COVID-19
HEALTH CARE PROVIDER UPDATE:

RECENT EPIDEMIOLOGY OF COVID-19 IN NEW YORK CITY
COVID-19 VACCINE BOOSTER DOSES AND VACCINATION FOR CHILDREN AGES 5 TO 11 YEARS

NOVEMBER 5, 2021

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Our understanding of COVID-19 is evolving rapidly.
This presentation is based on our knowledge as of November 4, 2021, 5 PM.

OUTLINE

- RECENT EPIDEMIOLOGY, NYC
- BRIEF UPDATE: OUTPATIENT COVID-19 THERAPEUTICS
- VACCINE BOOSTERS AND VACCINATION OF CHILDREN 5-11 YEARS
- QUESTIONS AND ANSWERS

Recent Epidemiology of COVID-19, NYC

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Outpatient COVID-19 Therapeutics and Other Updates

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COVID-19 Outpatient Therapeutics

Two new products may be authorized by December 2021

- Both will be provided for free by U.S. government – allocated by states
- Initial supplies will be very limited

Oral antiviral

- Mulnupiravir (Merck) has pending EUA application
  - Nucleoside analog
  - Taken twice a day for 5 days (1 dose = 4 capsules)

Long-acting monoclonal antibodies for pre-exposure prophylaxis

- AZD7442 (AstraZeneca), a combination of two long-acting monoclonal antibodies
  - Intramuscular injection
  - Likely dosing: every 6 months

Flu Season Updates

- Influenza activity in Southern hemisphere has been low to date
  - This may not be predictive of what will occur in U.S.
- Be prepared to 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
- When influenza is circulating in a community, prescribe empiric oseltamivir based on a clinical diagnosis of influenza for patients with progressive illness or risk factors for influenza complications
  - Should be prescribed even if symptoms have been present > 48 hours

Updated CDC guidance on flu testing and treatment : https://www.cdc.gov/flu/professionals/diagnosis/index.htm

COVID-19 Vaccine Updates

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COVID-19 VACCINE ADMINISTRATION, NYC

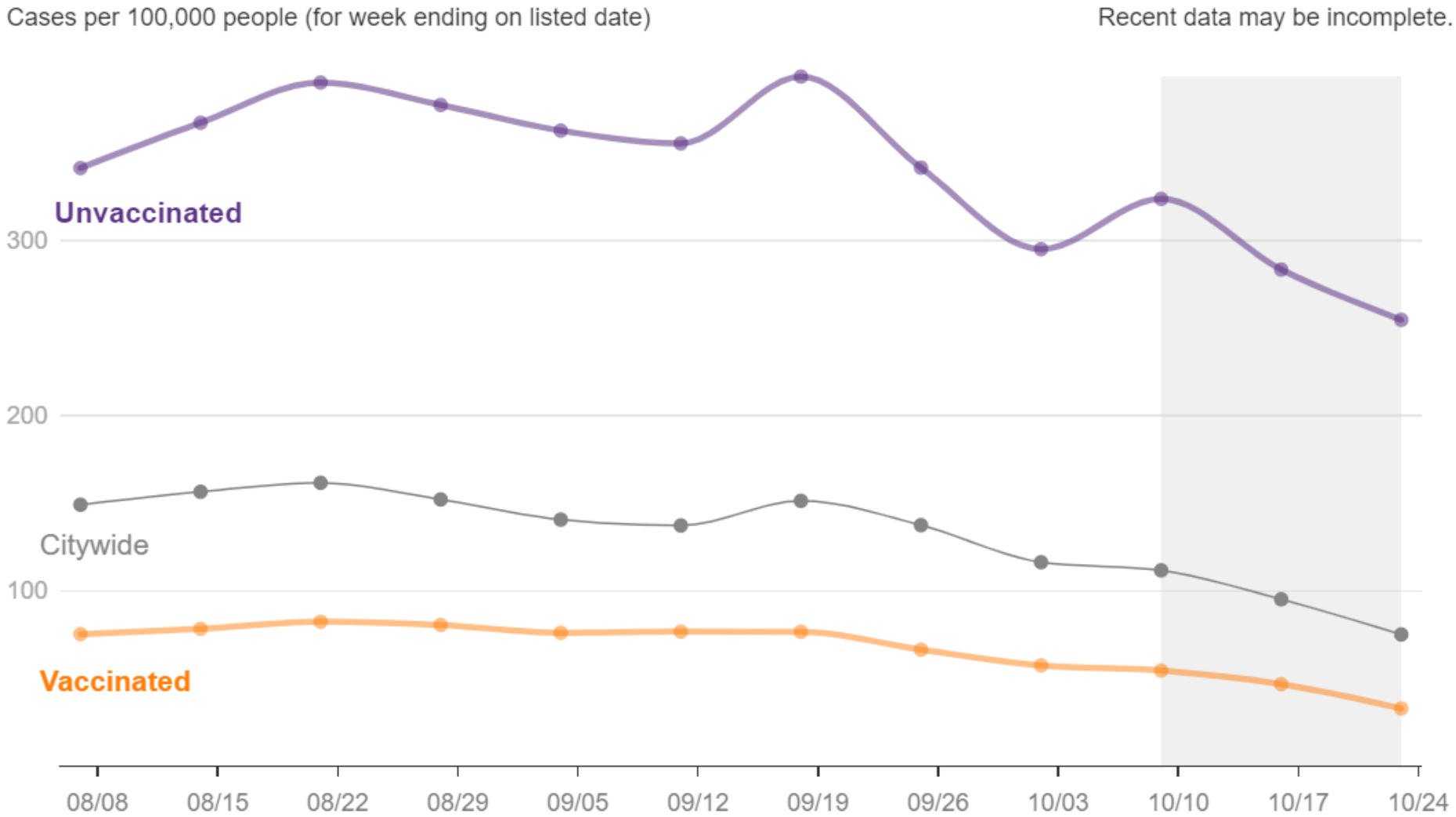
- Over 12 million doses administered
- Of NYC residents aged ≥ 18 years:
  - 87% received ≥ 1 dose
  - 79% fully vaccinated

