Building Vaccine Confidence in Health Systems and Clinics
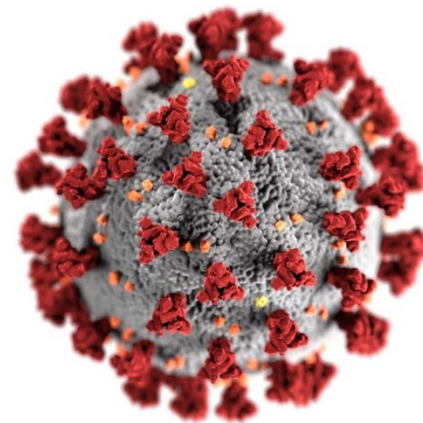
Tips for Immunization Coordinators

Developed by:

CDC COVID-19 Response

Vaccine Task Force

January 2021

cdc.gov/coronavirus

Presentation Overview

- COVID-19 vaccines
- mRNA technology
- Vaccine safety monitoring
- Elements of vaccine confidence
- Strategies for building vaccine confidence in your facility or system

COVID-19 Vaccines and Vaccine Safety Monitoring

Healthcare personnel: A priority for COVID-19 vaccination

- On the front lines and at risk of exposure.
- Can potentially transmit the virus that causes COVID-19 to patients, their families, and their communities.
- Can positively influence vaccination decisions of peers, patients, friends, and family.
- Healthcare personnel = paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials – not exclusive to medical personnel, includes administration, support staff, etc.
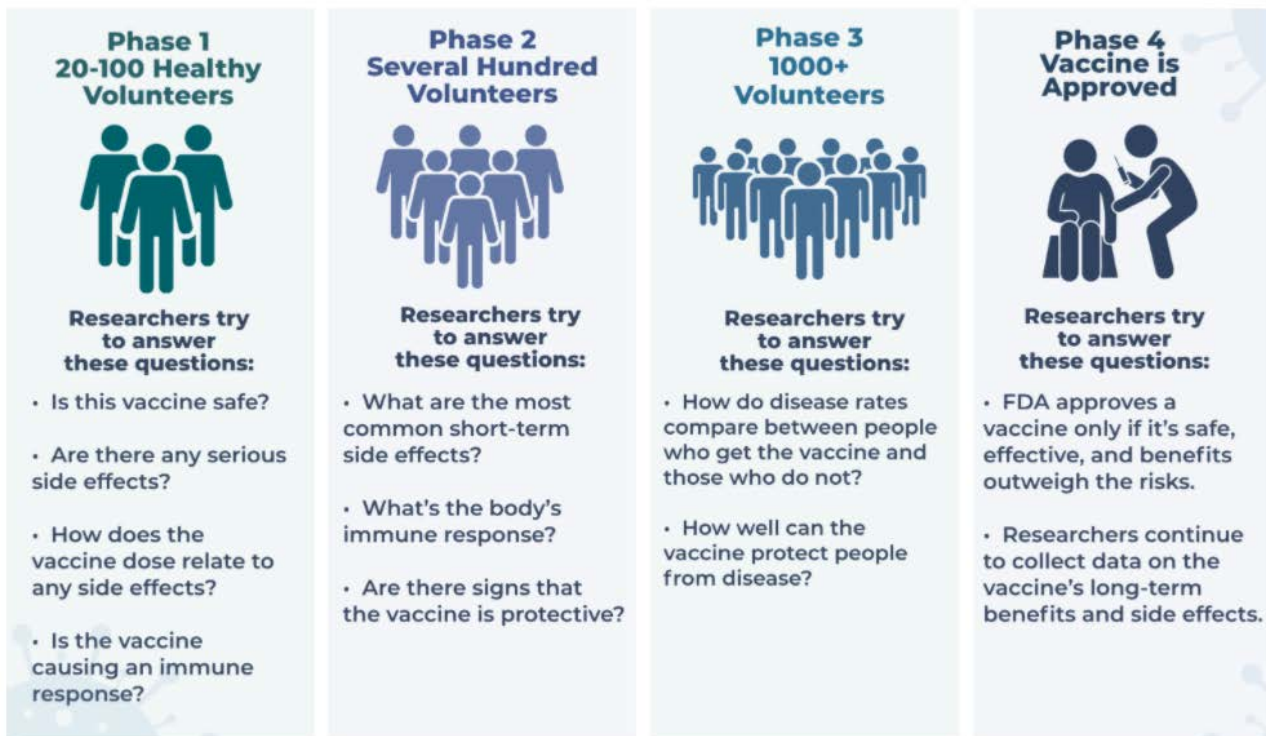
COVID-19 vaccines under development

