

COVID-19 Update Moderna COVID-19 Vaccine

COVID-19 ECHO Presentation December 16, 2020

Alexander Wu, ScD, MPH
Past CDC Epidemic Intelligence Service Officer assigned to NPAIHB, 2018–2020

Global, U.S. Situation

What works

Moderna COVID-19 Vaccine, mRNA-1273

Global, U.S. Situation

What works

Moderna COVID-19 Vaccine, mRNA-1273

U.S.

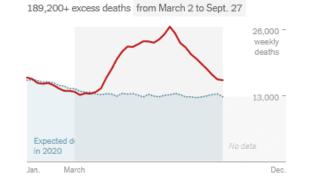
329,300+ excess deaths from March 1 to Nov. 7

79,000 - weekly deaths

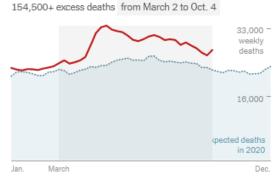
39,000 - deaths

n 2020

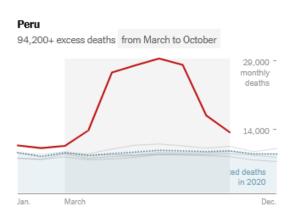
Jan. March Dec.

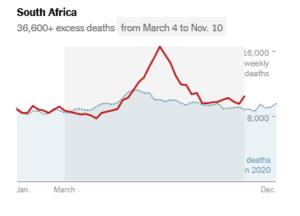


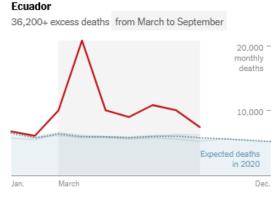
Mexico

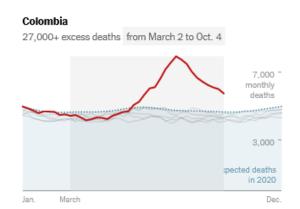


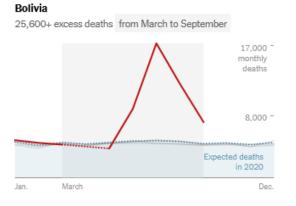
Brazil

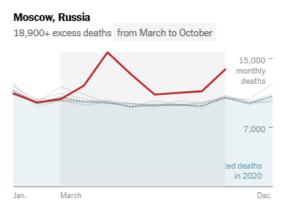






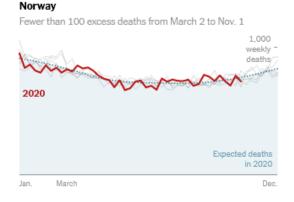


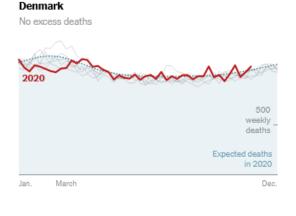


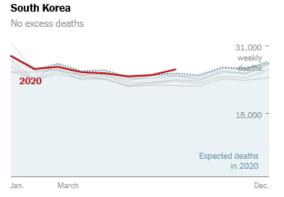


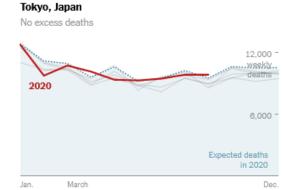
Germany Finland Czech Republic 3,600+ excess deaths from March 2 to Oct. 25 600+ excess deaths from March 2 to Sept. 27 1,100+ excess deaths from March 2 to Nov. 1 26,000 weekly deaths 2020 2020 weekly 2,000 2020 deaths weekly deaths 13,000 1,000 ted deaths d deaths Expected deaths in 2020 in 2020 in 2020 Dec. Dec. Dec. Jan. March Jan. March March













COVID-19 Dashboard by the Center for Systems Science and Engineering (CSSE) at Johns Hopkins University (JHU)

