Our understanding of COVID-19 is evolving rapidly. This presentation is based on our knowledge as of December 17, 2020, 5 PM.
CME Accreditation Statement for Joint Providership
NYC Health + Hospitals is accredited by The Medical Society of the State of New York (MSSNY) to provide continuing medical education for physicians. This activity has been planned and implemented in accordance with the Accreditation Requirements and Policies of the MSSNY through the joint providership of NYC Health + Hospitals and the NYC Department of Health and Mental Hygiene. NYC Health + Hospitals designates this continuing medical education activity for a maximum of 1 *AMA PRA Category 1 Credit™*. Physicians should claim only credit commensurate with the extent of their participation in the activity.
OUTLINE

WHERE WE ARE NOW

NEW GUIDANCE

RECENT EPIDEMIOLOGY OF COVID-19 IN NYC

VACCINE UPDATES AND STRATEGIES FOR NYC

QUESTIONS AND DISCUSSION
Mary Foote, MD, MPH
Health Systems Planning and Strategies Lead, COVID-19 Response
NYC Department of Health and Mental Hygiene
HAN #39
PROPER USE AND
INTERPRETATION
OF SARS-COV-2
ANTIGEN TESTS

• Consider pretest probability before using SARS-CoV-2 antigen tests and when interpreting results, especially in the context of increasing community transmission

• Conduct confirmatory testing when someone who:
  • Has symptoms, tests negative
  • Has no symptoms, and no known exposure in the past 14 days, tests positive

• Confirmatory testing should be done using a nucleic acid amplification (NAA)-based test performed at a clinical laboratory on a specimen collected within 48 hours of the initial specimen
  • Individuals should isolate while awaiting confirmatory test results
The NYC Commissioner of Health issued an advisory for:

- Older adults (in particular, aged 65 and older)
- People with underlying health conditions that put them at increased risk of severe COVID-19
- Household members and caregivers of these individuals

Advises that these groups take increased precautions as COVID-19 increases in NYC:

- Avoid public spaces and gatherings and wear a face covering at all times outside the home, indoors and outdoors
- Do not leave home, except for work, school or essential activities, including COVID-19 testing and other medical care, or to go to the grocery store or pharmacy
- If you feel sick do not leave your home, except for COVID-19 testing or other essential medical care

CDC OPTIONS TO REDUCE QUARANTINE

- CDC Options to Reduce Quarantine
  - On December 2, the CDC released a scientific brief outlining options to shortening the period of quarantine

- Quarantine Period in NYC Remains 14 days
  - The quarantine period in NYC and NYS remains 14-days
  - The NYC Health Department will issue guidance if the current quarantine period is modified
FDA AUTHORIZES FIRST OVER-THE-COUNTER AT HOME COVID-19 DIAGNOSTIC TEST

• Antigen-based test approved for use in symptomatic and asymptomatic individuals ≥ 2 years using nasal swab
• Bluetooth connected analyzer and a smartphone app used to perform the test with results within 20 minutes
• Requires zip code and date of birth, with optional fields for name and email address; app reports results to public health authorities
• In asymptomatic individuals, correctly identified 91% of those who were infected and 96% of those who were not infected
• In symptomatic individuals, correctly identified 96% of those who were infected and 100% of those who were not infected
• Costs approximately $30


https://www.ellumehealth.com
EPIDEMIOLOGY OF COVID-19 IN NYC

Corinne Thompson, PhD
Co-Lead, Epi Data Unit, COVID-19 Response
NYC Department of Health and Mental Hygiene
DOHMH COVID-19 VACCINATION PROGRAM

Bindy Crouch, MD, MPH
Clinical Planning and Operations
Vaccine Section
NYC Department of Health and Mental Hygiene
I. Covid-19 Vaccine Overview and Planning
   • Vaccine Timelines
   • Availability and Prioritization
   • Participating in the NYC COVID-19 Vaccination Program

II. Pfizer-BioNTech COVID-19 Vaccine
   • Results of Phase 2/3 Studies
   • Clinical Recommendations
COVID-19 VACCINATION OVERVIEW AND PLANNING
COVID-19 VACCINE DEVELOPMENT AND APPROVAL PROCESS

