Together We Can Prevent HPV-Related Cancers

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Health

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The learner should be able to:

- 1. Discuss latest trends in HPV disease prevalence and prevention.
- 2. Employ evidence-based techniques for increasing HPV vaccination rates in your own practice.
- 3. Apply useful & compelling communication strategies and practical tips to inform parents about HPV.



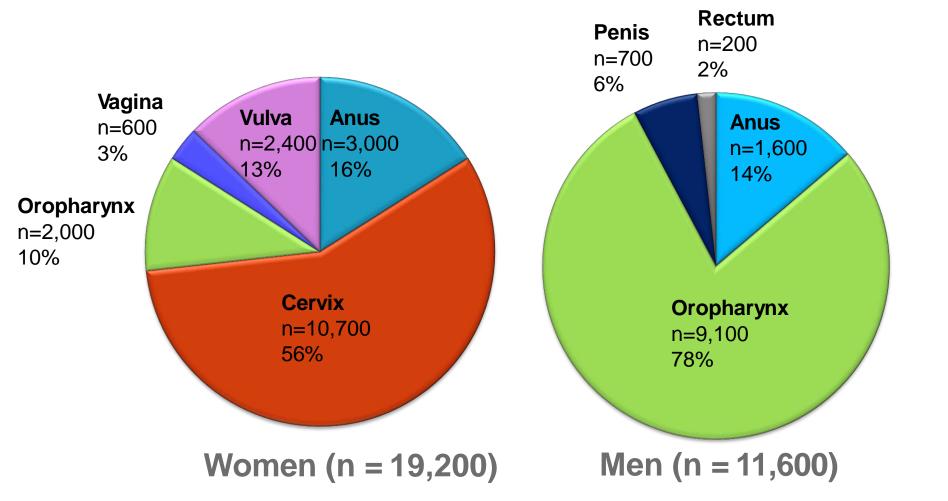
Every year in the United States over 30,000 people are diagnosed with a cancer caused by HPV.



That's 1 case every 20 minutes.



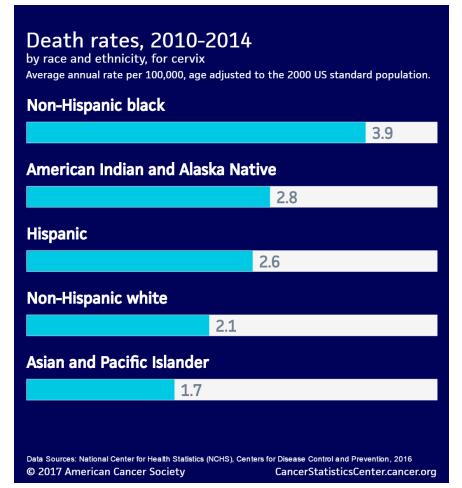
Average Number of New Cancers Probably Caused by HPV, by Sex, United States, 2008-2012





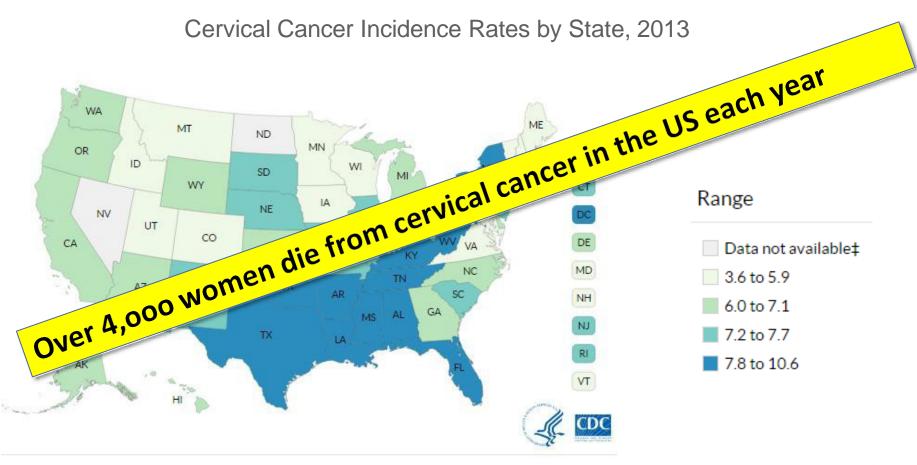
Disparities in Cervical Cancer Incidence and Death Rates

Incidence rates, 2009–2013 by race and ethnicity, for cervix Average annual rate per 100,000, age adjusted to the 2000 US standard population.						
Hispanic						
	9.9					
Non-Hispanic black						
	9.8					
American Indian and Alaska Native						
	9.7					
Non-Hispanic white						
7						
Asian and Pacific Islander						
6.1						





State Variation in Rates of Cervical Cancer

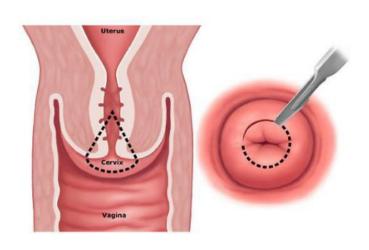




Implications of Pre-Cancerous Lesions

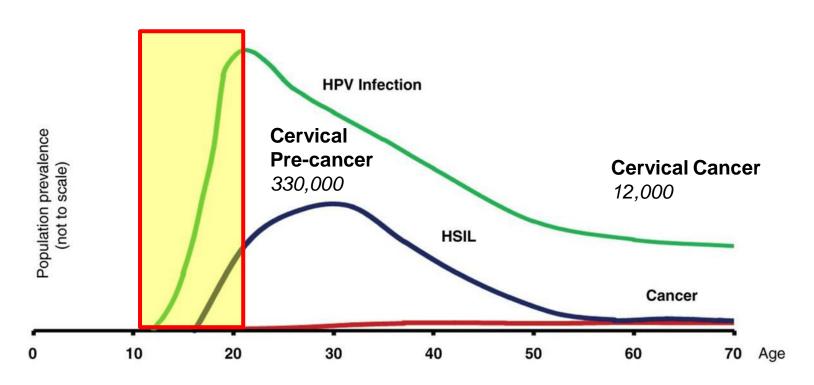
- Ongoing medical follow-up isrecommended
- Cervical conization and LEEP (loop electrosurgical excision procedure) are associated with adverse obstetric morbidity
- Subsequent pregnancies are at riskof:
 - Perinatal mortality
 - Pretermdelivery
 - Low birthweight







