DEPARTMENT OF HEALTH

Minnesota Respiratory Syncytial Virus (RSV) Vaccination Guide

INFORMATION FOR THE 2024-25 RESPIRATORY SEASON

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Respiratory Syncytial Virus (RSV)

Each year, respiratory viruses are responsible for millions of illnesses and thousands of hospitalizations and deaths in the United States. In addition to the virus that causes COVID-19, there are many other types of respiratory viruses, including flu and respiratory syncytial virus (RSV). The good news is there are actions you can take to help protect yourself and others from health risks caused by respiratory viruses.

For information about currently circulating respiratory viruses visit Viral Respiratory Illness in Minnesota (Data & Statistics) (www.health.state.mn.us/diseases/respiratory/stats/index.html).

Who is most at risk for getting very sick from RSV?

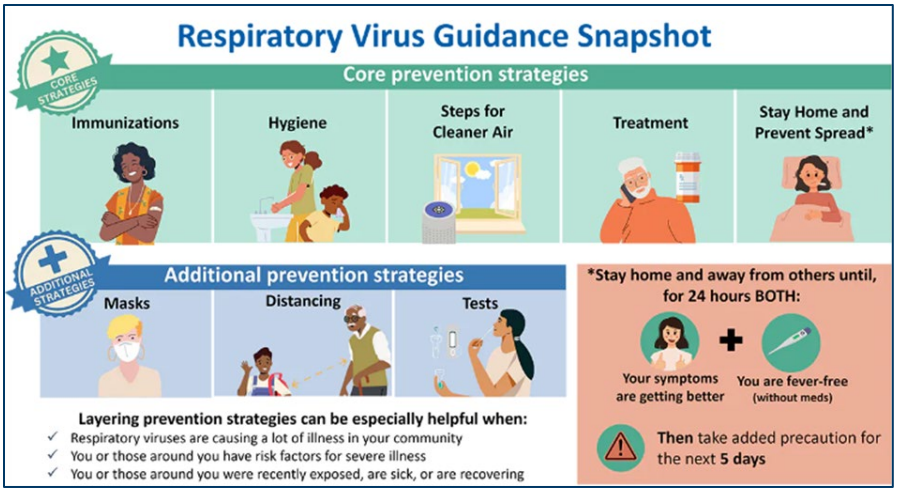
Infants, young children, people with a weak immune system, and adults 60 years and older are most at risk for severe disease. This includes premature infants, infants under 6 months, children younger than 2 years old with chronic lung disease or congenital heart disease, or children with weakened immune systems and young American Indian and Alaskan Native children.

Adults at highest risk include those 65 years and older, those with certain chronic diseases (including heart, lung, or immunocompromising conditions), and residents in congregate care settings. Risk for older adults does differ by race and ethnicity. Black, Hispanic, and American Indian or Alaska Native adults who are 60 years and older are at higher risk for hospitalization as well.

Take precautions to prevent transmission

The Centers for Disease Control and Prevention (CDC) updated their Respiratory Virus Guidance in February 2024. This guidance provides practical recommendations and information on core prevention strategies (masks, cleaner air, hygiene, treatment, physical distancing and testing) as well as guidelines for when to stay home and away from others to help lower risk from flu, RSV, COVID-19 and other common respiratory viral illnesses: Respiratory Virus Guidance (www.cdc.gov/respiratory-viruses/guidance/).

Respiratory virus guidance snapshot



Respiratory Virus Guidance (www.cdc.gov/respiratory-viruses/guidance/)

Use of this guide

Anyone who handles and/or administers RSV vaccine should read this guide. Bookmark this guide for easy reference and check back for updates.

RSV vaccines for older adults

RSV is a major cause of respiratory illness and hospitalization in older adults during fall and winter in the United States. The 2023–2024 RSV season was the first during which RSV vaccination was recommended for U.S. adults aged ≥60 years, using shared clinical decision-making.

On June 26, 2024, the Advisory Committee on Immunization Practices (ACIP) voted to update this recommendation as follows: a single dose of any Food and Drug Administration–approved RSV vaccine (Arexvy [GSK]; Abrysvo [Pfizer]; or mRESVIA [Moderna]) is now recommended for all adults aged ≥75 years and for adults aged 60–74 years who are at increased risk for severe RSV disease. Adults who have previously received RSV vaccine should not receive another dose.

These updated recommendations are intended to maximize RSV vaccination coverage among persons most likely to benefit, by clarifying who is at highest risk and by reducing implementation barriers associated with the previous shared clinical decision-making recommendation.

