

# Talking with Family PACT Clients About HPV Immunization

## August 18, 2022

Nicole Nguyen:

Hi everyone. Good afternoon. Thank you for joining us today for our webinar titled Talking with Family PACT Clients About HPV Immunization. We hope you are all doing well and staying safe. My name is Nicole Nguyen, program manager of the Family Planning Program at the California Prevention Training Center. The CAPTC under contract with the California Department of Healthcare Services, Office of Family Planning is sponsoring today's event, so we really want to welcome you. And so, before we get started, let's just go over some really quick, some housekeeping slides. First please check your audio and select your desired settings to join through your computer audio or to call through your phone. And if your internet connection is shaky, we highly recommend that you call in through your phone for the best possible sound. And then of course, next is please check that you're able to see the viewer screens with the slides on your left, and then the go to webinar control panel on your right.

Nicole Nguyen:

You'll see this orange box with the white arrow. So, this is how you can hide or show your dashboard. If you don't want to see it, or if you accidentally click it, this is how you can make it appear again. And then under the audio tab is where you can change your audio preference at any time. And then of course, please submit all your comments and questions via the questions box today's webinar will take about 90 minutes. It will include time at the end for the presenters to answer all your questions. So please send them in, our presenter will try to address as many of them as possible at the end, this webinar will be recorded and then responses to questions that we run at time for or didn't get a chance to answer will be collected and sent to our presenters to send out to participants later, along with the recording and the slide deck. There is an evaluation at the end, so please fill it out when you get a chance, because your feedback is really important to us. And it really helps guide us in developing our future content.

Dr. Michael Policar:

Nicole, you're not sharing slide sharing at this point.

Nicole Nguyen:

Oh, I'm so sorry. Let me do it.

Dr. Michael Policar:

There we go.

Nicole Nguyen:

See all the hiccups of virtual webinars, no matter how hard you try, can't prevent it. And then, so of course, so let me just go back to make sure people see the slides, so to make sure for your audio settings, and of course, to be able to see the [inaudible 00:02:24] slide and a go to webinar dashboard and then for your audio preference. And then of course, any questions or comments in the question box, please. And then for disclosure policies, we just want to acknowledge that we are working with the

University of Nevada, Reno School of Medicine to offer CMEs for this event. This webinar qualifies for 1.5 CME credits and is available to those who watch the entire webinar live today and who registered. Those who watch recording afterward unfortunately will not be eligible for the credits. And then we'll make sure to send out the link to the certificates, along with all the materials from the webinars today, along with recording, slides, and evaluation. And then the Q&A, we'll try to get them out, but they usually take about four weeks after the webinar ends to collect everything.

Nicole Nguyen:

And then of course, just also for transparency's sake, we want to acknowledge that our presenters, planners and anything, and anyone with the position to control the content of this activity, does not have any financial relationship or commercial interest related to the content of this activity. All right, so now we're going to get to introducing our presenters. First, I would really like to introduce Patty. We are really thrilled to have Patty join us again. I don't know if you remember, but back in July 2020, Patty along with Mike also collaborated to deliver a fantastic webinar on the new ASCCP guidelines for cervical cancer screening. So, when we were discussing potential topics on who to invite for this topic, we're like, who's better than Patty to talk to us about HPV immunization and importance of preventing cervical cancer. So, Patty is a family nurse practitioner, trainer, educator with a specialty in sexual reproductive health.

Nicole Nguyen:

She has practiced for over 40 years in a variety of clinical and academic settings. She's also an assistant clinical professor and a guest lecturer at the UCLA school of nursing. And her goal is centering patient with a sex positive trauma inform anti-racist lens. Patty also helped develop the PATH framework, P, A, T, H and the ASA cycle for person-centered conversation and counseling. She's also recently helped revise the CDCs in the five Ps in a guide to taking a sexual health history, to make them more inclusive. So, thank you so much, Patty, for joining us again today.

Patty Cason:

Happy to be here.

Nicole Nguyen:

Hey, and then of course, next as always, we are always excited to have Dr. Michael Policar with us. He's our superstar for the Family PACT program. Dr. Policar serves as the clinical professor of obstetrics, gynecology, and reproductive sciences at the university of California, San Francisco School Of Medicine. And from 2005 through 2014, he was also the medical director of program support and evaluation for the Family PACT program administered by the California department of healthcare services, office of Family Planning. And now he currently serves as professor emeritus of Obstetric Gynecology and Reproductive Sciences at UCSF. Thank you so much Dr. Policar, for joining us as well. So, with that, Mike and Patty, the floors yours, I'm going to stop sharing and I'll let you share your screen.

Dr. Michael Policar:

Great. Thank thanks, Nicole. And I'm going to watch for my ability to do that. Here we go.

Nicole Nguyen:

Go for it.

Dr. Michael Policar:

Show my screen. Here we go. And can you see that now? Patty or Nicole? Can you see my screen?

Nicole Nguyen:

Yes.

Patty Cason:

Yeah, I can.

Dr. Michael Policar:

Yeah. Good. Okay. Terrific. Well, I'm absolutely delighted to be able to join you today, was just thinking about how long it took for us to be able to have the benefit of HPV vaccination in Family PACT. Remember that the first versions of HPV vaccines came out in 2006 and we actually had a discussion 16 years ago about the possibility of making HPV vaccination, a benefit of Family PACT, but there have been a variety of reasons that we could not do that until recently. And so as most of you know, as of last month, HPV immunization within Family PACT finally became a benefit. So what we're going to talk about today is a little bit about the CDC guidelines about how the HPV immunization process should be done.

Dr. Michael Policar:

We'll talk a little about how the Family PACT benefit works for GARDASIL®9. And then I'm going to pass the microphone over to Patty who is going to talk about having conversations with clients about immunization for HPV. So these are our learning objectives. We're going to be talking about safety and natural history of HPV and a lot about counseling in a way which is not coercive. Now, one of the things you'll see Patty and I try to pay a lot of attention to, is the wording that we use. And one of the terms we try to avoid actually, is HPV vaccination. And instead we want to talk about HPV immunization. And of course, most of us think about those terms as being interchangeable, but there is a very specific reason for using the term, immunization. If you were to do a Google search or another type of search for this particular product, and you typed in, "HPV vaccine." You'd come up with a fair number of anti-vaccine links.

Dr. Michael Policar:

Most of which do not have accurate information. On the other hand, if you type in, "HPV immunization." You're much more likely to actually find accurate scientific information and less likely to find misinformation in the anti-vaccine links. So whenever possible, both Patty and I are going to be using the term, "HPV immunization." We hope you do the same.

Dr. Michael Policar:

So, let's start with the big picture about. What is the value of HPV immunization in the first place. And I particularly like this slide because it looks at various kinds of cancers, which are due to HPV, particularly high risk HPV type 16 to 18, but some of the others as well, and specifically, how many cases are prevented by the use of the 9-valent HPV immunization product. So as you can see in females, and by the way, this is CDC data from a few years ago, what you see in the dark blue part of the bar are the cases of, on the top section, cervical cancer, which are due to HPV 16 and 18, that are prevented by HPV vaccination.

Dr. Michael Policar:

In the light blue part of the bar, you see additional cases of cervical cancer that are prevented, in this case, due to intermediate risk types of HPV, 31, 33, 45, 52 and 58. So you can see that there are over 10,000 cases of cervical cancer in the United States that are prevented every year as a result of the 9-valent HPV vaccine. And again, to define terms up to the top, when you see 9-v, it refers to 9-valent, the GARDASIL®9 product, which is the only one on the market right now. Now in addition to preventing cervical cancer, we also prevent other kinds of genital skin cancers in females. So you can see that there is prevention of vaginal squamous cell carcinoma, vulva carcinoma, anal cancers in females, rectal cancers and oropharyngeal cancers as well. Now, those numbers of cases presented are smaller because they are much more rare cancers than this cervical cancer.

Dr. Michael Policar:

But this immunization is not only helpful for females, but it's helpful for males as well. So it prevents penile squamous cell carcinoma, anal carcinoma, rectal carcinoma and you can see that very long blue line down at the bottom, which is oropharyngeal carcinomas in males, particularly in males who smoke, they are much more likely to get throat cancer, for example, which is actually due to HPV, particularly a 16 and 18. And in that circumstance, being vaccinated, not only will prevent genital warts, but will also protect them against oropharyngeal cancers as well, particularly if they're a smoker. Now, let me say a word about how this vaccine is made, because oftentimes questions come up from patients about, "Oh, is this a live virus that you're injecting into me? What's the likelihood I'm actually going to develop some manifestation of HPV infection?" And the answer is, is that the way that the vaccine is manufactured, there is no risk of that at all.

Dr. Michael Policar:

So basically, what this graphic shows, is that what's done in the manufacturing plant, is to take a small piece of the DNA from an HPV virus, that's shown over on the left side with that red bar. Then what they do, is to put that little piece of genetic material into a plasma, which then is multiplied in a manufacturing plant to make what are called the capsid proteins. The capsid proteins are the outer shell of the virus. And what happens is that those capsid proteins come together and they basically make an empty shell of what looks like an HPV virus. So in that circumstance, it will cause an immune response as if it is an HPV fragment, but on the other hand, because it has no viral DNA in it, is completely incapable of causing any sort of actual infection because we're only injecting the shell rather than a live virus or dead virus or attenuated virus, it's simply the shell of the virus. That's what's injected with the HPV immunization, and then people make both a cellular immune response and a humoral immune response with antibodies as a result.

