Immunization Branch

- The Immunization Branch works to reduce the incidence of VPD and ensures access to vaccine services for all Coloradans.

- **Colorado Immunization Information System**
  - 77.2 million immunizations, 6.8 million patients
  - 3,405 clinics - 84.2% of known immunizing providers

- **Vaccines for Children/317 Program**
  - 550 providers (LPHAs, private providers, IHS, Community/Rural Health Clinics, Hospitals)
  - 5,870 orders for 996,627 doses valued at more than $56 million (annually)
COVID-19 Vaccine Candidates

**Pfizer Vaccines**
- 2 doses (28d)
- Efficacy: 95%
- Ultra cold: 6 mos; fridge: 5 days
- 975 dose min order
- Begins arriving in December
- Produced in US and Belgium

**Moderna**
- 2 doses (21d)
- Efficacy: 94.5%
- Frozen: 6 mos; fridge 30 days
- 100 dose min order
- Begins arriving in December
- Produced in US

**Janssen**
- 1 or 2 doses
- Efficacy: UNK
- Frozen: 2 yrs; fridge 3 mos
- Expect EUA Jan/Feb
- Produced in US

**Oxford Biomedica**
- 2 doses (28d)
- Efficacy: 90% - 62%
- Fridge: 6 mos
- Expect EUA Feb/Mar
- Produced in UK
- AKA Astrazeneca

All come with Ancillary Kit containing: syringes, needles, alcohol pads, masks, face shields, vaccination cards. Pfizer also comes with diluent for mixing prior to administration.
<table>
<thead>
<tr>
<th>PRIMARY</th>
<th>Pfizer (BNT162b2) - EUA submitted 11/20/20</th>
<th>Moderna (mRNA-1273) - EUA submitted 11/30/2020</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trial Size</strong></td>
<td>41,135 already received 2nd dose (43,661 total enrolled)</td>
<td>25,654 already received 2nd dose (&gt;30,000 enrolled)</td>
</tr>
<tr>
<td><strong>Efficacy</strong></td>
<td>95% (162 cases placebo group vs 8 cases in vaccine group)</td>
<td>94.5% (185 cases placebo group vs 11 cases in vaccine group)</td>
</tr>
<tr>
<td><strong>Immunity onset</strong></td>
<td>7 days from 2nd dose</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Severe cases</strong></td>
<td>9 in placebo group vs 1 in vaccine group</td>
<td>30 in placebo (1 death) vs 0 in vaccine group</td>
</tr>
</tbody>
</table>
| **Side effects** | Fatigue 3.8%  
Headache 2.0%  
No severe adverse events  
Older adults fewer side effects | Injection site pain 2.7%  
Fatigue 9.7%  
Myalgia 8.9%  
Arthralgia 5.2%  
Headache 4.5%  
Pain 4.1%  
Erythema/redness 2.0%  
No severe adverse events |
<table>
<thead>
<tr>
<th>Sub-Groups</th>
<th>Pfizer (BNT162b2)</th>
<th>Moderna (mRNA-1273)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Older adults</td>
<td>45% age 56-85 (40.9% internationally) 94% efficacy for those ≥65 years in subgroup analysis</td>
<td>&gt;7,000 (23%) age ≥65 No difference in efficacy or side effects in subgroup analysis</td>
</tr>
<tr>
<td>Minorities</td>
<td>30% racially/ethnically diverse backgrounds in US, 42% internationally</td>
<td>&gt;11,000 from communities of color</td>
</tr>
<tr>
<td></td>
<td>-10.1% black (10.0% internationally)</td>
<td>-&gt;6,000 (&gt;20%) self-identify as Hispanic/LatinX</td>
</tr>
<tr>
<td></td>
<td>-13.1% Hispanic (26.1% internationally)</td>
<td>-&gt;3,000 (&gt;10%) self-identify as Balck</td>
</tr>
<tr>
<td></td>
<td>No difference in efficacy or side effects in subgroup analysis</td>
<td>No difference in efficacy or side effects in subgroup analysis</td>
</tr>
<tr>
<td>High Risk Conditions</td>
<td>N/A</td>
<td>17% age 18-65 with high risk condition (many people 65+ also had another high risk condition)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>-36% with DM among high risk group</td>
</tr>
<tr>
<td></td>
<td></td>
<td>-25% with severe obesity among high risk group</td>
</tr>
<tr>
<td></td>
<td></td>
<td>No difference in efficacy or side effects in subgroup analysis</td>
</tr>
</tbody>
</table>
Pfizer Vaccine - Shipment Assumptions