Vaccine recommendations for older adults

ACIP recommends adults 75 years of age and older and adults 60–74 years of age who are at increased risk of severe RSV disease receive a single dose of RSV vaccine. Risk factors for severe respiratory syncytial virus disease among adults aged 60–74 years:

- Chronic cardiovascular disease (e.g., heart failure, coronary artery disease, or congenital heart disease [excluding isolated hypertension]).
- Chronic lung or respiratory disease (e.g., chronic obstructive pulmonary disease, emphysema, asthma, interstitial lung disease, or cystic fibrosis).
- End-stage renal disease or dependence on hemodialysis or other renal replacement therapy.
- Diabetes mellitus complicated by chronic kidney disease, neuropathy, retinopathy, or other end-organ damage, or requiring treatment with insulin or sodium-glucose cotransporter-2 (SGLT2) inhibitor.
- Neurologic or neuromuscular conditions causing impaired airway clearance or respiratory muscle weakness (e.g., poststroke dysphagia, amyotrophic lateral sclerosis, or muscular dystrophy [excluding history of stroke without impaired airway clearance]).
- Chronic liver disease (e.g., cirrhosis).
- Chronic hematologic conditions (e.g., sickle cell disease or thalassemia).
- Severe obesity (body mass index ≥40 kg/m2).
- Moderate or severe immune compromise.
- Residence in a nursing home.
- Other chronic medical conditions or risk factors that a health care provider determines would increase the risk for severe disease due to viral respiratory infection (e.g., frailty, situations in which health care providers have concern for presence of undiagnosed chronic medical conditions, or

residence in a remote or rural community where transportation of patients with severe RSV disease for escalation of medical care is challenging).

Patient attestation is sufficient evidence of the presence of a risk factor. Vaccinators should not deny RSV vaccination to a person because of lack of medical documentation.

The official CDC vaccine recommendation can be found in the published MMWR: Use of Respiratory Syncytial Virus Vaccines in Adults Aged ≥60 Years: Updated Recommendations of the Advisory Committee on Immunization Practices — United States, 2024 (www.cdc.gov/mmwr/volumes/73/wr/mm7332e1.htm).

2024-25 vaccine products for older adults

Manufacturer	Trade Name	Age	Dose-Presentation	Route
Pfizer	ABRYSVO	60 years and older	0.5 mL – Act-O-Vial, vial and prefilled syringe, or vial and vial. Reconstitution is needed for all presentations.	IM (intramuscular)
GlaxoSmithKline	AREXVY	60 years and older	0.5 mL - single-dose vial of lyophilized antigen component to be reconstituted with accompanying vial of adjuvant suspension component.	IM (intramuscular)
Moderna	mRESVIA	60 years and older	Pre-filled syringe	IM (intramuscular)

Timing of vaccination for older adults

Eligible, older adults who have not previously received RSV vaccination may be vaccinated at any time of year, but vaccination will have the most benefit if administered in late summer or early fall, just before the RSV season. In most of the continental United States, this corresponds to vaccination during August–October.

Contraindications and precautions for older adults

Refer to CDC: Adult Immunization Schedule Appendix (www.cdc.gov/vaccines/hcp/imz-schedules/adult-appendix.html) to review the contraindications and precautions for vaccine types.

Infant protection

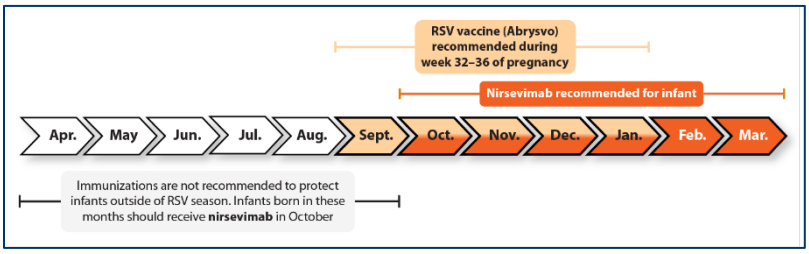
RSV is the leading cause of hospitalization among U.S. infants. The ACIP and CDC recommend RSV (Abrysvo) vaccine using seasonal administration (i.e., during September through end of January in most of the continental United States) for pregnant persons as a one-time dose at 32–36 weeks of gestation for prevention of RSV-associated lower respiratory infection (LRTI) in infants aged less than 6 months. For infants born to pregnant persons who did not receive vaccine, nirsevimab (Bevfortus) is recommended to prevent RSV-associated LRTI in infants given between October and March of the infant's first RSV season.

Either maternal RSV vaccination during pregnancy or nirsevimab administration to the infant is recommended to prevent RSV-associated LRTI among infants, but both are not needed for most infants. All infants should be protected against RSV-associated LRTI through use of one of these products.

