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## The Advisory Committee on Immunization Practices (ACIP)

The Advisory Committee on Immunization Practices (ACIP) is a committee of nonfederal experts who make recommendations to the Department of Health and Human Services (HHS) regarding the use of vaccines and related agents for the control of vaccine-preventable disease in the U.S. civilian population. As a critical function, ACIP recommendations inform the Centers for Disease Control and Prevention's (CDC's) annual immunization schedules of recommended vaccines for both children and adolescents (18 years of age and younger) and adults (19 years of age and older). ACIP may also make recommendations regarding nonroutine vaccines, including for travel or for use in emergency situations such as the Coronavirus Disease 2019 (COVID-19) pandemic or mpox outbreaks.

### ACIP Establishment and History

The Surgeon General established ACIP in March 1964 under Section 222 of the Public Health Service Act (PHSA; 42 U.S.C. §217a), a general authority that allows the HHS Secretary to convene advisory committees. ACIP was created to provide ongoing expert advice to the Secretary on federal immunization policy in response to expanded federal immunization programs and the licensure of several new vaccines. In 1972, ACIP was designated a federal advisory committee under the Federal Advisory Committee Act (FACA, P.L. 92-463; provisions of FACA have moved to 5 U.S.C. Chapter 10).

### Overview

Today, ACIP provides recommendations to CDC, a leading federal agency for immunization programs. The committee remains authorized under general authority and is governed by its official charter per FACA requirements. However, under several federal laws, ACIP and its recommendations play a role in defining the relevant statutory requirements (as explained in the “Statutory Roles” section.)

### Structure and Membership

Per its charter, ACIP can consist of up to 19 voting members who have clinical, scientific, and public health expertise in immunization. One lay member is a consumer representative with knowledge about social and community aspects of immunization programs. In addition, several federal health officials and representatives from national health organizations (e.g., American Academy of Pediatrics) serve as nonvoting representatives.

Voting members are appointed by the HHS Secretary and serve overlapping terms of up to four years. Anyone can apply to become a member, with selection based on meeting certain qualifications. Per HHS policy, the department seeks to balance committee membership in terms of points of view, professional training, and backgrounds.

### Recommendation Process and Criteria

ACIP recommendations regarding vaccines and their use are related to, but distinct from, the U.S. Food and Drug Administration's (FDA's) licensure or authorization of vaccines. Per its charter, ACIP recommendations are focused on the control of vaccine-preventable diseases, whereas FDA generally focuses its review on the safety and efficacy of vaccines and the processes used to manufacture them. ACIP typically makes its recommendations after FDA has approved or authorized a new vaccine (or an existing vaccine for a new indication). Per a requirement added by the 21<sup>st</sup> Century Cures Act of 2016 (Cures Act; P.L. 114-255, §3091), ACIP must consider any newly licensed vaccine (or new indication) at the committee's next regularly scheduled meeting. In addition, ACIP may also make recommendations regarding other medical products (e.g., antimicrobial therapy) shown to be effective against a disease for which a vaccine is available.

In its review and recommendation process, ACIP weighs whether the benefits of recommending a certain vaccine for a certain population—including the impact of such a recommendation on disease transmission or reduction in disease, hospitalizations, and deaths—outweigh any possible harms at an individual or population level. Harms could include, for example, considerations around vaccine safety (individual level) or disease distribution within the population (population level). ACIP also considers the potential public health importance, quality of the evidence used, implementation considerations, equity, and values and preferences of the people affected. In a few cases, ACIP's recommendations have differed from FDA-approved indications for use, resulting in recommendations for “off-label” use of vaccines.

ACIP recommendations can be informed by the FDA-approved vaccine label, published and unpublished clinical data from the vaccine manufacturer, and other independent studies. ACIP follows the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach for determining the quality and strength of evidence for recommendations. The GRADE approach is commonly used for formulating health recommendations in the United States and around the world.

ACIP holds full-committee public meetings at least three times per year to review evidence and vote on new recommendations. Outside these meetings, ACIP members serve on work groups to review evidence regarding specific vaccines on an ongoing basis. ACIP work groups can solicit and consider public comments. ACIP work groups present evidence reviews and draft recommendations to the full committee for consideration. Final recommendations must receive a vote from a majority of the committee.

