Welcome to the NJ COVID-19 Project ECHO

ECHO will begin at 11:15AM EST
Session Agenda

Welcome and Introductions
• Mary Bridgeman, PharmD, Clinical Professor at the Rutgers Ernest Mario School of Pharmacy, Moderator

Greetings from the New Jersey Department of Health
• David J. Adinaro MD, M.Eng., FACEP, Deputy Commissioner, Public Health Services, New Jersey Department of Health

COVID-19 Vaccination Essentials: Safety Process and New Jersey’s Phase 1A of Vaccination
• Eddy A. Bresnitz, MD, MS, Medical Consultant and Chair of the New Jersey Department of Health COVID-19 Professional Advisory Committee, New Jersey Department of Health
• Noelle Bessette, MPH, Surveillance Specialist, Vaccine Preventable Disease Program, New Jersey Department of Health
• Amanda Medina Forrester, MA, MPH, Director, Office of Minority and Multicultural Health

Q&A

ECHO will begin at 11:15 EST
This session will be recorded and may be distributed
Greetings from the New Jersey Department of Health

David J. Adinaro MD, M.Eng., FACEP
Deputy Commissioner
Public Health Services
New Jersey Department of Health
Strategic Aims of New Jersey’s COVID-19 Vaccination Program

(from Executive Summary of New Jersey’s Interim Vaccination Plan)

Provide equitable access to all who live, work, and/or are educated in New Jersey

Achieve community protection, assuming vaccine effectiveness, availability, and uptake

Build sustainable trust in COVID-19 and other vaccines

COVID-19 vaccines

What we know

- Several vaccines are in Phase 3 clinical trials – Pfizer, Moderna and AstraZeneca/Oxford Phase 3 results have been announced
- New Jersey submitted a vaccines rollout plan to the CDC on Oct 16th with a 70% vaccination target of eligible population
- New Jersey can expect ~273K doses of Pfizer and ~218K of Moderna vaccines by the end of December (1st dose prorated by population) post EUA – allocation decisions, including for LTCs, to be made by the State post EUA
- COVID-19 vaccine and some ancillary supplies will be procured and distributed by the federal government at no cost
- Operationalization will be complex given scale, safeguarding, cold-chain and dosing needs
- Given the novel nature of the vaccine, likely under EUA, will result in varying levels of public confidence

What is likely

- FDA could issue emergency use authorization (EUA) of a coronavirus vaccine pre-approval – EUA for Pfizer and Moderna vaccine candidates may be expected by mid- to late December
- Vaccine allotments to jurisdictions will be based on multiple factors, including populations recommended by the ACIP with input from NASEM, current local spread/prevalence, and vaccine availability
- COVID-19 pandemic may not resolve without community protection (herd immunity) or effective vaccination

What we don’t know

- Complete adverse event profile for specific potential vaccines; efficacy for other candidates
- Likelihood of community protection through vaccination
- Detailed understanding of funding mechanisms to provide large-scale vaccination; while vaccines themselves are expected to be free of cost to “Americans” from the federal govt., Centers for Medicare and Medicaid Services is exploring coverage options for vaccine administration costs

1 Call with CDC on 11/30/2020 and Ron Merchant on 11/24/2020; 2 HHS answers to National Governors Association Questions on Vaccine Distribution and Planning week of Oct 26th

SOURCE: CDC guidance on 8/27
What do we need from you?

- Seek knowledge and be informed
- Participate in setting up vaccination sites
- Work with us to build public confidence
- Engage with community as vaccination ambassadors
- Stay safe, stay healthy, …
...and get vaccinated!
COVID-19 Vaccination Essentials: Vaccine Approvals Process

Eddy A. Bresnitz, MD, MS
Medical Consultant and Chair
COVID-19 Professional Advisory Committee
New Jersey Department of Health
Importance of SARS-COV-2 Spike Protein

Spike Protein

SARS-COV-2 (3D Model)

SARS-COV-2 Spike Protein 3D Structure

1. Wrapp et al., 2020, Science.
Advantages of mRNA Vaccine Platform

Safety

Non-infectious, chemically defined, no viral foreign proteins

Efficacy

Broad immune responses, minimal risk of anti-vector immunity, and permits frequent boosting

Rapid Response

Technology enables rapid development and quick production scaling
Review of Efficacy and Safety of Pfizer-BioNTech COVID-19 Vaccine EUA Request
Excerpts from Vaccines and Related Biological Products Advisory Committee (VRBPAC), 12/11/20

Mode of Action of the BNT162 Vaccine Candidates

1. mRNA formulated in LNP enters cell
2. mRNA is released
3. Spike protein is made and processed
4. CD4+ Helper T Cell
   - Activates T and B cells
   - APCs present S protein fragments
5. CD8+ Cytotoxic T Cell
   - Eliminates virus infected cells; potentially increases length of protection
6. B Cell
   - Virus Neutralizing Antibodies
     - Bind Spike proteins and prevent virus infection of human cells
7. Memory T and B cells
   - Provide immune memory to ensure longer-term protection against SARS-CoV-2

Preliminary, pre-decisional, and deliberative. Based on input provided by State agency leaders and staff, to date, and subject to change. Content is descriptive only and is not meant to constitute legal, clinical, or policy advice.
## Vaccine candidate updates – Pfizer and Moderna

