Advisory Committee on Immunization Practices

COVID-19 Session

Coronavirus and Other Respiratory Viruses Division

June 25, 2025

Agenda COVID-19 session: June 25, 2025

Introduction	Dr. Adam MacNeil (CDC/NCIRD)
COVID-19 epidemiology	Dr. Adam MacNeil (CDC/NCIRD)
COVID-19 vaccine effectiveness update	Dr. Adam MacNeil (CDC/NCIRD)
COVID-19 vaccine safety update	Dr. Sarah Meyer (CDC/NCEZID)
COVID-19 vaccine coverage and implementation	Dr. Georgina Peacock (CDC/NCIRD)
Evidence to recommendations (partial)	Dr. Adam MacNeil (CDC/NCIRD)

Federal COVID-19 vaccine updates, June 2024–May 2025

- **June 2024:** ACIP recommended 2024–2025 COVID-19 vaccination for all people ages 6 months and older (published in September 2024 MMWR[1]).
- **August 2024:** FDA approved or authorized the Novavax, Moderna, and Pfizer-BioNTech 2024–2025 COVID-19 vaccines.
- **October 2024:** ACIP recommended additional doses for adults ages 65 years and older and people ages 6 months and older with moderate or severe immunocompromise (published December 2024 MMWR[2]).
- **August, September, October 2024:** The Interim Clinical Considerations for Use of COVID-19 vaccines was updated with detailed guidance.[3]
- **May 2025:**
  - Per HHS directive, CDC updated COVID-19 vaccine recommendations to shared clinical decision-making for healthy children ages 6 months–17 years and no guidance/not applicable for pregnant women.
  - FDA approved Novavax's NUVAXOVID (2024–2025 Formula) and Moderna's MNEXSPIKE (2024–2025 Formula) for people ages 12–64 years at high risk for severe COVID-19 and all adults ages 65 years and older.
  - FDA's Vaccines and Related Biological Products Advisory Committee met to discuss strain selection for the 2025–2026 COVID-19 vaccines. FDA advised manufacturers that 2025–2026 Formula COVID-19 vaccines should be monovalent JN.1-lineage-based, preferentially using the LP.8.1 strain.[4]

1. Panagiotakopoulos L, et al. Use of COVID-19 Vaccines for Persons Aged ≥6 Months: Recommendations of the Advisory Committee on Immunization Practices — United States, 2024–2025. MMWR Morb Mortal Wkly Rep 2024;73:819–824. DOI: 10.15585/mmwr.mm7337e2.
2. Roper LE, et al. Use of Additional Doses of 2024–2025 COVID-19 Vaccine for Adults Aged ≥65 Years and Persons Aged ≥6 Months with Moderate or Severe Immunocompromise: Recommendations of the Advisory Committee on Immunization Practices — United States, 2024. MMWR Morb Mortal Wkly Rep 2024;73:1118–1123. DOI: 10.15585/mmwr.mm7349a2.
3. https://www.cdc.gov/covid/hcp/vaccine-considerations/index.html
4. https://www.fda.gov/vaccines-blood-biologics/industry-biologics/covid-19-vaccines-2025-2026-formula-use-united-states-beginning-fall-2025

ACIP: Advisory Committee on Immunization Practices | FDA: Food and Drug Administration | MMWR: Morbidity and Mortality Weekly Report

Overview of the current COVID-19 vaccination schedule: *Routine vaccination*

- **Children ages 6 months–4 years**
  - Unvaccinated: May receive a multidose initial series with a 2024–2025 mRNA vaccine using shared clinical decision-making
  - Previously completed an initial series: May receive 1 dose of a 2024–2025 mRNA vaccine from the same manufacturer as the initial series using shared clinical decision-making
- **People ages 5–17 years:**
  - May receive 1 dose of an age-appropriate 2024–2025 COVID-19 vaccine using shared clinical decision-making
- **Adults ages 18–64 years:**
  - Should receive 1 dose of any 2024–2025 COVID-19 vaccine
- **Adults ages 65 years and older:**
  - Should receive 2 doses of any 2024–2025 COVID-19 vaccine, spaced 6 months apart (minimum interval 2 months)

https://www.cdc.gov/covid/hcp/vaccine-considerations/routine-guidance.html

Overview of the current COVID-19 vaccination schedule: *Moderate or severe immunocompromise*

- **Unvaccinated:**
  - Should receive a multidose initial vaccination series with an age-appropriate 2024–2025 vaccine and receive 1 dose of 2024–2025 vaccine 6 months after completing the initial series (minimum interval 2 months)
- **Previously completed an initial series:**
  - Should receive 2 doses of an age-appropriate 2024–2025 COVID-19 vaccine, spaced 6 months apart (minimum interval 2 months)
- **May receive additional age-appropriate 2024–2025 COVID-19 vaccine doses under shared clinical decision-making** (minimum interval 2 months)

https://www.cdc.gov/covid/hcp/vaccine-considerations/immunocompromised.html

Previous Work Group considerations of COVID-19 vaccine non-universal recommendations