Immunization recommendations

To prevent severe RSV disease in infants, CDC recommends either maternal RSV vaccination or infant immunization with RSV monoclonal antibodies during specific months to maximize protection during RSV season. Most infants will not need both.

RSV vaccine (Abrysvo) is recommended during week 32-36 of pregnancy from September through January. No vaccine should be administered to pregnant people after January 31. The maternal antibodies would be circulating during a time when RSV is not typically in the community. Infants born in April through September should receive nirsevimab in October.



Health care providers of pregnant people should provide information on both maternal vaccines and infant monoclonal antibody products, preferably early in a person's pregnancy. Providers should consider patient preferences when determining whether to vaccinate the pregnant patient or to not vaccinate and rely on administration of nirsevimab to the infant after birth.

Communication between providers for pregnant persons and infants will be important for identifying which babies need nirsevimab. For Immunization card examples and infographics to help with discussions with families visit Respiratory Syncytial Virus (RSV) for Health Professionals (www.health.state.mn.us/diseases/rsv/hcp.html).

Vaccine for pregnant people

CDC recommends one dose of maternal RSV vaccine during weeks 32 through 36 of pregnancy, administered September through January. Pfizer Abrysvo is the only RSV vaccine recommended during pregnancy.

When someone gets an RSV vaccine, their body responds by making a protein that protects against the virus that causes RSV. The process takes about 2 weeks. When a pregnant person gets an RSV vaccine, their protective proteins (called antibodies) also pass to their baby. Babies who are born at least 2 weeks after their mother gets RSV vaccine are protected at birth, when infants are at the highest risk of severe RSV disease.

Currently there is no recommendation for pregnant persons to receive more than once dose of RSV vaccine. Infants born after subsequent pregnancies should receive nirsevimab after birth.

MMWR: Use of the Pfizer Respiratory Syncytial Virus Vaccine During Pregnancy for the Prevention of Respiratory Syncytial Virus–Associated Lower Respiratory Tract Disease in Infants: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023 (www.cdc.gov/mmwr/volumes/72/wr/mm7241e1.htm).

2024-25 vaccine product for pregnant people

Manufacturer	Trade Name	Age	Dose - Presentation	Route
Pfizer	ABRYSVO	Pregnant individuals at 32 through 36 weeks gestational age	0.5 mL – Act-O-Vial, vial and prefilled syringe, or vial and vial. Reconstitution is needed for all presentations.	IM (intramuscular)

Contraindications and precautions for pregnant people

Refer to CDC: Adult Immunization Schedule Appendix (www.cdc.gov/vaccines/hcp/imz-schedules/adult-appendix.html) and CDC: Child Immunization Schedule Appendix (www.cdc.gov/vaccines/hcp/imz-schedules/child-adolescent-appendix.html) to review the contraindications and precautions for vaccine types.

Monoclonal antibodies for infants

Nirsevimab (Beyfortus) is a long-acting antibody used for the prevention of respiratory syncytial virus (RSV) lower respiratory tract disease in neonates and 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.

Nirsevimab contains monoclonal antibodies, which are man-made proteins that protect against RSV. Though it does not activate the immune system the way an infection or vaccine would, a nirsevimab shot provides protection like that of a vaccine.

The protection that nirsevimab provides is called "passive immunity" because it does not come from the person's own immune system. Instead, the protection comes from antibodies produced outside a person's body.

Nirsevimab reduces the risk of severe RSV disease by about 80%. One dose of nirsevimab protects infants for at least 5 months, the length of an average RSV season.

Nirsevimab (Beyfortus) is recommended:

- For all infants less than 8 months of age born during or entering their first RSV season if the mother was not vaccinated with Abrysvo at least 2 weeks before delivery:
  - 50mg for infants weighing less than 5kg (11 pounds).
  - 100mg for infants weighing 5kg (11 pounds) or more.
- For infants and children aged 8–19 months who are at increased risk of severe RSV disease entering their second RSV season. This includes children who were born prematurely and have chronic lung disease, with severe immunocompromise, with cystic fibrosis who have severe disease, or are American Indian or Alaska Native.
  - 200mg (given as two 100 mg injections at the same time at different injection sites).

The American Academy of Pediatrics has published a helpful visual guide: AAP: Nirsevimab Administration Visual Guide (https://downloads.aap.org/AAP/PDF/Nirsevemab-Visual-Guide.pdf)

MMWR: Use of Nirsevimab for the Prevention of Respiratory Syncytial Virus Disease Among Infants and Young Children: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023 (www.cdc.gov/mmwr/volumes/72/wr/mm7234a4.htm).

