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ILLINOIS DEPARTMENT OF PUBLIC HEALTH
IDPH
PROTECTING HEALTH, IMPROVING LIVES

Nearing the End of the Respiratory Virus Season and Changes Coming for the 2024/2025 Season

February 9, 2024

Speakers

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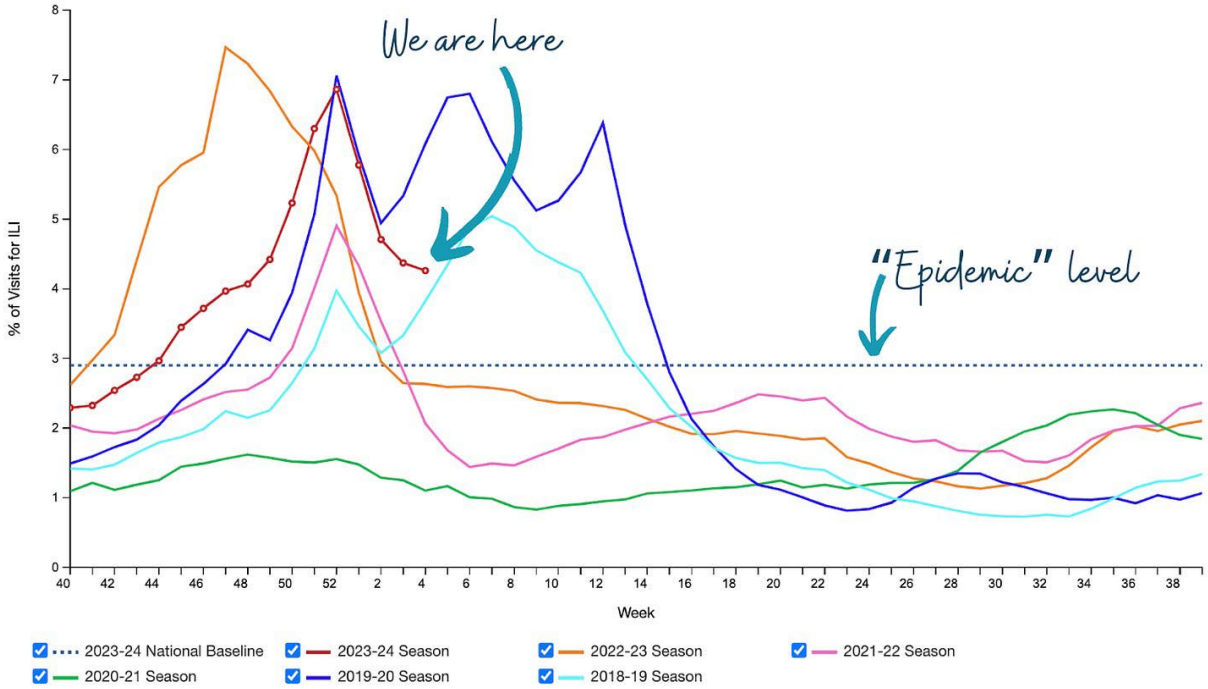
- **Kyran Quinlan, MD, MPH, FAAP:** Pediatric Medical Advisor
- **Karyn Lyons, MS, RN**: Chief of the Immunizations Section

Chicago Department of Public Health

- **Alexander Sloboda, MD, MPH:** Medical Director of Immunization and Emergency Preparedness Programs, Health Protection Bureau
- **Kevin Hansen**: Vaccines for Children Manager