- Vaccine discovery and development by manufacturers
- Clinical trial Phases I, II, III by manufacturer to assess safety and efficacy
- Manufacturer submits Emergency Use Authorization (EUA) request
- Advisory Committee for FDA votes whether to recommend EUA
- FDA decides whether to issue EUA
- ACIP reviews data and votes to recommend vaccine and appropriate use
- Vaccine shipped for use in phases and post vaccine monitoring

https://www.fda.gov/media/143890/download
### COVID-19 Vaccine Summary

Six vaccine manufacturers received funding from the federal program “Operation Warp Speed” to produce a COVID-19 vaccine.

<table>
<thead>
<tr>
<th>Company</th>
<th>Mechanism</th>
<th>Efficacy</th>
<th>Storage</th>
<th>Doses</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer-BioNTech</td>
<td>mRNA</td>
<td>95%</td>
<td>-70° C</td>
<td>2</td>
<td>Received EUA* and in use</td>
</tr>
<tr>
<td>Moderna</td>
<td>mRNA</td>
<td>94%</td>
<td>-20° C</td>
<td>2</td>
<td>Applied for EUA*</td>
</tr>
<tr>
<td>AstraZeneca</td>
<td>DNA</td>
<td>70%</td>
<td>2-8° C</td>
<td>2</td>
<td>Phase III trial</td>
</tr>
<tr>
<td>Janssen</td>
<td>DNA</td>
<td>Unk</td>
<td>-20° C</td>
<td>1</td>
<td>Phase III trial</td>
</tr>
<tr>
<td>Novavax</td>
<td>Protein subunit</td>
<td>Unk</td>
<td>2-8° C</td>
<td>2</td>
<td>Phase III trial</td>
</tr>
<tr>
<td>Sanofi; GlaxoSmithKline</td>
<td>Protein subunit</td>
<td>Unk</td>
<td>2-8° C</td>
<td>2</td>
<td>Phase II/III trial</td>
</tr>
</tbody>
</table>

*Emergency Use Authorization
COVID-19 VACCINE TIMELINES

PFIZER-BIONTECH & MODERNA

Pfizer-BioNTech COVID-19 Vaccine
• Pfizer application for Emergency Use Authorization (EUA) submitted 11/20/2020
• FDA issued EUA on 12/11/2020
• ACIP recommended use for individuals ages 16 and older on 12/12/2020

Moderna COVID-19 Vaccine
• Moderna EUA application submitted 11/30/2020
• Vaccines and Related Biological Products Advisory Committee (VRBPAC) recommended FDA authorize the use of the Moderna COVID-19 vaccine
• ACIP meeting planned for 12/19/2020

Expecting to have licensed products sometime in 2021
Given limited supply of vaccine at this time, vaccine will be allocated in three Phases and subphases based on recommendations from ACIP:

- Phase Ia, Ib, Ic: Limited availability for highest priority groups
- Phase II: Greater availability for general public
- Phase III: Shift to routine vaccination
COVID-19 VACCINE AVAILABILITY

PHASE I

• Limited supply for the country
• Vaccine available under an FDA EUA and not yet a licensed product
• Vaccine to be offered at a limited number of sites that can reach the target populations
  • Hospitals
  • Large medical facilities
  • DOHMH-supported and DOHMH-run PODS for other high-risk healthcare personnel
COVID-19 VACCINE AVAILABILITY

PHASE II

- Greater availability to general public
- NYC Health Department would oversee vaccine distribution
- Broad distribution and availability
- Will expand on existing vaccination infrastructure:
  - Federally Qualified Health Centers
  - Independent health care providers
  - Pharmacies
  - Urgent care
  - Hospitals
  - H+H facilities
  - NYC Health Department COVID-19 testing sites
  - Community vaccinators
- DOHMH-run Points of Distribution (PODs) for the general public that fall into priority groups
COVID-19 VACCINE ALLOCATION

• ACIP principles include:
  • Reduce health impact of COVID-19
  • Reduce transmission
  • Vaccine safety and effectiveness
  • Equitable allocation and availability

