

In partnership with:



COVID-19 Vaccines:

Juneau Reentry Coalition

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2/17/21

The information shared within this presentation is subject to change due to rapidly developing information

Summary

- ★ Both FDA-authorized COVID-19 vaccines are remarkably effective and safe
- ★ Vaccine Thoughtfulness is OK
- ★ We all need to be informed about the COVID-19 vaccine so we can make a decision about vaccination

COVIDVAX.ALASKA.GOV

Presentation Objectives

 Review the scientific process of vaccine development and authorization for emergency use

 Review COVID-19 vaccine efficacy and safety

 Review vaccine allocation process in Alaska



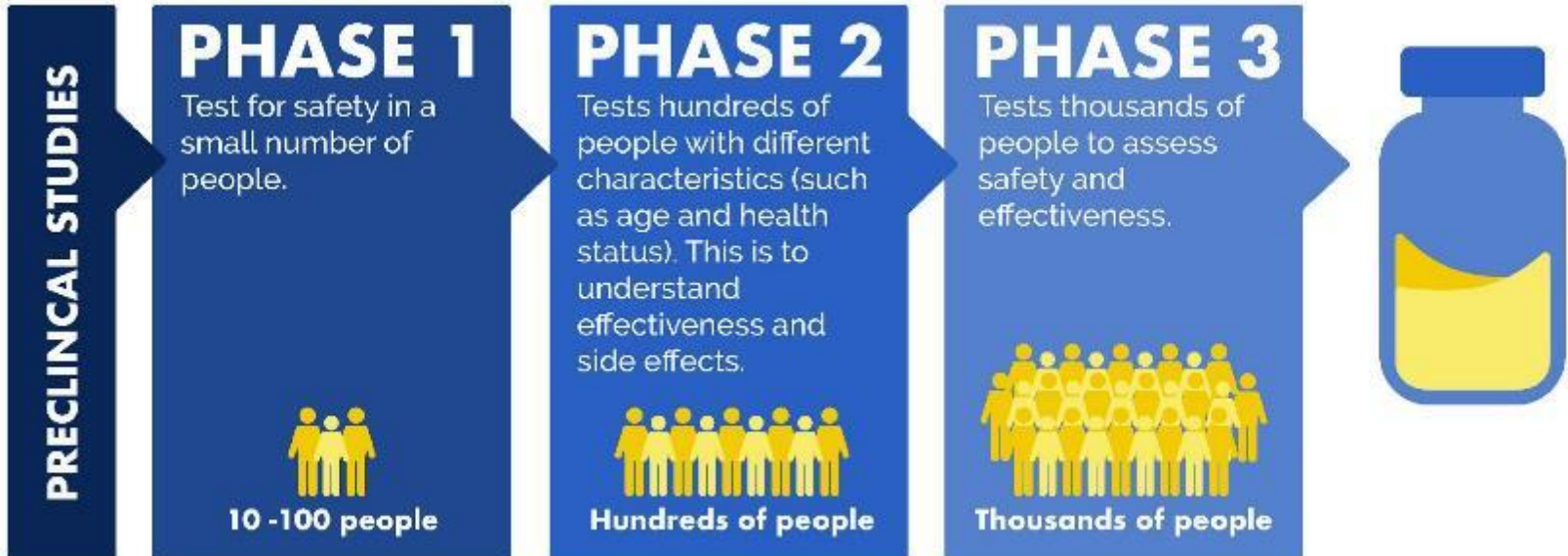
Vaccine Science and Safety Overview



How do vaccines get authorized?

COVID-19 Vaccine Clinical Trials

Any vaccine we receive will have been authorized by the U.S. Food and Drug Administration and will have completed:








No steps were skipped during the clinical trial process for a COVID-19 vaccine.

Currently two FDA-authorized COVID vaccines

- **Pfizer** (16 and older), 2 doses, 21 days apart
- **Moderna** (18 and older), 2 doses, 28 days apart
- Johnson & Johnson submitted application to FDA, 1 dose






COVID-19 VACCINE

PFIZER

-  **PHASE 3 CLINICAL TRIALS**
Thousands of people participate in clinical trials to assess safety and efficacy.
-  **EUA APPLICATION SUBMITTED**
Vaccine manufacturers submit an emergency use authorization application to the FDA.
-  **FDA AUTHORIZATION**
Scientists and medical experts review the data and decide whether to authorize the vaccine.
-  **CDC RECOMMENDATIONS**
The Advisory Committee on Immunization Practices recommends who should receive the vaccine first to control disease.
-  **LIMITED VACCINE AVAILABLE**
Expect regular shipments of vaccine throughout 2021.