- Separately acquired components mixed onsite
  - Vaccine
    - Direct to site from manufacturer on dry ice (riced or pelleted)
    - Multidose vials (5 doses per vial)
  - Diluent
    - Direct to site at room temperature
  - Ancillary supply kits (for administration and mixing)
    - Direct to site at room temperature
    - Does NOT include gloves, bandages, sharps
    - Additional PPE may be needed depending on vaccination provider needs
- Orders - large capacity
  - Minimum order ~1,000 doses (1 tray = 975 doses)
  - Maximum order ~5,000 doses (5 trays = 4,875 doses)
**Pfizer Vaccine - Onsite Storage Options**

1. **Ultra-Low Temperature Freezer**
   - Store as frozen liquid at -75°C±15°C for long term storage.
     - Emergency Use vials are labeled as -70°C±10°C, however they can be safely stored in a freezer set to -75°C±15°C
   - Different size of ULT freezers are available in the market.

   A small size (under or over the countertop ULT Freezers can store as much as 30K doses)

   ![Ultra-Low Temperature Freezer Image]

2. **Thermal Shipper Designed for Temporary Storage**
   - Within 24 hours of receipt and after opening the thermal shipper, replenish/inspect with dry ice (using proper personal protective equipment and dry ice handling).
   - With every re-icing, thermal shipper can maintain ultra-low temperature storage for 5 days with 2 openings per day.
   - Multiple dry ice replenishments possible; up to 3 re-icings.
   - Local dry ice suppliers can be used for re-icing the thermal shipper.
   - The thermal shipper to be returned within 10 business days and no later than 20 business days including temperature data logger (picked up by Pfizer/BioNTech contracted supplier)
   - Apply appropriate dry ice monitor

   ![Thermal Shipper Designed for Temporary Storage Image]

3. **2 to 8°C Refrigerator**
   - Can be stored at 2 to 8°C up to 5 days
   - Room temperature hold time is no more than 2 hours.
   - Thawing: 3 hours at 2 to 8°C or 30 min at room temperature.
   - Post-dilution in use period is 6 hours.

   ![2 to 8°C Refrigerator Image]
**Vaccine Storage**

Shipped CONUS < 24 hours
Thermal shipping container maintains -60°C to -80°C up to 10 days without opening at room temperature

**Option 1**
Placed in ultra-cold temperature freezer

**Option 2**
Maximize use of thermal shipping container
- 5 Days
- Re-ice

**Option 3**
One-time re-ice of thermal shipping container
- 5 Days
- Re-ice
- Refrigeration 2°-8°C

**Option 4**
Immediately placed in refrigerator
- 5 Days
- Refrigeration 2°-8°C

If the thermal shipping container will be used for storage, it must be re-iced within 24 hours of initial inspection and then every 5 days thereafter. Up to 3 re-icings are authorized. Product stable for ~6 months.

**Vaccine Thawing**

Minimum shipper quantity: 1 tray (195 vials, 975 doses)
Maximum shipper quantity: 5 trays (975 vials, 4875 doses)

If removed directly from ultra-cold temperatures, thaw vial at room temperature 30 minutes to 2 hours before dilution.

