PFIZER BIONTECH COVID-19 VACCINE

OUTLINE

• Food and Drug Administration - Emergency Use Authorization
• Interim Advisory Committee on Immunization Practices Recommendations
• Review of the Data
• Clinical Guidance
• Managing Post-Vaccination Signs and Symptoms
• Storage and Handling
• Resources
PFIZER-BIONTECH COVID-19 VACCINE

EMERGENCY USE AUTHORIZATION

• December 10, 2020
  • Vaccines and Related Biological Products Advisory Committee (VRBPAC) recommended that the Food and Drug Administration (FDA) authorize the use of the Pfizer-BioNTech COVID-19 vaccine

• December 11, 2020*
  • FDA issued an Emergency Use Authorization (EUA) for emergency use of the Pfizer-BioNTech COVID-19 vaccine in persons ages 16 years and older

December 1, 2020*

- Advisory Committee on Immunization Practices (ACIP) recommended, as interim guidance, that 1) health care personnel (HCP) and 2) residents of long-term care facilities (LTCF) be offered COVID-19 vaccine in the initial phase of the vaccination program.

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
### Demographic Characteristics

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

<table>
<thead>
<tr>
<th></th>
<th>BNT162b2 (30 μg)</th>
<th>Placebo</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N=21,720 n (%)</td>
<td>N=21,728 N (%)</td>
<td>N=43,448 n (%)</td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>11,183 (51.5)</td>
<td>10,942 (50.4)</td>
<td>22,125 (50.9)</td>
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<tr>
<td>Female</td>
<td>10,537 (48.5)</td>
<td>10,786 (49.6)</td>
<td>21,323 (49.1)</td>
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<tr>
<td><strong>Race</strong></td>
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<td></td>
</tr>
<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>
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<tr>
<td>All others</td>
<td>1,790 (8.2)</td>
<td>1,764 (8.1)</td>
<td>3,554 (8.2)</td>
</tr>
<tr>
<td><strong>Ethnicity</strong></td>
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<td></td>
</tr>
<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>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<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>

Gruber, William. BNT162b2 Vaccine Candidate Against COVID-19. Available at: 
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>First COVID-19 occurrence ≥7 days after Dose 2</td>
<td>8 2.214 (17,411)</td>
<td>162 2.222 (17,511)</td>
</tr>
</tbody>
</table>

Gruber, William. BNT162b2 Vaccine Candidate Against COVID-19. Available at:
### First COVID-19 Occurrence From 7 Days After Dose 2

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

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

<table>
<thead>
<tr>
<th></th>
<th>BNT162b2 N=18,196</th>
<th>Placebo N=18,325</th>
<th>VE (%)</th>
<th>(95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td></td>
<td></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 (n=143)</td>
<td>162</td>
<td>95.1</td>
<td>(89.6, 98.1)</td>
</tr>
<tr>
<td>65-74 years</td>
<td>1 (n=14)</td>
<td>14</td>
<td>92.9</td>
<td>(53.1, 99.8)</td>
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<tr>
<td>≥75 years</td>
<td>0 (n=5)</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 (n=81)</td>
<td>81</td>
<td>96.4</td>
<td>(88.9, 99.3)</td>
</tr>
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<td>Female</td>
<td>5 (n=81)</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 (n=146)</td>
<td>162</td>
<td>95.2</td>
<td>(89.8, 98.1)</td>
</tr>
<tr>
<td>Black or African American</td>
<td>0 (n=7)</td>
<td>143</td>
<td>100.0</td>
<td>(31.2, 100.0)</td>
</tr>
<tr>
<td>All Others</td>
<td>1 (n=9)</td>
<td>142</td>
<td>89.3</td>
<td>(22.6, 99.8)</td>
</tr>
<tr>
<td>Ethnicity</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Hispanic/Latino</td>
<td>3 (n=53)</td>
<td>162</td>
<td>94.4</td>
<td>(82.7, 98.9)</td>
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<td>Non-Hispanic/Non-Latino</td>
<td>5 (n=109)</td>
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<td>95.4</td>
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</tr>
<tr>
<td>Country</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Argentina</td>
<td>1 (n=35)</td>
<td>162</td>
<td>97.2</td>
<td>(83.3, 99.9)</td>
</tr>
<tr>
<td>Brazil</td>
<td>1 (n=8)</td>
<td>162</td>
<td>87.7</td>
<td>(8.1, 99.7)</td>
</tr>
<tr>
<td>USA</td>
<td>6 (n=119)</td>
<td>162</td>
<td>94.9</td>
<td>(88.6, 98.2)</td>
</tr>
</tbody>
</table>

