

**Advisory Committee on Immunization Practices (ACIP),
Centers for Disease Control and Prevention (CDC)
Childhood and Adolescent Immunization Schedule Workgroup
Terms of Reference
UPDATED: October 8, 2025**

PURPOSE

This document defines the activities, membership, and administrative requirements associated with the establishment of a **Childhood and Adolescent Immunization Schedule Workgroup** under the Advisory Committee on Immunization Practices (ACIP), Centers for Disease Control and Prevention (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 ACIP utilizes subgroups of the Committee, known as Workgroups (WGs), to review relevant published and unpublished data, and clinical and scientific knowledge, and develop options for presentation to the full ACIP parent committee during its public meetings to facilitate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 to the CDC Director. 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, and by the need for expert input to inform development of CDC immunization policy. ACIP WGs are task oriented and convene in response to specific policy needs. WGs serve a key role in providing expertise for the use of immunizations in support of the full committee deliberations and recommendations. Each WG operates under specific terms of reference and disbands when current WG activities are completed. The Childhood and Adolescent Immunization Schedule WG has been specifically established to review data, as well as clinical and scientific knowledge related to the childhood and adolescent immunization schedule to help develop childhood and adolescent immunization schedule policy options for ACIP consideration to formulate recommendations to the Director of the CDC.

For the purposes of this document, immunization refers to vaccines and other antibody protective products, to prevent disease, e.g., immunoglobulins.

BACKGROUND

While many vaccines are universally recommended worldwide, different countries have different vaccine schedules for a variety of reasons, both in terms of the collection of vaccines given and the timing and order of the vaccines. These reasons can include implementation considerations (differences in healthcare systems, and variance in practices related to pediatric medicine practice) and concerns about vaccine safety and adverse events. As part of ACIP's core mission to develop recommendations on the use of vaccines in the civilian population of the United States, the committee is standing up a WG focused on assessing the safety and effectiveness of the childhood and adolescent schedule. The rationale for this WG includes considerations such as the use of new vaccine technologies and ingredients, and the rise of vaccine hesitancy. These

activities should not only be based on past research but also future vaccine studies. If such studies reveal unexpected but scientifically validated concerns, the schedule should be adjusted accordingly.

In 2002, the Institute of Medicine (IOM), now the National Academy of Medicine, published Immunization Safety Review: Multiple Immunizations and Immune Dysfunction¹ and noted that:

“The committee was unable to address the concern of some that repeated exposure of a susceptible or fragile child to multiple vaccines over the developmental period may also produce atypical or nonspecific immune or nervous system injury that could lead to severe disability or death...There are no epidemiological studies that address this, either in terms of exposure or outcome. That is, there is no study that compares an unvaccinated control group with children exposed to the complete immunization schedule, or are there any studies that looked at health outcomes other than those classically defined, such as infections, allergy, or diabetes. Thus the committee recognizes with some discomfort that this report addresses only part of the overall set of concerns of some who are most wary about the safety of childhood vaccines.” (page 36)

The report also noted that one-quarter of parents expressed concern about the number of immunizations children were receiving and concluded that,

“Concern about multiple immunizations has been, and could continue to be, of societal significance in terms of parental worries, potential health burdens, and future challenges for immunization policy making.” (pages 104-105)

Over a decade later, in 2013, the IOM published The Childhood Immunization Schedule and Safety: Stakeholder Concerns, Scientific Evidence, and Future Studies,² the report of an expert committee that had been tasked with reviewing “scientific findings and stakeholder concerns related to the safety of the recommended childhood immunization schedule,” and identifying “potential research approaches, methodologies, and study designs that could inform this question, including an assessment of the potential strengths and limitations of each approach, methodology and design, as well as the financial and ethical feasibility of doing them.” (page 3) The committee noted:

“Few studies have comprehensively assessed the association between the entire immunization schedule or variations in the overall schedule and categories of health outcomes, and no study has directly.”...“Studies designed to examine the long-term effects of the cumulative number of vaccines or other aspects of the immunization schedule have not been conducted. Nevertheless, and its literature review, the committee found useful designs for studies to measure exposures and outcomes and identified strategies for expanding or adapting conventional study designs to clearly address whether any adverse health outcomes are associated with the overall immunization schedule.” (page 5-6)

