

**Advisory Committee on Immunization Practices (ACIP)
Centers for Disease Control and Prevention (CDC)
Human Papillomavirus (HPV) Vaccine Workgroup
Terms of Reference
UPDATED: December 18, 2025**

PURPOSE

This document defines the activities, membership, and administrative requirements associated with the establishment of a **Human Papillomavirus (HPV) Vaccine Workgroup** under the Advisory Committee on Immunization Practices, Centers for Disease Control and Prevention (ACIP, CDC). ACIP utilizes subgroups of the Committee, known as Workgroups (WGs), to review relevant published and unpublished data, and clinical and scientific knowledge, and develop options for presentation to the full ACIP parent committee during its public meetings to facilitate discussion, deliberation, and development of recommendations. ACIP WGs are intended to augment the effectiveness of ACIP. The direction, focus, and pace of both ACIP and the individual WGs are guided by CDC and HHS policies and priorities, as well as the need for expert input to inform development of CDC immunization policy. ACIP WGs play a key **scientific role** supporting immunization recommendations. The HPV Vaccines WG has been specifically established to review data, as well as clinical and scientific knowledge on HPV vaccines and their role in preventing infection and cancer and their effect on prevalence and carcinogenicity of subtypes, to help develop HPV immunization policy options for ACIP consideration to formulate recommendations to the Director of the CDC.

For purposes of this document, “Immunization” refers to vaccines and other antibody protective products used to prevent disease such as immunoglobulins.

BACKGROUND

HPV is a common virus spread through intimate skin-to-skin contact. Although most HPV infections become undetectable within two years, some HPV infections will persist and can cause cancers in women and men. In the United States, HPV vaccination is currently recommended in early adolescence to protect against HPV infection. A 9-valent HPV vaccine, 9vHPV, is the only HPV vaccine currently available in the United States. This vaccine targets nine HPV types (HPV 6, 11, 16, 18, 31, 33, 45, 52, and 58) that cause the majority of cervical and other HPV-related cancers and anogenital warts.

An ACIP HPV Vaccine Work Group met almost continuously from 2005 through 2019 to address policy for new vaccines and new FDA indications. The work of the HPV Vaccine WG was reconvened in July 2024 to review and discuss the number of vaccine doses in the recommended HPV vaccination series and the recommended age for routine HPV vaccination. The HPV Vaccine WG will continue this work and, per ACIP charter, will also conduct a comprehensive review of the cumulative data, knowledge, and evidence regarding the efficacy, effectiveness and the safety of the HPV vaccine.

In accordance with the 21st Century Cures Act (PL 114-255), ACIP shall also, as appropriate, consider new vaccines or new indications at its next regularly scheduled meeting after licensure; if the Committee defers making a recommendation, it will provide an update on the status of its review. Additionally, ACIP shall make recommendations in a timely manner for vaccines that are designated as breakthrough interventions or could be used in a public health emergency. In case of any new HPV immunizations, the ACIP parent committee requests that the HPV Vaccine WG include consideration of the new immunizations to assist the parent committee in implementing its 21st Century Cures Act requirements.

The purpose of this HPV Vaccine WG is to review available data, as well as clinical and scientific knowledge, to support the development of recommendations for ACIP consideration that are used to advise the Director of the CDC.

The HPV Vaccine WG will also assist and support the ACIP parent committee, in accordance with Section 1928 of the Social Security Act (42 USC 1396s), to be able to establish and periodically review and, as appropriate, revise the list of immunizations for administration to children and adolescents eligible to receive immunizations through the Vaccines for Children Program, along with schedules regarding the appropriate dose and dosing intervals, and contraindications to administration of the pediatric immunization.

TOPICS UNDER DISCUSSION BY THE WORKGROUP

The following topics relevant to a comprehensive review of the efficacy, effectiveness and safety of the HPV vaccine, as well as to specific vaccination policies regarding the use of HPV vaccine and effective control of HPV infection and related disease in the population of the United States will be under discussion in the HPV Vaccine WG in multi-year efforts and include, for presentation to the parent committee for its deliberation and development of recommendations to CDC, evaluation of:

- 1) HPV vaccination schedules with fewer doses;
- 2) Wording of the age for routine HPV vaccination; and
- 3) Draft policy recommendations following a comprehensive review of the cumulative scientific and clinical data, knowledge, and evidence regarding the efficacy, effectiveness, and the safety of the HPV vaccine. This includes assessment of the long term effects of HPV vaccination programs on population level incidence (per subtype), morbidity and mortality of cervical cancer.

