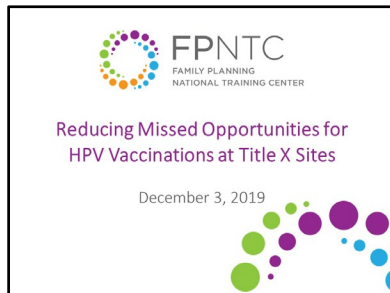


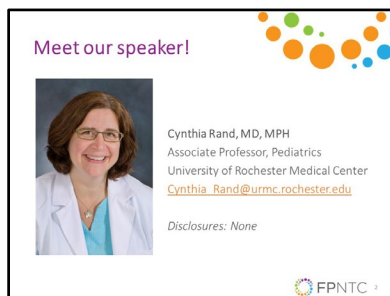
# Webinar Transcript:

## Reducing Missed Opportunities for HPV Vaccinations at Title X Sites



### Slide 1 - Katie Quimby:

Hello everyone, and welcome to today's webinar, Reducing Missed Opportunities for HPV Vaccinations at Title X Sites. This is Katie Quimby from the Title X Family Planning National Training Center and I am very pleased that you are here joining us today. A few things before we begin, everyone on the webinar today is muted given the large number of participants, so please use the pod on the left of your screen labeled, ask a question to ask your questions at any time. We will address all questions at the end of the presentation. Our recording of today's webinar along with the slide deck and a transcript will be posted to [fpntc.org](http://fpntc.org) within the next few days.



### Slide 2 - Katie Quimby:


Now I'd like to introduce our speaker for today's webinar. Dr. Cynthia Rand is a General Pediatrician and Health Services Researcher who focuses on providing preventative care to pediatric clients in Rochester New York. For research experience combined expertise in adolescent immunization and preventive services delivery, quality improvement and health informatics. Dr. Rand was involved nationally in the American Cancer Society HPV Vaccine Roundtable and as a member of the New York State HPV Vaccine Coalition. She is co-PI of a multi-center project funded by the CDC to improve HPV vaccination rates using QI methods in residency clinics and private practices nationwide. In addition, Dr. Rand supervises

residents and sees her own patients in a busy pediatric clinic which provides the context for her translational research. With that, I'm going to turn it over to Dr. Rand to get started.

**Learning Objectives**

By the end of this session, participants will be able to:


- Describe the **burden of HPV** infection and disease
- Describe **HPV vaccination rates** in the U.S.
- Explain HPV vaccine **guidelines, insurance coverage, effectiveness, and safety**
- Implement **strategies to increase HPV vaccination rates** in family planning sites



### Slide 3 - Cynthia Rand:

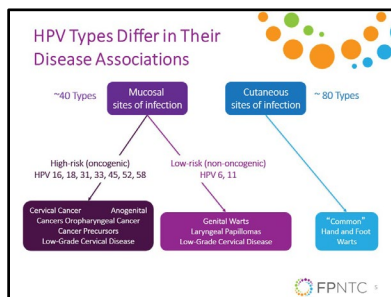
Thanks, Katie and thanks so much everyone for joining today. The learning objectives of this are to describe the burden of HPV infection and disease. To describe HPV vaccination rates in the U.S. and to explain HPV vaccine guidelines, insurance coverage, effectiveness and safety. Finally, we'll talk about implementing strategies to increase HPV vaccination rates and family planning sites.

**OBJECTIVE 1**  
Burden of HPV  
infection and disease



### Slide 4 - Cynthia Rand:

First, to focus on the burden of HPV infection and disease.




## Slide 5 - Cynthia Rand:

HPV types differ in their tendency to infect cutaneous and mucosal or genital epithelium. There are approximately 40 types that are frequently found in the genital tract. These are grouped as high risk or oncogenic types that include HPV 16 and 18. Persistent infection with these types can result in cancers that include cervical, other Anogenital and Oropharyngeal cancer, and low grade cervical disease. Those low risk or non-oncogenic types such as 6 and 11, cause Anogenital warts as well as laryngeal papilloma and low grade cervical disease, whereas the cutaneous types cause common hand and foot warts.

**HPV Infection**

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

Source: Jemal A et al. J Natl Cancer Inst. 2013;105:175-201




## Slide 6 - Cynthia Rand:

We know that most HPV infections happen during the teen and young adult years, because HPV infection usually occurs soon after sexual debut, but most people never know that they've been infected. Women might find out they're infected because of an abnormal Pap test with a positive HPV test, or a diagnosis of genital warts. Men may find out because of a genital wart diagnosis as well.

**Number of HPV-Associated and HPV-Attributable Cancer Cases per Year U.S., 2011–2015**

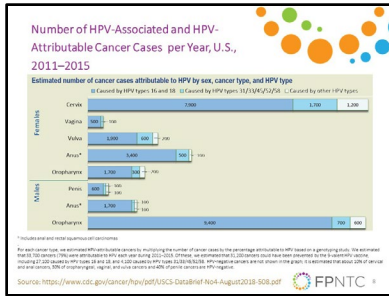
Cancer site	Number of HPV-associated cancers	Percentage probably caused by any HPV type	Number probably caused by any HPV type		
			Female	Male	Both Sexes
Cervix	11,866	91%	10,751	0	10,751
Vagina	846	75%	635	0	635
Vulva	3,934	69%	2,707	0	2,707
Penis	1,269	63%	0	803	803
Anus*	6,530	91%	4,008	1,949	5,957
Oropharynx	18,226	70%	2,160	10,725	12,885
<b>TOTAL</b>	<b>42,671</b>	<b>79%</b>	<b>20,260</b>	<b>13,477</b>	<b>33,737</b>

\*Includes anal and rectal squamous cell carcinomas  
Sources: <https://www.cdc.gov/cancer/hpv/statistics> and Saraiya M et al. J Natl Cancer Inst. 2015;107



## Slide 7 - Cynthia Rand:

This slide focuses on the number of cancers that are attributable to HPV per year in the United States from 2010 to 2015. An HPV attributable cancer is a cancer as it's probably caused by HPV, and the column was percentage probably caused by any HPV type comes from a CDC genotyping study. You can see the HPV causes nearly all cervical cancers and many cancers of the vagina, vulva, penis and anus, including rectal squamous cell carcinoma, as well as the oropharynx. CDC estimated that during 2010 to 2015 HPV caused 33,737 cancers in the U.S. each year with over 20,000 cancers in men and over 20,000 in women over 13,000 men where most HPV associated cancers in women were cervical cancers, and most in men were oropharyngeal cancers.

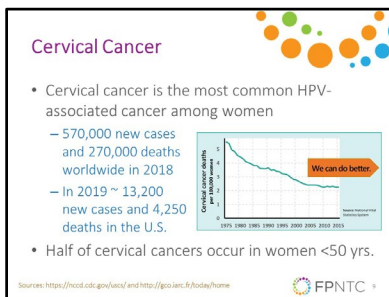


## Slide 8 - Cynthia Rand:

The original Gardasil vaccine prevented HPV type 6 and 11 that causes 90% of genital warts, plus it prevented type 16 and 18. This slide shows that most of the cases of cancer that we speak about cervical and all of the anogenital cancers as well as oropharyngeal are related to those types in the original Gardasil vaccine 16 and 18 in the medium blue here. In the lighter blue, you can see that another 15% of cervical cancers plus some oropharyngeal cancers are prevented from the additional five types that were added to the nine-valent vaccine. The vaccine that's available now is called Gardasil 9 and covers those additional types. There are a few caused by other HPV types that are not covered by the vaccine. The vaccine is expected to cover over 90% of cases of cervical cancer and over 70% of cases of oropharyngeal cancer.

