

The Latest Updates on **Human Papillomavirus or HPV** Vaccination in the United States

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- Merck & Co. (external data monitoring committee)
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- Employment outside of Mayo Clinic: *Academic Pediatrics*

All relevant financial relationships have been mitigated



Learning Objectives

- Upon completion of this activity, you will be able to:
 - Outline the **latest evidence** supporting HPV vaccination
 - Identify **questions** that remain regarding HPV vaccines
 - List **proven strategies** to improve HPV vaccine uptake

Human Papillomavirus or HPV

- HPV causes most if not all cervical cancer
- Also, leading cause of other genital and oral cancers
- **39,300** new cases in the US in 2025
 - 11,100 cervical, 16,000 oral, 16,800 in males
- Nearly all of us exposed to HPV infection by 50 years of age
- Most exposed with adolescent/young adult sexual contact
- Most clear it in a couple years
- Small percent have enduring infections causing dysplasia
- That dysplasia leads to cancers

HPV Vaccines Debuted In 2005

- Before, just Pap smears, colposcopies, aggressive therapies
- By 2010 **universally recommended** for teens 11-12 yrs old
 - Start as early as 9 years of age, catch up thru 26 years
 - Optionally available for those 27-45 years of age
- Rocky uptake from the beginning
 - Preteens and teens **rarely** in clinic for preventive care
 - Parents associated it with accepting **promiscuity**
 - Manufacturers promoted vaccines **directly** to parents
 - Manufacturers also **lobbied** states calling for mandates

The Latest Data for US HPV Vaccines Uptake

- Pingali et al *MMWR* 2025;74(30):466-472
- Annual national immunization survey of teens 13-17 years
- Latest data from 2024
- Only **78%** of 13-17 years old have had 1 HPV vaccine dose
- 91% for the tetanus-diphtheria-acellular pertussis vaccine
- 90% for the first meningococcal or MenACWY vaccine dose
- All three due at 11-12 years of age
- HPV though is 2 doses at 11-12 years of age
- Only **63%** up-to-date for HPV at age 13-17 years of age

Latest Data for Efficacy of HPV Vaccination

- Bergman et al *Cochrane Database Syst Rev* 2025;11(11)
- Network meta-analysis of 60 randomized controlled trials
- Duration of follow-up too short for cervical cancer
- Focus here instead on pre-cancerous outcomes
- Cervical intraepithelial neoplasia or CIN stage 2, 3
- 30% reduction of CIN2+ regardless of HPV type
- **60% reduction** of CIN2+ for vaccine-types

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Latest on Safety Signals from HPV Vaccination Across Trials

- Bergman *Cochrane Database Syst Rev* **2025** CD015364
- Pairwise analysis of 39 randomized controlled trials
- 97,272 participants vaccinated or unvaccinated
- **No difference** in serious adverse events at up to 72 months

Latest on Real World Effectiveness of HPV Vaccination

- Henschke *Cochrane Database Syst Rev* **2025** CD015363
- Systematic review of 227 studies
- Long enough duration to study actual rates of cancer
- The vaccines were first licensed in 2005
- **Reduces risk** of cervical cancer by 63%
- Reduces risk cervical cancer by 80% if rec'd by 16 years

Latest on Real World Safety of HPV Vaccination

- Henschke *Cochrane Database Syst Rev* **2025** CD015363
- Same systematic review of 227 studies
- **No association**
 - Postural orthostatic tachycardia syndrome
 - Chronic fatigue syndrome/myalgic encephalomyelitis paralysis
 - Complex regional pain syndrome
 - Premature ovarian failure
 - Infertility or sexual activity
 - Guillain-Barré syndrome

New Real-World Effectiveness of HPV Vaccination in Males

- Kitano and Yoshida *JAMA Oncology* 2026
- Retrospective cohort study of global database
- At least 1 dose 9-valent HPV vaccine in males 2016-2024
- Examined HPV-related cancers
 - Head and neck, esophageal, anal, or penile
 - Up to 10-year follow-up
- 615,155 vaccinated males versus 2,290,623 unvaccinated
- 46% reduction in HPV-related cancers

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Latest Systematic Review on Safety and Effectiveness

- Vaccine Integrity Project, May 5, **2025**, www.cidrap.umn.edu/
- Added studies from September 2024 thru January 2026
- Combined with 2 previous systematic reviews
- Synthesized 274 studies
 - **No association** with serious adverse events
 - **Substantial protection** against:
 - Cervical cancer
 - High-grade cervical lesions
 - HPV infection

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Q. An astute colleagues points out that none of the actual randomized controlled trials show a reduction in cervical cancer but only high-grade cervical dysplasia. How should you answer that colleague?

