Safety and efficacy of COVID-19 vaccine

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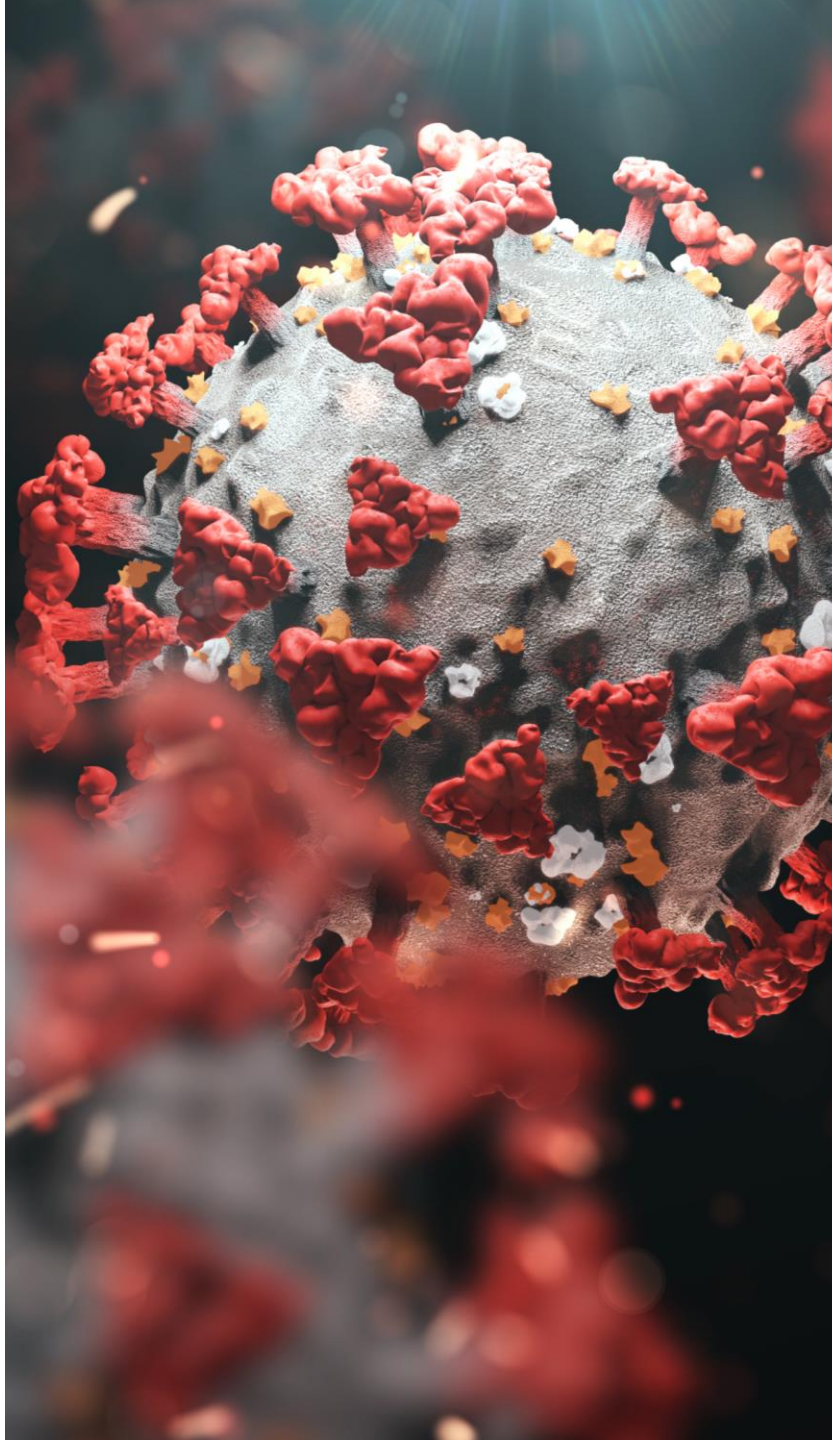
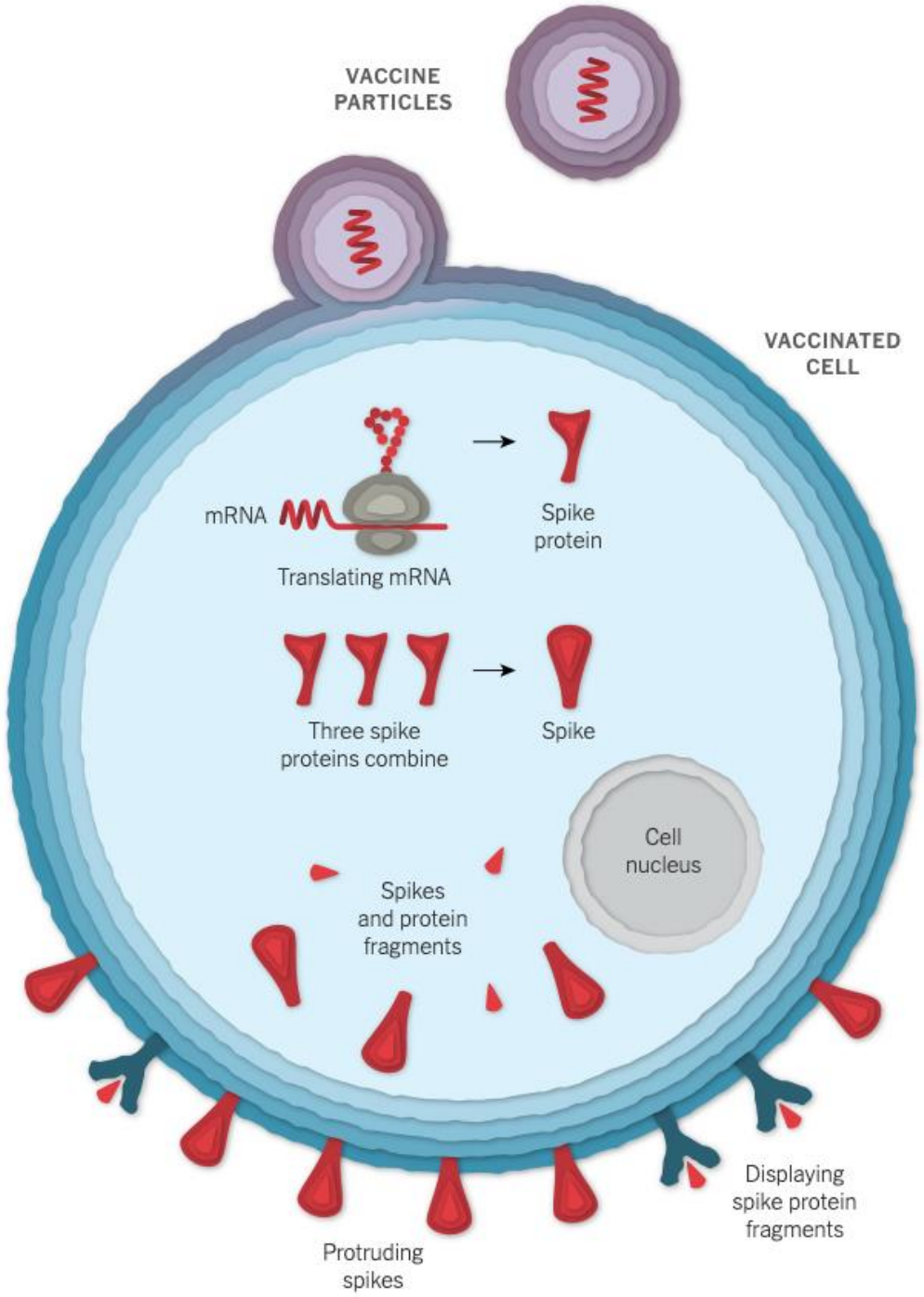
Messenger RNA (mRNA) Vaccines

