

COVID-19 VACCINES: WHAT YOU NEED TO KNOW



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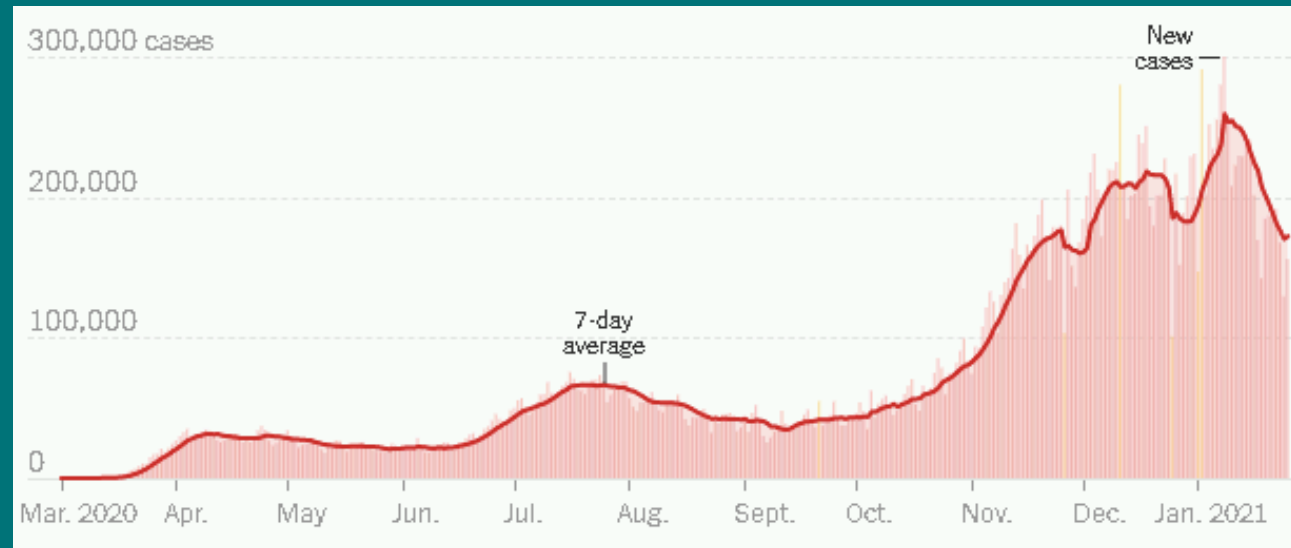
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COVID-19: The Impact

- Up to 300,000 new cases per day, >25.5 million total cases in U.S.
- More than 425,000 people have died of COVID-19
- In Massachusetts, we have had 506,000 total cases and 14,200 lives lost





COVID-19 Vaccines:

Hope for the future

- For the pandemic to end, we need at least 70% of the U.S. population to be immune from previous infection or vaccination
 - An estimated 7-15% have been infected thus far with immunity thought to last up to 3 months
 - If we were to try and achieve immunity without vaccines, an estimated 4-11 million people could lose their lives to COVID-19
- Vaccination offers us an opportunity to prevent significant severe illness, hospitalization, long-term pulmonary, cardiovascular, & neurologic complications, and death
- The vaccines are safe and effective
- Vaccines are a key component to help us fight the pandemic

How a new vaccine is developed, approved and manufactured

The Food and Drug Administration (FDA) sets rules for the three phases of clinical trials to ensure the safety of the volunteers. Researchers test vaccines with adults first.

PHASE 1

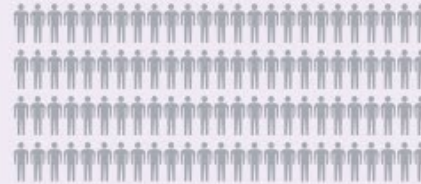


**20-100
healthy volunteers**



- Is this vaccine safe?
- Does this vaccine seem to work?
- Are there any serious side effects?
- How is the size of the dose related to side effects?

PHASE 2



**several hundred
volunteers**

- What are the most common short-term side effects?
- How are the volunteers' immune systems responding to the vaccine?

PHASE 3



**hundreds or thousands
of volunteers**

- How do people who get the vaccine and people who do not get the vaccine compare?
- Is the vaccine safe?
- Is the vaccine effective?
- What are the most common side effects?

