



MICHIGAN PHARMACISTS ASSOCIATION

National HPV Vaccination Roundtable
Pharmacy-located HPV Vaccination
Pilot Project

Final Report

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Executive Summary

Michigan Pharmacists Association, with its expertise in pharmacist and pharmacy technician education and training, and its history of dedication to expanding immunization services provided in pharmacies, partnered with a regional chain, SpartanNash Pharmacies, to conduct a pilot project focused on HPV vaccination administration in community pharmacies. Outcomes for the project focused on identifying barriers, challenges and successes for increasing HPV vaccination rates within communities while building an HPV Immunization Neighborhood. The major findings of this project are categorized into two groups: pharmacy-specific challenges or HPV vaccination in the pharmacy challenges.

Pharmacy Challenges

Since a key outcome for this pilot project was the documentation of barriers and challenges associated with HPV vaccinations delivered in the pharmacy setting, the planning team selected an approach similar to what many community pharmacies use when launching a new program or service for patients. This “grass-roots” approach began with pharmacist and pharmacy technician education and training, workflow tools development and vaccine stock acquisition. Then the pharmacies began screening patients, offering HPV vaccine to appropriate candidates and documenting their results.

Many of the challenges identified during this pilot relate to pharmacy service implementation, not necessarily just HPV vaccination. These real-world barriers must be addressed before pharmacies can successfully implement programs in their communities to help improve their patients’ health.

- **Pharmacist Project Leaders.** Having strong support and belief in the project from the pharmacist-in-charge leading the project is critical for long-term success. An individual pharmacist’s willingness to fully embrace the project can be variable, so special care should be taken in selecting the best project leaders.
- **Pharmacy Patient Demographics.** The patient demographics at any given pharmacy may or may not be appropriate for HPV vaccination efforts. For example, pharmacies with a vast majority of Medicaid patients (adolescents would be required to receive vaccines through a VFC provider) or Medicare patients (patients are outside of approved age range) might not be good candidates to offer HPV vaccination. Additionally, the challenges from language barriers during traditional patient counselling can be amplified when explaining something like HPV vaccination.
- **Pharmacy Staffing.** This challenge is not new for pharmacies but must be accounted for when determining the workflow for new services. If a pharmacy is understaffed to perform its typical daily functions, offering a new service for patients may add too great of a burden on existing staff. Resolving staffing issues before launching a new service is highly advised.

HPV Vaccination in the Pharmacy Challenges

In addition to challenges at the pharmacy level, many barriers surfaced related to HPV vaccinations being administered in the pharmacy setting.

- **HPV is Not Influenza.** Pharmacists have been very successful with interventions to increase influenza vaccination rates, especially among adults especially seniors. However, there are a number of factors that

make HPV vaccination much different than influenza. First, influenza is an annual vaccine recommended for nearly everyone, so pharmacies have the opportunity to reach patients every year, and patients have come to expect influenza vaccines from pharmacies. HPV, on the other hand, is recommended only for a specific, narrow age range for a set number of doses during a set time frame. Patients and parents may be less comfortable with HPV vaccine being administered in a pharmacy because it is less publicized and less common than influenza. Second, while anti-vaccine campaigns refute vaccine safety and effectiveness, most are not targeted specifically at influenza. HPV vaccine has a history of negative mass media coverage and avid, vocal social media instigators touting their own fear-laden messages that are not backed by proven science. Patients are often more fearful of HPV because of the negative media. Third, influenza is easily spread through mechanisms without social stigma and discussions about preventing influenza do not tend to conflict with individual's personal or religious belief systems. Since HPV is largely spread through sexual contact, many patients and parents are unwilling to discuss HPV vaccination with healthcare providers for personal or religious reasons. These challenges related to starting a conversation with patients and parents about HPV vaccination can make pharmacists hesitant to broach the subject given the myriad of other responsibilities they have.

- **Pharmacists' Confidence about HPV Vaccination.** While many pharmacists feel confident in recommending HPV vaccination without additional education (e.g., recent graduates who receive a great deal of training and education about immunizations), many also lack comprehensive education about HPV vaccine to make them feel confident making a recommendation to patients. Pharmacists who might be experts regarding influenza vaccination may still feel uncomfortable about HPV due to a lack of knowledge. They too have experienced the negative media and need to be provided with the science showing its effectiveness and safety.
- **Cost of HPV Vaccine.** The cash price for HPV vaccine during the pilot was around \$250 per dose. For all three doses, that would cost a patient \$750 if not covered by insurance. Patients up through age 18 on Medicaid must receive vaccines through the Vaccines for Children (VFC) program, which does not include pharmacies as VFC providers. During the pilot period, most third party insurance payers did not cover the cost of HPV vaccine administered in the pharmacy. Pharmacies may be able to bill medical insurance coverage, but the claim may also be rejected, which would result in the patient receiving a bill for the cost of the vaccine. The issue of the lack of third party payment for HPV vaccine administration in the pharmacy is also a barrier when trying to establish an HPV immunization neighborhood because it severely restricts the patients that are able to receive the vaccine in the pharmacy. It does not make sense for a physician to refer the patient for the second dose at the pharmacy only to have the pharmacy send them back to the physician because the patient's insurance does not cover the cost in the pharmacy.

Strategy 1: HPV Vaccine Administration in Ten Pilot Pharmacies

Pilot Processes

Ten pilot pharmacies were identified within SpartanNash Pharmacies through a collaborative partnership. Five stores were located in the Grand Rapids area of Michigan (Kent County) and each of the five remaining stores was located in one of five rural counties (Ottawa, Barry, Clare, Cass and Tuscola). In Michigan, pharmacists are able to administer vaccinations through the state's delegation of authority statute. Pharmacists obtain standing orders for different immunizations from collaborating physicians. SpartanNash pharmacies had an existing standing order in place for HPV vaccination for adult patients 18 through 26 years old. The physician of the adult standing order was not willing to provide a standing order for adolescents. A physician at Cherry Health in Grand Rapids, Michigan, partnered with the pilot pharmacies by providing a new standing order for HPV vaccination for patients 11 through 17 years old.

Prior to launching the pilot, the pharmacists and pharmacy technicians at each of the pilot pharmacies completed an intensive training program about HPV and HPV vaccination. The training programs were developed by Michigan Pharmacists Association (MPA) utilizing a variety of resources from Centers for Disease Control and Prevention (CDC), Immunization Action Coalition (IAC) and American Cancer Society (ACS) (see Appendix A for copies of the educational materials). Pharmacists and technicians completed a home study course covering background information and then attended either a live, classroom-based training session or completed a hybrid training session utilizing videos and a follow-up conference call. Pharmacists and pharmacy technicians had to successfully complete posttests after the training sessions in order to receive continuing education credit.

After analyzing the workflow at one of the pilot pharmacies, a process was established for all of the pilot pharmacies to use for identifying patients eligible for HPV vaccination. Since HPV vaccination is appropriate for only certain age groups, a screening tool was developed. Two versions of the screening tool were created, one for patients 11 through 17 years of age and another for patients 18 through 26 years of age. The 11 through 17 years of age screening tool was provided to parents for completion. Copies of the screening tools were available at the pharmacy counter for pharmacists and pharmacy technicians to hand to potential candidates. They also printed automatically with specific prescriptions. For the first month of the pilot program, the screening tools printed with prescriptions for patients in the appropriate age ranges. In the second month, to expand the potential pool of eligible patients, the 11 through 17 years of age screening tool also printed for patients picking up prescriptions who might be parents of a child 11 through 17 years of age. The tool only printed one time per patient during the pilot period to avoid redundancy.

The screening tools printed at the point of prescription verification along with other prescription paperwork. Additionally, an age-appropriate patient education handout printed along with the screening tool for the patient or parent to take home. The pharmacist put the screening tool in the bag with the patient's prescription in a way that flagged that patient at pickup. When the patient arrived to pick up his or her prescription, the pharmacist or pharmacy technician retrieved the bag, identified the screening tool present and asked the patient to complete the screening tool while completing the prescription transaction. The pharmacist then reviewed the screening tool and discussed HPV vaccination options with the patient or parent as indicated. A resource guide was developed to guide the pharmacists through counseling the patients or parents based on their answers to the questions on the screening tool.

If a patient expressed interest in receiving the vaccine, the pharmacist assessed his or her insurance status. Only a limited number of commercial insurance plans in Michigan allow pharmacists to administer HPV vaccine within the pharmacy. Medicaid patients ages 18 years and younger must receive vaccines through the VFC program. Michigan pharmacies are not part of the VFC program currently (see the "VFC Providers in Michigan" section for further

information about VFC). Most patients rely on third party coverage for the cost of medications and vaccines and are unable or unwilling to pay cash. Many commercial insurance plans in Michigan do cover HPV vaccination for adolescents through the medical benefit when administered in a physician's office but do not cover it when provided by a pharmacist in a pharmacy. Convincing patients to pay cash in the pharmacy for a benefit covered at no cost in the provider's office was a significant barrier. For patients whose insurance did cover administration in the pharmacy or were willing to pay cash, the pharmacist administered the vaccine and documented the service. When contact information was provided for the patient's primary care provider, the pharmacist faxed a record of the service to the provider.

Michigan also utilizes an electronic statewide system for tracking childhood and adolescent vaccination called the Michigan Care Improvement Registry (MCIR). Pharmacists used MCIR to help assess patient vaccination needs. Additionally, all immunizations provided in the pharmacy were documented in MCIR according to state laws and SpartanNash policy. All immunizations provided were reported.

By mid-April, all pilot pharmacies had received their stock of Gardasil® 9 and screening tools began printing with prescriptions. Pharmacists and pharmacy technicians tracked the number of screening tools handed to patients and parents along with the number of screening tools that were completed and returned. They also tracked the outcomes of patient interest in HPV vaccination, e.g., if the vaccine was administered or if the patient was referred to another provider for any reason. The pilot program officially ran through July 31, 2016, for data collection purposes, but all of the pilot pharmacies are continuing to offer the vaccine to eligible patients.

Pilot Data

Table 1 shows how many screening tools and educational handouts were distributed per pharmacy for each age group as well as how many screening tools were returned to the pharmacy. The extreme variability in return rates for three of the pharmacies (numbers 2, 8 and 10 in Table 1) occurred because they altered the recommended workflow. In two of the cases, the screening tool was primarily sent home with patients rather than completed while at the pharmacy counter. In the third case, the pharmacist educated any patient with the screening form about HPV rather than using the screening tool to screen for potentially eligible patients. In this situation, the pharmacist did not have any patients or parents complete the screening tool despite repeated corrective sessions. The pharmacist did talk to patients and educate them, but the interventions were not able to be captured through the documentation mechanisms originally established.

Pharmacists administered three HPV vaccine doses during the pilot project. One administration was a first dose for a previously unvaccinated 25-year-old female. The other administrations were third doses, and thus series completion, for two 23-year-old males. No HPV vaccine doses were administered to adolescents in the pilot pharmacies during the pilot period from May 1, 2016, through July 31, 2016. However, the screening tools also asked about other recommended vaccines. Two doses of meningococcal and one dose of influenza vaccine were also administered as a result of the pilot program.

Additionally, after initial interest, 62 patients were specifically referred to another provider, either back to a primary care provider or to the local health department. Patients were referred elsewhere for a variety of reasons including pregnancy, preference of talking to a physician, not being ready at that time and being too young (10 years old) to be covered by the protocol in the pharmacy. However, 71percent (44 out of 62) of referrals were due to lack of insurance coverage for administration by a pharmacist within a pharmacy.

Table 1.

Number of screening tools and educational materials distributed and screening tools returned per pharmacy.

Pharmacy #	No. of Screening Tools & Educational Handouts Distributed		No. of Screening Tools Returned	
	Ages 11-17	Ages 18-26	Ages 11- 17	Ages 18-26
1	104	179	14	41
2	33	49	0	4
3	103	89	37	26
4	246	79	8	14
5	229	101	30	53
6	103	40	16	32
7	49	93	35	67
8	137	137	1	0
9	38	33	22	29
10	265	235	0	0
Subtotal	1307	1035	163	266
TOTAL	2342		429	

County-level MCIR Data

De-identified county-level data from MCIR was obtained from Michigan Department of Health and Human Services. Data from each of the counties in which a pilot pharmacy was located was compared for three time frames: (1) May through July 2016 (pilot three months), (2) February through April 2016 (previous three months) and (3) May through July 2015 (previous year). The number of first, second and third doses administered in pharmacies versus non-pharmacies were analyzed for both the 11 through 17 years age range and the 18 through 26 years age range. It is important to note that the SpartanNash pharmacies involved in this pilot project were not necessarily the only pharmacies in the counties providing HPV vaccinations. Some large chain pharmacies offer HPV vaccinations as well as other community pharmacies, so county-level data included information from all pharmacies and non-pharmacies.

After evaluating the data, no trends were discernable at the county level for any of the time frames included in the data set. The number of HPV doses given in non-pharmacies far exceeded the number of doses given in pharmacies that analysis was not insightful. Table 2 shows the total number of doses administered during each of the time frames for the counties studied

However, there was an interesting finding when looking at only the pharmacy doses given across all of the months of data in all of the counties. Figure 1 shows the number of first, second and third dose HPV vaccinations given in pharmacies during all of the months reported (May through July of 2015 plus February through July of 2016). While the data does not represent a continuous time frame, it does show the total from nine months of data across 11 counties. Of the 94 total doses given, 64 percent were first doses while only 22 percent were second doses and 14 percent were third doses. This indicates that pharmacists and other healthcare providers share the challenge of having patients complete the HPV vaccination series. Additionally, of the 94 total doses given in pharmacies, 37 percent (35 doses) were administered to adolescents in the 11 through 17 age range. One concern raised was that pharmacists are not comfortable administering vaccines to adolescents. Another concern was that parents may not feel comfortable

allowing pharmacists to immunize their children. Based on this data, those concerns may be minor factors in HPV vaccine administration in pharmacies. Further study on this finding is warranted.

Table 2.

Total HPV doses administered in non-pharmacy and pharmacy locations in 11 counties in Michigan.

		Total HPV Doses Administered (includes 1 st , 2 nd and 3 rd doses)											
		Non-Pharmacy Locations*						Pharmacies					
		11 through 17 years			18 through 26 years			11 through 17 years			18 through 26 years		
		A [†]	B [‡]	C [§]	A [†]	B [‡]	C [§]	A [†]	B [‡]	C [§]	A [†]	B [‡]	C [§]
Pilot Counties	Barry	368	309	393	60	52	50	-	-	-	-	-	-
	Cass	158	159	198	20	23	20	-	-	-	-	-	1
	Clare	127	124	125	17	16	25	-	-	-	-	-	-
	Kent	5701	4903	6019	1302	1231	1454	5	7	1	6	5	10
	Ottawa	2452	2058	2464	522	433	567	3	2	3	2	2	1
	Tuscola	233	244	285	33	31	45	-	-	-	-	-	-
Comparison Counties ^{§§}	Chippewa	150	166	179	21	24	25	-	1	-	-	-	-
	Ionia	386	271	481	65	49	76	2	-	-	1	2	1
	Macomb	4261	4034	4529	773	869	997	-	7	3	6	6	6
	Newaygo	264	227	290	49	62	63	-	-	-	1	1	2
	Washtenaw	3110	2469	3514	960	1384	1457	1	-	-	1	2	3
TOTALS		17210	14964	18477	3822	4174	4779	11	17	7	17	18	24
*: Non-pharmacy locations include the aggregate of any vaccine delivery location not specifically identified as a pharmacy and may include locations such as primary care practices, hospitals, pediatrician offices, etc.													
†: Timeframe A represents May through July of 2015, the same timeframe of the pilot one year prior.													
‡: Timeframe B represents February through April of 2016, three months prior to the pilot period.													
§: Timeframe C represents May through July of 2016, the three months of the pilot project.													
§§: Comparison counties (zero pilot pharmacies located in those counties) were matched based on population of adolescents ages 13 through 17 (Kent with Macomb, Ottawa with Washtenaw, Barry and Tuscola with Ionia, Clare with Chippewa and Cass with Newaygo).													

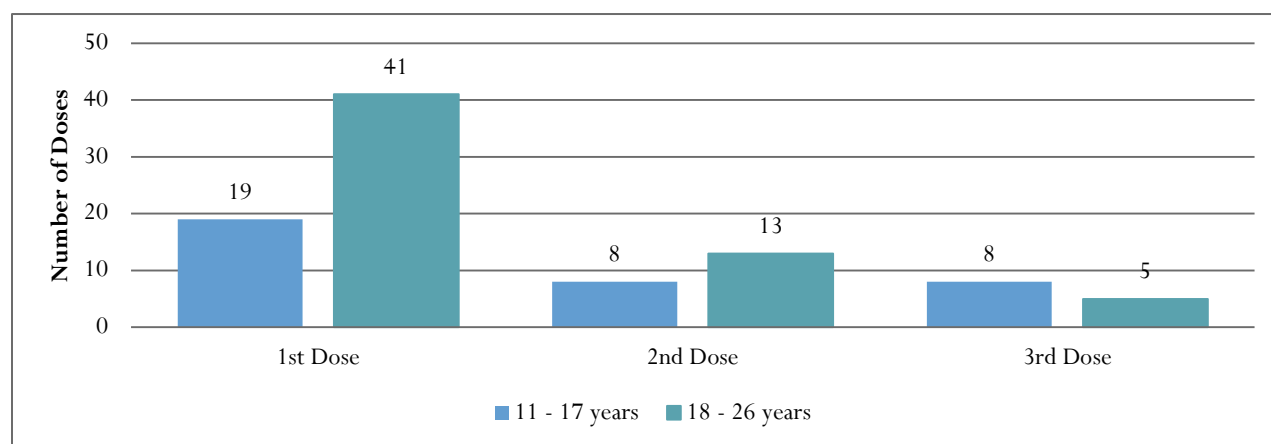


Figure 1: Number of HPV doses administered in pharmacies located in 11 counties during a non-continuous nine month period. Counties include Barry, Cass, Chippewa, Clare, Ionia, Kent, Macomb, Newaygo, Ottawa, Tuscola and Washtenaw. The months include May through July of 2015 and February through July of 2016.

Feedback from Pilot Pharmacists

After the pilot project was complete, the pharmacists managing each of the pilot stores completed a debrief phone call with Michigan Pharmacists Association (MPA) to ascertain their opinions about how the project progressed. When asked if other pharmacies should offer HPV vaccination, nine of the pharmacists said yes, and one pharmacist was on the fence. Those who said yes felt strongly that increasing access to the vaccine is in the best interest of public health, and pharmacies are a great way to increase that access. Select responses to additional questions are included in Tables 3, 4, 5 and 6 show the pharmacists' perceptions of the impact of the pilot project on their communities.

Table 3.

Pilot pharmacist responses to the question, "In your opinion, what was the most valuable part of participating in the HPV pilot program?"

Utilizing the screening tools to begin talking about immunizations in general. We had lots of discussions about the importance of vaccines. It was valuable getting pharmacy technicians involved in the process.
Starting conversations with parents is good even if they are not particularly interested yet. They still received information pamphlets.
I liked the CE to gain more knowledge about HPV, so I could better talk to patients because it's a misunderstood vaccine.
Educating the public about why we need to vaccinate our kids. A lot of people don't realize it's needed.
Education for myself because I felt a lot more confident about recommending the vaccine to patients.
I was impressed with some doctors' offices because their patients were up-to-date and didn't even know it. I saw two extremes when I talked to people: (1) people who trust professionals and get vaccinated or (2) people who had no clue, didn't care and were uninformed.
Even though not many vaccines were given, patient awareness about the importance of HPV vaccination was important. I had no previous knowledge about this topic.
I am now more aware of the HPV vaccine, scheduling, dosing, etc. It encouraged me to get more involved.
Bringing greater awareness to the community.
Education for the patient.

Table 4.

Pilot pharmacist responses to the question, "What kind of impact do you think you had on your patients and community as part of this project?"

Lots of awareness; many people were from out-of-town, so they wanted to talk to their doctor first.
A lot of patients had already received the vaccine, so I was surprised by the number of parents who had already taken those steps. I have mostly Medicaid patients so not able to vaccinate many who might have been interested.
Not many patients were receptive, but some people did open their minds to consider new information. I hope it didn't negatively impact their opinion of pharmacy.
I am not sure because we were not able to get many surveys back. I was able to talk to patients if people filled the surveys out in the store. I hope I had some impact. I do plan on giving the vaccine to my own child (age 20).
Patients realized we were able to give the vaccines and that we can check MCIR to see what vaccines they might need.
Many people don't actively seek out information. They just wait to talk to a physician. It is very different for a pharmacist to convince them. It did bring some awareness by actively talking about HPV to get patients to start thinking about it. It is a health issue people should be able to talk about.
I think I had a minor to moderate impact. Based on my patient population, it would have been better timing for the pilot if students were on campus since we are across the street from Aquinas College.

In my store, I was not very successful because of many of my patients are Medicaid. Of the two pediatricians in town, one is fairly new. The older one highly recommends the vaccine so his patients are up-to-date. The 18 through 26 year old patients were not very educated about the vaccine but were also not interested in talking about it.

I believe I had an impact on getting some people to get vaccinated - all vaccines, not just HPV. People who wanted me to check MCIR were receptive. I was surprised at how many people were up-to-date. We have a good pediatrician and physician assistant in our area that do a good job with vaccinations. I was surprised because the data for my county overall is really low, so I expected to encounter more patients without vaccinations. I think we may be missing people who do not seek any healthcare or even come to the pharmacy.

Awareness about the disease, issues with the disease and the vaccine.

Table 5.

Pilot pharmacist responses to the question, "What was the most challenging aspect of offering HPV vaccination in your pharmacy?"

Taking the time when the opportunity presented itself. We have so many details and competing priorities in the pharmacy, e.g., the list of waiting patients, that sometimes we did not have the time when the patient did have the time to talk.

Most of my patients are Medicaid and were therefore not able to receive the vaccine in the pharmacy.

The forms. I tried my best to get people to fill out the form, but some people got mad. It was also hard to get follow-ups done, so it was good that a workflow was created to schedule follow-up vaccines as a prescription refill.

Getting the questionnaires back was the hardest part. Patients did them if I went through it with them, but if they took it home, they never brought it back.

Insurance. Anyone who wanted the vaccine either had no insurance or had to have the vaccine billed through a physician's office. Fewer screening tools printed after May and June, so there were fewer triggers to talk to patients.

It was difficult to get people to agree to get immunizations from pharmacists. I believe that eventually all immunizations will be done in pharmacies, but insurance coverage expansion would make this much better.

Having people fill out the survey and bring it back was difficult because a lot of times there were other people behind them in line, and they didn't have time to complete it.

Reaching the 18 through 26 year olds was really challenging. I'm not sure if it was because of time or just a lack of interest. The attitude of whole age group was, "I don't have to worry about it."

Patient time constraints meant they did not want to spend a couple of minutes to fill out the screening tool or discuss it. If patients were willing to spend the time, they were much more open to discussing the vaccine.

Talking about the same thing for 12 weeks got to be a burden after eight weeks.

Table 6.

Pilot pharmacist responses to the question, "What other challenges did you experience?"

When the surveys started printing for adults with possible children, it was more difficult. There were sometimes too many opportunities all at once and not enough time to help each patient. It could back up workflow if you had quality conversations with each person.

One of my pharmacists quit during this time period, so I was understaffed. I was also participating in a naloxone pilot which put even greater stress on my time.

I was on maternity leave for the first month and a half. The staff pharmacist filling in was not good at implementing the pilot, so I tried to get people more involved when I got back. Also, my primary pharmacy technician does not believe in the vaccine, so it was hard to get her engaged she believes in one partner for life).

It was strange in my store. I didn't have as many eligible patients as I expected because they were already current on their vaccines. Medicaid patients seem to be getting a lot of preventative care and were already up-to-date.

I have a really small store and am by myself a lot. I felt like I had to talk really quickly to patients.
Knowing which insurances I could bill and having to refer patients elsewhere. They weren't going to get it if insurance didn't cover it in the pharmacy.
Some area pediatricians are not carrying HPV vaccine because of price, and they have been sending everyone to the health department. This ended up being a good thing for us now that they know we offer the vaccine because they will refer patients here as well. I also went to a community hospital health fair, but did not have much success in getting people interested. It may have been the wrong population.
I experienced some sporadic issue with MCIR where I couldn't pull up records on the spot. I offered to call the patients back with the information, and then followed up with them later, but this took a lot of time.
Dealing with the public, patients not interested or had already received it elsewhere, repetition.

Some other issues identified by the pharmacists included:

- **Language barriers.** One store has a large refugee population that speaks very little English. It is difficult to counsel these patients on their prescriptions much less explain the importance of vaccinations.
- **Pharmacy staffing issues.** Several stores had employee turnover during the pilot project time period. When they were able to hire new people, getting new staff members trained in the basic aspects of their jobs was challenging enough. Adding pilot project training on top of that was not practical. Some stores were not able to fill the vacancies and were thus understaffed for the entirety of the project which made time and workflow challenges more significant.
- **Pharmacy staff resistance to HPV vaccination.** Three stores had a pharmacy staff member who did not believe in the vaccine for personal reasons. One store overcame this by having the technician refer any patient with the screening form to the pharmacist. One pharmacist was able to discuss the issue with the technician to overcome the objections and the technician was on board after that. The third store continued to experience a lack of engagement from the one technician, but other staff members were highly engaged.

Strategy 2: HPV Advisory Committee

Advisory Committee Meeting Background and Objectives

Michigan Pharmacists Association (MPA) extended invitations to participate in the 2016 HPV Vaccination Roundtable Advisory Committee to more than twenty individuals and organizations that represent a diverse group of stakeholders including physicians, pharmacists, other healthcare providers, pharmaceutical industry representatives, public health officials and parents of children aged nine to 26 years. Seventeen individuals were able to participate in a meeting held on February 8, 2016, either live or via conference call, and one individual provided written comments prior to the meeting. The meeting objectives were to (1) develop a comprehensive list of barriers and obstacles to implementing adolescent HPV vaccinations in community pharmacies, and (2) brainstorm creative ideas for overcoming identified barriers and obstacles.

Meeting Processes

Advisory Committee participants were asked to consider three questions prior to the meeting all of which were placed as the first three agenda items during the meeting. The questions were: (1) their role and interests relative to the HPV vaccination discussion (see Appendix D for complete meeting materials), (2) pros and cons related to HPV vaccination in general and (3) pros and cons related to HPV vaccinations delivered within a community pharmacy. Participants then conducted a SWOT analysis to identify internal strengths and weaknesses and external opportunities and threats for HPV vaccination in provider offices and community pharmacies, as well as the communications and messages about HPV vaccination. The results of these discussions were captured on flip charts so participants could see identified information. The information listed was not ranked in order of importance. The final portion of the meeting included brainstorming ideas to overcome some of the obstacles and challenges identified during the pros and cons discussion and the SWOT analyses.

Key Takeaways

Messaging should focus on HPV vaccination as cancer prevention

The vaccine protects males and females from many forms of cancer, and this message needs to be the primary message that all healthcare providers reinforce to parents and patients. All providers need to maintain a consistent message, ranging from the physician to the medical assistant who often administers the vaccines to the pharmacist in the community making vaccination recommendations and administering vaccines. By shifting the focus of discussions from the sexual transmission of HPV to the need to complete the vaccination series before potential exposure, providers may see an increase in vaccination rates. Messaging also needs to increase awareness of vaccination as prevention for both males and females. Cervical cancer is so closely tied to the public's perception of HPV that the risks for males from HPV-related cancers are not as well known, which could contribute to the extremely low vaccination rates in adolescent boys.

Importance of well-child visits within the medical home

Because well-child visits are no longer required for school attendance, many children are not visiting their primary care physicians on a regular basis. Mandatory vaccinations bring those children into the family medicine or pediatrician offices, and changes that decrease this contact between physician and child threaten the medical practices and the health of the children. Increasing the rates of first dose administration, along with the other recommended adolescent vaccines, is an important part of well-child visits.

Community pharmacists as extenders of vaccination efforts

Because of increased accessibility at community pharmacies, and the difficulty of getting children back into the physician's office for the second and third doses of the HPV vaccine, community pharmacists can be an essential method for extending the reach of the medical home and increase vaccine series completion rates. Increasing the information exchanges between pharmacists and physicians is an important component, including, but not limited to, utilization of MCIR.

Public awareness of pharmacists' training and knowledge of vaccination

Pharmacists have increased influenza vaccination rates throughout the country, but other healthcare providers, patients and parents may not understand the full capabilities of pharmacists. Pharmacists are knowledgeable about all vaccines, not just influenza, and have the training and ability to immunize children, adolescents and adults. Increasing the public's knowledge about the training pharmacists receive for providing HPV vaccines to adolescents in addition to adults is an important component of increasing HPV vaccination within the pharmacy.

Third party reimbursement for vaccination within pharmacies

While pharmacies typically have better abilities to obtain vaccines quickly and store them properly than small physician practices, third-party reimbursement for vaccination within the pharmacy continues to be limited. Some plans are beginning to cover HPV vaccination as a pharmacy benefit, though often not for adolescents. Pharmacies can bill the medical benefit in some instances, but there is no guarantee of payment, and the patient could receive a bill if his or her plan does not cover the cost. There is no consistency across plans and knowing which plans will cover which vaccines for which patients is a challenge.

Required versus non-required vaccines

HPV vaccination is not currently required in Michigan for school attendance. Because it is not required, some providers may not routinely have it available in their practice or provide the same strength of recommendation as the required vaccines.

First dose versus series completion

First dose vaccination rates are higher than series completion rates in both males and females. This is a challenge because it indicates children are being lost to follow-up, but it is also an opportunity for community pharmacies to make an impact.

Strategy 3: Stakeholder Assessments

Four stakeholder assessments were conducted with four different stakeholder populations: non-pharmacist healthcare providers (referred to as “healthcare providers” moving forward), parents of children less than 27 years of age, patients in the 18 through 26 year age range and pharmacists. The assessments were created as electronic surveys, and the links to the surveys were sent through a variety of electronic channels. Respondents had to meet qualifying criteria for the survey including living or practicing in Michigan to ensure consistency of healthcare practice laws. A \$5 Amazon e-gift card was offered as token incentive for completing the survey.

Reaching the parent and healthcare provider audiences was challenging. The following qualified responses to each survey were received:

- Healthcare providers – 29
- Parents – 41
- Patients – 46
- Pharmacists – 159

Each survey had slightly different questions based on the audience to determine opinions about HPV vaccinations, but all four surveys had several questions in common. All survey questions can be found in Appendix B.

Common Questions

The first question asked respondents to use a sliding scale from zero through 100 percent to indicate how important they felt vaccination was in general. Results are shown in Figure 2 with responses broken into quintiles. Healthcare providers felt vaccinations were very important. Many pharmacists felt vaccinations were important, but approximately 30% rated the overall importance of vaccines at 60% or less. The patients and parents who responded were in favor of vaccination overall.

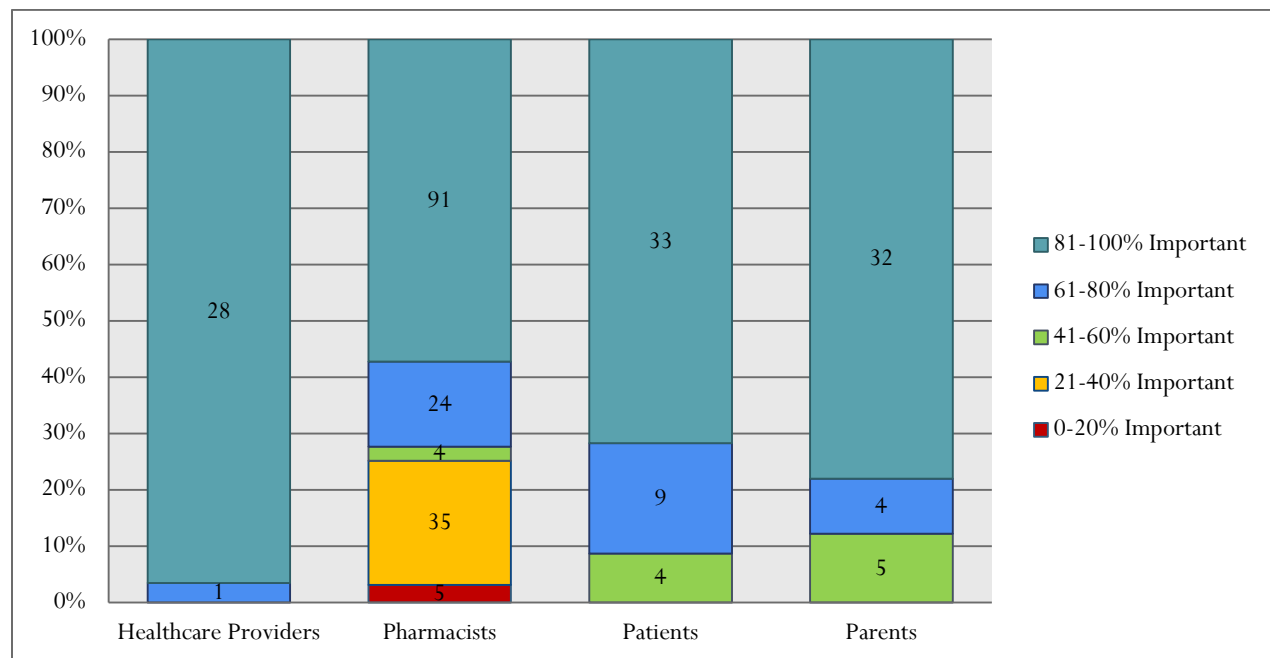


Figure 2: Rating of overall vaccination importance for each survey population.

The second question common to all surveys asked respondents to rate their confidence in their knowledge about HPV using a sliding scale of zero through 100 percent. Responses were aggregated into quintiles and are shown in Figure 3. Respondents of all types showed variability in their knowledge confidence. Approximately 90% of healthcare providers, 70% of pharmacists, 55% of patients and 60% of parents were at least 61% confident in their knowledge about HPV. While those numbers can be seen as encouraging, there are still large gaps in provider knowledge as well as public knowledge about HPV and the vaccines.

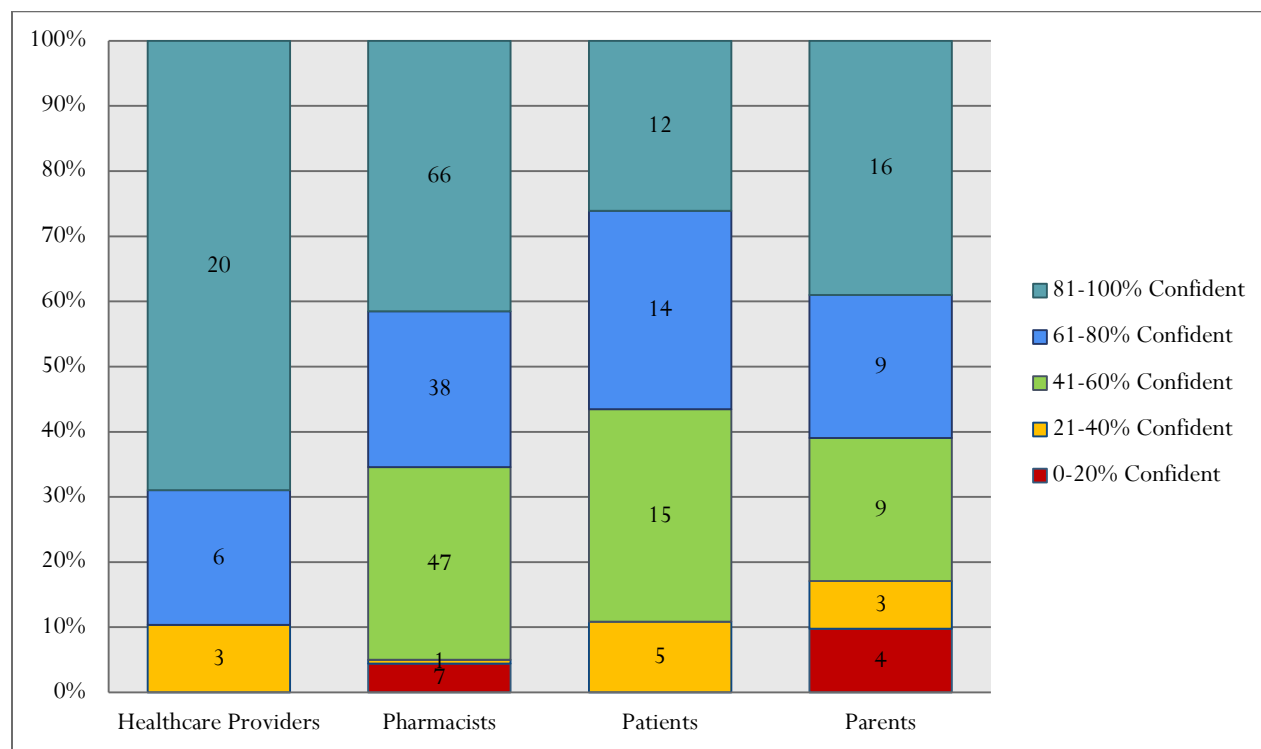


Figure 3: Confidence in respondents own knowledge about HPV for each survey population.

Each survey also asked about how supportive respondents were of HPV vaccination for different age groups and different practice settings. The results for those questions are separated by survey audience below. For free response answers provided below, responses are presented as respondents typed them. Some of the responses may not be clear or make sense.

Healthcare Provider Assessment Responses

Do you administer any vaccines in your practice?

- Yes = 23
- No = 6

If no, why not?

- Do mostly procedures
- Our team does, not me personally
- Limited due to my role

Do you administer HPV vaccine in your practice?

- Yes = 19
- No = 10

If no, why not?

- I work in the ER
- Not at the hospital but we have 25 hospital-owned clinics we provide HPV to.
- Do mostly procedures
- I work in the hospital on a Med-Surg floor
- Post Bone Marrow Transplant patients get the "baby" vaccinations at this point, not the others.
Not sure why not.

Have you ever referred a patient to a pharmacy to receive a vaccine?

- Yes = 13
- No = 16

If no, why not?

- Because vaccines are offered at my agency
- We do not see patients in this Pharmacy.
- I believe a vaccination should be given in a clinical setting that is equipped to handle adverse reactions
- No need to. We give flu & pneumonia shots on my floor as needed
- Cause we give them in our office why send them somewhere else
- Our clinic is able to accommodate them
- Not sure which locations they can go to and if not I will do at my own office
- Not comfortable
- I don't know what kind of training they get
- I have given pharmacists their needed vaccines and discussed this topic with them. They stated they had some training on giving vaccination, but did not feel real confident providing. I think parents and clients also need the education prior to vaccination and I don't know if they would get this getting these vaccines through a pharmacy.
- Our department and hospital covers it and provides what is needed.
- No opportunity

How supportive are you of people in the following age groups receiving HPV vaccine?

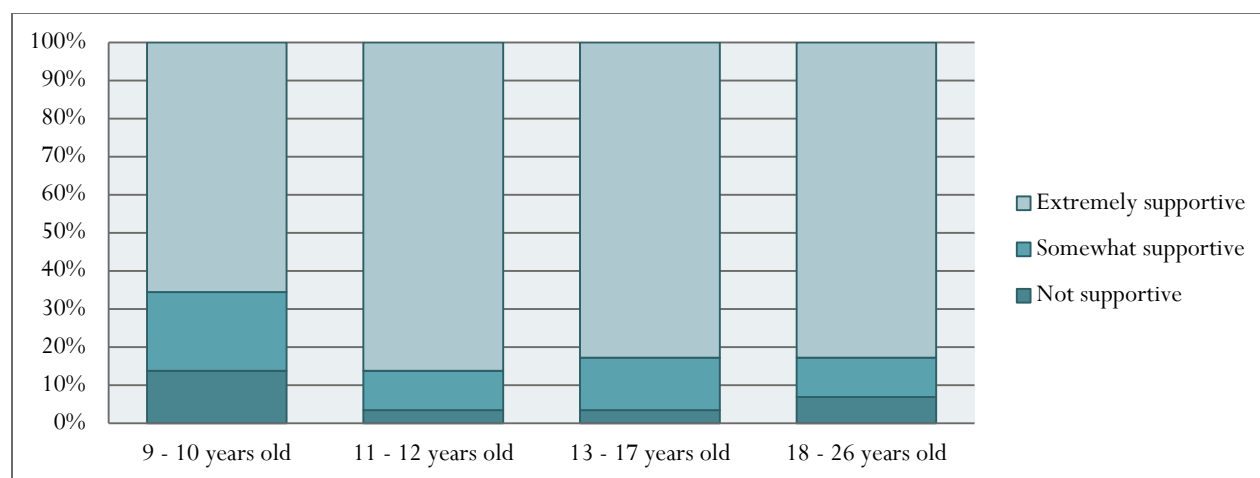


Figure 4: Healthcare provider support for different age groups receiving HPV vaccine.

Please provide any comments if you would like to explain your answers.

- I won't be getting it for my children.
- I would like to see more data on long term outcomes following the vaccination (e.g., negative side effects)
- At our practice we do not give HPV to children under the age of 11
- Prior to working at a Health Department I worked in a busy Labor and Delivery unit and saw firsthand the alarming number of people infected with this disease.
- Anything we can do to protect people is a must in my book as both a healthcare professional and a mother. The general public is overall very ignorant of all the diseases out there partially because there are so many things to worry about.

How supportive are you of HPV vaccine being provided in the following settings?

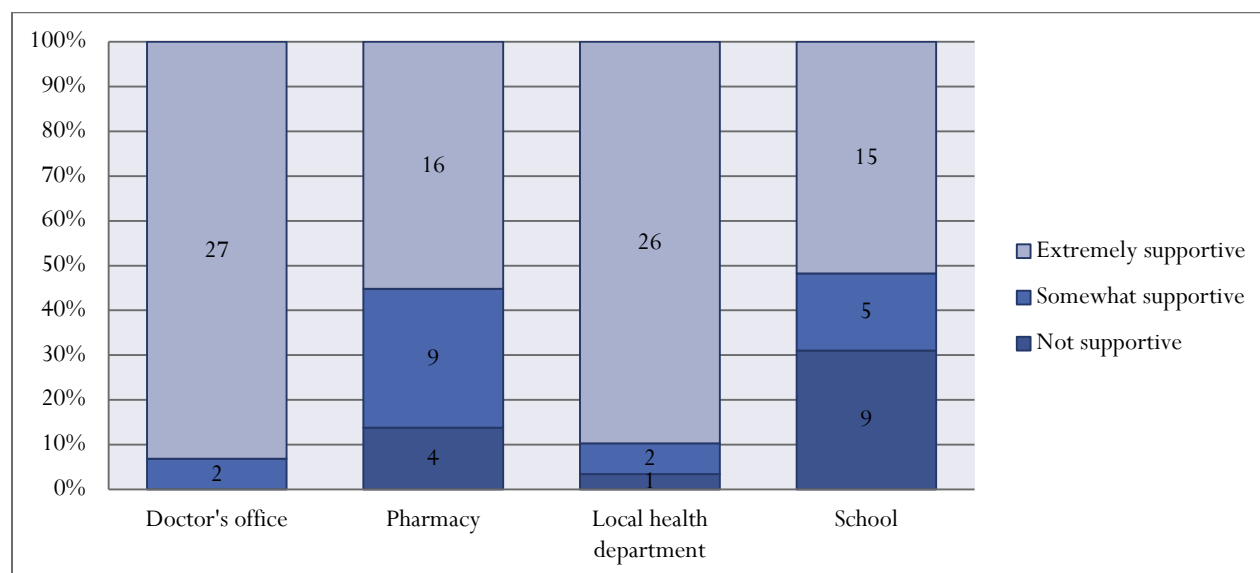


Figure 5: Healthcare provider support for HPV vaccine provision in different settings.

Please provide any comments if you would like to explain your answers.

- ESPECIALLY not the schools.
- Vaccinations should be given in a clinical setting that is equipped with staff who are knowledgeable and able to handle adverse potentially lethal reactions. There is also better documentation if done at a PCP office.
- Parents should be informed & discuss this vaccine with their children first before getting it.
- It very important that when immunizations are given at schools and pharmacies that the MCIR record is checked beforehand to assure that ALL needed/recommended vaccines are given, not just HPV.
- Best practice would be to administer all vaccines the person was eligible to receive at same visit, not just HPV. Some schools and pharmacies may not be prepared to manage the challenges of vaccinating preteens and teens
- It is a needed vaccine. The reason I somewhat support receiving in a Pharmacy is that I have had conversations with some and they did not feel confident in providing and answering parents questions.
- Same. Make them as accessible as possible for those seeking the vaccines.

Parent Assessment Responses

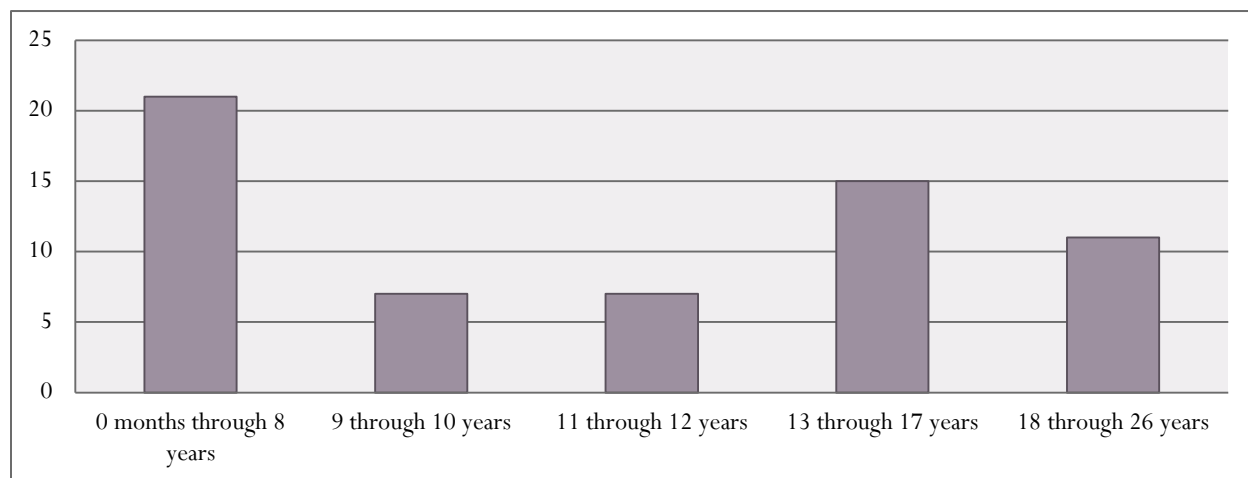


Figure 6: Percent of parents responding to survey with children in different age ranges.

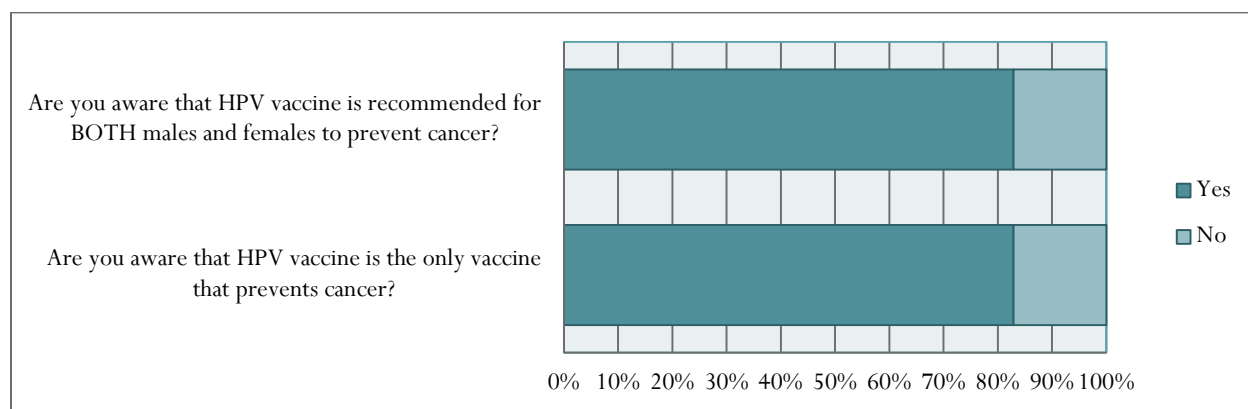


Figure 7: Parent responses to questions about HPV vaccine recommendations.

How supportive are you of people in the following age groups receiving HPV vaccine?

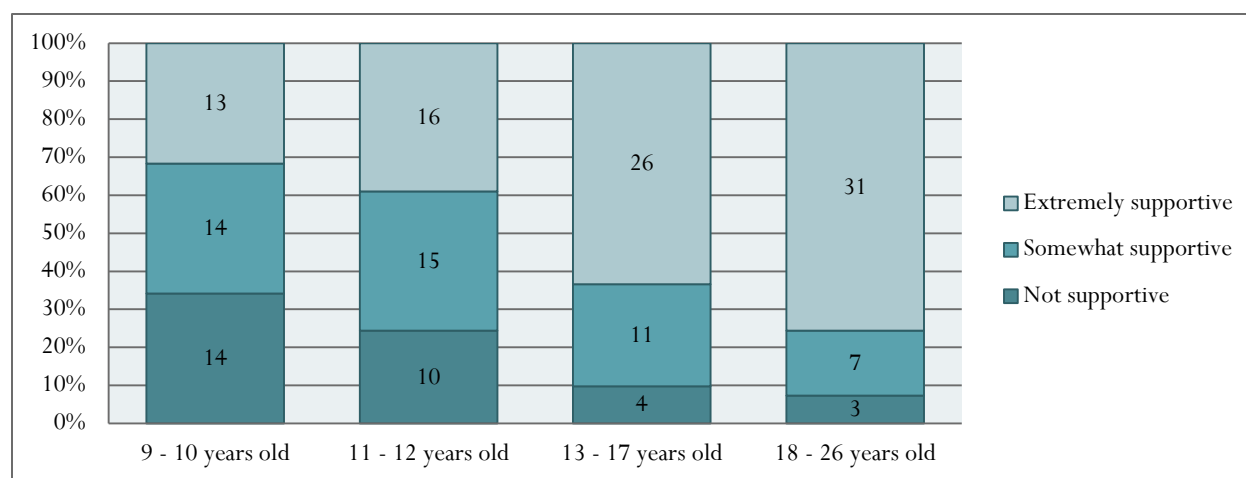


Figure 8: Parent support for different age groups receiving HPV vaccine.

Please provide any comments if you would like to explain your answers.

- I need to learn more.
- I'm unsure of the controversial long-term effects no matter what age the vaccine is given.
- I have not vaccinated my children because there are other ways to avoid getting HPV. I want them to choose whether or not to receive it, even though the recommended age is 12 years old.
- It should be their choice.
- The side effects of the HPV vaccine aren't worth it.
- I'm supportive of people over the age of 18 making the informed choice themselves about this particular vaccine.
- I think the best time to get parents to allow vaccinations is the 11-12 visit, or any time after. Before that, it wouldn't hurt to introduce information.

How supportive are you of HPV vaccine being provided in the following settings?

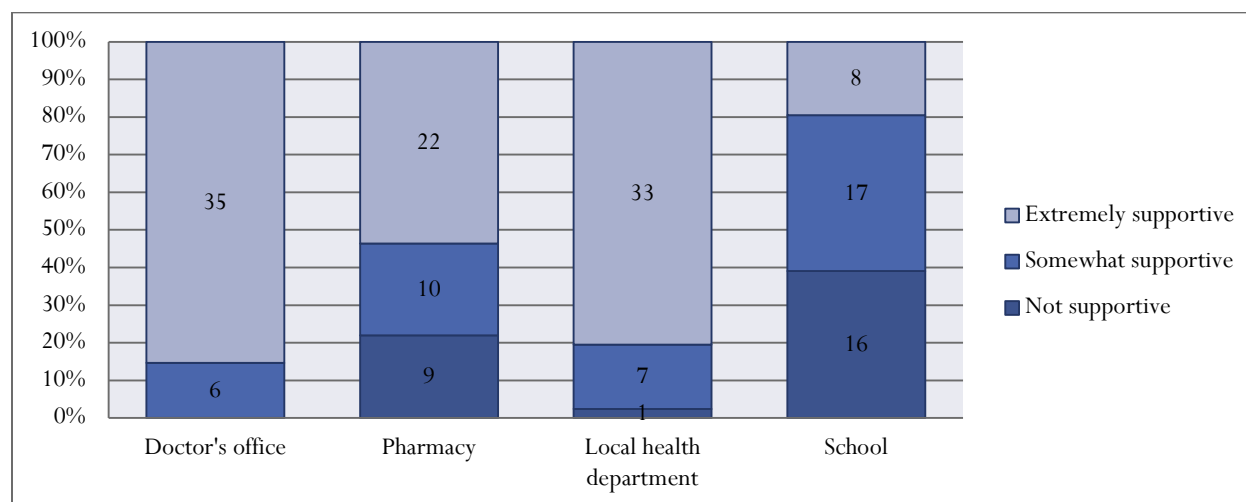


Figure 9: Parent support for HPV vaccine provision in different settings.

Please provide any comments if you would like to explain your answers.

- I would be supportive for the vaccine in school as long as the one administering it was an RN or higher.
- There is other information than just the vaccine that needs to be communicated to the patients in a confidential setting. Doctors and their setting are in the best position to do that.
- I feel that the doctor's office and health department would be better environments to educate the person receiving the vaccine on the risks and benefits.
- The more settings a tween/teenager is exposed to information, the better.

Patient Assessment Responses

How supportive are you of people in the following age groups receiving HPV vaccine?

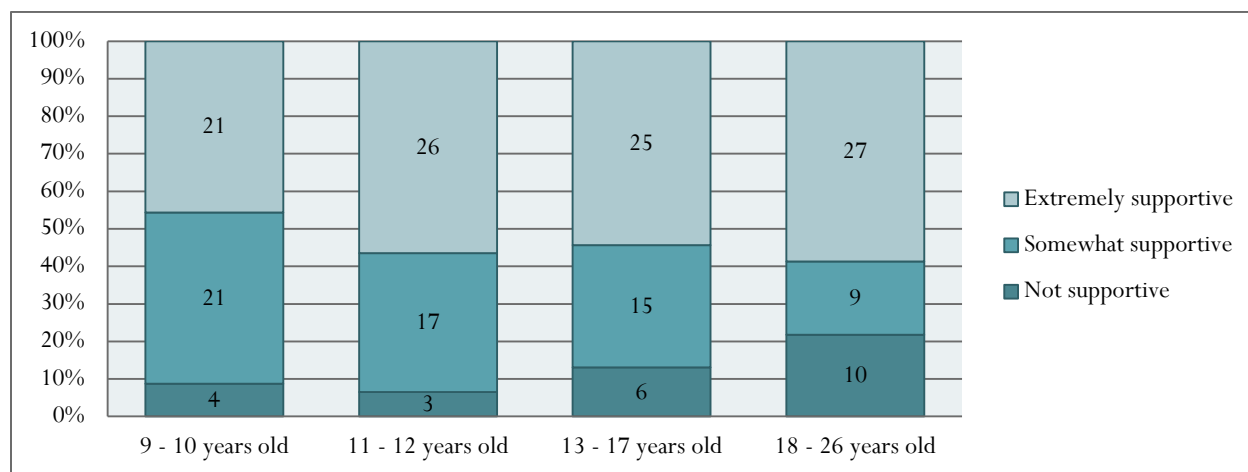


Figure 10: Patient support for different age groups receiving HPV vaccine.

Please provide any comments if you would like to explain your answers.

- Everyone should get vaccinated
- I feel every recommended age group should get vaccinated.

How supportive are you of HPV vaccine being provided in the following settings?

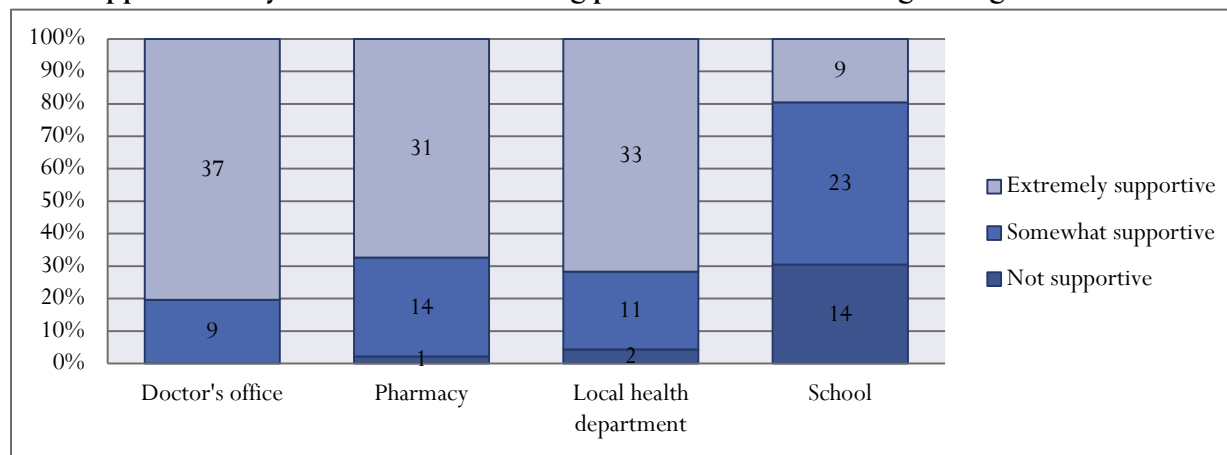


Figure 11: Patient support for HPV vaccine provision in different settings.

Pharmacist Assessment Responses

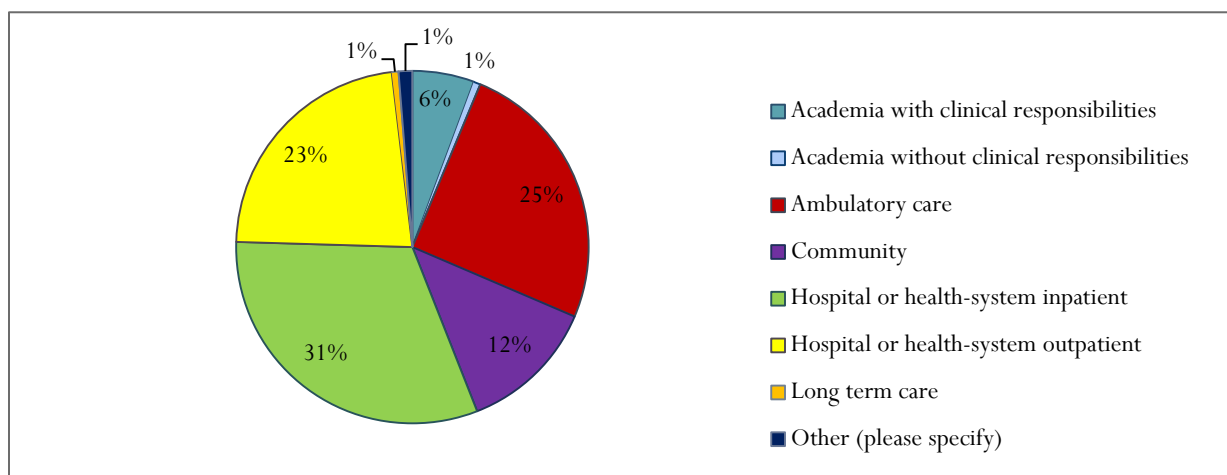


Figure 12: Percentage of pharmacist respondents working in different practice settings.

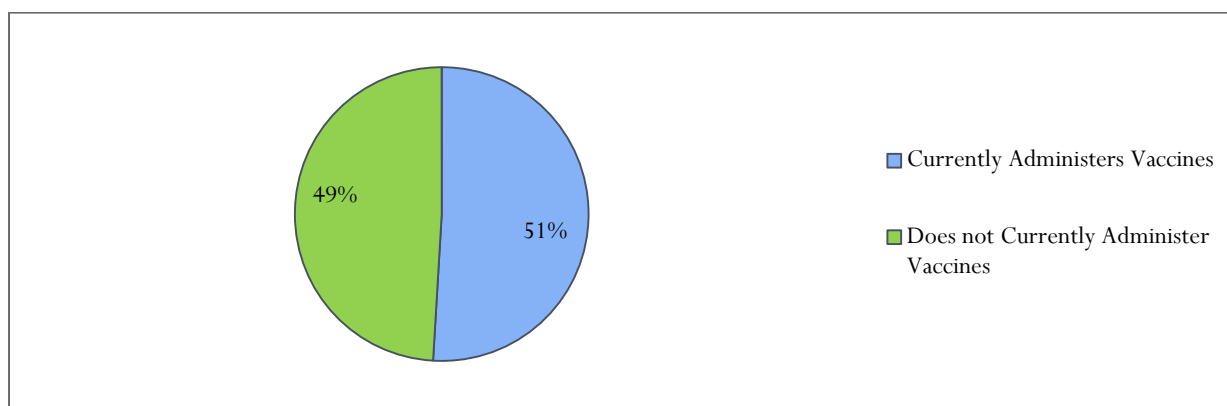


Figure 13: Percentage of pharmacist respondents who currently administer vaccines in practice.

Reasons for Not Offering HPV Vaccines in Your Pharmacy

- We offer no vaccines currently
- I'm a relief pharmacist
- I work in a BMT inpatient unit; vaccines are not routinely given until 6-12 months post transplant
- I'm in the process of preparing for CLIA waiver in order to provide immunization at my practice.
- Academia
- We don't administer vaccines in my practice setting
- Inpatient & long-term care and most patients out of age recommendation
- No patient contact
- I feel that due to the young nature of patients getting vaccinated with this, this discussion about sex & STI's should've when the patient, parents, and physician
- My practice setting is specialty (outpatient oncology)
- It's offered, but not by me
- Not given to inpatients
- Corporate rules

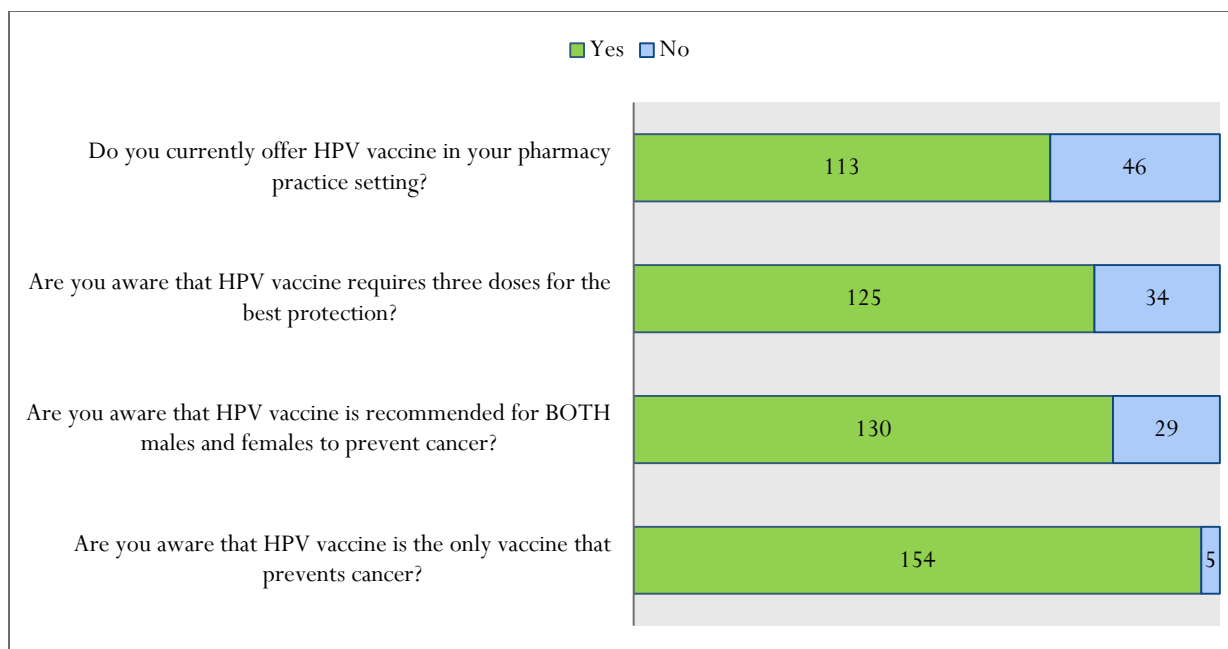


Figure 14: Pharmacist responses to questions about HPV vaccine.