Once vaccine is thawed, it must be diluted within 2 hours; if unable to dilute within 2 hours, store at 2°-8°C

Must use diluted vaccine within 6 hours (discard any unused, diluted vaccine after 6 hours)

FOR OFFICIAL USE ONLY - DO NOT DISTRIBUTE
# Site Types for Vaccine A Product

<table>
<thead>
<tr>
<th>Vaccination provider site</th>
<th>Order size</th>
<th>Storage conditions</th>
<th>Patient flow</th>
<th>Number of immunizers</th>
<th>Operating assumptions</th>
<th>Operating assumptions</th>
<th>Operating assumptions</th>
<th>Operating assumptions</th>
<th>Operating assumptions</th>
<th>Operating assumptions</th>
</tr>
</thead>
<tbody>
<tr>
<td>A – large outpatient center (mass vx)</td>
<td>1 tray</td>
<td>Thermal box with dry ice, 2-8°C fridge, for product estimated at site (5 days)</td>
<td>~500/day</td>
<td>10 immunizers</td>
<td>Patients per immunizer: 6 patients/hour (~10 min/Vx)</td>
<td>Hours per day: 8 hours</td>
<td>Vaccines per day: 480 vaccinations</td>
<td>Shipment model: 1 tray; 2-3 times per week</td>
<td></td>
<td></td>
</tr>
<tr>
<td>B – hospital or outpatient center</td>
<td>1 tray</td>
<td>Ultra-cold freezer, Thermal box with dry ice, 2-8°C fridge, for product estimated at site (5 days)</td>
<td>Variable</td>
<td>4 immunizers</td>
<td>Patients per immunizer: 6 patients/hour (~10 min/Vx)</td>
<td>Hours per day: 8 hours</td>
<td>Vaccines per day: 192 vaccinations</td>
<td>Shipment model: 1 tray; every week</td>
<td></td>
<td></td>
</tr>
<tr>
<td>C – large hospital with affiliated outpatient center</td>
<td>5 trays</td>
<td>Ultra-cold freezer, Thermal box with dry ice, 2-8°C fridge, for product estimated at site (5 days)</td>
<td>Variable</td>
<td>7 immunizers</td>
<td>Patients per immunizer: 6 patients/hour (~10 min/Vx)</td>
<td>Hours per day: 8 hours</td>
<td>Vaccines per day: 340 vaccinations</td>
<td>Shipment model: 1 tray; 1-2 times a week</td>
<td></td>
<td></td>
</tr>
<tr>
<td>D – outdoor parking lot vaccination hub at large retail pharmacy</td>
<td>1 tray</td>
<td>2-8°C fridge, for product estimated at site (5 days)</td>
<td>~200/day</td>
<td>5 immunizers</td>
<td>Patients per immunizer: 6 patients/hour (~10 min/Vx)</td>
<td>Hours per day: N/A</td>
<td>Vaccines per day: 240 vaccinations</td>
<td>Shipment model: 1 tray; every week</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E – mobile vaccination in targeted geographic areas</td>
<td>5 trays</td>
<td>2-8°C fridge, for product estimated in mobile unit (5 days)</td>
<td>Variable</td>
<td>3 immunizers</td>
<td>Patients per immunizer: 6 patients/hour (~10 min/Vx)</td>
<td>Hours per day: Not specified</td>
<td>Vaccines per day: 150 vaccinations</td>
<td>Shipment model: 1 tray; every week</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Site Types for Vaccine A Product

<table>
<thead>
<tr>
<th>Vaccination provider site</th>
<th>Order size</th>
<th>Storage conditions</th>
<th>Patient flow</th>
<th>Number of immunizers</th>
<th>Patients per HCP (~10 min/Vx)</th>
<th>Hours per day</th>
<th>Vaccines per day</th>
<th>Shipment model</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>F</strong> – large indoor spaces not used during pandemic (convention hall)</td>
<td>5 trays (4,675 doses)</td>
<td>Thermal box with dry ice, 2-8C fridge, for product estimated at site (5 days)</td>
<td>Variable</td>
<td>10 immunizers</td>
<td>6 patients/hour</td>
<td>8 hours</td>
<td>480 vaccinations</td>
<td>2-3 trays; every week</td>
</tr>
<tr>
<td><strong>G</strong> – Drive-through vaccination clinic</td>
<td>3 trays (2,925 doses)</td>
<td>Thermal box with dry ice, 2-8C fridge, for product estimated at site (5 days)</td>
<td>Variable</td>
<td>10 immunizers</td>
<td>6 patients/hour</td>
<td>8 hours</td>
<td>480 vaccinations (by 7 days)</td>
<td>2-3 trays; very week</td>
</tr>
</tbody>
</table>
Pfizer Vaccine - Administration

**Removing the Vials to Thaw**
From storage, remove 1 vial for every 5 recipients according to planned vaccinations schedule.
Vials may be stored in the refrigerator for 5 days (120 hours).

