HPV VACCINATION 'AT 26+': SHARED DECISION AND VALUE

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COI

- I have no financial conflicts

LEGEND

- HPV vaccine recommendations
- HPV impacts
- SDM
- SDM for HPV

HPV HUMAN BIOLOGY

- Family of small dsDNA viruses that infect basal epithelium [surface layer of human skin, mucous membranes]

  >200 distinct types, most infect cutaneous epithelium and cause warts. ~40 types infect mucosal epithelium.

- HPV is most common STI in US [Can be transmitted by any direct contact, sex not required…]
  - LOW RISK types 6, 11 cause benign and low-grade cervical neoplasia, anogenital warts, respiratory papillomas
  - HIGH RISK types detected in 99% cervical precancers. Type 16 causes ~50% worldwide [16+18 ~66% cervical cancers]

    types 31, 33, 45, 52, 58 responsible for another 15% cervical cancers [11% of all HPV-associated cancers]

    anogenital cancers and oropharyngeal cancers less common than cervical but still cause significant M&M
- Majority of infections are asymptomatic and resolve spontaneously within 1-2 years

  BUT persistent infections can develop into warts [verruca], precancers and cancers

  Infection with high risk HPV is necessary for development of cervical cancer but infection alone is not sufficient to cause cervical cancer. [Epidemiologic link suspected 1960's, HPV DNA found in Cervical CA 1980's]

  Most common HPV-associated cancers: cervical, anogenital, oropharyngeal

https://www.cdc.gov/pinkbook/hcp/table-of-contents/chapter-11-human-papillomavirus.html?CDC_AAref_Val=https://www.cdc.gov/vaccines/pubs/pinkbook/hpv.html

HPV: CURRENT VACCINE 9-VALENT

Initial ACIP recommendation: 2006 women 2011 men

- Critically important CANCER PREVENTION vaccine
  - Genital Cancers and precancers
  - Oropharyngeal Cancers
  - HPV-associated genital warts (verruca) and respiratory papillomas
- Ongoing implementation challenges despite dramatic cancer reductions with sustained high vaccination rates…
- Recommended* for:
  - ALL 9-26 years: CAN start at 9 years, SHOULD be given 11-12 years.
    - Start series before 15, No IC: 2 doses at 6 months+ interval
    - Start series at 15+ and/or IC: 3 doses at time 0, 1-2 mo, 6+ months
  - SDM for 27-45 years

*ACIP workgroup is currently evaluating some potential changes…

https://www.cdc.gov/vaccines/vpd/hpv/hcp/recommendations.html
https://sjr-redesign.stjude.org/content/dam/research-redesign/centers-initiatives/hpv-cancer-prevention-program/hpv-advocacy-campaign/history-hpv-vaccination.pdf

