

Dec 2, 2020

COVID-19 Vaccine Planning Update



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



- 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



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



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



- 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.



	Data is accurate as of 11/30/2020.	Pfizer (BNT162b2) - EUA submitted 11/20/20	Moderna (mRNA-1273) - EUA submitted 11/30/2020
PRIMARY	Trial Size	41,135 already received 2nd dose (43,661 total enrolled)	25,654 already received 2 nd dose (>30,000 enrolled)
	Efficacy	95% (162 cases placebo group vs 8 cases in vaccine group)	94.5% (185 cases placebo group vs 11 cases in vaccine group)
	Immunity onset	7 days from 2 nd dose	N/A
	Severe cases	9 in placebo group vs 1 in vaccine group	30 in placebo (1 death) vs 0 in vaccine group
	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

		Pfizer (BNT162b2)	Moderna (mRNA-1273)
Sub-Groups	Older adults	45% age 56-85 (40.9% internationally) 94% efficacy for those ≥ 65 years in subgroup analysis	>7,000 (23%) age ≥ 65 No difference in efficacy or side effects in subgroup analysis
	Minorities	30% racially/ethnically diverse backgrounds in US, 42% internationally -10.1% black (10.0% internationally) -13.1% Hispanic (26.1% internationally) No difference in efficacy or side effects in subgroup analysis	>11,000 from communities of color ->6,000 (>20%) self-identify as Hispanic/LatinX ->3,000 (>10%) self-identify as Balck No difference in efficacy or side effects in subgroup analysis
	High Risk Conditions	N/A	17% age 18-65 with high risk condition (many people 65+ also had another high risk condition) -36% with DM among high risk group -25% with severe obesity among high risk group No difference in efficacy or side effects in subgroup analysis

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)



Weights and Dimensions	
Tare Weight (Inc. Dry-Ice)	8.5kg (31.5kg)
Volumetric Weight	15.0kg
Payload Space L x W x H	245x245x241mm
Shipper Dimensions L x W x H	400x400x560mm



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



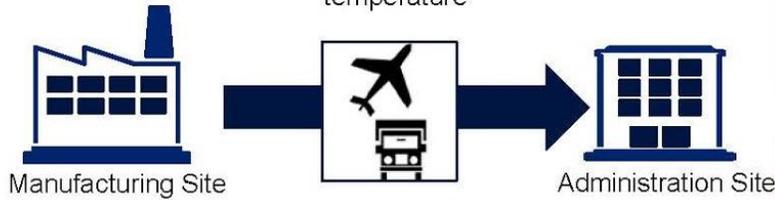
- Can be stored at 2 to 8°C up to 5 days
- Room temperature hold time is no more than 2 hours.
- Thawing: 3 hours at 2 to 8°C or 30 min at room temperature.
- Post-dilution in use period is 6 hours.

Pfizer Vaccine

Vaccine Storage

Shipped CONUS < 24 hours

Thermal shipping container maintains -60° C to -80° C up to 10 days without opening at room temperature



