Information on COVID-19 vaccines is evolving rapidly. This presentation was last updated February 22, 2021.
OUTLINE

- COVID-19 VACCINE DEVELOPMENT
- CLINICAL CONSIDERATIONS
- SAFETY MONITORING
- VACCINE DISTRIBUTION IN NYC
- PREPARING TO OFFER VACCINATION
- RESOURCES FOR COUNSELING PATIENTS
Impact of COVID-19

Global
• > 112 million cases
• > 2.4 million deaths*

U.S.
• > 28 million cases
• > 515,000 deaths

New York City
• > 704,000 cases
• > 23,900 confirmed deaths

Updated 2/24/2021
Preventing COVID-19

• To date, prevention has focused on minimizing transmission
  • Individual level: face coverings, physical distancing, isolation and quarantine
  • Community/societal level: contact tracing, economic and travel restrictions

• Safe and effective vaccines have become available in some nations, including U.S.
  • Powerful addition to prevention measures

• Individual-level benefits of vaccination:
  • Prevent disease
  • Reduce severity of illness

• Community-level benefits of vaccination:
  • May reduce transmission
  • Resume economic, educational, and other societal-level endeavors
Understanding Herd Immunity

- Vaccination or infection provide immunity
- When a sufficient portion of population is immune, protection is also provided to remainder of community
- This includes people who are unable to receive vaccination
Vaccination Coverage Needed to Achieve Herd Immunity

• How much COVID-19 vaccine coverage is needed?
  • Scientists do not yet know what level is necessary

• Estimates depend on various factors, including vaccine efficacy, duration of vaccine effectiveness, use of other prevention strategies (e.g. masking, distancing), effective reproductive number, susceptibility of the population

• Example based on modeling by Iboi et al.
  • Assuming vaccine efficacy of 80%, at least 83% of susceptible population needs to be vaccinated to achieve threshold
  • Combined with 30% of public using face covering, threshold decreases to 79%

COVID-19 Vaccine Development
COVID-19 Vaccine Development Process

• Same process that has been used for previous vaccines, but expedited because:
  • Built on years of research on related coronaviruses, including research on vaccines for other coronaviruses
  • Substantial funding allowed multiple trials to be run in parallel
  • Funding also allowed companies to began manufacturing vaccines early, enabling immediate distribution upon approval
• Safety was monitored closely during every phase of development
  • Tens of thousands of clinical trial participants received vaccines safely
• Federal government, state and local health departments, and health care providers have spent months planning for storage, distribution, supplies, and other logistics
Emergency Use Authorization vs. Licensure or Approval

• During a public health emergency, the Food and Drug Administration (FDA) can use Emergency Use Authorization (EUA) to allow use of vaccines before they are officially licensed so that they can be used sooner
• Certain criteria must be met, including that there are no adequate, approved, and available alternatives and that evidence strongly suggests that benefits outweigh any risks to patients
• Vaccines issued an EUA must go through the same clinical trials as all other licensed vaccines
• To support licensure of a vaccine, FDA generally requires at least 6 months of safety follow-up for serious and other medically attended adverse events

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 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; post-vaccination monitoring begins

ACIP – Advisory Committee on Immunization Practices; EUA – Emergency Use Authorization; FDA – Food and Drug Administration
https://www.fda.gov/media/143890/download
First U.S. COVID-19 Vaccines Authorized and Recommended for Emergency Use

- Emergency Use Authorizations issued for two vaccines
  - Pfizer-BioNTech - 12/11/2020
  - Moderna - 12/18/2020
- Both are mRNA vaccines

https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html
mRNA Vaccines

- Contain genetic material from SARS-CoV-2 but not the actual virus
- mRNA provides instruction directly to the immune system
- Creates specific immune memory in a natural context
- mRNA never enters nucleus of cell; it can neither interact with nor integrate into the cell’s DNA and is broken down quickly
- Although this is a new type of vaccine, mRNA vaccines have been studied for over 30 years

Image: https://www.fda.gov/media/144583/download
Pfizer-BioNTech and Moderna Vaccine Clinical Trial Findings