≡

Global Cases 73,773,321

Cases by Country/Region /Sovereignty

16,769,765 US

9,932,547 India

6,970,034 Brazil

2,708,940 Russia

2,447,458 France

1,928,165 Turkey

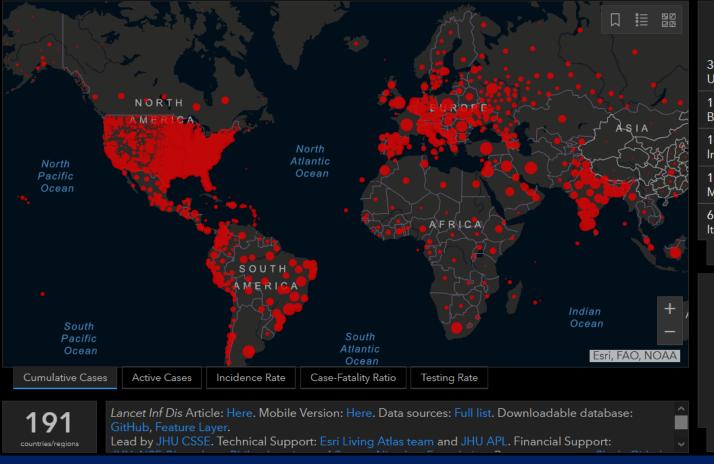
1,893,568 United Kingdom

1,888,144 Italy

1,762,212 Spain

Admin0 Admin1 Admin2

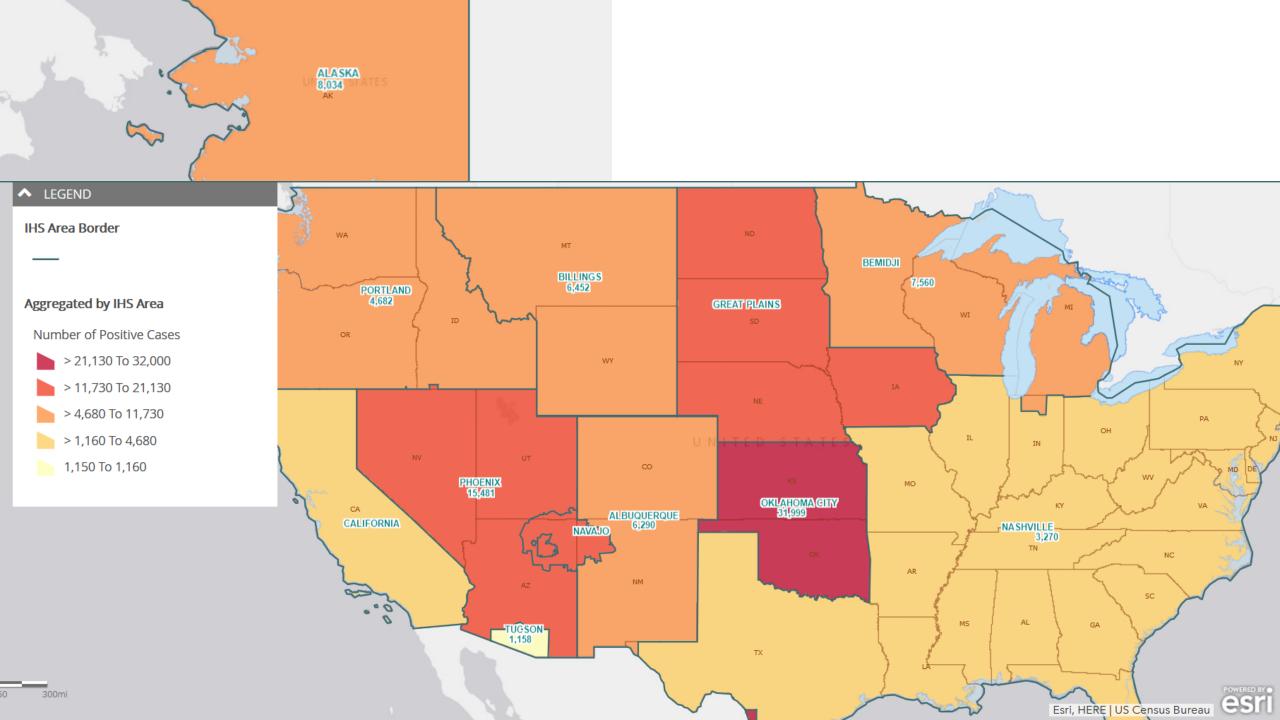
Last Updated at (M/D/YYYY)
12/16/2020, 9:28 AM





