Comments for Centers for Disease Control and Prevention [Docket No. CDC–2025–0017]

Meeting of the Advisory Committee on Immunization Practices

April 15-16, 2025

The Infectious Diseases Society of America, the Pediatric Infectious Diseases Society, the Society for Healthcare Epidemiology of America and the HIV Medicine Association are pleased to provide comments about the importance of the Advisory Committee on Immunization Practices (ACIP) to preserving vaccine access for Americans who want to be vaccinated and providing evidence-based information to enable clinicians to offer the highest quality care and empower individuals to make the best-informed decisions about their own health and their families' health. **It is critical to preserve the trusted role of ACIP in helping to determine recommendations for vaccines offered to Americans of all ages.**

- **Role in Vaccine Access and Public Health Policy:** For more than 60 years, ACIP has provided expert recommendations to the Department of Health and Human Services regarding vaccines used to control vaccine-preventable diseases in the U.S. civilian population. ACIP recommendations are critical to determine which vaccines are covered under federal programs like Vaccines for Children (VFC) and to determine guidelines for insurance coverage for vaccines.[1][2] In addition, ACIP provides recommendations for vaccine use by health care personnel, which is crucial to protecting the workforce who are on front lines in providing care to patients with potentially highly communicable diseases such as pertussis and measles.

- **Transparency and Public Engagement:** ACIP meetings are open to the public, fostering transparency in decision making. Stakeholders routinely observe deliberations and provide input on important considerations to the committee. Each meeting is required to include a public comment period so that stakeholders can air their views publicly, building stakeholder buy-in and ensuring that all perspectives are considered.[1][2]

- **Expert Composition and Conflicts of Interest:** The committee is composed of up to 19 voting members, including individuals of the undersigned societies as current and past liaisons as well as recent past chairs. In addition, the committee includes liaison members representing our professional societies. We support ACIP's longstanding accountability processes to prevent and manage conflicts of interest. In our experience, ACIP and its workgroups have been successful in

documenting connections between committee members and private industry and excluding members with conflicts of interest from workgroup deliberation, committee deliberation and votes.

- **Evidence-Based Framework:** ACIP employs the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach to evaluate and communicate the quality of evidence and strength of recommendations for vaccines.[1][2]

  After reviewing the evidence, ACIP considers the following factors in making recommendations:

  - Benefits – such as reduced disease transmission, hospitalizations and deaths – which are weighed against potential risks at both individual and population levels[1]
  - Values and preferences of the population
  - Resource use (cost-effectiveness)
  - Feasibility and acceptability

- **Independence From Federal Government:** Importantly, ACIP recommendations influence public health policy and advise policymakers but do not regulate or approve vaccines. Without ACIP, independent assistance to federal regulators would arguably have a larger role in selecting the vaccines that are regulated and determining policies related to vaccine eligibility.

- **Integration of Data Systems:** Evidence-based decision making relies on systematic use of data from clinical trials, epidemiological studies and real-world surveillance systems like the Vaccine Adverse Event Reporting System. This approach enables ACIP to comprehensively evaluate vaccine safety, effectiveness and population-level impact[2]

- **Emergency Preparedness:** During public health emergencies, ACIP issues interim recommendations to guide vaccine allocation and administration. For example, during the early stages of COVID-19 vaccine distribution, ACIP prioritized health care workers and long-term care residents who were at heightened risk to maximize impact amid limited supply. ACIP also ensures that its guidance addresses both public health priorities and resource allocation challenges.[1][2]

Agenda Items for April 2025 Meeting

Below is a very brief overview of key topics for the April 2025 meeting that highlights why ACIP's consideration of these topics is important for patients and public health.

Mpox Vaccine:

- Evaluating the immunogenicity and safety of the JYNNEOS vaccine in adolescents aged 12–17 years is crucial for expanding protection against mpox.

Lyme Disease Vaccine:

- Receiving updates on Lyme disease vaccine development is essential because Lyme disease is the most common vector-borne illness in the United States, with increasing incidence rates. A new vaccine could significantly reduce disease burden, prevent long-term complications and alleviate economic costs associated with diagnosis and treatment.

Influenza Vaccines:

- Reviewing influenza vaccine effectiveness updates is vital for optimizing vaccination strategies to protect against hospitalizations and deaths from seasonal influenza and determine the optimal vaccine composition, timing and target populations to maximize public health impact.
- Exploring FluMist administration for self or caregiver use addresses challenges in vaccine access and delivery. This approach enhances vaccine uptake, reduces the strain on health care resources and provides broader community protection.

COVID-19 Vaccines:

- Examining updates on Moderna's mRNA-1283 COVID-19 vaccine ensures ongoing adaptation to emerging variants. Continuous assessment of vaccine efficacy helps inform decisions on booster doses and formulations to maintain high levels of protection against severe disease.
- Analyzing epidemiological data on COVID-19 hospitalizations identifies risk factors and vulnerable populations. This informs targeted vaccination efforts to reduce hospitalizations, decrease morbidity and alleviate health care system strain.

Meningococcal Vaccines:

- Reviewing data on GSK's pentavalent meningococcal vaccine is crucial for broadening protection against invasive meningococcal disease. A pentavalent vaccine could simplify immunization schedules, improve coverage rates and prevent outbreaks caused by multiple serogroups.
- Discussing updates to the VFC resolution for meningococcal vaccines ensures access to immunization to better protect populations at higher risk of severe disease and long-term complications.
- Considering the MenQuadfi label change for infants alongside safety and immunogenicity data informs decisions on expanding vaccine use to those in the youngest age group.

Respiratory Syncytial Virus (RSV) Vaccines – Adults:

- Analyzing RSV vaccine immunogenicity data in adults at increased risk identifies candidates for vaccination. Targeted strategies protect the elderly and individuals with chronic conditions, reducing hospitalizations and deaths associated with RSV infection.
- Exploring re-vaccination strategies for Moderna's mRNA-1345 and GSK's Arexvy informs decisions on long-term vaccine effectiveness. These data are crucial for guiding booster recommendations to sustain protection against RSV-associated illness.

Please contact Eli Briggs, IDSA director of public policy, at ebriggs@idsociety.org with any questions about these comments.

Sources:

1. https://www.congress.gov/crs_external_products/IF/PDF/IF12317/IF12317.3.pdf
2. https://uknowledge.uky.edu/cgi/viewcontent.cgi?article=1048&context=frontiersinphssr