<table>
<thead>
<tr>
<th>Dosing Regimen</th>
<th>Pfizer(^1)</th>
<th>Moderna(^2)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0+21 days</td>
<td>0+28 days</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Storage Requirements</th>
<th>Ultra-cold chain (-70°C)</th>
<th>Frozen cold chain (-20°C)</th>
</tr>
</thead>
<tbody>
<tr>
<td>▪ Ship and store at -70°C (dry ice)</td>
<td>▪ Ship at -20°C</td>
<td></td>
</tr>
<tr>
<td>▪ Replenish with dry ice within 24 of receiving, and then every 5 days</td>
<td>▪ Store in refrigeration at 2°C to 8°C up to 30 days</td>
<td></td>
</tr>
<tr>
<td>▪ Shipping container (thermal shipper) can be used to store the vaccines</td>
<td>▪ After thawing, use within 12 hours</td>
<td></td>
</tr>
<tr>
<td>▪ On day 15, transfer to refrigeration at 2°C to 8°C.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>▪ Refrigerate up to 5 days</td>
<td></td>
<td></td>
</tr>
<tr>
<td>▪ After diluting, use within 6 hours</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cold chain shipping and storage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Min 975 dose shipments</td>
</tr>
<tr>
<td>December 2020</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Reported efficacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>95% (as of 11/18/2020)</td>
</tr>
</tbody>
</table>

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3Call with CDC on 11/30/2020
# Review of Efficacy and Safety of Pfizer-BioNTech COVID-19 Vaccine EUA Request

Excerpts from Vaccines and Related Biological Products Advisory Committee (VRBPAC), 12/11/20

## 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>n</td>
<td>Surveillance Time (n)</td>
</tr>
<tr>
<td>First COVID-19 occurrence &gt;7 days after Dose 2</td>
<td>8</td>
<td>2.214 (17,411)</td>
</tr>
</tbody>
</table>

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

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### 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>Subgroup</th>
<th>BNT162b2 N=18,198</th>
<th>Placebo N=18,325</th>
<th>VE (%)</th>
<th>(95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Overall</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>n</td>
<td></td>
<td></td>
</tr>
<tr>
<td>18-64 years</td>
<td>7</td>
<td>143</td>
<td>95.1</td>
<td>(89.6, 98.1)</td>
</tr>
<tr>
<td>65-74 years</td>
<td>1</td>
<td>14</td>
<td>92.9</td>
<td>(53.1, 99.8)</td>
</tr>
<tr>
<td>≥75 years</td>
<td>0</td>
<td>5</td>
<td>100.0</td>
<td>(-13.1, 100.0)</td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>3</td>
<td>81</td>
<td>96.4</td>
<td>(88.9, 99.3)</td>
</tr>
<tr>
<td>Female</td>
<td>5</td>
<td>81</td>
<td>93.7</td>
<td>(84.7, 98.0)</td>
</tr>
<tr>
<td><strong>Race</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>7</td>
<td>146</td>
<td>95.2</td>
<td>(89.8, 98.1)</td>
</tr>
<tr>
<td>Black or African American</td>
<td>0</td>
<td>7</td>
<td>100.0</td>
<td>(31.2, 100.0)</td>
</tr>
<tr>
<td>All Others</td>
<td>1</td>
<td>9</td>
<td>89.3</td>
<td>(22.6, 99.8)</td>
</tr>
<tr>
<td><strong>Ethnicity</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hispanic/Latino</td>
<td>3</td>
<td>53</td>
<td>94.4</td>
<td>(82.7, 98.9)</td>
</tr>
<tr>
<td>Non-Hispanic/Non-Latino</td>
<td>5</td>
<td>109</td>
<td>95.4</td>
<td>(88.9, 98.5)</td>
</tr>
<tr>
<td><strong>Country</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Argentina</td>
<td>1</td>
<td>35</td>
<td>97.2</td>
<td>(83.3, 99.9)</td>
</tr>
<tr>
<td>Brazil</td>
<td>1</td>
<td>8</td>
<td>87.7</td>
<td>(8.1, 99.7)</td>
</tr>
<tr>
<td>USA</td>
<td>6</td>
<td>119</td>
<td>94.9</td>
<td>(88.6, 98.2)</td>
</tr>
</tbody>
</table>

**CC-41**

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

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

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

<table>
<thead>
<tr>
<th></th>
<th>BNT162b2 N=18,198</th>
<th>Placebo N=18,325</th>
<th>VE (%)</th>
<th>(95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Overall</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>At risk(^1)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>4</td>
<td>86</td>
<td>95.0</td>
<td>(90.0, 97.9)</td>
</tr>
<tr>
<td>No</td>
<td>4</td>
<td>76</td>
<td>94.7</td>
<td>(85.9, 98.6)</td>
</tr>
<tr>
<td>Age group at risk</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>16-64 and not at risk</td>
<td>4</td>
<td>69</td>
<td>94.2</td>
<td>(84.4, 98.5)</td>
</tr>
<tr>
<td>16-64 and at risk</td>
<td>3</td>
<td>74</td>
<td>95.9</td>
<td>(87.6, 99.2)</td>
</tr>
<tr>
<td>≥65 and not at risk</td>
<td>0</td>
<td>7</td>
<td>100.0</td>
<td>(29.0, 100.0)</td>
</tr>
<tr>
<td>≥65 and at risk</td>
<td>1</td>
<td>12</td>
<td>91.7</td>
<td>(44.2, 99.8)</td>
</tr>
<tr>
<td>Obese(^2)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>3</td>
<td>67</td>
<td>95.4</td>
<td>(86.0, 99.1)</td>
</tr>
<tr>
<td>No</td>
<td>5</td>
<td>95</td>
<td>94.8</td>
<td>(87.4, 98.3)</td>
</tr>
<tr>
<td>Age group and obese</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>16-64 and not obese</td>
<td>4</td>
<td>83</td>
<td>95.2</td>
<td>(87.3, 98.7)</td>
</tr>
<tr>
<td>16-64 and obese</td>
<td>3</td>
<td>60</td>
<td>94.9</td>
<td>(84.4, 99.0)</td>
</tr>
<tr>
<td>≥65 and not at obese</td>
<td>1</td>
<td>12</td>
<td>91.8</td>
<td>(44.5, 99.8)</td>
</tr>
<tr>
<td>≥65 and obese</td>
<td>0</td>
<td>7</td>
<td>100.0</td>
<td>(27.1, 100.0)</td>
</tr>
</tbody>
</table>

