

# Immunization Policy Development in the United States: The Role of the Advisory Committee on Immunization Practices

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The Advisory Committee on Immunization Practices (ACIP) consists of 15 experts in immunization and related fields, selected by the Secretary of the U.S. Department of Health and Human Services, to provide advice and guidance on control of vaccine-preventable diseases. In its role as a federal advisory committee, the ACIP develops written recommendations, subject to approval of the Director of the Centers for Disease Control and Prevention, for administration of U.S. Food and Drug Administration–licensed vaccines to children, adolescents, and adults in the U.S. civilian population. On the basis of careful review of available scientific data, including disease morbidity and mortality in the general U.S. population and in specific risk groups, vaccine safety and efficacy, cost-effectiveness, and related factors, the ACIP recommends vac-

cines and age for vaccine administration, number of doses and dosing interval, and precautions and contraindications. The ACIP works closely with several liaison organizations, including the American College of Physicians, to develop immunization recommendations that are harmonized among key professional medical organizations in the United States. This report includes a description of the member composition of the ACIP, the degree to which Committee members are screened for conflicts of interest, the workgroups that gather information before full Committee consideration, and the process and types of evidence used to formulate recommendations.

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In the United States, development of immunization policy is accomplished through interactions among federal and state government agencies, professional medical societies, and other organizations. This coordinated effort results in development and implementation of immunization recommendations for infants, children, adolescents, and adults.

## ROLE OF THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES

Recommendations for routine use of vaccines in adults are issued by the Centers for Disease Control and Prevention (CDC) and are harmonized to the greatest extent possible with recommendations made by the American College of Gynecologists and Obstetricians, the American Academy of Family Physicians, and the American College of Physicians. The Advisory Committee on Immunization Practices (ACIP), established in 1964 by the Surgeon General of the U.S. Public Health Service, is chartered as a federal advisory committee to provide expert external advice and guidance to the Director of the CDC and the Secretary of the U.S. Department of Health and Human Services (DHHS) on use of vaccines in the civilian population (1–3). The ACIP makes policy recommendations for vaccines and related agents that are licensed by the U.S. Food and Drug Administration (FDA) for prevention of diseases; guidance for use of unlicensed vaccines may be developed if circumstances warrant it (Figure).

In recent years, the number of vaccines licensed for routine use in the United States has increased, and the role of the ACIP in development of national immunization policy has become more visible (Table 1). This article describes the structure and function of the ACIP, outlines the process by which ACIP members develop and vote on im-

munization recommendations, and reviews how these recommendations apply to adult populations.

## STRUCTURE OF THE ACIP

The ACIP consists of 15 voting members: a chair, a consumer representative, and 13 members with expertise in specific disciplines. Membership selection criteria include expertise in vaccinology; immunology; pediatrics; internal medicine; infectious diseases; preventive medicine; public health; or, in the case of the consumer representative, consumer perspectives or social and community aspects of immunization programs. Members, who must be U.S. citizens and cannot be employed by the U.S. government, are appointed to 4-year, overlapping terms by the Secretary of the DHHS. Efforts are made to ensure that the voting membership is balanced on the basis of geography, race and ethnicity, sex, and such other relevant factors as expertise. In addition to the 15 voting members, the Committee includes 8 ex officio members representing federal agencies and 26 nonvoting representatives of liaison organizations with broad responsibilities for vaccine development, administration of vaccines to various segments of the population, and operation of immunization programs (Table 2). Appointment of liaison organizations is approved by the Secretary of the DHHS. Individuals and liaison organiza-