Dr. Michael Policar:

Next, let's talk a little bit about the evolution of the HPV vaccine products themselves. As I mentioned a moment ago, the first product came out in 2006. That was the original Gardasil, which was a 4-valent HPV vaccine product that was active against HPV six and 11, which caused genital warts and HPV 16/18, which are the types of HPV, which caused about two thirds of invasive cervical cancer. Year two, after that, there was another product which was a 2-valent HPV vaccine only against HPV 16, 18, so it did not protect against genital warts. Then in 2015, the next generation product came out, which was a 9-valent HPV vaccine that covered four from the original vaccine, six, 11 to prevent warts, 16, 18 to prevent cervical cancer, but also a number of intermediate risk HPV viral types as well.

Dr. Michael Policar:

So, 31, 33, 45, 52 and 58. So now we had coverage against nine different types of HPV. Now, notice where those cross hatches are, the original Gardasil and the original Cervarix are no longer in the market in the United States. And in fact, they've been off the market long enough, you probably don't have the supply of those any longer. So the only one which is available in the US, this is the 9-valent HPV vaccine product, which is GARDASIL<sup>®</sup>9. And the next question is, how well does it work? So I'm not going to overburden you with a whole lot of statistics about this, but I did pull a slide from the original studies that had to do with the 4-valent vaccine, the six, 11 and 16, 18, and start by looking at the blue circle in the center. So these are people who are naive basically to any kind of HPV infection.

Dr. Michael Policar:

They looked at 14 different HPV types, people had no evidence of having been infected with them before. And over on the left side, you'll see how well the vaccine worked in preventing CIN 3 high grade dysplasia that is due to HPV 6, 11, 16, 18. And if a person had never come in contact with any HPV in the past, the efficacy of the vaccine in preventing CIN 3 with one of the types that was in the vaccine, was 100% efficacy. It worked incredibly well. Now on top of that, is what's called the intention to treat population. And those are people where they didn't even test in advance, have you ever been infected with HPV or not? These were thousands of people who were sexually active, were in the age group of being in these multinational studies, but they didn't look whether or not there was prior HPV infection.

Dr. Michael Policar:

And in that population, there was about a 45% reduction in CIN 3 lesions due to those four types of HPV. So even in people in the general population, those are the ones who were going to be vaccinating going forward, there's still obviously a beneficial effect. Now over on the right side, what that refers to, is, how well did the original 4-valent vaccine work in preventing CIN 3 irrespective of the HPV type? It included not only 6, 11, 16, 18, but any HPV type. And you can see that it was successful in preventing CIN 3, although not nearly as effective as it was in people who had never been infected in the first place. And of course, that was the main reason for the recommendation that we start at a young age, as you'll see in a moment, before people start sexual activity. So they will be naive to HPV at the time when they first go through immunization.

Dr. Michael Policar:

And that's when we see the nearly 100% success rate. So the next step in this was the development of the 9-valent HPV vaccine that we have now, GARDASIL<sup>®</sup>9. And this particular study published in 2015,

was, what's called a non-inferiority study. And basically what it looked at, was, over a 48 month period, how effective was the 9-valent HPV vaccine in comparison to the 4-valent HPV vaccine. And basically, what you see over on the left side, again, are people who were not HPV infected at the beginning of this study and then followed for four years. And it looks at the cumulative incidents of CIN 3. And what you find is that is much less likely with the 9-valent HPV vaccine than it is with the QHP that refers to 4-valent vaccine. Now, over on the right side, it was again, all trial participants, the intention to treat analysis, where they just had no look at whether or not you had ever had a previous HPV infection.

Dr. Michael Policar:

[inaudible 00:17:52] the two were more equivalent. They did prevent CIN 3 for the most part, but they did so equally well. So again, we had data that, with the 9-valent HPV vaccine and people who had never been infected with HPV, but not only worked really well, but it worked marginally better than the earlier version before valent HPV vaccine.

Dr. Michael Policar:

This is the last that I'll show you about efficacy, but this was a nice Cochran database review that was published in 2018. Lots of really good studies included in this from all over the world. They ask the question, how effective is HPV immunization? And this looks specifically at females between 15 years old and 26 years of age. So the first four lines are people who have never had HPV before. And you can see that for 10,000 people who are immunized, oftentimes the rate of a case of nine CIN 3 was zero.

Dr. Michael Policar:

Then the bottom four lines refer, again, to the intention to treat population people who have any HPV status, they weren't even evaluated. But again, across the board, we see lower rates of CIN3 and of adenocarcinoma in [inaudible 00:19:08] as well. Not only squamous lesions, but [inaudible 00:19:12] are less likely in people who are immunized in comparison to those who are not. So we know it works and it works particularly well in people who have not been infected with HPV before. So that now gets us to the next section in my discussion, which is, what is the CDC and its advisory committee on immunization practices, say about how to do routine HPV immunization? Hopefully the kind of immunization that you're going to be doing in your office with this new Family PACT benefit, if you're not doing it already. And by the way, ACIP stands for the Advisory Committee on Immunization Practices of the Center For Disease Control.

Dr. Michael Policar:

So, the centerpiece of their recommendation is that both females and males should be routinely vaccinated, ideally at 11 or 12 years old. And they chose that time because for most kids, it's before the onset of sexual activity and therefore they should be HPV uninfected, HPV naive at that point. And also, 11- and 12-year old's have a very robust immune response when they come into contact with this particular vaccination product. And so they are the ones who are most likely to make lots of antibodies that last a long time. So that's where the 11 and 12 year old recommendation comes from. Now the first set of guidelines had to do with immunizing only females, but a few years later there started to be a trend to say, we'll not only vaccinate females, but we'll also vaccinate boys and men as well.

Dr. Michael Policar:

So, what's the logic of that? Well, obviously boys and men, particularly males, not older men, can get HPV associated cancers. The anal carcinoma, penile carcinoma, oropharyngeal carcinomas, especially if they smoke. So here's a way of vaccination for HPV, being protective of men. Secondly, it protects them against developing genital warts, which are not life threatening, but there's certainly a cosmetic problem when they occur. And then of course, it has the value of, if we can prevent HPV infection in males, then we may prevent horizontal transmission of high risk HPV to their sexual partners, whether they're females or male sexual partners. So the sequence of events that happened was, that in 2009, the 4-valent HPV vaccine was licensed in males to prevent genital warts. Then in 2010, the FDA added the indication of prevention of anal cancers in males. And in 2011, basically both the FDA in licensing the product, and the CDC said, "Look, there's lots of value for males and therefore we are going to make our recommendations such that the age considerations are the same for both males and females."

Dr. Michael Policar:

Now, going a little bit further in terms of the timing of the vaccination, the series can be started as early as nine years of age. And the recommendation is, that for people who were not vaccinated at 11 or 12, that they should be offered what is referred to as catch up immunization of both females and males. Initially, that recommendation was made for people between 13 and 26 years of age. So in other words, if you were seeing a 20 year old patient who was not immunized against HPV when they were younger, then they would be a prime candidate for having the discussion about having an HPV immunization at their age.

Dr. Michael Policar:

Immunization is not recommended for everyone older than age 26 up to age 45, but a lot of people may choose to do that, I'll talk more about that group in just a moment. So here to quote the CDC directly, "Some adults between 27 and 45 might decide to be immunized against HPV. However, that should be based on the discussion with their clinician through a process of shared decision making." And Patty is going to be discussing that in detail, what does shared decision making mean in the context of having these conversations about HPV immunization for people that are in the group between 27 and 45 years of age? And the last bullet is important, where the CDC tells us that, there's no expectation that we're necessarily going to discuss HPV immunization with every patient we see between 27 and 45 years of age. We can consider having that discussion with people that we think are most likely to fit to benefit, but it really does not have to be discussed with most people.

Dr. Michael Policar:

Now, next, just a quick reminder about the rules regarding HPV, that immunization schedule. Each dose is a half milliliter administered IM. When it was first approved in 2006, it was administered in a three dose schedule. So the first dose was given, the second was given one or two months after the first dose and then the third dose was given six months after the first dose. Things changed in 2016, when it was realized that for people who are between nine and 14 years of age, if they have such a good immune response, when they are immunized for HPV, that they only need two doses rather than three. So they get a first dose and then a second dose, somewhere between six and 12 months later. But remember that only applies to nine to 14 year old, not the older people that you'll be seeing in your clinic.

Dr. Michael Policar:

You can give this vaccination with other vaccines, like Tdap, MCV4 and so on, and we should avoid using it if a person has a hypersensitivity to yeast, because remember, it's manufactured with yeast in the process. Now, some other rules about candidates for HPV immunization, includes females who've had an abnormal cervical cytology or a positive HPV test, or even genital warts in the past. The reason why, is because their abnormal cervical cytology, their [inaudible 00:25:39], or even their [inaudible 00:25:40] might have been due to one particular type of HPV. But remember that in GARDASIL<sup>®</sup>9, it prevents a total of nine different types of HPV. So being immunized, even when you've previously been infected, may cover types of HPV that you had not been infected with before. We can also immunize women who are breastfeeding, lactating and feeding their newborn in that way.

Dr. Michael Policar:

And it also can be used in people who are immune compromised. Although the CDC points out that the degree of the immune response and efficacy of the vaccine might be a little less than it is in people who are immune competent. Now, next is, what about people who started the vaccination series with one of the earlier products with the 4-valent or the 2-valent, and now they need injection number two, or maybe injection number three? And in that circumstance, we can basically accept what they've already had and then use the 9-valent vaccine, GARDASIL<sup>®</sup>9, in order to be able to finish the series. Now, question also comes up, what about people who were vaccinated years ago with a full schedule of either the 2-valent or the 4-valent? Are those antique [inaudible 00:27:04].