## Recommendation Types

ACIP structures its recommendations to inform clinical and public health practice. ACIP recommendations include (1) the age and other population groups (e.g., by sex, occupation) recommended to receive that vaccine; (2) the recommended age or frequency to receive each dose and the interval between doses (for multidose vaccines); and (3) any precautions and contraindications. Some ACIP recommendations are made for all people in a certain age group, whereas others are risk-based or targeted to specific patients in specific circumstances (e.g., travel vaccines). ACIP recommendations are also made in two categories:

- **Standard Recommendation:** Vaccination recommendations are made for all people in an age or risk-based group.
- **Shared Clinical Decisionmaking:** Vaccination should be based on shared clinical decisionmaking between providers and patients.

ACIP may revise its previous recommendations based on new evidence or new circumstances, such as disease outbreaks or vaccine shortages. Some ACIP recommendations are issued as “interim” recommendations, meaning that they may be subject to change.

## Agency Adoption of Recommendations

ACIP’s recommendations are not automatically adopted as official federal recommendations. The CDC Director reviews and decides whether to formally adopt ACIP’s recommendations. Official recommendations are published in the CDC *Morbidity and Mortality Weekly Report*. In emergency situations, CDC may issue a vaccine recommendation without consultation from ACIP.

## Immunization Schedules

ACIP votes on the entire child and adult immunization schedules once per year, which compiles recommendations ACIP already made that year. The immunization schedules provide a structured reference for clinicians on the recommended ages and dosing schedules for vaccines, along with any contraindications or precautions. The current immunization schedules adopted by CDC represent a harmonized set of recommendations made by ACIP and other medical associations, such as the American Academy of Pediatrics and American Academy of Family Physicians. Vaccines listed on the immunization schedules are considered recommended for routine use.

## Emergency Recommendations

ACIP may make recommendations for the use of vaccines in emergency situations, such as the COVID-19 pandemic. As required by the Cures Act (P.L. 114-255, §3091), ACIP is to make recommendations “in a timely manner, as appropriate” for vaccines that could be used in a public health emergency. During the pandemic, ACIP made two types of recommendations. First, ACIP made recommendations regarding the *use* of vaccines and dosing by age group following FDA authorizations or approvals. Second, in the early stages of the vaccine distribution program, ACIP made recommendations regarding the *allocation* of vaccines, specifically priority groups to receive the limited supply of vaccines. For example, in

December 2020, ACIP recommended that health care personnel and residents of long-term care facilities be the first to receive COVID-19 vaccines. Again, these were recommendations; some states set their own priority groups.

## Statutory Roles

Some laws, such as the Cures Act (P.L. 114-255), have addressed ACIP and its recommendation process. In addition, ACIP’s recommendations play a role in defining some statutory requirements, including the following:

- **Vaccines for Children (VFC):** Under Social Security Act Section 1928 (42 U.S.C. §1396s) ACIP is tasked with developing the list of vaccines covered under the VFC program, which provides vaccines at no cost to eligible children.
- **Health care coverage:** Several laws reference ACIP recommendations in the context of health care coverage requirements, including for private health insurance (PHSA Section 2713; 42 U.S.C. §300gg–13), and more recently for Medicare Part D, Medicaid, and the State Children’s Health Insurance Coverage Program as added by P.L. 117-169, “The Inflation Reduction Act.” See CRS Report R47396, *Health Care Provisions of the Budget Reconciliation Measure P.L. 117-169*.
- **Immigration:** The Immigration and Nationality Act Section 212 (8 U.S.C. §1182) makes certain foreign nationals inadmissible to the United States if, among other things, they cannot demonstrate that they have received certain vaccinations as recommended by ACIP. CDC determines which ACIP-recommended vaccines are required, reflected in its technical instructions.
- **Vaccine Injury Compensation Program (VICP):** Under PHSA Section 2114 (42 U.S.C. §300aa-14), when the CDC recommends a vaccine for routine administration to children and pregnant women, the Secretary must add it to the table of covered vaccines under VICP, a no-fault system to compensate individuals injured as a result of a covered vaccine. While not specifically mentioned in the statute, ACIP informs CDC recommendations. A CDC recommendation alone does not guarantee compensation under VICP for a certain vaccine. Other actions are required, including addition of that vaccine type to the list of taxable vaccines under 26 U.S.C. §4131.

## Immunization Requirements

ACIP recommendations are simply that: *recommendations*. They are not *requirements*. Immunization requirements are primarily imposed by state law on specified populations, such as students. There are some federal requirements for limited populations, such as for military personnel and immigrants. Some state laws and regulations direct state health agencies to consider ACIP recommendations when determining school requirements. No state, however, automatically incorporates new ACIP-recommended vaccines into their immunization requirements.

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