<table>
<thead>
<tr>
<th></th>
<th>Pfizer-BioNTech</th>
<th>Moderna</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase III study</strong></td>
<td>• &gt; 44,000 volunteers in U.S. and other countries</td>
<td>• &gt; 30,000 volunteers in U.S.</td>
</tr>
<tr>
<td><strong>population</strong></td>
<td>• 26.2% of participants were Hispanic/Latino, 9.8% Black/African-American, and 4.4% Asian</td>
<td>• 20% of participants were Latino, 9.7% Black/African-American, and 4.7% Asian</td>
</tr>
<tr>
<td></td>
<td>• 21.4% of participants were age 65 and older</td>
<td>• 25.3% of participants were age 65 and older</td>
</tr>
<tr>
<td><strong>Efficacy</strong></td>
<td>• Overall: 95%</td>
<td>• Overall: 94.1%</td>
</tr>
<tr>
<td></td>
<td>• High efficacy maintained across age, gender, race and ethnicity</td>
<td>• High efficacy maintained across age, gender, race and ethnicity</td>
</tr>
<tr>
<td><strong>Safety</strong></td>
<td>• No serious safety concerns found</td>
<td>• No serious safety concerns found</td>
</tr>
</tbody>
</table>

Pfizer: Information about the Pfizer-BioNTech COVID-19 Vaccine | CDC
Moderna: Information about the Moderna COVID-19 Vaccine | CDC
Pfizer-BioNTech vs. Moderna Vaccine: Similarities

- Lipid nanoparticle-formulated mRNA vaccines that encode the prefusion spike glycoprotein (S protein) of SARS-CoV-2
- Require two doses
- Are administered by intramuscular injection
- Cause local and systemic reactogenicity, particularly after second dose
- Are highly effective
- No serious safety concerns identified during Phase III clinical trials
## Pfizer-BioNTech vs. Moderna Vaccine: Differences

<table>
<thead>
<tr>
<th></th>
<th>Pfizer-BioNTech</th>
<th>Moderna</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>VIALS</strong></td>
<td>6 doses per vial**</td>
<td>10 doses per vial</td>
</tr>
<tr>
<td><strong>DOSAGE</strong></td>
<td>0.3 mL</td>
<td>0.5 mL</td>
</tr>
<tr>
<td><strong>STORAGE</strong></td>
<td>Ultracold (-70°C)</td>
<td>-20°C</td>
</tr>
<tr>
<td><strong>AGE INDICATIONS</strong></td>
<td>≥ 16 years</td>
<td>≥ 18 years</td>
</tr>
<tr>
<td><strong>SCHEDULE</strong></td>
<td>2 doses separated by 21 days</td>
<td>2 doses separated by 28 days</td>
</tr>
</tbody>
</table>

*Additional doses have been reported for Pfizer and occasionally Moderna vials; use these doses to vaccinate

** EUA for Pfizer-BioNTech vaccine has been amended to reflect 6 doses per vial (previously 5)
Other COVID-19 Vaccine Candidates in Development

<table>
<thead>
<tr>
<th>Company</th>
<th>Mechanism</th>
<th>Storage</th>
<th>Doses</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Johnson &amp; Johnson (Janssen)</td>
<td>Viral vector</td>
<td>-20° C</td>
<td>1</td>
<td>FDA to review EUA 2/26/21</td>
</tr>
<tr>
<td>AstraZeneca</td>
<td>Viral vector</td>
<td>2-8° C</td>
<td>2</td>
<td>Phase III trial</td>
</tr>
<tr>
<td>Novavax</td>
<td>Protein subunit</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>2-8° C</td>
<td>2</td>
<td>Phase I/II trial</td>
</tr>
</tbody>
</table>
Effect of Emerging SARS-CoV-2 Variants on COVID-19 Vaccine Efficacy

• SARS-CoV-2 mutates regularly, so changes in its genome are expected
• Several recently identified variants appear to be more easily transmitted than other circulating strains
• Whether these variants can evade immunity induced by vaccines or natural infection is an area of active study
  • Preliminary studies suggest several currently available vaccines, including Pfizer-BioNTech and Moderna, may have decreased efficacy against B.1.351 (South Africa) variant
  • In-vitro studies show Moderna and Pfizer vaccines are likely to be effective against B.1.1.7 (U.K.) variant
• Even if a new variant cannot evade vaccine-induced immunity, widespread circulation of a highly infectious new strain may require higher vaccine coverage than previously estimated to achieve control of the pandemic
• This underscores the importance of implementing vaccination as quickly and rigorously as possible

