Advisory Committee on Immunization Practices (ACIP)
Centers for Disease Control and Prevention (CDC)
Respiratory Syncytial Virus (RSV) Immunization Workgroup, Maternal, Infant, Adult
Terms of Reference
UPDATED: December 18, 2025

PURPOSE

This document defines the activities, membership, and administrative requirements associated with the establishment of a Respiratory Syncytial Virus (RSV) Immunization Workgroup for patients of all ages under the Advisory Committee on Immunization Practices, Centers for Disease Control and Prevention (ACIP, CDC). ACIP utilizes subgroups of the Committee, known as Workgroups (WGs), to review relevant published and unpublished data, and clinical and scientific knowledge, and develop options for presentation to the full ACIP parent committee during its public meetings to facilitate discussion, deliberation and development of recommendations. ACIP WGs are intended to enhance the effectiveness of ACIP. The direction, focus and pace of both ACIP and the individual WG's are guided by CDC and HHS priorities, and by the need for expert advice to inform development of immunization policy. ACIP WGs serve a key **scientific role** in support of immunization recommendations.

The RSV Immunization WG has been established to review data as well as scientific and clinical knowledge on RSV vaccine products and monoclonal antibodies currently in use or under consideration for the prevention of severe RSV infection in both the infant and at-risk adult population. These findings will be presented to the full ACIP parent committee in a public forum and will be considered in the formulation of recommendations regarding the use of these products to the Director of the CDC.

BACKGROUND

RSV is a viral illness primarily affecting infants, but older children and adults with certain co-morbidities or of older age are also at risk of serious disease. Infants who get RSV almost always have symptomatic disease. While the majority of RSV infections are mild—70%-- and localized to the upper airway, RSV can also cause severe illness such as bronchiolitis (inflammation of the small airways in the lungs) and pneumonia (infection of the lungs). Before the introduction of universal RSV immunization recommendations for infants in 2023, RSV was the leading cause of hospitalization among U.S. infants (aged <12 months): an estimated one (1)%–three (3)% of infants were hospitalized for RSV each year, accounting for the largest non-birth hospitalization health care expenditures in the US for children under five (5). Adults, unlike infants, may not always show symptoms after infection with RSV. However, some adults, including those with certain medical conditions, especially those associated with respiratory compromise and immune compromise, are at risk of severe disease including pneumonia, exacerbation of underlying chronic conditions such as heart failure and chronic obstructive pulmonary disease (COPD), and death. Older adults are also at increased risk of severe RSV disease and at increased risk of declining functional status after RSV infection.

CDC recommends several U.S. Food and Drug Administration (FDA)-approved products to provide active or passive immunity to the at-risk populations. One such product is a recombinant protein subunit vaccine with ASO1E adjuvant approved by FDA on May 3, 2023 for adults 60 years of age and older for the prevention of lower respiratory tract disease (LRTD) caused by RSV. In July 2025 FDA announced the agency also accepted an application to review use of this same product for adults aged 18-49 years at increased risk of LRTD caused by RSV.

A second product is a bivalent recombinant protein subunit vaccine with no adjuvant, approved by FDA on:

- May 31,2023 for adults 60 years of age and older for the prevention of LRTD;
- August 21, 2023 for maternal vaccination at 32-36 weeks' gestation for prevention of LRTD in infants through 6 months of age; and approved
- October 22,2024 for adults ages 18-59 with risk factors for the prevention of LRTD.

Both protein subunit vaccines target sites on the pre-fusion F (preF) protein on the surface of the RSV virus.

A third product is an mRNA-based vaccine approved by FDA on May 31, 2024, for adults 60 years of age and older for the prevention of LRTD caused by RSV, and approved by FDA on June 12, 2025 for those aged 18-59 years at increased risk of LRTD caused by RSV. This product also targets the preF protein.

For the indication of protection of adults, two of the products have shown significant efficacy in randomized clinical trials against preventing lower respiratory tract illness (LRTI) and effectiveness in post-licensure observational studies against hospitalization. For the indication of maternal use of RSV vaccine to protect infants after birth, randomized clinical trials for one of these products have also demonstrated efficacy and a postmarketing real world effectiveness study also showed the vaccine to be effective.

Two of the available products have been associated with rare but significant adverse reactions in older adults, notably Guillain-Barrè Syndrome. There was also an imbalance of atrial fibrillation in the clinical trials for the use of these vaccines in adults 60 and older, but no signal has emerged in post-marketing studies to date, though safety surveillance is ongoing. No cases of Guillain-Barrè Syndrome have been reported in pregnant women after RSV vaccination.

One product has also shown significant efficacy in preventing LRTI in randomized clinical trials. Because approval of this product was more recent than for other available products and uptake of this product has been lower, there are not yet post-licensure observational studies of vaccine effectiveness available.

