Role of ACIP in Evaluating and Recommending Vaccines

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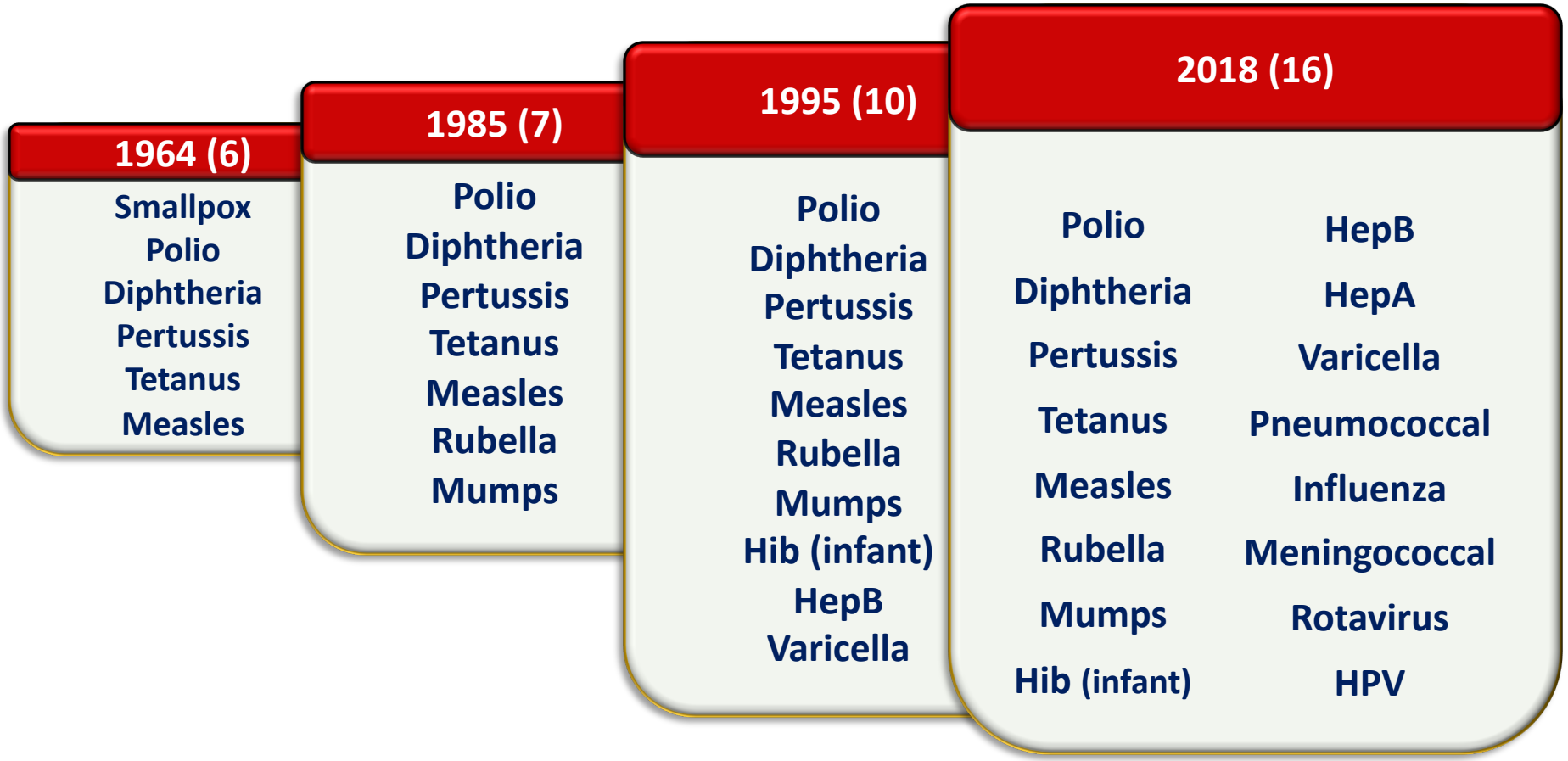
Disclaimer and Conflicts of Interest