How supportive are you of people in the following age groups receiving HPV vaccine?

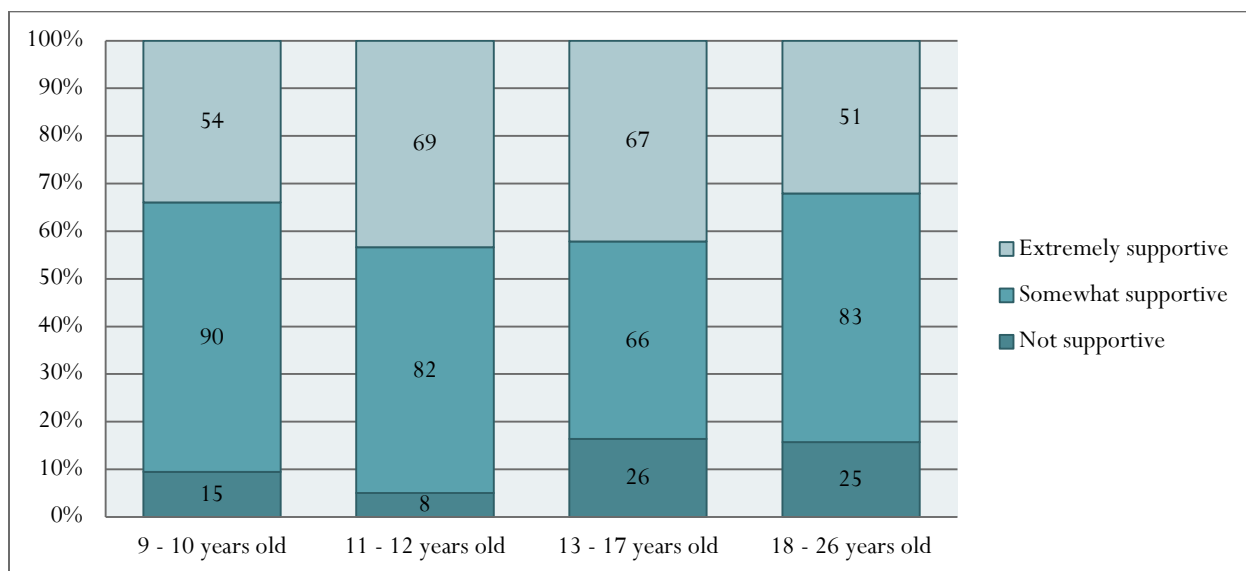


Figure 15: Pharmacist support for different age groups receiving HPV vaccine.

Please provide any comments if you would like to explain your answers.

- According to studies, the vaccine is most effective in the age group range of 12-14
- Depending on sex
- I feel like the 18-26 year old group is the best demographic to receive the vaccine. At this point, they should be able to make their own decisions.
- Pre-marital sex should continue to be discouraged in all matters. HPV suggests an encouragement of sex outside of marriage.

- I would only administer HPV vaccine to child age who are at high risk - history of sexual abuse or assault
- Some insurances have age restrictions

How supportive are you of HPV vaccine being provided in the following settings?

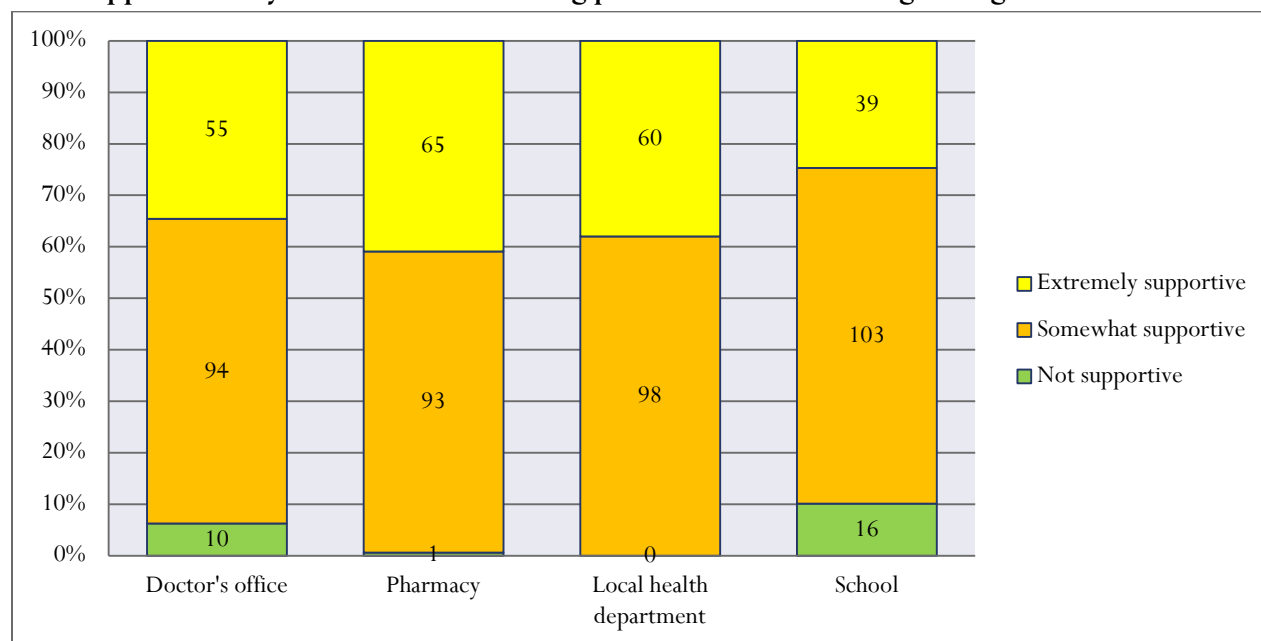


Figure 16: Pharmacist support for HPV vaccine provision in different settings.

Please provide any comments if you would like to explain your answers.

- For safety and privacy reasons, I prefer a healthcare setting to administer the vaccine
- As long as the immunizer is qualified
- If the parent/patient wants the vaccine, it should be readily available in any setting
- Not at taxpayer expense
- Peers

Please rate your confidence in providing counseling about HPV vaccination to different ages.

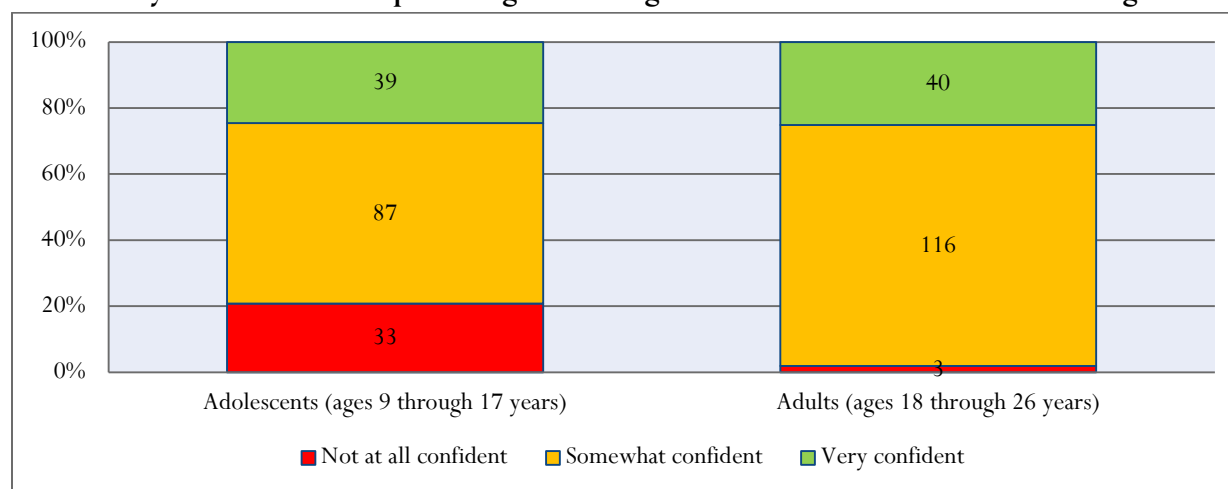


Figure 17: Pharmacist confidence in providing HPV vaccine counseling to different age groups.

Please rate your confidence in the administering HPV vaccine to different age groups.

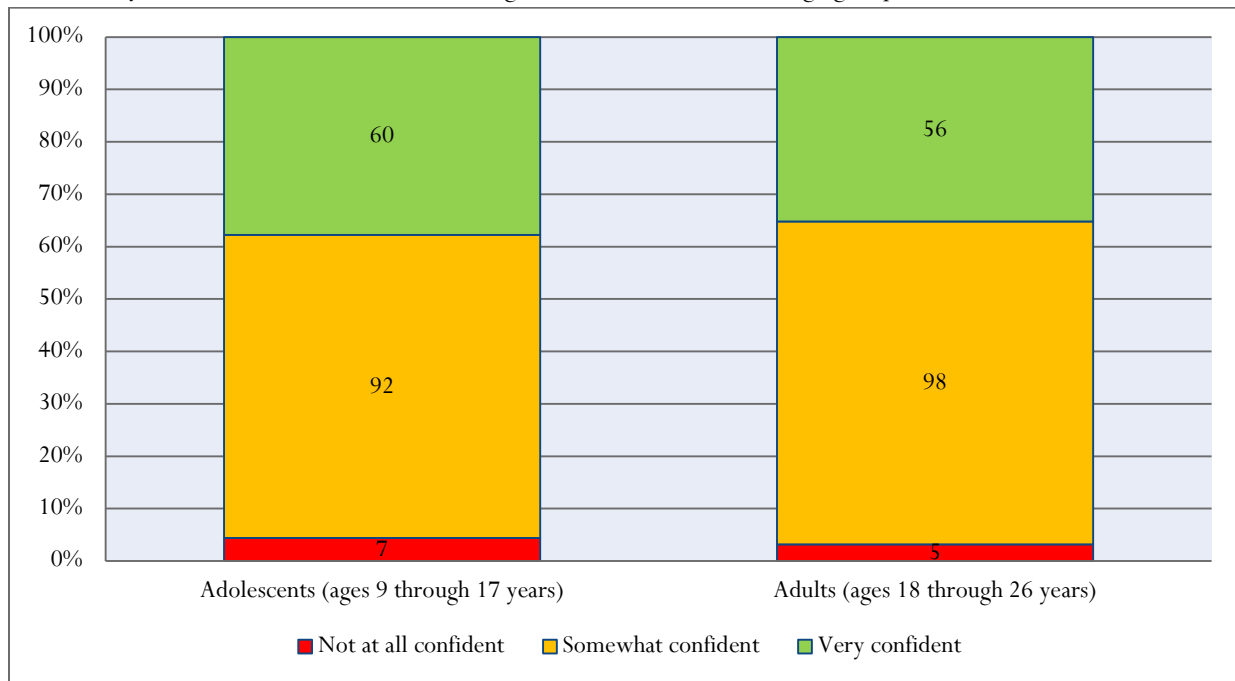


Figure 18: Pharmacist confidence in administration of HPV vaccine to different age groups.

Strategy 4: Healthcare Provider Outreach

Two methods of outreach to healthcare providers were utilized. Providers who wrote significant numbers of prescriptions filled by the pilot pharmacies and located within geographic proximity to each of the pilot pharmacies were identified. Five targeted providers for each pilot pharmacy were mailed packets of information about the pilot program and support for HPV vaccination efforts along with some educational materials. Then, the pharmacists made follow-up phone calls to the provider offices to establish a personal connection. Originally, the pharmacists were planning to visit the providers in person, but schedules and workflow made this not feasible.

As a result of the outreach efforts, written contact was made with 54 provider offices. Personal contact was made with 24 of those offices. In some cases the pharmacists were not able to make contact with the provider offices after repeated phone calls. Based on the number of completed calls and the number of providers in each practice, the indirect impact was with 103 physicians, 17 physician assistants, 15 nurse practitioners, six nurses and 112 other office personnel.

Data was captured from some of the provider offices regarding their practices.

- 12 out of 15 provided vaccines through the VFC program
- 12 out of 18 practices stocked and administered HPV vaccine
 - Of the four practices that do not stock the HPV vaccine, one refers patients to a health clinic and three refer patients to the health department.
- 18 out of 18 recommended HPV vaccine to all patients in the 11 through 26 age range

The providers were asked if they would be willing to be on the pharmacy's referral list, so the pharmacists could send patients not able to get the vaccine in the pharmacy to a specific office. Eight out of 15 practices said they would like to be on the list. Reasons that practices did not want to be on the referral list included the following: not carrying the vaccine; working in a closed system that does not accept outside patients; working with a different chain pharmacy and having their patients come back directly for the second and third doses.

The providers were then asked if they would be willing to send patients to the pharmacy to complete the HPV series. Ten of seventeen provider offices that responded to the question said they would be willing to refer patients to the pharmacy. Reasons for not being willing to refer patients to the pharmacy include the following: they are doing just fine with having their patients complete the series; the pharmacy is too far away; they use nursing visits so patients just stop by and they prefer to administer the follow-up doses in their own office.

One pharmacist noted that one office she spoke with did not carry the HPV vaccine because of the cost and was excited to learn that the pharmacy stocked it. Unfortunately, not all of the interactions with the provider offices were pleasant. Some offices were unreceptive to the calls and would not allow the pharmacist to speak to anyone beyond the receptionist. Some offices were even offended by the phone calls and felt the pharmacists should not be asking them any questions about their immunization practices.

An unexpected barrier was actually being able to get past the receptionist or office manager in the physician practices to speak with other providers about partnership for this project. Since an introductory letter was sent first and then the pharmacists followed up with a phone call, the expectation was an enhanced ability to establish a relationship and partnership. The planning team felt it was important for the pharmacies to be providing HPV vaccination within the pharmacy before beginning outreach to the local physicians so that they could present an established, functional

service for partnership. Given the relatively short duration of the pilot project, it may not have been enough time to build the community connections. Perhaps the relationship development cycle for partnership is longer than anticipated and better relationships could have been established given more time.

Other ideas for approaching this differently might be for the pharmacists to go to a local or state medical society meeting to introduce the concept of partnering on a larger level and then ask for partners and others to help disseminate the project to other members. This idea was not attempted during the course of the pilot. Another strategy might be to have a pharmacist team up with a local industry representative who has an existing (and hopefully positive) relationship with the physician practices. Perhaps a joint effort could help start the conversation and get past that initial entry barrier. This possibility was discussed but was not executed during the pilot project due to time constraints.

Strategy 5: Education about HPV

Many of the education efforts to different audiences were incorporated into the other strategies previously discussed. Pharmacists and pharmacy technicians involved in the pilot program received significant education since they would be providing direct patient care. Michigan Pharmacists Association (MPA) updated its immunization resources section of its website to include information specifically about HPV. A flyer was mailed to 2,550 pharmacist members notifying them about the new website resources. Information about HPV was also included in a continuing education presentation delivered in August to 50 pharmacists and pharmacy technicians in Traverse City, Michigan.

Patient education occurred in several forms as well. Age-appropriate, patient-friendly handouts printed along with the screening tools with each prescription meeting the defined criteria. These education handouts went home with 2,342 patients and parents, along with their other prescription paperwork, for their reference at home. Even patients who did not want to complete the screening tool or to speak with the pharmacist about HPV vaccination received the written education to take home. The best patient education occurred through conversations between the patients and pharmacists. These conversations were difficult to quantify. At least 429 pharmacist-patient conversations occurred based on the 429 completed screening tools.

Provider education was conducted as part of the provider outreach strategy discussed above.

VFC Providers in Michigan

State law in Michigan does not preclude pharmacies from becoming VFC providers. Initial contact with the Michigan Department of Health and Human Services (MDHHS) indicated that there might be potential for pharmacies to be involved. Through subsequent conversations after the pilot project began, the planning team discovered that MDHHS began a pilot program with a single pharmacy in Allegan County outside of the HPV vaccination project. MDHHS contracts with local health departments to conduct the mandatory inspections and site visits for all VFC providers. Current staffs at the local health departments already have a difficult time meeting the inspection requirements due to time and financial constraints. At this time, opening up the VFC program to a large number of pharmacies would put too much additional strain on the system. The state is still conducting the pilot program and will not make decisions regarding further expansion of the program for pharmacy involvement until the pilot is complete at some undetermined point in the future.

Discussions with the pharmacist running the pharmacy VFC pilot program yielded some additional information. The pharmacist found that the VFC pilot went really well during “back to school” time when adolescents needed their mandatory school vaccines. She even had one patient come back for the second HPV vaccination already. After the “back to school” time ended, her patients have not shown any interest in VFC vaccines. The VFC pilot pharmacy is still not able to bill Medicaid HMO prescription plans for any vaccines from the pharmacy, meaning the pharmacy does not receive any compensation if they provide those vaccines. If patients have straight Medicaid, the pharmacy does receive a small dispensing/administration fee. The pharmacist also mentioned that getting used to the requirements of providing VFC vaccines takes time, but she has developed an effective system for balancing inventory.

HPV Roundtable Questions

If you had to do this all over again, what would you do the same? What would you do differently?

One significant challenge we faced was the short timeline of the project. To be able to get the pilot pharmacies up and running in time to get several months of data, we started the pharmacist training and workflow tool development process first. It would have been better to complete the stakeholder assessments first and the provider outreach visits or calls. The training program we created for the pharmacists and pharmacy technicians was very successful. All of the pharmacists said they felt confident and comfortable talking about HPV with patients after the training. Most felt they needed the additional focused education to reach that level of confidence in making a strong recommendation.

If you had another 18 months, what would you put in place now?

We would need to come up with a different strategy to target patients. We used a screening tool to target potential patients, but those become less effective as time progresses. We would continue to work on the provider collaboration route and work with those offices not stocking the HPV vaccine willing to work with the pharmacies. We would select pharmacies near college campuses while classes were in session to target the 18 through 26 year old patients. Health fairs on college campuses might also be a way to reach those young adults.

Based on your experience, what state-specific activities would you suggest that the 'state' task group should focus on?

Adolescent Medicaid patients are required to see VFC providers for vaccines. Currently, becoming a VFC provider is not an option for pharmacies in Michigan. Changes that would open Medicaid coverage to pharmacy-delivered vaccines or changes to the VFC program to decrease administrative requirements so that pharmacies can become providers without taxing the system would be advantageous. Another piece of information that was discovered during one of the pharmacist interviews is that we might be missing a large part of the population that is just not accessing healthcare at all. If patients do not visit providers, they do not get prescriptions. If they do not get prescriptions filled, they may not visit a pharmacy. Working on addressing those issues would also be helpful. Additionally, any public education efforts to dispel the myths about HPV vaccine safety would also be important to work on at a state level.

If the target audience is adolescents >15 years old, how would you structure the program?

We felt it was important to screen for any patient who would be an appropriate candidate for HPV vaccine so we developed the screening tools to identify anyone in the 11 through 26 age range. If the target of the program was only adolescents 15 years and older, we could have changed the screening tool to be more selective to that age group. We also would consider outreach through high schools and colleges to target the older demographic which still needs all three doses of the vaccine.

Are there other partners you wish you'd had helping with the project?

One of the major barriers we had in the pharmacy was insurance coverage for the HPV vaccine to be administered by the pharmacist. We have since learned that as of Oct. 1, 2016, Blue Cross Blue Shield of Michigan is expanding its vaccine coverage for commercial patients with prescription drug coverage for additional vaccines, including HPV for the recommended aged patients, as a prescription drug benefit. This eliminates a huge barrier for many commercially insured patients in Michigan. However, this is still only one payer. Having additional payers on board to work on this project would have been helpful. We made repeated attempts to engage with payers and find someone to talk to about the project but no one was willing to engage in such a discussion.

Recommendations for the Future

Nine of the 10 pharmacists involved in the HPV pilot strongly recommended expanding HPV vaccination to more pharmacies. Most cited the need for better protection against cancer among the residents of their communities. Michigan Pharmacists Association (MPA) also highly encourages other pharmacies to learn from this pilot project and take steps to implement HPV vaccination programs to further solidify pharmacy's partnership for public health efforts.

For pharmacies interested in getting an HPV vaccination program going, there are a few suggestions that might make things easier.

- If using a screening tool to help identify eligible patients, ask patients to complete it while at the pharmacy. Patients typically will not complete the survey after they leave the pharmacy. Having a pharmacist or pharmacy technician walk them through the questions greatly improves the success rate. If available, accessing a state immunization registry before a potentially eligible patient visits the pharmacy to pick up a prescription can prepare the pharmacist with a list of recommended vaccines customized for that patient.
- If possible, partnering with the state health department or a major payer in the state to help identify patients needing second and third doses could increase the ability to reach those specific patients. Targeted communications could be sent directly to them letting them know about the pharmacies offering HPV vaccine.
- Beginning the relationship-building process with local physician groups before launching the service in the pharmacy may help get healthcare collaborators on board earlier, which may result in a better collaborative network. Face-to-face interactions with the local physician groups, perhaps by partnering with industry representatives or by visiting medical association meetings, may help overcome the initial contact barriers encountered from receptionists and office managers.
- Training for pharmacists and pharmacy technicians about HPV specifically is crucial. This vaccine comes with a lot of negative press and social media, so arming the frontline staff with tools for communicating about HPV with patients and parents will make them feel more comfortable about recommending and discussing this vaccine. Ensuring that all staff members are presenting the same message to patients and parents is also imperative, regardless of what staff members' personal opinions might be. Patients and parents hear enough confusing messages from other sources; they need to be able to trust the consistency and strength of the recommendation from their pharmacist, a trusted healthcare provider.
- Utilizing a refill reminder mechanism within pharmacy dispensing software can be useful for identifying patients who need second and third doses. Some additional steps or changes may be needed to for the technology to work for follow-up dose reminders, but it can be a great tool for helping patients complete their series.
- Program success is highly dependent on the enthusiasm and commitment of the pharmacist leading the project. For small chain pharmacies, working with a committed team in one pharmacy to optimize the workflow processes before spreading it to more locations may be a good way to start.
- Protocols must be in place and pharmacists must be trained on managing adverse events related to vaccination. Fainting is a more common side effect from vaccination in adolescents than in adults. With increased vaccine administration to younger patients, the possibility of a patient fainting in the pharmacy setting also increases. Pharmacies can easily plan for this and have proper procedures in place in the event that it occurs. Pharmacists are capable of handling the situation according to those procedures.

Appendix A: Education and Training Materials

Healthcare Provider Education Materials

Two educational documents were sent with the provider outreach letter (see Appendix F for a sample letter) to the targeted healthcare provider practices. Clicking on the images will open PDF versions of the documents.

HPV Vaccine Information for Clinicians

CDC recommends HPV vaccination for girls and boys at ages 11 or 12 years to protect against cancers caused by HPV infections. CDC encourages clinicians to recommend HPV vaccination the same way and same day they recommend other routinely recommended vaccines for adolescents.

Background

Human papillomavirus (HPV) is a very common virus that infects epithelial tissue. More than 120 HPV types have been identified. Most HPV types infect cutaneous epithelial cells and cause common warts, such as those that occur on the hands and feet. Approximately 40 HPV types infect mucosal epithelial cells on the genital, oral, and anal areas. Although most HPV infections are asymptomatic and resolve spontaneously or become undetectable, some HPV infections can persist and lead to cancer.

Persistent infections with high-risk (oncogenic) HPV types can cause cancers of the anus, cervix, penis, vulva, and vagina, as well as the oropharynx (located at the back of the throat, including the base of the tongue and tonsils). The most common high-risk types are 16 and 18.

Infection with low-risk (non-oncogenic) HPV types can cause genital warts and rarely laryngeal papillomas. These types can also cause benign or low-grade cervical cell abnormalities. The most common low-risk HPV types are 6 and 11.

About 79 million Americans are infected with HPV and roughly 14 million people become infected each year, mostly occurring among teens and young adults. Almost every person who is sexually active will acquire HPV at some time in their life.

Every year in the United States, an estimated 17,000 women and 9,000 men are diagnosed with a cancer caused by HPV.

Of the women diagnosed with an HPV cancer, cervical cancer is the most common with about 11,000 women diagnosed annually in the United States; subsequently about 4,400 women die every year from cervical cancer in our country.

Of the men in the United States diagnosed with an HPV cancer, oropharyngeal cancer is the most common. Around 7,200 U.S. men each year are diagnosed with oropharyngeal cancer caused by HPV infection. HPV infection and precancerous/dysplastic lesions of the oropharynx cannot be screened for, making prevention of infection a priority.

HPV Vaccines

Three HPV vaccines have been licensed by the U.S. Food and Drug Administration (FDA) since 2006. CDC recommends these HPV vaccines for routine use among girls and boys at ages 11 or 12. HPV vaccines are administered as a 3-dose series with doses given at 0, 2, and 6 months.

Vaccine	Indication (HPV Types)	Age Group	Notes
Cervarix	HPV 16, 18	Girls 9-14	Approved for use in the United States
HPV vaccine (Gardasil)	HPV 6, 11, 16, 18	Girls 9-14	Approved for use in the United States
HPV vaccine (Gardasil 9)	HPV 6, 11, 16, 18, 31, 33, 45, 52, 58	Girls 9-14	Approved for use in the United States

Prevention of HPV-associated disease by vaccination

- Three vaccines (Bivalent/2vHPV, quadrivalent/4vHPV, and 9vHPV) are available to protect against HPV 16 and 18, types that cause about 66% of cervical cancers and the majority of other HPV-unbearable cancers in the United States. 2vHPV protects against five additional types (31, 33, 45, 52, and 58), which account for about 12% of cervical cancers. 4vHPV and 9vHPV also protect against HPV 6 and 11, types that cause anogenital warts.*
- The Advisory Committee on Immunization Practices (ACIP) recommends routine vaccination of girls age 11 or 12 years with the 3-dose series of any HPV vaccine and routine vaccination of boys age 11 or 12 years with the 3-dose series of 4vHPV or 9vHPV.*
- The ACIP also recommends vaccination for females through age 26 years and for males through age 21 years who were not vaccinated when they were younger. Males aged 22 through 26 years may be vaccinated.*

Letter adapted with permission from the Immunization Action Coalition.

Give a strong recommendation for HPV vaccine to increase uptake!

Dear Colleagues:

The Michigan Department of Health and Human Services (MDHHS), along with leading health professional organizations serving adolescents and adults, are asking you to vaccinate your patients against human papillomavirus (HPV).

HPV vaccine is cancer prevention. However, HPV vaccine is underutilized in the United States and Michigan, despite the overwhelming evidence of its safety and effectiveness. HPV vaccination rates are far below rates of other routinely recommended vaccines for adolescents.

Missed opportunities data suggest that providers are not giving strong recommendations for HPV vaccine when patients are 11 or 12 years old. The health care provider recommendation is the single best predictor of vaccination. Recent studies show that a patient who receives a provider recommendation is 4 to 5 times more likely to receive the HPV vaccine.^{1,2}

What you say, and how you say it, matters. A half-hearted recommendation to a patient may not only result in the patient leaving your practice unvaccinated, but may lead the patient to believe that HPV vaccine is not as important as the other adolescent vaccines.

The undersigned organizations hope that this letter, which provides key facts about HPV vaccine safety and effectiveness, will lead you to recommend HPV vaccination – firmly and strongly – to your adolescent and adult patients. Your recommendation will reflect your commitment to prevent HPV-associated cancers and disease in Michigan.

HPV-associated disease*

- Approximately 79 million persons in the United States are infected with HPV, and approximately 14 million persons in the United States will become newly infected with HPV each year.
- Each year, an estimated 26,000 cancers are attributable to HPV, about 17,000 in women and 9,000 in men.
- Cervical cancer is the most common HPV-associated cancer among women, and oropharyngeal cancers are the most common among men.

Despite these statistics, the use of HPV vaccination to prevent HPV infection is limited and immunization rates remain low.

Prevention of HPV-associated disease by vaccination

- Three vaccines (Bivalent/2vHPV, quadrivalent/4vHPV, and 9vHPV) are available to protect against HPV 16 and 18, types that cause about 66% of cervical cancers and the majority of other HPV-unbearable cancers in the United States. 2vHPV protects against five additional types (31, 33, 45, 52, and 58), which account for about 12% of cervical cancers. 4vHPV and 9vHPV also protect against HPV 6 and 11, types that cause anogenital warts.*
- The Advisory Committee on Immunization Practices (ACIP) recommends routine vaccination of girls age 11 or 12 years with the 3-dose series of any HPV vaccine and routine vaccination of boys age 11 or 12 years with the 3-dose series of 4vHPV or 9vHPV.*
- The ACIP also recommends vaccination for females through age 26 years and for males through age 21 years who were not vaccinated when they were younger. Males aged 22 through 26 years may be vaccinated.*

Patient Education Materials – Ages 11 through 17 and Ages 18 through 26

These documents printed with the screening tools for patients in the different age groups and were provided to the patients to take home. Clicking on the images will open PDF versions of the educational flyers. Ages 11 through 17 is on the left and ages 18 through 26 is on the right.

TEEN VACCINES INFORMATION FOR PARENTS

Meningococcal Vaccines (MCV, MenB)	Adolescent Catch-Up	Tetanus, Diphtheria, Pertussis (Tdap)	Human Papillomavirus (HPV)
Meningococcal vaccines protect you against meningitis, which affects the brain and spinal cord.	Many vaccines are given during childhood to give you life-long protection against diseases.	Tdap vaccine protects you against pertussis (whooping cough), diphtheria, and tetanus.	HPV vaccine protects against cervical cancer in women and genital warts in men and women. It will also protect you against several other cancers.*
If you contract meningitis, it can cause brain damage, severe disabilities or death.	If you have not received all of the below vaccines, it is not too late!	Tetanus causes painful tightening of the muscles and is very serious. It is found in soil and enters the body through a cut or wound.	HPV is a common infection transmitted by skin-to-skin contact during sexual activity. Even if you do not have sex, you can still get HPV. HPV infection often has no symptoms so you could have it and not know.
Common symptoms include a fever, rash, headache, or stiff neck.	3 doses of hepatitis B vaccine (Hep B)	Diphtheria can make you unable to breathe or move body parts. It is spread by coughing or sneezing.	The best time to get HPV vaccine is at 11-12 years of age, well before sexual activity starts. However, if you missed your doses, you should still get the vaccine through 26 years of age.
It is spread through close contact with an infected person, such as coughing, kissing, and sharing food or drinks. This disease is easily spread.	2 doses of hepatitis A vaccine (Hep A)	Pertussis can cause severe coughing and choking, making it difficult for you to breathe or eat. It is spread by coughing, sneezing or close contact with an infected person.	This vaccine is very effective against several types of HPV and works best if you get all three doses prior to exposure.
MCV is given at 11-12 years of age with a second dose at 16. MenB is given at 16-18 years of age in a series of doses. If you have not received these vaccines before you get your diploma, talk to your health care provider about catch-up.	2 doses of measles, mumps, rubella vaccine (MMR)		
	2 doses of varicella (chickenpox) vaccine		
	At least 3 doses of polio vaccine (IPV or OPV)		
	Flu vaccine every year		

MDHHS is a part of the Michigan Department of Health and Human Services. For more information on vaccines for teens and young adults, visit www.vaccineinformation.org/teens or www.vaccineinformation.org/adults.

HPV* Vaccine A Guide for Young Adults

HPV is a very common virus that can lead to:

- Cancers of the mouth and throat
- Cancer of the cervix
- Cancer of the penis, vagina, vulva, or anus
- Genital warts

HPV vaccine can prevent these!

Do I really need HPV vaccine? Yes!

You should get HPV vaccine because it can prevent some types of cancer and genital warts.

- You don't have to have sex to catch HPV, but sex increases your risk.
- You can get HPV by skin-to-skin intimate contact.
- People can get and spread HPV without knowing it.
- It's best to get vaccinated before you ever have sex.

Do I need it if I haven't had sex yet? Yes!

You still need to get vaccinated even if you have had sex. The vaccine provides a lot of protection.

Should I get HPV vaccine if I've already had sex? Yes!

You still need to get vaccinated even if you have had sex. The vaccine provides a lot of protection.

Why do I need 3 shots?

You need 3 HPV shots to be fully protected.

I didn't get the vaccine at age 11 or 12. Should I get it now? Yes!

HPV vaccination is recommended for people ages 9 through 26. Even though it is ideal to get HPV vaccine as a preteen, it is still highly effective in teens and young adults.

Is HPV vaccine safe? Yes!

- Millions of doses of HPV vaccine have been given without any problems.
- You may get a sore arm.
- Occasionally, a few people faint, so sit for 15 minutes after getting the vaccine.

When Should I Get HPV Vaccine?

Have your healthcare provider fill in this chart about when you should be vaccinated.

Vaccine Dose	RECOMMENDED	SHOTS DUE OVER 6 MONTHS
#1	For people ages 9-26 years	
#2	1-2 months after vaccine dose #1	
#3	At least 6 months after vaccine dose #1	

Adapted with permission from the American Pediatric Association. © 2014. All rights reserved. For more information on vaccines for teens and young adults, visit www.vaccineinformation.org/teens or www.vaccineinformation.org/adults. State of Minnesota - 651-647-0000 - www.immunize.org - www.vaccineinformation.org. www.immunize.org/teens 12/14/13 (1/14)

Pharmacist Education Materials – Pharmacists Not Involved in the Pilot

Because of this project, Michigan Pharmacists Association (MPA) updated its Immunization Resources section of its website to include information about HPV. Members were notified of the new content through a flyer included in their annual membership renewal notice. Immunization resources are a member-only benefit.

New Immunization Resources!

Login to MichiganPharmacists.org

Find Practice Resources then Immunizations

Immunizations

- + Adult Immunization Standards
- + Immunization Schedules
- + Human Papillomavirus (HPV) **New Sections like HPV**
- + Influenza **Flu Updates for 2016-2017**

Clicking on the image will open a PDF version of MPA's Immunizations section of its website.

MPA | Immunizations

ABOUT | NEWS & PUBLICATIONS | CALENDAR | MEMBERSHIP | ONLINE STORE | CART | LOGOUT

ADVOCACY | PRACTICE SECTIONS | **PRACTICE RESOURCES** | EDUCATION & EVENTS | COMMITTEES | FOR PATIENTS | CONTACT

Immunizations

Antimicrobial Stewardship

Ambulatory Care Pharmacy Practice

Ambulatory Care Toolkit

Emergency Preparedness

Immunizations

Medicare Information

Medication Therapy Management

Michigan Residency Programs

Patient Education Library

Health Observances

Michigan Pharmacy Week

That's My Pharmacist Campaign

Practice Toolkit

Patient Safety Resource Center

Professional Resources

Pharmacists as Providers

Pharmacy Practice FAQs

Pharmacy Practice Guidance

Pharmacy Practice Model Initiative of Michigan

Pharmacist-Provided Immunizations

Along with managing medication therapy and educating patients on healthy lifestyle practices, certified pharmacists can also administer critical immunizations, ensuring that any treatment received will not interfere with other therapies.

The majority of American adults are inadequately vaccinated, leading to an average of 90,000 deaths each year from vaccine-preventable infections.

As the most accessible health care providers, pharmacists can help ensure that patients are up-to-date on all their immunizations, as well as answer questions and provide necessary protection from harmful diseases.

Click on the black bars below to get started with the resources you need for providing seasonal flu and other vaccines in your pharmacy, educating patients on immunizations, receiving training to provide immunizations and more.

- + Adult Immunization Standards
- + Immunization Schedules
- + Herpes Zoster (Shingles)
- + Human Papillomavirus (HPV)

<http://www.michiganpharmacists.org/resources/immunizations/> (10/1/2016 3:16:34 PM)

Pharmacist and Pharmacy Technician Home Study Education Materials –Pilot Participants

The home study course consisted of required and optional readings for pharmacists and pharmacy technicians. The learning objectives and posttest questions were slightly different for each audience. Clicking on the images will open PDF versions of the documents.

Vaccine Information Statement – Gardasil® 9 – Required for Pharmacists and Pharmacy Technicians

VACCINE INFORMATION STATEMENT

HPV Vaccine Gardasil®-9 (Human Papillomavirus)

What You Need to Know

1 Why get vaccinated?

Gardasil-9 prevents many cancers caused by human papillomavirus (HPV) infections, including:

- cervical cancer in females,
- vaginal and vulvar cancers in females, and
- anal cancer in females and males.

In addition to these cancers, Gardasil-9 also prevents genital warts in both females and males.

In the U.S., about 12,000 women get cervical cancer every year, and about 4,000 women die from it. Gardasil-9 can prevent most of these cancers.

HPV infection usually comes from sexual contact, and most people will become infected at some point in their life. About 14 million Americans get infected every year. Many infections will go away and not cause serious problems. But females who have had one HPV infection or more are more likely to get cervical cancer and diseases from HPV.

2 HPV vaccine


Gardasil-9 is one of three FDA-approved HPV vaccines. It is recommended for both males and females. It is routinely given at 11 or 12 years of age, but it may be given beginning at age 9 years through age 26 years for females and males.

Three doses of Gardasil-9 are recommended with the second and third dose 2 months and 6 months after the first dose.

Vaccination is not a substitute for cervical cancer screening. This vaccine does not protect against all HPV types that can cause cervical cancer. Women should still get regular Pap tests.

3 Some people should not get this vaccine

- Anyone who has had a severe, life-threatening allergic reaction to a dose of HPV vaccine should not get another dose.
- Anyone who has a severe (life threatening) allergy to any component of HPV vaccine should not get the vaccine.
- Tell your doctor if you have any severe allergic reaction you have of, including a severe allergy to yeast.
- HPV vaccine is not recommended for pregnant women. If you learn that you were pregnant when you were vaccinated, there is no reason to expect any problems for you or the baby. Any woman who learns she was pregnant when she got this HPV vaccine is encouraged to register the vaccine's registry for HPV vaccination during pregnancy at 1-800-966-6999. Women who are breastfeeding may be vaccinated.
- If you have a mild illness you can probably get the vaccine today. If you are moderately or severely ill, you should probably wait until you recover. Your doctor can advise you.



Give a Strong HPV Recommendation Letter – Required for Pharmacists and Pharmacy Technicians

Give a strong recommendation for HPV vaccine to increase uptake!

Dear Colleague:

The American Academy of Family Physicians (AAFP), American Academy of Pediatrics (AAP), American College of Obstetricians and Gynecologists (ACOG), American College of Physicians (ACP), the Centers for Disease Control and Prevention (CDC), and the Immunization Action Coalition (IAC) are asking you to urge your patients to get vaccinated against human papillomavirus (HPV).

HPV vaccine is cancer prevention. However, HPV vaccine is underutilized in our country, despite the overwhelming evidence of its safety and effectiveness. While vaccination rates continue to improve for the other adolescent vaccines, HPV vaccination rates have not. Mixed opportunities data suggest that providers are not giving strong recommendations for HPV vaccine when patients are 11 or 12 years old. The healthcare provider recommendation is the single best predictor of vaccination. Recent studies show that a patient who receives a provider recommendation is 4-5 times more likely to receive the HPV vaccine.^{1,2}

What you say, and how you say it, matters. A halfhearted recommendation to a patient may not only result in the patient leaving your practice unvaccinated, but may lead the patient to believe that HPV vaccine is not as important as the other adolescent vaccines. The undersigned organizations hope that this letter, which provides key facts about HPV vaccine safety and effectiveness, will lead you to recommend HPV vaccination – firmly and strongly – to your patients. Your recommendation will reflect your commitment to prevent HPV-associated cancers and disease in the United States.

HPV-associated disease¹

- Approximately 79 million people in the United States are infected with HPV, and approximately 14 million people in the United States will become newly infected with HPV each year.
- Each year, an estimated 26,000 cancers are attributable to HPV; about 17,000 in women and 9,000 in men.
- Cervical cancer is the most common HPV-associated cancer among women, and oropharyngeal cancers are the most common among men.

► Despite these statistics, the use of HPV vaccination to prevent HPV infection is limited and immunization rates remain low.

Prevention of HPV-associated disease by vaccination

- Two vaccines (bivalent/HPV2 and quadrivalent/HPV4) are available to protect against HPV 16 and 18, the types that cause most cervical and other anogenital cancers, as well as some oropharyngeal cancers.

Ask the Experts about HPV – Required for Pharmacists, Optional for Pharmacy Technicians

302001

Ask the Experts about Human Papillomavirus (HPV) Vaccine. CDC experts answer Q&As.

Human papillomavirus (HPV)

Disease Issues Contraindications and Precautions
Vaccine Recommendations Vaccine Safety
Scheduling and Administering Vaccines

Disease Issues

How common is human papillomavirus (HPV) infection?

HPV is the most common sexually transmitted infection in the United States. In the United States, an estimated 79 million persons are infected, and an estimated 14 million new HPV infections occur every year among persons age 15 through 59 years. Approximately half of new infections occur among persons age 15 through 24 years. First HPV infection occurs within a few months to years of becoming sexually active.

How serious is disease caused by HPV?

HPV is associated with cervical, vulvar, and vaginal cancer in females, penile cancer in males, and anal and oropharyngeal cancer in both females and males. An annual average of approximately 26,000 new cancers were attributable to HPV during 2008 through 2012 including 17,600 (65%) among females and 8,400 (35%) among males. Cervical and oropharyngeal cancers were the most common with an estimated 10,400 cervical cancers and 8,000 oropharyngeal cancers (7,200 among men and 8,000 among women). HPV also causes almost all cases of genital warts.

Which types of HPV are most likely to cause disease?

Of the annual average of 26,000 HPV-related cancers in the United States, approximately 84% are attributable to HPV 16 or 18 (65% for females, 63% for males; approximately 21,300 cancers annually), which are included in all three HPV vaccines. Approximately 10% are attributable to HPV types 31, 33, 45, 52, and 58 (14% for females, 4% for males; approximately 3,400 cases annually), which are included in the bivalent HPV vaccine. HPV types 16, 18, 31, 33, 45, 52, or 58 account for about 81% of cervical cancers in the United States.

Approximately 80% of cervical precancers (CIN2 or greater) are caused by HPV 16 or 18 and 26% by HPV 31, 33, 45, 52, or 58. HPV 6 or 11 cause 90% of anogenital warts (condylomata) and most cases of recurrent respiratory papillomatosis.

More information about HPV and HPV-related cancers is available in the 2014 HPV ACP statement <http://www.aacp.org/immunization/2014.pdf>.

Is there a treatment for HPV infection?

There is no treatment for HPV infection. Only HPV-associated lesions including genital warts, recurrent respiratory papillomatosis, precancers, and cancers are treated. Recommended treatments vary depending on the diagnosis, site, and location of the lesion. Local treatment of lesions might not eradicate all HPV-containing cells fully; whether available therapies for HPV-associated lesions reduce effectiveness is unclear.

Are healthcare personnel at risk of occupational infection with HPV?

Occupational infection with HPV is possible. Some HPV-associated conditions (including anogenital and oral warts, anogenital intraepithelial neoplasia, and recurrent respiratory papillomatosis) are treated with laser or electrocautery procedures that could produce airborne particles. These procedures should be performed in an appropriately ventilated room using standard precautions and local exhaust ventilation. Workers in HPV research laboratories who handle wild-type virus or "quasi viruses" might be at risk of acquiring HPV from occupational exposures. In the laboratory setting, proper infection control should be instituted including, at minimum, biosecurity level 2. Whether HPV vaccination would be of benefit in these settings is unclear because no data exist on transmission risk or vaccine efficacy in this situation.

<http://www.cdc.gov/ncidod/diseases/zoonotic/hpv/ask.htm>

17

Gardasil® 9 Package Insert – Required for Pharmacists, Optional for Pharmacy Technicians

INDICATIONS FOR PRESCRIBING INFORMATION

This package insert does not contain all the information needed to use GARDASIL-9 safely and effectively. See full prescribing information for GARDASIL-9.

GARDASIL-9[®]
(Human Papillomavirus 9-valent Vaccine, Recombinant)
Indication for Intensive Cervical Cancer Prevention

RECENT MAJOR CHANGES 12/01/15

Indications and Usage: New and New (1.2)

INDICATIONS AND USAGE

GARDASIL-9 is a vaccine indicated in girls and women 9 through 45 years of age for the prevention of the following diseases:

- Cervical, vaginal, vulvar, and anal cancer caused by human Papillomavirus (HPV) types 16, 18, 31, 33, 45, 52, and 58 (1.1)
- Cervical intraepithelial neoplasia (CIN) grade 2 and grade 3 (1.1)
- Cervical intraepithelial neoplasia (CIN) grade 1 (1.1)
- Vaginal intraepithelial neoplasia (VIN) grade 2 and grade 3 (1.1)
- Anal intraepithelial neoplasia (AIN) grades 1, 2, and 3 (1.1)

GARDASIL-9 is indicated in boys and men 9 through 26 years of age for the prevention of the following diseases:

- Anal cancer caused by HPV types 16, 18, 31, 33, 45, 52, and 58 (1.2)
- Anal intraepithelial neoplasia (AIN) grades 1, 2, and 3 (1.2)

And the following precancers or precursors caused by HPV types 16, 18, 31, 33, 45, 52, and 58:

- Anal intraepithelial neoplasia (AIN) grades 1, 2, and 3 (1.2)

Limitations of Use and Effectiveness:

- GARDASIL-9 does not eliminate the necessity for women to continue to undergo recommended cervical cancer screening (1.2, 1.3)
- Response to GARDASIL-9 should not be used to determine if a woman has been vaccinated with a health care provider (1.2, 1.3)
- GARDASIL-9 has not been demonstrated to provide protection against disease from vaccine HPV types to which a person has previously been exposed through sexual activity (1.3)
- GARDASIL-9 has not been demonstrated to protect against diseases not in HPV types 16, 18, 31, 33, 45, 52, and 58 (1.3)
- GARDASIL-9 is not a treatment for existing genital lesions: cervical, vaginal, vulvar, and anal lesions; CIN, VIN, AIN, or AEN (1.3)
- Not all cancer, vulvar, and anal cancers are caused by HPV and GARDASIL-9 cannot prevent against these cancers (1.3)
- GARDASIL-9 does not protect against genital diseases not caused by HPV (1.3)

CONTRAINDICATIONS

- Anyone who has had a severe, life-threatening allergic reaction to a dose of HPV vaccine should not get another dose (3.1)
- Anyone who has a severe (life threatening) allergy to any component of HPV vaccine should not get the vaccine (3.1)
- Tell your doctor if you have any severe allergic reaction you have of, including a severe allergy to yeast (3.1)
- HPV vaccine is not recommended for pregnant women. If you learn that you were pregnant when you were vaccinated, there is no reason to expect any problems for you or the baby. Any woman who learns she was pregnant when she got this HPV vaccine is encouraged to register the vaccine's registry for HPV vaccination during pregnancy at 1-800-966-6999 (3.1)
- Women who are breastfeeding may be vaccinated (3.1)
- If you have a mild illness you can probably get the vaccine today. If you are moderately or severely ill, you should probably wait until you recover. Your doctor can advise you (3.1)

WARNINGS AND PRECAUTIONS

Because vaccines may develop groups, sometimes resulting in injury with HPV, vaccination for 12 months after administration is recommended. Symptoms associated with both-dose movements and other vaccine-related activity, has been reported following HPV vaccination. When symptoms are associated with both-dose movements, the activity is usually transient and usually responds to rest and/or pain relievers. If symptoms persist or worsen, contact your healthcare provider immediately (3.2)

ADVERSE REACTIONS

The most common (≥10%) local and systemic adverse reactions reported in clinical studies were:

- In girls and women 9 through 26 years of age: injection site pain (38.3%), injection site swelling (34.5%), injection site erythema (34.1%), and injection site bruising (14.1%) (3.3)
- In girls 9 through 10 years of age: injection site pain (38.3%), injection site swelling (34.5%), injection site erythema (34.1%), and injection site bruising (14.1%) (3.3)
- In boys and men 9 through 26 years of age: injection site pain (34.4%), injection site swelling (30.3%), and injection site erythema (26.1%) (3.3)
- In boys 9 through 10 years of age: injection site pain (37.1%), injection site swelling (30.3%), and injection site erythema (26.1%) (3.3)

TO REPORT SUSPECTED ADVERSE REACTIONS, contact MedWatch, a Division of the U.S. Food and Drug Administration, at 1-800-FDA-1088 or visit the MedWatch website at www.fda.gov/medwatch.

USE IN SPECIFIC POPULATIONS

Safety and effectiveness of GARDASIL-9 have not been established in the following populations:

- Pregnant women. A pregnancy registry is available. Patients and healthcare providers are encouraged to register women exposed (potentially by taking 1-800-966-6999 or 1-800-966-6999) (3.4)
- Nursing women (3.4)
- Breastfeeding women (3.4)
- Immunocompromised individuals. Responses to GARDASIL-9 may be decreased (3.4)

See 17 for patient counseling information and FDA-approved patient labeling. Revised: 12/01/15

FULL PRESCRIBING INFORMATION: CONTENTS

1 INDICATIONS AND USAGE

1.1 Girls and Women

1.2 Boys and Men

1.3 Limitations of Use and Effectiveness

2 DOSAGE AND ADMINISTRATION

2.1 Dosage

2.2 Method of Administration

2.3 Storage and Handling

2.4 Immunization Schedule

2.5 Contraindications

2.6 Warnings and Precautions

2.7 Adverse Reactions

2.8 Use in Specific Populations

2.9 Description

IAC: Questions & Answers – Required for Pharmacy Technicians, Optional for Pharmacists

Human Papillomavirus (HPV): Questions and Answers

INFORMATION ABOUT THE DISEASE AND VACCINES

How common is HPV in the United States?

HPV is the most common sexually transmitted infection in the United States. About 79 million Americans are currently infected with HPV. About 14 million people become newly infected each year. HPV is so common that most sexually active men and women will get at least one type of HPV at some point in their lives.

An estimated 26,600 HPV-associated cancers occur annually in the U.S., including an estimated 9,300 HPV-associated cancers in males. Of these HPV-associated cancers, approximately 64% are caused by HPV types 16 and 18, which are included in all three HPV vaccines available in the United States and about 10% are caused by the 5 HPV types also included in Gardasil 9.

How does HPV spread?

HPV is spread through contact with infected skin, usually through sexual contact. Most infected people have no symptoms and are unaware they are infected and can transmit the virus to a sex partner. Rarely, a pregnant woman passes HPV to her baby during vaginal delivery.

What are the symptoms of HPV?

Most people who become infected with HPV have no symptoms. Some people develop visible genital warts, or have pre-cancerous changes in the cervix, vulva, anus, or penis.

Genital warts usually appear as soft, moist, pink, or flesh-colored swellings, usually in the genital area. They can be raised or flat, single or multiple, small or large, and sometimes cauliflower shaped. They can appear on the vulva, in or around the vagina or anus, on the cervix, and on the penis, scrotum, groin, or thigh. After sexual contact with an infected person, warts may appear within weeks or months, or not at all.

How serious is HPV?

Most HPV infections don't cause any symptoms and eventually go away, as the body's own defense system clears the virus. Women with short-term HPV infections may develop mild Pap test abnormalities that go away with time.

A small percentage of people infected with HPV develop persistent (chronic) HPV infection. Women with persistent high-risk HPV infections are at greatest risk for developing cervical cancer precursor lesions (abnormal cells on the lining of the cervix) and cervical cancer. (See next question.)

What are possible complications from HPV?

Cancer is the most serious possible complication from HPV infection. Persistent infection with high-risk types of HPV is associated with almost all cervical cancers. The American Cancer Society (ACS) estimates that in 2015, approximately 12,900 new cases of invasive cervical cancer will occur in the U.S. and about 4,100 women will die from the disease. Worldwide, cervical cancer is the second most common cancer in women; it is estimated to cause over 470,000 new cases and 233,000 deaths each year.

Persistent infection with high-risk types of HPV is also associated with cancers of the vulva, vagina, penis, and anus. For example, ACS estimates that this year there will be about 1,820 new cases of penile cancer in the U.S. and 310 men will die. Genital HPV infection with low-risk types of HPV is associated with genital warts in men and women. About 1% of sexually active adults in the U.S. have visible genital warts at any point in time. It is estimated that approximately 360,000 cases of genital warts occur each year in the U.S. among sexually active people.

Occasionally, low-risk HPV infections can be transmitted during birth, resulting in respiratory tract warts in infants and children.

How is HPV infection diagnosed?

Genital warts in men and women are diagnosed by visual inspection.

Most women are diagnosed with HPV infection on the basis of abnormal Pap tests. Also, a specific test is available to detect HPV DNA in women. The test may be used in women with mild Pap test abnormalities or in women more than age 30 years at the time of Pap testing. In April 2014 the U.S. Food and Drug Administration approved the first HPV DNA test for women.

CONTINUED ON THE NEXT PAGE



Saint Paul, Minnesota • 651-647-9009 • www.immunize.org • www.vaccineinformation.org
www.immunize.org/tvg/4307.pdf • Item #V4307 (7/15)

HPV and HPV Testing – Required for Pharmacy Technicians, Optional for Pharmacists



HPV and HPV Testing

Human Papilloma Virus (HPV)

What are viruses?

Viruses are very small organisms – most cannot even be seen with a regular microscope. They cannot reproduce on their own. They must enter a living cell, which becomes the host cell, and “hijack” the cell’s machinery to make more viruses.

Viruses can enter the body through the mucous membranes, such as the nose, mouth, the lining of the eyes, or the genitals. Some enter through the digestive system (such as stomach or intestine), via insect bites, or through breaks in the skin. A few can enter unbroken skin. Once inside, they find their specific type of host cell to infect. For example, cold and flu viruses find and invade cells that line the respiratory tract (nose, sinuses, breathing tubes, and lungs). HIV (the virus that causes AIDS) infects the T-cells and macrophages of the immune system. HPV infects squamous epithelial cells – the flat cells that cover the surface of the skin and mucous membranes.

What is HPV?

HPV is short for human papilloma virus. HPV’s are a group of more than 150 related viruses. Each HPV virus in the group is given a number, which is called an HPV type. HPV’s are called papilloma viruses because some of the HPV types cause warts or papillomas, which are non-cancerous tumors. But some types of HPV are known for causing cancer, especially of the cervix (the base of the womb at the top of the vagina).

The papilloma viruses are attracted to and are able to live only in certain cells called squamous epithelial cells. These cells are found on the surface of the skin and on moist surfaces (called mucosal surfaces) like:

- the vagina, anus, cervix, vulva (around the outside of the vagina)
- the inner foreskin and urethra of the penis
- inner nose, mouth, throat
- trachea (the main breathing tube or windpipe), bronchi (smaller breathing tubes branching off the trachea)

HPV and Cancer – Optional for Pharmacists and Pharmacy Technicians



HPV and Cancer



Christine Baze’s Story – Optional for Pharmacists and Pharmacy Technicians

Unprotected People #91 Human Papillomavirus (HPV)

Christine Baze’s Story

PopSmeagor is a Boston-based non-profit organization whose purpose is to raise awareness and educate women about how to prevent cervical cancer and HPV. PopSmeagor was created in 2002 by Christine Baze, a Boston musician who is also a cervical cancer survivor. She was just 31 years old when she was diagnosed with cervical cancer. In recognition of her educational and outreach efforts, *Ms. Magazine* named Baze in their annual award: “30 women who made a difference.”

Christine Baze gave IAC permission to share her personal story:

I’m supposed to be a rock star — that’s what I thought until April 18th, 2000. I had just left my day job in January to pursue my passion: music. My band was doing well and I could not have been happier, but then there was blood. I called my gynecologist and he told me not to worry. So I didn’t. I went on gigging and booking and writing songs—the best 3 months ever. I was so happy and felt so lucky. Little did I know it would not last.

In March, I went for my yearly Pap test. I’ve had yearly Paps since I was 18 years old, and always had normal results, until this one. I was told that I had some dysplastic cell growth on my cervix and that he needed to do a colposcopy to biopsy the cells. I barely knew where my cervix was and certainly didn’t understand anything about cell mutation—that’s when I was told it could turn into cancer many years down the road if not treated. Cancer? Me! He assured me that I did NOT have cancer and that we would meet the following week to review the results of this biopsy and schedule a LEEP procedure [loop electrosurgical excision procedure], a mild surgery that would scrape off the bad cells.

He was wrong. At 8:15 the morning of April 18th, I received a phone call confirming an appointment

I did not have, with a doctor I did not know. Realizing I had not heard the news yet, the woman apologized on the other line, and stumbled over her words as she told me she was confirming an appointment with a gynecologic oncologist at a local cancer center. That’s how I found out I had cancer.

It all happened very quickly after that. I was diagnosed with invasive cervical cancer with extensive lymphatic invasion. I had a radical hysterectomy 10 days after my diagnosis, a laparoscopic procedure a month later to move my ovaries out of the “frying zone,” 5 weeks of daily pelvic radiation concurrent with 4 rounds of chemotherapy, followed by 3 rounds of internal radiation (brachytherapy). They gave me everything they had in order to save me. Within 4 months I was done with everything. Everything other than the deep dark depression, that is.

Everyone knows that treatment is hard, and everyone sees the toll it takes on your body. But for me, I think the depression that followed was almost worse. Once my body was no longer being assaulted, my mind started to digest all that had happened, and it wasn’t pretty. I felt like I lost everything. And through it all, the one thing that always centered me, that always made me happy, was gone. The music was gone. I couldn’t play, sing, or write. I had no desire for the thing I loved the most. I didn’t know who I was anymore.

I decided to attack with full force: Individual therapy, group therapy, anti-depressant, acupuncture, yoga, journaling, Reiki, and more. I did anything I could to fight off the depression, and eventually it started to work. Time, absolutely was a huge part of it. Time, and the fact that I just refused to quit. I had worked way too hard to stay alive, and I wanted my life back.

(continued on next page)

www.immunize.org/reports/report91.pdf • Item #V7201-1-1 (2/07)

Immunization Action Coalition • St. Paul, MN 55104 • (651) 647-9009 • www.vaccineinformation.org • www.immunize.org

Pharmacist Home Study Learning Objectives:

1. Identify the prevalence and incidence of HPV in the United States and the corresponding rates of HPV-related cancer.
2. List the indications for HPV vaccination in males and females.
3. Explain the importance of HPV vaccination in preventing cancer.
4. Identify the benefits, risks and potential side effects of the HPV vaccine.

Pharmacist Home Study Posttest Questions:

1. Approximately how many people in the United States are infected with HPV?

- a. **79 million (correct answer)**
- b. 2 billion
- c. 800,000
- d. 20 million

Explanation: According to data from the CDC, approximately 79 million people are currently infected with HPV in the United States.

2. Approximately how many new cases of HPV infection occur each year in the United States in persons age 15 through 59 years?

- a. 800,000
- b. **14 million (correct answer)**
- c. 65,000
- d. 1 million

Explanation: According to data from the CDC, approximately 14 million people become infected with HPV each year.

3. How many new cases of HPV-related cancers are reported annually?

- a. 150,000
- b. 1 million
- c. **27,000 (correct answer)**
- d. 5,000

Explanation: According to data from the CDC, somewhere between 26,000 and 27,000 new cases of cancer are related to HPV each year.

4. Which types of HPV cause approximately 64% of HPV-related cancers?

- a. 31 and 33
- b. 45 and 52
- c. **16 and 18 (correct answer)**
- d. 18 and 31

Explanation: According to data from the CDC, approximately 64% of HPV-related cancers are caused by HPV 16 and 18.

5. Which of the following is FALSE?

- a. **HPV vaccination is only recommended for females. (correct answer = false statement)**
- b. HPV vaccination is routinely given at age 11 or 12 but may be given beginning at age 9 years.
- c. The HPV vaccination series includes three doses: an initial dose followed by a second dose two months and a third dose six months after the first dose.
- d. Gardasil® 9 is one of three FDA-approved HPV vaccines.

Explanation: HPV vaccination is recommended for both males and females, therefore making (a) a false statement. The other statements are true.

6. True or False? HPV vaccines provide the most protection against HPV infection when given before onset of sexual activity.

a. True (correct answer)

b. False

Explanation: HPV is primarily transmitted through direct skin-to-skin contact during vaginal, oral or anal sex. The vaccine does not cure HPV infection and only works to protect against HPV types a person has not yet been exposed to so receiving the vaccine prior to sexual activity allows the vaccine to provide the most protection.

7. True or False? The HPV vaccines currently available provide protection against all types of HPV.

a. True

b. False (correct answer)

Explanation: Cervarix® protects against HPV 16 and 18, Gardasil® protects against HPV 6, 11, 16 and 18, and Gardasil® 9 protects against HPV 6, 11, 16, 18, 31, 33, 45, 52, and 58, but there are other HPV types not covered by any vaccine.

8. HPV vaccination assists in preventing some instances of cancer caused by specific types of HPV. Which of the following cancers is NOT associated with HPV?

a. Breast cancer (correct answer)

b. Cervical cancer

c. Anal cancer

d. Vaginal cancer

Explanation: Cervical, anal and vaginal cancers can be caused by HPV. The currently available HPV vaccines protect against many of the most common types of HPV that cause these cancers including types 16 and 18. Breast cancer is not linked to HPV.

9. Which of the following is NOT a common (>10% reported) side effect of the HPV vaccine?

a. Injection-site pain and swelling

b. Injection-site redness

c. Headache

d. Fever (correct answer)

Explanation: Fever was rarely reported in the clinical trials as compared to the injection-site reactions and headaches which were reported at rates >10%.

10. True or False? The only vaccine known to cause fainting in adolescents is the HPV vaccine.

a. True

b. False (correct answer)

Explanation: Fainting has been reported with all adolescent vaccines and is not specific to HPV.

Pharmacy Technician Home Study Learning Objectives:

1. Identify the prevalence and incidence of HPV in the United States and the corresponding rates of HPV-related cancer.
2. List the indications for HPV vaccination in males and females.
3. Explain the importance of HPV vaccination in preventing cancer.

Pharmacy Technician Home Study Posttest Questions:

1. Approximately how many people in the United States are infected with HPV?

- a. **79 million (correct answer)**
- b. 2 billion
- c. 800,000
- d. 20 million

Explanation: According to data from the CDC, approximately 79 million people are currently infected with HPV in the United States.

2. Approximately how many new cases of HPV infection occur each year in the United States in persons age 15 through 59 years?

- a. 800,000
- b. **14 million (correct answer)**
- c. 65,000
- d. 1 million

Explanation: According to data from the CDC, approximately 14 million people become infected with HPV each year.

3. How many new cases of HPV-related cancers are reported annually?

- a. 150,000
- b. 1 million
- c. **27,000 (correct answer)**
- d. 5,000

Explanation: According to data from the CDC, somewhere between 26,000 and 27,000 new cases of cancer are related to HPV each year.

4. Which of the following is FALSE?

- a. **HPV vaccination is only recommended for females. (correct answer = false statement)**
- b. HPV vaccination is routinely given at age 11 or 12 but may be given beginning at age 9 years.
- c. The HPV vaccination series includes three doses: an initial dose followed by a second dose two months and a third dose six months after the first dose.
- d. Gardasil® 9 is one of three FDA-approved HPV vaccines.

Explanation: HPV vaccination is recommended for both males and females, therefore making (a) a false statement. The other statements are true.

5. True or False? HPV vaccines provide the most protection against HPV infection when given before onset of sexual activity.

- a. **True (correct answer)**
- b. False

Explanation: HPV is primarily transmitted through direct skin-to-skin contact during vaginal, oral or anal sex. The vaccine does not cure HPV infection and only works to protect against HPV types a person has not yet been exposed to so receiving the vaccine prior to sexual activity allows the vaccine to provide the most protection.

6. True or False? The HPV vaccines currently available provide protection against all types of HPV.

- a. True
- b. **False (correct answer)**

Explanation: Cervarix® protects against HPV 16 and 18, Gardasil® protects against HPV 6, 11, 16 and 18, and Gardasil® 9 protects against HPV 6, 11, 16, 18, 31, 33, 45, 52, and 58, but there are other HPV types not covered by any vaccine.