- A. Current cervical cancer screening at nearly 100% has all but eliminated actual cervical cancer
- B. It's too expensive for those conducting the trials to make definitive diagnoses of cervical cancer
- C. The length of the trials are too short for cancers to emerge
- D. The vaccines are not designed to prevent cervical cancer



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Real-world studies show cancer success w/20 years' data

Remaining Questions in 2026 about HPV Vaccines

- Can we use just **one dose** versus two or three?
 - CDC changed recommendation in January 2026
 - Part of reduction of childhood vaccines from 17 to 11
 - CDC offered no rationale
 - AAP vs Kennedy results in CDC's return to previous dosing
- Vaccine Integrity Project, May 5, **2025**, www.cidrap.umn.edu/
 - Increasing evidence
 - 1 dose may be comparable with cervical cancer
 - No studies and thus no evidence yet
 - Cancers outside cervix and effectiveness in males

Another Remaining Question

- Can we achieve **herd immunity**?
- DeSieghardt et al *JAMA Pediatrics* **2025**;179(12):1326-34
- Cross-sectional study among 2335 US females
- Recruitment from surveillance studies from 2006 to 2023
- For the original strains in the 2006 vaccines:
 - Positivity reduced to nearly 0% for vaccinees
 - Positivity reduced to <10% for non-vaccinees
- For all 9 strains for the in the 2014 vaccines
 - Positivity reduced to <15% for vaccinees
 - Positivity reduced to <35% for non-vaccinees

A Third Remaining Question

- Can we cover **all HPV strains** that cause cancer?
- Twelve strains are known to be high risk
 - 16 and 18 cause most of these cancers
 - Others are 31, 33, 35, 39, 45, 51, 52, 56, 58, and 59
- Our current US licensed vaccine 9vHPV 9 is a valent vaccine
 - It covers 7 of those high-risk strains
 - 16, 18, 31, 33, 45, 52, and 58
- Trials with new vaccines have been recently reviewed
 - Wang et al *Front Immunol* **2024**;15:1362770
 - Current status and future directions for HPV vaccines

What Would It Take to Cover **More Strains**?

- The virus has two major parts
 - A center with a single double-stranded piece of DNA
 - A capsule made of two “late” proteins named L1 and L2
 - Each strain has a **different L1 capsid protein**
- The current vaccines present the various L1 capsid proteins
- Again, our 9-valent vaccine 9vHPV is really 9 vaccines
 - Each L1 is presented in tiny balls of viral-like particles
 - They are hollow spheres of L1 capsid proteins
 - There’s one L1 capsid protein for each of the 9 strains
- China has trials with an 11-, 14- and 15-valent vaccines

It's More Than Just Finding and Isolating Those New L1s

- Any new version of HPV vaccine
 - Must leave the immunogenicity of the current strains intact
 - Must obtain equivalent antibody levels of those strains
 - Must not create safety concerns
 - Must **demonstrate** dysplasia reduction, not just antibodies
 - Must not interfere with other vaccines due at that age



A Fourth Remaining Question

- Can we **treat** HPV infections and cancers with a vaccine?
- Current vaccines are only prophylactic
 - Infected cells do not express the L1 protein
 - L1 vaccines aren't effective against established infections
- Investigational vaccines stimulate cell-mediated immunity
 - Cellular immune response clear the infection, dysplasia
 - These target HPV's early proteins E6 and E7
 - Early proteins are made early on for genomic replication
 - Late proteins are made later on to make new virions
 - 15 such vaccines are currently in clinical trials

A Fifth Remaining Question

- Rates lag behind other 11-12-year-old vaccines
- Indeed, rates still lag all the way until 17 years of age
- The vaccine is routinely recommended for catch up thru 26
- Can we **wait** until the teens are mature adults to get 9vHPV?
- So far, the data argue against this
 - Recall Henschke *Cochrane Database Syst Rev* 2025
 - Real world effectiveness is much better by 16 years of age
 - First infections are often with first sexual contact
 - Average age of first sexual contacts is 16 years of age
 - Furthermore, we don't do a great job w/ those 18-26