Source:

[Estimated number of cancer cases attributable to HPV by sex, cancer type, and HPT type](https://www.cdc.gov/cancer/hpv/pdf/USCS-DataBrief-No4-August2018-508.pdf)  
<https://www.cdc.gov/cancer/hpv/pdf/USCS-DataBrief-No4-August2018-508.pdf>



## Slide 9 - Cynthia Rand:

A little more about cervical cancer, it was once the leading cause of cancer death for women in the United States, and now it's the most preventable of all the female cancers. The Pap test helped decrease the number of women in the U.S. diagnosed with cervical cancer by about 75% in the past 50 years. However, even with an excellent cervical cancer screening program in the U.S., there's still about 12,000 to 13,000 new cases of cervical cancer and 4,000 deaths each year in this country. Worldwide cervical cancer is the fourth most common cancer among women. In some countries, it's the most common.

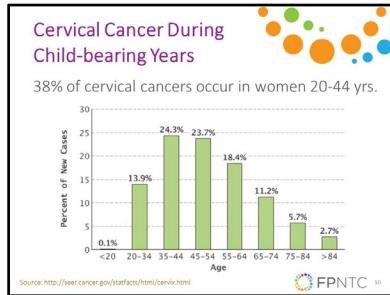
Sources:

[Leading Cancer Cases and Deaths, Male and Female, 2016](https://gis.cdc.gov/Cancer/USCS/DataViz.html)

<https://gis.cdc.gov/Cancer/USCS/DataViz.html>

[Cancer Today, International Association of Cancer Registries](http://gco.iarc.fr/today/home)

<http://gco.iarc.fr/today/home>



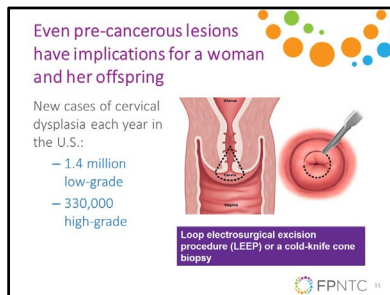
## Slide 10 - Cynthia Rand:

Half of cervical cancer cases in the U.S. occur in women who are younger than 50, with 1 and 4 cervical cancer cases among women aged 25 to 39 years during prime reproductive years. A cervical cancer diagnosis and treatment may be devastating to women and their families for a variety of reasons, including negative effects on their health, welfare, finances and ability to work. Cervical cancer is treated at a minimum amount with the removal of the cervix, but may also include a radical hysterectomy, radiation and chemotherapy.

Source:

[National Cancer Institute, Surveillance, Epidemiology, and End Results \(SEER\) Program](http://seer.cancer.gov/statfacts/html/cervix.html)

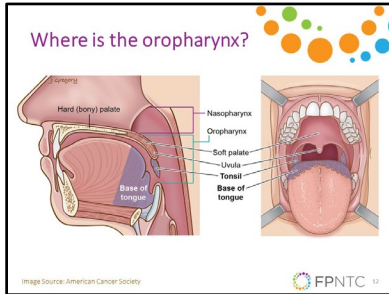
<http://seer.cancer.gov/statfacts/html/cervix.html>



## Slide 11 - Cynthia Rand:

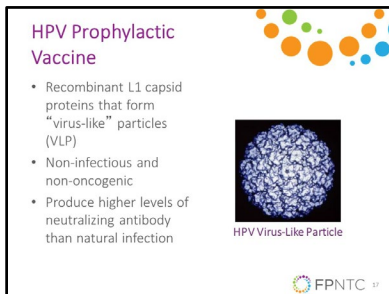
Even precancerous lesions have implications for a woman and her family. There are new cases of cervical dysplasia each year in the U.S. In the pre-vaccine era, every year 1.4 million were diagnosed

with low grade cervical dysplasia. Additionally, each year 330,000 women are diagnosed with high grade cervical dysplasia, or cervical pre cancer. To receive this diagnosis each of these women had a colposcopy with biopsy. Then after receiving the diagnosis, many will go on to have a loop electrosurgical excision procedure, or LEEP, or a cold-knife cone biopsy of the cervix as shown in the image.



### Slide 12 - Cynthia Rand:

The graphic on the right is designed to remind you of where the oropharynx is. It includes the base of the tongue, tonsils and the back of the throat right behind the soft palate. The image on the left shows the view that an ENT surgeon would see when they're evaluating someone who's suspected of oropharyngeal cancer. I know that most people think this is an uncommon cancer, but as I mentioned earlier, the annual number of HPV positive oropharyngeal cancers has surpassed the annual number of cervical cancers.



### Slide 13 - Cynthia Rand:

This graphic shows the trends, in the solid line at the top you can see cervical carcinomas declining over time and now there's that plateau. Unfortunately, that rate of oropharyngeal SCC, or squamous cell carcinoma, is rising and has surpassed those rates of cervical cancers.

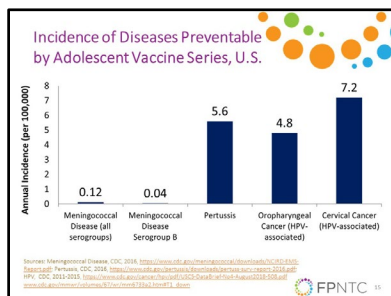
### Treatment of Oropharyngeal Cancer

- Treatment depends on cancer stage
  - Early stage cancers: radiation alone or surgery alone
  - Advanced staged cancers: require combinations of either surgery followed by radiation or concomitant chemotherapy + radiation therapy
- Side effects of treatment can be extensive and disruptive (e.g., may include dental decay and tooth loss, lack of saliva, eating and speech changes, permanent shoulder/arm weakness, fibrotic and atherosclerotic changes to carotid arteries)

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## Slide 14 - Cynthia Rand:

Oropharyngeal cancer treatment is really a good news bad news story. It's great that we have treatment that's very often effective. In the early stage, it's usually treated with radiation alone or surgery alone. However, advanced stage cancers often require combinations of either surgery followed by radiation, or concomitant chemotherapy with radiation therapy. The bad news is the side effects of treatment can be extensive and disruptive, such as the loss of saliva, teeth, speech pathology, damage to carotids or vital support of the shoulder. I know I'm preaching to the choir when I say how much better it is to prevent disease by vaccinating.



## Slide 15 - Cynthia Rand:

This slide shows the incidence of diseases that are preventable by adolescent vaccines. You can see that there are a lot more cases of cervical and oropharyngeal cancer that we can prevent, then there are cases of protest and these diseases are much more common than meningococcal disease. I advocate for all adolescent vaccines, but it does help to put the incidence of infections into perspective.

Sources:

[Meningococcal Disease, CDC, 2016](https://www.cdc.gov/meningococcal/downloads/NCIRD-EMS-Report.pdf)

<https://www.cdc.gov/meningococcal/downloads/NCIRD-EMS-Report.pdf>;

[Pertussis, CDC, 2016](https://www.cdc.gov/pertussis/downloads/pertuss-surv-report-2016.pdf)

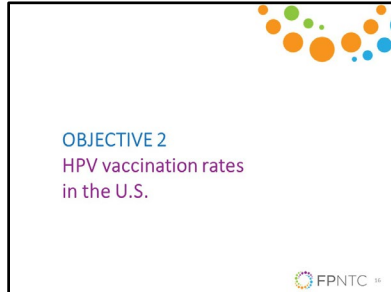
<https://www.cdc.gov/pertussis/downloads/pertuss-surv-report-2016.pdf>

[HPV, CDC, 2011-2015](https://www.cdc.gov/od/oc/media/pressrels/2015/s011501a.htm)

<https://www.cdc.gov/cancer/hpv/pdf/USCS-DataBrief-No4-August2018-508.pdf>

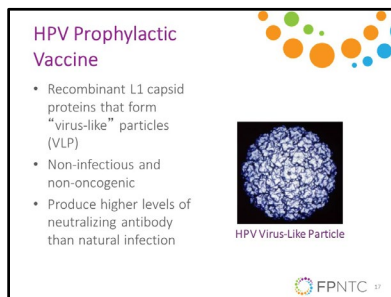
[Trends in Human Papillomavirus–Associated Cancers — United States, 1999–2015](https://www.cdc.gov/mmwr/volumes/67/wr/mm6733a2.htm#T1_down)

[www.cdc.gov/mmwr/volumes/67/wr/mm6733a2.htm#T1\\_down](https://www.cdc.gov/mmwr/volumes/67/wr/mm6733a2.htm#T1_down)



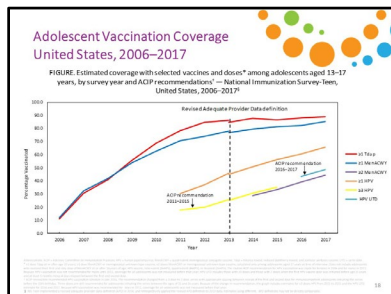
### Slide 16 - Cynthia Rand:

Next, we'll talk a little bit about the problem, which is the HPV vaccination rates in the United States.