Daily Cases

Daily New Cases per 100k people. Data shown from 1/22/20 to 12/14/20. ΑK VT NH ME ND IL WA ID MT MN ΜI NY MA OR SD IN ОН NV WY IA PΑ NJ CT RI CA UT со NE мо ΚY wv ٧A MD DE AR NC SC ΑZ NM KS TN DC οк LA MS ΑL GA ΗI TX FL PR



Global, U.S. Situation

What works

Moderna COVID-19 Vaccine, mRNA-1273

3 W's



Wash hands



Wear a mask



Watch distance



Test

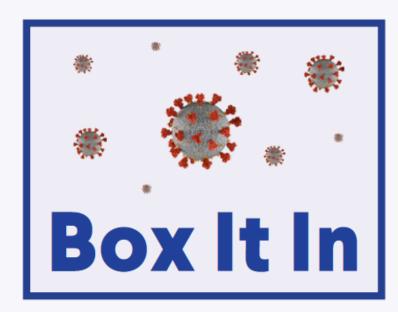
Widely





Quarantine

All contacts self-isolate for 14 days



To get us all working again



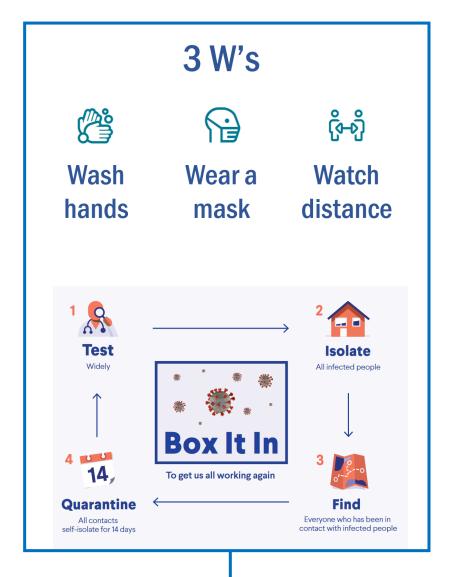
All infected people





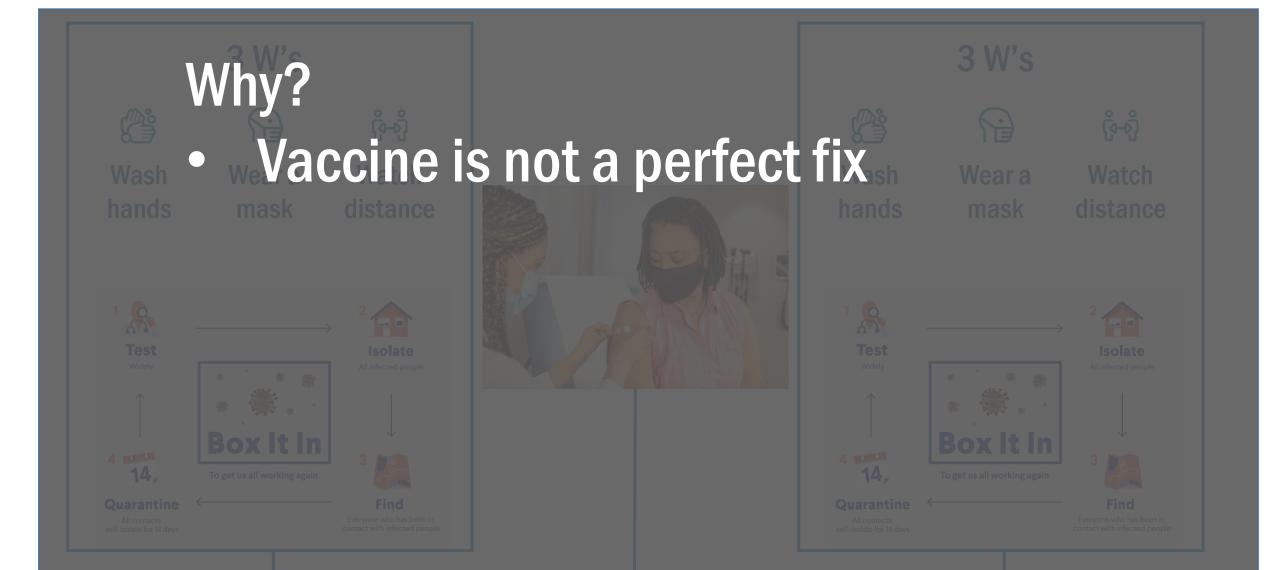
Find

Everyone who has been in contact with infected people

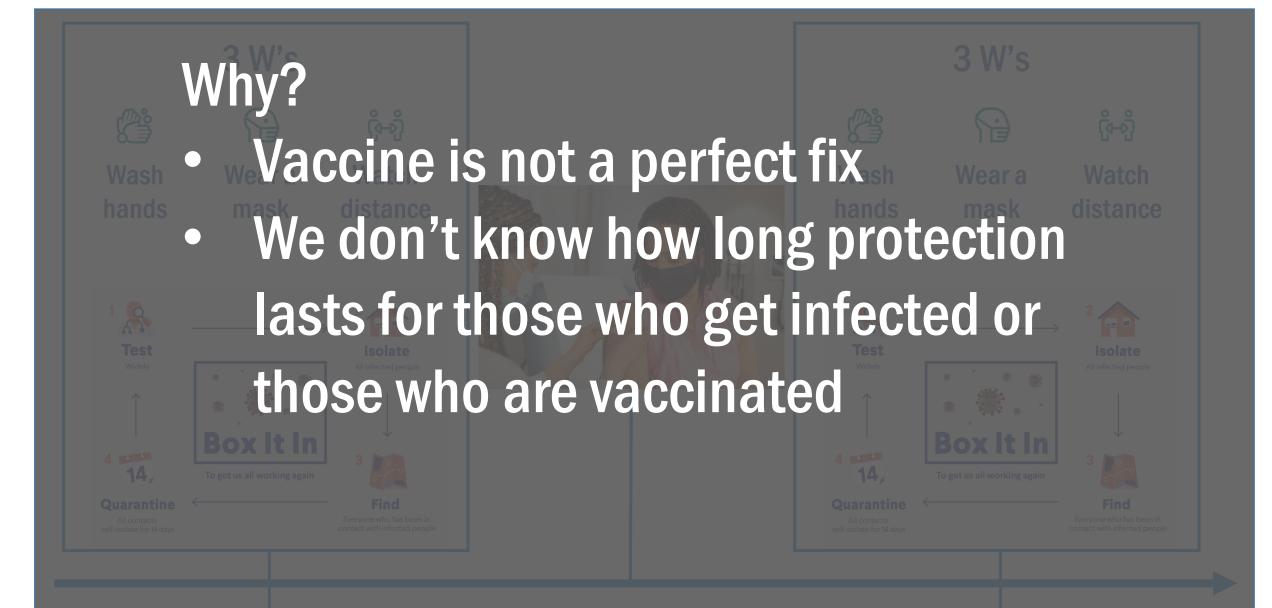




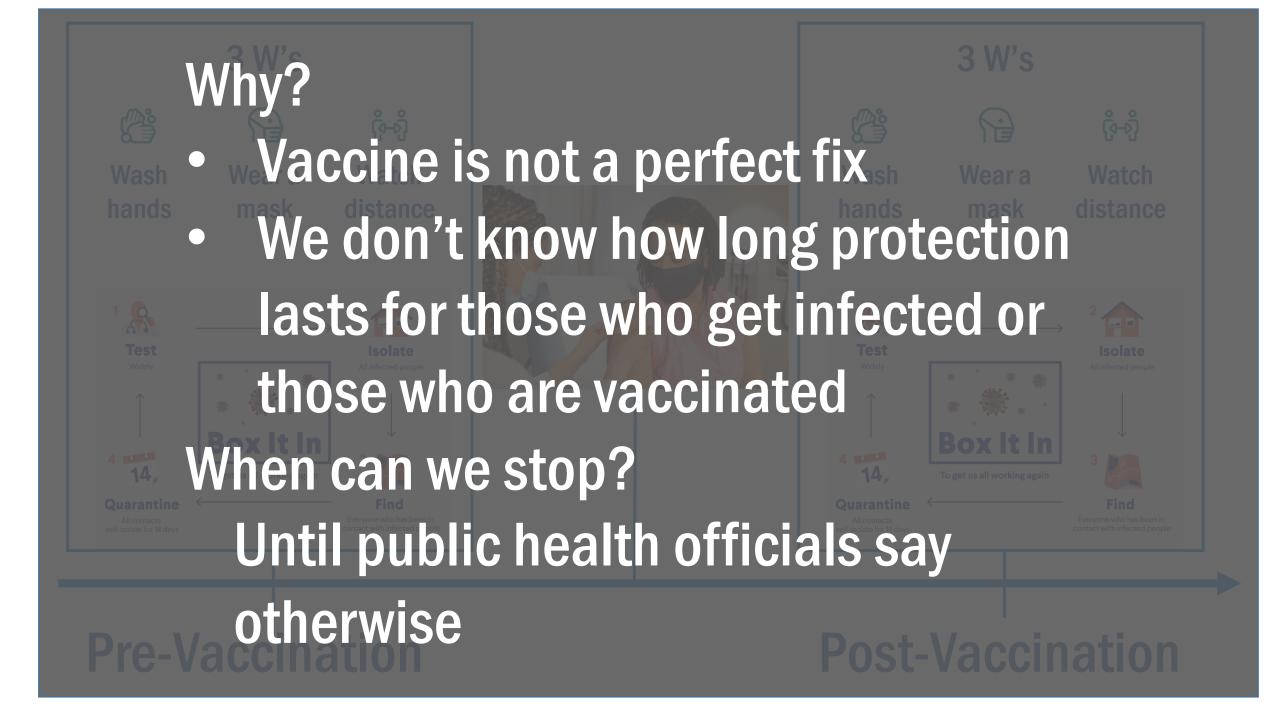
Post-Vaccination



Post-Vaccination



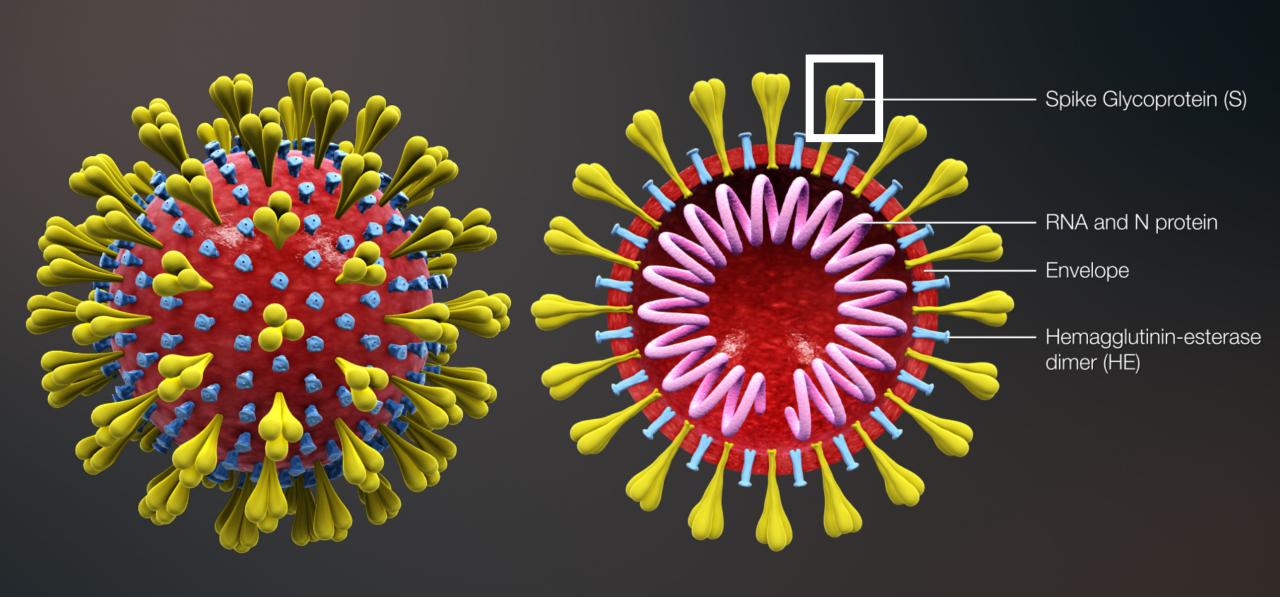
Post-Vaccination



Global, U.S. Situation

What works

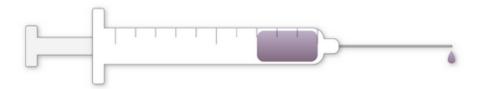
Moderna COVID-19 Vaccine, mRNA-1273



Yes, You'll Still Need a Mask

How the Pfizer-BioNTech Vaccine Works

By Jonathan Corum and Carl Zimmer Updated Dec. 14, 2020



The German company <u>BioNTech</u> partnered with Pfizer to develop and test a coronavirus vaccine known as **BNT162b2**. A clinical trial demonstrated that the vaccine has an <u>efficacy rate</u> of 95 percent in preventing Covid-19.