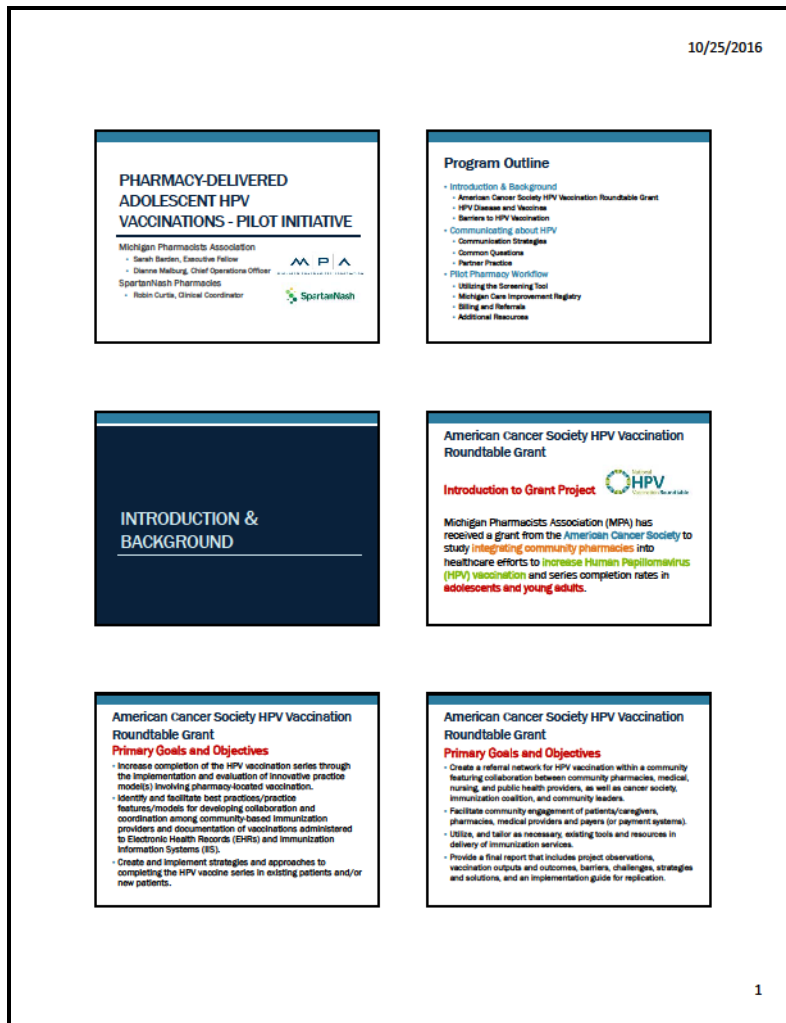
7. HPV vaccination assists in preventing some instances of cancer caused by specific types of HPV. Which of the following cancers is NOT associated with HPV?

- c. **Breast cancer (correct answer)**
- d. Cervical cancer
- e. Anal cancer
- f. Vaginal cancer

Explanation: Cervical, anal and vaginal cancers can be caused by HPV. The currently available HPV vaccines protect against many of the most common types of HPV that cause these cancers including types 16 and 18. Breast cancer is not linked to HPV.

Pharmacist and Pharmacy Technician Live and Hybrid Education Materials – Pilot Participants

Participants in the live training viewed this PowerPoint presentation. Participants in the hybrid training watched a video recording of the presentation. Clicking on the image will open a PDF version of the presentation with six slides to a page.



Pharmacist Live and Hybrid Program Learning Objectives

1. Discuss the public health implications of HPV infection and HPV-related cancers.
2. Describe approaches to effectively implement the HPV immunization neighborhood, including strategies to address vaccine initiation and series completion.
3. Discuss ways pharmacists can communicate with parents, patients and other healthcare providers about HPV vaccination.
4. Identify strategies for providing useful and compelling information about HPV vaccine to parents to aid in their decision to vaccinate.
5. List the steps for integrating the vaccination screening tool into the pharmacy workflow.

Pharmacist Live and Hybrid Program Posttest Questions:

1. True or False? The disease burden of HPV-related cancers is higher than the burden from meningococcal disease and tetanus (two other vaccine-preventable diseases) combined.

a. **True (correct answer)**
b. False

Explanation: Over 4,000 women die from cervical cancer caused by HPV each year, whereas there were only 550 cases of meningococcal disease reported in the United States in 2013 and only 26 deaths attributed to tetanus in total between the years 2001 and 2008.

2. True or False? As the grant progresses, one of the ways Michigan Pharmacists Association and SpartanNash will be attempting to create an HPV immunization neighborhood is by contacting providers near the pilot pharmacies to try to develop a mutual referral relationship.

a. **True (correct answer)**
b. False

Explanation: This is one of the strategies being employed as part of the grant project.

3. True or False? The largest predictor of whether a patient or parent will agree to HPV vaccination is what they read on the internet.

a. True
b. **False (correct answer)**

Explanation: The largest predictor of vaccination is the strength of the recommendation given by their healthcare provider.

4. Patients and parents rely on trusting relationships with healthcare providers when making decisions. When making decisions of high concern (for example, decisions to vaccinate), they rely more heavily on which component of trust?

a. Provider's factual knowledge
b. Provider's history and experience
c. Provider's ability to explain information
d. **Provider's personal relationship with the patient/parent (correct answer)**

Explanation: Research indicates that when people make decisions related to issues of "high concern" that they rely more heavily on their personal relationship with their provider rather than on the provider's knowledge or expertise.

5. As a healthcare provider, what is the best way to influence a patient's or parent's decision to receive HPV vaccination?

a. Provide a handout for the patient/parent to read
b. Encourage the patient/parent to research on the internet
c. **Provide a strong, clear recommendation to vaccinate today (correct answer)**
d. Suggest they speak to their friends

Explanation: A strong, clear recommendation to receive the HPV vaccine is the best way to influence patients and parents to receive the vaccine for themselves or their children. Informational handouts from reputable sources are helpful to provide additional information. Internet research and experiences of friends can provide unreliable, unscientific information.

6. We discussed a communication strategy about making the "CASE" for HPV vaccination. "C" represents "cancer prevention." "A" represents adolescent vaccination. "S" represents "safety profile." What does "E" represent?

a. Experience
b. **Exposure (correct answer)**
c. Excellence
d. Elegance

Explanation: Discussing exposure means talking about how common the HPV vaccine is and that nearly everyone will be exposed to at least one type in his/her lifetime. That is why vaccination prior to any exposure is so important.

7. At what point in the prescription process will the immunization screening tool/survey print for appropriate patients?
 - a. Data entry
 - a. Filling
 - b. Final verification by pharmacist (correct answer)**
 - c. Point-of-sale checkout

Explanation: The screening tool/survey will print during final verification by the pharmacist and will be placed in the bag with the prescription and other information so it is ready and available for the patient/parent when they pick up the prescription.

Pharmacy Technician Live and Hybrid Program Learning Objectives

1. Discuss the public health implications of HPV infection and HPV-related cancers.
2. Identify strategies for technicians to use when talking with patients about the vaccination screening tool and pharmacist recommendations.
3. List the steps for integrating the vaccination screening tool into the pharmacy workflow.

Pharmacy Technician Live and Hybrid Program Posttest Questions:

1. True or False? The disease burden of HPV-related cancers is higher than the burden from meningococcal disease and tetanus (two other vaccine-preventable diseases) combined.
 - a. **True (correct answer)**
 - b. False

Explanation: Over 4,000 women die from cervical cancer caused by HPV each year, whereas there were only 550 cases of meningococcal disease reported in the United States in 2013 and only 26 deaths attributed to tetanus in total between the years 2001 and 2008.

2. True or False? The largest predictor of whether a patient or parent will agree to HPV vaccination is what they read on the internet.
 - a. True
 - b. False (correct answer)**

Explanation: The largest predictor of vaccination is the strength of the recommendation given by their healthcare provider.

3. Patients and parents rely on trusting relationships with healthcare providers when making decisions. When making decisions of high concern (for example, decisions to vaccinate), they rely more heavily on which component of trust?
 - a. Provider's factual knowledge
 - b. Provider's history and experience
 - c. Provider's ability to explain information
 - d. Provider's personal relationship with the patient/parent (correct answer)**

Explanation: Research indicates that when people make decisions related to issues of "high concern" that they rely more heavily on their personal relationship with their provider rather than on the provider's knowledge or expertise.

4. As a pharmacy technician, what type of information are you NOT allowed to provide to patients and parents?
 - a. Information about your personal decision to receive the HPV vaccine for yourself or child
 - b. Factual information related to HPV-related diseases

c. Recommendations and clinical advice (correct answer)

d. Information about how to complete the screening tool/survey

Explanation: Pharmacy technicians may talk with patients and parents about factual information and personal stories related to HPV vaccination, but they may not make clinical recommendations, counsel on the vaccine itself or make recommendations about vaccination.

5. We discussed a communication strategy about making the “CASE” for HPV vaccination. “C” represents “cancer prevention.” “A” represents adolescent vaccination. “S” represents “safety profile.” What does “E” represent?

a. Experience

b. Exposure (correct answer)

c. Excellence

d. Elegance

Explanation: Discussing exposure means talking about how common the HPV vaccine is and that nearly everyone will be exposed to at least one type in his/her lifetime. That is why vaccination prior to any exposure is so important.

6. At what point in the prescription process will the immunization screening tool/survey print for appropriate patients?

a. Data entry

b. Filling

c. Final verification by pharmacist (correct answer)

d. Point-of-sale checkout

Explanation: The screening tool/survey will print during final verification by the pharmacist and will be placed in the bag with the prescription and other information so it is ready and available for the patient/parent when they pick up the prescription.

7. What is an important opportunity the technician will often have to increase utilization of the screening tool/survey?

a. Asking the patient/parent to complete the printed screening tool/survey which finalizing prescription checkout

b. Providing the screening tool/survey to patients/parents who ask about it

c. Alerting the pharmacist when a patient/parent completes the screening tool/survey so the pharmacist is able to counsel

d. All of the above (correct answer)

Explanation: The technician is often the point of the contact for the patient/parent and can take advantage of all of the opportunities listed to increase participation.

Appendix B: Workflow Materials

Each pharmacy received a “materials box” that contained additional educational materials, workflow tools, documentation forms and more. Each “tab” contained a specific set of resources.

Tab 1: Directions and Tools

- Medical Management of Vaccine Reactions (available from Immunization Action Coalition)

Medical Management of Vaccine Reactions in Children and Teens

All vaccines have the potential to cause an adverse reaction. In order to minimize adverse reactions, patients should be carefully screened for contraindications and contraindications before vaccine is administered. Even with careful screening, reactions may occur. These reactions can vary from trivial and inconvenient (e.g., soreness, itching) to severe and life threatening (e.g., anaphylaxis). If reactions occur, staff should be prepared with procedures for their management. The table below describes procedures to follow if various reactions occur.

reaction	symptoms	management
Localized	Soreness, redness, itching, or swelling at the injection site	Apply a cold compress to the injection site. Consider giving an analgesic (pain reliever) or antipruritic (anti-itch) medication.
	Slight bleeding	Apply an adhesive compress over the injection site.
	Continuous bleeding	Place thick layer of gauze pads over site and maintain direct and firm pressure; raise the bleeding injection site (e.g., arm) above the level of the patient's heart.
Psychological fright and syncope (fainting)	Fright before injection is given	Have patient sit or lie down for the vaccination.
	Extreme pallor, sweating, weakness of the hands and feet, nausea, light-headedness, dizziness, weakness, or visual disturbances	Have patient lie flat or sit with head between knees for several minutes. Loosen any tight clothing and maintain an open airway. Apply cool, damp cloths to patient's face and neck.
	Fall, without loss of consciousness	Examine the patient to determine if injury is present before attempting to move the patient. Place patient flat on back with feet elevated.
	Loss of consciousness	Check the patient to determine if injury is present before attempting to move the patient. Place patient flat on back with feet elevated. Call 911 if patient does not recover immediately.
Anaphylaxis	Sudden or gradual onset of generalized itching, swelling (hives), or urticaria (hives), angioedema (swelling of the lips, face, or throat), severe bronchospasm (difficulty breathing), shortness of breath, wheez, abdominal cramping, or cardiovascular collapse	See "Emergency Medical Protocol for Management of Anaphylactic Reactions in Children and Teens" on the next page for detailed steps to follow in treating anaphylaxis.

Continued on next page >

Medical Management of Vaccine Reactions in Adult Patients

All vaccines have the potential to cause an adverse reaction. In order to minimize adverse reactions, patients should be carefully screened for contraindications and contraindications before vaccine is administered. Even with careful screening, reactions may occur. These reactions can vary from trivial and inconvenient (e.g., soreness, itching) to severe and life threatening (e.g., anaphylaxis). If reactions occur, staff should be prepared with procedures for their management. The table below describes procedures to follow if various reactions occur.

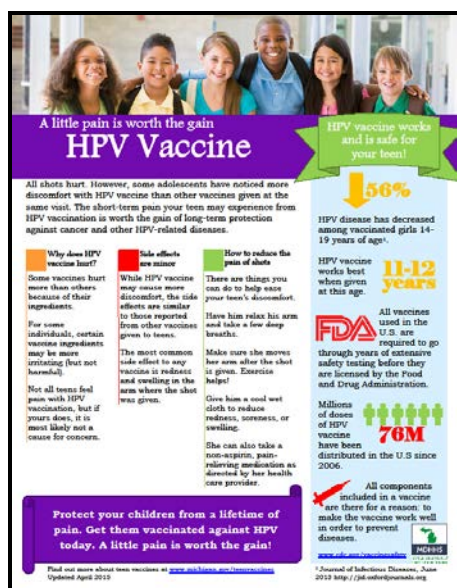
REACTION	SYMPTOMS	MANAGEMENT
Localized	Soreness, redness, itching, or swelling at the injection site	Apply a cold compress to the injection site. Consider giving an analgesic (pain reliever) or antipruritic (anti-itch) medication.
	Slight bleeding	Apply an adhesive compress over the injection site.
	Continuous bleeding	Place thick layer of gauze pads over site and maintain direct and firm pressure; raise the bleeding injection site (e.g., arm) above the level of the patient's heart.
Psychological fright and syncope (fainting)	Fright before injection is given	Have patient sit or lie down for the vaccination.
	Extreme pallor, sweating, weakness of the hands and feet, nausea, light-headedness, dizziness, weakness, or visual disturbances	Have patient lie flat or sit with head between knees for several minutes. Loosen any tight clothing and maintain an open airway. Apply cool, damp cloths to patient's face and neck.
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Anaphylaxis	Sudden or gradual onset of generalized itching, swelling (hives), or urticaria (hives), angioedema (swelling of the lips, face, or throat), severe bronchospasm (difficulty breathing), shortness of breath, wheez, abdominal cramping, or cardiovascular collapse	See "Emergency Medical Protocol for Management of Anaphylactic Reactions in Adults" on the next page for detailed steps to follow in treating anaphylaxis.

- Standing Orders (for HPV, Meningococcal and Tdap for adolescents and adults – SpartanNash specific)
- How to Process Multiple Doses of Vaccine in the SpartanNash Pharmacy System
- HPV Billing Cheat Sheet

**HPV Vaccination Pilot Project
Billing for HPV Vaccines**

- Blue Care Network**
 - Coverage good for age 11 to 26
 - Can bill for any member carrying medical coverage (they do not need to have BCN pharmacy coverage)
 - BIN: 610014 with or without PCN: MEDICARE
 - Cardholder ID: Run like any regular ID, without the alpha prefix
 - Group #: MBONR (commercial) or BCRNPD (Medicare advantage)
 - DUR/PPS segment: Professional Service Code (440-45) MA
 - Pricing segment: Incentive Amount Submitted (field 438-43) 19
- Blue Cross Blue Shield "Pharmacy Benefit"**
 - Our SpartanNash group (group # 71576) has been selected to participate in a vaccine pilot program by BCBS of MI. The purpose of the program is to allow for vaccine billing directly online as a pharmacy benefit. This pilot program will replace that process and allow us to bill the vaccines below to BCBS of Michigan like any other pharmacy claim. This will affect all employees/spouses/family members covered by SpartanNash BCBSM insurance. We can bill BCBS of Michigan (BIN: 610014 / No PCN) for any vaccine listed below. Any claim for a Non-Spartan BCBSM member should be sent to Alliant as a medical claim. For medical billing, you are required to verify the patient has vaccine coverage before billing Alliant. See #2 below.
 - Coverage good for age 11 to 26
 - SpartanNash Employee/Spouse/Family Member with Spartan Insurance:
 - TP Plan: "BCBS of MICHIGAN"
 - BIN: 610014 PCN: n/a
 - Submit to Medco like any other pharmacy claim
 - DUR/PPS segment: MA
 - Pricing segment: Incentive Amount Submitted (field 438-43) 19
- Blue Cross Blue Shield of Michigan "Medical Benefit"**
 - BCBS of MICHIGAN considers vaccinations a medical benefit and require an electronic CMS 1500 form be sent for medical billing. Alliant completes the electronic CMS 1500 forms for us ("BCBS – MEDICAL" BIN: 04746). Before billing Alliant, Patient benefits MUST be verified by calling BCBS's CAREN (Computer Assisted Response Environment Network) at 1-800-944-8925.
 - "Reminder" if a service is provided and it's not covered or the patient owes for any reason, the patient will receive a bill from SpartanNash in the mail.
 - Calling CAREN:
 - When asked for a Provider ID #: your BCBS Vaccine Pin # - See attached table
 - When asked what kind of service you provide say: Other Services
 - Will then prompt for
 - Member's contract number
 - Member's date of birth
 - First 5 letters of patient name
 - CAREN will state some contract information

- HPV and Pain Flyer (available from Michigan Department of Health and Human Services [MDHHS])



- HPV Vaccination Pilot Project Screening Tool Q & A Tool Guide: Ages 11-17 and Ages 18-26 – These guides walk through counseling points and recommendations based upon how respondents answer questions on the screening tool.

**HPV Vaccination Pilot Project
Screening Tool Q & A Guide - Ages 11-17**

Question 1: Do you have more than one child in the age group 11-17?

Question 2: How old is the child you are filling out this assessment for?

Question 3: Has your child had the meningococcal shot?

Question 4: Has your child started the HPV (Cervarix® or Gardasil®) shot series?

Question 5: Has your child had his/her tetanus, diphtheria and pertussis (whooping cough) shot?

Question 6: Is your child up-to-date on all of his/her childhood shots (recommended for ages 0 to 10)?

Question 7: If you answered "Don't Know" to any of the above questions, would you like us to check MCIR?

Question 8: Has your child ever fainted after any vaccination?

Question 9: Do you have any specific questions about immunizations for the pharmacist today?

**HPV Vaccination Pilot Project
Screening Tool Q & A Guide - Ages 18-26**

Question 1: Are you between the ages of 18 and 26?

Question 2: Are you currently enrolled in a college or university and living on campus?

Question 3: Have you had the meningococcal shot?

Question 4: Have you started the HPV (Cervarix® or Gardasil®) shot series?

Question 5: Have you ever had a tetanus, diphtheria and pertussis (Tdap) shot?

Question 6: Have you had a tetanus and diphtheria (Td) shot in the past 10 years?

Question 7: Do you come in contact with infants or small children or are you currently pregnant?

Question 8: If you answered "Don't Know" to any of the above questions, would you like us to check MCIR?

Question 9: Have you ever fainted after any vaccination?

Question 10: Do you have any specific questions about immunizations for the pharmacist today?

Tab 2: Weekly Log Forms – Blank

Week of April 18 – April 24, 2016				Weekly record for HPV Grant project									
	Number of surveys (with info sheets) distributed		Number of returned surveys		HPV Vaccine Outcomes Details								
	Age 11-17	Age 18-26	Age 11-17	Age 18-26	Pt. Age	Gender	# in Series			Outcome			
						M	F	1	2	3	Administered	Referred	Referral Reason
Monday	 				18		X		X		X		
Tuesday					11	X		X				X	Not covered
Wednesday	These 2 columns are for surveys DISTRIBUTED		These 2 columns are for surveys RETURNED		This section of the form is for vaccination ADMINISTRATION or REFERRAL								
Thursday													
Friday													
Saturday													
Sunday													
Weekly Totals	23	10	4	8									

Tab 3: Screening tool Ages 11-17

SpartanNash **M P A**
Immunization Assessment Version #3 - Age 11-17
 Please take a moment to answer the following questions for a free immunization assessment for your adolescent child.

Adolescent Vaccines

- Do you have a child in the age group 11-17?
 Yes ___ No ___
 If no, thank you for your time, please return the survey.
 If yes, please fill this out for one child. We would be happy to provide additional copies for each of your children in this age group.
- How old is the child you are filling out this assessment for?
 Age _____
- Has your child had the meningococcal shot?
 Yes, age at vaccination _____ No ___ Don't Know ___
- Has your child started the HPV (Cervarix® or Gardasil®) shot series?
 Yes, # doses _____ No ___ Don't Know ___
- Has your child had their Tdap - tetanus, diphtheria and pertussis (whooping cough) - shot?
 Yes, age at vaccination _____ No ___ Don't Know ___

General Immunization questions


- Is your child up to date on all of his/her childhood shots (recommended for age 0 to 10)?
 These include multiple doses of Hepatitis B, Hepatitis A, MMR (measles, mumps and rubella), Varicella (chickenpox) and polio.
 Yes ___ No ___ Don't Know ___
- If you answered "Don't Know" to any of the above questions and your child is from Michigan, would you like us to check the Michigan immunization registry, where all childhood vaccines given in Michigan are required to be reported?
 Yes ___ No ___
- Has your child ever fainted after any vaccination?
 Yes ___ No ___
- Do you have any specific questions about immunizations for the pharmacist today?
 Yes ___ No ___
 If yes, please write them here: _____

For Pharmacy Use Only Did you check MCR for this patient? <input type="checkbox"/> Yes <input type="checkbox"/> No Which vaccinations were given today? <input type="checkbox"/> None <input type="checkbox"/> HPV <input type="checkbox"/> Tdap <input type="checkbox"/> Meningococcal <input type="checkbox"/> Other _____ Month <input type="checkbox"/> April <input type="checkbox"/> May <input type="checkbox"/> June <input type="checkbox"/> July Store <input type="checkbox"/> 137 <input type="checkbox"/> 254 <input type="checkbox"/> 265 <input type="checkbox"/> 1523 <input type="checkbox"/> 1580 <input type="checkbox"/> 1586 <input type="checkbox"/> 1587 <input type="checkbox"/> 1922 <input type="checkbox"/> 1975 <input type="checkbox"/> 1990	Pharmacist Initials _____ Technician Initials _____
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Tab 4: Patient Information Ages 11-17

TEEN VACCINES

INFORMATION FOR PARENTS





Meningococcal Vaccines (MCV, MenB)	Adolescent Catch-Up	Tetanus, Diphtheria, Pertussis (Tdap)	Human Papillomavirus (HPV)
<p>Meningococcal vaccines protect you against meningitis, which affects the brain and spinal cord.</p> <p>If you contract meningitis, it can cause brain damage, severe disabilities or death.</p> <p>Common symptoms include a fever, rash, headache, or stiff neck.</p> <p>It is spread through close contact with an infected person, such as coughing, kissing, and sharing food or drinks. This disease is easily spread.</p> <p>MCV is given at 11-12 years of age with a second dose at 16. MenB is given at 16-18 years of age in a series of doses. If you have not received these vaccines before you get your diploma, talk to your health care provider about catch-up.</p>	<p>Many vaccines are given during childhood to give you life-long protection against diseases.</p> <p>If you have not received all of the below vaccines, it is not too late!</p> <p>3 doses of hepatitis B vaccine (Hep B)</p> <p>2 doses of hepatitis A vaccine (Hep A)</p> <p>2 doses of measles, mumps, rubella vaccine (MMR)</p> <p>2 doses of varicella (chickenpox) vaccine</p> <p>At least 3 doses of polio vaccine (IPV or OPV)</p> <p>Flu vaccine every year</p> <p>These vaccines are important, especially if you plan to travel. You need all doses for full protection.</p>	<p>Tdap vaccine protects you against pertussis (whooping cough), diphtheria, and tetanus.</p> <p>Tetanus causes painful tightening of the muscles and is very serious. It is found in soil and enters the body through a cut or wound.</p> <p>Diphtheria can make you unable to breathe or move body parts. It is spread by coughing or sneezing.</p> <p>Pertussis can cause severe coughing and choking, making it difficult for you to breathe or eat. It is spread by coughing, sneezing or close contact with an infected person.</p> <p>Tdap vaccine is usually given at the 11-12 years of age. However, anyone who has not had Tdap vaccine needs a dose.</p>	<p>HPV vaccine protects against cervical cancer in women and genital warts in men and women. It will also protect you against several other cancers.*</p> <p>HPV is a common infection transmitted by skin-to-skin contact during sexual activity. Even if you do not have sex, you can still get HPV. HPV infection often has no symptoms so you could have it and not know.</p> <p>The best time to get HPV vaccine is at 11-12 years of age, well before sexual activity starts. However, if you missed your doses, you should still get the vaccine through 26 years of age.</p> <p>This vaccine is very effective against several types of HPV and works best if you get all three doses prior to exposure.</p>

MMR and MMR2 are required by law (MSL 26C-102a) for students and make available to schools information on meningococcal and HPV vaccines. MMR2 is also required (MSL 26C-102b) for newly enrolled students. For more information on HPV educational materials, and encourage schools to make them available to parents.

*Other vaccines include anal, penile, vaginal, and rectal. Updated October 23, 2015

Tab 5: Screening tool Ages 18-26

Immunization Assessment Version #4 - Age 18-26

Please take a moment to answer the following questions for your free personalized immunization assessment.

Meningitis and HPV

- Are you between the ages of 18 and 26?
Yes ☐ No ☐
- Are you currently enrolled in a college or university and living on campus?
Yes ☐ No ☐
- Have you had the meningococcal shot?
Yes, date No ☐ Don't Know ☐
- Have you started the HPV (Cervarix® or Gardasil®) shot series?
Yes, # doses received No ☐ Don't Know ☐

Tetanus, diphtheria and pertussis (whooping cough)

- Have you ever had a tetanus, diphtheria and pertussis (Tdap) shot?
Yes, date No ☐ Don't Know ☐
- Have you had a tetanus and diphtheria (Td) shot in the past 10 years?
Yes, date No ☐ Don't Know ☐
- Do you come in contact with infants or small children or are you currently pregnant?
Yes ☐ No ☐

General immunization questions

- If you answered "Don't Know" to any of the above questions and you are from Michigan, would you like us to check the Michigan immunization registry for you?
Yes ☐ No ☐
- Have you ever fainted after any vaccination?
Yes ☐ No ☐
- Do you have any specific questions about immunizations for the pharmacist today?
Yes ☐ No ☐
If yes, please write them here: _____

For Pharmacy Use Only

Did you check MCIR for this patient? ☐ Yes ☐ No

Which vaccinations were given today? ☐ None ☐ HPV ☐ Tdap ☐ Meningococcal ☐ Other _____

Month ☐ April ☐ May ☐ June ☐ July

Store ☐ 137 ☐ 254 ☐ 265 ☐ 1523 ☐ 1580 ☐ 1586 ☐ 1587 ☐ 1922 ☐ 1975 ☐ 1990


Pharmacist Initials _____
Technician Initials _____

Tab 6: Patient Information Ages 18-26

HPV* Vaccine

A Guide for Young Adults

* human papillomavirus



HPV is a very common virus that can lead to:

- Cancers of the mouth and throat
- Cancer of the cervix
- Cancer of the penis, vagina, vulva, or anus
- Genital warts

HPV vaccine can prevent these!

Do I really need HPV vaccine? Yes!
You should get HPV vaccine because it can prevent some types of cancer and genital warts.

Do I need it if I haven't had sex yet? Yes!

- You don't have to have sex to catch HPV, but sex increases your risk.
- You can get HPV by skin-to-skin intimate contact.
- People can get and spread HPV without knowing it.
- It's best to get vaccinated before you ever have sex.

Should I get HPV vaccine if I've already had sex? Yes!
You still need to get vaccinated even if you have had sex. The vaccine provides a lot of protection.

Why do I need 3 shots?
You need 3 HPV shots to be fully protected.

I didn't get the vaccine at age 11 or 12. Should I get it now? Yes!
HPV vaccination is recommended for people ages 9 through 26. Even though it is ideal to get HPV vaccine as a preteen, it is still highly effective in teens and young adults.

Is HPV vaccine safe? Yes!

- Millions of doses of HPV vaccine have been given without any problem.
- You may get a sore arm.
- Occasionally, a few people faint, so sit for 15 minutes after getting the vaccine.

Make sure you get all 3 HPV shots. Complete your series!

When Should I Get HPV Vaccine?
Have your healthcare provider fill in this chart about when you should be vaccinated.

VACCINE DOSE	RECOMMENDED	DATE DOSE GIVEN OR DUE
#1	For people ages 9–26 years	
#2	1–2 months after vaccine dose #1	
#3	At least 6 months after vaccine dose #1	

For more information on vaccines for teens and young adults, visit www.vaccineinformation.org/teens or www.vaccineinformation.org/adults

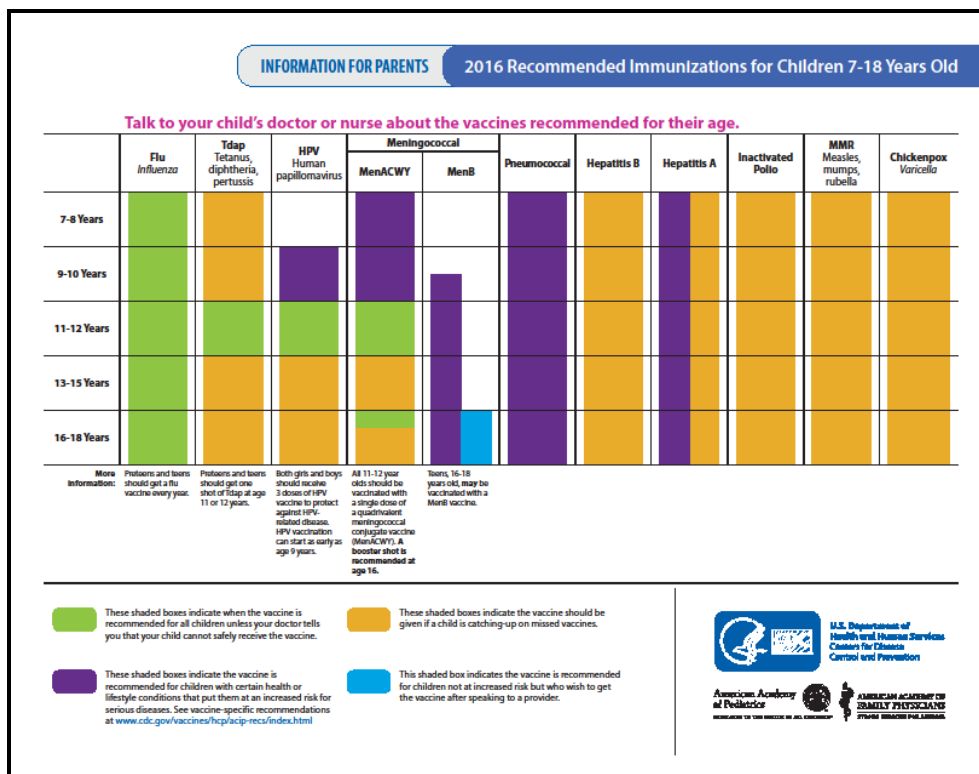
Adapted with permission from the American Pediatric Association

Immunization Action Coalition

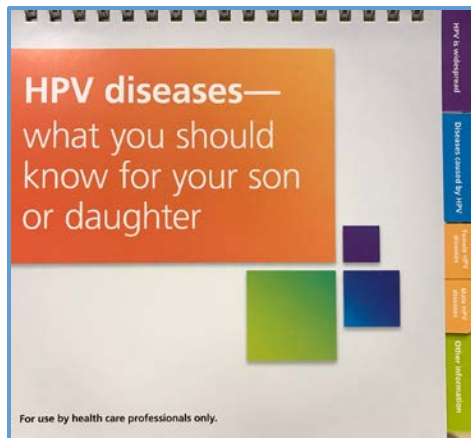
Saint Paul, Minnesota • 651-647-9009 • www.immunize.org • www.vaccineinformation.org

National content created by the Centers for Disease Control and Prevention
www.immunize.org/cdc/4/p4231.pdf • Item #4231 (2/15)

Tab 7: Immunization Schedules (laminated versions for children and adults available from Immunization Action Coalition plus a one-page patient-friendly version)



Tab 8: Talking with Patients Flip Chart (provided by Merck)



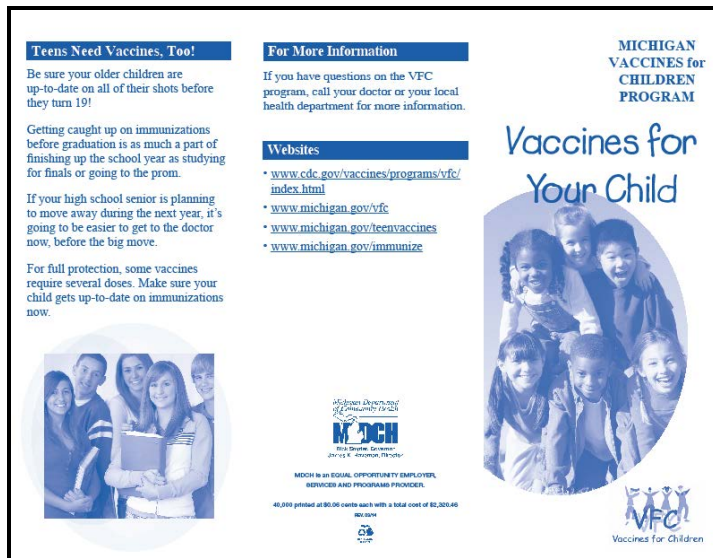
Tab 9: Brochure – Protect Preteens (available from MDHHS)



Tab 10: Brochure – HPV Vaccination (available from MDHHS)



Tab 11: Brochure – Vaccines for Children (available from MDHHS; pharmacists were given address labels with the location of the nearest health department to place on this brochure if they needed to refer patients to a VFC provider)



Tab 12: Vaccine Package Inserts (from the manufacturers for Boostrix[®], Gardasil[®] 9 and Menactra[®])

Tab 13: Weekly Log Forms – Completed (used for storing records until sent to MPA for data analysis)

Tab 14: Screening Tools – Completed (used for storing records until sent to MPA for data analysis)

Appendix C. Pilot Pharmacist Debrief Questions

1. In your opinion, what was **most valuable** part of participating in the HPV pilot program?
2. What kind of **impact** do you think you had **on your patients and community** as part of this project?
3. What was the **most challenging** aspect of offering HPV vaccination in your pharmacy?
4. What **other challenges** did you experience?
5. **How would you describe the majority of your patient population** (e.g., mostly Medicaid, mostly older adult, etc.)?
 - a. How did this affect the pilot?
6. Did you ever experience **patient resistance** to talking about vaccines in general?
 - a. About HPV specifically?
 - b. What comments did you hear?
 - c. Were they from parents or patients?
7. Did you follow the suggested **workflow**?
 - a. If not, what did you change and why?
 - b. What worked well about this process?
 - c. What did not work well?
8. Do you feel like you received adequate **training as the pharmacy manager**?
 - a. Which training session did you participate in (live or online)?
 - b. What could we have done better to prepare you?
9. Do you feel like your **staff** received adequate **training**?
 - a. What could we have done better to prepare them?
10. Do you feel like you had **adequate staffing** to fully participate in the pilot project?
 - a. How do you think staffing affected your ability to participate in the pilot?
11. Did you experience any **staff resistance** to the pilot project (e.g., staff unwilling to discuss HPV with patients)?
 - a. If so, how do you think that affected the pilot?
12. Do you have any suggestions to improve the **screening tool**?
13. Did you use the **materials box**?
 - a. What materials did you find most useful?
 - b. Can you identify other materials you would have liked in the box?
14. Did you post the **HPV posters**?
 - a. Did they stay up the whole time?
 - b. Did anyone ask about them?
15. Ignoring potential business competition, **would you recommend that other pharmacies provide HPV vaccinations to patients**?
 - a. Why or why not?
16. Any **other comments** about anything related to the grant process?

Appendix D. Advisory Committee Materials

Advisory Committee Participant Email Invitation

Greetings!

Michigan Pharmacists Association (MPA) has received a grant from the American Cancer Society to study integrating community pharmacies into healthcare efforts to increase HPV vaccination and series completion rates in adolescents and young adults. The grant period runs from January through June of 2016.

We cordially invite you to participate and share your expertise and perspectives as a member of MPA's 2016 HPV Vaccination Roundtable Advisory Committee. The purpose of the Committee is to provide input and suggestions that will help us obtain valuable information through this grant project. We are gathering a diverse group of stakeholders including physicians, pharmacists, industry representatives, public health officials and parents to solicit different opinions and perspectives on HPV vaccination as well as to discuss opportunities and challenges related to providing HPV immunizations in community pharmacies.

MPA's 2016 HPV Vaccination Roundtable Advisory Committee will have one live meeting (see details below) to get the project started and two follow up virtual meetings for additional input and progress updates.

Live Meeting

Date: Monday, February 8, 2016

Time: 12:00 – 3:00 p.m. (lunch will be provided)

Location: SpartanNash Corporate Office, Lake Michigan Conference Room

Address: 850 76th Street S.W., Byron Center, MI 49315

**Note: We can make arrangements to have virtual meeting capabilities if necessary for individuals who cannot attend in person.*

If you are personally unable to attend the meeting but know someone who would be interested in participating on our Advisory Committee, please respond to this email with his or her contact information so I may contact them personally.

Additional information will be provided to everyone who accepts the invitation to participate in MPA's 2016 HPV Vaccination Roundtable Advisory Committee prior to the meeting. Pre-meeting materials will provide additional details about the grant, expectations of Committee members and the desired outcomes from the live meeting.

Please click "Register for Meeting" above or follow this link to confirm or decline your participation in the Advisory Committee. The deadline for responding to this invitation is Monday, February 1, 2016.

Thank you for your consideration. We hope you are interested in participating. Please contact me if you have any questions.

Sarah M. Barden, Pharm.D., M.B.A

MPA/PSI Executive Fellow

Michigan Pharmacists Association

Pharmacy Services, Inc.

408 Kalamazoo Plaza

Lansing, MI 48933

Advisory Committee Meeting Details Email

Greetings!

Thank you so much for agreeing to serve on Michigan Pharmacists Association's 2016 HPV Vaccination Roundtable Advisory Committee. We are very excited about our live meeting on Monday, February 8th!

Attached are two important documents for your review prior to the meeting.

1. 2016-02-08 Live Meeting Agenda.FINAL.docx – document with details about meeting logistics, objectives, preparatory questions, and the agenda
2. IAC-Q&A-PreReading.pdf – short summary document from the Immunization Action Coalition about HPV vaccination

Please let me know if you have any questions or concerns prior to Monday. I can also be reached on my cell phone at 434-258-6321.

We look forward to seeing you there.

Advisory Committee Meeting Agenda

MPA'S 2016 HPV VACCINATION ROUNDTABLE ADVISORY COMMITTEE MEETING

Monday, February 8, 2016 – 12:00 p.m. – 3:00 p.m.

Lake Michigan Room, SpartanNash Corporate Headquarters,
Grand Rapids, MI

BACKGROUND & PREPARATION

Introduction to Grant Project and Advisory Committee

Michigan Pharmacists Association (MPA) has received a grant from the American Cancer Society to study integrating community pharmacies into healthcare efforts to increase Human Papillomavirus (HPV) vaccination and series completion rates in adolescents and young adults. The intent of the grant is to work towards building an HPV immunization neighborhood and to document opportunities and barriers to success. We are pursuing several activities as part of the grant:

- Establishing the MPA 2016 HPV Vaccination Roundtable Advisory Committee to utilize their expertise throughout the project
- Implementing adolescent HPV vaccination pilot programs in 10 grocery-store community pharmacies
- Assessing different stakeholder groups (pharmacists, other healthcare providers, patients and parents) for opinions about HPV vaccination in community pharmacies
- Conducting education and outreach for various stakeholders

Your active participation in MPA's 2016 HPV Vaccination Roundtable Advisory Committee will provide valuable input by sharing your expertise and perspectives. Our diverse group of stakeholders includes physicians, pharmacists, industry representatives, public health officials and parents. Each individual will contribute unique opinions and perspectives on HPV vaccination and challenges related to providing HPV immunizations in community pharmacies.

Meeting Objectives

- To develop a comprehensive list of barriers and obstacles to implementing adolescent HPV vaccinations in community pharmacies

- To brainstorm creative ideas for overcoming identified barriers and obstacles

Background Resources

- HPV Vaccine Information
 - See attached .pdf Q&A document from Immunization Action Coalition
- SWOT Analysis Introduction
 - <http://www.leadershipthoughts.com/how-to-use-a-swot-analysis/>
 - See diagram on page 4 for a quick summary

Thought Questions

To prepare for meeting discussion, each person should consider the following questions:

What is your role (e.g., physician, parent and pharmacist) in discussions around HPV vaccination?

What do you believe or have you heard that are pros and cons related to HPV vaccination?

What do you believe or have you heard that are pros and cons related to community pharmacies providing HPV vaccines?

Meeting Logistics

- Parking – Please park in the Visitor Lot next to the SpartanNash Corporate Headquarters. There is no charge for parking.
 - Address – 850 76th Street S.W., Byron Center, MI 49315
 - Corporate Phone – [\(616\) 878-2000](tel:6168782000)
- Onsite Registration – Once you enter the main entrance of the building, check in at the Registration Desk to receive your visitor pass. Someone will escort you to the meeting room.
- Lunch – Our meeting room is being used immediately prior to our meeting so participants will eat lunch while staff completes electronic setup. We appreciate your patience and understanding while facility preparation is completed.
- Contact Information – For any issues or concerns on Monday, please call Sarah Barden at 434-258-6321.

AGENDA

12:00 – 12:20 p.m.	Lunch
12:20 – 12:30 p.m.	Introductions & Roles
12:30 – 12:45 p.m.	Pros and Cons of HPV Vaccination
12:45 – 1:00 p.m.	Pros and Cons of Pharmacy-delivered HPV Vaccines for Adolescents
1:00 – 1:15 p.m.	Environmental Trends
1:15 – 1:30 p.m.	SWOT Analysis – HPV Vaccination in Physician Offices
1:30 – 1:50 p.m.	SWOT Analysis – HPV Vaccination in Community Pharmacies
1:50 – 2:10 p.m.	SWOT Analysis – Communication and Messages about HPV Vaccinations

2:10 – 2:50 p.m. Brainstorming – Overcoming Weakness and Threats

2:50 – 3:00 p.m. Wrap-up and Adjournment

SWOT ANALYSIS QUICK REFERENCE



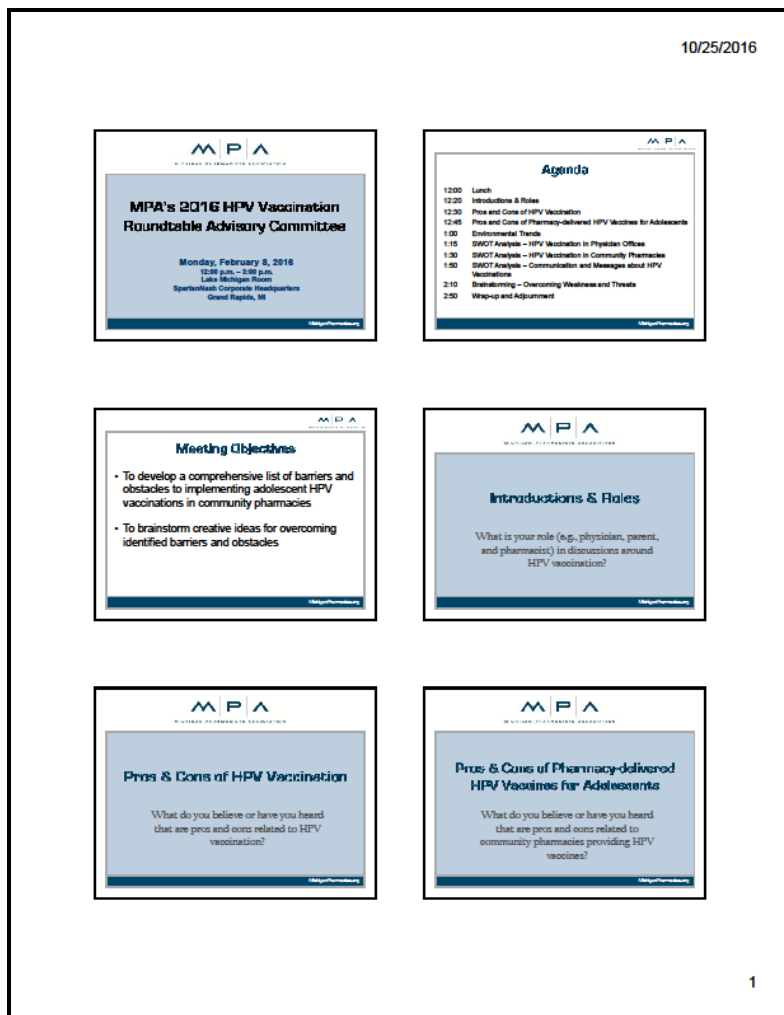
Image from <https://www.kvrwebtech.com/wp-content/uploads/2015/01/swot.png>.

The Q&A document referenced can be accessed at www.immunize.org/catg.d/p4207.pdf. Clicking on the image below will open a PDF version.



Advisory Committee PowerPoint Presentation

Clicking on the image will open a PDF version of the presentation showing six slides to a page.



Appendix D. Stakeholder Assessment Questions

HPV Vaccination in Pharmacies Survey - Healthcare Provider Version

HPV Vaccination in Pharmacies Survey - Healthcare Provider Version

Survey Introduction

This survey has 13 questions and should take approximately five to ten minutes to complete. It is designed for healthcare providers who practice in Michigan. If you are not a healthcare provider who practices in Michigan, you will not be able to complete this survey. We will send a \$5 Amazon e-gift card to the first 50 qualified survey respondents who complete the survey and provide an email address at the end of the survey.*

Please read the following information and then proceed to the next page.

Human papillomavirus (HPV) is a group of more than 150 related viruses. Each virus in the group is given a number to identify its type. More than 40 HPV types can infect the genital areas of males and females. HPV is named for the warts (papillomas) caused by some HPV types. Other HPV types can cause cervical, vaginal, and vulvar cancers in women; penile cancer in men; and anal cancer, cancer of the back of the throat (oropharynx), and genital warts in both men and women.

HPV vaccine can prevent infection with the most common types of HPV that lead to cancer and genital warts. HPV vaccine is recommended for both males and females. It is recommended to be given at 11 or 12 years of age, but it may be given beginning at age 9 through 26 years. Three doses of HPV vaccine are recommended to provide the best immune response and protection.

Some pharmacies in Michigan provide HPV vaccine to patients. The following questions ask about your opinions regarding HPV vaccine being given at the pharmacy.

Thank you for taking the time to complete this survey. Your feedback is valued. Personal, identifiable information will not be shared. Data will only be reported using aggregate measures.

*Your email address, if you choose to provide it, will be captured and used only to send you the \$5 Amazon e-gift card. Your email address will not be used for any other purpose. Please be sure you enter your email address correctly as we are not responsible for undeliverable e-gift cards. If you choose not to enter your email address, we appreciate your response but will be unable to provide a gift card.

HPV Vaccination in Pharmacies Survey - Parent Version

HPV Vaccination in Pharmacies Survey - Parent Version

Survey Introduction

This survey has 10 questions and should take approximately five to 10 minutes to complete. It is designed for parents who live in Michigan and have at least one child less than 27 years old. If you are not a parent who lives in Michigan, you will not be able to complete the survey. We will send a \$5 Amazon e-gift card to the first 50 qualified survey respondents who complete the survey and provide an email address at the end of the survey.*

Please read the following information and then proceed to the next page.

Human papillomavirus (HPV) is a group of more than 150 related viruses. Each virus in the group is given a number to identify its type. More than 40 HPV types can infect the genital areas of males and females. HPV is named for the warts (papillomas) caused by some HPV types. Other HPV types can cause cervical, vaginal, and vulvar cancers in women; penile cancer in men; and anal cancer, cancer of the back of the throat (oropharynx), and genital warts in both men and women.

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HPV Vaccination in Pharmacies Survey - Patient Version

Survey Introduction

Please read the following information and then proceed to the next page.

HPV vaccine can prevent infection with the most common types of HPV that lead to cancer and genital warts. HPV vaccine is recommended for both males and females. It is recommended to be given at 11 or 12 years of age, but it may be given beginning at age 9 through 26 years. Three doses of HPV vaccine are recommended to provide the best immune response and protection.

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HPV Vaccination in Pharmacies Survey - Pharmacist Version

Survey Introduction

Please read the following information and then proceed to the next page.

HPV vaccine can prevent infection with the most common types of HPV that lead to cancer and genital warts. HPV vaccine is recommended for both males and females. It is routinely given at 11 or 12 years of age, but it may be given beginning at age 9 through 26 years. Three doses of HPV vaccine are recommended to provide the best immune response and protection.

Thank you for taking the time to complete this survey. Your feedback is valued. Personal, identifiable information will not be shared. Data will only be reported using aggregate measures.

*Your email address, if you choose to provide it, will be captured and used only to send you the \$5 Amazon e-gift card. Your email address will not be used for any other purpose. Please be sure you enter your email address correctly as we are not responsible for undeliverable e-gift cards. If you choose not to enter your email address, we appreciate your response but will be unable to provide a gift card.

Appendix F. Healthcare Provider Outreach Materials

Healthcare Provider Outreach Letter Sample

Clicking on the image will open a PDF version of the letter sent to the targeted provider practices.



Healthcare Provider Outreach Flyer for Display Sample

Clicking on the image will open a PDF version of the flyer.



Healthcare Provider Outreach Instructions for Pharmacists

Clicking on the image will open a PDF version of the instructions, sample script and documentation form provided to the pharmacists to assist with their outreach to providers.

HPV Vaccination Roundtable Pilot Project
Provider Practice Outreach Goals and Guidelines

GOAL OF PROVIDER OUTREACH

To build HPV Immunization Neighborhoods between Pharmacists and Providers in Local Communities by:

1. Enhancing communication and relationships between pharmacists and providers in targeted practices
2. Developing a list of provider practices willing to accept patient referrals from the pharmacy for patients needing HPV vaccinations
3. Developing a list of provider practices willing to refer their patients to the pharmacy for second or third doses of the HPV vaccine (when the patient's insurance will cover the vaccine delivered in the pharmacy)

This document is a guide for HPV-related conversations with providers that must be used **ALONG WITH** the documentation form. The goal of each outreach session is to complete the documentation form in one interaction but pharmacists may contact the provider more than once if needed to collect the necessary information. You may complete the outreach sessions face-to-face or by telephone. Face-to-face communication is more effective for building relationships with other providers and is highly recommended, but, if that is not possible, a phone call resulting in a completed documentation form will accomplish the goal. **Compensation will be provided for all completed face-to-face interactions performed outside scheduled work hours.** If you choose to complete telephone interactions, those should be completed during your normally scheduled hours. A completed interaction is a completed documentation form with answers to all of the questions based on a conversation with someone knowledgeable in the provider's office that is submitted to Sarah Barden by email at Sarah@MichiganPharmacists.org or by fax at (517)-484-4893 by August 20, 2016.

Our understanding, from speaking with providers' offices, is that your first step will likely require you to speak with the office manager. The office manager is the gatekeeper of the provider's time and will determine whether you will be allowed to proceed further with the discussion. Once you connect with the office manager, you should be prepared to adapt the information being communicated as the conversation progresses. We are providing a sample script as a suggestion for an introduction to get the conversation started, but you may modify the script to make it your own.

Each pharmacy has been assigned FIVE specific practices to contact. Please make every effort to complete the interactions with all five assigned practices. You will receive five individualized documentation forms.

If you have any questions about the interactions, please contact Sarah Barden (Sarah@MichiganPharmacists.org) or Robin Curtis (Robin.Curtis@SpartanNash.com) **BEFORE** calling the provider's office.

COMPENSATION: Each pharmacy manager should devise a plan for which pharmacist(s) will complete the required interactions. **Face-to-face interactions done outside your regularly scheduled time are eligible for additional compensation.** The pharmacist who completes the face-to-face interaction will get up to 30 minutes of supplemental pay per completed interaction. This would be a maximum of 150 minutes (2.5 hours) for all five interactions. Document the time it took to complete the interaction (up to 30 minutes) on the form. If you are unable to complete all five face-to-face, please complete the remaining interactions on the phone during normal working hours.

NOTE: Speaking with the office receptionist is not sufficient. The office manager may or may not be able to answer the questions or determine if a partnership is possible. If the office manager does not have this authority, you must speak with someone who does have the authority (a provider) for the documentation to be valid.

HPV Vaccine Information for Clinicians

CDC recommends HPV vaccination for girls and boys at ages 11 or 12 years to protect against cancers caused by HPV infections. CDC encourages clinicians to recommend HPV vaccination the same way and same day they recommend other routinely recommended vaccines for adolescents.

Background

Human papillomavirus (HPV) is a very common virus that infects epithelial tissue. More than 120 HPV types have been identified. Most HPV types infect cutaneous epithelial cells and cause common warts, such as those that occur on the hands and feet. Approximately 40 HPV types infect mucosal epithelial cells on the genitals, and the mouth and throat. Although most HPV infections are asymptomatic and resolve spontaneously or become undetectable, some HPV infections can persist and lead to cancer.

Persistent infections with high-risk (oncogenic) HPV types can cause cancers of the anus, cervix, penis, vulva, and vagina, as well as the oropharynx (defined as the back of the throat, including the base of the tongue and tonsils). The most common high-risk types are 16 and 18.

Infection with low-risk (non-oncogenic) HPV types can cause genital warts and rarely laryngeal papillomas. These types can also cause benign or low-grade cervical cell abnormalities. The most common low-risk HPV types are 6 and 11.

About 79 million Americans are infected with HPV, and roughly 14 million people become infected each year, mostly occurring among teens and young adults. Almost every person who is sexually active will acquire HPV at some time in their life.

Every year in the United States, an estimated 17,600 women and 9,300 men are diagnosed with a cancer caused by HPV.

Of the women diagnosed with an HPV cancer, cervical cancer is the most common with about 11,000 women diagnosed annually in the United States; subsequently about 4,400 women die every year from cervical cancer in our country.

Of the men in the United States diagnosed with an HPV cancer, oropharyngeal cancer is the most common. Around 7,200 U.S. men each year are diagnosed with oropharyngeal cancer caused by HPV infection. HPV infection and precancerous/dysplastic lesions of the oropharynx cannot be screened for, making prevention of infection a priority.

HPV Vaccines

Three HPV vaccines have been licensed by the U.S. Food and Drug Administration (FDA) since 2006. CDC recommends these HPV vaccines for routine use among girls and boys at ages 11 or 12. HPV vaccines are administered as a 3-dose series with doses given at 0, 1-2, and 6 months.

	Bivalent/2vHPV (Cervarix)	Quadrivalent/4vHPV (Gardasil)	9-valent/9vHPV (Gardasil 9)
Manufacturer	GlaxoSmithKline	Merck	Merck
Year Licensed	October 2009 - females	June 2006 - females; October 2009 - males	December 2014 - males and females
HPV types in vaccine	16 and 18	6, 11, 16, and 18	6, 11, 16, 18, 31, 33, 45, 52, and 58
Adjuvant in vaccine	AS04: 500 µg aluminum hydroxide 50 µg 3-O-desacyl-4'-monophosphoryl lipid A	AAHS: 225 µg amorphous aluminum hydroxyphosphate sulfate	AAHS: 500 µg amorphous aluminum hydroxyphosphate sulfate
Recommended for...	<ul style="list-style-type: none">Females ages 11-12Females ages 13 through 26 who have not been previously vaccinated	<ul style="list-style-type: none">Females and males ages 11-12Females ages 13 through 26 and males ages 13 through 21 who have not been previously vaccinatedUnvaccinated males ages 22 through 26 who have sex with men or who are immunocompromised	<ul style="list-style-type: none">Females and males ages 11-12Females ages 13 through 26 and males ages 13 through 21 who have not been previously vaccinatedUnvaccinated males ages 22 through 26 who have sex with men or who are immunocompromised
Contraindicated for...	<ul style="list-style-type: none">People with hypersensitivity to latex	<ul style="list-style-type: none">People with hypersensitivity to yeast	<ul style="list-style-type: none">People with hypersensitivity to yeast

Bivalent, quadrivalent, and 9-valent HPV vaccine all protect against HPV 16 and 18, the HPV types that cause about 66% of cervical cancers and the majority of other HPV-attributable cancers in the United States. 9-valent HPV vaccine targets five additional cancer-causing types, which account for about 15% of cervical cancers (12). Quadrivalent and 9-valent HPV vaccine also protect against HPV 6 and 11, the HPV types that cause anogenital warts.

The additional five types in 9-valent HPV vaccine account for a higher proportion of HPV-associated cancers in women compared with men, and also cause cervical precancers in women. Therefore, the additional protection from 9-valent HPV vaccine will mostly benefit women.

HPV Vaccine Recommendations

HPV vaccine is routinely recommended for 11- or 12-year-old girls and boys. Any HPV vaccine can be given to girls. Either the quadrivalent or 9-valent HPV vaccine can be given to boys. Vaccination is also recommended for females ages 13 through 26 years and males ages 13 through 21 years who were not vaccinated when they were younger. Vaccination is also recommended for both men who have sex with men and men who are immunocompromised (including men with HIV infection) aged 22 through 26 years who were not vaccinated when they were younger.

Ideally, patients should be vaccinated before they are exposed to HPV. However, patients who have already been infected with one or more HPV types can still get protection from other HPV types in the vaccine that have not been acquired.

HPV vaccines can safely be given to...

- Patients with minor acute illnesses, such as diarrhea or mild upper respiratory tract infections, with or without fever.
- Women who have had an unclear or abnormal Pap test, a positive HPV test, or genital warts. However, these patients should be advised that the vaccine may not have any therapeutic effect on existing Pap test abnormalities, HPV infection, or genital warts.
- Patients who are immunocompromised, either from disease or medication. However, the immune response to vaccination and effectiveness of the vaccine might be less than in people with a normally functioning immune system.
- Women who are breastfeeding.

HPV vaccines should not be given to...

- Patients with a history of allergies to any vaccine component. Quadrivalent vaccine (4vHPV) is not recommended for people with a history of allergies to yeast. Bivalent vaccine (2vHPV) is not recommended for people with a life-threatening latex allergy.
- Patients with moderate or severe acute illnesses. In these cases, patients should wait until the illness improves before getting vaccinated.
- Pregnant women. However, the vaccine has not been linked to causing adverse pregnancy outcomes or possible side effects (adverse events) to the developing fetus.
 - If a woman is found to be pregnant after starting the HPV vaccine series, second and/or third doses should not be given until after delivery.
 - If a woman receives HPV vaccine and later learns that she is pregnant, there is no reason to be alarmed.
 - 9vHPV exposure during pregnancy should be reported to the Merck Pregnancy Registry at 1-800-986-8999.
 - 4vHPV exposure during pregnancy can be reported to Merck at 1-877-888-4231.
 - 2vHPV exposure during pregnancy can be reported to GlaxoSmithKline at telephone 1-888-825-5249.
 - 2vHPV exposure during pregnancy can be reported to GlaxoSmithKline at telephone 1-888-825-5249.

HPV Vaccine Safety

HPV vaccines are very safe. Scientific research shows the benefits of HPV vaccination far outweigh the potential risks. Like all medical interventions, vaccines can have some side effects. More than 80 million doses of HPV vaccine have been distributed since the vaccine was introduced in 2006. The most common side effects associated with HPV vaccines are mild, and include pain, redness, or swelling in the arm where the shot was given.

All vaccines used in the United States, including HPV vaccines, are required to go through years of extensive safety testing before they are licensed by the U.S. Food and Drug Administration (FDA). During clinical trials conducted before they were licensed:

- 9-valent HPV vaccine was studied in more than 15,000 males and females
- Quadrivalent HPV vaccine was studied in more than 29,000 males and females
- Bivalent HPV vaccine was studied in more than 30,000 females

Each HPV vaccine was found to be safe and effective.

Fainting (syncope) can occur after any medical procedure, including vaccination. Recent data suggest that syncope after any vaccination is more common in adolescents. Adolescents and adults should be seated or lying down during vaccination. Providers are encouraged to observe patients in seated or lying positions for 15 minutes after vaccination. This is to prevent any injuries that could occur from a fall during a syncopal event.

HPV Vaccine Effectiveness

The HPV vaccine works extremely well. In the four years after the vaccine was recommended in 2006 in the United States, quadrivalent type HPV infections in teen girls decreased by 56% and decreases in prevalence have also been observed in women in their early 20s. Research has also shown that fewer teens are getting genital warts since HPV vaccines have been in use in the United States. Decreases in vaccine-type prevalence, genital warts, and cervical dysplasia have also been observed in other countries with HPV vaccination programs.

There are no data to suggest HPV vaccines will treat existing diseases or conditions caused by HPV. However, people can still get protection from HPV types in the vaccine that have not been acquired.

Cervical cancer screening is recommended for women beginning at age 21 years and continuing through age 65 years. Women who have received the HPV vaccine series should still be screened for cervical cancer beginning at age 21 years, in accordance with currently published cervical cancer screening guidelines.

Duration of Vaccine Protection

Studies suggest that HPV vaccines offer long-lasting protection against HPV infection and therefore disease caused by HPV infection. Studies of the bivalent and quadrivalent vaccines have followed vaccinated individuals for eight to ten years and have found no evidence of protection decreasing over time. Duration of protection provided by HPV vaccination will continue to be studied.

HPV Vaccine Administration

HPV vaccines should be administered as a 3-dose series intramuscular injections given at 0, 1-2, and 6 months. The third dose should follow the first dose by at least 24 weeks.

While there is a minimum interval in the dosing schedule, there is no maximum interval. There is no reason to restart the vaccine series if the HPV vaccine schedule is interrupted; patients who have exceeded the minimum interval for the next dose by months or even years, may be given the next dose needed.

Vaccination of females is recommended with bivalent, quadrivalent (as long as this formulation is available), or 9-valent HPV vaccine. Vaccination of males is recommended with quadrivalent (as long as this formulation is available) or 9-valent HPV vaccine.

If vaccination providers do not know or do not have available the HPV vaccine product previously administered, or are in settings transitioning to 9-valent HPV vaccine, any available HPV vaccine product may be used to continue or complete the series for females for protection against HPV 16 and 18; 9vHPV or 4vHPV may be used to continue or complete the series for males. There are no data on efficacy or immunogenicity of fewer than 3 doses of 9vHPV.

HPV vaccine can safely be administered at the same visit as other vaccines recommended at ages 11 or 12 years, such as Tdap vaccine, quadrivalent meningococcal conjugate vaccine, and influenza vaccine. Administering all indicated vaccines at a single visit at ages 11 or 12 years increases the likelihood that patients receive their vaccinations on schedule.

As mentioned previously, patients should be observed for 15 minutes after receiving any shot, including HPV vaccine.

Paying for HPV Vaccine

As with all vaccines recommended by the Advisory Committee on Immunization Practices (ACIP), HPV vaccines are covered by insurance. For patients that need assistance paying for HPV vaccine, the Vaccines for Children (VFC) program may be able to help. VFC provides vaccines for children ages 18 years and younger who are uninsured, Medicaid-eligible, or American Indian/Alaska Native. Learn more about the VFC program at www.cdc.gov/Features/VFCprogram/.

Related Resources

[Epidemiology and Prevention of Vaccine-Preventable Diseases \(Pink Book\) 2015.](#)

Markowitz L, Dunne EF, Saraiya M, Curtis RC, Gee J, Bocchini JA, et al. [Human papillomavirus vaccination: recommendations of the Advisory Committee on Immunization Practices \(ACIP\)](#). MMWR. 2014 Aug 29; 63(rr05):1-30.