PERCENT OF NYC RESIDENTS VACCINATED

Borough	Population	At Least 1 Dose (%)	Fully Vaccinated (%)
Citywide	**8,336,817**	**74%**	**67%**
Bronx	1,421,021	69%	61%
Brooklyn	2,559,903	66%	61%
Manhattan	1,611,420	82%	75%
Queens	2,268,330	80%	74%
Staten Island	476,143	69%	64%

Data are reported by providers to the Citywide Immunization Registry and may be delayed.
https://www1.nyc.gov/site/doh/covid/covid-19-data-vaccines.page; updated 11/4/2021

Weekly Case Rates by Vaccination Status, NYC



https://www1.nyc.gov/site/doh/covid/covid-19-data.page#daily updated on 11/4/21

Updated COVID-19 Vaccine Booster Recommendations

Updated Booster Recommendations

- CDC recommends COVID-19 vaccine booster doses for:
  - All adults who received the Johnson & Johnson (Janssen) vaccine
  - Some adults who received the Moderna or Pfizer primary vaccine series
- Any FDA-approved or authorized COVID-19 vaccine can be used as booster, regardless of primary series
- Eligibility and timing of booster dose depends on which primary series was received

CDC's booster recommendations were updated October 21, 2021.

Mbaeyi S, Oliver SE, Collins JP, et al. The Advisory Committee on Immunization Practices' Interim Recommendations for Additional Primary and Booster Doses of COVID-19 Vaccines — United States, 2021. MMWR Morb Mortal Wkly Rep. ePub: 29 October 2021. DOI: http://dx.doi.org/10.15585/mmwr.mm7044e2

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Booster Dose After mRNA Primary Series

- **Should** receive a booster:
  - People ages ≥ 65 years
  - Residents ages ≥ 18 years in long-term care facilities
  - People ages 50 - 64 years who have a medical condition that increases their risk for severe COVID-19 illness
- **May** receive a booster, based on individual benefits and risks:
  - People ages 18 - 49 years who have a medical condition that increases their risk for severe COVID-19 illness
  - People ages 18 - 64 years who are at increased risk for COVID-19 exposure and transmission because of occupational or institutional setting
- Administered ≥ 6 months after completion of primary mRNA series