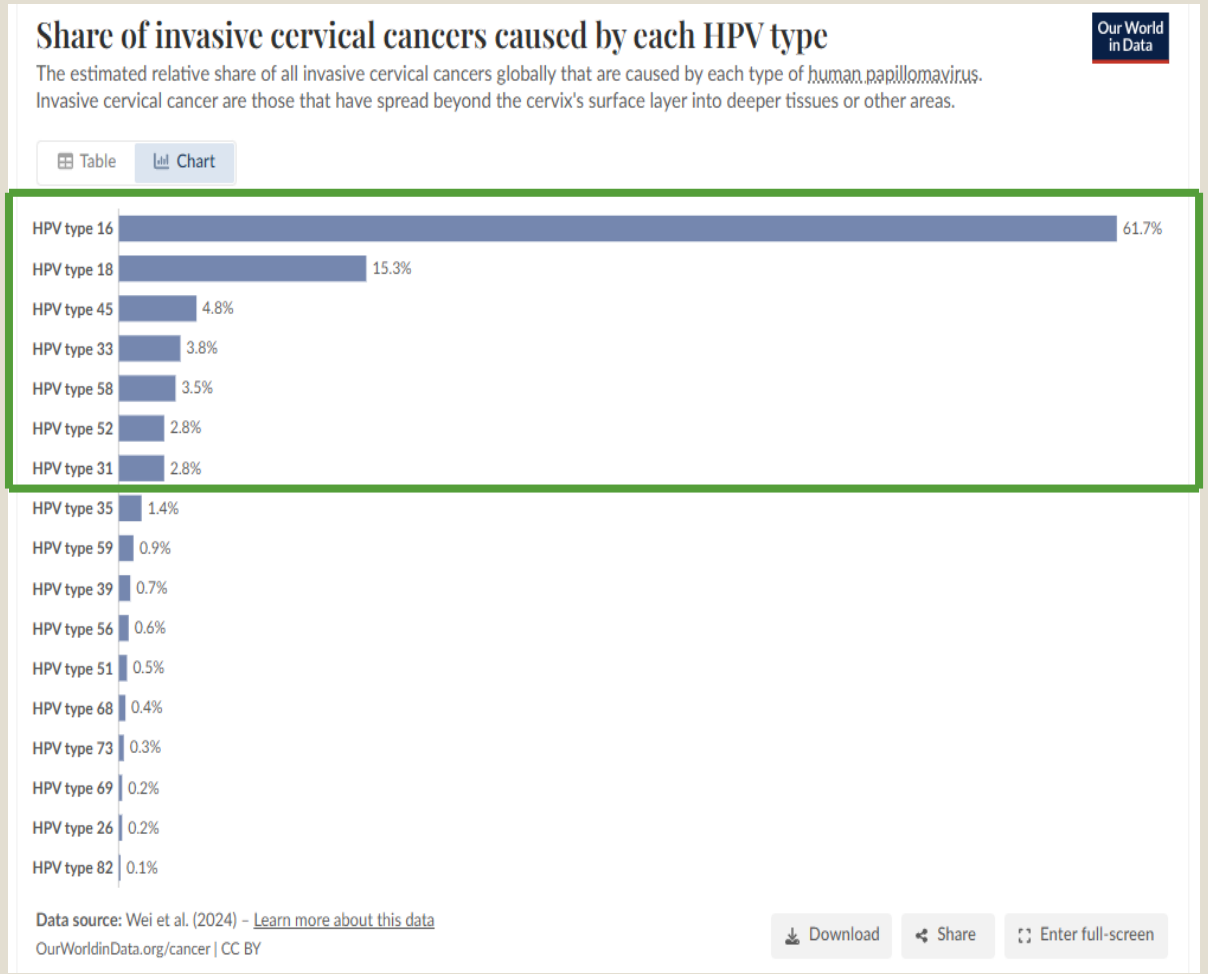
HPV VACCINATION DOES NOT ALTER RECOMMENDATIONS FOR CERVICAL CANCER SCREENING.

