What You Need to Know – Respiratory Season Edition

Abbi Berg, MPH

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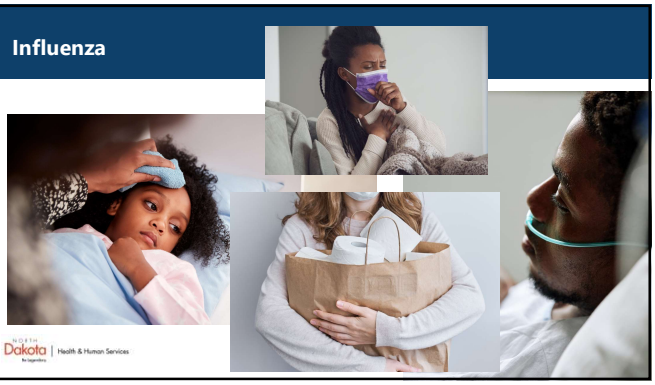
Influenza



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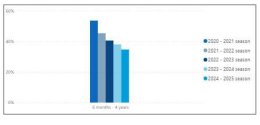
Why Flu Matters

The 2024-2025 influenza season saw the deadliest season for our children since the CDC began collecting influenza associated pediatric death data.

- 279 pediatric deaths
- 90% of reported pediatric deaths occurred in children who were not fully vaccinated.

Influenza vaccination rates amongst children have declined in North Dakota from pre-pandemic levels.



6 months – 4 years: 53.5% down to 34.6%

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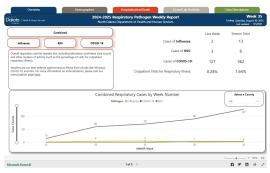
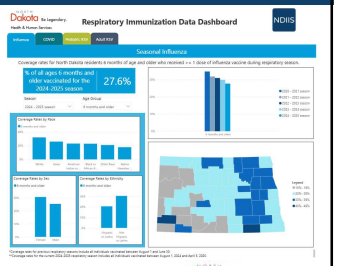
ND Respiratory Data

https://www.hhs.nd.gov/health/respiratory





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CDC Respiratory Data

- https://www.cdc.gov/respiratory-viruses/data/index.html
- https://www.cdc.gov/fluvaxview/index.html

Coverage by Season
About FluVaxView
Additional Publications

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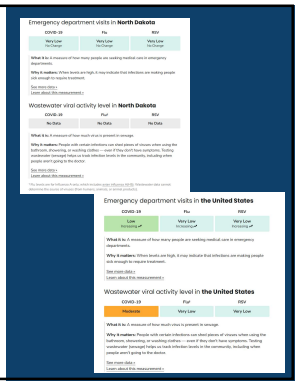

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Influenza Vaccine Recommendations

Who should be vaccinated?

ACIP reaffirms the recommendations for routine annual influenza vaccination of all persons aged ≥ 6 months who do not have contraindications for the 2025-2026 season.

ACIP recommends only single-dose formulations of annual influenza vaccines that are free of thimerosal as a preservative for three populations:

- Children 18 years or younger
- Pregnant women
- All adults

Note: AAP, ACOG, and ACC all are recommending influenza vaccines.

What is new this season?

- The Food and Drug Administration (FDA) has approved self-administered LAIV during the 2025-2026 respiratory season. LAIV for self-administration will not be available from the VFC program this respiratory season.
- Flublok® has been FDA approved for ages 9 years and up for the 2025-2026 respiratory season.

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Influenza Vaccine Timing

	What are the options?	Who is eligible?	How well do they work?	When should I get it?
INFLUENZA	A shot that targets 3 strains of seasonal flu	6 months+	Reduces the risk of going to the doctor by 30-60%	October is ideal, as vaccine protection wanes over a season

Recommended by CDC, American Academy of Pediatrics, American College of Obstericians and Gynecologists

Source: Your Local Epidemiologist

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Publicly Supplied Influenza Vaccine

Sanofi Pasteur
Fluzone® 0.5 IIV4 PFS – 2,910 (53%)

GSK
Fluarix® 0.5 IIV4 PFS – Fully allocated as of 8/25
FluLaval® IIV PFS – 4,490 (67%)

Seqirus
Flucelvax® 0.5 IIV4 PFS – 6,070 (74%)
Afluria® IIV4 PFS – 60 (46%)

AstraZeneca
Flumist® - 530 (47%)

- Publicly supplied influenza vaccine has begun to ship from McKesson
- Vaccine orders are being placed on behalf of facilities based on vaccine prebooks placed earlier in the year.
- Providers will receive automated emails when publicly supplied influenza vaccine has been ordered on their behalf.
- All influenza multi-dose vials were replaced with pre-filled syringes.

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Methylmercury vs Ethylmercury

Mercury is a naturally occurring element found in the earth's crust, air, soil and water. Since the earth's formation, volcanic eruptions, weathering of rocks and burning of coal have caused mercury to be released into the environment. Once released, certain types of bacteria in the environment can change mercury to methylmercury. Methylmercury makes its way through the food chain in fish, animals and humans. At high levels, it can be toxic to people.

