June 19, 2025

Melinda Wharton, MD, MPH
Associate Director for Vaccine Policy
Executive Secretary of the Advisory Committee on Immunization Practices
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention

Dear Dr. Wharton,

HealthyWomen, members of its HPV Coalition and additional stakeholders are writing the Advisory Committee on Immunization Practices (ACIP) regarding the upcoming June ACIP meeting June 25-27, 2025, docket number - CDC-2005-0024. Specifically, this letter seeks to: (1) reiterate the monumental impact that HPV vaccination has made on population health to-date; (2) provide targeted feedback on the HPV-related votes/discussion slated for the June 2025 meeting since ACIP recommendations directly impact health insurance coverage and patient out-of-pocket cost-sharing; and (3) emphasize the importance of clarity, continuity, and predictability of the ACIP moving forward. The HealthyWomen HPV Coalition consists of more than 50 health and advocacy stakeholder organizations that work together to increase HPV vaccination to prevent HPV cancers, promote early detection through essential screenings, and highlight the need for early treatment of HPV cancers.

Significant Public Health Impact of HPV Vaccination

Each year, approximately 13 million Americans are infected with the human papillomavirus (HPV), and over 36,000 individuals develop HPV cancers.[1] Fortunately, HPV vaccination has proven to be more than 90% effective at preventing the six cancers caused by HPV (cervical, vaginal, vulvar, penile, anal, and oropharyngeal).[2] The impact of HPV vaccination has brought the U.S. closer than ever before to its goal of eliminating cervical cancer and potentially other HPV-related cancers.

[1] "About HPV." Centers for Disease Control and Prevention, Centers for Disease Control and Prevention, 3 July 2024, www.cdc.gov/hpv/about/index.html#:~:text=HPV%20infections%20are%20very%20common,teens%2C%20become%20infected%20each%20year.
[2] "Cancers Caused by HPV." Centers for Disease Control and Prevention, Centers for Disease Control and Prevention, 3 July 2024, https://www.cdc.gov/hpv/about/cancers-caused-by-hpv.html#:~:text=Recommendations-,HPV%20vaccination%20can%20prevent%20over%2090%25%20of%20cancers%20caused%20by,contact%20with%20the%20HPV%20virus.

However, since the ACIP began recommending HPV vaccination in 2006, uptake rates have been suboptimal and have stagnated since the COVID-19 pandemic.[3] The CDC reported evidence of this stagnation in its August 22, 2024, Morbidity and Mortality Weekly Report, which noted that 76.8% of adolescents 13-17 years old had received at least one dose in 2023 compared to 76.0% in 2022. Meanwhile, 61.4% were up to date on the vaccine in 2023, compared to 62.6% in 2022.[4] Even at pre-pandemic levels, HPV vaccine rates are far below those of other routine childhood vaccines (i.e., MMR rates are typically around 90%). Going forward, addressing suboptimal HPV vaccine rates will be essential to expanding the vaccine's public health impact and preventing as many HPV-related cancers as possible.

Importance of Initiating HPV Vaccination at Age 9 and Providing Clear Guidance

Currently, ACIP recommends HPV vaccination for adolescents be initiated at age 11 or 12, with the option for initiation as early as age 9. On behalf of the countless constituencies our organizations represent, we strongly encourage the ACIP to harmonize its routine HPV vaccine recommendations with leaders in public health, cancer prevention, and childhood and adolescent health — including the American Cancer Society (ACS) and the American Academy of Pediatrics (AAP) — by updating the routine recommendation language for HPV vaccination to begin at age 9. Per the AAP, "The immune response is robust at younger ages, and there is no evidence of significant waning protection after antibody levels plateau approximately 18 to 24 months after series completion."