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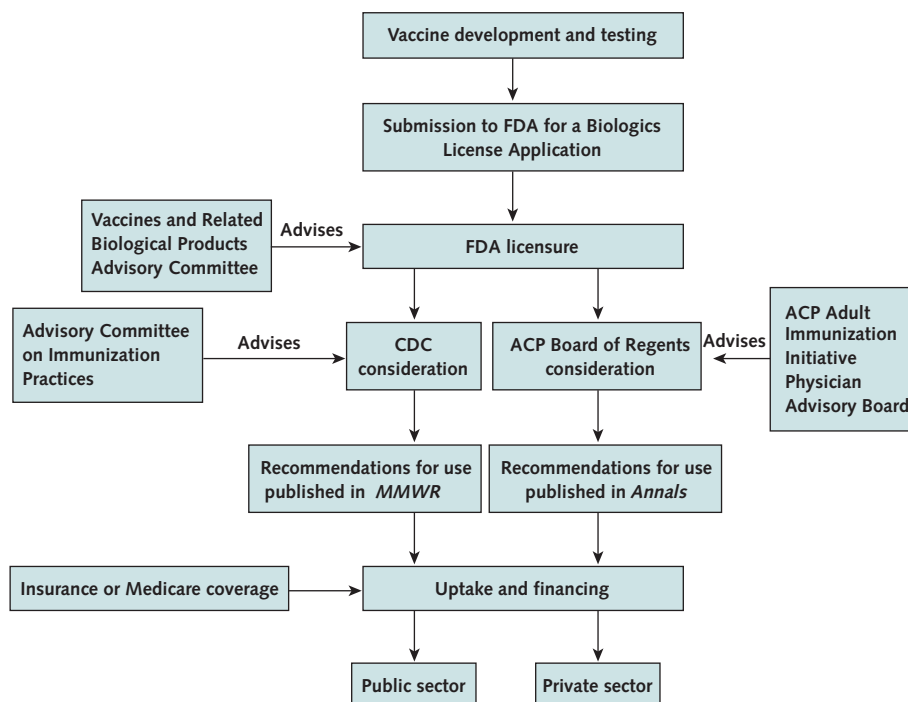
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**Figure. Development and dissemination of vaccine recommendations and policies.**

In parallel to the process followed by the American College of Physicians, the Committee on Infectious Diseases of the American Academy of Pediatrics makes recommendations to the American Academy of Pediatrics Board of Directors on immunization recommendations for infants, children, and adolescents. Harmonization of recommendations with the Advisory Committee on Immunization Practices (CDC) is optimized at several levels, including annual publication of the joint Recommended Immunization Schedule for Persons 0 Through 18 Years of Age. ACP = American College of Physicians; CDC = Centers for Disease Control and Prevention; FDA = U.S. Food and Drug Administration; MMWR = *Morbidity and Mortality Weekly Report*.

tions may apply for membership directly, but they are encouraged to submit applications to the ACIP Executive Secretary according to procedures detailed on the ACIP Web site ([www.cdc.gov/vaccines/recs/acip/](http://www.cdc.gov/vaccines/recs/acip/)). A formal process of review is performed by the ACIP Steering Committee, which comprises members of CDC divisions working in vaccine-related areas, a representative of the FDA, and the ACIP Chair. Recommendations for nominees (2 candidates for each vacant position) are forwarded to the CDC Director for review and are then forwarded with supporting documents to the Secretary of the DHHS, who makes the final selection of ACIP members. The complete membership roster is available on the ACIP Web site.

### CONFLICTS OF INTEREST

Given the substantial financial implications that ACIP recommendations may have for the public and private sectors, as well as for vaccine manufacturers, candidates who are nominated for ACIP membership undergo careful screening for potential conflicts of interest before their names are submitted for final consideration. To ensure integrity of the ACIP, all nominees are reviewed by the ACIP Steering Committee. Stringent measures are taken to assure that there is not only technical compliance with ethics

statutes and regulations regarding financial conflicts but also that more general concerns regarding potential for appearance of a conflict of interest are addressed or avoided altogether through both pre- and postappointment considerations. People with specific vaccine-related interests at the time of application are not considered for appointment to the Committee. Examples of such interests include direct employment of the candidate or an immediate family member by a vaccine manufacturer or its parent company, serving on a board of a vaccine manufacturer, and holding a patent on a vaccine or related product. Potential ACIP members are asked before submission of their names for final selection to recuse themselves during the term of membership from activities that are, or could be construed as, conflicts of interest. These activities include provision of advisory or consulting services to a vaccine manufacturer or its parent company and acceptance of honoraria or travel reimbursement from a vaccine manufacturer. Once accepted for membership, ACIP members are required every year to file confidential financial reports with the Office of Government Ethics and to disclose publicly all vaccine-related interests and work, including participation in clinical trials, at each meeting. If, despite all these safeguards, a conflict exists, limited waivers allow members to partici-