What We Found w/Initiating HPV vaccine **18-26 Years of Age**

- Submitted for publication
- Kong et al. “Catch-Up HPV Vaccine Among Young Adults”
- Examined Mayo Clinic primary care patients 18-26 years old
- Included only those who had not yet initiated HPV vaccine
- Examine percent each year who started HPV vaccine series
- Studied 55,507 from 2006 through 2025
- Only **3%** got the 1st dose HPV vaccine in a one-year period
- Simply waiting until our patients are 18 years old won't work

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But That Begs a Final Remaining Question

- Okay but rates lag behind other 11–12-year-old vaccines
- And yet this vaccine is just as old as Tdap and MenACWY
- What can **influence views** of caregivers and adolescents?
- Cooper *Cochrane Database Syst Rev* 2025; CD013430
- Qualitative evidence synthesis
- 206 studies reviewed, 71 sampled

What **Influences** Caregivers and Adolescents?

- A lack of biomedical **knowledge**
- **Perceptions** of a range of interrelated risks and benefits
- **Routine responses** to vaccination in general
- Complex nuclear **familial** decision making dynamics
- Extended familial and social relations and **networks**
- Interrelated **socio-cultural beliefs** and practices
- **Trust** and distrust in the institutions, systems, and experts
- **Access** to HPV vaccination

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Q. Current recommendations call for catching up young adults through 26 years even if they test positive for HPV infection, cervical dysplasia, or even cervical cancer. A colleague asks you why. What's the best answer?

- A. One dose will boost the immunity from the infection
- B. While it's too late to prevent any cancer, it will prevent warts
- C. The vaccine will protect from cancers from the other strains
- D. The current vaccine in use has therapeutic properties

Q. Current recommendations call for catching up young adults through 26 years even if they test positive for HPV infection, cervical dysplasia, or even cervical cancer. A colleague asks you why. What's the best answer?

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Seven of the 9 strains in 9vHPV prevent cancer

Study of **Influences** and Not Interventions

- Qualitative evidence synthesis of 206 studies
- Did not examine interventions
- Raised a lot of questions instead about what to do



But Proven Strategies To Improve Vaccine Uptake Do Exist

- Lots of studies published on **improving** vaccine uptake
- Many were well-performed trials
- Indeed, these formed the basis of a **landmark review**



Briss et al.'s Methods

- “Reviews of Evidence Regarding Interventions to Improve Vaccination Coverage in Children, Adolescents, and Adults”
- Published in 2000 by Peter A Briss et al
- *Amer J of Preventive Medicine* 2000;18(1S):97-140
- Community Preventive Services Task Force
- Basically, **a review of systematic reviews**
- Five electronic databases
- All studies published between 1980-1997
- Now regularly updated online by the task force

Community Preventive Services Task Force

- Established by Health and Human Services in 1996
- <https://www.thecommunityguide.org/>
- Independent, non-federal panel of 15 public health experts
- **19 systematic reviews on improving vaccine uptake**
- Updated now through June 10 2026
- Three categories
 - Enhancing Access to Vaccination Services
 - Increasing Community Demand for Vaccinations
 - Provider- or System-Based Interventions



Enhancing Access to Vaccination Services

- Strong evidence
 - Home visits
 - Vaccination in schools and childcare
 - Vaccination programs in Women-Infant-Children settings
 - Cutting **out-of-pocket costs (eg, Vaccines for Children)**
- Insufficient evidence
 - Expanding clinic access when used alone

Increasing Community Demand for Vaccinations

- Strong evidence
 - Vaccine mandates for child care & school attendance
 - **Client reminder and recall** systems
- Sufficient evidence
 - Client or family incentive rewards
- Insufficient evidence
 - Client-held paper immunization records
 - Community-wide education when used alone
 - Monetary sanctions when used alone
 - Clinic-based education when used alone

Provider- or System-Based Interventions

- Strong evidence
 - Provider reminder or provider point-of-prompts
 - Immunization information systems (vaccine registries)
 - **Provider assessment & feedback**
 - Standing orders
- Insufficient evidence
 - Provider education when used alone

But Specifically About Communication?

