





You are the Key to HPV Cancer Prevention

Understanding the Burden of HPV Disease,
the Importance of the HPV Vaccine Recommendation,
and Communicating about HPV Vaccination

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Funding



Funding for this workshop was made possible (in part) by the Centers for Disease Control and Prevention. The views expressed in written workshop materials or publications and by speakers and moderators do not necessarily reflect the official policies of the US Department of Health and Human Services or the NM Department of Health, nor does the mention of trade names, commercial practices or organizations imply endorsement by the US Government.



Faculty Disclosure

Has in the past spoken on behalf of Merck Vaccines (more than two years ago); has no other conflicts

▶ *Lance Chilton, MD*



Some of my pharmacist heroes



Dean Michel Disco Amy Bachrycz David Kuhl John Maito



Objectives

1. Describe why HPV vaccination is important for cancer prevention.
2. Identify the appropriate HPV vaccination schedule based on patient age.
3. Describe effective HPV vaccine recommendations for patients age 11 or 12 years, as well as for age 13 years and older.
4. Develop self-efficacy in delivering effective HPV vaccination recommendations
5. Provide useful tips via role playing and identify reassuring, confident, and concise responses to parental questions about HPV vaccination.



A little play

▶ **Ms. Aurelia Sánchez**

- ▶ 38 y.o. mother of
 - ▶ Sara, age 7
 - ▶ Saúl, age 9
 - ▶ Linda, age 11
- ▶ Generally healthy
- ▶ Highly intelligent, well-educated

▶ **Bala Desai, Pharm. D.**

- ▶ 47 y.o. pharmacist, pharmacy owner
- ▶ Married, mother of
 - ▶ Bijay, age 15
 - ▶ Neema, age 18
- ▶ Highly intelligent, well-educated
- ▶ Committed to prevention of disease



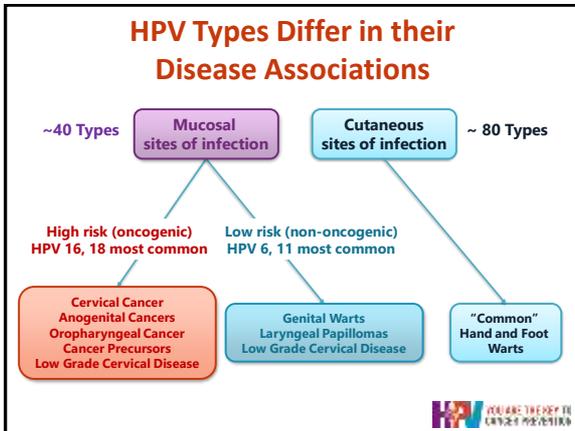


Understanding the Burden
HPV INFECTION & DISEASE



So, let's talk about HPV vaccine and its promotion





HPV Infection

- Most females and males will be infected with at least one type of mucosal HPV at some point in their lives
 - Estimated 79 million Americans currently infected
 - 14 million new infections/year in the US
 - HPV infection is most common in people in their teens and early 20s
- Most people will never know that they have been infected

