

PHILIP D. MURPHY
Governor

TAHESHA L. WAY
Lt. Governor

PO BOX 360 TRENTON, N.J. 08625-0360

www.nj.gov/health

JEFFREY A. BROWN Acting Commissioner

# Clinical Considerations for COVID-19 Vaccines and Vaccination in New Jersey

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### Introduction

Vaccination against COVID-19 remains the most effective defense to prevent severe disease outcomes. Based upon clear, scientific, and evidence-based recommendations from trusted medical professionals and organizations, the New Jersey Department of Health continues to ensure that individuals 6 months of age and older have access to a COVID-19 vaccine for the 2025-2026 respiratory illness season.

The following clinical considerations provide information to health care professionals and public health officials on the use of COVID-19 vaccines. They are informed by:

- COVID-19 vaccine <u>approval</u> (licensure) under a Biologics License Application by the U.S. Food and Drug Administration
- Centers for Disease Control and Prevention General Best Practices for Immunization and June 25, 2025 Evidence to Recommendations (partial) for 2025-2026 COVID-19
- New Jersey-specific data on SARS-CoV-2 morbidity and mortality
- Professional association guidance, including but not limited to:
  - American Academy of Pediatrics Immunization Schedule for Ages 18 years or younger
  - American Academy of Family Physicians Immunization Schedule for Adults 19+ years
  - American College of Obstetricians and Gynecologists COVID-19 Vaccination
     Considerations for Obstetrics-Gynecologic Care
  - Society for Maternal-Fetal Medicine COVID-19 Vaccination Recommendations during Pregnancy
- Expert reviews and guidance including, but not limited to:
  - Center for Infectious Disease Research and Policy (CIDRAP) Vaccine Integrity
     Project at the University of Minnesota
  - Northeast Public Health Collaborative, Recommendations for the 2025-2026
     COVID-19 Vaccine

# **Types of COVID-19 Vaccines**

Two types of COVID-19 vaccines are licensed in the United States for the 2025-2026 respiratory season:

mRNA vaccines

- Moderna
  - SPIKEVAX for people aged ≥6 months
  - mNEXSPIKE for people aged ≥12 years
- Pfizer
  - COMIRNATY for people aged ≥5 years
- Protein subunit vaccine
  - Novavax
    - NUVAXOVID for people ≥12 years

## **Summary of Public Health Situation**

- The burden from COVID-19 has been trending down year over year since 2021, but substantial morbidity and mortality continues to occur nationally and in New Jersey.
- Higher rates of COVID-19 hospitalization and deaths occur in the oldest and youngest age groups.
  - o Highest rates occur in adults ages ≥65 years and infants <6 months.
- Children ages <2 years have the highest morbidity and mortality of all pediatric ages, but deaths due to COVID-19 can occur at any age.
  - Maternal vaccination is the best protection against COVID-19 for pregnant women and infants <6 months of age (who are too young to be vaccinated).</li>
     Maternal vaccination has been shown to protect infants <6 months from severe outcomes of COVID-19.
- Pregnant people are at increased risk of severe disease and adverse pregnancy outcomes from COVID-19.
- 2024-2025 COVID-19 vaccination was effective in preventing hospitalizations and critical outcomes from COVID-19 in adults.
  - Data from prior vaccine formulations show that vaccine effectiveness has been similar across age groups.
- COVID-19 vaccines have been continuously monitored through robust safety surveillance.
  - Safety surveillance identified and characterized the risk of myocarditis and pericarditis after mRNA COVID-19 vaccination. The risk is highest in young males typically in the first week following vaccination.
  - No other risks confirmed in the current US-licensed vaccines except those seen with other vaccines (e.g., local and systemic reactions, allergic reactions).

## Recommendations for the Use of 2025-2026 COVID-19 vaccines

## Child and Adolescent Immunization Schedule (6 months through 18 years of age)\*

- Everyone aged 6 through 23 months should be vaccinated. For children needing more than one dose to complete the series, all vaccine doses should be from the same manufacturer.
  - o Those who are previously unvaccinated should receive an initial vaccine series.
  - Those who are previously vaccinated but did not complete their initial series should complete their initial series.