Respiratory Virus Season 2023/2024

Influenza-like illnesses: High and plateauing



https://yourlocalepidemiologist.substack.com/p/state-of-affairs-feb-6

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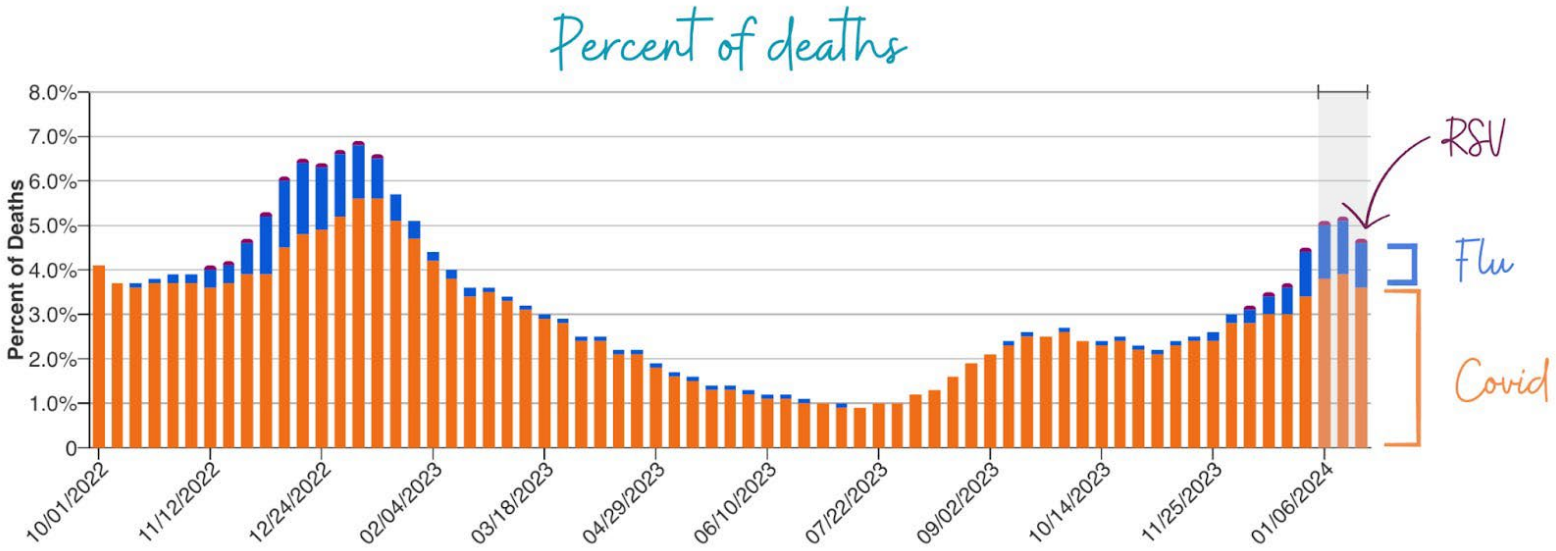
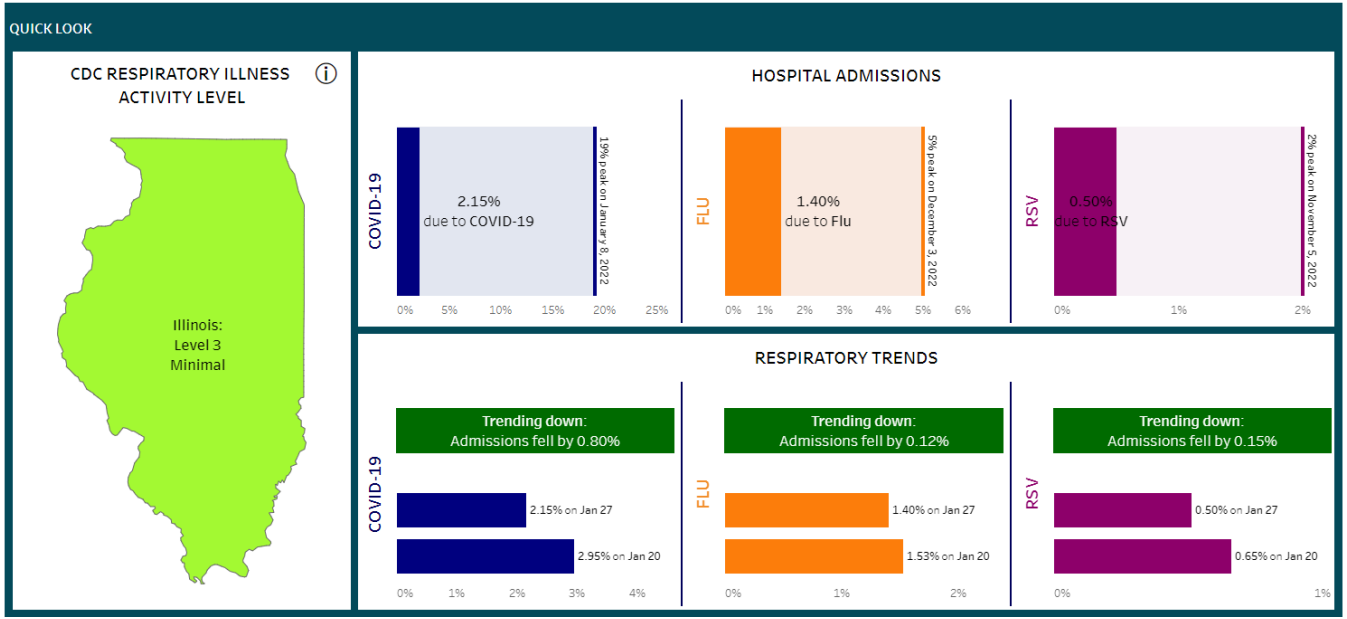
Respiratory Deaths



https://yourlocalepidemiologist.substack.com/p/state-of-affairs-feb-6

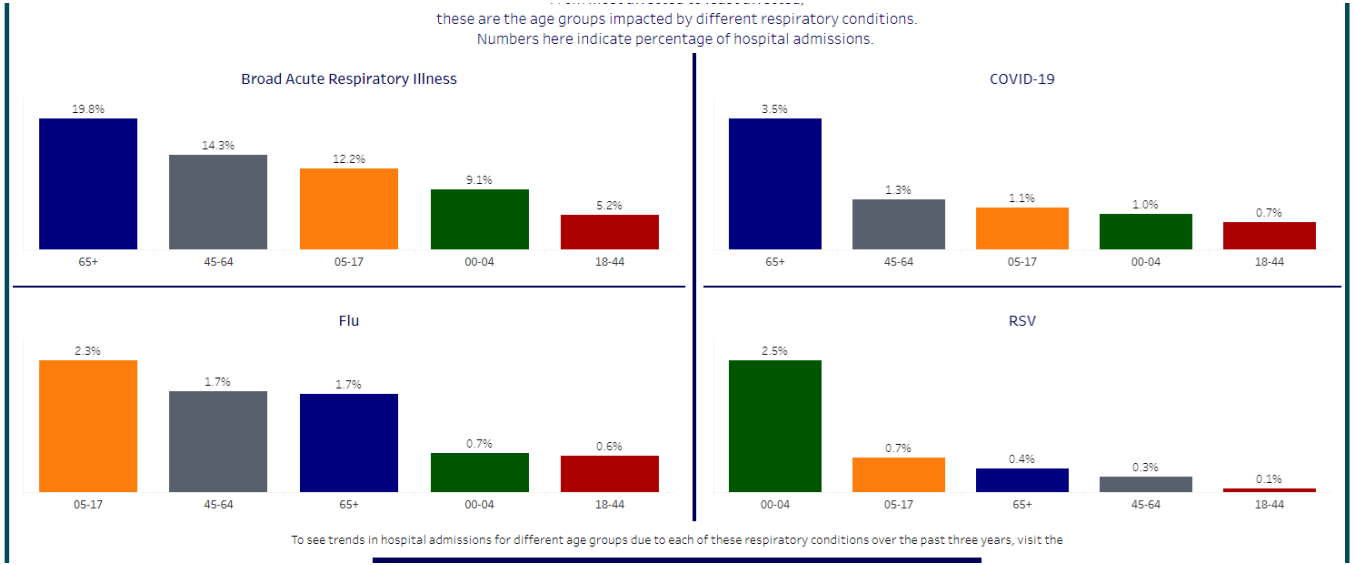
Seasonal Respiratory Illness Dashboard: Illinois