\(^1\) At least one of Charlson Comorbidity index or obesity

\(^2\) Obesity: BMI ≥ 30 kg/m\(^2\)
**First COVID-19 Occurrence From 7 Days After Dose 2 by Comorbidity Status – Evaluable Efficacy (7 Days) Population**

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

<table>
<thead>
<tr>
<th>Comorbidity</th>
<th>BNT162b2 (30 µg) N=18,198</th>
<th>Placebo N=18,325</th>
<th>VE (%)</th>
<th>(95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>8 (2.214 (17,411))</td>
<td>162 (2.222 (17,511))</td>
<td>95.0</td>
<td>(90.0, 97.9)</td>
</tr>
<tr>
<td>Comorbidity</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No comorbidity</td>
<td>4 (76)</td>
<td></td>
<td>94.7</td>
<td>(85.9, 98.6)</td>
</tr>
<tr>
<td>Any comorbidity</td>
<td>4 (86)</td>
<td></td>
<td>95.3</td>
<td>(87.7, 98.8)</td>
</tr>
<tr>
<td>Any malignancy</td>
<td>1 (4)</td>
<td></td>
<td>75.7</td>
<td>(-145.8, 99.5)</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>0 (5)</td>
<td></td>
<td>100.0</td>
<td>(-0.8, 100.0)</td>
</tr>
<tr>
<td>Chronic pulmonary disease</td>
<td>1 (14)</td>
<td></td>
<td>93.0</td>
<td>(54.1, 99.8)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>1 (19)</td>
<td></td>
<td>94.7</td>
<td>(66.8, 99.9)</td>
</tr>
<tr>
<td>Obese (≥30.0 kg/m²)</td>
<td>3 (67)</td>
<td></td>
<td>95.4</td>
<td>(86.0, 99.1)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>2 (44)</td>
<td></td>
<td>95.4</td>
<td>(82.6, 99.5)</td>
</tr>
<tr>
<td>Diabetes (including gestational diabetes)</td>
<td>1 (20)</td>
<td></td>
<td>95.0</td>
<td>(68.7, 99.9)</td>
</tr>
</tbody>
</table>

**CC-43**
Review of Efficacy and Safety of Pfizer-BioNTech COVID-19 Vaccine EUA Request
Excerpts from Vaccines and Related Biological Products Advisory Committee (VRBPAC), 12/11/20

### 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>30 µg 16-55</td>
<td>4.5%</td>
<td>5.8%</td>
<td>83.1%</td>
</tr>
<tr>
<td>Placebo 16-55</td>
<td>1.1%</td>
<td>0.5%</td>
<td>14.0%</td>
</tr>
<tr>
<td>30 µg &gt;55</td>
<td>4.7%</td>
<td>6.5%</td>
<td>71.1%</td>
</tr>
<tr>
<td>Placebo &gt;55</td>
<td>1.1%</td>
<td>1.2%</td>
<td>9.3%</td>
</tr>
</tbody>
</table>

| **Dose 2** |         |          |                        |
| 30 µg 16-55 | 5.9%    | 6.3%     | 77.8%                  |
| Placebo 16-55 | 0.7%    | 0.2%     | 66.1%                  |
| 30 µg >55   | 7.2%    | 7.5%     | 11.7%                  |
| Placebo >55 | 0.7%    | 0.7%     | 7.7%                   |

Redness and swelling severity definition: Mild = >2-5 cm, 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=4580; >55 yrs N=3594  Dose 2: 16-55 yrs N=4201 >55 yrs N=3306

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Review of Efficacy and Safety of Pfizer-BioNTech COVID-19 Vaccine EUA Request
Excerpts from Vaccines and Related Biological Products Advisory Committee (VRBPAC), 12/11/20

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

Systemic events: Green Mild, Blue Moderate, Gray Severe, Red Grade 4

Fever:
- BNT162b2: 16-55: 3.7%, >55: 1.4%
- Placebo: 16-55: 0.9%, >55: 0.4%

Fatigue:
- BNT162b2: 16-55: 47.4%, >55: 34.1%
- Placebo: 16-55: 33.4%, >55: 22.6%

Headache:
- BNT162b2: 16-55: 41.9%, >55: 25.2%
- Placebo: 16-55: 33.7%, >55: 18.1%