HPV Vaccination Eliminates HPV Infection and the Downstream Consequences



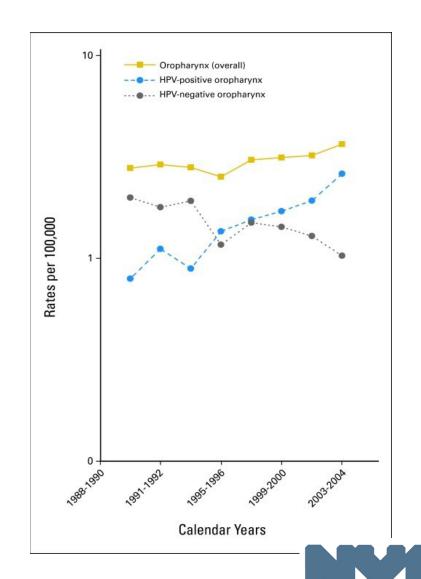


Oropharyngeal Cancers

More new oropharyngeal cancers than cervical cancers

- HPV negative
 - Smoking and alcoholrelated
 - Decreased50%

- HPV positive
 - Increased by225%



Health

Anatomy of the Oropharynx

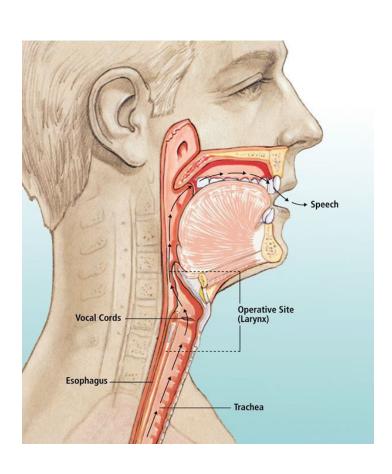






Photo Credit (left): www.inhealth.com/category_s/60.htm
Photo Credit (right): https://nn.wikipedia.org/wiki/S%C3%A5r_hals

Oropharyngeal Cancers







Side Effects of Non-surgical Therapy

Side Effect	Percent affected
Taste Disturbance	88%
Nausea/Vomiting	36%
Dry Mouth	29-38%
Esophageal Stricture	5%
Require G tube > 1 year	9%

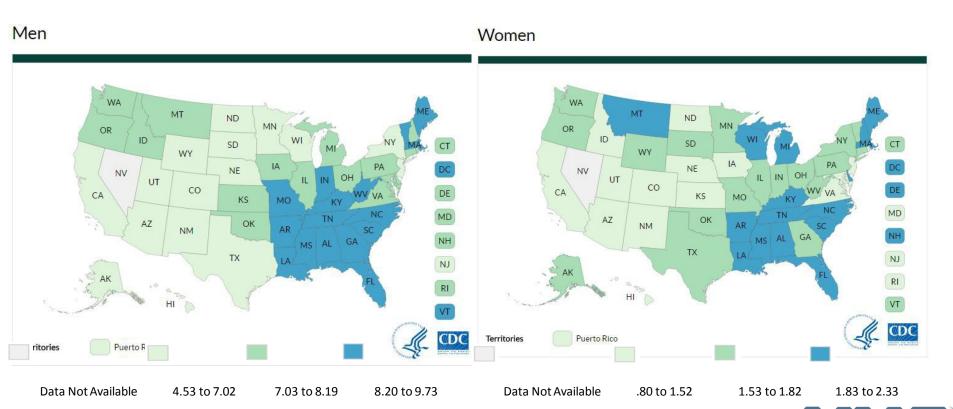




Data Source: Irune, et al, 2014; Kocak-Uzel, et al, 2014; Nutting, et al, 2011; McBride, et al, 2014

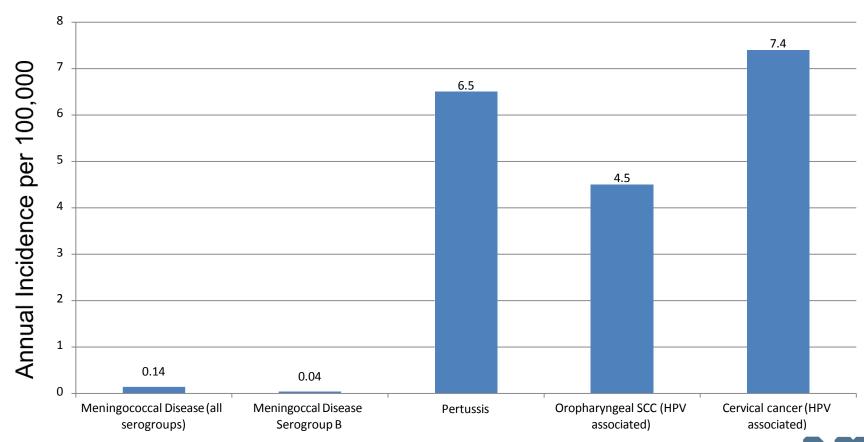
Photo Credit: http://www.jpalliativecare.com/viewimage.asp?img=IndianJPalliatCare_2010_16_2_74_68408_f3.jpg

