COVID-19 HEALTH CARE PROVIDER UPDATE:
COVID-19 VACCINE DISTRIBUTION IN NYC

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Our understanding of COVID-19 is evolving rapidly.
This presentation is based on our knowledge as of January 7, 2021, 5 PM.
CONTINUING MEDICAL EDUCATION

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OUTLINE

NEW DEVELOPMENTS AND GUIDANCE

RECENT EPIDEMIOLOGY OF COVID-19 IN NYC

UPDATES: COVID-19 VACCINES AND DISTRIBUTION

QUESTIONS AND DISCUSSION
Current Status of the COVID-19 Pandemic

- Worldwide: over 87.7 million cases; over 1.8 million deaths
- Disease activity is surging in multiple nations and much of the U.S., forcing new or repeat economic shutdowns
- Rollout of COVID-19 vaccines has begun in several areas, including China, India, U.S. and Europe
- SARS-CoV-2 variants that may be more easily transmitted than other variants have been identified recently
- Cases have increased steadily in New York City since September, although our health care system is not currently strained to the degree it was in spring 2020
Emerging SARS-CoV-2 Variants

• SARS-CoV-2 mutates regularly (~1 mutation every 2 weeks)

• Certain recently identified variants may be more easily transmitted than other variants
  • B.1.1.7, or VOC 2020012/01 – first detected in UK; subsequently detected in multiple parts of the world and several U.S. states, including in a New York State resident who had not traveled
  • B.1.351, or 501Y.V2 – first detected in South Africa, less widespread to date

• Understanding of these variants is limited; current consensus:
  • Do not appear to cause more severe disease or increased risk of death
  • Immunity from previous infection or vaccination expected to be effective
  • Currently available diagnostic tests are expected to detect these variants
  • Some monoclonal antibodies may be less effective against these variants

• A sample of NYC isolates undergoes genetic sequencing to monitor for emerging strains
  • NYC is collaborating with NYS, academic and CDC partners to expand sequencing capacity

• Measures including physical distancing and use of face coverings remain essential to preventing the spread of all variants
NY State Recommendations on Quarantine after Exposure to COVID-19

- December 26, 2020: reduced duration from 14 to 10 days
- Health care personnel (HCP) in hospital and direct care settings no longer permitted to work during quarantine, unless facility has a staffing shortage
- January 1, 2020: specified that HCP may be permitted to return to work early when:
  - Strategies are in place* to mitigate staffing shortages
  - A NYS Department of Health HCP Return to Work Waiver with signed CEO attestation is uploaded documenting (a) implementation of staffing mitigation strategies and (b) staffing shortage that threatens provision of essential patient services
  - Approval for waiver is received from NYS Commissioner of Health
- HCP at nursing homes and adult care facilities may not return to work until 14 days after an exposure

*As outlined in CDC’s Strategies to Mitigate Healthcare Personnel Staffing Shortages 12/14/2020
New York State Health Advisories:
New NYC Health Department Resources

- SARS-CoV-2 testing overview

- Framework for providing outpatient medical care during COVID-19 medical surge
Recent Epidemiology of COVID-19 in NYC

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UPDATES ON COVID-19 VACCINES AND VACCINE DISTRIBUTION IN NYC

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Outline

• COVID-19 Vaccination Distribution in NYC
• Update: Allergic Reactions, Contraindications, Precautions
• Preparing to Provide COVID-19 Vaccines
• Questions
COVID-19 Vaccine Distribution in NYC
First U.S. COVID-19 Vaccines Authorized and Recommended for Emergency Use

- Emergency Use Authorizations issued for Pfizer-BioNTech (12/11/2020) and Moderna (12/18/2020) vaccines
- Overall vaccine efficacy 95% (Pfizer) and 94% (Moderna)
- High efficacy maintained across age, race, and ethnic groups
- No significant safety concerns identified in clinical trials
- Local and systemic reactogenicity, particularly after second dose

https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html
COVID-19 Vaccine Distribution