Give a strong recommendation for HPV vaccine to increase uptake!

Dear Colleague:

The Michigan Department of Health and Human Services (MDHHS), along with leading health professional organizations serving adolescents and adults, are asking you to vaccinate your patients against human papillomavirus (HPV).

HPV vaccine is cancer prevention. However, HPV vaccine is underutilized in the United States and Michigan, despite the overwhelming evidence of its safety and effectiveness. HPV vaccination rates are far below rates of other routinely recommended vaccines for adolescents.

Missed opportunities data suggest that providers are not giving strong recommendations for HPV vaccine when patients are 11 or 12 years old. The health care provider recommendation is the single best predictor of vaccination. Recent studies show that a patient who receives a provider recommendation is 4 to 5 times more likely to receive the HPV vaccine.^{1,2}

What you say, and how you say it, matters. A half-hearted recommendation to a patient may not only result in the patient leaving your practice unvaccinated, but may lead the patient to believe that HPV vaccine is not as important as the other adolescent vaccines.

The undersigned organizations hope that this letter, which provides key facts about HPV vaccine safety and effectiveness, will lead you to recommend HPV vaccination – firmly and strongly – to your adolescent and adult patients. Your recommendation will reflect your commitment to prevent HPV-associated cancers and disease in Michigan.

HPV-associated disease³

- Approximately 79 million persons in the United States are infected with HPV, and approximately 14 million people in the United States will become newly infected with HPV each year.
- Each year, an estimated 26,000 cancers are attributable to HPV; about 17,000 in women and 9,000 in men.
- Cervical cancer is the most common HPV-associated cancer among women, and oropharyngeal cancers are the most common among men.

Despite these statistics, the use of HPV vaccination to prevent HPV infection is limited and immunization rates remain low.

Prevention of HPV-associated disease by vaccination

- Three vaccines (bivalent/2vHPV, quadrivalent/4vHPV, and 9vHPV) are available to protect against HPV 16 and 18, types that cause about 66% of cervical cancers and the majority of other HPV-attributable cancers in the United States. 9vHPV protects against five additional types (31, 33, 45, 52, and 58), which account for about 15% of cervical cancers. 4vHPV and 9vHPV also protect against HPV 6 and 11, types that cause anogenital warts.⁴
- The Advisory Committee on Immunization Practices (ACIP) recommends routine vaccination of girls age 11 or 12 years with the 3-dose series of any HPV vaccine and routine vaccination of boys age 11 or 12 years with the 3-dose series of 4vHPV or 9vHPV.⁴
- The ACIP also recommends vaccination for females through age 26 years and for males through age 21 years who were not vaccinated when they were younger. Males aged 22 through 26 years may be vaccinated.⁴

Give a strong recommendation for HPV vaccine to increase uptake!

- Administer HPV vaccine beginning at age 9 years to children and youth with any history of sexual abuse or assault who have not initiated or completed the 3-dose series.¹²
- Recommendations for use of HPV vaccine are based on age and not history of prior infection. Routine HPV vaccination is recommended for females and males regardless of their history of prior HPV infection. The chance of being infected with all nine vaccine-preventable strains of HPV included in the vaccine is very low, so there will most likely be benefit from the vaccine even in people with prior HPV infection.⁵

In Michigan, as of December 31, 2015, only 31.0% of teenage girls and 20.4% of teenage boys ages 13–17 years had received 3 doses of HPV vaccine.⁶

Additionally, four out of ten adolescent girls and six out of ten adolescent boys haven't started the HPV series (in Michigan and the U.S.).⁷

In 2013, in the U.S., 36.9% of women and 5.9% of men aged 19–26 years reported receiving 1 or more doses of HPV vaccine.⁸

Safety of HPV vaccine

- From June 2006 to March 2014, approximately 67 million doses of Gardasil were distributed in the United States.⁹
- Each HPV vaccine was closely studied in clinical trials to make sure it was safe⁹:
 - 9vHPV was studied in more than 15,000 females and males.
 - 4vHPV was studied in 29,000 females and males.
 - 2vHPV was studied in more than 30,000 females.
- These clinical trials showed HPV vaccines to be safe and effective. Each vaccine continues to be monitored for any safety problems. This monitoring is especially looking for any rare or new problems that may happen after vaccination.⁹
- Data on safety are also available from post-licensure monitoring in other countries for both vaccines and provide continued evidence of the safety of 2vHPV and 4vHPV.
- Syncope can occur among adolescents who receive any vaccines, including HPV vaccine. ACIP recommends that clinicians consider observing patients for 15 minutes after vaccination.

Regardless of a safety profile that is similar to the other adolescent vaccines, parents cite safety concerns as one of the top five reasons they do not intend to vaccinate daughters against HPV.

Efficacy of HPV vaccines

- Within 4 years of vaccine introduction, 4vHPV vaccine types (6, 11, 16, 18) prevalence declined 56% among females aged 14–19 years despite low vaccine uptake.¹⁰
- The vaccine effectiveness of at least 1 dose of 4vHPV is 82%.¹⁰
- In clinical trials of 9vHPV, efficacy with 3 doses for HPV serotype 31, 33, 45, 52 & 58 is 96.7%.⁴
- Studies suggest that HPV vaccine protection is long-lasting and there is no evidence of waning immunity. Available evidence indicates protection for at least 8–10 years and multiple cohort studies are in progress to monitor the duration of immunity.¹¹

Since the vaccine does not protect against all HPV types, it does not replace other prevention strategies, such as regular cervical cancer screening.

Give a strong recommendation for HPV vaccine to increase uptake!

What you say matters; how you say it matters even more.

Based on research conducted with parents and physicians, CDC suggests recommending the HPV vaccine series the same way you recommend the other adolescent and adult vaccines.

Parents and patients may be interested in vaccinating, yet still have questions. Taking the time to listen to questions helps you save time and give an effective response. CDC has created an excellent tip sheet to assist you in answering questions parents and patients may have about HPV vaccines. This tip sheet and many other tools on the HPV vaccine are available at <http://www.cdc.gov/hpv/hcp/index.html>.

As a healthcare provider, we urge you to improve the strength and consistency of your recommendation for HPV vaccination to your patients. Your recommendation is the number one reason why someone will get the HPV vaccine and be protected from HPV-associated cancers and disease.



Give a strong recommendation for HPV vaccine to increase uptake!

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Immunizations

- Antimicrobial Stewardship
- Ambulatory Care Pharmacy Practice
- Ambulatory Care Toolkit
- Emergency Preparedness
- Immunizations**
- Medicare Information
- Medication Therapy Management
- Michigan Residency Programs
- Patient Education Library
 - Health Observances
 - Michigan Pharmacy Week
 - That's My Pharmacist Campaign
 - Practice Toolkits
- Patient Safety Resource Center
 - Professional Resources
- Pharmacists as Providers
 - Pharmacists as Providers: For Health Care Providers
- Pharmacy Practice FAQs
- Pharmacy Practice Guidance
- Pharmacy Practice Model Initiative of Michigan



Pharmacist-Provided Immunizations

Along with managing medication therapy and educating patients on healthy lifestyle practices, certified pharmacists can also administer critical immunizations, ensuring that any treatment received will not interfere with other therapies.

The majority of American adults are inadequately vaccinated, leading to an average of 90,000 deaths each year from vaccine-preventable infections.

As the most accessible health care providers, pharmacists can help ensure that patients are up-to-date on all their immunizations, as well as answer questions and provide necessary protection from harmful diseases.

Click on the black bars below to get started with the resources you need for providing seasonal flu and other vaccines in your pharmacy, educating patients on immunizations, receiving training to provide immunizations and more.

- + Adult Immunization Standards**
- + Immunization Schedules**
- + Herpes Zoster (Shingles)**
- Human Papillomavirus (HPV)**

Pharmacy Technician Licensure

Point-of-Care Testing

Human Papillomavirus (HPV)

Human papillomavirus (HPV) is a group of more than 150 related viruses. Each virus in the group is given a number to identify its type. More than 40 HPV types can infect the genital areas of males and females. HPV is named for the warts (papillomas) caused by some HPV types. Other HPV types can cause cervical, vaginal, and vulvar cancers in women; penile cancer in men; and anal cancer, cancer of the back of the throat (oropharynx), and genital warts in both men and women

HPV vaccine can prevent infection with the most common types of HPV that can lead to cancer and genital warts. HPV vaccine is recommended for both males and females. It is routinely given at 11 or 12 years of age, but it may be given beginning at age 9 through 26 years. Three doses of HPV vaccine are recommended to provide the best immune response and protection.

- Disease Information
 - Centers for Disease Control and Prevention (CDC)
 - Immunization Action Coalition (IAC)
 - National Foundation for Infectious Diseases (NFID)
- HPV and Cancer
 - CDC
 - American Cancer Society (ACS)
 - National Cervical Cancer Coalition (NCCC)
- Vaccine Information
 - Vaccine Overview
 - ACIP Recommendation
 - Vaccine Options
 - Gardasil 9
 - Gardasil
 - Cervarix
 - "Give a Strong Recommendation" Letter to Healthcare Providers
- Talking to Patients and Parents
 - American Academy of Pediatrics: Tips and Time Savers for Talking to Patients
 - CDC: Answering Questions Parents May Have
 - American College of Obstetricians & Gynecologists: HPV FAQs
 - Children’s Hospital of Philadelphia: Questions and Answers about HPV and the Vaccine
- Patient-friendly Websites
 - CDC
 - IAC
 - Mayo Clinic
 - American Academy of Pediatrics

+ Influenza

+ Pertussis (Whooping Cough)

+ Pneumococcal Disease

+ Meningococcal Disease

+

- + Pharmacist Immunization Training
- + Immunization Documentation
- + Immunization Procedures
- + Immunization Billing and Coverage
- + Additional Immunization Resources



ADVOCACY	PRACTICE SECTIONS	PRACTICE RESOURCES	EDUCATION & EVENTS	COMMITTEES	FOR PATIENTS
Advocacy Action Center Advocacy User Profile Advocate For Pharmacy Legislative Events Michigan Pharmacy PAC Our Priorities And Talking Points Pharmacy Advocacy Response Team (PART)	Michigan Society Of Health-System Pharmacists	Antimicrobial Stewardship Ambulatory Care Pharmacy Practice Emergency Preparedness Immunizations Medicare Information Medication Therapy Management Michigan Residency Programs Patient Education Library Patient Safety Resource Center Pharmacists As Providers Pharmacy Practice FAQs Pharmacy Practice Guidance Pharmacy Practice Model Initiative Of Michigan Pharmacy Technician Licensure Point-Of-Care Testing	Annual Convention CE Requirements Events Calendar Exhibits And Sponsorship Joint Providership Program Live Programming Posttests Online CE Programs Online Book Club Pharmacy Tech Prep Online		Medication Disposal Patient Complaints Patient Safety Resource Center Pharmacists As Providers Pharmacy Careers That's My Pharmacist Campaign



MICHIGAN PHARMACISTS ASSOCIATION

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VACCINE INFORMATION STATEMENT

HPV Vaccine Gardasil®-9 (Human Papillomavirus)

What You Need to Know

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1 Why get vaccinated?

Gardasil-9 prevents many cancers caused by human papillomavirus (HPV) infections, including:

- **cervical cancer** in females,
- **vaginal and vulvar cancers** in females, and
- **anal cancer** in females and males.

In addition to these cancers, Gardasil-9 also prevents **genital warts** in both females and males.

In the U.S., about 12,000 women get cervical cancer every year, and about 4,000 women die from it. Gardasil-9 can prevent most of these cancers.

HPV infection usually comes from sexual contact, and most people will become infected at some point in their life. About 14 million Americans get infected every year. Many infections will go away and not cause serious problems. But thousands of women and men get cancer and diseases from HPV.

2 HPV vaccine

Gardasil-9 is one of three FDA-approved HPV vaccines. It is recommended for both males and females. It is routinely given at 11 or 12 years of age, but it may be given beginning at age 9 years through age 26 years for females and males.

Three doses of Gardasil-9 are recommended with the second and third dose 2 months and 6 months after the first dose.

Vaccination is not a substitute for cervical cancer screening. This vaccine does not protect against all HPV types that can cause cervical cancer. Women should still get regular Pap tests.

3 Some people should not get this vaccine

- Anyone who has had a severe, life-threatening allergic reaction to a dose of HPV vaccine should not get another dose.

Anyone who has a severe (life threatening) allergy to any component of HPV vaccine should not get the vaccine.

Tell your doctor if you have any severe allergies that you know of, including a severe allergy to yeast.

- HPV vaccine is not recommended for pregnant women. If you learn that you were pregnant when you were vaccinated, there is no reason to expect any problems for you or the baby. Any woman who learns she was pregnant when she got this HPV vaccine is encouraged to contact the manufacturer's registry for HPV vaccination during pregnancy at 1-800-986-8999. Women who are breastfeeding may be vaccinated.
- If you have a mild illness you can probably get the vaccine today. If you are moderately or severely ill, you should probably wait until you recover. Your doctor can advise you.



U.S. Department of
Health and Human Services
Centers for Disease
Control and Prevention

4 Risks of a vaccine reaction

With any medicine, including vaccines, there is a chance of side effects. These are usually mild and go away on their own, but serious reactions are also possible.

Most people who get HPV vaccine do not have any problems with it.

Mild or moderate problems following Gardasil-9

- Reactions in the arm where the shot was given:
 - Pain (about 9 people in 10)
 - Redness or swelling (about 1 person in 3)
- Fever:
 - Mild (100°F) (about 1 person in 10)
 - Moderate (102°F) (about 1 person in 65)
- Other problems:
 - Headache (about 1 person in 3)

Problems that could happen after any vaccine:

- People sometimes faint after a medical procedure, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting, and injuries caused by a fall. Tell your doctor if you feel dizzy, or have vision changes or ringing in the ears.
- Some people get severe pain in the shoulder and have difficulty moving the arm where a shot was given. This happens very rarely.
- Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at fewer than 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

As with any medicine, there is a very remote chance of a vaccine causing a serious injury or death.

The safety of vaccines is always being monitored. For more information, visit: www.cdc.gov/vaccinesafety/

To allow medical care provider(s) accurate immunization status information, an immunization assessment, and a recommended schedule for future immunizations, information will be sent to the Michigan Care Improvement Registry. Individuals have the right to request that their medical care provider not forward immunization information to the Registry.

DCH-1339b

AUTH: P. H. S., Act 42, Sect. 2126.

5 What if there is a serious reaction?

What should I look for?

- Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or behavior changes.

Signs of a **severe allergic reaction** can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would start a few minutes to a few hours after the vaccination.

What should I do?

- If you think it is a **severe allergic reaction** or other emergency that can't wait, call 9-1-1 or get the person to the nearest hospital. Otherwise, call your doctor.
- Afterward, the reaction should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor might file this report, or you can do it yourself through the VAERS web site at www.vaers.hhs.gov, or by calling **1-800-822-7967**.

VAERS is only for reporting reactions. They do not give medical advice.

6 The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling **1-800-338-2382** or visiting the VICP website at www.hrsa.gov/vaccinecompensation. *There is a time limit to file a claim for compensation.*

7 How can I learn more?

- Ask your doctor. He or she can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC): 1-888-767-4687
 - Call **1-800-232-4636 (1-800-CDC-INFO)** or
 - Visit CDC's website at www.cdc.gov/hpv

Vaccine Information Statement (Interim)
HPV Vaccine (Gardasil-9)

4/15/2015

42 U.S.C. § 300aa-26

Office Use Only



Give a strong recommendation for HPV vaccine to increase uptake!

Dear Colleague:

The American Academy of Family Physicians (AAFP), American Academy of Pediatrics (AAP), American College of Obstetricians and Gynecologists (ACOG), American College of Physicians (ACP), the Centers for Disease Control and Prevention (CDC), and the Immunization Action Coalition (IAC) are asking you to urge your patients to get vaccinated against human papilloma-virus (HPV).

HPV vaccine is cancer prevention. However, HPV vaccine is underutilized in our country, despite the overwhelming evidence of its safety and effectiveness. While vaccination rates continue to improve for the other adolescent vaccines, HPV vaccination rates have not. Missed opportunities data suggest that providers are not giving strong recommendations for HPV vaccine when patients are 11 or 12 years old. The healthcare provider recommendation is the single best predictor of vaccination. Recent studies show that a patient who receives a provider recommendation is 4–5 times more likely to receive the HPV vaccine.^{1,2}

What you say, and how you say it, matters. A half-hearted recommendation to a patient may not only result in the patient leaving your practice unvaccinated, but may lead the patient to believe that HPV vaccine is not as important as the other adolescent vaccines. The undersigned organizations hope that this letter, which provides key facts about HPV vaccine safety and effectiveness, will lead you to recommend HPV vaccination – firmly and strongly – to your patients. Your recommendation will reflect your commitment to prevent HPV-associated cancers and disease in the United States.

HPV-associated disease³

- Approximately 79 million persons in the United States are infected with HPV, and approximately 14 million people in the United States will become newly infected with HPV each year.
 - Each year, an estimated 26,000 cancers are attributable to HPV; about 17,000 in women and 9,000 in men.
 - Cervical cancer is the most common HPV-associated cancer among women, and oropharyngeal cancers are the most common among men.
- *Despite these statistics, the use of HPV vaccination to prevent HPV infection is limited and immunization rates remain low.*

Prevention of HPV-associated disease by vaccination

- Two vaccines (bivalent/HPV2 and quadrivalent/HPV4) are available to protect against HPV 16 and 18, the types that cause most cervical and other anogenital cancers, as well as some oropharyngeal cancers.

- The Advisory Committee on Immunization Practices (ACIP) recommends routine vaccination of girls age 11 or 12 years with the 3-dose series of either HPV vaccine and routine vaccination of boys age 11 or 12 years with the 3-dose series of HPV4.
 - Vaccination is recommended for females through age 26 years and for males through age 21 years who were not vaccinated when they were younger.
- *In 2012, only 33% of teenage girls ages 13–17 years had received 3 doses of HPV vaccine.⁴ This was the first year in which HPV vaccination coverage rates did not increase from the prior year.*

Safety of HPV vaccine

- More than 175 million doses of HPV vaccine have been distributed worldwide and 57 million doses have been distributed in the United States.
 - More than 7 years of post-licensure vaccine safety monitoring in the United States provide continued evidence of the safety of HPV4. Data on safety are also available from post-licensure monitoring in other countries for both vaccines and provide continued evidence of the safety of HPV2 and HPV4.
 - Syncope can occur among adolescents who receive any vaccines, including HPV vaccine. ACIP recommends that clinicians consider observing patients for 15 minutes after vaccination.
- *Regardless of a safety profile that is similar to the other adolescent vaccines, parents cite safety concerns as one of the top five reasons they do not intend to vaccinate daughters against HPV.*

Efficacy of HPV vaccines

- Among women who have not been previously infected with a targeted HPV type, both vaccines have over 95% efficacy in preventing cervical precancers caused by HPV 16 or 18.
 - HPV4 also demonstrated nearly 100% vaccine efficacy in preventing vulvar and vaginal precancers, and genital warts in women caused by the vaccine types.
 - In males, HPV4 demonstrated 90% vaccine efficacy in preventing genital warts and 75% vaccine efficacy in preventing anal precancers caused by vaccine types.
- *Since the vaccine does not protect against all HPV types, it does not replace other prevention strategies, such as regular cervical cancer screening.*

What you say matters; how you say it matters even more.


Based on research conducted with parents and physicians, CDC suggests recommending the HPV vaccine series the same way you recommend the other adolescent vaccines.

Parents may be interested in vaccinating, yet still have questions. Taking the time to listen to parents' questions helps you save time and give an effective response. CDC has created an excellent tip

sheet to assist you in answering questions parents may have about HPV vaccines. This tip sheet and many other tools on the HPV vaccine are available at www.cdc.gov/vaccines/youarethekey.

As a healthcare provider, we urge you to improve the strength and consistency of your recommendation for HPV vaccination to your patients. Your recommendation is the number one reason why someone will get the HPV vaccine and be protected from HPV-associated cancers and disease.

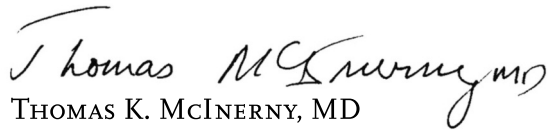
Signed:



REID B. BLACKWELDER, MD

President

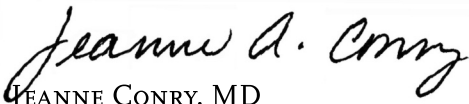
American Academy of Family Physicians



THOMAS K. MCINERNY, MD

President

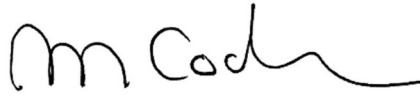
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Immunization Action Coalition

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Human papillomavirus (HPV)

[Disease Issues](#)[Contraindications and Precautions](#)[Vaccine Recommendations](#)[Vaccine Safety](#)[Scheduling and Administering Vaccines](#)

Disease Issues

How common is human papillomavirus (HPV) infection?

HPV is the most common sexually transmitted infection in the United States. In the United States, an estimated 79 million persons are infected, and an estimated 14 million new HPV infections occur every year among persons age 15 through 59 years. Approximately half of new infections occur among persons age 15 through 24 years. First HPV infection occurs within a few months to years of becoming sexually active.

How serious is disease caused by HPV?

HPV is associated with cervical, vulvar, and vaginal cancer in females, penile cancer in males, and anal and oropharyngeal cancer in both females and males. An annual average of approximately 26,900 new cancers were attributable to HPV during 2006 through 2010 including 17,600 (65%) among females and 9,300 (35%) among males. Cervical and oropharyngeal cancers were the most common with an estimated 10,400 cervical cancers and 9,000 oropharyngeal cancers (7,200 among men and 1,800 among women). HPV also causes almost all cases of genital warts.

Which types of HPV are most likely to cause disease?

Of the annual average of 26,900 HPV-related cancers in the United States, approximately 64% are attributable to HPV 16 or 18 (65% for females; 63% for males; approximately 21,300 cases annually), which are included in all three HPV vaccines. Approximately 10% are attributable to HPV types 31, 33, 45, 52, and 58 (14% for females; 4% for males; approximately 3,400 cases annually), which are included in the 9-valent HPV vaccine. HPV type 16, 18, 31, 33, 45, 52, or 58 account for about 81% of cervical cancers in the United States.

Approximately 50% of cervical precancers (CIN2 or greater) are caused by HPV 16 or 18 and 25% by HPV 31, 33, 45, 52, or 58. HPV 6 or 11 cause 90% of anogenital warts (condylomata) and most cases of recurrent respiratory papillomatosis.

More information about HPV and HPV-related cancers is available in the 2014 HPV ACIP statement at www.cdc.gov/mmwr/pdf/rr/rr6305.pdf

Is there a treatment for HPV infection?

There is no treatment for HPV infection. Only HPV-associated lesions including genital warts, recurrent respiratory papillomatosis, precancers, and cancers are treated. Recommended treatments vary depending on the diagnosis, size, and location of the lesion. Local treatment of lesions might not eradicate all HPV containing cells fully; whether available therapies for HPV-associated lesions reduce infectiousness is unclear.

Are healthcare personnel at risk of occupational infection with HPV?

Occupational infection with HPV is possible. Some HPV-associated conditions (including anogenital and oral warts, anogenital intraepithelial neoplasias, and recurrent respiratory papillomatosis) are treated with laser or electrosurgical procedures that could produce airborne particles. These procedures should be performed in an appropriately ventilated room using standard precautions and local exhaust ventilation. Workers in HPV research laboratories who handle wild-type virus or "quasi virions" might be at risk of acquiring HPV from occupational exposures. In the laboratory setting, proper infection control should be instituted including, at minimum, biosafety level 2. Whether HPV vaccination would be of benefit in these settings is unclear because no data exist on transmission risk or vaccine efficacy in this situation.

Can human papillomavirus (HPV) be transmitted by non-sexual transmission routes, such as clothing, undergarments, sex toys, or surfaces?

Nonsexual HPV transmission is theoretically possible but has not been definitely demonstrated. This is mainly because HPV can't be cultured and DNA detection from the environment is difficult and likely prone to false negative results.

Vaccine Recommendations[Back to top](#)**Please provide more information about the three HPV vaccines, Cervarix (GSK), Gardasil (Merck), and Gardasil 9 (Merck). How do they differ?**

- Cervarix (2vHPV, GlaxoSmithKline) is an inactivated bivalent vaccine that protects against HPV types 16 and 18. 2vHPV is licensed for females age 9 through 25 years.
- Gardasil (4vHPV, Merck) is an inactivated quadrivalent vaccine that protects against HPV types 16 and 18, and also against types 6 and 11, which cause genital warts and recurrent respiratory papillomatosis. 4vHPV is licensed for females and males age 9 through 26 years.
- Gardasil 9 (9vHPV, Merck) is an inactivated 9-valent vaccine that contains the 4 virus types included in 4vHPV and 5 additional oncogenic (cancer-causing) HPV types (31, 33, 45, 52 and 58). The 9vHPV vaccine is licensed for females and males age 9 through 26 years.

9vHPV was licensed by the FDA in December 2014 and will eventually replace 4vHPV. However, both vaccines will be available in the United States at least through mid-2016.

9vHPV has the same schedule as 4vHPV (three intramuscular doses spaced 0, 1, and 6 months apart). In a clinical trial comparing 9vHPV to 4vHPV, 9vHPV reduced the risk of disease caused by the 5 additional strains by 97%.

With the availability of 9vHPV, has the ACIP changed its recommendations for HPV vaccines?

The ACIP recommendations for HPV vaccination have not changed. ACIP recommends that routine HPV vaccination be initiated for females and males at age 11 or 12 years. The vaccination series can be started as early as age 9 years. Vaccination is also recommended for females aged 13 through 26 years and for males aged 13 through 21 years who have not been vaccinated previously or who have not completed the 3-dose series. In addition, vaccination is recommended for men age 22 through 26 years who 1) have sex with men or 2) are immunocompromised as a result of infection (including HIV), disease, or medication. Other males 22 through 26 years of age may be vaccinated at the clinician's discretion.

Vaccination of females is recommended with 2vHPV, 4vHPV (as long as this formulation is available), or 9vHPV. Vaccination of males is recommended with 4vHPV (as long as this formulation is available) or 9vHPV. Ideally, HPV vaccine should be administered before potential exposure to HPV through sexual contact.

All three HPV vaccines should be given as a 3-dose schedule, with the second dose given 1 to 2 months after the first dose and the third dose 6 months after the first dose. The minimum interval between the first and second doses of vaccine is 4 weeks. The minimum interval between the second and third doses of vaccine is 12 weeks. The minimum interval between the first and third doses is 24 weeks. If the vaccination series is interrupted the series does not need to be restarted.

The 2014 ACIP recommendations are available at www.cdc.gov/mmwr/pdf/rr/r6305.pdf (covers 2vHPV and 4vHPV) and the newly released 2015 ACIP recommendations (published March 27, 2015) are at www.cdc.gov/mmwr/pdf/wk/mm6411.pdf, pages 300–304 (covers 9vHPV).

Some parents resist HPV vaccination of their 11- and 12-year-olds because they are not sexually active. How should I counter this position?

Explain to the parent that vaccination starting at 11 or 12 years will provide the best protection possible long before the start of any kind of sexual activity. It is standard practice to vaccinate people before they are exposed to an infection, as is the case with measles and the other recommended childhood vaccines. Similarly, we want to vaccinate children before they get exposed to HPV. Studies of HPV vaccine indicate that younger adolescents respond better to the vaccine than older adolescents and young adults. Finally, there is no evidence that receipt of HPV vaccine increases the chance that a child will become sexually active.

My office recently changed HPV vaccine brands from Gardasil (4vHPV) to Cervarix (2vHPV). We

have several males who received doses of 2vHPV instead of 4vHPV. Do the males who received 2vHPV need to be revaccinated?

Yes. Cervarix (2vHPV, GlaxoSmithKline) is not approved or recommended for use in males. Doses of 2vHPV administered to males should not be counted and need to be repeated using 4vHPV (as long as this formulation is available) or 9vHPV (Gardasil 9, Merck).

If a vaccination series was started with 2vHPV or 4vHPV, can it be completed with 9vHPV? If the answer is yes, what are the spacing intervals that should be used for the remaining doses in the 3-dose series?

ACIP recommendations state that 9vHPV may be used to continue or complete a series started with a different HPV vaccine product. The intervals between doses remain the same regardless of what vaccine is used to complete the series. The second dose is given 1 to 2 months after the first dose and the third dose 4 months after the second AND at least 6 months after the first dose.

Are additional 9vHPV doses recommended for a person who started a series with 2vHPV or 4vHPV and completed the series with one or two doses of 9vHPV?

There is no ACIP recommendation for additional doses of 9vHPV for persons who started the series with 2vHPV or 4vHPV and completed the series with 9vHPV.

Does ACIP recommend revaccination with 9vHPV for patients who previously received a series of 2vHPV or 4vHPV?

ACIP has not recommended routine revaccination with 9vHPV for persons who have completed a series of another HPV vaccine. There are data that indicate revaccination with 9vHPV after a series of 4vHPV is safe. Clinicians should decide if the benefit of immunity against 5 additional oncogenic strains of HPV is justified for their patients.

Is use of HPV vaccine covered under the Vaccines For Children (VFC) program?

Yes.

Are pap smears still necessary for women who receive HPV vaccine?

Yes. Vaccinated women still need to see their healthcare provider for periodic cervical cancer screening. The vaccine does not provide protection against all types of HPV that cause cervical cancer, so even vaccinated women will still be at risk for some cancers from HPV.

Do women and men whose sexual orientation is same-sex need HPV vaccine?

Yes. HPV vaccine is recommended for females and males regardless of their sexual orientation.

Will patients who have already had genital warts benefit from receiving 4vHPV or 9vHPV?

A history of genital warts or clinically evident genital warts indicates infection with HPV, most often type 6 or 11. However, people with this history might not have been infected with both HPV 6 and 11 or with the other HPV types included in 4vHPV and 9vHPV. Vaccination will provide protection against infection with HPV vaccine types the patient has not already acquired. Both 4vHPV and 9vHPV protect against HPV types 6 and 11, which cause 90% of genital warts. 2vHPV does not protect against HPV types that cause genital warts. Providers should advise their patients/clients that the vaccine will not have a therapeutic effect on existing HPV infection or genital warts. It is important, however, that patients receive all 3 doses of 4vHPV or 9vHPV vaccine to get full protection from genital warts.

If a patient has been sexually active for a number of years, is it still recommended to give HPV vaccine or to complete the HPV vaccine series?

Yes. HPV vaccine should be administered to people who are already sexually active. Ideally, patients should be vaccinated before onset of sexual activity; however, patients who have already been infected with one or more HPV types still be protected from other HPV types in the vaccine that have not been acquired.

I read that HPV vaccination rates are still low. What can we do as providers to improve these rates?

Coverage levels for HPV vaccine are improving but are still inadequate. Results from the Centers for Disease Control and Prevention's 2013 National Immunization Survey-Teen (NIS-Teen) indicate that HPV vaccination rates in girls age 13 through 17 years increased between 2012 and 2013. Just over 57% of girls age 13 through 17 years had started the series that they should have completed by age 13 years and 38% had completed the series. In 2013 35% of boys age 13 through 17 years had received one dose but only 14% had received all three recommended doses. A summary of the 2013 NIS-Teen survey is available at www.cdc.gov/mmwr/pdf/wk/mm6329.pdf, pages 625–633.

Providers can improve uptake of this life-saving vaccine in two main ways. First, studies have shown that missed opportunities are a big problem. Up to 88% (depending on year of birth) of girls unvaccinated for HPV had a healthcare visit where they received another vaccine such as Tdap, but not HPV. If HPV vaccine had been administered at the same visit, vaccination coverage for one or more doses could be 91% instead of 57%. Second, the 2013 NIS-Teen data show that not receiving a healthcare provider's recommendation for HPV vaccine was one of the five main reasons parents reported for not vaccinating their daughters and the number one reason for not vaccinating their sons.

CDC urges healthcare providers to increase the consistency and strength of how they recommend HPV vaccine, especially when patients are age 11 or 12 years. The following resources can help providers with these conversations.

- CDC's "Tips and Time-savers for Talking with Parents about HPV Vaccine," available at www.cdc.gov/vaccines/who/teens/for-hcp-tipsheet-hpv.pdf.
- IAC's "Human Papillomavirus HPV: A Parent's Guide to Preteen and Teen HPV Vaccination," available at www.immunize.org/catg.d/p4250.pdf.

For more detailed information about HPV vaccination strategies for providers, visit www.cdc.gov/vaccines/who/teens/for-hcp/hpv-resources.html.

Scheduling and Administering Vaccines

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What is the recommended schedule for administering HPV vaccine?

All three HPV vaccines should be administered in a 3-dose schedule, with the second dose administered 1 to 2 months after the first dose and the third dose 6 months after the first dose. The minimum interval between the first and second doses of vaccine is 4 weeks. The minimum interval between the second and third doses of vaccine is 12 weeks. The minimum interval between the first and third doses is 24 weeks.

If a dose of HPV vaccine is significantly delayed, do I need to start the series over?

No, do not restart the series. You should continue where the patient left off and complete the series.

To accelerate completion of the HPV vaccine series, can doses be given at 0, 1, and 4 months?

No, there is no accelerated schedule for completing the HPV vaccine series. You should follow the recommended schedule of 0, 1-2, and 6 months.

What are the minimum intervals between doses of HPV vaccine?

Minimum intervals are used when patients have fallen behind on their vaccination schedule or when they need their dosing schedule expedited (for example if there is imminent travel). The minimum interval between the first and second doses of HPV vaccine is 4 weeks. The minimum interval between the second and third dose is 12 weeks. ACIP recommends an interval of 24 weeks between the first and third dose. However, the third dose can be considered to be valid if it was separated from the first dose by at least 16 weeks and from the second dose by at least 12 weeks.

I work with university students and many of them miss coming in on time for their next dose of HPV vaccine. What's the longest interval allowed before we need to start the series over?

No vaccine series needs to be restarted because of an interval that is longer than recommended (with the exception of oral typhoid vaccine in certain circumstances). You should continue the series where it was interrupted. If the HPV series is begun when the university student is age 26 or younger, it can be completed after the student turns 27.

Is it recommended that patients age 26 years start the HPV vaccination series even though they

will be older than 26 when they complete it?

Yes. HPV vaccine is recommended for all women through age 26 years and also may be given to men through that age. So, the 3-dose series can be started at age 26 even if it will not be completed at age 26. The series should be completed regardless of the age of the patient (i.e., even if the patient is older than 26). In certain situations, some clinicians choose to start the 3-dose HPV series in patients who are older than 26 years. This, however, is an off-label use.

We inadvertently gave HPV vaccine to a woman who didn't know she was pregnant at the time. How should we complete the schedule?

GlaxoSmithKline and Merck (for 4vHPV) have closed their formal pregnancy registries with the concurrence of the FDA (see next question). However, Merck has established a registry for women who inadvertently receive 9vHPV during pregnancy (telephone 800-986-8999). You should withhold further HPV vaccine until she is no longer pregnant. After the pregnancy is completed, administer the remaining doses of the series using the usual schedule. HPV#2 assuming 1-2 months have passed since HPV#1. Give HPV#3 6 months after HPV#1, but no earlier than 12 weeks after HPV#2.

Why did GlaxoSmithKline and Merck discontinue their registry for collecting reports of pregnant women who inadvertently received HPV vaccine during pregnancy?

Because HPV vaccine is not recommended for use during pregnancy, both companies facilitated a registry to document outcomes when HPV vaccine was inadvertently administered to pregnant women. These registries collected information for more than 6 years, and both companies fulfilled their FDA obligations to facilitate it. The data from the registries are reassuring with respect to safety after pregnancy exposures. Review of the registry data does not support a causal relationship between HPV vaccine and birth defects or other adverse outcomes of pregnancy.

Can HPV vaccine be administered at the same time as other vaccines?

Yes, administration of a different inactivated or live vaccine, either at the same visit or at any time before or after HPV vaccine, is acceptable because HPV is not a live vaccine.

If HPV vaccine is given subcutaneously instead of intramuscularly, does the dose need to be repeated?

Yes. No data exist on the efficacy or safety of HPV vaccine given by the subcutaneous route. All data on efficacy and duration of protection are based on a 3-dose series given on the approved schedule and administered by the intramuscular route. In the absence of data on subcutaneous administration, CDC and the manufacturers recommend that a dose of HPV vaccine given by any route other than intramuscular should be repeated. There is no minimum interval between the invalid (subcutaneous) dose and the repeat dose.

If a 30-year-old female patient insists that she wants to receive HPV vaccine, can I give it to her?

HPV vaccine is not approved for use in women older than age 26 years. Studies have shown that the vaccine is safe in women age 27 years and older. ACIP does not recommend the use of this vaccine outside the FDA licensing guidelines unless the series was started but not completed by age 26 years. Clinicians may choose to administer HPV vaccine off-label to men and women age 27 years or older and should decide if the benefit of the vaccine outweighs the hypothetical risk.

Contraindications and Precautions

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What are the contraindications and precautions to HPV vaccine?

Contraindications are the following:

- History of a severe (anaphylactic) reaction to a vaccine component or following a previous dose. 4vHPV and 9vHPV vaccines contain trace amounts of yeast protein. The tip cap and rubber plunger of 2vHPV prefilled syringes contain dry natural latex rubber that may cause allergic reactions in latex sensitive individuals.
- Pregnancy

The only precaution to HPV vaccine is a moderate or severe acute illness with or without fever. Vaccination should be deferred until the condition improves.

If a woman has had HPV infection, can she still be vaccinated?

Yes. Women who have evidence of present or past HPV infection and who are younger than age 27 years should be vaccinated. They should be advised that the vaccine will not have a therapeutic effect on existing HPV infection or cervical lesions.

Can a woman who is breastfeeding receive HPV vaccine?

Yes.

Is the history of an abnormal pap a contraindication to the HPV vaccine series?

No. Even a woman found to be infected with a strain of HPV that is present in the vaccine could receive protection from the other strains in the vaccine.

Vaccine Safety[Back to top](#)**What adverse events can be expected following HPV vaccine?**

In clinical trials involving more than 35,000 subjects, the most common adverse event was injection site pain, which was reported in 58% to 90% of recipients (depending on vaccine and dose number). Other local reactions, such as redness and/or swelling, were reported in 30% to 40% of recipients. Local reactions were reported more frequently among 9vHPV recipients than among 4vHPV recipients, probably because of the larger amount of aluminum adjuvant present in 9vHPV. Systemic reaction, such as fever, headache, and fatigue, were reported by 2% to 50% of recipients (depending on vaccine and dose number). These symptoms generally occurred at about the same rate in vaccine and placebo recipients.

We've heard stories in the media lately about severe reactions to the HPV vaccine. Is there any substance to these stories?

No. As of March 2014 more than 67 million doses of HPV vaccine have been distributed in the United States. The federal Vaccine Adverse Events Reporting System (VAERS) has received about 25,000 reports of adverse events following HPV vaccination. Of these, more than 92% were classified as nonserious, such as injection site reactions. Although deaths have been reported among vaccine recipients none has been conclusively shown to have been caused by the vaccine. Occurrences of rare conditions, such as Guillain-Barre Syndrome (GBS) have also been reported among vaccine recipients but there is no evidence that HPV vaccine increased the rate of GBS above what is expected in the population.

CDC, working with the FDA and other immunization partners, will continue to monitor the safety of HPV vaccines. You can find complete information on this and other vaccine safety issues at www.cdc.gov/vaccinesafety/Vaccines/HPV/Index.html.

Do HPV vaccines cause fainting?

Nearly all vaccines have been reported to be associated with the fainting (syncope). Post-vaccination syncope has been most frequently reported after three vaccines commonly given to adolescents (HPV, MCV4, and Tdap). However, it is not known whether the vaccines are responsible for post-vaccination syncope or if the association with these vaccines simply reflects the fact that adolescents are generally more likely to experience syncope.

Syncope can cause serious injury. Falls that occur due to syncope after vaccination can be prevented by having the vaccinated person seated or lying down. The person should be observed for 15 minutes following vaccination.

This page was updated on February 23, 2016.

This page was reviewed on February 22, 2016.

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use GARDASIL 9 safely and effectively. See full prescribing information for GARDASIL 9.

GARDASIL®9

(Human Papillomavirus 9-valent Vaccine, Recombinant)
Suspension for intramuscular injection

Initial U.S. Approval: 2014

RECENT MAJOR CHANGES

Indications and Usage, Boys and Men (1.2) 12/2015

INDICATIONS AND USAGE

GARDASIL 9 is a vaccine indicated in girls and women 9 through 26 years of age for the prevention of the following diseases:

- Cervical, vulvar, vaginal, and anal cancer caused by Human Papillomavirus (HPV) types 16, 18, 31, 33, 45, 52, and 58. (1.1)
- Genital warts (condyloma acuminata) caused by HPV types 6 and 11. (1.1)

And the following precancerous or dysplastic lesions caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58:

- Cervical intraepithelial neoplasia (CIN) grade 2/3 and cervical adenocarcinoma *in situ* (AIS). (1.1)
- Cervical intraepithelial neoplasia (CIN) grade 1. (1.1)
- Vulvar intraepithelial neoplasia (VIN) grade 2 and grade 3. (1.1)
- Vaginal intraepithelial neoplasia (VaIN) grade 2 and grade 3. (1.1)
- Anal intraepithelial neoplasia (AIN) grades 1, 2, and 3. (1.1)

GARDASIL 9 is indicated in boys and men 9 through 26 years of age for the prevention of the following diseases:

- Anal cancer caused by HPV types 16, 18, 31, 33, 45, 52, and 58. (1.2)
- Genital warts (condyloma acuminata) caused by HPV types 6 and 11. (1.2)

And the following precancerous or dysplastic lesions caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58:

- Anal intraepithelial neoplasia (AIN) grades 1, 2, and 3. (1.2)

Limitations of Use and Effectiveness:

- GARDASIL 9 does not eliminate the necessity for women to continue to undergo recommended cervical cancer screening. (1.3, 17)
- Recipients of GARDASIL 9 should not discontinue anal cancer screening if it has been recommended by a health care provider. (1.3, 17)
- GARDASIL 9 has not been demonstrated to provide protection against disease from vaccine HPV types to which a person has previously been exposed through sexual activity. (1.3)
- GARDASIL 9 has not been demonstrated to protect against diseases due to HPV types other than 6, 11, 16, 18, 31, 33, 45, 52, and 58. (1.3)
- GARDASIL 9 is not a treatment for external genital lesions; cervical, vulvar, vaginal, and anal cancers; CIN; VIN; VaIN; or AIN. (1.3)
- Not all vulvar, vaginal, and anal cancers are caused by HPV, and GARDASIL 9 protects only against those vulvar, vaginal, and anal cancers caused by HPV 16, 18, 31, 33, 45, 52, and 58. (1.3)
- GARDASIL 9 does not protect against genital diseases not caused by HPV. (1.3)

- Vaccination with GARDASIL 9 may not result in protection in all vaccine recipients. (1.3)
- Safety and effectiveness of GARDASIL 9 have not been assessed in individuals older than 26 years of age. (1.3)

DOSAGE AND ADMINISTRATION

0.5-mL suspension for intramuscular injection at the following schedule: 0, 2 months, 6 months. (2.1)

DOSAGE FORMS AND STRENGTHS

0.5-mL suspension for injection as a single-dose vial and prefilled syringe. (3, 11)

CONTRAINDICATIONS

Hypersensitivity, including severe allergic reactions to yeast (a vaccine component), or after a previous dose of GARDASIL 9 or GARDASIL®. (4, 11)

WARNINGS AND PRECAUTIONS

Because vaccinees may develop syncope, sometimes resulting in falling with injury, observation for 15 minutes after administration is recommended. Syncope, sometimes associated with tonic-clonic movements and other seizure-like activity, has been reported following HPV vaccination. When syncope is associated with tonic-clonic movements, the activity is usually transient and typically responds to restoring cerebral perfusion by maintaining a supine or Trendelenburg position. (5.1)

ADVERSE REACTIONS

The most common (≥10%) local and systemic adverse reactions reported:

- In girls and women 16 through 26 years of age: injection-site pain (89.9%), injection-site swelling (40.0%), injection-site erythema (34.0%) and headache (14.6%). (6.1)
- In girls 9 through 15 years of age: injection-site pain (89.3%), injection-site swelling (47.8%), injection-site erythema (34.1%) and headache (11.4%). (6.1)
- In boys and men 16 through 26 years of age: injection-site pain (63.4%), injection-site swelling (20.2%) and injection-site erythema (20.7%). (6.1)
- In boys 9 through 15 years of age: injection-site pain (71.5%), injection-site swelling (26.9%), and injection-site erythema (24.9%). (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., at 1-877-888-4231 or VAERS at 1-800-822-7967 or www.vaers.hhs.gov.

USE IN SPECIFIC POPULATIONS

Safety and effectiveness of GARDASIL 9 have not been established in the following populations:

- Pregnant women. A pregnancy registry is available. Patients and health care providers are encouraged to register women exposed to GARDASIL 9 around the time of conception or during pregnancy by calling 1-800-986-8999. (8.1)
- Children below the age of 9 years. (8.4)
- Immunocompromised individuals. Response to GARDASIL 9 may be diminished. (8.6)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 12/2015

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14.4 Immunogenicity

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16 HOW SUPPLIED/STORAGE AND HANDLING

17 PATIENT COUNSELING INFORMATION

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

1.1 Girls and Women

GARDASIL[®]9 is a vaccine indicated in girls and women 9 through 26 years of age for the prevention of the following diseases:

- Cervical, vulvar, vaginal, and anal cancer caused by Human Papillomavirus (HPV) types 16, 18, 31, 33, 45, 52, and 58
- Genital warts (condyloma acuminata) caused by HPV types 6 and 11

And the following precancerous or dysplastic lesions caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58:

- Cervical intraepithelial neoplasia (CIN) grade 2/3 and cervical adenocarcinoma *in situ* (AIS)
- Cervical intraepithelial neoplasia (CIN) grade 1
- Vulvar intraepithelial neoplasia (VIN) grade 2 and grade 3
- Vaginal intraepithelial neoplasia (VaIN) grade 2 and grade 3
- Anal intraepithelial neoplasia (AIN) grades 1, 2, and 3

1.2 Boys and Men

GARDASIL 9 is indicated in boys and men 9 through 26 years of age for the prevention of the following diseases:

- Anal cancer caused by HPV types 16, 18, 31, 33, 45, 52, and 58
- Genital warts (condyloma acuminata) caused by HPV types 6 and 11

And the following precancerous or dysplastic lesions caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58:

- Anal intraepithelial neoplasia (AIN) grades 1, 2, and 3

1.3 Limitations of Use and Effectiveness

The health care provider should inform the patient, parent, or guardian that vaccination does not eliminate the necessity for women to continue to undergo recommended cervical cancer screening. Women who receive GARDASIL 9 should continue to undergo cervical cancer screening per standard of care. [See *Patient Counseling Information* (17)].

Recipients of GARDASIL 9 should not discontinue anal cancer screening if it has been recommended by a health care provider [see *Patient Counseling Information* (17)].

GARDASIL 9 has not been demonstrated to provide protection against disease from vaccine HPV types to which a person has previously been exposed through sexual activity.

GARDASIL 9 has not been demonstrated to protect against diseases due to HPV types other than 6, 11, 16, 18, 31, 33, 45, 52, and 58.

GARDASIL 9 is not a treatment for external genital lesions; cervical, vulvar, vaginal, and anal cancers; CIN; VIN; VaIN; or AIN.

Not all vulvar, vaginal, and anal cancers are caused by HPV, and GARDASIL 9 protects only against those vulvar, vaginal, and anal cancers caused by HPV 16, 18, 31, 33, 45, 52, and 58.

GARDASIL 9 does not protect against genital diseases not caused by HPV.

Vaccination with GARDASIL 9 may not result in protection in all vaccine recipients.

Safety and effectiveness of GARDASIL 9 have not been assessed in individuals older than 26 years of age.

2 DOSAGE AND ADMINISTRATION

2.1 Dosage

Administer GARDASIL 9 intramuscularly as a 0.5-mL dose at the following schedule: 0, 2 months, 6 months.

2.2 Method of Administration

For intramuscular use only.

Shake well before use. Thorough agitation immediately before administration is necessary to maintain suspension of the vaccine. GARDASIL 9 should not be diluted or mixed with other vaccines. After thorough agitation, GARDASIL 9 is a white, cloudy liquid. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Do not use the product if particulates are present or if it appears discolored.

Administer GARDASIL 9 intramuscularly in the deltoid region of the upper arm or in the higher anterolateral area of the thigh.

Observe patients for 15 minutes after administration [see *Warnings and Precautions* (5)].

Single-Dose Vial Use

Withdraw the 0.5-mL dose of vaccine from the single-dose vial using a sterile needle and syringe and use promptly.

Prefilled Syringe Use

This package does not contain a needle. Shake well before use. Attach a needle by twisting in a clockwise direction until the needle fits securely on the syringe. Administer the entire dose as per standard protocol.

2.3 Administration of GARDASIL 9 in Individuals Who Have Been Previously Vaccinated with GARDASIL®

Safety and immunogenicity of GARDASIL 9 were assessed in individuals who previously completed a three-dose vaccination series with GARDASIL [see *Adverse Reactions* (6.1) and *Clinical Studies* (14.4)]. Studies using a mixed regimen of HPV vaccines to assess interchangeability were not performed for GARDASIL 9.

3 DOSAGE FORMS AND STRENGTHS

GARDASIL 9 is a suspension for intramuscular administration available in 0.5-mL single-dose vials and prefilled syringes. See *Description* (11) for the complete listing of ingredients.

4 CONTRAINDICATIONS

Hypersensitivity, including severe allergic reactions to yeast (a vaccine component), or after a previous dose of GARDASIL 9 or GARDASIL [see *Description* (11)].

5 WARNINGS AND PRECAUTIONS

5.1 Syncope

Because vaccinees may develop syncope, sometimes resulting in falling with injury, observation for 15 minutes after administration is recommended. Syncope, sometimes associated with tonic-clonic movements and other seizure-like activity, has been reported following HPV vaccination. When syncope is associated with tonic-clonic movements, the activity is usually transient and typically responds to restoring cerebral perfusion by maintaining a supine or Trendelenburg position.

5.2 Managing Allergic Reactions

Appropriate medical treatment and supervision must be readily available in case of anaphylactic reactions following the administration of GARDASIL 9.

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared to rates in the clinical trials of another vaccine and may not reflect the rates observed in practice.

The safety of GARDASIL 9 was evaluated in seven clinical studies that included 15,703 individuals who received at least one dose of GARDASIL 9 and had safety follow-up. Study 1 and Study 3 also included 7,378 individuals who received at least one dose of GARDASIL as a control and had safety

follow-up. The vaccines were administered on the day of enrollment and the subsequent doses administered approximately two and six months thereafter. Safety was evaluated using vaccination report card (VRC)-aided surveillance for 14 days after each injection of GARDASIL 9 or GARDASIL.

The individuals who were monitored using VRC-aided surveillance included 9,097 girls and women 16 through 26 years of age, 1,394 boys and men 16 through 26 years of age, and 5,212 girls and boys 9 through 15 years of age (3,436 girls and 1,776 boys) at enrollment who received GARDASIL 9; and 7,078 girls and women 16 through 26 years of age and 300 girls 9 through 15 years of age at enrollment who received GARDASIL. The race distribution of the integrated safety population for GARDASIL 9 was similar between girls and women 16 through 26 years of age (56.8% White; 25.2% Other Races or Multiracial; 14.1% Asian; 3.9% Black), girls and boys 9 through 15 years of age (62.0% White; 19.2% Other Races or Multiracial; 13.5% Asian; 5.4% Black), and boys and men 16 through 26 years of age (62.1% White; 22.6% Other Races or Multiracial; 9.8% Asian; 5.5% Black). The safety of GARDASIL 9 was compared directly to the safety of GARDASIL in two studies (Study 1 and Study 3) for which the overall race distribution of the GARDASIL cohorts (57.0% White; 26.3% Other Races or Multiracial; 13.6% Asian; 3.2% Black) was similar to that of the GARDASIL 9 cohorts.

Injection-Site and Systemic Adverse Reactions

Injection-site reactions (pain, swelling, and erythema) and oral temperature were solicited using VRC-aided surveillance for five days after each injection of GARDASIL 9 during the clinical studies. The rates and severity of these solicited adverse reactions that occurred within five days following each dose of GARDASIL 9 compared with GARDASIL in Study 1 (girls and women 16 through 26 years of age) and Study 3 (girls 9 through 15 years of age) are presented in Table 1. Among subjects who received GARDASIL 9, the rates of injection-site pain were approximately equal across the three reporting time periods. Rates of injection-site swelling and injection-site erythema increased following each successive dose of GARDASIL 9. Recipients of GARDASIL 9 had numerically higher rates of injection-site reactions compared with recipients of GARDASIL.

Table 1: Rates (%) and Severity of Solicited Injection-Site and Systemic Adverse Reactions Occurring within Five Days of Each Vaccination with GARDASIL 9 Compared with GARDASIL (Studies 1 and 3)

	GARDASIL 9				GARDASIL			
	Post-dose 1	Post-dose 2	Post-dose 3	Post any dose	Post-dose 1	Post-dose 2	Post-dose 3	Post any dose
Girls and Women 16 through 26 Years of Age								
Injection-Site Adverse Reactions	N=7069	N=6997	N=6909	N=7071	N=7076	N=6992	N=6909	N=7078
Pain, Any	70.7	73.5	71.6	89.9	58.2	62.2	62.6	83.5
Pain, Severe	0.7	1.7	2.6	4.3	0.4	1.0	1.7	2.6
Swelling, Any	12.5	23.3	28.3	40.0	9.3	14.6	18.7	28.8
Swelling, Severe	0.6	1.5	2.5	3.8	0.3	0.5	1.0	1.5
Erythema, Any	10.6	18.0	22.6	34.0	8.1	12.9	15.6	25.6
Erythema, Severe	0.2	0.5	1.1	1.6	0.2	0.2	0.4	0.8
Systemic Adverse Reactions	n=6995	n=6913	n=6743	n=7022	n=7003	n=6914	n=6725	n=7024
Temperature $\geq 100^{\circ}\text{F}$	1.7	2.6	2.7	6.0	1.7	2.4	2.5	5.9
Temperature $\geq 102^{\circ}\text{F}$	0.3	0.3	0.4	1.0	0.2	0.3	0.3	0.8
Girls 9 through 15 Years of Age								
Injection-Site Adverse Reactions	N=300	N=297	N=296	N=299	N=299	N=299	N=294	N=300
Pain, Any	71.7	71.0	74.3	89.3	66.2	66.2	69.4	88.3
Pain, Severe	0.7	2.0	3.0	5.7	0.7	1.3	1.7	3.3
Swelling, Any	14.0	23.9	36.1	47.8	10.4	17.7	25.2	36.0
Swelling, Severe	0.3	2.4	3.7	6.0	0.7	2.7	4.1	6.3
Erythema, Any	7.0	15.5	21.3	34.1	9.7	14.4	18.4	29.3
Erythema, Severe	0	0.3	1.4	1.7	0	0.3	1.7	2.0
Systemic Adverse Reactions	n=300	n=294	n=295	n=299	n=299	n=297	n=291	n=300
Temperature $\geq 100^{\circ}\text{F}$	2.3	1.7	3.0	6.7	1.7	1.7	0	3.3
Temperature $\geq 102^{\circ}\text{F}$	0	0.3	1.0	1.3	0.3	0.3	0	0.7

The data for girls and women 16 through 26 years of age are from Study 1 (NCT00543543), and the data for girls 9 through 15 years of age are from Study 3 (NCT01304498).

N=number of subjects vaccinated with safety follow-up

n=number of subjects with temperature data

Pain, Any=mild, moderate, severe or unknown intensity

Pain, Severe=incapacitating with inability to work or do usual activity

Swelling, Any=any size or size unknown

Swelling, Severe=maximum size greater than 2 inches

Erythema, Any=any size or size unknown

Erythema, Severe=maximum size greater than 2 inches

Unsolicited injection-site and systemic adverse reactions (assessed as vaccine-related by the investigator) observed among recipients of either GARDASIL 9 or GARDASIL in Studies 1 and 3 at a frequency of at least 1% are shown in Table 2. Few individuals discontinued study participation due to adverse experiences after receiving either vaccine (GARDASIL 9 = 0.1% vs. GARDASIL <0.1%).

Table 2: Rates (%) of Unsolicited Injection-Site and Systemic Adverse Reactions Occurring among $\geq 1.0\%$ of Individuals after Any Vaccination with GARDASIL 9 Compared with GARDASIL (Studies 1 and 3)

	Girls and Women 16 through 26 Years of Age		Girls 9 through 15 Years of Age	
	GARDASIL 9 N=7071	GARDASIL N=7078	GARDASIL 9 N=299	GARDASIL N=300
Injection-Site Adverse Reactions (1 to 5 Days Post-Vaccination, Any Dose)				
Pruritus	5.5	4.0	4.0	2.7
Bruising	1.9	1.9	0	0
Hematoma	0.9	0.6	3.7	4.7
Mass	1.3	0.6	0	0
Hemorrhage	1.0	0.7	1.0	2.0
Induration	0.8	0.2	2.0	1.0
Warmth	0.8	0.5	0.7	1.7
Reaction	0.6	0.6	0.3	1.0
Systemic Adverse Reactions (1 to 15 Days Post-Vaccination, Any Dose)				
Headache	14.6	13.7	11.4	11.3
Pyrexia	5.0	4.3	5.0	2.7
Nausea	4.4	3.7	3.0	3.7
Dizziness	3.0	2.8	0.7	0.7
Fatigue	2.3	2.1	0	2.7
Diarrhea	1.2	1.0	0.3	0
Oropharyngeal pain	1.0	0.6	2.7	0.7
Myalgia	1.0	0.7	0.7	0.7
Abdominal pain, upper	0.7	0.8	1.7	1.3
Upper respiratory tract infection	0.1	0.1	0.3	1.0

The data for girls and women 16 through 26 years of age are from Study 1 (NCT00543543), and the data for girls 9 through 15 years of age are from Study 3 (NCT01304498).

N=number of subjects vaccinated with safety follow-up

In an uncontrolled clinical trial with 639 boys and 1,878 girls 9 through 15 years of age (Study 2), the rates and severity of solicited adverse reactions following each dose of GARDASIL 9 were similar between boys and girls. Rates of solicited and unsolicited injection-site and systemic adverse reactions in boys 9 through 15 years of age were similar to those among girls 9 through 15 years of age. Solicited and unsolicited adverse reactions reported by boys in this study are shown in Table 3.

In another uncontrolled clinical trial with 1,394 boys and men and 1,075 girls and women 16 through 26 years of age (Study 7), the rates of solicited and unsolicited adverse reactions following each dose of GARDASIL 9 among girls and women 16 through 26 years of age were similar to those reported in Study 1. Rates of solicited and unsolicited adverse reactions reported by boys and men 16 through 26 years of age in this study are shown in Table 3.

Table 3: Rates (%) of Solicited and Unsolicited* Injection-Site and Systemic Adverse Reactions among Boys 9 through 15 Years of Age and among Boys and Men 16 through 26 Years of Age Who Received GARDASIL 9 (Studies 2 and 7)

	GARDASIL 9
Boys and Men 16 through 26 Years of Age	N=1394
Solicited Adverse Reactions (1-5 Days Post-Vaccination, Any Dose)	
Injection-Site Pain, Any	63.4
Injection-Site Pain, Severe	0.6
Injection-Site Erythema, Any	20.7
Injection-Site Erythema, Severe	0.4
Injection-Site Swelling, Any	20.2
Injection-Site Swelling, Severe	1.1
Oral Temperature $\geq 100.0^{\circ}\text{F}^{\dagger}$	4.4
Oral Temperature $\geq 102^{\circ}\text{F}$	0.6
Unsolicited Injection-Site Adverse Reactions (1-5 Days Post-Vaccination, Any Dose)	
Injection-Site Hypersensitivity	1.0
Injection-Site Pruritus	1.0
Unsolicited Systemic Adverse Reactions (1-15 Days Post-Vaccination, Any Dose)	
Headache	7.3
Pyrexia	2.4
Fatigue	1.4
Dizziness	1.1
Nausea	1.0
Boys 9 through 15 Years of Age	N=639
Solicited Adverse Reactions (1-5 Days Post-Vaccination, Any Dose)	
Injection-Site Pain, Any	71.5
Injection-Site Pain, Severe	0.5
Injection-Site Erythema, Any	24.9
Injection-Site Erythema, Severe	1.9
Injection-Site Swelling, Any	26.9
Injection-Site Swelling, Severe	5.2
Oral Temperature $\geq 100.0^{\circ}\text{F}^{\dagger}$	10.4
Oral Temperature $\geq 102^{\circ}\text{F}$	1.4
Unsolicited Injection-Site Adverse Reactions (1-5 Days Post-Vaccination, Any Dose)	
Injection-Site Hematoma	1.3
Injection-Site Induration	1.1
Unsolicited Systemic Adverse Reactions (1-15 Days Post-Vaccination, Any Dose)	
Headache	9.4
Pyrexia	8.9
Nausea	1.3

The data for GARDASIL 9 boys 9 through 15 years of age are from Study 2 (NCT00943722). The data for boys and men 16 through 26 years of age for GARDASIL 9 are from Study 7 (NCT01651949).

*Unsolicited adverse reactions reported by $\geq 1\%$ of individuals

N=number of subjects vaccinated with safety follow-up

[†]For oral temperature: number of subjects with temperature data for boys 9 through 15 years of age N=637; for boys and men 16 through 26 years of age N=1,386

Pain, Any=mild, moderate, severe or unknown intensity

Pain, Severe=incapacitating with inability to work or do usual activity

Swelling, Any=any size or size unknown

Swelling, Severe=maximum size greater than 2 inches

Erythema, Any=any size or size unknown

Erythema, Severe=maximum size greater than 2 inches

Serious Adverse Events in Clinical Studies

Serious adverse events were collected throughout the entire study period (range one month to 48 months post-last dose) for the seven clinical studies for GARDASIL 9. Out of the 15,705 individuals who were administered GARDASIL 9 and had safety follow-up, 354 reported a serious adverse event; representing 2.3% of the population. As a comparison, of the 7,378 individuals who were administered GARDASIL and had safety follow-up, 185 reported a serious adverse event; representing 2.5% of the population. Four GARDASIL 9 recipients each reported at least one serious adverse event that was determined to be vaccine-related. The vaccine-related serious adverse reactions were pyrexia, allergy to vaccine, asthmatic crisis, and headache.

Deaths in the Entire Study Population

Across the clinical studies, ten deaths occurred (five each in the GARDASIL 9 and GARDASIL groups); none were assessed as vaccine-related. Causes of death in the GARDASIL 9 group included one automobile accident, one suicide, one case of acute lymphocytic leukemia, one case of hypovolemic septic shock, and one unexplained sudden death 678 days following the last dose of GARDASIL 9. Causes of death in the GARDASIL control group included one automobile accident, one airplane crash, one cerebral hemorrhage, one gunshot wound, and one stomach adenocarcinoma.

Systemic Autoimmune Disorders

In all of the clinical trials with GARDASIL 9 subjects were evaluated for new medical conditions potentially indicative of a systemic autoimmune disorder. In total, 2.2% (351/15,703) of GARDASIL 9 recipients and 3.3% (240/7,378) of GARDASIL recipients reported new medical conditions potentially indicative of systemic autoimmune disorders, which were similar to rates reported following GARDASIL, AAHS control, or saline placebo in historical clinical trials.

