NEW YORK STATE AND NEW YORK CITY HEALTH DEPARTMENTS COVID-19 HEALTHCARE PROVIDER UPDATE

COVID-19 ORAL ANTIVIRAL TREATMENT, GENERAL UPDATES, AND CO-CIRCULATION WITH INFLUENZA

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RECENT EPIDEMIOLOGY, NYS & NYC

OUTLINE



COVID-19 ORAL ANTIVIRAL TREATMENT



GENERAL UPDATES, AND CO-CIRCULATION WITH INFLUENZA







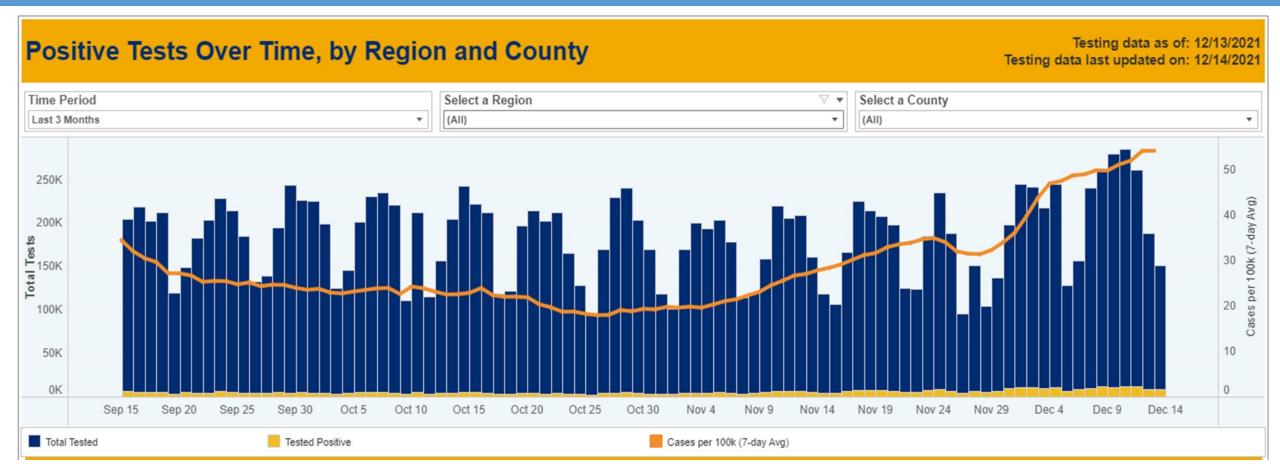
RECENT EPIDEMIOLOGY, NYS & NYC

OUTLINE





Positive Tests Last 3 Months, All NY State Counties

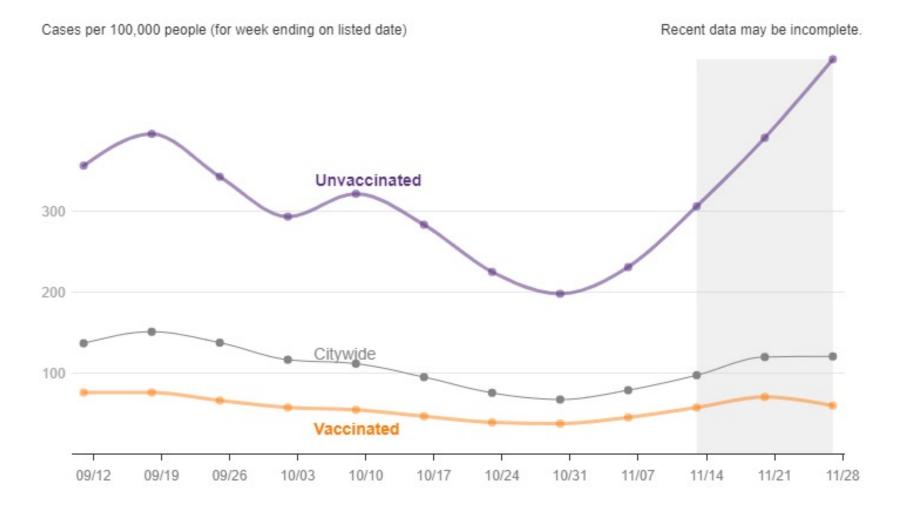






Weekly Case Rates by Vaccination Status, NYC

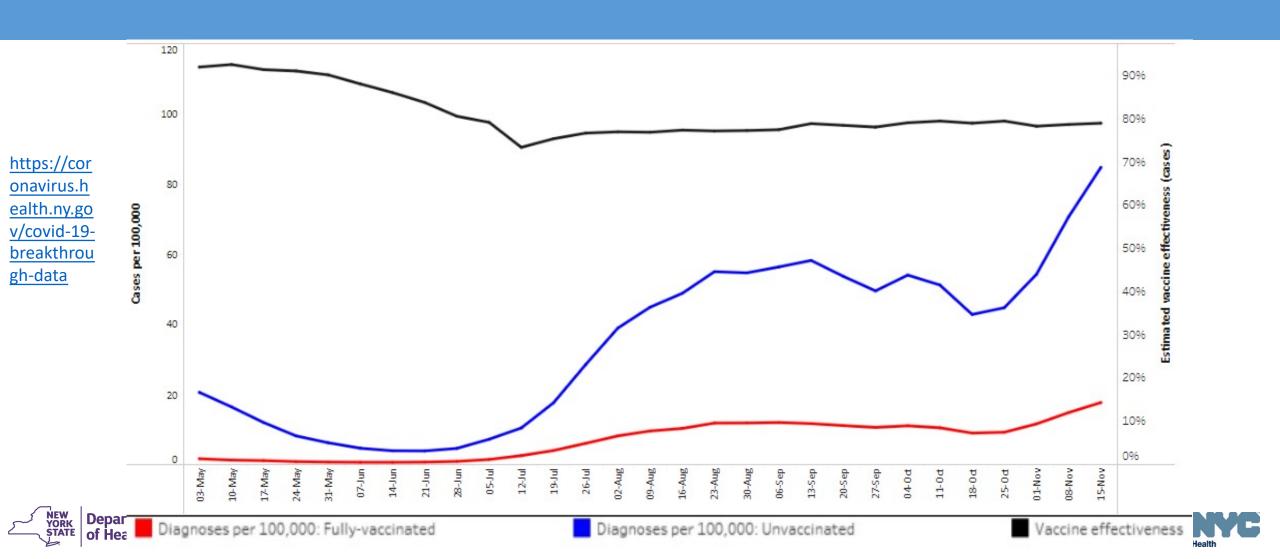
https://www1.nyc.gov/ site/doh/covid/covid-19-data.page#daily



