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

FEBRUARY 5, 2021

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Our understanding of COVID-19 is evolving rapidly.
This presentation is based on our knowledge as of February 4, 2021, 5 PM.
CME Accreditation Statement for Joint Providership
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OUTLINE

- NEW DEVELOPMENTS AND GUIDANCE
- RECENT EPIDEMIOLOGY OF COVID-19 IN NYC
- COVID-19 VACCINE CLINICAL CONSIDERATIONS AND SAFETY MONITORING
- QUESTIONS AND PANEL DISCUSSION
NEW DEVELOPMENTS AND GUIDANCE

Mary Foote, MD, MPH
Health Systems Planning and Strategies Lead,
COVID-19 Response
NYC Department of Health and Mental Hygiene
Current Status of the COVID-19 Pandemic

• Worldwide: over 103 million cases; over 2.2 million deaths
• In the U.S., case numbers, hospitalizations, and mortality numbers are falling nationwide
• A World Health Organization-led team of experts is investigating the origins of COVID-19 and plans to visit labs, markets and hospitals in Wuhan, China
• Interim results of Johnson & Johnson phase III trial show 66% overall efficacy* in preventing moderate to severe COVID and 85% efficacy in preventing severe COVID-19. J&J has applied for an FDA emergency use authorization.
• Interim results of Sputnik V vaccine phase III trial show 92% efficacy in preventing symptomatic COVID-19 and 100% efficacy in preventing severe COVID-19
• The U.S. will join the World Health Organization COVAX program to contribute toward providing access to COVID-19 vaccines in low- and middle-income nations

Efficacy = difference in new cases between the placebo group and the vaccine group
Emerging Variants and Vaccine Efficacy

• **Pfizer** and **Moderna** conducted in vitro studies of vaccine efficacy against recently identified variants to detect impacts on plaque reduction neutralization assay
  • B.1.1.7 (UK) variant - no significant impact on neutralization
  • B.1.351 (S. Africa) variant - reduced but still significant neutralization

• Moderna plans to test whether a third shot of the current vaccine or a strain-specific booster shot will enhance immunity to B.1.351

• In **Johnson & Johnson** adenovirus vector vaccine Phase III trial, efficacy was 57% in South Africa and 72% in the US; 95% of S. Africa COVID-19 cases were due to B.1.351

• **Novavax** protein subunit vaccine efficacy was 95.6% against the original COVID-19 strain, 85.6% against B.1.1.7 and 60% against B.1.351
Monoclonal Antibody Updates

- Monoclonal antibodies against SARS-CoV-2 spike protein for treatment and prevention
- EUA for treatment of outpatients at risk of severe illness with mild to moderate COVID-19
  - Bamlanivimab and casirivimab/imdevimab have shown reduced rate of ED visits/hospitalization in outpatients with confirmed mild to moderate disease, particularly among high-risk patients
  - Bamlanivimab/etesevimab combo reduced risk of hospitalizations or death by 70% in 1,035 newly diagnosed COVID-19 outpatients at high risk of serious illness
    - 10 deaths in placebo recipients, none in treatment group
- Prevention of symptomatic infection in contacts
  - Bamlanivimab reduced risk of symptomatic COVID by 80% in 299 residents of long term care facilities experiencing an outbreak. There were 4 deaths, all in placebo group.
  - Casirivimab/imdevimab completely prevented symptomatic COVID in housemates of someone with COVID-19 and reduced asymptomatic infections by 50%
    - Administered as an injection

Reporting of Race/ethnicity Data

• COVID-19 has laid bare enormous racial and ethnic inequities driven by historic and ongoing structural racism

• The NYC Health Department is requesting that providers enhance efforts to report race and ethnicity to the Citywide Immunization Registry for individuals receiving COVID-19 vaccine

• These data are important to target resources to groups who are not receiving vaccine

• Currently this information is unknown for 40% of vaccine recipients
Celebrating Black History Month
COVID Heroes Making History
Dr. Kizzmekia Corbett

• Viral immunologist and research fellow in the Vaccine Research Center of the National Institute of Allergy and Infectious Diseases

• Lead scientist on the Moderna Covid-19 vaccine team

• Built on research studying SARS and MERS vaccine antigens to develop SARS-CoV-2 vaccine
Sandra Lindsay

• Director of Critical Care Nursing at Long Island Jewish Hospital
• First American to get the Covid-19 vaccine outside of trials on December 14 in Queens, NYC
• Emigrated from Jamaica in 1986 and became a nurse in 1994
• Wanted to lead by example for her staff and as a Black woman

CNBC. 23 Black leaders who are shaping history today
RECENT EPIDEMIOLOGY OF COVID-19 IN NYC