• National Vaccine Allocation Framework*
  • Groups proposed for initial doses of vaccine include high risk health workers and first responders with high risk of exposure
  • Equity is a crosscutting consideration

ACIP Interim Recommendation – Phase 1a:

• Vaccination should be offered to:
  1) Health care personnel (HCP) and
  2) Staff and residents of long-term care facilities

• These considerations will be updated as additional information becomes available

Available at: https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19/clinical-considerations.html
CDC definition of health care personnel: https://www.cdc.gov/infectioncontrol/guidelines/healthcare-personnel/appendix/terminology.html
ACIP recommendations for Phases 1b and 1c expected on 12/20/2020

- Additional target populations likely to include:
  - Persons with increased risk of exposure to COVID-19
    - Essential workers
  - Persons with increased risk of COVID-19 complications
    - Adults aged ≥65 years
    - Persons with high-risk medical conditions

NYC COVID-19 VACCINATION PROGRAM

• Stepwise approach to facility enrollment to reach priority populations
  • 55 acute care hospitals and specialty hospitals have enrolled
  • FQHC enrollment almost complete
  • Enrollment for remaining NYC vaccination providers opened 12/7

• Almost all nursing homes and adult care facilities in NYC are enrolled in CDC’s Pharmacy Partnership for Long-term Care Program
• Medical facility networks and individual facilities are required to sign a federal provider agreement
  • Provider agreement must be completed and signed in the Citywide Immunization Registry (CIR)

• Once vaccine is available for your sector
  • Vaccine will be ordered via the CIR
  • Vaccine will ship directly from the manufacturer or CDC distributor to the vaccine provider
• Required reporting of ALL administered COVID-19 vaccines doses to CIR within 24 hours of administration

• Patient consent not required

• Authorizations include:
  • NYS Emergency Order 12/13*
  • NYC Commissioner Order 12/14**

• CIR Reporting Assistance
  • https://www1.nyc.gov/site/doh/providers/reporting-and-services/cir-how-to-report.page#electronic
  • BOI Hotline: 347-396-2400

• Ensure race and ethnicity are populated in electronic health records – fields must be submitted to CIR when reporting COVID-19 vaccine doses administered

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Adverse events that occur in a recipient following COVID-19 vaccination should be reported to 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 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](https://vaers.hhs.gov) or by calling 1-800-822-7967.
VACCINE MONITORING

- Vaccination coverage dashboards to track uptake and inform vaccination program decisions
- Monitor vaccination rates alongside COVID-19 positivity rates
- Monitor vaccine safety trends
- Ensure equitable distribution following utilization of racial equity and public health ethics tools and frameworks
- Post-incident response, learning, and improvement
PFIZER-BIONTECH COVID-19 VACCINE
PFIZER-BIONTECH COVID-19 VACCINE

ACIP RECOMMENDATIONS FOR USE

• December 12, 2020*
• ACIP recommended, as interim guidance, the use of the Pfizer-BioNTech COVID-19 vaccine for persons 16 years of age and older for the prevention of COVID-19

PFIZER-BIONTECH COVID-19 VACCINE DEMOGRAPHICS – PHASE 2/3 STUDIES
### Demographic Characteristics