Dr. Michael Policar:

Are those kinds of antiques now? Another way of saying that is even though you were fully vaccinated with the earlier versions, now that we have the 9-valent, should you be revaccinated? And the CDC says that is unnecessary particularly in the general population, as I showed you in an earlier slide. But if you've already been vaccinated with the 2 or the 4-valent, then you should have adequate protection going forward as long as you completely finish the series. And if the schedule was interrupted, you don't need to start over again. So if someone had the first shot, let's say three years ago, then they had the next one two months afterwards, and now three years have passed since that time, you can go ahead and get number 3 now without having to start over again. This tells you a little bit more about what the CDC basically has reminded us about it. That again, we can either use that 9-valent, or if you had some left, the 4-valent vaccine to be able to complete by the series.

Dr. Michael Policar:

What about using the HPV vaccine in pregnancy? And the answer is that they're not recommended for use in pregnant women. What if a person becomes pregnant after initiating the vaccine series? There's no evidence that they're teratogenic. So there's no reason to do anything unusual with the pregnancy based on the fact that you've got one of the doses during pregnancy itself. However, let's say for example, a person got their first dose four or five months ago. Now they're waiting for their second dose. It turns out that they're pregnant. The recommendation is to wait until the pregnancy is over in order to complete the series. Pregnancy testing is not needed before a person's vaccinated. With either a normal menstrual history or an unusual menstrual history, pregnancy testing might be indicated just because it's something we need to do to find out whether or not a person's pregnant based on their menstrual history, but it does not need to be routine. And as I mentioned a moment ago, if a vaccine dose is given during pregnancy, then no specific intervention is needed.



Dr. Michael Policar:

Now there is a pregnancy registry that the FDA has for the 9-valent HPV vaccine. There were registries for the 4-valent and the 2-valent. They've been closed simply because those products are no longer available and collecting information on thousands of people, it turns out that there were no adverse effects. There was no teratogenicity.

Dr. Michael Policar:

How about being immunized in the context of cervical cancer screening? And the answer is that if a person's been fully HPV immunized, there is no change in their screening for cervical cancer. So continue to do that starting at 21. For different options, starting at 30 and having been immunized really doesn't make a difference in that regard.

Dr. Michael Policar:

All right. Next is what about adverse effects? And fortunately, there are relatively few. Injection site reactions, and you will hear over and over and probably know this already, that because of the aluminum adjuvant which is with the vaccine product, it's uncomfortable, sometimes downright painful to have it injected. So there can be pain, redness, swelling in the upper arm, at the injection site, sometimes headache, occasionally even vasovagal responses with dizzy, fainting and nausea just because of the fact that the injection is relatively painful.

Dr. Michael Policar:

At this point, I'm going to hand things over to Patty just for a moment. She is so knowledgeable about vasovagal events, how they happen, why they happen and what to do about them. I'm going advance her slides, but I'm going to ask her to step in and tell us about vasovagal prevention.

Patty Cason:

Great. One thing is that the Gardasil 9 is significantly more painful than Gardasil 4. So there are going to be more vasovagal reactions. There's going to be more pain in general and all that comes along with that. But the good news is that this is the main side effect from getting this immunization and there is something to do about it. So you can prepare in advance to both advise the patient that there's something that they can do to prevent this vasovagal reaction from continuing. Or if you haven't told the patient about it beforehand, you can then intervene.

Patty Cason:

So, let's break that down to see what that looks like. The other thing is that for those of you who do colposcopy or any kind of procedures, IDs, implants, any primary care procedures, anything that might trigger a vagal. Cryo, big, big, big culprit for starting one of these reactions. The thing is that the reaction starts just like any other reflex, just like a Babinsky reflex or a patella reflex. Anything, same thing. It's just an unconscious and reflexive event that happens. And not really for any good reason. It just happens.

Patty Cason:

But what happens is that the blood pressure and the pulse come down at the same time because of this response. And that's because there's been pooling of blood in the hands and the arms and the feet and the legs, that's the first step of this vasovagal reaction. So it turns out that if you clench the muscles in your hands and your arms and your feet and your legs, you stop the reaction so that blood pressure and pulse that are going down at the same time don't take all the blood from your head, so that then you have a vasovagal episode. So to prepare in advance, you can just advise somebody and make sure that they've had enough to drink, that somebody's not dehydrated, make sure they've eaten. And that's true for all procedures that don't require somebody to be NPO, but definitely if somebody's in the office waiting for an immunization, make sure that they're not really, really hungry. Give them crackers if you have that and definitely make sure they've had something to drink. But that's just sort of across the board for everybody.

Patty Cason:

Go ahead back one, Mike, just for one second. So the other thing that we have up here is anticipatory guidance. And what that is in my opinion, the magic bullet. And what that is that we are going to tell our patients what to expect and in 45 seconds or less, show them how they can make it stop, which is really putting the control back in the hands of the patient and it also means that you're just going to see a whole lot less syncope in your office. And then the other one. Cross legs and contract opposite arm, that's just for immunization or for getting a shot of some kind or getting your blood drawn. This is obviously not going to be something you're going to do before a procedure, but if somebody's going to have their blood drawn here or get an immunization here, they can contract the other arm and cross their legs. And that will actually prevent that pooling of blood in the extremities.

Patty Cason:

Go ahead and advance. As everybody knows, the pre-syncope symptoms, if we were in a group together, you could be shouting them out. But these are all weakness, lightheadedness, sweating, blurring of the eyes, of the vision, headache. Really common would be the nausea, the dizziness, and the diaphoresis, the sweating. But one that people don't think about is a sudden feeling of being cold or hot. If your patient says, "Is it really cold in here, or is it just me?" Or, "Is it really hot in here, or is it just me?" Or a sudden need to go to the bathroom. If your patient's saying, "I really need to go, how much longer is this going to be?" with any kind of urgency, they're probably having a vagal.

Patty Cason:

Go ahead to the next slide. And then the signs. So this is the things that the patients would be experiencing. The signs where you'll be able to notice it. Probably everybody here has seen these. You know you get that sickening pallor. That color in the face is just awful. All the blood is draining from somebody's face, which it actually is. Yawning, dilated pupils, nervousness, but mostly you'll just pick up that something's changed. You were having a conversation and now something's changed a little bit.

Patty Cason:

Go ahead. So as I said, pooling of blood in the hands, arms, feet and legs of extremities is the initial thing that happens when you have a vasovagal reaction. So if we want to stop that response in its tracks, we just clench the muscles in our hands and our arms and our feet and our legs isometrically. Don't have to

be moving them around or pumping them or anything, just squeeze them. And this will just stop the reaction in its tracks.

Patty Cason:

So, here's what we say. Mike, could you advance? Here's what we say to the patient. And this is the important piece really because we all know what a vasovagal looks like, or at least if you're around longer, you will eventually, but we don't normally talk about it with our patients beforehand. So this takes less than a minute. It's been studied over and over. And in terms of how long it takes, it's measured, not studied officially. Well, there was one study, but actually having these measured, this takes less than a minute. So you just say to your patient, "Many people getting an injection can feel dizzy and sometimes they can even faint. And if that happens, it's probably not meaning that there's anything wrong, but it can be really scary. So I'll show you how you can stop that from happening."

Patty Cason:

Go ahead and advance the slide. "If you feel dizzy in any way or you feel nauseated or you just feel just weird in any way." Go ahead and advance the slide back. "Then just tense the muscles in your hands and your arms and your feet and your legs." And I would say for everybody today on the call, if you just do that right now, just try it hands, arm, feet and legs, relax your chest, relax your tummy and just your hands and arm and feet and legs. And that's what you're going to ask your patient to practice. I mean it takes maybe 10 seconds for them to do it and they just give you the reassurance that your message has sunk in. But it also gives them that motor instinct to know what to do if it were to happen to them. This has been shown in a very large family planning site in the Midwest to be pretty much a hundred percent effective. So hopefully you can use it whenever, early and often.

Dr. Michael Policar:

Okay, great. Thank you, Patty. And just a reminder that because of the fact that Gardasil 9 is more painful than the earlier ones, you not only want to do the anticipatory guidance that you just heard about, but particularly in the first few minutes after the injection, some people say five minutes, others say even a little bit longer, make sure that the patient is in a place where they can be monitored. Because early on, there were case reports of people who got a Gardasil injection, they were asked to sort of take it easy for a few minutes, an MA or a nurse left the room. And if the patient vasovagal when no one was available, they might fall and literally hit the floor and injure themselves. So again, that vasovagal may not happen immediately. It may be delayed. So do make sure that people are monitored immediately after the injection.

Dr. Michael Policar:

But let me finish the story before I hand the microphone back again to Patty. That is that in October of 2018, the FDA actually approved extending the age range for the use of Gardasil 9 beyond 26 to people who are between 27 and 45 years of age. That was based on a study that's called the VIVIANE study. It's cited at the bottom of the slide where the 9-valent HPV vaccine, Gardasil 9, was studied in about 3,200 females who are between 27 and 45 years of age for about three and a half years. And there was almost a 90% decrease in persistent HPV infection, genital warts and a variety of precancerous genital lesions. And in addition, the FDA approved Gardasil 9 for males in the 27 to 45 year old age group, even though they weren't studied in this VIVIANE study. Based on extrapolations of comparing males and females in earlier studies, they decided that males should be eligible between 27 and 45 as well.