Anne Fine, MD
Epidemiology and Data Co-lead
Surveillance and Epidemiology Branch
COVID-19 Response
NYC Department of Health and Mental Hygiene
## Summary of Key Data Points

<table>
<thead>
<tr>
<th>Measure</th>
<th>Last 7 days</th>
<th>Weekly average (last 4 weeks)</th>
<th>Trend</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Percent Positive</strong></td>
<td>8.48%</td>
<td>9.00%</td>
<td>Decreasing</td>
</tr>
<tr>
<td>Percent of people tested who test positive</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Confirmed Cases</strong></td>
<td>22,735</td>
<td>29,583</td>
<td>Decreasing</td>
</tr>
<tr>
<td>People with a positive molecular test</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Probable Cases</strong></td>
<td>7,222</td>
<td>8,145</td>
<td>Decreasing</td>
</tr>
<tr>
<td>People with a positive antigen test, or symptoms and confirmed exposure, or probable death</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total Cases</strong></td>
<td>29,957</td>
<td>37,727</td>
<td>Decreasing</td>
</tr>
<tr>
<td><strong>Hospitalizations</strong></td>
<td>1,938</td>
<td>2,345</td>
<td>Decreasing</td>
</tr>
<tr>
<td>People hospitalized within 14 days of diagnosis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Confirmed Deaths</strong></td>
<td>420</td>
<td>444</td>
<td>Decreasing</td>
</tr>
<tr>
<td>Deaths with a positive molecular test</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Updated: February 4, at 1 p.m.*

Data are preliminary and subject to change.
Citywide cases

- Case counts have stabilized citywide
- Latest 7-day average of cases from complete data is 5500 per day

*Probable cases are: (a) people with a positive COVID-19 antigen test; (b) people with COVID-like illness who had exposure to a known case of COVID-19; (c) people who died and had COVID or a similar term listed on their death certificate but did not have a positive laboratory test for COVID-19.
Citywide hospitalizations

- Graph showing daily number of admits
- 7-day average is ~350/day
- Steadily increasing, recent decline but we are watching to see if this holds
Citywide deaths

- Deaths by date of death
- Light grey: confirmed, dark grey: probable
- Steady increase, now close to 80 COVID-19 deaths per day

Produced by Surveillance and Epidemiology Branch, NYC DOHMH, February 5, 2021

Data are preliminary and subject to change
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- Jump in persons getting tested by PCR after the start of the new year
- 7-day average of persons tested by PCR: 65,000 per day (including weekends), stable
- 7-day average of persons tested by antigen: 18,000 per day (including weekends), increasing
- Average turnaround time is still 2 days citywide
Trends by modZCTA (ZIP code)

- modZCTA with the highest 7-day percent positivity include
  - (1) Flushing/Murray Hill in QN at 16%
  - (2) Brighton Beach/Manhattan Beach in BK at 14%
  - (3) Midwood in QN at 14%
  - (4) Woodhaven in QN at 14%
- Recent potential plateau generally in citywide and borough level percent positivity
Vaccine doses administered

Doses Administered in NYC
Select the indicator of interest using the filter below. These figures show the cumulative and daily number of COVID-19 vaccine doses administered in NYC. This includes doses administered by immunizing facilities in NYC regardless of residency status. Data from the most recent days may be incomplete due to delays in reporting.

Select Indicator
- Daily trends

Doses Administered
This table shows the total doses administered, and the number of first and second doses administered in NYC.

<table>
<thead>
<tr>
<th>Doses Administered</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Doses Administered</td>
<td>859,803</td>
</tr>
<tr>
<td>Dose 1 Administered by NYC-run programs</td>
<td>628,279</td>
</tr>
<tr>
<td>Dose 2 Administered by NYC-run programs</td>
<td>155,458</td>
</tr>
<tr>
<td>Doses administered by federal long-term care facility program in NYC</td>
<td>76,066</td>
</tr>
</tbody>
</table>
### Vaccine demographics

#### Among adults with known race/ethnicity who received at least 1 dose

This figure shows, among people with known race/ethnicity who have received at least one dose, adults by place of residence, race/ethnicity, and age group. Individuals who work in NYC but live outside of the city may be eligible for vaccination in NYC. Demographic data should be interpreted with caution due to the limited number of priority groups currently eligible for vaccination and incomplete reporting.

