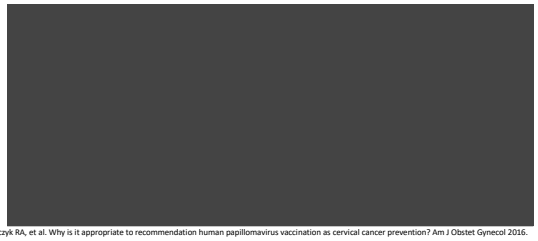
Yet another doctor is speaking out publicly about the fact that the HPV vaccine does not actually prevent cancer.

Leading OBGYN Dr. Uzi Beller, described as "an international authority on gynecological cancers who treats patients on a daily basis" was recently quoted in the Jerusalem Post:

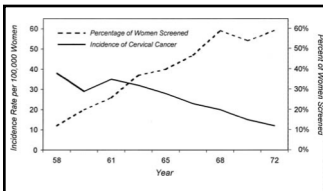
> If HPV vaccine ... were proven to prevent cervical cancer, that would be something else. But it hasn't. The US Food and Drug Administration checks for safety of the vaccine, but not for efficacy. There is no evidence that the vaccine protects against cervical cancer, only [that it] counters the virus itself. No decrease in invasive cervical cancer ... in the vaccinated population has been documented so far. [emphasis added]

http://www.activistpost.com/2013/09/another-doctor-testifies-hpv-vaccine.html

A



Bednarczyk RA, et al. Why is it appropriate to recommendation human papillomavirus vaccination as cervical cancer prevention? Am J Obstet Gynecol 2016.

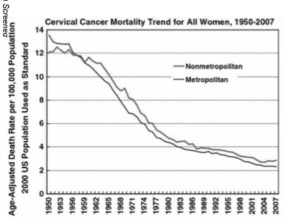


Wright TC, Ferenczy A, Kurman RJ: Carcinoma and other tumors of the cervix. In Kurman R (ed): Blavstein's Pathology of the Female Genital Tract. 5th ed. New York, Springer-Verlag, 2002.

Impact of pap smears

← Incidence

Mortality →



Singh GK. J Comm Health 2012;37(1):217-33.

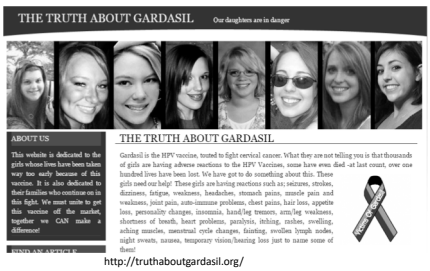
http://www.healthindicators.gov/Indicators/Pap-test-women-18-percent_115/Profile/Map

Pap smears are <u>not</u> the only way to prevent cancer

- HPV vaccination is primary prevention
- Pap smears are secondary prevention
  - Even with reductions in cervical cancer, what about other HPV-related diseases:
    - Anal, oropharyngeal, penile, vaginal, vulvar cancers
    - Genital warts

MYTH 3: HPV VACCINES ARE NOT SAFE OR TESTED ENOUGH

HPV vaccines are not safe?



http://truthaboutgardasil.org/

HPV vaccines are not safe?

http://www.nvic.org/NVIC-Vaccine-News/July-2009/Preventing-Gardasil-Vaccine-Injuries-Deaths.aspx

Preventing Gardasil Vaccine Injuries & Deaths

Posted: 7/14/2009 9:00:00 PM | with 67 comments

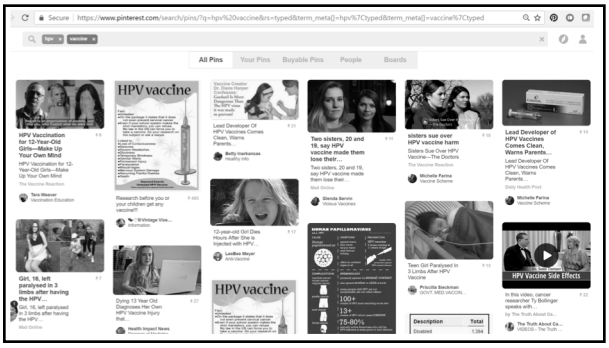
Fast-Tracked Vaccine

Gardasil vaccine was fast tracked to licensure by the Food and Drug Administration in 2006.[2] It contains genetically engineered virus-like protein particles (VLPs) and aluminum,[3,4,5] which affect immune function.[6,7,8] The exact mechanism of protection is unknown and the vaccine has not been evaluated for the potential to cause cancer or be toxic to the genes.[10]

It is a vaccine that, by the summer of 2009, already caused more than 15,000 thousand reports of vaccine reactions, including more than 3,000 injuries and 48 deaths.[11] 14 of the girls who died after getting Gardasil were under age 16 just like Gabrielle.