- The federal government is funding and coordinating the development of multiple vaccine candidates, several of which are in large-scale (Phase 3) trials and some of which have been authorized by the FDA.

- COVID-19 vaccines are being held to the **same safety standards** as all other vaccines.

Phases of clinical trials

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.

Source: https://covid19community.nih.gov/resources/understanding-clinical-trials

COVID-19 vaccines that have received FDA Emergency Use Authorizations

- Two vaccines have received FDA Emergency Use Authorizations (EUAs) :
    - **Pfizer/BioNTech (BNT162b2)** – 95% effective (manufacturer data)
    - **Moderna (mRNA-1273)** – 94.5% effective (manufacturer data)
- Both are mRNA vaccines with a 2-dose schedule. People being vaccinated should complete the two-dose series with the same vaccine product.
- Duration of protection is not yet known.
- For the latest information about authorized vaccines, visit www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines.

COVID-19 vaccine trials by the numbers

As of December 21, 2020

Pfizer/BioNTech

- **45,302** enrolled
  - **43,125** received 2nd dose
- **150** clinical sites
  - 39 U.S. states
- Racial/ethnic distribution
  - **13%** - Hispanic
  - **10%** - African American
  - **6%** - Asian
  - **1%** - Native American
- **40%** ages 56-85

Moderna

- **30,000** enrolled
  - **25,654** received 2nd dose
- **89** clinical sites
  - 32 U.S. states
- Racial/ethnic distribution
  - **63%** - White
  - **20%** - Hispanic
  - **10%** - African American/Black
  - **4%** - Asian
  - **3%** - All others
- **64%** ages 45 and older
  - **39%** ages 45-64
  - **25%** ages 65+

Sources: https://www.pfizer.com/science/coronavirus/vaccine;
https://www.modernatx.com/cove-study
For more information, visit www.clinicaltrials.gov

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How COVID-19 mRNA vaccines work

- mRNA vaccines carry genetic material that teaches cells how to make a harmless piece of "spike protein," which is found on the surface of the SARS-CoV-2 virus.
  - Genetic material from the vaccine is destroyed by our cells once copies of the spike protein are made and it is no longer needed.
- Cells display this piece of spike protein on their surface, and an immune response is triggered inside our bodies. This produces antibodies to protect us from getting infected if the SARS-CoV-2 virus enters our bodies.
- mRNA vaccines do not affect our DNA; mRNA does not enter the cell nucleus.
- mRNA COVID-19 vaccines cannot give someone COVID-19.
- mRNA vaccines are new, but the technology is not. mRNA vaccines have been studied for influenza, Zika, rabies, and cytomegalovirus (CMV).

About these COVID-19 mRNA vaccines

- At least 8 weeks of safety data were gathered after participants received their 2nd dose in the trials. It is unusual for side effects to appear more than 8 weeks after vaccination.

- These mRNA vaccines produce common side effects after vaccination, especially after the 2nd dose.
    - Side effects may include:
        - Fever
        - Headache
        - Muscle aches

- No significant safety concerns were identified in the clinical trials, although a small number of severe allergic reactions have been reported during the initial phases of rollout.