Clinical Trials Experience for GARDASIL 9 in Individuals Who Have Been Previously Vaccinated with GARDASIL

A clinical study (Study 4) evaluated the safety of GARDASIL 9 in 12- through 26-year-old girls and women who had previously been vaccinated with three doses of GARDASIL. The time interval between the last injection of GARDASIL and the first injection of GARDASIL 9 ranged from approximately 12 to 36 months. Individuals were administered GARDASIL 9 or saline placebo and safety was evaluated using VRC-aided surveillance for 14 days after each injection of GARDASIL 9 or saline placebo in these individuals. The individuals who were monitored included 608 individuals who received GARDASIL 9 and 305 individuals who received saline placebo. Few (0.5%) individuals who received GARDASIL 9 discontinued due to adverse reactions. The vaccine-related adverse experiences that were observed among recipients of GARDASIL 9 at a frequency of at least 1.0% and also at a greater frequency than that observed among saline placebo recipients are shown in Table 4. Overall the safety profile was similar between individuals vaccinated with GARDASIL 9 who were previously vaccinated with GARDASIL and those who were naïve to HPV vaccination with the exception of numerically higher rates of injection-site swelling and erythema among individuals who were previously vaccinated with GARDASIL (Tables 1 and 4).

Table 4: Rates (%) of Solicited and Unsolicited* Injection-Site and Systemic Adverse Reactions among Individuals Previously Vaccinated with GARDASIL Who Received GARDASIL 9 or Saline Placebo (Girls and Women 12 through 26 Years of Age) (Study 4)

	GARDASIL 9 N=608	Saline Placebo N=305
Solicited Adverse Reactions (1-5 Days Post-Vaccination, Any Dose)		
Injection-Site Pain	90.3	38.0
Injection-Site Erythema	42.3	8.5
Injection-Site Swelling	49.0	5.9
Oral Temperature $\geq 100.0^{\circ}\text{F}^{\dagger}$	6.5	3.0
Unsolicited Injection-Site Adverse Reactions (1-5 Days Post-Vaccination, Any Dose)		
Injection-Site Pruritus	7.7	1.3
Injection-Site Hematoma	4.8	2.3
Injection-Site Reaction	1.3	0.3
Injection-Site Mass	1.2	0.7
Unsolicited Systemic Adverse Reactions (1-15 Days Post-Vaccination, Any Dose)		
Headache	19.6	18.0
Pyrexia	5.1	1.6
Nausea	3.9	2.0
Dizziness	3.0	1.6
Abdominal pain, upper	1.5	0.7
Influenza	1.2	1.0

The data for GARDASIL 9 and saline placebo are from Study 4 (NCT01047345).

*Unsolicited adverse reactions reported by $\geq 1\%$ of individuals

N=number of subjects vaccinated with safety follow-up

[†]For oral temperature: number of subjects with temperature data GARDASIL 9 N=604; Saline Placebo N=304

Safety in Concomitant Use with Menactra and Adacel

In Study 5, the safety of GARDASIL 9 when administered concomitantly with Menactra [Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine] and Adacel [Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (Tdap)] was evaluated in a randomized study of 1,241 boys (n = 620) and girls (n = 621) with a mean age of 12.2 years [see *Clinical Studies (14.5)*].

Of the 1,237 boys and girls vaccinated, 1,220 had safety follow-up for injection-site adverse reactions. The rates of injection-site adverse reactions were similar between the concomitant group and non-concomitant group (vaccination with GARDASIL 9 separated from vaccination with Menactra and Adacel by 1 month) with the exception of an increased rate of swelling reported at the injection site for GARDASIL 9 in the concomitant group (14.4%) compared to the non-concomitant group (9.4%). The majority of injection-site swelling adverse reactions were reported as being mild to moderate in intensity.

6.2 Postmarketing Experience

There is limited post-marketing experience following administration of GARDASIL 9. However, the post-marketing safety experience with GARDASIL is relevant to GARDASIL 9 since the vaccines are manufactured similarly and contain the same antigens from HPV types 6, 11, 16, and 18. Because these events were reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency or to establish a causal relationship to vaccine exposure. The following adverse experiences have been spontaneously reported during post-approval use of GARDASIL and may also be seen in post-marketing experience with GARDASIL 9:

Blood and lymphatic system disorders: Autoimmune hemolytic anemia, idiopathic thrombocytopenic purpura, lymphadenopathy.

Respiratory, thoracic and mediastinal disorders: Pulmonary embolus.

Gastrointestinal disorders: Nausea, pancreatitis, vomiting.

General disorders and administration site conditions: Asthenia, chills, death, fatigue, malaise.

Immune system disorders: Autoimmune diseases, hypersensitivity reactions including anaphylactic/anaphylactoid reactions, bronchospasm, and urticaria.

Musculoskeletal and connective tissue disorders: Arthralgia, myalgia.

Nervous system disorders: Acute disseminated encephalomyelitis, dizziness, Guillain-Barré syndrome, headache, motor neuron disease, paralysis, seizures, syncope (including syncope associated with tonic-

clonic movements and other seizure-like activity) sometimes resulting in falling with injury, transverse myelitis.

Infections and infestations: Cellulitis.

Vascular disorders: Deep venous thrombosis.

7 DRUG INTERACTIONS

7.1 Use with Systemic Immunosuppressive Medications

Immunosuppressive therapies, including irradiation, antimetabolites, alkylating agents, cytotoxic drugs, and corticosteroids (used in greater than physiologic doses), may reduce the immune responses to vaccines [see *Use in Specific Populations* (8.6)].

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category B:

Reproduction studies have been performed in female rats at a dose approximately 240 times the human dose (mg/kg basis) and have revealed no evidence of impaired female fertility or harm to the fetus due to GARDASIL 9. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human responses, GARDASIL 9 should be used during pregnancy only if clearly needed.

Clinical Studies in Humans

In clinical studies, women underwent serum or urine pregnancy testing prior to administration of each dose of GARDASIL 9. Women who were found to be pregnant before completion of a three-dose regimen of GARDASIL 9 were instructed to defer completion of their vaccination regimen until resolution of the pregnancy.

The overall proportion of pregnancies occurring at any time during Studies 1, 2 and 4 that resulted in an adverse outcome defined as the combined numbers of spontaneous abortion, late fetal death and congenital anomaly cases out of the total number of pregnancy outcomes for which an outcome was known (and excluding elective terminations), was 14.1% (145/1,028) in women who received GARDASIL 9 and 17.0% (168/991) in women who received GARDASIL. The proportions of adverse outcomes observed were consistent with pregnancy outcomes observed in the general population.

Further sub-analyses were conducted to evaluate pregnancies with estimated onset within 30 days or more than 30 days from administration of a dose of GARDASIL 9 or GARDASIL. For pregnancies with estimated onset within 30 days of vaccination, no cases of congenital anomaly were observed in women who have received GARDASIL 9 or GARDASIL. In pregnancies with onset more than 30 days following vaccination, 20 and 21 cases of congenital anomaly were observed in women who have received GARDASIL 9 and GARDASIL, respectively. There was no clear pattern of anomaly types that differed from those occurring in pregnancies in the general population of the same age.

For pregnancies with estimated onset within 30 days of vaccination, the proportion of pregnancies that resulted in a spontaneous abortion out of the total number of pregnancies with a known outcome (excluding elective terminations) was 27.4% (17/62) and 12.7% (7/55) in women who received GARDASIL 9 or GARDASIL, respectively. For pregnancies with estimated onset more than 30 days following vaccination, that proportion was 10.9% (105/960) and 14.6% (136/933) in women who received GARDASIL 9 or GARDASIL, respectively.

Pregnancy Registry for GARDASIL 9

Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., maintains a Pregnancy Registry to monitor fetal outcomes of pregnant women exposed to GARDASIL 9. Patients and health care providers are encouraged to register women exposed to GARDASIL 9 around the time of conception or during pregnancy by calling 1-800-986-8999.

8.3 Nursing Mothers

It is not known whether GARDASIL 9 is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when GARDASIL 9 is administered to a nursing woman.

8.4 Pediatric Use

Safety and effectiveness have not been established in pediatric patients below 9 years of age.

8.5 Geriatric Use

The safety and effectiveness of GARDASIL 9 have not been evaluated in a geriatric population, defined as individuals aged 65 years and over.

8.6 Immunocompromised Individuals

The immunologic response to GARDASIL 9 may be diminished in immunocompromised individuals [see *Drug Interactions* (7.1)].

11 DESCRIPTION

GARDASIL 9, Human Papillomavirus 9-valent Vaccine, Recombinant, is a non-infectious recombinant 9-valent vaccine prepared from the purified virus-like particles (VLPs) of the major capsid (L1) protein of HPV Types 6, 11, 16, 18, 31, 33, 45, 52, and 58. The L1 proteins are produced by separate fermentations using recombinant *Saccharomyces cerevisiae* and self-assembled into VLPs. The fermentation process involves growth of *S. cerevisiae* on chemically-defined fermentation media which include vitamins, amino acids, mineral salts, and carbohydrates. The VLPs are released from the yeast cells by cell disruption and purified by a series of chemical and physical methods. The purified VLPs are adsorbed on preformed aluminum-containing adjuvant (Amorphous Aluminum Hydroxyphosphate Sulfate or AAHS). The 9-valent HPV VLP vaccine is a sterile liquid suspension that is prepared by combining the adsorbed VLPs of each HPV type and additional amounts of the aluminum-containing adjuvant and the final purification buffer.

GARDASIL 9 is a sterile suspension for intramuscular administration. Each 0.5-mL dose contains approximately 30 mcg of HPV Type 6 L1 protein, 40 mcg of HPV Type 11 L1 protein, 60 mcg of HPV Type 16 L1 protein, 40 mcg of HPV Type 18 L1 protein, 20 mcg of HPV Type 31 L1 protein, 20 mcg of HPV Type 33 L1 protein, 20 mcg of HPV Type 45 L1 protein, 20 mcg of HPV Type 52 L1 protein, and 20 mcg of HPV Type 58 L1 protein.

Each 0.5-mL dose of the vaccine also contains approximately 500 mcg of aluminum (provided as AAHS), 9.56 mg of sodium chloride, 0.78 mg of L-histidine, 50 mcg of polysorbate 80, 35 mcg of sodium borate, <7 mcg yeast protein, and water for injection. The product does not contain a preservative or antibiotics.

After thorough agitation, GARDASIL 9 is a white, cloudy liquid.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

HPV only infects human beings. Animal studies with analogous animal papillomaviruses suggest that the efficacy of L1 VLP vaccines may involve the development of humoral immune responses. Efficacy of GARDASIL 9 against anogenital diseases related to the vaccine HPV types in human beings is thought to be mediated by humoral immune responses induced by the vaccine, although the exact mechanism of protection is unknown.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

GARDASIL 9 has not been evaluated for the potential to cause carcinogenicity or genotoxicity.

Reproduction

GARDASIL 9 administered to female rats at a dose approximately 240 times the human dose (mg/kg basis) had no effects on mating performance, fertility, or embryonic/fetal survival.

Development

GARDASIL 9 administered to female rats at a dose approximately 160 times the human dose (mg/kg basis) had no effects on development, behavior, reproductive performance or fertility of the offspring. Antibodies against all 9 HPV types were transferred to the offspring during gestation and lactation.

14 CLINICAL STUDIES

In these studies, seropositive is defined as anti-HPV titer greater than or equal to the pre-specified serostatus cutoff for a given HPV type. Seronegative is defined as anti-HPV titer less than the pre-specified serostatus cutoff for a given HPV type. The serostatus cutoff is the antibody titer level above the assay's lower limit of quantification that reliably distinguishes sera samples classified by clinical likelihood of HPV infection and positive or negative status by previous versions of competitive Luminex Immunoassay (cLIA). The lower limits of quantification and serostatus cutoffs for each of the 9 vaccine HPV types are shown in Table 5 below. PCR positive is defined as DNA detected for a given HPV type. PCR negative is defined as DNA not detected for a given HPV type. The lower limit of detection for the multiplexed HPV PCR assays ranged from 5 to 34 copies per test across the 9 vaccine HPV types.

Table 5: Competitive Luminex Immunoassay (cLIA) Limits of Quantification and Serostatus Cutoffs for GARDASIL 9 HPV Types

HPV Type	cLIA Lower Limit of Quantification (mMU*/mL)	cLIA Serostatus Cutoff (mMU*/mL)
HPV 6	16	30
HPV 11	6	16
HPV 16	12	20
HPV 18	8	24
HPV 31	4	10
HPV 33	4	8
HPV 45	3	8
HPV 52	3	8
HPV 58	4	8

*mMU=milli-Merck Units

14.1 Efficacy and Effectiveness Data for GARDASIL

Efficacy and effectiveness of GARDASIL are relevant to GARDASIL 9 since the vaccines are manufactured similarly and contain four of the same HPV L1 VLPs.

Individuals 16 through 26 Years of Age

Efficacy of GARDASIL was assessed in five AAHS-controlled, double-blind, randomized clinical trials evaluating 24,596 individuals 16 through 26 years of age (20,541 girls and women and 4,055 boys and men). The results of these trials are shown in Table 6 below.

Table 6: Analysis of Efficacy of GARDASIL in the PPE* Population for Vaccine HPV Types

Disease Endpoints	GARDASIL		AAHS Control		% Efficacy (95% CI)
	N	Number of cases	N	Number of cases	
16- through 26-Year-Old Girls and Women†					
HPV 16- or 18-related CIN 2/3 or AIS	8493	2	8464	112	98.2 (93.5, 99.8)
HPV 16- or 18-related VIN 2/3	7772	0	7744	10	100.0 (55.5, 100.0)
HPV 16- or 18-related VaIN 2/3	7772	0	7744	9	100.0 (49.5, 100.0)
HPV 6-, 11-, 16-, or 18-related CIN (CIN 1, CIN 2/3) or AIS	7864	9	7865	225	96.0 (92.3, 98.2)
HPV 6-, 11-, 16-, or 18-related Genital Warts	7900	2	7902	193	99.0 (96.2, 99.9)
HPV 6- and 11-related Genital Warts	6932	2	6856	189	99.0 (96.2, 99.9)
16- through 26-Year-Old Boys and Men					
External Genital Lesions HPV 6-, 11-, 16-, or 18-related					
External Genital Lesions	1394	3	1404	32	90.6 (70.1, 98.2)
Condyloma	1394	3	1404	28	89.3 (65.3, 97.9)
PIN 1/2/3	1394	0	1404	4	100.0 (-52.1, 100.0)
HPV 6-, 11-, 16-, or 18-related Endpoint					
AIN 1/2/3	194	5	208	24	77.5 (39.6, 93.3)
AIN 2/3	194	3	208	13	74.9 (8.8, 95.4)
AIN 1	194	4	208	16	73.0 (16.3, 93.4)
Condyloma Acuminatum	194	0	208	6	100.0 (8.2, 100.0)
Non-acuminate	194	4	208	11	60.4 (-33.5, 90.8)

*The PPE population consisted of individuals who received all three vaccinations within one year of enrollment, did not have major deviations from the study protocol, were naïve (PCR negative and seronegative) to the relevant HPV type(s) (Types 6, 11, 16, and 18) prior to dose 1 and who remained PCR negative to the relevant HPV type(s) through one month post-dose 3 (Month 7).

[†]Analyses of the combined trials were prospectively planned and included the use of similar study entry criteria.

N=Number of individuals with at least one follow-up visit after Month 7

CI=Confidence Interval

Note 1: Point estimates and confidence intervals are adjusted for person-time of follow-up.

Note 2: Table 6 does not include cases due to HPV types not covered by the vaccine.

AAHS = Amorphous Aluminum Hydroxyphosphate Sulfate, CIN = Cervical Intraepithelial Neoplasia, VIN = Vulvar Intraepithelial Neoplasia, VaIN=Vaginal Intraepithelial Neoplasia, PIN=Penile Intraepithelial Neoplasia, AIN=Anal Intraepithelial Neoplasia, AIS=Adenocarcinoma *In Situ*

In an extension study in females 16 through 26 years of age at enrollment, prophylactic efficacy of GARDASIL through Month 60 against overall cervical and genital disease related to HPV 6, 11, 16, and 18 was 100% (95% CI: 12.3%, 100%) compared to AAHS control.

An extension study in girls and women 16 through 23 years of age used national healthcare registries in Denmark, Iceland, Norway, and Sweden to monitor endpoint cases of HPV 6-, 11-, 16-, or 18-related CIN (any grade), AIS, cervical cancer, vulvar cancer, or vaginal cancer among 2,650 girls and women 16 through 23 years of age at enrollment who were randomized to vaccination with GARDASIL. An interim analysis of the per-protocol effectiveness population included 1,902 subjects who completed the GARDASIL vaccination series within one year, were naïve to the relevant HPV type through 1 month post-dose 3, had no protocol violations, and had follow-up data available. The median follow-up from the first dose of vaccine was 6.7 years with a range of 2.8 to 8.4 years. At the time of interim analysis, no cases of HPV 6-, 11-, 16-, or 18-related CIN (any grade), AIS, cervical cancer, vulvar cancer, or vaginal cancer were observed over a total of 5,765 person-years at risk.

Girls and Boys 9 through 15 Years of Age

An extension study of 614 girls and 565 boys 9 through 15 years of age at enrollment who were randomized to vaccination with GARDASIL actively followed subjects for endpoint cases of HPV 6-, 11-, 16-, or 18-related persistent infection, CIN (any grade), AIS, VIN, VaIN, cervical cancer, vulvar cancer, vaginal cancer, and external genital lesions from the initiation of sexual activity or age 16 onwards. An interim analysis of the per-protocol effectiveness population included 246 girls and 168 boys who completed the GARDASIL vaccination series within one year, were seronegative to the relevant HPV type at initiation of the vaccination series, and had not initiated sexual activity prior to receiving the third dose of GARDASIL. The median follow-up from the first dose of vaccine was 7.2 years with a range of

0.5 to 8.5 years. At the time of interim analysis, no cases of persistent infection of at least 12 months' duration and no cases of HPV 6-, 11-, 16-, or 18-related CIN (any grade), AIS, VIN, VaIN, cervical cancer, vulvar cancer, vaginal cancer, or external genital lesions were observed over a total 1,105 person-years at risk. There were 4 cases of HPV 6-, 11-, 16-, or 18-related persistent infection of at least 6 months' duration, including 3 cases related to HPV 16 and 1 case related to HPV 6, none of which persisted to 12 months' duration.

Women 27 through 45 Years of Age

A clinical trial evaluated efficacy of GARDASIL in 3,253 women 27 through 45 years of age, based on a combined endpoint of HPV 6-, 11-, 16- or 18-related persistent infection, genital warts, vulvar and vaginal dysplastic lesions of any grade, CIN of any grade, AIS, and cervical cancer. These women were randomized 1:1 to receive either GARDASIL or AAHS control. The efficacy estimate for the combined endpoint was driven primarily by prevention of persistent infection. No statistically significant efficacy was demonstrated for GARDASIL in prevention of cervical intraepithelial neoplasia grades 2 and 3 (CIN 2/3), adenocarcinoma *in situ* (AIS) or cervical cancer related to HPV types 16 and 18.

14.2 Clinical Trials for GARDASIL 9

Efficacy and/or immunogenicity of GARDASIL 9 were assessed in six clinical trials. Study 1 evaluated the efficacy of GARDASIL 9 to prevent HPV-related cervical, vulvar, and vaginal disease using GARDASIL as a comparator.

The analysis of efficacy for GARDASIL 9 was evaluated in the per-protocol efficacy (PPE) population of 16- through 26-year-old girls and women, who were naïve to the relevant HPV type(s) by serology and PCR of cervicovaginal specimens prior to dose one and who remained PCR negative for the relevant HPV type(s) through one month post-dose 3 (Month 7). Overall, approximately 52% of subjects were negative to all vaccine HPV types by both PCR and serology at Day 1.

The primary analysis of efficacy against HPV Types 31, 33, 45, 52, and 58 is based on a combined endpoint of Cervical Intraepithelial Neoplasia (CIN) 2, CIN 3, Adenocarcinoma *in situ* (AIS), invasive cervical carcinoma, Vulvar Intraepithelial Neoplasia (VIN) 2/3, Vaginal Intraepithelial Neoplasia (VaIN) 2/3, vulvar cancer, or vaginal cancer. Other endpoints evaluated include cervical, vulvar and vaginal disease of any grade, persistent infection, cytological abnormalities and invasive procedures. For all endpoints, the efficacy against the HPV Types 31, 33, 45, 52 and 58 in GARDASIL 9 was evaluated compared with GARDASIL. Efficacy of GARDASIL 9 against anal lesions caused by HPV Types 31, 33, 45, 52, and 58 was not assessed due to low incidence. Effectiveness of GARDASIL 9 against anal lesions was inferred from the efficacy of GARDASIL against anal lesions caused by HPV types 6, 11, 16 and 18 in men and antibody responses elicited by GARDASIL 9 against the HPV types covered by the vaccine.

Effectiveness against disease caused by HPV Types 6, 11, 16, and 18 was assessed by comparison of geometric mean titers (GMTs) of type-specific antibodies following vaccination with GARDASIL 9 with those following vaccination with GARDASIL (Study 1 and Study 3). The effectiveness of GARDASIL 9 in girls and boys 9 through 15 years old and in boys and men 16 through 26 years old was inferred based on a comparison of type-specific antibody GMTs to those of 16 through 26-year-old girls and women following vaccination with GARDASIL 9. Immunogenicity analyses were performed in the per-protocol immunogenicity (PPI) population consisting of individuals who received all three vaccinations within one year of enrollment, did not have major deviations from the study protocol, and were naïve [PCR negative (in girls and women 16 through 26 years of age; Studies 1 and 2) and seronegative (Studies 1, 2, 3, 5 and 7)] to the relevant HPV type(s) prior to dose 1 and through Month 7.

Study 1 evaluated immunogenicity of GARDASIL 9 and efficacy to prevent infection and disease caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58 in 16- through 26-year-old girls and women. Study 2 evaluated immunogenicity of GARDASIL 9 in girls and boys 9 through 15 years of age and women 16 through 26 years of age. Study 3 evaluated immunogenicity of GARDASIL 9 compared with GARDASIL in girls 9 through 15 years of age. Study 4 evaluated administration of GARDASIL 9 to girls and women 12 through 26 years of age previously vaccinated with GARDASIL. Study 5 evaluated GARDASIL 9 concomitantly administered with Menactra and Adacel in girls and boys 11 through 15 years of age. Together, these five clinical trials evaluated 12,233 individuals who received GARDASIL 9 (8,048 girls and women 16 through 26 years of age at enrollment with a mean age of 21.8 years; 2,927 girls 9

through 15 years of age at enrollment with a mean age of 11.9 years; and 1,258 boys 9 through 15 years of age at enrollment with a mean age of 11.9 years. Study 7 evaluated immunogenicity of GARDASIL 9 in boys and men, including 1,106 self-identified as heterosexual men (HM) and 313 self-identified as men having sex with men (MSM), 16 through 26 years of age at enrollment (mean ages 20.8 years and 22.2 years, respectively) and 1,101 girls and women 16 through 26 years of age at enrollment (mean age 21.3 years).

The race distribution of the 16- through 26-year-old girls and women in the clinical trials was as follows: 56.8% White; 25.2% Other; 14.1% Asian; and 3.9% Black. The race distribution of the 9- through 15-year-old girls in the clinical trials was as follows: 60.3% White; 19.3% Other; 13.5% Asian; and 7.0% Black. The race distribution of the 9- through 15-year-old boys in the clinical trials was as follows: 46.6% White; 34.3% Other; 13.3% Asian; and 5.9% Black. The race distribution of the 16- through 26-year-old boys and men in the clinical trials was as follows: 62.1% White; 22.6% Other; 9.8% Asian; and 5.5% Black.

14.3 Efficacy – HPV Types 31, 33, 45, 52 and 58 in Girls and Women 16 through 26 Years of Age

Studies Supporting the Efficacy of GARDASIL 9 against HPV Types 31, 33, 45, 52, and 58

The efficacy of GARDASIL 9 in 16- through 26-year-old girls and women was assessed in an active comparator-controlled, double-blind, randomized clinical trial (Study 1) that included a total of 14,204 women (GARDASIL 9 = 7,099; GARDASIL = 7,105) who were enrolled and vaccinated without pre-screening for the presence of HPV infection. Subjects were followed up with a median duration of 40 months (range 0 to 64 months) after the last vaccination.

The primary efficacy evaluation was based on a composite clinical endpoint of HPV 31-, 33-, 45-, 52-, and 58-related cervical cancer, vulvar cancer, vaginal cancer, CIN 2/3 or AIS, VIN 2/3, and VaIN 2/3. Efficacy was evaluated in the PPE population of 16- through 26-year-old girls and women, who were naïve to the relevant HPV type(s) by serology and PCR of cervicovaginal specimens prior to dose 1 and who remained PCR negative to the relevant HPV type(s) through Month 7. Efficacy was further evaluated with the clinical endpoints of HPV 31-, 33-, 45-, 52-, and 58-related CIN 1, vulvar and vaginal disease of any grade, and persistent infection. In addition, the study also evaluated the impact of GARDASIL 9 on the rates of HPV 31-, 33-, 45-, 52-, and 58-related abnormal Papanicolaou (Pap) tests, cervical and external genital biopsy, and definitive therapy [including loop electrosurgical excision procedure (LEEP) and conization]. Efficacy for all endpoints was measured starting after the Month 7 visit.

GARDASIL 9 prevented HPV 31-, 33-, 45-, 52-, and 58-related persistent infection and disease and also reduced the incidence of HPV 31-, 33-, 45-, 52-, and 58-related Pap test abnormalities, cervical and external genital biopsy, and definitive therapy (Table 7).

Table 7: Analysis of Efficacy of GARDASIL 9 against HPV Types 31, 33, 45, 52, and 58 in the PPE* Population of 16- through 26-Year-old Girls and Women (Study 1)

Disease Endpoint	GARDASIL 9 N [†] =7099		GARDASIL N [†] =7105		GARDASIL 9 Efficacy % (95% CI)
	n [‡]	Number of cases	n [‡]	Number of cases	
HPV 31-, 33-, 45-, 52-, 58-related CIN 2/3, AIS, Cervical Cancer, VIN 2/3, VaIN 2/3, Vulvar Cancer, and Vaginal Cancer	6016	1	6017	30	96.7 (80.9, 99.8)
HPV 31-, 33-, 45-, 52-, 58-related CIN 1	5948	1	5943	69	98.6 (92.4, 99.9)
HPV 31-, 33-, 45-, 52-, 58-related CIN 2/3 or AIS	5948	1	5943	27	96.3 (79.5, 99.8)
HPV 31-, 33-, 45-, 52-, 58-related Vulvar or Vaginal Disease	6009	1	6012	16	93.8 (61.5, 99.7)
HPV 31-, 33-, 45-, 52-, 58-related Persistent Infection ≥6 Months [§]	5939	26	5953	642	96.2 (94.4, 97.5)
HPV 31-, 33-, 45-, 52-, 58-related Persistent Infection ≥12 Months [¶]	5939	15	5953	375	96.1 (93.7, 97.9)
HPV 31-, 33-, 45-, 52-, 58-related ASC-US HR-HPV Positive or Worse Pap [#] Abnormality	5881	35	5882	462	92.6 (89.7, 94.8)
HPV 31-, 33-, 45-, 52-, 58-related Biopsy	6016	7	6017	222	96.9 (93.6, 98.6)
HPV 31-, 33-, 45-, 52-, 58-related Definitive Therapy [‡]	6012	4	6014	32	87.5 (65.7, 96.0)

*The PPE population consisted of individuals who received all three vaccinations within one year of enrollment, did not have major deviations from the study protocol, were naïve (PCR negative and seronegative) to the relevant HPV type(s) (Types 31, 33, 45, 52, and 58) prior to dose 1, and who remained PCR negative to the relevant HPV type(s) through one month post-dose 3 (Month 7); data from Study 1 (NCT00543543).

[†]N=Number of individuals randomized to the respective vaccination group who received at least one injection

[‡]n=Number of individuals contributing to the analysis

[§]Persistent infection detected in samples from two or more consecutive visits at least six months apart

[¶]Persistent infection detected in samples from two or more consecutive visits over 12 months or longer

[#]Papanicolaou test

[‡]Including loop electrosurgical excision procedure (LEEP) and conization

CI=Confidence Interval

CIN=Cervical Intraepithelial Neoplasia, VIN=Vulvar Intraepithelial Neoplasia, VaIN=Vaginal Intraepithelial Neoplasia,

AIS=Adenocarcinoma *In Situ*, ASC-US=Atypical squamous cells of undetermined significance

HR=High Risk

14.4 Immunogenicity

The minimum anti-HPV titer that confers protective efficacy has not been determined.

Type-specific immunoassays (i.e., cLIA) with type-specific standards were used to assess immunogenicity to each vaccine HPV type. These assays measured antibodies against neutralizing epitopes for each HPV type. The scales for these assays are unique to each HPV type; thus, comparisons across types and to other assays are not appropriate. Immunogenicity was measured by (1) the percentage of individuals who were seropositive for antibodies against the relevant vaccine HPV type, and (2) the Geometric Mean Titer (GMT).

Studies Supporting the Effectiveness of GARDASIL 9 against HPV Types 6, 11, 16, and 18

Effectiveness of GARDASIL 9 against persistent infection and disease related to HPV Types 6, 11, 16, or 18 was inferred from non-inferiority comparisons in Study 1 (16- through 26-year-old girls and women) and Study 3 (9- through 15-year-old girls) of GMTs following vaccination with GARDASIL 9 with those following vaccination with GARDASIL. A low number of efficacy endpoint cases related to HPV types 6, 11, 16 and 18 in both vaccination groups precluded a meaningful assessment of efficacy using disease endpoints associated with these HPV types. The primary analyses were conducted in the per-protocol population, which included subjects who received all three vaccinations within one year of enrollment, did not have major deviations from the study protocol, and were HPV-naïve. HPV-naïve individuals were defined as seronegative to the relevant HPV type(s) prior to dose 1 and among female subjects 16 through 26 years of age in Study 1 PCR negative to the relevant HPV type(s) in cervicovaginal specimens prior to dose 1 through Month 7.

Anti-HPV 6, 11, 16 and 18 GMTs at Month 7 for GARDASIL 9 among girls 9 through 15 years of age and young women 16 through 26 years of age were non-inferior to those among the corresponding populations for GARDASIL (Table 8). At least 99.7% of individuals included in the analyses for each HPV type became seropositive by Month 7.

Table 8: Comparison of Immune Responses (Based on cLIA) Between GARDASIL 9 and GARDASIL for HPV Types 6, 11, 16, and 18 in the PPI* Population of 9- through 26-Year-Old Girls and Women (Studies 1 and 3)

Population	GARDASIL 9		GARDASIL		GARDASIL 9/ GARDASIL	
	N [†] (n [‡])	GMT mMU [§] /mL	N [†] (n [‡])	GMT mMU [§] /mL	GMT Ratio	(95% CI) [¶]
Anti-HPV 6						
9- through 15-year-old girls	300 (273)	1679.4	300 (261)	1565.9	1.07	(0.93, 1.23)
16- through 26-year-old girls and women	6792 (3993)	893.1	6795 (3975)	875.2	1.02	(0.99, 1.06)
Anti-HPV 11						
9- through 15-year-old girls	300 (273)	1315.6	300 (261)	1417.3	0.93	(0.80, 1.08)
16- through 26-year-old girls and women	6792 (3995)	666.3	6795 (3982)	830.0	0.80	(0.77, 0.83)
Anti-HPV 16						
9- through 15-year-old girls	300 (276)	6739.5	300 (270)	6887.4	0.97	(0.85, 1.11)
16- through 26-year-old girls and women	6792 (4032)	3131.1	6795 (4062)	3156.6	0.99	(0.96, 1.03)
Anti-HPV 18						
9- through 15-year-old girls	300 (276)	1956.6	300 (269)	1795.6	1.08	(0.91, 1.29)
16- through 26-year-old girls and women	6792 (4539)	804.6	6795 (4541)	678.7	1.19	(1.14, 1.23)

*The PPI population consisted of individuals who received all three vaccinations within pre-defined day ranges, did not have major deviations from the study protocol, met predefined criteria for the interval between the Month 6 and Month 7 visit, were naïve (PCR negative [among 16- through 26-year old girls and women] and seronegative) to the relevant HPV type(s) (types 6, 11, 16, and 18) prior to dose 1, and among 16- through 26-year-old girls and women were PCR negative to the relevant HPV type(s) prior to dose 1 through one month post-dose 3 (Month 7). The data for 16- through 26-year-old girls and women are from Study 1 (NCT00543543), and the data for 9- through 15-year-old girls are from Study 3 (NCT01304498).

[†]N=Number of individuals randomized to the respective vaccination group who received at least one injection

[‡]n=Number of individuals contributing to the analysis

[§]mMU=milli-Merck Units

[¶]Demonstration of non-inferiority required that the lower bound of the 95% CI of the GMT ratio be greater than 0.67

CI=Confidence Interval

GMT=Geometric Mean Titer

cLIA=competitive Luminex Immunoassay

Study Supporting the Effectiveness of GARDASIL 9 against Vaccine HPV Types in 9- through 15-Year-Old Girls and Boys

Effectiveness of GARDASIL 9 against persistent infection and disease related to vaccine HPV types in 9- through 15-year-old girls and boys was inferred from non-inferiority comparison in Study 2 of GMTs following vaccination with GARDASIL 9 among 9- through 15-year-old girls and boys with those among 16- through 26-year-old girls and women. The primary analyses were conducted in the per-protocol population, which included subjects who received all three vaccinations within one year of enrollment, did not have major deviations from the study protocol, and were HPV-naïve. HPV-naïve individuals were defined as seronegative to the relevant HPV type(s) prior to dose 1 and among female subjects 16 through 26 years of age PCR negative to the relevant HPV type(s) in cervicovaginal specimens prior to dose 1 through Month 7. Anti-HPV GMTs at Month 7 among 9- through 15-year-old girls and boys were non-inferior to anti-HPV GMTs among 16- through 26-year-old girls and women (Table 9).

Table 9: Comparison of Immune Responses (Based on cLIA) between the PPI* Populations of 16- through 26-Year-Old Girls and Women, 9- through 15-Year-Old Girls, and 9- through 15-Year-Old Boys for All GARDASIL 9 Vaccine HPV Types (Study 2)

Population	N [†]	n [‡]	GMT mMU [§] /mL	GMT Ratio relative to 16- through 26-year-old girls and women (95% CI) [¶]
Anti-HPV 6				
9- through 15-year-old girls	630	503	1703.1	1.89 (1.68, 2.12)
9- through 15-year-old boys	641	537	2083.4	2.31 (2.06, 2.60)
16- through 26-year-old girls and women	463	328	900.8	1
Anti-HPV 11				
9- through 15-year-old girls	630	503	1291.5	1.83 (1.63, 2.05)
9- through 15-year-old boys	641	537	1486.3	2.10 (1.88, 2.36)
16- through 26-year-old girls and women	463	332	706.6	1
Anti-HPV 16				
9- through 15-year-old girls	630	513	6933.9	1.97 (1.75, 2.21)
9- through 15-year-old boys	641	546	8683.0	2.46 (2.20, 2.76)
16- through 26-year-old girls and women	463	329	3522.6	1
Anti-HPV 18				
9- through 15-year-old girls	630	516	2148.3	2.43 (2.12, 2.79)
9- through 15-year-old boys	641	544	2855.4	3.23 (2.83, 3.70)
16- through 26-year-old girls and women	463	345	882.7	1
Anti-HPV 31				
9- through 15-year-old girls	630	506	1894.7	2.51 (2.21, 2.86)
9- through 15-year-old boys	641	543	2255.3	2.99 (2.63, 3.40)
16- through 26-year-old girls and women	463	340	753.9	1
Anti-HPV 33				
9- through 15-year-old girls	630	518	985.8	2.11 (1.88, 2.37)
9- through 15-year-old boys	641	544	1207.4	2.59 (2.31, 2.90)
16- through 26-year-old girls and women	463	354	466.8	1
Anti-HPV 45				
9- through 15-year-old girls	630	518	707.7	2.60 (2.25, 3.00)
9- through 15-year-old boys	641	547	912.1	3.35 (2.90, 3.87)
16- through 26-year-old girls and women	463	368	272.2	1
Anti-HPV 52				
9- through 15-year-old girls	630	517	962.2	2.21 (1.96, 2.49)
9- through 15-year-old boys	641	545	1055.5	2.52 (2.22, 2.84)
16- through 26-year-old girls and women	463	337	419.6	1
Anti-HPV 58				
9- through 15-year-old girls	630	516	1288.0	2.18 (1.94, 2.46)
9- through 15-year-old boys	641	544	1593.3	2.70 (2.40, 3.03)
16- through 26-year-old girls and women	463	332	590.5	1

*The PPI population consisted of individuals who received all three vaccinations within pre-defined day ranges, did not have major deviations from the study protocol, met predefined criteria for the interval between the Month 6 and Month 7 visit, were naïve (PCR negative [among 16- through 26-year old girls and women] and seronegative) to the relevant HPV type(s) prior to dose 1 and among 16- through 26-year-old girls and women were PCR negative to the relevant HPV types prior to dose 1 through one month post-dose 3 (Month 7). The data are from Study 2 (NCT00943722).

[†]N=Number of individuals randomized to the respective vaccination group who received at least one injection

[‡]n=Number of individuals contributing to the analysis

[§]mMU=milli-Merck Units

[¶]Demonstration of non-inferiority required that the lower bound of the 95% CI of the GMT ratio be greater than 0.67

cLIA=competitive Luminex Immunoassay

CI=Confidence Interval

GMT=Geometric Mean Titer

Study Supporting the Effectiveness of GARDASIL 9 against Vaccine HPV Types in 16- through 26-Year-Old Boys and Men

Effectiveness of GARDASIL 9 against persistent infection and disease related to vaccine HPV types in 16- through 26-year-old boys and men was inferred from non-inferiority comparison in Study 7 of GMTs following vaccination with GARDASIL 9 among 16- through 26-year-old HM with those among 16- through 26-year-old girls and women. The primary analyses were conducted in the per-protocol population, which included subjects who received all three vaccinations within one year of enrollment, did not have major deviations from the study protocol, and were seronegative to the relevant HPV type(s) prior to dose 1. Anti-HPV GMTs at Month 7 among 16- through 26-year-old HM were non-inferior to anti-HPV GMTs among 16- through 26-year-old girls and women (Table 10). Study 7 also enrolled 313 16- through 26-year-old HIV-negative MSM. At Month 7, anti-HPV GMT ratios for MSM relative to HM ranged from 0.6 to 0.8, depending on HPV type. The GMT ratios for MSM relative to HM were generally similar to those previously observed in clinical trials with GARDASIL.

Table 10: Comparison of Immune Responses (Based on cLIA) between the PPI* Populations of 16- through 26-Year-Old Girls and Women and 16- through 26-Year-Old Boys and Men Self-Identified as Heterosexual (HM) for All GARDASIL 9 Vaccine HPV Types (Study 7)

Population	N [†]	n [‡]	GMT mMU [§] /mL	GMT Ratio relative to 16- through 26-year- old girls and women (95% CI) [¶]
Anti-HPV 6				
16- through 26-year-old HM	1103	847	782.0	1.11 (1.02, 1.21)
16- through 26-year-old girls and women	1099	708	703.9	1
Anti-HPV 11				
16- through 26-year-old HM	1103	851	616.7	1.09 (1.00, 1.19)
16- through 26-year-old girls and women	1099	712	564.9	1
Anti-HPV 16				
16- through 26-year-old HM	1103	899	3346.0	1.20 (1.10, 1.30)
16- through 26-year-old girls and women	1099	781	2788.3	1
Anti-HPV 18				
16- through 26-year-old HM	1103	906	808.2	1.19 (1.08, 1.31)
16- through 26-year-old girls and women	1099	831	679.8	1
Anti-HPV 31				
16- through 26-year-old HM	1103	908	708.5	1.24 (1.13, 1.37)
16- through 26-year-old girls and women	1099	826	570.1	1
Anti-HPV 33				
16- through 26-year-old HM	1103	901	384.8	1.19 (1.10, 1.30)
16- through 26-year-old girls and women	1099	853	322.0	1
Anti-HPV 45				
16- through 26-year-old HM	1103	909	235.6	1.27 (1.14, 1.41)
16- through 26-year-old girls and women	1099	871	185.7	1
Anti-HPV 52				
16- through 26-year-old HM	1103	907	386.8	1.15 (1.05, 1.26)
16- through 26-year-old girls and women	1099	849	335.2	1
Anti-HPV 58				
16- through 26-year-old HM	1103	897	509.8	1.25 (1.14, 1.36)
16- through 26-year-old girls and women	1099	839	409.3	1

*The PPI population consisted of individuals who received all three vaccinations within pre-defined day ranges, did not have major deviations from the study protocol, met predefined criteria for the interval between the Month 6 and Month 7 visit, and were seronegative to the relevant HPV type(s) (types 6, 11, 16, 18, 31, 33, 45, 52, and 58) prior to dose 1. The data are from Study 7 (NCT01651949).

[†]Number of individuals randomized to the respective vaccination group who received at least one injection

[‡]Number of individuals contributing to the analysis

[§]mMU=milli-Merck Units

[¶]Demonstration of non-inferiority required that the lower bound of the 95% CI of the GMT ratio be greater than 0.67

cLIA=competitive Luminex Immunoassay.

CI=Confidence Interval

GMT=Geometric Mean Titer

Immune Response to GARDASIL 9 across All Clinical Trials

Across all clinical trials, at least 99.5% of individuals included in the analyses for each of the nine vaccine HPV types became seropositive by Month 7. Anti-HPV GMTs at Month 7 among 9- through 15-

year-old girls and boys and 16- through 26-year-old boys and men were comparable to anti-HPV responses among 16- through 26-year-old girls and women in the combined database of immunogenicity studies for GARDASIL 9.

Persistence of Immune Response to GARDASIL 9

The duration of immunity following a complete schedule of vaccination with GARDASIL 9 has not been established. The peak anti-HPV GMTs for each vaccine HPV type occurred at Month 7. Proportions of individuals who remained seropositive to each vaccine HPV type at Month 24 were similar to the corresponding seropositive proportions at Month 7.

Administration of GARDASIL 9 to Individuals Previously Vaccinated with GARDASIL

Study 4 evaluated the immunogenicity of GARDASIL 9 in 921 girls and women (12 through 26 years of age) who had previously been vaccinated with GARDASIL. Prior to enrollment in the study, over 99% of subjects had received three injections of GARDASIL within a one year period. The time interval between the last injection of GARDASIL and the first injection of GARDASIL 9 ranged from approximately 12 to 36 months.

Seropositivity to HPV Types 6, 11, 16, 18, 31, 33, 45, 52, and 58 in the per protocol population ranged from 98.3 to 100% by Month 7 in individuals who received GARDASIL 9. The anti-HPV 31, 33, 45, 52 and 58 GMTs for the population previously vaccinated with GARDASIL were 25-63% of the GMTs in the combined populations from Studies 1, 2, 3, and 5, who had not previously received GARDASIL, although the clinical relevance of these differences is unknown. Efficacy of GARDASIL 9 in preventing infection and disease related to HPV Types 31, 33, 45, 52, and 58 in individuals previously vaccinated with GARDASIL has not been assessed.

Concomitant Use of Hormonal Contraceptives

Among 7,269 female recipients of GARDASIL 9 (16 through 26 years of age), 60.2% used hormonal contraceptives during the vaccination period of clinical studies 1 and 2. Use of hormonal contraceptives did not appear to affect the type specific immune responses to GARDASIL 9.

14.5 Studies with Menactra and Adacel

In Study 5, the safety and immunogenicity of co-administration of GARDASIL 9 with Menactra [Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine] and Adacel [Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (Tdap)] (same visit, injections at separate sites) were evaluated in 1,237 boys and girls 11 through 15 years of age at enrollment.

One group received GARDASIL 9 in one limb and both Menactra and Adacel, as separate injections, in the opposite limb concomitantly on Day 1 (n = 619). The second group received the first dose of GARDASIL 9 on Day 1 in one limb then Menactra and Adacel, as separate injections, at Month 1 in the opposite limb (n = 618). Subjects in both vaccination groups received the second dose of GARDASIL 9 at Month 2 and the third dose at Month 6. Immunogenicity was assessed for all vaccines one month post vaccination (one dose for Menactra and Adacel and three doses for GARDASIL 9).

Assessments of post-vaccination immune responses included type-specific antibody GMTs for each of the vaccine HPV types at four weeks following the last dose of GARDASIL 9; GMTs for anti-filamentous hemagglutinin, anti-pertactin, and anti-fimbrial antibodies at four weeks following Adacel; percentage of subjects with anti-tetanus toxin and anti-diphtheria toxin antibody concentrations ≥ 0.1 IU/mL at four weeks following Adacel; and percentage of subjects with ≥ 4 -fold rise from pre-vaccination baseline in antibody titers against *N. meningitidis* serogroups A, C, Y, and W-135 at four weeks following Menactra. Based on these measures, concomitant administration of GARDASIL 9 with Menactra and Adacel did not interfere with the antibody responses to any of the vaccines when compared with non-concomitant administration of GARDASIL 9 with Menactra and Adacel.

16 HOW SUPPLIED/STORAGE AND HANDLING

GARDASIL 9 is supplied in vials and syringes.
Carton of one 0.5-mL single-dose vial. NDC 0006-4119-02

Carton of ten 0.5-mL single-dose vials. NDC 0006-4119-03

Carton of ten 0.5-mL single-dose prefilled Luer Lock syringes with tip caps. NDC 0006-4121-02

Store refrigerated at 2 to 8°C (36 to 46°F). Do not freeze. Protect from light.

GARDASIL 9 should be administered as soon as possible after being removed from refrigeration. GARDASIL 9 can be administered provided total (cumulative multiple excursion) time out of refrigeration (at temperatures between 8°C and 25°C) does not exceed 72 hours. Cumulative multiple excursions between 0°C and 2°C are also permitted as long as the total time between 0°C and 2°C does not exceed 72 hours. These are not, however, recommendations for storage.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information).

Inform the patient, parent, or guardian:

- Vaccination does not eliminate the necessity for women to continue to undergo recommended cervical cancer screening. Women who receive GARDASIL 9 should continue to undergo cervical cancer screening per standard of care.
 - Recipients of GARDASIL 9 should not discontinue anal cancer screening if it has been recommended by a health care provider.
 - GARDASIL 9 has not been demonstrated to provide protection against disease from vaccine and non-vaccine HPV types to which a person has previously been exposed through sexual activity.
 - Since syncope has been reported following HPV vaccination sometimes resulting in falling with injury, observation for 15 minutes after administration is recommended.
 - Vaccine information is required to be given with each vaccination to the patient, parent, or guardian.
 - Provide information regarding benefits and risks associated with vaccination.
 - Safety and effectiveness of GARDASIL 9 have not been established in pregnant women. A pregnancy registry is available. Women exposed to GARDASIL 9 around the time of conception or during pregnancy are encouraged to register by calling 1-800-986-8999.
 - It is important to complete the full vaccination series unless contraindicated.
 - Report any adverse reactions to their health care provider.
-

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Human Papillomavirus (HPV): Questions and Answers

INFORMATION ABOUT THE DISEASE AND VACCINES

How common is HPV in the United States?

HPV is the most common sexually transmitted infection in the United States. About 79 million Americans are currently infected with HPV. About 14 million people become newly infected each year. HPV is so common that most sexually active men and women will get at least one type of HPV at some point in their lives.

An estimated 29,600 HPV-associated cancers occur annually in the U.S., including an estimated 9,300 HPV-associated cancers in males. Of these HPV-associated cancers approximately 64% are caused by HPV types 16 and 18, which are included in all three HPV vaccines available in the United States and about 10% are caused by the 5 HPV types also included in Gardasil 9.

How does HPV spread?

HPV is spread through contact with infected skin, usually through sexual contact. Most infected people have no symptoms and are unaware they are infected and can transmit the virus to a sex partner. Rarely, a pregnant woman passes HPV to her baby during vaginal delivery.

What are the symptoms of HPV?

Most people who become infected with HPV have no symptoms. Some people develop visible genital warts, or have pre-cancerous changes in the cervix, vulva, anus, or penis.

Genital warts usually appear as soft, moist, pink, or flesh-colored swellings, usually in the genital area. They can be raised or flat, single or multiple, small or large, and sometimes cauliflower shaped. They can appear on the vulva, in or around the vagina or anus, on the cervix, and on the penis, scrotum, groin, or thigh. After sexual contact with an infected person, warts may appear within weeks or months, or not at all.

How serious is HPV?

Most HPV infections don't cause any symptoms and eventually go away, as the body's own defense system clears the virus. Women with short-term HPV infections may develop mild Pap test abnormalities that go away with time.

A small percentage of people infected with HPV develop persistent (chronic) HPV infection. Women with persistent high-risk HPV infections are at greatest risk for developing cervical cancer precursor lesions (abnormal cells on the lining of the cervix) and cervical cancer. (See next question.)

What are possible complications from HPV?

Cancer is the most serious possible complication from HPV infection. Persistent infection with high-risk types of HPV is associated with almost all cervical cancers. The American Cancer Society (ACS) estimates that in 2015, approximately 12,900 new cases of invasive cervical cancer will occur in the U.S. and about 4,100 women will die from the disease. Worldwide, cervical cancer is the second most common cancer in women; it is estimated to cause over 470,000 new cases and 233,000 deaths each year.

Persistent infection with high-risk types of HPV is also associated with cancers of the vulva, vagina, penis, and anus. For example, ACS estimates that this year there will be about 1,820 new cases of penile cancer in the U.S. and 310 men will die. Genital HPV infection with low-risk types of HPV is associated with genital warts in men and women. About 1% of sexually active adults in the U.S. have visible genital warts at any point in time. It is estimated that approximately 360,000 cases of genital warts occur each year in the U.S. among sexually active people.

Occasionally, low-risk HPV infections can be transmitted during birth, resulting in respiratory tract warts in infants and children.

How is HPV infection diagnosed?

Genital warts in men and women are diagnosed by visual inspection.

Most women are diagnosed with HPV infection on the basis of abnormal Pap tests. Also, a specific test is available to detect HPV DNA in women. The test may be used in women with mild Pap test abnormalities or in women more than age 30 years at the time of Pap testing. In April 2014 the U.S. Food and Drug Administration approved the first HPV DNA test for women

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age 25 years and older that can be used alone to help a health care professional assess the need for additional diagnostic testing for cervical cancer. The test also can provide information about the patient's risk for developing cervical cancer in the future.

No HPV tests are available for men.

Can genital HPV infection be cured?

There is no cure for HPV infection, although the immune system usually eliminates the virus from the body. Approximately 90% of women with HPV infection become HPV-negative within two years. However, a small percentage of infected people remain infected for many years, which may result in genital warts or cancer.

There are treatments for the health problems that HPV can cause, such as genital warts, cervical cell changes, and cancers of the cervix, vulva, vagina, and anus.

Visible genital warts can be removed by medications the patient applies, or by treatments performed by a health-care provider. No one treatment is best. Warts might return, especially in the first 3 months after treatment. It is not known whether treatment of genital warts will reduce the chance of passing the virus on to a sex partner. If left untreated, genital warts may go away, remain unchanged, or increase in size or number.

How can people reduce their risk for acquiring genital HPV infection?

The surest way to eliminate risk for genital HPV infection is to refrain from any genital contact with another individual.

For people who are sexually active, a long-term, mutually monogamous relationship with an uninfected partner is the strategy most likely to prevent future genital HPV infections. However, it is difficult to determine whether a partner who has been sexually active with another partner in the past is currently infected.

It is not known how much protection a condom provides against HPV, since skin that is not covered by a condom can be exposed to the virus. However, condoms may reduce the risk of genital warts and cervical cancer. People can also reduce their risk by getting the HPV vaccine.

When were the HPV vaccines licensed?

The first HPV vaccine (Gardasil, Merck) was licensed for females in 2006. Gardasil protects against four HPV types: 16, 18, 6, and 11. About 70% of cervical cancers are caused by HPV types 16 and 18, and more than 90% of genital warts are associated with HPV

types 6 and 11. In 2009, Gardasil was licensed for use in males. In 2009, a second HPV vaccine was licensed (Cervarix, GlaxoSmithKline) for use in females. Cervarix protects against HPV types 16 and 18. In 2014, a new version of Gardasil was licensed. This vaccine, called Gardasil 9, protects against the four HPV types included in the original Gardasil as well as 5 additional cancer-causing HPV types. These 5 additional types account for about 10% of all HPV-associated cancer in the United States (14% of HPV-associated cancers in females and 4% in males). Both versions of Gardasil will be available in the United States through 2015.

What kind of vaccine is it?

HPV vaccine is an inactivated (not live) vaccine.

How is this vaccine given?

This vaccine is given as an injection in the deltoid muscle of the arm.

Who should get this vaccine?

The CDC's Advisory Committee on Immunization Practices (ACIP) recommends routine vaccination of boys and girls at age 11 or 12 years with catch-up vaccination for females through age 26 years, and for males through age 21 years; males age 22 through 26 years may be vaccinated. In addition, vaccination is recommended for men age 22 through 26 years who have sex with men or are immunocompromised as a result of disease (including HIV) or medication. The vaccination series can also be started as young as age 9 years, at the clinician's discretion. Females can receive either Gardasil, Gardasil 9, or Cervarix. Males should receive only Gardasil or Gardasil 9, because Cervarix is not approved by the FDA for males.

How many doses are needed and on what schedule?

The schedule for all three HPV vaccines consists of three injections over a six-month period. The second dose should be given one to two months after the first dose and the third dose should be given six months after the first dose and at least 12 weeks after the second dose. The vaccine can be administered at the same visit as other needed vaccines.

The vaccine provides the best protection when given before onset of sexual activity. However, people who are sexually active also may benefit from vaccination. People who have not been infected with any vaccine HPV type would receive the full benefit of vaccination. Those who already have been infected with one or more HPV types

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would still get protection from the vaccine types they have not acquired. HPV vaccine can be given to females who have had an abnormal Pap test or genital warts. However, the vaccine will not have any helpful effect on existing Pap test abnormalities, HPV infection, or genital warts (that is, the vaccine is not a treatment for HPV infection or HPV-related disease).

Why is HPV vaccine licensed for use in people as young as 9 years of age?

This is because the vaccine is most effective in young people who have not yet been infected by any of the HPV types included in the vaccine so that they will receive the full benefits of the vaccine.

Why are HPV vaccines not licensed for adults older than 26 years?

HPV vaccines have been tested in people age 9 through 26 years. Although Gardasil has been tested in women age 27 through 45 years and found to be safe, data on the effectiveness of the vaccine in this age group was inconclusive, mainly because many of the participants in the trial had already been infected with HPV types included in the vaccine. The FDA will consider licensing the vaccines for older people if additional research shows that it is effective for them.

Should individuals be screened before getting vaccinated?

No. Girls/women do not need to get an HPV test or Pap test to find out if they should get the vaccine.

How effective are the HPV vaccines?

All three HPV vaccines are highly effective in preventing infection with types of HPV included in the vaccines. Studies have shown that all three vaccines prevent nearly 100 percent of the precancerous cervical cell changes caused by the types of HPV included in the vaccine for more than 8 years after vaccination. Among males, efficacy of Gardasil for prevention of genital warts was 89% and efficacy for the prevention of precancerous lesions of the anus was 78%.

How long does vaccine protection last? Will a booster shot be needed?

The length of immunity is usually not known when a vaccine is first introduced. So far, studies have shown people to still be protected after more than 8 years. More research is being done to find out how long protection will last, and if a booster dose will eventually be needed.

Who recommends HPV vaccine?

The Centers for Disease Control and Prevention (CDC), the American Academy of Pediatrics (AAP), the American Academy of Family Physicians (AAFP), and the American College of Obstetricians and Gynecologists (ACOG) all recommend routine HPV vaccination of boys and girls at 11 or 12 years of age.

What side effects have been reported from HPV vaccine?

Mild problems may occur with HPV vaccine, including pain, redness, swelling, and itching at the injection site. These problems do not last long and go away on their own. Fainting has been reported among adolescents who receive HPV vaccine (and other recommended vaccines as well). It's best for the patient to sit during vaccine administration and remain seated for 15–20 minutes after receiving the vaccine.

Like all vaccines, HPV vaccine will be monitored for more serious or unusual side effects.

Can HPV vaccine cause HPV?

No. HPV vaccines are inactivated so they cannot cause disease-like symptoms or HPV disease.

We've heard stories in the media lately about severe reactions to HPV vaccine. Is there any substance to these stories?

No. While serious events, including death and Guillain-Barre syndrome, have been reported among women who had recently received HPV vaccine, CDC and FDA follow-up on these reports has not found that the events occurred more frequently among vaccinees than among the general population, and has detected no pattern that would indicate an association with the vaccine. You can find complete information on this and other vaccine safety issues at www.cdc.gov/vaccinesafety/index.html.

Do women still need to get a Pap test if they've been vaccinated against HPV?

Yes. Women should continue to receive regular cervical cancer screening for three reasons. First, the vaccine does not provide protection against all types of HPV that cause cervical cancer. Second, women may not receive the full benefits of the vaccine if they do not complete the vaccine series. Third, women may not receive the full benefits of the vaccine if they were infected with HPV before receiving the vaccine.

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In addition, vaccinated people should continue to practice protective sexual behaviors since the vaccine will not prevent all cases of genital warts or other sexually transmitted infections.

Does the vaccine protect against all types of HPV?

No. Although there are more than 100 types of human papillomaviruses, only four (HPV 6, 11, 16, and 18) are included in Gardasil, 9 are included in Gardasil 9 (HPV 6, 11, 16, 18, 31, 33, 45, 52 and 58) and only two (HPV 16 and 18) are included in Cervarix. HPV 16 and 18 (included in all three vaccines) are responsible for 70% of cervical cancers; HPV 6 and 11 causes approximately 90% of genital warts. About 25% of HPV-associated cancers are not prevented by the vaccine.

What if a person doesn't get all of the recommended three doses?

It is not known how much protection people would get from receiving only one or two doses of the vaccine. For this reason, it is very important to receive all three doses of the vaccine. If there is a gap in the schedule longer than the recommended time, the series should be continued from where it left off – there is no need to restart the series. A person who starts the series before the 27th birthday should complete the series even if he or she is now older than age 26 years.

Can an HPV vaccine series begun with Cervarix or Gardasil be completed with Gardasil 9?

Yes. Any HPV vaccine may be used to continue or complete the series for females for protection against HPV 16 and 18. Gardasil or Gardasil 9 may be used to continue or complete the series for males. However, receiving only two doses of Gardasil or Gardasil 9 may provide less protection against genital warts caused by HPV types 6 and 11 than the usual 3 dose series. It is not known how much protection a person will have against the 5 additional HPV types included in Gardasil 9 if the person receives fewer than 3 doses.

Does CDC recommend revaccination with Gardasil 9 for people who previously received a series of Cervarix or Gardasil?

CDC has not recommended routine revaccination with Gardasil 9 for persons who have completed a series of another HPV vaccine. There are data that indicate

revaccination with Gardasil 9 after a series of Gardasil is safe. Discuss this issue with your healthcare provider to decide if the benefit of immunity against 5 additional oncogenic strains of HPV is worth the time and expense of revaccination.

Do women and men whose sexual orientation is same-sex need HPV vaccine?

Yes. HPV vaccine is recommended for females and males regardless of their sexual orientation.

Who should NOT receive HPV vaccine?

Anyone who has ever had a life-threatening allergic reaction to any component of HPV vaccine (such as baker's yeast), or to a previous dose of HPV vaccine, should not get the vaccine.

Pregnant women should not get the vaccine. Although the vaccine appears to be safe for both the woman and developing baby, this issue is still being studied. Inadvertently receiving HPV vaccine during pregnancy is not a reason to consider terminating the pregnancy. Patients and healthcare providers should report any exposure to HPV vaccine during pregnancy to the manufacturer of the vaccine, Gardasil at (877) 888-4231, Gardasil 9 at (800) 986-8999, or Cervarix at (888) 825-5249.

Breast-feeding women can safely get the vaccine.

People who have a moderate or severe acute illness should wait until their condition improves to be vaccinated.

Is HPV vaccine covered by insurance plans?

Many health insurance plans cover vaccines recommended for children and adolescents. The Vaccines for Children (VFC) program provides free vaccines to children and adolescents younger than 19 years of age, who are Medicaid-eligible, American Indian, or Alaska Native, uninsured, or receiving care in a Federally Qualified Health Clinic or Rural Health Center. This includes boys as well as girls. For adults, if you're not certain about your healthcare coverage, contact your health insurance plan for further information. If you don't have health insurance or if your plan doesn't cover this vaccine, ask your doctor or your local health department how you can obtain this vaccine.



HPV and HPV Testing

Human Papilloma Virus (HPV)

What are viruses?

Viruses are very small organisms – most cannot even be seen with a regular microscope. They cannot reproduce on their own. They must enter a living cell, which becomes the *host cell*, and “hijack” the cell’s machinery to make more viruses.

Viruses can enter the body through the mucous membranes, such as the nose, mouth, the lining of the eyes, or the genitals. Some enter through the digestive system (such as stomach or intestine), via insect bites, or through breaks in the skin. A few can enter unbroken skin. Once inside, they find their specific type of host cell to infect. For example, cold and flu viruses find and invade cells that line the respiratory tract (nose, sinuses, breathing tubes, and lungs). HIV (the virus that causes AIDS) infects the T-cells and macrophages of the immune system. HPV infects *squamous epithelial cells* – the flat cells that cover the surface of the skin and mucous membranes.

What is HPV?

HPV is short for *human papilloma virus*. HPVs are a group of more than 150 related viruses. Each HPV virus in the group is given a number, which is called an *HPV type*. HPVs are called *papilloma viruses* because some of the HPV types cause warts or papillomas, which are non-cancerous tumors. But some types of HPV are known for causing cancer, especially of the cervix (the base of the womb at the top of the vagina).

The papilloma viruses are attracted to and are able to live only in certain cells called squamous epithelial cells. These cells are found on the surface of the skin and on moist surfaces (called *mucosal surfaces*) like:

- the vagina, anus, cervix, vulva (around the outside of the vagina)
- the inner foreskin and urethra of the penis
- inner nose, mouth, throat
- trachea (the main breathing tube or windpipe), bronchi (smaller breathing tubes branching off the trachea)

- the inner eyelids.

Of the more than 150 known strains, about 3 out of 4 (75%) HPV types are called cutaneous because they cause warts on the skin. Sites for warts are the arms, chest, hands, and feet. These are common warts; they are not the genital type of wart.

The other 25% of the HPV types are considered mucosal types of HPV. “Mucosal” refers to the body’s mucous membranes, or the moist surface layers that line organs and cavities of the body that open to the outside. For example, the mouth, vagina, and anus have this moist mucosal layer. The mucosal HPV types are also called the *genital* (or *anogenital*) type HPVs because they often affect the anal and genital area. The mucosal (genital) HPVs prefer the moist squamous cells found in this area. Mucosal HPV types generally don’t grow in the skin or parts of the body other than the mucosal surfaces.

Low-risk genital HPV types

HPV types that tend to cause warts and not cancer are called *low-risk types*. Low-risk genital HPV infection can cause cauliflower-shaped warts on or around the genitals and anus of both men and women. In women, warts may appear in areas that aren’t always noticed, such as the cervix and vagina. This type of genital wart is called a *condyloma acuminatum* and is most often caused by HPV-6 or HPV-11. Infection with low-risk types of HPV can also cause *low-grade changes* in the cells, which don’t develop into cancer as often as more serious (*high-grade*) changes. (*Grade* describes how much the changed cells differ from normal cells.)

