# COVID-19 Vaccine

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PHARMACY MADE SIMPLE

# Vaccinating Against COVID-19

Importance, herd immunity, continued safety practices

# Why Vaccinate?

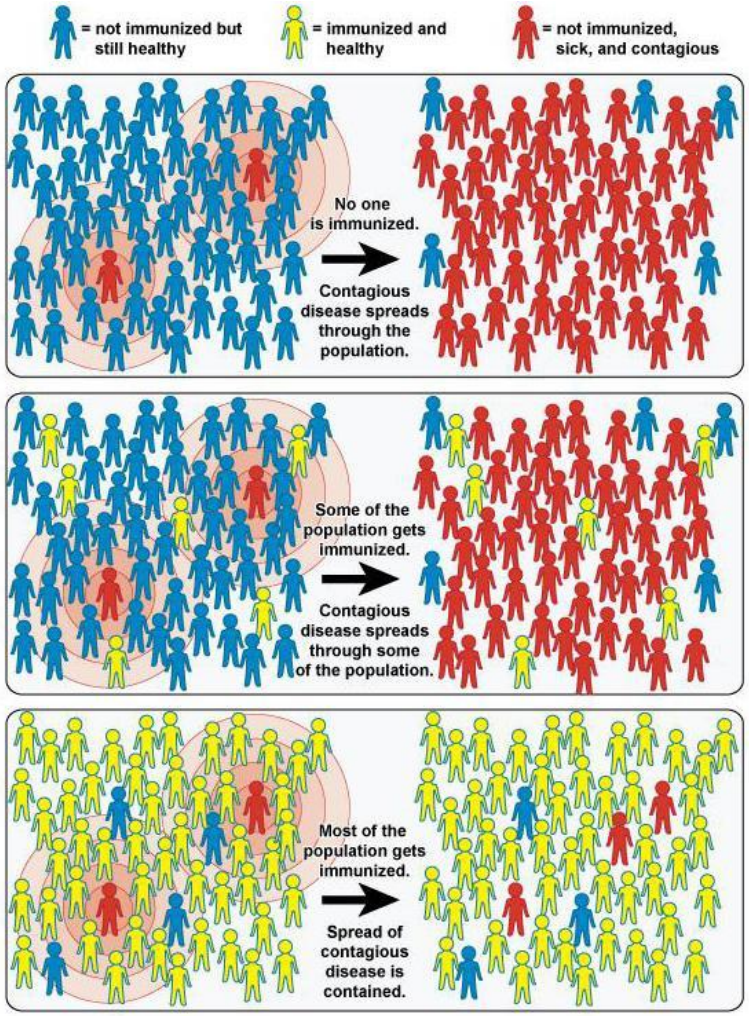
- Vaccinating against COVID-19 is essential to combat the global coronavirus pandemic
  - Lessens disease spread and protects against future outbreaks
  - Decreases risk of contracting the virus

- Benefit of the vaccine exceeds risk of potentially serious, life-threatening complications associated with COVID-19

https://www.medicalnewstoday.com/articles/324619

# Herd Immunity & Continued Safety Practices

- Success of the vaccine relies on:
  - Herd Immunity: a situation where the more people in a community that are immune to a pathogen, the fewer people there are for the pathogen to infect
  - Continuing to follow the Centers for Disease Control and Prevention (CDC) guidelines
    - Stay six feet apart from others
    - Wear a mask that covers the nose and mouth
    - Wash your hands often
    - Avoid touching your face