As with any vaccine, vaccination providers should be familiar with identifying immediate-type allergic reactions, including anaphylaxis, and be competent in treating these events at the time of vaccine administration. Providers should also have a plan in place to contact emergency medical services immediately in the event of a severe acute vaccine reaction.

Source: https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19/clinical-considerations.html

Strategies for mitigating post-vaccination absenteeism

- Strategies are needed to mitigate possible healthcare personnel absenteeism and resulting personnel shortages due to the occurrence of post-vaccination side effects. Considerations might include:
  - Stagger scheduling of the delivery of vaccine so that personnel from a single department or unit are not all vaccinated at the same time. Based on data from the clinical trials, staggering considerations may be more important following the second dose.
  - Planning for personnel to have time away from work if they develop side effects following COVID-19 vaccination.

Safety of COVID-19 vaccines is a top priority

- COVID-19 vaccines are being held to the same safety standards as all vaccines.

- FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) reviews applications for EUAs.

- The Advisory Committee on Immunization Practices (ACIP) considers safety and efficacy data before recommending use.

- VRBPAC and ACIP are independent committees composed of scientific and clinical experts.

- FDA and CDC monitor vaccine safety and side effects once vaccines are in use.

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Robust vaccine safety monitoring systems exist

- **Existing** systems and data sources are used to monitor safety of vaccines post-authorization and post-licensure, such as:

  - Vaccine Adverse Event Reporting System (VAERS)

  - Vaccine Safety Datalink (VSD)

  - Clinical Immunization Safety Assessment (CISA)

  - Biologics Effectiveness and Safety System (BEST)

- **New** systems have been developed to monitor COVID-19 vaccine safety, such as **v-safe**:

  - Active surveillance that uses text messaging to initiate web-based survey monitoring.

  - Will provide telephone follow up to anyone who reports medically significant adverse events.

How was the vaccine development timeline accelerated while ensuring safety?

- Researchers used existing clinical trial networks to begin conducting COVID-19 vaccine trials.*

- Manufacturing started while the clinical trials were still underway. Normally, manufacturing doesn't begin until after completion of the trials.

- mRNA vaccines are faster to produce than traditional vaccines.

- FDA and CDC are prioritizing review, authorization, and recommendation of COVID-19 vaccines.
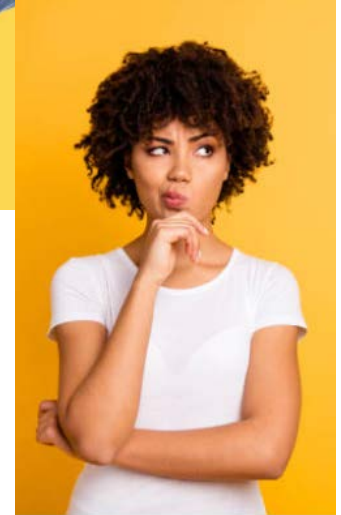
*For more, visit the COVID-19 Prevention Network:
www.coronaviruspreventionnetwork.org/about-covpn

Elements of Vaccine Confidence

The Challenge: Need to instill vaccine confidence

- Only **58%** of the general public said they would receive a COVID-19 vaccine

  (Data from October 2020 Harris poll)

- Factors weighing on acceptance

  - Are there side effects?

  - Does it work?

  - Is it safe?

  - How much does it cost?

Tyson, A, Johnson, C, & Funk, C. (2020, September 17). *U.S. Public Now Divided Over Whether to Get COVID-19 Vaccine.* Pew Research Center. https://www.pewresearch.org/science/2020/09/17/u-s-public-now-divided-over-whether-to-get-covid-19-vaccine/

The Challenge: Increasing acceptability

- COVID-19 vaccine would more acceptable if
  - Healthcare team said it was safe
  - No costs to the individual
  - It would help get back to school and work
  - They could get it easily

Jackson, C., & Newall, M. (2020, September 29). *Despite COVID-19 spike, few individual behaviors are changing.* Ipsos. https://www.ipsos.com/en-us/news-polls/axios-ipsos-coronavirus-index/

Vaccine hesitancy among healthcare providers

- American Nursing Foundation Survey (Oct 2020)
  - 63% were somewhat or very confident that the vaccine will be safe and effective.
  - 34% would voluntarily receive COVID-19 vaccine.
  - 57% are comfortable discussing COVID-19 vaccines with patients.
- CDC web survey with healthcare providers (Sept–Oct 2020)
  - 63% said they would get a COVID-19 vaccine.