pate in committee discussions with the condition that they are prohibited from voting on matters involving the specific or competing vaccine manufacturers. A member who develops an important conflict of interest during the 4-year term will be required to resign from the ACIP.

Screening for conflicts of interest is rigorous and balances the possibility of bias caused by a conflict with the need for vaccine and immunization expertise, including cross-cutting knowledge and experience in the various components of the immunization field. Some data important to the committee can be obtained only through working relationships with vaccine manufacturers. Representatives of vaccine manufacturers may present data on vaccine immunogenicity, effectiveness, and safety to ACIP workgroups and at meetings of the full ACIP, but they are not permitted to serve as members of workgroups, or have any input into ACIP deliberations.

## PROCESS FOR DEVELOPMENT OF RECOMMENDATIONS

### Workgroups

Committee workgroups are formed as a resource for gathering, analyzing, and preparing information for presentation to the Committee. Workgroups must be chaired by an ACIP member and must include at least 2 ACIP members and a CDC subject-matter expert. Other workgroup members include relevant ex officio members, liaison representatives, members of academia, and invited consultants as required. Vaccine manufacturer representatives may not serve as workgroup members. Workgroups meet throughout the year to do in-depth reviews of vaccine-related data and to develop options for policy recommendations for presentation to the Committee. Four ACIP workgroups are permanent, and the remaining workgroups, which typically focus on 1 vaccine or a group of vaccines, are established and then disbanded as appropriate (Table 3). All workgroup findings and options are presented to the ACIP in an open meeting, and this information is deliberated until members reach a majority decision. A recommendation, when voted on and approved by a majority of voting ACIP members, includes guidance on target groups for immunization, route of administration and dosing intervals, and precautions and contraindications.

To formulate policy recommendations, the ACIP reviews many factors, including morbidity and mortality associated with the disease in the general U.S. population and in specific risk groups; available scientific literature (both published and unpublished) on the safety, efficacy, effectiveness, cost-effectiveness, and acceptability of the immunizing agent, with consideration of the relevant quality and quantity of published and unpublished data; clinical trial results and use information provided in the manufacturer's labeling or package insert; recommendations of other professional liaison organizations; and the feasibility of incorporating the vaccine into existing domestic immunization programs. Recommendations of the ACIP may be

developed and issued jointly with nongovernmental professional organizations or other public health service advisory committees. Examples of joint recommendations include the Adult Immunization Schedule (issued jointly by the American College of Physicians, American Academy of Family Physicians, American College of Obstetricians and Gynecologists, and CDC) and Immunization of Health-Care Workers (issued jointly by the ACIP and the Healthcare Infection Control Practices Advisory Committee).

### Factors and Evidence Considered in Immunization Policy Development

When data permit, specific rules of evidence, such as those followed by the U.S. Preventive Services Task Force, are used to judge the quality of data and make decisions regarding the nature and strength of recommendations. In the absence of data or when data are inadequate, expert opinions of voting members and other experts are used to make recommendations. Depending on the relative importance of the issue, either formal (for example, Delphi, nominal group techniques) or informal methods for soliciting expert opinions are used. Published statements of the ACIP explicitly describe the methods used for developing recommendations and provide the evidence used to develop the recommendations (for example, results of controlled trials, case-control studies, case series, expert opinion, meta-analyses, Delphi surveys, focus groups, cost-effectiveness analyses, and other inputs). The

**Table 1. Licensed Vaccines in Routine Use in the United States, 1980 and 2008**

#### FDA-licensed vaccines in routine use in 1980

Diphtheria  
Tetanus  
Pertussis  
Polio  
Measles  
Mumps  
Rubella  
Influenza  
Pneumococcal

#### FDA-licensed vaccines in routine use in 2008

Diphtheria  
Tetanus  
Pertussis  
Polio  
Measles  
Mumps  
Rubella  
Influenza  
Pneumococcal  
*Haemophilus influenzae* type b  
Hepatitis A  
Hepatitis B  
Herpes zoster (shingles)  
Human papillomavirus  
Meningococcal  
Rotavirus  
Varicella

FDA = U.S. Food and Drug Administration.