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

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

### 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)</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>N=18,198</strong></td>
<td><strong>Surveillance Time (n)</strong></td>
<td><strong>Surveillance Time (n)</strong></td>
</tr>
<tr>
<td>First Severe COVID-19 occurrence &gt;7 days after Dose 2</td>
<td>0</td>
<td>5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Efficacy Endpoint</th>
<th>BNT162b2 (30 μg)</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>N=21,669</strong></td>
<td><strong>Surveillance Time (n)</strong></td>
<td><strong>Surveillance Time (n)</strong></td>
</tr>
<tr>
<td>First Severe COVID-19 occurrence after Dose 1</td>
<td>1</td>
<td>14</td>
</tr>
</tbody>
</table>

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

**eDiary: Local Events Within 7 Days From Dose 1 and 2 in 16-55 and >55 Year Olds (N=8,183)**

<table>
<thead>
<tr>
<th></th>
<th>Redness</th>
<th>Swelling</th>
<th>Pain at Injection Site</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dose 1</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>16-55</td>
<td>4.5%</td>
<td>5.8%</td>
<td>83.1%</td>
</tr>
<tr>
<td>30 µg</td>
<td>11.1%</td>
<td>0.5%</td>
<td>14.0%</td>
</tr>
<tr>
<td>Placebo</td>
<td>11.1%</td>
<td>1.2%</td>
<td>9.3%</td>
</tr>
<tr>
<td>&gt;55</td>
<td>4.7%</td>
<td>6.5%</td>
<td>71.1%</td>
</tr>
<tr>
<td>30 µg</td>
<td>11.1%</td>
<td>1.2%</td>
<td>14.0%</td>
</tr>
<tr>
<td>Placebo</td>
<td>11.1%</td>
<td>9.3%</td>
<td>9.3%</td>
</tr>
<tr>
<td><strong>Dose 2</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>16-55</td>
<td>5.9%</td>
<td>6.3%</td>
<td>77.8%</td>
</tr>
<tr>
<td>30 µg</td>
<td>7.2%</td>
<td>0.2%</td>
<td>11.7%</td>
</tr>
<tr>
<td>Placebo</td>
<td>0.7%</td>
<td>7.7%</td>
<td>66.1%</td>
</tr>
<tr>
<td>&gt;55</td>
<td>7.2%</td>
<td>0.2%</td>
<td>7.7%</td>
</tr>
<tr>
<td>30 µg</td>
<td>0.7%</td>
<td>7.7%</td>
<td>66.1%</td>
</tr>
<tr>
<td>Placebo</td>
<td>0.7%</td>
<td>7.7%</td>
<td>66.1%</td>
</tr>
</tbody>
</table>

Redness and swelling severity definition: Mild = >2-5cm, Moderate = >5-10 cm; Severe = >10 cm; Grade 4 = necrosis

Pain at injection site severity definition: Mild=no interference; Moderate=some interference; Severe=prevents daily activity; Grade 4=ER visit or hospitalization

Dose 1: 16-55 yrs N=4589; >55 yrs N=3594  Dose 2: 16-55 yrs N=4201 >55 yrs N=3306