Sources:
1. American Nurses Foundation, Pulse on the Nation's Nurses COVID-19 Survey Series: COVID-19 Vaccine, October 2020. https://www.nursingworld.org/practice-policy/work-environment/health-safety/disaster-preparedness/coronavirus/what-you-need-to-know/covid-19-vaccine-survey
2. Lindley, et al. CDC COVID-19 Response Team. Report in progress.
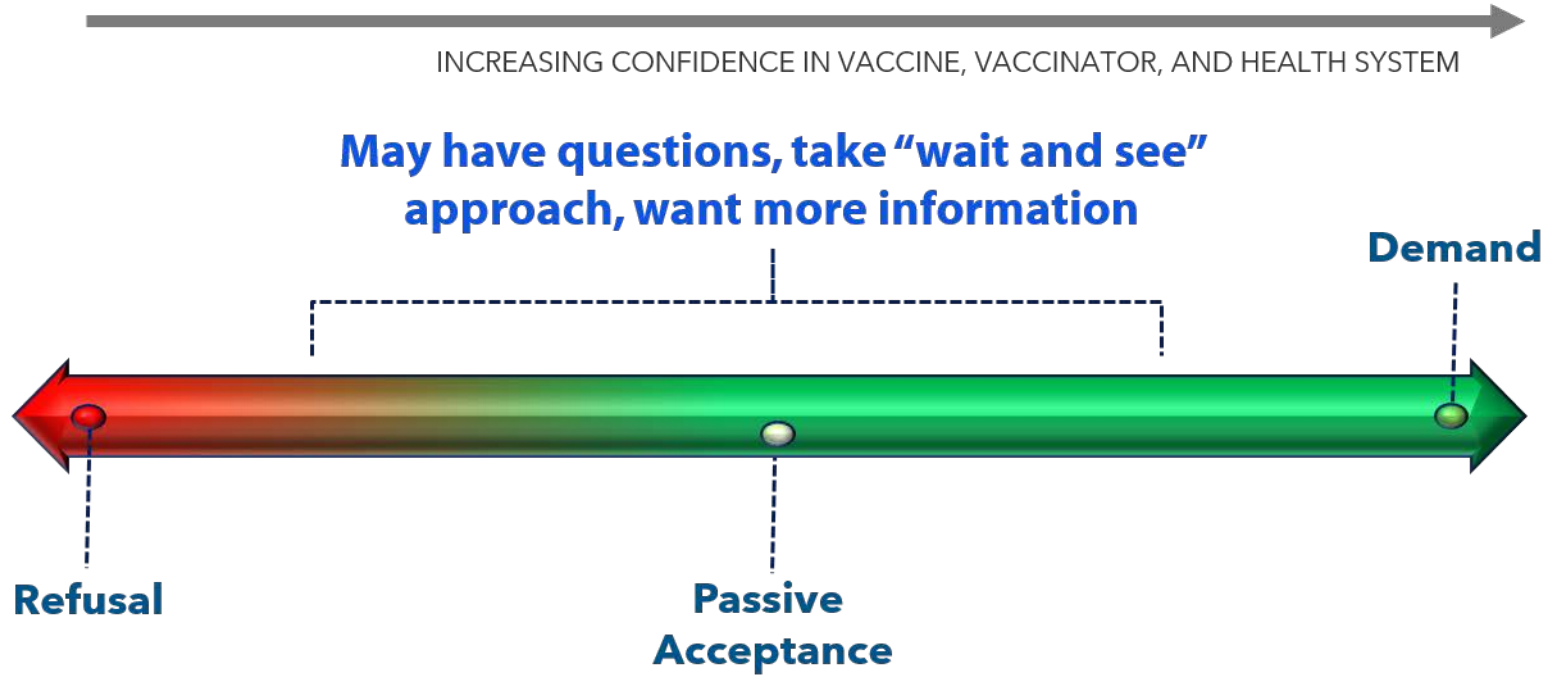
Defining vaccine confidence