State-based Disparities in HPV-Associated Oropharyngeal Cancer





Incidence of Diseases Covered in Adolescent Vaccine Series

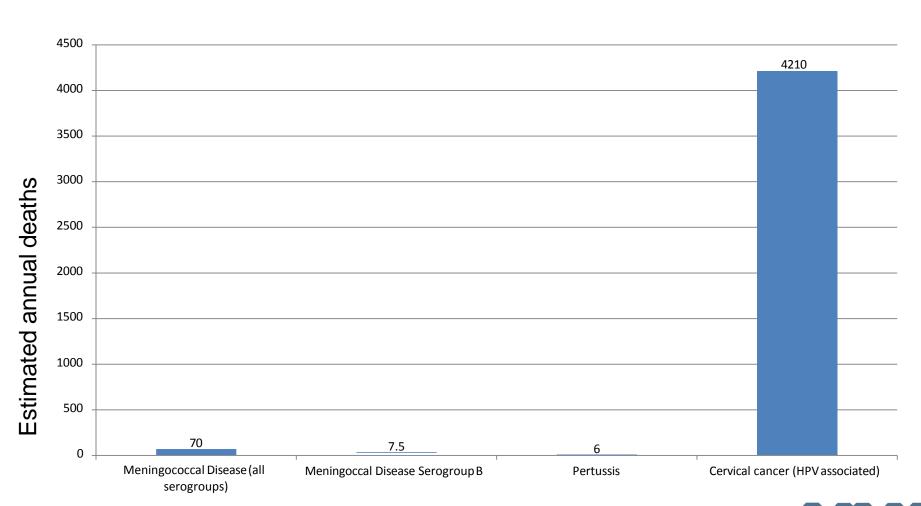


Meningococcal Data Source: 2014 CDC ABCs Pertussis Data Source: 2015 CDC ABCs

Cervical & Oropharyngeal Data Source: 2008-2012 SEER



Deaths from Diseases Covered in Adolescent Vaccine Series

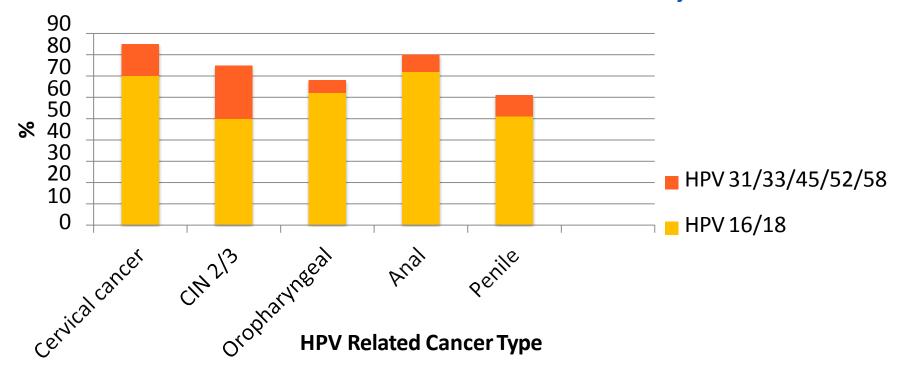


Meningococcal Data Source: 2014 CDC ABCs Pertussis Data Source: 2015 CDC ABCs

Cervical Data Source: 2016 American Cancer Society



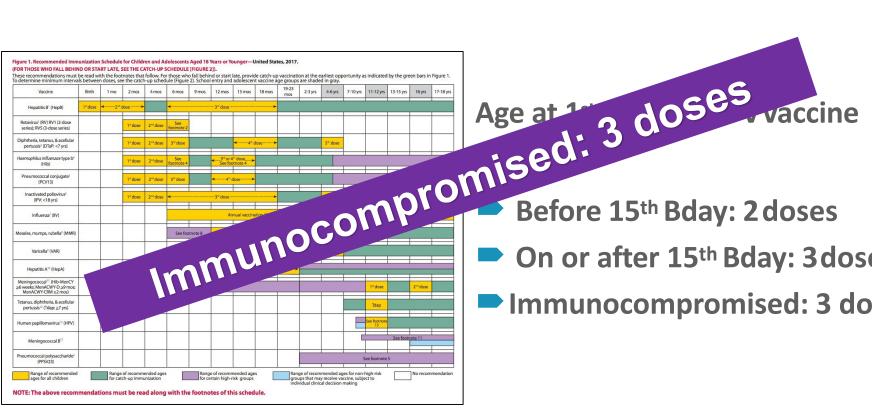
Percentage of HPV types found in common HPV related cancers, US Data



9-valent vaccine is estimated to prevent: 85% of cervical, 70% of oropharyngeal, 80% of anal, and 60% of penile cancers



2017 Immunization Schedule



- On or after 15th Bday: 3 doses
- Immunocompromised: 3 doses



What Forms of "Immunocompromise" Necessitate a 3-dose HPV Vaccine Series?

Needs 3 doses irrespective of age:

Primary or secondary conditions that might reduce cell-mediated or humoral immunity

Examples:

- B lymphocyte Ab deficiencies
- T lymphocyte complete or partial defects
- HIV infections
- Malignant neoplasm
- Transplantation
- Autoimmune disease
- Immunosuppressive therapy

Can use 2-dose series for those initiating before 15th birthday:

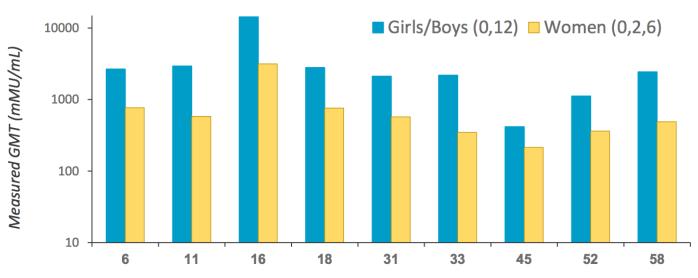
- Asthma
- Asplenia
- Diabetes mellitus
- Sickle cell disease
- Chronic granulomatous disease
- Chronic disease of liver, lung, kidneys
- Heart disease
- CNS barrier defects (eg, cochlearimplant)
- Complement deficiency, persistent complement component deficiency



2 -Dose Immunogenicity Trial

9vHPV 2-Dose Immunogenicity Trial

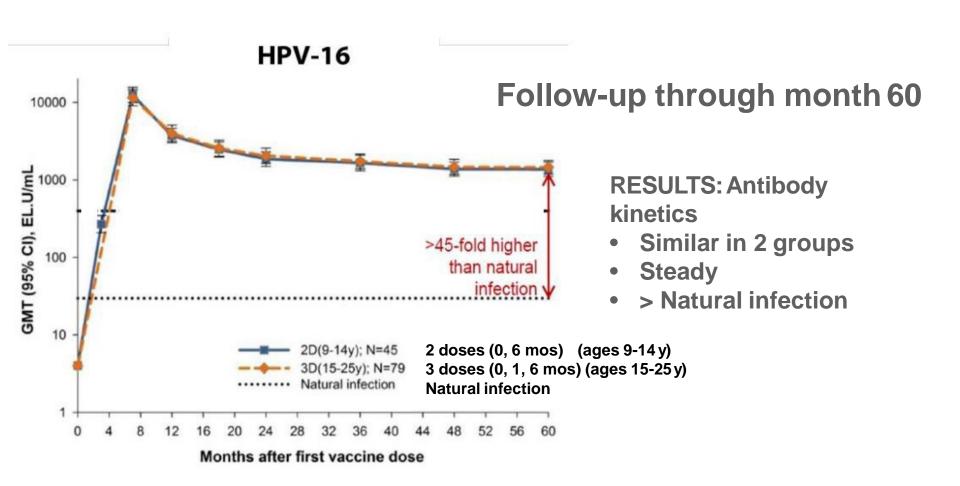
Non-inferior GMT at 1 month post-last dose in 2-dose girls/boys vs. 3-dose women



Fold difference (girls & boys /women)	3.47	5.07	4.54	3.69	3.70	6.31	1.96	3.08	4.98
95% CI	(2.93,	(4.32,	(3.84,	(3.06,	(3.08,	(5.36,	(1.61,	(2.64,	(4.23,
	4.11)	5.94)	5.37)	4.45)	4.45)	7.43)	2.37)	3.61)	5.86)



Does Immunity Last?





