

# COVID-19 VACCINE ADVISORY COMMITTEE MEETING

Tuesday, January 12, 2021, 5:30-6:30 pm

Join ZoomGov Meeting

<https://www.zoomgov.com/j/1611668304?pwd=dTZCeEdGWDFsYVJ2UUd5ZTY0bkJBZz09>

Meeting ID: 161 166 8304

Passcode: 715988

One tap mobile

+16692545252,,1611668304#

Meeting objectives:

- Discuss COVID-19 vaccine safety
- Discuss COVID-19 distribution in Oregon

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## Welcome

Nhu To-Haynes,  
Facilitator

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## Background information

- Vaccine information
- Vaccine distribution in Oregon

Oregon Health  
Authority staff

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## Closing

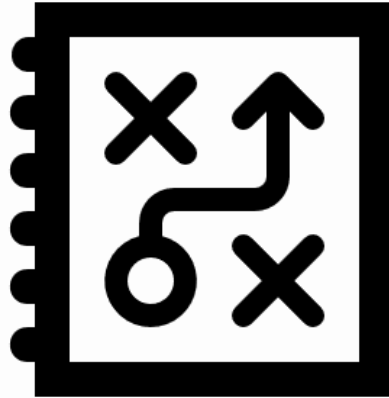
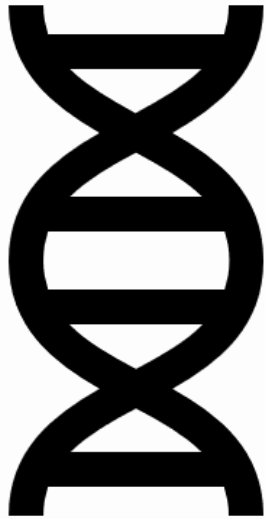
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Everyone has a right to know about and use Oregon Health Authority (OHA) programs and services. OHA provides free help. Some examples of the free help OHA can provide are:

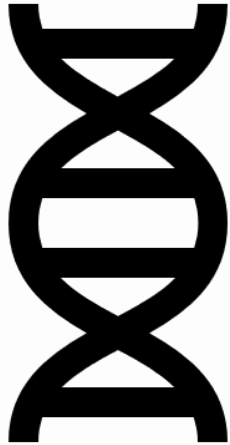
- Sign language and spoken language interpreters
- Written materials in other languages
- Braille
- Large print
- Audio and other formats

If you need help or have questions, please contact COVID-19 Vaccine Advisory Committee staff at 971-673-1222, or [covid.vaccineadvisory@dhsoha.state.or.us](mailto:covid.vaccineadvisory@dhsoha.state.or.us) or 711 TTY.



## Background on COVID-19 vaccination

*mRNA vaccines, safety and side effects*



## mRNA COVID-19 vaccines

Your body naturally uses mRNA to send instructions when building proteins.



mRNA technology is new in vaccine production but is already being used in cancer treatment.

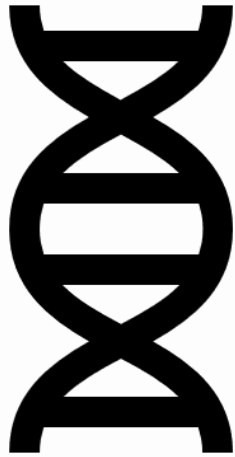
It has been studied for more than ten years.

# mRNA COVID-19 vaccines



**Spike Protein**

The COVID-19 mRNA vaccines give instructions to our cells to make a **harmless piece** that looks like the “spike protein” on the surface of the COVID-19 virus.



## mRNA COVID-19 vaccines

Our immune system sees these fake spike proteins and builds antibodies that recognize them. In the future our immune system will now recognize when the COVID-19 virus enters the body and can fight it.