In addition to vaccines there are three monoclonal antibody products now available for newborn infants and some older children, each providing long-term passive immunity (One product was

approved by FDA in 2023 for use in infants born during or entering their first RSV season and children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season. A second product clesrovimab was approved by FDA in June 2025 for infants born during or entering their first RSV season. CDC recommends either product for infants younger than 8 months born during or entering their first RSV season; for children ages 8 through 19 months who are at increased risk of severe RSV disease and entering their second RSV season, only one is recommended. A third product, was first approved in the United States on June 19, 1998 and will be available until the end of December, 2025. Two of the products have both shown significant efficacy in randomized clinical trials against preventing RSV-associated medically attended lower respiratory tract illness (RSV MA-LRTI) and RSV MA-LRTI with hospitalization. Post-licensure observational studies have demonstrated that one product is effective in preventing RSV-associated hospitalization.

The WG will engage external subject matter experts, as needed, to support presentations to the WG members and development of materials for presentation to the parent committee for its deliberations.

TOPICS FOR DISCUSSION BY THE WORKGROUP

The topics for discussion by the RSV immunization workgroup can be most efficiently described by breaking them into two groups: 1) adult populations (18-49 with risk factors, 50 and older with risk factors, and those 75 and above); and 2) the maternal-infant group (for which there is currently a recommendation for all newborns), as well as use of a monoclonal antibody product in the second RSV season for young children susceptible to serious RSV disease, including groups such as all American Indian/Alaska Native infants. The WG will work on questions and topics described below and prepare deliverables for the ACIP parent committee to consider.

Adults:

Ages 18-49 years. The CDC is being asked to consider a recommendation for vaccination of persons in this age cohort with 'risk factors' making them susceptible to severe RSV infection. This raises several questions for the WG, for example:

- What is the scope of the problem? How many patients in this cohort are admitted to the hospital annually for RSV LRTI. What are the outcomes data? What is the total number of hospitalizations for LRTI of all causes in this group?
- What are the specific risk factors that have been identified as being significant?
- How are these risk-factors measured for severity?
- What are the critical values, (i.e. FEV1 in the case of obstructive airway disease, cardiac output for those with congestive heart failure, A1C for diabetics, Creatinine levels for chronic renal failure patients, psychiatric assessments for patients with psychoses, etc.).
- What congenital or other anatomic abnormalities are of concern?
- What living situations, in addition to a nursing home environment, are considered to be high risk? This information is essential for both patients and for the physicians caring for them responsible for providing adequate education for informed consent (noting that informed consent is a matter under state law).
- Will boosters be necessary, and if so, how often?
- What are the results of ongoing monitoring of post-licensure safety and adverse events?

Age 50 and older with risk factors:

- What is the scope of the problem?
- What are the defined risk factors, how they are measured, and the critical values?
- Will boosters be needed? The duration of immunity in this cohort is currently unknown.

Age 75 and older:

- Currently this is a universal recommendation. The WG should provide updates on hospitalization rates of those vaccinated and unvaccinated, outcomes, and deaths attributed to RSV infection. How many admissions for LRTI for any etiology are there in this cohort?
- The WG should provide updates on the incidence of serious adverse events for all who have been vaccinated, broken down by specific vaccine. This cohort is particularly susceptible.

Maternal-Infant and young children with risk factors:

- What is the uptake of the maternal vaccine and how does it compare with administration of monoclonal antibodies to newborns?
- The WG should provide updates on rates of RSV-associated hospitalization in infants who do not receive protection from either maternal vaccination or a monoclonal antibody, in infants born to mothers that received maternal vaccination, and in infants that have received monoclonal antibodies only.
- What is the number needed to treat to prevent a hospital admission, an ICU admission, or death? How does that compare with the number needed to vaccinate to see a significant adverse event for each product?
- The WG should provide a thorough review of the data presented at the last ACIP meeting in June 2025 regarding the safety of relevant RSV products. This would include the study design, the original description of the study groups. and a reanalysis of the safety data using more sophisticated methodologies.
- The WG should review all raw data on the RCTs including data from the ongoing trials of RSV products.
- The WG should address any significant aberration or discrepancy between what was presented in June and what is found on re-analysis that may trigger a review of the ACIP recommendation regarding other RSV products?What are the results of on-going reviews of post-marketing surveillance of the immunization products?

MEMBERSHIP AND LEADERSHIP

Workgroup Leadership: The RSV Immunization WG is chaired by one of the ACIP, CDC parent committee members. The Workgroup Lead (WGL) is a federal employee, identified by the Immediate Office of the Director in consultation with the appropriate CDC program. The WG Chair, in consultation with the WGL, and ACIP CDC Designated Federal Official (DFO), determines the WG's membership and work priorities and deliverables to the full committee. The DFO may further assign some of the DFO-related roles and responsibilities, as appropriate, to the WGL.