Clinical Considerations
Expected Reactions After COVID-19 Vaccination

- Clinical trials suggest COVID-19 vaccines often elicit mild to moderate reactions, especially after second dose
- More common in younger compared to older age groups
- Usually occur within the first 3 days of vaccination and resolve within 1-3 days of onset

<table>
<thead>
<tr>
<th></th>
<th>Moderna vaccine(^1)</th>
<th>Pfizer vaccine(^2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain at injection site</td>
<td>100%</td>
<td>83%</td>
</tr>
<tr>
<td>Fatigue</td>
<td>80%</td>
<td>75%</td>
</tr>
<tr>
<td>Headache</td>
<td>60%</td>
<td>67%</td>
</tr>
<tr>
<td>Myalgia</td>
<td>53%</td>
<td>58%</td>
</tr>
<tr>
<td>Fever</td>
<td>40%</td>
<td>17%</td>
</tr>
</tbody>
</table>

Prepare Patients for Reactions Expected After COVID-19 Vaccination

• Before vaccination, counsel patients on expected post-vaccination symptoms

• Unless a person develops a contraindication* to vaccination, they should be encouraged to complete the series even if they develop post-vaccination symptoms, to optimize protection against COVID-19

• Antipyretic or analgesic medications may be taken for treatment of post-vaccination symptoms

• Routine prophylaxis to prevent symptoms is not recommended due to lack of information on impact of use on vaccine-induced antibody responses

*Contraindications to COVID-19 mRNA vaccines:
• 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)

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: Does employee have a fever?
       - Yes: 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: Is employee feeling well enough and willing to work?
         - Yes: Employee can return to work; notify occupational health if their symptoms persist for >2 days.
         - No: Continue to follow usual protocols.

2. 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.

Post Vaccine Considerations for Residents of Long-Term Care Facilities

• The Centers for Disease Control and Prevention (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 settings

• See CDC post-vaccine considerations for long-term care facility residents
Timing of Second Vaccine Dose

- **Recommended schedule**
  - Pfizer-BioNTech: 3 weeks (21 days) apart
  - Moderna: 1 month (28 days) apart

- **Second doses administered within 4 days before the recommended date will be considered valid**
  - Grace period for Pfizer: day 17-21; for Moderna: day 24-28
  - However, grace period should not be used routinely to schedule second dose
  - Doses inadvertently administered earlier than the grace period do not need to be repeated

- **Second dose should be administered as close to the recommended interval as possible**
  - If it is not feasible to adhere to recommended interval, second dose of Pfizer-BioNTech or Moderna vaccine may be scheduled for up to 6 weeks (42 days) after first dose
  - There are limited data on efficacy of COVID-19 vaccines administered beyond this window, though it is expected that immune response following the second dose would remain high
  - If second dose is administered beyond these intervals, there is no need to restart the series

https://www.cdc.gov/vaccines/covid-19/info-by-product/cl...Administration
Interchangeability of COVID-19 Vaccines

• Either mRNA vaccine can be used; there is no preference between products

• However, the two vaccines are **not** interchangeable – both doses should be completed with same product

• Strategies to ensure that patients receive the second dose with the appropriate product:
  • Provide COVID-19 vaccination record cards; encourage recipients to bring them to their second dose appointments
  • Record vaccine administration information in the CIR (and the patient’s medical record, if applicable)

• In exceptional situations in which the first-dose vaccine product cannot be determined or is no longer available, any available mRNA COVID-19 vaccine may be administered at a minimum interval of 28 days between doses to complete the vaccination series

• If two doses of different mRNA COVID-19 vaccine products are administered in these situations (or inadvertently), no additional doses of either product are recommended at this time

