

Nov 19, 2020

COVID-19 Vaccine Planning

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



moderna

- Phase III
- mRNA vaccine
- 2 doses (28d)
- Requires frozen storage
- 30K volunteers in USA-34.5% from diverse communities
- 18+ years



Pfizer
Vaccines

- Phase II/III
- mRNA vaccine
- 2 doses (21d)
- Requires ultra cold storage
- 30K in USA plus Argentina, Brazil, and Germany
- 16-85 years



Oxford
Biomedica

- Phase II/III
- Adenoviral vector vaccine
- 1 or 2 doses (28d)
- 42K volunteers in the USA & UK
- 18+ years



janssen

- Phase III
- Adenoviral vector vaccine, 1 dose
- 60K volunteers USA and several countries
- 18+ years
- Separate trial in UK for 2 doses.

COVID-19 Vaccine Assumptions

- Limited doses may be available in 2020, but 2021 is more likely.
- Initial doses may be available under an Emergency Use Authorization.
- One and two-dose series (separated by >21 or >28 days); products not interchangeable
 - Second-dose reminders for patients will be necessary.
- Cold chain requirements for each vaccine will vary.
 - Refrigerated (2° to 8°C)
 - Frozen (-20°C)
 - Ultra cold (-60° to -80°C)
- Some vaccines will require reconstitution with diluent or adjuvant.

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 $-75^{\circ}\text{C} \pm 15^{\circ}\text{C}$ for long term storage.
 - Emergency Use vials are labeled as $-70^{\circ}\text{C} \pm 10^{\circ}\text{C}$, however they can be safely stored in a freezer set to $-75^{\circ}\text{C} \pm 15^{\circ}\text{C}$
- 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)



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

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.

Pfizer Vaccine - Administration

Removing the Vials to Thaw

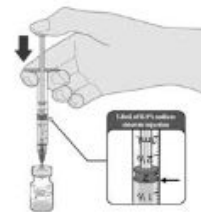


From storage, **remove 1 vial for every 5 recipients** according to planned vaccinations schedule.

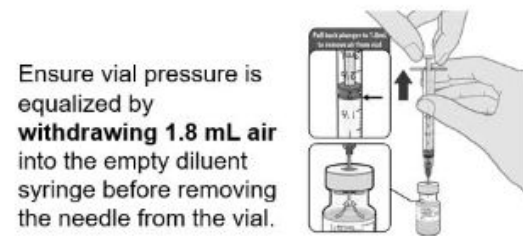
Vials may be stored in the refrigerator for 5 days (120 hours).

Dilute the Vaccine

Obtain 0.9% Sodium Chloride Injection, USP for use as a diluent. Do not use any alternate diluents.



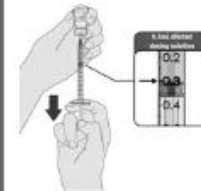
Dilute the thawed vial by adding **1.8 mL of 0.9% Sodium Chloride Injection** into the vial.



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



**Pfizer BioNTech
COVID-19
Vaccine
30 mcg/0.3 mL**

Diluted 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).

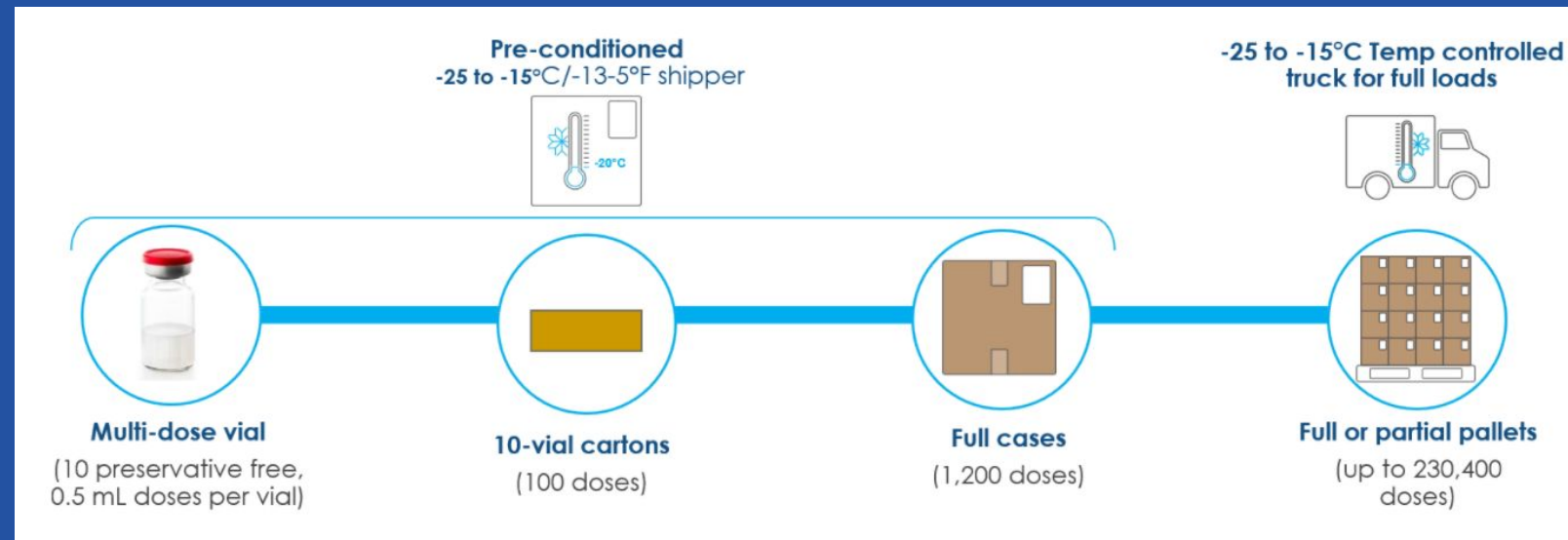
A single 30 mcg/0.3 mL dose followed by a second dose 21 days later.