Dr. Michael Policar:

So, an obvious question is, does it work in older individuals? And the answer is it does. It doesn't work nearly as well as if they were immunized at an earlier age because exposure to different types of HPV can accumulate over time. That even for people in their thirties into their early forties, there may be HPV types that they have not been exposed to sexually. And now they can gain protection against those HPV types that they haven't encountered yet. So the CDC Advisory Community on Immunization Practices says that the use of Gardasil 9 for people between 27 and 45 is acceptable. It is permissive. It is not recommended, but it is permissive based on shared decision making. However, it's not subject to the no cost sharing feature of the affordable care act for other ACIP recommended vaccines. Now that's kind of irrelevant in Family PACT, but with other commercial payers for the HPV vaccine, they may choose not to cover it for people who are 27 to 45 because this is not like a hard recommendation from the CDC. Instead, it's a permissive recommendation based on shared decision making.

Dr. Michael Policar:

And then these are some of the other rules basically saying be sure to use clinical decision making as well as the fact that the vaccines are not licensed for people who are older than 45 years of age. Now, just to close out my section, there are newish guidelines from the American College of Obstetricians and Gynecologists about HPV vaccination. And they say that OBGYNs and other healthcare providers should strongly recommend HPV immunization for patients and stress the benefits and safety of the vaccine.

Dr. Michael Policar:

So, this wasn't kind of a wishy washy you may or may not make that recommendation. They say that you should strongly recommend it as well as educating parents that you see who have children at home that their children should be vaccinated for HPV as well once they hit the ideal age range. And ACOG endorses this idea that for some individuals between 27 and 45, that they may be candidates based on shared decision making. OBGYNs are encouraged to stock and administer HPV vaccine in their office. And they also point out about the fact that it can be given to a person who's postpartum and who is chest feeding their baby.

Dr. Michael Policar:

All right. So last couple of slides, and that is how well are we doing in getting people vaccinated for HPV? I know that this is a rather busy slide, but what it tells us down at the bottom is it looks at among males and females that are adolescents between 13 and 17 years of age, what percentage of people were given at least a single injection, as opposed to people who got all three. Basically you can see rates in the ballpark of around 40 to 50%. Now that was through 2014 and there is more recent data looking at rates of vaccination. It goes all the way basically to 2020. What we can see is now the percentage of people who have had at least one shot of the HPV vaccination is now up to 72%. That percentage of people who have gotten all three injections is about 54% among adolescents. So we still have a way to go. It's getting a little bit better, but it could be even better yet.

Dr. Michael Policar:

Okay. Hang on one second. Oh, there we go. I'm going to skip this one. And here's my last slide. And that is I just wanted to tell you a little bit about the Family PACT benefit for HPV vaccination. So coverage is restricted to individuals who are between 19 and 45 years of age. And an obvious question is, well in our

Family PACT clinic, we see lots of people who are 18 or younger, why isn't it covered for them? And the answer is that the CDC has a wonderful program that's been available for decades called DFC Vaccines for Children. And it's federal dollars that are given to the CDC to pay for childhood vaccinations through 18 years of age. It's widely used in California. So the idea is that the expectation is that the DFC program should be used for HPV immunization for people through 18 years of age and then Family PACT coverage can start at 19 and available through 45 years of age.

Dr. Michael Policar:

This is the CPT code for the vaccine product itself, 90651. And then there's also a payment for administration of the vaccine, which is 90471, and both MediCal and Family PACT adopt exactly what the recommendation of the advisory committee and immunization practices is. And that is that the decision to be immunized has to be based on shared decision making, and that shared decision making process has to be documented in the note for the patient who's being vaccinated.

Dr. Michael Policar:

Okay. Now one little nuance in Family PACT is that, of course, in any Family PACT visit, you not only have to bill for whatever diagnosis you've made about STI or something like that. But in addition, always include the client's contraceptive, the Z code, the ICD-10 code for the person's contraceptive method. So the HPV immunization through Family PACT is not reimbursable with diagnosis code Z30.012, which is emergency contraception, Z 30.09, which is the generic contraceptive counseling or Z31.61, which is a fertility awareness based method. So with that, I am going to stop sharing and hand things over to Patty so that she can spend roughly a half hour talking about counseling for HPV immunization. And then we'll take your questions afterwards.

Patty Cason:

Let's see.

Dr. Michael Policar:

I think all you have to do is click on the full screen down at the bottom.

Patty Cason:

Yeah. It's not there. It was. Oh well. Let me see if this works if I pull up the screen. Can you see that?

Dr. Michael Policar:

I can still see your title slide Counseling About HPV Immunization.

Patty Cason:

Now can you see the practice guidelines? Can you see a practice guideline now?

Dr. Michael Policar:

Yeah, but I can only see part of it.

Patty Cason:

You can see part of it? Okay. I think that's because I have my box in the way. There we go. How's that?  
You still can't see it all. I can see it all. No?

Nicole Nguyen:

No. Are you able to show which... Oh, sorry, everyone.

Patty Cason:

Let me try it again.

Nicole Nguyen:

Yes. You can also specify which monitors you wanted to show. Make sure to pick the right monitors.

Patty Cason:

How's that?

Nicole Nguyen:

No, it's still only showing half of your screen. It's very strange.

Patty Cason:

I have no idea why it's showing half.

Dr. Michael Policar:

Okay. So you want me to [inaudible 00:47:59] back up or Nicole, do you want do yours?

Nicole Nguyen:

Yes. [inaudible 00:48:13].

Patty Cason:

Oh, it says... Okay.

Nicole Nguyen:

All right. Would you like me to share my screen, Patty?

Patty Cason:

Sure.

Nicole Nguyen:

Okay.

Patty Cason:

Okay. Thank you.

Nicole Nguyen:

Okay. Yeah.

Patty Cason:

Okay. Go ahead and change slides. This is the old deck. Okay, Nicole, let's go ahead and get out of that one and I'll try again if you want to give me control.

Nicole Nguyen:

Sorry about that one. Yeah. I just give you back control.

Patty Cason:

Okay. Now can you see it? No. I don't understand how... You still can't see it. No?

Nicole Nguyen:

We can see it, but we can only see half of it for some reason.

Patty Cason:

That's so strange. Okay. Maybe we put this down below.

Nicole Nguyen:

Okay [inaudible 00:50:00].

Patty Cason:

You want to just go back again? You do? Okay.

Nicole Nguyen:

Yes, I have [inaudible 00:50:14].

Patty Cason:

I don't know why you can only see half of it.

Nicole Nguyen:

Yes. Let me...

Patty Cason:

It's a mystery. I'm sorry, everybody. In the meantime, somebody had asked whether you can use the same techniques for preventing vasovagal in children and in adults. And yes, you can use that in people of any age.

Nicole Nguyen:

There you go, Patty.

Patty Cason:

Okay. I can see that.

Dr. Michael Policar:

Yep. Agree.

Patty Cason:

So, this is really just... It's reiterating what Dr. Policar was just talking about. It's basically just showing you where on CDC, it's where the document is. So go ahead and next slide. So you can see here that they're pretty much talking about the difference between an individual level benefit and a population level benefit. And I think this is a really important concept when we're thinking about people 27 to 45. There's not been shown to be a population level benefit, but we are seeing individuals in the room. When we're taking care of somebody, we are concerned about the benefit potentially to that individual. I will say at the beginning of this, and hopefully I will also say it at the end, that the person who's probably in the best position to know whether they're going to benefit from an HPV immunization when they're 27 to 45 is that person themselves.

Patty Cason:

So, they call out a few very clear ones. Somebody who hopes to have a new sexual partner or plans to. Somebody who's not already. This is all for people who are not already immunized obviously. Somebody who's never had sex and will potentially be having sex in the future. And depending on risk factors for people that... You may be able to sort out a particular risk factor because of somebody's particular partnership in the future.

Patty Cason:

Next slide. But I would really underline the fact that we're not looking to try to make that decision as clinicians. It's not our role to really basically say you can or can't have this benefit. Our role is to help somebody figure out whether it's something that they want to do and then help them by giving them the immunization once they've said that's something they want.

Patty Cason:

Next slide. So this is just further where they describe it. HPV is extremely common. I mean, they say very. It's extremely common. It's by far more common than any of the other things we will be thinking about with any immunization. And most of these infections are transient. People don't know they have



them and they naturally clear them and don't cause any problem. The problem with that is that we, humans, naturally clear HPV, but that doesn't mean we can't get it again. And it doesn't mean, especially if we are somebody who is "male" has been studied to show that they don't develop a good natural immunity when they've been infected with HPV. So in the future, they are vulnerable to get the HPV strain again.

Patty Cason:

This really starts to ask the question about if we're not getting good natural immunity from natural infection, isn't there a lovely possibility that even in that older age range, you can be protecting patients against future infections? Because just having had a past infection does not guarantee you won't get the same infection again in the future, particularly if you're, I'm saying quote male because that's where the studies have been in people that identify as cis male. They have a bullet about people who are in long term mutual and monogamous relationships not likely to acquire a new infection, which is a hundred percent true if it is in fact-

Patty Cason:

Likely to acquire a new infection, which is a hundred percent true if it is, in fact, a mutually monogamous relationship. That's something that only that person and their partner can know. Then they do make the point that most sexually active adults have been exposed, because it is such a very common infection, but not necessarily to the types that are in the nonavalent. Nine types of HPV, that's a lot of different types for a given individual to be already exposed to, probably very, very, very few people have been exposed to all 9 strains. Oh, next slide.