- Teach cells how to make a harmless piece of the “spike protein” for SARS-CoV-2.
- Cells display this piece of spike protein on their surface, and an immune response is triggered inside our bodies.
- **DO NOT** use the live virus that causes COVID-19. They **CANNOT** give someone COVID-19.
- **DO NOT** affect or interact with our DNA in any way.



mRNA Vaccine Mechanism of Action



How to Quickly Develop a Safe and Effective Vaccine

1. Fund the effort

- Readily supported by private and government funding

- US government supported with > $10 billion

2. Parallel Processing

- Trials and manufacturing simultaneously

- Continuous and rapid review of data/safety data by FDA

3. Build it based on past knowledge

- Past outbreaks of MERS/SARS identified spike proteins as possible vaccine targets for coronaviruses

- mRNA first tried in 1990s to treat Diabetes Insipidus through production of vasopressin but unstable and effect not lasting

How to Quickly Develop a Safe and Effective Vaccine

4. Make it globally

- Chinese scientist sequenced the genome Jan 2020 and shared

- US, Britain and other countries collaborated more than ever before

5. Continue real time safety monitoring

- V-Safe CDC application with real time tracking of symptoms

- Vaccine Adverse Events Reporting System (VAERS)

How is a vaccine tested?

Phase 1
20-100 Healthy Volunteers

Researchers try to answer these questions:

- Is this vaccine safe?
- Are there any serious side effects?
- How does the vaccine dose relate to any side effects?
- Is the vaccine causing an immune response?

Phase 2
Several Hundred Volunteers

Researchers try to answer these questions:

- What are the most common short-term side effects?
- What's the body's immune response?
- Are there signs that the vaccine is protective?

Phase 3
1000+ Volunteers

Researchers try to answer these questions:

- How do disease rates compare between people who get the vaccine and those who do not?
- How well can the vaccine protect people from disease?

Phase 4
Vaccine is Approved

Researchers try to answer these questions:

- FDA approves a vaccine only if it's safe, effective, and benefits outweigh the risks.
- Researchers continue to collect data on the vaccine's long-term benefits and side effects.

Phase III Trials for mRNA Vaccines

Pfizer/BioNTech

EUA issued 12/13/2020
52% effective after 1st dose
95% effective after 2nd dose
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

EUA issued 12/18/2020
94% effective after 2nd dose
30,000 enrolled
89 clinical sites
32 U.S. states

Racial/ethnic distribution
20% - Hispanic, 10% - African American/Black
4% - Asian, 3% - All others
64% ages 45 and older, 39% ages 45-64,
25% ages 65+

Common side effects seen more often after 2nd dose

Pfizer/BioNTech

(Side effects after second dose in the 16-55 year old group)

50.0% - Fatigue
33.3% - Headache
25.0% - Chills
25.0% - Myalgias

Moderna

(adverse reactions in participants 18 years of age and older)

92.0% - Pain at the injection site
70.0% - Fatigue
64.7% - Headache
61.5% - Myalgia
46.4% - Arthralgia
45.4% - Chills
23.0% - Nausea/vomiting
19.8% - Axillary swelling/tenderness
15.5% - Fever
14.7% - Swelling at the injection site
10.0% - Erythema at the injection site

Who Should Get the mRNA Covid-19 Vaccine?