COVID-19 VACCINE

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Safety of COVID-19 vaccines is a top priority

COVID-19 vaccines are being held to the **same safety standards** as all vaccines.

Before Authorization



ACIP

- **FDA** carefully reviews all safety data from clinical trials.
- **ACIP** reviews all safety data before recommending use.

After Authorization



- **FDA** and **CDC** closely monitor vaccine safety and side effects. There are systems in place that allow CDC and FDA to watch for safety issues.

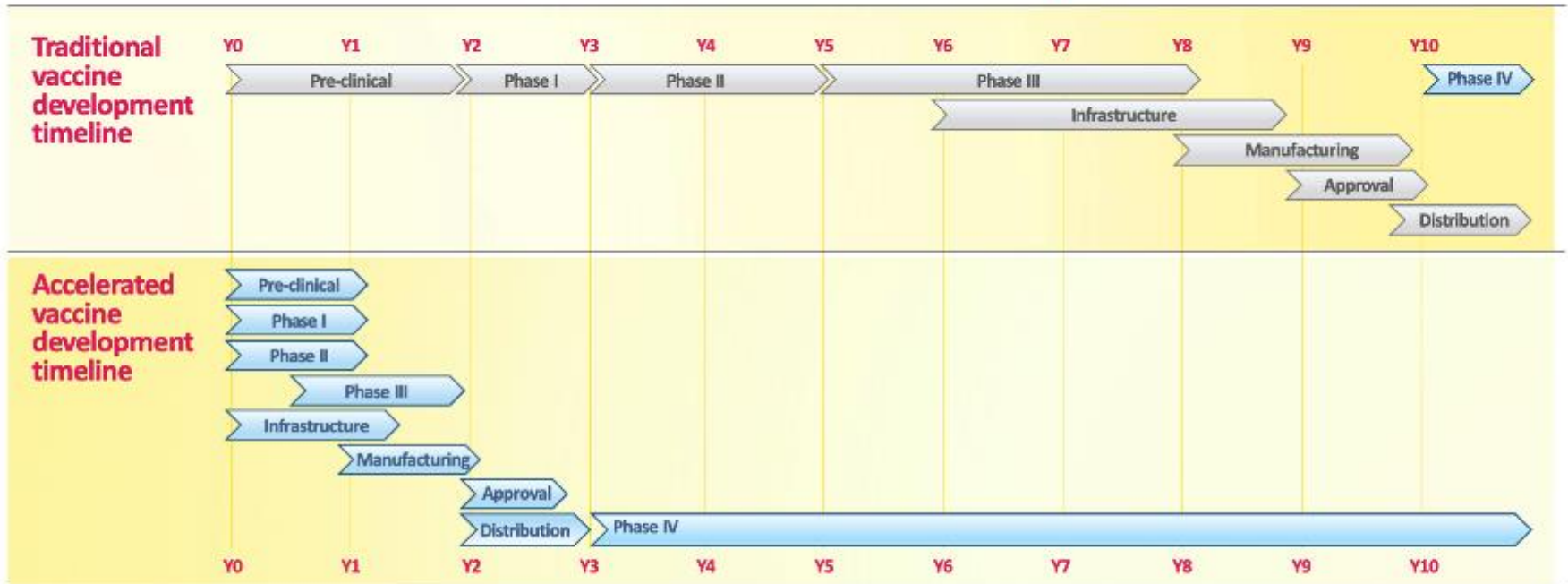
VAERS Vaccine Adverse Event Reporting System
www.vaers.hhs.gov



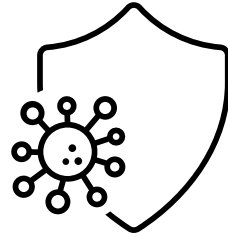


**Didn't this happen
kinda fast tho?**

COVID-19 vaccine accelerated development



- Normal vaccine development performs each step in sequence
- To accelerate COVID-19 vaccine development, **steps are done in parallel**
- All usual safety and efficacy monitoring mechanisms remain in place; such as adverse event surveillance, safety data monitoring & long-term follow-up
- **Phase IV post-marketing surveillance** for side effects is critical and essential