Workgroup Membership: The RSV Immunization WG is composed of experts who are appointed based on their professional, scientific, technical, or other expertise. They are experts who are regarded as an authority or a practitioner of unique competence and skill by other persons in their profession, or occupation. Upon request, HHS federal agencies named in the ACIP charter may also appoint members to serve on WGs. The RSV Immunization WG will be composed of members from a variety of disciplines. The WG will engage with the following disciplines on WG activities:

- Public health science and practice;
- Public health policy development, analysis, and implementation, including development and execution of immunization programs for children and adults;
- Clinical and medical practice, and patient-care experience;
- Epidemiology;
- Molecular biology;
- Immunology;
- Virology;
- Diagnostics and correlates of protection;
- Drug and vaccine safety;
- Bioethics; and
- Consumer perspectives and/or social and community aspects of immunization programs

Due to the complexity and variability of the information to be gathered, additional external subject matter experts may also be invited to provide data and presentations to the WG and answer questions during RSV Immunization WG meetings on an ad-hoc basis. Such additional external subject matter experts will not be members of the WG and will not participate in any deliberations or WG discussions.

MEETINGS, ADMINISTRATION, and TIMELINES

1. Administrative Oversight: The WGL will work with the WG Chair to arrange meetings, document meeting proceedings, and report to the ACIP on the RSV Immunization WG's activities and findings.
2. Meeting frequency and location: The RSV Immunization WG will meet on an as needed basis as determined by the WG Chair and WGL. All RSV Immunization WG meetings are convened virtually via teleconference.
3. Meeting structure: In addition to the WGL, at least two ACIP parent committee members (one of whom serves as the RSV Immunization WG Chair) must be present at each meeting for a quorum. An agenda, relevant publications, and background documents will be circulated as read-ahead material before each meeting.
4. Conflicts of Interest: WG members will complete an ACIP WG Agreement and Conflict of Interest Certification process before participation on the WG. The WGL will screen for conflict-of-interest declarations and share any conflicts that need to be elevated to the DFO/ACIP Secretariat. The ACIP Secretariat and DFO, in collaboration with the WGL will work with Ethics office within the Office of Strategy Business Initiatives (OSBI) and the Office of General Counsel (OGC), as needed, to resolve any conflicts that the WGL identified. WG members will consent to abide by guiding principles and disclose

interests (e.g., employment, special interests, grants, or contracts) that a reasonable person could view as conflicts or potential conflicts of interest with their RSV Immunization WG participation. Members will also disclose any potential conflicts of interest before each meeting. If an RSV Immunization WG member indicates a potential or actual conflict of interest to the WGL, the WGL or a delegate will forward any conflicts to the DFO to determine whether the individual must recuse themselves from participating in WG discussions that implicate such a conflict-of-interest concern. If needed, the DFO will engage OSBI and OGC to assist with making COI determination.

5. Confidentiality: The discussions by the RSV Immunization WG may include information that is unpublished, protected, privileged, or confidential. WG deliberations, including policy options under consideration by the WG, are also considered confidential. Information of this nature must not be disseminated, distributed, or copied to persons not authorized to receive such information. When these types of information are distributed, the person presenting will identify the information as such, so all members are duly informed; and written materials shall be clearly marked as such. Unlike ACIP parent committee meetings, which are open to the public, RSV Immunization WG teleconferences are not subject to the open meeting requirements of the Federal Advisory Committee Act or the GSA Final Rule; data presented during these meetings/teleconferences are often proprietary and should not be distributed to people other than approved RSV Immunization WG members.
6. CDC Staff Involvement: CDC staff do not serve as members of the RSV Immunization WG but may provide administrative support and technical expertise to ACIP WGs, as appropriate, bringing subject matter expertise and current professional focus in areas relevant to the goals of the RSV Immunization WG. Consultation or informational presentations by CDC staff will be transparent and evident to minimize the risk of, or the appearance of, undue influence that would compromise the independence of the WG. The DFO and WGL of the RSV Immunization WG, in consultation with the Chair of the RSV Immunization WG, will monitor the interaction between the WG and the agency staff to ensure that the WG activities and work products are appropriate and that there is no undue influence by the CDC or by any special interest group on the activities or work products of the WG.
7. Timelines: ACIP WGs are established when needed and terminated once the activities and work products stated in the terms of reference have been completed and the WG's charge has been fulfilled.
8. Workgroup Meeting Summaries: Meeting minutes will be created to capture the information gathered during each RSV Immunization WG meeting and teleconference.
9. Workgroup findings: The RSV Immunization WG will present findings (briefing documents, background materials, and presentations) to the ACIP parent committee for consideration and deliberation in a public meeting. Final versions of all slides presented at the ACIP parent committee meeting will be posted on the ACIP website following the meeting and included in the committee's official records.
10. Workgroup Record Keeping: All CDC FACA committees, subcommittees, and WGs are subject to the Federal Records Act. All records will be uploaded to the Federal Advisory Committee Management Portal. The summary report of WG meeting activities and other WG documents will become part of the ACIP's official records as required by GENERAL RECORDS SCHEDULE 6.2: Federal Advisory Committee Records.

RECORDKEEPING and REPORTING

The WG Chair and WGL will present findings/outcomes/observations/recommendations to the ACIP parent committee for discussion, deliberations, further development of recommendations, and vote in an open public forum. Approved ACIP recommendations adopted by the CDC Director will be posted on CDC's ACIP website and also published in the Morbidity and Mortality Weekly Report (MMWR). In addition, approved ACIP recommendations will be included in the ACIP meeting minutes and annual report.