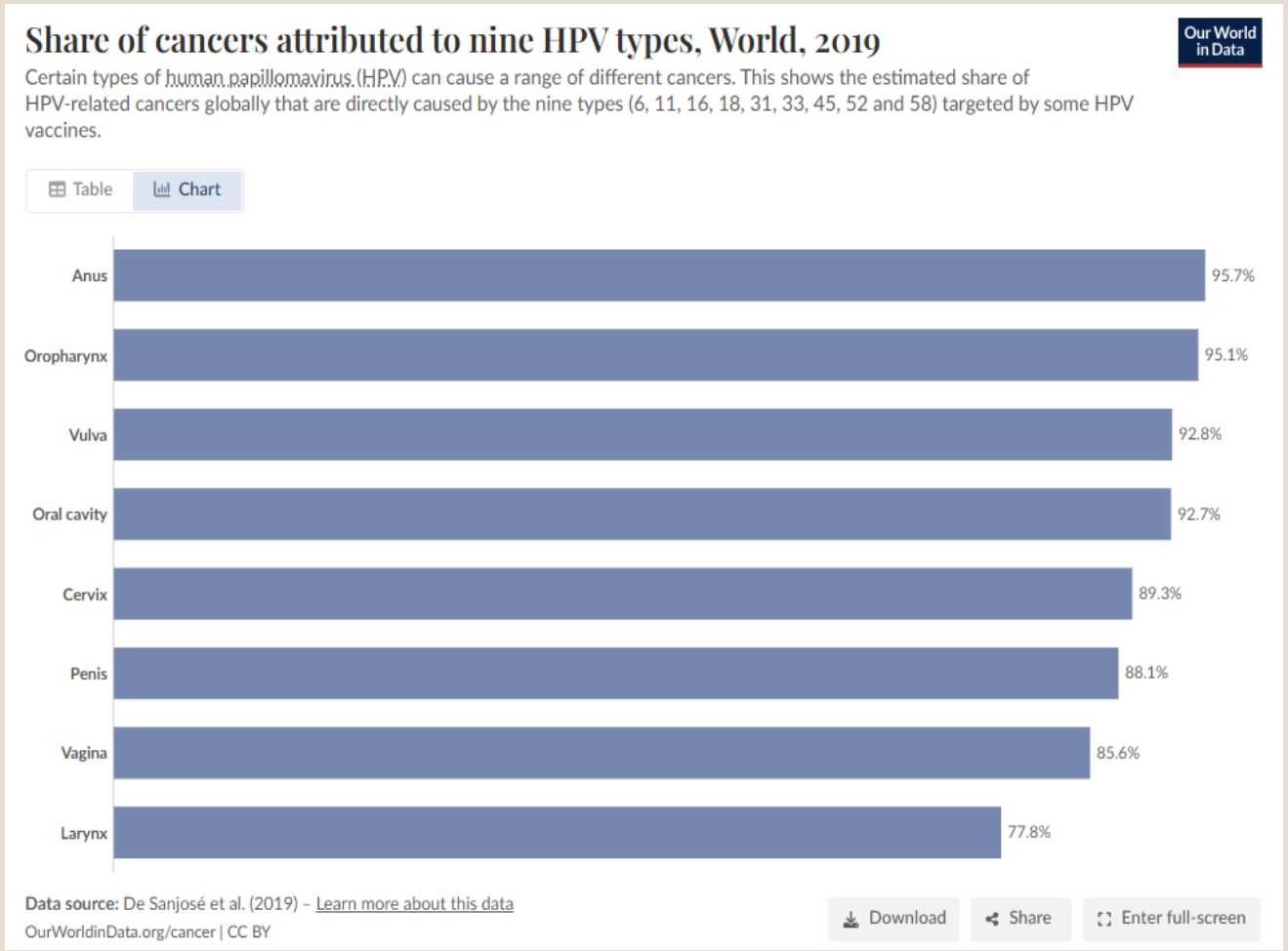
Cervical Cancer Screening

- Annual cervical cancer screening not recommended for average-risk individuals
- For ages 21 through 29 years, screen with cytology testing every 3 years
- For ages 30 through 65 years, screen with choice of cytology test every 3 years, an HPV test alone every 5 years, or cytology test plus HPV test every 5 years
- USPSTF and ACOG have similar screening recommendations; ACS recommends that screening start at age 25 years for average-risk persons.
- HPV vaccination does not eliminate the need for cervical cancer screening

https://www.cdc.gov/pinkbook/hcp/table-of-contents/chapter-11-human-papillomavirus.html?CDC_AAref_Val=https://www.cdc.gov/vaccines/pubs/pinkbook/hpv.html

HPV CANCER EPIDEMIOLOGY





https://ourworldindata.org/hpv-vaccination-world-can-eliminate-cervical-cancer?ref=morningtech.it

HPV VACCINE IMPACTS: US

- Gargano, et.al. [MMWR] "During 2008–2022, cervical precancer incidence decreased 79% and higher-grade precancer incidence decreased 80% among screened women aged 20–24 years, the age group most likely to have been vaccinated."
- Dorali, et.al. [JAMA]: "study found a steep decline in cervical cancer mortality among US women younger than 25 years between 2016 and 2021. This cohort of women is the first to be widely protected against cervical cancer by HPV vaccines. The findings from this study in the context of other published research[2,3,5] suggest that HPV vaccination affected the sequential decline in HPV infection prevalence, cervical cancer incidence, and cervical cancer mortality. Since its introduction, HPV vaccination coverage (≥1 doses) has increased steadily, reaching 78.5% in 2021.[5] The gradual decline in mortality observed from 1992 to 2015 was likely due to improved screening coverage and approaches."
- DeKloe, et.al. [JCO] "Males vaccinated for HPV (n = 760,540) were at decreased odds for HPV-related cancers (odds ratio (OR) = 0.46, 95 % confidence interval (CI) = 0.29-0.72, p-value = 0.001). This finding was primarily driven by a significant reduction in HNC (OR = 0.44, CI = 0.26-0.73, p = 0.0016). Females vaccinated for HPV (n = 945,999) had lower odds for cervical (OR = 0.71, CI = 0.52-0.96, p-value = 0.027) cancers and HPV-related cancers overall (OR = 0.73, CI = 0.57-0.94, p = 0.013)."