### Slide 17 - Cynthia Rand:

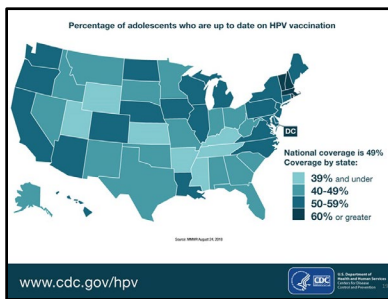
First, a little bit more about the vaccine, all of the available prophylactic HPV vaccines are made from virus like particles. The vaccines do not contain any viral DNA, and therefore they're not infectious and can't cause actual disease or cancer. HPV vaccines produce a better immune response than an HPV infection.





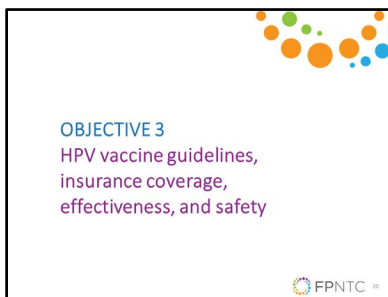
## Slide 18 - Cynthia Rand:

As you can see, the rates of the first dose and third dose of HPV vaccine, which are shown here in orange and in yellow, are not nearly as high as the coverage rates for the other vaccines that are routinely recommended for 11 and 12 year olds. We recommend the Tdap, which is the tetanus diphtheria pertussis vaccine, as well as the meningococcal vaccine regularly at this age, and you can see that in red and blue at the top of the curve. Also, these vaccines came on the market about the same time, the HPV vaccine has been available and recommended for girls since 2006, and then began to be recommended for boys in 2010. However, the real important piece of information that this slide provides is that the strong coverage rates for Tdap vaccine demonstrate that not only are most preteens and teens getting to the doctor, but they're also getting at least one of the recommended adolescent vaccines. That takes out the issue of access, we know there's something else going on here with these low rates of HPV vaccination.



## Slide 19 - Cynthia Rand:

This shows the percentage of adolescents aged 13 to 17 in each state who are up to date on HPV vaccination. Take a look at and find the state that you're in and you can see where you stand. The darker colors have a rate of 60% or greater, and then the lightest color has 39% and under. The highest rate in the country is in Rhode Island, which is at 78% and the lowest is in Mississippi at 33% with an average of 51% of the teens who are up to date. Remember, this includes 13 to 17 year olds, we're really recommend the vaccine at 11 to 12. If we just looked at 13 year olds who should be vaccinated, these numbers are much lower. It means that only half of teens nationally are up to date, rates are becoming much more similar for boys and girls. Nationally 54% of females and 49% of males are up to date. The boys are catching up, which is good news.



## Slide 20 - Cynthia Rand:

Let's talk more in detail about HPV vaccine guidelines, insurance coverage, vaccine effectiveness and safety.

**Dosing Schedules**

Starting the vaccine series at ages 9–14 (ideally before age 13)

- Recommended schedule is 2 doses of HPV vaccine
  - Second dose should be administered 6–12 months after the first dose
  - Minimum interval between doses is 5 months

Starting the vaccine series at age 15–26

- 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
  - Minimum interval between dose 1 and dose 3 in a 3-dose schedule is 5 months

Source: Melles et al. MMWR. 2016. FPNTC 21

## Slide 21 - Cynthia Rand:

Recommendations for the HPV vaccine dosing schedules have changed over the past few years. For those who initiate the vaccine before they turned 15, the schedule is just two doses of the HPV vaccine. The second dose should be administered six to 12 months after the first dose. For those who are initiating the vaccine on or after their 15th birthday, the recommendation for a three dose schedule remains. That was the schedule we used to have for everybody. The second dose should be administered one to two months after the first dose and the third dose should be administered six months after the first. I think of this as a zero, one-to-two-months, and six-months schedule, same as we were giving previously. If somebody initiated with the nine-valent, the quadrivalent or the bivalent HPV vaccine before they turned 15, they got two doses of any HPV vaccine on the recommended schedule or they got three doses at the recommended dosing schedule, they're considered adequately vaccinated. If someone received the Gardasil for vaccine, for instance, and have the appropriate doses, then it's not suggested that they get a Gardasil 9 vaccines. Similarly, if anybody had the bivalent vaccine, although that wasn't available very much in the United States. Also, you can complete the series with the nine-valent vaccine if you had a prior dose. If you had one dose of Gardasil 4, and you're due for your second dose, you can complete the series with the nine-valent vaccine that's now available. As I mentioned, there's no recommendation for those who had a bivalent or quadrivalent vaccine and completed the series, no recommendation for getting a nine-valent vaccine. I know it's confusing because it has evolved over time, but only the nine-valent vaccine is available in the United States now.

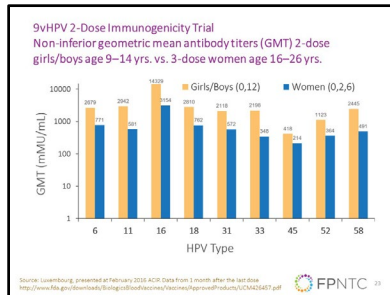
**Catch Up**

- Catch-up vaccination is recommended for all persons through age 26 years.
- Nine-valent HPV vaccine may be used to continue or complete a vaccination series started with quadrivalent or bivalent HPV vaccine.
- If completed valid vaccination series with any HPV vaccine, no additional doses needed.

Source: Melles et al. MMWR. 2016. FPNTC 22

## Slide 22 - Cynthia Rand:

A little bit about catch-up vaccination--and this is fairly new--it's recommended for all people through age 26. This did change recently, it was up to age 21 for males, and up to age 26 for females. Now the recommendation is catch-up for everybody through age 26, there may be some lag and insurance coverage for males up to age 26 just because that part is a new recommendation. The nine-valent HPV vaccine, as I mentioned, can be used to continue or complete a vaccination series that has started with any of the other vaccines. If you completed the valid vaccination series, you need no additional doses.



## Slide 23 - Cynthia Rand:

This change in recommendation that occurred over the last two years for today's schedule, what is the science little bit behind that? There were not inferior antibody titers in 9 to 14 year olds, who received the two doses at 0 and 12 months that's shown in blue compared to women who received... Sorry, shown in yellow, and blue shows the women who received the doses at 0, 2 and 6 months in older women. The younger girls and boys were age 9 to 14 in yellow, and blue, the women at 0, 2 and 6 months are 16 to 26. You can see that the titers are higher in the younger age group for each HPV type that's in the Gardasil 9 vaccine.