**Table 2. Ex Officio Members and Liaison Organizations of the Advisory Committee on Immunization Practices****Ex officio members**

Centers for Medicaid & Medicare Services (CMS)  
 Department of Defense (DOD)  
 Department of Veterans Affairs (DVA)  
 U.S. Food and Drug Administration (FDA)  
 Health Resources and Services Administration (HRSA)  
 Indian Health Service (IHS)  
 National Vaccine Program Office (NVPO)  
 National Institutes of Health (NIH)

**Liaison organizations**

American Academy of Family Physicians (AAFP)  
 American Academy of Pediatrics (AAP)  
 American College Health Association (ACHA)  
 American Geriatrics Society (AGS)  
 America's Health Insurance Plans (AHIP)  
 American College of Obstetricians and Gynecologists (ACOG)  
 American College of Physicians (ACP)  
 American Medical Association (AMA)  
 American Osteopathic Association (AOA)  
 American Pharmacists Association (APhA)  
 Association of Teachers of Preventive Medicine (ATPM)  
 Biotechnology Industry Organization (BIO)  
 Canadian National Advisory Committee on Immunization (NACI)  
 Council of State and Territorial Epidemiologists (CSTE)  
 Department of Health, United Kingdom  
 Healthcare Infection Control Practices Advisory Committee (HICPAC)  
 Infectious Diseases Society of America (IDSA)  
 National Association of County and City Health Officials (NACCHO)  
 National Association of Pediatric Nurse Practitioners (NAPNAP)  
 National Foundation for Infectious Diseases (NFID)  
 National Immunization Council and Child Health Program (Mexico)  
 National Medical Association (NMA)  
 National Vaccine Advisory Committee (NVAC)  
 Pharmaceutical Research and Manufacturers of America (PhRMA)  
 Society for Adolescent Medicine (SAM)  
 Society for Healthcare Epidemiology of America (SHEA)

ACIP Evidence Based Recommendations Workgroup is in the process of developing a standardized and more explicit process for characterizing quality of evidence in immunization recommendation development. The workgroup anticipates that the recommended methods will be presented and finalized in early 2009 and will be applied in preparation of all new statements.

Published and unpublished economic analyses relevant to vaccine recommendations routinely are reviewed and presented to the ACIP. In June 2007, the ACIP adopted a mandatory internal peer-review process, initiated at the June 2008 ACIP meeting, whereby all economic analyses are reviewed by a CDC health economist or other qualified economist before presentation to the ACIP (4). The reviewing economist evaluates the description and presentation of methods used to examine the economics of a vaccine-related issue to ensure that economic data presented to the Committee and its workgroups are uniform in presentation, are understandable, and are of high quality. The ACIP does not use a "cutoff" to determine whether a vaccine is considered to be cost-effective. Cost-effectiveness is

only 1 factor considered in development of immunization recommendations.

After formulation by the relevant workgroup, draft recommendations are subjected to further extensive review by staff of the CDC, FDA, other relevant federal agencies, ACIP members, liaison members, and external expert consultants. Workgroup members or ACIP members may identify a need for additional data, corrections in data content, and modifications of the interpretation of the data, and members may critique and challenge expert opinions. Public comments also are solicited during each ACIP meeting and are considered in the decision-making process. These inputs are synthesized by the workgroup in an iterative process, and options are presented to the ACIP for final consideration and vote.