Moderna Vaccine

- Cambridge, Massachusetts (2010)
- mRNA-1273 delivered in a lipid nanoparticle "bubble"
- mRNA does not enter cell nucleus or interact with genome

Moderna Vaccine

- Cambridge, Massachusetts (2010)
- mRNA-1273 delivered in a lipid nanoparticle "bubble"
- mRNA does not enter cell nucleus or interact with genome
- Phase 1: consistent immune response and lasted >=3 months
- Phase 2: produced antibodies to SARS-CoV-2 spike protein
 - 2 doses of 100ug vaccine had similar levels of neutralizing antibody titers in 250ug dose
 - Decided on 2 doses of 100ug

- 30,351 participants randomized to two groups
 - 15,181 people received mRNA-1273 vaccine
 - 15,170 received placebo
 - Received two doses total: Day 1 and Day 29

- 30,351 participants randomized to two groups
 - 15,181 people received mRNA-1273 vaccine
 - 15,170 received placebo
 - Received two doses total: Day 1 and Day 29
- 99 vaccine study sites in the U.S.
- 36.5% of participants representing communities of color
- 230 AI/AN people, 0.8% of participants

- Primary efficacy endpoint: Vaccine efficacy in preventing COVID-19 occurring at least 14 days after dose 2
- 196 cases of Covid-19: 185 in placebo group 11 in vaccine group
 - Efficacy = 94.1% (89.3%, 96.8%)

- Primary efficacy endpoint: Vaccine efficacy in preventing COVID-19 occurring at least 14 days after dose 2
- 196 cases of Covid-19: 185 in placebo group 11 in vaccine group
 - Efficacy = 94.1% (89.3%, 96.8%)
- Efficacy lowest for severely obese (BMI>40 kg/m²): 91.2% (32.0%, 98.9%)
- Efficacy in > 64 year-old group = 86.4% (61.4%, 95.5%)
- Zero severe COVID-19 cases in vaccine group; 30 in placebo group

- Primary efficacy endpoint: Vaccine efficacy in preventing COVID-19 occurring at least 14 days after dose 2
- 196 cases of Covid-19: 185 in placebo group 11 in vaccine group
 - Efficacy = 94.1% (89.3%, 96.8%)
- Efficacy lowest for severely obese (BMI>40 kg/m²): 91.2% (32.0%, 98.9%)
- Efficacy in > 64 year-old group = 86.4% (61.4%, 95.5%)
- Zero severe COVID-19 cases in vaccine group; 30 in placebo group
- EUA application submitted to FDA November 30, 2020
- Efficacy of one dose: 80.2% (55.2%, 92.5%); ? beyond 28 days

- No anaphylactic or severe hypersensitivity reactions
- Common solicited adverse reactions

Injection site pain	91.6%	Muscle pain	59.6%
Fatigue	68.5%	Joint pain	44.8%
Headache	63.0%	Chills	43.4%

- No anaphylactic or severe hypersensitivity reactions
- Common solicited adverse reactions

Injection site pain	91.6%	Muscle pain	59.6%
Fatigue	68.5%	Joint pain	44.8%
Headache	63.0%	Chills	43.4%

- 0.2% to 9.7% (fatigue) reported as severe (more frequent after dose 2 and less frequent in participants aged ≥65 years)
- 4 cases of Bell's palsy: 3 in vaccine group, 1 in the placebo (frequency not above that expected in general population)