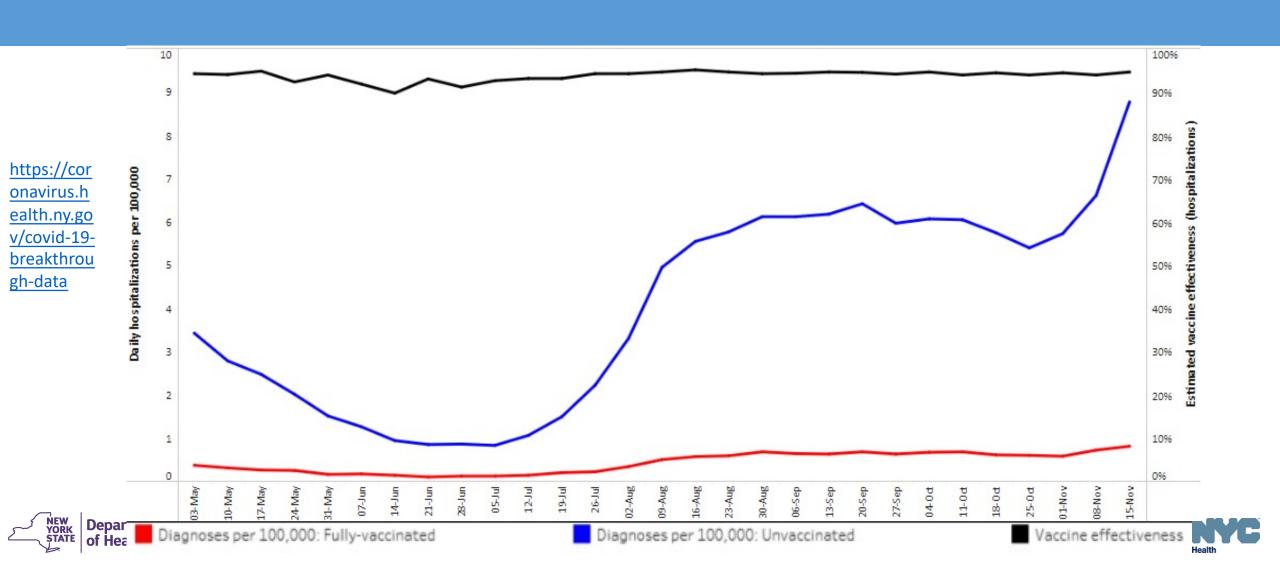




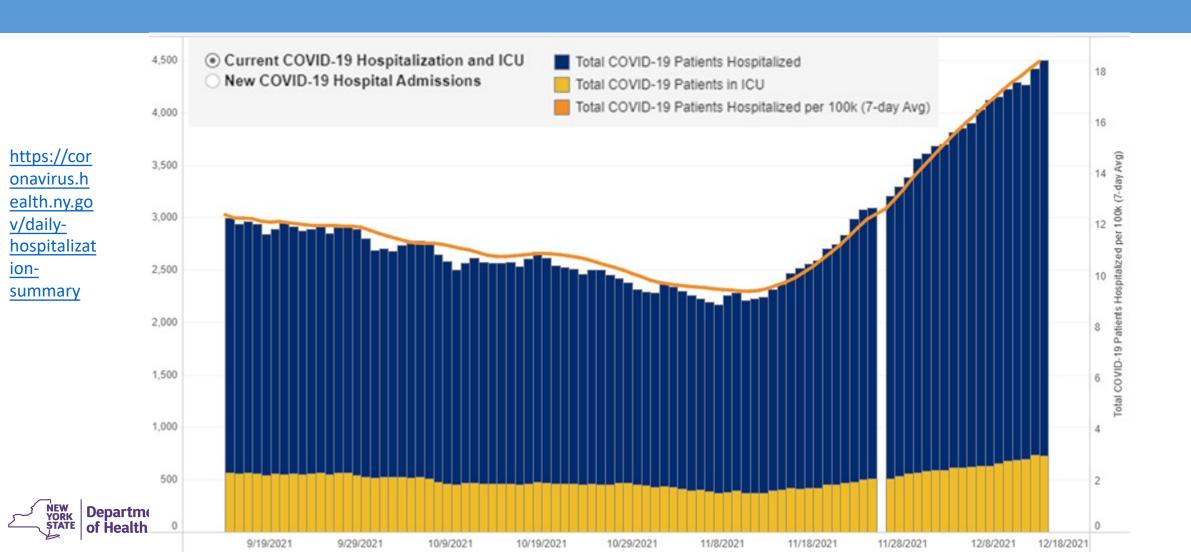
New Daily Cases by Vaccination Status, NY State Adults 18 year and older



New Daily Hospital Admissions by Vaccination Status, NY State Adults 18 year and older



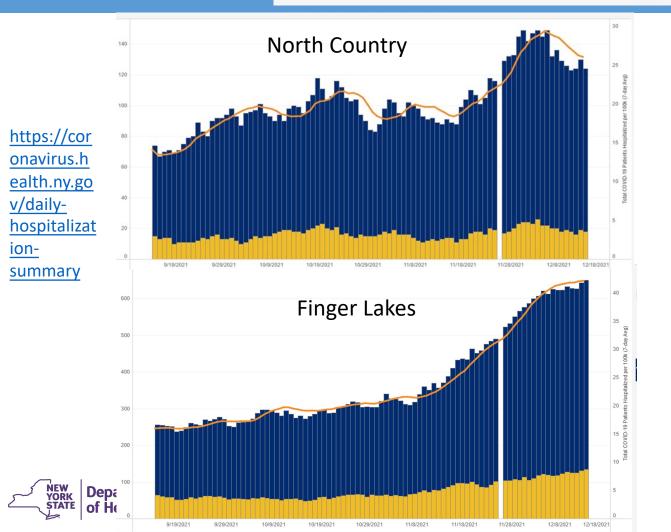
Daily Hospitalization Summary, NY State 9/14/2021 – 12/13/20201

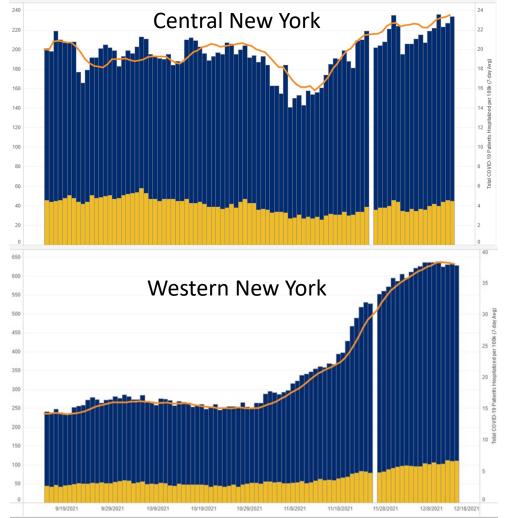




Daily Hospitalization Summary by Region, NY State 9/14/2021 – 12/13/20201

◆ Current COVID-19 Hospitalization and ICU
 ◆ New COVID-19 Hospital Admissions
 ■ Total COVID-19 Patients Hospitalized
 ■ Total COVID-19 Patients in ICU
 ■ Total COVID-19 Patients Hospitalized per 100k (7-day Avg)