Seasonal Respiratory Illness Dashboard

Influenza Vaccine Coverage Dashboard

Most Affected by Age Group: Illinois



Seasonal Respiratory Illness Dashboard

Influenza Vaccine Coverage Dashboard

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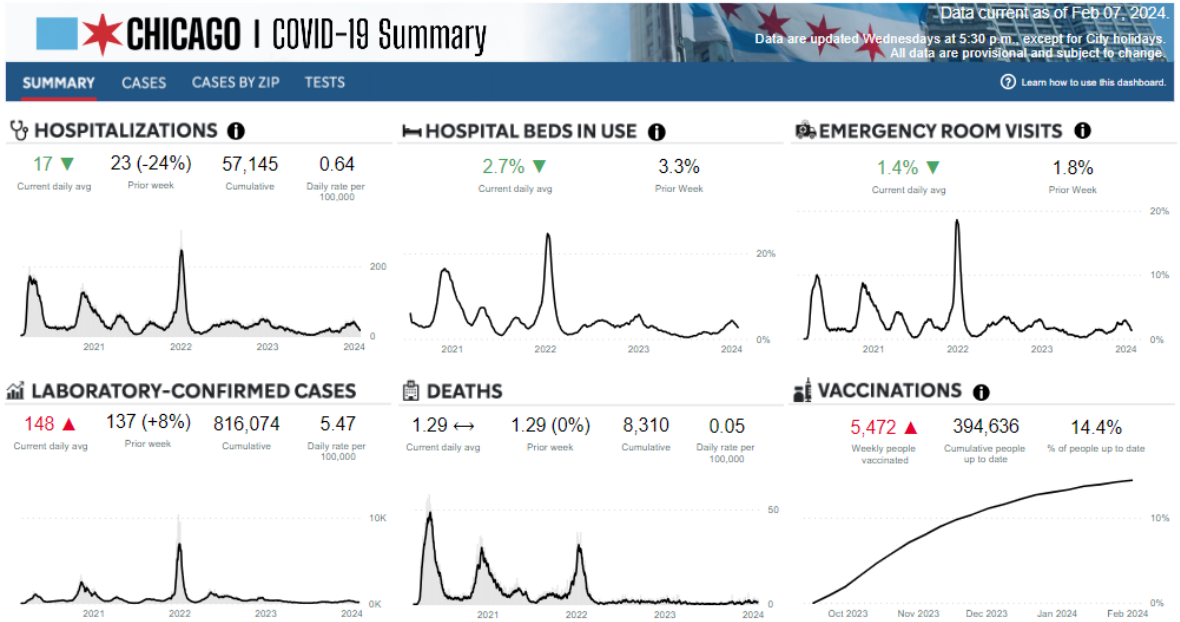
2023 – 2024 Season: Chicago COVID



Latest Data | COVID19 (chicago.gov)

RSV Immunizations

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CDC: Immunize all eligible children against RSV

- Clinicians can return to the original recommendations for using respiratory syncytial virus (RSV) immunization nirsevimab (Beyfortus).
- CDC continues to recommend nirsevimab for eligible newborns throughout RSV season, ending **March 31, 2024**.

https://emergency.cdc.gov/newsletters/coca/2024/010524a.html

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Preparation and Administration

- Available in 50mg and 100mg pre-filled syringes (single use):
  - 50 mg: purple plunger rod (for those < 5kg body weight).
  - 100mg: light blue plunger rod (for those ≥ 5kg body weight).
- Should not be mixed with any vaccines or medications in the same syringe or vial.
- Administered intramuscularly as one or two injections*
  - Preferably in the anterolateral aspect of the thigh.
    - Gluteal muscle should not be used due to risk of damage to the sciatic nerve

Per the AAP: Avoid using two 50mg doses for infants weighing ≥5 kilograms (≥11 pounds), because 50mg doses should be reserved only for infants weighing <5 kilograms (<11 pounds), for example, those born during the season who will be at increased risk for severe RSV illness because of their young age. Furthermore, providers should be aware that some insurers may not cover the cost of two 50mg doses for an individual infant.

Beyfortus (nirsevimab-alip) [package insert]. AstraZeneca AB; 2023
ACIP Meeting notes (August 2023)- Proposed Clinical Consideration Updates for Nirsevimab
Esposito S, Abu-Raya B, Bonanni P et al. *Frontiers in Immunology* 2021
Beyfortus. Product information. AstraZeneca AB. Accessed August 10, 2023: https://www.ema.europa.eu/en/documents/product-information/beyfortus-epar-product-information_en.pdf

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Administration

- May be given concomitantly with childhood vaccines.
  - Administer in separate syringes, at different injection sites.
- Palivizumab should not be administered if nirsevimab was administered in the same season.
- If palivizumab was administered initially for the RSV season and < 5 doses were administered, 1 dose of nirsevimab may be administered. No further palivizumab should be administered.