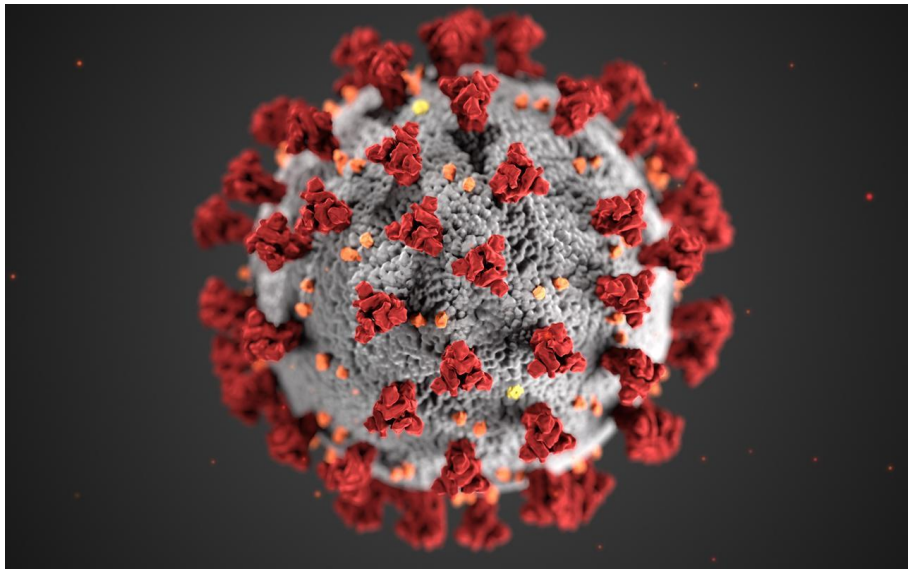



https://blogs.cdc.gov/publichealthmatters/2012/04/vaccines-test-your-knowledge-2/

# COVID-19 Vaccine Development

mRNA vaccine, Emergency Use Authorization, Safety

# COVID-19 Vaccine Development: mRNA Vaccines



https://www.cdc.gov/media/dpk/diseases-and-conditions/coronavirus/coronavirus-2020.html

- mRNA vaccines contain genetic code for the SARS-CoV-2 spike protein
- mRNA enters cells and encodes for spike protein
- Immune system recognizes spike protein as foreign object and produces antibodies
- Results in pre-formed antibodies if the real virus is encountered
- Important reminder: The COVID vaccine does not alter an individual's DNA or genetic make up
- The mRNA vaccines are NOT live vaccines and do not contain any inactivated virus particles

# COVID-19 Vaccine Development: Emergency Use Authorization (EUA)

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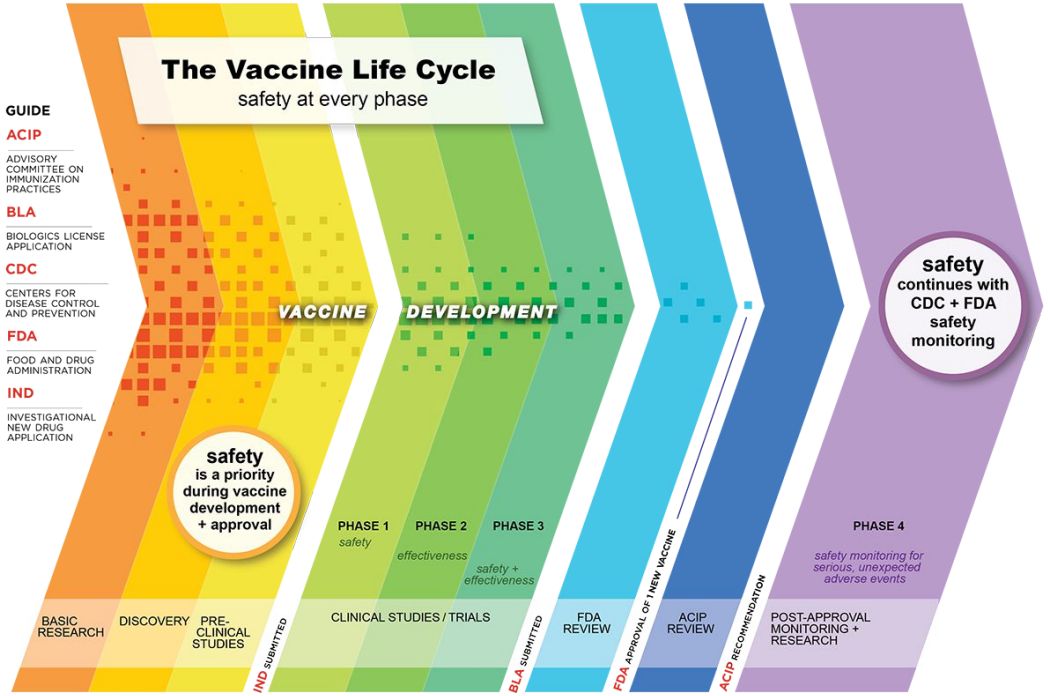
- FDA approves EUA during public health emergencies to allow availability of medical products helpful to the situation