Evidence of lasting immunity

- For 2-or 3-dose series?
 - No evidence of waning protection after a 3-doseseries
 - So far, antibody persistence after a 2-dose series appears similar to 3-dose series
- **■**How long?
 - Data available through ~10 years for 2vHPV and 4vHPV
 - Longer follow-up, through 14 years, ongoing insome studies



9vHPV Vaccine Safety

7 pre-licensure studies including 15,000 males and females

- Generally well-tolerated
 - Adverse event profile similar to that of 4vHPV across age, gender, race, and ethnicity
 - More injection-site reactions expected among those who receive 9vHPV



HPV Vaccine Long-Term Safety Data No increased risk of:

- 2011- Allergic reactions, anaphylaxis, GBS, stroke, bloodclots, appendicitis, or seizures (than unvaccinated or who received other vaccines)
- 2013 –Blood clots or AEs related to the immune & CNS (almost 1 million girls)
- 2014 Venous thromboembolism or blood clots (>1 million women)
- 2012 & 2014 Autoimmune disorders (2 studies)
- 2015 Multiple sclerosis or other demyelinating diseases
- 2016- Over 60 conditions
- 2012 Vaccine may be associated with skin infections where the shot is given during the two weeks after vaccination and fainting on the day the shot is received

Vaccine Efficacy from Clinical Trials

Vaccine	Disease	Efficacy, Females	Efficacy, Males
	High-grade abnormalities in cervix	100%	N/A
	High-grade abnormalities in vagina	100%	N/A
HPV4	High-grade abnormalities in vulva	100%	N/A
	High-grade abnormalities in anus	N/A	75%*
	Genital Warts	99%	89%
HPV2	High-grade abnormalities in cervix	93%	N/A

^{*} Only among men-who-have-sex-with-men

Efficacy vs Effectiveness

- Efficacy reduction in disease under experimental conditions
 - Clinical trials

- Effectiveness reduction in disease in "real world" setting
 - Observational/ecological studies
 - Linked studies



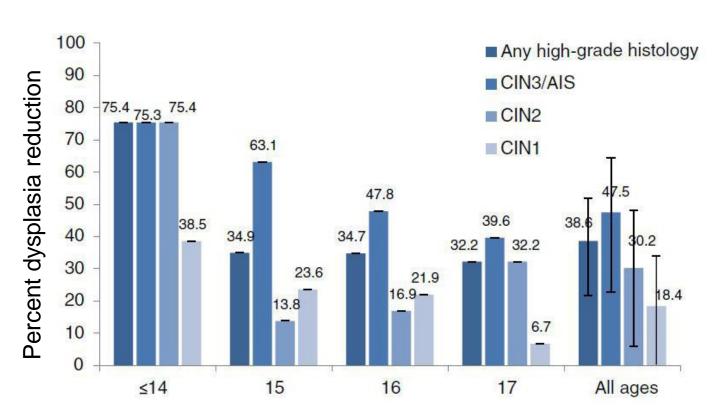
HPV Vaccine Effectiveness from NHANES 2003-2014

Age Group	4v HPV Prevalence Prevaccine Era (2003-2006)	4v HPV Prevalence Vaccine Era (2011-2014)
14-19 y	11.5%	3.3%
20-24 y	18.5%	7.2%
25-29 y	11.8%	8.8%



HPV Vaccine Effectiveness

Percent reduction in cervical dysplasia 5 years after vaccination, by age in 2007



Age at introduction of vaccination



HPV Vaccine Effectiveness from NHANES 2003-2014

	Unvaccinated (2011-2014)	Vaccinated (2011-2014)
4v HPV Prevalence	12.2%	2%

This corresponds to a vaccine effectiveness of 83%



HPV Vaccine Effectiveness

Table 1. Vaccine Effectiveness Against Human Papillomavirus (HPV) 16/18-Related Cervical Intraepithelial Neoplasia 2 or Worse 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 ^e (%)
HPV16/18-related CIN2+	2084	0	13c794.9	0.0 (0.0-0.0)	100
By time since day 1 of base study					
4 years or less	1930	0	803.5	0.0 (0.0–0.5)	
>4 to 6 years	2083	0	4119.9	0.0 (0.0-0.1)	
>6 to 8 years	2037	0	3978.7	0.0 (0.0-0.1)	
>8 to 10 years	1914	0	3393.1	0.0 (0.0-0.1)	
>10 to 12 years	1333	0	1479.0	0.0 (0.0–0.2)	
>12 to 14 years	124		20.6	0.0(0.0–17.9)	
By HPV type					
HPV16-related CIN2+	1787	0	11 809.9	0.0 (0.0-0.0)	
HPV18-related CIN 2+	1981	0	13115.5	0.0 (0.0-0.0)	
By lesion type					
CIN 2	2084	0	13 794.9	0.0 (0.0-0.0)	
CIN 3	2084	0	13 794.9	0.0 (0.0-0.0)	
Adenocarcinoma in situ	2084	0	13 794.9	0.0 (0.0-0.0)	
Cervical cancer	2084	0	13 794.9	0.0 (0.0-0.0)	

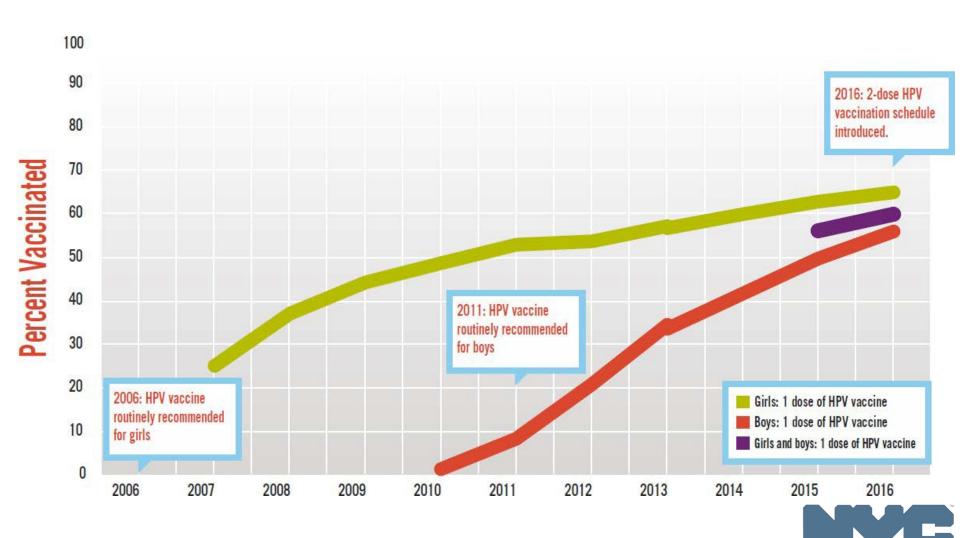
Abbreviations: CIN, cervical intraepithelial neoplasia; HPV, human papillomavirus.

^aVaccine effectiveness measures the relative reduction of the disease incidence in vaccine recipients compared to the baseline incidence rate of 0.287 per 100 person-years established from the incidence rate in an unvaccinated cohort.