HPV Vaccines are not safe?

http://www.naturalnews.com/047024_HPV_vaccine_Gardasil_Geoffrey_Swain.html



HPV vaccines are safe and tested!

- Clinical trials (N = 10s of thousands)
  - Local and systemic reactions similar between HPV4 and placebo
    - Most common: headache, fever, nausea, dizziness; injection site pain, bruising, erythema, pruritus, and swelling
    - Autoimmune disease incidence similar in HPV4 and placebo recipients (2.3% in females, 1.5% in males)

HPV vaccines are safe and tested!

- **600,558** doses of HPV4 evaluated through the Vaccine Safety Datalink
- Outcomes
  - Guillain-Barré Syndrome
  - Stroke
  - Venous thromboembolism
  - Appendicitis
  - Seizure
  - Syncope
  - Allergic reaction
  - Anaphylaxis

No statistically significant associations between HPV4 receipt and outcome

Gee J, et al. Vaccine 2011;29(46):8279-84

HPV vaccines are safe and tested!

- Two assessments at Kaiser Permanente California
  - **346,972** HPV doses evaluated
  - Study 1: General safety assessment
    - Syncope on day of vaccination and skin infections w/in 2 weeks
    - No other safety signals detected
  - Study 2: 16 pre-specified autoimmune conditions
    - No confirmed signals for monitored conditions

Klein NP, et al. Arch Pediatr Adolesc Med 2012;166:1140-8
Chao C, et al. J Intern Med 2012;271:193-203

HPV vaccines are safe and tested!

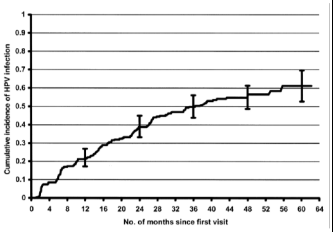
- Denmark and Sweden Health Registry – 2 studies
  - 997,585 adolescent girls aged 10-17 years
    - Evaluated 23 autoimmune conditions, 5 neurologic conditions, and VTE
    - Three significantly elevated risks identified – Bechet's syndrome, Raynaud's Disease, Type 1 diabetes
  - 3,126,790 adult women aged 18-44 years
    - Evaluated 45 autoimmune and neurological conditions
    - One significantly elevated risk identified when controlling for multiple comparisons – Celiac disease
  - No consistent patterns in AE development, and unmasking was a plausible explanation for these findings

Arnheim-Dahlsrom L, et al. BMJ 2013;347:f5906.

MYTH 4: HPV VACCINES ARE NOT NECESSARY – PEOPLE CLEAR HPV INFECTIONS

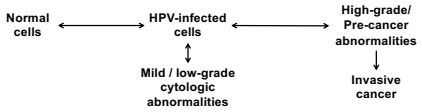
Most HPV infections are cleared anyway

- Incident HPV infection is common after initiation of sexual activity
  - 39% cumulative incidence by 2 years
  - Median time to clearance: 8 months
    - 70% resolved by 12 months
    - 91% resolved by 24 months



Winer RL, et al. Am J Epidemiol 2003;157:218-26. Ho GF, et al. NEJM 1998;338:423-8.

HPV Natural History



Adapted from Figure 1 of Schiffman M, Kjaer SK. *J Natl Cancer Inst Monogr.* 2003(31):14-19.

Natural History of Cervical Intraepithelial Neoplasia Lesions

	Regression (%)
CIN 1	57
CIN 2	43
CIN 3	32

Östör AG. Natural history of cervical intraepithelial neoplasia: A critical review. Int J Gynecol Path 1993;12:186-92.