2024-25 vaccine product for infants

Manufacturer	Trade Name	Age	Dose - Presentation	Route
Sanofi	Beyfortus	Newborn through 7 months during the RSV season	Less than 5 kg (11 pounds): ▪ 50 mg ▪ 0.5 mL in pre-filled syringe	IM (intramuscular)
Sanofi	Beyfortus	Newborn through 7 months during the RSV season	5 kg (11 pounds) or more: ▪ 100 mg ▪ 1 mL in pre-filled syringe	IM (intramuscular)
Sanofi	Beyfortus	Children 8-19 months at increased risk during their second season	200 mg: Give 2 syringes of 100 mg Two syringes of 1 mL in each syringe	IM (intramuscular)

Nirsevimab contraindications and precautions

Refer to CDC: Child Immunization Schedule Appendix (www.cdc.gov/vaccines/hcp/imz-schedules/child-adolescent-appendix.html) to review the contraindications and precautions for vaccine types.

Prevent errors!

Do not inadvertently give RSV vaccines (Abrysvo, Arexvy or mRESVIA) to infants. Vaccine providers who carry both nirsevimab (for use in infants and young children) and RSV vaccines (for use in older adults and pregnant people) should be especially diligent in following vaccine administration safety procedures to prevent errors. To minimize risk of errors, store RSV vaccine and monoclonal antibodies in their original packaging on different shelves and clearly label them.

In the event RSV vaccine (Abrysvo, Arexvy or mRESVIA) was administered to an infant:

- Inform the provider and the parent/guardian of the error.
- Promptly report the error to the Vaccine Adverse Event Reporting System (VAERS).
- Administer nirsevimab, as there is no data on efficacy or effectiveness of RSV vaccines in preventing RSV disease in this age group. There is no specific recommendation for a minimum interval between administration of RSV vaccine and nirsevimab. Some experts suggest it could be reasonable to consider waiting 48 to 72 hours before proceeding with nirsevimab administration. This time frame is when side effects are expected after receipt of the RSV vaccine.
- Determine how the error occurred and implement strategies to prevent it from happening again.
- Email CDC nipinfo@cdc.gov and "cc" MDH health.vaccineSME@state.mn.us for further questions or concerns.

Resources for families

- CDC: Immunizations to Protect Infants (www.cdc.gov/rsv/immunizations-protect-infants/index.html).
- CDC: Immunization Information Sheet-RSV Preventive Antibody: What You Need to Know-September 25, 2023 (www.cdc.gov/vaccines/vpd/rsv/downloads/immunization-information-statement.pdf).

Vaccine ordering

All respiratory vaccines, including COVID-19 vaccine, are commercially available and should be ordered through your routine ordering process. Providers enrolled in MnVFC or UUAV will order vaccine in MIIC.

Vaccine storage and handling

Proper storage and handling of vaccine is critical to its effectiveness. Vaccines are especially sensitive to freezing temperatures. Here are some key tips to help ensure that your flu vaccine remains viable:

- Follow CDC and manufacturer specifications for maintaining the recommended temperature range:
  - Refrigerated vaccines: 36° through 46°F or 2° through 8°C, aim for 40°F/5°C.
  - Frozen vaccines: -58° through 5°F or -50°C through -15°C, aim for 0°F/-18°C.
  - Ultra-low cold vaccines: -130°F through -76°F or -90°C through -60°C.
- Optimal storage units include “stand alone” or pharmacy grade units; they provide uniform temperatures inside the unit. If using a combination unit, do not use the freezer compartment to store vaccines because the freeze-thaw cycles impact the temperatures in the refrigerator portion and increase the risk of exposure to freezing temperatures. Include water bottles in the refrigerator to add additional temperature buffering.
- Use a calibrated temperature monitoring device; a continuous temperature monitoring device, such as a data logger, is recommended.
- Check and document the minimum and maximum temperature once a day and the current temperature twice a day.
- Take action if the temperature goes out of range. Review managing out of range temperatures section.
- Visit CDC: Vaccine Storage and Handling (www.cdc.gov/vaccines/hcp/storage-handling/) for full guidance on storage and handling of vaccines.

Note: There are specific storage requirements for those that participate in the Minnesota Vaccine for Children Program (MnVFC) (www.health.state.mn.us/people/immunize/hcp/mnvfc/index.html). Refer to your site's Policies and Procedures Manual for guidance.

Managing out-of-range temperatures (excursions)

Take immediate action on out-of-range temperatures and mishaps

When your continuous temperature monitoring device is reading a temperature that falls outside the recommended range, it is considered an excursion or out-of-range temperature. Vaccines exposed to out-of-range temperatures may become nonviable (unusable, especially if frozen).