Source: Kjaer. CID2018

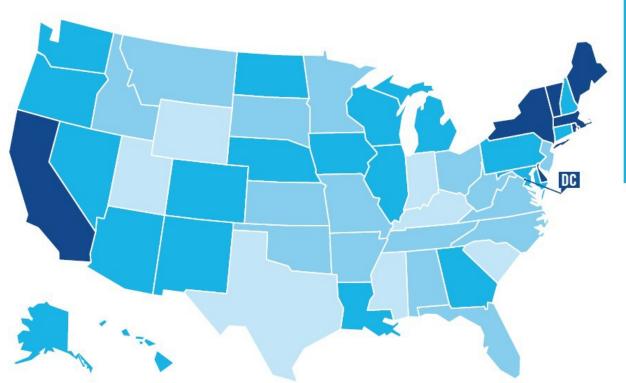
One or More Doses HPV Vaccine Among Females and Males 13-17 Years of Age, US

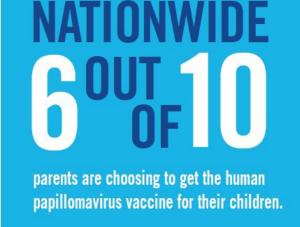


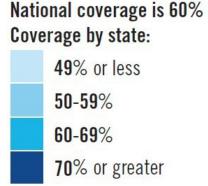
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One or More Doses HPV Vaccine Among Females and Males 13-17 Years of Age, US

Percentage of adolescent boys and girls who have received one or more doses of HPV vaccine*

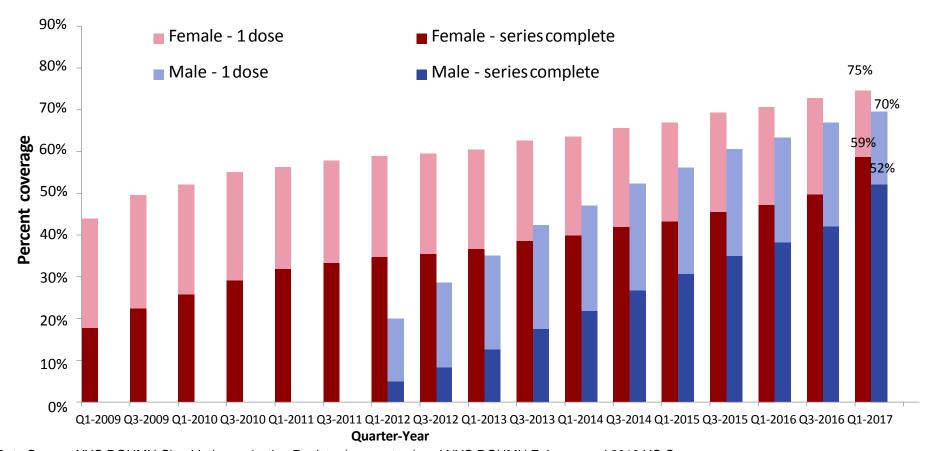








HPV Vaccine Coverage Among Females and Males 13-17 Years of Age, NYC

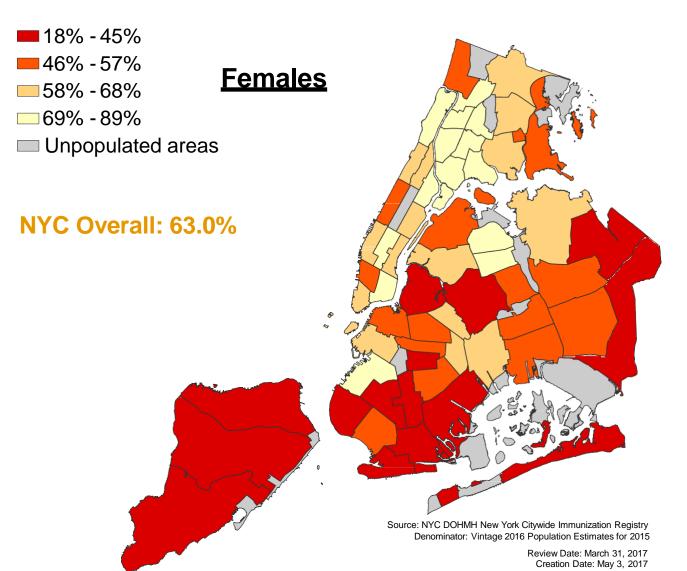


Data Source: NYC DOHMH Citywide Immunization Registry (numerators) and NYC DOHMH Epiquery and 2010 US Census (population estimates). ¹ACIP has recommended routine HPV vaccination for females ages 9-26 since 2006 and for males ages 11-21 since 2011.

² Series can be completed with 2 or 3 doses depending on series initiation at <15 years of age and interval between dose 1 and dose 2 is >5 months

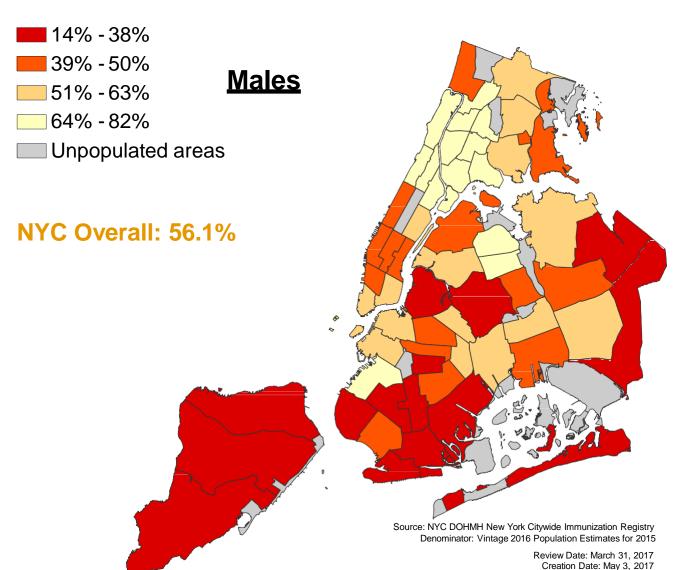


Disparities in HPV Vaccine Coverage, NYC, Series Complete



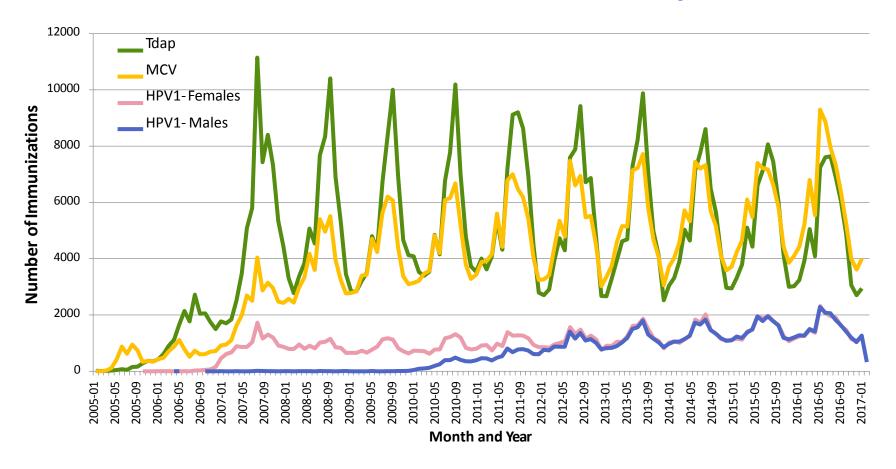


Disparities in HPV Vaccine Coverage, NYC, Series Complete





Missed Opportunities for HPV Vaccine Administration, NYC



Tdap, MCV4, and first HPV doses administered to 11 year-olds each month from January 2005 – April 2017. Overall Tdap and MCV4 dosesare shown. HPV vaccine doses are reported separatelyfor males and females. Reference: Sull M, et al. Pediatrics, 2014;134(6):e1576-1583



How Should We Introduce the Vaccine?