Nirsevimab may be administered prior to or during second RSV season in children 8-19 months old who are eligible for nirsevimab and who received palivizumab in their first RSV season.

- If nirsevimab is not available, palivizumab should be administered.

Beyfortus (nirsevimab-alip) [package insert]. AstraZeneca AB; 2023
ACIP and AAP Recommendations for nirsevimab. Red Book: 2021–2024 Report of the Committee on Infectious Diseases (32nd edition)

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Contraindications/Warnings

Contraindications:

- Infants and children with a history of serious hypersensitivity reactions, including anaphylaxis, to nirsevimab or to any of its excipients.
  - Excipients: arginine hydrochloride, histidine, L-histidine hydrochloride monohydrate, polysorbate 80, sucrose, and water for injection.

Warnings/Precautions:

- Serious hypersensitivity reactions, including anaphylaxis, have been observed with other human immunoglobulin G1 (IgG1) monoclonal antibodies.
  - Initiate appropriate medications and/or supportive therapy if signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur.
- As with other intramuscular (IM) injections, nirsevimab-alip should be given with caution to infants and children with thrombocytopenia, any coagulation disorder, or to individuals on anticoagulation therapy.

Beyfortus (nirsevimab-alip) [package insert]. AstraZeneca AB; 2023
ACIP Meeting notes (August 2023)- Nirsevimab: Implementation Considerations

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ACIP Recommendations: First RSV Season

All infants aged < 8 months born during or entering their first RSV season

Infants born October 2023 – March 2024	• Immunize within 1 week of birth during birth hospitalization or in outpatient setting • Infants with prolonged birth hospitalizations due to prematurity or other causes should receive nirsevimab shortly before or promptly after hospital discharge
All other infants younger than age 8 months	• Administer nirsevimab as infant enters their first RSV season

Optimal time: Before the start of the RSV season (typically October through the end of March)

Jones JM, Fleming-Dutra KE, Prill MM, et al. 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. MMWR Morb Mortal Wkly Rep 2023;72:920–925. DOI: http://dx.doi.org/10.15585/mmwr.mm7234a4.

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ACIP Recommendations: Second RSV Season

Infants and children aged 8–19* months with increased risk for severe disease:

- Children with chronic lung disease of prematurity who required medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) any time during the 6-month period before the start of the second RSV season.
- Children with severe immunocompromise.
- Children with cystic fibrosis who have either 1) manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest imaging that persist when stable), or 2) weight-for-length <10th percentile.
- American Indian or Alaska Native children.
- This group should receive (2) 100mg doses administered at the same time.

**Package inserts state the product may be administered up to 24 months of age. Follow the ACIP recommendation and only administer up to 19 months.*

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Administration for Premature Infants

- There are no lower age and/or weight cut-offs for eligibility for nirsevimab.
- There are limited data available in extremely premature infants <8 weeks of age.
- No clinical data available in infants with a postmenstrual age (gestational age at birth plus chronological age) of <32 weeks.
- Dosing in infants with a body weight <1.6kg is based on extrapolation and no clinical data are available.
- IM dosing maybe challenging in smallest infants.
- ACIP and AAP guidance states that infants with prolonged hospitalizations because of prematurity or other causes should receive nirsevimab shortly before or promptly after discharge.

https://publications.aap.org/redbook/resources/25379/ACIP-and-AAP-Recommendations-for-Nirsevimab

Maternal RSV Vaccination

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Abrysvo

- Vaccine for RSV prevention in those 60+ and pregnant individuals.
- Mechanism of Action
  - Active Immunization: ABRYSVO induces an immune response against RSV pre F that protects against lower respiratory tract disease caused by RSV.
  - Passive Immunization: Antibodies to RSV antigens from individuals vaccinated in pregnancy are transferred transplacentally to protect infants younger than 6 months of age against lower respiratory tract disease (LRTD) and severe LRTD caused by RSV.

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Abrysvo

- Approved for 32-36 weeks gestational age as a single IM dose for prevention of lower respiratory tract disease in infants from birth to 6 months.
  - Infants born 14+ days after vaccination of the mother will **not** need nirsevimab.
- Should not be administered to a person with a history of severe allergic reactions, such as anaphylaxis, to any component of this vaccine.
- Seasonal RSV vaccination for pregnant individuals ended **January 31, 2024** per CDC and ACIP recommendations.
  - **Ordering Abrysvo through VFC Program is deactivated.**

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Scenarios to Consider Administration of Nirsevimab When Mother Has Been Vaccinated

- Receipt of maternal vaccine not confirmed by healthcare record.
- Infant born within 14 days of vaccination.
- Infant born premature.
- Healthcare provider recommends maximizing protection because infant at high risk of severe disease.
  - Especially important if born >3 months prior to peak of RSV season.
  - High risk infants in their second RSV season should receive nirsevimab regardless of maternal vaccination.

Abrysvo is **not** approved for and should **not** be administered to infants.

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RSV Updates in I-CARE

Forecasting is available in I-CARE:

- for the RSV vaccines for adults 60 years and older.
- for the RSV monoclonal antibody for infants and toddlers under 8 months of age.

Forecasting is not available for high-risk infants and toddlers 8-19 months of age.

RSV Vaccine for Older Adults

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RSV Vaccines for Older Adults (≥60 years)

- Two brands available:
  - Abrysvo
  - Arexvy
- ACIP recommendations on RSV vaccination timing:
  - RSV vaccination is currently approved and recommended for administration as a single dose; sufficient evidence does not exist at this time to determine the need for revaccination.
  - Optimally, vaccination should occur before the onset of the RSV season; however, typical RSV seasonality was disrupted by the COVID-19 pandemic and has not returned to pre-pandemic patterns.