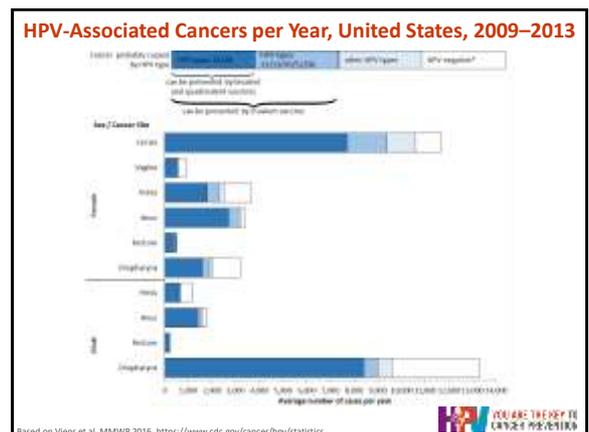
Satterwhite et al. Sex Transm Dis. 2013

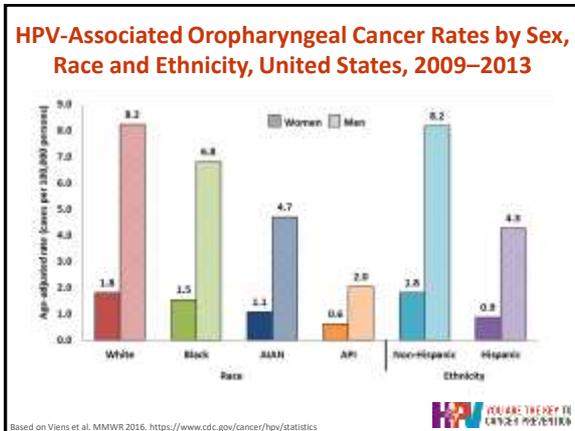
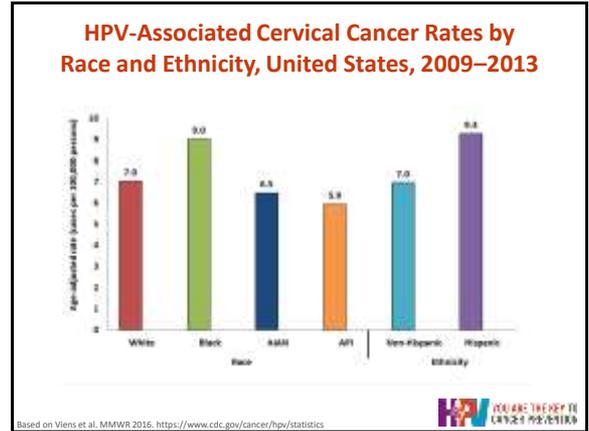
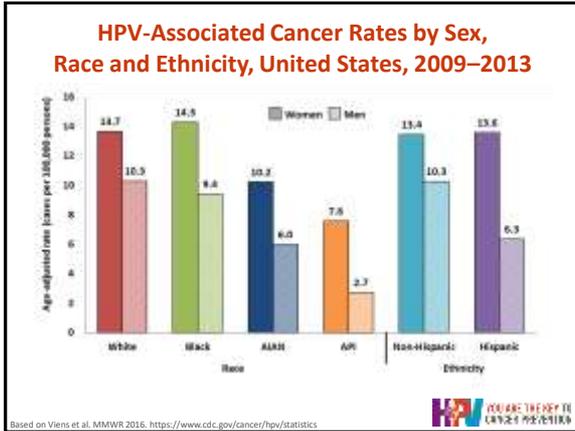


Cancers Caused by HPV per Year, U.S., 2009-2013

Cancer site	Percentage probably caused by any HPV type	Number probably caused by any HPV type		
		Female	Male	Both Sexes
Cervix	91%	10,600	0	10,600
Vagina	75%	600	0	600
Vulva	69%	2,500	0	2,500
Penis	63%	0	700	700
Anus	91%	3,200	1,600	4,800
Rectum	91%	500	200	700
Oropharynx	70%	2,000	9,600	11,600
TOTAL		19,400	12,100	31,500

Based on Viens et al. MMWR 2016. <https://www.cdc.gov/cancer/hpv/statistics>



Cervical Cancer

- Cervical cancer is the most common HPV-associated cancer among women
 - 528,000 new cases and 266,000 deaths world-wide in 2012
 - 12,000 new cases and 4,000 deaths in the U.S. in 2013

- Half of cervical cancers occur in women <50 years
 - A quarter of cervical cancers occur in women 25-39 years

<https://cccr.cdc.gov/uscd/> and <http://go.larc.fr/today/home>

Cervical pre-cancer in U.S. females

- 1.4 million new cases of low grade cervical dysplasia
- 330,000 new cases of high grade cervical dysplasia

Roshal Sex Transm Dis. 2004.
Schiffman Arch Pathol Lab Med. 2003.

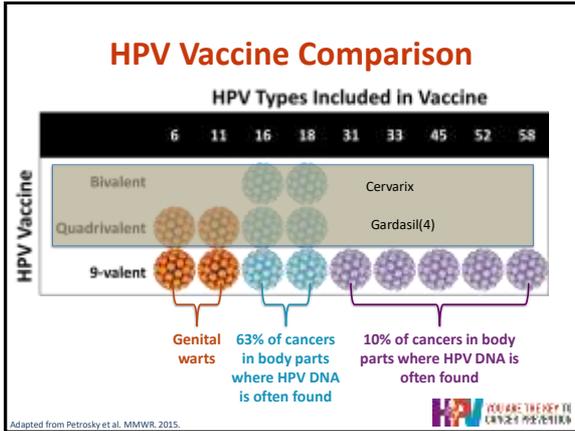
HPV vaccine is cancer prevention.