Thimerosal contains a different form of mercury called ethylmercury. Studies comparing ethylmercury and methylmercury suggest that they are processed differently in the human body. Ethylmercury is broken down and excreted much more rapidly than methylmercury. Therefore, ethylmercury (the type of mercury in the influenza vaccine) is much less likely than methylmercury (the type of mercury in the environment) to accumulate in the body and cause harm.

https://www.chop.edu/vaccine-education-center/vaccine-safety/vaccine-ingredients/thimerosal

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Is Thimerosal Still In Vaccines?

Thimerosal was removed from vaccines after an amendment to the Food and Drug Administration (FDA) Modernization Act was signed into law on Nov. 21, 1997.

Thimerosal, as a preservative, is no longer contained in any childhood vaccine, with the exception of the influenza vaccine.

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Thimerosal and Autism

- **Centers for Disease Control and Prevention (CDC):** Cites multiple studies it has conducted or funded since 2003 that found no link between thimerosal-containing vaccines and autism spectrum disorders (ASD). The CDC also notes that autism rates continued to rise even after thimerosal was removed from most childhood vaccines.
- **Institute of Medicine (now the National Academy of Medicine):** A 2004 review of over 200 scientific studies concluded that the evidence consistently provided no association between thimerosal-containing vaccines and autism. It explicitly rejected the hypothesis that thimerosal or the MMR vaccine causes autism.


Thimerosal and autism

Evidence that mercury doesn't cause autism

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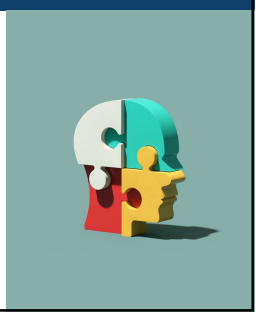
Thimerosal and Autism, cont.

World Health Organization (WHO): After an independent review, the WHO concluded that thimerosal in vaccines poses no health risks and is safe for global use.
Johns Hopkins University: Public health experts state that 16 large, well-conducted, population-based studies from different countries have found no relationship between thimerosal in vaccines and autism.
Danish studies: One major study looked at all children born in Denmark between 1990 and 1996, comparing children vaccinated with a thimerosal-containing vaccine to those who received a thimerosal-free version. The study found no significant difference in autism risk between the two groups. Researchers also found that autism rates increased in Denmark and Sweden even after thimerosal was removed from vaccines in the early 1990s.



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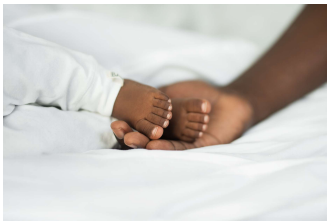
Pediatric RSV



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Why RSV Matters

Around 80% of infants hospitalized with RSV have no underlying medical conditions and are otherwise healthy infants

It is the most common cause of bronchiolitis and pneumonia in children younger than 1 year of age

Nearly all children will have been infected with RSV by two years of age

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Pediatric RSV

	What are the options?	Who is eligible?	How well do they work?	When should I get it?
RSV (INFANTS)	Monoclonal antibody called nirsevimab or clesrovimab. This is not a vaccine (doesn't teach the body to make antibodies) but rather a medication (provides antibodies)	All infants <8 months old and children 8-19 months with risk factors (if mother didn't receive vaccine during pregnany)	Reduces risk of hospitalization by 80-96%	Typically from October-March, if maternal RSV vaccine not received Protection lasts 4-6 months

Source: Your Local Epidemiologist

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Infant RSV Antibody Recommendations

Administer RSV Antibody to infants October 1st – March 31st.

- There may be special circumstances where the doses should be administered outside of this timeframe based on positivity rate of RSV in a specific region or state. Those extended recommendations would be communicated by the Immunization Unit.

Doses should be given to all infants less than 8 months during their first RSV season. **Preferably before they are discharged from birthing hospital.**

-Only 54% of ND Medicaid newborns see a provider within seven days of life.

Children 8 – 19 months of age who have certain high-risk conditions. This includes American Indian Children.

Consider plans for children who need their second dose.

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Infant RSV Monoclonal Antibody Products

Nirsevimab (Beyfortus®)

- Manufactured by Sanofi Pasteur
- Two different dosages depending on current weight.
  - 0.5 mL and 1.0 mL
- Licensed for 0 – 24 months

Clesrovimab (Enflonsia®)

- Manufactured by Merck
- One dosage regardless of age or weight, 105 mg/0.7 mL
- Not approved for use in older age group during their second RSV season
- Will be available through the VFC program but is not currently

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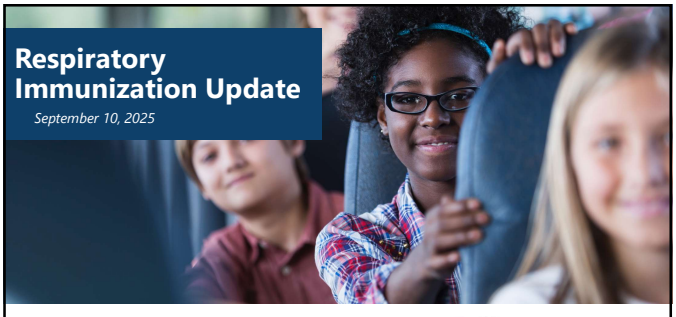

Respiratory Immunization Update

September 10, 2025

Jenny Galbraith
Adult Immunization Manager

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Respiratory Syncytial Virus (RSV)

- RSV is a common respiratory virus that generally causes mild, cold-like symptoms including runny nose, coughing, sneezing, fever, wheezing, and decreased appetite.
- RSV season is generally during the fall and winter months, October – March .
- Most people recover in 1-2 weeks.
- People may have recurrent infections throughout their lifetime.