Co-Administration with Other Vaccines

• There are no data on safety and efficacy of COVID-19 vaccines when administered simultaneously with other vaccines
  • Ideally, administer COVID-19 vaccines at least 14 days before or after any other vaccine
• However, COVID-19 and other vaccines may be administered within a shorter period if:
  • Benefits of vaccination outweigh potential risks (e.g., tetanus vaccine for wound management) or
  • To avoid potential barriers or delays to COVID-19 vaccination (e.g., long-term care facility residents who received influenza vaccine prior to COVID-19 vaccine availability)
• If inadvertently administered within 14 days of another vaccine, do not repeat doses of either vaccine

### Reported Anaphylaxis After Vaccination

**Updated Information, as of January 18, 2021**

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Number of anaphylaxis cases</th>
<th>Number of doses administered</th>
<th>Rate of anaphylaxis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer-BioNTech</td>
<td>50</td>
<td>9,943,247</td>
<td>5.0 per million doses</td>
</tr>
<tr>
<td>Moderna</td>
<td>21</td>
<td>7,581,429</td>
<td>2.8 per million doses</td>
</tr>
</tbody>
</table>

- Previously reported rate for Pfizer vaccine: 11.1 per million doses administered [here](https://www.cdc.gov/mmwr/volumes/70/wr/mm7002e1.htm)
- Previously reported rate for Moderna vaccine: 2.5 per million doses administered [here](https://www.cdc.gov/mmwr/volumes/70/wr/mm7004e1.htm)

*ACIP meeting, January 27, 2021: [here](https://www.cdc.gov/vaccines/acip/meetings.slides-2021-1-27-21.html)*
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/clinical-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

• A history of reaction to a vaccine or injectable therapy with multiple components, one of which is PEG, another mRNA vaccine component or polysorbate, but where it is unknown which component caused the allergic reaction is a precaution to vaccination (not a contraindication)

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

• Delayed, local injection-site reactions after the first mRNA vaccine dose are not a contraindication or precaution to the second dose

https://www.cdc.gov/vaccines/covid-19/info-by-product/clini...
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

Trained personnel qualified to recognize and treat anaphylaxis symptoms should be available at vaccination locations at all times

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, pregnant people and homebound persons
  • 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 some underlying medical conditions, including those that place people at increased risk for severe COVID-19, compared to persons without comorbidities.

• Individuals in all the following groups may receive COVID-19 vaccination (unless they have a contraindication to vaccination):
  • Immunocompromised persons
  • Persons with autoimmune conditions
  • Persons with a history of Guillain-Barré syndrome
  • Persons with a history of Bell’s palsy
Persons with HIV or Immunosuppression

• May be at increased risk for severe COVID-19
• May receive COVID-19 vaccine if they have no vaccine contraindications*
• Data not currently available to establish vaccine safety and efficacy in immunocompromised persons
• Persons with stable HIV infection were included in mRNA COVID-19 vaccine clinical trials, though data remain limited
• Counsel patients about the unknown vaccine safety profile and effectiveness in immunocompromised populations, as well as the potential for reduced immune responses

*Contraindications to COVID-19 mRNA vaccines:
• 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)
Persons with Autoimmune Conditions

• May receive COVID-19 vaccine if they have no vaccine contraindications
• Were eligible for enrollment in clinical trials
• Inform patients that no data are currently available on the safety of mRNA COVID-19 vaccines for people with autoimmune conditions
• No imbalances were observed in occurrence of symptoms consistent with autoimmune conditions or inflammatory disorders in clinical trial participants who received vaccine compared to placebo
Persons with History of Guillain-Barré or Bell’s Palsy

• May receive COVID-19 vaccine if they have no vaccine contraindications

• No cases of Guillain-Barré syndrome (GBS) have been reported following vaccination among participants in the vaccine clinical trials

• Cases of Bell’s palsy were reported following vaccination in participants in both the Pfizer-BioNTech and Moderna COVID-19 clinical trials
  • FDA does not consider these above the frequency expected in the general population and has not concluded that these cases were causally related to vaccination
Pregnant or Lactating People

• May choose to be vaccinated
• 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 people 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 people
  • Should be offered to lactating people