**Phase 2/3 (N=43,448)**

<table>
<thead>
<tr>
<th>BNT162b2 (30 µg)</th>
<th>Placebo</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>N=21,720 n (%)</td>
<td>N=21,728 N (%)</td>
<td>N=43,448 n (%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Sex</strong></th>
<th>BNT162b2</th>
<th>Placebo</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>11,183 (51.5)</td>
<td>10,942 (50.4)</td>
<td>22,125 (50.9)</td>
</tr>
<tr>
<td>Female</td>
<td>10,537 (48.5)</td>
<td>10,786 (49.6)</td>
<td>21,323 (49.1)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Race</strong></th>
<th>BNT162b2</th>
<th>Placebo</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>White</td>
<td>17,839 (82.1)</td>
<td>17,857 (82.2)</td>
<td>35,696 (82.2)</td>
</tr>
<tr>
<td>Black or African American</td>
<td>2,091 (9.6)</td>
<td>2,107 (9.7)</td>
<td>4,198 (9.7)</td>
</tr>
<tr>
<td>All others</td>
<td>1,790 (8.2)</td>
<td>1,764 (8.1)</td>
<td>3,554 (8.2)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Ethnicity</strong></th>
<th>BNT162b2</th>
<th>Placebo</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hispanic/Latino</td>
<td>5,672 (26.1)</td>
<td>5,668 (26.1)</td>
<td>11,340 (26.1)</td>
</tr>
<tr>
<td>Non-Hispanic/non-Latino</td>
<td>15,928 (73.3)</td>
<td>15,940 (73.4)</td>
<td>31,868 (73.3)</td>
</tr>
<tr>
<td>Not reported</td>
<td>120 (0.6)</td>
<td>120 (0.6)</td>
<td>240 (0.6)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Age</strong></th>
<th>BNT162b2</th>
<th>Placebo</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>16-55 Years</td>
<td>12,780 (58.8)</td>
<td>12,822 (59.0)</td>
<td>25,602 (58.9)</td>
</tr>
<tr>
<td>&gt;65 Years</td>
<td>8,940 (41.2)</td>
<td>8,906 (41.0)</td>
<td>17,846 (41.1)</td>
</tr>
<tr>
<td>16-64 Years</td>
<td>17,176 (79.1)</td>
<td>17,190 (79.1)</td>
<td>34,366 (79.1)</td>
</tr>
<tr>
<td>65-74 Years</td>
<td>3,620 (16.7)</td>
<td>3,646 (16.8)</td>
<td>7,266 (16.7)</td>
</tr>
<tr>
<td>≥75 Years</td>
<td>924 (4.3)</td>
<td>892 (4.1)</td>
<td>1,816 (4.2)</td>
</tr>
</tbody>
</table>

PFIZER-BIONTECH COVID-19 VACCINE EFFICACY – PHASE 2/3
## Phase 2/3 Studies: Pfizer-Biontech COVID-19 Vaccine

### First COVID-19 Occurrence From 7 Days After Dose 2

**Phase 2/3 Efficacy – Final Analysis**

Subjects WITHOUT Evidence of Infection Prior to 7 days after Dose 2

<table>
<thead>
<tr>
<th>Efficacy Endpoint</th>
<th>BNT162b2 (30 µg) N=18,198</th>
<th>Placebo N=18,325</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Surveillance Time (n)</td>
<td>Surveillance Time (n)</td>
</tr>
<tr>
<td><strong>First COVID-19 occurrence ≥7 days after Dose 2</strong></td>
<td>8 2.214 (17,411)</td>
<td>162 2.222 (17,511)</td>
</tr>
</tbody>
</table>

Total surveillance time: 1000 person-years for all subjects within each group at risk for the endpoint.

Pr=Posterior probability

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**PHASE 2/3 STUDIES: PFIZER-BIONTECH COVID-19 VACCINE**

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**First COVID-19 Occurrence From 7 Days After Dose 2**