The Architecture of Provider-Parent Vaccine Discussions at Health Supervision Visits

Douglas J. Opel, John Heritage, James A. Taylor, Rita Mangione-Smith, Halle Showalter Salas, Victoria DeVere, Chuan Zhou and Jeffrey D. Robinson Pediatrics 2013;132;1037; originally published online November 4, 2013;

Announcements Versus Conversations to Improve HPV Vaccination Coverage: A Randomized Trial

Noel T. Brewer, PhD, 8,6 Megan E. Hall, MPH, 8 Teri L. Malo, PhD, 6 Melissa B. Gilkey, PhD, 6 Beth Quinn, BS, 6 Christine Lathren, MD8



How Should We Introduce the Vaccine?

- Opel et al: 'Presumptive recommendation'
 - "We have some shots to do today"
 - Observational study
- Brewer et al: 'Announcements'
 - "Your child is due for 3 vaccines today..."
 - **RCT**



Putting Presumptive into Practice: Same Day, Same Way

"Your child needs 3 vaccines today- Tdap, HPV and meningococcal"

"Today, your child should have 3 vaccines. They're designed to protect him from meningitis, cancers caused by HPV and tetanus, diphtheria, and pertussis."

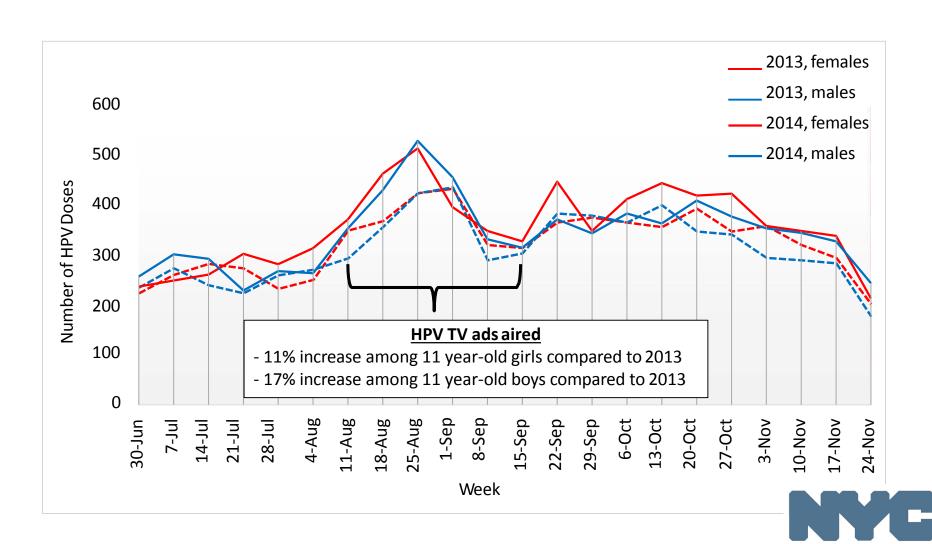


NYC Advertising Campaign



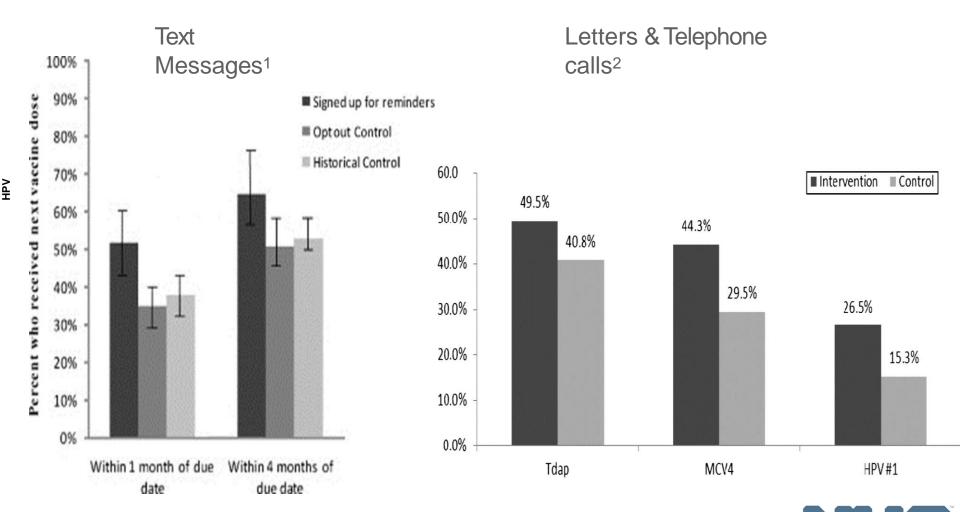


Effectiveness Evaluation of Citywide HPV Campaigns, 2014



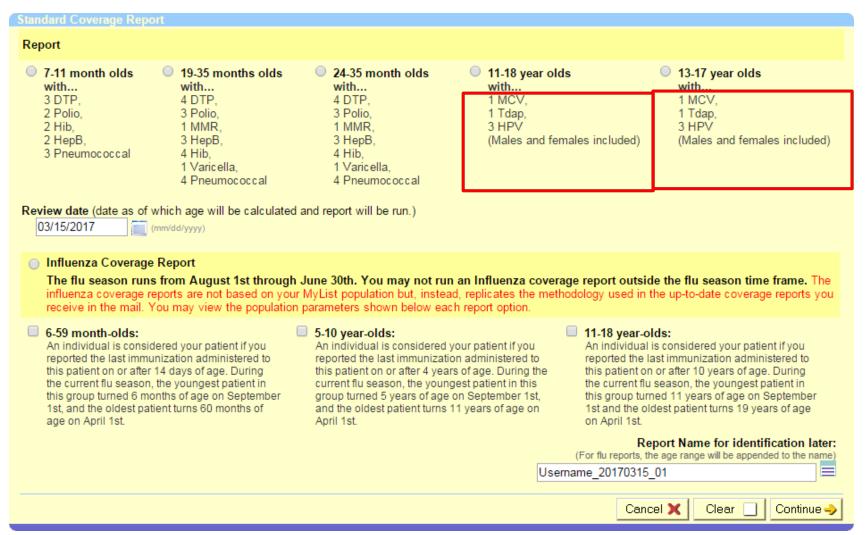
Health

Reminder/Recall Strategies Can Increase HPV Vaccination Rates





CIR for Coverage Reports





CIR for Recall: Customizable

Create Custom Reca	II Job					
A Specific A 7-1	Age 1 month olds	year olds year olds ear olds	Any age-app Any age-app Influenza HepB	s who are missing: propriate immunization	om the series below only Pneumo. Conjugate Pneumo. Polysaccharide	MMR Varicella
Age F From To < DOB Include and Gender M: B Gender	e patients born between	o months months	Rotavirus DTaP Hib Include patie -0- ▼ Influe -0- ▼ Rota -0- ▼ DTaF -0- ▼ Hib	enza 3 virus	# of specified valid doses from to	0 ▼ MMR



CIR for Recall: Lists Letters

4 A		В	С	D	Е	F	G	Н		J	K		M	N	
		Jsername N	NyList Due	Any 2017	The second secon							_			
			2:20:59 PM												
3 Created	d By: 229	904													
4 Based	On: Pati	ents in 'My	List'												
			Gender: Male												
6 Total P	atients:	19, Patients	not UTD: 1	9 (100%)	Patients UT	D: 0 (0%)									
7 Doses:	Patients	s missing a	ny age appro	opriate im	munization										
8						Line and								10.00	
9 Last N	ame F	irst Name	DOB	Gender	CIR Id	Medrec Num	Address	City	State	Zip	Home Phone	Cell Phone	Opted Out Text Msg	Due Now	
10 ALCOT	T LC	DUISA	02/01/2008	F	543222663		13 Downing Street, 1ST FLOC	RBROOKLY	YNY	11215	212-676-2312	917-319-0521	N	HPV-1	
11 KATZ	FE	ELIX	05/26/1950	M	601854063		195 Main Street, 3C	BROOKLY	YNY	11205	646-479-8426		N	Influenza-1	
12 RODGE	ERS A	ARON	03/13/1980	M	908399945		4209 28th Street, 5	QUEENS	NY	11105	347-396-2544		N	DTP-1, MMR-1, Varicella-1	
13 RUBBL			04/05/2007		883622687		50 Gravel Pit Way	BEDROCK	NY	10101	718-666-6666	718-666-6666		Influenza-1, HepB-1, Polio-1, MMR-1, V	/aricella-1,
14 TESTO	ISNE'TE	STRUGS	12/23/1980	M	908386384		4209 28th Street 5	OUFFNS	NY	11101	374-396-2544		N	DTP-1 MMR-1 Varicella-1	