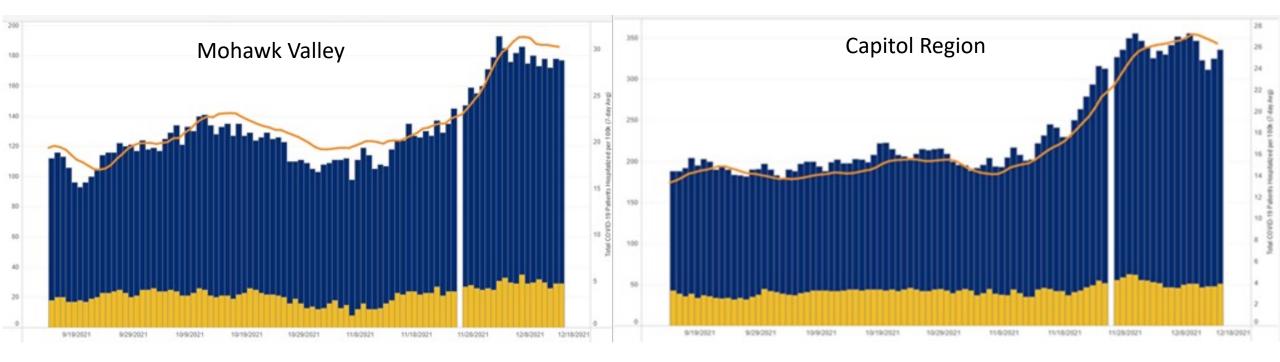






Daily Hospitalization Summary by Region, NY State 9/14/2021 – 12/13/20201



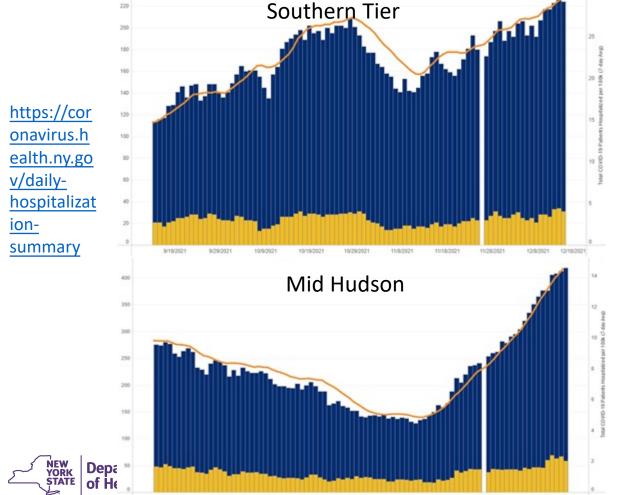


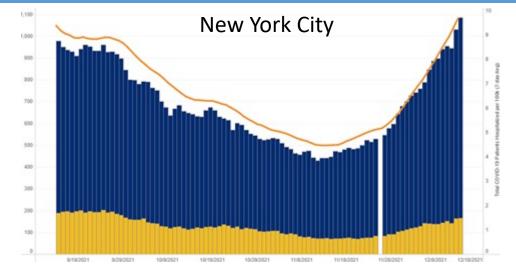


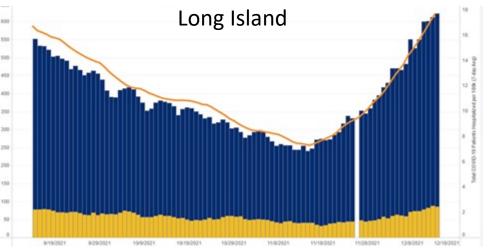


Daily Hospitalization Summary by Region, NY State









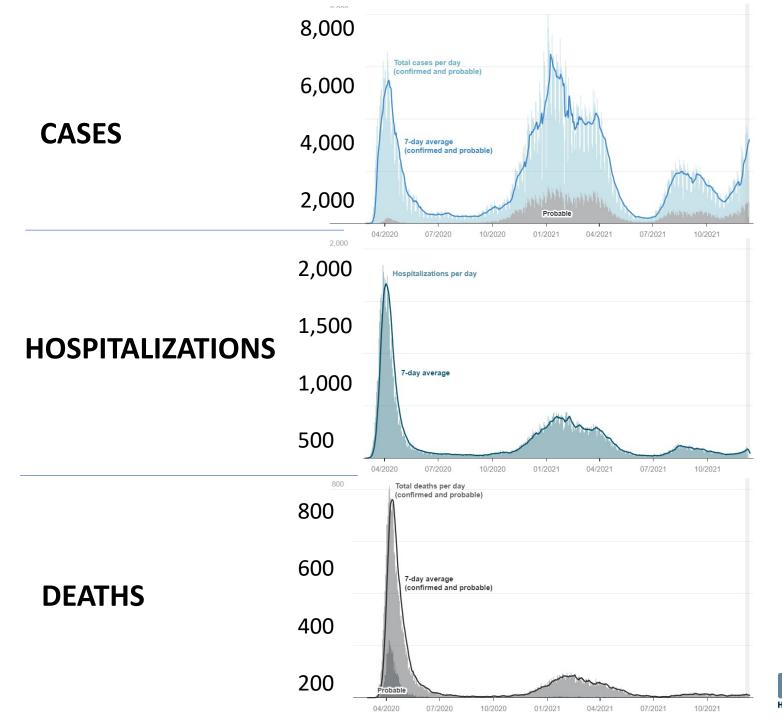


COVID-19, NYC, 3/1/2020-12/15/2021

Figures:
Daily COVID-19 cases,
hospitalizations, and deaths

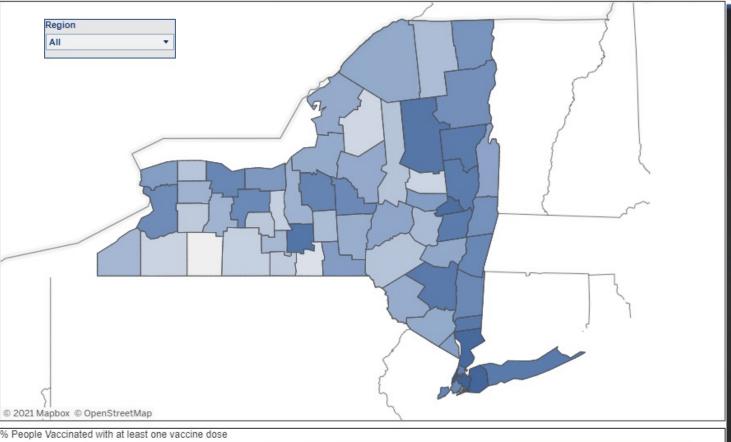
NYC Health Department, COVID-19 data https://www1.nyc.gov/site/doh/covid/covid-19-data-totals.page

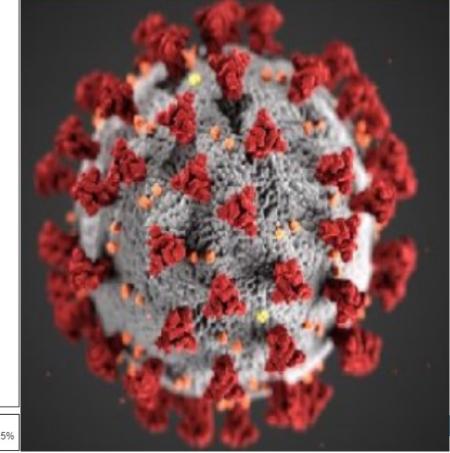






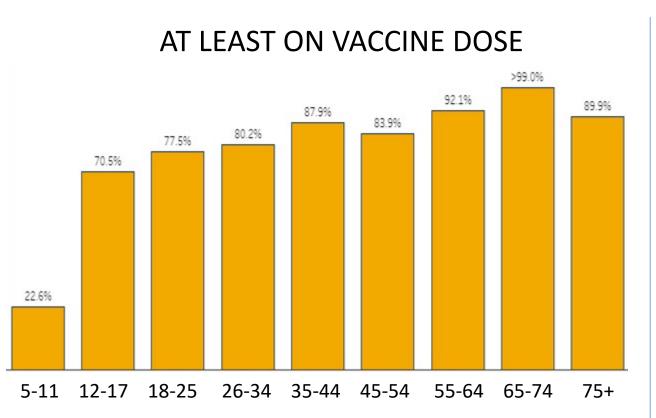
Po	eople with at leas	t one Vaccine Dos	se	People with completed Vaccine Series			
% of Total Population (CDC) ¹ 81.1%		% of 18+ Population (CDC) 1 93.5%		% of Total Population (CDC) ¹ 70.5%		% of 18+ Population (CDC) ¹ 82.0%	
Total ² 15,209,777	% of Total Population ³	Age 18+ ² 13,877,474	% of 18+ Population ³	Total ² 13,595,167	% of Total Population ³	Age 18+ ² 12,531,636	% of 18+ Population ³