**Dilute the Vaccine**
Obtain 0.9% Sodium Chloride Injection, USP for use as a diluent. Do not use any alternate diluents.
Dilute the thawed vial by adding 1.8 mL of 0.9% Sodium Chloride Injection into the vial.
Ensure vial pressure is equalized by withdrawing 1.8 mL air into the empty diluent syringe before removing the needle from the vial.

**Preparing the Dose**
Draw up 0.3 mL of the diluted dosing solution into a new sterile dosing syringe with a needle appropriate for intramuscular injection.
For each additional dose, use a new sterile syringe and needle and ensure the vial stopper is cleansed with antiseptic before each withdrawal.

**Vaccine Administration**
For each dose, use a new syringe and needle. Do not reuse needles. Use a new needle for each dose. Avoid using single-use needles that have a开启less valve. For each dose, use a new sterile syringe and needle.

Pfizer Biontech COVID-19 mRNA vaccine 30 mcg/0.3 mL
A single 30 mcg/0.3 mL dose followed by a second dose 21 days later.

Dioted vials must be used within 6 hours from the time of dilution and stored between 2°C to 25°C (35°F to 77°F).

21 DAYS
Additional Pfizer Vaccine Logistics

- USG will be providing first dry ice recharge for Pfizer product.
  - Will include dry ice and starter kit (gloves, scoop, instructions).
  - Auto ordered with vaccine. Sites may opt out of ordering dry ice.

- Thermal shipper temperature monitoring device.
  - For Pfizer thermal shippers, temperature device will deactivate at time of product receipt.
  - For sites using the thermal shipper as a storage unit, temp monitoring smart device may be reactivated for continued use for duration of product storage and handling.
  - Additional details on reactivation process and monitoring device plan will be forthcoming.
Modernata Vaccine - Shipping Assumptions

- 2 separately shipped components
  - Vaccine
    - To central distributor (at -20°C)
    - Multidose vial (10 doses per vial)
  - Ancillary supply kits
    - Direct to site at room temperature
Moderna Vaccine - Storage and Administration

- Frozen (-20°C)
- Refrigerated (2°C to 8°C)
  - Viable up to 7 days (30 days pending)
- Room temperature
  - Viable up to 12 hours (discard any punctured vial after 6 hours)
- Administration
  - 2 dose series (28 days between doses)
  - No onsite mixing required
  - Administer by IM injection
Phased Vaccination Approach

The COVID-19 Vaccination Program will require a phased approach:

**Phase 1**
- Potentially Limited Doses Available
- Projected short period of time for when doses may be limited
- Key factors: Supply may be constrained, tightly focus vaccine administration, administer vaccine in closed settings best suited for reaching initial critical populations (workplaces, other vaccination sites) specific to Phase 1-A populations

**Phase 2**
- Large Number of Doses Available
- Likely sufficient supply to meet demand, expand beyond initial populations, use a broad provider network and settings including healthcare settings (doctors’ offices, clinics), commercial sector settings (retail pharmacies), public health venues (public health clinics, mobile clinics, FQHCs, community settings)

**Phase 3**
- Continued Vaccination, Shift to Routine Strategy

- Likely sufficient supply
- Open access to vaccination
- Administer through additional private partner sites
- Maintain public health sites where required
CDC deadline for states to enroll in all Phase 1 providers. Moderna submitted EUA to FDA.

Pfizer submitted EUA to the FDA.

Receive first virtual allocation and place order. Estimate 46,800 - 150,000 doses

FDA’s advisory committee meeting to discuss EUA

Pfizer EUA approved. Pfizer vaccine shipped to states within 24 hours

Moderna vaccine virtually allocated. Estimate 15,000 - 95,600 doses

CDC Advisory Committee on Immunization Practices (ACIP) guidelines for use in public.