Talk to the doctor about vaccinating your 11–12 year old sons and daughters against HPV.

#UCanStopHPV

HPV VACCINE

Evidence-Based HPV Disease Prevention



HPV Vaccination is Recommended at Age 11 or 12 Years

Girls & Boys can start HPV vaccination at age 9
Preteens should finish the HPV vaccine series before their 13th birthday

Plus girls 13-26 years old who haven't started or finished HPV vaccine series
Plus boys 13-21 years old who haven't started or finished HPV vaccine series

Meites et al. MMWR, 2016.

HPV Vaccine Recommendation

CDC recommends routine vaccination at age 11 or 12 years to prevent HPV cancers

- The vaccination series can be started at age 9 years
- Two doses of vaccine are recommended
- The second dose of the vaccine should be administered 6 to 12 months after the first dose.

Meites et al. MMWR, 2016.

Dosing Schedules

Starting the vaccine series before the 15th birthday
Recommended schedule is **2 doses** of HPV vaccine

- Second dose should be administered 6–12 months after the first dose (0, 6–12 month schedule)
- Minimum interval between dose one and dose two in a 2-dose schedule is 5 months

Starting the vaccine series on or after the 15th birthday*
Recommended schedule is **3 doses** of HPV vaccine

- Second dose should be administered 1–2 months after the first dose, and the third dose should be administered 6 months after the first dose (0, 1–2, 6 month schedule)
- Minimum interval between dose one and dose three in a 3-dose schedule is 5 months

*and immunocompromised persons 9-26 years

Meites et al. MMWR, 2016.

HPV VACCINE SAFETY



Meites et al. MMWR, 2016.

United States Vaccine Safety System

System	Collaborators	Description
Vaccine Adverse Event Reporting System (VAERS)	CDC and FDA	Frontline spontaneous reporting system to detect potential vaccine safety issues
Vaccine Safety Datalink (VSD)	CDC and 9 Integrated Health Care Systems	Large linked database system used for active surveillance and research ~9.4 million members (~3% of US pop.)
Clinical Immunization Safety Assessment (CISA) Project	CDC and 7 Academic Centers	Expert collaboration that conducts individual clinical vaccine safety assessments and clinical research
Post-Licensure Rapid Immunization Safety Monitoring Program (PRISM)	FDA and 6 partner organizations	Large distributed database system used for active surveillance and research ~170 million individuals

Meites et al. MMWR, 2016.

Over 10 Years of HPV Vaccine Safety Data

- HPV vaccine is safe
- Reactions after vaccination may include
 - Injection site reactions: pain, redness, and/or swelling in the arm where the shot was given
 - Systemic: fever, headaches
- HPV vaccines should not be given to anyone who has had a previous allergic reaction to the vaccine or who has an allergy to yeast (Gardasil/Gardasil 9)
- Brief fainting spells (syncope) and related symptoms (such as jerking movements) can happen soon after any injection, including HPV vaccine
- Patients should be seated (or lie down) during vaccination and remain in that position for 15 minutes

Geer, et al. Hum Vaccin Immunother. 2016.



Evaluating and Monitoring 9-valent HPV Vaccine Safety in the United States

Monitoring of VAERS Reports

- Clinical review of deaths and other pre-specified adverse events
- Data mining to identify disproportional reporting

Vaccine Safety Datalink

- Near real time monitoring of 10 pre-specified outcomes
- Evaluation of spontaneous abortion

Sentinel System

- Near real time active surveillance and surveillance of serious, unexpected events
- Evaluation of spontaneous abortion

Manufacturer post-marketing commitments

- Two, 10-year studies to assess long term safety
- Observational study to further characterize the safety profile in 10,000 persons
- Pregnancy registry



Early Outcomes
(Years)