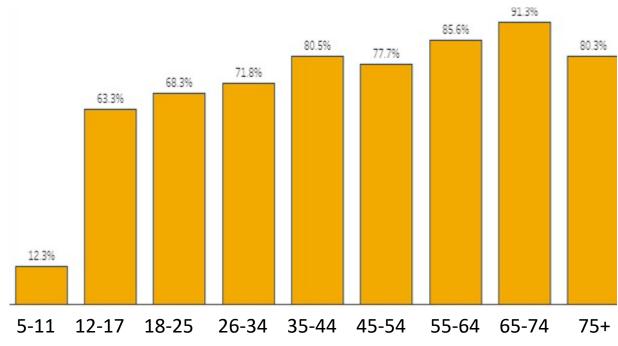




Percent of Population Vaccinated in New York State By Age, as of 12/14/2021



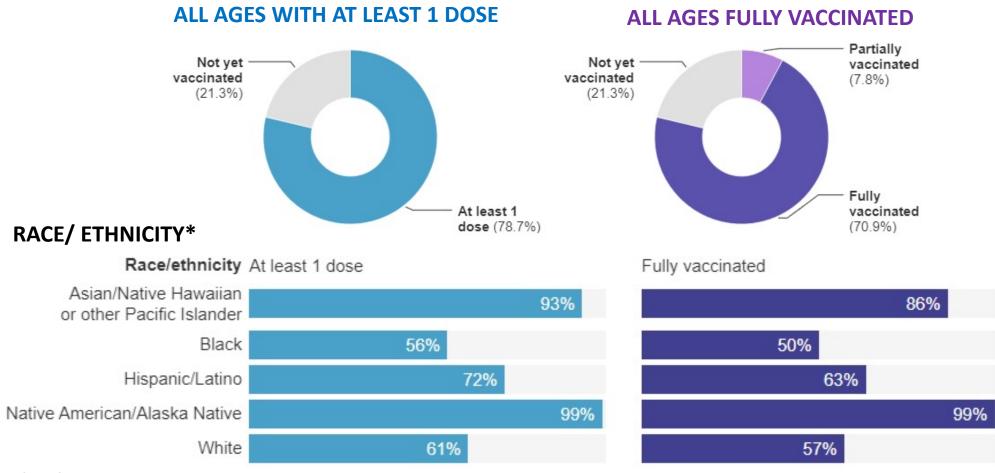
COMPLETED VACCINE SERIES







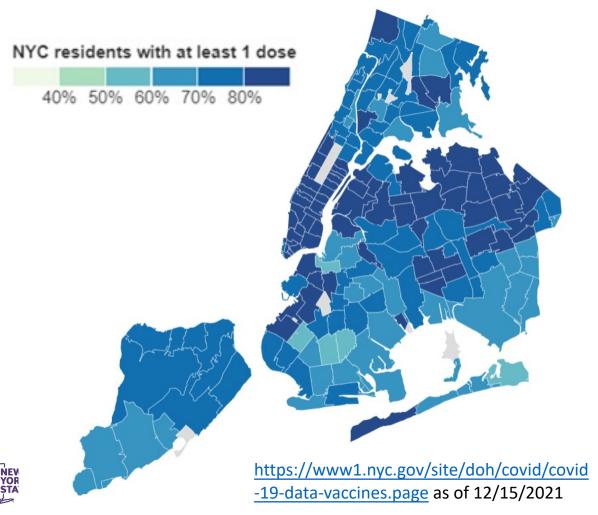
Percent of New York City Residents Vaccinated by Race/Ethnicity

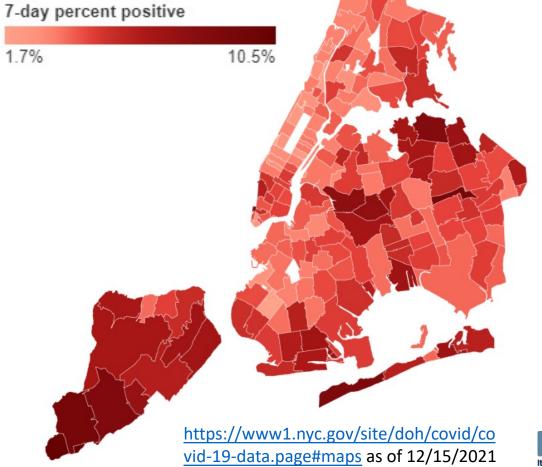






Vaccination Coverage Compared to Recent Average Daily COVID-19 Percent Positive by NYC Zip Code









OUTLINE



COVID-19 ORAL ANTIVIRAL TREATMENT

The information presented here is preliminary and based on regular discussions with Federal partners. The content is subject to change based upon official EUA release.





Oral Antivirals to Treat COVID-19 Clinical Use and Indications

- Two oral antivirals under FDA review to treat non-hospitalized, symptomatic adults diagnosed with COVID-19 who are at increased risk of progressing to severe illness
 - Paxlovid (Pfizer) -Reduced risk of hospitalization by ≥88%
 - Molnupiravir (Merck) Reduced risk of hospitalization by 30%
- Target certain surface proteins on SARS-CoV-2 to prevent efficient replication of the virus in host cells
- Both would be taken twice daily x 5 days
- Supplies will be limited, and providers should prioritize oral antivirals for patients unable to receive monoclonal antibody (mAb) treatment





Paxlovid (PF-07321332; ritonavir)

- Phase 2/3 placebo-controlled clinical trial, interim analysis (N=2,246)
 - High-risk, non-hospitalized adults, mild to moderate symptoms for ≤5 days
 - Primary endpoint: hospitalization or death

	N	Hospitalized (D#28)	Death	% Reduction
Paxlovid bid x 5d	1039	8 (0.8%)	0	88% (p<0.0001)
Placebo	1046	66 (6.3%)	12 (1.1%)	

- Subgroup analysis of patients treated within 3 days of symptom onset = 89%
- Adverse events similar between treatment and placebo group, fewer emergent events in treatment group (1.6% vs. 6.6%)





Molnupiravir (MK-4482, EIDD-2801)

• Phase 3 placebo-controlled clinical trial, interim analysis (N=775)

- High-risk, non-hospitalized adults, mild to moderate symptoms
- Symptom onset within 5 days
- Excluded pregnancy, verified by a negative pregnancy test