**Phase 2/3 Efficacy – Final Analysis: Subgroups**

<table>
<thead>
<tr>
<th>Subjects WITHOUT Evidence of Infection Prior to 7 days after Dose 2</th>
<th>BNT162b2 N=18,198</th>
<th>Placebo N=18,325</th>
<th>VE (%)</th>
<th>(95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>8</td>
<td>162</td>
<td>95.0</td>
<td>(90.0, 97.9)</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18-64 years</td>
<td>7</td>
<td>143</td>
<td>95.1</td>
<td>(89.6, 98.1)</td>
</tr>
<tr>
<td>65-74 years</td>
<td>1</td>
<td>14</td>
<td>92.9</td>
<td>(53.1, 99.8)</td>
</tr>
<tr>
<td>≥75 years</td>
<td>0</td>
<td>5</td>
<td>100.0</td>
<td>(-13.1, 100.0)</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>3</td>
<td>81</td>
<td>96.4</td>
<td>(88.9, 99.3)</td>
</tr>
<tr>
<td>Female</td>
<td>5</td>
<td>81</td>
<td>93.7</td>
<td>(84.7, 98.0)</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>7</td>
<td>146</td>
<td>95.2</td>
<td>(89.8, 98.1)</td>
</tr>
<tr>
<td>Black or African American</td>
<td>0</td>
<td>7</td>
<td>100.0</td>
<td>(31.2, 100.0)</td>
</tr>
<tr>
<td>All Others</td>
<td>1</td>
<td>9</td>
<td>89.3</td>
<td>(22.6, 99.8)</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hispanic/Latino</td>
<td>3</td>
<td>53</td>
<td>94.4</td>
<td>(82.7, 98.9)</td>
</tr>
<tr>
<td>Non-Hispanic/Non-Latino</td>
<td>5</td>
<td>109</td>
<td>95.4</td>
<td>(88.9, 98.5)</td>
</tr>
<tr>
<td>Country</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Argentina</td>
<td>1</td>
<td>35</td>
<td>97.2</td>
<td>(83.3, 99.9)</td>
</tr>
<tr>
<td>Brazil</td>
<td>1</td>
<td>8</td>
<td>87.7</td>
<td>(8.1, 99.7)</td>
</tr>
<tr>
<td>USA</td>
<td>6</td>
<td>119</td>
<td>94.9</td>
<td>(88.6, 98.2)</td>
</tr>
</tbody>
</table>

### First COVID-19 Occurrence From 7 Days After Dose 2 by Comorbidity Status – Evaluable Efficacy (7 Days) Population

#### Subjects WITHOUT Evidence of Infection Prior to 7 days after Dose 2

<table>
<thead>
<tr>
<th>Comorbidity</th>
<th>BNT162b2 (30 μg)</th>
<th>Placebo</th>
<th>VE (%) (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>8 (2.214 (17,411)</td>
<td>162 (2.222 (17,511))</td>
<td>95.0 (90.0, 97.9)</td>
</tr>
<tr>
<td>No comorbidity</td>
<td>4 76</td>
<td></td>
<td>94.7 (85.9, 98.6)</td>
</tr>
<tr>
<td>Any comorbidity</td>
<td>4 86</td>
<td></td>
<td>95.3 (87.7, 98.8)</td>
</tr>
<tr>
<td>Any malignancy</td>
<td>1 4</td>
<td></td>
<td>75.7 (-145.8, 99.5)</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>0 5</td>
<td></td>
<td>100.0 (-0.8, 100.0)</td>
</tr>
<tr>
<td>Chronic pulmonary disease</td>
<td>1 14</td>
<td></td>
<td>93.0 (54.1, 99.8)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>1 19</td>
<td></td>
<td>94.7 (66.8, 99.9)</td>
</tr>
<tr>
<td>Obese (≥30.0 kg/m²)</td>
<td>3 67</td>
<td></td>
<td>95.4 (86.0, 99.1)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>2 44</td>
<td></td>
<td>95.4 (82.6, 99.5)</td>
</tr>
<tr>
<td>Diabetes (including gestational diabetes)</td>
<td>1 20</td>
<td></td>
<td>95.0 (68.7, 99.9)</td>
</tr>
</tbody>
</table>

Gruber, William. BNT162b2 Vaccine Candidate Against COVID-19. Available at:  
BNT162b2 Protects Against Severe Disease
Phase 2/3 Efficacy – Final Analysis (CDC definition)

Severe Disease Severe illness - CDC definition: hospitalization, admission to the ICU, intubation or mechanical ventilation, or death

<table>
<thead>
<tr>
<th>Efficacy Endpoint</th>
<th>BNT162b2 (30 µg) N=18,198</th>
<th>Placebo N=18,325</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Severe COVID-19 occurrence &gt;7 days after Dose 2</td>
<td>0 2.215 (17,399)</td>
<td>5 2.229 (17,495)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Efficacy Endpoint</th>
<th>BNT162b2 (30 µg) N=21,669</th>
<th>Placebo N=21,686</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Severe COVID-19 occurrence after Dose 1</td>
<td>1 4.018 (21,299)</td>
<td>14 4.001 (21,238)</td>
</tr>
</tbody>
</table>