- The findings and opinions expressed in this presentation are those of the author and do not necessarily reflect the view of the Indian Health Service or the Department of Health and Human Services.
- The presenter has no conflicts of interest to disclose

ACIP Origins and History

- ACIP established in 1964 by the Surgeon General of the U.S. Public Health Service
- First meeting of the ACIP occurred on May 25-26, 1964
- ACIP designated as a Federal Advisory Committee in 1972

Number of Diseases Prevented by Vaccines Included in the Routine Child/Adolescent Immunization Schedule



Role of ACIP

To provide advice and guidance to the Director of the Centers for Disease Control and Prevention (CDC) and the Office of the Secretary of the Department of Health and Human Services (HHS) on most effective means to prevent vaccine-preventable diseases in the civilian population of the United States

- Vaccines and related agents (e.g., antisera, immune globulins, antiviral agents)
- FDA-licensed vaccines (and unlicensed vaccines if warranted)

ACIP Charter Language

For each vaccine, the committee advises on population groups and/or circumstances in which a vaccine or related agent is recommended

Committee deliberations on use of vaccines to control disease in the U.S. shall include consideration of disease epidemiology and burden of disease, vaccine efficacy and effectiveness, vaccine safety, economic analyses and implementation issues

The committee may revise or withdraw their recommendation(s) regarding a particular vaccine as new information on disease epidemiology, vaccine effectiveness or safety, economic considerations or other data become available

Structure of ACIP

ACIP Voting Members

15 voting members (including Chair and Vice Chair)

- Includes one consumer representative, and 14 members with expertise in specific disciplines

US citizens; external to federal government

4-year, overlapping terms

ACIP steering committee nominates, HHS selects

Members screened for conflicts of interest upon appointment, annually through term, and at every ACIP meeting

Expertise & Perspective of ACIP Members

Medicine (Pediatrics, Internal Medicine, Family Medicine, Infectious Diseases, Ob/Gyn, others)

State/local health departments

Public health, preventive medicine

Nursing

Immunology

Vaccine research and policy

Economics and cost-effectiveness

Consumer concerns

Ex-Officio Members

Eight *ex-officio* members represent other government agencies involved in immunization

Agencies represented:

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

Liaison Organizations

Thirty one organizations with broad involvement in immunization; organization funds participation of representative

Designated representative brings perspective of the organization; keeps organization & membership apprised of ACIP deliberations and recommendations

Members serve on work groups

Members attend and participate in every ACIP meeting

Four organizations assist with development and publication of immunization schedules “harmonized” with ACIP (AAFP, AAP, ACOG, ACP)

ACIP Work Groups

ACIP Workgroups

- Subcommittees that augment the effectiveness of ACIP through in-depth review of specific topics to facilitate informed and efficient decision-making.
- Responsible for the collection, analysis, and preparation of information for presentation, discussion, deliberation, and vote by ACIP.
- COVID-19 Workgroup has been meeting weekly
  - Workgroup meeting materials are confidential until shared publicly at the convened ACIP meeting

Conflicts of Interest of Work Group Members

ACIP ~~Work Groups serve a key scientific role in support of vaccine policy development by ACIP.~~ Conflicts of interest could interfere with the effective functioning of a Work Group

To avoid undue influence or the appearance/perception of a conflict of interest in Work Group discussions, screening is conducted upon establishment of the Work Group and annually

- Balance of ensuring limited potential conflicts of interest and need for expertise in the subject matter
- Goal to be transparent about potential conflicts

What is a Conflict of Interest for Work Group members?