https://www.cdc.gov/mmwr/volumes/74/wr/mm7406a4.htm
https://jamanetwork.com/journals/jama/fullarticle/2827212
https://ascopubs.org/doi/abs/10.1200/JCO.2024.42.16_suppl.10507

HPV VACCINE IMPACTS: BEYOND US

- Scotland: "No cases of invasive cancer were recorded in women immunized at 12 or 13 years of age irrespective of the number of doses. Women vaccinated at 14-22 years of age and given 3 doses of the bivalent vaccine showed a significant reduction in incidence compared with all unvaccinated women (3.2/100K v. 8.4)…"
- Germany: "The incidence of cervical cancer which had been rising in the previous decades, has been falling since 2010, with a marked decline among women in all age groups eligible for vaccination (e.g., from 70-41.8 cases/100K persons per year from 2010 to 2018 in women aged 24-26. Women born in 1992 were the first to become eligible for vaccination and have a 24% lower incidence than the reference cohort of women born in 1989 (RR 0.76), larger effects were found in later birth cohorts, in which vaccination was more widespread."
- Norway: "The findings suggest a significant reduction in the incidence of high-grade cervical precursors following the introduction of the HPV vaccine in Norway's national immunization program, highlighting its effectiveness in cervical cancer prevention among young women in Northern Norway."

https://academic.oup.com/jnci/article/116/6/857/7577291
https://pmc.ncbi.nlm.nih.gov/articles/PMC11465478/
https://www.mdpi.com/2076-393X/12/4/421

WHY NOT ROUTINELY VACCINATE AGAINST HPV BEYOND AGE 26?

"Expanding 9-valent HPV vaccination to all mid-adults, those with more lifetime partners, and those who have just separated was projected to cost an additional $2 005 000, $763 000, and $1 164 000 per quality-adjusted life-year (QALY) gained, respectively. The NNVs to prevent 1 additional HPV-related cancer case were 7670, 3190, and 5150, respectively, compared with 223 for vaccination of persons aged 9 to 26 years (vs. no vaccination)."

"Vaccination of mid-adults against HPV is substantially less cost-effective and produces higher NNVs than vaccination of persons younger than 26 years under all scenarios investigated. However, cost-effectiveness and NNV are projected to improve when higher-risk mid-adult subgroups are vaccinated, such as mid-adults with more sex partners and who have recently separated, and women who are underscreened."

https://www.acpjournals.org/doi/full/10.7326/M24-0421

SDM: SHARED DECISION MAKING

- Unlike routine, catch-up, and risk-based recommendations, shared clinical decision-making vaccinations are not recommended for everyone in a particular age group or everyone in an identifiable risk group. Rather, shared clinical decision-making recommendations are individually based and informed by a decision process between the health care provider and the patient or parent/guardian.
- The key distinction between routine, catch-up, and risk-based recommendations and shared clinical decision-making recommendations is the default decision to vaccinate. For routine, catch-up, and risk-based recommendations, the default decision should be to vaccinate the patient based on age group or other indication, unless contraindicated. For shared clinical decision-making recommendations, there is no default—the decision about whether or not to vaccinate may be informed by the best available evidence of who may benefit from vaccination; the individual's characteristics, values, and preferences; the health care provider's clinical discretion; and the characteristics of the vaccine being considered. There is not a prescribed set of considerations or decision points in the decision-making process.

https://www.cdc.gov/acip/vaccine-recommendations/shared-clinical-decision-making.html

CURRENT CDC/ACIP SDM RECOMMENDATIONS

- Meningococcal B (MenB) vaccination for adolescents and young adults aged 16–23 years
- Hepatitis B (HepB) vaccination for adults aged 60 years and older ~~with diabetes mellitus~~
- Human papillomavirus (HPV) vaccination for adults aged 27–45 years
- Pneumococcal conjugate vaccination (PCV20 or PCV21) for adults aged 65 years and older who have completed the recommended vaccine series with both PCV13 (at any age) and PPSV23 (which was administered at age ≥65 years)
- Additional doses of COVID-19 vaccination for people who are moderately or severely immunocompromised

https://www.cdc.gov/acip/vaccine-recommendations/shared-clinical-decision-making.html