• Demand is expected to exceed supply during first months of U.S. vaccination program

• Advisory Committee on Immunization Practices (ACIP) provided recommendations on how to prioritize vaccination during limited supply
  • Prioritizes persons at high risk for exposure to or severe illness from COVID-19

• States use these recommendations to make decisions about vaccine distribution in their populations
COVID-19 Vaccine Allocation, NYC, Phase 1a

- High-risk hospital workers (emergency room workers, ICU staff, pulmonary department staff), Federally Qualified Health Center employees, Urgent Care providers
- Residents and staff at nursing homes and other congregate care facilities
- EMS workers
- Coroners, medical examiners and certain funeral workers
- Staff and residents at OPWDD, OMH and OASAS facilities
- Individuals administering COVID-19 vaccines, including local health department staff

As of January 4, 2021:
- Outpatient/ambulatory front-line, high-risk health care workers of any age who provide direct in-person patient care
- Staff who are in direct contact with patients (i.e., intake staff)
- Front-line, high-risk public health workers who have direct contact with patients, including those conducting COVID-19 tests, handling COVID-19 specimens and COVID-19 vaccinations
- Includes, but is not limited to: doctors who work in private medical practices and their staff, doctors who work in hospital-affiliated medical practices and their staff, doctors who work in public health clinics and their staff, Registered Nurses, specialty medical practices of all types, dentists and orthodontists and their staff, psychiatrists and psychologists and their staff, physical therapists and their staff, optometrists and their staff, pharmacists and pharmacy aides, home care workers, hospice workers, staff of nursing homes/skilled nursing facilities who did not receive COVID vaccination through the Pharmacy Partnership for Long-Term Care Program

https://covid19vaccine.health.ny.gov/phased-distribution-vaccine#phase-1a
Anticipated COVID-19 Vaccine Allocation, NYC

• Following vaccinations for the health care sector, New York will move to Phase 1b of distribution, which will include:
  • Teachers and education workers
  • First responders
  • Public safety workers
  • Public transit workers
  • People ≥ aged 75 years

• Anticipated groups after 1b:
  • People aged 65-74, persons with underlying comorbidities, other essential workers
  • Summer 2021: all other people

https://covid19vaccine.health.ny.gov/phased-distribution-vaccine#phase-1a
https://www1.nyc.gov/site/doh/covid/covid-19-vaccines.page
Where to Get Vaccinated

For individuals who are currently eligible to receive vaccination
• Contact your employer if you work at or are affiliated with:
  • Hospital network
  • Urgent care center
  • Federally Qualified Health Center
  • Congregate setting associated with the New York State Offices for People With Developmental Disabilities, Mental Health, or Addiction Services and Supports
• All other eligible groups should check with their employers to see if vaccination plans have already been made
• If your facility/employer does not have plans to offer vaccination, and you are in an eligible group, visit nyc.gov/vaccinelocations for information on where to receive vaccination
COVID-19 Vaccine Campaign: NYC Health Department Role

• Allocate vaccines based on ACIP recommendations and NYS guidance
• Assist with Citywide Immunization Registry registration, completion of COVID-19 vaccine agreement, and vaccine ordering and distribution
• Ensure equitable allocation across NYC residents
• Provide guidance and recommendations to providers and the public
  • Proper vaccine administration, storage and handling, best practices to ensure high uptake
• Administration of vaccine to targeted groups via Points of Distribution – called Vaccine Hubs
COVID-19 Vaccine Tracker
1/8/2021, 12 a.m.