Patty Cason:

We don't do any antibody tests to see if somebody is immune, so we can't go back and say, "Well, have you been exposed and did you develop natural immunity?" We don't have that capacity, but we do know that for somebody who's not been exposed to that type, or perhaps somebody who has been exposed to that type, the body got it under control, but now they have no natural immunity. They could get it again. It has been shown that the vaccine efficacy is there, as Dr. Paula Carr showed us. In either case, if the person's not currently got immunity to the given strain, this vaccine will help. However, there is the possibility that somebody has been exposed to many of the strains and so for that person, there may be more limit to the individual benefit that they could get. But again, really important for that person to be able to identify their own risk. Go ahead and go to the next slide.

Patty Cason:

Then we look at ASCCP. There are three guideline producing entities in this country who have opinions about this and one of them is ASCCP. That's sort of the gold standard and that's why we've really focused on that, because that's from CDC. ASCCP is the American Society of Colposcopy and Cervical Pathology, which is really just now not just about cervix. It's about all HPV related disease. So ASCCP, they're the ones that make all the management guidelines. They have an opinion about this, and I'm also going to mention ACOG. They also, the American College of Obstetrics and Gynecology has also guidelines for this. But essentially what ASCCP is saying, offer it regardless of whether they're going through surgical treatment or not in people that have current disease or have been treated for cervical disease.

Patty Cason:

So pretty much across the board, if somebody has had, or is it currently undergoing treatment for CIN 2+, so anything CIN 2 or above, this would be a very good time to offer a vaccine, but with the understanding that that vaccine is not going to treat this particular strain of HPV that the person has in their body that has caused the problem. It's not going to be therapeutic, but it's been shown to really help in terms of preventing recurrences and that's really important. Doing this immunization for this population doesn't change anything else about the follow up or management. Go ahead. Next slide.

Patty Cason:

For somebody who has disease other than in the cervix, so people who have vaginal disease, or anal warts, or anal cancer, or anal pre cancer, people that have vulva disease, so any other site where HPV tends to cause cancers, those same folks, if they have disease in those other sites, it is recommended that they be offered an HPV immunization. Next slide.

Patty Cason:

There's also one more population, and that is also from ASCCP, and that is that we, healthcare providers who are actually routinely exposed to HPV, because we're caring for patients with HPV, many different contexts to think about that, but it's recommended that all healthcare providers in that category also get immunized, next slide.

Patty Cason:

This is what the letter looks like from ASCCP, when they sent it out to all of the members. Go ahead and go to the next slide.

Patty Cason:

Dr. Paula Carr talked about avoiding the word vaccine. We really want to think about not using all the catch phrases that are in the lexicon right now. Things like vaccine hesitancy, anti-vaxxers, this concept of herd immunity, which was so much talked about with COVID, and definitely the concept of mandatory vaccination, which makes people crazy and then people start to have a completely different conversation with you than the conversation we want you to be having, which is about what do they want, and then helping them to get that. Next slide.

Patty Cason:

There's a three-tiered strategy, in general, about HPV vaccine. The first one is that the default is to vaccinate, and as much as I want to talk to you about communicating with your patient, this is not about communication with your patient. This is about assuming that this is a service that they are due for. That's all. Very simple. Just like with anything else, we don't normally get into long explanations about services that are just, that's what you do for today. The second tier is for somebody who that's not okay with them. They need to have a little conversation. They need to be talked to about it. They maybe have some amount of concern, hesitancy questions, but they want a conversation. The next strategy is a strong recommendation. We, as providers, have a lot of sway over people's thinking about safety and efficacy with this immunization, and we need to go ahead and very clearly state our recommendation. Now, for the person for whom we would really like them to go ahead and get the vaccine, but they are really hesitant, and that conversation, that strong recommendation wasn't enough. Then you go into a

conversation where you give the patient an opportunity repeatedly to talk about what their concern is and you address it. We're going to call that as one of the things that falls under that very wide umbrella of shared decision making. Next slide.

Patty Cason:

Because you really do need to know what the barrier is for that person. Let's start with the first tier, routine immunization. The default is if the person based on age, catch up, or based on risk, is somebody that we would recommend that they get the HPV immunization, we just go ahead and tell them with the least discussion that you possibly can, you're due. Present it like you would a flu shot or a TDAP or a meningococcal vaccine. Just in the same kind of way we would say, "You're due for your cervical cancer screening or PAP," and not to exceptionalize it. The important thing is not to pull it out from all of their vaccines, but to keep it lodged safely within other vaccines.

Patty Cason:

This is one of the reasons that thinking about that age range of 11 to 12, which is considered "ideal", may not be as ideal as, perhaps, nine-to-10-year old's, which is a population that, frankly, is absolutely nobody is going to think about these folks as being sexual or even getting ready to be sexual. They're still children, clearly, so the whole concept of thinking about this, about sex, gets taken out of the picture. The other thing about being a nine to 10 year old is your immune system is even better, newer, fresher than it is at 11 and 12 so it's going to be extremely effective at producing antibodies at that young age. Go ahead and change slides.

Patty Cason:

Again, routine immunization. You can present it as, "Today you're due for TDAP, HPV, and meningococcal vaccine." Very simple, just sandwich it in. Next slide.

Patty Cason:

The reason for that is that we don't exceptionalize other vaccines. We don't exceptionalize other routine screening things. We certainly don't talk about sexual behaviors when it comes to vaccines or routine screens. Next.

Patty Cason:

I was talking about one of the reasons it's good to do this at nine to 10, is because people are really afraid of their children having sex, which that's kind of universal. People don't want their 11 and 12 year old having sex. People don't want to talk about an immunization that is really about protecting somebody if they're sexual behavior is X, Y, or Z. We really want to take the focus away from the fear about sex because of the difficulty in discussing it, but also because it's irrelevant. This is a vaccine that prevents cancer. Everything about the way that we phrase this, the way that we put forward our recommendations, the way we talk about the entire topic of why HPV is important. It's always about cancer. Really to pull back from any concept about an STI or sexual behaviors, and really, really thinking about this prevents cancer. Next slide.

Patty Cason:

The way that you can have these other communications, communications that go beyond just, "You're due today. Which arm would you like it in?" Is something we call the affirm, share, ask cycle. Now, if you look at the right side of the slide, share, it's about sharing information. If somebody's considering getting immunized, but they have concerns, we want to find out what their concerns are and we want to share information, accurate, medically accurate, scientifically accurate, information that will allow them to have the information they need to make an informed choice. That's the point of the share. We're really good at that as healthcare providers. We share information. We do patient education really well. What we don't do is, if we back up to the other side of the slide, we don't really affirm the human being we're talking to. We don't really give a little bit of an acknowledgement to the patient before we start sharing. Next slide.

Patty Cason:

What we're going to say is the first step in your communications, especially if this is somebody who has some amount of concern, somebody for whom you have made a strong recommendation, and that wasn't enough. They needed to have much more of a dialogue, much more of a back and forth. In most people, you're just offering, just saying "You're due," will work, and then in a lot of other people it'll work super well, lots of data, your strong recommendation, they'll go ahead and follow it. We're talking now about the people that aren't going to have that be enough. Now we're going to want to have our first thing we do, before we launch into how safe it is or addressing their concern or anything else that we want to tell them, we want to first acknowledge them as a human being. Next slide.

Patty Cason:

That can be done either by agreeing with some kernel of truth that they've said. If they were showing some sort of fear or frustration or some even anger, any emotion that's negative, no need to label it, but it is a really good idea to acknowledge it. If somebody's had a feeling the way that you would do this affirmation is with an empathy statement. Empathy display. Validation always works and strength based positive. Somebody has been using condoms consistently with a partner with whom they've had chlamydia twice. You notice that, you point that out. That's another way to affirm or acknowledge somebody. Next slide.

Patty Cason:

Before you actually go into sharing any information. Let's say somebody was giving you some really inaccurate science, which we've seen a bit of in the internet online lately, certainly with all of the COVID vaccine hoopla. We've seen a lot of misinformation, but your patient in this conversation may have some kernel of true information that's mixed in there with their misinformation. Rather than saying, "No, no, no, you're wrong," which doesn't usually go well, you address that kernel of that information they have that is true, and point it out, and then add the correct information, without addressing, "No, no, no. You're wrong. That's not true. That's just something that Dr. Google came up with." Again, we're trying to avoid any of that anti-vaxxer language. We're really trying to just talk to the individual about what their concerns are. They give you a piece of misinformation. You will, if possible, not if it's not possible, if they don't say anything that's true, you wouldn't agree with anything. But if there's any part of it that's true, you would acknowledge that and then add the science. Go ahead, next slide.

Patty Cason:

Also, a way to do an empathy demonstration or display to let somebody know that you get it, that they're having a hard time, that they're concerned, they're afraid is to not label, "You seem afraid. You seem angry. You seem man anxious." But just to be generally aware that they're feeling something negative. "It sounds like this is really concerning to you. Certainly anybody would find that really hard to deal with." Or just a wow. "Wow." Or, "Yeah. That sounds like, I can see why that would be really concerning to you." Okay. Just acknowledging what they're feeling is all. Obviously, everybody knows not to say, "Yeah, I know how you feel." Next slide.