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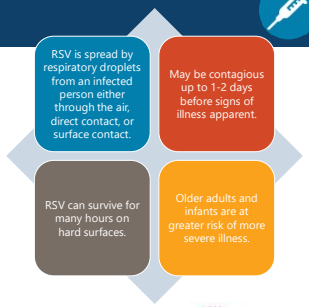
Respiratory Syncytial Virus (RSV)



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RSV Disease Burden in Adults 65+

- RSV is a major cause of hospitalization and mortality for adults 65+.
- Estimated 60,000-160,000 hospitalizations annually in the US.
- Estimated 6,000-10,000 deaths annually in the US.

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RSV Disease Burden in Adults 65+

Older adults at highest risk:

- Adults with chronic heart or lung disease
- Adults with weakened immune systems
- Adults with certain underlying medical conditions
- Adults living in nursing homes or long-term care facilities
- Average age of American Indian adults hospitalized is 56 years versus 73 years for non-Hispanic Whites

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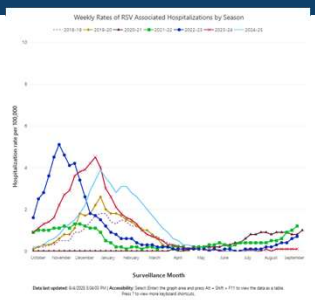
RSV National Data



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RSV Prevention

Older Adults

- 3 RSV vaccines, Arexvy™, Abrysvo™ and mResvia™ are approved for older adults.
- Recommended for all adults 75 years and older.
- Recommended for adults aged 50-74 years who are at increased risk of severe RSV disease due to certain health conditions.
- Currently recommended to receive one lifetime dose

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RSV Disease Underlying Conditions

Adults aged 50-74 years who are at increased risk of severe RSV:

- Chronic lung disease
- Chronic cardiovascular disease
- Diabetes with end-organ damage
- Severe obesity
- Neurologic or neuromuscular conditions
- Chronic kidney disease, advanced
- Decreased immune function (ie., immunocompromising conditions)
- Liver disorders
- Frailty
- Hematologic disorders
- Residence in a nursing home or other long-term care facility
- Other chronic medical conditions that a healthcare provider determines increases risk of severe disease due to respiratory infection

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RSV Prevention – Maternal

Maternal RSV vaccine (Abrysvo™)

- Given to pregnant woman between 32-36 weeks gestation between Sept-Jan to protect infant.
- If received at least 14 days prior to birth, infant generally will not need to receive nirsevimab.
- Currently only recommended for one lifetime dose. Infants in subsequent pregnancies should receive a monoclonal antibody.

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Maternal RSV Vaccine - Safety

Conclusions from 2023–2024 respiratory season findings

- **RSVpreF vaccine <u>not</u> associated with increased risk for**
  - Acute safety outcomes
  - Preterm birth
  - SGA at birth
  - Stillbirth
- **RSVpreF vaccine associated with small but statistically increased risk for HDP**
  - Potential residual confounding or outcome misclassification
  - Severity of HDP similar between vaccinated and unvaccinated women based on rates of c-section, admission following birth hospitalization, and length of stay
- **2024–2025 season analysis pending**

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RSV Prevention – Maternal

Both nirsevimab and the maternal RSV vaccine provide short-term protection to infants through their first RSV season when they are at highest risk of severe RSV infection.

- The maternal RSV vaccine was 76% effective in studies at preventing severe medically attended RSV-associated lower respiratory tract infections in infants from birth through 180 days.
- The maternal RSV vaccine may be administered at the same time as other recommended immunizations

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RSV Prevention – Maternal

The maternal RSV vaccine is

- Covered by private insurance.
- Included in the North Dakota Vaccines for Children (VFC) Program for those ages 18 years and younger.

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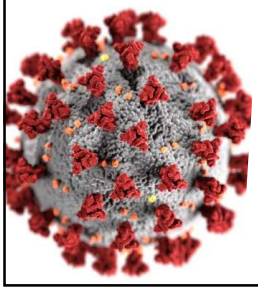
COVID-19



COVID-19 is very contagious and spreads quickly when an infected person breathes out small droplets and particles and sometimes from contact with contaminated surfaces.

COVID-19 can spread when people are asymptomatic

It can cause mild or severe illness.

It causes respiratory symptoms, but can also impact other parts of the body.

People who are older, immunocompromised, have certain disabilities, or certain health conditions are at increased risk of more severe infection.