RSV Products Visual Guide

- CDC Job Aid to Prevent Administration Errors:
  - Pregnant Individuals: Administer Pfizer Abysvo (never Arexvy).
  - Infants: Administer Beyfortus (Nirsevimab). ("**B**" is for **B**aby)
  - **A**rexvy and **A**brysvo are for **A**dults Only.
- ICAAP's visual guide is available here

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RSV Products Visual Guide

FOR PATIENTS WHO ARE:
Pregnant

Administer **ABRYSVO.** Abrysvo is supplied in a kit that includes a vial of Lyophilized Antigen Component, a prefilled syringe containing diluent, and a vial adapter.

Timing: a single dose during weeks 32 through 36 of pregnancy during September through January

FOR PATIENTS WHO ARE:

A newborn or infant

Administer **BEYFOTRUS**. Beyfortus is supplied in a prefilled syringe. 50mg doses of Beyfortus are light blue and 100mg doses are purple.

Timing: One dose just before or during RSV season.

Premature/at high risk

Administer **SYNAGIS**. Synagis is supplied in single-use vials. 50mg vials are pink and 100mg vials are blue.

Timing: one injection given once a month throughout RSV season.

FOR PATIENTS WHO ARE:
60 years or older

Administer **AREXVY**. Arexvy is supplied in two vials that must be combined prior to administration.

Timing: One dose just before RSV season.

Influenza Key Points

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Influenza

- Continue to offer flu vaccine as flu activity can continue into the spring.
- Everyone aged ≥6 months, with rare exception, should get an annual flu vaccine.
- Seasonal influenza activity remains elevated nationally.
- The current flu season meets criteria for a preliminary classification as a moderately severe flu season so far.
  - So far this season, CDC estimates that there have been at least **20 million illnesses, 230,000 hospitalizations, and 14,000 deaths from flu.**
- Through 1/27/24, CDC has received reports of **65 pediatric deaths due to flu**.
  - Approximately 90% of the children who were eligible for the vaccine and had known vaccine status had not received influenza vaccine this season.

COVID-19 Vaccines

2023-2024 Storage & Handling

	PFIZER				
AGE INDICATIONS AND FORMULATION	6 Months–4 Years	5–11 Years	12+ Years	12+ Years Prefilled Plastic Syringe	12+ Years Prefilled Glass Syringe
VIAL CAP COLOR	Yellow	Blue	Gray	N/A	N/A
VIAL LABEL BORDER COLOR	Yellow	Blue	Gray	N/A	N/A
PREPARATION	Dilute	Do Not Dilute	Do Not Dilute	N/A	N/A
DOSE	3 mcg/ 0.3 mL dosage	10 mcg/ 0.3 mL dosage	30 mcg/ 0.3 mL dosage	30 mcg/ 0.3 mL dosage	30 mcg/ 0.3 mL dosage
DOSES PER VIAL	3	1	1	1 – Prefilled Syringe	1 – Prefilled Syringe
ULT FREEZER (-90°C TO -60°C)	12 Months	12 Months	18 Months	9 Months	DO NOT STORE
FREEZER (-50°C TO -15°C)	DO NOT STORE	DO NOT STORE	DO NOT STORE	DO NOT STORE	DO NOT STORE
REFRIGERATOR (2°C TO 8°C)	10 Weeks	10 Weeks	10 Weeks	10 Weeks	Up to 6 Months
ROOM TEMPERATURE (8°C TO 25°C)	12 Hours Prior to First Puncture	12 Hours Prior to Use	12 Hours Prior to Use	4–12 Hours*	12 Hours*
AFTER FIRST PUNCTURE (2°C TO 25°C)	Discard After 12 Hours	N/A	N/A	N/A	N/A
THAW TIME	In Refrigerator: Up to 2 hours At Room Temp: 30 mins	In Refrigerator: Up to 2 hours At Room Temp: 30 mins	In Refrigerator: Up to 2 hours At Room Temp: 30 mins	**Thawed in carton:** In Refrigerator: Up to 2 hours At Room Temp: 60 mins	N/A

*Thawed in carton: 12 hours prior to use. Thawed outside of carton: Use within 4 hours of thawing.

https://www.illinoisvaccinates.com/vaccine-resources/#_handouts

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Updated Guidance: Interim Clinical Considerations for Use of COVID-19 Vaccines

- January 18, 2024, CDC updated guidance on COVID-19 vaccine administration errors and deviations (Appendix B).

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Moderna

- When administering Moderna COVID-19 Vaccine (2023-2024 Formula) to individuals ages 6 months through 11 years ensure the correct volume of the vaccine (0.25 mL) is withdrawn from the vial and administered to the recipient.
- Discard the vial and excess volume after extracting a single dose.
- For additional information, see FDA Announcement and Moderna COVID-19 Vaccine (2023-2024 Formula) Healthcare Provider Fact Sheet (fda.gov).

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Reporting in I-CARE

Per Illinois' Immunization Registry Code, providers shall report all COVID-19 immunizations administered in Illinois to the Registry.