21 DAYS

Moderna 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)
 - Storage in shipping container OK
- Refrigerated (2°C to 8°C)
 - Viable up to 7 days
- 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

Storage Conditions for a non-punctured vial*



Freezer: -25 to -15°C / -13 to 5°F for 6 months

+



Refrigerator: 2-8°C / ~36-46°F for up to 7 days. Do not refreeze

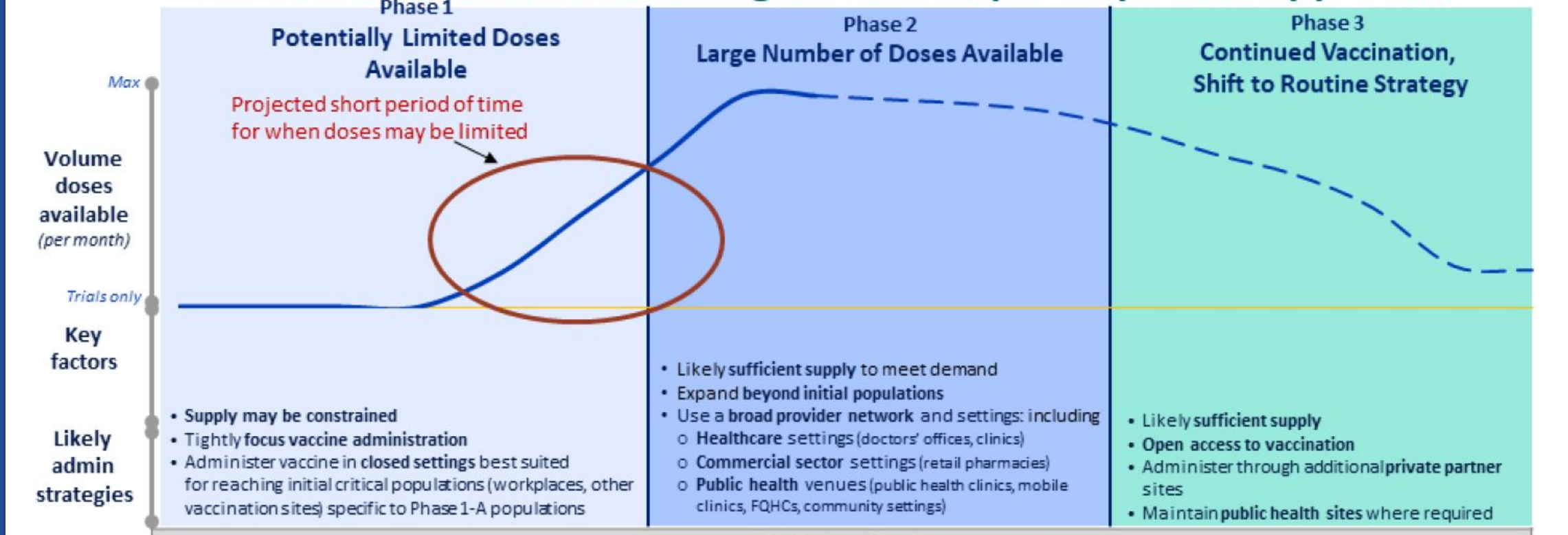
+



Room temperature: up to 12 hours

Phased Vaccination Approach

The COVID-19 Vaccination Program will require a phased approach



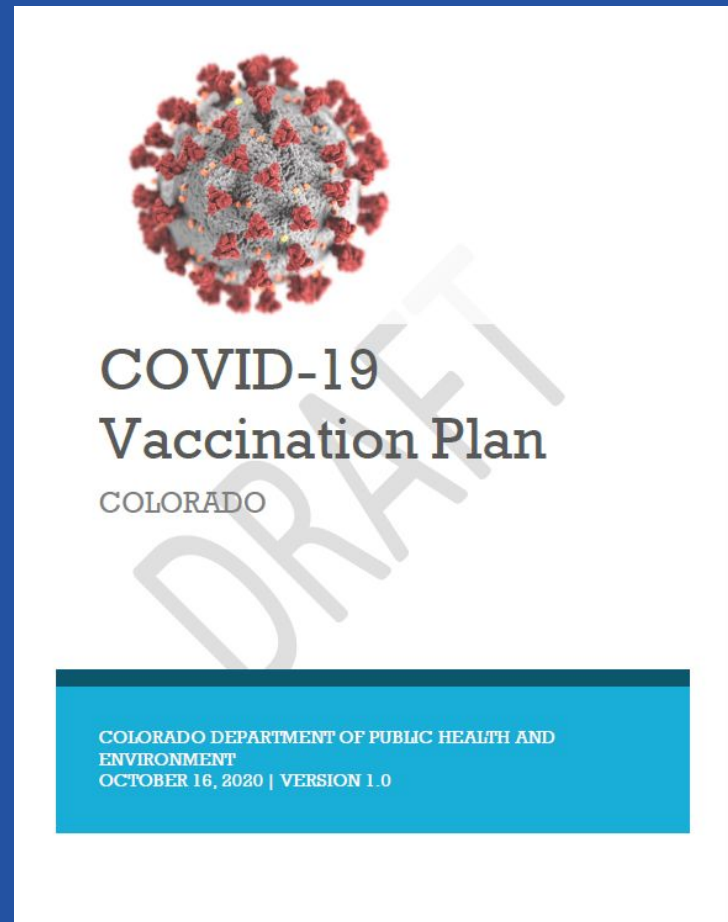
Vaccine Allocation

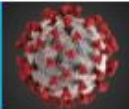
- National Academy of Science, Engineering, and Medicine - NASEM
- Advisory Committee on Immunization Practices - ACIP
- Governor's Expert Emergency Epidemic Response Committee - Medical Advisory Group - GMAG
- Fairness
- Transparency
- Consistency
- Proportionality
- Accountability
- Duty to care
- 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

Phased Vaccine Allocation

PHASE	CATEGORY	MEMBERS
1A	Critical Workforce	Inpatient Healthcare workers, including those at assisted living facilities
		Outpatient Healthcare Workers, including home health workers and outpatient pharmacists
1B	Critical Workforce	EMS, Firefighters, Police, Public Health Personnel, Correctional Workers
1C	Highest Risk Individuals	Residents/patients of assisted living, long-term care, and nursing home facilities
2A	Congregate Housing Essential Workers	<p>Congregate Housing:</p> <ul style="list-style-type: none"> • Adults experiencing homelessness • Incarcerated adults • Adults living in group homes • Workers living in congregate settings (e.g. ski industry workers, agricultural workers, etc.) • Students living in college dorms or other congregate housing <p>Essential workers:</p> <ul style="list-style-type: none"> • 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, group home workers, etc.)
2B	Higher Risk Individuals	<p>Adults 65 or older</p> <p>Adults with obesity, diabetes, chronic lung disease, significant heart disease, chronic kidney disease requiring dialysis, active cancers, and/or immunocompromised status</p> <p>Adults who received placebo during a COVID-19 vaccine clinical trial</p>