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

**eDiary: Systemic Events Within 7 Days From Dose 2 in 16-55 and >55 Year Olds (N=8,183)**

Fatigue, headache, chills, muscle pain, joint pain severity definition: Mild=no interference; Moderate=some interference; Severe=Prevents daily activity; Grade 4=ER visit or hospitalization

Vomiting severity definition: Mild=1-2 time in 24h; Moderate=>2 times in 24h; Severe=Requires IV hydration; Grade 4=ER visit or hospitalization

Diarrhea severity definition: Mild=2-3 times in 24h; Moderate=4-5 times in 24h; Severe=6 or more times in 24h; Grade 4=ER visit or hospitalization

Dose 1: 18-55 yrs N=3529; 56-65 yrs N=3027  Dose 2: 18-55 yrs N=3345; 56-65 yrs N=2899

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, Amanda and Sarah Mbaeyi. 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

CO-ADMINISTRATION WITH OTHER VACCINES

• 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

Cohn, Amanda and Sarah Mbaeyi. 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
- 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

Cohn, Amanda and Sarah Mbaeyi. 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

KNOWN SARS-COV-2 EXPOSURE

- Community/outpatient:
  - Defer vaccination until end of quarantine period to avoid possible exposures

- Congregate healthcare settings
  - May be vaccinated (would not lead to additional/new exposures)

- Other congregate settings
  - May be vaccinated to avoid delays and missed opportunities to vaccinate
  - Take precautions to limit exposure to other residents or non-essential staff

Cohn, Amanda and Sarah Mbaeyi. 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

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, Amanda and Sarah Mbaeyi. 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

PFIZER-BIONTECH COVID-19 VACCINE

BREASTFEEDING/ LACTATING PERSONS

• No data on safety in lactating women 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, Amanda and Sarah Mbaeyi. 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

REACTOGENICITY

- 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

Cohn, Amanda and Sarah Mbaeyi. 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

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, Amanda and Sarah Mbaeyi. 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, Amanda and Sarah Mbaeyi. 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, Amanda and Sarah Mbaeyi. 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
MANAGING POST-VACCINATION SIGNS AND SYMPTOMS AMONG HEALTHCARE PERSONNEL
• Systemic signs and symptoms
  • Most are mild to moderate in severity
  • Most occur within the first three days of vaccination (day 1= day of vaccination)
  • Most resolve within 1-2 days of onset
  • Usually more frequent and severe following the second dose
  • Usually more severe among younger persons compared to those over 55 years

• Cough, shortness of breath, rhinorrhea, sore throat, or loss of taste or smell are not consistent with post-vaccination symptoms

PFIZER-BIONTECH COVID-19 VACCINE

STRATEGIES

• Vaccinate HCP preceding 1-2 days off
• Stagger delivery of vaccine to HCP in the facility
• Inform HCP about the potential for short-term systemic signs and symptoms (counsel on options for mitigating symptoms – e.g., NSAIDs or acetaminophen)
• Develop a strategy to provide timely assessment of HCP
• Offer non-punitive sick leave options

PFIZER-BIONTECH COVID-19 VACCINE

EVALUATING AND MANAGING POST-VACCINATION SIGNS AND SYMPTOMS IN HCP

Suggested Approaches:

- Signs and symptoms unlikely to be from COVID-19 vaccination (cough, SOB, rhinorrhea, sore throat, loss of taste or smell)
  - Exclude from work pending evaluation for possible etiologies, including COVID-19 as appropriate

PFIZER-BIONTECH COVID-19 VACCINE

EVALUATING AND MANAGING POST-VACCINATION SIGNS AND SYMPTOMS IN HCP

CDC’s Suggested Approach:

• Signs and symptoms that may be from either COVID-19 vaccination, COVID-19, or another infection
  • Evaluate the HCP
  • Consider return to work without viral testing for SARS-CoV-2 – if the HCP feels well enough and is willing to work, afebrile, and systemic signs and symptoms are limited only to those observed following COVID-19 vaccination
  • If symptoms not improving or persist more than 2 days, exclude and consider viral testing for SARS-CoV2