A large number of HPV infections are <u>not</u> cleared

- ~10.6M females aged 20-24 (2010)
  - HPV4 Vaccine-type infection prevalence: 19.9%
    - 2.1 M females 20-24 with a prevalent vaccine-type infection
  - 91% of infections cleared by the immune system within 2 years
    - 193,000+ with infections that persist > 2 years

https://www.census.gov/prod/cen2010/briefs/c2010br-03.pdf

MYTH 5: VACCINATING PRE-TEENS WILL TELL THEM IT'S OKAY TO HAVE SEX

11-12 years is too young to vaccinate?

- Because HPV is a sexually transmitted virus, concerns have been raised about the recommended age of vaccination
  - Concerns often expressed about "what message will this send"

Dina Rickman
Dina.Rickman@huffingtonpost.com

Cervical Cancer Jab 'Gives Youngsters Green Light For Promiscuity', Charity LIFE Says

Posted: 25/07/2012 13:52 BST | Updated: 25/07/2012 13:52 BST

Catholic school refuses to promote promiscuity via HPV vaccination

http://www.huffingtonpost.co.uk/2012/07/24/hpv-vaccine-green-light-promiscuity-government-advisers_n_1697840.html
http://blogs.telegraph.co.uk/news/geraldwarner/5296955/Catholic_school_refuses_to_promote_promiscuity_via_HPV_vaccination/

11-12 years is too young to vaccinate?

- Parent
  - "It's like blaming a kid before they even get a chance to do anything."
- Provider
  - "I'd honestly say it's rare that I spend more than 20 seconds on it at 11…So few 11 year olds are physically mature to be sexually active that it's, I find it's almost sort of an awkward conversation."
  - "I rarely give it at 11 or 12. I most commonly give it in the like 8th, 8th to 10th grade range when sexual activity would put them at risk, rather than just an age. This is what I tell parents: it's very different than other vaccines because you can quantify your risk."

Perkins RB, et al. Pediatrics 2014;doi: 10.1542/peds.2014-0442

June 30, 2008

Alberta Bishops' statement on Gardasil vaccine

So-called "casual" or "recreational" sexual activity carries with it profound risks to a young person's spiritual, emotional, moral and physical health. We note that, at best, a vaccine can only be potentially effective against one of these risks, that to physical health, and may have other unintended and unwanted consequences.

Secondly, although school-based immunization delivery systems generally result in high numbers of students completing immunization, a school-based approach to vaccination sends a message that early sexual intercourse is allowed, as long as one uses "protection."

http://hugyourkids.org/correspondence/HPV%20Alberta%20Bishops'%20Letter.pdf

11-12 years is NOT too young to vaccinate!

- Cohort study of 1,398 girls
  - Received HPV or other vaccines at 11-12 years of age
  - Followed for up to 3 years
    - Monitored for pregnancy or STI testing/diagnosis or contraceptive counseling

Unadjusted incidence rate and rate difference

	HPV vaccine exposed (N = 493)	HPV vaccine unexposed (N = 905)	HPV vaccine exposed versus HPV vaccine unexposed	
Outcome	IR (/100 py)	IR (/100 py)	IRD (95% CI) (/100 py)	aIRR (95% CI)
Test/Dx/ Counsel	5.51	3.91	1.61 (-0.03, 3.24)	1.29 (0.92, 1.80)
Diagnosis Only	0.26	0.25	0.01 (-0.35, 0.38)	1.11 (0.26, 4.64)

Bednarczyk et al. Pediatrics 2012;130:798-805.

Study sparks renewed push for Calgary Catholic trustees to allow HPV vaccine in schools 17

BY BILL KAUFMANN ,CALGARY SUN
FIRST POSTED: MONDAY, OCTOBER 15, 2012 02:42 PM MDT | UPDATED: TUESDAY, OCTOBER 16, 2012 09:11 AM MDT

http://www.calgarysun.com/2012/10/15/study-sparks-renewed-push-for-calgary-catholic-trustees-to-allow-hpv-vaccine-in-schools

Calgary Bishop Fred Henry backs policy review for HPV vaccinations in separate schools 94

BY BILL KAUFMANN ,CALGARY SUN
FIRST POSTED: THURSDAY, OCTOBER 25, 2012 03:58 PM MDT | UPDATED: THURSDAY, OCTOBER 25, 2012 04:08 PM MDT

http://www.calgarysun.com/2012/10/25/calgary-bishop-fred-henry-backs-policy-review-for-hpv-vaccinations-in-separate-schools