	N	Hospitalized or Death (D#29)	Percent Reduction
Molnupiravir	709	48 (6.8%)	30% (p=0.0218)
Placebo	699	68 (9.7%)	

- Efficacy against variants Gamma, Delta, Mu (40% of cases sequenced)
- Adverse event similar between treatment and placebo group



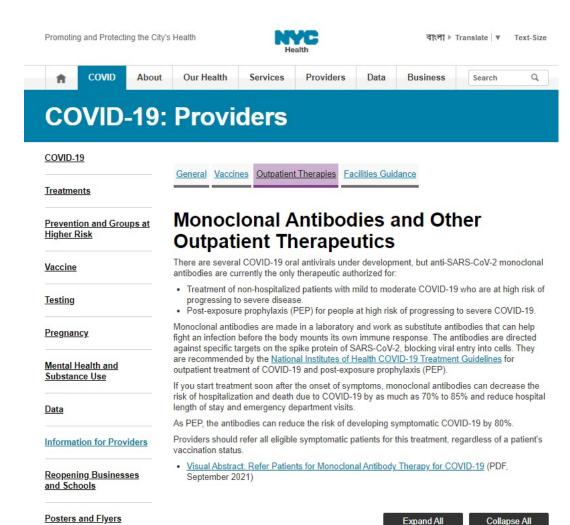


Oral Antivirals to Treat COVID-19 Expected Eligibility With EUA

- Therapy will likely only be available for people who meet all the following conditions:
 - Age 18 years and older
 - Have a medical condition or other factors that increase their risk for severe illness
 - Consider race and ethnicity when assessing individual risk. Longstanding systemic health and social inequities may put individual patients at increased risk of getting sick and dying from COVID-19
- In addition to receive the therapy, patients need to:
 - Test positive for SARS-CoV-2 on a nucleic acid amplification test or antigen test
 - Have mild to moderate COVID-19 symptoms
 - Be within 5 days of symptom onset
 - Not be hospitalized or receiving oxygen therapy due to COVID-19
- Pregnant and lactating women were excluded from clinical oral antiviral trials

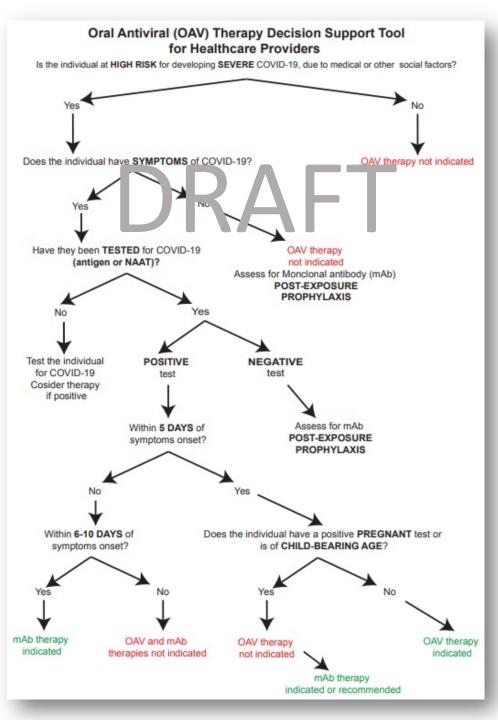






nyc.gov/health/covidprovidertreatments







Oral Antivirals to Treat COVID-19 Distribution NYS and NYC

- Initial supplies have been purchased by U.S. Government
 - Will be provided to States/treatment sites for free
- Initial allocations to states will be extremely limited
 - Focus will be on ensuring equitable access for highest risk outpatients
 - Sites able to provide mAbs (e.g., hospital EDs) will likely be lower priority to receive at first
 - Biweekly allocations
 - Similar to all initial new product allocations, delivery is a push to the counties and boroughs, this is not going to be a request system





Oral Antivirals to Treat COVID-19 Distribution NYC

- Initially in NYC, oral medications will only be distributed by Alto Pharmacy
 - Retail pharmacy selected through competitive process to ensure equitable access for all New Yorkers
 - Allows easier supply management, reducing burden on patients and providers
- Will offer free courier delivery across all five boroughs
 - COVID-19 antiviral prescriptions should be routed to Alto Pharmacy
 - Once received, patients can schedule delivery on the Alto mobile app, by text or by phone
 - Prescriptions confirmed by 5 pm weekdays or 1pm on weekends are delivered the same day
- As supplies increase, additional pharmacies will be added as access points based on local needs





Oral Antivirals to Treat COVID-19 Prescribing NYC

- For e-prescribing add Alto Pharmacy to your electronic medical record (EMR)
- Locate Alto Pharmacy in your ePrescribing platform or EMR, by searching on any of the following data points:
 - Name: Alto Pharmacy
 - Address: 100 Park Ave, Front E, New York, NY 10017
 - NPI: 1417578899
 - NCPDP: 5831866
 - Ensure search filters do not include a mileage or radius limit and that you are not on a "favorites" or "recently viewed" filter
- Alternatively, Alto Pharmacy accepts prescriptions via phone (800) 874-5881 or fax at (415) 484-7058





Oral Antivirals to Treat COVID-19 Prescribing NYC

- Verify patient phone number and address for delivery in the chart
- Record patient's race/ethnicity in the note for pharmacist section
- Send prescription to Alto Pharmacy
- Advise patient they will receive a call or text message from the pharmacy ((800) 874-5881) to schedule delivery. The patient must respond to the call or text to confirm delivery
- For questions or concerns, contact Alto Pharmacy at (800) 874-5881





- The amount of product New York State receives will be distributed to counties and regions using an algorithm that will be based on multiple factors, including:
 - Population density
 - At-risk population (e.g., unvaccinated population)
 - COVID-19 case burden
- First initial phase:
 - Push system of distribution
 - 2-3 pharmacy sites per county
 - Prioritizing communities within each county with a high Medicaid population
 - Partnering with Federal Retail Pharmacy Partners
- As supplies increase, additional pharmacies will be added as access points



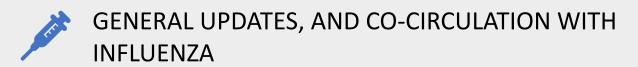


- Initial allocation, paired with utilization data, will be used to determine future allocations
- Sites will be required to adhere to a daily reporting requirement
- Reporting of product will support the release of a product finder tool supported by the Federal Government (details TBD)





OUTLINE







New SARS-CoV-2 Variant of Concern: Omicron (B.1.1.529) Variant

- First detected in Botswana November 11, 2021, and South Africa on November 14, 2021; now numerous countries and states
- Omicron cases have been detected in NYC and elsewhere in New York State, including in people without travel history
- Assume community transmission of this variant is occurring, however, <u>delta</u> remains the dominant strain in New York and NYC





New SARS-CoV-2 Variant of Concern: Omicron (B.1.1.529) Variant

- About 50 mutations compared to original SARS-CoV-2 virus, > 30 within spike protein of the virus
- We know more about what we don't know that what we know, studies are underway, expect to know more in the coming weeks
 - Preliminary evidence suggests it is highly transmissible
 - Spectrum of illness not yet described, unknown if more severe illness compared to other variants
 - Vaccines
 - Expect decreased neutralization from vaccine and prior infection
 - Expect vaccines to remain effective against severe illness and death