- Those who are previously vaccinated and completed their initial series should receive a single dose. This dose should be at least eight weeks after the last dose was received.
- Those with a previous asymptomatic infection or symptomatic disease caused by SARS-CoV-2 should also receive COVID-19 vaccination.
- Children aged 2 through 18 years who are moderately or severely immunocompromised
   (Table 1) and those in high-risk groups (Table 2) should be vaccinated including:
  - Persons at high-risk of severe COVID-19;
  - Residents of long-term care facilities or other congregate settings;
  - o Persons who have never been vaccinated against COVID-19;
  - o Persons whose household contacts are at high risk for severe COVID-19.
- Children aged 2 through18 years not included in the groups above whose parent or guardian desires protection from COVID-19 may receive a single dose of ageappropriate vaccine.

## Adult Immunization Schedule (aged 19+ years)\*

- Everyone aged ≥19 years should be vaccinated.
- Vaccination is especially important for people who:
  - Are moderately or severely immunocompromised;
  - Have never received a COVID-19 vaccine;
  - Are at high-risk of exposure to COVID-19 or who care for people at high-risk for severe COVID-19 (Table 2) (e.g., health care personnel);
  - Are at high-risk of severe COVID-19 (Table 2) including:
    - People aged ≥65 years\*;
    - People with underlying conditions;
    - People whose household contacts are at high-risk for severe COVID-19.

## **Pregnancy and Lactation**

Pregnant people are at increased risk of severe disease and adverse pregnancy outcomes from COVID-19. COVID-19 vaccination during any trimester protects both the pregnant person and the infant ≤6 months from severe illness due to COVID-19.

- Everyone who is pregnant should be vaccinated. Vaccination may occur in any trimester;
   vaccination at the earliest opportunity maximizes maternal and fetal health.
- Everyone who is planning pregnancy, is in the post-partum period, and who is lactating should be vaccinated.

## **Co-administration**

COVID-19 vaccines may be administered at the same time as other commonly recommended vaccines, including those that provide protection against influenza; respiratory syncytial virus (RSV); tetanus, pertussis, and diphtheria (Tdap); and pneumococcal disease. The vaccines should be administered at different sites.

### **Self-attestation**

People can self-attest to their moderately or severely immunocompromised status and/or their high-risk conditions. Vaccinators should not deny COVID-19 vaccine to a person due to lack of documentation.

\*See the American Academy of Pediatrics Immunization Schedule for Ages 18 years or younger for the schedule for additional information on dosing and the schedule for children who are moderately or severely immunocompromised. See the American Academy of Family Physicians, Adults 19 and Older Immunization Schedule for additional information on dosing and the schedule for moderately or severely immunocompromised adults and for people 65+ years.

# Table 1 - CDC List of Moderate and Severe Immunocompromising Conditions#

## Conditions include but are not limited to the following:

Active treatment for solid and hematologic malignancies

Hematologic malignancies associated with poor response to COVID-19 vaccines regardless of current treatment status (e.g., chronic lymphocytic leukemia, non-Hodgkin's lymphoma, multiple myeloma, acute leukemia)

Receipt of solid-organ transplant or an islet transplant and taking immunosuppressive therapy

Receipt of chimeric antigen receptor (CAR)-T-cell therapy or hematopoietic cell transplant (HCT) (within two years of transplantation or taking immunosuppressive therapy)

Moderate or severe primary immunodeficiency (e.g., common variable immunodeficiency disease, severe combined immunodeficiency, DiGeorge syndrome, Wiskott-Aldrich syndrome)

Advanced HIV infection (people with HIV and CD4 cell counts less than 200/mm<sup>3</sup>, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV) or untreated HIV infection

Active treatment with high-dose corticosteroids (i.e.,20 mg or more of prednisone or equivalent per day when administered for two or more weeks), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor necrosis factor (TNF) blockers, and other biological agents that are immunosuppressive or immunomodulatory (e.g., B-cell-depleting agents)

\*Factors to consider in assessing the general level of immune competence in a patient include disease severity, duration, clinical stability, complications, comorbidities and potentially immune-suppressing treatment.