FDA licenses the vaccine only if:

- It's safe and effective
- Benefits outweigh risks

Vaccines are made in batches called lots.



Manufacturers must test all lots to make sure they are safe, pure and potent. The lots can only be released once FDA reviews their safety and quality.

The FDA inspects manufacturing facilities regularly to ensure quality and safety.



The Vaccine Life Cycle

safety at every phase

GUIDE

ACIP

ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES

BLA

BIOLOGICS LICENSE APPLICATION

CDC

CENTERS FOR DISEASE CONTROL AND PREVENTION

FDA

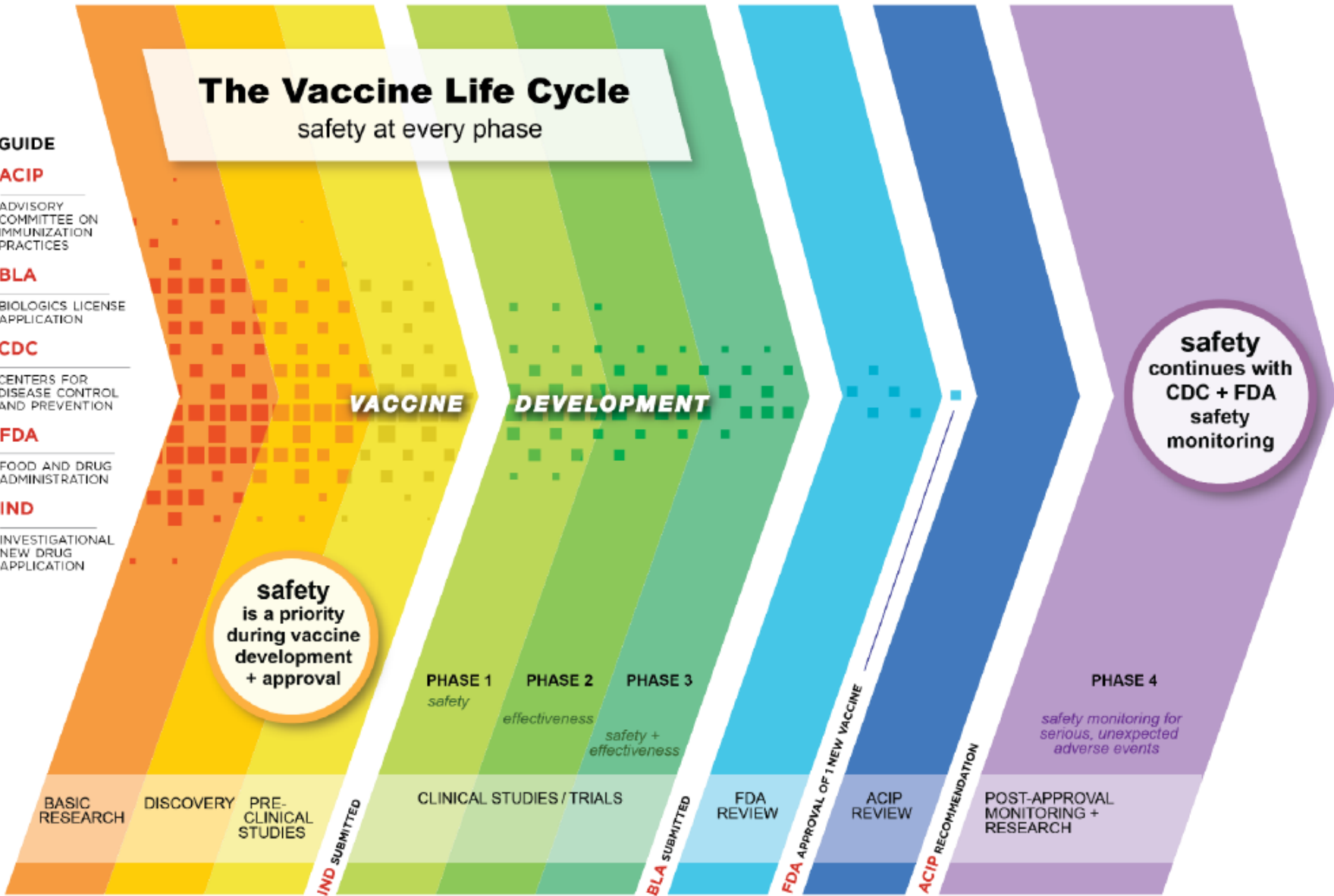