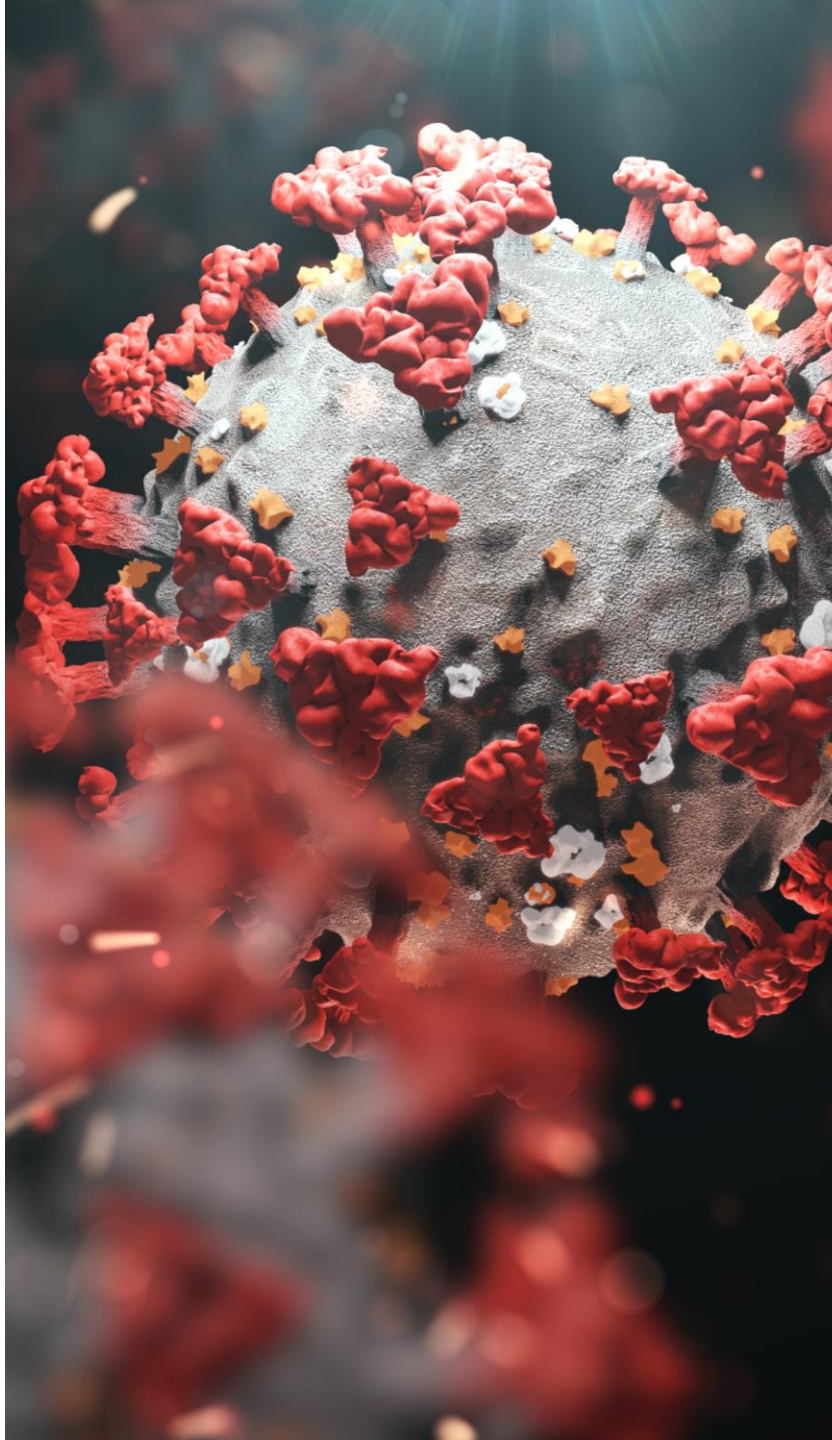
	MAY PROCEED WITH VACCINATION	PRECAUTION TO VACCINATION	CONTRAINDICATION TO VACCINATION
CONDITIONS	•**CONDITIONS** Immunocompromising conditions •Pregnancy •Lactation **ACTIONS** •Additional information provided* •15 minute observation period	•**CONDITIONS** Moderate/severe acute illness **ACTIONS** •Risk assessment •Potential deferral of vaccination •15-minute observation period if vaccinated	•**CONDITIONS** None **ACTIONS** •N/A
ALLERGIES	**ALLERGIES** History of allergies that are unrelated to components of an mRNA COVID-19 vaccine†, other vaccines, injectable therapies, or polysorbate, such as: •Allergy to oral medications (including the oral equivalent of an injectable medication) •History of food, pet, insect, venom, environmental, latex, etc., allergies •Family history of allergies **ACTIONS** •30-minute observation period: Persons with a history of anaphylaxis (due to any cause) •15-minute observation period: All other persons	•**ALLERGIES** History of any immediate allergic reaction‡ to vaccines or injectable therapies (except those related to component of mRNA COVID-19 vaccines† or polysorbate, as these are contraindicated) **ACTIONS:** •Risk assessment •Consider deferral of vaccination and/or referral to allergist-immunologist •30-minute observation period if vaccinated	**ALLERGIES** History of the following are contraindications to receiving either of the mRNA COVID-19 vaccines†: •Severe allergic reaction (e.g., anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine or any of its components •Immediate allergic reaction‡ of any severity to a previous dose of an mRNA COVID-19 vaccine or any of its components^ (including polyethylene glycol)# •Immediate allergic reaction of any severity to polysorbate^# **ACTIONS** •Do not vaccinate# •Consider referral to allergist-immunologist