Source:

[Luxembourg, presented at February 2016 ACIP. Data from 1 month after the last dose](http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM426457.pdf)

<http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM426457.pdf>

**Vaccinating Adults, Ages 27-45**

- Vaccination is not recommended for everyone older than age 26 years
- Some adults ages 27-45 years may decide to get the HPV vaccine based on discussion with their clinicians
- HPV vaccination of people in this age range provides less benefit, as more have been already exposed to HPV
- Shared clinical decision making is recommended

Source: Human Papillomavirus Vaccination for Adults: Updated Recommendations of the Advisory Committee on Immunization Practices, CDCMMWR, August 16, 2015, 64(32):698-702

## Slide 24 - Cynthia Rand:

That doesn't make it simpler for those who start under 15. There's a brand new recommendation, MMWR came out in August 2019 for vaccinating adults 27 to 45. The vaccine is not recommended for everyone older than age 26, but some adults who are 27 to 45 might decide to get the HPV vaccine based on discussion with their condition. HPV vaccination of people in this age range provides less benefit, as more has been already exposed to HPV and shared clinical decision making is recommended.

Source:

[Human Papillomavirus Vaccination for Adults: Updated Recommendations of the Advisory Committee on Immunization Practices. MMWR Morb Mortal Wkly Rep 2019;68:698–702.](http://dx.doi.org/10.15585/mmwr.mm6832a3)  
<http://dx.doi.org/10.15585/mmwr.mm6832a3>

**Patients' Questions**  
**Ages 27–45**

- Most sexually active adults have already been exposed to HPV
- Having a new sex partner is a risk factor for getting a new HPV infection
- HPV vaccination prevents new HPV infections but does not treat existing infections or diseases

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## Slide 25 - Cynthia Rand:

Most sexually active adults have already been exposed to HPV. We do know that having a new sex partner is a risk factor for getting a new HPV infection. An HPV vaccination prevents new HPV infections, but does not treat existing infections or diseases. That is a caveat, we don't want people believing that if they get vaccinated when they're older, that it will protect them as well because it's not meant to be a therapeutic vaccine, it is meant to be a preventive vaccine. They're still definitely at risk of developing HPV-related diseases if they had been exposed when they were younger prior to being vaccinated.

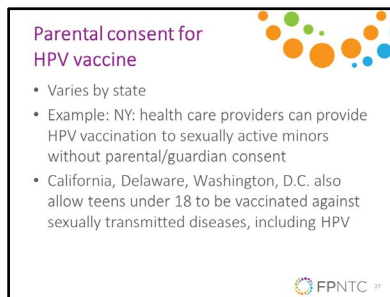
**Insurance Coverage for HPV Vaccine**

- Cost of HPV vaccine is about \$250 per dose
- The Affordable Care Act requires private insurance plans to cover recommended vaccines
- Generally covered by insurance for ages 9–26 females, males to 21 (ACIP vote June 2019 to age 26 for males)
- Vaccines for Children (VFC) if uninsured, Medicaid eligible to age ≤18 years
- Merck has patient assistance program for ages 19–26
- Ages 26–45 likely not covered yet

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## Slide 26 - Cynthia Rand:

A little bit about insurance coverage, the cost of the HPV vaccine is quite expensive at \$250 per dose. The good news is that the Affordable Care Act requires private insurance plans to cover recommended vaccines and it will generally be covered by insurance for age 9 to 26 for females. As I mentioned before, up to age 21 for male, however, that recent vote from ACIP in June, change that age to 26. We may see that coverage changing over the next year for males up to age 26. Also, vaccines for children are VFC covers patients who are uninsured and Medicaid eligible up to age 19. Once they turn 19, they're no longer eligible for VFC. However, Merck does have a Patient Assistance Program for age 19 to 26. It is very likely that age 26 to 45 is not covered quite yet. Because insurance companies are allowed a year after an MMWR publication to cover those recommended vaccines. It's a little bit tricky because it's a provider discussion, but it should hopefully be covered, ideally, by August of next year; there might be some lag in certain areas.



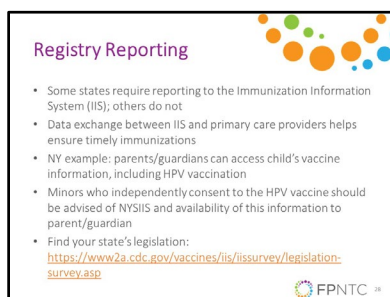
**Parental consent for HPV vaccine**

- Varies by state
- Example: NY: health care providers can provide HPV vaccination to sexually active minors without parental/guardian consent
- California, Delaware, Washington, D.C. also allow teens under 18 to be vaccinated against sexually transmitted diseases, including HPV

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## Slide 27 - Cynthia Rand:

Parental consent for HPV vaccine does vary by state. An example in New York is that healthcare providers can provide the HPV vaccine to sexually active minors without parental or guardian consent. A few other areas California, Delaware and Washington also allow teens under 18 to be vaccinated against sexually transmitted diseases, including HPV. You do need to look for a specific legislation in your own area because these are specific rules that are brought up to the legislature for these permissive consents by teens themselves.



**Registry Reporting**

- Some states require reporting to the Immunization Information System (IIS); others do not
- Data exchange between IIS and primary care providers helps ensure timely immunizations
- NY example: parents/guardians can access child's vaccine information, including HPV vaccination
- Minors who independently consent to the HPV vaccine should be advised of NYSIIS and availability of this information to parent/guardian
- Find your state's legislation:  
<https://www2a.cdc.gov/vaccines/iis/iissurvey/legislation-survey.asp>

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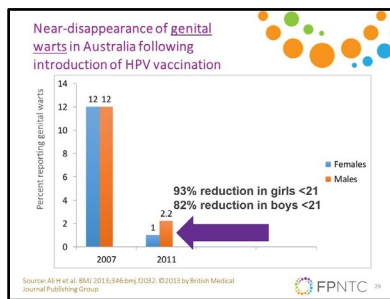
## Slide 28 - Cynthia Rand:

The other issue is about registry reporting, some states require reporting to the Immunization Information System or IIS and others do not. It's very helpful because data exchange between the IIS and primary care providers helps to ensure timely immunizations. In New York, for instance, parents and guardians can access their child's vaccine information, including HPV vaccination. It is important to let patients know if they're a minor, and they independently consent to the HPV vaccine. They should know that, that information is going to our own state registry, and that it could be available to the parent or guardian. The CDC does keep track of state legislation; this resource should be able to help you to figure out what the legislation is for state registries in your own state.

Find your state's legislation:

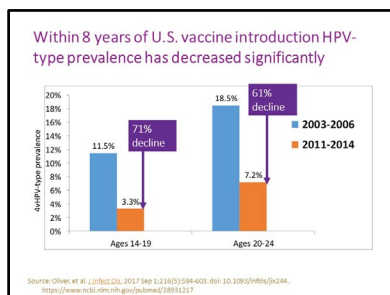
[CDC Survey of State Immunization Information System Legislation](https://www2a.cdc.gov/vaccines/iis/iissurvey/legislation-survey.asp)

<https://www2a.cdc.gov/vaccines/iis/iissurvey/legislation-survey.asp>



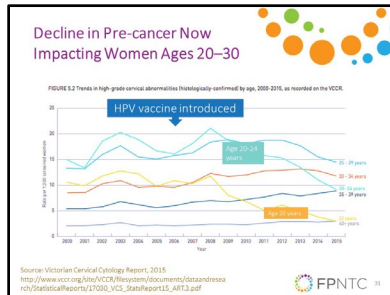
## Slide 29 - Cynthia Rand:

Some wonderful news about the vaccine effectiveness is that there's been a near disappearance of genital warts in Australia, following the introduction of HPV vaccination. In Australia, 70% of their girls received all three doses of the quadrivalent vaccine. It was given at age 12 because they have a school based vaccination program. They started in 2007, and very quickly vaccinated most of their 12 year olds. Prior to 2007, up to 10% of girls and boys under the age of 21 had a visit for genital warts. By 2011, four years after the program started, genital warts had nearly disappeared in this age group, with 93% reduction in girls and an 82% reduction in boys. There was no decrease in rates of genital warts among older men and women during this time.