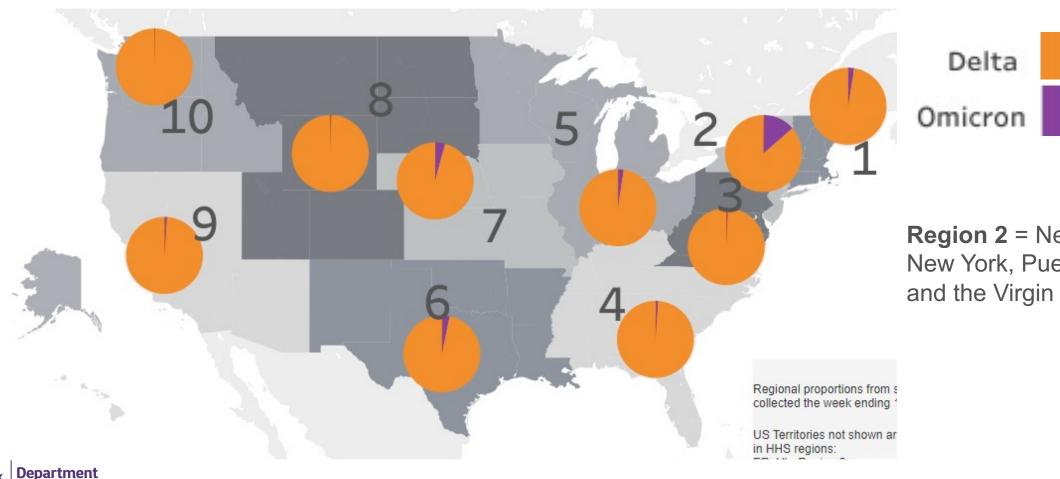
New SARS-CoV-2 Variant of Concern: Omicron (B.1.1.529) Variant

- Omicron's emergence underscores the need for COVID-19 prevention measures for all New Yorkers, including those who are fully vaccinated. Remind patients to:
 - Complete a primary COVID-19 vaccination series
 - Get a COVID-19 booster
 - Wear a mask in indoor public settings; consider the type of mask or respirator to use
 - Get tested for COVID-19 if symptomatic or recently exposed to someone with COVID-19, and before and after attending a gathering or travel
 - Stay home when sick, including when symptoms are mild
 - Take other measures to prevent exposure and transmission
- Continue to follow existing quarantine, isolation and testing guidance





CDC Nowcast Estimate of Proportion of SARS-CoV-2 Variants by HHS Region, USA 12/5/2021-12/11/2021



of Health



Region 2 = New Jersey, New York, Puerto Rico, and the Virgin Islands



Omicron and Monoclonal Antibodies

- Bamlanivimab + etesevimab
 - Active against Delta (B.1.617.2)
 - May have significant loss of activity against Omicron
- Casirivimab + imdevimab (REGEN-COV)
 - Active against Delta
 - May have significant loss of activity against Omicron
- Sotrovimab
 - Likely active against all variants of concern including Omicron





FDA Expands EUA of mAb to Younger Pediatric Patients, Including Newborns

- The U.S. Food and Drug Administration on December 3, 2021, revised the EUA of bamlanivimab and etesevimab
- Now authorized to administer together in ALL pediatric patients, including newborns for;
 - Treatment of mild to moderate COVID-19 with positive COVID-19 test who
 are at high risk for progression to severe COVID-19, including hospitalization
 or death
 - **Post-exposure prophylaxis** for prevention of COVID-19 in those at high risk of progression to severe COVID-19, including hospitalization or death





Long-Acting Antibody Combination Therapy

- EVUSHELD Pre-exposure prophylaxis LAAB from AstraZeneca
 - FDA Authorized
 - Combination of tixagevimab (AZD8895) and cilgavimab (AZD1061)
 - Derived from B-cells donated by convalescent patients after SARS-CoV-2 virus infection
 - 77% reduction in risk of symptomatic COVID-19
 - 75% of participants had co-morbidities that put them at high risk for severe COVID-19 including people who are immunocompromised and may have a reduced immune response to vaccination





Long-Acting Antibody Combination Therapy

- Intramuscular (IM) injection of each of the 2 products, every 6 months
- For persons 12 years of age and older who weigh at least 88 pounds [40 kg]) in persons who are:
 - Not currently infected with SARS-CoV-2 and no recent close contact with someone who is infected with SARS-CoV-2 and
 - Who have moderate to severe immune compromise due to a medical condition or have received immunosuppressive medicines or treatments and
 - May not mount an adequate immune response to COVID-19 vaccination or
 - For whom vaccination with an available COVID-19 vaccine, according to the approved or authorized schedule, is not recommended due to a history of severe adverse reaction to a COVID-19 vaccine or ingredient





Expanded CDC COVID-19 Booster Recommendations

- CDC strengthened the recommendation on booster doses on November 29 and FDA expanded the Pfizer EUA on December 9
 - Everyone ages 18 years and older should get a booster dose six months after their initial Pfizer or Moderna series, or two months after their initial Johnson & Johnson vaccine
 - Based on expansion, NYC DOHMH recommends that adolescents ages 16-17 years should receive a Pfizer booster dose six months after their initial Pfizer series





NYS COVID-19 Executive Order #11

- Declares a disaster emergency in NYS
 - Increasing transmission and hospitalizations
 - Limit non-essential elective procedures for in hospitals or systems with limited capacity as of December 9
 - Does NOT apply to single specialty facilities (e.g., cancer treatment facility), non-hospital owned ambulatory surgery centers, office-based surgery practices, or free-standing diagnostic and treatment centers
 - Coordinated, collaborative approach to ensure hospital capacity meets regional needs while maintaining the long-term resiliency of the State's healthcare infrastructure





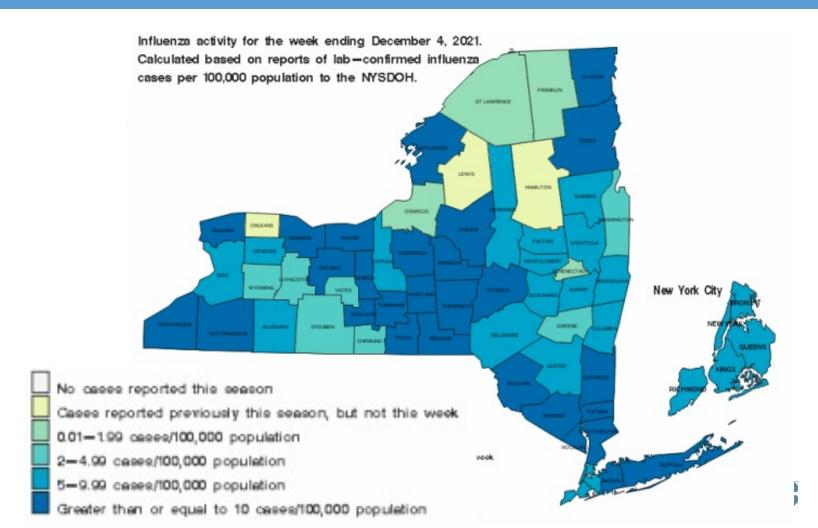
Influenza Season Updates

- Influenza activity in Southern hemisphere has been low to date
 - This may not be predictive of what will occur in U.S.
- Offer flu and COVID-19 vaccines together, if possible
- Start testing patients with influenza-like illness for flu and COVID-19
- Start messaging to high-risk patients:
 - Get vaccinated for flu and COVID-19
 - Get tested for flu and COVID-19 immediately if symptoms develop
 - Important to access timely treatment for COVID-19 or flu if needed