Ingredients included in Pfizer-BioNTech and Moderna mRNA COVID-19 vaccines

Description	Pfizer-BioNTech COVID-19 vaccine	Moderna COVID-19 vaccine
mRNA	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2
Lipids	2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide	PEG2000-DMG: 1,2-dimyristoyl-rac-glycerol, methoxypolyethylene glycol
	1,2-distearoyl-sn-glycero-3-phosphocholine	1,2-distearoyl-sn-glycero-3-phosphocholine
	Cholesterol	Cholesterol
	(4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)	SM-102: heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate
Salts, sugars, buffers	Potassium chloride	Tromethamine
	Monobasic potassium phosphate	Tromethamine hydrochloride
	Sodium chloride	Acetic acid
	Dibasic sodium phosphate dihydrate	Sodium acetate
	Sucrose	Sucrose

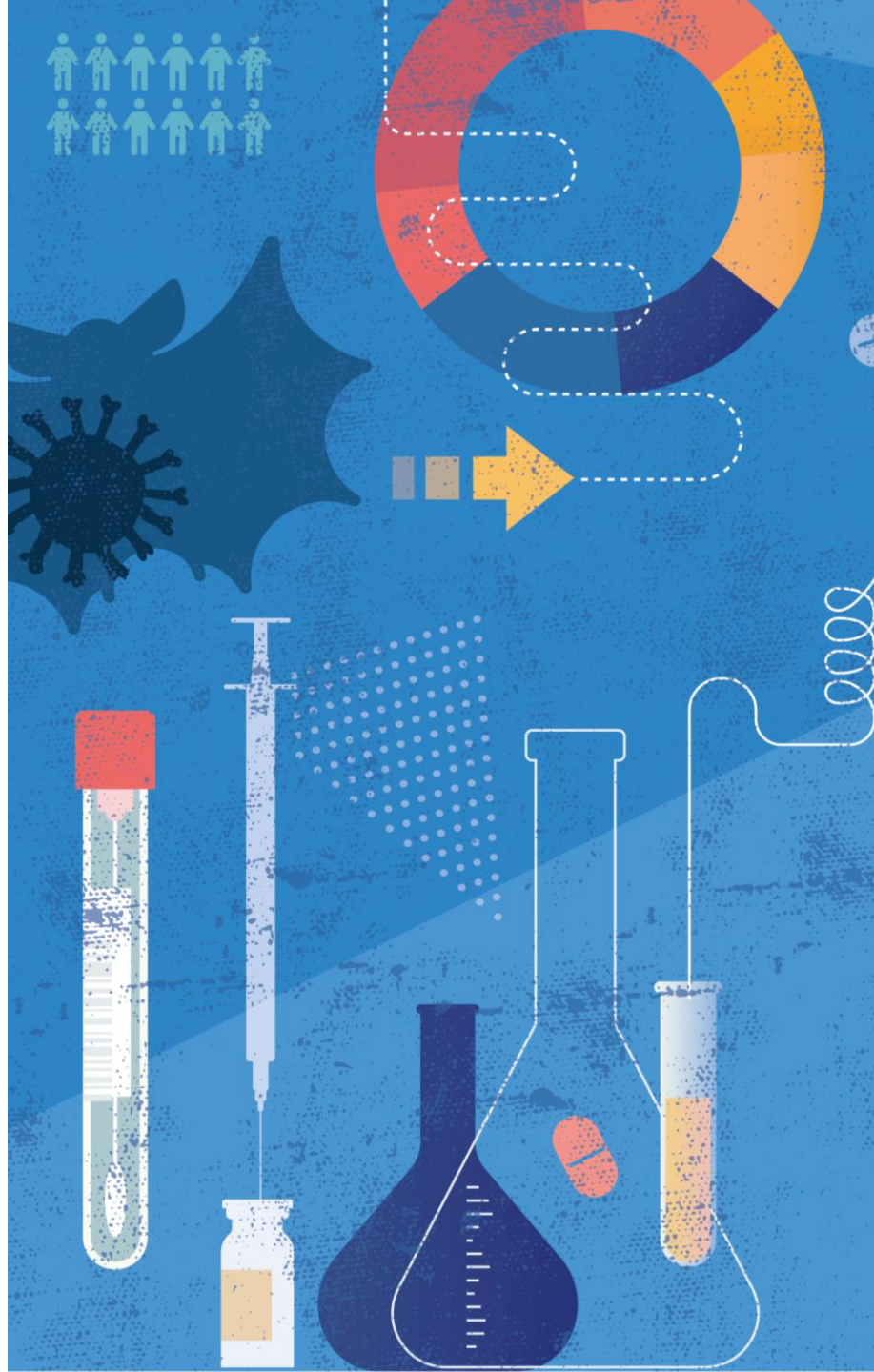
Challenges to distribution

- Limited unpredictable allocations
- Storage challenges to achieve no doses wasted:
  - Pfizer ultra-cold storage -80 C to -60 C, refrigerator 5 days, once diluted 6 hours
  - Moderna freezer storage -21 C to -15 C, refrigerator 30 days, once diluted 6 hours
- **2 Doses required 21 days and 28 days with return visits**
- **High costs of vaccine**



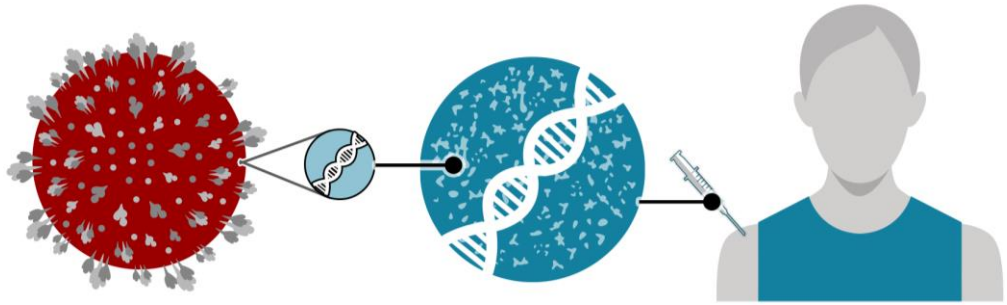
Next up: Oxford-AstraZeneca/J&J

- Easier to mass-produce
- Available at a much cheaper price of around $4
- The vaccine can be stored, transported and handled for at least six months at 35-46F degrees
- Average efficacy of 62%, but may improve with different dosing strategies (based on current data)
- Two doses required at a 12 weeks interval, or single dose
- Awaiting approval in US still sometime in early April with 29,000 participant phase III trial underway

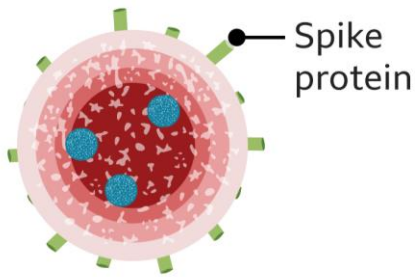


1 Scientists take genes for the spike protein on the surface of the coronavirus and put them into a harmless virus to make a vaccine