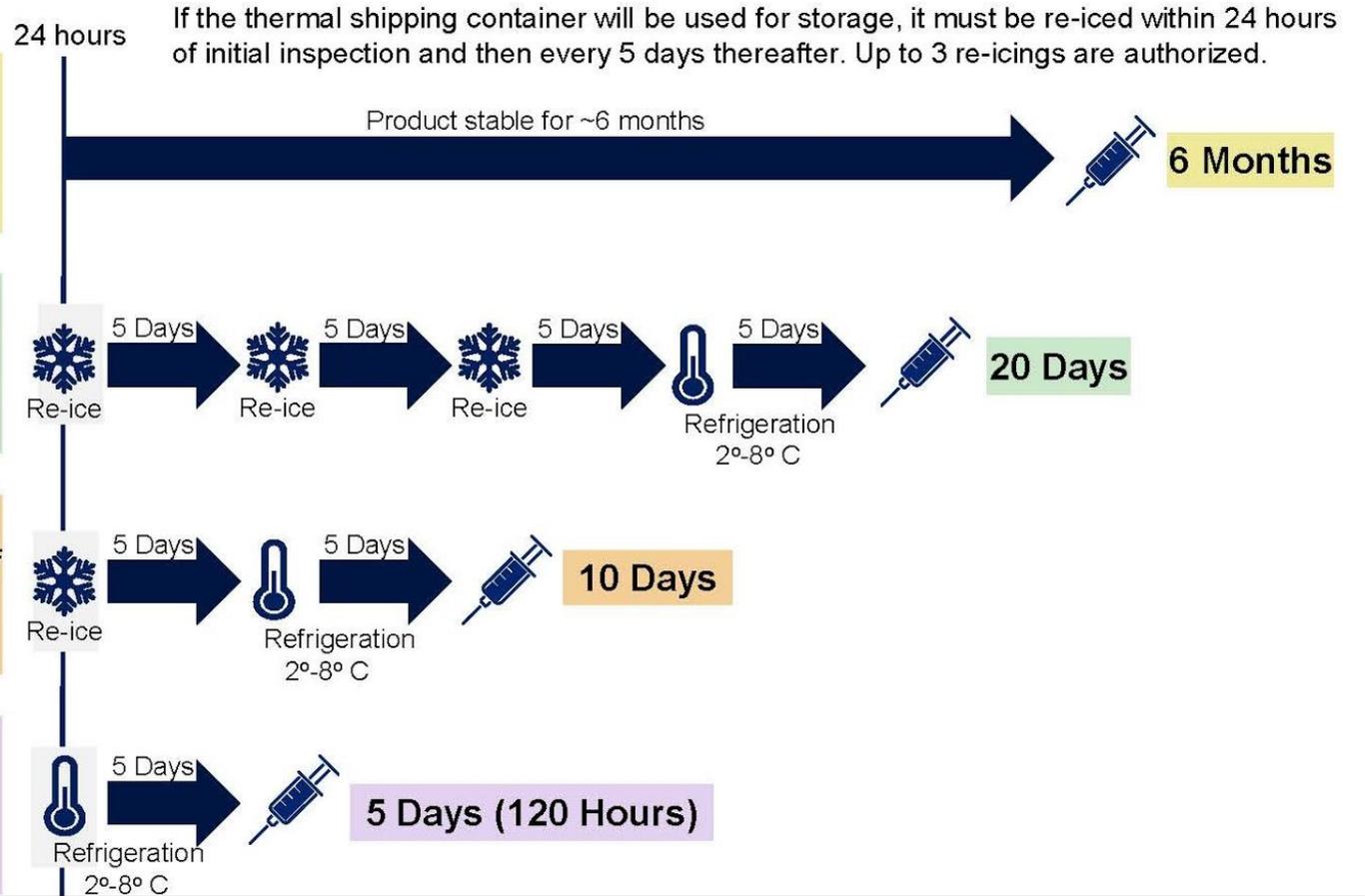
- Thermal shipping container must be opened and inspected upon receipt
- Initial inspection must be completed in less than 5 minutes
- The thermal shipping container can only be opened twice per day for 2 minutes during each opening

Option 1
Placed in ultra-cold temperature freezer

Option 2
Maximize use of thermal shipping container

Option 3
One-time re-ice of thermal shipping container

Option 4
Immediately placed in refrigerator



Vaccine Thawing



Thermal shipping container

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)

Site Types for Vaccine A Product

Vaccination provider site		Ordering assumptions			Operating assumptions				
		Order size	Storage conditions	Patient flow	Number of immunizers	Patients per immunizer	Hours per day	Vaccines per day	Shipment model
	A – large outpatient center (mass vx)	1 tray (975 doses)	Thermal box with dry ice, 2-8C fridge, for product estimated at site (5 days)	~500/day	10 immunizers	6 patients/hour (~10 min/Vx)	8 hours	480 vaccinations	1 tray; 2-3 times per week
	B – hospital or outpatient center	1 tray (975 doses)	Ultra-cold freezer, Thermal box with dry ice, 2-8C fridge, for product estimated at site (5 days)	Variable	4 immunizers	6 patients/hour (~10 min/Vx)	8 hours	192 vaccinations	1 tray; every week
	C – large hospital with affiliated outpatient center	5 trays (4,875 doses)	Ultra-cold freezer, Thermal box with dry ice, 2-8C fridge, for product estimated at site (5 days)	Variable	7 immunizers (hospital outpatient clinic)	6 patients/hour (~10 min/Vx)	8 hours	340 vaccinations	1 tray; 1-2 times a week
	D – outdoor parking lot vaccination hub at large retail pharmacy	1 tray (975 doses)	2-8C fridge, for product estimated at site (5 days)	~200/day	5 immunizers	6 patients/hour (~10 min/Vx)	N/A	240 vaccinations	1 tray; every week
	E – mobile vaccination in targeted geographic areas	5 trays (4,875 doses)	2-8C fridge, for product estimated in mobile unit (5 days)	Variable	3 immunizers	6 patients/hour (~10 min/Vx)	Not specified	150 vaccinations	1 tray; every week