- Criteria for EUA:
  - Used for serious or life-threatening disease or condition
  - Product believed to be effective based on scientific evidence
  - Benefits outweigh risks of product
  - No adequate FDA-approved alternative available


https://www.studentnewsdaily.com/world-current-events/issue-3-fda-approved-use-of-anti-malaria-drug-as-possible-coronavirus-treatment/

# COVID-19 Vaccine Development Safety

- COVID-19 vaccine developed in under 1 year (most other vaccines took years to develop)
- Phase 3 Trials for COVID-19 Vaccine
  - Similar size/nature to phase 3 trials of other vaccines
  - Data undergoes many rounds of reviews in the following areas:
    - Immunology
    - Statistics
    - Infectious diseases
    - Virology
    - Vaccinology
- Undergoes further rounds of review once submitted/approved for EUA




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

# Vaccines in Development

Pfizer-BioNTech, Moderna, and others

# Vaccines in Development

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**Pfizer-BioNTech**

- mRNA, 2 doses separated by 21 days
- Efficacy rate: 95%
- Storage:
  - -70˚C ± 10˚C for up to 15 days
  - Once thawed: 2-8˚C for up to 5 days
- Adverse Effects: fatigue, headache, muscle aches

EUA Submission Date: 11/20/2020
FDA Meeting Date for EUA Approval: 12/10/2020
EUA Approval Date: 12/12/2020

**Moderna**

- mRNA, 2 doses separated by 28 days
- Efficacy rate: 94.5%
- Storage:
  - -20˚C for up to 6 months
  - Once thawed: 2-8˚C for up to 30 days within 6-month shelf life
  - Once removed from refrigerator for administration: room temp for up to 12 hours
- Adverse Effects: Pain/redness at injection site, fatigue, muscle or bone pain, headache

EUA Submission Date: 11/30/2020
FDA Meeting Date for EUA Approval: 12/17/2020

# Other Vaccines in Development

- **Viral Vector**
  - Johnson & Johnson
  - Oxford/AstraZeneca
  - Merck
- **DNA Plasmid**
  - Inovio
- **Protein Subunit**
  - Novovax
  - Sanofi Pasteur/GSK
- **Inactivated**
  - Sinovac


https://www.medicalnewstoday.com/articles/316824

# COVID-19 Vaccine Distribution

Phase distribution, considerations, vaccine availability

# Phases for Distribution

- **Phase 1a**
  - Healthcare personnel and residents of long-term care facilities
- **Phase 1b**
  - Essential workers
- **Phase 1c**
  - Adults with high risk medical conditions and adults age 65+
- **Phase 2**
  - Teachers, school staff, childcare workers, and food supply chain workers
- **Phase 3**
  - Children and adults ages 30 and younger
- **Phase 4**
  - All others

# Phase 1

- **Phase 1a:** Healthcare personnel and residents of long-term care facilities
  - Ex. Healthcare personnel: hospitals, outpatient clinics, long-term care facilities, home health care, pharmacies, emergency medical services, public health
  - Ex. Long-term care facilities: skilled nursing facilities, assisted living facilities, other residential care
- **Phase 1b:** Essential workers
  - Ex. Education, food and agriculture, utilities, police, firefighters, corrections officers, transportation
- **Phase 1c:** Adults with high risk medical conditions and those 65+
  - Ex. Obesity, diabetes, cancer, transplant, heart conditions, chronic kidney

# Groups to Consider

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- **Pregnant/breastfeeding**
  - Pfizer and Moderna vaccine trials excluded pregnant and breastfeeding women
  - No evidence on safety/effectiveness in this population
  - Recommended to consult your obstetrician regarding vaccination

- **Those on other medications**
  - Pfizer and Moderna issued no statement about their vaccines interfering with any particular medication
  - Both trials included females on birth control
  - Both trials included those with chronic lung disease, heart disease, diabetes, liver disease, and HIV infection
  - Pfizer trial excluded those on immunosuppressive therapy (cytotoxic agents and systemic corticosteroids)