# What Makes mRNA Vaccines Different?

- New technology
- No infectious material but very **delicate**
- **Genetic material** coated in a **cholesterol/fat “envelope”**
- **Hard to store**
  - Pfizer -70 Centigrade (Ultra cold)
  - Moderna -20 Centigrade (Cold)
- Once transported to facility, can only sit in a **regular fridge for 24 hours**
- Once a vial (containing 6 doses) is opened, needs to be used in **6-12 hours**



# Vaccine Safety and Testing



# mRNA vaccines

## Pfizer

- 2 doses **21 days apart**
- Vaccine efficacy = **95%**
- 162 cases of symptomatic disease in placebo; 8 in vaccine group
- 10 cases of severe disease; 9 in placebo, 1 in vaccine
- Efficacy in those over 65 years old = 94%
- Requires ultra-cold transport

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## Moderna

- 2 doses **28 days apart**
- Vaccine efficacy = **94.1%**
- 185 cases of symptomatic disease in placebo; 11 in vaccine group
- 30 cases of severe COVID and 1 death, all in placebo group
- No difference in efficacy by age or ethnicity
- Normal freezer temp

# Who was included in the vaccine trials?

	<b>Pfizer (BNT162b2)</b>	<b>Moderna (mRNA-1273)</b>
Number of people enrolled	<b>Over 43,000</b>	<b>Over 30,000</b>
Race and ethnicity of participants	Total 30% racially diverse 10% black, 13% Hispanic	37% racially diverse 10% black, 20% Hispanic/Latino
Older adults	45% were 56-85 years	23% were >65 years

# Emergency Use Authorization

Emergency Use Authorization (EUA) is a mechanism to facilitate the availability and use of medical countermeasures, including vaccines, during public health emergencies, such as the current COVID-19 pandemic.

Under an EUA, FDA may allow the use of unapproved medical products, or unapproved uses of approved medical products in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when certain statutory criteria have been met, including that there are no adequate, approved, and available alternatives.

# Restrictions on COVID-19 Vaccines with EUA

- Not authorized for use in children under age 16
- Further studies and approval necessary before children can be vaccinated

# Are the COVID-19 Vaccines rigorously tested?

Yes- over 70,000 people participated in trials.

- No skipped steps
- Both trials included a minimum of 8 weeks of follow-up for at least 50% of their participants by the time of EUA application
- Does NOT imply that the authorization was done too quickly or that the vaccine is not safe

# Safety evaluations

Three **independent advisory committees** reviewed the results:

1. The Vaccine and Related Biological Products Advisory Committee (VRBPAC) that advises the FDA
2. The Advisory Committee on Immunization Practices (ACIP) that advises the CDC
3. Western States Vaccine Safety Committee

# Side effects after vaccination

Mild to moderate, more common after second dose

Generally, more frequent and severe in those <55

- Systemic adverse reactions usually occur in 1-2 days and usually last 24 hours
- The most common:
  - injection site reactions (84.1%)
  - fatigue (62.9%)
  - headache (55.1%)
  - muscle pain (38.3%)
  - chills (31.9%)
  - joint pain (23.6%)
  - fever (14.2%);



# Frameworks for sequencing of limited supply vaccines



# Federal Vaccine Allocation Process

- The first vaccines for prevention of COVID-19 in the United States were authorized for emergency use by the Food and Drug Administration (FDA) in December 2020.
- **Advisory Committee on Immunization Practices (ACIP)** provides advice to the Director of the Centers for Disease Control and Prevention (CDC) regarding the use of vaccines.

# ACIP Goals

- Health minimize disruption to society and the economy, including maintaining healthcare capacity
- Ensure equity in vaccine allocation and distribution

Balancing goals of preventing death and harm from COVID-19 and preserve societal functioning



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Long Term Care  
Facility Residents



Healthcare personnel

# Need to balance these goals

From ACIP:

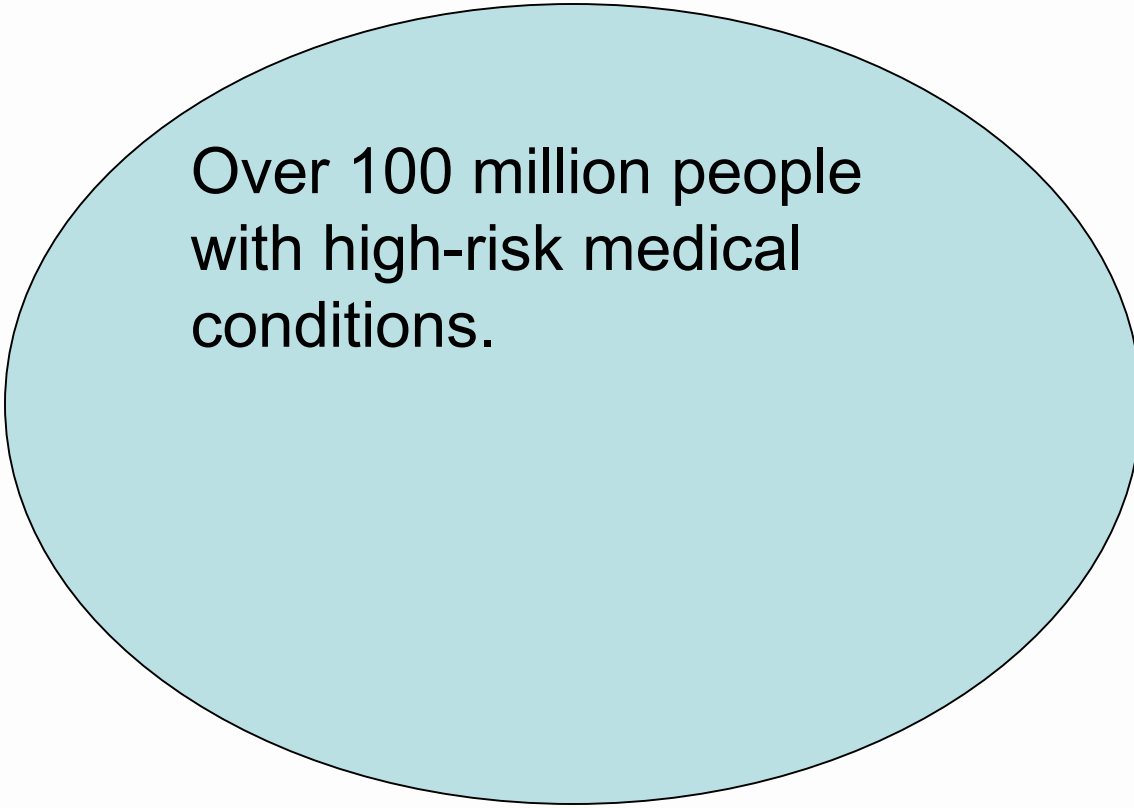
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Long Term Care  