Chills:
- BNT162b2: 16-55: 14.0%, >55: 6.3%
- Placebo: 16-55: 6.4%, >55: 3.2%

Vomiting:
- BNT162b2: 16-55: 1.2%, >55: 0.5%
- Placebo: 16-55: 1.2%, >55: 0.5%

Diarrhea:
- BNT162b2: 16-55: 11.1%, >55: 8.2%
- Placebo: 16-55: 11.7%, >55: 6.6%

Muscle Pain:
- BNT162b2: 16-55: 21.3%, >55: 13.9%
- Placebo: 16-55: 10.8%, >55: 8.3%

Joint Pain:
- BNT162b2: 16-55: 11.0%, >55: 8.6%
- Placebo: 16-55: 6.0%, >55: 6.1%

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 times in 24h; Moderate=>2times 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: 16-55 yrs N=4589; >55 yrs N=3594  Dose 2: 16-55 yrs N=4201 >55 yrs N=3306

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Review of Efficacy and Safety of Pfizer-BioNTech COVID-19 Vaccine EUA Request
Excerpts from Vaccines and Related Biological Products Advisory Committee (VRBPAC), 12/11/20

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

- **Systemic events:** Mild, Moderate, Severe, Grade 4
- **Fever:** 38.0 °C-38.4 °C, 38.4 °C-38.9 °C, 38.9 °C-40.0 °C, >40.0 °C

**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 times 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: 16-55 yrs N=4589; >55 yrs N=3594  Dose 2: 16-55 yrs N=4201 >55 yrs N=3306*
Efficacy

- The totality of the clinical data submitted with the EUA request meets the expectations for duration of follow-up.
- In the final efficacy analysis, vaccine efficacy after 7 days post Dose 2 was **95%** (95% CI: 90.3; 97.6) in participants without prior evidence of SARS-CoV-2 infection.
- Efficacy outcomes were consistent (≥93%) across demographic subgroups.
- Efficacy against severe COVID-19 occurring after the first dose was **88.9%** (95% CI: 20.1, 99.7).
  - The small number of severe cases is a limitation to these data.
- A trend of potential efficacy following a single dose is observed in the data, however a conclusion is limited because almost all participants received a second dose.

Safety

- The totality of the clinical data submitted with the EUA request meets the expectations for duration of follow-up and evaluation of the all-enrolled population provided additional safety data from a total of >43,000 participants.
- Reactogenicity was generally more frequent after Dose 2 (all ages), mostly mild to moderate, and with less frequency and severity in adults >55 yrs than in younger adults.
  - There were no other specific safety concerns identified in subgroup analyses by age, race, ethnicity, medical comorbidities, or prior SARS-CoV-2 infection.
- As of data the cutoff, 4 cases of Bell’s palsy were reported in vaccine recipients, and none in placebo recipients. Although there is no clear basis upon which to conclude a causal relationship at this time, FDA recommends further surveillance if vaccine is authorized for widespread use.

https://www.fda.gov/media/144245/download
Sequence of steps and estimated timeline for the Pfizer vaccine and Moderna vaccine

**COVID-19 VACCINE TIMELINE**
**DECEMBER 2020**

- **FDA Issues Emergency Use Authorization**
- **Operation Warp Speed Ships Limited Doses to Select Hospitals**
  - **PFIZER: DECEMBER 11-12**
  - **MODERNA: DECEMBER 18-20**
- **VRBPAC* Federal Advisory Committee Makes Recommendations to FDA†**
  - **PFIZER: DECEMBER 10**
  - **MODERNA: DECEMBER 17**
- **CDC Immunization Group Reviews Vaccine Data**
  - **CDC Director Approves Their Recommendations**
  - **Recommendations Become Official CDC Guidance**
  - **PFIZER: DECEMBER 11-14**
  - **MODERNA: DECEMBER 18-21**

**Vaccination Begins in Hospitals Where Vaccine Was First Shipped**
**Operation Warp Speed Ships Initial Doses Allocated to States**
**Vaccination Commences at State-Allocated Sites**

**PFIZER: DECEMBER 15-31**
**MODERNA: DECEMBER 22-31**

* VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE
† CENTERS FOR DISEASE CONTROL
‡ U.S. FOOD AND DRUG ADMINISTRATION

SOURCE: Operation Warp Speed
COVID-19 Vaccination Essentials: Post-Administration Safety Monitoring

Noelle Bessette, MPH
Surveillance Specialist
Vaccine Preventable Disease Program
New Jersey Department of Health
Adverse Event (AE) Reporting Under the EUA

**Vaccine Recipients**
- Voluntary Reporting
  - Spontaneous reports
  - Solicited reports from V-SAFE program

**Vaccination Providers**
- Mandatory Reporting
  - Vaccination administration errors
  - Serious adverse events (SAEs)
  - Multisystem Inflammatory Syndrome
  - Cases of COVID-19 that result in hospitalization or death

**Vaccine EUA Sponsor**
- Monthly Periodic Safety Reports
  - Analysis of aggregate AE data
  - Newly identified safety concerns

**CDC**
- Review of all Adverse Events of Special Interest (AESI)
- Data Abstraction

**FDA**
- Screening of all incoming SAEs
- Literature review
- Data Mining
- Potential safety signals will be further evaluated

**Coordination Data Sharing**
VAERS Overview

Vaccine Adverse Event Reporting System

Co-managed by CDC and FDA

http://vaers.hhs.gov

VAERS is the nation’s frontline system for monitoring vaccine safety

https://www.nj.gov/health/cd/vaersindex.shtml
VAERS: What can be tracked according to CDC