Patty Cason:

Validation always works before you launch into sharing patient education. "I hear that all the time." Even if it's completely incorrect, "I hear that all the time," or "Yeah, I can totally understand why you would think that." Validating. Validating just means any person who's reasonable could come up with a similar conclusion because rational people, reasonable people could clearly have come to the same conclusion you do. It's a way of validating, essentially, and that's one of the ways to affirm before you start to share information. "Lots of people have that question." That's one that's really common. Next slide.

Patty Cason:

You've affirmed or acknowledged your patient, and now you're going to share that information that they really need. You want to find that kernel of information that they really need that's going to be the key that opens the lock that's keeping them uncomfortable about the vaccine. You're going to really try to find out what's bothering them and now you're going to share specifically relevant, a small bit, and this is an important piece, a small bit of digestible information. Next slide.

Patty Cason:

The concept is we're giving somebody information in a way that they can understand it, hear it, integrate it, use that information to make an informed choice. That means that it has to not have too much content all at once. These cycles, ASA cycle, affirm, share, and then ask, that goes on over and over. Okay? So each time you give a small piece of information that you really think is important to them, for them to have, to make an informed choice. Each time you do that, you make sure that little bit of information is a digestible amount. You make sure that it's relevant to the individual, as I said, and really actually trying to address specifically what it is that their concern is, or their misinformation is, using plain language, not using medical language. Using the same words that any sixth grader would be able to understand. Regular, plain words.

Patty Cason:

I said limit the amount of information and that does not mean that in the course of the conversation, you're limiting the information, because in the course of the conversation, hopefully, with these ASA cycles, you will have shared all the information that they need and not shared information that's not relevant to them, because they have their specific concern. It might not be the same concern. In fact, I would pause it that it isn't going to be the exact same concern as the next person you're going to talk to. You need to find out specifically what that is that they need to know and then that information will be, hopefully, covered in the context of the conversation, just not all at once. Using their words always

helps. If you're not clear about how somebody refers to something, particularly when it's anything to do with their genitals or sexual contacts. It's a really good idea to use their own words. Consider not using percentages, but instead, how many out of how many, five out of a hundred or three out of a hundred. Consider those natural frequencies. They're more understood by more people. Next slide.

Patty Cason:

Paraphrasing is really, really helpful beyond what we're going to talk about today, but it really is a way to let somebody know that you're listening, to check that you're getting it right, that you're understanding what they're saying. It's a way to move that conversation to the next step. You feel like you've given the person the information that you need to have given them based on what you've identified as their need. Now you want to move the conversation to, "Let's get that shot in the arm." You can do this very nicely by paraphrasing. You're summarizing what you've talked about. You go to the next service. You're going to the next part of the visit. It's an ASA cycle all on its own of paraphrase, because it starts with an acknowledgement of some kind and saying, "I'm hearing you say, in other words," I'm focusing on you. Then you paraphrase and then you follow it with a question. That's the thing about an ASA cycle. You don't share information in large amounts, you share it in small digestible amounts, and then ask a follow up question before giving more information so it breaks it up. Next slide.

Patty Cason:

We talked about the fact that this is something people are afraid about and a lot of that is because of sex. I just wanted to show you this one article in the New York Times, but some of the misconceptions that people have, that may have maybe things that you're going to want to be addressing with ASA cycles, are concerns about safety and the sexual promiscuity one is quite important. It's much more important if you get the sense that their concern is about sexual promiscuity and you want to rush in and reassure, first let them speak what it is that's really concerning about that. Let them really get... What do they mean by that precisely? Then let them know you heard it, then tell them that the studies show that it doesn't cause any change in sexual behavior, getting immunized. Next slide.

Patty Cason:

One way that you can also present information, this is the share part of it, would be to say that the HPV immunization prevents, and then talk about all the kinds of cancer that it prevents, including head and neck, which clearly nobody's going to think. The first thing you think about when you look at your head and your neck is not sex, right? It's taking it out of the realm of talking about sex into the realm of talking about cancer prevention. I love that you can give somebody this study, this number, which is almost 30,000 individuals are affected by cancer caused by HPV every single year. That's a new case every 20 minutes and we have a vaccine that can prevent it in the majority of cases.

Patty Cason:

The thing is that people are likely to get a personal benefit from having an HPV vaccine, immunization. If somebody gets immunized against polio, up until recently, very, very unlikely to ever have a benefit from that. Smallpox. I was vaccinated against smallpox. I was immunized against smallpox. What are the chances I'm going to be exposed to smallpox? Even tetanus. The chance that we're, in our society today, going to be exposed to the majority of the things that we're getting immunized for, against, the value benefit and the risk with all these vaccines, if you look at all of them, we're going to get the most

benefit, personally, individually, from HPV vaccine. That's the one that's going to be most likely to help us in our lifetime, and actually, we'll be able to see the measurable difference in ourselves. Next slide.

Patty Cason:

We're comparing. I said, getting an HPV infection and a cancer from it is much more likely than the downside effect of any of the other vaccines. You can see here, meningococcal pneumonia, 150 deaths per year. There's a really big difference. Pertussis is 20. Tetanus 4. Diphtheria is zero. HPV related cancers, more than 4,000. Next slide.

Patty Cason:

I think when we're talking about natural frequencies, 20 times more likely, that sounds very dramatic and that's a really nice number to remember and to bring up. If somebody's okay with other vaccines and not this one, that's the person that these kinds of pieces of information are going to make all the difference for. Next slide.

Patty Cason:

Using visual aids is a really, really important way to share information. People take in information auditorily, but visually, also tactually, if you can give somebody something to hold. Anything you can do to help somebody receive the information through more than just their ears or more than just you talking to them or reading something. Visual aids are very, very helpful. People don't necessarily know where all these parts are that we're talking about that can get cancer from HPV. Next slide.

Patty Cason:

Again, good way to show parts. Next slide.

Patty Cason:

I had mentioned a few times that the other part of the ASA cycle is, you've affirmed or acknowledged the person, you've shared a small amount of digestible information in a way that they can really understand it. Now, before sharing more, ask a follow up question. Next slide.

Patty Cason:

That follow up question should be absolutely related to the content you just shared. It should be focused on what it is that you just shared, but it should be open ended to allow the person to really consider the information and give you their response. Things like, "How would that be for you? Has that ever happened to you before? How did you manage it? Do you have a sense of how you would manage that? Knowing that, how would this be for you?" Those are follow up questions. Generic, open ended, but also focused on the topic, the specific subject you just were talking about when you gave information. Next slide.

Patty Cason:

The provider recommendation, as we said, is the most important single factor across all population studies. When I say strong recommendation, we're talking about something really simple. "I strongly

recommend you get this immunization," or, "This immunization protects you from many types of cancer." Again, this is in the share portion of the ASA cycle. Next slide.

Patty Cason:

This is just showing you one study. I thought this was very dramatic. 66% of the patients who did get a provided recommendation for flu shot, got it within 12 months versus 16, who didn't get a recommendation. It's a huge spread. That's what we're talking about. We need to be comfortable not exceptionalizing this, and we need to be comfortable just giving it a flat out, clear provider recommendation. Rather than saying, "Are we doing shots today?" Or, "Are you going to get immunizations today?" Instead saying, "We have some shots to do today." In other words, put it forward as the expected routine, they'd have to opt out, kind of recommendation. Next slide.

Patty Cason:

Summary. People who have been treated or are undergoing treatment for any kind of cervical disease, CIN 2 or above, people, whether or not they've had surgical treatment, this is applicable. People who are healthcare providers exposed routinely to HPV through our occupation, or people who... How about individuals who, and again, these are only people who have not previously then immunized. Because immunization is, so far as we can tell, lasting all our lives. If a booster someday is needed, we'll talk about it, but that's not what this is. This is only people who haven't already had an immunization. People who have not had an immunization, but plan to have a new partner or may want a new partner or are open to having a new partner. People who have never had any sexual contact with another person or somebody who's breaking up with a current long term partner. Another really good time to start bringing this up. Next slide.

Patty Cason:

There's no default, right? There's not a right answer. The patient is the one... For the age range of 27 to 45, the patient is the one who has the information in their own knowledge of themselves. That's where that decision's going to land, their knowledge about their own life and their risk and we will share that in terms of explaining whatever we need to do to clarify. But what we don't want to do, is give the patient a pathophysiology lecture like Dr. Paula Carr just gave us. He was clear. We all got it, but this is not the kind of information you want to give your patient.

Patty Cason:

Your patient, you're giving them a piece of information in response to their concern, in response to their fear, in response to their question, their hesitancy, if you will. We do want to give them evidence in response. We do want to definitely query them about their own values, their own preferences, their own sexual life. When we talk about our clinical discretion, if we see somebody that we really believe is going to benefit, then I do think this is a place where even though this is a shared decision making situation, let's say we have somebody who is in their twenties or thirties. They have never had any sexual contact with any other person in their life and now they are going to be having sexual contact with other people. This would be a situation where it wouldn't just be finding out what their preferences are. It would be where we would be giving a recommendation. That's why our clinical discretion comes into this as well. Next slide.



Patty Cason:

We want to address the barrier.

Patty Cason:

So, we want to address the barrier, use the ASA cycle, affirm before giving information, explore their concerns before offering any counter. Before offering data, before offering a response, first understand what it is that the concern is and be as specific as possible about what it is. Let them know you heard it, that you care by, "I see that that's concerning to you." And then give information. And then ask a follow up question. Next slide.

Patty Cason:

So, this is just the last slide. It's recommendations for how to improve coverage overall. So these are sort of more generic, not about counseling, but recall systems have been shown to be quite effective. Standing orders, when you don't have a person who's able to write the order right on site at that moment, standing orders have been used and can be very effective. I know we do that in a lot of areas with contraception.