Characteristic	Moderna
Vaccine name	mRNA-1273
Vaccine type	Messenger RNA (mRNA)
Trial registration #	NCT04470427
Target enrollment	30,000 (39% ages 45-64; 25% ages 65+)
US diverse enrollment	37% (20% - Hispanic; 10% - African American/Black; 4% - Asian; 3% - All others)
Ages eligible for trial	18+
Part of OWS	Did accept Operation Warp Speed funding for vaccine development as well as advance agreement for purchase of at least 100M doses
Number of doses	2 doses (28 days apart)
Diluent required	No
Vial volume & dosage	5mL multidose (10 doses/vial)
Cold storage	Conventional freezer (-20°C)
Storage duration	 up to 6 months in -20°C freezer (Pfizer 6 months at -80 to -60 C) up to 30 days in 2°C-8°C fridge (Pfizer 5 days refrigerated at 2 to 8 C) up to 12 hours (unopened vial, 6 hours after first draw) at room temp (Pfizer 6 hours diluted with sterile saline)

Characteristic	Moderna
Vaccine name	mRNA-1273
Vaccine type	Messenger RNA (mRNA)
Demonstrated efficacy	 - 94.1% at final results 196 cases, measured starting from 14 days post second dose, (185 placebo/11 vaccine) - 100% against severe disease - Efficacy consistent across age, race and ethnicity
Adverse events	 No significant safety concerns at this time; longer term safety unknown Prominent events included: fatigue (9.7%) and myalgia (8.9%)
Doses available	- Up to 15M for US by end 2020 - Up to 1B doses by end 2021
Shipping details	- Sent from manufacturer through central distributor (i.e., McKesson); most likely arriving via UPS or FedEx

Global, U.S. Situation

What works

Moderna COVID-19 Vaccine, mRNA-1273

Resources

Vaccines site ▼



Advanced Search

Vaccines & Immunizations

CDC > Vaccines and Immunizations Home > COVID-19 Vaccination > For Healthcare Professionals











For Healthcare Professionals

For Pregnant Women

COVID-19 Vaccination

For Healthcare Professionals

Preparing to Provide COVID-19 Vaccines

Answering Patients' Questions

Some patients won't have questions about coronavirus disease 2019 (COVID-19) vaccination when you give your strong recommendation and use language that assumes patients will get vaccinated when doses are widely available. If a patient questions your recommendation about COVID-19 vaccination, this does not necessarily mean they will not accept a COVID-19 vaccine. This is a new vaccine, and some questions are to be expected. Your patients consider you their most trusted source of information when it comes to vaccines, and sometimes they simply want *your* answers to their questions.

This page outlines some topics patients ask about most vaccines and tips for how to answer their questions.



Questions about Vaccine Safety and the Speed of Vaccine Development

The federal government, under the umbrella of <u>Operation Warp Speed</u> , has been working since the start of the pandemic to make a COVID-19 vaccine available as soon as possible. This accelerated timeline is unprecedented and has raised concerns for some people that safety may be sacrificed in favor of speed. However, as with all vaccines, safety is a top priority.

For Specific Groups of People	
Basics and Common Questions	+
Vaccines and Preventable Diseases	+
News and Media Resources	+



Questions about Whether It Is Better to Get Natural Immunity Rather than Immunity from Vaccines

Because some people with COVID 19 can have very mild symptoms, some may see natural infection as

preferable to receiving a new vaccine. Others may be concerned that getting a COVID-19 vaccine could make a later illness worse. Help your patients understand the risks and benefits so they can be confident choosing to get vaccinated.

Patients may ask: Is the vaccine that helpful? I heard getting COVID-19 gives you better and longer immunity than the protection a vaccine can give. Can it actually make my illness worse if I do end up getting COVID-19? **To respond, you can:**

- Explain the potential serious risk COVID-19 infection poses to them and their loved ones if they get the illness or spread it to others. Remind them of the potential for long-term health issues after recovery from COVID-19 disease.
- Explain that scientists are still learning more about the virus that causes COVID-19. And it is not known whether getting COVID-19 disease will protect everyone against getting it again, or, if it does, how long that protection might last.
- Describe how the vaccine was tested in large clinical trials and what is currently known about its safety and effectiveness.

Be transparent that the vaccine is not a perfect fix. Patients will still need to practice other precautions like wearing a mask, social distancing, handwashing and other hygiene measures until public health officials say otherwise.

Example:

Example: Questions about Whether It Is Better to Get Natural Immunity

"Both this disease and the vaccine are new. We don't know how long protection lasts for those who get infected or those who are vaccinated. What we do know is that COVID-19 has caused very serious illness and death for a lot of people. If you get COVID-19, you also risk giving it to loved ones who may get very sick. Getting a COVID-19 vaccine is a safer choice."