- **Those with penicillin allergies**
  - Allergic reactions possible with any vaccination (1 in 450,000 that do not contain gelatin/egg protein)
  - Penicillins/cephalosporins generally not used in vaccines
  - No full list of vaccine components available at this time

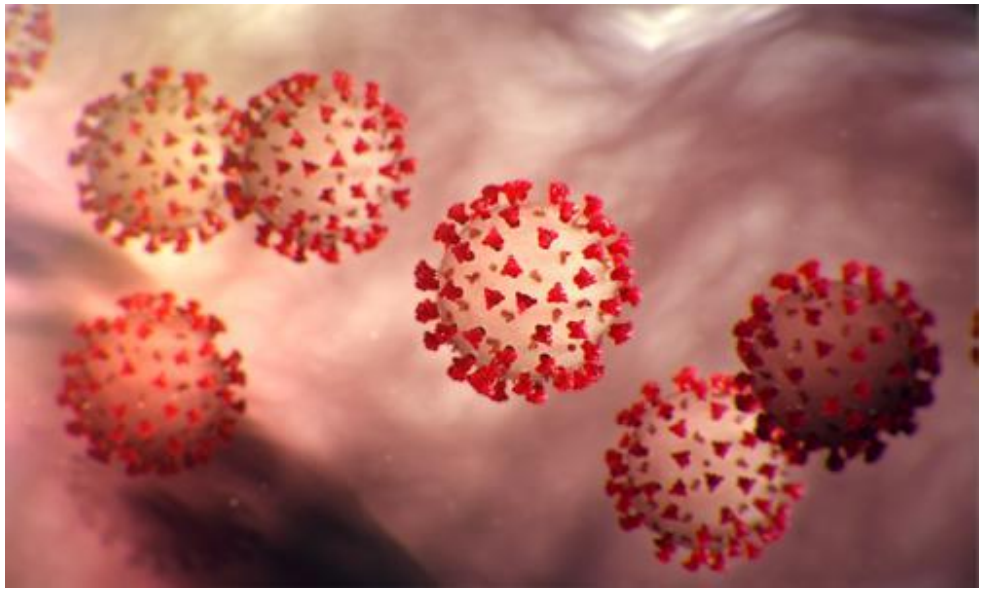
# Groups to Consider

- Those who already had COVID-19
  - Previous infection not considered a contraindication to the vaccine
  - Experts unsure how long someone is protected after having infection
    - Natural immunity varies from person to person
  - Antibody testing not necessary/recommended prior to vaccination
  - Healthcare workers testing positive within the previous 90 days may delay receiving the vaccine until the end of the 90 days to allow other workers to be vaccinated first

https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing.html

# Anticipated Vaccine Availability

- Vaccine expected to be released late 2020 or early 2021
- Limited supply at first release, however enough vaccine by mid 2021
- Currently, no more than 20,000,000 doses are projected to be produced by the end of 2020



https://www.cdc.gov/media/index.html

# Post-Vaccination

Potential side effects, protection duration, safety

# Potential Side Effects After Vaccination

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- Proteins in vaccine will not cause illness, however side effects possible
- Short term side effects include headache, muscle pain, fatigue, chills, fever, and pain at injection site
  - Normal effects due to the body developing immunity
- Second dose may create more pronounced side effects
- If you have a history of severe allergic reaction (anaphylaxis) to a vaccine, you may want to wait until there is additional information available about allergic response to the vaccine
- CDC implementing smartphone-based tool "V-SAFE" to follow those after receiving a vaccine
  - Information sheets will be distributed with the vaccine
  - If you opt-in, surveys will be sent through text message
  - May report problems or adverse reactions experienced