PFIZER-BIONTECH COVID-19 VACCINE SAFETY – PHASE 2/3
PHASE 2/3 STUDIES: PFIZER-BIONTECH COVID-19 VACCINE

PHASE 2/3 STUDIES: PFIZER-BIONTECH COVID-19 VACCINE

CLINICAL RECOMMENDATIONS
PFIZER-BIONTECH COVID-19 VACCINE

ADMINISTRATION AND INTERVALS

- Intramuscular administration
- 1 dose = 0.3mL
- 2-dose series administered 3 weeks apart
- 4-day grace period (i.e., day 17-21 is valid)
- If > 21 days since 1st dose, administer 2nd dose at earliest opportunity (do not repeat 1st dose)
- Both doses necessary for protection

Cohn A, Mbaeyi S. What Clinicians Need to Know About the Pfizer-BioNTech COVID-19 Vaccine. Available at: https://www.cdc.gov/vaccines/covid-19/downloads/pfizer-biontech-vaccine-what-Clinicians-need-to-know.pdf
• Do not co-administer with other vaccines
• Minimum 14 days before or after administration with any other vaccines
• If inadvertently administered within 14 days of another vaccine, do not repeat doses of either vaccine
  • The second dose of the Pfizer/BioNTech vaccine (if not already given) should still be administered 21 days after the first dose
• Offer vaccination regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection
• Viral testing for acute infection not recommended for vaccine decision-making
• Serologic testing for prior infection not recommended for vaccine decision-making
• Defer vaccination until recovery from acute illness (if person was symptomatic) and criteria for discontinuation of isolation met
<table>
<thead>
<tr>
<th>PFIZER-BIONTECH COVID-19 VACCINE</th>
<th>KNOWN SARS-COV-2 EXPOSURE</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Community/outpatient:</td>
<td>• Defer vaccination until end of quarantine period to avoid possible exposures</td>
</tr>
<tr>
<td>• Congregate healthcare settings</td>
<td>• May be vaccinated (as it likely would not lead to additional/new exposures)</td>
</tr>
<tr>
<td>• Other congregate settings</td>
<td>• May be vaccinated to avoid delays and missed opportunities to vaccinate</td>
</tr>
<tr>
<td></td>
<td>• Take precautions to limit exposure to other residents or non-essential staff</td>
</tr>
</tbody>
</table>

PFIZER-BIONTECH COVID-19 VACCINE

IMMUNO-COMPROMISED PERSONS

- Individuals may be at increased risk for severe COVID-19
- No data to establish safety or efficacy
- May be vaccinated unless otherwise contraindicated
- Counseling:
  - Unknown safety/efficacy
  - Potential for reduced immune response
  - Continue to follow all guidance to protect against COVID-19

Cohn A, Mbaeyi S. What Clinicians Need to Know About the Pfizer-BioNTech COVID-19 Vaccine. Available at: https://www.cdc.gov/vaccines/covid-19/downloads/pfizer-biontech-vaccine-what-Clinicians-need-to-know.pdf
PFIZER-BIONTECH COVID-19 VACCINE

PREGNANT PERSONS

- No data on safety
- mRNA vaccines and pregnancy
  - Not live vaccines
  - Degraded quickly by normal cellular processes and do not enter nucleus of cell
- COVID-19 and pregnancy
  - Increased risk of severe illness
  - May be increased risk of adverse pregnancy outcomes (e.g., preterm birth)
- If a person is a part of a group (e.g., HCP) recommended to receive a COVID-19 vaccine and is pregnant, the individual may choose to be vaccinated
  - Encourage informed decision making in consultation with HC provider

Cohn A, Mbaeyi S. What Clinicians Need to Know About the Pfizer-BioNTech COVID-19 Vaccine. Available at: https://www.cdc.gov/vaccines/covid-19/downloads/pfizer-biontech-vaccine-what-Clinicians-need-to-know.pdf
No data on safety in lactating persons or the effects of mRNA vaccines on breastfed infant or mild production/excretion

mRNA vaccines not considered live virus vaccines – not thought to be a risk to the breastfeeding infant

If a lactating person is part of a group (e.g., HCP) recommended to receive a COVID-19 vaccine, they may choose to be vaccinated

Cohn A, Mbaeyi S. What Clinicians Need to Know About the Pfizer-BioNTech COVID-19 Vaccine. Available at: https://www.cdc.gov/vaccines/covid-19/downloads/pfizer-biontech-vaccine-what-Clinicians-need-to-know.pdf
Before vaccination, counsel recipients about expected local and systemic post-vaccination symptoms:
- Include fever, fatigue, headache, chills, myalgia, and arthralgia

Unless individual develops a contraindication to vaccine, encourage them to complete the series.