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

Booster Dose After Johnson & Johnson Primary Series

- Single booster dose recommended for all people aged ≥ 18 years who received a primary Johnson & Johnson vaccine
- Administered ≥ 2 months after the primary series

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

FDA-Authorized or Approved COVID-19 Vaccines for Primary or Booster Vaccination

Vaccine	Primary series/dose				Booster dose	
	Dose (volume)	No. doses (interval)	Age (yrs)	Interval from primary to booster dose	Dose (volume)	Age (yrs)
Pfizer-BioNTech	30 µg (0.3 ml)	2 (21 days)	≥12	≥6 months	30 µg (0.3 ml)	≥18
Moderna	100 µg (0.5 ml)	2 (28 days)	≥18	≥6 months	**50 µg (0.25 ml)**	≥18
Janssen	5×10^{10} VP (0.5 ml)	1 (N/A)	≥18	≥2 months	5×10^{10} VP (0.5 ml)	≥18

- Note: booster dose of Moderna vaccine is half the amount used for the primary Moderna series; half dose given regardless of what vaccine product used for the primary series

CDC Clinician Outreach and Communication Activity call 10/26/21 https://emergency.cdc.gov/coca/ppt/2021/102621_slide.pdf

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Heterologous ("Mix-and-Match") Doses may be Considered for Boosters but Not Additional Doses

- A dose of a different product from that used in primary series may be considered for boosters
- This does not apply to "additional doses" recommended for moderately to severely immunocompromised people who received two mRNA doses
  - Additional dose should be of the same vaccine product as the primary series (with limited exceptions)
- People who are moderately or severely immunocompromised who receive an additional mRNA dose are eligible for a single COVID-19 booster dose (Pfizer, Moderna, or Johnson & Johnson) ≥ 6 months after their third dose
  - Total of four COVID-19 vaccine doses

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

Individual Risk-Benefit Assessment for Choice of Booster Product

- May take risk of rare adverse events associated with specific vaccine products into account
- Johnson & Johnson
  - Thrombosis with thrombocytopenia, highest risk for women aged 18-49 years
  - Guillain-Barre Syndrome, highest risk for men aged 50-64 years
- mRNA vaccines
  - Myocarditis and pericarditis, highest risk for males aged 12-30 years

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

COVID-19 Vaccine for Children Ages 5-11 Years

Background: COVID-19 in U.S. Children Ages 5-11

- Approximately 9% of COVID-19 cases reported in the U.S. have been in children ages 5-11 years
  - > 8,300 COVID-19 hospitalizations and 94 COVID-19 deaths reported in this age group
- Multisystem inflammatory syndrome in children (MIS-C)
  - > 5,200 cases have been reported in U.S.; 2,316 (44%) among age 5-11
  - 61% of MIS-C cases occurred in children who are Hispanic/Latino or Black
  - Typically occurs after asymptomatic or mild infection
- Post-COVID conditions can occur in children (including after mild infection)
  - Most common symptoms: fatigue, headache insomnia, trouble concentrating
  - May have long-lasting impact on quality of life
- Young children can transmit SARS-CoV-2 infection in households and school settings

https://emergency.cdc.gov/coca/ppt/2021/110421_slide.pdf
https://www.fda.gov/media/153508/download
https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-2-3/03-COVID-Jefferson-508.pdf

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Efficacy of Two-Dose Pfizer Vaccine, Children Ages 5-11 Years

- 2,268 participants enrolled starting June 2021 (Delta variant predominated)
  - Median follow-up time 2.3 months
- Dose studied was one-third of that used for people aged ≥ 12 years
- Efficacy against symptomatic COVID-19 among children with no evidence of prior SARS-CoV-2 infection: 90.7%

https://www.fda.gov/media/153510/download
https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-2-3/02-COVID-Gurtman-508.pdf