Calgary Catholic School District approves controversial HPV vaccinations 148

BY DAMIEN WOOD ,CALGARY SUN
FIRST POSTED: WEDNESDAY, NOVEMBER 28, 2012 07:36 PM MST | UPDATED: THURSDAY, NOVEMBER 29, 2012 08:16 AM MST

http://www.calgarysun.com/2012/11/28/calgary-catholic-school-district-approves-controversial-hpv-vaccinations

<7 Weeks

Limitations of this study

- Relatively small sample size
  - Sufficient power to detect a IRR of 1.5 (*a priori* power estimate based on known vaccine coverage of cohort)
- Only included 11-12 year olds who received at least one adolescent vaccine
- One managed care organization in one local geographic area
- Little ability to assess potential "confounding by indication"
  - Higher risk populations seeking vaccination more often which can bias results to show association

CMAJ Smith LM, et al. CMAJ 2015;187(2):E74-E81 RESEARCH

Effect of human papillomavirus (HPV) vaccination on clinical indicators of sexual behaviour among adolescent girls: the Ontario Grade 8 HPV Vaccine Cohort Study

Leah M. Smith MSc, Jay S. Kaufman PhD, Erin C. Strumpf PhD, Linda E. Lévesque PhD

- Exposure:
  - Program: In 8th grade either in (a) two school years before HPV vaccine program and (b) two school years after HPV vaccine program
  - Vaccine: receipt of HPV vaccine
- Outcomes: Pregnancy and non-HPV STI
  - Diagnosed in Grade 10-12 school years

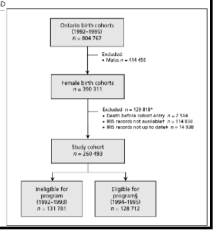


Table 2: Cumulative risk of outcomes, according to eligibility for Ontario's quadrivalent human papillomavirus vaccination program and birth year

	Program eligibility; birth year; no. (%) of participants				
	Ineligible		Eligible		
Clinical indicator of sexual behaviour	1992 (*n* = 66 653)	1993 (*n* = 65 128)	1994 (*n* = 64 818)	1995 (*n* = 63 894)	Total (*n* = 260 493)
Composite outcome	4 203 (6.3)	4 032 (6.2)	3 801 (5.9)	3 405 (5.3)	15 441* (5.9)
Pregnancy	2 854 (4.3)	2 658 (4.1)	2 476 (3.8)	2 199 (3.4)	10 187 (3.9)
STIs	1 609 (2.4)	1 653 (2.5)	1 541 (2.4)	1 456 (2.3)	6 259 (2.4)

STI = sexually transmitted infection.
*This number is smaller than the sum of the 2 subsequent rows (for pregnant participants and those with sexually transmitted infections not related to human papillomavirus) because some cohort members had both outcomes.

Table 3: Effect of quadrivalent human papillomavirus vaccination on clinical indicators of sexual behaviour*

Outcome	No. of excess cases per 1000 girls (95% CI)	RR (95% CI)	Adjusted† RR (95% CI)
Effect of vaccine			
Composite outcome	−0.61 (−10.71 to 9.49)	0.96 (0.81 to 1.14)	0.98 (0.84 to 1.14)
Pregnancy	0.70 (−7.57 to 8.97)	0.99 (0.79 to 1.23)	1.00 (0.83 to 1.21)
STIs	−4.92 (−11.49 to 1.65)	0.81 (0.62 to 1.05)	0.81 (0.63 to 1.04)
Effect of program			
Composite outcome	−0.25 (−4.35 to 3.85)	0.99 (0.93 to 1.06)	1.00 (0.93 to 1.07)
Pregnancy	0.29 (−3.07 to 3.64)	1.00 (0.92 to 1.09)	1.01 (0.93 to 1.10)
STIs	−2.00 (−4.67 to 0.67)	0.92 (0.83 to 1.03)	0.92 (0.83 to 1.03)

Smith LM, et al. CMAJ 2015;187(2):E74-E81

Original Investigation

Incidence of Sexually Transmitted Infections After Human Papillomavirus Vaccination Among Adolescent Females

Anupam B. Jena, MD, PhD; Dana P. Goldman, PhD; Seth A. Seabury, PhD

Jena AB, et al. JAMA Intern Med 2015;175:617-23.