585,850
Doses reserved for NYC

489,325
Doses delivered to NYC

157,905
Received dose 1

10,044
Received dose 2

Data on doses administered are reported by providers to the Citywide Immunization Registry and may be delayed. Data updated daily:
Anticipated COVID-19 Vaccine Availability

- Increased supply will enable broader distribution
- NYC will continue to follow NY State requirements
- As vaccine becomes more widely available, vaccine will likely be distributed by:
  - Federally Qualified Health Centers
  - Independent health care providers
  - Pharmacies
  - Urgent care
  - Hospitals
  - H+H facilities
  - NYC Health Department COVID-19 testing sites
  - Community vaccinators
- NYC Health Department is preparing to operate Vaccine Hubs to reach large numbers of the general public eligible for vaccination as needed
Anaphylaxis, Contraindications, Precautions, and Other Clinical Considerations
Anaphylaxis Following COVID-19 Vaccination

- Anaphylactic reactions after mRNA COVID-19 vaccines have been reported, though uncommon
- 21 reports (11.1 per million doses) detected by the Vaccine Adverse Event Reporting System, Dec 14-23, 2020
- Time from vaccination to onset: median 13 min (range 2-150 min); 71% <15 min
- Age: median 40 years (range 27-60 years)
- Outcomes: 19% hospitalized (3 ICU); 81% treated in EDs; 95% discharged home or recovered at time of VAERS report; no deaths
- Allergy history: 17 (81%) had documented history of allergies or allergic reactions, including to drugs, medical products, food, insect bites; 7 (33%) had past anaphylaxis (including after rabies and flu vaccine)
- No geographic clustering; occurred after doses from multiple vaccine lots
Contraindications to COVID-19 Vaccination

• Contraindications and precautions are updated as experience with the Pfizer and Moderna vaccines increases

• A history of the following is currently considered a contraindication:
  • Severe allergic reaction (e.g., anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine or any of its components
  • Immediate allergic reaction of any severity to a previous dose of an mRNA COVID-19 vaccine or any of its components (including polyethylene glycol [PEG])
  • Immediate allergic reaction of any severity to polysorbate (due to potential cross-reactive hypersensitivity with the vaccine ingredient PEG)

*Unless allergist-immunologist determined they can safely receive vaccine (e.g., under observation, in a setting with advanced medical care)

https://www.cdc.gov/vaccines/covid-19/info-by-product/clnical-considerations.html
Precautions to COVID-19 Vaccination

• A history of any immediate allergic reaction to any other vaccine or injectable therapy (IM, IV, SC) is considered a precaution (not a contraindication)
  • Counsel persons with such a history regarding unknown risk for severe reaction and balance this against benefits of vaccination
  • Consider consultation with an allergist-immunologist

• Allergic reactions not related to vaccines, injectable therapies, components of mRNA COVID-19 vaccines, or polysorbates are not a contraindication or precaution

https://www.cdc.gov/vaccines/covid-19/info-by-product клинические рассмотрения.html
Observation Period After COVID-19 Vaccination

• 30 minutes: Persons with a history of an immediate allergic reaction of any severity to a vaccine or injectable therapy and persons with a history of anaphylaxis due to any cause
• 15 minutes: All other persons

https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html
Preparing to Manage Anaphylaxis after COVID-19 Vaccination

- CDC provides guidance on:
  - Early recognition
  - Medication and supplies for assessing and managing
  - Steps to take if anaphylaxis is suspected
  - Considerations for management in older adults and pregnant people
  - Reporting

https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html
Vaccination of Persons with Underlying Medical Conditions

• Clinical trials demonstrated similar safety and efficacy in persons with certain underlying medical conditions, including those associated with increased risk for severe COVID-19, compared to persons without comorbidities

• Persons with any of the following may receive COVID-19 vaccination (unless they have a contraindication to vaccination):
  • HIV or immunosuppression
    • May be at increased risk for severe COVID-19
    • Persons with stable HIV were included in COVID-19 vaccine clinical trials, though data remain limited
    • Counsel persons with immunosuppression or HIV about the unknown safety profile and effectiveness in immunocompromised populations and potential for reduced immune responses
  • Autoimmune conditions
    • No data are currently available on the safety of mRNA COVID-19 vaccines for this population
  • History of Guillain-Barré syndrome or Bell’s palsy
Pregnant or Lactating People