# Vaccine Protection Duration

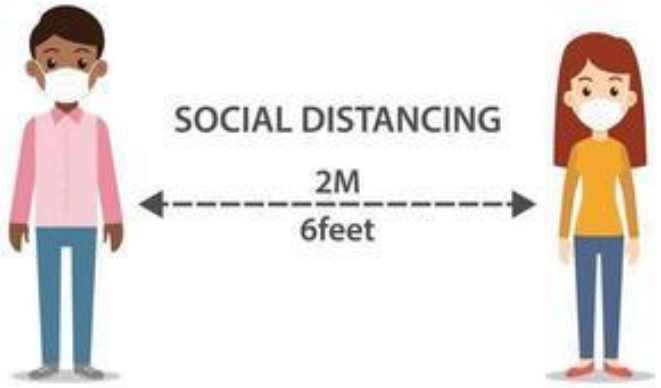
- Vaccine may be similar to annual flu vaccine
  - Research still needed to determine how long antibodies last
  - Depends on how much virus changes

- Once received, there is not immediate protection
  - Protection usually occurs about 2 weeks after the second dose (2 dose vaccine separated by a 3-4 weeks)


https://homelandprepnews.com/stories/50860-janssen-pharmaceuticals-accelerates-timeline-for-development-of-covid-19-vaccine/

# Safety After Receiving the Vaccine

- After vaccination, continue to:
  - Wear masks
  - Practice social distancing
  - Frequently wash hands
  - Avoid touching your face




- No current information on continued COVID testing after vaccination
- While the COVID vaccine will significantly reduce risk of contracting the virus, it is possible that a person may still contract the infection (although risk is greatly diminished)
  - A person may also be infected with the virus and asymptomatic prior to receiving their vaccine. This does not mean they got the infection from the vaccine

# Common Questions

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- Is the vaccine mandatory?
  - The vaccine is not mandatory; however, it is strongly encouraged to protect yourself, family, residents and co-workers.
- If I am younger, do I really need to get vaccinated since I am not at high risk?
  - Yes. Getting vaccinated is one of many steps that you can take to protect yourself and others from COVID-19.
  - Protection from COVID-19 is critically important because for some people it can cause severe illness or death.
- Is there a fee for the vaccine?
  - There is no cost for the vaccine or administration. Your insurance will be billed only for the administration fee. HRSA will be used for uninsured individuals.

# Common Questions

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- Who will be administering the vaccines?
  - CVS or Walgreens will be conducting three clinic days at the facility. During the clinic days, vaccine will be administered to residents and staff
- Will residents be able to go back to normal activities and dining if they get the vaccine? Will families be able to visit again?
  - We will continue to monitor updated guidance from CMS and DOH and communicate to the facilities any changes.
- If the staff receives the vaccine, can they go back to wearing regular masks instead of N95's and stop universally wearing gowns?
  - We will continue to monitor updated guidance from CMS and DOH and communicate to the facilities any changes.

# Common Questions

- Does the vaccine contain a tracking device?
  - No. This is a conspiracy theory. Theorists feel the vaccines contain microchips that would track people with digital ID. The focus should be on the science of the vaccine.
- Are we going to be injected with a serum to lower immunity?
  - No, the opposite is actually true. The COVID vaccine provides protection by creating an antibody response without having to experience sickness.
  - Both natural immunity and immunity produced by the vaccine are important aspects of COVID-19 that experts are trying to learn more about. The CDC will keep the public informed as new evidence becomes available.

# References


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- CVS-Omnicare COVID-19 Vaccine Resource Guide. https://www.omnicare.com/covid-19-vaccine-resource
- Dooling K, McClung N, Chamberland M, et al. The Advisory Committee on Immunization Practices' Interim Recommendation for Allocating Initial Supplies of COVID-19 Vaccine — United States, 2020. MMWR Morb Mortal Wkly Rep. ePub: 3 December 2020. DOI: http://dx.doi.org/10.15585/mmwr.mm6949e1
- Interim Considerations for COVID-19 Vaccination of Healthcare Personnel and Long-Term Care Facility Residents. https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19/clinical-considerations.html
- A Phase 3, Randomized, Stratified, Observer-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Immunogenicity of mRNA-1273 SARS-CoV-2 Vaccine in Adults Aged 18 Years and Older. 20 Aug 2020, ModernaTX, Inc.
- A Phase 1/2/3 Study to Evaluate the Safety, Tolerability, Immunogenicity, and Efficacy of RNA Vaccine Candidates Against COVID-19 in Healthy Individuals. 2020, Pfizer.