## Slide 30 - Cynthia Rand:

Some other good news in the United States, even though we're not the leader when it comes to HPV vaccination, and other countries do a better job of getting their population vaccinated, we have also seen a population wide reduction in disease and a national survey found 71% decline in vaccine type of HPV among teenage girls, and 61% decline in young adults, but it did not find a decline among those who are too old to be vaccinated. That's quite remarkable that we saw such a dramatic decline, even with our rates of 50% of our adolescence being vaccinated.



## Slide 31 - Cynthia Rand:

Those are the HPV incidents and the genital warts incidents. Now, we can continue to monitor the effects of vaccinations. In Australia, all girls start getting pap tests every year at 18, and you can see that high grade cervical dysplasia or pre cancer has essentially disappeared in women under age 20 and fallen by nearly 70% in women aged 20 to 24. This is population level evidence that the most important effect of HPV vaccination, which is a reduction in cervical cancer is already a reality in countries that have a high vaccination rate. In fact, Australia is expecting to eliminate cervical cancer in the next 20 years.

**Over 10 Years of HPV Vaccine Safety Data**

- HPV vaccines are 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 HPV vaccine or who has an allergy to yeast
- Brief fainting spells (syncope) and related symptoms (such as jerking movements) can happen soon after any injection, including HPV vaccine
- Clients should be seated (or lying down) during vaccination and remain in that position for 15 minutes

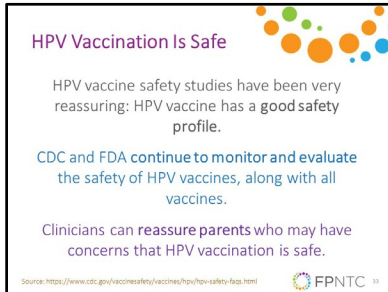
Source: Geis, et al. Hum Vaccine Immunother. 2016.

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## Slide 32 - Cynthia Rand:

We have some very good safety data about the vaccine, there's post licensure HPV safety data from the U.S. and many other countries in the past 10 years that are robust and reassuring. We know that we can expect HPV vaccination to cause some injection site reactions, potentially a fever and headache. We know that anyone who has severe allergies such as an allergy to yeast, or a life threatening allergic reaction to a component of the vaccine, or a previous dose of the vaccine shouldn't be vaccinated, but

this is exceedingly rare. We also know that fainting spells or syncope is very common and adolescence when they receive injections. It doesn't have to be an HPV vaccine, it could be a blood draw, or a meningococcal vaccine. If you have a patient where you think they might faint they should be seated while vaccinated and remain in that position, or should lie down for 15 minutes.



**HPV Vaccination Is Safe**

HPV vaccine safety studies have been very reassuring: HPV vaccine has a good safety profile.

CDC and FDA continue to monitor and evaluate the safety of HPV vaccines, along with all vaccines.

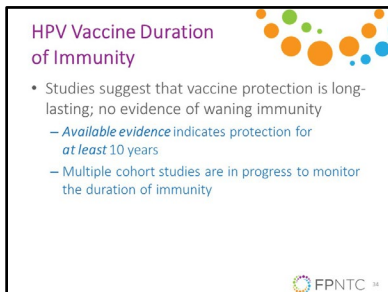
Clinicians can reassure parents who may have concerns that HPV vaccination is safe.

Source: <https://www.cdc.gov/vaccinesafety/vaccines/hpv/hpv-safety-faq.html>

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### Slide 33 - Cynthia Rand:

The good news is that the safety profile for HPV vaccines is well established, it's been very reassuring and the CDC and FDA continue to monitor and evaluate the safety of HPV vaccines along with all vaccines. However, despite the availability of reassuring data concerns still persist and have been highlighted in the media, and especially social media that's leave some parents hesitant to initiate the vaccine series for their children. It's very important for clinicians to reassure parents who may have concerns that there have been over 10 years of safety data collected for HPV vaccines, and that the vaccination is safe.



**HPV Vaccine Duration of Immunity**

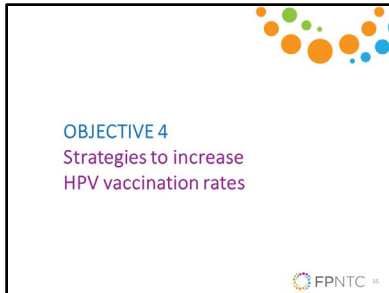
- Studies suggest that vaccine protection is long-lasting; no evidence of waning immunity
  - Available evidence indicates protection for at least 10 years
  - Multiple cohort studies are in progress to monitor the duration of immunity

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### Slide 34 - Cynthia Rand:

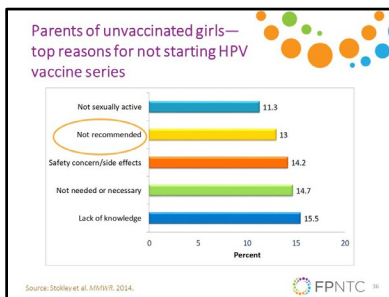
The HPV vaccine is made in the same way as the Hepatitis B vaccine and uses the same adjuvant. Hepatitis B vaccination confirmed lifelong immunity, and so it's expected the HPV vaccination will be similar. As I mentioned, it's been available in the United States for over 10 years, and long term studies from clinical trials also provide data, that there's no evidence that protection against vaccine types will decrease over time.





### Slide 35 - Cynthia Rand:

Let's move on to some strategies to increase HPV vaccination rates in your own office.



### Slide 36 - Cynthia Rand:

Unfortunately, studies consistently show that a strong recommendation from you is the single best predictor of vaccination for any vaccines. I shouldn't say unfortunately, I should say fortunately. Unfortunately, many people are not recommending the vaccine. In 2013, the NIS team or National Immunization Survey team showed that almost 15% of parents who said they would not be getting their child vaccinated against HPV in the next 12 months identified not receiving a recommendation is one of the top reasons not to vaccinate.

Make an Effective  
Recommendation

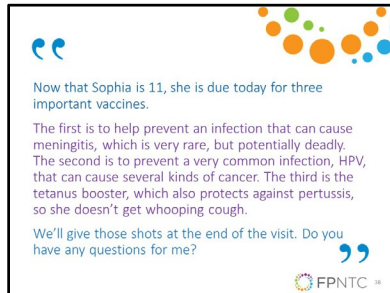
- **Same way:** Effective recommendations group all of the adolescent vaccines  
Recommend HPV vaccination the same way you recommend Tdap and meningococcal vaccines
- **Same day:** Recommend HPV vaccine TODAY  
Recommend HPV vaccination the same day you recommend Tdap and meningococcal vaccines

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

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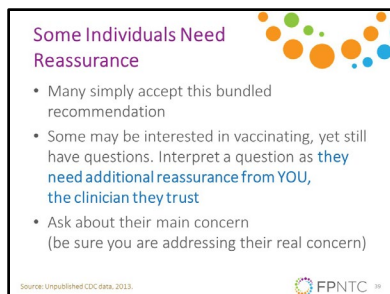
## Slide 37 - Cynthia Rand:

The first thing is to make an effective recommendation. To do so, you want to do it in the same way and the same day as other adolescent vaccines. The same way is to recommend the vaccine as you would Tdap, meningococcal or flu vaccine. On the same day is to do it today, the same day that you're giving the other vaccines. Don't separate it out and don't treat it as special.



## Slide 38 - Cynthia Rand:

You could say, "Now that Sophia is 11, she's due today for three important vaccines. The first 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 cancers. The third is the tetanus booster which also protects against pertussis, so she doesn't get whooping cough. We will give those shots at the end of the visit. Do you have any questions for me?"



## Slide 39 - Cynthia Rand:

Many parents will accept that bundled recommendation without any questions, but other parents might still be interested in vaccinating but still have some questions for you. Questions from parents about HPV vaccine doesn't mean that they're refusing or delaying. Many parents with questions about HPV vaccine or looking for additional reassurance from you. Taking the time to listen to parent's questions, helps you save time and give an effective response. Be sure to verify that you're addressing the right concern. You don't want to start talking and explaining a concern that you assume the client or parent might have. You want to really figure out what their concern is so that you don't overwhelm them with information.