- *Vaccine confidence* is the trust that patients, parents, or providers have in:
  - Recommended <u>vaccines</u>
  - <u>Providers</u> who administer vaccines
  - <u>Processes and policies</u> that lead to vaccine development, licensure, manufacturing, and recommendations for use

Willingness to accept a vaccine falls on a continuum

INCREASING CONFIDENCE IN VACCINE, VACCINATOR, AND HEALTH SYSTEM

May have questions, take "wait and see" approach, want more information

Demand

Refusal

Passive Acceptance

Strategies for Building Vaccine Confidence

Vaccinate with Confidence

A National Strategy to Reinforce Confidence in COVID-19 Vaccines

Build Trust
Objective: Share clear, complete, and accurate messages about COVID-19 vaccines and take visible actions to build trust in the vaccine, the vaccinator, and the system in coordination with federal, state, and local agencies and partners.

Empower Healthcare Personnel
Objective: Promote confidence among healthcare personnel in their decision to get vaccinated and to recommend vaccination to their patients.

Engage Communities & Individuals
Objective: Engage communities in a sustainable, equitable, and inclusive way—using two-way communication to listen, build trust, and increase collaboration.

Vaccinate with **Confidence**

A component of the National Strategy to Reinforce Confidence in COVID-19 Vaccines

Empower Healthcare Personnel

Objective: Promote confidence among healthcare personnel in their decision to get vaccinated and to recommend vaccination to their patients.

Tactics
- ✓ Engage local and national professional associations, health systems, and healthcare personnel often and early to ensure a clear understanding of the vaccine development and approval process, new vaccine technologies, and the benefits of vaccination.
- ✓ Ensure healthcare systems and medical practices are equipped to create a culture that builds confidence in COVID-19 vaccination.
- ✓ Strengthen the capacity of healthcare professionals to have empathetic vaccine conversations, address myths and common questions, provide tailored vaccine information to patients, and use motivational interviewing techniques when needed.

Top 6 strategies for building COVID-19 vaccine confidence among healthcare personnel

1. Encourage senior leaders to be vaccine champions.

2. Host discussions where personnel at different levels can provide input and ask questions.

3. Share key messages with staff through emails, breakroom posters, and other channels.

4. Provide information and resources to healthcare teams about COVID-19 vaccines, how they are developed and monitored for safety, and how teams can talk to others about the vaccines.

5. Talk to non-medical staff about the importance of getting vaccinated.

6. Make the decision to get vaccinated visible and celebrate it!

1. Encourage senior leaders to be vaccine champions

- Talk to your leaders about vaccine confidence and why it's important.

- Ask leaders to lead by example and be photographed while getting COVID-19 vaccine.

- Invite leaders to share their personal reasons for getting vaccinated and the importance of vaccination for all staff. Share via:

  - Testimonials given during elevator conversations, meetings, and staff presentations

  - Short videos

  - Email blasts

  - Social media

  - Blogs or web articles

Photo credit: National Foundation for Infectious Diseases

2. Host discussions with personnel at different levels

- <u>Purpose</u>: To provide a forum for questions and generate ideas for how to increase COVID-19 vaccine confidence and make it visible

- <u>Format</u>: Facilitated meeting (suggest 60-minutes)

- <u>Participants</u>: People representing management, healthcare teams, labor unions, local racial and ethnic minority healthcare groups, and support staff. Involve COVID-19 Incident Command Teams as appropriate.