FOOD AND DRUG ADMINISTRATION

IND

INVESTIGATIONAL NEW DRUG APPLICATION

safety is a priority during vaccine development + approval

safety continues with CDC + FDA safety monitoring

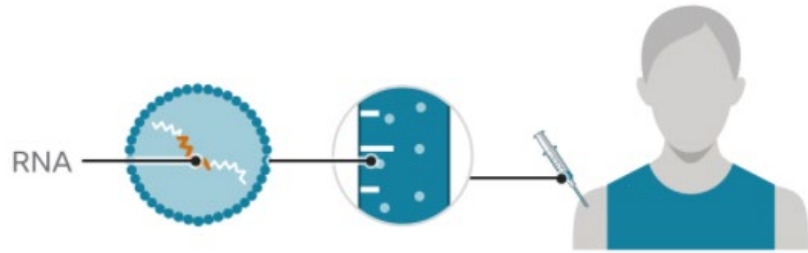


https://www.cdc.gov/vaccinesafety/ensuringsafety/history/index.html#anchor_1593624850886

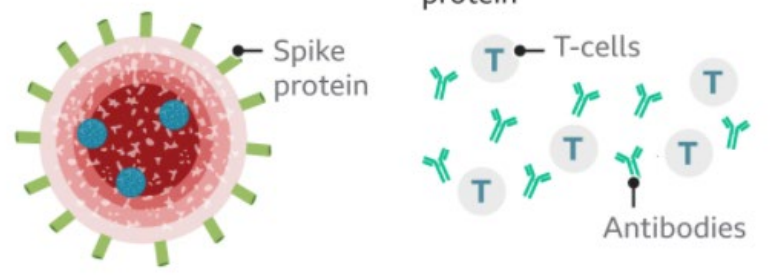


How an RNA vaccine works

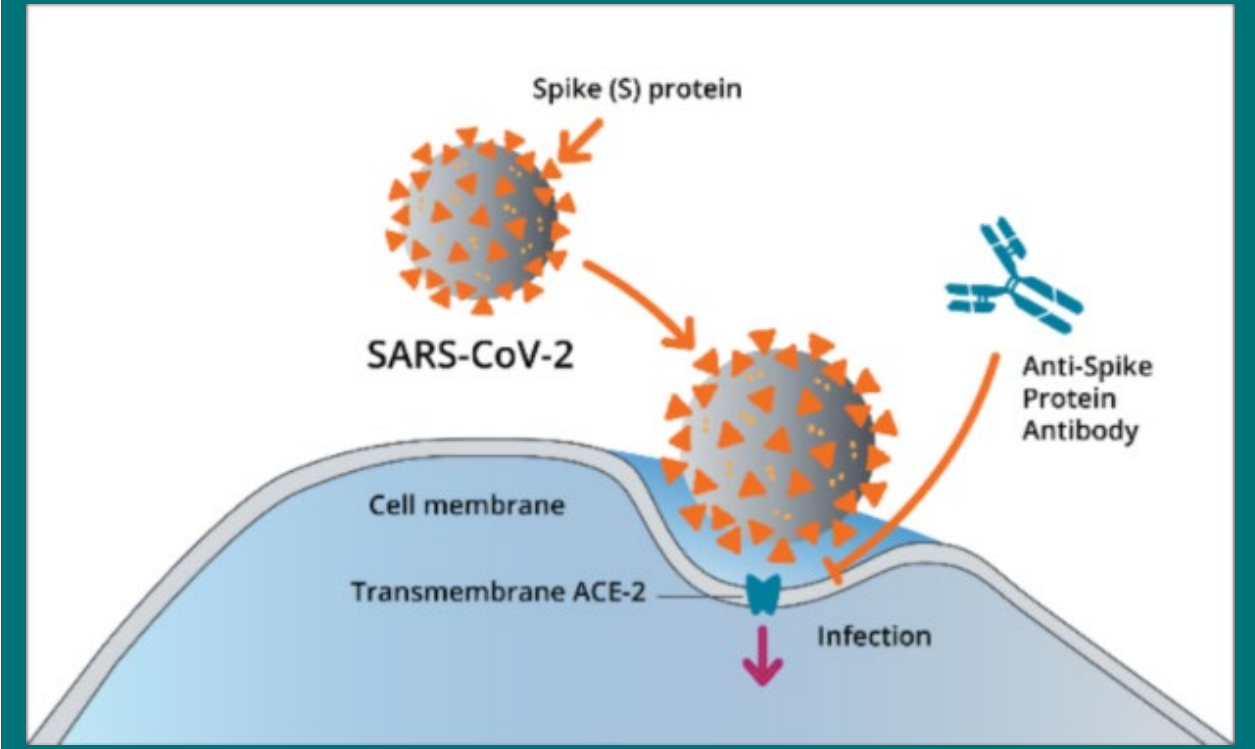
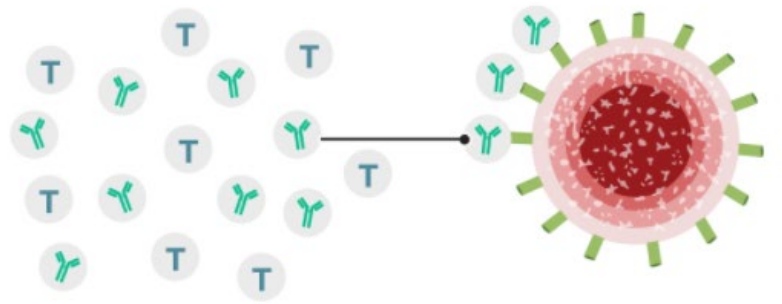
- 1 Scientists take part of the virus's genetic code and turn it into a vaccine that is injected into the patient