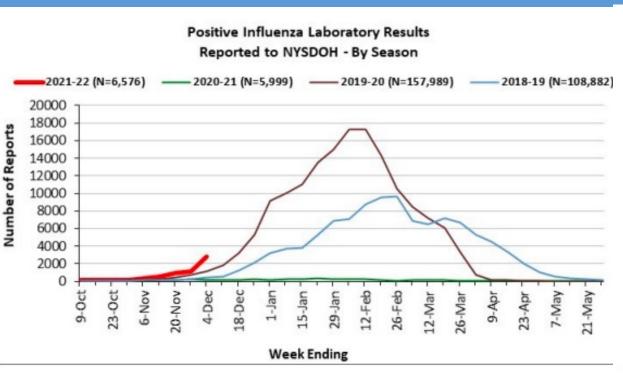


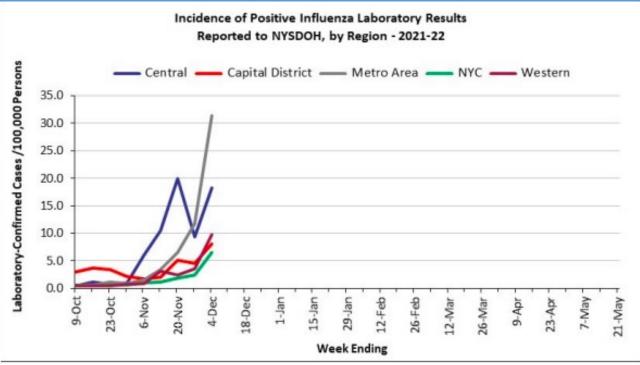
Influenza Surveillance NYS by Region WIDESPREAD - Week Ending December 4, 2021

https://www.health.ny.gov/diseases/communicable/influenza/surveillance/https://www1.nyc.gov/site/doh/providers/health-topics/flu-alerts.page



Influenza Surveillance NYS by Region Week Ending December 4, 2021

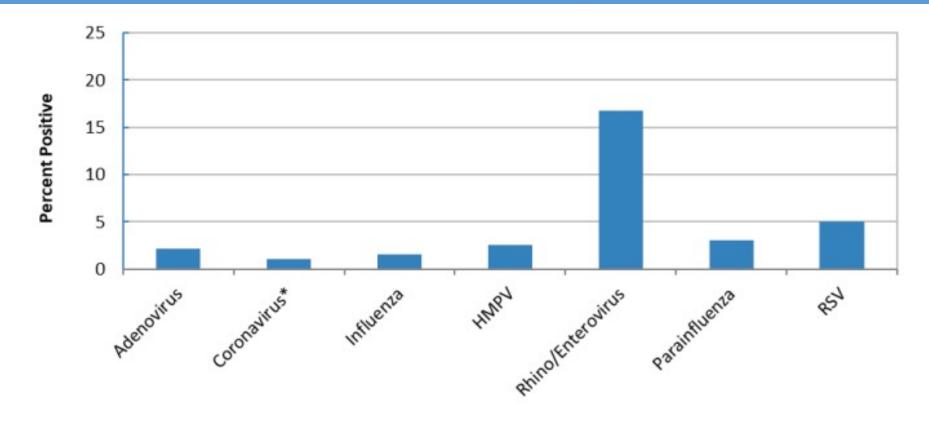








Respiratory Virus Results, Selected NYC Labs November 28-December 4, 2021



^{*} Human coronavirus types 229E, NL63, OC43, and HKU1





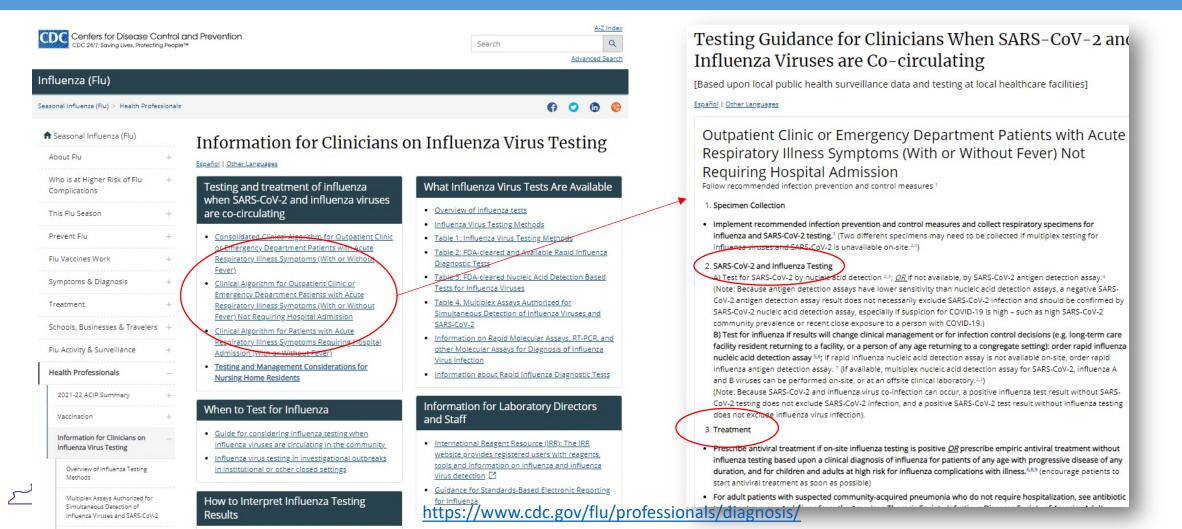
Influenza Season Updates CDC Testing strategies during co-circulation SARS-Cov-2

- Options for testing respiratory specimens in patients with acute respiratory illness
 - Outpatient clinical and emergency department
 - Test for SARS-CoV-2 and use judgement to clinically diagnose influenza and prescribe antiviral treatment of influenza if needed, OR
 - Test for both SARS-CoV-2 and influenza viruses
 - Hospitalized or Nursing Home
 - Test for both SARS-CoV-2 and influenza viruses
- Do not order viral culture for initial or primary diagnosis of influenza
- Do not order serology for influenza
- When influenza is circulating, prescribe empiric oseltamivir based on a clinical diagnosis of influenza for patients with progressive illness or risk factors for influenza complications
 - Prescribe even if symptoms have been present > 48 hours





Influenza Season Updates CDC Testing strategies during co-circulation SARS-Cov-2



NYC

Influenza Season Updates Testing strategies during co-circulation SARS-Cov-2

- For more information about influenza
 vaccines and antivirals for influenza treatment
 and prophylaxis visit:
 - NYS and NYC Health Department provider influenza pages
 - NYC Community Health Information for Influenza Prevention and Control
 - CDC

https://www.health.ny.gov/diseases/communicable/influenza/seasonal/providers/https://www1.nyc.gov/site/doh/providers/health-topics/influenza.pagehttps://www1.nyc.gov/assets/doh/downloads/pdf/chi/chi-40-3.pdfhttps://www.cdc.gov/flu/professionals/index.htm