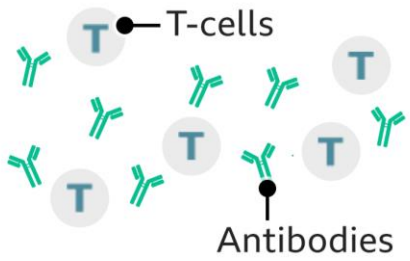
This is injected into the patient



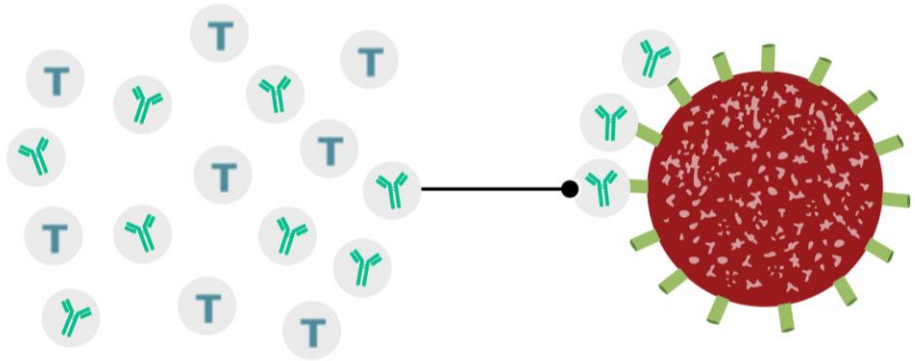
2 The vaccine enters cells which then start to produce the spike protein



The body's immune system reacts, produces antibodies and activates T-cells to destroy cells with the spike protein



3 If the patient later catches coronavirus, antibodies and T-cells are triggered to fight the virus



Source: Nature

BBC

New COVID-19 strain variant B.1.1.7

- Likely in low level since September in US
- Prior strain sequencing not routine in US but identified in Britain
- Could be as much as 50% more transmissible with unclear mechanism
- May have some evidence of increased severity of illness
- Two deletions on spike protein that is a target of vaccine with some suggestion there may be some modest reduction in efficacy in vaccine

Phase 1A Started on December 12, 2020

Everyone in Phase 1A, Groups 1,2,3 and 4 are currently eligible for the vaccine.

Group 1

- Hospital staff with patient care responsibilities
- Urgent care
- Skilled nursing and memory care facility healthcare personnel (HCP) and residents
- Tribal health programs
- Emergency medical services (EMS) providers and other first responders
- All health care interpreters and traditional health workers in any setting within Phase 1a

Group 2

- Other long-term care facilities, including all paid and unpaid HCP, all staff and contractors, including residents who meet the age requirements of:
  - Residential care facilities
  - Adult foster care
  - Group homes for people with intellectual and developmental disabilities
  - Other similar congregate care sites
- Hospice programs
- Mobile crisis care and related services
- Individuals working in a correctional setting
- Adults and youth in custody 16 years and older

Group 3

- HCPs in outpatient settings serving specific high-risk groups
- Day treatment services
- Non-emergency medical transport (NEMT)
- Paid or unpaid caregivers (including parents or foster parents) of medically fragile children or adults who live at home
- Adults and age-eligible children who have a medical condition or disability who receive services in their homes

Group 4

- All other outpatient HCPs
- Other HCP who provide direct service to people with I/DD and other high-risk populations.
- Other public health settings, such as HCP serving WIC, or CBO's with direct or indirect exposures

People eligible:
400,000 approximately

Phase 1B Started on January 25, 2021

Oregon's vaccine supply is limited. It is estimated to take until early April 2021 to administer first doses to everyone who is likely to want a vaccine in Groups 1-5 of Phase 1B.

Group 1

- Childcare providers, early learning and K-12 educators and staff
  Eligible week of January 25, 2021

Group 2

- People 80 and older
  Eligible February 8, 2021

Group 3

- People 75 and older
  Eligible February 15, 2021

Group 4

- People 70 and older
  Eligible February 22, 2021

Group 5

- People 65 and older
  Eligible March 1, 2021

Educators:
152,000 approximately
People over 65:
795,000 approximately

Beyond Date TBD

Subsequent groups will be determined in coordination with the Vaccine Advisory Committee and shared on OHA's COVID-19 vaccine web page. These are examples of groups of people who may included:

- Critical workers in high-risk settings — workers who are in industries essential to the functioning of society and substantially higher risk of exposure
- People of all ages with underlying conditions that put them at moderately higher risk
- General population

Oregon Health Authority

OHA 3527A (02/12/2021)


DON'T
HESITATE.
JUST
VACCINATE.