• May choose to be vaccinated if part of a group recommended to receive a COVID-19 vaccine (e.g., health care personnel)

• Pregnant people are at risk for severe illness due to COVID-19

• Limited or no data on safety and effectiveness of vaccines in pregnant and lactating people; however, based on current knowledge, vaccines unlikely to pose risk to pregnant person, fetus, or breastfed infant

• Consider level of COVID-19 community transmission and risk of COVID-19 to the patient and potential risk to the fetus

• Pregnant persons who receive COVID-19 vaccine should take acetaminophen if they develop a fever after vaccination, as fever during pregnancy can negatively affect a fetus (acetaminophen is safe in pregnancy)

• American College of Obstetricians and Gynecologists (ACOG) recommends COVID-19 vaccines:
  • Should not be withheld from pregnant persons
  • Should be offered to lactating persons

Persons with Prior Infection or Exposure to COVID-19

• People with a history of COVID-19 should be offered vaccination to reduce likelihood of reinfection
  • Since reinfection is uncommon in the 90 days after initial infection, persons with documented acute SARS-CoV-2 infection in the preceding 90 days may delay vaccination until near the end of this period, if desired

• People with acute infection should wait until illness has improved and isolation period has ended (to decrease risk of exposing others to COVID-19)

• Testing asymptomatic persons for evidence of current or past SARS-CoV-2 infection for the purpose of vaccine decision-making is not recommended

• Persons exposed to someone with COVID-19 should defer vaccination until completion quarantine to avoid potentially exposing healthcare personnel and patients to SARS-CoV-2 during the vaccination visit

https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html
Persons who Received Monoclonal Antibodies or Convalescent Plasma

• Persons who received monoclonal antibodies or convalescent plasma for COVID-19 treatment therapies should defer vaccination for at least 90 days
  • Precautionary measure until additional information becomes available to avoid interference of the antibody treatment with vaccine-induced immune responses

https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html
COVID-19 Prevention for Vaccinated Persons

• Protection afforded by vaccine is not optimal until 1-2 weeks after 2nd dose
• No vaccine is 100% effective
• Information is limited on:
  • Vaccine effectiveness in the general population
  • Extent to which vaccination reduces ability to transmit infection
  • Duration of vaccine-related immunity
• Vaccinated persons should continue to:
  • Wear a face covering
  • Stay at least 6 feet away from others whenever possible
  • Avoid crowding
  • Observe quarantine recommendations

Post Vaccine Considerations for Residents of Long-Term Care Facilities

• CDC offers guidance on managing post-vaccination signs and symptoms during the first 3 days after vaccination to avoid:
  • Unnecessary COVID-19 testing and implementation of transmission-based precautions for residents who have only post-vaccination signs and symptoms
  • Inadvertently allowing residents with infectious COVID-19 or another transmissible infectious disease to expose others in the facility

• Guidance could also be applied to patients in other healthcare setting

• CDC page on Post Vaccine Considerations for Residents
Post Vaccine Considerations for Health Care Workers

1. Is employee reporting signs or symptoms that may be related to the vaccine?
   - Yes: Are any of employee’s signs or symptoms not typically related to the vaccine?
     - Yes: Exclude employee from work and evaluate them for COVID-19 or other infections as appropriate.
     - No: Exclude employee from work until they are feeling well and fever-free for at least 24 hours. Consider testing for COVID-19* or the flu.
   - No: Follow usual protocols.

2. Does employee have a fever?
   - Yes: Is employee feeling well enough and willing to work?
     - Yes: Exclude employee from work and reassess the next day; if symptoms persist for >2 days, evaluate employee for COVID-19 or other infections as appropriate.
     - No: Employee can return to work; notify occupational health if their symptoms persist for >2 days.
   - No: Follow usual protocols.

*A nucleic acid amplification (NAA) test is preferred. If an antigen test is used, negative results should be confirmed with an NAA.

