

Comments to the Advisory Committee on Immunization Practices (ACIP)

September 18-19, 2025 Meeting Docket ID: CDC-2025-0454

Agency: Centers for Disease Control and Prevention (CDC)

The <u>National Foundation for Infectious Diseases</u> (NFID) appreciates the opportunity to submit written comments for the September 18-19, 2025 Advisory Committee on Immunization Practices (ACIP) meeting.

NFID strongly supports the continued use of expert, evidence-based guidance to inform public health policy and protect the health of people across the US. NFID would like to emphasize the importance of the ACIP's systematic review of scientific evidence and disease impact to guide US vaccine policy.

The agenda for the September meeting includes important discussions and potential votes on vaccines that have a profound impact on public health, including vaccines for COVID-19, hepatitis B, combined measles, mumps, rubella, varicella (MMRV), and respiratory syncytial virus (RSV). NFID also notes the potential consideration of Vaccines for Children (VFC) program coverage, which plays a critical role in ensuring equitable access to recommended vaccines, as well as a possible discussion of the safety of vaccine ingredients.

- restrictions and strongly urges ACIP to make recommendations grounded in the best available evidence. Recent changes in COVID-19 policy have resulted in confusion, inconsistency, and lack of access in pharmacies and healthcare settings across the US. COVID-19 vaccines have saved millions of US lives and should be available to all US children and adults who want them. More than 1 million people have died from COVID-19 in the US since the virus first emerged in December 2019. According to preliminary estimates from the Centers for Disease Control and Prevention (CDC), there were at least 10 million COVID-19-related illnesses, 300,000 hospitalizations, and 35,000 deaths during the 2024-2025 US respiratory season. COVID-19 vaccines have been studied in multiple clinical trials with thousands of participants, and billions of doses have been administered in the US and globally. Ongoing safety monitoring shows that serious vaccine side effects are rare and are much less severe than the effects of COVID-19 itself. Vaccination remains the most effective tool to prevent severe illness, hospitalization, and death across all age groups, including children, pregnant women, and healthy adults.
- Hepatitis B vaccine: Hepatitis B is a serious liver disease that can lead to liver cirrhosis, liver cancer, and death. Many US adults are not fully protected against hepatitis B, and most people with hepatitis B do not know they are infected. According to CDC, approximately 90% of infants with hepatitis B infection and 30% of children between ages 1–5 years with hepatitis B infection will develop a chronic infection.² Vaccination is the best way to prevent hepatitis B infection and its complications. A lifespan vaccination approach, including birth dose and broad adult vaccination, is key to reducing transmission, preventing chronic infection, and eliminating hepatitis B as a public health threat in the US.
- MMRV vaccine: High vaccination coverage is essential to prevent outbreaks of measles, mumps, rubella, and varicella, especially given recent increases in vaccine-preventable disease activity worldwide. As of September 9, 2025, a total of 1,454 confirmed measles cases have been reported by 42 US jurisdictions, with 3 confirmed deaths. 92% of reported cases were among individuals who were unvaccinated or whose vaccination status was unknown.³ This is the highest number of reported US cases since the disease was eliminated from the US in 2000. Vaccination is the most effective way to ensure that

individuals, families, and communities are protected from measles. In the US, 2 doses of MMR and Varicella vaccines are recommended for children. Infants normally receive their first dose between 12-15 months followed by another dose between 4-6 years. The combined MMRV vaccine carries a slightly higher risk of febrile seizures when given as the 1st dose compared to separate MMR and varicella vaccines, especially in younger children. Parents currently have the option to receive the MMR and varicella vaccines separately or the combination. Parental choice should be preserved unless and until a formal ACIP Evidence-to-Recommendation (EtR) review and analysis demonstrates that one alternative strategy is clearly inferior to the other. Any changes to current recommendations should undergo a rigorous scientific review and should be evidence-based.

- RSV vaccines and immunizations: NFID supports ongoing efforts to protect both infants and older adults, who are at greatest risk of severe RSV disease. Each year in the US, RSV is estimated to cause 100,000-160,000 hospitalizations in adults age 60 years and older and 58,000-80,000 hospitalizations among children younger than age 5 years. RSV is the most common cause of hospitalization in US children younger than 1 year old, and roughly 80% of US children younger than age 2 years who are hospitalized with RSV do not have risk factors. A recent meta-analysis confirmed the benefits of long-acting monoclonals against severe RSV from observational studies in the US and 4 EU countries since licensure. The current vaccine products and monoclonal antibodies are critically important advances that have already resulted in reductions in severe RSV disease and have great potential for further societal and individual benefit with increases in immunization rates.
- Vaccine safety and aluminum adjuvants: Aluminum salts have been safely used in vaccines for more than 70 years. They function as adjuvants, ingredients that help the body build a stronger immune response to vaccination. Extensive research has shown that the amount of aluminum in vaccines is very small and well within safe limits. In fact, individuals are exposed to more aluminum every day through food, water, and even breast milk than they receive from vaccines. NFID emphasizes that the overwhelming scientific evidence shows the benefits of vaccination far outweigh any theoretical risks of aluminum exposure. Adjuvanted vaccines remain a safe and effective way to help protect against serious infectious diseases.

As ACIP considers these vaccines and other immunization policy issues, NFID emphasizes that ACIP recommendations directly affect insurance coverage, Medicare and Medicaid benefits, and access through the VFC program. Equitable access to recommended vaccines is essential to help protect individuals, families, and communities across the US from serious infectious diseases.

NFID will continue to follow the evidence and strongly supports immunization recommendations that are science-based, protect those at risk, and advance health equity.

Sincerely,

Robert H. Hopkins, Jr., MD NFID Medical Director

References

- 1. Preliminary Estimates of COVID-19 Burden for 2024-2025. Centers for Disease Control and Prevention (CDC), December 6, 2024. https://www.cdc.gov/covid/php/surveillance/burden-estimates.html
- 2. Clinical Overview of Perinatal Hepatitis B. CDC, July 2, 20225. https://www.cdc.gov/hepatitis-b/hcp/perinatal-provider-overview/index.html
- 3. Measles Cases and Outbreaks. CDC, September 10, 2025. https://www.cdc.gov/measles/data-research/index.html
- 4. Q&As About Vaccination Options for Preventing Measles, Mumps, Rubella, and Varicella. CDC, January 26, 2021. https://www.cdc.gov/vaccines/vpd/mmr/hcp/vacopt-faqs-hcp.html
- 5. Measles Vaccine. American Academy of Pediatrics, Accessed September 10, 2025. https://www.aap.org/en/patient-care/measles/measles-vaccine/

- 6. Respiratory Syncytial Virus. National Foundation for Infectious Diseases, Updated July 2025, https://www.nfid.org/infectious-disease/rsv/
- 7. Systematic Review and Expert Consensus on the Use of Long-acting Monoclonal Antibodies for Prevention of Respiratory Syncytial Virus Disease: ARMADA (Advancing RSV Management And Disease Awareness) Taskforce. Open Forum Infectious Diseases. July 2025. https://academic.oup.com/ofid/article/12/7/ofaf396/8181044
- 8. Niklas Worm Andersson, Ingrid Bech Svalgaard, Stine Skovbo Hoffmann, et al. <u>Aluminum-Adsorbed Vaccines and Chronic Diseases in Childhood</u>: A Nationwide Cohort Study. Ann Intern Med. [Epub 15 July 2025]. doi:10.7326/ANNALS-25-00997