Vaccine Adverse Event Reporting System (VAERS)

**Strengths**
- National data
- Accepts reports from anyone
- Rapidly detects safety signals
- Can detect rare adverse events
- Data available to public

**Limitations**
- Reporting bias
- Inconsistent data quality and completeness
- Lack of unvaccinated comparison group
- Generally cannot assess causality

- VAERS accepts all reports from all reporters without making judgments on causality or clinical seriousness of the event
- As a hypothesis generating system, VAERS identifies potential vaccine safety concerns that can be studied in more robust data systems

https://www.nj.gov/health/cd/vaersindex.shtml
V-safe overview from CDC

- **v-safe** is a new smart-phone based active surveillance program for COVID-19 vaccine safety
  - Uses text messaging to initiate web-based survey monitoring
  - Conducts electronic health checks on vaccine recipients
    - Daily for first week post-vaccination; weekly thereafter until 6 weeks post-vaccination
    - Additional health checks at 3, 6, and 12 months post-vaccination
  - Includes active telephone follow-up through the VAERS program with vaccine recipients reporting a clinically important event during any **v-safe** health check
    - A VAERS report will be taken during telephone follow-up, if appropriate
  - Captures information on pregnancy status and enables follow-up on pregnant women
V-safe pathway from CDC

1. Text message check-in or email from CDC (daily 1st week post-vaccination and weekly thereafter until 6 weeks post-vaccination)

Vaccine recipient completes web survey

2. Clinically important event(s) reported
   - Missed work
   - Unable to do normal daily activities
   - Received medical care

VAERS call center

3. A VAERS customer service representative conducts active telephone follow-up on a clinically important event and completes a VAERS report if appropriate
COVID-19 Vaccination Essentials: Phased Approach and NJ’s Phase 1A

Amanda Medina Forrester, MA, MPH
Director
Office of Minority and Multicultural Health
New Jersey Department of Health
Who can get vaccinated when (estimated) in NJ?

Where can you get vaccinated in NJ?

How can you get vaccinated?

12/11/20 ECHO Webinar

12/14/20 ECHO Webinar
Who and when can we expect a vaccine in NJ?

New Jersey’s current Phase
as of December 11, 2020

Phase 1A
- Healthcare workers
- Long-Term Care residents

Mid-December 2020

Phase 1B
- Other essential workers

Phase 1C
- Adults 65+ years of age
- Adults with high-risk medical conditions

Phase 2
- General Population

Spring 2021

Preliminary, pre-decisional, and deliberative. Based on input provided by State agency leaders and staff, to date, and subject to change. Content is descriptive only and is not meant to constitute legal, clinical, or policy advice.
Recommendations by the Advisory Committee on Immunization Practices (ACIP) to the Centers for Disease Control and Prevention (CDC)

Health Care Personnel

“Paid and unpaid persons serving in a health care setting who have the potential for direct or indirect exposure to patients or infectious materials”

- High-risk locations for SARS-CoV-2 exposure and transmission
- Early protection of health care personnel is critical to preserve capacity to care for patients with COVID-19 or other illnesses.

Long-Term Care Facility Residents

“Adults who reside in facilities that provide a range of services, including medical and personal care, to persons who are unable to live independently.”

- High-risk locations for SARS-CoV-2 exposure and transmission
- At high risk for infection and severe illness due to age, high rates of underlying medical conditions, and congregate living situation

https://www.cdc.gov/mmwr/volumes/69/wr/mm6949e1.htm
What is considered a healthcare setting?

Hospitals of any type

Long-term care facilities, for example:
- Skilled nursing facilities
- Veteran's homes
- Assisted living facilities, continuing care retirement communities, and personal care homes
- HUD Supportive Housing for the Elderly Program housing
- Group homes like residential care homes, residential dementia care homes, comprehensive care homes, adult family homes, adult foster homes, and intellectual and developmental disabilities IDD group homes
- Other vulnerable, congregate, long-term settings

Other settings or contexts, for example:
- Ambulatory care facilities
- Community health centers
- Dental and other physician offices
- Dialysis centers
- Emergency Medical Services
- Family planning centers
- Federally Qualified Health Centers (FQHCs)
- Funeral homes, cemeteries, crematoria
- Harm reduction centers
- Health clinics in workplaces, K-12 schools, universities, shelters, jails
- HIV/Sexually Transmitted Disease clinics
- Home care or visiting nurse agencies

Hospice centers
Intermediate care facilities
Local public health departments, LINCS agencies
Medical Marijuana Program Dispensary
Medical Reserve Corps
Other health settings like rehabs
Pharmacies
Psychiatric facilities
School nursing and health centers
Shelter health clinics
Transitional living facilities
Urgent care clinics
Other settings where healthcare is provided

For more information please visit our website
Who is considered a healthcare worker?