- <u>Facilitator</u>: Staff member who is well-respected and seen as a neutral convener on the topic

- <u>Discussion Guide</u>:
  https://www.cdc.gov/vaccines/covid-19/health-systems-communication-toolkit.html

3. Share these key messages with staff

- Share key messages through emails, breakroom posters, and other channels:
  - While we don't yet know if the vaccine reduces transmission of SARS-CoV-2, it helps protect you from serious illness and potentially reduces the risk to patients, peers, friends, and family.
  - Vaccine confidence starts with you! Building defenses against COVID-19 in this facility is a team effort.
  - Getting the COVID-19 vaccine gives you an added layer of protection against COVID-19 and could also protect your colleagues and your patients.
  - A COVID-19 vaccine can help protect you from mild to severe COVID-19 illness.

3. Additional key messages to share

- COVID-19 vaccines were tested in diverse adult populations, including among communities of color and older adults. Vaccine safety is being continually monitored moving forward.

- There are several things you can do to help build vaccine confidence:
    - Choose to get vaccinated (and get the recommended number of doses).
    - Share your reasons for getting vaccinated and encourage others.
    - Learn how to have effective COVID-19 vaccine conversations.

- Keep covering your mouth and nose with a mask, washing hands often, and staying at least 6 feet away from others, even after you have been vaccinated.

4. Provide information and resources to healthcare teams

- Inform teams about COVID-19 vaccines, how they are developed and monitored for safety, and how teams can talk to others about vaccines.

- Teach teams how to have effective COVID-19 vaccine conversations and answer common questions.

- CDC Resources:
    - *COVID-19 Vaccine Basics: What Healthcare Personnel Need to Know (PowerPoint)*
    - *Building Confidence in COVID-19 Vaccines Among Your Patients (PowerPoint)*

www.cdc.gov/vaccines/covid-19/health-systems-communication-toolkit.html

4. Provider resources for COVID-19 vaccine conversations with patients

- Preparing to Provide COVID-19 Vaccines

- Talking to Patients about COVID-19 Vaccines

- Understanding and Explaining mRNA COVID-19 Vaccines

- Making a Strong Recommendation for COVID-19 Vaccination

- Answering Patients' Questions

- *More tools coming soon!*

www.cdc.gov/vaccines/hcp/covid-conversations

4. COVID-19 vaccine clinical training resources

- *COVID-19 Vaccine Training: General Overview of Immunization Best Practices for Healthcare Professionals*
- Webinars about ACIP recommendations and vaccine products
- Clinical forms, trackers, and FAQs
- Educational materials about each authorized vaccine:
  - Online training module
  - Vaccine preparation and administration summary
  - Storage and handling summary
  - Temperature log for freezer units
  - Beyond use date tracker labels for refrigerator storage
  - Standing orders template

https://www.cdc.gov/vaccines/covid-19/vaccination-resources.html

# 5. Talk to non-medical staff about the importance of getting vaccinated

- Talk to non-medical staff about COVID-19 vaccines and the vaccine development and safety monitoring process.

- Emphasize the benefits of COVID-19 vaccination.

- Create a feedback mechanism for asking questions.

- Let them know they also have an important role to play in making vaccine confidence visible.

- CDC resources:
  - *COVID-19 Vaccine Basics: What Healthcare Personnel Need to Know (PowerPoint)*

www.cdc.gov/vaccines/covid-19/health-systems-communication-toolkit.html

# 6. Make the decision to get vaccinated visible and celebrate it!

- Provide "I got my COVID-19 vaccine!" pins, lanyards, masks, bracelets, etc.

- Post a photo gallery in common or break areas or online showing cheerful staff who just got vaccinated.

- Offer a small, sincere token of gratitude for early adopters.

- Record testimonials on why healthcare personnel in your facility decided to get vaccinated and share with the media.

- Share inclusive, positive, behind-the-scenes moments showing staff caring for patients.