People 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, people with documented acute SARS-CoV-2 infection in the preceding 90 days may choose to temporarily delay vaccination until near the end of this period, if desired
- Testing people without symptoms for evidence of current or past SARS-CoV-2 infection for the purpose of vaccine decision-making is not recommended
- Defer vaccination for people with acute infection or in quarantine to avoid potentially exposing healthcare personnel or patients to SARS-CoV-2 during the vaccination visit
  - People with acute infection should wait until isolation period has ended
  - Persons exposed to someone with COVID-19 should defer vaccination until after quarantine

https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html
People Who Received Monoclonal Antibody or Convalescent Plasma Treatment

• Currently, there are no data on the safety or efficacy of mRNA COVID-19 vaccines in people who received these treatments for COVID-19

• People who received either of these as treatment for COVID-19 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 response

COVID-19 Prevention for Vaccinated Persons

• Protection afforded by vaccine is not optimal until 1-2 weeks after 2\textsuperscript{nd} 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:
  • Stay home if sick
  • Wear a face covering
  • Stay at least 6 feet from others whenever possible
  • Practice hand hygiene

CDC Recommendations for Vaccinated Persons Exposed to Someone with COVID-19

• Quarantine recommendations for vaccinated persons updated
  • Vaccinated persons not required to quarantine after exposure to someone with COVID-19 if they are:
    • Fully vaccinated against COVID-19 (≥ 2 weeks following completion of series) AND
    • Within 3 months following final dose in series AND
    • Asymptomatic
  • Inpatients and residents in health care settings should continue to quarantine following an exposure
  • These recommendations have not been adopted in New York State, but the Governor has stated an intent to do so

CDC recommendations 2/10/2021 https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html
What is Not Yet Known About COVID-19 Vaccines?

• Duration of immunity provided by vaccination
• Whether vaccination prevents transmission of the virus to others
• Whether additional doses will be needed in the future
• Safety and efficacy for children (clinical trials are ongoing)
• Efficacy in persons with immunosuppression
Safety Monitoring
## Multiple COVID-19 Vaccine Post-Authorization Safety Monitoring Systems

<table>
<thead>
<tr>
<th>Monitoring System</th>
<th>Population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccine Adverse Event Reporting System (VAERS)</td>
<td>All vaccine recipients in U.S.</td>
</tr>
<tr>
<td>• VAERS</td>
<td>VA patient populations</td>
</tr>
<tr>
<td>• Veterans Affairs Adverse Drug Event Reporting System</td>
<td>DoD patient populations</td>
</tr>
<tr>
<td>• Department of Defense Vaccine Adverse Event Clinical System</td>
<td>Acute care and long-term care facilities</td>
</tr>
<tr>
<td>• CDC National Healthcare Safety Network</td>
<td>All COVID-19 vaccine recipients eligible</td>
</tr>
<tr>
<td>V-Safe</td>
<td>Insured patients in VSD sites</td>
</tr>
<tr>
<td>Vaccine Safety Datalink (VSD)</td>
<td>Referred cases from US population</td>
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<tr>
<td>Clinical Immunization Safety Assessment Project (CISA)</td>
<td>Long-term care facility residents</td>
</tr>
<tr>
<td>Genesis Healthcare</td>
<td>Medicare recipients</td>
</tr>
<tr>
<td>FDA and Centers for Medicare and Medicaid Services</td>
<td>Insured patients in BEST sites</td>
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<td>FDA BEST Initiative</td>
<td>Insured patients in PRISM sites</td>
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<tr>
<td>FDA Post-licensure Immunization Safety Monitoring System</td>
<td>Enrolled VA patients</td>
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<tr>
<td>Veterans Administration Data</td>
<td>Active duty military</td>
</tr>
<tr>
<td>Department of Defense Medical Surveillance System</td>
<td></td>
</tr>
</tbody>
</table>
Vaccine Adverse Event Reporting System (VAERS)

• Rapid, early warning system for safety signals
• Co-managed by the CDC and FDA
• Clinical review of individual reports received nationwide
• Statistical methods to detect disproportionate reporting of specific vaccine-adverse event
Reporting Adverse Events to VAERS

• Adverse events that occur 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 or by calling 1-800-822-7967
V-Safe Tool for Patients

• CDC’s new smartphone-based, after-vaccination health checker for people who receive COVID-19 vaccines

• Health checks via text message
  • Daily for the first week after vaccination
  • Weekly thereafter for 6 weeks post-vaccination
  • Active telephone follow-up with people who report clinically important events*

• All COVID-19 vaccine recipients eligible

• Health care providers should encourage patient participation and provide patients with v-safe handout

*Symptoms or health conditions that cause one to miss work, forego normal daily activities, or seek health care

Results of First Month of Vaccine Safety Monitoring, U.S.