Site Types for Vaccine A Product

Vaccination provider site	Order size	Storage conditions	Patient flow	Number of immunizers	Patients per HCP	Hours per day	Vaccines per day	Shipment model
 <p>F – large indoor spaces not used during pandemic (convention hall)</p>	5 trays (4,875 doses)	Thermal box with dry ice, 2-8C fridge, for product estimated at site (5 days)	Variable	10 immunizers	6 patients/hour (~10 min/Vx)	8 hours	480 vaccinations	2-3 trays; every week
 <p>G – Drive-through vaccination clinic</p>	3 trays (2,925 doses)	Thermal box with dry ice, 2-8C fridge, for product estimated at site (5 days)	Variable	10 immunizers	6 patients/hour (~10 min/Vx)	8 hours	480 vaccinations (by 7 days)	2-3 trays; very week

Pfizer Vaccine - Administration

Removing the Vials to Thaw

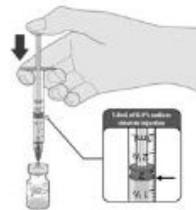


From storage, **remove 1 vial for every 5 recipients** according to planned vaccinations schedule.

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

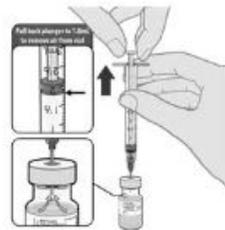
Dilute the Vaccine

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.

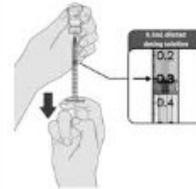
Ensure vial pressure is equalized by **withdrawing 1.8 mL air** into the empty diluent syringe before removing the needle from the vial.



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



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

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.

Moderna Vaccine - Shipping Assumptions

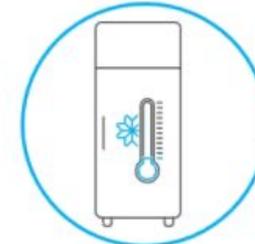
- 2 separately shipped components
 - Vaccine
 - To central distributor (at -20°C)
 - Multidose vial (10 doses per vial)
 - Ancillary supply kits
 - Direct to site at room temperature



Moderna Vaccine - Storage and Administration

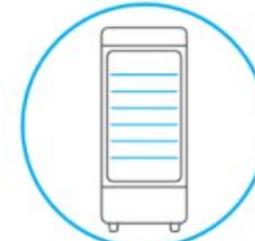
- Frozen (-20°C)
- Refrigerated (2°C to 8°C)
 - Viable up to 7 days (30 days pending)
- Room temperature
 - Viable up to 12 hours (discard any punctured vial after 6 hours)
- Administration
 - 2 dose series (28 days between doses)
 - No onsite mixing required
 - Administer by IM injection