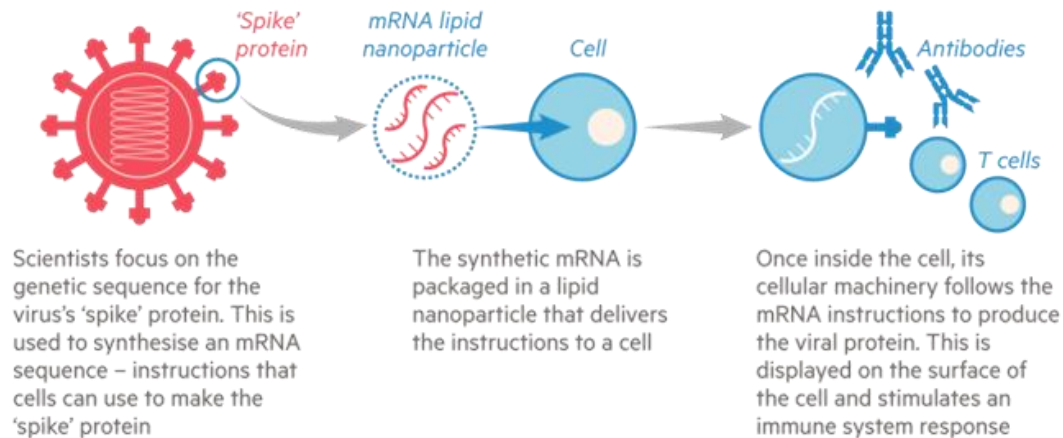


How do mRNA vaccines work?

Pfizer and Moderna are mRNA vaccines

How the Pfizer-BioNTech vaccine works

mRNA vaccines give the immune system genetic instructions to recognise the virus



Source: Pfizer
© FT

- Messenger RNA (mRNA) vaccines teach cells how to make a protein that triggers an immune response inside our bodies.
- Our immune system will remember this protein so it can respond later on.
- mRNA vaccines cannot become a permanent part of the body and they do not contain any virus.

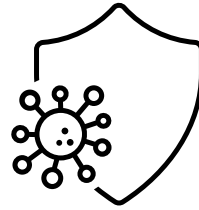
What are the vaccine ingredients?

The COVID-19 vaccines contain only four types of ingredients:
mRNA, lipids, salts, and sugars.

They do **NOT** contain any of the following ingredients:

- NO antibiotics
- NO eggs
- NO fetal material
- NO DNA
- NO pork gelatin
- NO blood products





**Are the COVID-19 vaccines
effective?**

COVID-19 vaccine trials by the numbers

As of November 30, 2020

Pfizer/BioNTech

43,931 enrolled

150 clinical sites

39 U.S. states

Racial/ethnic distribution

13% - Hispanic

10% - African American

6% - Asian

1% - Native American

45% ages 56-85

Moderna

30,000 enrolled

89 clinical sites

32 U.S. states

Racial/ethnic distribution

63% - White

20% - Hispanic

10% - African American/Black

4% - Asian

3% - All others

64% ages 45 and older

39% ages 45-64

25% ages 65+

Sources: <https://www.pfizer.com/science/coronavirus/vaccine>;
<https://www.modernatx.com/cove-study>

For more information, visit www.clinicaltrials.gov

Pfizer and Moderna Phase 3 Trial Data



- Moderna vaccine = **94.1%** effective at preventing COVID-19
- Pfizer vaccine = **95%** effective at preventing COVID-19

Phase 3 Trial Data Breakdown

Pfizer:

→ Of 170 people who developed COVID-19, 162 were in the placebo group and 8 were in the vaccine group.

→ Of the 10 people who developed severe illness from COVID-19, 9 were in the placebo group and 1 was in the vaccine group.

Moderna:

→ Of 196 people who developed COVID-19, 185 were in the placebo group and 11 were in the vaccine group.

→ Of the 30 people who developed severe illness from COVID-19, including one death, all were in the placebo group. No one in the group that received the vaccine developed severe illness.