- Vaccine must be stored within the following temperature ranges:
  - Refrigerator between 36°F and 46°F (between 2°C and 8°C), aim for 40°F (5°C).
  - Freezer between -58°F and +5°F (between -50°C and -15°C), aim for 0°F (-18°C).

Move vaccine immediately for refrigerated vaccine that is less than 2 degrees Celsius (36 degrees Fahrenheit) and follow action steps for out-of-range temperatures. Vaccines exposed to freezing temperatures for even a brief time may become nonviable (unusable).

- If you find an out-of-range temperature, take immediate action:
  - Determine the problem. Attempt to fix the cause, if possible. It might be easily corrected (e.g., door not shut, power outage, unit malfunction).
  - Adjust the storage unit's temperature, if necessary.
  - Report the excursion to the vaccine coordinator or backup, if available.
- Monitor the temperature. If the temperature is too warm and doesn't stabilize in the correct range within 30 minutes, follow these action steps:
  - Stop using the vaccine.
  - Mark the vaccine "Do Not Use" so no one administers it.
  - Move the vaccine to a storage unit that is maintaining the correct temperature.
- Collect the lot numbers, expiration dates, storage unit temperatures, the room temperature, and the time the unit was out-of-range.
  - Determine the length of time the storage unit was out of range and how high/low the temperature got.
  - Determine if any of this vaccine was involved in a previous storage and handling mishap.
- Be aware that open multidose vials and refrigerated MMR vaccine are especially sensitive to out-of-range temperatures. Confirm viability with vaccine manufacturer(s) with every excursion even if the temperature stabilized within 30 minutes.
- Call the vaccine manufacturer(s) and ask to speak to a medical consultant or quality assurance staff. Manufacturer contact information can be found on Immunize.org: Vaccine Manufacturers (www.immunize.org/clinical/external/manufacturers/).
- Document your actions. You can use MDH forms or your own site's form to document out-of-range temperatures and actions taken.
  - Storage and Handling Mishap Log (www.health.state.mn.us/people/immunize/hcp/mnvfc/mishaplog.pdf).
  - Storage and Handling Mishap Checklist (www.health.state.mn.us/people/immunize/hcp/mnvfc/vaxchklst.pdf).
- Keep these logs for three years.

Recommending vaccinations

Provide a strong recommendation to your patients about flu, RSV and COVID-19 immunizations. Trusted health care providers are a powerful influence on patients' decisions to vaccinate. Prepare for questions about vaccine effectiveness, safety and when and why to get vaccinated and re-vaccinated:

- CDC: Conversation Guide For Healthcare Providers (www.cdc.gov/respiratory-viruses/tools-resources/downloads/HCP-conversation-guide-508.pdf).
- CDC: Healthcare Worker Vaccination is Important for Respiratory Virus Season (https://blogs.cdc.gov/safehealthcare/hcw-vaccination-respiratory-virus-season/).
- CDC: COVID-19 Vaccine Confidence (www.cdc.gov/vaccines/covid-19/vaccinate-with-confidence.html).
- Immunization Information for Health Care Providers (www.health.state.mn.us/people/immunize/hcp/index.html).

Vaccine screening templates

Screen for possible contraindications and precautions before vaccinating. Some sample screening forms include:

- Immunize.org: Screening Checklist for Contraindications to Vaccines for Adults (www.immunize.org/wp-content/uploads/catg.d/p4065.pdf).
- Immunize.org: Screening Checklist for Contraindications to Vaccines for Children and Teens (www.immunize.org/wp-content/uploads/catg.d/p4060.pdf).
- Template: COVID-19 Vaccine Screening and Agreement (www.health.state.mn.us/diseases/coronavirus/vaccine/screening.docx).
- Influenza Vaccine: IIV (www.health.state.mn.us/diseases/flu/hcp/vaccine/iivall.docx).
- Influenza Vaccine: Flu (www.health.state.mn.us/diseases/flu/hcp/vaccine/laivall.docx).

Verify patient immunization data

Prior to administering a dose of vaccine, please review the patient's immunization history. The primary source of vaccine administration data should be the Minnesota Immunization Information Connection (MIIC). If the data for a patient is not in MIIC, other acceptable sources include:

1. Their CDC vaccination card.
2. An official document from a health care provider or another state's Immunization Information System (IIS) with day, month, year, and product administered as well as the patient's name and date of birth.
3. Electronic documentation from a health care provider or another state's Immunization Information System (IIS) such as the MyChart app or another consumer access application (app) that includes day, month, year, and product administered as well as the patient's name and date of birth.
4. A patient's U.S. Department of State's Vaccination Documentation form DS-3025 that includes a patient's verified past immunizations.