Any paid or unpaid person working or volunteering in a healthcare setting who may have direct or indirect contact with infectious persons or materials. For example:

- Doctors, nurses, pharmacists, dentists and any other licensed or registered health professionals

- Staff in areas like Facilities management, Security, Food services, Environmental Services, Administrative services, Human Resources, Reception, Language Services, Information Technology, Laboratory and any other support areas

- Community health workers / promotoras, doulas, health educators and public health professionals

- Trainees, students, volunteers, essential caregivers, vaccinating site staff, contractors

- Other personnel like Emergency Medical Services (EMS), paramedics, funeral staff, mortuary staff and autopsy workers

... and other paid or unpaid persons working in a healthcare setting
# Expected cost associated with COVID-19 vaccines

<table>
<thead>
<tr>
<th>Vaccine costs</th>
<th>Administration costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consumers</td>
<td>Providers</td>
</tr>
<tr>
<td>• Free of charge</td>
<td>• Free of charge</td>
</tr>
<tr>
<td>• Free of charge from federal government¹</td>
<td>• Reimbursement of $16.90 for first dose and $28.40 for second dose expected</td>
</tr>
<tr>
<td></td>
<td>• Insured persons: To be billed to private insurer, Medicaid, Medicare, etc.</td>
</tr>
<tr>
<td></td>
<td>• Uninsured persons: To be reimbursed through the federal uninsured fund managed by Health Resources and Services Administration (HRSA), which has already been covering the cost of care for uninsured COVID-19 patients¹</td>
</tr>
</tbody>
</table>

¹ From U.S. Department of Health and Human Services Answers to National Governors Association Questions on Vaccine Distribution and Planning
Public confidence building is critical

3000+ Stakeholders engaged across federal, state and local leaders; healthcare providers and professional associations, community and faith based organizations employers and unions, consumer groups

Provider survey analyzed, and consumer confidence surveys launched using existing call centers. Provider survey call volumes to help desk also monitored

~12 Listening Sessions hosted to understand attitudes towards vaccines across consumer and provider groups

Multi-pronged public awareness campaign being launched in December

Vaccine webpage updated consistently as new CDC and other information and guidance becomes available

Weekly newsletter launched (maiden Dec. 4th, 2020) to keep stakeholders abreast with the latest vaccine related developments
In the News

Pfizer BioNTech Gets UK Emergency OK

Britain is the first country to grant emergency approval for a COVID-19 vaccine developed by Pfizer and BioNTech, and officials said a mass immunization program would begin. The Washington Post reported.

CDC Advisory Panel Recommends Priority Populations for Initial Vaccine

Healthcare workers and residents of long-term care facilities would be the first recipients of a COVID-19 vaccine in the initial rollout under recommendations approved by the Advisory Committee for Immunization Practices (ACIP) on Dec. 1 and sent to the CDC for final approval. According to the CDC’s COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations, healthcare workers are defined as “all paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infection materials.” NIDOH’s vaccination planning aligns with including these populations in Phase 1A.

CDC Offers Quarantine Options

While continuing to recommend a 14-day quarantine period for people exposed to COVID-19, the CDC has recommended two options for ending the period earlier: 10 days if a test and no symptoms or 7 days with a negative test and no symptoms. The CDC said the recommendations were made on extensive modeling.

Providers Signing On To Administer COVID-19 Vaccines

Throughout the state, healthcare providers are signing up to be able to provide vaccines. More than 300 provider sites in New Jersey have completed the steps to be enrolled as providers of the vaccine with more applications pending. This includes hospitals, local health departments and Federally Qualified Health Centers, among other providers.

“People are very interested in being part of the vaccination effort in one way or another,” said Barbara Mottola, MD, MPH, Medical Director, Communicable Disease Service/Vaccine Preventable Disease Program, New Jersey Department of Health (NJDH).

Under the agreements, providers must follow CDC guidelines in administering the vaccine and submit dosage data to the New Jersey Immunization Information System (NJIIS). Providers also must comply with CDC requirements for vaccine management including proper storage and handling of the vaccine, and must administer the vaccine regardless of the recipient’s ability to pay.

A COVID-19 Vaccine On-demand webinar is available on the NJIIS page for healthcare providers who will be administering the COVID-19 vaccine and is required for all vaccinators.

Some facilities, such as local health departments, can also serve as a Point of Distribution (POD) in their communities. Pre-registration is available for providers interested in hosting a POD.

What is a POD?

A POD (Point of Distribution) is a temporary site where vaccinated adults can be safely administered to people in large numbers. There are several PODs already established in every county in New Jersey.

Pharmacies to Bring Vaccines to Long-Term Care Facilities

Residents and staff of long-term care facilities (LTCF) have been a priority throughout the state’s vaccine planning. Reflecting this prioritization, New Jersey is participating in the Pharmacy Partnership for Long-Term Care Vaccine Distribution. Federal agencies have partnered with CVS and Walgreens to provide end-to-end management of the vaccination process, including storage, handling, cold chain management, on-site vaccinations, and fulfillment of reporting requirements.

During the October sign-up period, NIDOH actively promoted this opportunity to long-term care providers and now is working with CDC and Operation Warp Speed to optimize the number of facilities accepted into the program.

For enrolled facilities, the partnership will facilitate safe and effective vaccination for their population as well as for those serving in LTCFs who are eligible in Phase 1A and who have not yet been vaccinated off-site. CVS and Walgreens will work with partners to make sure these persons are vaccinated.

How much of COVID vaccine will be needed?

Both the Pfizer (21 days apart) and Moderna (28 days apart) vaccine candidates that are pending emergency use authorization require two shots. Other vaccines in clinical trials require two or more shots.