- 2 The vaccine enters the cells and tells them to produce the coronavirus 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, the antibodies and T-cells are triggered to fight the virus





BENEFITS OF mRNA VACCINES

SAFETY



- mRNA vaccine technology has been around for decades
 - Has performed safely in clinical trials for other infections and cancer but never previously had the funding or support for large trials until now
- COVID-19 vaccines are being held to same safety standards as all other vaccines and have been rigorously tested for safety and efficacy before being authorized for use in the United States
- Vaccines contain NO virus, only the lab-created mRNA and a lipid nanoparticle carrier to cover and stabilize the mRNA



BENEFITS OF mRNA VACCINES

SAFETY



- Vaccines are relatively lower cost, easy, and quick to manufacture
 - Can be more easily adjusted to match genetic variants
- mRNA does not enter the cell nucleus or interact with your genome, therefore it cannot alter your DNA and is rapidly degraded by normal cellular processes
- Vaccines only encode the spike protein, not the whole virus, which means that there is no risk of infection from the vaccine itself
- The spike protein is broken down within days to weeks like other proteins in the body



BENEFITS OF mRNA VACCINES



EFFICACY

- These were large trials
 - 44,000 patients were randomized equally to receive 2 doses of Pfizer vaccine or placebo
 - 30,420 patients were randomized equally to receive 2 doses of Moderna vaccine or placebo
- Pfizer vaccine demonstrated an overall **95%** efficacy and Moderna vaccine demonstrated an overall **94.1%** efficacy in preventing symptomatic COVID-19 infection compared to placebo



BENEFITS OF mRNA VACCINES

EFFICACY



- We are still learning about the long-term efficacy
 - Likely to continue beyond 4 months and possibly 1 year as vaccination produces higher levels of antibody than natural infection
- Both vaccines are $\geq 50\%$ effective 1-2 weeks after the first dose
- Full efficacy and longer duration of protection are achieved at least 1-2 weeks after the second dose
- Second dose should be completed with the same vaccine on the recommended schedule



WHAT IS IN THE VACCINE?