Patty Cason:

Obviously, the out-of-pocket expense is not a concern with Family Pact. And then just very specifically at your site, think about are there hours that a working person... Let's say they got their first immunization and they're coming back for their second. Are there hours that are going to be convenient for them to get their follow up immunizations? It's really hard to get that second and third shot in. So addressing the barriers that you might have in your site to having people just maybe stop in when it's convenient for them or have extended or weekend hours.

Patty Cason:

So, I'm going to pass this right back to Dr. [inaudible 01:22:39] and we'll see what we have for questions and...

Patty Cason:

You're muted.

Nicole Nguyen:

Yes. You're muted, [inaudible 01:22:49]. So I know we have some questions coming in, and thank you everyone for being patient with the technical difficulties. And I know we also have some questions in, but both Patty and Dr. [inaudible 01:23:00] also graciously agreed to stay on for extra 10, 15 minutes. So, keep those questions coming in and we'll try to get all of them answered for you as much as we can.

Dr. Michael Policar:

Yeah, so hopefully you've been following the question box, because while Patty was speaking, I answered virtually all of the questions. But I'll tell you about some of the more important ones just to

elaborate a little bit. And then there are a couple that I specifically want Patty to answer if she knows the answer.

Dr. Michael Policar:

Patty, here is one. How do we acquire the HPV vaccine product for our family planning patients? Do we have to purchase it in advance and get reimbursed?

Dr. Michael Policar:

So, the answer is yes, you do have to purchase it in advance. And then once you administer it to a patient, then you use the CPT code for the vaccine product. And I mentioned that both in the slides and in the Q and A box, it's CPT code 90651 for the product. And so when your biller bills that code, you'll be reimbursed with the product and 90471 for the administration of the vaccine.

Dr. Michael Policar:

And by the way, that's not built into the E and M code for the visit, it's separate from. So you can bill for that.

Dr. Michael Policar:

Now the question I have for Patty, I don't know if you do know the answer, is ordering Gardasil 9 directly from Merck the only way that you can actually get a supply of the product, or do you know if there are other ways to acquire a supply of the product?

Patty Cason:

I don't know.

Dr. Michael Policar:

Okay. Well, I know as a fact that you can obtain it from Merck. And I can also anticipate your question, what about writing a prescription that's sent to a pharmacy and then the patient picks it up at the pharmacy and brings it back to the clinic? And the answer is that Family Pact doesn't cover that. We've had that question about bicillin for syphilis. We've had that question about DMPA for a Depo-Provera shot.

Dr. Michael Policar:

And the answer is there are problems with what's called chain of custody in that circumstance when someone picks up something at a pharmacy and brings it back to the clinic, so that wouldn't be covered. So do talk to your local Merck representative, or of course go to the Merck website and it will give you details about how to order it. Let's-

Patty Cason:

I'm seeing that for those that were diagnosed with HPV and over 27, do you recommend an HPV immunization if never given a vaccine? So HPV infection alone, that has not been addressed by anybody giving recommendations, but you have to think that it's probably... If somebody's got an HPV infection,

then that is actually clear. The reason that people get CIN2 and above is because of high risk HPV infections.

Patty Cason:

So, you could make an argument that person has demonstrated that they have risk because they have just had a positive test or a positive infection that is causing warts. Because the only two contexts in which you'll know somebody has an HPV infection is A, they've been screened for routine cervical cancer screening with a high risk HPV test and it's positive, or they're coming up with genital warts.

Patty Cason:

So, I would say this. I would agree with Dr. [inaudible 01:26:26]. I wouldn't make a strong recommendation for this like I would with somebody who had already demonstrated disease, but this is definitely a gray area where it wouldn't just be agnostic. They've already shown that they have been infected with an HPV strain.

Patty Cason:

So, I think it takes it a little bit... It's kind of halfway in between, if you will, between somebody who has not had any history of CIN2 or above, and somebody who has CIN2 or above.

Dr. Michael Policar:

Great, thank you. A question... Actually, a recommendation just came in from Gail saying, "Here is a link to standing orders from the immunization action coalition for HPV vaccination for adults." And then there's a URL listed as well. So please take advantage of that. I have looked at that particular website, the immunization action coalition for HPV, it's really helpful. It has a lot of very, very good information in it, a lot of which is quite California-centric. And here's sort of a shortcut for developing standing orders for that, if you're able to go to that website.

Dr. Michael Policar:

I also got an interesting question about do minors need consent from parents to get HPV vaccination? And the answer is that is different state by state. And there are a couple of websites that actually quite authoritatively and up to in an up to date way will tell you about what the rules are in different states.

Dr. Michael Policar:

However, in California, where I'm assuming virtually all of you are practicing, minors that are 12 years old and older can give their own consent to HPV immunization, okay? They don't have to have parent's consent.

Dr. Michael Policar:

Now, there was also a question or an observation that came in from Nikki, which basically said, "We're a part of the Vaccines for Children program, and VFC does require parental consent."

Dr. Michael Policar:

And I thank you for sending that in, Nikki. Unfortunately I'm not very knowledgeable about the specific rules of VFC, although I know that all of that is listed on a Vaccine For Children's website to find out about what the parental consent requirements are specifically for that program.

Dr. Michael Policar:

But as a more general issue, let's say a person is getting vaccinated at 16 or 17 outside of the VFC program. Not as part of Family Pact, but maybe a different insurer, for example. In California, they are able to give their own consent without parental consent.

Dr. Michael Policar:

Patty, here's another one for you that I kind of started with, but I think it's important just to make sure that everybody understands it. Can you elaborate on the recommendation for healthcare providers to get the HPV vaccine due to possible exposure in the workplace?

Dr. Michael Policar:

And the way that I answered that was to say, "Well, yeah, that's especially true for clinicians who perform COPO or who do cervical biopsies, LEEPs, laser vaporizations." But say again about the ASCCP recommendation. Is this true for all clinicians, or is it really more focused on people who are doing colposcopy services?

Patty Cason:

Yeah, I wish they were more specific. They haven't been. So they're just saying for people that are seeing patients and treating patients with HPV and therefore may be occupationally exposed. And they don't give specifics, but the specifics that you called out are absolutely clearly... We know from data that you can get HPV exposure from plumes, from laser, and vaporization. But the thing is that what we don't know is what we don't know.

Patty Cason:

So, I would say personally, I would take that recommendation to mean anybody who's really... Not necessarily anybody who's doing any PAPS and HPV testing and other cervical tests, but anybody who goes beyond that, and I would agree somebody who's doing colposcopy, certainly anybody who's doing LEEP or cryo, although cryo, I can't see how it would do that, but we don't know what we don't know.

Patty Cason:

And it just seems like there's... Oh, what about people who are doing a lot of treatment of external general warts?

Dr. Michael Policar:

Yeah. That's a good point.

Patty Cason:

Not high risk, but still, that's a wart virus that you're having a lot of contact with.

Dr. Michael Policar:

Right. Yeah. Would seem to me, particularly if you're doing the kinds of techniques that might be potentially vaporizing the virus, and here I'm thinking kind of more about cryotherapy than I am about applying TCA... But yeah, that absolutely makes sense that you don't want to come in contact with HPV 611.

Dr. Michael Policar:

And that particular type of HPV is more attracted to genital skin than it is to other skin surfaces. But nonetheless, you don't want a big dose of coming in contact with that virus or inhaling it. That's really-

Patty Cason:

Or inhaling it. Exactly. For micro papillomatosis.

Dr. Michael Policar:

Right.

Patty Cason:

Papillomatosis. Why is that word so hard to say? Yeah. And if you put laryngeal in front of it, that's really hard. Laryngeal papillomatosis.

Dr. Michael Policar:

Right. Okay. So is HPV immunization covered with all contraceptive methods? I did point that out very, very quickly in my very last slide, but I will remind you. And here I'm reading directly from the PPBI, the policies, procedures, and building instructions published by Family Pact in July of 2022.

Dr. Michael Policar:

And it says, "HPV vaccine is not reimbursable with the ICD 10 diagnosis codes of C 30.012, that's emergency contraception, Z 30.09, which is sort of general counseling about contraception, or Z 31.61, which is fertility awareness-based methods

Patty Cason:

And preconception, right? Also?

Dr. Michael Policar:

Yes. Yeah. Yeah. The same code is used for that. The most recent question is, is Family Pact currently covering HPV immunization? Or is this coming soon?

Dr. Michael Policar:

No, it is. It was added to the PPBI in just this past July and became effective on August 1st. So we are three weeks into it being a benefit. So this is something where you can bill both for the vaccine product using the CPT code that I gave you earlier, 90651, as well as being paid for the administration 9047.

Dr. Michael Policar:

Okay. Well that is actually most of the questions that I haven't answered. Patty, can you see the questions or is there anything else?

Patty Cason:

Yeah, answer the questions.

Nicole Nguyen:

Oh, there's also questions about... Sorry. Just, I think there was two about this. Do you both know of any HPV immunization information in Spanish that's available?

Dr. Michael Policar:

I don't, but Patty, go ahead.

Patty Cason:

Yeah, no, I'm pretty sure CDC has extensive immunization patient education materials. And I think, I mean, there's a lot of resources available on the CDC website. And I know they do that in multiple languages. So that's where I would look. That's the first place I would look.