To assess the feasibility of studying the vaccine schedule, the IOM solicited a report from Dr. Martin Kulldorff, a biostatistician and epidemiologist at Harvard Medical School. He concluded that *“a wide variety of different vaccine schedule components can be studied”*, including *“the timing of individual vaccines, the timing between doses of the same vaccine, the interaction effect between vaccines and concurrent health conditions or pharmaceutical medications, the interaction effects of different vaccines given on the same day, the ordering of different vaccines, and the effect of cumulative summary metrics such as the total number of vaccines or the total amount of some vaccine ingredient”*. He also outlined possible *“study designs for the comparative evaluation of one or more complete schedules”*, considering methods *“both for adverse events with an early onset, which are the easiest to study, and for adverse events with a late onset, including serious chronic conditions”*.

A recommendation of the IOM committee was:

“that the Department of Health and Human Services incorporate study of the safety of the overall childhood immunization schedule into its processes for setting priorities for research, recognizing stakeholder concerns, and establishing the priorities on the basis of epidemiological evidence, biological plausibility, and feasibility.” (page 132)

In accordance with the ACIP Charter, the Childhood and Adolescent Immunization Schedule WG and its members will prepare information for the ACIP members to enable them to make recommendations that consider:

- The timing and order of different vaccines.
- The concurrent administration of various vaccines.
- The safety of ingredients that are present in multiple different vaccines.
- The efficacy and safety of different vaccine schedules used in different countries.
- Implementation considerations, including burden on healthcare and payor systems, economic impact, and acceptability and feasibility with input from pediatric healthcare providers and parents.

The WG will also consider these issues for particular subgroups of children, such as children born pre-maturely, children with immune deficiencies, or children with cancer.

The WG will engage external subject matter experts, as needed, to support implementation of key activities.

TOPICS UNDER DISCUSSION BY THE WORKGROUP

In accordance with the ACIP Charter and in a multi-year effort, the Childhood and Adolescent Immunization Schedule WG members will work with expert consultants as appropriate and in accordance with FACA statutory requirements and policies, to prepare information for the ACIP members to enable them to make recommendations on:

- The timing and order of different vaccines. For example, should the last toddler dose of the non-live DTaP vaccine be given before, on the same day, or after the MMR vaccine?
- The concurrent administration of various vaccines and other immunizing products such as monoclonal antibodies. For example, does the risk of post-vaccination febrile seizures increase or decrease with concomitant administration?
- The safety of ingredients that are present in multiple different vaccines. For example, do either of the two different aluminum adjuvants increase the risk of asthma?
- The efficacy and safety of different vaccine schedules used in different countries. For example, are there differences in efficacy or safety between the U.S. and Danish childhood vaccine schedules?

DESCRIPTION OF WORKGROUP ACTIVITIES

The following activities provide a framework for the Childhood and Adolescent Immunization Schedule WG multi-year efforts, which may involve data requests from other Federal and non-Federal entities: Review and summarize existing knowledge from published and unpublished research and safety surveillance systems. This work may include the following three multi-faceted tasks, which may be completed in sequence or in parallel:

- Identify gaps in and collaborate accordingly to address new research studies that ascertain important aspects of the vaccine schedule, particularly from CDC's Vaccine Safety Datalink (VSD), from Food and Drug Administration's Biologics Efficacy and Safety System (BEST), and the National Institutes of Health through their extramural grant awards program.
- Based on the highest quality studies, determine whether a change in the vaccine schedule may be warranted, outline various options, and vote on which option to recommend to the full ACIP for consideration.
- Communicate the deliberations and recommendations to the full ACIP, for them to review and vote on. Together with the WG majority views, minority views will also be communicated to the full ACIP, with rationales for the different opinions.

MEMBERSHIP

Workgroup Leadership: The Childhood and Adolescent Immunization Schedule WG is chaired by one of the ACIP members appointed to serve as a Special Government Employee. The Workgroup Lead (WGL) is a WG designated federal employee (DFO), identified by the Immediate Office of the Director (IOD) in consultation with the appropriate CDC program. The WG Chair, in consultation with the WGL, ACIP DFO,

and CDC IOD, determines the WG's membership and work priorities and deliverables to the full ACIP committee.