DESCRIPTION of WORKGROUP ACTIVITIES

The following activities provide a framework for the HPV Vaccine WG multi-year efforts, which may involve data requests from other Federal and private partners, for development of

presentations to the parent ACIP for its deliberations as it develops recommendations to the CDC Director:

1. Summarize and review the cumulative data on temporal trends in the U.S. and other countries of HPV infection, precancers, cervical cancer incidence; other HPV attributable outcomes; and mortality per different age groups and how they potentially correlate with evolving vaccination rates and screening policies.
2. Summarize and review, using existing systematic reviews, where possible, the cumulative data and knowledge regarding vaccine efficacy and effectiveness in relation to cervical cancer and surrogate outcomes, including a meta-analysis of clinical trials and observational studies.
3. Summarize and review the cumulative data and knowledge regarding vaccine safety and related adverse events, including VAERS source and other safety data and meta-analysis of clinical trials and observational studies.
4. Characterize the nature of the safety reports in men and women and timing of the report post vaccination with the first and second dose.
5. Summarize and review existing data and knowledge regarding the potential toxicity of HPV vaccine, adjuvants, and potential contaminants and/or impurities.
6. Summarize and review existing knowledge related to the efficacy, effectiveness and safety of HPV vaccination when given to individuals with prior exposure to HPV infections.
7. Summarize and review the existing data on potential HPV type replacement (i.e., increase in oncogenic types not targeted by HPV vaccine, after introduction of HPV vaccination programs, as well as data and knowledge related to the potential impact of vaccination rates.
8. Review and summarize existing data, including published and as available and appropriate, unpublished research, as well as clinical knowledge, related to the efficacy, effectiveness, and immunogenicity of HPV vaccination with fewer than two doses in individuals aged 9 through 14 years.
9. Review and summarize existing data including published and, as available and appropriate, unpublished research, as well as clinical knowledge related to the efficacy, effectiveness, and immunogenicity of HPV vaccination with fewer than three doses in individuals to inform vaccination recommendations for persons aged 15 years and older.
10. Review programmatic data on age at vaccination in the United States.
11. Develop HPV vaccination policy options for presentation to and deliberation by, the ACIP parent committee.

Overall, the HPV Vaccine WG will prepare information for the ACIP members to enable them to:

- Advise on population groups and/or circumstances in which a vaccine or related agent is recommended.
- Provide recommendations on contraindications and precautions for use of the vaccine and related agents and provide information on recognized adverse events.
- Provide recommendations that address the general use of vaccines and if applicable, immune globulin preparations as a class of biologic agents, use of specific antibody products for prevention of infectious diseases, and special situations or populations that may warrant modification of the routine recommendations.
- Support committee deliberations on use of immunization to control disease including consideration of disease epidemiology and burden of disease, immunization safety, immunization efficacy and effectiveness, the quality of evidence reviewed, economic analyses, medical ethics, and implementation issues including informed consent language.
- Revise or withdraw their recommendation(s) regarding a particular immunization should new information on disease epidemiology, immunization effectiveness or safety, economic considerations, or other data become available.

MEMBERSHIP

Workgroup Leadership: The HPV Vaccine WG is chaired by a member of ACIP committee. The Workgroup Lead (WGL) is a federal employee, identified by the ACIP parent committee Designated Federal Official (DFO) (within the Immediate Office of the Director) in consultation with the relevant CDC programs. The ACIP DFO will determine which roles and responsibilities will be further assigned, as appropriate, to the WGL, who will then be responsible for carrying them out. The WG Chair, in consultation with both the WGL and the DFO, establishes the WG's membership, work priorities, and deliverables for presentation to the full committee.

Workgroup Membership: The HPV Vaccine WG is composed of experts who are appointed based on their professional, scientific, technical, or other expertise. They are experts who are regarded as an authority or a practitioner of unique competence and skill by other individuals in their profession or occupation. Upon request, HHS federal agencies named in the ACIP charter may also appoint members to serve on WGs. The HPV Vaccine WG will be composed of members from a variety of disciplines. The HPV Vaccine WG will engage with the following disciplines on WG activities:

- Public health science and practice;
- Public health policy development, analysis, and implementation, including development and execution of immunization programs for children and adults;
- Clinical and medical practice, and patient-care experience;
- Epidemiology;
- Immunology;
- Virology;
- Neurology;

- Oncology;
- Pathology;
- Toxicology;
- Drug and vaccine safety;
- Medical ethics; and
- Consumer perspectives and/or social and community aspects of immunization programs

Due to the complexity and variability of information to be gathered, additional external subject matter experts may also be invited to provide data and presentations to the HPV Vaccine WG and answer questions during HPV Vaccine WG meetings on an ad hoc basis. Such additional external subject matter experts will not be members of the HPV Vaccine WG and will not participate in any deliberations or HPV Vaccine WG discussions.