3	General Public	Adults 18-64 without high-risk conditions

Colorado COVID-19 Vaccine Plan



COLORADO COVID-19 VACCINATION PLAN	
	
Table of Contents	
Record of Changes	2
Section 1: Preparedness Planning	4
Section 2: COVID-19 Organizational Structure and Partner Involvement	8
Section 3: Phased Approach to COVID-19 Vaccination	16
Section 4: Critical Populations	18
Section 5: COVID-19 Provider Recruitment and Enrollment	36
Section 6: COVID-19 Vaccine Administration Capacity	43
Section 7: COVID-19 Vaccine Allocation, Ordering, Distribution, and Inventory Management	46
Section 8: COVID-19 Vaccine Storage and Handling	50
Section 9: COVID-19 Vaccine Administration Documentation and Reporting	52
Section 10: COVID-19 Vaccination Second-Dose Reminders	59
Section 11: COVID-19 Requirements for IISs or Other External Systems	61
Section 12: COVID-19 Vaccination Program Communication	74
Section 13: Regulatory Considerations for COVID-19 Vaccination	90
Section 14: COVID-19 Vaccine Safety Monitoring	91
Section 15: COVID-19 Vaccination Program Monitoring	92
Acronyms and Abbreviations	96

Vaccine distribution and handling

- COVID-19 vaccine will be distributed in a phased approach using existing infrastructure (McKesson, CDC's Vaccine Tracking System and CIIIS).
 - 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 198 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 16 locations for potential vaccine pre-positioning with plans to add more.

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).

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.

	Men	Women
General Population	76%	57%
Hispanic	67%	51%
African American	58%	50%

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 have not yet completed the COVID-19 Vaccine Provider Interest Form, please do so by November 20!

<https://fs9.formsite.com/ColoradoIMMprogram/COVID-19-Interest-Form/index.html>

How Information Will Be Shared

- COVID-19 website (www.covid19.colorado.gov)
 - General [vaccine webpage](#) is live
 - Webpage for providers/partners will be published in 2-3 weeks
- Health Alert Network messages (HANs)
 - To register for HANs, please email cdphe_epr_sit@state.co.us
- CDPHE Immunization Branch distribution list
- Via partners organizations

Questions?