Preparing to Provide COVID-19 Vaccines in NYC
Review Background Information

• Review [Preparing to Enroll in the COVID-19 Vaccination Program Guide](https://www.cdc.gov/vaccines/covid-19/downloads/COVID-19-Clinical-Training-and-Resources-for-HCPs.pdf) to understand program requirements and enrollment process

• Review CDC guidance on preparing to administer COVID-19 vaccines:
  • COVID-19 Vaccination Training Programs and Reference Materials for Healthcare Professionals
    [https://www2.cdc.gov/vaccines/ed/covid19/](https://www.cdc.gov/vaccines/ed/covid19/)
  • COVID-19 Vaccine Training Modules
    [https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html](https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html)
  • Vaccination Guidance During a Pandemic
Enroll in the NYC COVID-19 Vaccination Program

• Enrollment is now open for private practices, independent pharmacies and other facilities that will immunize adults in the NYC COVID-19 Vaccination Program

• Facilities choosing to participate must complete the CDC COVID-19 Vaccination Program Provider Agreement (Provider Agreement) in the online Citywide Immunization Registry (CIR)

• Facilities that are not already registered with the CIR or have not reported to the CIR in over a year should register now

• After registering, a CIR facility code is issued which is used to set up a CIR account and enroll in the COVID-19 Vaccination Program upon completing the Provider Agreement
Enroll in the NYC COVID-19 Vaccination Program (continued)

- Only one enrollment form should be submitted per facility
- Facility groups or networks should complete a single Provider Agreement (Section A) AND a Provider Profile (Section B) for each vaccination site
- The Provider Agreement must be signed by the Chief Medical Officer (or equivalent) and Chief Executive Officer (or Chief Fiduciary)
- The Provider Profile for each vaccination site must be signed by a designated COVID-19 Vaccine Coordinator or the Medical/Pharmacy Director
Enroll in the NYC COVID-19 Vaccination Program (continued)

• General providers and facilities should not anticipate being able to order COVID-19 vaccine until spring or summer of 2021

• Once vaccine is available for your sector
  • Can only be ordered via the CIR
  • Will ship directly from the manufacturer or CDC distributor to the vaccine provider

• Nursing homes and adult care facilities in NYC are enrolled in CDC’s Pharmacy Partnership for Long-term Care Program
  • https://www.cdc.gov/vaccines/covid-19/long-term-care/pharmacy-partnerships.html
Prepare to Order, Track and Report Vaccination

• The CIR is the primary database for capturing vaccine data
• Become familiar with using the CIR to report administration of vaccine
  • ALL administered COVID-19 vaccine doses must be reported to the CIR
  • NY State requires reporting within 12 hours of administration (NYS Executive Order 1/4/21*)
• Patient’s written consent not required
  • Authorizations include:
    • NYS Emergency Order 12/13/20**
    • NYC Commissioner Order 12/14/20***
• Ensure race and ethnicity are populated in electronic health records – fields must be submitted to CIR when reporting COVID-19 vaccine doses administered
• CIR may also be used to provide reminders about second doses

Prepare Your Facility or Practice

• Identify refrigerators and freezers to store vaccine
• Assess capacity to monitor vaccine, including continuous temperature monitoring
• Identify and order materials needed for vaccine administration
• Develop plans to safely vaccinate staff and patients by reducing crowding and following physical distancing recommendations
• Develop triage systems to screen patients for symptoms of COVID-19 in advance of vaccine administration
Prepare to Offer Vaccines to Staff

• Develop a plan to vaccinate staff
  • Consider staggered vaccination, especially of the second dose, after which systemic symptoms such as fever are more common
  • Consider vaccinating staff 1-2 days before scheduled time off

• Prepare staff and build confidence in COVID-19 vaccination
  • Provide education on the importance and safety of COVID-19 vaccination
  • Give staff tools they can use to educate patients and answer questions about COVID-19 vaccines
  • Use or adapt CDCs ready-made materials: https://www.cdc.gov/vaccines/covid-19/health-systems-communication-toolkit.html
Prepare to Offer Vaccines to Patients