HPV Prevalence
Genital warts



Mid Outcomes
(Years to Decades)

CIN/Precancers



Late Outcomes
(Decades)

HPV-associated cancers

HPV VACCINE IMPACT

Monitoring and Evaluation of the Impact of HPV Vaccines on HPV-Associated Outcomes



HPV vaccine impact monitoring

- Post licensure evaluations are important to evaluate real world effectiveness of vaccines
- Population impact against early and mid outcomes have been reported:

Genital warts

- Australia, New Zealand, Denmark, Sweden, Germany, Quebec, US

HPV prevalence

- Australia, Norway, Denmark, Sweden, UK, US

Cervical lesions

- Australia, British Columbia, Denmark, Sweden, US



Systematic Review and Meta-Analysis: Population-Level Impact of HPV Vaccination

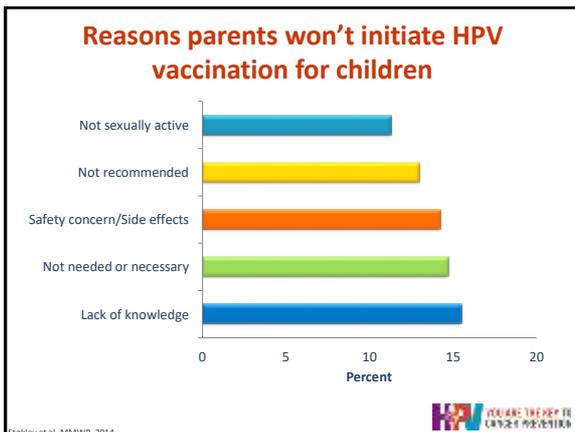
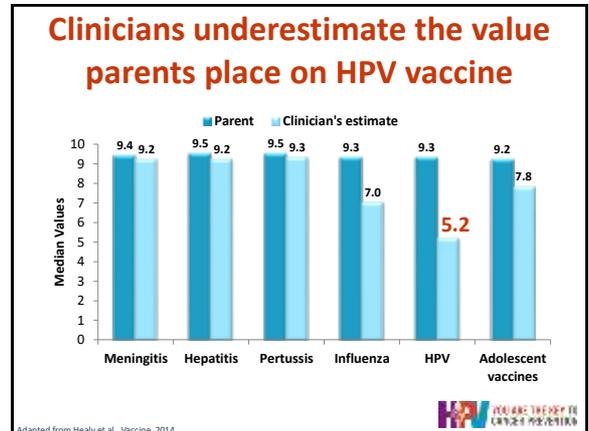
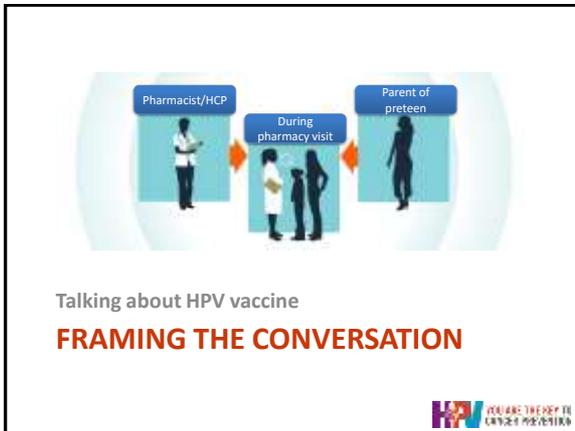
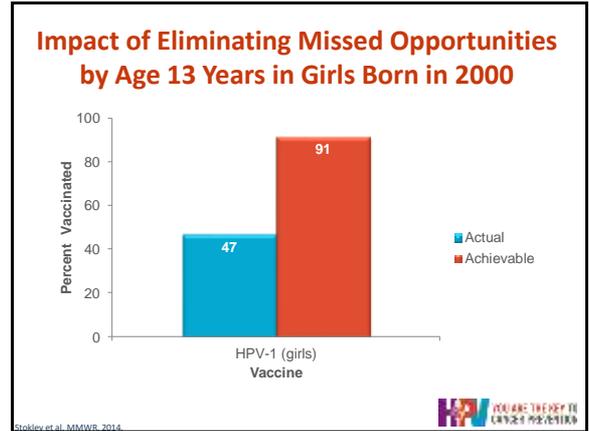
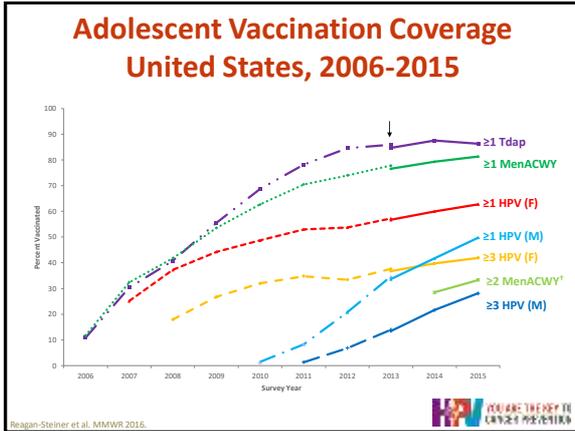
- Review of 20 studies in 9 high income countries
- In countries with **>50% coverage**, among 13-19 year olds
 - HPV 16/18 prevalence **decreased at least 68%**
 - Anogenital warts decreased by ~61%
- Evidence of herd effects
- Some evidence of cross protection against other types