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COVID-19 National Data

COVID-19 continues to impact Americans' health.

Preliminary 2024-2025 U.S. COVID-19 Burden Estimates

CDC estimates* that, from October 1, 2024 through June 7, 2025, there have been:

9.8 million–16.1 million	2.4 million–3.8 million	270,000–440,000	32,000–51,000
COVID-19 Illnesses	COVID-19 Outpatient Visits	COVID-19 Hospitalizations	COVID-19 Deaths

* Based on data from September 29, 2024 through June 7, 2025.
Source: https://www.cdc.gov/covid/php/surveillance/burden-estimates.html

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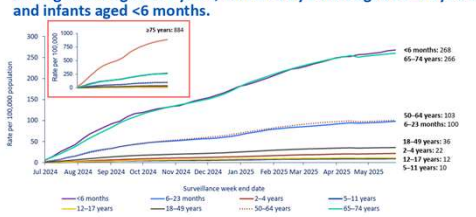
COVID-19 National Data

Cumulative COVID-19-associated hospitalization rates are highest among adults aged ≥75 years, followed by adults aged 65–74 years and infants aged <6 months.



Weekly rates of COVID-19–associated hospitalizations per 100,000 population by age group—COVID-NET, July 2024–May 2025.
Note that rates are not adjusted for testing. Rates are not limited to admissions where the respiratory infection is the likely primary reason for admission.

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COVID-19 Pediatric National Data

More than half of pediatric COVID-19-associated hospitalizations occur in children aged <2 years.

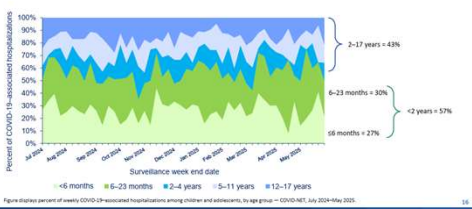

Figure displays percent of weekly COVID-19–associated hospitalizations among children and adolescents, by age group — COVID-NET, July 2024–May 2025.

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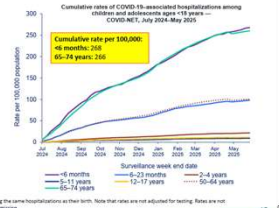
COVID-19 Pediatric National Data

COVID-19 causes severe disease in infants ages <6 months.

- **Highest rate of COVID-19-associated hospitalization among all pediatric age groups**
  - Rates comparable to adults ages 65–74 years



Data reported from July 2024–May 2025. Excludes newborns who were admitted during the same hospitalizations as their birth. Note that rates are not adjusted for testing. Rates are not limited to admissions where the respiratory infection is the likely primary reason for admission.

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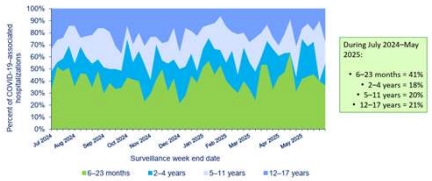
COVID-19 Pediatric National Data

Among vaccine-eligible children and adolescents ages 6 months–17 years, 41% of COVID-19-associated hospitalizations occurred among children ages 6–23 months.



During July 2024–May 2025:

- 6–23 months = 41%
- 2–4 years = 18%
- 5–11 years = 20%
- 12–17 years = 21%

Figure displays the percent of weekly COVID-19–associated hospitalizations among children and adolescents, by age group — COVID-NET, October 2024–May 2025.

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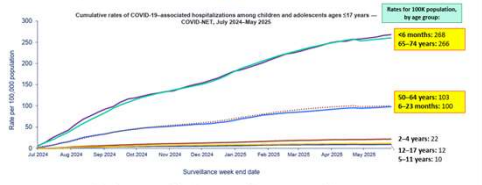
COVID-19 Pediatric National Data

The youngest age groups have comparable rates of cumulative COVID-19-associated hospitalization to some adult age groups, but direct comparisons are challenging.



Note that rates are not adjusted for testing. Rates are not limited to admissions where the respiratory infection is the likely primary reason for admission.

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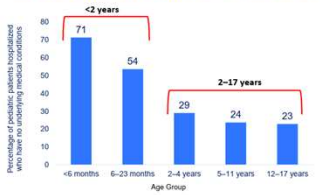
COVID-19 Pediatric National Data

Proportion of children hospitalized for COVID-19 who had no underlying medical conditions



Most hospitalized children ages <2 years did not have any underlying medical condition.

Figure displays the weighted percent of children and adolescents hospitalized for COVID-19 with no underlying medical conditions, by age group — COVID-NET, April 2024–March 2025. Hospitalizations are limited to those with COVID-19 as the presenting complaint upon admission. Pregnant adolescents ages 15–17 years are excluded from proportions presented.

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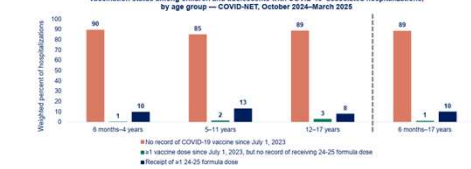
COVID-19 Pediatric National Data

89% of COVID-19 vaccine-eligible children and adolescents who were hospitalized with COVID-19 had no record of receiving the most recently recommended COVID-19 vaccines.