Consult New York State Department of Health HCP isolation and exclusion guidance

PFIZER-BIONTECH COVID-19 VACCINE

CIR REPORTING

• Required reporting of ALL administered COVID-19 vaccines doses to CIR within 24 hours of administration
• No consent required
• Authorizations include:
  • NYS Emergency Order 12/13
  • NYC Commissioner Order 12/14
• CIR Reporting Assistance
  • BOI Hotline: 347-396-2400
• Ensure race and ethnicity are populated in EHR – fields must be submitted to CIR when reporting COVID-19 vaccine doses administered
PFIZER-BIONTECH COVID-19 VACCINE

VACCINE ADVERSE EVENT REPORTING

• 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 or by calling 1-800-822-7967.
KEY MATERIALS
FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE
(VACCINATION PROVIDERS)

EMERGENCY USE AUTHORIZATION (EUA) OF
THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS
DISEASE 2019 (COVID-19)

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use
Authorization (EUA) to permit the emergency use of the unapproved product,
Pfizer-BioNTech COVID-19 Vaccine, for active immunization to prevent
COVID-19 in individuals 16 years of age and older.

SUMMARY OF INSTRUCTIONS FOR COVID-19 VACCINATION PROVIDERS

Vaccination providers enrolled in the federal COVID-19 Vaccination Program must
report all vaccine administration errors, all serious adverse events, cases of
Multisystem Inflammatory Syndrome (MIS) in adults and children, and cases of
COVID-19 that result in hospitalization or death following administration of
Pfizer-BioNTech COVID-19 Vaccine. See “MANDATORY REQUIREMENTS FOR
PFIZER-BIONTECH COVID-19 VACCINE ADMINISTRATION UNDER
EMERGENCY USE AUTHORIZATION” for reporting requirements.

The Pfizer-BioNTech COVID-19 Vaccine is a suspension for intramuscular injection
administered as a series of two doses (0.3 mL each) 3 weeks apart.

See this Fact Sheet for instructions for preparation and administration. This Fact

Available at: https://www.fda.gov/media/144413/download
COVID-19 Vaccination

Getting Vaccinated
- How CDC Is Making COVID-19 Vaccine Recommendations
- Benefits of Getting a COVID-19 Vaccine
- Ensuring the Safety of COVID-19 Vaccines in the United States

Preparing Your Patients
- Answering Patients' Questions about COVID-19 Vaccination
- Understanding and Explaining mRNA COVID-19 Vaccines

COVID-19 Vaccine Resources for Providers
- What Clinicians Need to Know About the Vaccine [PDF – 36 pages]
- Post Vaccine Considerations for Healthcare Personnel
- Post Vaccine Considerations for Residents
- COVID-19 Vaccination Training Programs and Reference Materials [PDF – 3 pages]

Available at: https://www.cdc.gov/coronavirus/2019-ncov/hcp/vaccination.html
COVID-19 (Coronavirus Disease)

HEALTHCARE WORKERS

Post Vaccine Considerations for Healthcare Personnel

Infection prevention and control considerations for healthcare personnel with systemic signs and symptoms following COVID-19 vaccination

Note: Strategies are needed for healthcare facilities to appropriately evaluate and manage post-vaccination signs and symptoms among healthcare personnel (HCP). The approach described in this document is intended to reduce the risks for disruptions in care and pathogen (e.g., SARS-

Available at: https://www.cdc.gov/coronavirus/2019-ncov/hcp/post-vaccine-considerations-healthcare-personnel.html
COVID-19 Vaccination Communication Toolkit

For Medical Centers, Clinics, and Clinicians

Available at: https://www.cdc.gov/vaccines/covid-19/health-systems-communication-toolkit.html
• 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