Antipyretic or analgesic medication may be taken for treatment of symptoms following vaccination.
PFIZER-BIONTECH COVID-19 VACCINE

PREVENTION OF COVID-19 POST-VACCINATION

- Protection is not immediate
- Takes 1-2 weeks following Dose #2 to be considered fully vaccinated
- No vaccine is 100% effective
- Continue to follow all guidance to protect themselves and others, including:
  - Stay home if sick
  - Keep physical distance
  - Wash hands frequently
  - Wear a face covering

Cohn A, Mbaeyi S. What Clinicians Need to Know About the Pfizer-BioNTech COVID-19 Vaccine. Available at: https://www.cdc.gov/vaccines/covid-19/downloads/pfizer-biontech-vaccine-what-Clinicians-need-to-know.pdf
PFIZER-BIONTECH
COVID-19 VACCINE
CONTRAINDICATIONS

• Severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine is a contraindication to vaccination

• Ensure appropriate medical treatment for managing immediate allergic reactions is immediately available

Cohn A, Mbaeyi S. What Clinicians Need to Know About the Pfizer-BioNTech COVID-19 Vaccine. Available at: https://www.cdc.gov/vaccines/covid-19/downloads/pfizer-biontech-vaccine-what-Clinicians-need-to-know.pdf
PFIZER-BIONTECH COVID-19 VACCINE

PRECAUTIONS

- Reports of anaphylactic reactions in persons vaccinated outside of clinical trials have occurred
- A severe allergic reaction to any vaccine or injectable therapy (IM, IV, SC) is a precaution to vaccination at this time
  - Seasonal allergies and allergies to foods, oral medications, and pets not included as precaution
  - Family history of anaphylaxis is not included as a precaution
- Observe patients following vaccination
  - Persons with history of anaphylaxis – observe 30 minutes
  - All other persons – observe 15 minutes

Cohn A, Mbaeyi S. What Clinicians Need to Know About the Pfizer-BioNTech COVID-19 Vaccine. Available at: https://www.cdc.gov/vaccines/covid-19/downloads/pfizer-biontech-vaccine-what-Clinicians-need-to-know.pdf
KEY MATERIALS
COVID-19: Vaccine Information for Providers

Recent News and Recommendations
The COVID-19 vaccine developed by Pfizer-BioNTech has received an Emergency Use Authorization from the FDA for people 16 years and older. A vaccine from Moderna may receive similar authorization after a December 17 FDA advisory committee meeting. Both of the vaccines are mRNA vaccines.

- MMWR: The Advisory Committee on Immunization Practices’ Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine (December 13)
- CDC: Interim Clinical Considerations for Use of Pfizer-BioNTech COVID-19 Vaccine
- CDC: Pfizer-BioNTech COVID-19 Vaccine

Webinars
Upcoming
- Tuesday, December 15, at 1 p.m.: NYC Health Department: Enrollment in the NYC COVID-19 Vaccination Program
- Thursday, December 17, at 3 p.m.: ASCO/IDSA Webinar: The COVID-19 Vaccine & Patients with Cancer
- Friday, December 18, at 1 p.m.: NYC Health Department: Updates on the Epidemiology of COVID-19 in NYC; Updates on COVID-19 Vaccination and the NYC Campaign

Recent
- CDC: COVID-19 Vaccination Implementation and the “Vaccinate with Confidence Strategy” (December 3)

For general information about the vaccine, including updates on development, approvals and distribution, see our main COVID-19 Vaccines page.

All COVID-19 vaccinations must be reported through the CIR within 24 hours of administration.

Required Factsheets
Health care providers administering the vaccine must review the following health care provider factsheet and distribute the patient fact sheet to patients receiving the vaccine or their caregivers.