<table>
<thead>
<tr>
<th>Race/Ethnicity</th>
<th>18 - 64</th>
<th>65+</th>
<th>All Adults</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>At least 1 dose</td>
<td>At least 1 dose</td>
<td>At least 1 dose</td>
</tr>
<tr>
<td>NYC</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>57,207</td>
<td>93,187</td>
<td>150,394</td>
</tr>
<tr>
<td>Asian</td>
<td>27,000</td>
<td>20,368</td>
<td>47,377</td>
</tr>
<tr>
<td>Latino</td>
<td>22,803</td>
<td>24,015</td>
<td>46,818</td>
</tr>
<tr>
<td>Black</td>
<td>15,795</td>
<td>19,524</td>
<td>35,320</td>
</tr>
<tr>
<td>AI/AN</td>
<td>577</td>
<td>401</td>
<td>978</td>
</tr>
<tr>
<td>NH/PI</td>
<td>294</td>
<td>204</td>
<td>498</td>
</tr>
<tr>
<td>Other</td>
<td>15,999</td>
<td>16,053</td>
<td>32,052</td>
</tr>
<tr>
<td>Total</td>
<td>130,685</td>
<td>173,752</td>
<td>313,437</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Race/Ethnicity</th>
<th>18 - 64</th>
<th>65+</th>
<th>All Adults</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>At least 1 dose</td>
<td>At least 1 dose</td>
<td>At least 1 dose</td>
</tr>
<tr>
<td>Non- NYC</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>26,312</td>
<td>31,650</td>
<td>57,962</td>
</tr>
<tr>
<td>Asian</td>
<td>6,896</td>
<td>4,524</td>
<td>11,420</td>
</tr>
<tr>
<td>Latino</td>
<td>6,445</td>
<td>3,520</td>
<td>9,965</td>
</tr>
<tr>
<td>Black</td>
<td>3,764</td>
<td>2,576</td>
<td>6,440</td>
</tr>
<tr>
<td>AI/AN</td>
<td>150</td>
<td>132</td>
<td>282</td>
</tr>
<tr>
<td>NH/PI</td>
<td>123</td>
<td>52</td>
<td>175</td>
</tr>
<tr>
<td>Other</td>
<td>6,146</td>
<td>5,395</td>
<td>12,041</td>
</tr>
<tr>
<td>Total</td>
<td>49,836</td>
<td>48,449</td>
<td>98,285</td>
</tr>
</tbody>
</table>

- Race and ethnicity data now posted
- High proportion of data is missing
- For patients that have non-missing race/ethnicity data: majority of patients are white

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**Notes:**

- AI/AN: American Indian or Alaska Native; NH/PI: Native Hawaiian or Other Pacific Islander
- The Hispanic/Latino category includes people of any race; all other categories exclude those who identified as Hispanic/Latino.

**Produced by Surveillance and Epidemiology Branch, NYC DOHMH, February 5, 2021**

**Data are preliminary and subject to change**
COVID-19 Vaccines—Clinical Considerations and Safety Monitoring

Martha Iwamoto, MD
COVID-19 Vaccine Operations Center
Epidemiology and Adverse Effects
NYC Department of Health and Mental Hygiene
PRESENTATION AGENDA

• Clinical considerations for COVID-19 vaccination
  • Who should NOT get vaccinated
  • Who can get vaccinated

• Vaccine safety monitoring
  • Description of systems
  • Initial results of adverse events monitoring
CLINICAL CONSIDERATIONS FOR mRNA COVID-19 VACCINATION
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 groups, racial and ethnic groups
• No significant safety concerns identified in clinical trials

https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html
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>Reaction</th>
<th>Moderna vaccine¹</th>
<th>Pfizer vaccine²</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>

²Walsh et al. Safety and immunogenicity of two RNA-Based COVID-19 vaccine candidates. NEJM 2020; online publication Oct 14.
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)

Who should NOT get mRNA COVID-19 vaccine?

• Anyone with a previous severe or immediate allergic reaction to a COVID-19 mRNA vaccine dose, a vaccine component, or polysorbate
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 an 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
Who MAY get COVID-19 mRNA vaccine, after considering risks and benefits?

- People with history of severe or immediate allergic reaction to any vaccine or injectable
- Pregnant and breastfeeding persons
- People with certain immunocompromising conditions
- People with autoimmune disease
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/clínical-considerations.html
Observation Period After COVID-19 Vaccination

• 30 minutes: People 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
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

Persons with Underlying Medical Conditions

• Clinical trials demonstrated similar safety and efficacy in people 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 contraindications 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
Who should wait to get vaccinated?