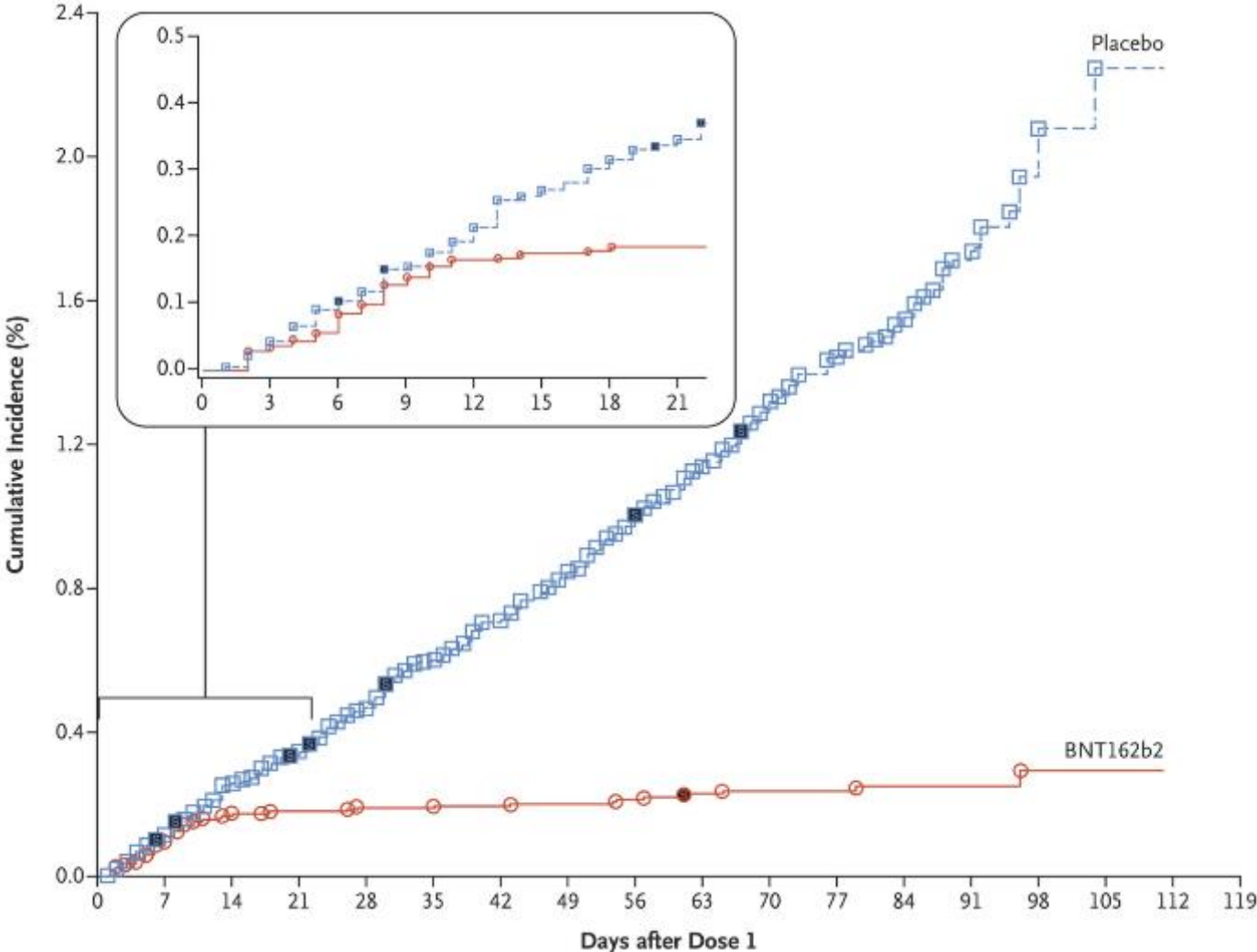
Pfizer and Moderna Phase 3 Trial Data



Protection against Severe Disease

- Out of approximately 36,965 people who got the vaccine, only 1 patient developed “severe” disease.
- And their “severe” disease was manifested by an oxygen level was 93%. They were not hospitalized and did not need further medical care

Efficacy (Pfizer)



Protection Builds Over 6 Weeks

MODERNA COVID-19 VACCINE EFFICACY OVER TIME

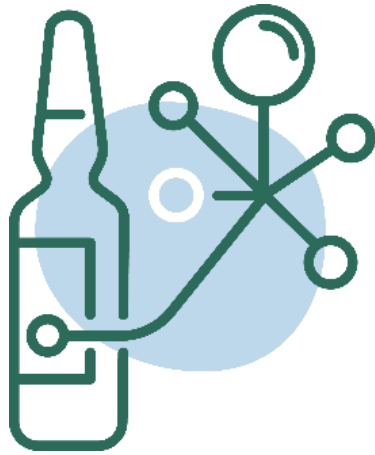


PFIZER COVID-19 VACCINE EFFICACY OVER TIME



Two doses are important

Getting a COVID-19 vaccine...