Safety and Reactogenicity, Two-Dose Pfizer Vaccine, Children Ages 5-11 Years

- Most reactions after vaccination were mild to moderate and resolved within 1-2 days
  - Most common: pain at injection site, fatigue, headache
  - Comparable to those observed among 16-25-year-old Pfizer vaccine recipients
- No severe adverse events attributable to vaccination were observed among 3,082 children with at least 7 days of follow-up*
  - No cases of myocarditis or pericarditis (but study not large enough to detect rare events)

* Includes children in the intervention arm of the efficacy trial and children in an expanded short-term safety study
https://www.fda.gov/media/153510/download
https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-2-3/02-COVID-Gurtman-508.pdf

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CDC Recommended Pfizer COVID-19 Vaccine for Children Ages 5-11 Years

- Food and Drug Administration (FDA) issued Emergency Use Authorization (EUA) October 29, 2021
- Advisory Committee on Immunization Practices (ACIP) recommended use in all children in this age group November 2, 2021
- CDC endorsed the ACIP recommendation that evening

Pfizer Vaccine for Children Ages 5-11: Different Product than Vaccine for ≥ 12 Years

Description	Current Adult/Adolescent Formulation	Future Pediatric Formulation
	Dilute Prior to Use	*Dilute Prior to Use*
Age Group	12 years and older	5 to <12 years**
Vial Cap Color	PURPLE 	ORANGE 
Dose	30 mcg	10 mcg
Injection Volume	0.3 mL	0.2 mL
Fill Volume (before dilution)	0.45 mL	1.3 mL
Amount of Diluent* Needed per Vial	1.8 mL	1.3 mL
Doses per Vial	6 doses per vial (after dilution)	10 doses per vial (after dilution)
Storage Conditions		
ULT Freezer (-90°C to -60°C)	9 months	6 months
Freezer (-25°C to -15°C)	2 weeks	N/A
Refrigerator (2°C to 8°C)	1 month	10 weeks

- Vaccine product for people ages ≥ 12 years cannot be used for children ages 5-11 years
- Facilities that provide COVID-19 vaccination for children ages 5-11 and for other age groups should establish workflows to prevent vaccine administration errors

https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-2-3/07-COVID-Woodworth-508.pdf

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Dosage for Children Ages 5-11

- Vaccine dosage is based on age, not size or weight
  - Children should receive age-appropriate formulation
- Dosage should be based on child's age on the day of vaccination
- A child who received a first dose at age 11, then turned 12 by the time of the second dose, should get the **30 microgram (adolescent/adult) dose**
  - However, if a child turns from 11 to 12 years of age between their first and second doses and receives the 5-to-11-year **10 microgram** (orange cap) second dose, they do not need to repeat the dose and this is not considered an error per the EUA

https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-2-3/07-COVID-Woodworth-508.pdf
https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

Coadministration with Other Vaccines

- COVID-19 vaccines may be administered without regard to timing of other vaccines, including on the same day as other vaccines.
- If multiple vaccines are administered during a single visit
  - Administer each in a different injection site
  - Separate injection by ≥ 1 inch
  - For people ≥ 11 years, deltoid muscle can be used
  - For children 5-10 years, if ≥ 2 vaccines are injected in a single limb, vastus lateralis muscle of anterior thigh is the preferred site due to greater muscle mass

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

Risk of Myocarditis

- Counsel parents/guardians that myocarditis and pericarditis have occurred rarely following receipt of mRNA COVID-19 vaccines
  - Risk is highest among males ages 12-29 years
  - Onset typically occurs within a few days following receipt of the second dose
  - Patients should seek medical care if they develop chest pain, dyspnea, or palpitations
- FDA and CDC have determined that the benefits of COVID-19 vaccination outweigh the risks in this population
  - Risk of myocarditis or pericarditis after receipt of an mRNA COVID-19 vaccine is lower than the risk of myocarditis associated with SARS-CoV-2 infection in adolescents and adults

https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-2-3/07-COVID-Woodworth-508.pdf
https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html
Gargano JW, et al. Use of mRNA COVID-19 Vaccine After Reports of Myocarditis Among Vaccine Recipients: Update from the Advisory Committee on Immunization Practices — United States, June 2021. MMWR 2021;70:977–982.
DOI: http://dx.doi.org/10.15585/mmwr.mm7027e2
Boehmer TK, et al. Association Between COVID-19 and Myocarditis Using Hospital-Based Administrative Data — United States, March 2020–January 2021. MMWR 2021;70:1228–1232. DOI: http://dx.doi.org/10.15585/mmwr.mm7035e5