• People currently isolating or experiencing COVID-19 symptoms
  ➢ Wait until symptoms have resolved and they are finished with isolation

• People who recently had COVID-19 and were treated with antibody-based therapies
  ➢ Wait until 90 days after treatment to be vaccinated

• People who recently got another non-COVID-19 vaccine
  ➢ Wait until at least 14 days before getting COVID-19 vaccine
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
  • People 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
COVID-19 VACCINE SAFETY MONITORING
Safety of Pfizer-BioNTech and Moderna Vaccines

• These vaccines were developed more quickly than previous vaccines due to urgent need and special funding, but underwent the same level of robust study as previously approved vaccines
  • Safety was monitored closely during every phase of vaccine development
  • Tens of thousands of participants in clinical trials safely received vaccines
  • Safety and efficacy data from clinical trials were reviewed carefully before authorization by FDA and recommendation by ACIP

• Vaccine safety monitoring continues after authorization
  • COVID-19 vaccine safety is currently being monitored closely through multiple large, robust systems covering many groups of people
  • During this time, the U.S. government has implemented the most intense and comprehensive vaccine safety monitoring program in history
## 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>US population</td>
</tr>
<tr>
<td>VAERS</td>
<td></td>
</tr>
<tr>
<td>Veterans Affairs Adverse Drug Event Reporting System</td>
<td>VA patient populations</td>
</tr>
<tr>
<td>Department of Defense Vaccine Adverse Event Clinical System</td>
<td>DoD patient populations</td>
</tr>
<tr>
<td>CDC National Healthcare Safety Network</td>
<td>Acute care and long-term care facilities</td>
</tr>
<tr>
<td>V-Safe</td>
<td>All COVID-19 vaccine recipients eligible</td>
</tr>
<tr>
<td>Vaccine Safety Datalink (VSD)</td>
<td>Insured patients in VSD sites</td>
</tr>
<tr>
<td>Clinical Immunization Safety Assessment Project (CISA)</td>
<td>Referred cases from US population</td>
</tr>
<tr>
<td>Genesis Healthcare</td>
<td>Long-term care facility residents</td>
</tr>
<tr>
<td>FDA and Centers for Medicare and Medicaid Services</td>
<td>Medicare recipients</td>
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<tr>
<td>FDA BEST Initiative</td>
<td>Insured patients in BEST sites</td>
</tr>
<tr>
<td>FDA Post-licensure Immunization Safety Monitoring System</td>
<td>Insure patients in PRISM sites</td>
</tr>
<tr>
<td>Veterans Administration Data</td>
<td>Enrolled VA patients</td>
</tr>
<tr>
<td>Department of Defense Medical Surveillance System</td>
<td>Active duty military</td>
</tr>
</tbody>
</table>
Vaccine Adverse Event Monitoring System (VAERS)

• Rapid, early warning system for safety signals
• Co-managed by the Centers for Disease Control and Prevention (CDC) and FDA
• Covers the entire US population (~320 million)
• Clinical review of individual reports
• 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 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 and provide patients with v-safe enrollment form

*Symptoms or health conditions that cause one to miss work, do normal daily activities, or seek health care
INITIAL RESULTS OF ADVERSE EVENTS MONITORING
Anaphylaxis after COVID-19 vaccination

- Dec 9, 2020 – two reports of anaphylaxis reported in UK with Pfizer vaccine
- Pfizer and Moderna COVID-19 vaccines included information on anaphylaxis in their product information
- ACIP considered anaphylaxis risk during their deliberations
- CDC recommended risk mitigation strategies
  - Screening for risk before vaccination
  - Monitoring for symptoms post-vaccination
  - Early recognition and management of anaphylaxis at vaccination sites
- Enhanced monitoring for anaphylaxis in VAERS
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
Anaphylaxis Reports to VAERS
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 (https://www.cdc.gov/mmwr/volumes/70/wr/mm7002e1.htm)
- Previously reported rate for Moderna vaccine: 2.5 million doses administered (https://www.cdc.gov/mmwr/volumes/70/wr/mm7004e1.htm)

What have the vaccine safety monitoring systems told us so far?

- Safety profiles of COVID-19 vaccines are reassuring and consistent with that observed from the pre-authorization clinical trials
- Anaphylaxis has been observed following mRNA COVID-19 vaccines, though rarely
- Data do not suggest a signal with respect to overall safety or deaths following vaccination
- Additional population-based monitoring systems will continue to gather safety data safety as vaccination increases and the immunization program broadens
  - CDC’s Vaccine Safety Datalink, FDA monitoring in CMS data, VA electronic health record
Healthcare Providers’ Role

- Provide Emergency Use Authorization (EUA) Fact Sheet to your patients
- Talk to your patients about possible reactions after vaccination and vaccine safety
- Report adverse events to VAERS
- Encourage participation in v-safe
THANK YOU
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, February 19, 1 p.m. (sign up on provider page)