**HPV Vaccine: Same Way Same Day Mobile App**

- A brief 15-minute, interactive, role-play simulation
- Learn how to:
  - avoid common conversation pitfalls and improve communication skills during HPV vaccine conversations
- Download this complimentary App today from the [Apple iTunes Store](#) or [Google Play Store](#).

**Save Time And Increase HPV Vaccination Rates**



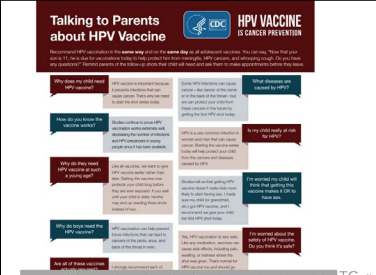
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## Slide 40 - Cynthia Rand:

There's a terrific app that's been developed, it's called HPV Vaccine: Same Way, Same Day Mobile App, and it's a brief 15-minute interactive role play where you can avoid common conversation pitfalls, and improve your communication skills during HPV vaccine conversations. It's available freely at the Apple iTunes Store or at the Google Play Store.

**Talking to Parents about HPV Vaccine**

HPV VACCINE  
CANCER PREVENTION



<https://www.cdc.gov/hpv/hcp/for-hcp-tipsheet-hpv.pdf>

TC

## Slide 41 - Cynthia Rand:

CDC has also developed a really excellent resource for answering common questions and it's posted at the site that's noted below.

Source:

[Talking to Parents About Infant Vaccines \(CDC\)](https://www.cdc.gov/hpv/hcp/for-hcp-tipsheet-hpv.pdf)

<https://www.cdc.gov/hpv/hcp/for-hcp-tipsheet-hpv.pdf>

**Will my teen see this as "permission" to have sex?**

- Kaiser Permanente Center for Health Research
- 1,398 girls who were 11 or 12 in 2006, 30% of whom were vaccinated, followed through 2010
- No difference in markers of sexual activity, including
  - Pregnancies
  - Counseling on contraceptives
  - Testing for, or diagnoses of STIs

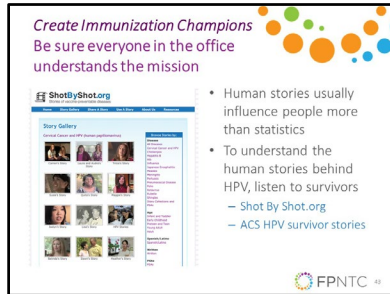
Receipt of HPV vaccine does not increase sexual activity or decrease age of sexual debut

Source: [Bachmann, Pediatrics Oct 2012](#)

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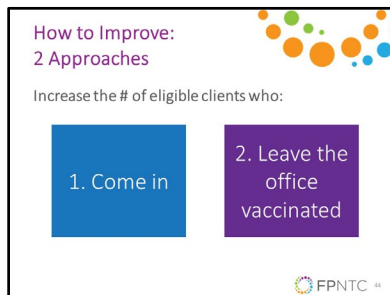
## Slide 42 - Cynthia Rand:

Getting into some of those common questions, one common question might be, "Will my teen see this is as permission to have sex." Reassuringly, multiple studies have demonstrated that girls who receive HPV vaccine do not engage in sexual intercourse sooner than their peers who did not receive HPV vaccine. When such study was done by the Kaiser Permanente Center for Health Research, and among almost 1,400 girls who were 11 or 12 and 2006, 30% of them were vaccinated and all of these girls were followed through 2010. There were no difference markers of sexual activity that included pregnancies, counseling on contraceptive, testing or diagnosis of sexually transmitted infections.



## Slide 43 - Cynthia Rand:

It does help to have immunization champions in your practice, and be sure that everyone in the office understands your mission. One really great way to get everyone on board is by watching the videos on Shot By Shot or the American Cancer Society survivor stories. If you take a look at those, those human stories behind the HPV cancers often influence people more than statistics.



## Slide 44 - Cynthia Rand:

How can you improve? You have two options. You can increase the number of clients who come into your office or you can increase the number who be vaccinated.

1. Increase number who come in

Reminders:

- For clients who haven't been in
  - Phone, text, patient portal
- Follow-up doses
  - Consider a reminder in your own system to send a text or phone call reminder 6–12 months later

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## Slide 45 - Cynthia Rand:

That sounds really simple. First, let's talk about how do you get more patients to come in. You can send reminders to patients who haven't been in. All of the methods noted here has been well studied and are quite effective. You could set up some auto dialer, a text message reminder, or if you have access to a patient portal, all of those methods can help to remind patients to come in. Something that's also quite helpful to complete the series is to set up some reminder for follow up doses. If you give that first dose, maybe you can set up a reminder in your own system to send a text or a phone call reminder six to 12 months later, to bring back that adolescent or young adult for the second dose.

2. Increase number who leave vaccinated

A) By vaccinating at every visit type

- Preventive care
- Chronic care
- Acute care

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## Slide 46 - Cynthia Rand:

Let's think about what you can do in your own office to increase the number who leave vaccinated. First, you can vaccinate any type of visit, anytime a patient comes in, if they are there for any visit unless they're currently pregnant because the vaccine is not recommended during pregnancy. If they're planning to continue with the pregnancy, you would not want to vaccinate them. If they're there for any type of preventive care, for an STD check, for any chronic care, for any acute care. If you see them, offer the vaccine.

2. Increase number who leave vaccinated (cont'd 2)

B) Standing Orders

- Empower non-physician personnel to vaccinate clients (after assessing for specific contra-indications) without direct provider involvement
  - Follow state laws for administration e.g., RN, LPN, LVN, MA
- Preapproved orders to vaccinate on file, as allowed
  - Verify laws with state medical/nursing boards
  - Templates available for all routine vaccines at [www.immunize.org/standing-orders/](http://www.immunize.org/standing-orders/)
  - Update clinic protocols and agency policies if adopted
- Need staff buy-in for all vaccines due

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## Slide 47 - Cynthia Rand:

Other ways to increase the number who leave vaccinated. First, is to develop a standing order in your practice, that allows non physician personnel to vaccinate clients after assessing for specific country indications without direct provider involvement. You can follow state laws for administration, such as RN, LPN, LVN or MA. You have pre-approved orders to vaccinate on file, as allowed. You should verify the laws with your state medical and nursing boards, make sure that you're allowed to have them vaccinate. For instance, in New York State RNs can vaccinate but MAs can't, but that's different in different states. Templates are available for all routine vaccines at immunize.org. If you take a look at that link, they're standing orders for every type of vaccine including HPV vaccine. Then you would want to update your clinic protocols and your agency policies as adopted. However, you really need staff buy in for all vaccines do. If you have a standing order, say for flu vaccine and your nurses haven't learned sufficiently about why HPV vaccine is so important. You might want to share with them some of the resources that are included here.

2. Increase number who leave vaccinated (cont'd 3)

C) Provider Prompts

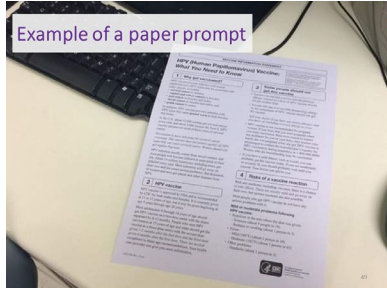
- Paper or EHR (better to use both)
- Engage nurses/MAs to help
- Pre-visit planning
- Huddling

FPNTC

## Slide 48 - Cynthia Rand:

Another way you can increase the number who will be vaccinated is to do some provider prompt. We found over multiple studies that if you just have your electronic health record, give you a prompt, it's very easy to ignore it. It's much better to use two methods to prompt. It also helps to engage the nurses or the medical assistance. It helps to do some pre visit planning, if you know you have a scheduled list of patients coming in, then you take a look at the schedule, and preview the EHR to see who's due for which vaccines, and then document on some paper. People have tried different methods, you might look at the schedule and document on the schedule, you might put a sticky note on the computer, or other electronic sticky note in the electronic template. Having huddles also certainly helps, if you have a huddle twice a day, say, for how things are going over the course of your day, you might take a few

minute break, gather around the computer with the nurses and the providers, and take a look at the schedule and see who needs what each day. A little bit of time ahead of time can really improve the way that your flow goes and can help you manage multiple things and helps you to remember things that patients are eligible for.