Considerations for Children with a History of COVID-19

- COVID-19 vaccination is recommended for everyone age 5 or older, including people with a history of symptomatic or asymptomatic SARS-CoV-2 infection or seropositivity
  - People with known current COVID-19 should defer vaccination until they have recovered from the acute illness and meet criteria to discontinue isolation
- Prior infection can protect against reinfection, but protection is not 100% and likely decreases over time
  - Delta-wave surges of pediatric COVID-19 hospitalizations occurred even with seroprevalence of ~38% among children, suggesting that additional protection is needed
- In clinical trial in children ages 5-11: compared to those who were seronegative at baseline, children who were seropositive at baseline had
  - Higher post-vaccination antibodies
  - Lower rates of local and systemic reactions and adverse events
- Serologic testing is not recommended for the purpose of making decisions about COVID-19 vaccination

https://emergency.cdc.gov/coca/ppt/2021/110421_slide.pdf
https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-2-3/02-COVID-Gurtman-508.pdf
https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

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Considerations for Children and Adolescents with a History of MIS-C

- Benefits of vaccination are likely to outweigh a theoretical risk of MIS-C-like illness or the known risks of COVID-19 vaccination for children or adolescents with a history of MIS-C who meet all the following criteria:
  - Have recovered clinically, including return to normal cardiac function
  - ≥ 90 days have passed since diagnosis of MIS-C
  - They are in an area of high or substantial transmission of SARS-CoV-2, or otherwise have an increased risk for SARS-CoV-2 exposure and transmission
  - Onset of MIS-C occurred before any COVID-19 vaccination
- Vaccination may also be considered for people with a history of MIS-C who do not meet all of the above criteria
  - Experts view clinical recovery, including return to normal cardiac function, as an important factor

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

Summary: Benefits and Risks of COVID-19 Vaccination among Children ages 5-11

Benefits

Prevention of COVID-19 cases

Likely prevention of hospitalizations, MIS-C and deaths and post-COVID conditions

Possible prevention of transmission

Greater confidence in safer return to school and social interactions

Risks

Myocarditis or other rare events after mRNA vaccines?

Short-term reactogenicity

https://emergency.cdc.gov/coca/ppt/2021/110421_slide.pdf

COVID-19 Vaccination for Children Ages 5-11, NYC

- Vaccine for this age group can be ordered now
  - Must order pediatric vaccine separately
  - Minimum order: 100 doses
  - Vaccine can be stored in refrigerator units with other pediatric vaccines
- Vaccine being distributed to hospitals, Federally Qualified Health Centers, providers' offices, independent and chain pharmacies and City vaccination sites
- Visit the Citywide Immunization Registry for information on COVID-19 vaccination program enrollment and ordering
  - https://www1.nyc.gov/site/doh/providers/reporting-and-services/citywide-immunization-registry-cir.page

Other COVID-19 Vaccine Updates: Medical Exemption to Vaccination

- Because of COVID-19 vaccine mandates for work, travel or other reasons, patients may request a medical exemption in lieu of vaccination
- Only valid medical exemptions should be provided
- There are very few contraindications to vaccination; refer to CDC clinical considerations
- Many employers and institutions are reviewing these requests and invalid exemptions are likely to be rejected
- Patterns of inappropriate exemptions reported to the NYC Health Department will be investigated

Updated Contraindications

CONTRAINDICATION TO COVID-19 VACCINATION
History of the following: • Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of a COVID-19 vaccine • Known (diagnosed) allergy to a component of a COVID-19 vaccine
Actions: • Do no vaccinate • Consider referral to allergist-immunologist

For footnotes and more information see https://www.cdc.gov/vaccines/covid-19/clinical-considerations

