COVID-19 Vaccines and the Harm Reduction Community

NHRC Office Hours | 03/17/21

Dr. Hansel Tookes, MD, MPH
Dr. Kimberly Sue, MD, PhD

NATIONAL HARM REDUCTION COALITION

National Harm Reduction Coalition creates spaces for dialogue and action that help heal the harms caused by racialized drug policies.

Policy & Advocacy

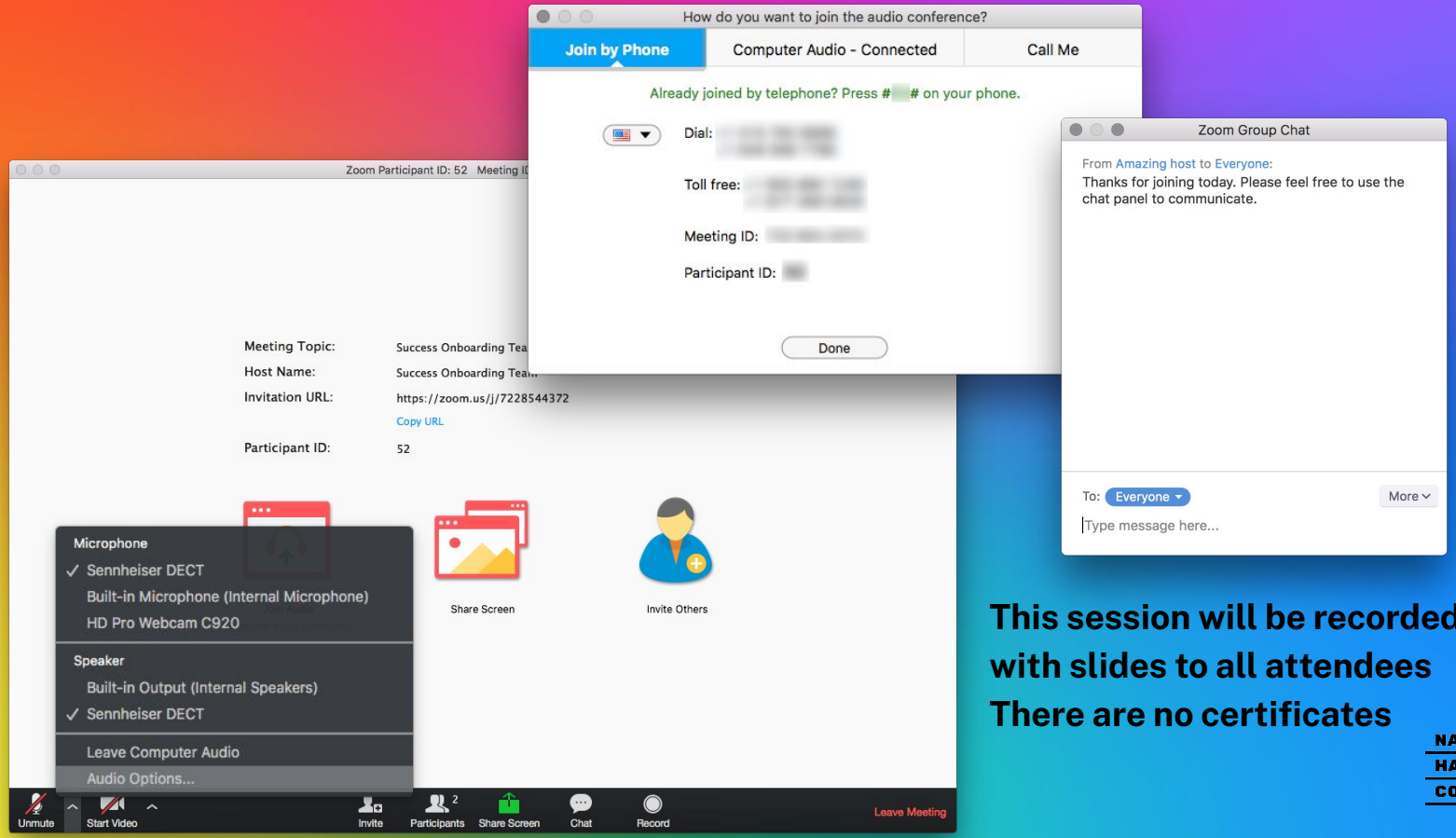
National & Regional Conferences

Trainings & Technical Assistance

Overdose Prevention

Resources & Publications

Zoom Housekeeping



This session will be recorded and sent with slides to all attendees

There are no certificates

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QUESTIONS WE WILL ADDRESS

NATIONAL HARM REDUCTION COALITION

How do the vaccines work?