Phase 1 Timeline:

- Nov 20: Pfizer submitted EUA to the FDA
- Nov 30: CDC deadline for states to enroll in all Phase 1 providers. Moderna submitted EUA to FDA.
- Dec 2-4: Receive first virtual allocation and place order. Estimate 46,800 - 150,000 doses
- Dec 10: FDA’s advisory committee meeting to discuss EUA
- Dec 11-14: Pfizer EUA approved. Pfizer vaccine shipped to states within 24 hours
- Dec 13-16: Moderna vaccine virtually allocated. Estimate 15,000 - 95,600 doses
- Jan: CDC Advisory Committee on Immunization Practices (ACIP) guidelines for use in public.

1 week later
Vaccine Prioritization Frameworks

- National Academy of Science, Engineering, and Medicine - NASEM
- Advisory Committee on Immunization Practices - ACIP
- Governor’s Expert Emergency Epidemic Response Committee - Medical Advisory Group - GMAG

- Fairness
- Transparency
- Consistency
- Proportionality
- Accountability
- Duty to care
- Duty to steward scarce resources
- Saving the most number of lives
- Maintaining societal function and cohesion during and after the pandemic
- Reciprocity
- Multiplier effect
- Equity
# CO Vaccination Plan Phases - Subject to Changes

<table>
<thead>
<tr>
<th>Phase</th>
<th>Category</th>
<th>Members</th>
</tr>
</thead>
</table>
| 1A    | Critical Workforce        | Inpatient Healthcare workers, including those at assisted living facilities, State Continuity of Government (3)  
|       |                            | Outpatient Healthcare Workers, including home health workers and outpatient pharmacists |
| 1B    | Critical Workforce        | EMS, Firefighters, Police, Public Health Personnel and Correctional Workers |
| 1C    | Highest Risk Individuals  | Residents/patients of assisted living, long-term care, and nursing home facilities |
| 2A    | Congregate Housing        | Congregate Housing:                                                     |
|       | Essential Workers         |   - Adults experiencing homelessness living in congregate shelters       |
|       |                            |   - Incarcerated adults                                                 |
|       |                            |   - Adults living in group homes                                        |
|       |                            |   - Workers living in congregate settings (e.g. ski industry, some agricultural workers, etc.) |
|       |                            |   - Students living in college dorms or other congregate housing         |
|       | Essential workers         |   - With direct interaction with the public (e.g. grocery store workers, teachers, childcare, etc.) |
|       |                            |   - Working in high-density settings (e.g. agricultural, meat-packing workers, etc.) |
|       |                            |   - Serving persons that live in high-density settings (e.g. homeless shelter or group home workers) |
| 2B    | Higher Risk Individuals   | Adults 65 or older                                                       |
|       |                            | Adults with obesity, diabetes, chronic lung disease, significant heart disease, chronic kidney disease requiring dialysis, active cancers, and/or immunocompromised status |
| 3     | General Public            | Adults 18-64 without high-risk conditions                                |
COLORADO COVID-19 VACCINATION PLAN

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https://drive.google.com/file/d/1bxacXFm3ZsdXVG9RQavew1ck5W7D52bt/view?usp=sharing
Vaccine distribution and handling

- COVID-19 vaccine will be distributed in a phased approach using existing infrastructure (McKesson, CDC’s Vaccine Tracking System and CIIS).
  - COVID-19 vaccines requiring ultra cold storage (-60°C to -80°C) will be distributed exclusively to providers with demonstrated capacity to properly store the vaccine. [Ultra cold vaccine logistics](#)

- CDPHE invited 233 Phase 1 providers to complete enrollment in the COVID Vaccination Program. All COVID vaccination providers must meet [program requirements](#).