High-risk genital HPV types

HPV types that tend to cause cancer are called *high-risk types*. These types have been linked to cancers in both men and women. These types can also cause low-grade and high-grade changes in the cells and pre-cancers. Doctors worry more about the high-grade changes and pre-cancers, because they are more likely to grow into cancers over time. Common high-risk HPV types include:

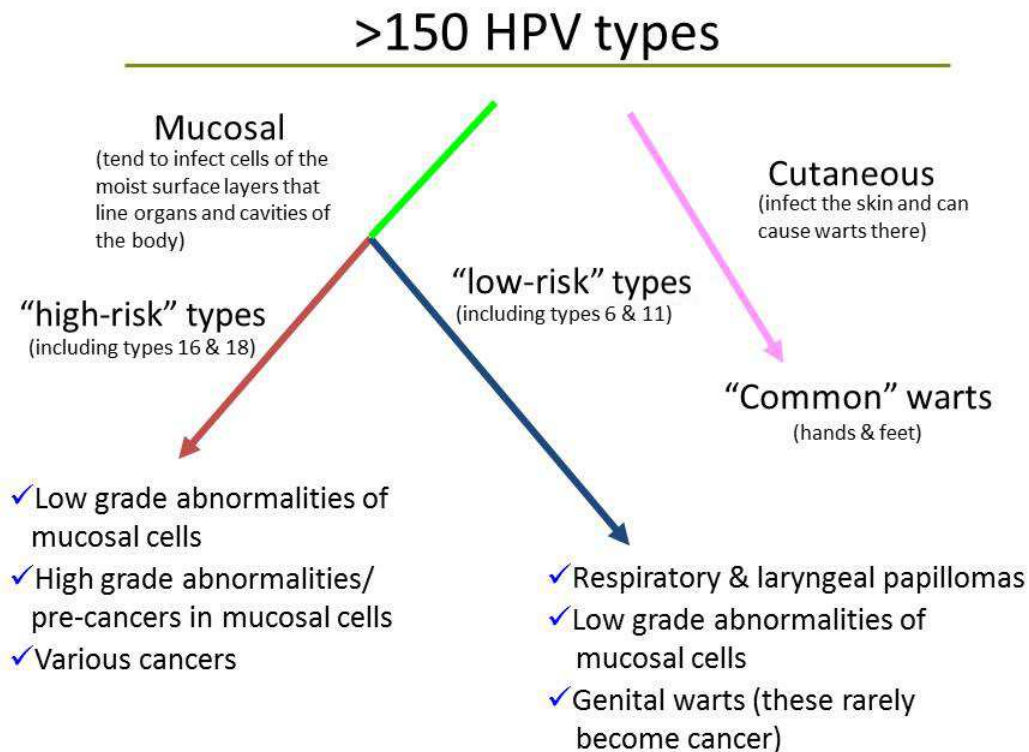
- HPV-16
- HPV-18
- HPV-31
- HPV-33
- HPV-35
- HPV-39
- HPV-45
- HPV-51
- HPV-52
- HPV-56
- HPV-58
- HPV-59

- HPV-68

Warts and cancer are caused by different types of HPV

In summary, low-risk genital HPV types can cause genital warts and low-grade changes in the cells; they rarely cause cancer. High-risk genital HPV types can cause low-grade changes, high-grade changes, pre-cancer, and cancer.

This diagram shows the different groups of HPV types and the problems each group can cause.



How do you get genital HPV?

Genital human papilloma virus (HPV) is spread mainly by direct skin-to-skin contact during vaginal, oral, or anal sex. It’s not spread through blood or body fluids. Infection is very common soon after a person starts having sex with one or more partners.

The virus most often spreads from one person to another during sexual intercourse. It’s possible to spread by genital contact without intercourse, but this is not common. Oral-genital and hand-genital spread (transmission) of some genital HPV types has been reported. And there may be other ways to become infected with HPV that aren’t yet clear. For instance, it may be spread through deep kissing or shared sex toys.

Transmission from mother to newborn during delivery is rare, but it can happen, too. When it does, it can cause warts (papillomas) in the infant's breathing tubes (trachea and bronchi) and lungs, which is called *respiratory papillomatosis*. These papillomas can also grow in the voice box, which is called *laryngeal papillomatosis*. Both of these infections can cause life-long problems.

You don't get genital HPV from:

- Toilet seats
- Hugging or holding hands
- Swimming in pools or hot tubs
- Family history (heredity)
- Sharing food or utensils
- Being unclean

How common is HPV? Who gets it?

Genital human papilloma virus (HPV) is a very common virus. Some doctors think it's almost as common as the cold virus. In the United States, over 14 million people get a new HPV infection every year. About half of these new infections are in people aged 15 to 24. It's so common, in fact, that 1 in 5 people with genital HPV has more than one HPV type.

Nearly all sexually-active men and women get at least one type of genital HPV at some time in their lives. This is true even for people who only have sex with one person in their lifetime.

What are the risk factors for genital HPV?

Risk factors for women

- Having many sex partners
- Having a partner who has had many partners
- Being younger than 25 years of age
- Starting to have sex at an early age (16 years or younger)
- Having a male partner who is not circumcised (who haven't had the foreskin of the penis removed). Men who still have their foreskins are more likely to get and stay infected with human papilloma virus (HPV) and pass it on to their partners. The reasons for this are unclear.

Risk factors for men

- Having many sex partners.
- Not being circumcised (not having had the foreskin of the penis removed). Men who are circumcised have a lower chance of getting and staying infected with HPV. Men who still have their foreskins are more likely to be infected with HPV and pass it on to their partners. The reasons for this are unclear. Circumcision does not completely protect against HPV infection – men who are circumcised can still get HPV and pass it on to their partners.

Can genital HPV be prevented?

Completely avoiding contact of the areas of your body that can become infected with genital human papilloma virus (HPV) (like the mouth, anus, and genitals) with those of another person may be the only way to keep from becoming infected with HPV. This means not having vaginal, oral, or anal sex, but it also means not allowing those areas to come in contact with someone else's skin.

For those who are young and haven't started having sex or have not yet been infected with HPV, getting one of the HPV vaccines can prevent infection with some types of HPV. See *HPV Vaccines* for more on this.

Having fewer sex partners and avoiding sex with people who have had many other sex partners helps lower a person's risk of exposure to genital HPV.

Condoms can help protect you from genital HPV infection, but HPV might be on skin that's not covered by the condom. And condoms must be used every time, from start to finish. The virus can spread during direct skin-to-skin contact before the condom is put on, and male condoms don't protect the entire genital area, especially for women. The female condom covers more of the vulva in women, but hasn't been studied as carefully for its ability to protect against HPV. Condoms are very helpful, though, in protecting against other infections that can be spread through sexual activity.

It's usually not possible to know who has genital HPV infection, and HPV is so common that even using these measures doesn't guarantee that a person will not get the virus. But they can help reduce the number of times a person is exposed to HPV.

If you find out that you have a genital HPV infection, you may want to let your partner know. Tell them that HPV is a very common virus and that most people who have sex will get HPV. Most people don't know they have it. If they do, they usually don't know when they got it or from whom.

What are the symptoms of HPV?

Genital human papilloma virus (HPV) infection usually has no symptoms, unless it's an HPV type that causes genital warts. Genital warts may appear within weeks or months

after contact with a partner who has HPV. The warts may also show up years after exposure, but this is rare. The warts usually look like small bumps or groups of bumps in the genital area. They can be small or large, raised or flat, or shaped like a cauliflower. If they are not treated, genital warts might go away, stay and not change, or increase in size or number. But warts rarely turn into cancer.

Most people will never know they have HPV because they have no symptoms. In most people, their immune system attacks the virus and clears the HPV infection within 2 years. This is true of both high-risk and low-risk HPV types. But sometimes HPV infections are not cleared. This can lead to cell changes that over many years may develop into cancer.

Can HPV be treated?

No. There's no treatment for the virus itself. But most genital human papilloma virus (HPV) infections go away with the help of a person's immune system, usually within 2 years.

Even though HPV itself cannot be treated, the cell changes caused by an HPV infection can. For example, genital warts can be treated. Pre-cancer cell changes caused by HPV can be found by Pap tests and treated. And head and neck, cervical, anal, and genital cancers can be treated, too.

Testing for HPV

What's the difference between a Pap test and an HPV test?

A Pap test is used to find cell changes or abnormal cells in the cervix. (These abnormal cells may be pre-cancer or cancer, but they may also be other things.) Cells are lightly scraped or brushed off the cervix. They are processed, and then looked at under a microscope to see if the cells are normal or if changes can be seen. The Pap test is a very good test for finding cancer cells and cells that might become cancer.

Human papilloma virus (HPV) is a virus that can cause cervix cell changes. The HPV test checks for the virus, not cell changes. The test can be done at the same time as the Pap test, with the same swab or a second swab. You won't notice a difference in your exam if you have both tests. A Pap test plus an HPV test (called *co-testing*) is the preferred way to find early cervical cancers or pre-cancers in women 30 and older.

An HPV DNA test has been approved by the FDA to be used without a Pap test to screen for cervical cancer. At this time, the American Cancer Society is considering the evidence supporting the use of this test for screening and may issue updates to our screening guidelines in 2015. Other testing (which could include a Pap test) would be needed if HPV is found.

Should I be tested for HPV?

If you are a woman under age 30

The American Cancer Society recommends that women between ages 21 and 29 should have a Pap test every 3 years (at ages 21, 24, and 27) to test for cervical cancer. These women should *not* get the HPV test with the Pap test (co-testing) because HPV is so common in women these ages that it's not helpful to test for it. But HPV testing may be used in this age group *after* an abnormal Pap test result.

The most common abnormal Pap test result seen is called *ASC-US* (your doctor may say this as "ask us"). ASC-US cells usually are not pre-cancer, but they aren't quite normal either. If there are ASC-US cells in your Pap test result, one option is to do an HPV test to see if HPV is causing the cell changes. If HPV is found, you will need more tests.

In these cases the HPV test is used to help decide if further testing is needed. This is not the same as using the HPV test with the Pap test as part of your normal health visit.

Women who are HIV positive or who have been diagnosed or treated for a cervical cancer or pre-cancer should talk to their doctors about how often they should be tested for cervical cancer and what tests should be used.

If you are a woman aged 30 to 65

The American Cancer Society recommends that women aged 30 to 65 have an HPV test with their Pap test (co-testing) every 5 years to test for cervical cancer. Talk to your doctor or nurse about co-testing. You also may want to ask about the cost and what your health insurance covers. It's also OK to continue just to have Pap tests every 3 years.

Women who are HIV positive or who have been diagnosed or treated for a cervical cancer or pre-cancer should talk to their doctors about how often they should be tested for cervical cancer and what tests should be used.

Why should women over age 30 with normal test results change to co-testing every 5 years and start doing HPV testing? Is that safe?

Cell changes in the cervix happen very slowly. It usually takes more than 10 years for cell changes to become cancer. Pap tests have been done yearly in the past, but now we know that Pap tests are not needed yearly – every 3 years is enough. In fact, doing Pap tests every year can lead to unneeded treatment of cell changes that would never go on to cause cancer.

One of the benefits of adding testing for HPV is that women can get cervical cancer testing even less often. Getting the Pap test and HPV test (co-testing) every 5 years means fewer tests, follow-up visits, and treatments may be needed. Women with normal Pap and HPV test results have almost no chance of getting cervical cancer within at least 5 years. There's no added safety to co-testing more often than every 5 years.

Co-testing is preferred, but it's also OK to continue to have the Pap test alone every 3 years.

What about testing other sites on the body, or testing men?

There's no FDA-approved HPV test for men at this time, nor is there an FDA-approved HPV test to find the virus anywhere besides the cervix, including the mouth or throat. The FDA has only approved tests to find HPV in a woman's cervix, where positive results can be managed with extra testing and prompt treatment if the infection causes abnormal cell growth. Although HPV tests might be used in research studies to look for HPV in other sites, there's no proven way to manage positive findings. Also, the accuracy of the test itself may be affected by the site it's taken from and the way the sample is taken.

Finally, there is no useful test to find out a person's "HPV status," because an HPV test result can change over a period of months or years as the body fights the virus. (See the section "If I have a positive HPV test, what does it mean?")

If I have a positive HPV test, what does it mean?

If you have cervical human papilloma virus (HPV) infection and an abnormal Pap test result, your doctor or nurse will explain what other tests you might need.

If you have cervical HPV infection and a normal Pap test result, it means that you have genital HPV, but no cell changes were seen on your Pap test. There are 2 options:

- You'll most likely be tested with an HPV test and a Pap test again in 12 months.

In most cases, re-testing in 12 months shows no sign of the virus.

If the virus does go away and your Pap test is normal you can go back to normal screening.

If the virus is still there or changes are seen on the Pap test, you'll need more testing.

- As another option, the doctor may suggest testing specifically for HPV-16 or both -16 and -18 (the 2 types that are most likely to cause cervical cancer).

If testing shows that you have HPV-16 and/or -18, more testing will be needed.

If the test doesn't show infection with HPV-16 and/or -18, you should be retested in 12 months with both an HPV test and a Pap test.

It's usually not possible to know when a person got an HPV infection or who gave it to them. HPV may be found right away or not until many years later. Most men and women with HPV don't know they have it.

If HPV goes away, can you get it again?

There are many types of HPV. You may have one type that goes away, but you can get another different type. It's possible to get the same type again, but the risk of this is low.

Will HPV affect my pregnancy or my baby?

HPV infection does not directly affect the chances of getting pregnant.

If HPV infection leads to cervical changes that need to be treated, the treatment should not affect your chances of getting pregnant. But if you have many treatments and biopsies, which can happen with more frequent screening, the risk of pre-term labor and low birth weight babies can go up.

HPV is rarely passed from a mother to her baby. The rare cases where this has happened do not involve the types of HPV that can cause cancer. The section called "How do you get genital HPV?" has more on how HPV is transmitted from mother to baby during pregnancy.

To learn more

From your American Cancer Society

American Cancer Society Recommendations for Human Papilloma Virus (HPV) Vaccine Use to Prevent Cervical Cancer and Pre-Cancers (also in Spanish)

HPV Vaccines

What Women Should Know About Cervical Cancer and the Human Papilloma Virus

HPV and Cancer

Other organizations

American Sexual Health Association (ASHA)

Telephone: 1-919-361-8400

Website: www.ashastd.org

Website for teen sexual health in English: www.iwannaknow.org

Website for teen sexual health in Spanish: www.quierosaber.org

The Centers for Disease Control and Prevention (CDC)

Toll-free number: 1-800-232-4636 (1-800-CDC-INFO)

Website: www.cdc.gov/std/HPV/STDFact-HPV.htm

No matter who you are, we can help. Contact us anytime, day or night, for information and support. Call us at **1-800-227-2345** or visit www.cancer.org.

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For additional assistance please contact your American Cancer Society
1-800-227-2345 or www.cancer.org

Unprotected People #91

Human Papillomavirus (HPV)

Christine Baze's Story

PopSmear.org is a Boston-based non-profit organization whose purpose is to raise awareness and educate women about how to prevent cervical cancer and HPV. PopSmear.org was created in 2002 by Christine Baze, a Boston musician who is also a cervical cancer survivor. She was just 31 years old when she was diagnosed with cervical cancer. In recognition of her educational and outreach efforts, Ms. Magazine named Baze in their annual award: "50 women who made a difference."

Christine Baze gave IAC permission to share her personal story:

I'm supposed to be a rock star — that's what I thought until April 18th, 2000. I had just left my day job in January to pursue my passion: music. My band was doing well and I could not have been happier, but then there was blood. I called my gynecologist and he told me not to worry. So I didn't. I went on gigging and booking and writing songs—the best 3 months ever. I was so happy and felt so lucky. Little did I know it would not last.

In March, I went for my yearly Pap test. I've had yearly Paps since I was 18 years old, and always had normal results, until this one. I was told that I had some dysplastic cell growth on my cervix and that he needed to do a colposcopy to biopsy the cells. I barely knew where my cervix was and certainly didn't understand anything about cell mutation—that's when I was told it could turn into cancer many years down the road if not treated. Cancer? Me? He assured me that I did NOT have cancer and that we would meet the following week to review the results of this biopsy and schedule a LEEP procedure [loop electrosurgical excision procedures], a mild surgery that would scrape off the bad cells.

He was wrong. At 8:15 the morning of April 18th, I received a phone call confirming an appointment

I did not have, with a doctor I did not know. Realizing I had not heard the news yet, the woman apologized on the other line, and stumbled over her words as she told me she was confirming an appointment with a gynecologic oncologist at a local cancer center. That's how I found out I had cancer.

It all happened very quickly after that. I was diagnosed with invasive cervical cancer with extensive lymphatic invasion. I had a radical hysterectomy 10 days after my diagnosis, a laparoscopic procedure a month later to move my ovaries out of the "frying zone," 5 weeks of daily pelvic radiation concurrent with 4 rounds of chemotherapy, followed by 3 rounds of internal radiation (brachytherapy). They gave me everything they had in order to save me. Within 4 months I was done with everything. Everything other than the deep dark depression, that is.

Everyone knows that treatment is hard, and everyone sees the toll it takes on your body. But for me, I think the depression that followed was almost worse. Once my body was no longer being assaulted, my mind started to digest all that had happened, and it wasn't pretty. I felt like I lost everything. And through it all, the one thing that always centered me, that always made me happy, was gone. The music was gone. I couldn't play, sing, or write. I had no desire for the thing I loved the most. I didn't know who I was anymore.

I decided to attack with full force: Individual therapy, group therapy, anti-depressant, acupuncture, yoga, journaling, Reiki, and more. I did anything I could to fight off the depression, and eventually it started to work. Time, absolutely was a huge part of it. Time, and the fact that I just refused to quit. I had worked way too hard to stay alive, and I wanted my life back.

(continued on next page)

By the fall of 2001, I finally got back to my day job, felt strong physically and emotionally, but still hadn't found the music. I sort of felt like that side of me was gone, it left with my uterus and was never returning. But then I saw the movie "Harold and Maude." Maude is an older woman who embraces everything there is to embrace in life. Every sensation—touch, taste, smell—she lives in the moment and teaches this young boy Harold how to do the same. I was completely inspired by Maude's spirit and enthusiasm, as well as the Cat Stevens soundtrack. I heard the song "trouble" and was drawn back to the piano—I felt like the song had been written for me, that it was the story of the last year and a half of my life. This is when I returned to the piano.

Since then, my life has brought me all kinds of new and wonderful experiences. I decided I wanted to give back to the cancer community by raising money and awareness so other women don't have to go through what I did. I decided to do a benefit concert and call it "PopSmear." I was going to do it in my back yard, but soon it spiraled into a great big event. Jim's Big Ego, The Mudhens, and Catie Curtis all agreed to perform. Amy Brooks from WBOS emceed the night. We sold out the Paradise Rock Club in Boston and raised \$10,000 for the cause! It was truly one of the best nights of my life as a person, as a musician, and as a cancer survivor.

In 2003, I decided to take it on the road, created The Yellow Umbrella Tour, and went to six cities. Ms. Magazine named me one of the "50 women who made a difference in 2003." I've done the Tour every year since, and we have hit 86 cities, raising awareness and educating women about cervical cancer, HPV, and the modern technologies available to help women feel confident in maintaining their cervical health.

It is so important that women understand that cervical cancer is caused by HPV—a virus—and that there are new, fantastic technologies to help prevent it. Now there is an HPV vaccine to prevent the majority of cases of cervical cancer (for girls and women 9-26), there is an HPV test that can be done at the same time as your Pap (for women 30+), and there is a better Pap (a liquid Pap, for all

women). These technologies were not available for me, but they are available today, and can totally PREVENT cervical cancer. My case is the perfect example that the standard Pap is NOT enough, because even though I had my annual gyn visit every year, the Pap test missed the cell changes year after year (squamous cell cancers take 5-10 years to develop). The Pap can be wrong up to 50% of the time. But the liquid Pap in combination with the HPV test is almost 100% accurate. And the HPV test is the ONLY way you can know if you are carrying the virus BEFORE it becomes invasive, which is why it is so important to know your HPV status. It's amazing and every woman should know about it.

So my message is clear:

- Every woman (9-26) should get the HPV vaccine.
- Every woman (18+) should get screened with the liquid Pap.
- Every woman (30+) should be screened with the HPV test along with the liquid Pap

Ladies: Don't blow off your annual gyn visit. Go in and have a conversation with your doctor. Learn the facts about cervical health, be proactive and empowered. Protect yourself with the vaccine, and then continue screening with the best — a liquid Pap and HPV test.

I feel so fortunate to be given this opportunity to share my story, share my music, and make a difference. I'm grateful to all the sponsors, volunteers, friends, and family for their support and love. When people believe in what they are doing, wonderful things can happen, and this is a wonderful thing.

Thanks for the support.

Christine Baze

For more information about Christine and her organization PopSmear, go to www.popsmeat.org/

PHARMACY-DELIVERED ADOLESCENT HPV VACCINATIONS - PILOT INITIATIVE

Michigan Pharmacists Association

- Sarah Barden, Executive Fellow
- Dianne Malburg, Chief Operations Officer

SpartanNash Pharmacies

- Robin Curtis, Clinical Coordinator



Program Outline

- **Introduction & Background**
 - American Cancer Society HPV Vaccination Roundtable Grant
 - HPV Disease and Vaccines
 - Barriers to HPV Vaccination
- **Communicating about HPV**
 - Communication Strategies
 - Common Questions
 - Partner Practice
- **Pilot Pharmacy Workflow**
 - Utilizing the Screening Tool
 - Michigan Care Improvement Registry
 - Billing and Referrals
 - Additional Resources

INTRODUCTION & BACKGROUND

American Cancer Society HPV Vaccination Roundtable Grant

Introduction to Grant Project



Michigan Pharmacists Association (MPA) has received a grant from the **American Cancer Society** to study **integrating community pharmacies** into healthcare efforts to **increase Human Papillomavirus (HPV) vaccination** and series completion rates in **adolescents and young adults**.

American Cancer Society HPV Vaccination Roundtable Grant

Primary Goals and Objectives

- Increase completion of the HPV vaccination series through the implementation and evaluation of innovative practice model(s) involving pharmacy-located vaccination.
- Identify and facilitate best practices/practice features/models for developing collaboration and coordination among community-based immunization providers and documentation of vaccinations administered to Electronic Health Records (EHRs) and Immunization Information Systems (IIS).
- Create and implement strategies and approaches to completing the HPV vaccine series in existing patients and/or new patients.

American Cancer Society HPV Vaccination Roundtable Grant

Primary Goals and Objectives

- Create a referral network for HPV vaccination within a community featuring collaboration between community pharmacies, medical, nursing, and public health providers, as well as cancer society, immunization coalition, and community leaders.
- Facilitate community engagement of patients/caregivers, pharmacies, medical providers and payers (or payment systems).
- Utilize, and tailor as necessary, existing tools and resources in delivery of immunization services.
- Provide a final report that includes project observations, vaccination outputs and outcomes, barriers, challenges, strategies and solutions, and an implementation guide for replication.

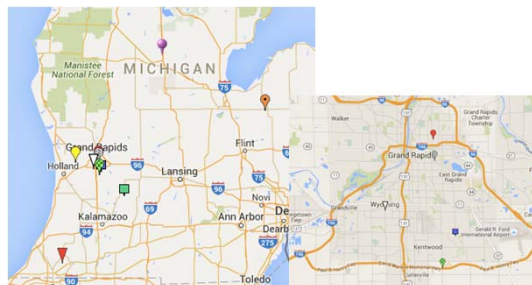
American Cancer Society HPV Vaccination Roundtable Grant

MPA's Approach

- Establishing the MPA 2016 HPV Vaccination Roundtable Advisory Committee to utilize their expertise throughout the project
- Implementing adolescent HPV vaccination pilot programs in 10 grocery-store community pharmacies (5 stores in Grand Rapids and 5 rural locations)
- Assessing different stakeholder groups (pharmacists, other healthcare providers, patients and parents) for opinions about HPV vaccination in community pharmacies
- Conducting education and outreach for various stakeholders

American Cancer Society HPV Vaccination Roundtable Grant

10 Pilot Stores



HPV Disease and Vaccines



Video: <https://www.youtube.com/watch?v=E36aShFIEYo>

HPV Disease and Vaccines

HPV Infections

79 million CURRENT infections in U.S.

14 million NEW HPV infections each year

HPV Disease and Vaccines

HPV-related Cancers

17,500 Women

+

9,300 Men

=

26,800

total HPV-related cancers each year

HPV Disease and Vaccines

Cervical Cancers

4,000

deaths due to cervical cancer each year

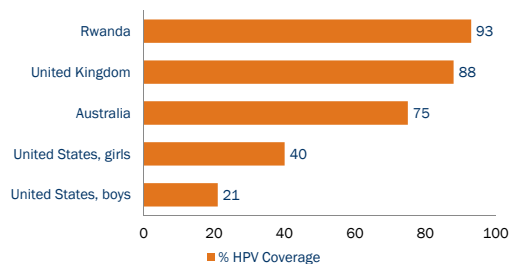
HPV Disease and Vaccines

How does HPV morbidity and mortality compare?

- In 2013, there were roughly **550 cases** of **meningococcal disease** reported.
- From 2001 through 2008, **233 cases** of **tetanus** were reported resulting in **26 deaths**.

Source: Data from CDC Surveillance data for meningococcal disease and tetanus

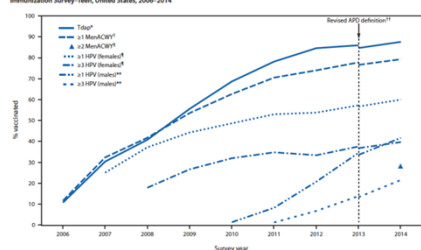
International HPV Vaccination Rates



Source: Data from CDC

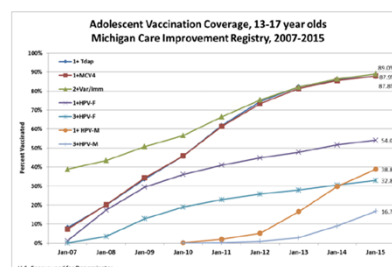
National Adolescent Vaccination Rates

FIGURE 1. Estimated vaccination coverage with selected vaccines and doses among adolescents aged 13–17 years, by survey year — National Immunization Survey–Teen, United States, 2006–2014



Source: Data from CDC, MMWR, July 31, 2015

Michigan Adolescent Vaccination Rates



Source: Data from MDHHS

Michigan Adolescent Vaccination Rates

TABLE 3. Estimated vaccination coverage with selected vaccines and doses* among adolescents aged 13–17 years, by HHS region and state or selected local areas — National Immunization Survey–Teen (NIS–Teen), United States, 2014

HHS region and state/local area	Female (N = 10,703)						Male (N = 10,743)					
	≥1 Tdap ^a % (95% CI) ^b	≥1 MenACWY ^a % (95% CI) ^b	≥1 HPV ^a % (95% CI) ^b	≥2 HPV ^a % (95% CI) ^b	≥3 HPV ^a % (95% CI) ^b	≥1 HPV ^a % (95% CI) ^b	≥2 HPV ^a % (95% CI) ^b	≥3 HPV ^a % (95% CI) ^b	≥1 HPV ^a % (95% CI) ^b	≥2 HPV ^a % (95% CI) ^b	≥3 HPV ^a % (95% CI) ^b	≥1 HPV ^a % (95% CI) ^b
United States overall	87.3 (86.8–87.8)	79.3 (78.7–79.9)	60.2 (59.5–60.9)	36.3 (35.6–37.0)	26.2 (25.5–26.9)	41.7 (41.1–42.3)	31.4 (30.7–32.1)	21.6 (20.9–22.3)	41.7 (41.1–42.3)	31.4 (30.7–32.1)	21.6 (20.9–22.3)	41.7 (41.1–42.3)
HHS Region V	86.7 (86.2–87.2)	80.1 (79.5–80.7)	61.0 (60.3–61.7)	32.7 (32.0–33.4)	22.7 (22.0–23.4)	33.6 (32.9–34.3)	21.1 (20.4–21.8)	10.6 (10.0–11.2)	33.6 (32.9–34.3)	21.1 (20.4–21.8)	10.6 (10.0–11.2)	33.6 (32.9–34.3)
Illinois	91.0 (90.4–91.6)	77.3 (76.7–77.9)	64.4 (63.7–65.1)	38.0 (37.3–38.7)	27.7 (27.0–28.4)	46.7 (46.0–47.4)	34.2 (33.5–34.9)	22.0 (21.3–22.7)	46.7 (46.0–47.4)	34.2 (33.5–34.9)	22.0 (21.3–22.7)	46.7 (46.0–47.4)
U.S. City of Chicago	86.6 (86.0–87.2)	78.4 (77.8–79.0)	59.1 (58.4–59.8)	35.0 (34.3–35.7)	25.0 (24.3–25.7)	44.0 (43.3–44.7)	31.1 (30.4–31.8)	20.1 (19.4–20.8)	44.0 (43.3–44.7)	31.1 (30.4–31.8)	20.1 (19.4–20.8)	44.0 (43.3–44.7)
U.S. Rest of state	86.6 (86.0–87.2)	78.4 (77.8–79.0)	59.1 (58.4–59.8)	35.0 (34.3–35.7)	25.0 (24.3–25.7)	44.0 (43.3–44.7)	31.1 (30.4–31.8)	20.1 (19.4–20.8)	44.0 (43.3–44.7)	31.1 (30.4–31.8)	20.1 (19.4–20.8)	44.0 (43.3–44.7)
Michigan	79.2 (78.6–79.8)	80.7 (80.1–81.3)	58.0 (57.3–58.7)	30.9 (30.2–31.6)	20.8 (20.1–21.5)	39.8 (39.1–40.5)	31.9 (31.2–32.6)	21.1 (20.4–21.8)	39.8 (39.1–40.5)	31.9 (31.2–32.6)	21.1 (20.4–21.8)	39.8 (39.1–40.5)
Westmoreland	87.3 (86.8–87.8)	79.3 (78.7–79.9)	60.2 (59.5–60.9)	36.3 (35.6–37.0)	26.2 (25.5–26.9)	41.7 (41.1–42.3)	31.4 (30.7–32.1)	21.6 (20.9–22.3)	41.7 (41.1–42.3)	31.4 (30.7–32.1)	21.6 (20.9–22.3)	41.7 (41.1–42.3)
Ohio	83.0 (82.4–83.6)	73.7 (73.1–74.3)	61.0 (60.3–61.7)	32.7 (32.0–33.4)	22.7 (22.0–23.4)	33.6 (32.9–34.3)	21.1 (20.4–21.8)	10.6 (10.0–11.2)	33.6 (32.9–34.3)	21.1 (20.4–21.8)	10.6 (10.0–11.2)	33.6 (32.9–34.3)
Wisconsin	91.3 (90.7–91.9)	73.8 (73.2–74.4)	61.0 (60.3–61.7)	32.7 (32.0–33.4)	22.7 (22.0–23.4)	33.6 (32.9–34.3)	21.1 (20.4–21.8)	10.6 (10.0–11.2)	33.6 (32.9–34.3)	21.1 (20.4–21.8)	10.6 (10.0–11.2)	33.6 (32.9–34.3)

Source: Data from CDC, MMWR, July 31, 2015

Michigan & County HPV Vaccination Series Completion Rates (MCIR)

	MI	Barry	Cass	Clare	Kent	Ottawa	Tuscola
3+ HPV Girls	31.0	36.7	26.5	29.7	42.0	40.6	28.6
3+ HPV Boys	20.4	22.9	15.8	16.9	28.2	25.7	21.8

Source: Data from MDHHS, through Dec. 2015

Michigan Pharmacy Vaccination Data

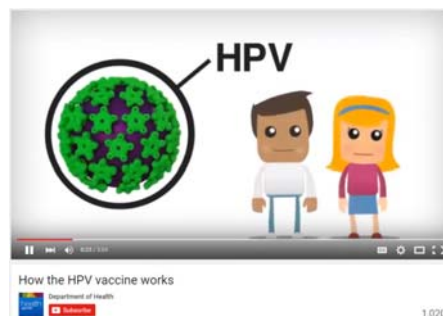
Pharmacy Vaccination Data

Table 1. Select Vaccines Reported to MCIR by Pharmacies since 2007 to children and adults aged 9 through 27 years

Pharmacy Type	Flu	HPV	MCV	Tdap	Total
Hospital (Outpatient)	1,318	792	173	3,637	5,920
Independent	5,557	41	82	122	5,822
Large Chain	210,145	889	2,106	4,604	217,744
Small Chain/Group	1,157	3	3	18	1,181
Total	218,197	1,725	2,364	8,381	230,667

Source: From MDHHS HPV Pharmacy Snapshot

HPV Disease and Vaccines



Video: <https://www.youtube.com/watch?v=FaHrhKvPZ2w>

HPV Disease and Vaccines

HPV DOES spread by

- Vaginal sex
- Anal sex
- Oral sex
- Skin-to-skin contact with areas infected with HPV

HPV does NOT spread by

- Toilet seats
- Hugging
- Holding hands
- Sharing food or utensils
- Sharing swimming pools or spas

HPV Disease and Vaccines

Silent Disease

Most people never know they have HPV because they do not experience any symptoms.

It spreads easily between people because they do not know they have it.

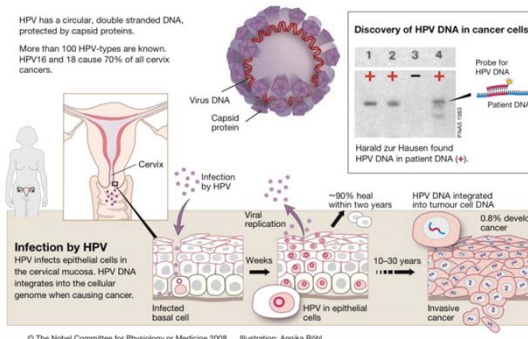
HPV Disease and Vaccines

Disease Progression

HPV infections usually go away on their own thanks to our immune systems but not always.

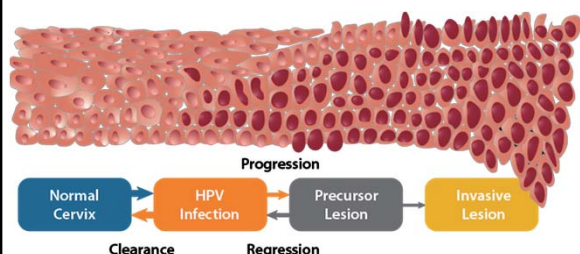
We cannot predict who will clear the virus and who will have the virus progress to pre-cancer or cancer.

HPV Disease and Vaccines



HPV Disease and Vaccines

Disease Progression



HPV Disease and Vaccines

Treatment

No treatment for HPV itself
No cure available

May treat genital warts
 May treat cancers

HPV Disease and Vaccines

	Cervarix® Manufactured by GlaxoSmithKline FDA Approved 2006	Females only HPV 16 and 18
	Gardasil® Manufactured by Merck FDA Approved 2006	Males and Females HPV 6, 11, 16 and 18
	Gardasil® 9 Manufactured by Merck FDA Approved 2014	Males and Females HPV 6, 11, 16, 18, 31, 33, 45, 52 and 58

HPV Disease and Vaccines



Video: <https://www.youtube.com/watch?v=vk17WjjJfk4>

HPV Disease and Vaccines

Vaccine Safety

- Over 76 million doses of HPV vaccine have been given in U.S. since 2006 with no serious safety concerns identified.
- There are multiple vaccine adverse event reporting systems in use and monitored by the CDC and other agencies.

HPV Disease and Vaccines

Focus on Gardasil® 9

GARDASIL® 9 is a vaccine given to females and males ages 9 through 26 years to help protect against diseases caused by some types of Human Papillomavirus (HPV).

HPV Disease and Vaccines

What diseases can GARDASIL® 9 (Human Papillomavirus 9-valent Vaccine, Recombinant) help protect against?

In girls and women 9 through 26 years of age, GARDASIL® 9 helps protect against:

- Cervical cancer
- Vaginal and vulvar cancers
- Anal cancer
- Precancerous cervical, vulvar, vaginal and anal lesions
- Genital warts

In boys 9 through 26 years of age, GARDASIL® 9 helps protect against:

- Anal cancer
- Precancerous anal lesions
- Genital warts

HPV Disease and Vaccines

What important information about GARDASIL 9 should I know?

- It does not remove the need for cervical cancer screening; women should still get routine cervical cancer screening.
- It does not protect the person from a disease that is caused by other types of HPV, other viruses or bacteria.
- It does not treat HPV infection.
- It does not protect the person from HPV types that he/she may already have.
- It may not fully protect each person who gets it.

HPV Disease and Vaccines

Who should not get GARDASIL® 9?

It is contraindicated in anyone with an allergic reaction to:

- A previous dose of GARDASIL® 9
- A previous dose of GARDASIL®
- Yeast (severe allergic reaction)
- Amorphous aluminum hydroxyphosphate sulfate
- Polysorbate 80

Use caution in anyone

- With a moderate or severe acute illness
- Who is pregnant

HPV Disease and Vaccines

What should I tell the healthcare professional before getting GARDASIL® 9?

If the person getting GARDASIL 9:

- Is pregnant or planning to get pregnant.
- Has immune problems, like HIV or cancer.
- Takes medicine that affect the immune system.
- Has a fever over 100° F (37.8° C).
- Might have had an allergic reaction to a previous dose of GARDASIL 9 or GARDASIL.
- Takes any medications, even those you can buy over the counter.

The health care professional will help decide if you or your child should get the vaccine.

HPV Disease and Vaccines

How do you administer GARDASIL® 9?

- The injection is usually given in the arm (deltoid) muscle.
- It is 3 shot series
 - Dose 1
 - Dose 2 two months after the first dose
 - Dose 3 four months after the second dose (six months after first dose).
- The health care professional should ask the person to sit or lie down for 15 minutes after getting the vaccine to prevent fainting and possible injury from falling.

HPV Disease and Vaccines

What are the common side effects of GARDASIL® 9?

- | | |
|------------|--|
| • Pain | • A lump where the shot was administered |
| • Swelling | • Headache |
| • Redness | • Fever |
| • Itching | • Nausea |
| • Bruising | • Dizziness |
| • Bleeding | |

Communication Strategies



Communication Strategies

Trust with the provider

Expertise/Competence

- Knowing your facts
- Communicating effectively
- Backing up your facts with references

Personal Relationship

- Dedication/commitment
- Having patient's best interests at heart
- Listening/caring/empathy
- Taking the time to answer questions
- Honesty/openness

Source: Presentation by P. Ann Ryan, DO, PhD at the MDHHS Fall Regional Immunization Conferences, Oct. 2015.

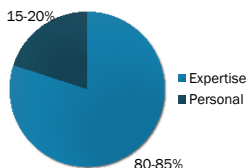
Communication Strategies

Trust with the provider

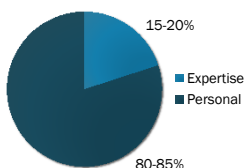
Issue of Low Concern

Issue of High Concern

% of Trust Relationship



% of Trust Relationship



Source: Presentation by P. Ann Ryan, DO, PhD at the MDHHS Fall Regional Immunization Conferences, Oct. 2015.

Communication Strategies

- Build a personal, trusting relationship with patients
- Give a **STRONG, CLEAR, CONFIDENT** recommendation for vaccination
- Address patients' questions calmly and clearly
 - Do NOT assume that questions mean vaccine refusal!
- Recommend HPV vaccine the same way you recommend Meningococcal, Tdap, and Influenza
 - ACIP recommends all 4 vaccines for adolescents at ages 11-12

Communication Strategies



You Are the Key to HPV Cancer Prevention
 CDC Centers for Disease Control and Prevention (CDC) 10
 YouTube 502,907

Video: <https://www.youtube.com/watch?v=E36aShFIEYo>

Communication Strategies

Make the "CASE" for Vaccination

- **C**ancer prevention
- **A**dolescent vaccination
- **S**afety profile
- **E**xposure

Source: <https://www.merckvaccines.com/Products/Gardasil9/recommendations-for-parents>

Communication Strategies

Cancer prevention

You might consider saying:

"This vaccine helps prevent HPV-related cancers and diseases caused by 9 HPV types in both males and females."

There are potentially serious outcomes of HPV. Let parents and patients know that HPV can cause cervical cancer, vulvar cancer, vaginal cancer, anal cancer, and genital warts.

Source: <https://www.merckvaccines.com/Products/Gardasil9/recommendations-for-parents>

Communication Strategies

Adolescent vaccination

You might consider saying:

"Today there are several CDC-recommended vaccines for 11- and 12-year-olds, including meningococcal, HPV, and Tdap."

Remember to provide a clear, same-day recommendation for HPV vaccination just as you do for meningococcal and Tdap at the 11- and 12-year-old visit.

Source: <https://www.merckvaccines.com/Products/Gardasil9/recommendations-for-parents>

Communication Strategies

Safety profile

You might consider saying:

"The HPV vaccine has been studied in both males and females. Side effects include pain, swelling, redness, itching, bruising, bleeding, and a lump where your child got the shot; and headache, fever, nausea, and dizziness. Fainting can happen after getting the vaccine."

Sharing information regarding the safety of a vaccine can be very important.

Source: <https://www.merckvaccines.com/Products/Gardasil9/recommendations-for-parents>

Communication Strategies

Exposure

You might consider saying:

"HPV is a widespread virus that infects both males and females. According to estimates for males and females, 9 HPV types can lead to approximately 11,000 cervical cancer cases, 3,000 vulvar and vaginal cancer cases, and 9,000 anal cancer cases every year."

Remind parents that as with other vaccines, the best time to vaccinate is prior to exposure to HPV. Data suggest that boys and girls 12 years of age and younger have a lower likelihood of exposure to HPV than older adolescents.

Source: <https://www.merckvaccines.com/Products/Gardasil9/recommendations-for-parents>

Common Questions

Question: *Why does my child need the HPV vaccine?*

Try saying:

"HPV vaccine is important because it prevents certain cancers: cervical, vaginal and vulvar cancers in females and anal cancers in both males and females."

Pharmacists:

"That is why I recommend that your child be vaccinated."

Common Questions

Question: *What diseases are caused by HPV?*

Try saying:

"Certain types of HPV can cause cervical, vaginal and vulvar cancers in females and anal cancer in both males and females."

Pharmacists:

"We can help prevent these cancers, and I recommend we start the HPV vaccine series for your child today."

Common Questions

Question: *Is my child really at risk for HPV?*

Try saying:

"HPV is a widespread virus that infects males and females. Vaccination can help protect your child from HPV-related cancers."

Pharmacists:

"I recommend starting HPV vaccine series today."

Common Questions

Question: *Why do they need HPV vaccine at such a young age?*

Try saying:

"With every vaccine, it is important to vaccinate before exposure, and we can't predict when exposure might occur. Like other vaccines, the HPV vaccine works to help prevent disease when given before there is any contact with the virus."

Pharmacists:

"This is why we need to start protecting your child with the HPV vaccine today."

Common Questions

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

Try saying:

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

Pharmacists:

"However, I want you to know that HPV vaccine has been carefully studied for many years by medical and scientific experts. HPV vaccine is very safe, and it is effective at protecting against some HPV types that cause cancer. Vaccines, like any medication, can cause side effects. With HPV vaccination this can include pain, swelling and redness where you got the shot as well as headache."

Common Questions

Question: *Could HPV vaccine cause my child to have problems with infertility?*

Try saying:

"There is no data available to suggest that getting HPV vaccine will have an effect on future fertility."

Pharmacists:

"However, persistent HPV infection can cause cervical cancer and the treatment of cervical cancer can leave women unable to have children. Even treatment for cervical pre-cancer can put a woman at risk for problems with her cervix during pregnancy causing preterm delivery or problems."

Common Questions

Question: *I'm just worried that my child will perceive this as a green light to have sex.*

Try saying:

"Numerous research studies have shown that getting the HPV vaccine does not make kids more likely to be sexually active or start having sex at a younger age."

Pharmacists:

"I recommend completing the HPV vaccine series at a young age before any exposure occurs to provide the most protection."

Common Questions

Question: *How do you know if the vaccine works?*

Try saying:

"In clinical trials, the vaccine was shown to be very effective at helping to prevent certain HPV-related cancers and diseases."

Pharmacists:

"Because HPV vaccine has been so effective at decreasing the rates of HPV-related cancer and disease, I recommend starting the series today."

Common Questions

Question: *Why do boys need HPV vaccine?*

Try saying:

"HPV infection can cause cancers of the anus in men and it can also cause genital warts in men. HPV vaccine can help prevent these diseases in men."

Pharmacists:

"I recommend all adolescents, girls and boys, get the vaccine at 11-12 years of age."

Common Questions

Question: *Would you get HPV vaccine for your kids?*

Try saying:

"Yes, I have given HPV vaccine to my child (or grandchild, etc.) because I believe in the importance of this vaccine for preventing against certain cancers."

Pharmacists:

"I, along with the American Academy of Pediatrics, cancer doctors, and the CDC, believe that getting the HPV vaccine is very important for your child."

Common Questions

Question: *Why now? Can't I wait until my child is older?*

Try saying:

"HPV vaccine produces a more robust immune response in preteens than in older teens."

Pharmacists:

"That is why I recommend starting the series today."

Common Questions

Question: *My daughter will wait until marriage so she will not be exposed to HVP. Why would she need the vaccine?*

Try saying:

"HPV is so common that almost everyone will be infected at some time. When your daughter marries, she could catch HPV from her husband. He might have been infected before he ever met her."

Pharmacists:

"Since it's always better to have protection before any exposure, I recommend starting the series today."

Common Questions

Question: *What are the possible side effects?*

Try saying:

"Vaccines, like other medications, can cause side effects. HPV has not been linked with any serious or long-term side effects."

Pharmacists:

"With HPV vaccine, most side effects are mild, primarily pain or redness in the arm. These usually go away quickly."

Common Questions

Question: *What if I only want my child to get the "required" vaccines?*

Try saying:

"The CDC recommends all 11 to 12 year olds receive meningococcal, HPV and Tdap. While not required for school, HPV is recommended and provides protection against HPV-related cancers in boys and girls."

Pharmacists:

"I recommend your child receive HPV along with the other recommended teen vaccines to provide them with the most protection available."

Common Questions

Question: *I got the first dose of HPV awhile ago. Can I get the second dose now?*

Try saying:

"Yes. There is no need to restart the HPV series. You can resume the vaccine series with the second dose. All three doses are necessary to provide full protection."

Pharmacists:

"I recommend continuing the HPV vaccine series and getting your second dose today and your third dose four months after the second dose."

Common Questions

Question: *I got one dose with Gardasil but I know Gardasil 9 is available now. Do I need to start over?*

Try saying:

"No. At this time, the CDC does not recommend starting the series over. You can finish the vaccine series with Gardasil 9 even if you started it with Gardasil or Cervarix."

Pharmacists:

"I recommend continuing the HPV vaccine series with Gardasil 9 when your next dose is due to increase your protection against more types of HPV."

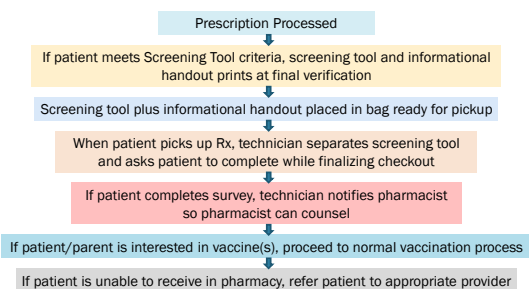
Partner Practice ~20 min.

Round	Partner 1's Role	Partner 2's Role
#1	Pharmacist or Technician	21-year-old female patient
#2	19-year-old male patient	Pharmacist or Technician
#3	Pharmacist or Technician	Parent of 11 year old boy
#4	Parent of 12 year old girl	Pharmacist or Technician

PILOT PHARMACY WORKFLOW

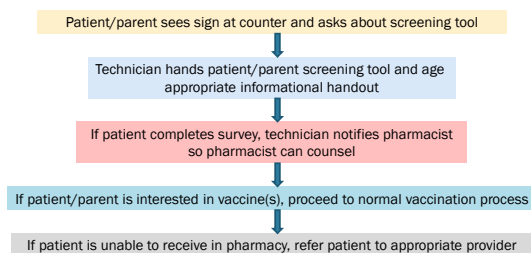
Utilizing the Screening Tool

Workflow tied to Prescription



Utilizing the Screening Tool

Workflow without a Prescription



Utilizing the Screening Tool

Immunization Schedule – Parent Version

2015 Recommended Immunizations for Children from 7 Through 18 Years Old



These shaded boxes indicate when the vaccine is recommended for all children unless your doctor tells you that your child cannot safely receive the vaccine.

These shaded boxes indicate the vaccine should be given if a child is catching up on missed vaccines.

These shaded boxes indicate the vaccine is recommended for children with certain health conditions that put them at high risk for serious diseases. Note that healthy children may get the 'high risk' shot. See vaccine-specific recommendations at www.dhs.gov/childrenspublichealth.

Utilizing the Screening Tool

Version 1 – Ages 18 – 26 – With Rx

Immunization Assessment (#1 - for age 18-26)

Meningitis and HPV

- Are you over the age of 18?
Yes ___ No ___
- Are you currently enrolled in a college or university?
Yes ___ No ___
- Do you live on campus?
Yes ___ No ___
- Have you had the meningitis (MCV4) shot?
Yes, date ___ No ___ Don't Know ___
- Have you started the HPV (Cervarix® or Gardasil®) shot series?
Yes, # doses received ___ No ___ Don't Know ___

Tetanus, diphtheria and pertussis (whooping cough)

- Have you had a tetanus and diphtheria (Td) shot in the past 10 years?
Yes, date ___ No ___ Don't Know ___

Utilizing the Screening Tool

Version 2 – Ages 11 – 17 – With Rx

Immunization Assessment (#2 for age 11-17)

Adolescent Vaccines

- Do you have more than one child in the age group 11-17?
Yes ___ No ___ If yes, please fill this out for one child. We would be happy to provide additional copies for each of your children in this age group.
- How old is the child you are filling out this assessment for?
Age ___
- Has your child had the meningitis (MCV4) shot?
Yes, age at vaccination ___ No ___ Don't Know ___
- Has your child started the HPV (Cervarix® or Gardasil®) shot series?
Yes, # doses ___ No ___ Don't Know ___
- Has your child had their Tdap - Tetanus, diphtheria and pertussis (whooping cough) shot?
Yes, age at vaccination ___ No ___ Don't Know ___

General immunization questions

Utilizing the Screening Tool

Version 3 – Ages 11 – 17 – Without Rx

Immunization Assessment (#3 for age 11-17)

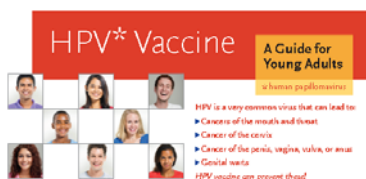
Adolescent Vaccines

- Do you have a child in the age group 11-17?
Yes ___ No ___ If no, thank you for your time, please return the survey. If yes, please fill this out for one child. We would be happy to provide additional copies for each of your children in this age group.
- Has your child had the meningitis (MCV4) shot?
Yes ___ No ___ Don't Know ___
- Has your child started the HPV (Cervarix® or Gardasil®) shot series?
Yes, # of doses ___ No ___ Don't Know ___
- Has your child had their Tdap - Tetanus, diphtheria and pertussis (whooping cough) shot?
Yes ___ No ___ Don't Know ___

General immunization questions

Utilizing the Screening Tool

Informational Handout – Ages 18 - 26



Do I really need HPV vaccine? Yes!
You should get HPV vaccine because it can prevent some types of cancer and genital warts.

Do I need it if I haven't had sex yet? Yes!
* You don't have to have sex to catch HPV, but sex increases your risk.
* You can get HPV by skin-to-skin intimate contact.

Why do I need 3 shots?
You need 3 HPV shots to be fully protected.

I didn't get the vaccine at age 11 or 12. Should I get it now? Yes!
HPV vaccination is recommended for people ages 9 through 26. Even though it is ideal to get HPV vaccine at a younger age, it is still highly effective in teens and young adults.

Utilizing the Screening Tool

Informational Handout – Ages 11 - 17

TEEN VACCINES INFORMATION FOR PARENTS			
Meningococcal Vaccines (MCV, MenB)	Adolescent Catch-Up	Tetanus, diphtheria, Pertussis (Tdap)	Human Papillomavirus (HPV)
Meningococcal vaccines protect you against meningitis, which affects the brain and spinal cord. If you contract meningitis, it can cause brain damage, seizures, disabilities or death.	Many vaccines are given during childhood to give you life-long protection against diseases. If you have not received all of the below vaccines, it is not too late!	Tdap vaccine protects you against pertussis (whooping cough), diphtheria, and tetanus. Tetanus causes painful tightening of the muscles and is very serious. It is found in soil and enters the body through a cut or wound.	HPV vaccine protects against cervical cancer in women and genital warts in men and women. It will also protect you against several other cancers.* HPV is a common infection transmitted by skin-to-skin contact during sexual activity, even if you do not have sex.
Common symptoms look like a flu or "stomach" trouble.	3 doses of hepatitis B vaccine (Hep B)		

Utilizing the Screening Tool

- April 2016

- Version 1 – Ages 18 – 26 – With Rx
 - Prints 1 x per eligible person
- Version 2 – Ages 11 – 17 – With Rx
 - Prints 1 x per eligible adolescent
- Version 3 – Ages 11 – 17 – Without Rx
 - Available at drop-off/counter area

- **May/June 2016**

- Continue with above
- Version 2 – Ages 11 – 17 – With Rx
 - ALSO prints 1 x per eligible adult age 30-60

Utilizing the Screening Tool

Documentation

- Record as you go – one tally in the corresponding boxes
- Add comments for referrals and additional immunizations given
- Total weekly and fax/email to Robin Curtis
robin.curtis@spartanash.com

	Number of people aged 16-64 infected with HIV		Number of people aged 15-49		Number of HIV cases diagnosed		Treatment facilities
	Age 15-49	Age 16-64	Age 15-49	Age 16-64	Age 15-49	Age 16-64	
Prevalence							
Prevalence							
Prevalence							
Prevalence							
Prevalence							
Prevalence							
Prevalence							
Prevalence							
Prevalence							

The data are presented for each week, starting from the first week of the survey. The data are presented for each week, starting from the first week of the survey.

Michigan Care Improvement Registry (MCIR)

MCIR record for adult born in 1976

Service	Immunizations					Other	Status
	Dose 1	Dose 2	Dose 3	Dose 4	Dose 5		
DTaP/DTaP- aP/DTaP- aP						Tdap DUE N/A	
MMR						MMR DUE N/A	
Hepatitis B						Complete Next Due 11/10/2009	
Varicella						Varicella DUE N/A	
Hepatitis A	1/10/2008 18 (0.75 mL)	6/22/2011 18 (0.75 mL)	5/4/2013 18 (0.75 mL)			Hepatitis A DUE N/A	
Seasonal Influenza	10/2/2009 18 (0.5 mL)	10/2/2010 18 (0.5 mL)	10/2/2011 18 (0.5 mL)			Regular Injection DUE N/A	
Other Administrations							
Services	12/2/2009 18 (0.5 mL)	12/2/2010 18 (0.5 mL)					Status
Age	10/2/2009	10/2/2010					
Reason	Not Administered						
Non-Administrated Doses/Positive Immunity							
Immunizations							
Age							
Reason							
Non-Administrated Doses/Positive Immunity Found							
Immunizations							
Age							
Reason							
Non-Administrated Doses Found							
Immunizations							
Age							
Reason							
Unvaccinated Doses							
Immunizations							
Age							
Reason							

Michigan Care Improvement Registry (MCIR)

MCIR record for child born in 2013

[illegible]

Michigan Care Improvement Registry (MCIR)

MCIR record for child born in 2002

[illegible]

Michigan Care Improvement Registry (MCIR)

- Link to MCIR Region 2 [website](#) for help
- Find Records
 - Find a record quickly
 - Wildcard Search
- Update Records
 - Immunization reporting rules
 - VIM Tip Sheet #3
 - Vaccine/Mfr/Brand Cheat Sheet



MCIR Training Video

- [Training Videos link](#)
- Wildcard search
- Add Imms
- Edit Imms

Billing and Referrals

- Several plans have coverage but may have some restrictions.
- We will review the following plans:
 - Blue Care Network
 - Blue Cross Blue Shield of Michigan
 - SpartanNash group
 - All other groups
 - Priority Health

Billing and Referrals

Blue Care Network (BCN)

- Any member carrying medical coverage
- Coverage good for age 11 to 26

Billing and Referrals

Blue Cross Blue Shield of Michigan (BCBS)

- Pharmacy benefit for all in SpartanNash group
 - Group # 71575
 - For covered employees, spouses and family members
- Medical Benefit for all other groups
 - Use Allwin for medical billing
 - MUST call CAREN first
 - Use Fax option

Billing and Referrals

Fax Response

MEDICAL EMERGENCY
Out-Of-Network Medical Emergencies And Accidental Injuries Are Processed As In-Network Based On Current Blue Cross Blue Shield Of Michigan Criteria.
For Outpatient Services
An In-Network Copay Of \$50.00 Applies
When Performed In An Office Setting
A Copay Of \$50.00 Applies
There Is No Deductible Or Coinsurance

EMERGENCY FIRST AID
Out-Of-Network Medical Emergencies And Accidental Injuries Are Processed As In-Network Based On Current Blue Cross Blue Shield Of Michigan Criteria.
For Outpatient Services
An In-Network Copay Of \$50.00 Applies
When Performed In An Office Setting
No Deductible Or Coinsurance For In-Network

VACCINATIONS
For Routine Services
Benefits Available In-Network Only.
Immunization Benefits Are Available For Both Child And Adult Patients Based On Current Guidelines.
No Deductible Or Coinsurance For In-Network.

DIAGNOSTIC SERVICES
When Medically Necessary
When Indicated For In-Network
For Routine Services
Benefits Available In-Network Only.
1 Visit
For Routine Period
No Deductible Or Coinsurance For In-Network.

Billing and Referrals

Priority Health

- Pharmacy Benefit for age 18 to 26
- 18 and younger are covered at a providers office

Billing and Referrals

Billing is a work in progress

We will send updates if billing opportunities change throughout the pilot period.

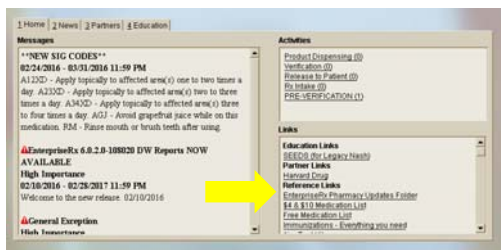
Billing and Referrals

What if someone wants the vaccine but it is not covered from the pharmacy?

REFER
to
Primary Care Provider
Health Department

Additional Resources

Accessing the “Z” Drive



Additional Resources

Pharmacy Practice –NEW–

spartanshare - /erx/

[illegible]

Additional Resources

Immunization Tab

spartanshare - /erx/Pharmacy Practice -- NEW! --/

To: Parent, Baleswood		
Tuesday, January 24, 2016	1:53 PM	cd127 Admission Tooltips
Monday, February 08, 2016	9:11 AM	cd127 Health Topics
Tuesday, January 24, 2016		cd127 Immunisation
Tuesday, January 26, 2016	2:29 PM	cd127 Medication Management (MTH)
Tuesday, January 26, 2016	3:14 PM	cd127 Medication Resources
Tuesday, January 26, 2016	3:54 PM	cd127 Nursing Regulatory Landscape
Tuesday, January 26, 2016	3:54 PM	cd127 Pharmacy Intervention Program (PIP)
Monday, March 14, 2016	3:19 PM	cd127 Pharmacy Practice Tools - Newsletter Archive
Monday, February 08, 2016	9:17 PM	cd127 Point of Care Training (POCT)

Additional Resources

Michigan Standing Orders and Medical Management of Vaccine reaction

spartanshare - /erx/Pharmacy Practice -- NEW! --
/Immunization/Standing orders/Michigan 2015-16 standing orders/

Team: <u>Samuel Gumpert</u>			
Tuesday, September 01, 2015	01:20	01:30 AM	109666 http://hacker.signed.pdf
Tuesday, September 01, 2015	01:30	01:40 AM	109667 http://hacker.signed.pdf
Tuesday, September 01, 2015	01:30	01:40 AM	109672 http://hacker.signed.pdf
Tuesday, September 01, 2015	01:30	01:40 AM	109673 http://hacker.signed.pdf
Tuesday, September 01, 2015	01:30	01:40 AM	110420 http://hacker.signed.pdf
Tuesday, September 01, 2015	01:30	01:40 AM	110421 http://hacker.signed.pdf
Tuesday, September 01, 2015	01:30	01:40 AM	143894 http://hacker.signed.pdf
Tuesday, September 01, 2015	01:30	01:40 AM	243894 http://hacker.signed.pdf
Tuesday, September 01, 2015	01:30	01:40 AM	243895 http://hacker.signed.pdf
Tuesday, September 01, 2015	01:30	01:40 AM	139705 http://hacker.signed.pdf
Tuesday, September 01, 2015	01:30	01:40 AM	139706 http://hacker.signed.pdf
Tuesday, September 01, 2015	01:30	01:40 AM	101023 http://hacker.signed.pdf
Tuesday, September 01, 2015	01:30	01:40 AM	101024 http://hacker.signed.pdf
Tuesday, September 01, 2015	01:30	01:40 AM	100713 http://hacker.signed.pdf
Tuesday, September 01, 2015	01:30	01:40 AM	100714 http://hacker.signed.pdf
Tuesday, September 01, 2015	01:30	01:40 AM	100908 http://hacker.signed.pdf
Tuesday, September 01, 2015	01:30	01:40 AM	100909 http://hacker.signed.pdf
Tuesday, September 01, 2015	01:30	01:40 AM	100917 http://hacker.signed.pdf
Tuesday, September 01, 2015	01:30	01:40 AM	100917 http://hacker.signed.pdf

Additional Resources

Medical Management of Vaccine Reactions – Children and Teens

Medical Management of Vaccine Reactions in Children and Teens

REACTION	Symptoms	MANAGEMENT
Local ¹	Swelling, redness, itching, or swelling at the injection site	Apply a cold compress to the injection site. Consider giving an antihistamine (oral or topical) for itching.
	Slight bleeding	Apply an adhesive compress over the injection site.
	Continuous bleeding	Place thick layer of gauze pads over site and maintain direct pressure. If bleeding persists, place the blood pressure cuff (e.g., arm) above the level of the patient's head.
Psychological (fright and distress) (Barnett)	Slight before injection is given	Place patient sit or lie down for the reaction.
	Distress patterns, sweating, pallor of the face and feet, muscle tightness, dizziness, weakness, or faintness	Place patient lie flat or sit with head between knees for several minutes. Loosen any tight clothing and provide oral or nasal oxygen. Apply cool, damp cloths to patient's face and neck.
	Not without loss of consciousness	Examine the patient to determine if signs in patient before attempting to move the patient. Place patient flat on back with feet elevated.
Anaphylaxis	Loss of consciousness	Check the patient's pulse and if pulse is present, attempt to move the patient. Place patient flat on back with feet elevated. Call 911 if patient does not recover immediately.
	Sudden or gradual onset of generalized itching, weakness, pallor, or dizziness; respiratory swelling of the face, lips, or throat; severe hives; or severe abdominal cramping or diarrhea	See Emergency Medical Protocol for Management of Anaphylaxis. Reactions in children and teens are the same as in adults. If the patient is not breathing, use the resuscitation steps for a child or infant.

All reactions have the potential to cause an adverse reaction. In order to receive adverse reactions, patients should be carefully monitored for reactions and symptoms. Patients should be advised that with careful monitoring, reactions are rare. These reactions are not from food and are not due to the vaccine itself, but to the ingredients in the vaccine.

Epinephrine Dose

First-Line Treatment: Epinephrine				Epinephrine Dose	
Age group	Range of weight (kg)	Range of weight (mg)	1 mg/mL, injectable (1:1000) dilution; intramuscular	Minimum dose	Epinephrine auto-injector
Infants	1-6 months	2-3 kg	0.05 mL (0.05 mg)	0.05 mL	off label
Infants and children	7-36 months	3-10 kg	0.1 mL (0.1 mg)	0.1 mL	off label
	37-59 months	10-17.5 kg	0.1 mL (0.1 mg)	0.1 mL	0.1 mg/0.5 mL
	60-119 months	18-25 kg	0.25-0.5 mL (0.25-0.5 mg)	0.25-0.5 mL	0.1 mg/0.5 mL
	120-179 months	26-34.5 kg	0.25-0.5 mL (0.25-0.5 mg)	0.25-0.5 mL	0.1 mg/0.5 mL
Teens	180-249 months	35-45 kg	0.5 mL (0.5 mg)	0.5 mL	0.3 mg/0.3 mL
	250-349 months	46-60 kg	0.5 mL (0.5 mg)	0.5 mL	0.3 mg/0.3 mL

Recommended dose is 0.01 mg/kg body weight up to 0.5 mg maximum dose. May be repeated every 5-15 minutes for a total of 3 doses.