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

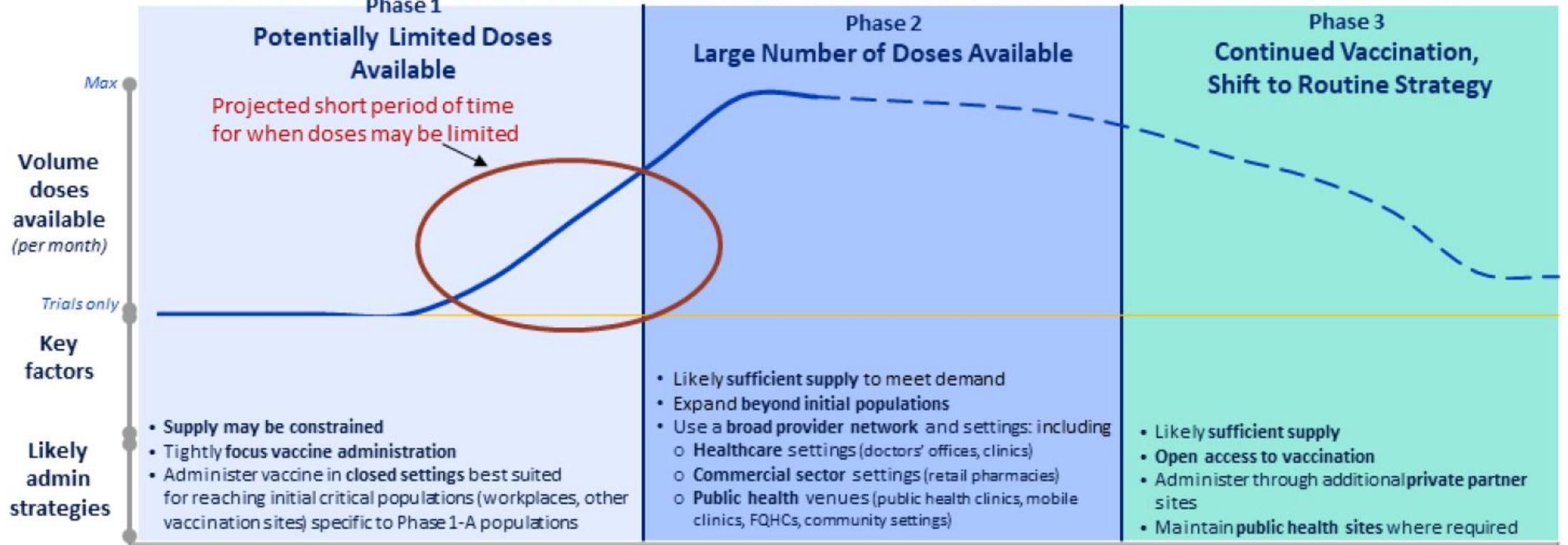
+



Room temperature: up to 12 hours

Phased Vaccination Approach

The COVID-19 Vaccination Program will require a phased approach



Phase 1 Timeline

Pfizer submitted
EUA to the FDA

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

Pfizer EUA
approved
Pfizer vaccine
shipped to states
within 24 hours

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

CDC deadline for states
to enroll in all Phase 1
providers.
Moderna submitted EUA
to FDA.

FDA's advisory
committee
meeting to
discuss EUA

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

Nov 20

Nov 30

Dec 2-4

Dec 10

Dec
11-14

Dec
13-16

1 week
later

NOV
2020

DEC
2020

JAN
2021

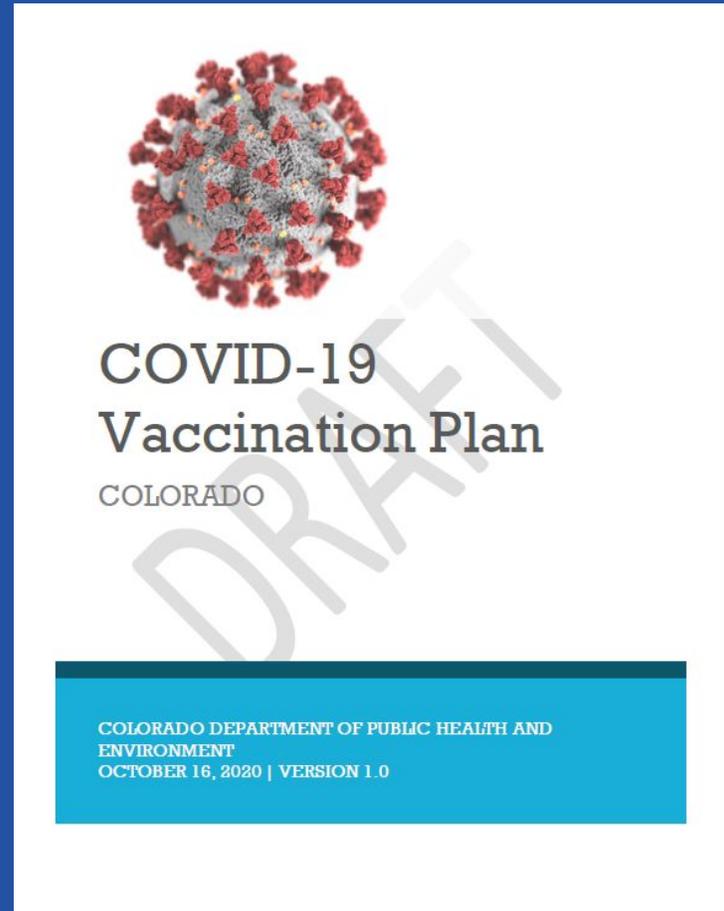
Vaccine Prioritization Frameworks

- 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

Phase	Category	Members
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 Essential Workers	<p>Congregate Housing:</p> <ul style="list-style-type: none"> • 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 <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 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 Vaccine Plan