Initiating the HPV vaccine series at age 9 has proven to be an effective approach to addressing suboptimal vaccination rates in the U.S., with evidence demonstrating the impact on vaccination uptake. Earlier initiation of HPV vaccination among children is associated with several implementation benefits, such as increasing the likelihood that children and adolescents will be vaccinated before their first exposure to HPV.[5] Evidence suggests that initiating HPV vaccination before age 11 or 12 may also increase the chances of series completion by age 13, giving individuals more time to get vaccinated.[6]

Additionally, uptake and series completion of the HPV vaccine will be impacted by the clarity and consistency of recommendations across various clinical guidelines. Harmonizing the recommendations from ACIP, ACS, and AAP will help streamline education, awareness, and administrative updates across health systems, payers, providers, and parents and caregivers.[7] Since ACIP recommendations directly impact health insurance coverage and patient out-of-pocket cost-sharing, any ambiguity in the recommendation can lead to inconsistent payer coverage, potentially adding cost barriers and administrative challenges that can discourage

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[3] Pingali C, Yankey D, Chen M, et al. National Vaccination Coverage Among Adolescents Aged 13–17 Years — National Immunization Survey-Teen, United States, 2023. MMWR Morb Mortal Wkly Rep 2024;73:708–714. DOI: http://dx.doi.org/10.15585/mmwr.mm7333a1

[4] Pingali C, Yankey D, Chen M, et al. National Vaccination Coverage Among Adolescents Aged 13–17 Years — National Immunization Survey-Teen, United States, 2023. MMWR Morb Mortal Wkly Rep 2024;73:708–714. DOI: http://dx.doi.org/10.15585/mmwr.mm7333a1

[5] O'Leary, Sonja C, and Holly M Frost. "Does HPV vaccination initiation at age 9, improve HPV initiation and vaccine series completion rates by age 13?." Human vaccines & immunotherapeutics vol. 19,1 (2023): 2180971. doi:10.1080/21645515.2023.2180971

[6] O'Leary, Sonja C, and Holly M Frost. "Does HPV vaccination initiation at age 9, improve HPV initiation and vaccine series completion rates by age 13?." Human vaccines & immunotherapeutics vol. 19,1 (2023): 2180971. doi:10.1080/21645515.2023.2180971

[7] Perkins, Rebecca B et al. "Evidence supporting the initiation of HPV vaccination starting at age 9: Collection overview." Human vaccines & immunotherapeutics vol. 19,3 (2023): 2269026. doi:10.1080/21645515.2023.2269026

vaccination, resulting in missed opportunities to prevent HPV cancers. Updating the ACIP recommendation for routine HPV vaccination to clearly begin at age 9 is critical to ensuring first-dollar coverage and to advancing our shared goal of preventing HPV cancers and eliminating cervical cancer in the U.S.

Need for Complete Data to Inform Proposed Dosing Changes

We appreciate that the ACIP and CDC are considering many ways to improve the uptake of the HPV vaccine and agree that increasing vaccination rates is a key issue that must be addressed to ensure we are preventing as many HPV-related cancers as possible. While we understand that there could be benefits to a future reduced dosing regimen, we have concerns that moving forward with a change in recommendation at this time without the appropriate level of data could undermine our shared goal of preventing HPV-related cancers and diseases. While we are encouraged by the initial data on females and cervical cancer outcomes that has been presented from the KEN SHE, PRISMA, and ESCUDDO trials, we are concerned that these studies do not include findings on males or rates of non-cervical HPV-related cancers (e.g., vaginal, vulvar, penile, anal, and oropharyngeal). This is especially concerning because the incidence of HPV-related cancers in men is higher than the rate of cervical cancer in women in the U.S.[8] Furthermore, there are currently no approved head and neck cancer screening tests for asymptomatic patients, leaving no early detection safety net — making it even more critical to have extensive male data before implementing changes in dosing recommendations.[9]

We implore the ACIP to consider the importance of these significant data gaps — and the potential long-term implications — before making any broad-brush changes to the current dosing recommendation. Alternatively, if the ACIP chooses to revise the recommendation to include flexibility for providers to implement reduced dosing with appropriate individuals (e.g., shared clinical decision-making (SCDM), permissive recommendations), it will be critical that ACIP is extremely clear about the appropriate use of this flexibility. This language should not be overly broad or create any uncertainty about payer coverage of the current dosing regimen.

Call for ACIP Predictability, Continuity, and Transparency

Predictability is foundational to ensuring the success of any public-facing service, and the extensive immunization network across the U.S. is no exception. Each ACIP meeting is critical to spur scientific discussion and ensure coordination across providers, public health departments, payers, manufacturers, suppliers, and others. Holding ACIP meetings on time is incredibly important to the broader vaccine ecosystem; these decisions set into action key next steps that underpin access to and coverage of immunizations.