Vaccination status among children and adolescents with COVID-19–associated hospitalizations, by age group — COVID-NET, October 2024–March 2025



No record of COVID-19 vaccine since July 1, 2023*: No recorded doses of any COVID-19 vaccine dose since July 1, 2023.* ***≥1 vaccine dose since July 1, 2023, but no 2024–2025 dose:*** *Received at least one COVID-19 vaccination since July 1, 2023, but no record of receiving 2024-2025 vaccine dose.* ***Receipt of ≥1 24-25 formula dose:*** *Received at least 1 dose of the 2024-2025 vaccine dose. Persons with unknown vaccination status (6.4%) are excluded. Hospitalizations are limited to those with COVID-19 as the presenting complaint upon admission.*

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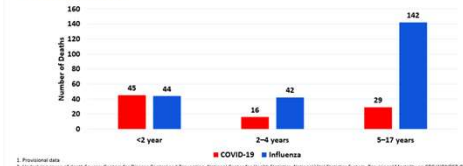
COVID-19 Pediatric National Data

Total number of COVID-19- and Influenza-associated deaths[1,2], among ages 0–17 years in July 2024–June 2025, United States



1. Provisional data
2. Underlying cause of death Source: Centers for Disease Control and Prevention, National Center for Health Statistics. National Vital Statistics System, Provisional Mortality on CDC WONDER Online Database. Data are from the final Underlying Cause of Death Files, provisional data for 2024 and provisional and partial data from 2025, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program. Number of deaths includes influenza codes (J09-J11) or COVID-19 code (U07.1) as the underlying cause of death. http://wonder.cdc.gov/mcd-icd9-provisional.html, accessed June 20, 2025.
Note: Estimates of pediatric influenza deaths reported to CDC can be found here: https://www.cdc.gov/flu/view/surveillance/2025-week-15.html. Estimates will vary due to differences in reporting methods and timeframes used.

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COVID-19 Pregnant Women National Data

Pregnant women with COVID-19–associated hospitalizations, April 2024–March 2025

- Pregnancy status collected from hospitalized women ages 15–49 years
- 28.5% of women ages 15–49 years hospitalized with laboratory-confirmed SARS-CoV-2 infection were pregnant
  - 50% of those had COVID-19-related signs or symptoms

Source: COVID-NET, unpublished data.

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COVID-19 Pregnant Women National Data

Pregnant women with COVID-19–associated hospitalization, April 2024–March 2025

Among 131 hospitalized pregnant women with a laboratory-confirmed SARS-CoV-2-positive test result and COVID-19-related signs or symptoms:

- 50% had no underlying conditions
- 68% were no longer pregnant at discharge, among whom:
  - 83% had a healthy newborn, 11% had a pre-term infant, 1% had an ill infant, and 5% had pregnancy loss*
- 92% have no record of vaccination since July 1, 2023
  - 5.8% received recommended 2024-25 COVID-19 vaccine dose**

* Includes spontaneous miscarriage and abortion.
** Vaccination might have occurred before the pregnancy period and is not necessarily indicative of maternal vaccination status.
Source: COVID-NET, unpublished data.

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COVID-19 Older Adult National Data

Adults ages ≥65 years comprise more than 2/3 of all COVID-19–associated hospitalizations among adults.

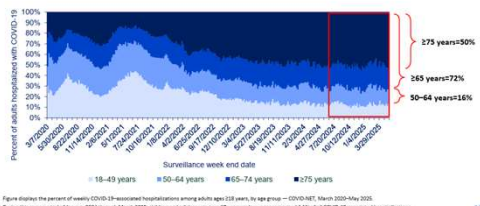

Figure displays the percent of weekly COVID-19–associated hospitalizations among adults ages ≥18 years, by age group — COVID-NET, March 2020–May 2025.
During this same period of January 2024 through March 2025, children and adolescents ages 17 years and younger comprised 4.1% of all COVID-19-associated hospitalizations

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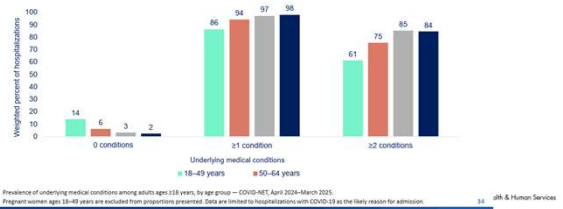
COVID-19 Older Adult National Data

Most adults hospitalized for COVID-19 have ≥1 underlying medical condition; a majority have ≥2.



Prevalence of underlying medical conditions among adults ages ≥18 years, by age group — COVID-NET, April 2024–March 2025.
Pregnant women ages 18–49 years are excluded from proportions presented. Data are limited to hospitalizations with COVID-19 as the likely reason for admission.

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COVID-19 Older Adult National Data

Most adults hospitalized for COVID-19 had received no COVID-19 vaccine since July 2023.