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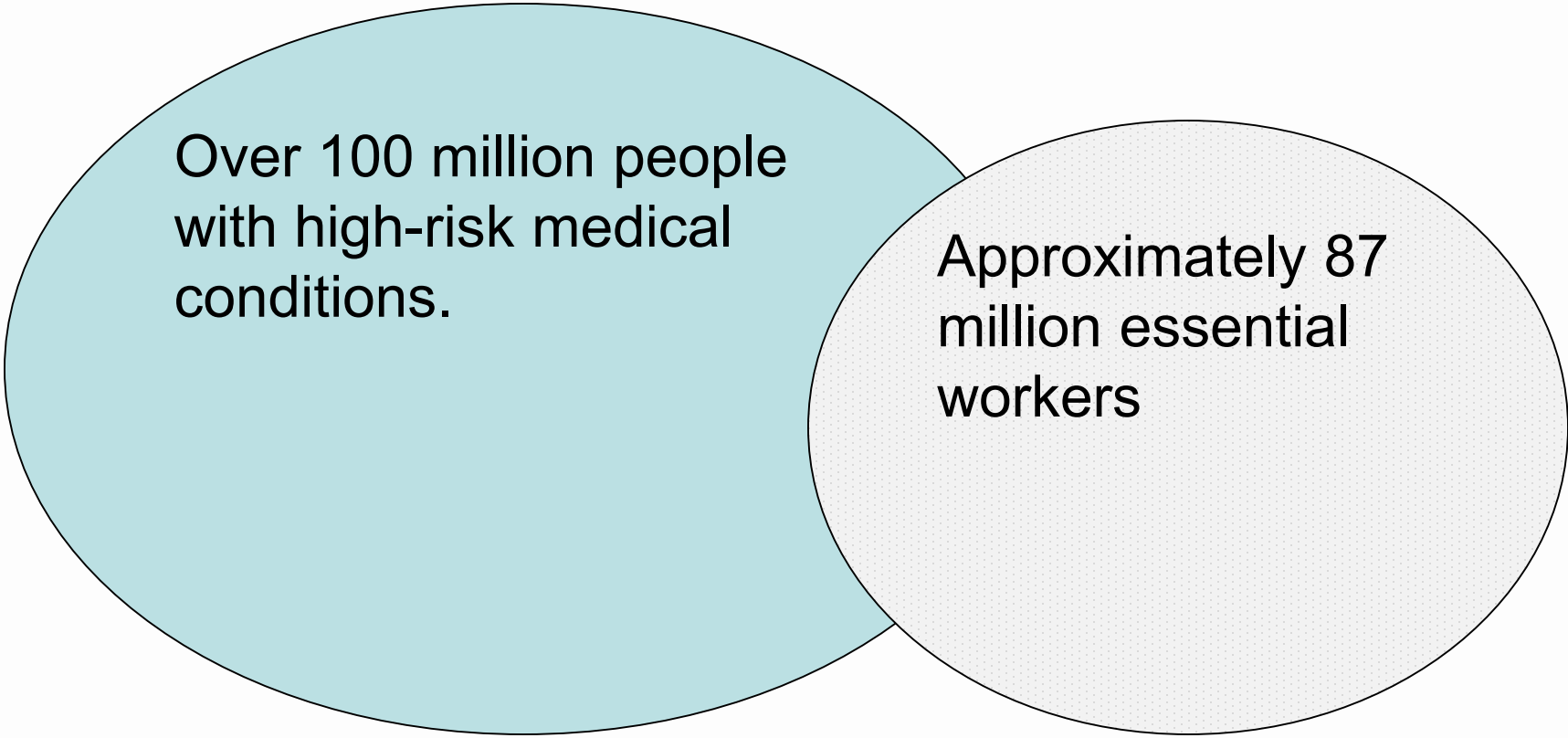
# Population profiles