Coronavirus

Latest news

U.S. map

World map

Vaccine tracker

Symptoms

Vaccine FAQ

Coronavirus Living

Health

Tracking vaccine distribution, state by state



Updated Dec. 12 at 12:39 p.m.

PLEASE NOTE

The Washington Post is providing this story for free so that all readers have access to this important information about the coronavirus. For more free stories, sign up for our Coronavirus Updates newsletter.

First in line

17M Health-care workers

3.7M Nursing home residents

Second in line

14M Essential workers

9.6M Teachers

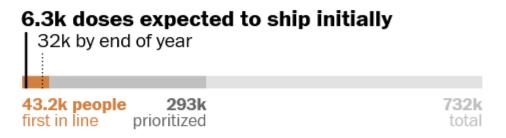
2.3M First responders

Third in line

89M With preexisting conditions

6.7M Age 65+

Alaska



Over the last week, Alaska has seen an average of **587** confirmed cases and **5** deaths per day. Alaska has the **12th** most confirmed cases per capita among states and D.C. during the same period.

Alaska is expected to get about **6,300** doses in the first set of Pfizer vaccines. If the Moderna vaccine is approved, the state could get a total of **32,000** doses before the end of the year. That is enough to vaccinate **4.4 percent** of the state population.

Opinion

Find Your Place in the Vaccine Line

By Stuart A. Thompson Illustrations by Jorge Colombo











Based on your risk profile, we believe you're in line behind **268.7 million** people across the United States.

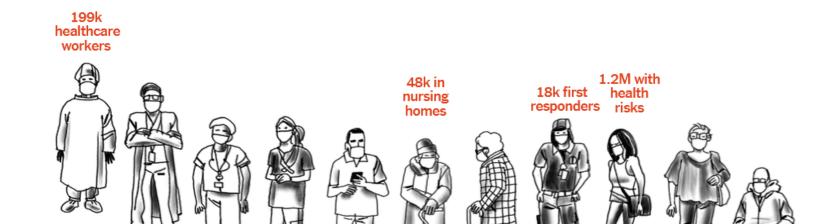
When it comes to **Oregon**, we think you're behind **3.3 million** others who are at higher risk in your state.

And in Washington County, you're behind 444,700 others.

These are just estimates and the line may ultimately be shorter. The order isn't yet finalized and children could be skipped entirely if the vaccine isn't approved for <u>people under 18</u>.

If the line in **Oregon** was represented by about 100 people, this is where you'd be standing:

The article continues below the graphic.



References

- https://www.nytimes.com/interactive/2020/04/21/world/coronavirus-missing-deaths.html
- https://coronavirus.jhu.edu/map.html
- https://coronavirus.jhu.edu/data/new-cases-50-states
- https://maps.ihs.gov/portal/apps/StoryMapBasic/index.html?appid=5411113222c74d23bf09d6fa8c5909fd
- https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html
- https://preventepidemics.org/wp-content/uploads/2020/04/BoxItInBriefingDoc.pdf
- https://www.cdc.gov/vaccines/covid-19/hcp/answering-questions.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fhcp%2Fcovid-conversations%2Fanswering-questions.html
- https://www.nytimes.com/interactive/2020/health/pfizer-biontech-covid-19vaccine.html?action=click&state=default®ion=hub&context=storyline_vaccine_hub&module=styln-coronavirus-vaccines&variant=show&pgtype=LegacyCollection
- https://www.fda.gov/media/144452/download
- https://www.fda.gov/media/144434/download
- https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-primary-efficacy-analysis-phase-3-cove-study
- https://www.fda.gov/media/144413/download
- https://www.cdc.gov/vaccines/covid-19/hcp/answering-questions.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fhcp%2Fcovid-conversations%2Fanswering-questions.html
- https://www.washingtonpost.com/graphics/2020/health/covid-vaccine-states-distribution-doses/?itid=hp-top-table-main
- https://www.nytimes.com/interactive/2020/12/03/opinion/covid-19-vaccine-timeline.html?action=click&module=0pinion&pgtype=Homepage



Thank You

COVID-19 ECHO Presentation December 16, 2020

Alexander Wu, ScD, MPH

The findings and conclusions of this presentation are those of the author alone.