- In collaboration with local public health agencies, CDPHE has identified locations for potential vaccine pre-positioning.
CDC COVID-19 Vaccination Program Provider Agreement

- Administer vaccines per ACIP and regardless of patient’s ability to pay admin fees.
- Cannot charge for vaccine, adjuvant, syringes, needles or other supplies.
- Report administered doses to CIIS within 24 hours of vaccine administration.
- Comply with all CDC vaccine storage and handling requirements.
- Provide an EUA fact sheet at time of administration.
- Provide a completed COVID-19 vaccination record card to patient.
- Report the # of COVID-19 doses and adjuvants that were unused, spoiled, expired or wasted.
- Report moderate and severe adverse events following vaccination to the Vaccine Adverse Events Reporting System (VAERS).
Phase 1 Landscape

Vaccination providers:
- Hospitals
- Local public health agencies
- Kaiser facilities
- Select FQHCs
- Some pharmacies

Priority groups:
- Health care workers,
- First responders,
- Long-term care facility residents
Phase 1 Sites in Colorado
Phase 1 Roles & Responsibilities

CDPHE:
- Approve and enroll providers into the CDC COVID Vaccine Program & submit to CDC
- Coordinate allocation and distribution of vaccines to pre-positioned hubs and providers
- Provide technical assistance and guidance to LPHAs & providers
- Track and report daily vaccine allocation, orders, distribution, & usage

LPHAs:
- Lead vaccine response planning for their county(ies)
- Administer vaccine to Phase 1 priority populations (small #) and report to CIIS
- Identify providers to enroll in CDC COVID Vaccine Program
- Provide technical assistance to providers

Providers (hospitals, pharmacies, FQHCs, doctor offices):
- Complete CDC COVID Vaccine Program enrollment
- Abide by CDC’s Advisory Committee on Immunization Practices (ACIP)
- Administer vaccine to Phase I priority populations and report to CIIS

CDC’s Pharmacy Partnership for LTC Program
- Retail pharmacy chains to provide end-to-end management of the COVID-19 vaccination process
COVID-19 Vaccine Acceptance Survey

- Survey administered online from September 15 - October 3
- Explored attitudes, intent, messages and messengers
- Survey was conducted statewide among 811 adults aged 18+ along with an additional oversample to boost African-American response.
- Will inform our approach moving forward for engagement and outreach
COVID-19 Vaccine Acceptance Differs Among R/E and Gender

Overall, 66% would get vaccinated with an FDA approved vaccine in early 2021, while 34% would not.

<table>
<thead>
<tr>
<th></th>
<th>Men</th>
<th>Women</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Population</td>
<td>76%</td>
<td>57%</td>
</tr>
<tr>
<td>Hispanic</td>
<td>67%</td>
<td>51%</td>
</tr>
<tr>
<td>African American</td>
<td>58%</td>
<td>50%</td>
</tr>
</tbody>
</table>

Among those who would get vaccinated, 48% would as soon as they could, while 45% would wait and 7% are not sure.
Motivators for Getting Vaccinated

Reasons for saying “Yes”
- Protect myself, my family
- End the pandemic

Reasons for waiting, or saying “No”
- Not tested enough
- Side effects, long-term effects
- General concerns about vaccination
- Political influence on the process
- Too rushed
Messaging Considerations

- Scores for trusted sources of information and messaging
  - Doctors, scientists/researchers and nurses are strongest messengers
  - CDPHE is the most trusted organization of those tested (including CDC, FDA)

- One message emerged as most effective, with 52% of all respondents saying it was “very convincing:”
  - Vaccines must be proven to be safe and effective before they are given to people, and the COVID-19 vaccine is no different.

- Other messages tested at 40% approximately, including the idea that A vaccine is a gateway to a more normal life, that The best scientists in the world are working on this, and that We are in this together to end the pandemic.
Call to Action

If you are interested in participating in the COVID vaccine response and did not complete an initial COVID-19 Vaccine Provider Interest Form, please reach out to us to express your interest: cdphe_covidvax@state.co.us
Communication Resources

- CDPHE COVID-19 website (www.covid19.colorado.gov)
  - General vaccine webpage is live
  - Webpage for providers/partners will be published shortly
- COVID-19 Vaccine Talking Points
- CDC COVID-19 Vaccination Resources
Questions?