For more information, review MIIC user guidance for looking up a client at Client Search and Printing Immunization Records MIIC User Guidance and Training Resources (www.health.state.mn.us/people/immunize/miic/train/clientsearch.html) and entering immunization data at Adding Immunizations Not Using Inventory MIIC User Guidance and Training Resources (www.health.state.mn.us/people/immunize/miic/train/addnoinv.html).

Vaccine Information Statements (VIS) and Emergency Use Authorizations (EUA)

Vaccine information sheets (VIS)

Vaccines licensed through the FDA and added to the vaccine injury table are required to have a vaccine information sheet (VIS). Federal law requires that patients receive the most current VIS prior to administration of a licensed vaccine. For more information and current VISs, refer to Vaccine Information Statements (www.cdc.gov/vaccines/hcp/vis/index.html).

EUA fact sheets

- EUA fact sheets for vaccination providers are product-specific information sheets that replace the usual package insert. The fact sheet for vaccine recipients is similar to a licensed product's VIS.
- The EUA fact sheet for vaccine recipients explains the vaccine risks and benefits, specific vaccine product information and its use, and information from clinical trials that support the FDA's emergency use authorization.
- You are legally required to give an EUA fact sheet to each recipient/parent/legal representative prior to vaccination. Be prepared to answer questions about the vaccine.
- EUA fact sheets for providers and recipients are available on FDA, CDC, MDH, and vaccine manufacturer websites. Translated fact sheets in multiple languages are on FDA: COVID-19 Vaccines (www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines).

Vaccine protocols

MDH vaccine protocol information and templates can be found on Vaccine Protocols (www.health.state.mn.us/people/immunize/hcp/protocols/index.html).

Co-administration

- Influenza, COVID and RSV (both vaccine and monoclonal antibody) can be given with any other vaccines. If giving intranasal live influenza vaccine (FluMist), it must be given at the same time as any other live virus vaccine or at least 28 days later.
- Vaccines should be given in different sites or at least one inch apart if given in the same limb.
- Vaccines should never be mixed in the same syringe.

Administration of vaccines

All people who administer vaccines should receive comprehensive, competency-based staff training and education based on their scope of practice, including the "rights of vaccine administration," patient care before, during, and after vaccine administration, vaccine preparation, and skill validation.

Vaccine administration resources for all people who vaccinate, including staff who are new to vaccination and staff who need a refresher:

- CDC: ACIP Vaccine Administration Guidelines for Immunization (www.cdc.gov/vaccines/hcp/acip-recs/general-recs/administration.html).
- CDC: Vaccine Administration Route and Site (www.cdc.gov/vaccines/hcp/admin/administer-vaccines.html)
- Immunize.org: Clinical Resources: Administering Vaccines (www.immunize.org/clinical/topic/admin-vaccines/).
- How to hold your child during a vaccination (www.health.state.mn.us/diseases/coronavirus/vaccine/comforthold.pdf).

Take precautions to prevent transmission. Vaccination activities should include precautions to prevent respiratory disease transmission. Providers should use precautions (e.g., mask requirements, social distancing, etc.) depending on disease circulation in your community. Consult Situation Update for

COVID-19 (www.health.state.mn.us/diseases/coronavirus/stats/index.html) and Weekly Influenza and Respiratory Activity: Statistics (www.health.state.mn.us/diseases/flu/stats/index.html) for information on disease activity.

Post-vaccination care

Post-vaccination instructions

Preparing people for what to expect after vaccination and when to follow up with a health care provider is a best practice and expectation. Patient instructions should include information specific to the product they are receiving. This information should include:

- Common side effects (listed in the VIS and EUA fact sheet).
- When to contact their health care provider (such as signs of an allergic reaction or medical concerns that may or may not be related to vaccination).
- For vaccine(s) requiring more than one dose, the importance of receiving all recommended dose(s) of vaccine to build an adequate immune response.

Observation periods following vaccination

Syncope (fainting) might occur in association with any injectable vaccine, especially in adolescents. In accordance with CDC: General Best Practice Guidelines for Immunization (GBPG) (www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html), vaccination providers, particularly when vaccinating adolescents, should consider observing vaccine recipients for 15 minutes after vaccination.

Additionally, providers should consider observing people with the following medical histories for 30 minutes after COVID-19 vaccination to monitor for allergic reactions:

- Allergy-related contraindication to a different type of COVID-19 vaccine.
- Non-severe, immediate (onset within 4 hours) allergic reaction after a previous dose of COVID-19 vaccine.
- Anaphylaxis after non-COVID-19 vaccines or injectable therapies.

Emergency preparation

Administer vaccines in settings where staff are trained to recognize and respond to reactions.