• Identify and estimate the number of your patients you may vaccinate in each vaccine allocation phase
  • Start with patients 75 years of age and older

• Educate patients on the importance of getting vaccinated
  • As the most trusted source of information on vaccines, providers play a critical role in helping patients understand the importance of COVID-19 vaccination and in addressing hesitancy
  • Let patients know if and when COVID-19 vaccine is likely to be recommended for them
  • Use CDC materials, including proven communication strategies and tips, to effectively set expectations and address questions [https://www.cdc.gov/vaccines/covid-19/hcp/index.html](https://www.cdc.gov/vaccines/covid-19/hcp/index.html)
Report Adverse Events

• Adverse events that occur in a recipient following COVID-19 vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS)

• Vaccination providers are required by the FDA to report the following that occur after COVID-19 vaccination under EUA:
  • Vaccine administration errors
  • Serious adverse events
  • Cases of Multisystem Inflammatory Syndrome
  • Cases of COVID-19 that result in hospitalization or death

• Reporting is also encouraged for any other clinically significant adverse event, even if it is uncertain whether the vaccine caused the event

• Information on how to submit a report to VAERS is available at https://vaers.hhs.gov or by calling 1-800-822-7967
Learn About V-Safe

- CDC’s new smartphone-based, after-vaccination health checker for people who receive COVID-19 vaccines
- Health checks via text messages and email
  - Daily for the first week after vaccination
  - Weekly thereafter for 6 weeks post-vaccination
  - Active telephone follow-up with person who report clinically important events*
- All COVID-19 vaccine recipients eligible
- Health care providers should encourage patient participation

*Symptoms or health conditions that cause one to miss work, do normal daily activities, or seek health care
Review Vaccine Administration Fact Sheets

• Review vaccine-specific provider fact sheet
  • Pfizer-BioNTech: https://www.fda.gov/media/144413/download
  • Moderna: https://www.fda.gov/media/144637/download

• Consent for adult vaccination is not required, but patients must be provided with a vaccine-specific fact sheet

• Prepare to distribute the patient fact sheet to vaccinated patients or their caregivers (available in multiple languages)
  • Pfizer-BioNTech: https://www.fda.gov/media/144414/download
  • Moderna: https://www.fda.gov/media/144638/download

• CDC guidance on what to expect during the vaccination visit and after getting vaccinated
Prepare to Counsel Patients

• Start from a place of empathy and understanding
• Assume patients will want to be vaccinated but may not know when to expect it
• Give your strong recommendation
  • A provider recommendation is one of the strongest predictors of vaccine receipt
• Listen to and respond to patient questions in an understandable way
  • Resources: CDC, CHOP, NYC Health Department website and materials
• Wrapping up the conversation
  • After answering questions, let patients know you are open to continuing discussion
  • Encourage patients to schedule another appointment or read about vaccine
  • Continue to remind them about the importance of vaccine in future visits

CDC. Making a strong recommendation for vaccine
Children’s Hospital of Philadelphia, Vaccine Education Center. Evidence to Action Brief: Addressing Vaccine Hesitancy to Protect Children and Communities against Preventable Diseases.
Additional Resources

COVID-19 Vaccines

- NYC Health Department - COVID-19 Vaccine:
  - Public: nyc.gov/covidvaccine
  - Providers: nyc.gov/health/covidvaccineprovider

- Citywide Immunization Registry Reporting Assistance
  - https://www1.nyc.gov/site/doh/providers/reporting-and-services/cir-how-to-report.page#electronic

- Vaccine Provider Assistance:
  - Email nycimmunize@health.nyc.gov

General COVID-19 Resources

- Provider page: https://www1.nyc.gov/site/doh/covid/covid-19-providers.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

Next NYC Health Department provider webinar

- Friday, January 22, 1 p.m. (sign up on provider page)