SDM AND HPV VACCINATION

June 2019, ACIP recommended shared clinical decision-making for HPV vaccination of adults aged 27–45 years. HPV acquisition generally occurs soon after first sexual activity. Vaccine effectiveness is lower in older age groups because of prior infections and lower risk of exposure (for example, among persons who are in a long-term, mutually monogamous sexual partnership). ACIP recommended shared clinical decision-making rather than catch-up vaccination because most adults in this age group would have no or minimal benefits from vaccination. However, some individuals who are not already immune to HPV through vaccination or natural infection (e.g., a previously unvaccinated person who has never had sex) and who might be at risk for acquiring a new HPV infection in the future (e.g., plans to have sex with a new partner in the future) might benefit from vaccination.

https://www.cdc.gov/acip/vaccine-recommendations/shared-clinical-decision-making.html

SDM AND HPV VACCINATION: HOPKINS APPROACH

- Age: 27-45 years
- Relationship: New, anticipated new and/or Not mutually monogamous
- Prior HPV vaccination: No or incomplete series
- HPV+: No or unknown
- Add'l Risks: STD's, Smoker, ETOH, Illicits
- Potential benefits: Reduction in risk for GU/OP CA and Precancers
- Unknowns: No effect on HPV types you may already have been infected with

  Purely preventive- No known treatment benefit on HPV associated diseases
- Potential AE: Sore arm, faint

SDM AND HPV VACCINATION: VIGNETTES

- 30 man for preventive visit, in process of divorce. No HPV vaccination. + Smoker + ETOH
- 42 woman PhD works in Cancer research. Married. No HPV vaccination. Asks for HPV vaccination
- 29 woman for followup. Unmarried, lesbian. Recent Pap/HPV found HPV+.
- 28 man with 2 prior doses HPV vaccine. Stable monogamous relationship.
- 44 woman with no prior HPV vaccination. Wants HPV vaccination.
- 55 man with many cutaneous warts- just learned HPV viruses cause warts and wants HPV vaccination.

Shared Clinical Decision-Making

HPV Vaccination for Adults Aged 27-45 Years

Shared clinical decision-making (SCDM) is recommended regarding Human papillomavirus (HPV) vaccination for persons 27-45 year of age. Shared clinical decision-making recommendations are intended to be flexible and should be informed by the characteristics, values, and preferences of the individual patient and the clinical discretion of the healthcare provider.

HPV vaccination does not need to be discussed with most adults in this age group.
If you do decide to discuss HPV vaccination with an adult patient:

Remember:

- Most HPV infections clear on their own within a year or two, but persistent infections can lead to development of precancers or cancers, usually after several decades.
- HPV vaccination is not routinely recommended for adults 27-45 years of age.
- HPV vaccine effectiveness is highest in people who have never had sex.
- HPV vaccination prevents new HPV infection, it does not treat existing HPV infection or disease.
- Most adults who have had sex have been exposed to HPV before.
- HPV vaccine effectiveness might be low among people with more risk factors for HPV, such as having had sex with more than one person or having certain immunocompromising conditions.

Consider:

- At any age, having a new sex partner is a risk factor for getting a new HPV infection. However, this is only one possible consideration for SCDM.
- Adults with more HPV risk factors (for example, multiple previous sex partners or certain immunocompromising conditions) might have been infected with HPV in the past, so might have a lower chance of getting a new HPV infection in the future.
- Adults with fewer HPV risk factors (for example, few or no previous sex partners) might not have been infected with HPV in the past, so might have a higher chance of getting a new HPV infection from a new sex partner in the future.

If you vaccinate:

- If you and your previously unvaccinated adult patient decide to initiate HPV vaccination, offer a 3-dose series of HPV vaccine at 0, 2, and 6 months.
- If your patient is pregnant, delay HPV vaccination until after pregnancy.
- HPV vaccination is safe, unless a patient had a severe allergic reaction after a previous dose or to a vaccine component.