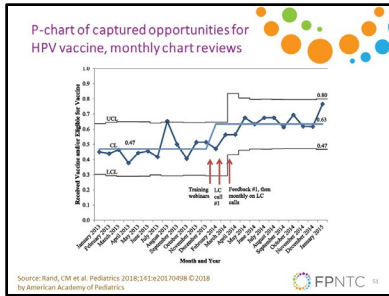
### Slide 49 - Cynthia Rand:

One very simple thing to do is to make a colored copy of the VIF form or vaccine Information Statement. This is what we do in our practice, even though in my practice I have the EHR telling me a patient might be due for a vaccine, if I see this purple sheet of paper on my keyboard, I know that somebody has looked at the immunization schedule. It's another reminder for me physically to remember to offer the patients that vaccine and our days are busy and complicated, and so any little bit really helps.



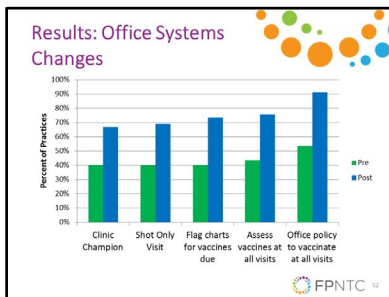
### Slide 50 - Cynthia Rand:

Our experience with reducing missed opportunities has been gained through five years of learning collaboratives, where we have practices that collect monthly data from their practice. They focus on integrating quality improvement, a strong or effective recommendation, meaning the same way in the same day as other vaccines, starting at least age 11 to 12, if not sooner and consistency in their practice change. They adopt a common schedule, they train the front desk staff, the nurses and the MAs that everybody's going to follow the same schedule. Most of them are implementing some provider prompt.



## Slide 51 - Cynthia Rand:

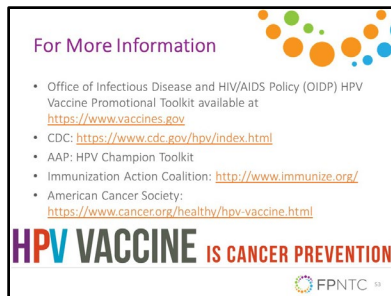
This is some data from our first cohort, which was actually just with continuity clinics in pediatric practices in pediatric residency programs. You can see the baseline data started at that point four, seven, where you see the CL, and that was their baseline data for missed opportunities. That meant that 47% of the time, they were having a captured opportunity, sorry for vaccines. In this case, it's good to improve on captured opportunities, meaning a patient was eligible for the vaccine and they received it. You can see that after having some training webinars about learning about a strong recommendation, and getting together on learning collaborative calls and giving practices feedback, they really dramatically improve their captured opportunities to 63%. Over time, they're continuing to do so, because they've implemented those changes in their practice, and they're really integral to how they operate now. You can make a really dramatic change in captured opportunities or in reducing missed opportunities for vaccination.



## Slide 52 - Cynthia Rand:

A little bit more about the office systems that I mentioned that they chose to implement. They either assigned or encouraged a clinic champion, usually someone rose to the surface, who was really interested in improving immunization in their practice. They developed shot only visit, instead of just having a flu vaccine only clinic, they add HPV vaccine to times when patients could just walk in for a vaccine, and they didn't have to appear at a well visit or a chronic care visit. They could come to see the nurse for the shot. They also flag the charts for vaccines that were due, and assessed vaccines at all visits, and then developing a policy where they would be willing to vaccinate at all visits made a dramatic difference.





## Slide 53 - Cynthia Rand:

There are a lot of resources available and I know it can be overwhelming when you're trying to figure out where to go for information. Imagine for patients and clients how overwhelming that can be and we know that they're getting a lot of misinformation, both on vaccine information sites that are pseudoscience or on the Facebook and other social media sites. These are reliable resources, there's [www.vaccines.gov](https://www.vaccines.gov). The CDC has excellent resources available to you. The American Academy of Pediatrics has developed an HPV champion toolkit and the immunization Action Coalition where I mentioned those disease cases where patients talk about the diseases that are preventable with vaccines are at [immunize.org](http://www.immunize.org). Then the American Cancer Society also has some of those terrific videos. They're very short, just a two-minute clip about a patient with oropharyngeal cancer, or a patient with cervical cancer, and then their physicians also advocating for the vaccine, and the things that can be prevented. I highly recommend taking a look at the American Cancer Society site as well. This is really what it comes down to.

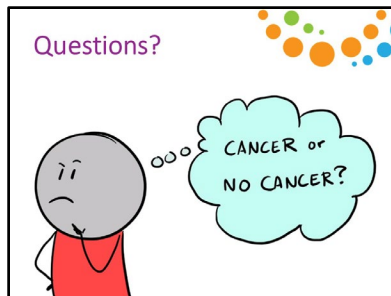
Resources:

[Office of Infectious Disease and HIV/AIDS Policy \(OIDP\) HPV Vaccine Promotional Toolkit](https://www.vaccines.gov)  
<https://www.vaccines.gov>

[CDC HPV resources](https://www.cdc.gov/hpv/index.html)  
<https://www.cdc.gov/hpv/index.html>

[AAP: HPV Champion Toolkit - Immunization Action Coalition](http://www.immunize.org/)  
<http://www.immunize.org/>

[American Cancer Society](https://www.cancer.org/healthy/hpv-vaccine.html)  
<https://www.cancer.org/healthy/hpv-vaccine.html>



## Slide 54

Cynthia Rand: I'm happy to take questions and I'm going to hand it back to Katie.

Katie Quimby: Thank you so much, Dr. Rand. That was great. We are opening up for audience questions now. You can ask your questions again by on the left hand of your screen there is a pod labeled, "Ask a question." Type in your question there and click send and we will address the questions as they come in. We have already received a few questions that I will direct to Dr. Rand here. The first question is, is it recommended to get the vaccine even if the patient actively has HPV or has been exposed?

Cynthia Rand: That's a terrific question. We don't typically test patients for HPV before we vaccinate them, but you might be doing so in their settings. I would say if they're at least under the age of 26, and they haven't been vaccinated, I would say to vaccinate them because they fall within the recommended age group. Earlier would be better because they're less likely to have been exposed to multiple types. Because the vaccine is covering nine types, it's possible that they were exposed to type 16 and 18 but not to one of the other types of the vaccine. I would say if they're in the appropriate age group and they haven't been vaccinated, then yes, vaccinate them. Great question.

Katie Quimby: The next question is....

Cynthia Rand: Let me just add, because they would have been exposed potentially to other types, it won't be as effective because it's not going to prevent the type that they've already been exposed to. They're still certainly at risk for those cervical and other cancers, which is why we would prefer to vaccinate them younger, but I wouldn't use that as a reason not to vaccinate. Go ahead.

Katie Quimby: Great. Next question is, and I know you talked a little bit already about how to recommend the vaccine to parents. Here's a situation that's probably not too uncommon that hopefully you can address in terms of a little bit more specific situation. The question is, Kansas requires the Tdap and meningitis vaccine for children entering seventh grade. HPV is highly recommended but not required. We have many parents that choose only to get the required vaccination even after discussion and education around the importance of a few vaccines. Any suggestions for navigating that discussion?