- Fact Sheet for Health Care Providers Administering Vaccine (PDF, December)
- Fact Sheet for Recipients and Caregivers (PDF, December)

Nursing Homes and Assisted Living Facilities
The CDC is partnering with pharmacies to provide on-site vaccination services for residents of nursing homes and assisted living facilities.

- CDC: Pharmacy Partnership for Long-Term Care Program for COVID-19 Vaccination

Additional Resources

- Patient Communication
- Safety and Side Effects
- Costs and Reimbursements
- Training

- FDA: COVID-19 Vaccines
- FDA: Pfizer-BioNTech Vaccine Information
- New York State Department of Health: Vaccine Information for Providers
- New York State COVID-19 Vaccination Program (PDF, October)

nyc.gov/health/covidvaccineprovider
COVID-19 (Coronavirus Disease)

COVID-19 Vaccination

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For Medical Centers, Clinics, and Clinicians

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Getting Vaccinated

How CDC is Making COVID-19 Vaccine

Benefits of Getting a COVID-19 Vaccine

Preparing Your Patients

Answering Patient Questions about COVID-19 Vaccination

Potential Exposure at Work

COVID-19 Vaccination

COVID-19 Vaccine Resources for Providers

What Clinicians Need to Know About the Pfizer-BioNTech COVID-19 Vaccine

Amanda Cohn, MD
Sarah Mbaeyi, MD, MPH

December 13, 2020


https://www.cdc.gove/vaccines/covid-19/health-systems-communication-toolkit.html

VACCINE PROVIDER ASSISTANCE

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

• Vaccine Provider Assistance:
  • Email
    • nycimmunize@health.nyc.gov
  • Bureau of Immunization Hotline:
    • 347-396-2400
A New York Executive Order No. 202.82 issued earlier this week waives the requirement for a patient-specific physician order to administering vaccine.

The CDC created a non-patient-specific standing order template for the administration of the Pfizer-BioNTech COVID-19 vaccine.
HOLIDAY GUIDANCE: BE FESTIVE, STAY SAFE!

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

Available in multiple languages at nyc.gov/health/safeholidays

Discourages gatherings and traveling (except for household gatherings) but provides tips on how to do so safely

Provides idea for safe holiday activities

TRAVELING DURING COVID-19: DON’T DO IT

- Available in multiple languages at nyc.gov/health/covidtravel
- Discourages traveling
- Provides a summary of NYS travel quarantine requirements

RETRIEVING CME CREDITS

- Log onto the CPE website - [http://cme.nychhc.org](http://cme.nychhc.org)
- Look for the login section (on the right side)
- Create a profile if you have not logged in before
- Enter your username (email address) and password. Click on the Go button.
- The Welcome Screen will appear. Click on the Go button.
- The next screen will display three tabs. “My Programs”, “CPE Tracker” and “My Account Info.”
- Click the tab “CPE Tracker”
- On the same row look to your right. Locate the ‘Select Year’ section. Click on the down arrow and select the year to view. Certificates will be listed by program name.
- View credits or print certificates by clicking on the certificate located under the view/print column.
- Note: It may take up to 8 weeks for H+H to process credits
NYC Health Department
- Provider page: [https://www1.nyc.gov/site/doh/covid/covid-19-providers.page](https://www1.nyc.gov/site/doh/covid/covid-19-providers.page)
- Provider COVID-19 Vaccine page: [nyc.gov/health/covidvaccineprovider](nyc.gov/health/covidvaccineprovider)
- Next provider webinar: Friday, January 15, 1 p.m. (sign up on provider page)
- Dear Colleague COVID-19 newsletters (sign up for City Health Information subscription at: [nyc.gov/health/register](nyc.gov/health/register))
- NYC Health Alert Network (sign up at [https://www1.nyc.gov/site/doh/providers/resources/health-alert-network.page](https://www1.nyc.gov/site/doh/providers/resources/health-alert-network.page))
- Provider Access Line: 866-692-3641

NYC COVID-19 Citywide Information Portal
- Includes information on >150 testing sites in NYC: [NYC.gov/covidtest](NYC.gov/covidtest)

Learn more below about zone restrictions

Other sources