- Both EpiPen and EpiPen Jr.
- Minimum of 3 of each (2 boxes)

QUESTIONS?

Sarah Barden sarah@michiganpharmacists.org

Dianne Malburg dianne@michiganpharmacists.org

Robin Curtis robin.curtis@spartannash.com

Medical Management of Vaccine Reactions in Children and Teens

All vaccines have the potential to cause an adverse reaction. In order to minimize adverse reactions, patients should be carefully screened for precautions and contraindications before vaccine is administered. Even with careful screening, reactions may occur. These reactions can vary from trivial and inconvenient (e.g., soreness, itching) to severe and life threatening (e.g., anaphylaxis). If reactions occur, staff should be prepared with procedures for their management. The table below describes procedures to follow if various reactions occur.

reaction	symptoms	management
Localized	Soreness, redness, itching, or swelling at the injection site	Apply a cold compress to the injection site. Consider giving an analgesic (pain reliever) or antipruritic (anti-itch) medication.
	Slight bleeding	Apply an adhesive compress over the injection site.
	Continuous bleeding	Place thick layer of gauze pads over site and maintain direct and firm pressure; raise the bleeding injection site (e.g., arm) above the level of the patient's heart.
Psychological fright and syncope (fainting)	Fright before injection is given	Have patient sit or lie down for the vaccination.
	Extreme paleness, sweating, coldness of the hands and feet, nausea, light-headedness, dizziness, weakness, or visual disturbances	Have patient lie flat or sit with head between knees for several minutes. Loosen any tight clothing and maintain an open airway. Apply cool, damp cloths to patient's face and neck.
	Fall, without loss of consciousness	Examine the patient to determine if injury is present before attempting to move the patient. Place patient flat on back with feet elevated.
	Loss of consciousness	Check the patient to determine if injury is present before attempting to move the patient. Place patient flat on back with feet elevated. Call 911 if patient does not recover immediately.
Anaphylaxis	Sudden or gradual onset of generalized itching, erythema (redness), or urticaria (hives); angioedema (swelling of the lips, face, or throat); severe bronchospasm (wheezing); shortness of breath; shock; abdominal cramping; or cardio-vascular collapse	See "Emergency Medical Protocol for Management of Anaphylactic Reactions in Children and Teens" on the next page for detailed steps to follow in treating anaphylaxis.

Continued on next page ♦

Needed medications for a community immunization clinic

First Line Medication

- ☐ Epinephrine, aqueous 1:1000 (i.e., 1 mg/mL) dilution, in ampules, vials of solution, or prefilled syringes, including epinephrine autoinjectors (e.g., EpiPen and Auvi-Q). If autoinjectors are stocked, at least three should be available.

Optional medication: H_1 antihistamines

- ☐ Diphenhydramine (e.g., Benadryl) oral (12.5 mg/5 mL liquid, 25 or 50 mg capsules/tablets) or injectable (50 mg/mL solution).

Needed supplies for a community immunization clinic

- ☐ Syringes (1 and 3 cc) and needles.
- ☐ Alcohol wipes
- ☐ Pediatric and adult size pocket mask with one-way valve
- ☐ Stethoscope
- ☐ Sphygmomanometer (blood pressure measuring device) with child, adult size and extra-large cuffs
- ☐ Cell phone or access to onsite phone

Emergency medical protocol for management of anaphylactic reactions in children and teens

- 1 If itching and swelling are confined to the injection site where the vaccination was given, observe patient closely for the development of generalized symptoms.
- 2 If symptoms are generalized, activate the emergency medical system (EMS; e.g., call 911) and notify patient's physician. This should be done by a second person, while the primary healthcare professional assesses the airway, breathing, circulation, and level of consciousness of the patient.
- 3 **drug dosing information: The first-line and most important therapy in anaphylaxis is epinephrine. There are NO contraindications to epinephrine in the setting of anaphylaxis.**
 - a **First-line treatment:** Administer aqueous **epinephrine** 1:1000 dilution (i.e., 1 mg/mL) intramuscularly; the standard dose is 0.01 mg/kg body weight, up to 0.5 mg maximum single dose in children and adolescents. See dosing chart on page 3.
 - b **Optional treatment:** H_1 **antihistamines** for hives or itching, you may also administer **diphenhydramine** (either orally or by intramuscular injection; the standard dose is 1–2 mg/kg body weight, up to 50 mg maximum dose in children and adolescents.

* According to AAP's *Red Book*, for children age ≥ 12 years, the diphenhydramine maximum single dose is 100 mg.
- 4 Monitor the patient closely until EMS arrives. Perform cardiopulmonary resuscitation (CPR), if necessary, and maintain airway. Keep patient in supine position (flat on back) unless he or she is having breathing difficulty. If breathing is difficult, patient's head may be elevated, provided blood pressure is adequate to prevent loss of consciousness. If blood pressure is low, elevate legs. Monitor blood pressure and pulse every 5 minutes.
- 5 If EMS has not arrived and symptoms are still present, repeat dose of epinephrine every 5–15 minutes for up to 3 doses, depending on patient's response.
- 6 Record all vital signs, medications administered to the patient, including the time, dosage, response, and the name of the medical personnel who administered the medication, and other relevant clinical information.
- 7 Notify the patient's primary care physician.

Continued on next page ♦

For your convenience, approximate dosages based on weight and age is provided in the following charts.
Please confirm that you are administering the correct dose for your patient.

First-Line Treatment: Epinephrine				Epinephrine Dose		
Recommended dose is 0.01 mg/kg body weight up to 0.5 mg maximum dose. May be repeated every 5–15 minutes for a total of 3 doses.		Age group	Range of weight (lb)	Range of weight (kg)*	1 mg/mL injectable (1:1000 dilution); intramuscular Minimum dose: 0.05 mL	Epinephrine auto-injector, 0.15 mg or 0.3 mg
	Infants and children	1–6 months	9–19 lb	4–8.5 kg	0.05 mL (or mg)	off label
		7–36 months	20–32 lb	9–14.5 kg	0.1 mL (or mg)	off label
		37–59 months	33–39 lb	15–17.5 kg	0.15 mL (or mg)	0.15 mg/dose
		5–7 years	40–56 lb	18–25.5 kg	0.2–0.25 mL (or mg)	0.15 mg/dose
		8–10 years	57–76 lb	26–34.5 kg	0.25–0.3 mL (or mg)	0.15 mg or 0.3 mg/dose
	Teens	11–12 years	77–99 lb	35–45 kg	0.35–0.4 mL (or mg)	0.3 mg/dose
		13 years & older	100+ lb	46+ kg	0.5 mL (or mg) – max. dose	0.3 mg/dose

note: If body weight is known, then dosing by weight is preferred.
If weight is not known or not readily available, dosing by age is appropriate.

* Rounded weight at the 50th percentile for each age range

Optional Treatment: Diphenhydramine				Diphenhydramine Dose	
	Age group	Range of weight (lb)	Range of weight (kg)*	Liquid: 12.5 mg/5 mL Tablets: 25 mg or 50 mg Injectable: 50 mg/mL (IV or IM)	
commonly known as Benadryl Recommended dose is 1–2 mg/kg body weight every 4–6 hrs	Infants and children	7–36 months	20–32 lb	9–14.5 kg	10–15 mg/dose
		37–59 months	33–39 lb	15–17.5 kg	15–20 mg/dose
		5–7 years	40–56 lb	18–25.5 kg	20–25 mg/dose
		8–12 years	57–99 lb	26–45 kg	25–50 mg/dose†
	Teens	13 years & older	100+ lb	46+ kg	50 mg/dose (up to 50 mg or 100 mg† single dose)

note: If body weight is known, then dosing by weight is preferred.
If weight is not known or not readily available, dosing by age is appropriate.

* Rounded weight at the 50th percentile for each age range

† According to AAP's *Red Book*, for children age ≥12 years, the diphenhydramine maximum single dose is 100 mg.

references

- Simons FE, Camargo CA. Anaphylaxis: Rapid recognition and treatment. In: UpToDate, Bochner BS (Ed). UpToDate: Waltham, MA, 2013.
- Charts adapted from American Academy of Pediatrics. *Red Book: 2012 Report of the Committee on Infectious Diseases*. Pickering LK, ed. 29th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2012: pp. 67–69.
- Boyce JA, Assa'ad A, Burks AW, et al. Guidelines for the Diagnosis and Management of Food Allergy in the United States: Report of the NIAID-Sponsored Expert Panel. *Allergy Clin Immunol* 2010; 126(6): S1–S57.

Medical Management of Vaccine Reactions in Adult Patients

All vaccines have the potential to cause an adverse reaction. In order to minimize adverse reactions, patients should be carefully screened for precautions and contraindications before vaccine is administered. Even with careful screening, reactions may occur. These reactions can vary from trivial and inconvenient (e.g., soreness, itching) to severe and life threatening (e.g., anaphylaxis). If reactions occur, staff should be prepared with procedures for their management. The table below describes procedures to follow if various reactions occur.

REACTION	SYMPTOMS	MANAGEMENT
Localized	Soreness, redness, itching, or swelling at the injection site	Apply a cold compress to the injection site. Consider giving an analgesic (pain reliever) or antipruritic (anti-itch) medication.
	Slight bleeding	Apply an adhesive compress over the injection site.
	Continuous bleeding	Place thick layer of gauze pads over site and maintain direct and firm pressure; raise the bleeding injection site (e.g., arm) above the level of the patient's heart.
Psychological fright and syncope (fainting)	Fright before injection is given	Have patient sit or lie down for the vaccination.
	Extreme paleness, sweating, coldness of the hands and feet, nausea, light-headedness, dizziness, weakness, or visual disturbances	Have patient lie flat or sit with head between knees for several minutes. Loosen any tight clothing and maintain an open airway. Apply cool, damp cloths to patient's face and neck.
	Fall, without loss of consciousness	Examine the patient to determine if injury is present before attempting to move the patient. Place patient flat on back with feet elevated.
	Loss of consciousness	Check the patient to determine if injury is present before attempting to move the patient. Place patient flat on back with feet elevated. Call 911 if patient does not recover immediately.
Anaphylaxis	Sudden or gradual onset of generalized itching, erythema (redness), or urticaria (hives); angioedema (swelling of the lips, face, or throat); severe bronchospasm (wheezing); shortness of breath; shock; abdominal cramping; or cardiovascular collapse.	See "Emergency Medical Protocol for Management of Anaphylactic Reactions in Adults" on the next page for detailed steps to follow in treating anaphylaxis.

CONTINUED ON NEXT PAGE ►

Needed medications for a community immunization clinic

FIRST-LINE medication

☒ Epinephrine, aqueous 1:1000 (i.e., 1 mg/mL) dilution, in ampules, vials of solution, or prefilled syringes, including epinephrine autoinjectors (e.g., EpiPen and Auvi-Q). If autoinjectors are stocked, at least three should be available.

Optional medication: H₁ antihistamines

☒ Diphenhydramine (e.g., Benadryl) oral (12.5 mg/5 mL liquid, 25 or 50 mg capsules/tablets) or injectable (50 mg/mL solution).

☐ Hydroxyzine (e.g., Atarax, Vistaril) oral (10 mg/5 mL or 25 mg/5 mL liquid, 25 mg capsules).

Needed supplies for a community immunization clinic

☒ Syringes (1 and 3 cc) and needles (22 and 25 g, 1", 1½", and 2") for epinephrine, diphenhydramine, or hydroxyzine. For ampules, use filtered needles.

☒ Alcohol wipes

☐ Tourniquet

☒ Adult airways (small, medium, and large)

☒ Adult size pocket mask with one-way valve

☐ Oxygen (if available)

☐ Stethoscope

☒ Sphygmomanometer (blood pressure measuring device) with adult-size and extra-large cuffs

☐ Tongue depressors

☐ Flashlight with extra batteries (for examination of the mouth and throat)

☐ Wristwatch with a second hand or other timing device

☒ Cell phone or access to onsite phone

REFERENCES

Simons FE, Camargo CA. Anaphylaxis: Rapid recognition and treatment. In: UpToDate, Bochner BS (Ed). UpToDate: Waltham, MA, 2013.

Boyce JA, Assa'ad A, Burks AW, et al. Guidelines for the Diagnosis and Management of Food Allergy in the United States: Report of the NIAID-Sponsored Expert Panel. *Allergy Clin Immunol* 2010; 126(6): S1-S57.

Emergency medical protocol for management of anaphylactic reactions in adults

- 1 If itching and swelling are confined to the injection site where the vaccination was given, observe patient closely for the development of generalized symptoms.
- 2 If symptoms are generalized, activate the emergency medical system (EMS; e.g., call 911) and notify the patient's physician. This should be done by a second person, while the primary healthcare professional assesses the airway, breathing, circulation, and level of consciousness of the patient.
- 3 **DRUG DOSING INFORMATION:** The first-line and most important therapy in anaphylaxis is epinephrine. There are NO contraindications to epinephrine in the setting of anaphylaxis.
 - a First-line treatment: Administer aqueous epinephrine 1:1000 dilution intramuscularly, 0.01 mL/kg/dose (adult dose ranges from 0.3 mL to 0.5 mL, with maximum single dose of 0.5 mL).
 - b Optional treatment: H₁ antihistamines for hives or itching; you may also administer diphenhydramine (either orally or by intramuscular injection; the standard dose is 1–2 mg/kg every 4–6 hrs, up to 50 mg maximum single dose) or hydroxyzine (standard oral dose is 0.5–1 mg/kg every 4–6 hrs up to 100 mg maximum single dose).
- 4 Monitor the patient closely until EMS arrives. Perform cardiopulmonary resuscitation (CPR), if necessary, and maintain airway. Keep patient in supine position (flat on back) unless he or she is having breathing difficulty. If breathing is difficult, patient's head may be elevated, provided blood pressure is adequate to prevent loss of consciousness. If blood pressure is low, elevate legs. Monitor blood pressure and pulse every 5 minutes.
- 5 If EMS has not arrived and symptoms are still present, repeat dose of epinephrine every 5–15 minutes for up to 3 doses, depending on patient's response.
- 6 Record all vital signs, medications administered to the patient, including the time, dosage, response, and the name of the medical personnel who administered the medication, and other relevant clinical information.
- 7 Notify the patient's primary care physician.

These standing orders for the medical management of vaccine reactions in adult patients shall remain in effect for patients of the

Family Fare LLC

NAME OF CLINIC

until rescinded or until 9-1-16

DATE

[Signature]

MEDICAL DIRECTOR'S SIGNATURE

8-26-15

DATE OF SIGNING

HPV Vaccination Pilot Project

Billing for HPV Vaccines

1. Blue Care Network

- a. Coverage good for age 11 to 26
- b. Can bill for any member carrying medical coverage (they do not need to have BCN pharmacy coverage)
 - i. BIN: 610014 with or without PCN: MEDDPRIME
 - ii. Cardholder ID: Run like any regular Rx, without the alpha prefix
 - iii. Group #: MIBCNRX (commercial) or BCNRXPD (Medicare advantage)
 - iv. DUR/PPS segment: Professional Service Code (440-E5): **MA**
 - v. Pricing segment: Incentive Amount Submitted (field 438-E3): **19**

2. Blue Cross Blue Shield *Pharmacy Benefit*

- a. Our SpartanNash group (group # 71575) has been selected to participate in a vaccine pilot program by BCBS of MI. The purpose of the program is to allow for vaccine billing directly online as a pharmacy benefit. This pilot program will replace that process and allow us to bill the vaccines below to BCBS of Michigan like any other pharmacy claim. This will affect **all employees/spouses/family members covered by SpartanNash BCBSM insurance**, we can bill BCBS of Michigan (BIN: 610014 / No PCN) for any vaccine listed below. Any claim for a Non-Spartan BCBSM member should be sent to Allwin as a medical claim. For medical billing, you are required to verify the patient has vaccine coverage before billing Allwin. See #3 below.
- b. Coverage good for age 11 to 26
- c. SpartanNash Employee/Spouse/Family Member **with** Spartan Insurance:
 - i. TP Plan: "BCBS of MICHIGAN"
 - ii. BIN: 610014 PCN: n/a
 - iii. Submit to Medco like any other pharmacy claim
 - iv. DUR/PPS segment: **MA**
 - v. Pricing segment: Incentive Amount Submitted (field 438-E3): **19**

3. Blue Cross Blue Shield of Michigan *Medical Benefit*

- a. BCBS OF MICHIGAN considers vaccinations a medical benefit and require an electronic CMS 1500 form be sent for medical billing. Allwin completes the electronic CMS 1500 forms for us ("BCBS – MEDICAL" BIN: 004766). Before billing Allwin, Patient benefits MUST be verified by calling BCBS's CAREN (Computer Assisted Response Environment Network) at **1-800-344-8525**.
- b. *Reminder* If a service is provided and it's not covered or the patient owes for any reason, the patient will receive a bill from SpartanNash in the mail.
- c. Calling CAREN:
 - i. When asked for a Provider ID # say: your BCBS Vaccine Pin #— **See attached table**
 - ii. When asked what kind of service you provide say: Other Services
 - iii. Will then prompt for
 - 1. Member's contract number
 - 2. Member's date of birth
 - 3. First 5 letters of patient name
 - iv. CAREN will state some contract information

- v. **Say Fax – to have the benefits fax sent to you**
 - 1. Give CAREN your fax number and fax is sent quickly
- d. **MUST SEE MEDICAL CARD;** with exception to the SpartanNash group
 - i. If medical group = 71575 - *see #2. SpartanNash Employee **with** Spartan Insurance* section
 - ii. If card says “Advantage” anywhere- *see BCBS Advantage Plan guidelines*
 - iii. BIN: 004766 PCN: COM SB710
 - iv. Cardholder ID #: MUST contain a 3-letter prefix for medical billing. Ex: XXX,XYQ, MMJ etc.
 - v. Group #: 5 Digit Group from medical card, **not** BCBSMAN or BCBSMRX1
 - vi. Person code & Relationship code required
 - vii. If patient is not the Cardholder, Cardholder field must be populated with Cardholder name

4. **Priority Health**

- a. Pharmacy Benefit for age 18 to 26
 - i. 18 and younger are covered at a providers office
- b. BIN: 610014 PCN: various
- c. DUR/PPS segment: **PH, MA, 3N**
- d. Pricing segment: Incentive Amount Submitted (438-E3): **20**
- e. Priority Health Help Desk: (800) 466-6642

5. **Michigan Medicaid**

- a. Straight Medicaid
 - i. Pharmacy coverage for adults age 19 to 26
 - ii. DUR/PPS segment: **PH, MA, 3N**
 - iii. Pricing segment: Incentive Amount Submitted (438-E3): **7**
- b. Medicaid Health Plan
 - i. Coverage depends on individual health plan
 - ii. *Please let us know as you find plans that do and do not cover this so we can work to update this section better*
 - 1. Plans that do cover
 - Priority Health
 - 2. Plans that do NOT cover
 - Meridian Rx – Health Plan of Michigan

6. **Our cash Price**

- a. \$224.99 per dose
- b. Similar price to Meijer and Walgreens
- c. CVS and Rite Aid do not offer the vaccine

Pin number to use when Calling CAREN:

Store #	BCBS PIN
254	0D10149
265	0D10148
1580	0D10127
1586	0D10128
1587	0D10129
137	0G00031
1523	0A80010
1922	0B50104
1975	0A40018
1990	0Z80015

Misc. Info:

Diagnosis Code = Z23

CPT code for Gardasil 9 = 90651

CPT code for Administration of Gardasil 9 = 90471



A little pain is worth the gain

HPV Vaccine

HPV vaccine works
and is safe for
your teen!

All shots hurt. However, some adolescents have noticed more discomfort with HPV vaccine than other vaccines given at the same visit. The short-term pain your teen may experience from HPV vaccination is worth the gain of long-term protection against cancer and other HPV-related diseases.

Why does HPV vaccine hurt?

Some vaccines hurt more than others because of their ingredients.

For some individuals, certain vaccine ingredients may be more irritating (but not harmful).

Not all teens feel pain with HPV vaccination, but if yours does, it is most likely not a cause for concern.

Side effects are minor

While HPV vaccine may cause more discomfort, the side effects are similar to those reported from other vaccines given to teens.

The most common side effect to any vaccine is redness and swelling in the arm where the shot was given.

How to reduce the pain of shots

There are things you can do to help ease your teen's discomfort.

Have him relax his arm and take a few deep breaths.

Make sure she moves her arm after the shot is given. Exercise helps!

Give him a cool wet cloth to reduce redness, soreness, or swelling.

She can also take a non-aspirin, pain-relieving medication as directed by her health care provider.

↓ **56%**

HPV disease has decreased among vaccinated girls 14-19 years of age¹.


HPV vaccine works best when given at this age.

**11-12
years**



All vaccines used in the U.S. are required to go through years of extensive safety testing before they are licensed by the Food and Drug Administration.

Millions of doses of HPV vaccine have been distributed in the U.S since 2006.


76M



All components included in a vaccine are there for a reason: to make the vaccine work well in order to prevent diseases.

www.cdc.gov/vaccinesafety



Protect your children from a lifetime of pain. Get them vaccinated against HPV today. A little pain is worth the gain!

Find out more about teen vaccines at www.michigan.gov/teenvaccines
Updated April 2015

¹ Journal of Infectious Diseases, June 2013 <http://jid.oxfordjournals.org>

HPV Vaccination Pilot Project

Screening Tool Q & A Guide - Ages 11-17

Question 1: Do you have more than one child in the age group 11-17?

Question 2: How old is the child you are filling out this assessment for?

Question 3: Has your child had the meningococcal shot?

Question 4: Has your child started the HPV (Cervarix® or Gardasil®) shot series?

Question 5: Has your child had his/her tetanus, diphtheria and pertussis (whooping cough) shot?

Question 6: Is your child up-to-date on all of his/her childhood shots (recommended for ages 0 to 10)?

Question 7: If you answered “Don’t Know” to any of the above questions, would you like us to check MCIR?

Question 8: Has your child ever fainted after any vaccination?

Question 9: Do you have any specific questions about immunizations for the pharmacist today?

Question 1

Do you have more than one child in the age group 11-17?

Yes___ No___

YES

This screening tool should be used for only one child.
Offer to provide additional copies for each child.

NO

Perfect. This screening tool is for one child.

Question 2

How old is the child you are filling out this assessment for?

Age_____

Verify that the child is between the ages of 11 and 17. If the child is younger or older, explain to the parent that this screening tool is only designed for children and adolescents between the ages of 11 and 17.

IMPORTANT NOTE

SpartanNash's protocols for immunizations cover children as young as 11 years of age.

Question 3

Has your child had the meningococcal shot?

Yes, age at vaccination_____ No____ Don't Know____

YES

Good. Verify the age of the child to see if he/she needs the booster dose.

NO

The child should receive the first dose of MenACWY (MCV4) as soon as possible.

DON'T KNOW

Refer to the parent's answer to Question 7, and check MCIR if the parent authorized it. You may also let the parent know that the child's immunization history should be in MCIR (if the child received immunizations in Michigan), and you are able and willing to check the registry for additional information.

EXPLANATION

All adolescents should get two doses of MenACWY (MCV4), the first between ages 11 and 12 and a booster between ages 16 and 18. Vaccination against serogroup B (MenB) is a Class B recommendation from the CDC's Advisory Committee on Immunization Practices and requires a separate vaccine. You may recommend the vaccine and administer it with a valid prescription. SpartanNash does NOT have a standing order for MenB. If the child lacks a prescription, refer him/her to another provider or health department.

Question 4

Has your child started the HPV (Cervarix® or Gardasil®) shot series?

Yes, # doses received _____ No ____ Don't Know ____

YES

If the child received all three doses, that is great! If the child has only received one or two doses, he/she may be ready for the next dose in the series depending on when the previous dose was given.

NO

If the child has no contraindications to the vaccine, he/she should start the series today.

DON'T KNOW

Refer to the parent's answer to Question 7, and check MCIR if the parent authorized it. You may also let the parent know that the child's immunization history should be in MCIR (if the child received immunizations in Michigan), and you are able and willing to check the registry for additional information.

EXPLANATION

The HPV vaccine is cancer prevention. It is important to provide a strong, clear recommendation for HPV vaccination for males and females ages 11 to 17. The standard dosing schedule is at zero months, two months and six months. You may continue the series at any point (as long as at least four weeks have passed between the first and second doses).

Question 5

Has your child had his/her tetanus, diphtheria and pertussis (whooping cough) shot?

Yes, age at vaccination ____ No ____ Don't Know ____

YES

Great! Remind the parent that the child will be due for a Td booster 10 years after the Tdap shot.

NO

It is recommended that the child receive one dose of Tdap today. Everyone should have one dose of Tdap in his/her lifetime.

DON'T KNOW

Refer to the parent's answer to Question 7, and check MCIR if the parent authorized it. You may also let the parent know that the child's immunization history should be in MCIR (if the child received immunizations in Michigan), and you are able and willing to check the registry for additional information.

EXPLANATION

Tdap is recommended for everyone between the ages of 11 and 12. If a child does not receive Tdap during that time, he/she should receive the recommended dose of Tdap as soon as possible.

Question 6

Is your child up-to-date on all of his/her childhood shots (recommended for ages 0 to 10)? These include multiple doses of Hepatitis B, Hepatitis A, MMR (measles, mumps and rubella), Varicella (chickenpox) and Polio.

Yes___ No___ Don't Know___

YES

Great! No further action is needed.

NO

Assess which vaccine(s) the child is missing by checking MCIR if the parent grants permission. All children should have received the following before age 11:

- Three doses of Hepatitis B
- Two doses of Hepatitis A
- Two doses of MMR (measles, mumps and rubella)
- Two doses of Varicella (chickenpox)
- Five doses of DTaP (this is NOT the same as Tdap—this is the childhood version)

DON'T KNOW

Refer to the parent's answer to Question 7, and check MCIR if the parent authorized it. You may also let the parent know that the child's immunization history should be in MCIR (if the child received immunizations in Michigan), and you are able and willing to check the registry for additional information.

Question 7

If you answered “Don’t Know” to any of the above questions, and your child is from Michigan, would you like us to check the Michigan immunization registry, where all childhood vaccines given in Michigan are required to be reported?

Yes___ No___

YES

Check MCIR and share findings with the parent.

NO

Let the parent know that the child’s immunization history should be in MCIR (if the child received immunizations in Michigan) and that you are able and willing to check the registry for them.

IMPORTANT NOTE

If any patient intends to receive any vaccine (other than influenza), it is SpartanNash policy that the pharmacist **MUST** check MCIR prior to administering the vaccine.

Question 8

Has your child ever fainted after any vaccination?

Yes____ No____

YES

Ask more questions.

- How old was the child when it happened?
- Which vaccine(s) did he/she receive?
- Did it happen more than once?
- Did any medical staff come to any conclusions about the fainting (e.g., a cause other than the vaccine)?

Just because this happened in the past, it does not mean it will happen again, but extra caution should be taken in monitoring the child.

NO

Fainting is a possible reaction to any vaccination. The child should be seated while the vaccination is administered and should remain seated for another 15 minutes after vaccination. This allows for monitoring and reduces the risk of fainting and possible injury from falling.

EXPLANATION

Fainting is more common in children and adolescents than adults, so knowing a child's history is important. If the child is not willing or able to wait 15 minutes after vaccination for monitoring, ask the parent to bring the child back at a time when they are able to wait.

Question 9

Do you have any specific questions about immunizations for the pharmacist today?

Yes ___ No ___

If yes, please write it here: _____

YES

Respond appropriately to any questions the patient has.

NO

Let the parent know that you are a resource if he/she has any questions in the future.

Standing Order Information

Ages 11-17

Prescriber: Dr. Janet Arrowsmith

NPI # 1558330126

HPV Vaccination Pilot Project

Contact Information

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Local Health Department

HPV Vaccination Pilot Project

Screening Tool Q & A Guide - Ages 18-26

Question 1: Are you between the ages of 18 and 26?

Question 2: Are you currently enrolled in a college or university and living on campus?

Question 3: Have you had the meningococcal shot?

Question 4: Have you started the HPV (Cervarix® or Gardasil®) shot series?

Question 5: Have you ever had a tetanus, diphtheria and pertussis (Tdap) shot?

Question 6: Have you had a tetanus and diphtheria (Td) shot in the past 10 years?

Question 7: Do you come in contact with infants or small children or are you currently pregnant?

Question 8: If you answered “Don’t Know” to any of the above questions, would you like us to check MCIR?

Question 9: Have you ever fainted after any vaccination?

Question 10: Do you have any specific questions about immunizations for the pharmacist today?

Question 1

Are you between the ages of 18 and 26?

Yes___ No___

YES

This is the appropriate survey for the patient to complete.

NO

If younger than 18 years, a parent may fill out the ages 11-17 survey.

If older than 26 years, let the patient know you are a resource for any immunization questions he/she may have. If the patient has children between the ages of 11 and 17, you may ask if he/she would like to complete the ages 11-17 screening tool for the children.

Question 2

Are you currently enrolled in a college or university and living on campus?

Yes___ No___

YES

The meningococcal vaccine is recommended if the patient has not already received it (see Question 3).

NO

The meningococcal vaccine may still be recommended for this patient if he/she has never received it.

EXPLANATION

Living on a college campus is a common risk factor for contracting *Neisseria meningitidis*, the cause of bacterial meningococcal disease. All adolescents should receive two doses of MenACWY (MCV4): one between ages 11 and 12 and a booster between ages 16 and 18. If the patient has not received the booster AND lives on a college campus, it is recommended that he/she receive the booster. See the vaccine package insert and VIS for additional high risk indications. Vaccination against serogroup B (MenB) is a Class B recommendation from the CDC's Advisory Committee on Immunization Practices and requires a separate vaccine. You may recommend the vaccine and administer it with a valid prescription. At this time, SpartanNash does NOT have a standing order for MenB. If the patient lacks a prescription, refer him/her to another provider or health department.

Question 3

Have you had the meningococcal shot?

Yes, date_____ No___ Don't Know___

This question relates to Question 2.

YES

Check the date. If the patient received a booster dose on or after his/her 16th birthday, the patient is up-to-date on meningococcal vaccination. If the patient has not received the booster dose AND if the patient answered “Yes” to Question 2, it is recommended he/she get the booster dose of MenACWY (MCV4).

NO

If the patient also answered “Yes” to Question 2, it is recommended that the patient receive MenACWY (MCV4). The vaccine may also be recommended for this patient if he/she has never received it and has another indication (see Question 2 and the 2016 Adult Immunization Schedule for additional information).

DON'T KNOW

Refer to the patient's answer to Question 8, and check MCIR if the patient authorized it. You may also let the patient know that his/her immunization history is in MCIR (if the patient received immunizations in Michigan), and you are able and willing to check the registry for additional information.

Question 4

Have you started the HPV (Cervarix® or Gardasil®) shot series?

Yes, # doses received _____ No ____ Don't Know ____

YES

If the patient received all three doses, congratulate him/her on being up-to-date! If the patient has only received one or two doses, he/she may be ready for the next dose depending on the date of the last dose.

NO

If the patient has no contraindications to the vaccine, he/she should start the series today.

DON'T KNOW

Refer to the patient's answer to Question 8, and check MCIR if the patient authorized it. You may also let the patient know that his/her immunization history is in MCIR (if the patient received immunizations in Michigan), and you are able and willing to check the registry for additional information.

EXPLANATION

The HPV vaccine is cancer prevention. It is important to provide a strong, clear recommendation for HPV vaccination for males and females through age 26. The standard dosing schedule is at zero months, two months and six months. You may continue the series at any point (as long as at least four weeks have passed between the first and second doses).

Question 5

Have you ever had a tetanus, diphtheria and pertussis (Tdap) shot?

Yes, date_____ No____ Don't Know____

YES

Great! This patient does not need another dose unless she is pregnant (see Question 7).

NO

It is recommended that the patient receive one dose of Tdap if he/she has never received one. Everyone should have one dose of Tdap in his/her lifetime.

DON'T KNOW

Refer to the patient's answer to Question 8, and check MCIR if the patient authorized it. You may also let the patient know that his/her immunization history is in MCIR (if the patient received immunizations in Michigan), and you are able and willing to check the registry for additional information.

EXPLANATION

Tdap is recommended for everyone between the ages of 11 and 12. If a patient does not receive Tdap during that time, he/she should receive the recommended dose of Tdap as soon as possible. Tdap is especially important for healthcare professionals, all pregnant women and anyone having close contact with a baby younger than 12 months old.

Question 6

Have you had a tetanus and diphtheria (Td) shot in the past 10 years?

Yes, date _____ No ____ Don't Know ____

YES

Great! Check Question 5, and if the patient has already received one dose of Tdap, remind the patient to receive another dose of Td 10 years after their last Td or Tdap vaccine.

NO

If the patient has not had a Td booster, but did have one dose of Tdap, recommend he/she receive the Td booster 10 years after last Tdap or Td dose. If it has been more than 10 years, recommend the patient get the Td booster (or Tdap if they have never had it) as soon as possible.

DON'T KNOW

Refer to the patient's answer to Question 8, and check MCIR if the patient authorized it. You may also let the patient know that his/her immunization history is in MCIR (if the patient received immunizations in Michigan), and you are able and willing to check the registry for additional information.

EXPLANATION

Adults should get a Td booster every 10 years with one dose being replaced by Tdap for adults who did not get Tdap between the ages of 11 and 12.

Question 7

Do you come in contact with infants or small children or are you currently pregnant?

Yes___ No___

YES

If the patient is not pregnant, but is around small children, a dose of Tdap is indicated if he/she has never received one. If the patient is currently pregnant, she should receive a dose of Tdap between gestational weeks 27 and 36.

NO

Also refer to Question 5. If the patient has never received a Tdap vaccine, one dose of Tdap is recommended in his/her lifetime.

EXPLANATION

Pertussis is very dangerous for infants and children, so vaccinating adolescents and adults helps protect infants and children. According to the CDC's Advisory Committee on Immunization Practices, pregnant women should receive a dose of Tdap during *EACH* pregnancy irrespective of the patient's prior history of receiving Tdap. This strategy helps protect the mother from getting and passing pertussis on to her infant and provides passive immunity to the infant. To maximize the maternal antibody response and passive antibody transfer, Tdap should be administered between 27 and 36 weeks gestation.

Question 8

If you answered “Don’t Know” to any of the above questions, and you are from Michigan, would you like us to check the Michigan immunization registry for you?

Yes____ No____

YES

Check MCIR and share findings with the patient.

NO

Let the patient know that his/her immunization history may be in MCIR (if the patient received immunizations in Michigan) and that you are able and willing to check the registry for them.

IMPORTANT NOTE

If the patient intends to receive any vaccine (other than influenza), it is SpartanNash policy that the pharmacist **MUST** check MCIR prior to administering the vaccine.

Question 9

Have you ever fainted after any vaccination?

Yes____ No____

YES

Ask more questions.

- How old was the patient when it happened?
- Which vaccine(s) did the patient receive?
- Did it happen more than once?
- Did any medical staff come to any conclusions about the fainting (e.g., a cause other than the vaccine)?

Just because this happened in the past, it does not mean it will happen again, but extra caution should be taken in monitoring the patient.

NO

Fainting is a possible reaction to any vaccination. The patient should be seated while the vaccination is administered and should remain seated for another 15 minutes after vaccination. This allows for monitoring and reduces the risk of fainting and possible injury from falling.

EXPLANATION

Fainting is more common in adolescents than adults, but knowing a patient's history is important. If the patient is not willing or able to wait 15 minutes after vaccination for monitoring, ask the patient to come back at a time when he/she is able to wait.

Question 10

Do you have any specific questions about immunizations for the pharmacist today?

Yes ___ No ___

If yes, please write it here: _____

YES

Respond appropriately to any questions the patient has.

NO

Let the patient know that you are a resource if he/she has any questions in the future.

Standing Order Information

Ages 18-26

Prescriber: Dr. Corrine Garner

NPI # 1275540825

HPV Vaccination Pilot Project

Contact Information

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Local Health Department

Week of April 18 – April 24, 2016

Weekly record for HPV Grant project

	Number of surveys (with info sheets) distributed		Number of returned surveys	
	Age 11-17	Age 18-26	Age 11-17	Age 18-26
Monday	 			
Tuesday				
Wednesday				
Thursday				
Friday				
Saturday				
Sunday				
Weekly Totals	23	10	4	8

[illegible]

Week of April 18 – April 24, 2016

Comments about Pilot Project

Getting patients to fill out the surveys has been hard because they are in a hurry

The materials boxes work well to keep everything organized

[illegible]

Immunization Assessment Version #3 - Age 11-17

Please take a moment to answer the following questions for a free immunization assessment for your adolescent child.

Adolescent Vaccines

1. Do you have a child in the age group 11-17?
 Yes___ No___
 If no, thank you for your time, please return the survey.
 If yes, please fill this out for one child. We would be happy to provide additional copies for each of your children in this age group.
2. How old is the child you are filling out this assessment for?
 Age _____
3. Has your child had the meningococcal shot?
 Yes, age at vaccination_____ No___ Don't Know___
4. Has your child started the HPV (Cervarix® or Gardasil®) shot series?
 Yes, # doses_____ No___ Don't Know___
5. Has your child had their Tdap - tetanus, diphtheria and pertussis (whooping cough) - shot?
 Yes, age at vaccination_____ No___ Don't Know___

General immunization questions

6. Is your child up to date on all of his/her childhood shots (recommended for age 0 to 10)?
 These include multiple doses of Hepatitis B, Hepatitis A, MMR (measles, mumps and rubella), Varicella (chickenpox) and polio.
 Yes___ No___ Don't Know___
7. If you answered "Don't Know" to any of the above questions and your child is from Michigan, would you like us to check the Michigan immunization registry, where all childhood vaccines given in Michigan are required to be reported?
 Yes___ No___
8. Has your child ever fainted after any vaccination?
 Yes___ No___
9. Do you have any specific questions about immunizations for the pharmacist today?
 Yes___ No___
 If yes, please write them here: _____

For Pharmacy Use Only

Pharmacist Initials _____

Did you check MCIR for this patient? ☐ Yes ☐ No

Technician Initials _____

Which vaccinations were given today? ☐ None ☐ HPV ☐ Tdap ☐ Meningococcal ☐ Other _____

Month ☐ April ☐ May ☐ June ☐ July

Store ☐ 137 ☐ 254 ☐ 265 ☐ 1523 ☐ 1580 ☐ 1586 ☐ 1587 ☐ 1922 ☐ 1975 ☐ 1990

TEEN VACCINES

INFORMATION FOR PARENTS



Meningococcal Vaccines (MCV, MenB)	Adolescent Catch-Up	Tetanus, Diphtheria, Pertussis (Tdap)	Human Papillomavirus (HPV)
<p>Meningococcal vaccines protect you against meningitis, which affects the brain and spinal cord.</p> <p>If you contract meningitis, it can cause brain damage, severe disabilities or death.</p> <p>Common symptoms include a fever, rash, headache, or stiff neck.</p> <p>It is spread through close contact with an infected person, such as coughing, kissing, and sharing food or drinks. This disease is easily spread.</p> <p>MCV is given at 11-12 years of age with a second dose at 16. MenB is given at 16-18 years of age in a series of doses. If you have not received these vaccines before you get your diploma, talk to your health care provider about catch-up.</p>	<p>Many vaccines are given during childhood to give you life-long protection against diseases.</p> <p>If you have not received all of the below vaccines, it is not too late!</p> <p>3 doses of hepatitis B vaccine (Hep B)</p> <p>2 doses of hepatitis A vaccine (Hep A)</p> <p>2 doses of measles, mumps, rubella vaccine (MMR)</p> <p>2 doses of varicella (chickenpox) vaccine</p> <p>At least 3 doses of polio vaccine (IPV or OPV)</p> <p>Flu vaccine every year</p> <p>These vaccines are important, especially if you plan to travel. You need all doses for full protection.</p>	<p>Tdap vaccine protects you against pertussis (whooping cough), diphtheria, and tetanus.</p> <p>Tetanus causes painful tightening of the muscles and is very serious. It is found in soil and enters the body through a cut or wound.</p> <p>Diphtheria can make you unable to breath or move body parts. It is spread by coughing or sneezing.</p> <p>Pertussis can cause severe coughing and choking, making it difficult for you to breathe or eat. It is spread by coughing, sneezing or close contact with an infected person.</p> <p>Tdap vaccine is usually given at the 11-12 years of age. However, anyone who has not had Tdap vaccine needs a dose.</p>	<p>HPV vaccine protects against cervical cancer in women and genital warts in men and women. It will also protect you against several other cancers.*</p> <p>HPV is a common infection transmitted by skin-to-skin contact during sexual activity. Even if you do not have sex, you can still get HPV. HPV infection often has no symptoms so you could have it and not know.</p> <p>The best time to get HPV vaccine is at 11-12 years of age, well before sexual activity starts. However, if you missed your doses, you should still get the vaccine through 26 years of age.</p> <p>This vaccine is very effective against several types of HPV and works best if you get all three doses prior to exposure.</p>

Immunization Assessment Version #4 - Age 18-26

Please take a moment to answer the following questions for your free personalized immunization assessment.

Meningitis and HPV

1. Are you between the ages of 18 and 26?
Yes___ No___
2. Are you currently enrolled in a college or university and living on campus?
Yes___ No___
3. Have you had the meningococcal shot?
Yes, date_____ No___ Don't Know___
4. Have you started the HPV (Cervarix® or Gardasil®) shot series?
Yes, # doses received_____ No___ Don't Know___

Tetanus, diphtheria and pertussis (whooping cough)

5. Have you ever had a tetanus, diphtheria and pertussis (Tdap) shot?
Yes, date_____ No___ Don't Know___
6. Have you had a tetanus and diphtheria (Td) shot in the past 10 years?
Yes, date_____ No___ Don't Know___
7. Do you come in contact with infants or small children or are you currently pregnant?
Yes___ No___

General immunization questions

8. If you answered "Don't Know" to any of the above questions and you are from Michigan, would you like us to check the Michigan immunization registry for you?
Yes___ No___
9. Have you ever fainted after any vaccination?
Yes___ No___
10. Do you have any specific questions about immunizations for the pharmacist today?
Yes___ No___
If yes, please write them here: _____

For Pharmacy Use Only

Did you check MCIR for this patient? ☐ Yes ☐ No

Which vaccinations were given today? ☐ None ☐ HPV ☐ Tdap ☐ Meningococcal ☐ Other _____

Month ☐ April ☐ May ☐ June ☐ July

Store ☐ 137 ☐ 254 ☐ 265 ☐ 1523 ☐ 1580 ☐ 1586 ☐ 1587 ☐ 1922 ☐ 1975 ☐ 1990

Pharmacist Initials _____

Technician Initials _____

HPV* Vaccine

A Guide for Young Adults

* human papillomavirus



HPV is a very common virus that can lead to:

- ▶ Cancers of the mouth and throat
- ▶ Cancer of the cervix
- ▶ Cancer of the penis, vagina, vulva, or anus
- ▶ Genital warts

HPV vaccine can prevent these!

Do I really need HPV vaccine? **Yes!**

You should get HPV vaccine because it can prevent some types of cancer and genital warts.

Do I need it if I haven't had sex yet? **Yes!**

- You don't have to have sex to catch HPV, but sex increases your risk.
- You can get HPV by skin-to-skin intimate contact.
- People can get and spread HPV without knowing it.
- It's best to get vaccinated before you ever have sex.

Should I get HPV vaccine if I've already had sex? **Yes!**

You still need to get vaccinated even if you have had sex. The vaccine provides a lot of protection.

Why do I need 3 shots?

You need 3 HPV shots to be fully protected.

I didn't get the vaccine at age 11 or 12. Should I get it now? **Yes!**

HPV vaccination is recommended for people ages 9 through 26. Even though it is ideal to get HPV vaccine as a preteen, it is still highly effective in teens and young adults.

Is HPV vaccine safe? **Yes!**

- Millions of doses of HPV vaccine have been given without any problem.
- You may get a sore arm.
- Occasionally, a few people faint, so sit for 15 minutes after getting the vaccine.

Make sure you get all 3 HPV shots. Complete your series!

When Should I Get HPV Vaccine?

Have your healthcare provider fill in this chart about when you should be vaccinated.

VACCINE DOSE	RECOMMENDED	DATE DOSE GIVEN OR DUE
#1	For people ages 9–26 years	
#2	1–2 months after vaccine dose #1	
#3	At least 6 months after vaccine dose #1	

For more information on vaccines for teens and young adults, visit www.vaccineinformation.org/teens or www.vaccineinformation.org/adults

Adapted with permission from the Academic Pediatric Association

Talk to your child's doctor or nurse about the vaccines recommended for their age.

	Flu <i>Influenza</i>	Tdap Tetanus, diphtheria, pertussis	HPV Human papillomavirus	Meningococcal		Pneumococcal	Hepatitis B	Hepatitis A		Inactivated Polio	MMR Measles, mumps, rubella	Chickenpox <i>Varicella</i>
				MenACWY	MenB							
7-8 Years												
9-10 Years												
11-12 Years												
13-15 Years												
16-18 Years												
More information:	Preteens and teens should get a flu vaccine every year.	Preteens and teens should get one shot of Tdap at age 11 or 12 years.	Both girls and boys should receive 3 doses of HPV vaccine to protect against HPV-related disease. HPV vaccination can start as early as age 9 years.	All 11-12 year olds should be vaccinated with a single dose of a quadrivalent meningococcal conjugate vaccine (MenACWY). A booster shot is recommended at age 16.	Teens, 16-18 years old, may be vaccinated with a MenB vaccine.							



These shaded boxes indicate when the vaccine is recommended for all children unless your doctor tells you that your child cannot safely receive the vaccine.



These shaded boxes indicate the vaccine should be given if a child is catching-up on missed vaccines.



These shaded boxes indicate the vaccine is recommended for children with certain health or lifestyle conditions that put them at an increased risk for serious diseases. See vaccine-specific recommendations at www.cdc.gov/vaccines/hcp/acip-recs/index.html



This shaded box indicates the vaccine is recommended for children not at increased risk but who wish to get the vaccine after speaking to a provider.



**U.S. Department of
Health and Human Services**
Centers for Disease
Control and Prevention

American Academy
of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN™



**AMERICAN ACADEMY OF
FAMILY PHYSICIANS**
STRONG MEDICINE FOR AMERICA

Vaccine-Preventable Diseases and the Vaccines that Prevent Them

Diphtheria (Can be prevented by Tdap vaccination)

Diphtheria is a very contagious bacterial disease that affects the respiratory system, including the lungs. Diphtheria bacteria can be passed from person to person by direct contact with droplets from an infected person's cough or sneeze. When people are infected, the diphtheria bacteria produce a toxin (poison) in the body that can cause weakness, sore throat, fever, and swollen glands in the neck. Effects from this toxin can also lead to swelling of the heart muscle and, in some cases, heart failure. In serious cases, the illness can cause coma, paralysis, and even death.

Hepatitis A (Can be prevented by HepA vaccination)

Hepatitis A is an infection in the liver caused by hepatitis A virus. The virus is spread primarily person-to-person through the fecal-oral route. In other words, the virus is taken in by mouth from contact with objects, food, or drinks contaminated by the feces (stool) of an infected person. Symptoms can include fever, tiredness, poor appetite, vomiting, stomach pain, and sometimes jaundice (when skin and eyes turn yellow). An infected person may have no symptoms, may have mild illness for a week or two, may have severe illness for several months, or may rarely develop liver failure and die from the infection. In the U.S., about 100 people a year die from hepatitis A.

Hepatitis B (Can be prevented by HepB vaccination)

Hepatitis B causes a flu-like illness with loss of appetite, nausea, vomiting, rashes, joint pain, and jaundice. Symptoms of acute hepatitis B include fever, fatigue, loss of appetite, nausea, vomiting, pain in joints and stomach, dark urine, grey-colored stools, and jaundice (when skin and eyes turn yellow).

Human Papillomavirus (Can be prevented by HPV vaccination)

Human papillomavirus is a common virus. HPV is most common in people in their teens and early 20s. It is the major cause of cervical cancer in women and genital warts in women and men. The strains of HPV that cause cervical cancer and genital warts are spread during sex.

Influenza (Can be prevented by annual flu vaccination)

Influenza is a highly contagious viral infection of the nose, throat, and lungs. The virus spreads easily through droplets when an infected person coughs or sneezes and can cause mild to severe illness. Typical symptoms include a sudden high fever, chills, a dry cough, headache, runny nose, sore throat, and muscle and joint pain. Extreme fatigue can last from several days to weeks. Influenza may lead to hospitalization or even death, even among previously healthy children.

Measles (Can be prevented by MMR vaccination)

Measles is one of the most contagious viral diseases. Measles virus is spread by direct contact with the airborne respiratory droplets of an infected person. Measles is so contagious that just being in the same room after a person who has measles has already

left can result in infection. Symptoms usually include a rash, fever, cough, and red, watery eyes. Fever can persist, rash can last for up to a week, and coughing can last about 10 days. Measles can also cause pneumonia, seizures, brain damage, or death.

Meningococcal Disease (Can be prevented by meningococcal vaccination)

Meningococcal disease is caused by bacteria and is a leading cause of bacterial meningitis (infection around the brain and spinal cord) in children. The bacteria are spread through the exchange of nose and throat droplets, such as when coughing, sneezing or kissing. Symptoms include nausea, vomiting, sensitivity to light, confusion and sleepiness. Meningococcal bacteria also cause blood infections. About one of every ten people who get the disease dies from it. Survivors of meningococcal disease may lose their arms or legs, become deaf, have problems with their nervous systems, become developmentally disabled, or suffer seizures or strokes.

Mumps (Can be prevented by MMR vaccination)

Mumps is an infectious disease caused by the mumps virus, which is spread in the air by a cough or sneeze from an infected person. A child can also get infected with mumps by coming in contact with a contaminated object, like a toy. The mumps virus causes swollen salivary glands under the ears or jaw, fever, muscle aches, tiredness, abdominal pain, and loss of appetite. Severe complications for children who get mumps are uncommon, but can include meningitis (infection of the covering of the brain and spinal cord), encephalitis (inflammation of the brain), permanent hearing loss, or swelling of the testes, which rarely results in decreased fertility.

Pertussis (Whooping Cough) (Can be prevented by Tdap vaccination)

Pertussis is caused by bacteria spread through direct contact with respiratory droplets when an infected person coughs or sneezes. In the beginning, symptoms of pertussis are similar to the common cold, including runny nose, sneezing, and cough. After 1-2 weeks, pertussis can cause spells of violent coughing and choking, making it hard to breathe, drink, or eat. This cough can last for weeks. Pertussis is most serious for babies, who can get pneumonia, have seizures, become brain damaged, or even die. About two-thirds of children under 1 year of age who get pertussis must be hospitalized.

Pneumococcal Disease (Can be prevented by pneumococcal vaccination)

Pneumonia is an infection of the lungs that can be caused by the bacteria called pneumococcus. This bacteria can cause other types of infections too, such as ear infections, sinus infections, meningitis (infection of the covering around the brain and spinal cord), bacteremia and sepsis (blood stream infection). Sinus and ear infections are usually mild and are much more common than the more serious forms of pneumococcal disease. However, in

some cases pneumococcal disease can be fatal or result in long-term problems, like brain damage, hearing loss and limb loss. Pneumococcal disease spreads when people cough or sneeze. Many people have the bacteria in their nose or throat at one time or another without being ill—this is known as being a carrier.

Polio (Can be prevented by IPV vaccination)

Polio is caused by a virus that lives in an infected person's throat and intestines. It spreads through contact with the stool of an infected person and through droplets from a sneeze or cough. Symptoms typically include sore throat, fever, tiredness, nausea, headache, or stomach pain. In about 1% of cases, polio can cause paralysis. Among those who are paralyzed, About 2 to 10 children out of 100 die because the virus affects the muscles that help them breathe.

Rubella (German Measles) (Can be prevented by MMR vaccination)

Rubella is caused by a virus that is spread through coughing and sneezing. In children rubella usually causes a mild illness with fever, swollen glands, and a rash that lasts about 3 days. Rubella rarely causes serious illness or complications in children, but can be very serious to a baby in the womb. If a pregnant woman is infected, the result to the baby can be devastating, including miscarriage, serious heart defects, mental retardation and loss of hearing and eye sight.

Tetanus (Lockjaw) (Can be prevented by Tdap vaccination)

Tetanus is caused by bacteria found in soil, dust, and manure. The bacteria enters the body through a puncture, cut, or sore on the skin. When people are infected, the bacteria produce a toxin (poison) that causes muscles to become tight, which is very painful. Tetanus mainly affects the neck and belly. This can lead to "locking" of the jaw so a person cannot open his or her mouth, swallow, or breathe. Complete recovery from tetanus can take months. One out of five people who get tetanus die from the disease.

Varicella (Chickenpox) (Can be prevented by varicella vaccination)

Chickenpox is caused by the varicella zoster virus. Chickenpox is very contagious and spreads very easily from infected people. The virus can spread from either a cough, sneeze. It can also spread from the blisters on the skin, either by touching them or by breathing in these viral particles. Typical symptoms of chickenpox include an itchy rash with blisters, tiredness, headache and fever. Chickenpox is usually mild, but it can lead to severe skin infections, pneumonia, encephalitis (brain swelling), or even death.

If you have any questions about your child's vaccines, talk to your healthcare provider.

Measles

- Causes a rash, cough, sore eyes, and high fever

Mumps

- Causes fever, headache, and swelling under the jaw

Rubella (German Measles)

- Causes fever, rash, and soreness or swelling in the joints
- If you are pregnant, you can pass rubella to your unborn baby

One vaccine (MMR) protects against these three diseases.

All school-age children and teens need two shots of MMR vaccine.

Polio

- Causes flu-like symptoms and can lead to paralysis and death
- Older children and teens need three doses of polio vaccine



More Vaccines?

- Teens who have health problems or are traveling outside the United States may need other vaccines
- Check with your health care provider about other vaccines your teen may need

Your Child’s Vaccination Record

You should have a record of your child’s vaccines. Keep it and carry it with you to every health care visit. A great way to keep track of anyone’s vaccine record is by using the Michigan Care Improvement Registry (MCIR). Ask if all your child’s vaccines are in MCIR and make sure they have all needed vaccines.

Paying for Vaccines

Check to see if your health insurance will pay for these vaccines. If your child does not have health insurance, or does not have insurance that covers these vaccines, ask your health care provider or local health department about the Vaccines for Children (VFC) program. VFC provides no- or low-cost vaccines to eligible children, 18 years of age and younger.

Where to go for more information

- Your health care provider
- Your local health department
- Michigan Department of Community Health:
www.michigan.gov/immunize
www.michigan.gov/teenvaccines
- Vaccine Education Center:
www.chop.edu/vaccine
- Immunization Action Coalition:
www.immunize.org
- Vaccines for Children (VFC) program:
www.michigan.gov/vfc
- Centers for Disease Control and Prevention (CDC):
www.cdc.gov/vaccines
 - o English and Spanish
 - o 800-CDC-INFO
 - o 800-232-4636
 - o TTY 1-888-232-6348

Michigan Department
of Community Health



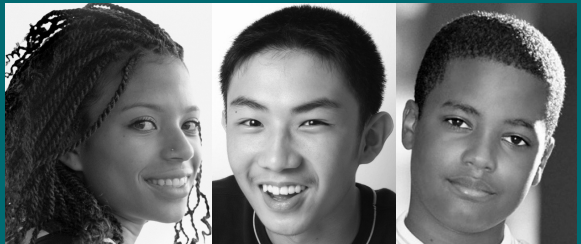
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James K. Haveman, Director

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**PROTECT
PRE-TEENS
AND TEENS
FROM SERIOUS
DISEASES**

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Getting vaccines and staying protected from serious diseases is a lifelong job. Some pre-teens and teens are missing doses of vaccine. All doses of vaccines are needed to protect against diseases.



Meningitis

- An illness that affects the brain and spinal cord
- Spread through sneezing, coughing, kissing, and sharing food or drinks with an infected person
- It's easy for meningitis to spread in places where teens are in close contact, such as classrooms or college dorms
- Adolescents need one dose at 11-12 years and a second (booster) dose at age 16 years

One vaccine (Tdap) protects against these three diseases.

Tetanus

- Causes painful tightening of the muscles and is very serious
- Tetanus is usually found in soil and enters the body through a cut or wound.

Diphtheria

- Can make you unable to breathe or move body parts
- Spread by coughing or sneezing

Pertussis (Whooping Cough)

- Causes coughing and choking, making it hard to eat or breath
- If pertussis is passed on to infants, it may be life-threatening
- Spread by coughing, sneezing or close contact with an infected person

Tdap should be given at the 11-12 year old check-up.



Human Papillomavirus (HPV)

- HPV is a common virus; most men and women will get at least one type in their lifetime
- Can cause genital warts and cervical cancer
- Three shots of HPV vaccine are recommended for girls and boys at 11-12 years of age.



Influenza (Flu)

- Causes fever, headache, tiredness, cough, runny or stuffy nose, and sore muscles
- It's easy for flu to spread in places like college dorms, classrooms or at school activities
- Even healthy people can get the flu and it can be serious
- Everyone 6 months of age and older should receive flu vaccine every year

Hepatitis A

- Can cause fever, tiredness, loss of appetite, nausea, and jaundice (yellowing of the skin and eyes)
- Anyone who wants to be protected from hepatitis A needs two shots

Hepatitis B

- Can cause different kinds of liver disease including cancer
- Children need three shots of hepatitis B vaccine

Varicella (Chickenpox)

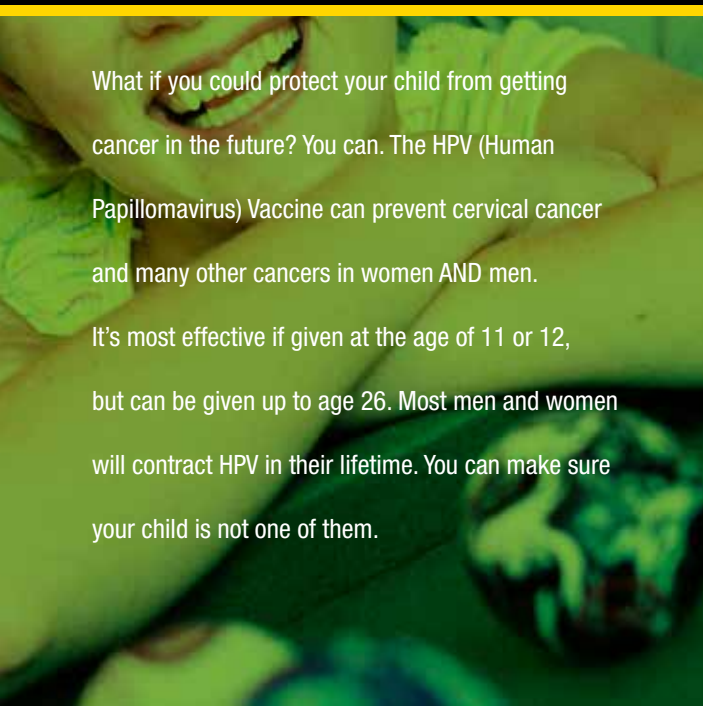
- Causes an itchy rash all over the body, fever and tiredness. It can lead to severe skin infections, scars and pneumonia
- All school-age children and teens who have not had chickenpox need two shots of varicella vaccine





GETTING YOUR CHILD THE
HPV VACCINE NOW, HELPS

PREVENT
SEVERAL CANCERS LATER



What if you could protect your child from getting cancer in the future? You can. The HPV (Human Papillomavirus) Vaccine can prevent cervical cancer and many other cancers in women AND men. It's most effective if given at the age of 11 or 12, but can be given up to age 26. Most men and women will contract HPV in their lifetime. You can make sure your child is not one of them.

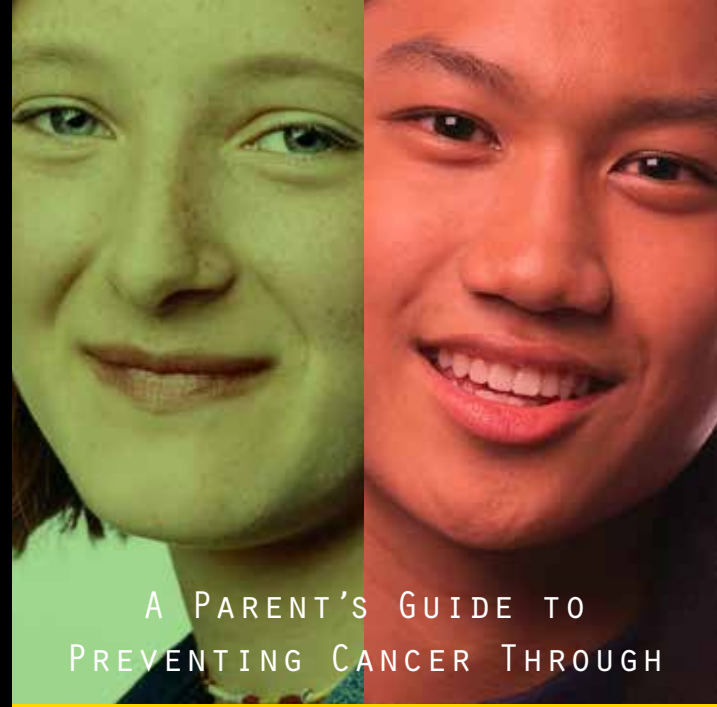
This publication was supported by Cooperative Agreement 5U58DP003921 from the Centers for Disease Control and Prevention. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the Centers for Disease Control and Prevention.



To learn about how HPV is spread, cancers that are caused by HPV and what the vaccine protects against, visit:

MICHIGAN.GOV/HPV

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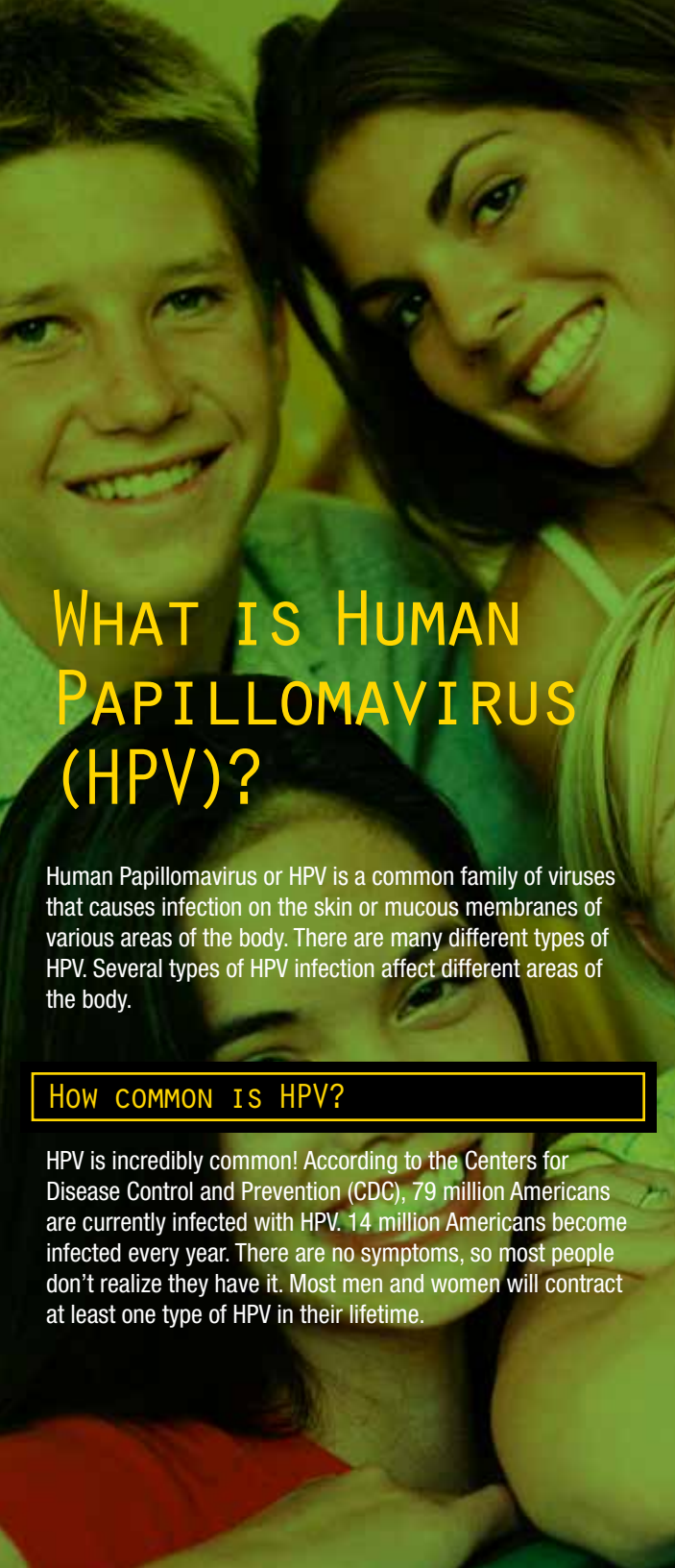


A PARENT'S GUIDE TO
PREVENTING CANCER THROUGH

HPV VACCINATION



MICHIGAN.GOV/HPV



WHAT IS HUMAN PAPILLOMAVIRUS (HPV)?