- **This includes both publicly available and privately purchased COVID-19 vaccines.**
- Per the same code, section 689.10, the definition of provider is as follows: *"Health care provider" or "Provider" means any person licensed and authorized to administer or order the administration of any immunization in Illinois. Health care provider includes the clinics, facilities, hospitals, and pharmacies where the licensed health care provider works, as well as Illinois licensed long term care facilities.*

Additional Items

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V-Safe

Open to anyone who gets a 2023-2024 updated COVID-19 vaccine. V-safe enrollment is now open for:

- **2023-2024 updated COVID-19 vaccine:** 6 months+
- **RSV vaccine for pregnant people**: RSVpreF vaccine (ABRYSVO by Pfizer).
- **RSV vaccines for older adults, aged 60+:**
  - RSVPreF3 vaccine (AREXVY by GSK)
  - RSVpreF vaccine (ABRYSVO by Pfizer)

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Adult Vaccines

- Updates to CDC's AdultVaxView and FluVaxView websites.
- State, selected local areas, and national adult vaccination coverage estimates from the 2022 Behavioral Risk Factor Surveillance System (BRFSS) are added to the interactive data dashboard on AdultVaxView.
- Confidence intervals are available through the data collected.

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HFS Coverage and FQHCs Reimbursement

	VFC	Bridge*
Physicians, advance practice nurses, physician assistants, local health departments, FQHCs, and school-based health clinics	$16.71	$43.06

- Updated reimbursement rates announced by HFS, effective January 1, 2024.

Bridge Access Program Reimbursement announced 1/29/2024.

- For CDPH and IDPH jurisdictions.
- Payments will be backdated to the date that the first COVID-19 vaccines for the 2023-2024 season were administered or the date that each provider enrolled in the HFS Impact application, whichever is later.
- This agreement will expire on May 12, 2024, or when funds have been exhausted, whichever is first.
- IDPH sites: Providers need to complete and submit a signed agreement by Monday, February 12, 2024.

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Ordering COVID-19 Vaccines - Chicago

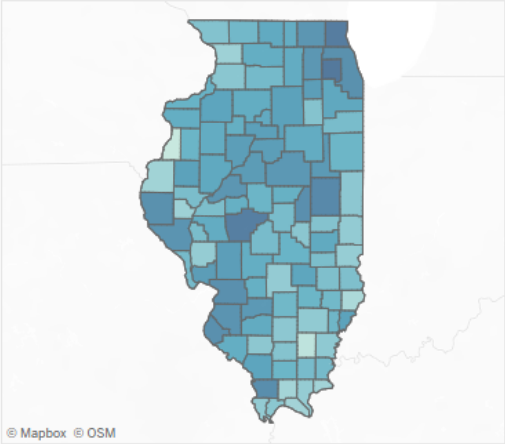
- Email both covid19vaccine@cityofchicago.org and chicagovfc@cityofchicago.org to request doses.

*Must have completed a Bridge Access Program Enrollment form and been approved for doses.

Vaccine Coverage in Chicago

2023 – 2024 IL Flu Vaccine Uptake

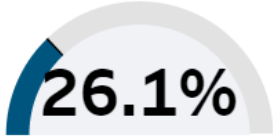
Illinois map of flu vaccination coverage (number of flu shots / estimated population)
Select to filter or use county filter in Filters section
Darker shading = higher coverage

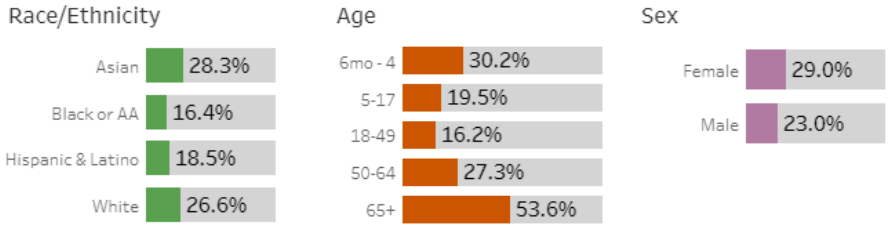


Some vaccines were given to people where County = 'Unknown'

Flu Season = 2023-2024 | Month = All | County = All

Flu Coverage %
Statewide = **26.1%** | Goal = **70%**

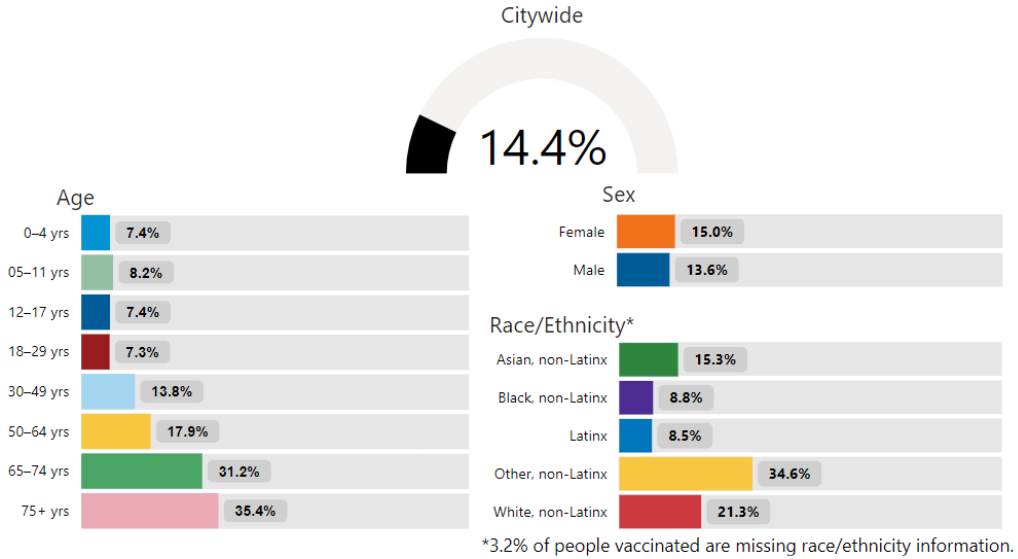




*Some vaccines are missing race/ethnicity information.