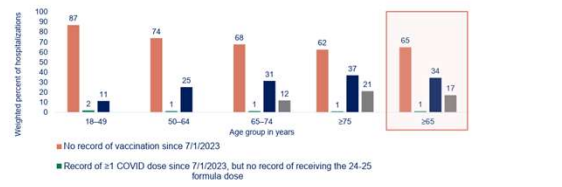

Figure displays the COVID-19 vaccination status among adults hospitalized for COVID-19, by age group — COVID-NET, October 2024–March 2025.
Data are limited to hospitalizations where COVID-19 is a likely primary reason for admission.

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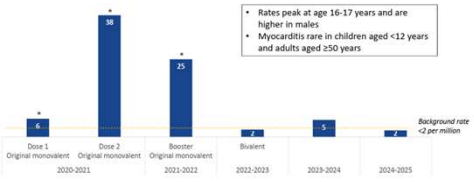
COVID-19 Vaccine Safety

Myocarditis Following mRNA COVID-19 Vaccination Among People Ages 12–39 Years in the Vaccine Safety Datalink

Incidence of myocarditis within 7 days of vaccination per million mRNA vaccine doses administered



*Statistically significant increased rate ratio in vaccinated concurrent comparator analysis. Source: CDC Immunization Safety Office

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COVID-19 Vaccine Safety

Follow-up CDC Studies Demonstrate Most Adolescents and Young Adults Have Recovered From Myocarditis

- Surveys of individuals aged 12-29 years with myocarditis after mRNA COVID-19 vaccine, and their healthcare providers, for whom a VAERS report was filed during January 12-November 5, 2021
- Based on cardiologist or other healthcare provider assessment:

83% Fully or probably fully recovered by at least 90 days after myocarditis onset → **>90%** Overall, fully or probably fully recovered by at least a 1 year after myocarditis onset

- Among patients with abnormal cardiac MRI at 1-year evaluation, most common abnormality was late gadolinium enhancement
  - clinical significance unclear; majority considered recovered and cleared for all physical activity
- No known deaths or cardiac transplants

Outcomes at least 90 days since onset of myocarditis after mRNA COVID-19 vaccination in adolescents and young adults in the USA: a follow-up surveillance study - The Lancet Child & Adolescent Health. Outcomes at ≥1 year based on unpublished data.

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COVID-19 Vaccine Safety

COVID-19 Vaccine Safety in Children Ages 6 Months to 11 Years

- Risk of myocarditis following COVID-19 vaccines in children aged <12 years is low, particularly for those aged 6 months to 5 years
  - Active, sequential analyses in the Vaccine Safety Datalink have demonstrated no statistical signals for myocarditis in children
  - No confirmed myocarditis cases in children aged <5 years in VAERS or VSD
- Rapid cycle analyses in the VSD demonstrate no increased risks for 22 other pre-specified outcomes following COVID-19 vaccination
- Evaluations to assess multisystem inflammatory syndrome in children (MIS-C) following COVID-19 vaccination demonstrated that most patients had evidence of preceding SARS-CoV-2 infection

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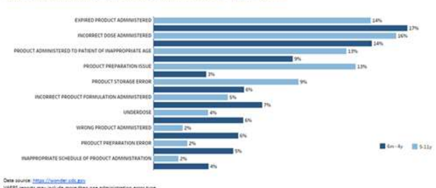
COVID-19 Vaccine Safety

Majority of COVID-19 Vaccine Reports to VAERS in Children Aged <12 Years Include at Least One Vaccine Administration Error

Approximately 77% of reports in children aged 6 months-4 years and 70% of reports in children aged 5-11 years related to administration errors between October 21, 2021 – April 30, 2025



Data source: https://wonder.cdc.gov
VAERS reports may include more than one administration error type

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COVID-19 Vaccine Safety

COVID-19 Vaccine Safety During Pregnancy

Across CDC studies, evidence shows NO increased risk of:

Maternal outcomes
- 25 medically-attended adverse events
- Serious adverse events
- Pregnancy-related conditions
- Maternal ICU admission

Pregnancy outcomes
- Miscarriage
- Stillbirth
- Preterm birth
- Small-for-gestational age

Infant outcomes
- Major birth defects
- Neonatal ICU admission
- Infant death

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COVID-19 Vaccine Safety

Safety Monitoring of Death Reports Following mRNA COVID-19 Vaccination in VAERS

- As of May 30, 2025, there have been 19,417 domestic deaths reported to VAERS after COVID-19 vaccination
- Important considerations related to evaluation of death reports in VAERS
  - FDA Emergency Use Authorizations and CDC COVID-19 Vaccination Provider Enrollment Agreements required healthcare provider to report **all deaths** following COVID-19 vaccination to VAERS, regardless of cause or circumstances surrounding death (requirement does not apply to other vaccines)
  - VAERS generally cannot assess causality of adverse reports, including deaths
- We conducted an evaluation of deaths following mRNA COVID-19 vaccination in VAERS through January 31, 2023

'accine Adverse Event Reporting System. VAERS Reporting Information for COVID-19 Vaccines. https://vaers.hhs.gov/reportevent.html