- 12-18 year old girls in large insurance database (41 employers nationally)
  - Data from January 1, 2005 to December 31, 2010
- Outcomes: any medical claim for:
  - Chlamydia
  - Gonorrhea
  - Herpes
  - HIV/AIDS
  - Syphilis

Remember "Confounding by Indication"?

Table 2. Change in STI Rates After HPV Vaccination in Vaccinated Females vs Matched Nonvaccinated Females

Vaccination Status	Total No. of Females	Year After HPV Vaccination		
		Unadjusted STI Rate, No. (Rate per 1000)	OR (95% CI) [P Value]	
			Unadjusted	Adjusted
Full Sample				
Vaccinated	21 610	147 (6.8)	1.63 (1.37-1.94) [<.001]	1.50 (1.25-1.79) [<.001]
Nonvaccinated	186 501	781 (4.2)		
Females Aged 12-14 Years				
Vaccinated	9024	33 (3.7)	1.63 (1.12-2.36) [.01]	1.53 (1.05-2.22) [.03]
Nonvaccinated	81 797	184 (2.2)		
Females Aged 15-18 Years				
Vaccinated	12 586	114 (9.1)	1.59 (1.30-1.95) [<.001]	1.49 (1.21-1.83) [<.001]
Nonvaccinated	104 704	597 (5.7)		

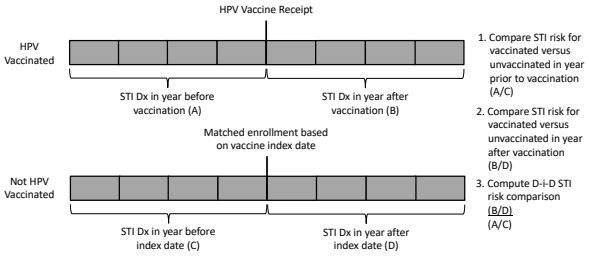
- If you do not account for population-level differences in risk between vaccinated and unvaccinated, before vaccination, you miss the potential for confounding by indication.

Jena AB, et al. JAMA Intern Med 2015;175:617-23.

Accounting for baseline difference in risk

- Difference-in-difference analysis of HPV vaccinated females compared to matched unvaccinated females (all aged 12-18)
  - D-i-D can account for baseline levels of sexual activity and possible confounding by indication

Difference in Difference Analysis



1. Compare STI risk for vaccinated versus unvaccinated in year prior to vaccination (A/C)
2. Compare STI risk for vaccinated versus unvaccinated in year after vaccination (B/D)
3. Compute D-i-D STI risk comparison (B/D) (A/C)

Jena AB, et al. JAMA Intern Med 2015;175:617-23.

Table 2. Change in STI Rates After HPV Vaccination in Vaccinated Females vs Matched Nonvaccinated Females

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Vaccinated	12 586	114 (9.1)	1.59 (1.30-1.95) [<.001]	1.49 (1.21-1.83) [<.001]
Nonvaccinated	104 704	597 (5.7)		

- Overall, no difference in sexual activity after HPV vaccination, when accounting for prior year sexual activity outcomes
  - Similar results seen when restricted to females prescribed hormonal birth control

Jena AB, et al. JAMA Intern Med 2015;175:617-23.

MYTH 6: 11-12 YEARS IS TOO YOUNG TO VACCINATE. IT WON'T LAST LONG ENOUGH

11-12 years is NOT too young to vaccinate!

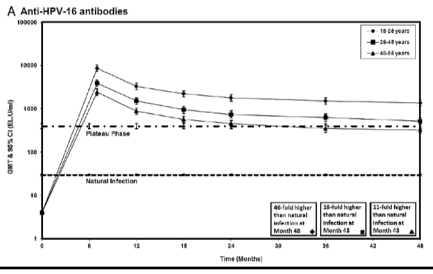
TABLE 6. Geometric mean antibody titers after quadrivalent HPV vaccine among females and males aged 9–15 and 16–26 years, one month after third dose (per-protocol immunogenicity population)*