Subscribe here:
https://www.state.nj.us/health/cd/topics/vmsignup.shtml

Pre-decisional, and deliberative. Based on input provided by State agency leaders and staff, to date, and subject to change. Content is descriptive only and is not meant to constitute legal, clinical, or policy advice.
Key Resources

- CDC Interim COVID-19 Vaccination Playbook
- CDC Checklist of Best Practices for Vaccination Clinics Held at Satellite, Temporary or Off-Site Locations
- CDC Vaccine Storage and Handling Toolkit
- CDC Skills Checklist for Vaccine Administration
- CDC Epidemiology and Prevention of Vaccine-Preventable Diseases
- New Jersey COVID-19 Vaccination Plan
- New Jersey COVID-19 Vaccination Plan Executive Summary
- CDC Vaccine Administration Resource Library
Appendix: Resources
COVID–19 Vaccine Frequently Asked Questions (1/4)

General Vaccine Information

What is Operation Warp Speed?
Operation Warp Speed is a partnership among components of the U.S. Department of Health and Human Services (HHS) and the U.S. Department of Defense to help develop, make, and distribute millions of vaccine doses for COVID–19 as quickly as possible while ensuring that the vaccines are safe and that they work. Learn more about Operation Warp Speed by visiting https://www.hhs.gov/coronavirus/explaining-operation-warp-speed/index.html.

Who is the CDC and what is their role with the COVID–19 vaccine?
The Centers for Disease Control and Prevention (CDC) is the national public health institute in the United States under the Department of Health and Human Services. The CDC’s overall responsibility is to address health and safety. The CDC is focused on vaccine planning, working closely with health departments and partners to prepare for when a vaccine is available. The CDC does not have a role in developing COVID19 vaccines. Learn more about the vaccine planning process by visiting https://www.cdc.gov/coronavirus/2019-ncov/vaccines/8-things.html.

What is New Jersey doing to plan for the COVID–19 vaccine?
The New Jersey Department of Health collaborated with health care partners and immunization stakeholders to submit a vaccine plan to the CDC on October 16, 2020. This plan encompasses suggested priority groups for vaccination, logistics of vaccine storage and handling, health care provider recruitment, tracking and reporting of immunizations, etc. Since no vaccine is currently available, we are closely following progress on COVID–19 vaccine trials and potential U.S. Food and Drug Administration (FDA) authorized vaccine(s). The Department will continue to update the plan as we receive new information and federal guidance.

What is New Jersey doing to plan for the COVID–19 vaccine?

Is a COVID–19 vaccine necessary?
COVID–19 can be a minor illness in some or lead to severe disease or even death in previously healthy people. This means, everyone should take the virus seriously — if not for themselves, then for those around them. Many treatments and medications are being studied, but there is no cure. Prevention is key. Vaccination is an important step in helping to prevent this illness and its potentially devastating consequences.

How much will a vaccine reduce the risk of COVID–19 and its complications?
The U.S. Food and Drug Administration (FDA) guidance expects that an authorized or approved COVID–19 vaccine would prevent disease or decrease its severity in at least 50% of people who are vaccinated. In some cases, COVID–19 vaccines may protect against severe infection, but not necessarily prevent mild or asymptomatic infection. If this is the case, an infected person could still spread the virus. This is why it is expected that even after a vaccine becomes available, people will need to use masks and practice social distancing measures for some time.

How many COVID–19 vaccines are under development?
Multiple COVID–19 vaccines are under development. As of October 13, 2020, four vaccines have begun large-scale (phase 3) clinical trials in the United States. For additional information, please see the WHO website at https://www.who.int/emergencies/diseases/novel-coronavirus-2019/covid-19-vaccines?gclid=EAIaIQobChMIroXC2uvD7AlVNgilCR3pCg1JEAYAAAEgJi7_D_BwE.

When will NJ receive the COVID–19 vaccine(s)?
At first, there may be limited supply of COVID–19 vaccine(s). The Centers for Disease Control and Prevention (CDC) and Operation Warp Speed (OWS) will work together to get those first vaccines doses out once a vaccine is authorized or approved and recommended. New Jersey will receive an allocation of vaccine from the federal government when the vaccine is authorized or approved. When a safe and effective vaccine(s) is available, it will be distributed in a manner that is fair, ethical, transparent and timely for New Jerseyans.

Who is likely to be among the first to receive the vaccine?

Final decisions are being made about use of initially available limited supplies of COVID-19 vaccines. These decisions will be informed by the proven efficacy of the vaccines coming out of Phase 3 trials; recommendations from the Advisory Committee on Immunization Practices; and guidance from the Centers for Disease Control and Prevention and other federal agencies. The CDC has provided guidance to states that populations of focus for initial COVID-19 vaccination may include:

- Healthcare personnel likely to be exposed to or treat people with COVID-19.
- Long-term care residents
- People at risk for severe illness from COVID-19, including those with underlying medical conditions and people 65 years of age and older
- Other essential workers

Plans will be reviewed and adjusted accordingly once the amount of vaccine coming to New Jersey is known.

How many shots of COVID vaccine will be needed?

Three clinical trials in the United States use two shots. The other COVID-19 vaccine uses one shot.

Who is paying for COVID-19 vaccine?

According to the CDC, "Vaccine doses purchased with U.S. taxpayer dollars will be given to the American people at no cost. However, vaccination providers will be able to charge an administration fee for giving the shot to someone. Vaccine providers can get this fee reimbursed by the patient’s public or private insurance company or, for uninsured patients, by the Health Resources and Services Administration’s Provider Relief Fund."


Do I need to wear a mask when I receive a COVID-19 vaccine?