Influenza Vaccination Coverage Dashboard (illinois.gov)

2023 – 2024 Chicago COVID Vaccine Uptake

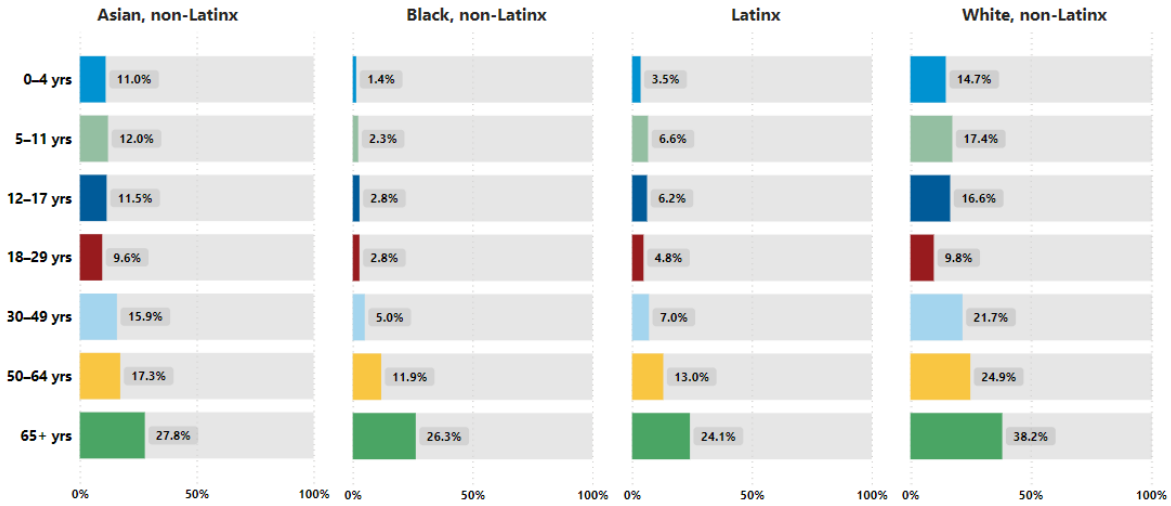


Last updated: Feb 08, 2024. Data reported through Feb 03, 2024.

Data are updated Wednesdays at 3:30 p.m., except for City holidays.

Latest Data | COVID19 (chicago.gov)

2023 – 2024 Chicago COVID Vaccine Uptake



Data reported through: February 03, 2024.
Data are updated every Wednesday 3:30 p.m., except for City holidays. All data are provisional and subject to change.

Latest Data | COVID19 (chicago.gov)

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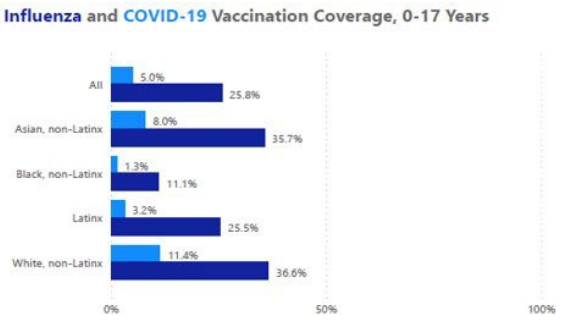
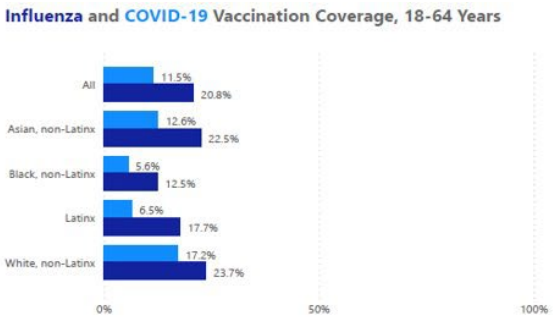
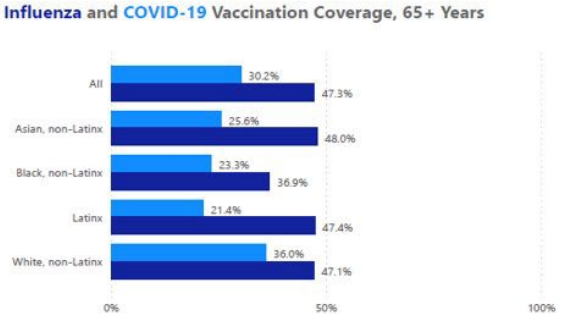
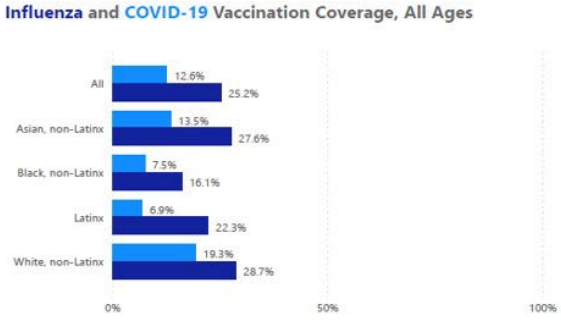
2023 – 2024 Chicago COVID/Flu Vaccine Uptake









Latest Data | COVID19 (chicago.gov) Data Source: I-CARE from December 30, 2023

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IDPH Immunization Ordering

- Vaccines for Children:
  - Influenza vaccine: orders open to all VFC providers; no limitations.
  - COVID-19 vaccine: orders open to all VFC providers; no limitations.
  - RSV vaccine for pregnant people: Abrysvo ordering has been shut down due to seasonal timing of vaccination.
  - Nirsevimab
    - Initial strategy was allocation to LHDs, FQHCs, and RHCs.
    - Recently opened ordering to other providers via Limited Quantity Orders.