Over 100 million people  
with high-risk medical  
conditions.

People can fit into more than one category in this visual.

# ACIP: Where to start



Over 100 million people with high-risk medical conditions.

Approximately 87 million essential workers

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Approximately 53 million adults 65 and older



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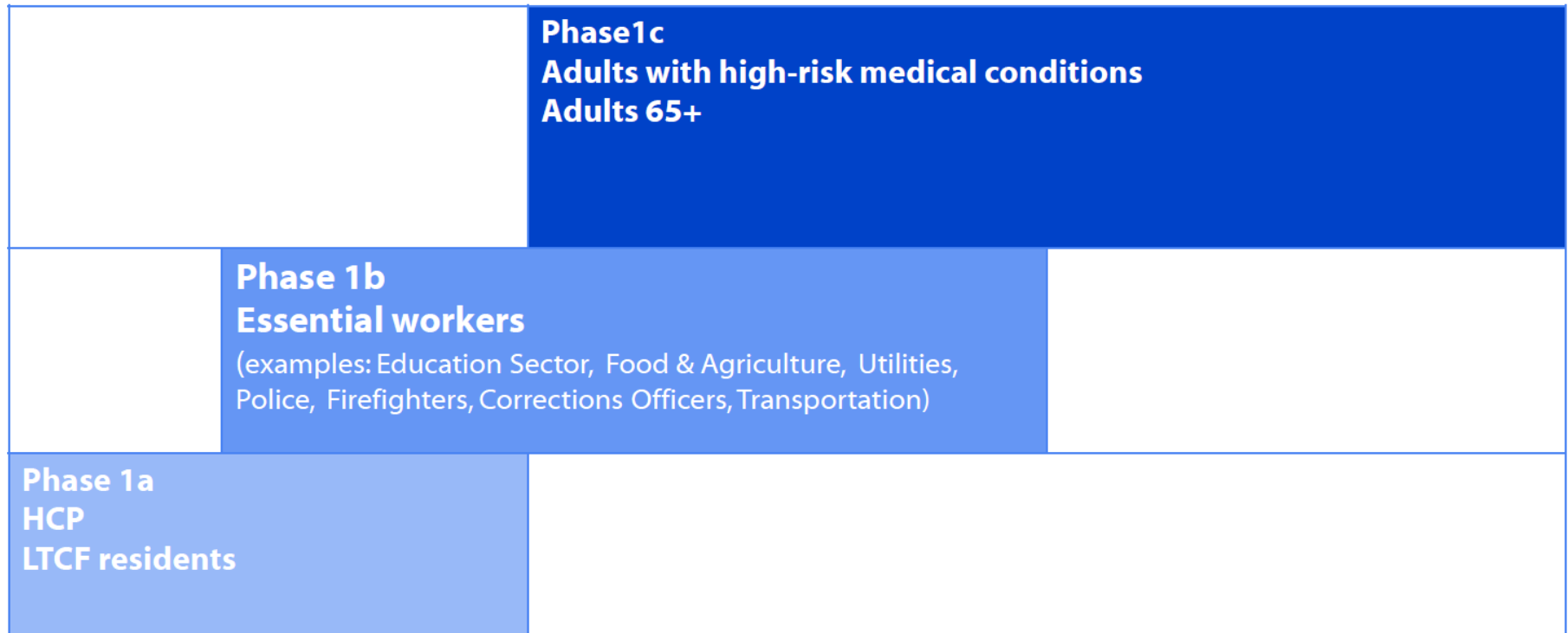
Approximately 87 million essential workers

21 million healthcare personnel

Approximately 53 million adults 65 and older

# ACIP- Oregon is different

## Proposed Interim Phase 1 Sequence



Time

# ACIP's definition of essential workers

## Essential Workers\* (total ~87M)

### Frontline Essential Workers (~30M)

- First Responders (Firefighters, Police)
- Education (teachers, support staff, daycare)
- Food & Agriculture
- Manufacturing
- Corrections workers
- U.S. Postal service workers
- Public transit workers
- Grocery store workers

### Other Essential Workers (~57M)

- Transportation and logistics
- Food Service
- Shelter & Housing (construction)
- Finance
- IT & Communication
- Energy
- Media
- Legal
- Public Safety (Engineers)
- Water & Wastewater

**Frontline Essential Workers:** workers who are in sectors essential to the functioning of society and are at substantially higher risk of exposure to SARS-CoV-2

# ACIP: Principles to guide sequencing

- **High throughput** to increase pace of vaccination to get to 12000 doses per day
  - Throughput is how quickly we can get through things. An example in Oregon is the Salem fair grounds where they are set up and giving out a high volume of vaccines

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- **Disease-based principles** for who to vaccinate first:
  - Those at high risk for dying and death (*morbidity and mortality*) versus
  - Those at high risk of infecting others (increased *transmission*)

# Other considerations for group sizes and pace

- **Shipping considerations :**
  - Moderna vaccine has to be shipped in allotments of **100 doses**
  - Pfizer has to be shipped in allotments of **975 doses**

# Other considerations for group sizes and pace

- **Storage and use considerations**
  - Pfizer needs to sit in ultra cold freezer until ready to use. It can stay in regular fridge for only 5 days. After regular freezer, one vial needs to be used in room temperature for no longer than 2 hours (undiluted) or 6 hours (diluted). Vial needs to be **discarded in 6 hours after it is opened**
  - Moderna can sit in regular freezer but then needs to thaw for 2.5 hours in fridge. Then sit out for 15 minutes. No need to dilute. Vial needs to be **discarded in 6 hours after it is opened.**