March 15, 2017

Dear Parent/Guardian:

Our records show that your child may need the following vaccines:

Patient Name: FELIX KATZ

Immunizations Due Now: Influenza-1

Please call our office at 347-396-2400 to schedule an appointment at your earliest

convenience.

Thank you,

To the Parent/Guardian of: To the Parent/Guardian of: To the Parent/Guardian of: LOUISA ALCOTT FELIX KATZ AARON RODGERS 13 Downing Street, 1ST FLOOR 195 Main Street, 3C 4209 28th Street, 5 Queens, NY 11105 Brooklyn, NY 11215 Brooklyn, NY 11205 To the Parent/Guardian of: To the Parent/Guardian of: To the Parent/Guardian of: BARNEY RUBBLE TESTBUGS TESTDISNEY **TESTAARON TESTRODGERS** 50 Gravel Pit Way 4209 28th Street, 5 4209 28th Street, 5 Bedrock, NY 10101 Queens, NY 11101 Queens, NY 11105



CIR Text Message Recall

Select message (default recommended.) This message will be sent to each patient on your recall list.

- Use default message
- Fill in the fields for the sample message provided.

- Use custom message
- Type in your custom message. Make sure to include your facility name.

(Messages are limited to Latin alphabets.)

FACILITY NAME (up to 42 characters):
Characters remaining: 42
at CONTACT NUMBER:

130 character limit

Characters remaining: 130

NOTE: To allow patients to opt out of receiving text message reminders, the line "To stop reminders, text STOP" will be added to the end of your message.

Patients who text "STOP" will not receive any future text messages via the CIR.

Please note that it is your responsibility to adhere to the laws, rules, and regulations that apply to the disclosure of confidential and sensitive information in the content of your custom text message.



Impact of Text Message Recall

171 text message recall jobs completed by 62 facilities, 8/27/15 – 12/31/15



Patients included in text message recall jobs n=70,890





NOT TEXTED n=39,502 (56%)

2,345 (6%) vaccinated within 28 days



Standing Orders

- Single physician order for all patients for recommended vaccines
- Stipulate that all patients meeting certain criteria should be vaccinated – age, underlying medical condition
- Components
 - 1. Nurse/MA tracks immunization history
 - 2. Nurse/MA identifies eligible patients
 - 3. Nurse/MA educates patients –alert provider if patient still has questions or wants to talk with the provider
 - 4. Nurse administers vaccines



Benefits of Standing Orders

- Shown to be effective in both adults and children
 - For children, use of standing orders is associated witha median increase in vaccination coverage of 28%
 - Most effective evidence-basedmethod
- Overcome administrative barriers and save time

'Presumptive' recommendation in action



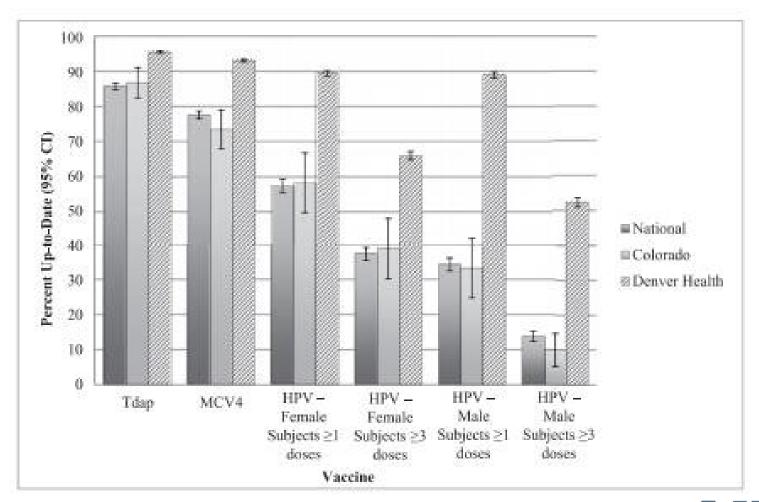
The Denver Health Story

- Large vertically integrated community health system
 - Cares for about 1/3 ofall children in Denver
 - 8 community healthcenters,16 school-based healthcenters
- For many years, had 'typical' immunization process, with similar rates to national average