PFIZER

Two equivalent doses of 0.3 mL 21 days apart, no preservatives or adjuvants

- 30 mcg mRNA encoding the SARS-CoV-2 Spike protein
- lipids
- polyethylene glycol
- potassium chloride
- monobasic potassium phosphate
- sodium chloride (saline)
- dibasic sodium phosphate dihydrate
- sucrose (sugar)

MODERNA

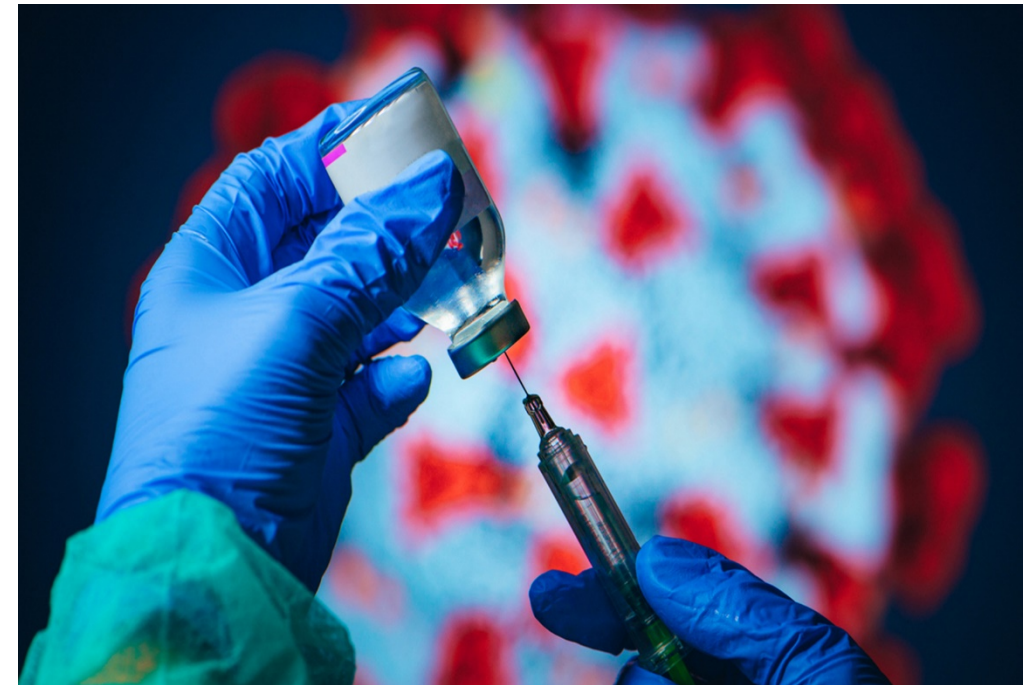
Two equivalent doses of 0.5 mL 28 days apart, no preservatives or adjuvants

- 100 mcg mRNA encoding the SARS-CoV-2 Spike protein
- lipids
- polyethylene glycol
- cholesterol
- acetic acid
- tromethamine and tromethamine hydrochloride
- sodium acetate
- sucrose (sugar)



COVID-19 VACCINE SAFETY

- Over 70 million people have received a COVID-19 vaccine worldwide
- No deaths have been due to COVID-19 vaccination
- There have been no cases of Guillain-Barré Syndrome, transverse myelitis, or autoimmune disorders attributed either to COVID-19 infection or vaccination
- Bell's palsy has been reported in both vaccine and placebo groups, and in equal incidence observed in the general population thus not due to the vaccine





COVID-19 VACCINE SAFETY

- The incidence of severe allergic reactions (i.e. anaphylaxis) to a COVID-19 vaccine is 1/200,000, which is far lower than the incidence of anaphylaxis to food and penicillin (~1/2,500)
- Anaphylaxis typically occurs within minutes to an hour, and severe reactions to vaccines occur within days to weeks of administration
- All adverse outcomes related to COVID-19 are reported to the Vaccine Adverse Event Reporting System (VAERS)





POTENTIAL SIDE EFFECTS VS. ACTUAL COVID INFECTION

Potential Vaccine Side Effects

- Fever (14%)
- Chills (32%)
- Fatigue (63%)
- Muscle aches (38%)
- Joint aches (24%)
- Headache (55%)
- Nausea (1%)
- Local injection-site redness, swelling, or pain (>84%)
- Swollen lymph nodes (0.3%)

COVID-19 Infection Symptoms

- Fever
- Chills
- Fatigue
- Muscle aches
- Joint aches
- Headache
- Nausea
- Cough
- Shortness of breath
- Congestion/Runny nose
- Sore throat
- Loss of taste or smell
- Vomiting
- Diarrhea