CME Activity Online, 2 Credits (See Page 46)

City Health Information

Volume 40 (2021) | No 3; 31-46

New York City Department of Health and Mental Hygiene

INFLUENZA PREVENTION AND CONTROL, 2021-2022

- Provider recommendation is the strongest predictor of vaccination. Ensure that you and your entire staff
 receive flu vaccine and counsel patients and caregivers on the benefits of flu vaccination.
- Use every opportunity to vaccinate all patients aged 6 months and older against influenza, especially those
 at risk for severe illness from influenza and coronavirus disease 2019 (COVID-19). All routine vaccines can be
 coadministered with flu vaccine, including COVID-19 vaccine.
- Vaccinate all children aged 6 through 59 months attending City-licensed and City-regulated childcare against influenza by December 31st of each year, as required by the New York City Board of Health.
- Give inactivated flu vaccine to all pregnant persons in any trimester to prevent influenza infection and complications in both the patient and infant.
- · Administer high-dose or adjuvanted flu vaccine to patients aged 65 years and older.

INSIDE THIS ISSUE (click to access)

Important groups to vaccinate against influenza (box)
Medical conditions that increase risk for severe complications
from influenza (box)

ACCINATION COVERAGE AND INEQUITIES

STRONGLY RECOMMEND VACCINATION

Common questions about the importance of flu vaccination (box) What to tell patients about flu vaccine safety (box) Immunization and pharmacists (box)

VACCINATE SAFELY DURING COVID-19

ENSURE YOU AND YOUR STAFF ARE VACCINATED

IMPROVE VACCINATION COVERAGE

National Vaccine Advisory Committee (NVAC) Standards for Adult Immunization Practice (box)

VACCINATE CHILDREN AS EARLY AS POSSIBLE

VACCINATE PREGNANT PEOPLE AGAINST INFLUENZA AND PERTUSSIS

Reasons to give flu vaccine in any trimester of pregnancy (box)

VACCINATE OLDER ADULTS TIMING OF FLU VACCINES

THIS SEASON'S VACCINES

Available flu vaccines for the 2021-2022 season (table)

ASSESS FOR CONTRAINDICATIONS AND PRECAUTIONS Administering the flu vaccine to patients with egg allergies (figu Contraindications and orecautions for persons with previous

severe allergic reaction to flu vaccine (table)

VACCINATE AGAINST PNEUMOCOCCAL DISEASE

Pneumococcal vaccine administration for adults aged 19

and older (table)

Influenza is a highly contagious viral infection that results in serious illness, hospitalizations, and deaths every season. Infants, pregnant persons, older adults, and people of any age with chronic medical conditions are at higher risk for serious complications.1 During the 2020-2021 influenza season, which occurred concurrently with the coronavirus disease 2019 (COVID-19) pandemic, rates of influenza were the lowest recorded.23 There were no influenza-associated deaths among children in New York City (NYC); 1 child died from influenza in the United States.34 In addition to flu vaccination, precautions taken during the COVID-19 pandemic, including social distancing and mask wearing, may have limited the spread of influenza.2

Vaccination is our best defense against influenza and its complications. An estimated





Be Festive, Stay Safe! Tips for a Safer Holiday Season

Get vaccinated against COVID-19 to enjoy a safer holiday season. For more information, visit **nyc.gov/covidvaccine**. Here are some other tips to keep you and your friends and family safe.

No matter how you celebrate, help prevent the spread of COVID-19.

Stay home if sick:

Celebrate at home if you or your family members are not feeling well or have recently tested positive for COVID-19. If you are not fully vaccinated and were recently exposed to someone with COVID-19, you should also stay home.

Get vaccinated: It is the best way to protect yourself and those around you from COVID-19. Once fully vaccinated, all activities become safer. Get a booster dose if you are eligible, particularly if you are at higher risk.

Wear a face mask:

You can have COVID-19 and not know it. Everyone should wear a face mask when in public indoor spaces or in crowded outdoor spaces.

Keep your hands clean: Wash your hands often or use alcohol-based hand sanitizer. Avoid touching your face with unwashed hands and cover your

coughs and sneezes.

Safer holiday activities

 Host a virtual party. If you or your friends and family are not fully vaccinated, celebrate with a video dinner party.
 Ring in the new year at a virtual costume party.



- Deck the halls. Put up decorations to get in the holiday spirit.
 Walk around your neighborhood and enjoy the decorated homes and shops. Stop for a hot drink to stay warm.
- Spread the holiday cheer. Surprise your neighbor by dropping off some holiday cookies. Mail holiday cards to your co-workers or call a friend you have not spoken to in a while. Invite someone who may be alone to join your holiday dinner.
- Let it snow. Make a snowperson, go sledding or snow shoeing, or have a snowball fight.
- Holiday shopping. Shop online to avoid crowds or call for curbside pickup at your favorite local store. If you shop in person, wear a face mask even if vaccinated, use hand sanitizer and go during off-hours.
- Have a feast. Make your favorite holiday meal and share it with your loved ones – you've earned it!



Gatherings

Gathering with others increases the risk of COVID-19 especially if not everyone is vaccinated. Group settings make physical distancing difficult and it is not possible to wear a face mask when eating and drinking. If you meet up with others:

- Consider risks: If you or a loved one are an older adult or have a health condition that increases your risk of severe COVID-19, consider staying home and enjoying the holidays from afar, especially if you are not fully vaccinated.
- Get tested. Get a COVID-19 test before and after you attend a gathering or travel, especially if you will be with older adults or others at increased risk of severe COVID-19.

Tips for a Safer Holiday Season

Advise your patients to:

- Get COVID-19 vaccination and boosters
- Get tested before and after gatherings and travel
 - If using a rapid antigen test before a gathering,
 time it as close possible to the actual gathering
 - Antigen tests are not as sensitive as PCR and perform best when a person is actively shedding virus

https://www1.nyc.gov/assets/doh/downloads/pdf/covid/covid-19-safer-holidays.pdf







NYSDOH - Provider COVID-19 Resources

- Mask or vax requirement:
 https://coronavirus.health.ny.gov/frequently-asked-questions-proof-full-vaccination-or-mask-requirement-businesses-and-venues
- COVID-19 information for providers:
 https://coronavirus.health.ny.gov/information-healthcare-providers
- COVID-19 Data: https://coronavirus.health.ny.gov/vaccination-progress-date
- Monoclonal antibody therapeutics: https://coronavirus.health.ny.gov/monoclonal-antibody-therapeutics

NYC DOHMH - Provider COVID-19 Resources

- Provider page: https://www1.nyc.gov/site/doh/covid/covid-19-providers.page
- Monoclonal antibodies/outpatient therapeutics: <u>nyc.gov/health/covidprovidertreatments</u>
- Data page: https://www1.nyc.gov/site/doh/covid/covid-19-data.page
- Dear Colleague COVID-19 newsletters sign up for *City Health Information* subscription at: nyc.gov/health/register
- NYC Health Alert Network sign up at: https://www1.nyc.gov/site/doh/providers/resources/health-alert-network.page
- Provider Access Line: 866-692-3641