- Have a signed hardcopy of a medical management of vaccine reaction plan and protocol that staff have reviewed and are ready to implement.
- Immediate systemic reactions can include syncope (fainting) and anaphylaxis.
  - To minimize syncope, have a place for patients to sit down while they are vaccinated, and be ready to lower them to a laying position if needed.
  - Although rare, anaphylaxis to a vaccine can occur and is a life-threatening event. Have the appropriate equipment on hand and have trained staff available to administer epinephrine and maintain an airway in settings where vaccinations are given.

- Learn more about how to prepare for anaphylactic reactions at CDC: Interim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination (www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html).
- Immunize.org has examples of emergency plans. Refer to Immunize.org: Medical Management of Vaccine Reactions in Children and Teens (www.immunize.org/catg.d/p3082a.pdf) and Immunize.org: Medical Management of Vaccine Reactions in Adult Patients (www.immunize.org/catg.d/p3082.pdf) for more information.

Report vaccine adverse events and administration errors

- Health care providers are required to report any event after vaccination that requires medical attention, regardless of whether it is related to vaccination.
- Learn more about VAERS at CDC: Vaccine Safety Systems (www.cdc.gov/vaccine-safety-systems/). To submit an event, go to VAERS: Report an Adverse Event (vaers.hhs.gov/reportevent.html). Use this HHS: VAERS 2.0 Checklist.pdf (https://vaers.hhs.gov/docs/VAERS%202.0_Checklist.pdf) to help gather information needed when submitting a report
- HIPAA permits reporting of vaccine adverse events and medical documentation to VAERS for public health purposes under 45 CFR, section 164.512(b), as authorized by 42 USC 300aa-25.

Documenting vaccination and vaccination records

Documenting vaccine

Vaccine documentation must include:

- Site/facility address where the vaccine was administered (in the chart somewhere, does not need to be on the immunization screen).
- Date vaccine was administered.
- Vaccine type.
- Vaccine manufacturer.
- Vaccine lot number.
- Signature and title of person(s) administering vaccine.
- Publication date of VIS (located at the bottom of VIS).
- Date VIS was given to the patient, parent, or legal representative (usually the same as the vaccine administration date, but still needs to be documented).
- VFC eligibility if vaccinating children.

Vaccines should also be uploaded or entered into MIIC within 7 days of administration. MIIC cannot be used as the medical record. Minnesota Immunization Information Connection (MIIC) (www.health.state.mn.us/people/immunize/miic/index.html).

Billing and reimbursement

Insurance plans should reimburse providers for the cost of the vaccine and the administration fee. Vaccine providers may seek appropriate reimbursement from a program or plan that covers vaccine for the vaccine recipient.

For patients who have a Minnesota Health Care Plan (MHCP), providers will be reimbursed for the administration fee. Children with a MHCP should get MnVFC vaccine and not billed for the cost of the vaccine. Adults with a MHCP should get privately purchased vaccine and bill the MHCP for the cost of the vaccine. MHCP also covers vaccine counseling that occurs during visits and for those vaccines they can administer. For details, refer to the MHCP Provider Manual: Immunizations and Vaccinations (www.dhs.state.mn.us/main/idcplg?IdcService=GET_DYNAMIC_CONVERSION&RevisionSelectionMethod=LatestReleased&dDocName=dhs16_136660). Contact the MHCP Provider Call Center at 651-431-2700 with any related questions.

Additional billing resources

Find vaccine administration codes from CDC at Data Code Sets (www.cdc.gov/vaccines/programs/iis/code-sets.html).

Additional resources

Clinical resources

- CDC: Respiratory Virus Guidance (www.cdc.gov/respiratory-viruses/guidance/).
- CDC: ACIP General Best Practice Guidelines for Immunization (www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html).
- Immunize.org: Influenza (www.immunize.org/vaccines/a-z/influenza/).
- Immunize.org: COVID-19 (www.immunize.org/vaccines/a-z/covid-19/).
- Immunize.org: RSV (Respiratory Syncytial Virus) (www.immunize.org/vaccines/a-z/rsv/).

Influenza, COVID-19, and RSV testing

It is important that providers distinguish between influenza, COVID-19 and, RSV through PCR testing whenever possible. Multiplex PCR tests for all 3 pathogens, as well as a dualplex PCR test for influenza and COVID-19 are available. Each pathogen also has rapid antigen testing available. At this time, PCR testing is considered to be the gold-standard diagnostic test for influenza, COVID-19, and RSV.

Rapid flu testing

While rapid flu testing can be useful, it has limitations.

- False negative flu rapid testing results are common, and a negative rapid test result does not rule out flu.
- Likewise, a positive rapid test does not confirm flu, especially during times of low prevalence of disease in the community.
- Antiviral treatment should not be withheld from patients with signs and symptoms suggestive of flu and a negative rapid flu test result.