Additional Information:
Supplemental information and guidance for vaccination providers regarding use of 9-valent HPV:
www.cdc.gov/hpv/downloads/9vhpv-guidance.pdf
CDC Adult Immunization Schedule:
www.cdc.gov/vaccines/schedules/hcp/imz/adult.html
CDC/ACIP recommendations on HPV vaccination for adults:
www.cdc.gov/mmwr/volumes/68/wr/mm6832a3.htm
CDC/ACIP all current HPV vaccine recommendations:
www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/hpv.html
CDC HPV vaccination information for clinicians:
www.cdc.gov/vaccines/vpd/hpv/hcp/index.html

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

05/05/22

https://www.cdc.gov/vaccines/hcp/admin/downloads/ISD-job-aid-SCDM-HPV-shared-clinical-decision-making-HPV.pdf

COVERAGE?

Under the Affordable Care Act and its implementing regulations, ACIP recommendations that have been adopted by CDC "with respect to the individual involved" and are "listed on the Immunization Schedules of the Centers for Disease Control and Prevention" generally are required to be covered by group health plans and health insurance issuers offering group or individual health insurance coverage without imposing any cost-sharing requirements (such as a copayment, coinsurance, or deductible).* This coverage requirement includes shared clinical decision-making recommendations when they have been adopted by CDC and are listed on the immunization schedules.

*Section 2713(a)(2) of the Public Health Service Act, as added by section 1001 of the Affordable Care Act, implemented at 26 CFR 54.9815-2713(a)(1)(ii), 29 CFR 2590.715-2713(a)(1)(ii), and 45 CFR 147.130(a)(1)(ii). This requirement does not apply to grandfathered health plan coverage under section 1251 of the Affordable Care Act, implemented at 26 CFR 54.9815-1251, 29 CFR 2590.715-1272, and 45 CFR 147.140.

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QUESTIONS?

Talking to Parents about HPV Vaccine

HPV VACCINE IS CANCER PREVENTION

Recommend HPV vaccination in the **same way** and on the **same day** as all adolescent vaccines. You can say, "Now that your son is 11, he is due for vaccinations today to help protect him from meningitis, HPV cancers, and whooping cough. Do you have any questions?" Taking the time to listen and understand parents' concerns can help you respond to their concerns more effectively.

Why does my child need HPV vaccine?

HPV vaccine is important because it prevents infections that can cause cancer. That's why we need to start the shot series today.

How do you know the vaccine works?

Studies continue to prove HPV vaccination works extremely well, decreasing the number of infections and HPV precancers in young people since it has been available.

Why do they need HPV vaccine at such a young age?

Vaccines protect your child before they are exposed to a disease. That's why we give the HPV vaccine earlier rather than later, to protect them long before they are ever exposed.

Also, if your child gets the shot now, they will only need two doses. If you wait until your child is older, they may end up needing three shots.

Why do boys need the HPV vaccine?

HPV vaccination can help prevent future infections that can lead to cancers of the penis, anus, and back of the throat in men.

Are all of these vaccines actually required?

I strongly recommend each of these vaccines and so do experts at the CDC and major medical organizations. School entry requirements are developed for public health and safety, but don't always reflect the most current medical recommendations for your child's health.

What diseases are caused by HPV?

Some HPV infections can cause cancer—like cancer of the cervix or in the back of the throat—but we can protect your child from these cancers in the future by getting the first HPV shot today.

Is my child really at risk for HPV?

HPV is a very common infection in women and men that can cause cancer. Starting the vaccine series today will help protect your child from the cancers and diseases caused by HPV.

I'm worried my child will think that getting this vaccine makes it OK to have sex.

Studies tell us that getting HPV vaccine doesn't make kids more likely to start having sex. I made sure my child (or grandchild, etc.) got HPV vaccine, and I recommend we give your child her first HPV shot today.

I'm worried about the safety of HPV vaccine. Do you think it's safe?

Yes, HPV vaccination is very safe. Like any medication, vaccines can cause side effects, including pain, swelling, or redness where the shot was given. That's normal for HPV vaccine too and should go away in a day or two. Sometimes kids faint after they get shots and they could be injured if they fall from fainting. We'll have your child stay seated after the shot to help protect him/her.

Can HPV vaccine cause infertility in my child?

There is no evidence available to suggest that getting HPV vaccine will have an effect on future fertility. However, women who develop an HPV precancer or cancer could require treatment that would limit their ability to have children.

For more information, visit
cdc.gov/vaccines/conversations

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CS269453B
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https://www.cdc.gov/hpv/media/pdfs/2024/07/talking_to_parents_hpv.pdf?CDC_AAref_Val=https://www.cdc.gov/hpv/hcp/for-hcp-tipsheet-hpv.pdf