- Descriptive analysis of VAERS and v-safe reports from December 14, 2020-January 13, 2021 (during which first and second Pfizer doses and first Moderna doses were administered)

- Most frequently reported symptoms after vaccination:
  - Headache (22%), fatigue (17%), dizziness (17%)

- Anaphylaxis was reported after both types of vaccine
  - 4.5 cases of anaphylaxis per million doses – a rate comparable to that associated with other widely used vaccines

- No unexpected patterns of reactions or safety concerns identified

COVID-19 Vaccine Distribution in NYC
Ensuring Equitable Vaccine Distribution in NYC

• Equity is at the core of all NYC Health Department planning, including vaccine operations

• The Health Department has developed a 3-part equity strategy:
  1. Equitable Access
     • Chose vaccine hub locations to eliminate physical, transportation and other barriers
     • Prioritize neighborhoods that have been disproportionately impacted by COVID-19
     • Ensure equitable access to information about vaccines so all New Yorkers can make informed decisions about COVID-19 vaccination
Ensuring Equitable Vaccine Distribution in NYC (continued)

2. Equitable Uptake
   • Tailor approaches to individual communities’ interests and needs
   • Work with community-based organizations, faith-based organizations and trusted messengers to disseminate accurate and culturally sensitive information
   • Engage community members that have experienced institutional betrayal and racism to guide community engagement

3. Equitable Outcomes
   • Monitor vaccine safety trends and vaccination rates within each neighborhood
   • Facilitate community feedback to identify barriers and solutions to vaccine distribution
COVID-19 Vaccine Distribution

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

• ACIP issued 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 Campaign:

• Procure and distribute vaccine throughout NYC in accordance with federal and state guidance and help ensure equitable allocation

• Assist with Citywide Immunization Registry (CIR) registration, completion of COVID-19 vaccine agreement, and vaccine ordering and distribution

• Execute comprehensive community education and outreach

• Provide guidance to health care providers
  • Vaccine administration, storage and handling, best practices to increase uptake

• Administration of vaccine to eligible groups at NYC Health Department and Health + Hospitals vaccine sites

• Monitor key data points, track progress, and identify gaps in operations.
COVID-19 Vaccine Eligibility, NYS

- Groups eligible as of February 3, 2021 include:
  - Healthcare workers
  - People aged 65 years or older
  - Residents and staff in nursing homes and certain other group living facilities
  - Certain frontline essential workers, such as first responders, teachers and school staff, day care workers, transit workers, grocery store workers, restaurant workers and NYC Taxi and Limousine Commission licensed drivers

- Groups eligible as of February 15, 2021 include:
  - New Yorkers with certain underlying conditions
  - Pregnant individuals

- A detailed, up-to-date list of currently eligible groups and anticipated future availability may be found at: nyc.gov/covidvaccinedistribution
Documenting COVID-19 Vaccine Eligibility, NYC

- If vaccine provider has records showing person has eligible condition, that serves as proof of eligibility
- Vaccine recipients do NOT need to obtain documentation of underlying condition from a provider
Where to Get Vaccinated

For individuals who are currently eligible to receive vaccine:
• 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/vaccinefinder to find a vaccination site near you and make an appointment.
  • Call 977-VAX-4NYC (977-829-4692) for help making an appointment
1,578,362
Total doses administered

911,842
Dose 1 administered by NYC-run programs

512,025
Dose 2 administered by NYC-run programs

154,495
Doses administered by federal pharmacy programs in NYC

NYC COVID-19 Vaccine Tracker
2/24/2021, 12 a.m.