Drolet et al. Lancet Infect Dis. 2015.



Genital Warts – An Even Better Selling Point?





“The perceived and real concerns of parents influence how the pharmacist or clinician recommends and administers HPV vaccine.”

Adapted from Healy et al. Vaccine 2014.

Give an Effective Recommendation to Receive HPV Vaccine at Ages 11 or 12

- *An effective recommendation from you is the main reason parents decide to vaccinate*
- Many moms in focus groups stated that they trust their child's doctor and would get the vaccine for their child as long as they received a recommendation from the doctor

Smith et al. Vaccine. 2016. Unpublished CDC data, 2013.



What is an **EFFECTIVE** recommendation for HPV vaccination?



Same Way Same Day



Make an Effective Recommendation

- **Same way:** Effective recommendations group all of the adolescent vaccines
Recommend HPV vaccination the **same way** you recommend Tdap & meningococcal vaccines.
- **Same day:** Recommend HPV vaccine **today**
Recommend HPV vaccination the **same day** you recommend Tdap & meningococcal vaccines.

Brewer et al. Pediatrics. 2017. Unpublished CDC data, 2013.



*Your preteen not only needs Tdap, but also needs two other vaccines **today** to protect against meningitis and HPV cancers.*

Brewer et al. Pediatrics. 2017.



Brief Option

Now that Sophia is 11, she is due for three vaccines today. These will help protect her from the infections that can cause meningitis, HPV cancers, and pertussis. I'd recommend we give all three vaccines at the same time, today.



“

Longer Option

Now that Sophia is 11, she is due **today** for three important vaccines, not just Tdap. **One is to help prevent an infection that can cause meningitis, which is very rare, but potentially deadly. The second is to prevent a very common infection, HPV, that can cause several kinds of cancer. The Tdap, or “tetanus booster” also protects against pertussis, so your child doesn’t get whooping cough, but also to protect babies too young to be vaccinated. I’d suggest we give all those shots here today. Do you have any questions for me?**”

 YOU ARE THE KEY TO CANCER PREVENTION

Some Parents Need Reassurance

- Many parents simply accept this bundled recommendation. *Stop there; don’t apologize.*
- Some parents may be interested in vaccinating, yet still have questions. Interpret a question as **their needing additional reassurance from YOU, the clinician they trust with their child’s health care**
- Ask parents about their main concern (be sure you are addressing their real concern)

Unpublished CDC data, 2013

 YOU ARE THE KEY TO CANCER PREVENTION

Why does my child need HPV vaccine?

 YOU ARE THE KEY TO CANCER PREVENTION

“

HPV vaccination is important because it prevents cancer. That’s why I’m recommending that your child start the HPV vaccine series today.

”

 YOU ARE THE KEY TO CANCER PREVENTION

What cancers are caused by HPV infection?