- Recall studies that **communicating to educate fails**
 - Community-wide education when used alone
 - Clinic-based education when used alone
- Specifically regarding the HPV vaccine
 - Systematic review conducted by Linda Fu et al.
 - “Educational Interventions To Increase HPV Vaccination Acceptance: A Systematic Review”
 - *Vaccine* 2014; 32(17): 1901-20
 - 33 studies: 7 with parents, 8 with teens/adults, 18 mixed
 - Few measured uptake; overall, showed **education failed**

Indeed Some Studies Showed Education Alone Can Backfire

- Three studies demonstrated a **worsening of vaccine intent**
 - Nyhan et al *Pediatrics* 2014;133(4):e835-42
 - MMR, measles, and autism
 - Nyhan et al *Vaccine* 2015;33(3):459-64
 - Influenza vaccine and its effectiveness
 - Pluviano et al *PLoS One* 2017;12(7):e0181640
 - MMR, measles, and autism
 - Reddinger et al *Prev Med Rep* 2022 Oct:29:101903
 - COVID-19 vaccine with targeted messages, endorsers

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Clinicians Communicating Their Recommendations Do Matter

- Observational studies regarding HPV vaccine uptake
- Uptake associated w/reported **clinician's recommendation**
 - Guerry et al *Vaccine* 2011;29(12):2235-41
 - Darden et al *Pediatrics* 2013;131(4):645-51
 - Darden et al *Hum Vacc Immunother* 2014;10(9):2632-5
 - Caldwell et al *Hum Vacc Immunother* 2021;17(4):1059-67

Communicating a **Strong** Recommendations Even Better

- Rosenthal et al *Vaccine* 2011;29(5):890-5.
- 19-to 26-year-old females regarding the HPV vaccine
- All due for an HPV dose; all had a clinic visit in last 4 months
- 1375 who had received 1 dose in 4 months
- Compared to 1375 who did not
- Rated their clinician's recommendation 1 thru 5 in strength
 - 1 “did not strongly recommend the HPV vaccine”
 - 5 “strongly recommended the HPV vaccine”
- Strong recommendation **4 times more likely** to get vaccine

But What Makes a Clinician's Recommendation **Strong**?

- Opel et al *Pediatrics* 2013 Dec;132(6):1037-46
- 111 parents of children aged 1 to 19 months old
- Oversampled vaccine hesitant parents
- Videotaped health-maintenance visits
- 74% providers **presumptive language**
 - E.g., “Well, we have to do some shots”
- 26% **optional language**
 - E.g, “What do you want to do about shots?”

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Who initiated the vaccine recommendation or plan specifically? (n =111)

No plan verbalized (3%; n = 3)

Parent (13%; n = 15)

Clinician (84%; n = 93)

How does the CLINICIAN initiate the vaccine recommendation? (n = 93)

Presumptive (74%; n = 69)

Optional (26%; n = 24)

How does the PARENT respond to the provider's initiation?

Accepts (74%; n = 51)

Resists (26%; n = 18)

Accepts (4%; n = 1)

Provides own plan
(13%; n = 3)

Resists (83%; n = 20)

Examples of Presumptive Language

- “Your child is **due** for three vaccines today”
- “You’ll get two vaccines today”
- “After the exam, we will review the plan & the vaccines due”
- “The nurse will be back with the vaccines due”

Examples of Optional Language

- "Would you **like** to get this vaccine?"
- "What are you doing about the vaccinations?"
- "Were you planning to get any vaccines today?"

What Else Do We Know about Preteens and Teens

- Cannot just wait until preteens show up
- Preteens rarely have visits to the clinic
- Preteens and teens rarely make visits
 - Nordin et al *Ann Fam Med* 2010;8(6):511-6
 - Retrospective analysis claims data over at least 4 years
 - Large Minnesota health plan of 700,000 members
 - One preventive care visit a year as recommended?
 - **1%** for commercially insured, 2% for gov't insured
 - Preventive visits ranged from **0.15** to 0.45 a year
 - Nonpreventive visits ranged from **1** to 1.5 a year

Mayo Clinic's Primary Care Sites Practices in 2018

- Used **every visit** and not just well child visits
- **Prompted providers** at every visit for HPV vaccines due
- Used **standing orders** to support provider-less visits
 - In Minnesota, known as nurse vaccine protocols
- Participated in the state **immunization information system**
 - Also known as our vaccine registry
 - Minnesota Immunization Information Connection or MIIC
- Participated in Minnesota **Vaccines for Children** or MnVFC
- Initiated the HPV vaccine series routinely at **9 years of age**

Initiation at 9 or 10 Years of Age?