	Females aged 9–15 years				Females aged 16–26 years			
Assay (cLIA)	No.	GMT (mMU/mL)	(95% CI)	Seropositivity %	No.	GMT (mMU/mL)	(95% CI)	Seropositivity %
Anti-HPV 6	917	929	(875–987)	99.9	3,329	545	(530–560)	99.8
Anti-HPV 11	917	1,305	(1,225–1,390)	99.9	3,353	749	(726–773)	99.8
Anti-HPV 16	915	4,919	(4,557–5,309)	99.9	3,249	2,409	(2,309–2,514)	99.8
Anti-HPV 18	922	1,043	(968–1,123)	99.8	3,566	475	(459–492)	99.4
	Males aged 9–15 years				**Males aged 16–26 years**			
Assay (cLIA)	No.	GMT (mMU/mL)	(95% CI)	Seropositivity %	No.	GMT (mMU/mL)	(95% CI)	Seropositivity %
Anti-HPV 6	884	1,038	(963–1,117)	99.9	1,093	448	(419–479)	98.9
Anti-HPV 11	885	1,387	(1,298–1,481)	99.9	1,093	624	(588–662)	99.2
Anti-HPV 16	882	6,056	(5,601–6,549)	99.8	1,136	2,403	(2,243–2,575)	98.8
Anti-HPV 18	887	1,357	(1,249–1,475)	99.8	1,175	403	(375–433)	97.4

Markowitz LE, et al. MMWR Morbid Mortal Wkly Rep 2014;63(RR-5):1-36.

HPV Antibody Persistence

Schwarz TF, et al. Human Vaccines 2011;7(9):958-65.



Long-term follow-up

Table 2. Vaccine Effectiveness Against Human Papillomavirus (HPV) 6/11/16/18-Related Cervical Intraepithelial Neoplasia, Vulvar Cancer, and Vaginal Cancer Among Women Receiving Quadrivalent HPV Vaccine at the Start of the Baseline Study: Per-Protocol Efficacy Population

Endpoint	n	Number of Cases	Person-Years at Risk	Incidence Rate per 100 Person-Years at Risk (95% Confidence Interval)	Vaccine Effectiveness (%)
Human papillomavirus 6/11/16/18-related CIN, vulvar cancer, and vaginal cancer	2236	1	15242.4	0.0 (0.0, 0.0)	100
By time since day 1 of base study					
4 years or less	2169	0	9076	0.0 (0.0, 0.4)	
>4 to 6 years	2273	0	4511.5	0.0 (0.0, 0.1)	
>6 to 8 years	2302	1	4367.4	0.0 (0.0, 0.1)	
>8 to 10 years	2111	0	3760.7	0.0 (0.0, 0.1)	
>10 to 12 years	1495	0	1671.8	0.0 (0.0, 0.2)	
>12 to 14 years	140	0	23.0	0.0(0.0, 16.0)	
By lesion type					
CIN 1	2126	1	14070.9	0.0 (0.0, 0.0)	
CIN 2 or worse	2126	0	14070.9	0.0 (0.0, 0.0)	
CIN 2	2126	0	14070.9	0.0 (0.0, 0.0)	
CIN 3 or worse	2126	0	14070.9	0.0 (0.0, 0.0)	
CIN 3	2126	0	14070.9	0.0 (0.0, 0.0)	
Adenocarcinoma in situ	2126	0	14070.9	0.0 (0.0, 0.0)	
Cervical cancer	2126	0	52479	0.0 (0.0, 0.0)	
Vulvar cancer	2276	0	15215.9	0.0 (0.0, 0.0)	
Vaginal cancer	2276	0	15215.9	0.0 (0.0, 0.0)	

Kjaer SK, et al. Clin Infect Dis 2017.

Resources

- Centers for Disease Control and Prevention: https://www.cdc.gov/hpv/
- National HPV Vaccination Roundtable: https://www.cancer.org/health-care-professionals/national-hpv-vaccination-roundtable.html
- Vaccine Safety Datalink publications: https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vsd/publications.html
- Cervivor (cervical cancer survivor advocacy group): http://cervivor.org/
- Someone You Love (HPV movie): http://www.hpvepidemic.com/
- Lady Ganga (Nilza's Story) – advocacy video: https://www.youtube.com/watch?v=u5yMCzx0ctU

Thank you!

Any questions?

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