Human Papillomavirus or HPV is a common family of viruses that causes infection on the skin or mucous membranes of various areas of the body. There are many different types of HPV. Several types of HPV infection affect different areas of the body.

How COMMON IS HPV?

HPV is incredibly common! According to the Centers for Disease Control and Prevention (CDC), 79 million Americans are currently infected with HPV. 14 million Americans become infected every year. There are no symptoms, so most people don't realize they have it. Most men and women will contract at least one type of HPV in their lifetime.

CAN HPV INFECTION BE TREATED?

There is no treatment or cure for HPV infection. There are only treatments available for the health problems HPV can cause. In most cases, the body fights off the virus naturally.

In the cases where the virus cannot be fought off naturally, the body is at risk for serious complications such as cancer.

WHAT IS THE HPV VACCINE?

There are two HPV Vaccines licensed by the U.S. Food and Drug Administration (FDA) and are recommended by the CDC. Two vaccines (Cervarix® and Gardasil®) protect against cancer-causing HPV, and both are available for females. Gardasil® is available for males. HPV Vaccines are given in three shots over six months; it is important to get all three doses for the best protection.

ARE THE VACCINES SAFE AND EFFECTIVE?

The vaccines have been proven to be highly effective in protecting against the HPV types that cause cancers, with few to no side effects.

All vaccines used in the U.S. are required to go through years of extensive safety testing before they are licensed by the FDA. Both vaccines had extensive clinical trials before licensure, where more than 28,000 males and females participated. Now in use, the vaccines are continually monitored for their safety and effectiveness through three monitoring systems. These systems can monitor adverse events already known to be caused by a vaccine as well as detect rare events.

As of July 2012, approximately 46 million doses of Gardasil® were distributed in the U.S. Since its recommendation for routine use in the U.S. in 2007, no serious side effects have been reported. Common, mild side effects included pain where the shot was given, fever, headache and nausea.

WHEN SHOULD MY CHILD GET THE HPV VACCINE?

Routine vaccination with three doses of HPV Vaccine is recommended for all 11- and 12-year-old boys and girls. The vaccines can be given as early as 9 years of age. Catch-up ages for girls are from 13-26 years and 13-21 years for boys. If your son or daughter did not receive the vaccine at the recommended ages, they may still be eligible for doses up to age 26.

For the HPV Vaccine to work best, it is very important for everyone to get all three doses. The vaccine produces better immunity to fight infection when given at the younger ages compared to the older ages.

WHY VACCINATE AGAINST HPV AT 11-12 YEARS OF AGE?

- The vaccine produces better immunity to fight infection when given at younger ages, compared with older ages
- Like all vaccines, the HPV Vaccine is much more effective at preventing cancer if all three doses are administered before contact with the target viruses
- Most men and women will contract at least one type of HPV in their lifetime
- Both vaccines against HPV have been tested in thousands of people around the world and are proven to have no serious side effects
- Both vaccines are highly effective against the HPV types most likely to cause cancers

HOW CAN I GET MY CHILD THE HPV VACCINE?

Help reduce the risk of your child getting cancer later; get the HPV Vaccine now. Contact your local health care provider or county health department to find out when and where you can get your child the HPV Vaccine. Or visit:

MICHIGAN.GOV/HPV

Teens Need Vaccines, Too!

Be sure your older children are up-to-date on all of their shots before they turn 19!

Getting caught up on immunizations before graduation is as much a part of finishing up the school year as studying for finals or going to the prom.

If your high school senior is planning to move away during the next year, it's going to be easier to get to the doctor now, before the big move.

For full protection, some vaccines require several doses. Make sure your child gets up-to-date on immunizations now.



For More Information

If you have questions on the VFC program, call your doctor or your local health department for more information.

Websites

- www.cdc.gov/vaccines/programs/vfc/index.html
- www.michigan.gov/vfc
- www.michigan.gov/teenvaccines
- www.michigan.gov/immunize



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MICHIGAN VACCINES for CHILDREN PROGRAM

Vaccines for Your Child



What is the Vaccines for Children program?

The Vaccines for Children (VFC) program gives childhood vaccines to eligible children. The government pays for the vaccines. Doctors and clinics enroll in VFC and give vaccines to children who qualify. This program helps kids stay healthy.

Is my child eligible?

Children from birth through 18 years of age can get VFC vaccine if they:

- are on Medicaid
- are eligible for Medicaid
- do not have health insurance
- are American Indian or Alaskan Native
- are under-insured

If your health insurance does not pay anything for vaccines, your child may be able to get VFC vaccine. Check with your doctor or your local health department.



How much will I have to pay?

Your doctor will not charge you for the vaccine, but may ask you to pay a small fee to give the vaccine to your child. Talk with your doctor or nurse if you cannot afford the fee.



Where can I get VFC vaccines for my child?

You may be able to get VFC vaccine at your child's health care provider and at local health departments. Call and ask your child's health care provider if they have VFC vaccine. If your provider does not have VFC vaccine, ask them to sign up! Your local health department can give them, and you, more information about how your child can get VFC vaccine.

Diseases that VFC vaccines can prevent:

- Diphtheria, tetanus, and pertussis (whooping cough)
- *Haemophilus influenzae* type b (Hib)
- Hepatitis A and hepatitis B
- Human papillomavirus (HPV)
- Influenza (flu)
- Measles, mumps, and rubella
- Meningococcal disease
- Pneumococcal disease
- Polio
- Rotavirus
- Varicella (chickenpox)



Human Papillomavirus (HPV): Questions and Answers

INFORMATION ABOUT THE DISEASE AND VACCINES

How common is HPV in the United States?

HPV is the most common sexually transmitted infection in the United States. About 79 million Americans are currently infected with HPV. About 14 million people become newly infected each year. HPV is so common that most sexually active men and women will get at least one type of HPV at some point in their lives.

An estimated 29,600 HPV-associated cancers occur annually in the U.S., including an estimated 9,300 HPV-associated cancers in males. Of these HPV-associated cancers approximately 64% are caused by HPV types 16 and 18, which are included in all three HPV vaccines available in the United States and about 10% are caused by the 5 HPV types also included in Gardasil 9.

How does HPV spread?

HPV is spread through contact with infected skin, usually through sexual contact. Most infected people have no symptoms and are unaware they are infected and can transmit the virus to a sex partner. Rarely, a pregnant woman passes HPV to her baby during vaginal delivery.

What are the symptoms of HPV?

Most people who become infected with HPV have no symptoms. Some people develop visible genital warts, or have pre-cancerous changes in the cervix, vulva, anus, or penis.

Genital warts usually appear as soft, moist, pink, or flesh-colored swellings, usually in the genital area. They can be raised or flat, single or multiple, small or large, and sometimes cauliflower shaped. They can appear on the vulva, in or around the vagina or anus, on the cervix, and on the penis, scrotum, groin, or thigh. After sexual contact with an infected person, warts may appear within weeks or months, or not at all.

How serious is HPV?

Most HPV infections don't cause any symptoms and eventually go away, as the body's own defense system clears the virus. Women with short-term HPV infections may develop mild Pap test abnormalities that go away with time.

A small percentage of people infected with HPV develop persistent (chronic) HPV infection. Women with persistent high-risk HPV infections are at greatest risk for developing cervical cancer precursor lesions (abnormal cells on the lining of the cervix) and cervical cancer. (See next question.)

What are possible complications from HPV?

Cancer is the most serious possible complication from HPV infection. Persistent infection with high-risk types of HPV is associated with almost all cervical cancers. The American Cancer Society (ACS) estimates that in 2015, approximately 12,900 new cases of invasive cervical cancer will occur in the U.S. and about 4,100 women will die from the disease. Worldwide, cervical cancer is the second most common cancer in women; it is estimated to cause over 470,000 new cases and 233,000 deaths each year.

Persistent infection with high-risk types of HPV is also associated with cancers of the vulva, vagina, penis, and anus. For example, ACS estimates that this year there will be about 1,820 new cases of penile cancer in the U.S. and 310 men will die. Genital HPV infection with low-risk types of HPV is associated with genital warts in men and women. About 1% of sexually active adults in the U.S. have visible genital warts at any point in time. It is estimated that approximately 360,000 cases of genital warts occur each year in the U.S. among sexually active people.

Occasionally, low-risk HPV infections can be transmitted during birth, resulting in respiratory tract warts in infants and children.

How is HPV infection diagnosed?

Genital warts in men and women are diagnosed by visual inspection.

Most women are diagnosed with HPV infection on the basis of abnormal Pap tests. Also, a specific test is available to detect HPV DNA in women. The test may be used in women with mild Pap test abnormalities or in women more than age 30 years at the time of Pap testing. In April 2014 the U.S. Food and Drug Administration approved the first HPV DNA test for women

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age 25 years and older that can be used alone to help a health care professional assess the need for additional diagnostic testing for cervical cancer. The test also can provide information about the patient's risk for developing cervical cancer in the future.

No HPV tests are available for men.

Can genital HPV infection be cured?

There is no cure for HPV infection, although the immune system usually eliminates the virus from the body. Approximately 90% of women with HPV infection become HPV-negative within two years. However, a small percentage of infected people remain infected for many years, which may result in genital warts or cancer.

There are treatments for the health problems that HPV can cause, such as genital warts, cervical cell changes, and cancers of the cervix, vulva, vagina, and anus.

Visible genital warts can be removed by medications the patient applies, or by treatments performed by a health-care provider. No one treatment is best. Warts might return, especially in the first 3 months after treatment. It is not known whether treatment of genital warts will reduce the chance of passing the virus on to a sex partner. If left untreated, genital warts may go away, remain unchanged, or increase in size or number.

How can people reduce their risk for acquiring genital HPV infection?

The surest way to eliminate risk for genital HPV infection is to refrain from any genital contact with another individual.

For people who are sexually active, a long-term, mutually monogamous relationship with an uninfected partner is the strategy most likely to prevent future genital HPV infections. However, it is difficult to determine whether a partner who has been sexually active with another partner in the past is currently infected.

It is not known how much protection a condom provides against HPV, since skin that is not covered by a condom can be exposed to the virus. However, condoms may reduce the risk of genital warts and cervical cancer. People can also reduce their risk by getting the HPV vaccine.

When were the HPV vaccines licensed?

The first HPV vaccine (Gardasil, Merck) was licensed for females in 2006. Gardasil protects against four HPV types: 16, 18, 6, and 11. About 70% of cervical cancers are caused by HPV types 16 and 18, and more than 90% of genital warts are associated with HPV

types 6 and 11. In 2009, Gardasil was licensed for use in males. In 2009, a second HPV vaccine was licensed (Cervarix, GlaxoSmithKline) for use in females. Cervarix protects against HPV types 16 and 18. In 2014, a new version of Gardasil was licensed. This vaccine, called Gardasil 9, protects against the four HPV types included in the original Gardasil as well as 5 additional cancer-causing HPV types. These 5 additional types account for about 10% of all HPV-associated cancer in the United States (14% of HPV-associated cancers in females and 4% in males). Both versions of Gardasil will be available in the United States through 2015.

What kind of vaccine is it?

HPV vaccine is an inactivated (not live) vaccine.

How is this vaccine given?

This vaccine is given as an injection in the deltoid muscle of the arm.

Who should get this vaccine?

The CDC's Advisory Committee on Immunization Practices (ACIP) recommends routine vaccination of boys and girls at age 11 or 12 years with catch-up vaccination for females through age 26 years, and for males through age 21 years; males age 22 through 26 years may be vaccinated. In addition, vaccination is recommended for men age 22 through 26 years who have sex with men or are immunocompromised as a result of disease (including HIV) or medication. The vaccination series can also be started as young as age 9 years, at the clinician's discretion. Females can receive either Gardasil, Gardasil 9, or Cervarix. Males should receive only Gardasil or Gardasil 9, because Cervarix is not approved by the FDA for males.

How many doses are needed and on what schedule?

The schedule for all three HPV vaccines consists of three injections over a six-month period. The second dose should be given one to two months after the first dose and the third dose should be given six months after the first dose and at least 12 weeks after the second dose. The vaccine can be administered at the same visit as other needed vaccines.

The vaccine provides the best protection when given before onset of sexual activity. However, people who are sexually active also may benefit from vaccination. People who have not been infected with any vaccine HPV type would receive the full benefit of vaccination. Those who already have been infected with one or more HPV types

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would still get protection from the vaccine types they have not acquired. HPV vaccine can be given to females who have had an abnormal Pap test or genital warts. However, the vaccine will not have any helpful effect on existing Pap test abnormalities, HPV infection, or genital warts (that is, the vaccine is not a treatment for HPV infection or HPV-related disease).

Why is HPV vaccine licensed for use in people as young as 9 years of age?

This is because the vaccine is most effective in young people who have not yet been infected by any of the HPV types included in the vaccine so that they will receive the full benefits of the vaccine.

Why are HPV vaccines not licensed for adults older than 26 years?

HPV vaccines have been tested in people age 9 through 26 years. Although Gardasil has been tested in women age 27 through 45 years and found to be safe, data on the effectiveness of the vaccine in this age group was inconclusive, mainly because many of the participants in the trial had already been infected with HPV types included in the vaccine. The FDA will consider licensing the vaccines for older people if additional research shows that it is effective for them.

Should individuals be screened before getting vaccinated?

No. Girls/women do not need to get an HPV test or Pap test to find out if they should get the vaccine.

How effective are the HPV vaccines?

All three HPV vaccines are highly effective in preventing infection with types of HPV included in the vaccines. Studies have shown that all three vaccines prevent nearly 100 percent of the precancerous cervical cell changes caused by the types of HPV included in the vaccine for more than 8 years after vaccination. Among males, efficacy of Gardasil for prevention of genital warts was 89% and efficacy for the prevention of precancerous lesions of the anus was 78%.

How long does vaccine protection last? Will a booster shot be needed?

The length of immunity is usually not known when a vaccine is first introduced. So far, studies have shown people to still be protected after more than 8 years. More research is being done to find out how long protection will last, and if a booster dose will eventually be needed.

Who recommends HPV vaccine?

The Centers for Disease Control and Prevention (CDC), the American Academy of Pediatrics (AAP), the American Academy of Family Physicians (AAFP), and the American College of Obstetricians and Gynecologists (ACOG) all recommend routine HPV vaccination of boys and girls at 11 or 12 years of age.

What side effects have been reported from HPV vaccine?

Mild problems may occur with HPV vaccine, including pain, redness, swelling, and itching at the injection site. These problems do not last long and go away on their own. Fainting has been reported among adolescents who receive HPV vaccine (and other recommended vaccines as well). It's best for the patient to sit during vaccine administration and remain seated for 15–20 minutes after receiving the vaccine.

Like all vaccines, HPV vaccine will be monitored for more serious or unusual side effects.

Can HPV vaccine cause HPV?

No. HPV vaccines are inactivated so they cannot cause disease-like symptoms or HPV disease.

We've heard stories in the media lately about severe reactions to HPV vaccine. Is there any substance to these stories?

No. While serious events, including death and Guillain-Barre syndrome, have been reported among women who had recently received HPV vaccine, CDC and FDA follow-up on these reports has not found that the events occurred more frequently among vaccinees than among the general population, and has detected no pattern that would indicate an association with the vaccine. You can find complete information on this and other vaccine safety issues at www.cdc.gov/vaccinesafety/index.html.

Do women still need to get a Pap test if they've been vaccinated against HPV?

Yes. Women should continue to receive regular cervical cancer screening for three reasons. First, the vaccine does not provide protection against all types of HPV that cause cervical cancer. Second, women may not receive the full benefits of the vaccine if they do not complete the vaccine series. Third, women may not receive the full benefits of the vaccine if they were infected with HPV before receiving the vaccine.

CONTINUED ON THE NEXT PAGE ►

In addition, vaccinated people should continue to practice protective sexual behaviors since the vaccine will not prevent all cases of genital warts or other sexually transmitted infections.

Does the vaccine protect against all types of HPV?

No. Although there are more than 100 types of human papillomaviruses, only four (HPV 6, 11, 16, and 18) are included in Gardasil, 9 are included in Gardasil 9 (HPV 6, 11, 16, 18, 31, 33, 45, 52 and 58) and only two (HPV 16 and 18) are included in Cervarix. HPV 16 and 18 (included in all three vaccines) are responsible for 70% of cervical cancers; HPV 6 and 11 causes approximately 90% of genital warts. About 25% of HPV-associated cancers are not prevented by the vaccine.

What if a person doesn't get all of the recommended three doses?

It is not known how much protection people would get from receiving only one or two doses of the vaccine. For this reason, it is very important to receive all three doses of the vaccine. If there is a gap in the schedule longer than the recommended time, the series should be continued from where it left off – there is no need to restart the series. A person who starts the series before the 27th birthday should complete the series even if he or she is now older than age 26 years.

Can an HPV vaccine series begun with Cervarix or Gardasil be completed with Gardasil 9?

Yes. Any HPV vaccine may be used to continue or complete the series for females for protection against HPV 16 and 18. Gardasil or Gardasil 9 may be used to continue or complete the series for males. However, receiving only two doses of Gardasil or Gardasil 9 may provide less protection against genital warts caused by HPV types 6 and 11 than the usual 3 dose series. It is not known how much protection a person will have against the 5 additional HPV types included in Gardasil 9 if the person receives fewer than 3 doses.

Does CDC recommend revaccination with Gardasil 9 for people who previously received a series of Cervarix or Gardasil?

CDC has not recommended routine revaccination with Gardasil 9 for persons who have completed a series of another HPV vaccine. There are data that indicate

revaccination with Gardasil 9 after a series of Gardasil is safe. Discuss this issue with your healthcare provider to decide if the benefit of immunity against 5 additional oncogenic strains of HPV is worth the time and expense of revaccination.

Do women and men whose sexual orientation is same-sex need HPV vaccine?

Yes. HPV vaccine is recommended for females and males regardless of their sexual orientation.

Who should NOT receive HPV vaccine?

Anyone who has ever had a life-threatening allergic reaction to any component of HPV vaccine (such as baker's yeast), or to a previous dose of HPV vaccine, should not get the vaccine.


Pregnant women should not get the vaccine. Although the vaccine appears to be safe for both the woman and developing baby, this issue is still being studied. Inadvertently receiving HPV vaccine during pregnancy is not a reason to consider terminating the pregnancy. Patients and healthcare providers should report any exposure to HPV vaccine during pregnancy to the manufacturer of the vaccine, Gardasil at (877) 888-4231, Gardasil 9 at (800) 986-8999, or Cervarix at (888) 825-5249.

Breast-feeding women can safely get the vaccine.

People who have a moderate or severe acute illness should wait until their condition improves to be vaccinated.

Is HPV vaccine covered by insurance plans?

Many health insurance plans cover vaccines recommended for children and adolescents. The Vaccines for Children (VFC) program provides free vaccines to children and adolescents younger than 19 years of age, who are Medicaid-eligible, American Indian, or Alaska Native, uninsured, or receiving care in a Federally Qualified Health Clinic or Rural Health Center. This includes boys as well as girls. For adults, if you're not certain about your healthcare coverage, contact your health insurance plan for further information. If you don't have health insurance or if your plan doesn't cover this vaccine, ask your doctor or your local health department how you can obtain this vaccine.




MICHIGAN PHARMACISTS ASSOCIATION

MPA's 2016 HPV Vaccination Roundtable Advisory Committee

Monday, February 8, 2016
12:00 p.m. – 3:00 p.m.
Lake Michigan Room
SpartanNash Corporate Headquarters
Grand Rapids, MI

MichiganPharmacists.org




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Agenda

- 12:00 Lunch
- 12:20 Introductions & Roles
- 12:30 Pros and Cons of HPV Vaccination
- 12:45 Pros and Cons of Pharmacy-delivered HPV Vaccines for Adolescents
- 1:00 Environmental Trends
- 1:15 SWOT Analysis – HPV Vaccination in Physician Offices
- 1:30 SWOT Analysis – HPV Vaccination in Community Pharmacies
- 1:50 SWOT Analysis – Communication and Messages about HPV Vaccinations
- 2:10 Brainstorming – Overcoming Weakness and Threats
- 2:50 Wrap-up and Adjournment

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Meeting Objectives

- To develop a comprehensive list of barriers and obstacles to implementing adolescent HPV vaccinations in community pharmacies
- To brainstorm creative ideas for overcoming identified barriers and obstacles

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Introductions & Roles

What is your role (e.g., physician, parent, and pharmacist) in discussions around HPV vaccination?

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Pros & Cons of HPV Vaccination

What do you believe or have you heard that are pros and cons related to HPV vaccination?

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Pros & Cons of Pharmacy-delivered HPV Vaccines for Adolescents


What do you believe or have you heard that are pros and cons related to community pharmacies providing HPV vaccines?

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Environmental Trends

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HPV Disease Burden

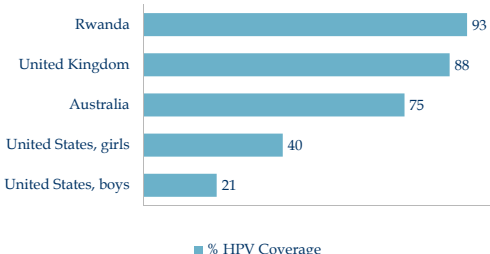
- 79 million Americans infected with HPV virus
- 14 million new infections each year
- 27,000 people diagnosed with HPV-related cancer each year

Data from CDC

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International HPV Vaccination Rates



■ % HPV Coverage

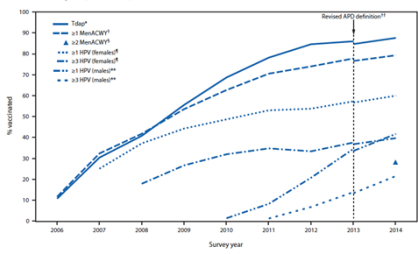
Data from CDC

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National Adolescent Vaccination Rates

FIGURE 1. Estimated vaccination coverage with selected vaccines and doses among adolescents aged 13-17 years, by survey year – National Immunization Survey-Teen, United States, 2006-2014



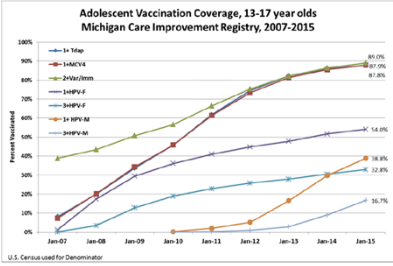
Data from CDC, MMWR, July 31, 2015

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Michigan Adolescent Vaccination Rates


Adolescent Vaccination Coverage, 13-17 year olds
Michigan Care Improvement Registry, 2007-2015



U.S. Census used for Denominator

Data from MDHHS

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Michigan Adolescent Vaccination Rates

TABLE 3. Estimated vaccination coverage with selected vaccines and doses* among adolescents aged 13-17 years, by HHS region and state or selected local areas – National Immunization Survey-Teen (NIS-Teen), United States, 2014

HHS region and state or local area	Females (N = 10,084)						Males (N = 10,743)					
	a1 Tdap†	a1 MenaCV1†	a1 HPV†	a2 HPV†	a3 HPV†	a3 HPV†	a1 Tdap†	a1 MenaCV1†	a1 HPV†	a2 HPV†	a3 HPV†	
	% (95% CI)	% (95% CI)	% (95% CI)	% (95% CI)	% (95% CI)	% (95% CI)	% (95% CI)	% (95% CI)	% (95% CI)	% (95% CI)	% (95% CI)	
United States overall	87.6 (86.6-88.6)	79.3 (78.3-80.3)	60.0 (58.9-61.1)	50.3 (49.2-51.4)	39.7 (38.6-40.8)	41.7 (40.6-42.8)	35.4 (34.3-36.5)	21.4 (20.3-22.5)	21.4 (20.3-22.5)	21.4 (20.3-22.5)	21.4 (20.3-22.5)	
HHS Region V	86.7 (85.8-87.6)	80.1 (79.1-81.1)	61.0 (59.9-62.1)	52.7 (51.6-53.8)	41.9 (40.8-43.0)	39.6 (38.5-40.7)	31.2 (30.1-32.3)	20.6 (19.5-21.7)	20.6 (19.5-21.7)	20.6 (19.5-21.7)	20.6 (19.5-21.7)	
Illinois	91.0 (90.0-92.0)	77.1 (76.1-78.1)	64.4 (63.4-65.4)	58.0 (57.0-59.0)	47.7 (46.7-48.7)	46.7 (45.7-47.7)	34.2 (33.2-35.2)	22.6 (21.6-23.6)	22.6 (21.6-23.6)	22.6 (21.6-23.6)	22.6 (21.6-23.6)	
U. City of Chicago	88.6 (87.6-89.6)	80.4 (79.4-81.4)	70.1 (69.1-71.1)	60.0 (59.0-61.0)	52.6 (51.6-53.6)	48.9 (47.9-49.9)	40.2 (39.2-41.2)	28.1 (27.1-29.1)	28.1 (27.1-29.1)	28.1 (27.1-29.1)	28.1 (27.1-29.1)	
U. West of state	93.6 (92.6-94.6)	78.6 (77.6-79.6)	61.2 (60.2-62.2)	51.5 (50.5-52.5)	40.5 (39.5-41.5)	40.0 (39.0-41.0)	31.9 (30.9-32.9)	21.8 (20.8-22.8)	21.8 (20.8-22.8)	21.8 (20.8-22.8)	21.8 (20.8-22.8)	
Michigan	79.3 (78.3-80.3)	90.7 (89.7-91.7)	58.0 (57.0-59.0)	50.9 (49.9-51.9)	40.9 (39.9-41.9)	39.8 (38.8-40.8)	31.9 (30.9-32.9)	22.1 (21.1-23.1)	22.1 (21.1-23.1)	22.1 (21.1-23.1)	22.1 (21.1-23.1)	
Illinois	87.7 (86.7-88.7)	77.7 (76.7-78.7)	61.0 (60.0-62.0)	52.7 (51.7-53.7)	42.9 (41.9-43.9)	40.9 (39.9-41.9)	31.9 (30.9-32.9)	22.1 (21.1-23.1)	22.1 (21.1-23.1)	22.1 (21.1-23.1)	22.1 (21.1-23.1)	
Ohio	83.0 (82.0-84.0)	75.7 (74.7-76.7)	61.0 (60.0-62.0)	47.3 (46.3-48.3)	35.2 (34.2-36.2)	36.8 (35.8-37.8)	29.3 (28.3-30.3)	23.3 (22.3-24.3)	23.3 (22.3-24.3)	23.3 (22.3-24.3)	23.3 (22.3-24.3)	
Wisconsin	93.3 (92.3-94.3)	73.8 (72.8-74.8)	61.0 (60.0-62.0)	52.1 (51.1-53.1)	40.9 (39.9-41.9)	40.3 (39.3-41.3)	30.3 (29.3-31.3)	23.6 (22.6-24.6)	23.6 (22.6-24.6)	23.6 (22.6-24.6)	23.6 (22.6-24.6)	

Data from CDC, MMWR, July 31, 2015

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Michigan & County HPV Vaccination Series Completion Rates (MCIR)

HPV Series Completion Rates for Adolescents aged 13 through 17 years

	MI	Barry	Cass	Clare	Kent	Ottawa	Tuscola
3+ HPV Girls	31.0	36.7	26.5	29.7	42.0	40.6	28.6
3+ HPV Boys	20.4	22.9	15.8	16.9	28.2	25.7	21.8

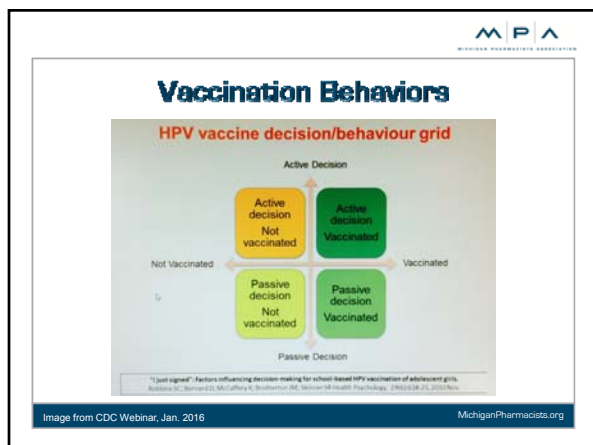
Data from MDHHS, through Dec. 2015 MichiganPharmacists.org

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Strength of Recommendation

- The single largest predictor of whether parents will vaccinate their children is the strength of the recommendation from their healthcare provider(s)

Data from CDC MichiganPharmacists.org



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Michigan Pharmacy Vaccination Data

Pharmacy Vaccination Data

Table 1. Select Vaccines Reported to MCIR by Pharmacies since 2007 to children and adults aged 9 through 27 years

Pharmacy Type	Flu	HPV	MCV	Tdap	Total
Hospital (Outpatient)	1,318	792	173	3,637	5,920
Independent	5,557	41	82	122	5,822
Large Chain	210,145	889	2,106	4,604	217,744
Small Chain/Group	1,157	3	3	18	1,181
Total	218,197	1,725	2,364	8,381	230,667

Image from MDHHS MichiganPharmacists.org

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SWOT Analysis

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S STRENGTHS

- What are you doing well?
- How do you stand apart from your competitors?
- Do you provide better service and customer satisfaction?
- What special resources do you have?
- What kind of unique assets (people, staff, technology) do you have?

W WEAKNESSES

- What are your biggest weaknesses?
- What do your customers think?
- Are there any hidden weaknesses?
- Is your business in a poor position?

O OPPORTUNITIES

- What opportunities exist in your market?
- How can these benefit?
- Is the potential of your business untapped?
- What have been any changes in the market recently?
- Is your business in a good position?

T THREATS

- Who are your potential competitors?
- Which factors you need to control to prevent the risks to your business?
- Is there anything threatening your business or profits?
- What business your marketing efforts?

Image from <https://www.kurwebtech.com/wp-content/uploads/2015/01/swot.png> MichiganPharmacists.org

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SWOT Analysis

HPV Vaccination in Physician Offices

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SWOT Analysis

HPV Vaccination in Community Pharmacies

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SWOT Analysis

Communication and Messages about HPV Vaccinations

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Brainstorming

Overcoming Weakness & Threats

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Thank you!

Contact Us

Sarah Barden – Sarah@MichiganPharmacists.org
 Dianne Malburg – Dianne@MichiganPharmacists.org
 Robin Curtis – Robin.Curtis@SpartanNash.com

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HPV Vaccination in Pharmacies Survey - Healthcare Provider Version

Survey Introduction

This survey has 13 questions and should take approximately five to ten minutes to complete. It is designed for healthcare providers who practice in Michigan. If you are not a healthcare provider who practices in Michigan, you will not be able to complete this survey. We will send a \$5 Amazon e-gift card to the first 50 qualified survey respondents who complete the survey and provide an email address at the end of the survey.*

Please read the following information and then proceed to the next page.

Human papillomavirus (HPV) is a group of more than 150 related viruses. Each virus in the group is given a number to identify its type. More than 40 HPV types can infect the genital areas of males and females. HPV is named for the warts (papillomas) caused by some HPV types. Other HPV types can cause cervical, vaginal, and vulvar cancers in women; penile cancer in men; and anal cancer, cancer of the back of the throat (oropharynx), and genital warts in both men and women

HPV vaccine can prevent infection with the most common types of HPV that lead to cancer and genital warts. HPV vaccine is recommended for both males and females. It is recommended to be given at 11 or 12 years of age, but it may be given beginning at age 9 through 26 years. Three doses of HPV vaccine are recommended to provide the best immune response and protection.

Some pharmacies in Michigan provide HPV vaccine to patients. The following questions ask about your opinions regarding HPV vaccine being given at the pharmacy.

Thank you for taking the time to complete this survey. Your feedback is valued. Personal, identifiable information will not be shared. Data will only be reported using aggregate measures.

***Your email address, if you choose to provide it, will be captured and used only to send you the \$5 Amazon e-gift card. Your email address will not be used for any other purpose. Please be sure you enter your email address correctly as we are not responsible for undeliverable e-gift cards. If you choose not to enter your email address, we appreciate your response but will be unable to provide a gift card.**

HPV Vaccination in Pharmacies Survey - Healthcare Provider Version

Healthcare Provider Qualifier

* 1. Are you a healthcare provider?

☐ Yes

☐ No

HPV Vaccination in Pharmacies Survey - Healthcare Provider Version

Michigan Qualifier

* 2. Do you practice in Michigan?

☐ Yes

☐ No

HPV Vaccination in Pharmacies Survey - Healthcare Provider Version

Healthcare Provider Questions

* 3. I am a _____.

- ☐ Nurse
- ☐ Nurse Practitioner
- ☐ Physician
- ☐ Physician Assistant
- ☐ Other (please specify)

* 4. What is your healthcare specialty?

- ☐ Primary care
- ☐ Internal Medicine
- ☐ Pediatrics
- ☐ Family Medicine
- ☐ Other (please specify)

* 5. How important do you think vaccinations are in general? (Please move the slider to indicate your answer.)

Not important

Somewhat important

Extremely important

* 6. How confident are you in your knowledge about HPV vaccine? (Please move the slider to indicate your answer.)

Not at all confident

Somewhat confident

Very confident

* 7. Do you administer any vaccines in your practice?

☐ Yes

☐ No

If no, why not?

* 8. Do you administer HPV vaccine in your practice?

☐ Yes

☐ No

If no, why not?

* 9. Are you aware that pharmacists can legally provide immunizations through collaborative practice agreements and standing orders?

☐ Yes

☐ No

* 10. Have you ever referred a patient to a pharmacy to receive a vaccine?

☐ Yes

☐ No

If no, why not?

* 11. How supportive are you of people in the following age groups receiving HPV vaccine?

	Not supportive	Somewhat supportive	Extremely supportive
9 - 10 years old	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
11 - 12 years old	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
13 - 17 years old	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
18 - 26 years old	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Please provide any comments if you would like to explain your answers.

* 12. How supportive are you of HPV vaccine being provided in the following settings?

	Not supportive	Somewhat supportive	Extremely supportive
Doctor's office	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Pharmacy	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Local health department	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
School	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Please provide any comments if you would like to explain your answers.

HPV Vaccination in Pharmacies Survey - Healthcare Provider Version

Email

If you would like to be eligible to receive the \$5 Amazon e-gift card, please enter your email address below. This is optional. Your email address will only be used to send your e-gift card if you are one of the first 50 respondents to complete the survey; it will not be used for any other purpose. Be sure to enter your email address correctly; we are not responsible for undeliverable e-gift cards. Please allow two to four weeks for e-gift card processing.

13. Email address (required only if you wish to be eligible to receive the \$5 Amazon e-gift card)

Email Address

HPV Vaccination in Pharmacies Survey - Healthcare Provider Version

Thank You

Thank you for completing our survey. Your feedback is important.

Click on the "Done" button below to submit your responses.

HPV Vaccination in Pharmacies Survey - Parent Version

Survey Introduction

This survey has 10 questions and should take approximately five to 10 minutes to complete. It is designed for parents who live in Michigan and have at least one child less than 27 years old. If you are not a parent who lives in Michigan, you will not be able to complete the survey. We will send a \$5 Amazon e-gift card to the first 50 qualified survey respondents who complete the survey and provide an email address at the end of the survey.*

Please read the following information and then proceed to the next page.

Human papillomavirus (HPV) is a group of more than 150 related viruses. Each virus in the group is given a number to identify its type. More than 40 HPV types can infect the genital areas of males and females. HPV is named for the warts (papillomas) caused by some HPV types. Other HPV types can cause cervical, vaginal, and vulvar cancers in women; penile cancer in men; and anal cancer, cancer of the back of the throat (oropharynx), and genital warts in both men and women

HPV vaccine can prevent infection with the most common types of HPV that lead to cancer and genital warts. HPV vaccine is recommended for both males and females. It is recommended to be given at 11 or 12 years of age, but it may be given beginning at age 9 through 26 years. Three doses of HPV vaccine are recommended to provide the best immune response and protection.

Some pharmacies in Michigan provide HPV vaccine to patients. The following questions ask about your opinions regarding HPV vaccine being given at the pharmacy.

Thank you for taking the time to complete this survey. Your feedback is valued. Personal, identifiable information will not be shared. Data will only be reported using group measures.

***Your email address, if you choose to provide it, will be captured and used only to send you the \$5 Amazon e-gift card. Your email address will not be used for any other purpose. Please be sure you enter your email address correctly as we are not responsible for undeliverable e-gift cards. If you choose not to enter your email address, we appreciate your response but will be unable to provide a gift card.**

HPV Vaccination in Pharmacies Survey - Parent Version

Parent Qualification

* 1. Are you a parent of at least one child less than 27 years old?

☐ Yes

☐ No

HPV Vaccination in Pharmacies Survey - Parent Version

Michigan Qualifier

* 2. Do you live in Michigan?

☐ Yes

☐ No

HPV Vaccination in Pharmacies Survey - Parent Version

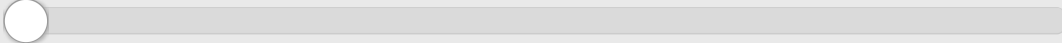
Parent Questions

* 3. I have a child or children in the following age categories: (Please select all that apply.)

- ☐ 0 months through 8 years
- ☐ 9 through 10 years
- ☐ 11 through 12 years
- ☐ 13 through 17 years
- ☐ 18 through 26 years

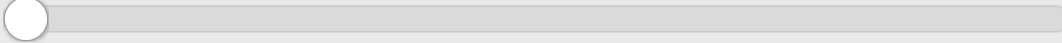
* 4. How important do you think vaccinations are in general? (Please move the slider to your desired response.)

Not important Somewhat important Extremely important



* 5. How confident are you in your knowledge about HPV vaccine? (Please move the slider to your desired response.)

Not at all confident Somewhat confident Very confident



* 6. Are you aware that HPV vaccine is the only vaccine that prevents cancer?

- ☐ Yes
- ☐ No

* 7. How supportive are you of people in the following age groups receiving HPV vaccine?

	Not supportive	Somewhat supportive	Extremely supportive
9 - 10 years old	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
11 - 12 years old	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
13 - 17 years old	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
18 - 26 years old	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Please provide any comments if you would like to explain your answers.

* 8. Are you aware that HPV vaccine is recommended for BOTH males and females to prevent cancer?

- ☐ Yes
- ☐ No

* 9. How supportive are you of HPV vaccine being provided in the following settings?

	Not supportive	Somewhat supportive	Extremely supportive
Doctor's office	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Pharmacy	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Local health department	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
School	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Please provide any comments if you would like to explain your answers.

HPV Vaccination in Pharmacies Survey - Parent Version

Email

If you would like to be eligible to receive the \$5 Amazon e-gift card, please enter your email address below. This is optional. Your email address will only be used to send your e-gift card if you are one of the first 50 respondents to complete the survey; it will not be used for any other purpose. Be sure to enter your email address correctly; we are not responsible for undeliverable e-gift cards. Please allow two to four weeks for e-gift card processing.

10. Email Address (required only if you wish to be eligible to receive the \$5 Amazon e-gift card)

Email Address

HPV Vaccination in Pharmacies Survey - Parent Version

Thank You

Thank you for completing our survey. Your feedback is important.

Click on the "Done" button below to submit your responses.

HPV Vaccination in Pharmacies Survey - Patient Version

Survey Introduction

This survey has seven questions and should take approximately five to 10 minutes to complete. It is designed for people in the age range of 18 through 26 years who live in Michigan. If you are not within this age range and living in Michigan, you will not be able to complete the survey. We will send a \$5 Amazon e-gift card to the first 50 qualified survey respondents who complete the survey and provide an email address at the end of the survey.*

Please read the following information and then proceed to the next page.

Human papillomavirus (HPV) is a group of more than 150 related viruses. Each virus in the group is given a number to identify its type. More than 40 HPV types can infect the genital areas of males and females. HPV is named for the warts (papillomas) caused by some HPV types. Other HPV types can cause cervical, vaginal, and vulvar cancers in women; penile cancer in men; and anal cancer, cancer of the back of the throat (oropharynx), and genital warts in both men and women

HPV vaccine can prevent infection with the most common types of HPV that lead to cancer and genital warts. HPV vaccine is recommended for both males and females. It is recommended to be given at 11 or 12 years of age, but it may be given beginning at age 9 through 26 years. Three doses of HPV vaccine are recommended to provide the best immune response and protection.

Some pharmacies in Michigan provide HPV vaccine to patients. The following questions ask about your opinions regarding HPV vaccine being given at the pharmacy.

Thank you for taking the time to complete this survey. Your feedback is valued. Personal, identifiable information will not be shared. Data will only be reported using group measures.

***Your email address, if you choose to provide it, will be captured and used only to send you the \$5 Amazon e-gift card. Your email address will not be used for any other purpose. Please be sure you enter your email address correctly as we are not responsible for undeliverable e-gift cards. If you choose not to enter your email address, we appreciate your response but will be unable to provide a gift card.**

HPV Vaccination in Pharmacies Survey - Patient Version

Patient Qualifier

* 1. Are you between the ages of 18 and 26 years old?

☐ Yes

☐ No

HPV Vaccination in Pharmacies Survey - Patient Version

Michigan Qualifier

* 2. Do you live in Michigan?

☐ Yes

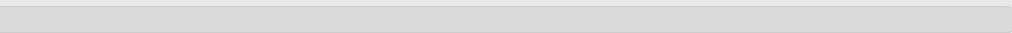
☐ No

HPV Vaccination in Pharmacies Survey - Patient Version

Patient Survey Questions

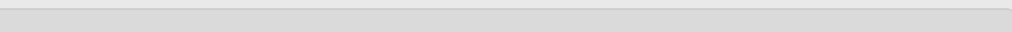
- * 3. How important do you think vaccinations are in general? (Please move the slider to indicate your answer.)

Not important Somewhat important Extremely important

☐  ☐

- * 4. How confident are you in your knowledge about HPV vaccine? (Please move the slider to indicate your answer.)

Not at all confident Somewhat confident Very confident

☐  ☐

- * 5. How supportive are you of people in the following age groups receiving HPV vaccine?

	Not supportive	Somewhat supportive	Extremely supportive
9 - 10 years old	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
11 - 12 years old	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
13 - 17 years old	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
18 - 26 years old	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Please provide any comments if you would like to explain your answers.

* 6. How supportive are you of HPV vaccine being provided in the following settings?

	Not supportive	Somewhat supportive	Extremely supportive
Doctor's office	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Pharmacy	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Local health department	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
School	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Please provide any comments if you would like to explain your answers.

HPV Vaccination in Pharmacies Survey - Patient Version

Email

If you would like to be eligible to receive the \$5 Amazon e-gift card, please enter your email address below. This is optional. Your email address will only be used to send your e-gift card if you are one of the first 50 respondents to complete the survey; it will not be used for any other purpose. Be sure to enter your email address correctly; we are not responsible for undeliverable e-gift cards. Please allow two to four weeks for e-gift card processing.

7. Email Address (required only if you wish to be eligible to receive the \$5 Amazon e-gift card)

Email Address

HPV Vaccination in Pharmacies Survey - Patient Version

Thank you

Thank you for completing our survey. Your feedback is important.

Click on the "Done" button below to submit your responses.

HPV Vaccination in Pharmacies Survey - Pharmacist Version

Survey Introduction

This survey has 14 questions and should take approximately five to 10 minutes to complete. This survey is designed for pharmacists practicing in Michigan. If you are not a pharmacist practicing in Michigan, you will not be able to complete the survey. We will send a \$5 Amazon e-gift card to the first 50 qualified survey respondents who complete the survey and provide an email address at the end of the survey.*

Please read the following information and then proceed to the next page.

Human papillomavirus (HPV) is a group of more than 150 related viruses. Each virus in the group is given a number to identify its type. More than 40 HPV types can infect the genital areas of males and females. HPV is named for the warts (papillomas) caused by some HPV types. Other HPV types can cause cervical, vaginal, and vulvar cancers in women; penile cancer in men; and anal cancer, cancer of the back of the throat (oropharynx), and genital warts in both men and women

HPV vaccine can prevent infection with the most common types of HPV that lead to cancer and genital warts. HPV vaccine is recommended for both males and females. It is routinely given at 11 or 12 years of age, but it may be given beginning at age 9 through 26 years. Three doses of HPV vaccine are recommended to provide the best immune response and protection.

Some pharmacies in Michigan provide HPV vaccine to patients. The following questions ask about your opinions regarding HPV vaccine being given at the pharmacy.

Thank you for taking the time to complete this survey. Your feedback is valued. Personal, identifiable information will not be shared. Data will only be reported using aggregate measures.

***Your email address, if you choose to provide it, will be captured and used only to send you the \$5 Amazon e-gift card. Your email address will not be used for any other purpose. Please be sure you enter your email address correctly as we are not responsible for undeliverable e-gift cards. If you choose not to enter your email address, we appreciate your response but will be unable to provide a gift card.**

HPV Vaccination in Pharmacies Survey - Pharmacist Version

Pharmacist Qualifier

* 1. Are you a pharmacist?

☐ Yes

☐ No

HPV Vaccination in Pharmacies Survey - Pharmacist Version

Michigan Qualifier

* 2. Do you practice in Michigan?

☐ Yes

☐ No

HPV Vaccination in Pharmacies Survey - Pharmacist Version

Pharmacist Survey Questions

* 3. In which pharmacy practice setting do you work? (Please select the option that best represents how you spend most of your time.)

- ☐ Community
- ☐ Hospital or health-system inpatient
- ☐ Hospital or health-system outpatient
- ☐ Ambulatory care
- ☐ Long term care
- ☐ Academia with clinical responsibilities
- ☐ Academia without clinical responsibilities
- ☐ Other (please specify)

* 4. Which of the following is accurate regarding your immunization abilities and practice?

- ☐ I am certified to provide immunizations AND I REGULARLY immunize patients in my practice.
- ☐ I am certified to provide immunization AND I RARELY immunize patients in my practice.
- ☐ I am certified to provide immunizations but I NEVER immunize patients in my practice.
- ☐ I am not certified to provide immunizations but I do immunize patients in my practice.
- ☐ I am not certified to provide immunizations but am interested in becoming certified.
- ☐ I am not certified to provide immunizations and have no interest in becoming certified.
- ☐ Other (please specify)

* 5. How important do you think vaccinations are in general? (Please move the slider to your desired response.)

Not important

Somewhat important

Extremely important

* 6. How confident are you in your knowledge about HPV vaccine? (Please move the slider to your desired response.)

Not at all confident Somewhat confident Very confident

* 7. Are you aware that HPV vaccine is the only vaccine that prevents cancer?

- ☐ Yes
- ☐ No

* 8. Are you aware that HPV vaccine is recommended for BOTH males and females to prevent cancer?

- ☐ Yes
- ☐ No

* 9. Are you aware that HPV vaccine requires three doses for the best protection?

- ☐ Yes
- ☐ No

* 10. Do you currently offer HPV vaccine in your pharmacy practice setting?

- ☐ Yes
- ☐ No

If no, why not?

* 11. How supportive are you of people in the following age groups receiving HPV vaccine?

	Not supportive	Somewhat supportive	Extremely supportive
9 - 10 years old	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
11 - 12 years old	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
13 - 17 years old	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
18 - 26 years old	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Please provide any comments if you would like to explain your answers.

* 12. How supportive are you of HPV vaccine being provided in the following settings?

	Not supportive	Somewhat supportive	Extremely supportive
Doctor's office	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Pharmacy	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Local health department	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
School	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Please provide any comments if you would like to explain your answers.

* 13. Please rate your confidence in the following:

	Not at all confident	Somewhat confident	Very confident
Providing counseling on HPV vaccine for adolescents and their parents (ages 9 through 17)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Providing counseling on HPV vaccine for adults (ages 18 through 26)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Administering HPV vaccine series to adolescents (ages 9 through 17)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Administering HPV vaccine series to adults (ages 18 through 26)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

HPV Vaccination in Pharmacies Survey - Pharmacist Version

Email

If you would like to be eligible to receive the \$5 Amazon e-gift card, please enter your email address below. This is optional. Your email address will only be used to send your e-gift card if you are one of the first 50 respondents to complete the survey; it will not be used for any other purpose. Be sure to enter your email address correctly; we are not responsible for undeliverable e-gift cards. Please allow two to four weeks for e-gift card processing.

14. Email Address (required only if you wish to be eligible to receive the \$5 Amazon e-gift card)

Email Address

HPV Vaccination in Pharmacies Survey - Pharmacist Version

Thank You

Thank you for completing our survey. Your feedback is important.

Click on the "Done" button below to submit your responses.



July 15, 2016

Cherry Valley Family Physicians
490 Edward St

Middleville, MI 49333

Dear Healthcare Provider:

Human papillomavirus is so common that almost everyone will be infected with HPV at some point in their life.¹ HPV vaccination rates for adolescents in Michigan are well below the Healthy People 2020 goal of 80% with only 31.6% of females and 21% of males receiving all three recommended doses of the HPV vaccine.² HPV vaccination can prevent cancer and is recommended by a broad array of national and state healthcare associations.

The American Cancer Society (ACS) is strategically focused on increasing HPV vaccination rates nationwide and has provided funding for a pilot project in Michigan to develop an HPV immunization neighborhood utilizing community pharmacies as an additional access point for vaccine delivery and education. Michigan Pharmacists Association (MPA) and SpartanNash Pharmacies (operated under the Family Fare, D&W and VG's banners) have partnered with ACS to develop the pilot program.

We wanted to let you know that one of the SpartanNash pharmacies in your area is now offering HPV vaccines to adolescents as young as 11 years of age through adults aged 26. We know that many adolescents and young adults who receive the first dose of HPV vaccine never complete the vaccination series. Pharmacies offer an additional avenue to reach these patients. **We would like to partner with your practice to offer follow up dose administration for your patients in our pilot pharmacy in your area.** We believe that the key to increasing HPV vaccination series completion rates—and thus cancer prevention—within our communities is collaboration among a variety of healthcare providers, including pharmacists.

Pharmacists are certified to provide immunizations in accordance with state law. The SpartanNash pharmacies have standing orders for administration of the HPV vaccine to adolescents 11 through 17 years of age and adults 18 through 26 years of age. Additionally, the pharmacists and pharmacy technicians in the pilot stores have received special training through this pilot project specific to the HPV vaccine. The pilot store pharmacists are utilizing a short screening tool to help identify patients eligible for ACIP recommended adolescent or adult vaccines and providing education to parents and patients as appropriate. SpartanNash reports all adolescent immunizations to the Michigan Care Improvement Registry (MCIR) within 72 hours of administration and all adult immunizations within 14 days. Pharmacists also fax vaccine administration information to the patient's primary care provider when that information is provided by the patient.

Insurance coverage for the HPV vaccine delivered in the pharmacy is highly variable depending on the plan. At the time this letter is being sent, patients with the following insurance plans may be covered for HPV vaccine administration delivered by a pharmacist in a pharmacy:

- Blue Care Network Medical Benefit – patients ages 11 through 26
- Blue Cross Blue Shield Pharmacy Benefit – patients ages 11 through 26 in the SpartanNash group (Group # 71575)
- Blue Cross Blue Shield of Michigan Medical Benefit – patients may be covered but coverage is plan dependent
- Priority Health Pharmacy Benefit – patients ages 18 through 26
- Michigan Medicaid (Straight Medicaid and some Medicaid Health Plans) – patients ages 19 through 26.

If vaccination at the pharmacy is not covered by the patient's insurance, the pharmacist will strongly recommend the patient follow up with you or the local public health department to receive the necessary doses. If a patient does not have a primary care provider, the pharmacists would like to refer him or her to you as part of our collaborative efforts.

A pharmacist from the store below will be contacting you to further discuss collaboration with your practice. We believe that together we can increase vaccination rates through mutual referral and collaboration.

Pharmacy Location: Family Fare Pharmacy
Pharmacy Address: 902 W. State St
Hastings, MI 49058
Pharmacy Phone: (269) 945-2466
Pharmacy Hours: Mon. - Fri. 8 am - 8 pm, Sat. 9 am - 5 pm, Sun. 10 am - 4 pm

We have enclosed some additional information related to HPV vaccination along with a flyer showcasing collaboration with your local SpartanNash pharmacy participating in the pilot program.

If you have any questions about the pilot project in general, please contact the grant's primary investigator, Sarah Barden, Pharm.D., M.B.A., with Michigan Pharmacists Association at Sarah@MichiganPharmacists.org or (517) 377-0240.

1. <http://www.cdc.gov/hpv/hcp/known-facts.html>
2. Data from Michigan Care Improvement Registry (MCIR) First Quarter 2016.

Immunizations are important. They can protect you from many diseases, but sometimes they can be confusing.

SpartanNash Pharmacists Can Help.

Through collaboration with your other healthcare providers, our pharmacists can provide vaccines to adolescents and adults. Call or visit one of our pharmacies for more information today.

Family Fare Pharmacy
6370 Lake Michigan Dr.
Suite 100
Allendale, MI 49401
(616) 895-7426
Hours: Mon. - Fri. 8 am - 8 pm,
Sat. 9 am - 5 pm, Sun. 10 am - 4 pm



HPV Vaccination Roundtable Pilot Project

Provider Practice Outreach Goals and Guidelines

GOAL OF PROVIDER OUTREACH

To build HPV Immunization Neighborhoods between Pharmacists and Providers in Local Communities by:

1. Enhancing communication and relationships between pharmacists and providers in targeted practices
2. Developing a list of provider practices willing to accept patient referrals from the pharmacy for patients needing HPV vaccinations
3. Developing a list of provider practices willing to refer their patients to the pharmacy for second or third doses of the HPV vaccine (when the patient's insurance will cover the vaccine delivered in the pharmacy)

This document is a **guide** for HPV-related conversations with providers that must be used **ALONG WITH** the **documentation form**. The goal of each outreach session is to complete the documentation form in one interaction but pharmacists may contact the provider more than once if needed to collect the necessary information. You may complete the outreach sessions face-to-face or by telephone. Face-to-face communication is more effective for building relationships with other providers and is highly recommended, but, if that is not possible, a phone call resulting in a completed documentation form will accomplish the goal. **Compensation will be provided for all completed face-to-face interactions performed outside scheduled work hours.** If you choose to complete telephone interactions, those should be completed during your normally scheduled hours. A completed interaction is a completed documentation form with answers to all of the questions based on a conversation with someone knowledgeable in the provider's office that is submitted to Sarah Barden by email at Sarah@MichiganPharmacists.org or by fax at (517)-484-4893 by August 20, 2016.

Our understanding, from speaking with providers' offices, is that your first step will likely require you to speak with the office manager. The office manager is the gatekeeper of the provider's time and will determine whether you will be allowed to proceed further with the discussion. Once you connect with the office manager, you should be prepared to adapt the information being communicated as the conversation progresses. We are providing a sample script as a suggestion for an introduction to get the conversation started, but you may modify the script to make it your own.

Each pharmacy has been assigned FIVE specific practices to contact. Please make every effort to complete the interactions with all five assigned practices. You will receive five individualized documentation forms.

If you have any questions about the interactions, please contact Sarah Barden (Sarah@MichiganPharmacists.org) or Robin Curtis (Robin.Curtis@SpartanNash.com) BEFORE calling the provider's office.

COMPENSATION: Each pharmacy manager should devise a plan for which pharmacist(s) will complete the required interactions. **Face-to-face interactions done outside your regularly scheduled time are eligible for additional compensation.** The pharmacist who completes the face-to-face interaction will get up to 30 minutes of supplemental pay per completed interaction. This would be a maximum of 150 minutes (2.5 hours) for all five interactions. Document the time it took to complete the interaction (up to 30 minutes) on the form. If you are unable to complete all five face-to-face, please complete the remaining interactions on the phone during normal working hours.

NOTE: Speaking with the office receptionist is not sufficient. The office manager may or may not be able to answer the questions or determine if a partnership is possible. If the office manager does not have this authority, you must speak with someone who does have the authority (a provider) for the documentation to be valid.

HPV Vaccination Roundtable Pilot Project

Provider Practice Outreach Sample Introductory Scripts

[To receptionist]

Hello, my name is _____(name)_____, and I'm a pharmacist at _____Family Fare or VG's_____ Pharmacy in _____(location)_____. I would like to discuss a possible partnership between my pharmacy and your practice. May I speak with the office manager?

[To office manager]

Hello. Thank you for taking my call today. My name is (name) , and I'm a pharmacist at Family Fare or VG's Pharmacy in (location) . I wanted to take a minute to talk to you about HPV vaccinations and ways we can work together to increase vaccination rates in our practices and community. Our pharmacy is involved in a pilot project with Michigan Pharmacists Association funded by a grant from the American Cancer Society. The long term outcome of this project is to increase HPV vaccination rates and increase the number of patients who complete the vaccination series to ultimately decrease HPV-related cancers.

We sent a letter earlier this month to your practice about our desire to work together. Do you know if you received it yet?

- If **YES**: Do you have a few minutes to talk about the project? **SEE TALKING POINTS SECTION**
- If **NO**: Is there an email address or fax number where I could re-send the letter? **DOCUMENT EMAIL AND SEND FOLLOW UP EMAIL WITH MATERIALS FROM ORIGINAL LETTER**
 - **Email address:** _____
 - I would like to speak with someone in the office—you or perhaps one of the providers—at a time that is convenient about this project and how we can work together. If now is not a good time, when can we schedule a time to talk? **DOCUMENT APPOINTMENT TIME AND FOLLOW UP WHEN PROMISED**
 - **Follow up appointment time:** _____

[At this point the conversation will become less scripted as you describe what you hope to accomplish through a partnership with the practice.]

HPV Vaccination Roundtable Pilot Project

Provider Practice Outreach Talking Points

TALKING POINTS – Use these to help guide the conversation WHILE COMPLETING THE DOCUMENTATION FORM

1. **We know that HPV vaccination rates in Michigan are very low even though this is the only vaccine available to prevent cancer.**
 - a. We know that many adolescents are either not starting or not completing the HPV vaccination series, and we think that by working together, we can increase these rates.
 - b. We believe pharmacists can help increase those rates by adding access points to the healthcare system for vaccine delivery.
 - c. Pharmacists have already proven that we can increase flu vaccination rates, which provides better immunity for our communities. Using that success, we can work to help prevent cancer too.
 - d. HPV vaccination rates for adolescents in Michigan are well below the Healthy People 2020 goal of 80% with only 31.6% of females and 21% of males receiving all three recommended doses of the HPV vaccine according to first quarter data from MCIR for 2016.
2. **We are working to create an HPV Immunization Neighborhood.**
 - a. Just like any neighborhood, an immunization neighborhood is a group of people who communicate and collaborate with common goals of meeting the immunization needs of patients and protecting the community from vaccine-preventable diseases.
 - b. Together, we can create an immunization neighborhood that increases immunization access points, provides standardized patient education, improves documentation and increases quality measures which may help with performance incentives.
 - c. Immunization neighborhoods involve all immunization stakeholders—including patients, physicians, pharmacists, other health care providers, payers and the local and state health departments.
 - d. We are focused on creating an HPV immunization neighborhood specifically through this grant since the vaccine helps protect people from HPV-related cancers.
3. **Our pilot pharmacies have vaccine in stock and our pharmacists in these locations have received specific training on HPV and vaccinating adolescents.**
 - a. Our pharmacists are all certified to provide immunizations and have been offering a variety of vaccines in their locations for years. (see list at end of available vaccines through SpartanNash pharmacies)
 - b. All of the pharmacists and pharmacy technicians in our pilot stores completed home study and/or live training sessions about HPV-related diseases, the HPV vaccine options, handling adverse reactions to the vaccine, and delivering education about these topics to patients and parents.
4. **Our pharmacists use a screening tool and MCIR to assess adolescent and young adult patients to determine vaccines needed and provide education about HPV.**
 - a. We check for Tdap, Meningococcal and HPV for ages 11 through 17.
 - b. We check for Tdap and HPV for ages 18 through 26.
 - c. We check MCIR for current records.
 - d. We provide education targeted at HPV vaccination for those in need about the importance of the vaccine and its ability to prevent many HPV-related cancers.
5. **We have some questions about your practice and how we might be able to work together.**
 - a. SEE DOCUMENTATION FORM QUESTIONS

Extra: List of Vaccines Available through SpartanNash Pharmacies

1. Hepatitis A adult
2. Hepatitis B adult
3. HPV adolescent (age 11-18)
4. HPV adult
5. Influenza adolescent (age 9-18)
6. Influenza adult
7. Meningococcal (MenACWY) adolescent (age 11-18)
8. Meningococcal (MenACWY) adult
9. MMR adult
10. Pneumococcal adult (PPSV23, PCV13)
11. Tdap/Td adolescent (age 11-17)
12. Tdap/Td adult
13. Tdap/Td pregnancy
14. Varicella adolescent (age 11-18)
15. Varicella adult
16. Zoster adult (60+)

HPV Vaccination Roundtable Pilot Project

Provider Practice Outreach Documentation Form – Due by August 20th

Provider Practice Name:

Spartan Nash Store #:

Provider Practice Address:

Pharmacist Name: _____

Provider Practice Phone:

Pharmacist Signature: _____

Completion Date: __/__/____ Time to Complete: ____ min. (max 30) Contact Method: ☐ Face-to-Face ☐ Phone

Person you spoke with to complete documentation: _____

☐ Effort made to contact practice
but practice unwilling to engage
in discussion/collaboration

Role in practice: ☐ MD/DO ☐ NP ☐ PA ☐ Office Manager

Provider Practice Demographics

of MDs/DOs _____ # of PAs _____ # of NPs _____ # of RNs _____ # of Other Staff _____

Questions for Providers

1. Did they remember receiving the letter we mailed about partnering to increase HPV vaccination rates?
☐ Yes ☐ No
2. Are they a VFC provider? ☐ Yes ☐ No
3. Do they stock and administer HPV vaccine in their practice? ☐ Yes ☐ No
 - a. If NO, where do they send patients to receive it? _____
4. Do they recommend HPV vaccine to ALL male and female patients ages 11 through 26? ☐ Yes ☐ No
 - a. If NO, who do you recommend the HPV vaccine to? _____

5. Would their practice be willing to be on our "Referral List" for patients who need HPV vaccination but either lack a primary care provider or have insurance that will not cover the cost if given in the pharmacy? ☐ Yes ☐ No
 - a. If NO, why not? _____
 - b. If YES, what contact information should we give patients? _____

6. Would their practice be willing to refer patients to our pharmacy for their second or third doses of HPV vaccine if their insurance covers the cost in the pharmacy? ☐ Yes ☐ No
 - a. If NO, why not? _____

 - b. If YES, what information can we provide to make referral to our pharmacy easier? _____

Additional Notes from Outreach Conversations(s): _____