RACE/ETHNICITY & COVID-19 INFECTION

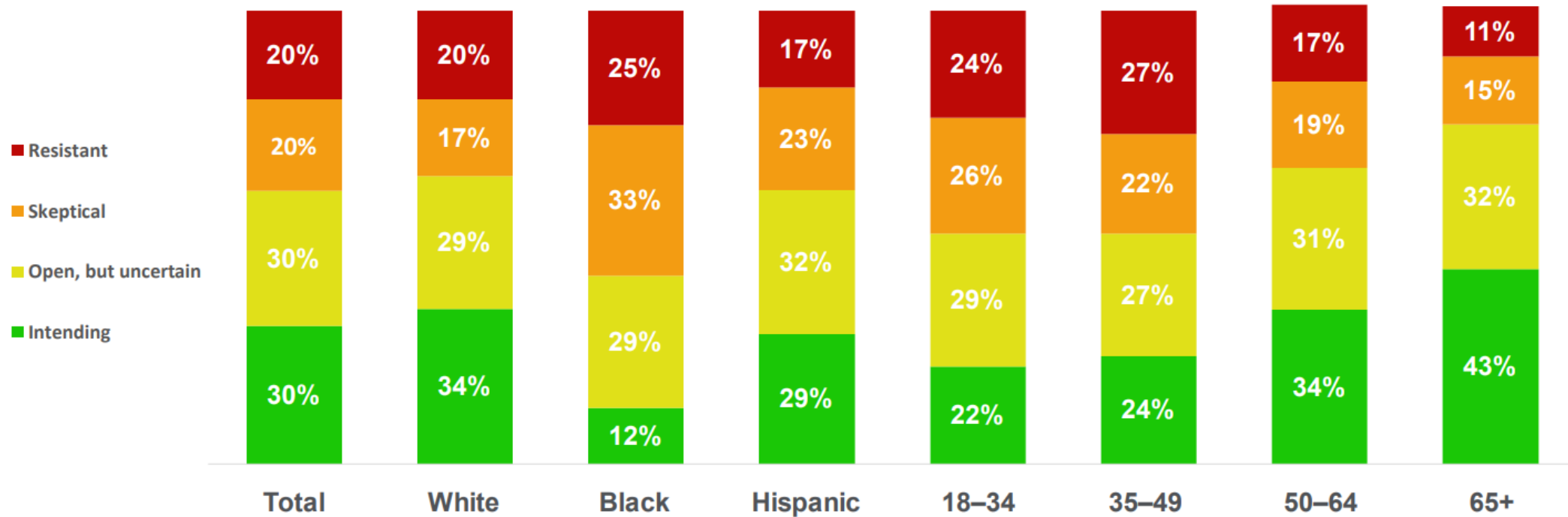
Rate ratios compared to White, Non-Hispanic persons	American Indian or Alaska Native, Non-Hispanic persons	Asian, Non-Hispanic persons	Black or African American, Non-Hispanic persons	Hispanic or Latino persons
Cases ¹	1.8x	0.6x	1.4x	1.7x
Hospitalization ²	4.0x	1.2x	3.7x	4.1x
Death ³	2.6x	1.1x	2.8x	2.8x

<https://www.cdc.gov/coronavirus/2019-ncov/covid-data/investigations-discovery/hospitalization-death-by-race-ethnicity.html>



RACE/ETHNICITY & COVID-19 VACCINE

COVID-19 Vaccination Intent





WHO CAN GET THE VACCINE



INDICATIONS

- Pfizer: Anyone 16 years of age or older
- Moderna: Anyone 18 years of age or older
- Both provided free of charge

CONTRAINDICATIONS

- Anyone with a severe allergic reaction (ex. anaphylaxis) or other immediate allergic reaction to any component of the COVID-19 vaccine or to a previous dose of mRNA COVID-19 vaccine

PRECAUTIONS

- Anyone with a history of anaphylactic reaction to any vaccine or injectable therapy (intramuscular, intravenous, or subcutaneous)
- NOTE: no other vaccine is to be administered within 14 days before or after the COVID-19 vaccine