September 2023[1]

Summary and Work Group Interpretation: Considerations Regarding a Universal vs. Non-universal Policy

- Work Group considered non-universal policy options, with considerable discussion around the magnitude of benefits in the young, healthy population
- As part of these deliberations, Work Group requested additional data on severe illness due to COVID-19 in those with and without underlying conditions
  - No group that clearly had no risk of severe illness
  - The vast majority of the US population has an underlying condition that would qualify under a risk based recommendation
    - Prevalence of overweight and obesity alone is >70% of adults[1]
  - Risk based recommendation would not allow access to COVID-19 vaccines for all that wanted them
- Shared clinical decision making could create barriers to vaccination and may not effectively target those at highest risk
- COVID-19 epidemiology remains uncertain and non-universal recommendations would need to be quickly revisited if there was an increase in burden
- Still substantial COVID-19 disease burden and simple, stable recommendations may increase vaccine coverage over time
- Work Group emphasized that COVID-19 recommendations should be reviewed on an ongoing basis as more is learned about COVID-19 seasonality and disease burden in the future

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[1]National Health Statistics Reports; https://stacks.cdc.gov/view/cdc/106273

June 2024[2]

Work Group Interpretation: Considerations for Universal Recommendation

- Work Group began deliberations considering both universal and non-universal policy options, but non-universal options had significant implementation challenges
  - Risk based recommendations would not allow access to COVID-19 vaccines for those not in a defined risk group
    - The current list of conditions that increase risk of severe illness due to COVID-19[1] is extensive and includes the majority of the US adult population[2]
    - There are no groups without a risk of severe illness
  - Shared clinical decision (SCDM) making would create barriers to vaccination, may not effectively target those at highest risk, and would likely increase inequities in vaccine access
  - COVID-19 epidemiology remains uncertain and universal recommendations would need to be considered if there was an unexpected increase in burden following a risk-based or SCDM decision
- COVID-19 disease burden remains substantial, and consistent recommendations may increase coverage over time

1. https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/underlyingconditions.html
2. Overweight and obesity are considered conditions with conclusive or suggestive evidence of increasing risk and have a combined prevalence >70%. National Health Statistics Reports; https://stacks.cdc.gov/view/cdc/106273

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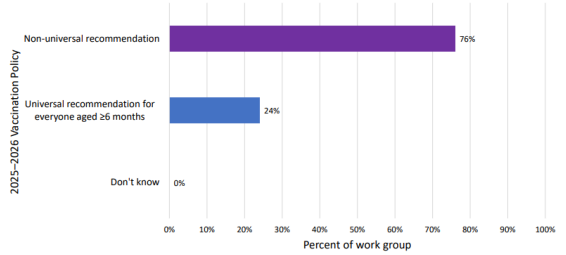
April 2025[3]

When polled on April 3, 2025, the majority of the work group continued to support a non-universal (risk-based) recommendation for 2025–2026 COVID-19 vaccination



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June 2025

1 September 12, 2023. ACIP presentation, slide 124. https://www.cdc.gov/acip/downloads/slides-2023-09-12/11-COVID-Wallace-508.pdf
2 June 27, 2024. ACIP presentation, slide 83. https://www.cdc.gov/acip/downloads/slides-2024-06-26-28/06-COVID-Panagiotakopoulos-508.pdf
3 April 15, 2025. ACIP presentation, slide 65. https://www.cdc.gov/acip/downloads/slides-2025-04-15-16/05-Panagiotakopoulos-COVID-508.pdf

Summary of recent COVID-19 Work Group discussions

- **Age-appropriate 2025–2026 COVID-19 vaccines* for all infants and children ages 6–23 months**

- **Age-appropriate 2025–2026 COVID-19 vaccine for persons ages 2–64 years for the following groups:**
  - Persons at high risk of severe COVID-19, including pregnant women (for infant and maternal protection)
  - Persons at high risk of exposure to SARS-CoV-2
  - Shared clinical decision-making for persons desiring additional protection from COVID-19

- **2 doses of 2025–2026 COVID-19 vaccine for all adults ages ≥65 years and persons ages ≥6 months with moderate or severe immunocompromise****

*Number of doses depends on age, vaccine manufacturer, and vaccine history.

** Persons with immunocompromise who are unvaccinated or did not complete an initial series with 2024-2025 vaccine should complete the initial series followed by 1 dose of 2025-2026 vaccine 6 months after the initial series.