- Always permitted by ACIP recommendations since 2007
- Always done at Mayo Clinic since first ACIP recommendation
- Takes advantage of better immunologic response
- Now needs only 2 doses unlike teens starting at 15 years old
- Studies show parental acceptance
- Studies show higher rates of completion
- Mayo Clinic compared those starting at 9-10 v 11-12 years
 - St Sauver et al *Prev Med* 2016;89:327–333
 - **22.6** times more likely to be complete at 15 years of age

What We Had as Our Population to Study

- **Six practices**

- An all-pediatric downtown clinic
- An all-family medicine downtown clinic
- A northeast suburban mixed clinic
- A northwest suburban mixed clinic
- A southeast suburban mixed clinic
- A rural all-family medicine clinic
- All had physicians and nurse practitioners
- All had leadership supportive of trial participation

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Our Overarching Goal of an Ambitious Randomized Trial

- Sought to improve HPV vaccine uptake in our adolescents
- Federal funds for HPV vaccine research limited at the time:
 - Nat'l Cancer Institute funding opportunity for a clinical trial
 - **Multi-level interventions**
 - More than one intervention
 - Interventions had to target different groups
 - Focus had to be **11- and 12-year-old children**
- We wanted to test interventions we were not yet doing
- We wanted to avoid ones dependent on education alone

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Our Chosen Interventions

- We chose to layer on two interventions
 - One directed toward parents
 - Send a **parent reminder-recall** for their children
 - Target those 11 & 12 years old due for an HPV vaccine
 - Mail a birthday letter with all vaccines due
 - One directed at providers
 - Send a **provider audit-feedback**
 - Share with each their own missed opportunities rate
 - Compare their rates with their peers
 - Review presumptive language and C.A.S.E. approach
 - C.A.S.E.: Corroborate-About Me-Science-Advise

Two Factor, Stepped-wedge, Cluster Randomized Trial

Clinical Practice	Step 1 Year 1	Step 2 Year 2	Step 3 Year 3	Step 4 Year 4
A	Usual care	Usual care	Parent reminder	Both
B	Usual care	Parent reminder	Both	Both
C	Usual care	Provider audit	Provider audit	Both
D	Usual care	Usual care	Provider audit	Both
E	Usual care	Parent reminder	Parent reminder	Both
F	Usual care	Provider audit	Both	Both

Funding Details

- R01 CA217889 funded March 27, 2018, for 5 years
- Interrupted for 6 months by the pandemic in 2020
- Rutten et al *JAMA Pediatrics* 2024;178(1)

Final Study Cohort over the Four-Year, Four-Step Trial

- Demographic characteristics (**N=9,142**)
 - 55.9% 11-year-olds
 - 41.1% 12-year-olds
 - 52.5% male
 - 72.5% white, non-Hispanic patients
- Vaccine eligibility
 - 70.9% eligible for initiation
 - 29.1% eligible for completion



Rates of HPV Vaccine Dose Received*

	Usual Care (n=3572)	Parent Reminder/Recall (n=1670)	Provider Audit/Feedback (N=1340)	Reminder/Recall and Audit/Feedback (n=2660)
	n/d (%)	n/d (%)	n/d (%)	n/d (%)
All	782/3572 (21.9)	578/1670 (34.6)	408/1340 (30.4)	1056/2660 (39.7)
Males	397/1905 (20.8)	282/871 (32.4)	220/692 (31.8)	539/1380 (39.1)
Females	385/1667 (23.1)	296/799 (37.0)	188/648 (29.0)	517/1280 (40.4)
Initiation	482/2738 (17.6)	329/1167 (28.2)	251/946 (26.5)	490/1705 (28.7)
Completion	300/834 (36.0)	249/503 (49.5)	157/394 (39.8)	566/955 (59.3)

*From the time one became eligible (11-or-12-year birthday & due for a dose) to the step's end