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ILLINOIS DEPARTMENT OF PUBLIC HEALTH IDPH PROTECTING HEALTH, IMPROVING LIVES

IDPH Immunization Ordering

- Adult Immunization Program (Section 317):
  - Influenza vaccine: orders open to all eligible[1] providers; no limitations.
  - RSV vaccine for adults >60 years of age: eligible[1] providers may continue to order Abrysvo and Arexvy via Limited Quantity Order.

- Bridge Access Program:
  - COVID-19 vaccine: orders open to enrolled[2] providers; no limitations.

[1]Adult Immunization Program is open to LHDs, FQHCs, and RHCs that are also enrolled in VFC.
[2]Bridge Access Program is open to LHDs, FQHCs, and RHCs, and requires a separate enrollment.

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IDPH Immunization Department will be closed, and vaccine deliveries will not be available on the following days. This will apply to VFC, 317, and COVID-19 vaccines:

- **Monday Feb. 12 — Lincoln's Birthday**
- **Monday Feb. 19 — President's Day**

2024/2025 Changes

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Beyfortus Reservation Program

Sanofi launching a reservation program:

- For privately purchased doses.
- Clinicians can work with Sanofi to forecast their needs from **February 5 through April 30, 2024.**
- Participants can reserve doses in **July and August** allowing for these benefits:
  - Priority shipping, preferred monthly shipping schedules, 90-day payment terms, and cancellation up to 14 days before scheduled shipments.
  - Returns accepted on expired products.
  - No minimum orders are needed to participate in the program.

https://publications.aap.org/aapnews/news/28108/Sanofi-launching-reservation-program-for-infant

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Beyfortus Reservation Program

- Clinicians are not required to participate in this program.
- The normal order window will be available from September 2024 through February 2025.
  - Clinicians ordering during this time would have payment terms of 60 days and no ability to schedule future shipments.
- Does not apply to the VFC program.
- Beyfortus is being manufactured well in advance of the RSV season, with most doses expected to be available before October.
- For private customers who are interested in participating in the Beyfortus Reservation Program, they should contact their Sanofi representative or request a representative at Beyfortus.com.

https://www.news.sanofi.us/2023-02-01-Sanofi-launches-Beyfortus-R-nirsevimab-alip-Reservation-Program-for-2024-2025-RSV-season-in-U-S

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Flu Vaccine Changes

Following the October 5, 2023, Vaccines and Related Biological Products Advisory Committee (VRBPAC) Meeting, FDA provided direction for manufacturers to plan for a transition to trivalent flu vaccine.

- As a result, flu vaccines available for the 2024-2025 season may reflect a mixture of trivalent and quadrivalent vaccines.
- If a mixture of vaccines is available, both trivalent and quadrivalent flu vaccines will be recommended to protect children and adults against influenza during the 2024-2025 season.

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Flu Availability 2024 - IDPH

- For the 2024-2025 influenza season, IDPH intends to have the following vaccines available for its VFC and 317 programs:
  - Afluria
  - Fluarix (only available for Adult 317 program)
  - Flucelvax
  - Flulaval (only available for VFC program)
  - FluMist
  - Fluzone
- Currently, valency of each prebooked vaccine is unknown.
- All vaccines prebooked by IDPH are preservative free.

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Flu Availability 2024 - CDPH

- For the 2024-2025 influenza season, CDPH intends to have the following vaccines available for its VFC programs:
  - Flucelvax syringes
  - Flulaval syringes
  - FluMist sprayer
  - Fluzone syringes
- Currently, the valency of each pre-booked vaccine is unknown.
- All vaccines prebooked by CDPH are preservative-free.
- Prebook information will be released in mid-June.

Communicating With Families About How to Protect Against Fall and Winter Respiratory Viruses

Your patients depend on you as a trusted source of accurate health information and actionable guidance. You can help patients and their families stay safe and reduce the risk of severe disease by strongly recommending vaccination.

https://www.aap.org/en/patient-care/immunizations/communicating-with-families-about-how-to-protect-against-fall-and-winter-respiratory-viruses/

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Outreach

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Resources

- Full prescribing information
- AAP's RedBook Online
- AAP's Nirsevimab Frequently Asked Questions
- CDC information
- AAP Page on RSV Prevention Products
- How to use new CPT codes for administration of RSV immunizations

ICAAP handouts

- Handout for patients on Nirsevimab
  - English
  - Spanish
- Handout for providers (FAQ on Nirsevimab)

Immunize.org

- **RSV Vaccines and Adults**

Q: What are the two RSV vaccines and how are they different?
Q: How well do the RSV vaccines work for older adults?
Q: What is the ACIP recommendation for RSV vaccination of older adults?
Q: What is the recommendation for use of RSV vaccine during pregnancy?

- **RSV Preventive Antibody and Infants**

Q: How is nirsevimab (Beyfortus, Sanofi) different from a vaccine?
Q: How well does nirsevimab work?
Q: What is the ACIP recommendation for nirsevimab?

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Upcoming Events

- **Vaccine Hesitancy and Misinformation**
  - Wednesday February 21, 12PM-1PM
- **Managing Obesity in Adolescent Patients: The New Obesity Guidelines**
  - Thursday February 22, 2024 12PM-1PM
- **Preparing for Adolescent Immunization Week**
  - Tuesday March 19, 12PM-1PM
- **Sexual Orientation & Gender Identity: The Impact on Adolescent Patients & What Pediatricians Can Do**
  - Thursday March 21, 2024 12PM-1PM

Register at illinoisaap.org/events

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Thank You!