- Will help create an immune response in your body against the virus



- May help keep you from getting severely ill, even if you do get COVID-19

COVID Vaccine Safety

- No significant safety concerns identified in the clinical trials (8 wks).
It is unusual for side effects to appear more than 8 weeks after vaccination.
- The mRNA vaccines are **expected to produce a reaction** after vaccination, especially after the 2nd dose.
 - Fever
 - Headache
 - Muscle aches
- **Allergic Reactions**
There is a rare chance that the COVID-19 vaccine will cause anaphylaxis (Pfizer 0.62 cases and Moderna 0.21 cases per 100,000 people vaccinated VAERS)

Anaphylaxis reports to VAERS following COVID-19 vaccines*

Characteristics	Pfizer-BioNTech (N = 50)	Moderna (N = 21)
Median age, years (range)	38.5 (26–63)	39 (24–63)
Female (%)	47 (94)	21 (100)
Minutes to symptom onset, median (range)	10 (<1–1200 [20 hr]) [†]	10 (<1–45)
Symptom onset ≤15 minutes (%)	37 (74)	18 (86)
Symptom onset ≤30 minutes (%)	45 (90)	19 (90)
Documented h/o of allergies or allergic rxns (%)	40 (80)	18 (86)
Documented h/o of prior anaphylaxis (%)	12 (24)	5 (24)
Dose number (1 st , 2 nd , unknown)	42, 3, 5	19, 1, 1

- Common allergies and allergic reactions included to drugs and foods
- Anaphylaxis cases occurred following drugs, foods, contrast media, vaccines, insect stings, unspecified

* Reports received through January 18, 2021; Includes case reports that met Brighton Collaboration case definition criteria for anaphylaxis at Levels 1, 2, or 3

[†]20 hour onset was an outlier, the remaining onset for cases with onset >30 minutes were 34, 54, 90, and 150 minutes

- Vaccine clinics are prepared with anaphylactic response kits in case treatment is needed.
- Early data shows severe allergic reactions are rare and treatable
 - 2.1 cases of anaphylaxis per 1 million administered doses of Moderna
 - 6.2 cases per 1 million administered doses of Pfizer
- CDC has not reported any deaths associated with the vaccine in Alaska or other states

Considerations



94-95% protection from COVID-19.

Near 100% protection from severe COVID-19.

Helping my community reach herd immunity and recover from the pandemic.

**RISK OF:
INFECTION WITH COVID
DEATH
LONG COVID**

A sore arm and muscle aches for a day or two.

Rare risk of allergic reaction.

Unlikely unidentified safety concern.

One in seven

Alaskans are on their way to full vaccination.



Over 100,000 Alaskans have received their first dose of COVID-19 vaccine.



Keep up the good work Alaska!



For more information:
covidvax.alaska.gov

Vaccine Eligibility in Alaska





Phase 1a – fully open

Tier 1 Open	Tier 2 Open	Tier 3 Open
<p>Long term care* facility staff and residents</p> <p>Hospital-based frontline health care workers and hospital personnel who are frequently exposed to COVID-19 patients*</p>	<p>Frontline EMS and Fire Service personnel providing medical services, who are frequently exposed to COVID-19 patients*</p> <p>Community Health Aides/Practitioners</p> <p>Health care workers providing vaccinations to identified populations in Phase 1a</p>	<p>Workers in health care settings who meet all of the following criteria*:</p> <ol style="list-style-type: none">1. Have direct human patient contact, or have direct contact with infectious materials from patients; AND2. Provide essential services in a hospital, clinic, home, or community based setting that cannot be offered remotely or performed via telework; AND3. Provide essential health care service in a health care setting that cannot be postponed without serious negative impact to the patient's health.