Odds Ratios of HPV Vaccine Dose Receipt

	Usual Care	Parent Reminder/Recall	Provider Audit/Feedback	Reminder/Recall and Audit/Feedback	
		Odds ratio (95% CI)	Odds ratio (95% CI)	Odds ratio (95% CI)	P value
Overall	reference	1.56 (1.23,1.97)	1.19 (0.94,1.51)	2.03 (1.44,2.85)	<0.001
Males	reference	1.45 (1.06,1.98)	1.39 (1.01,1.90)	2.13 (1.37,3.30)	0.010
Females	reference	1.60 (1.15,2.22)	1.04 (0.74,1.47)	1.78 (1.11,2.85)	0.003
Initiation	reference	1.50 (1.13,2.00)	1.28 (0.95,1.73)	2.01 (1.34,3.04)	0.006
Completion	reference	1.63 (1.07,2.46)	0.94 (0.62,1.44)	1.91 (1.08,3.39)	0.004

What We Have Learned Since Our Trial: C.A.S.E. No More

- Dempsey et al *JAMA Pediatrics* 2018;172(5):e180016
- Cluster randomized trial (providers and not patients)
- 188 medical professionals & 48,132 adolescents
- Two arms: experimental provider training versus no training
- Presumptive language; if hesitant, **motivational interviewing**
- Target: human papillomavirus (HPV) vaccine
- Absolute **9.5% increase** in initiation of HPV vaccine series
- Absolute 4.5% increase in completion of HPV vaccine series

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Motivational Interviewing

- First described by Miller in 1983
- Developed as a theory and procedure with Rollnick in 1991
- First developed to treat alcoholism
- Directive, patient-centered counseling style
- Pursue behavior-change by addressing the **ambivalence**
- Successful across entire range of health conditions



The Spirit Of Motivational Interviewing

- What it **is**:
 - Compassion for the patient
 - Collaboration with the patient
 - Acceptance of the patient's role as decision maker
 - Empowerment of the patient
- What it is **not**:
 - An educational solution for health illiteracy
 - A spirited debate to determine a winner and a loser

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Motivational Interviewing with Hesitancy in the Office

- **Ask** permission to learn the specific concern
- **Acknowledge** the concern
- **Affirm** the journey, affirm the parent's role as the decider
- **Answer** concern but only after getting permission to do so



Get Training in Motivational Interviewing

- Go to North Dakota State University to access training
- **Center for Immunization Research and Education (CIRE)**
- ndsu.edu/centers/immunize/motivational-interviewing-modules
- Four-part online video series
- 10-15 minutes each
- Continuing education credit available



Q. Your colleagues are meeting with you considering practice change for plan-do-study-act (PDSA) cycle to improve adolescent vaccines. Which potential practice change has a strong evidence basis for improving HPV vaccine uptake?

- A. Train staff in shared decision making
- B. Provide parents reminder texts of vaccines due
- C. Offer early and late clinic hours
- D. Pay families to get their teens vaccinated



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Many, valid, reliable, & generalizable studies support reminder-recalls for HPV vaccines and other vaccines

Summary

- Outline the **latest evidence** supporting HPV vaccination
 - Really works, better if given before 16 years of age
 - Really safe, no safety signals of concern
- Identify the **questions** that remain regarding HPV vaccines
 - 1 dose? Herd immunity? More strains? Therapeutic ones?
 - Waiting till adulthood? Improving the uptake?
- List **proven strategies** to improve HPV vaccine uptake
 - Point of care prompts, parent reminder-recalls
 - Starting at 9 years, presumptive language for a strong rec
 - And when that meets hesitation, motivational interviewing

Additional References

- Slides 4-5: <https://www.cdc.gov/united-states-cancer-statistics/publications/hpv-associated-cancers.html>
- Slide 15: <https://www.immunize.org/news/official-release-repository/cdc/> and <https://vaxintegrity.cidrap.umn.edu/>
- Slide 17: <https://www.cancer.gov/about-cancer/causes-prevention/risk/infectious-agents/hpv-and-cancer>
- Slides 18-21: Wang et al *Front Immunol* **2024**;15:1362770
- Slides 39-40: Opel et al *Pediatrics* 2013 Dec;132(6):1037-46
- Slides 49-51: Rutten et al *JAMA Pediatrics* 2024;178(1)
- Slide 55: <https://www.voicesforvaccines.org/>