Furthermore, delays in ACIP recommendations can directly impact access and coverage to nearly all public and private payers, including the Vaccines for Children (VFC) Program, the

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[8] Centers for Disease Control and Prevention. Cancers Associated with Human Papillomavirus. Centers for Disease Control and Prevention, U.S. Department of Health and Human Services; 2024.
https://www.cdc.gov/united-states-cancer-statistics/publications/hpv-associated-cancers.html

[9] Winship Cancer Institute. Head and Neck Cancer Screening. Emory University.
https://winshipcancer.emory.edu/cancer-types-and-treatments/head-and-neck-cancer/screening.php

Children's Health Insurance Program (CHIP), Medicare, Medicaid, and commercial health plans. Without an ACIP recommendation, plans are under no statutory obligation to provide patients seeking immunization with appropriate access or first-dollar coverage. This lack of recommendation not only impacts access to new vaccines, but also expansions of coverage for existing vaccines. The ACIP is also responsible for recommending immunizations for inclusion in VFC; without this action, the most vulnerable children would be denied access to the latest immunization products.
Aside from coverage, ACIP meetings are also a critical mechanism for facilitating public transparency into the clinical data and discussions informing ACIP recommendations. In the same vein, the public comment process is a valuable tool for the public to provide feedback on considerations ahead of a recommendation, including any potential impact to special populations that may not have otherwise been considered.

Additionally, preserving ACIP's well-functioning body of unique immunization experts is essential to supporting the nation's immunization system. ACIP members must undergo a rigorous vetting process, including requirements related to disclosures of conflicts of interest. Once appointed, ACIP members are required to continuously disclose any conflicts of interest if they arise and recuse themselves from discussions or votes where a conflict of interest exists. Keeping this balance of scientific expertise and transparency is vital to ensuring the most thorough, data-driven review necessary to inform a recommendation upon which all Americans depend. We urge HHS and CDC to continue supporting this structure and maintain a high standard of scientific expertise.

Extensive data have made it clear that the HPV vaccine is an important public health and cancer prevention tool. We appreciate ACIP's work to improve the uptake of the vaccine going forward, allowing us to build upon the significant progress made to date in cancer prevention. We thank you for the opportunity to provide comments on the items to be voted on/discussed at the June ACIP meeting. Furthermore, we especially appreciate the ACIP's ongoing work to protect our nation's health through the development of public health guidance for the safe use of vaccines in the U.S.

Sincerely,

Academy of Managed Care Pharmacy (AMCP)
Alliance for a Healthier Generation
Alliance for Immunization in Michigan
Alliance for Women's Health and Prevention
American Association of Nurse Practitioners (AANP)
American Cancer Society Cancer Action Network
American College of Obstetricians and Gynecologists
American Medical Women's Association (AMWA)
Arkansas Immunization Action Coalition (Immunize Arkansas)
ASHA
Black Women's Health Imperative
Byrd Cancer Education and Advocacy Foundation
Cancer Care
Cervivor
Friends of Cancer Research
FTI Consulting

Hager Sharp
Head & Neck Cancer Alliance
Healthy Men Inc.
HealthyWomen
HPV Cancers Alliance
HPVANDME
Illinois Public Health Association (IPHA)
Immunize Colorado
Immunize Kentucky Coalition
Indiana Immunization Coalition
ITAVFoundation
Journi For Two
Kelsey Seybold
Kentucky Rural Health Association
Louisiana Families for Vaccines
Men's Health Network
Miami Cancer Institute
Moffitt Cancer Center
National Association of Pediatric Nurse Practitioners
National Caucus and Center on Black Aging
National Consumers League
National Grange
National League for Nursing
National Women's Health Network
Northwest Georgia Cancer Coalition
Nurse Practitioners in Women's Health
Nurses Who Vaccinate
Oncology Nursing Society
PA Coalition for Oral Health
PA Statewide HPV/HBV Workgroup
Prevent Cancer Foundation
Society for Women's Health Research
STC Health
Team Maureen
Tennessee Families for Vaccines
The Shot Nurse
The Anal Cancer Foundation
The Balm In Gilead, Inc.
TOUCH The Black Breast Cancer Alliance
Unity Consortium
VAX 2 STOP CANCER
Voices for Vaccines
Casey L. Daniel, PhD, MPH
Deborah Overall, RN
Heather Brandt, PhD
Jennifer M Forsyth, PharmD
Katherine M. Nicol, MS