Providers are encouraged to use clinical judgment for treatment and infection control decisions. More information on rapid tests can be found at Rapid Influenza Diagnostic Testing (www.health.state.mn.us/diseases/flu/hcp/rapid.html).

MDH will communicate any changes in guidelines on Specimen Collection and Testing for Seasonal Influenza (www.health.state.mn.us/diseases/flu/hcp/lab.html) and through the Health Alert Network (www.health.state.mn.us/communities/ep/han/index.html).

COVID-19 testing

- Similar to rapid flu tests, at-home COVID-19 antigen tests are less accurate than PCR tests and false-negative results can occur.
- Patients are not required to have a positive COVID-19 test to be treated with antivirals.
  - If a provider feels COVID-19 is likely despite a negative test (or no test) result (e.g., a patient with signs/symptoms consistent with COVID-19 following a recent known exposure to someone with COVID-19), antiviral treatment should not be withheld if patients are otherwise eligible.

Antiviral treatment recommendations

Influenza antivirals

Antiviral use is recommended as soon as possible for patients with suspected or confirmed flu who are:

- Hospitalized.
- Have severe, complicated, or progressive illness.
- Outpatients at higher risk for influenza complications (e.g., children under age 2 years, pregnant women, those with immunosuppression, etc.).
- Residents of nursing homes and other chronic-care facilities.
- Have uncomplicated influenza and present within 48 hours of illness (based on clinical judgment).

For more information on influenza antivirals visit, CDC: Influenza Antiviral Medications (www.cdc.gov/flu/professionals/antivirals/index.htm): CDC: Influenza Antiviral Medications: Summary for Clinicians (www.cdc.gov/flu/professionals/antivirals/summary-clinicians.htm).

COVID-19 antivirals

For information about COVID-19 antiviral treatment visit IDSA Guidelines on the Treatment and Management of Patients with COVID-19 (www.idsociety.org/practice-guideline/covid-19-guideline-treatment-and-management/) and Therapeutic Options for COVID-19 Patients (www.health.state.mn.us/diseases/coronavirus/hcp/therapeutic.html).

Stay informed!

Immunization updates

- For information on flu activity in Minnesota, subscribe to our Weekly Influenza & Respiratory Activity: Statistics (www.health.state.mn.us/diseases/flu/stats/index.html).
- Get an email alert when updates are made to Immunization Information for Health Care Providers (www.health.state.mn.us/people/immunize/hcp/index.html) by signing up at the bottom of the webpage.
- Subscribe to Got Your Shots? News (www.health.state.mn.us/people/immunize/hcp/gys/index.html) for monthly immunization updates from MDH.

Respiratory disease and vaccination coverage data

- Viral Respiratory Illness in Minnesota (Data & Statistics) (www.health.state.mn.us/diseases/respiratory/stats/index.html) for current and past trends on weekly rates of influenza, RSV and COVID-19 hospitalizations and cases in Minnesota and submit your email address at the bottom of the webpage to sign-up for weekly updates.

- CDC: Respiratory Virus Data Channel Weekly Snapshot (www.cdc.gov/respiratory-viruses/data-research/dashboard/snapshot.html).
- CDC: RespVaxView (www.cdc.gov/vaccines/imz-managers/coverage/respvaxview/index.html) for vaccination coverage data for all ages.
- CDC COVID Data Tracker (https://covid.cdc.gov/covid-data-tracker/#datatracker-home).
- CDC: Weekly U.S. Influenza Surveillance Report (www.cdc.gov/flu/weekly/index.htm).

Clinical questions

MDH Immunization program

- Health.vaccineSME@state.mn.us regarding clinical vaccine recommendations, schedules, resources.
- Health.Miichelp@state.mn.us regarding MIIC application, data, user accounts, client search, reports, reminder recall.
- Health.mnvfc@state.mn.us regarding Minnesota Vaccines for Children (MnVFC) policies and procedures, enrollment, reports, vaccine storage and handling, and MnVFC ordering. 651-201-5522.
- Health.uuadultvax@state.mn.us regarding Uninsured and Underinsured Adult Vaccine (UUAV) policies and procedures, enrollment, reports, vaccine storage and handling, and MnVFC ordering.
- Call 651-201-5414 or 1-800-657-3970.

Centers for Disease Control and Prevention (CDC)

- CDC-Info line: 1-800-232-4636.
- CDC-INFO (www.cdc.gov/cdc-info/index.html).

Minnesota Department of Health
PO Box 64975, St. Paul, MN 55164-0975
health.vaccineSME@state.mn.us
www.health.state.mn.us/immunize

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To obtain this information in a different format, call: 651-201-5414.