Updated Precautions

PRECAUTION TO COVID-19 VACCINATION
Among people without a contraindication, a history of: • Any immediate allergic reaction to other vaccines (non-COVID-19) or injectable therapies • Non-severe, immediate (onset <4 hours) allergic reaction after a previous dose of COVID-19 vaccine
Actions: • Risk assessment • 30-minute observation period if vaccinated • Consider referral to allergist-immunologist

For footnotes and more information see https://www.cdc.gov/vaccines/covid-19/clinical-considerations

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Updated Precautions

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For footnotes and more information see https://www.cdc.gov/vaccines/covid-19/clinical-considerations

Guidance for People with Other Allergies

MAY PROCEED WITH COVID-19 VACCINATION
Among people without a contraindication or precaution, a history of: • Allergy to oral medications (including the oral equivalent of an injectable medication) • History of food, ped, insect, venom, environmental, latex, etc., allergies • Family history of allergies
Actions: • 30-minute observation period: people with history of anaphylaxis (due to any cause) • 15-minute observation period: all other people

For footnotes and more information see https://www.cdc.gov/vaccines/covid-19/clinical-considerations

Other COVID-19 Vaccine Updates: People Vaccinated Outside U.S.

- People who were vaccinated outside the U.S. with a COVID-19 vaccine that is FDA-approved or authorized or WHO-emergency use listed and received all recommended doses are considered fully vaccinated
  - This includes people who received a “mix-and-match” vaccine series
- People who received the first of a 2-dose FDA-approved or authorized mRNA vaccine outside the U.S. do not need to re-start series
  - Should receive second dose as close to recommended time as possible
- See CDC guidance for information on boosters and extra doses for people vaccinated outside the U.S.

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#people-vaccinated-outside-us

CDC Science Brief: SARS-CoV-2 Infection-induced and Vaccine-induced Immunity

- Both fully vaccinated people and those previously infected with SARS-CoV-2 have a low risk of subsequent infection for at least 6 months
- Full vaccination, especially with mRNA vaccines, leads to a more consistent and higher-titer initial antibody response compared to SARS-CoV-2 infection
- Protective antibody titers for individuals remain unknown
  - There is no authorized or approved test that can be used to determine if a person is protected from infection
- Delta and other variants have shown increased resistance to neutralization by both post-infection and post-vaccination sera, but reduction in efficacy is modest
  - Protection remains strong against hospitalization, severe disease and death
- Accumulating evidence indicates that vaccination after infection further reduces risk of reinfection
- CDC recommends vaccination for all eligible people, including those previously infected with SARS-CoV-2

https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/vaccine-induced-immunity.html#anchor_1635546906501

Anticipated Developments in COVID-19 Vaccines

- Moderna:
  - Has applied to FDA for Emergency Use Authorization (EUA) for children ages 12-17 years
  - Moderna has delayed EUA filing for vaccination of children ages 6-11 years pending decision for older children/adolescents
- Pfizer vaccine for children younger than 5 years
  - Trial data may be available early next year

Recommend Flu Vaccination for Your Patients

Visit https://vaccinefinder.nyc.gov/ for information on where to get COVID-19 and flu vaccinations

Additional COVID-19 Resources

COVID-19 Vaccines

- NYC Health Department - COVID-19 Vaccine:
  - Providers:
    - Vaccine information: nyc.gov/health/covidvaccineprovider
    - Provider hotline to schedule vaccine appointments: **877-VAX-4NYC (877-8229-4692)**; press 2 at second prompt
  - Public: nyc.gov/covidvaccine
- Citywide Immunization Registry Reporting Assistance
  - https://www1.nyc.gov/site/doh/providers/reporting-and-services/cir-how-to-report.page#electronic
- Vaccine Provider Assistance: nycimmunize@health.nyc.gov

General COVID-19 Resources

- Provider page: https://www1.nyc.gov/site/doh/covid/covid-19-providers.page
- Monoclonal antibodies/outpatient therapeutics: https://www1.nyc.gov/site/doh/covid/covid-19-providers-treatments.page
- 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**

CONTINUING MEDICAL EDUCATION

CME Accreditation Statement for Joint Providership

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