A financial conflict of interest exists when a participant has an interest in a vaccine product or pharmaceutical company that may bias his/her approach to development of options for recommendations for use of that vaccine

- Research grants from a vaccine manufacturer will be evaluated and considered on a case-by-case basis

Regardless of the level of financial involvement or other interest, if the participant feels unable to provide objective advice, he/she must recuse him/herself

- The ACIP Work Group process relies on the integrity of each participant to disclose to the Work Group Chair or Work Group Lead any real or apparent conflicts of interest that are likely to bias the reviewer's evaluation of an application or proposal

Confidentiality

- Unlike ACIP meetings, Work Group discussions are considered confidential
  - Only Work Group members and invited consultants should participate in Work Group meetings
  - If the parent organization of a liaison representative wishes to obtain information about Work Group proceedings, the organization should contact the Work Group Lead to request a presentation
  - Slides distributed at Work Group meetings or shown during teleconferences should be marked as confidential
- Work Group members should not discuss Work Group deliberations with anyone representing or employed by a vaccine manufacturer

Pharmaceutical Company Interaction with Work Groups

Presentations given by pharmaceutical companies to ACIP provide critical information to Work Groups

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Work Groups should provide opportunities for companies with plans to submit a biologics licensing application (BLA) to FDA for a vaccine product to update the Work Group if new data are available

- All information, data, and slides are confidential
- After pharmaceutical presentations to the Work Group and time for questions, the company should exit the call

All presentation topics by pharmaceutical companies on the ACIP agenda must be presented to the Work Group first

- The Work Group Lead (or other CDC staff member serving on the Work Group) should present a summary of the Work Group's interpretation of the data presented by the company during the same ACIP session, if appropriate

ACIP Recommendations Process

ACIP Recommendations Process

Research evidence is systematically collected, and *Grading of Recommendations Assessment, Development and Evaluation* (GRADE) is used to develop evidence-based recommendations

Key factors for developing recommendations include the balance of benefits and harms, type or quality of evidence, values and preferences, and health economic analyses

The ACIP GRADE recommendation categories are:

- Category A: Recommendation that applies to all persons in an age- or risk-based group
- Category B: Recommendation for individual clinical decision making
- No recommendation/unresolved issue

Evidence-Based Recommendations Work Group updating GRADE process to include an Evidence to Recommendations Framework

Evidence to Recommendation Framework

PROBLEM

- Is the disease of public health importance?

BENEFITS & HARMS

- How substantial are the expected benefits?
- Are there harms? How substantial?

Evidence to Recommendation Framework

VALUES

- Does the target population value the vaccination?

ACCEPTABILITY

- Is the vaccine program acceptable to key stakeholders?

FEASIBILITY

- Is the vaccine program feasible to implement?