PREGNANCY/LACTATION



- Limited data on use of COVID-19 vaccine in pregnant or lactating women
 - No adverse pregnancy outcomes observed in 11 pregnant women who received the Pfizer vaccine and 6 pregnant women who received the Moderna vaccine in clinical trials
- CDC and ACOG do NOT consider pregnancy or breastfeeding contraindications to COVID-19 vaccination
- WHO currently does not recommend vaccination in pregnant patients due to lack of data in this population NOT due to any adverse effects seen in pregnant patients
- ACOG recommends vaccination of individuals who are actively trying to become pregnant or are contemplating pregnancy
- If pregnant and breastfeeding women are part of a group that is recommended to receive COVID-19 vaccine, they should be offered the vaccine and may choose to be vaccinated

mRNA VACCINES & FERTILITY

Misinformation regarding mRNA COVID-19 vaccines have been circulating on the internet. Claims have been made that the antigen created by the vaccine (the SARS-CoV-2 Spike protein) is similar to another protein that is important for placental attachment (syncytin-1), and that vaccination results in antibodies that target syncytin-1. This has since been debunked. The vaccines have not been shown to cause infertility.

- Neither COVID-19 mRNA vaccines contain syncytin-1, nor does the mRNA used in the vaccines encode for syncytin-1
 - The spike protein formed as a result of COVID-19 mRNA vaccination and syncytin-1 are structurally very dissimilar
 - No data indicates the antibodies formed as a result of COVID-19 mRNA vaccination target syncytin-1
 - No safety concerns were demonstrated in rats that received Moderna COVID-19 vaccine prior to or during gestation in terms of female reproduction, fetal/embryonal development, or postnatal development
- No adverse pregnancy outcomes observed in 11 pregnant women who received the Pfizer vaccine and 6 pregnant women who received the Moderna vaccine in clinical trials
 - The human body generates its own supply of Spike antibodies when it fights off COVID-19 infection, and there is currently no evidence that these antibodies attack the placenta or may cause infertility





CURRENT OR RECENT HISTORY OF COVID-19



- Do not get the vaccine until you have improved and can stop isolation
- There is no required time between illness and vaccination
- If you have had monoclonal antibody therapy or convalescent plasma therapy, you must wait at least 90 days before COVID-19 vaccination
- Re-infection is uncommon in the 90 days after initial infection, therefore you may delay vaccination until after this period if desired



COVID-19 EXPOSURE AND VACCINATION



- Defer vaccination until quarantine period has ended to avoid exposing healthcare personnel or other persons during vaccination visit, and to avoid confusion as to whether symptom development could be due to COVID-19 infection or vaccination itself

COVID-19 VACCINATION RECOMMENDATIONS FOR:

INDIVIDUALS WITH UNDERLYING MEDICAL CONDITIONS

- Vaccine may be administered to persons with underlying medical conditions who have no contraindication to vaccine

IMMUNOCOMPROMISED PERSONS

- No contraindication to receiving vaccine
- May have a diminished immune response to vaccination
- A discussion with one's healthcare provider can help make an informed decision related to the risks of COVID-19 infections vs. the potential risks of vaccination





WHO CAN GET THE VACCINE

	Proceed with Vaccination	Precaution to Vaccination	Contraindication to Vaccination
Conditions	<ul style="list-style-type: none">• Immunocompromising conditions• Autoimmune disease• Pregnancy• Lactation• Anticoagulation therapy or coagulopathy	<ul style="list-style-type: none">• Moderate/severe acute illness	<ul style="list-style-type: none">• None
Allergies	<ul style="list-style-type: none">• History of food, pet, insect, venom, environmental, etc. allergies• History of allergy to oral medications (including the oral equivalent of an injectable medication)• Non-severe allergy to vaccine or other injectables• Family history of anaphylaxis	<ul style="list-style-type: none">• History of severe allergic reaction to another vaccine• History of severe allergic reaction to an injectable medication	<ul style="list-style-type: none">• History of severe allergic reaction to any component of the Pfizer vaccine



INFORMATION ABOUT SEVERE ALLERGIC REACTIONS

- Typically occurs within a few minutes to 1 hour after vaccination
- Symptoms of a severe allergic reaction include:
 - Difficulty breathing
 - Swelling of your face or throat
 - A fast heartbeat
 - A bad rash all over your body
 - Dizziness and weakness
- If you develop any of the above symptoms after your 15 min post-vaccination monitoring period, call 9-1-1 or go to the Emergency Department for immediate evaluation
- Your medical provider will report your serious allergic reaction or any other severe adverse event related to vaccination to the national Vaccine Adverse Event Reporting System (VAERS)
- You should not receive any further doses of the vaccine if this occurs



WHAT TO DO AFTER GETTING THE VACCINE

- Report any side effects from the vaccine to V-SAFE as instructed
- You will need to continue masking, social distancing, avoiding large crowds, and good hand hygiene
- You do not have to quarantine before or after receiving the vaccine but you must continue to follow quarantine guidance after an exposure to someone with COVID-19
- Be aware that prior COVID-19 vaccination does NOT cause a positive COVID-19 PCR or antigen test, but may cause a positive antibody test



PHASED VACCINATION TIMELINE

When can I get a **COVID-19** vaccine in MA?