*See [availability page at covidvax.Alaska.gov](https://covidvax.Alaska.gov) for further clarifications



Phase 1b – Tier 1 and 2 Open

Tier 1 Open	Tier 2 Open 2/11/21	Tier 3 Timeline to be determined
People 65 years and above	<ul style="list-style-type: none"> - People 50 years and above with a high-risk medical condition - Frontline essential workers age 50 and above who must work within 6 feet of others - Education staff (childcare, PreK-12th grade, indigenous language and culture bearers) - People living or working in other congregate settings not covered in Phase 1a - Pandemic response staff (limited to those at risk) 	<ul style="list-style-type: none"> - People 55 years and above - People 40 years and above who have a high-risk medical condition - People 16-49 who are frontline essential workers with a high-risk medical condition - People 16 years and above who live in a multigenerational household (i.e. a grandchild living with an Elder). - People 16 years and above who live in communities where at least 45% of homes don't have water systems

*See [availability page at covidvax.Alaska.gov](https://covidvax.alaska.gov) for further clarifications



Phase 1b – Tier 2

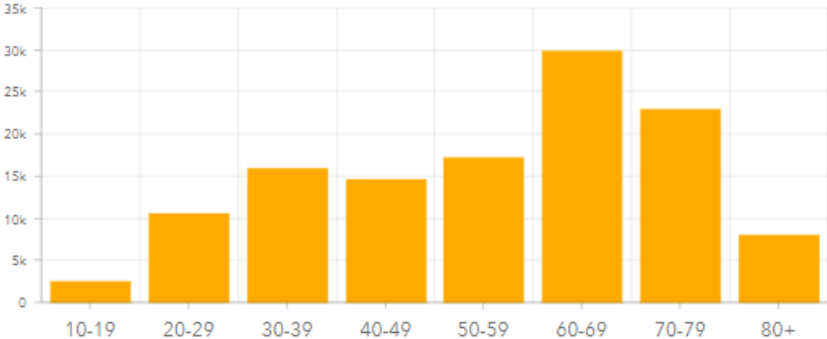
• People living or working in congregate settings not covered in Phase 1a, limited to:

- Acute psychiatric facilities;
- Correctional settings;
- Group homes for individuals with disabilities or mental and behavioral health conditions;
- Homeless and domestic violence shelters;
- Substance misuse and treatment residential facilities;
- and
- Transitional living homes

Vaccine Data Dashboard

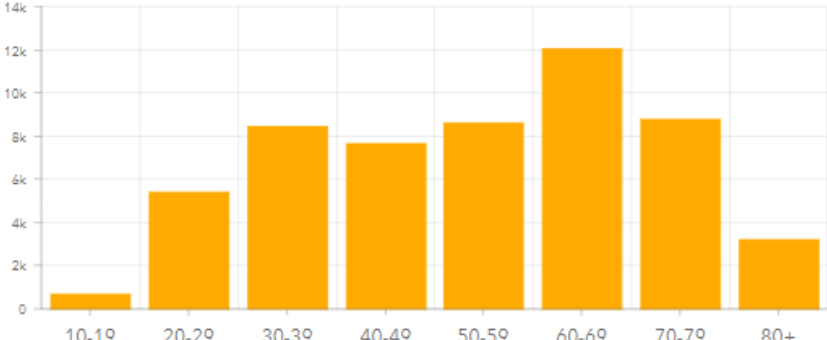
Data reported 2/15/2021

Persons Vaccinated by Age Group



Age Race Gender Ethnicity

Vaccination Series Complete by Age Group



Age Race Gender Ethnicity

Moderna Allocation
56,700

State IHS

Pfizer Allocation
62,400

State IHS

Total State Allocation
119,100

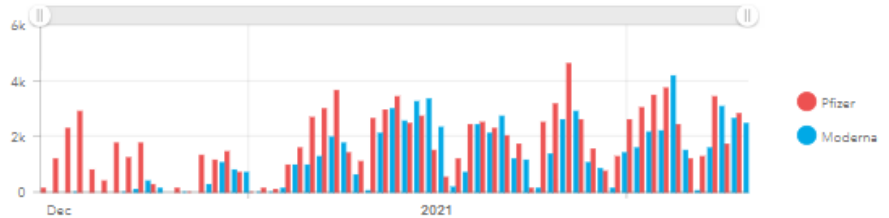
State IHS

Persons Vaccinated
120,396

Vaccination Series Complete
54,739

Total Doses Administered
175,135

Administered Doses by Manufacturer by Date



Administered Doses by Manufacturer by Date Administered Doses by Manufacturer



Questions?



**How much does the vaccine
cost?**



What if I already had COVID and recovered?



**Will there be a statewide
vaccine mandate?**



What about COVID-19 variants?

So, will I still need to wear a mask/distance after I get the vaccine? Both doses?

**YES! Wait...why is that?
For how long?**



Thank you!