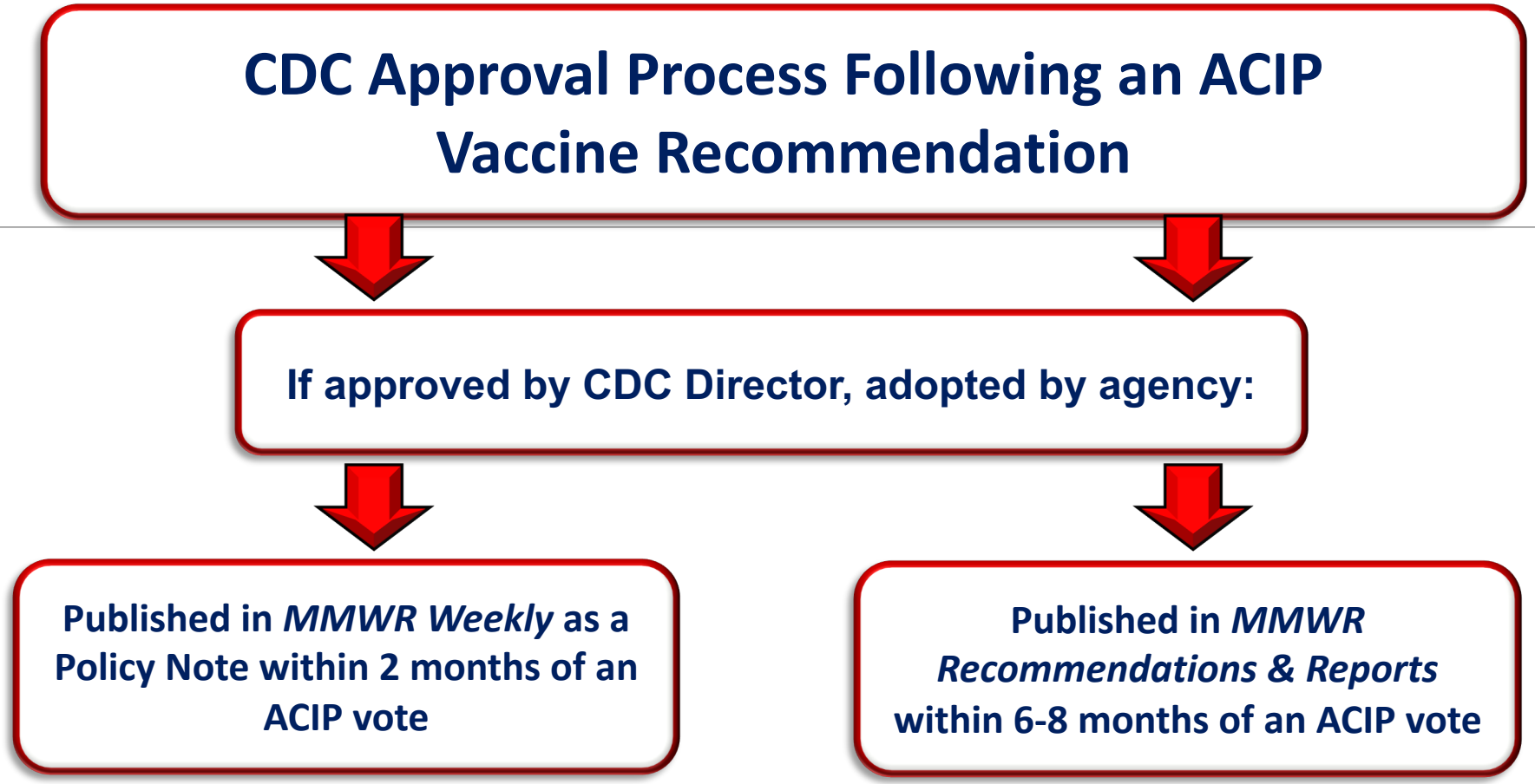
Health Economic Analyses in Vaccine Decision Making

- ACIP Charter: "deliberations… shall include consideration of…economic analyses."
- 2008: formal criteria established for presentation to ACIP of CE analyses – ensure standardization & quality of economic data presented
- U.S.: no use of CE "threshold" to determine if a vaccine should be routinely recommended