Dr. Michael Policar:

And then the other place I would look is that is where I just mentioned a moment ago, based on Gail's recommendation. That immunization action coalition for HPV. And as I said, it's included in the Q and A, but it's [www.immunized.org/catg.d/p3091/..pdf](http://www.immunized.org/catg.d/p3091/..pdf). So I know I went through fast on that, but again, look in the question and answer section of the webinar, you'll find that link.

Dr. Michael Policar:

And my estimation is you will be able to find patient education in both English and Spanish and probably other languages as well. But I'm also with Patty that the CDC probably has that.

Dr. Michael Policar:

Another place you might look as ACOG, but I couldn't tell you...@acog.org, whether or not you would need a password for being able to get that in Spanish.

Patty Cason:

I think you do. The other thing about ACOG, they have wonderful materials, but they're at a high educational level. So I think that you need to be really cautious for health literacy concerns when looking at ACOG patient education materials.

Patty Cason:

I wanted to make a comment about the question about person who started their HPV immunization before age 14, and did they need to have two or one more dose when they came back at 16? I.

Patty Cason:

Just wanted to talk a little about the way this works from a physiologic basis, is that the immune system is so ripe and ready when you're nine or 10 or 12 or any of those ages. Earlier. And the older you get, the less good your immune system is.

Patty Cason:

So, the idea behind this is that if you start before 14, you've got such a very good basic immunization with that first shot, that the second shot is a booster. We really want to think of that as a booster.

Patty Cason:

And the reason that's important is that six-month timeframe is a bare minimum. So more is fine, less is not fine. So for a two shot series, what you don't want to do is one, and then another 1, 2, 3, 4 months later. You want to wait at least that full six months so that child's immunization, their immune response has really gotten to a good level before you then boost it with that second shot.

Patty Cason:

And I just wanted to put the physiology out there, because I think it's confusing for some of us to think about immunizing earlier. Well, isn't that a problem because potentially it'll wear off sooner? But that's actually not true, the way that the immune system works. It's actually better to get it earlier and it'll last longer, bizarrely. What else is like that in the world?

Dr. Michael Policar:

Okay. Got another billing question that I think is worth sharing, and that is, does HPV vaccine education and counseling get billed, or just the product and the administration?

Dr. Michael Policar:

So, in reality, it's unlikely that a person is going to come in for a Family Pact visit solely for the purpose of HPV vaccination. This is going to come up in the context of a visit almost certainly for family planning. So you'll be seeing a person who's in because they are there for a contraceptive method, or maybe they're a contraceptive user as part of Family Pact and they're in because of an STD concern, something like that.

Dr. Michael Policar:

And at the same time of the visit, you take the opportunity to have the discussion about the availability of HPV vaccination. So in that circumstance, if it's only the counselor who sees a patient and not a clinician, then you could bill an ENC visit based on time.

Dr. Michael Policar:

Remember there are three levels of ENC codes that are specifically for counselors based on the amount of time with the patient. In addition to the CPT code for the vaccine itself and the CPT code that I told you about for the administration of the vaccine.

Dr. Michael Policar:

Now, on the other hand, if it's a visit with a clinician, and so the clinician is caring for the client in regard to contraception, STIs, your bladder infection and so on, and the issue about HPV vaccination comes up, then you would bill the EMM code for the visit in addition to... And of course, ICD 10 code for the method of contraception that the person's using. Whatever secondary diagnosis there are around STIs, but you can also bill, in that case, the CPT code for the vaccine and the separate CPT code for the administration of the vaccine.

Dr. Michael Policar:

So, it's going to be really unusual that you provide this service without an E and M code for a clinician visit or an E and C code for a visit with a counselor.

Patty Cason:

There was a question about whether HPV immunization is given to people with an upper respiratory infection, and it's not a therapeutic vaccine in general. An upper respiratory infection not really the same symptoms as a person would have with head and neck cancers, oropharyngeal cancers. But in general, it's just not a therapeutic vaccine. We give it to people who have a history or have a recent diagnosis of disease on the vulva, the vagina, anus, penis, and certainly cervix. Because the data has shown that it prevents... Not prevents, but that it's less likely that person will have a recurrence. But it's not going to be treating the actual acute HPV infection, it's not therapeutic in that way.

Dr. Michael Policar:

Okay. Okay. Just a couple important questions here about sort of Family Pact PPBI rules. Is it mandatory for all Family Pact clinics to offer HPV immunization?

Dr. Michael Policar:

The answer to that is no. Completely optional. It's optional whether or not you sign up for VFC. We hope you do, because that is a sister program in the way of Family Pact through that immunization branch in the Department of Public Health. So we would recommend that you sign up for VFC. We would also recommend that you make HPV vaccination available to people who are 19 and older, but if that's not possible for you to do it in your clinic, then that's fine. It's not something which is required in the Family Pact program.



Dr. Michael Policar:

Another question that just came in is can we bill for HPV vaccine for males? And the answer is absolutely. Sure. In exactly the same context that you've heard me talk about this benefit starting at 19 through 26, being available routinely, and then for people that are 27 up to 45, based on shared decision making that applies equally to males and females.

Patty Cason:

Somebody had a concern about giving too many injections in one visit. And we do routinely give multiple immunizations in one visit for children across the board. And we also do it for adults who are going to be traveling. It's just something that has been part of an immunization program for years, is to be okay with multiple vaccines for the most part. And certainly when we're talking about HPV, it is okay to combine with other vaccines.

Patty Cason:

Somebody also is asking about a woman who's 60 with HPV DNA-positive tests needing repeat colposcopy. So it's not licensed for people by FDA for over the age of 45. It's not ASIP recommended by CDC for anybody over the age of 45.

Patty Cason:

That said, two points are very relevant to this. So one of them is there should not be a safety concern. There's probably no safety concern in somebody over 60. So that's just to put that to rest. There's no reason we would think there would be a safety concern.

Patty Cason:

The only question is whether it would be effective. Now somebody's immune system at age 60 is not as good as it is when they're below 45, but we also don't have reason to believe that they would not mount an immune response to an immunization. So they probably will mount an immune response, and it is undoubtedly safe and it is not covered. So any of that would always be out of pocket at this time.

Patty Cason:

The other point I wanted to say is we have people currently with the screening guidelines exiting screening at age 65, but I will tell you that the data are not really supporting that. And I think this is being looked at in terms of the guidelines very closely right now, because there is not actually a taper off or a decrease in the way that we thought there was in that older age group.

Patty Cason:

So, this is sort of like a stay tuned, but there will be more information coming, and there will be some changes to guidelines about this in the future as things unfold. As we start to get more data about the people who are currently over 60, over 65, there are people that were in a very different social situation than the people who were 65 20 years ago. There was something called the sexual revolution. And now those people that went through the sexual revolution are now those people who are over 65 or this person that you're talking about.

Patty Cason:

So that's why a lot of these data that we've looked at have been... They're really outdated, for one thing. And also they're not as comprehensive as you would think. So over age sixty's very interesting population to be thinking about, not at all related to Family Pact, obviously.

Dr. Michael Policar:

Okay. Let's see. Well, we're almost at the end. I'm just typing one more answer, but I'll tell you what I'm saying in just a minute. Here we go. Okay.

Dr. Michael Policar:

So just to clarify... Oops, where did that one go? All right. So just to clarify, for patients under 19 we're seeing for Family Pact, confirming that Family Pact will not pay for those vaccines, correct?

Dr. Michael Policar:

That is correct. What the policy is for Family Pact is that for anyone who has not had their 19th birthday yet. So in other words, 18 and younger, that Family Pact will not cover the Gardasil 9 because of the fact that the VFC program does cover it. And hopefully you are part of VFC. If you're not, then you may have to refer the patient to another site like a FQHC or federal qualified health center or something like that that is a part of the VFC program. Let's see.

Patty Cason:

I wanted to make one more clarification. I had not seen this question about men 45 years old. 45 and above 45. Sexually active having sex with other men. So I'm going to put that in the same category as the woman that was described in the other case who's 60.

Patty Cason:

So, for people over age 45, all those same things I said about the sixty-year-old that was in the question apply. In other words, it's not covered, it's undoubtedly safe, and it's probably going to have some amount of efficacy, but not a lot of data.

Dr. Michael Policar:

Okay. I'm going to do one last question.

Nicole Nguyen:

Yes. One last thing, because I know we're a little time and I'm going to make sure people get out. But thank you Dr. Policar.

Dr. Michael Policar:

This one's really easy, Nicole. Where can I find those non-covered diagnosis codes for the methods that are excluded? And in the policy procedures and billing instructions, which is on the [familypact.org](http://familypact.org) website, there are maybe 30 different chapters in the PPBI. One is called ben family. Benefits that are

family planning related. So it's in that policy on the bottom of page six where you'll see it. Okay, Nicole, back to you.

Nicole Nguyen:

Yes, no, thank you so much Patty, Mike, thank you for staying an extra 15, 20 minutes to answer all these questions. We got really good questions. So for those who stay with us, we will be collecting these questions and getting them out. So if you have to leave early at 1:30 sharp, we'll get you your questions and the answers.

Nicole Nguyen:

And of course, please feel free to fill out the survey at the end of this webinar when it closes, and then we'll make sure you get the CME link for your certificates, the recording and slides and the Q and A. We'll get them out in the coming weeks.

Nicole Nguyen:

So, thank you again, Patty, Mike, for the amazing webinar. Always a pleasure to have you both tag teaming on our topics. And thank you all and have a great rest of your week. Okay.

Patty Cason:

Thank you.

Nicole Nguyen:

Thanks everybody.