 YOU ARE THE KEY TO CANCER PREVENTION

“

Certain HPV types can cause cancer of the cervix, vagina, and vulva in females, cancer of the penis in men, and in both females and males, cancers of the anus and the throat. We can help prevent infection with the HPV types that cause these cancers by starting the HPV vaccine series today.

”

 YOU ARE THE KEY TO CANCER PREVENTION

Is my child really at risk for HPV?



HPV is a very common and widespread virus that infects both females and males. We can help protect your child from the cancers and diseases caused by the virus by starting HPV vaccination today.



Why at 11 or 12 years old?



When should the bike helmet go on?



- A. Before they get on their bike
- B. When they are riding their bike in the street
- C. When they see the car heading directly at them
- D. After the car hits them



Temte II, Pediatrics 2014

When do we put our seat belts on?

A. Before turning on car

B. When leaving driveway

C. After a near accident



Temte II, Pediatrics 2014



As with all vaccine-preventable diseases, we want to protect your child early. If we start now, it's one less thing for you to worry about.

Also, your child will only need two shots of HPV vaccine at this age. If you wait until 15, your child will need three shots.

We'll give the first shot today and then you'll need to bring your child back 6 to 12 months from now for the second shot.



I'm just worried that my child will perceive this as a green light to have S-E-X.



Numerous research studies have shown that getting the HPV vaccine does not make kids more likely to be sexually active or start having sex at a younger age. Starting the HPV vaccine series today will give your child the best protection possible for the future.



“How long can we wait and still give just two doses?”



The two-dose schedule is recommended if the series is started before the 15th birthday.

However, I don't recommend waiting to give this cancer-preventing vaccine. As children get older and have busier schedules, it becomes more difficult to get them back in.

I'd feel best if we started the series today to get your child protected as soon as possible.



I have some concerns about the safety of the vaccine—I keep reading things online that says HPV vaccination isn't safe. Do you really know if it's safe?



It sounds like you are generally in support of vaccines, but you have concerns about the safety of HPV. Is that right?

So if you had information that convinced you the HPV vaccine was safe you might consider letting your daughter get it?

I'd like to share with you what I know about the safety of HPV vaccine...





I know there are stories in the media and online about vaccines, and I can see how that could concern you.

However, I want you to know that HPV vaccine has been carefully studied for many years by medical and scientific experts.

Based on all of the data, I believe HPV vaccine is very safe.



Vaccines, like any medication, can cause side effects. With HPV vaccination this could include pain, swelling, and/or redness where the shot is given, or possibly headache.

Sometimes kids faint when they get shots and they could be injured if they fall from fainting.

We'll protect your child by having her stay seated after the shot.



Could HPV vaccine cause my child to have problems with having a baby later on?



There are no data suggesting that HPV vaccine will affect future fertility.

On the other hand, women who develop cervical cancer or pre-cancer could require treatment that would limit their ability to have children.

Starting the HPV vaccine series today could prevent that from happening and protect your daughter's ability to bear children.



More than a decade of HPV vaccine safety studies have been very reassuring.

To date, we have not observed any signal that shows that HPV vaccination causes

death/ neurologic conditions/ autoimmune conditions/ venous thromboembolism/ postural orthostatic tachycardia syndrome/ complex regional pain syndrome *or anything else except protection!*



How do you know if the vaccine works?





Ongoing studies continue to show that HPV vaccination works very well.

HPV infections, genital warts, and cervical precancers in young people have all decreased in the years since the vaccine has been available.

Starting the vaccine series today will help ensure your child gets the best protection possible.



Why do boys need HPV vaccine?



HPV infection can cause cancers of the penis, anus, and throat in men, *and men are usually the source of the virus that causes such trouble in women.*

HPV infection can also cause genital warts.

Getting HPV vaccine today for your son can help prevent the infection that can lead to these diseases *and transmission of the virus to someone he loves.*



We only want the vaccines needed for school.



All three vaccines are strongly and equally recommended by the CDC.

All three are also recommended by Pediatric, Adolescent, and Family Medicine doctors and groups.

School-entry requirements don't always reflect the current recommendations for your child's health.



Would you get HPV vaccine for your kids?





Yes, I have given HPV vaccine to my child. I believe strongly in the importance of this cancer-preventing vaccine.