ACIP Meetings

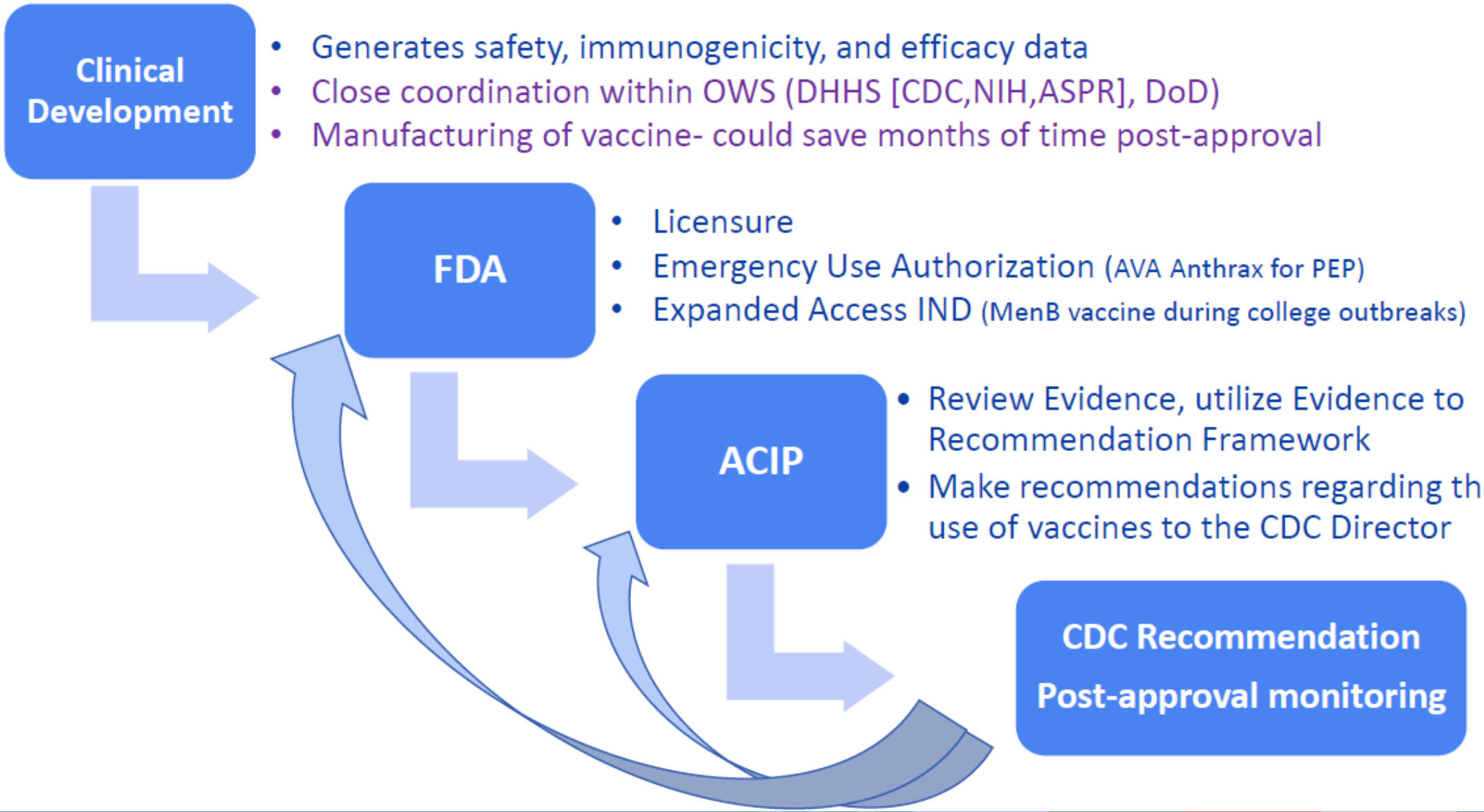
- Meetings must be open to the public with time for public comment
- Meeting slides, live webcast archive, minutes posted on ACIP website
- Recommendations become final once approved by CDC Director, adopted by HHS/CDC and published in MMWR
- Vaccine recommendations are recommendations only – not mandates
- States and professional organizations usually endorse or follow ACIP recommendations

CDC Approval Process Following an ACIP Vaccine Recommendation



Recommendation becomes official HHS/CDC policy upon publication in MMWR

Path from clinical development to recommendation

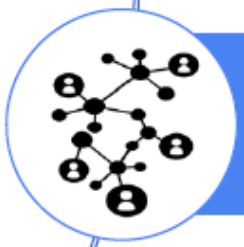


ACIP COVID-19 Vaccine Work Group: Proposed Guiding Principles

EQUITY

Safety is paramount. Vaccine safety standards will not be compromised in efforts to accelerate COVID-19 vaccine development

Inclusive clinical trials. Study participants should reflect groups at risk for COVID-19 to ensure safety and efficacy data are generalizable



Efficient Distribution. During a pandemic, efficient, expeditious and equitable distribution and administration of approved vaccine is critical

Flexibility. Within national guidelines, state and local jurisdictions should have flexibility to administer vaccine based on local epidemiology and demand

Issues Around Timing And ACIP Recommendations

- A majority of ACIP votes take place the meeting after licensure of a new vaccine
  - No vote needed for new products unless indication, target group different
- Need to maintain flexibility to ensure ACIP members have the data to inform decision making process
- Emergency meetings can and have taken place to develop recommendations when there is public health urgency