PHASE ONE

In order of priority

- Clinical and non-clinical healthcare workers doing direct and COVID-facing care
- Long term care facilities, rest homes and assisted living facilities
- First responders (EMS, Fire, Police)
- Congregate care settings (including corrections and shelters)
- Home-based healthcare workers
- Healthcare workers doing non-COVID-facing care

December - February

Estimated timeframes



PHASE TWO

In order of priority

- Individuals 75+
- Individuals 65+, Individuals with 2+ comorbidities (those that are at increased risk for severe illness)
- Early education and K-12 workers, transit, grocery, utility, food and agriculture, sanitation, public works and public health workers
- Individuals with one comorbidity

February - April



PHASE THREE

Vaccine available to general public

April - June

Updated 1/25/2021



WHY DOES PHASE 2 PRIORITIZE BY AGE

- Patients age 65 and older have a much higher risk of death from COVID-19
 - Only 14% of patients diagnosed with COVID-19 were older than 65, but almost 80% of deaths were in patients older than 65
- Risk of death is even higher in those 75 and older which is why these patients are in the first part of Phase 2 followed by patients age 65 and older
- Co-morbid medical conditions also significantly increases the risk of severe COVID-19 and death; thus, patients with co-morbid conditions are prioritized in Phase 2



CONDITIONS THAT INCREASE RISK FOR SEVERE COVID-19 INFECTION

- Age 65 and older
- Cancer
- Cardiovascular disease
 - heart failure
 - coronary artery disease
 - cardiomyopathy
- Chronic kidney disease
- Type II Diabetes Mellitus
- COPD (Chronic Obstructive Pulmonary Disease)
- Down Syndrome
- Obesity (BMI \geq 30)
- Pregnancy
- Sickle Cell Disease
- Smoking
- Solid organ transplant



CONDITIONS THAT MIGHT INCREASE RISK FOR SEVERE COVID-19

- Asthma
- Cerebrovascular disease
- Cystic fibrosis
- Immunocompromised state from
 - bone marrow transplant
 - immune deficiencies
 - HIV
 - use of corticosteroids
 - other immune-weakening medicines
- Hypertension
- Liver disease
- Neurologic conditions such as dementia
- Overweight (BMI >25 but <30)
- Pulmonary fibrosis
- Thalassemia
- Type I Diabetes Mellitus



WHEN CAN I GET MY VACCINE?

- Vaccination for patients 75 years and older will begin on Monday, February 1st
- Patients in this category will be able to start making appointments at vaccine clinics beginning Wednesday, January 27th



WHERE CAN I GET A VACCINE?

The screenshot shows the Massachusetts Department of Public Health website. At the top, there is a navigation bar with "EMERGENCY ALERTS" and "Coronavirus Updates and Information". Below this, there is a search bar and a "Menu" button. A prominent yellow notice states: "Due to high demand and constrained vaccine supply, COVID-19 Vaccination appointments are limited. More appointments will be available based on supply from the Federal Government. Appointments will be added on a rolling basis." The main content area features a blue header with the text "COVID-19 vaccination locations for individuals in eligible groups and phases" and a map of Massachusetts with numerous colored pins indicating vaccination sites. The map is titled "COVID-19 vaccination locations" and includes a note: "This map was created by a user. Learn how to create your own."

Sturdy is currently working on plans to provide vaccination both through clinics at Sturdy Memorial Associates and Sturdy Memorial Hospital once the Department of Public Health has allocated further vaccine to the organizations.

Other vaccine clinic locations can be found at the website below. All sites require a scheduled appointment.

<https://www.mass.gov/info-details/covid-19-vaccine-locations-for-individuals-in-phase-1#find-a-location-to-get-vaccinated-if-eligible->

QUESTIONS???