Data are reported by providers to the Citywide Immunization Registry and may be delayed. Data updated daily: https://www1.nyc.gov/site/doh/covid/covid-19-data-vaccines.page
Preparing to Offer COVID-19 Vaccination
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
  - COVID-19 Vaccine Training Modules
    [https://www2.cdc.gov/vaccines/ed/covid19/](https://www2.cdc.gov/vaccines/ed/covid19/)
  - COVID-19 Vaccine Storage and Handling Tool Kits
    [https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html](https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html)
  - [Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/index.html)
Enroll in the NYC COVID-19 Vaccination Program

• Enrollment is now open for private practices, independent pharmacies and other facilities that intend to 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 an online CIR account and enroll in the COVID-19 Vaccination Program by completing the Provider Agreement in the provider’s online account
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, for each vaccination site, a Provider Profile (Section B)
• 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)

• Once a facility is approved to participate in the COVID-19 vaccination program and they have proper vaccine storage they can order COVID-19 vaccine in the CIR Online Registry
  • General providers and facilities should not anticipate being able to receive COVID-19 vaccine until spring or summer of 2021
  • Vaccine will ship directly from the manufacturer or CDC distributor to the vaccine provider

• Nursing homes and adult care facilities in NYC may be enrolled in CDC’s Pharmacy Partnership for Long-term Care Program by which certain pharmacies already contracted with CDC go to these sites to vaccinate
  • 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
• Three methods of reporting vaccination:
  • Preferred option is via direct connection from your electronic health record (EHR)
  • CIR Online Registry website
  • Flat file transfer
• All administered COVID-19 vaccine doses must be reported to the CIR within 24 hours*
• Patient’s written consent not required
  • Authorizations include: NYS Executive Order 202.82**; NYC Commissioner’s Order***
• Ensure race and ethnicity are populated in EHR – 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 and Patients

• 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
• Identify and estimate the number of patients you may vaccinate in each vaccine allocation phase
  • Start with patients aged 65 years or older
• Use or adapt CDC’s ready-made communication materials: https://cdc.gov/vaccines/covid-19/health-systems-communication-toolkit.html
Review Vaccine Administration Fact Sheets

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

• Written 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://fda.gov/media/144414/download](https://fda.gov/media/144414/download)
  • Moderna: [https://fda.gov/media/144638/download](https://fda.gov/media/144638/download)

• CDC guidance on what to expect during the vaccination visit and after getting vaccinated
COVID-19 Vaccine Reimbursement

• Providers are required to administer COVID-19 vaccines at no cost to patients, regardless of insurance status or ability to pay
• Providers may not bill for the cost of the vaccine, but they may bill the patient’s health insurance for an administration fee
• If a person does not have health insurance, or their insurance does not cover the administration fee, providers can request reimbursement through the Provider Relief Fund
• For additional information: www.cms.gov/covidvax-provider
Begin Discussing Vaccination with Patients

• Even if a patient is not yet eligible to be vaccinated, lay the groundwork for when vaccine becomes more available

• Let patients know that you plan to recommend the vaccine for them
  • Provide information on the benefits and safety of vaccination

• If a patient questions your recommendation, this does not necessarily mean they will not accept it; some questions are to be expected

• Patients consider their providers the most trusted source of information on vaccines, and may simply want your answers

CDC. https://www.cdc.gov/vaccines/covid-19/hcp/answering-questions.html#
Counseling Patients who Express Concerns

• Start from a place of empathy and understanding
• Assume patients will want to be vaccinated but may have questions
• Give your strong recommendation
  • A provider recommendation is one of the strongest predictors of vaccine receipt
• Listen to and respond to questions in an understandable way
  • Resources: CDC, CHOP, NYC Health Department website and materials
• Wrap up the conversation
  • After answering questions, let patients know you are open to continuing discussion
  • Encourage them to consider scheduling a follow-up visit with you for this reason
  • Tell them where they can find additional information
  • 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 Vaccines:
  - Public: nyc.gov/covidvaccine
  - Providers: nyc.gov/health/covidvaccineprovider
  - Vaccine eligibility: https://www1.nyc.gov/site/doh/covid/covid-19-vaccine-eligibility.page
  - Where to get vaccinated (vaccine finder): https://vaccinefinder.nyc.gov/

- 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