Yes. CDC recommends that during the pandemic people wear a mask that covers their nose and mouth when in contact with others outside your household, when in healthcare facilities, and when receiving any vaccine, including a COVID-19 vaccine. Anyone who has trouble breathing or is unable to remove a mask without assistance should not wear a mask. For more information, visit considerations for wearing masks.


Is this a "live" virus vaccine?

There are different types of vaccines being tested, but we will have to wait for results before seeing which vaccines will be available. For detailed information about the various kinds of vaccines, visit https://www.chop.edu/centers-programs/vaccine-education-center/makingvaccines/prevent-covid

Can mRNA vaccines change the DNA Of a person?

An mRNA vaccine causes cells to make viral proteins, in this case it is making proteins found in the SARS-CoV-2 virus which is the virus that causes COVID-19. When the proteins are made, they are released from the cell and cells from the immune system recognize them as foreign and attack them, creating an immune response. Since mRNA is active only in a cell’s cytoplasm and DNA is located in the nucleus, mRNA vaccines do not operate in the same part of the cell where DNA is located. The mRNA would not change a person’s DNA.

SOURCE: COVID-19 Vaccine Healthcare Provider Frequently Asked Questions, December 1, 2020 and CDC Frequently asked questions about vaccination
COVID–19 Vaccine Frequently Asked Questions (3/4)

Safety Concerns

**Will the COVID-19 vaccine be safe and effective?**
The safety of COVID-19 vaccines is a top priority. Currently, clinical trials are evaluating investigational COVID-19 vaccines in many thousands of study participants to generate scientific data and other information for the FDA to determine their safety and effectiveness. These clinical trials are being conducted according to rigorous safety standards. For detailed information, visit [https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html](https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html)

**What are clinical trials? I am concerned that this vaccine was made too quickly and did not undergo enough testing as other vaccines.**
Clinical trials are research studies performed in people that are aimed at evaluating a medical, surgical, or behavioral intervention. They are the primary way that researchers find out if a new treatment, like a new drug, vaccine, or medical device is safe and effective in people. Currently, clinical trials are evaluating investigational COVID-19 vaccines in many thousands of study participants to generate scientific data and other information for the FDA to determine their safety and effectiveness. These clinical trials are being conducted according to rigorous standards set forth by the FDA. For detailed information, visit [https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html](https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html)

**How can I sign up for a clinical trial?**

**Is the COVID-19 vaccine safe for pregnant women? Breastfeeding women?**
In early clinical trials for various COVID-19 vaccines, only non-pregnant adults participated. For this reason, the vaccine will not be available for use in pregnant women when it first becomes available. However, clinical trials continue to expand those recruited to participate. Based on data from the expanded clinical trials, groups recommended to receive the vaccines could change in the future.

**Can children get the COVID-19 vaccine?**
In early clinical trials for various COVID-19 vaccines, only non-pregnant adults participated. For this reason, the vaccine will not be available for use in children when it first becomes available. The groups recommended to receive the vaccines could change in the future.

Vaccine Availability

**What should I do to protect myself since the COVID vaccine is not available?**
You should cover your mouth and nose with a mask when around others, avoid close contact with people who are sick, stay 6 feet away from others, avoid crowds, and wash your hands often. Get more information about these and other steps you can take to protect yourself and others from COVID-19.

**Will the vaccine be available to everyone in New Jersey?**
Final decisions are being made about use of initially available limited supplies of COVID-19 vaccines. These decisions will be informed by the proven efficacy of the vaccines coming out of Phase 3 trails; recommendations from the Advisory Committee on Immunization Practices; and guidance from the Centers for Disease Control and Prevention and other federal agencies. The CDC has provided guidance to states that populations of focus for initial COVID-19 vaccination may include:

- Healthcare personnel likely to be exposed to or treat people with COVID-19.
- People at risk for severe illness from COVID-19, including those with underlying medical conditions and people 65 years of age and older
- Other essential workers

The Department is developing plans to distribute vaccines in a fair, ethical, and transparent way and relying on guidance from federal agencies. Plans will be reviewed and adjusted accordingly once the amount of vaccine coming to New Jersey is known.

SOURCE: COVID-19 Vaccine Healthcare Provider Frequently Asked Questions, December 1, 2020, CDC Frequently asked questions about vaccination and NIH National Institute on Aging on Clinical trials and studies
If I had COVID-19 antibody serology done and have antibodies, do I still need to get vaccinated?

There is not enough information currently available to say if or for how long after infection someone is protected from getting COVID-19 again; this is called natural immunity. Early evidence suggests natural immunity from COVID-19 may not last very long, but more studies are needed to better understand this. Until we have a vaccine available and know more about natural immunity to COVID-19, CDC cannot comment on whether people who had COVID-19 should get a COVID-19 vaccine.

Once a vaccine has been authorized or approved, ACIP will make recommendations to CDC on who should get a COVID-19 vaccine.

If I had COVID-19 and recovered do I need to get the vaccine?

There is not enough information currently available to say if or for how long after infection someone is protected from getting COVID-19 again; this is called natural immunity. Early evidence suggests natural immunity from COVID-19 may not last very long, but more studies are needed to better understand this. Until we have a vaccine available and the Advisory Committee on Immunization Practices makes recommendations to CDC on how to best use COVID-19 vaccines, CDC cannot comment on whether people who had COVID-19 should get a COVID-19 vaccine.

Can I get the flu shot and the new COVID-19 vaccine on the same day?

Once COVID-19 vaccine(s) are authorized or approved by FDA, CDC will provide administration guidance.