Cynthia Rand: Yeah. I think that's a really common concern, because that's the case in most states that those two are required in New York it's Tdap in sixth grade, it's a little bit sooner. The first thing is for you not to bring it up that way. I understand parents often will bring it up and ask what's required. I think the first thing is to not separate it as these are required, and these are not. As long as you're going

in with these are the vaccines that are recommended at this age, I recommend Tdap, HPV and meningococcal vaccine, do you have any questions? Then often a parent will say, "Well, are all of those required for school?" If they ask that certainly you're going to answer honestly, "No, these are not all recommended for school, it often takes time for legislation to catch up with what's recommended, but I strongly recommend this vaccine for all of my patients. Because I think it's so important and so effective in preventing cancer, it's so important to me."

Cynthia Rand: I think if you come at it with that passion, I think that really helps. You want to believe in it, and say how strongly you recommend it. As long as you're not introducing it separately, as not required or required, but then the parent brings it up, you answer honestly, but then you advocate strongly. It takes a little bit further, they might have another question. They might want to ask you about safety, or they might want to mention something that they heard on social media. You don't have 15 minutes probably to just talk about HPV vaccine. That's where you might want to go to maybe make one point and go to one of those resources and provide those resources to them to be able to take a look at on their own, and hopefully that can be helpful. I think this is really challenging and only Rhode Island right now has a true strong requirement for the vaccine. Certainly, there's pushback in other places where there are state requirements, but it might be coming down the pike in more states.

Katie Quimby: Great. Next question is, could you explain the trend in oropharynx cancer due to HPV? Has it surpassed cervical cancer because rates of cervical cancer are decreasing or is it increasing in general? Relatedly, I'm curious if you can talk more about the fact that anal cancer rates are higher in female we would have expected higher rates than male.

Cynthia Rand: First, let's take a look at the cervical carcinoma question. That's a great question. You can see, I don't know if you can see my slides still, but if you can, you can see that the rates of cervical cancer have declined, but now have leveled off. Yes, this oropharyngeal cancer incidence is increasing. One, there's no great screening for pharyngeal cancer. Two, it's probably related to oral sex and high rates of HPV in men and women. Some of it is changes in sexual behavior, but some of it is also because cervical cancers are declining. Unfortunately, it's mostly that we don't have a great screening mechanism. The rates are increasing and we don't have a great way to screen people for oropharyngeal cancer.

Cynthia Rand: I'm going to take a look at a second question again, anal cancer rates higher in females. Yes. Taking a look back at that those numbers and anal cancer you can see there 4,000 cases in females and almost 2,000 males. I don't know the answer to why that is. I don't know if that's sexual practice or if there's another reason. I think that's a great question, I'm happy to get back to you on that.

Katie Quimby: We'd like to learn something new on this. This is great. We will come back to that at a later point. Thanks for your question. The next question from the audience is, if a patient has completed the HPV four series, can you explain why we would not recommend getting HPV nine series to protect them against the extra five?

Cynthia Rand: Yeah, that's a great question. I think it gets to two points, first, take a look at the numbers. We certainly are preventing probably another 15% of cervical cancers with the newer vaccines, but we just don't tend to make changes when new vaccines become available. If you think

back to the old Prevnar vaccine that we had before we had Prevnar 13, we had an earlier type of Prevnar. I guess we feel that generally in the vaccine program, that you get what's recommended when it's recommended in your age group, and then the people benefit, if they're younger and a new vaccine comes out, they benefit from it. Older people don't tend to benefit from that vaccine. It's in part because we're recommending it, ideally at those younger ages, and people who are older don't benefit so much. Because once you've been exposed to those types of you're not benefiting as much.

Cynthia Rand: Part of it is cost effectiveness issue too, looking at who's going to be benefiting cost wise the most? That isn't to say that a person couldn't choose to have it, they would have to pay for it out of pocket. Probably it wouldn't be covered by insurance, because they would have already been considered up to date. They could choose to pay for it, but it's not something that's generally recommended. We just go with the new population, getting the newer vaccines. Great question.

Katie Quimby: Thanks. Next question, we talked a little bit already about some contraindications, but can you speak to any other contraindication for the vaccine?

Cynthia Rand: That is it. That's what's so nice is unless you have an allergic reaction, which I've never seen in, let's see, since 2006, we've been giving the vaccine. In my practice, I've never seen a patient with an allergic reaction. We have a practice of 12 to 13,000 patients, and it is patient should not receive the vaccine when they're pregnant. It's actually not even a contraindication, it's a caution. Then, as I mentioned, if patients faint with vaccines, and you can see them hyperventilating, when they come in you know that, that's a patient that you might want to have lie down before they get vaccinated. That's it, that makes it really simple. There's hardly anything that's contraindicating.

Cynthia Rand: I should say if a patient is immunosuppressed, I didn't mention that. If you're immunosuppressed or have HIV, you should actually receive the three dose series because you don't mount too strong of an immune response. You need the three doses to get a strong enough immune response. People who are immunosuppressed should especially be vaccinated, because they are more susceptible to HPV disease.

Katie Quimby: Right. We've got a lot of questions and we've got still more coming in. Again, if you haven't already had a chance to type in your questions. We do have a few more minutes for questions that you're you might have answered. The next question is, how would you counsel a patient for example, a male who is 27 years old. If they tell you their sexual partner has HPV now what? In terms of the vaccine or otherwise?

Cynthia Rand: Great question. I would say again, it's not a great reason to vaccinate because this person would have been exposed. It's not a therapeutic vaccine. I would say make sure your partner gets treated, certainly make sure your children and future relatives get vaccinated. The good news... we didn't really talk about the natural history, the good news is that much of HPV goes away on its own. Very few cases turn into cancer, we know that looking for cervical changes, about 90% of HPV does go away on its own. It's possible that it could be harbored in your body and we're learning more about that. I would say, I would not necessarily recommend the vaccine for that patient, because it is not going to be therapeutic and this patient has already had this partner and that's not its intention. It's really

intended preventively. It's a good learning experience, but also hopefully it will resolve as long as they're otherwise healthy if they have been exposed.

Katie Quimby: You've talked a little bit about the vaccine safety. This is a question, I think maybe a myth that's out there. Is there any evidence that links HPV vaccine to premature menopause and young women leading to infertility?

Cynthia Rand: No.

Katie Quimby: Good.

Cynthia Rand: I could add to that, but really no. There's no data that suggests that those are associated.

Katie Quimby: Great. Next question, if a minor can consent to private STI testing and treatment, or a minor who is also parent can consent to their child vaccination by their own. Does that present some logical or ethical problem? I think this may be as a thought question, but the question is instead of each state tackling minor self-consent for HPV vaccination, is there HIPAA or some other loophole that we could be looking more closely at? Otherwise, thank you for your presentation.

Cynthia Rand: Yeah, great. That's a great comment. It depends on your state, like in New York State, a minor was consenting to STI testing, then they could also consent in my state to HPV because they're presumably sexually active. If they're parents, they're an emancipated minor, so they can also if they're emancipated, they're considered as an adult, and then they can also vaccinate for themselves. It's really important to look at the state law, unfortunately, all of these rules are state dependent and it is not a federal rule. You need specific legislation in your state, but it's a really good point.

Katie Quimby: Great. That concludes the questions that we've received they've been a couple that we're going to have to take offline and respond and come back to you. We really appreciate all the questions we receive, that was a great Q & A session. I'm going to move us to close out here and say, really, thank you all so much for joining us today. Thank you again, for those great questions. We will have a recording of today's session available within the next few days and if you have any other questions, either for the FPNTC or Dr. Rand, please don't hesitate to email us at [fpntc@jsi.com](mailto:fpntc@jsi.com). Our final ask is that you please complete the evaluation today. The link to the evaluation will appear in the message section of your screen and we'll also email it to you after the webinar. We really, really do love getting your feedback, we use it to inform future webinars. Please, take a minute and share your thoughts with us. Thank you all again so much for joining us today. I hope you have a great rest of your day and that concludes today's webinar.