- Reach out to local news outlets to highlight your health facility's leadership in COVID-19 vaccine introduction.
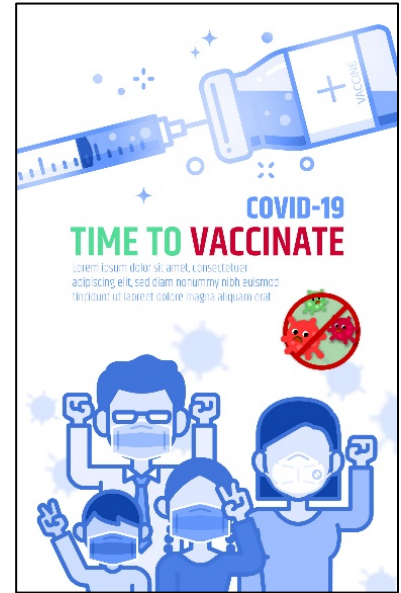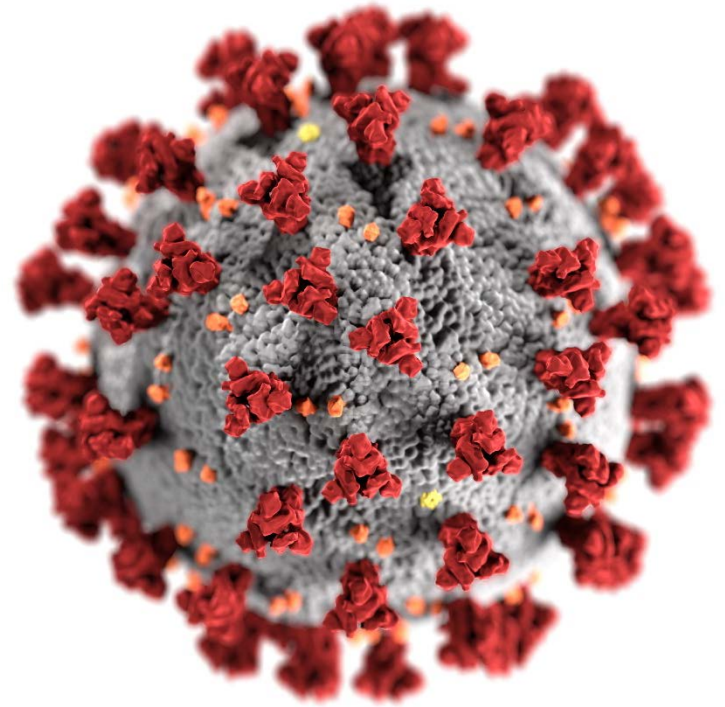

www.cdc.gov/vaccines/covid-19/health-systems-communication-toolkit.html

Tools and resources

- Posters
- Plain language fact sheets
- Drop-in articles/blogs
- "I got my COVID-19 vaccine!" button design
- Social media content and graphics
- Coming soon: videos
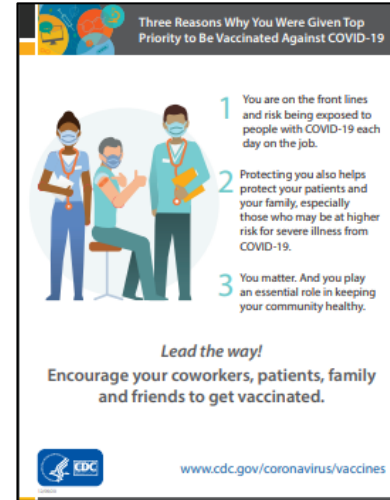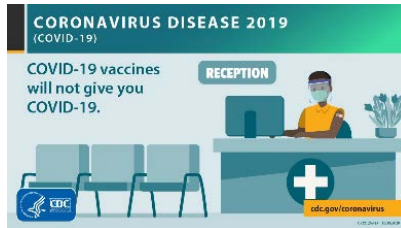
For more information, contact CDC
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