The American Pharmacists Association, the American Academy of Pediatrics, the American Academy of Family Physicians, NIH cancer centers, and the CDC all agree that getting the HPV vaccine is very important for your child.



I heard there is a new HPV vaccine that works better. Should I be getting that for my child who already was vaccinated?



The current vaccine is the best there is. Currently there is no recommendation for additional vaccination for someone who has already completed an HPV vaccine series with one of the previously available vaccines.

All HPV vaccines protect against the infections that cause most of the cancers.



When do we need to come back?



Since your child is younger than 15, she will need a second shot in 6 months to a year.

Before you leave, please put a reminder on your phone to come back to the pharmacy in 6 months. (And/Or, I can send you a message to come back [if the pharmacy can].)



My child is less than 15 years old and has already had two doses, so why does she need a third shot?





The recommended schedule is 2 shots given 6 to 12 months apart.

The minimum effective amount of time between those shots is five months.

Because your child received two shots *less* than five months apart, we'll need to give your child a third shot to protect her/him fully.



Will my child be protected with just two shots?



Yes! Studies have shown that just two shots given at least six months apart when kids are between 9 and 14 years worked as well as or better than three shots given to older adolescents and young adults.



If a parent doesn't say yes today...

Ask	<ul style="list-style-type: none"> Clarify & restate their concerns to make sure you understand
Acknowledge	<ul style="list-style-type: none"> Emphasize it is the parents' decision Acknowledge risks & conflicting info sources Applaud them for wanting what is best for their child Be clear that you are concerned for the health of their child, not just public health safety
Advise	<ul style="list-style-type: none"> Allow time to discuss the pros & cons of the vaccine Be willing to discuss parents' ideas Offer written resources for parents Tailor your advice using this presentation and info at http://www.pharmacist.com/test-sub-domain-page

Adapted from Hoopkin, Jov. Northwest 2016.



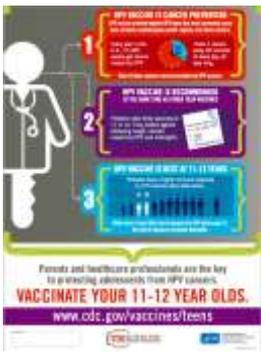
If a parent declines today...

- Declination is not final. The conversation can be revisited, and can be reinforced by the primary care provider.
- End the conversation with at least 1 action you both agree on.
- Because waiting to vaccinate is the risky choice, many pediatricians ask the parent to sign a Declination Form. Do pharmacists do this?



www.cdc.gov/hpv





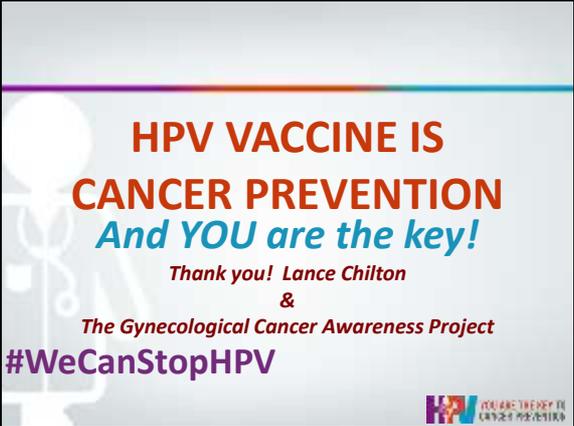
Take Action By:

1. Displaying free CDC resources including patient videos, posters, flyers, and PSAs in your waiting room and on your website.
2. Using prepared scripts to record phone hold-line messages or appointment reminders.
3. Signing up to receive CDC's #PreteenVax newsletter and listening in on our monthly webinars by emailing preteenvaccines@cdc.gov.

Free posters available for ordering in the following sizes: 8.5x11, 11x17, 18x24

<https://www.cdc.gov/hpv/hcp/tools-materials.html>

<https://www.cdc.gov/vaccines/partners/downloads/teens/hpv-cancer-prevention-11x17-p.pdf>



**HPV VACCINE IS
CANCER PREVENTION**
And YOU are the key!

*Thank you! Lance Chilton
&
The Gynecological Cancer Awareness Project*

#WeCanStopHPV

YOU ARE THE KEY TO CANCER PREVENTION