9-Valent HPV Vaccine FAQs

<table>
<thead>
<tr>
<th></th>
<th>2-valent HPV vaccine (Cervarix)</th>
<th>4-valent HPV vaccine (Gardasil)</th>
<th>9-valent HPV vaccine (Gardasil-9)</th>
</tr>
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<tbody>
<tr>
<td>High risk HPV strains covered</td>
<td>16, 18</td>
<td>16, 18</td>
<td>16, 18, 31, 33, 45, 52, 58</td>
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<tr>
<td>Low risk HPV strains covered</td>
<td>N/A</td>
<td>6, 11</td>
<td>6, 11</td>
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What is the difference between the 9-valent HPV vaccine and the other HPV vaccines? 2-valent (2v), 4-valent (4v) and 9-valent (9v) vaccines all protect against HPV strains 16 and 18, the types that cause about 66% of cervical cancers and the majority of other HPV-attributable cancers in the United States. 9v HPV targets five additional cancer causing types, which account for about 15% of cervical cancers. 4v and 9v HPV vaccines also protect against HPV 6 and 11, the types that cause genital warts.

What should I do with patients who have already completed the HPV vaccine series with the 4-valent or 2-valent HPV vaccine? The ACIP did not address revaccination with 9v vaccine in patients who have completed the series in their February meeting. This will likely be discussed at their next meeting in June 2015.

Why is the use of 9-valent HPV vaccine off-label in males over the age of 15? Merck sought and received FDA approval for 9v vaccine for females ages 9–25 and males ages 9–15. They have since submitted additional data on males ages 16–26, and are also seeking FDA approval for this age group. The ACIP has reviewed this data and has recommended off-label use for males ages 16–26.

Should I wait to vaccinate with 9-valent HPV vaccine? No. Practices should continue to vaccinate patients age 11–12 with any appropriate HPV vaccine (2v, 4v or 9v for females and 4v or 9v for males). It is important to initiate and complete the HPV vaccine series using any available HPV vaccine because more than half of vaccine-eligible children are not being protected against HPV-associated cancers.
Strong Recommendation PDSA Cycle 1

MODEL FOR IMPROVEMENT

Plan a Test of Change

Plan → Describe the proposed test. What performance gap will it address? What idea will you test? What barriers will you need to overcome?

Do → Try your change with a few patients over a short period of time. Collect data that can be measured. Describe what happened when you ran the test.

Study → Describe how the measured results compare to the predicted outcome.

Act → How will you modify the plan in the next test cycle based on “learnings” from this cycle? Or, describe a new idea to test to help you achieve your aim.

AIM of this project

Describe the aim of this project. What are you trying to accomplish? Every aim will require multiple small tests of change.

Within 1 year, we will increase the proportion of our patients who have had at least 2 doses of HPV vaccine by the time they turn 15 years of age. We can assess this by checking the state registry report function. Currently using that function we are at 35%; our goal is 55%.

Plan

Describe the proposed test. What performance gap will it address? What idea will you test? What barriers will you need to overcome?

Performance Gap:

Our QA team has been informally assessing what each provider does and we found that we’re all over the map, i.e., there is lots of variability in how the various providers are practicing. Each nurse has to check with each doctor for each adolescent to ask, “What vaccines should I get ready?” The nurses can pretty much count on Tdap being ordered because of the school requirement and most doctors are okay with giving Tdap and MCV4 at the same visit, but there’s lots of variability about giving three vaccines to an adolescent at one visit, whether the provider gives the vaccine to boys and girls at the same age (e.g., Dr. Jones gives HPV vaccine to boys at 12, but to girls at 14), etc. Because the nurses don’t know what to expect, things don’t run smoothly.

Idea for Test:

The providers will all go by the AAP recommendations for adolescent immunization, i.e., a strong recommendation for simultaneous Tdap, MCV4 and HPV at one visit.

Barriers:

Providers tend to want to act independently and to resist uniformity. Also, habit is strong. We will have to let the whole office (nurses, receptionists, providers) know what the plan is and get everyone on board, and there are a lot of us working here. Providers are concerned about parent resistance.
MEASURES

What is the desired goal that will close the performance gap? Describe the specific measures that will determine a successful outcome for the test.

Providers will recommend and order the first dose of HPV vaccine whenever they order Tdap and MCV4 and will be prepared to explain if parents have questions. This will lead to higher immunization rates for all patients by age 13, which we can get from the state registry.

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<th>Tasks and tools</th>
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<tr>
<td><strong>Who</strong></td>
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<td><strong>Tools</strong></td>
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Predicted outcomes: Describe your plan for change, list the tasks and tools needed to perform the test. Predict what will happen when the test is carried out.

The NPs all will be willing to give a strong recommendation. Of our 7 physicians, 2 are on-board, 2 seem willing, and there are 3 who are likely to resist.

Do

Make a change! Try your change with a few patients over a short period of time. Collect data that can be measured. Describe what happened when you ran the test.

We did the in-service and that went well. One doctor talked about her sister who had experience with cervical cancer and how hard it was to go through everything, so that was moving. That doctor and the NPs (as predicted) volunteered to get the ball rolling. We will try this for 1 week and see how it goes.
Study
Did the change lead to the desired improvement? Describe how the measured results compare to the predicted outcomes.

Here are the key problems we identified:

- There’s no easy way to look at immunization rates by provider so we can’t get the thrill of seeing our personal success.
- There’s no easy way to know if a parent “refused” the vaccine because of how it was presented (e.g., as optional).
- There is a rumor that a couple of nurses are against giving HPV vaccine because they feel it allows the kids to “get away” with having sex before marriage without consequences; those nurses give it if it’s ordered, but don’t remind the provider if he/she forgot to order it.

Act
Describe how you will modify the plan for the next test cycle based on learnings from this cycle. Or describe new methods to test to help you achieve your aims.

1. MEASURE: We’re going to measure something easier than immunization rates. Each week, when Janice does inventory on Friday, she’ll post on the bulletin board how many Tdap doses we gave that week and how many HPV doses. (This week it was 22: 8.) Each week that ratio should be at least 2:1 or even 1:2 or 3.

2. TRAIN: Karla will do more in-depth training with the nurses about talking to parents so the nurses are utterly confident and enthusiastic about this.

3. MOTIVATE: Karla is going to pull aside the nurses who are vocally against HPV vaccination and have a heart-to-heart about the value of HPV vaccine (and point out that a person can get HPV from their marital spouse, from non-consensual sex, while still a “Virgin”).

4. CONSIDER: We are going to think about tracking HPV vaccination refusals...we can’t take on too much in one week.

5. FOLLOW UP: We will have a discussion at the Monday a.m. meeting about co-administration, how it went, those who didn’t do it and what the concerns were.

END OF CYCLE 1