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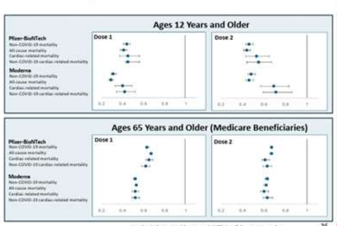
COVID-19 Vaccine Safety

Data From CDC's Vaccine Safety Datalink Shows No Increased Risk of Death Following mRNA COVID-19 Vaccines

- 2 self-controlled case series evaluations
- No increased risk in the 28 days after vaccination of:
  - Non-COVID mortality
  - All-cause mortality
  - Cardiac-related mortality
  - Non-COVID cardiac-related mortality
- Similar findings in VSD cohort study of people ages 12+ years



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Vaccine Integrity Project

- Vaccine Integrity Project (VIP): Convened a group of immunization experts to review the latest data regarding epidemiology, vaccine effectiveness, safety, and co-administration for influenza, COVID-19 and RSV immunizations.
  - Data presented August 19, 2025.
  - Data being utilized by numerous medical associations to make recommendations.
- Key Findings:
  - Respiratory viruses, including influenza, COVID-19, and respiratory syncytial virus (RSV) pose a significant threat to the health of all populations studied in this review.
  - This initial systematic review and meta-analysis reviewed the evidence for children, immunocompromised adults, and pregnancy, and searched for more than 15 severe adverse events of special interest.
  - Immunizations are an effective tool to reduce health risks for all populations from flu, COVID, and RSV, and have a strong safety profile. The studies reviewed since the 2023/2024 Advisory Committee on Immunization Practices (ACIP) meeting found no significantly elevated safety risks from US-licensed immunizations for these conditions.

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COVID-19 Vaccine Recommendations - AAP

- AAP recommends a COVID-19 vaccine for all children ages 6 through 23 months old to help protect against serious illness.
- AAP also recommends a single dose of age-appropriate COVID-19 vaccine for all children and adolescents 2 through 18 years of age in the following risk groups :
  - Persons at high risk of severe COVID-19
  - Residents of long-term care facilities or other congregate settings
  - Persons who have never been vaccinated against COVID-19
  - Persons whose household contacts are at high risk for severe COVID-19
- AAP also recommends the vaccine be available for children ages 2-18 who do not fall into these risk groups, but whose parent or guardian desires them to have the protection of the vaccine.

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COVID-19 Vaccine Recommendations - ACOG

- ACOG recommends that patients receive an updated COVID-19 vaccine or booster:
  - at any point during pregnancy;
  - in the postpartum period;
  - when planning to become pregnant; or
  - when lactating.

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COVID-19 Vaccine Recommendations - AAFP

All adults 18 years and older should receive a COVID-19 vaccine. It is especially important to get a COVID-19 vaccine if you are:

- 65 years and older;
- At increased risk for severe COVID-19 infection; and
- Have never received a COVID-19 vaccine.

All children aged 6 – 23 months receive a primary series and risk-based single dose for children and teen 2-18 years

- Recommendations align with the American Academy of Pediatrics (AAP).

Pregnant women any time during pregnancy and during lactation

- Aligned with the American College of Obstetrics and Gynecologists (ACOG)

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COVID-19 Vaccine – FDA Changes

- On August 27, 2025, the U.S. Food and Drug Administration approved COVID-19 vaccines for the 2025–2026 season manufactured by Moderna, Pfizer, and Sanofi/Novavax.
  - Indicated for use in adults 65+ and <64 with at least one high risk condition.
- Pfizer vaccine for children 6 months – 4 years of age was not reauthorized for use in the United States and will not be available for use this fall
- All other vaccines now have full approval from the FDA

- New this season - Moderna product, mNexspike, for ages 12 and older.
  - Lower dose (1/5th)

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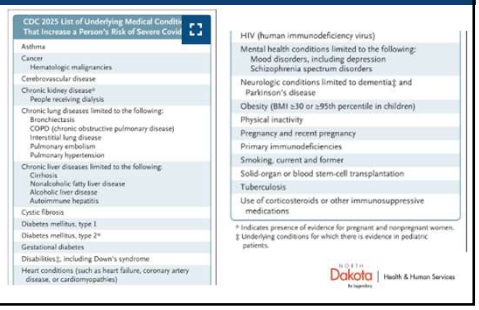
COVID-19 Vaccine – FDA Changes

- What is a high-risk condition?