# <u>Table 2</u> - CDC 2025 List of Underlying Medical Conditions That Increase a Person's Risk of Severe COVID-19

### Asthma

### Cancer

Hematologic malignancies

### Cerebrovascular disease

## Chronic kidney disease\*

People receiving dialysis°

## Chronic lung diseases limited to the following:

- Bronchiectasis
  - COPD (chronic obstructive pulmonary disease)
- Interstitial lung disease
- Pulmonary embolism
- Pulmonary hypertension

## Chronic liver disease limited to the following:

- Cirrhosis
- Nonalcoholic fatty liver disease
- Alcoholic liver disease
- Autoimmune hepatitis

## Cystic Fibrosis

Diabetes mellitus, type 1

Diabetes mellitus, type 2\*

Disabilities<sup>¥\*\*</sup>, including Down's syndrome

## Epilepsy

### Hemophilia

Heart conditions (such as heart failure, coronary artery disease, or cardiomyopathies)

HIV (human immunodeficiency virus)

# Mental health conditions limited to the following:

- Mood disorders, including depression
- Schizophrenia spectrum disorders

Neurologic conditions limited to dementia ‡ and Parkinson's disease

Obesity (BMI>30 or >95<sup>th</sup> percentile in children)

Overweight (BMI>25 kg/m² but <30kg/m²)

Physical inactivity

Pregnancy (pregnant, postpartum, lactating, or planning pregnancy)

Primary immunodeficiencies

Sickle cell disease

Smoking, current and former

Substance use disorders

Solid organ or blood stem cell transplantation

**Tuberculosis** 

Use of corticosteroids or other immunosuppressive medications

- \* Indicates presence of evidence for pregnant and non-pregnant people
- ¥ Underlying conditions for which there is evidence in pediatric populations
- ° Risk may be further increased for people receiving dialysis
- \*\* Attention-deficit/hyperactivity disorder (ADHD), Autism, Cerebral palsy, Charcot foot, Chromosomal disorders, Chromosome 17 and 19 deletion, Chromosome 18q deletion, Cognitive impairment, Congenital hydrocephalus, Congenital malformations. Deafness/hearing loss, Disability indicated by Barthel Index, Down syndrome, Fahr's syndrome, Fragile X syndrome, Gaucher disease, Hand and foot disorders, Learning disabilities. Leber's hereditary optic neuropathy (LHON) or Autosomal dominant optic atrophy (ADOA), Leigh syndrome, Limitations with self-care or activities of daily living, Maternal inherited diabetes and deafness (MIDD), Mitochondrial encephalopathy, lactic acidosis, and stroke-like episodes (MELAS) and risk markers. Mobility disability. Movement disorders. Multiple disability (referred to in research papers as "bedridden disability"), Multisystem disease, Myoclonic epilepsy with ragged red fibers (MERRF), Myotonic dystrophy, Neurodevelopmental disorders, Neuromuscular disorders, Neuromyelitis optica spectrum disorder (NMOSD), Neuropathy, ataxia, and retinitis pigmentosa (NARP), Perinatal spastic hemiparesis, Primary mitochondrial myopathy (PMM), Progressive supranuclear palsy, Senior-Loken syndrome, Severe and complex disability (referred to in research papers as "polyhandicap disability"), Spina bifida and other nervous system anomalies, Spinal cord injury, Tourette syndrome, Traumatic brain injury, Visual impairment/blindness, Wheelchair use cdc.gov/covid/hcp/clinical-care/underlying-conditions.html (Accessed: September 9, 2025, 2:00 p.m.)