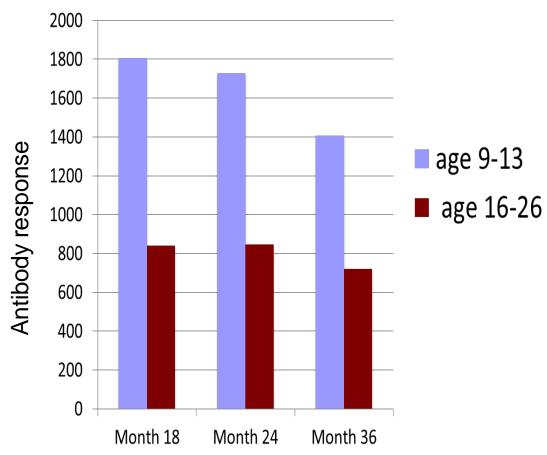


Adolescent Vaccine Rates with Standing Orders





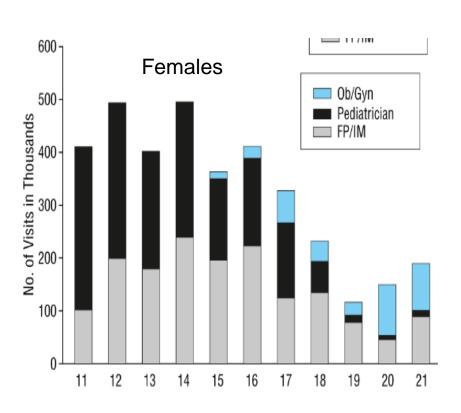
1) Better immune response

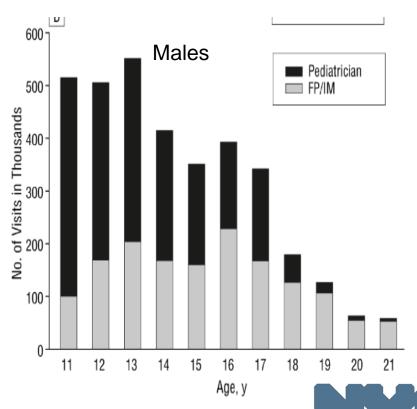




2) More chances to vaccinate

Early adolescents have 3 times more preventive care visits than late adolescents

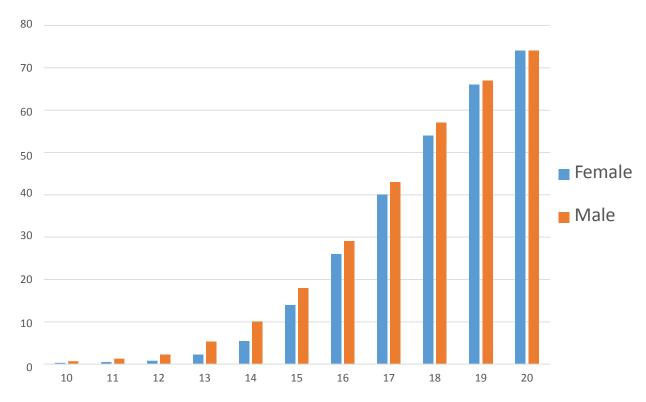




Health

3) Lack of exposure

U.S. Teen Sexual Activity
Percent of adolescents who have had sex





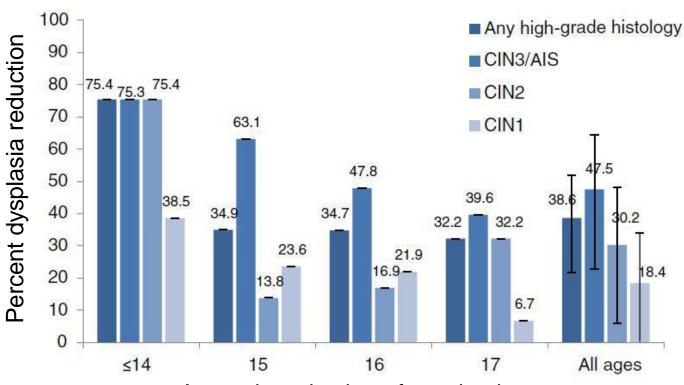
4) Long duration of immunity

- No evidence of waning protection up to 10 years after 3-dose schedule
- Antibody kinetics with 2-dose schedules are similar, suggesting there will be similar protection



5) Prevents twice as much pre-cancer

Percent reduction in cervical dysplasia 5 years after vaccination, by age at vaccination





Age at introduction of vaccination

What I say to patients:

"The HPV vaccine works better and prevents more cancers at younger ages.

If Ella gets the vaccine today she will only need 2 doses, but if we wait until she's older she may need 3 doses."





Why NOT Vaccinate at Ages 9 - 10?



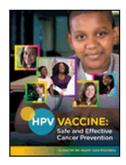
You can't vaccinate too early..... Only too late



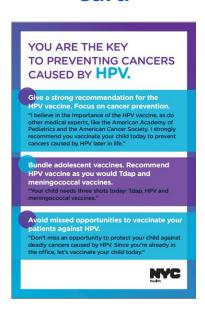
HPV VACCINATION RESOURCES



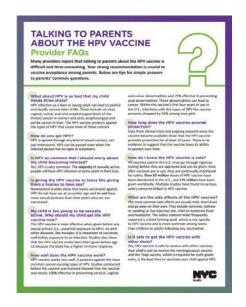
HPV Provider Toolkit



Key Strategies Card



Provider FAQs



Tear-off Pad* (for parents)



https://www1.nyc.gov/site/doh/providers/resources/public-health-action-kits-hpv.page

Double-sided English/Spanish. Also available in Chinese, Arabic, Bengali, Urdu, Haitian-Creole, Korean, French, Russian



For More Information

- NYC DOHMH
 - CIR
 - http://www1.nyc.gov/assets/doh/downloads/pdf/cir/ cir-recall-guide.pdf
- CDC
 - https://www.cdc.gov/hpv/hcp/index.html
- AAP
 - Info for parents (www.healthychildren.org)
 - Info for clinicians (https://www.aap.org/enus/advocacy-and-policy/aap-healthinitiatives/immunizations/HPV-Champion-Toolkit/Pages/HPV-Champion-Toolkit.aspx)
- CHOP Vaccine Education Center
 - http://www.chop.edu/centers-programs/vaccineeducation-center



Contact info

New York City Department of Health and Mental Hygiene
Bureau of Immunization

nycimmunize@health.nyc.gov

(347)396-2400