COLORADO COVID-19 VACCINATION PLAN	
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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

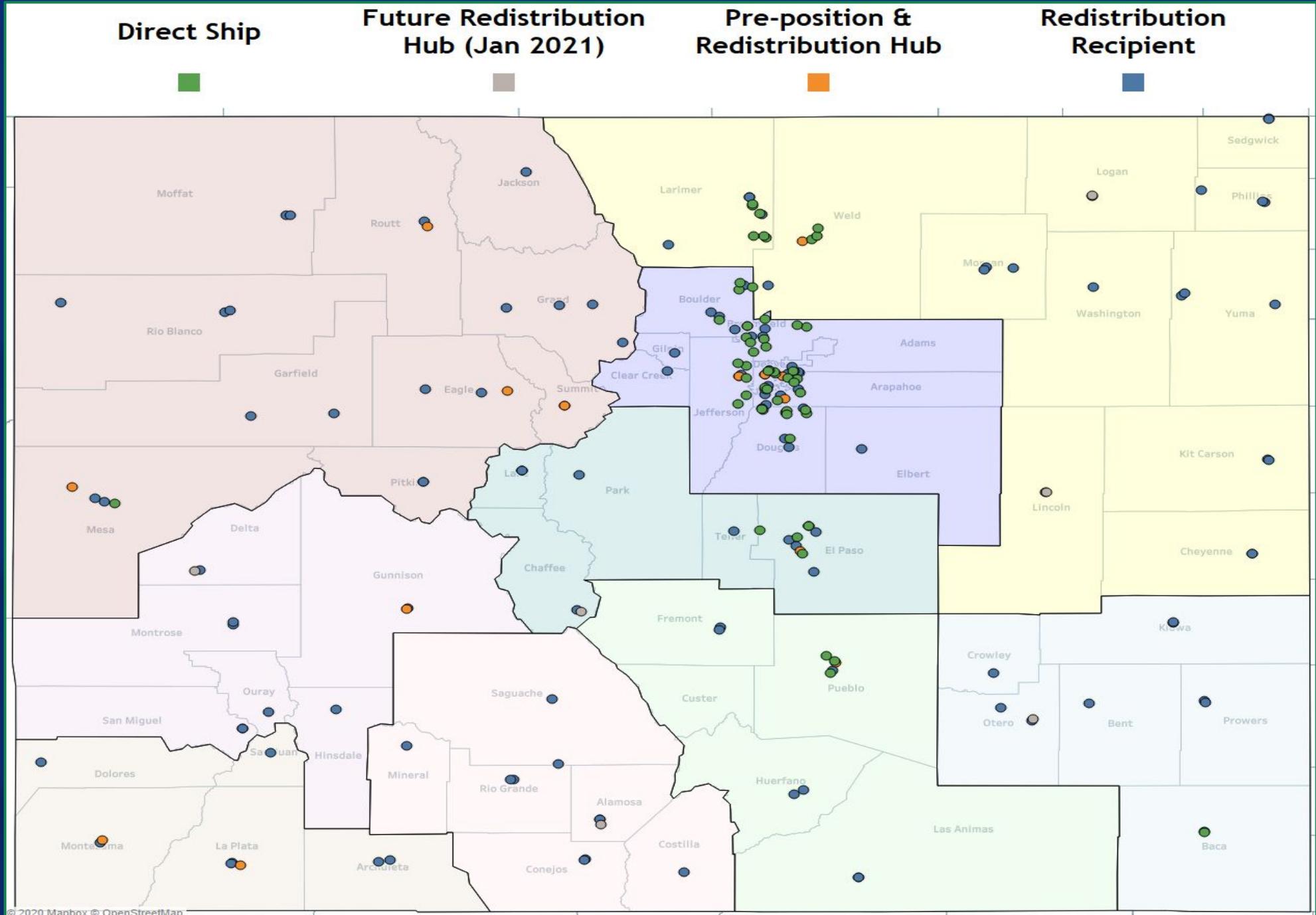
Vaccination providers:

- 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.

	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 did not completed 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?