MEETINGS, ADMINISTRATION, and TIMELINES

1. Administrative Oversight: The WGL will work with the WG Chair to arrange meetings, and document meeting proceedings and may provide presentations about the WG activities and findings to the ACIP. Staff from WGL's program may be assigned to assist with some of the WG's administrative activities including notetaking and required record keeping.
2. Meeting frequency and location: The HPV Vaccine WG will meet on an as needed basis as determined by the WG Chair and WGL. All HPV Vaccine WG meetings are convened virtually via teleconference.
3. Meeting structure: In addition to the WGL, at least two ACIP parent committee members (one of whom serves as the HPV Vaccine WG Chair) must be present at each meeting for a quorum. An agenda, relevant publications, and background documents will be circulated as read ahead material prior to each meeting.
4. Conflicts of Interest: HPV Vaccine WG members will complete an ACIP WG Agreement and Conflict of Interest Certification process prior to participation on the HPV Vaccine WG. The WGL will screen for conflict-of-interest declarations and share any conflicts that need to be elevated to the DFO/ACIP Secretariat. The ACIP parent committee DFO in collaboration with the WGL will work with the Office of Strategic Business Initiatives, Federal Advisory Committee Act Program and the Office of the General Counsel (OGC) as needed, to mitigate any conflicts identified. HPV Vaccine WG members will consent to abide by guiding principles and disclose interests (e.g., employment, special interests, grants, or contracts) that a reasonable person could view as conflicts or potential conflicts of interest with their HPV Vaccine WG participation. Members will also disclose any potential conflicts of interest before each meeting. If an HPV Vaccine WG member indicates a potential or actual conflict of interest, the DFO will review and make a determination as to whether the individual must recuse themselves from participating in HPV Vaccine WG discussions that implicate such a conflict-of-interest concern.

5. Confidentiality: The discussions of the HPV Vaccine WG may include information that is unpublished, protected, privileged, or confidential. HPV Vaccine WG deliberations, including policy options under consideration by the HPV Vaccine WG, are also considered confidential. Information of this nature must not be disseminated, distributed, or copied to persons not authorized to receive such information. When these types of information are distributed, the person/s presenting will identify the information as such, so all members are duly informed; and written materials shall be clearly marked as such. Unlike ACIP parent committee meetings, which are open to the public, HPV Vaccine WG teleconferences are not subject to the open meeting requirements of the Federal Advisory Committee Act or the GSA Final Rule; data presented during these meetings/teleconferences are often proprietary and should not be distributed to people other than approved HPV Vaccines WG members.
6. CDC Staff Involvement: CDC staff do not serve as members of the HPV Vaccine WG but may provide administrative support and technical expertise to ACIP WG, bringing subject matter expertise and current professional focus in areas relevant to the goals of the HPV Vaccine WG. Consultation or informational presentations by CDC staff will be transparent and evident to minimize the risk of, or the appearance of, undue influence that would compromise the independence of the WG. The ACIP, CDC parent committee DFO and WGL of the HPV Vaccine WG, in consultation with the Chair of the HPV Vaccine WG, will monitor the interaction between the WG and the agency staff to ensure that the WG activities and work products are appropriate and that there is not undue influence by the CDC or by any special interest group on the activities or work products of the WG.
7. Timelines: ACIP WGs are established when needed and terminated once the activities and work products stated in the terms of reference have been completed and the WG's charge has been fulfilled.
8. Subject content: Findings and opinions of the HPV Vaccine WG members will be discussed at meetings. The HPV Vaccine WG's findings will be presented to the ACIP parent committee for consideration for action (discussion, deliberation and decision, and recommendations).
9. Workgroup Meeting Summaries: Meeting minutes will be created to capture the information gathered during each HPV Vaccine WG meeting and teleconference.
10. Workgroup findings: The HPV Vaccine WG will present findings (briefing documents, background materials, presentations) to the ACIP parent committee for consideration and deliberation in a public meeting. Final versions of all slides presented at the ACIP parent committee meeting will be posted on the ACIP website following the meeting and included in the committee's official records.
11. Workgroup Record Keeping: All CDC FACA committees, subcommittees, and WGs are subject to the Federal Records Act. All records will be uploaded in the Federal Advisory Committee Management Portal. The summary report of WG meeting activities and other WG documents will become part of the ACIP's official records as required by GENERAL RECORDS SCHEDULE 6.2: Federal Advisory Committee Records.

RECORDKEEPING and REPORTING

The WG Chair and WGL, WG members and other experts will present findings/outcomes/observations to the ACIP parent committee for discussion, deliberations, further development of recommendations, and vote in an open public forum. Approved ACIP recommendations adopted by the CDC Director will be posted on CDC's ACIP website and also published in the Morbidity and Mortality Weekly Report (MMWR). In addition, approved ACIP recommendations will be included in the ACIP meeting minutes and annual report.