Workgroup Membership: The Childhood and Adolescent Immunization Schedule WG is composed of experts from a variety of disciplines 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 persons in their profession, or occupation. Upon request, HHS federal agencies named in the ACIP charter may also appoint members to serve on WGs. The 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 adolescents;
- Clinical and medical practice, and patient-care experience;
- Epidemiology;
- Biostatistics
- Molecular biology;
- Immunology;
- Virology;
- Toxicology
- Drug and vaccine safety; 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 WG and answer questions during Childhood and Adolescent Immunization Schedule WG meetings on an ad hoc basis. Such additional external subject matter experts will not be members of the WG and will not participate in any deliberations or WG discussions.

MEETINGS, ADMINISTRATION, and TIMELINES

1. Administrative Oversight: The WGL will work with the WG Chair to arrange meetings, document meeting proceedings, and report to the ACIP on the Childhood and Adolescent Immunization Schedule WG's activities and findings.
2. Meeting frequency and location: The Childhood and Adolescent Immunization Schedule WG will meet on an as needed basis as determined by the WG Chair and WGL. All Childhood and Adolescent Immunization Schedule WG meetings are convened virtually via teleconference.
3. Meeting structure: In addition to the WGL, at least two ACIP Special Government Employee members (one of whom serves as the Childhood and Adolescent

Immunization Schedule 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 before each meeting.

4. Conflicts of Interest: WG members will complete an ACIP WG Agreement and Conflict of Interest Certification process prior to participation on the WG. The WGL or designee will screen for conflict of interest declarations and share any conflicts with the ACIP DFO. The ACIP DFO in collaboration with the WGL will work with the CDC Ethics and Integrity Office within the Office of Strategic Business Initiatives (OSBI) and the Office of General Counsel (OGC), as needed, to resolve any conflicts. WG members will consent to abide by several 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 Childhood and Adolescent Immunization Schedule WG participation. Members will also disclose any potential conflicts of interest before each meeting. If a Childhood and Adolescent Immunization Schedule WG member indicates a potential or actual conflict of interest to the WGL, the WGL or a delegate will review and bring up any conflicts to the ACIP DFO to determine whether the individual must recuse themselves from participating in WG discussions that implicate such a conflict-of-interest concern. If needed, the ACIP DFO will engage OSBI and OGC to assist with making COI determination.
5. Confidentiality: The discussions of the Childhood and Adolescent Immunization Schedule WG may include information that is unpublished, protected, privileged, or confidential. WG deliberations, including, as appropriate, policy options under consideration by the 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 meetings, which are open to the public, Childhood and Adolescent Immunization Schedule 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 Childhood and Adolescent Immunization Schedule WG members.
6. CDC Staff Involvement: CDC staff do not serve as members of the Childhood and Adolescent Immunization Schedule WG but may provide administrative support and technical expertise to ACIP WGs, bringing subject matter expertise and current professional focus in areas relevant to the goals of the Childhood and Adolescent Immunization Schedule 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 DFO and WGL of Childhood and Adolescent Immunization Schedule WG, in consultation with the WG Chair of the Childhood and Adolescent Immunization Schedule 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. Workgroup Meeting Summaries: Meeting minutes will be created by the WGL or WGL's delegate to capture the information gathered during each Childhood and Adolescent Immunization Schedule WG meeting and teleconference.
9. Workgroup findings: The Childhood and Adolescent Immunization Schedule WG will present findings (briefing documents, background materials, presentations) to ACIP for consideration and deliberation in a public meeting. Final versions of all slides presented at the ACIP meeting will be posted on the ACIP website following the meeting and included in the committee's official records.
10. 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 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. WGL or the WGL's delegate is responsible for ensuring WG record keeping.

RECORDKEEPING and REPORTING

The WG Chair and/or WGL will present findings / outcomes / observations / recommendations 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 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.

REFERENCES

1. *Immunization Safety Review: Multiple Immunizations and Immune Dysfunction*. National Academies Press; 2002. doi:10.17226/10306
2. *The Childhood Immunization Schedule and Safety: Stakeholder Concerns, Scientific Evidence, and Future Studies*. National Academies Press; 2013. doi:10.17226/13563