**ACIP Meetings**

Regularly scheduled ACIP meetings are held 3 times per year. Meetings must be conducted according to requirements of the Federal Advisory Committee Act of 1972, which stipulates that meetings be announced in the *Federal Register* at least 15 days before the meeting date, that members of the public be permitted to attend meetings and to speak or file written statements, and that meeting minutes be maintained and made available to the public in a timely fashion. Meetings are convened at the Global Communications Center at the CDC, and meeting dates are posted 4 years in advance ([www.cdc.gov/vaccines/recs/acip/meetings.htm](http://www.cdc.gov/vaccines/recs/acip/meetings.htm)). United States citizens may register online up to 2 weeks before the meeting date and non-U.S. citizens up to 3 weeks before. As required by the Federal Advisory Committee Act, meeting minutes are posted on the ACIP Web site within 90 days of each ACIP meeting. Topics for inclusion in meetings are solicited from CDC subject-matter experts; ACIP members, including ex officio members and liaisons; academic consultants; and ACIP workgroup members. Meeting topics may in-

**Table 3. Advisory Committee on Immunization Practices Workgroups\*****Permanent workgroups**

Adult Immunization Schedule  
 Childhood/Adolescent ("Harmonized") Immunization Schedule  
 General Recommendations  
 Influenza Vaccines

**Task-oriented workgroups**

Anthrax Vaccine  
 Evidence Based Recommendations  
 Hepatitis Vaccines  
 Human Papillomavirus Vaccines  
 Japanese Encephalitis Vaccines  
 Measles–Mumps–Rubella–Varicella Vaccine Safety  
 Meningococcal Vaccines  
 Pneumococcal Vaccines  
 Rabies Vaccine  
 Yellow Fever Vaccine

\* As of November 2008.



clude items that do not require a vote but are presented for informational purposes. These topics may include data on vaccine-preventable disease epidemiology; vaccine efficacy, safety, effectiveness, or cost-effectiveness; data on a vaccine that is in development; information on vaccines that are newly licensed by the FDA for a decision on policy recommendations by ACIP members; or updates on outbreaks of vaccine-preventable diseases, changes in vaccine supply, or safety data on existing vaccines.

### Development of the Adult Immunization Schedule

One of the permanent workgroups of the ACIP is the Adult Immunization Schedule Workgroup. This workgroup meets monthly to discuss components of the adult immunization schedule, which is updated annually and published in January simultaneously in *Annals of Internal Medicine*, *American Family Physician*, and *Morbidity and Mortality Weekly Report*. As new vaccines are licensed for use in adults and subsequently recommended by the ACIP, they are incorporated into the adult immunization schedule. Changes in recommendations also are included as new data and FDA licensing regulations become available for specific vaccines—for example, an expansion in the target age range or new safety data that would lead to a change in a recommendation. In the past 2 years, new vaccines have been licensed for use in adults and included in the schedule (herpes zoster [shingles]; human papillomavirus; and combined tetanus, diphtheria, pertussis vaccine). New recommendations have been issued for several older vaccines, including influenza, mumps, varicella, and hepatitis A, and meningococcal conjugate vaccine for adults with risk factors for disease (5). In the coming years, additional new, safe, and effective vaccines may become available that would be considered for inclusion in the adult schedule: for example, pneumococcal conjugate vaccines (6).

### THE ROLE OF THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES: LOOKING TO THE FUTURE

Vaccines are among the most effective public health measures for prevention of disease and disability (7). The ACIP will continue to focus on development of policy recommendations for use of new vaccines and changes in recommendations for existing vaccines, in addition to ongoing review of vaccine safety, vaccine supply, cost-effectiveness of vaccines, vaccine acceptance by members of the public, and public-private partnerships. Building on suc-

cess in achieving widespread recognition in the United States of the importance of childhood immunization, the ACIP recently has begun to intensify efforts to enhance professional and public awareness of the importance of adult immunization. The Committee will continue to provide evidence-based immunization recommendations to ensure the health of infants, children, adolescents, and adults in the United States, and to continue to serve as a model for development of national vaccine advisory committees globally.

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**Disclaimer:** The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

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