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Description	Moderna (Spikevax) (6 months – 11 years)	Moderna (Spikevax) (12 years+)	Moderna (mNexspike) (12 years+	Pfizer-BioNTech (6 months – 4 years)	Pfizer-BioNTech (Comirnaty) (5-11 years)	Pfizer-BioNTech (Comirnaty) (12 years+)	Novavax (Nuvaxovid) (12 years +)
Age	6 months – 11 years	12+ years	12+ years	6 months – 4 years	5-11 years	12+ years	12+ years
Type of Vaccine	mRNA	mRNA	mRNA	mRNA	mRNA	mRNA	Protein Subunit
Regulatory Decision	Approved	Approved	Approved		Approved	Approved	Approved
Doses in Schedule	2 doses (6 months – 2 years) 1 dose (2 years – 11 years)	1	1		1	1	1
Dose Volume	.25 mL	0.5 mL	0.2 mL		0.3 mL	0.3 mL	0.5 mL
Diluent needed per vial	N/A	N/A	N/A		N/A	N/A	N/A
FDA Indication	6 months – 11 years with at least one underlying health condition that puts them at high risk for severe outcomes from COVID-19	65 years of age and older Or 12 - 64 years with at least one underlying health condition that puts them at high risk for severe outcomes from COVID-19	65 years of age and older Or 12 - 64 years with at least one underlying health condition that puts them at high risk for severe outcomes from COVID-19	Not reauthorized for use in the United States for the 2025-2026 season	5 years – 11 years with at least one underlying health condition that puts them at high risk for severe outcomes from COVID-19	65 years of age and older Or 12 - 64 years with at least one underlying health condition that puts them at high risk for severe outcomes from COVID-19	65 years of age and older Or 12 - 64 years with at least one underlying health condition that puts them at high risk for severe outcomes from COVID-19
Product Type	Prefilled syringes	Prefilled syringes	Prefilled syringes		Single dose vials	Prefilled Syringes	Prefilled Syringes
Doses Per Syringe	1 dose	1 dose	1 dose		1 dose	1 dose	1 dose
Minimum Package Quantity	10 doses Or 2 doses	10 doses Or 2 doses	10 doses		10 doses	10 doses	10 doses
NDIIS Vaccine Name	COVID Moderna <12	COVID Moderna 12+			COVID Pfizer 5-11	COVID Pfizer 12+	COVID Novavax 12+
Available on Federal Contract (VFC or VFA)	Yes	Yes	No		Yes	Yes	Yes

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COVID-19 Vaccine Recommendations – CDC/ACIP

- On 05/27/25, the HHS Secretary revised 2024-2025 COVID-19 vaccine recommendations.
  - Removed recommendations for healthy children and pregnant women.
- ACIP and CDC have not yet made COVID-19 vaccine recommendations for the 2025-2026 season.
  - Anticipating an ACIP meeting September 18-19.
- Per an X post by the HHS Secretary on 08/27/25: "FDA has now issued marketing authorization for those at higher risk: Moderna (6+ months), Pfizer (5+), and Novavax (12+). These vaccines are available for all patients who choose them after consulting with their doctors."

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What do FDA and potential ACIP changes mean for COVID-19 vaccine access?

- People who meet the label indications should be able to receive vaccines in ways similar to past years - through a pharmacist, physician, nurse or other healthcare providers.
- For those with high-risk conditions, Moderna's SPIKEVAX is approved for those **6 months and older,** Pfizer's COMIRNATY COVID-19 vaccine for those **5 years and older**, and Novavax's NUVAXOVID for those **12 years and older**. All 3 vaccines are approved for those **65 and older.**

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What do FDA and potential ACIP changes mean for COVID-19 vaccine access?

For patients who do not meet the "on label" indications:

- **Physicians** will still be able to prescribe and administer vaccines, including "off label," as they do for other off-label medications. As with any care they provide, physicians can use clinical guidelines, like those published by their professional societies (e.g., AAP and ACOG), to help them follow standards of care. If providers are considering offering the COVID-19 vaccine outside of the FDA-approved labeling, it's recommended that they consult with their organizations legal counsel.

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What do FDA and potential ACIP changes mean for COVID-19 vaccine access?

Pharmacists will likely be more restricted by Advisory Committee on Immunization Practices (ACIP) recommendations. The Immunization Protocol approved by the North Dakota Board of Pharmacy allows pharmacists to prescribe and administer vaccines per the ACIP recommendations. In past years, pharmacists have administered ~90% of COVID-19 vaccines, so restrictions on their ability to administer vaccines to all patients who want them may significantly limit vaccine access. Pharmacies can still administer COVID-19 vaccine off label using a collaborative agreement or an individual prescription/order from a practitioner.

Local Public health Providers likely have standing orders that reference ACIP recommendations. Local Public Health officers drafting standing orders that align with guidelines published by professional societies may wish to consult their organization's legal counsel prior to administering any doses "off-label". Additionally, an individual prescription/order from a practitioner could be followed.

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What do FDA and ACIP decisions mean for insurance coverage?

- The FDA label change does not have a direct effect on whether or how health plans cover vaccines.
- Most minimum coverage requirements are tied to ACIP recommendations rather than FDA licensing/labeling, and payers have broad flexibility to more than this minimum.
- VFC and VFA coverage are tied to ACIP recommendations

- **Providers should check with a patient's insurance prior to administration to determine coverage.**

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Post-Test

Successfully complete the five-question post-test to receive your certificate for nursing credit using the link below: https://ndhealth.co1.qualtrics.com/jfe/form/SV_3rBbofRwXtW2eaO

- Credit for this session will be available until October 7, 2025
- This presentation will be posted to our website at: www.hhs.nd.gov/immunizations

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North Dakota Immunization Unit

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