Who was enrolled in the trials?

What reactions can people expect?

Are the vaccines safe for people living with HIV and other chronic illnesses?

How does this relate to LGB TGNC communities, BIPOC and people who use drugs?

How can people who don't want /don't have the opportunity to get vaccinated keep themselves safe?

QUESTIONS WE WILL ADDRESS IN OUR NEXT SESSION

NATIONAL HARM REDUCTION COALITION

How can harm reduction programs support participants and staff in accessing the vaccine?

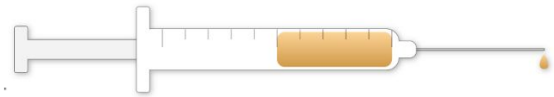
How can harm reduction programs support those who don't want/don't have the opportunity to get vaccinated keep themselves safe?

What role can harm reduction programs play in vaccine distribution?

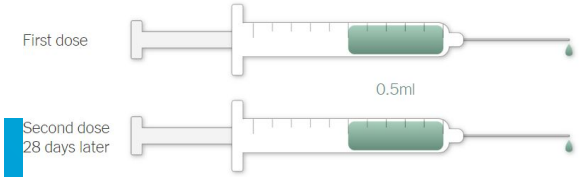
How can we use a harm reduction framing to avoid making those who choose not to be vaccinated feel stigmatized?

Register at: bit.ly/nhrcvax2

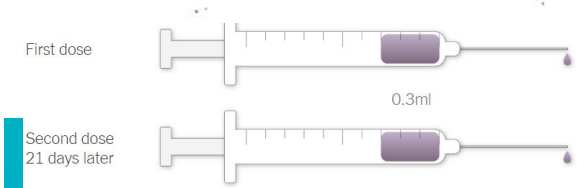
VACCINES



Johnson & Johnson



Moderna

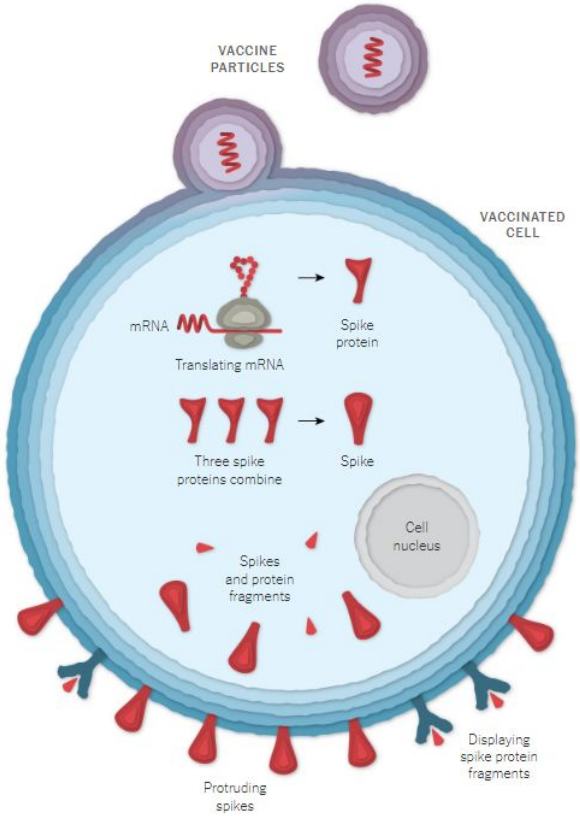


Pfizer

mRNA Vaccines

HOW DO THE mRNA VACCINES (PFIZER AND MODERNA) WORK?

- mRNA vaccines carry genetic material that teaches our 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 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).

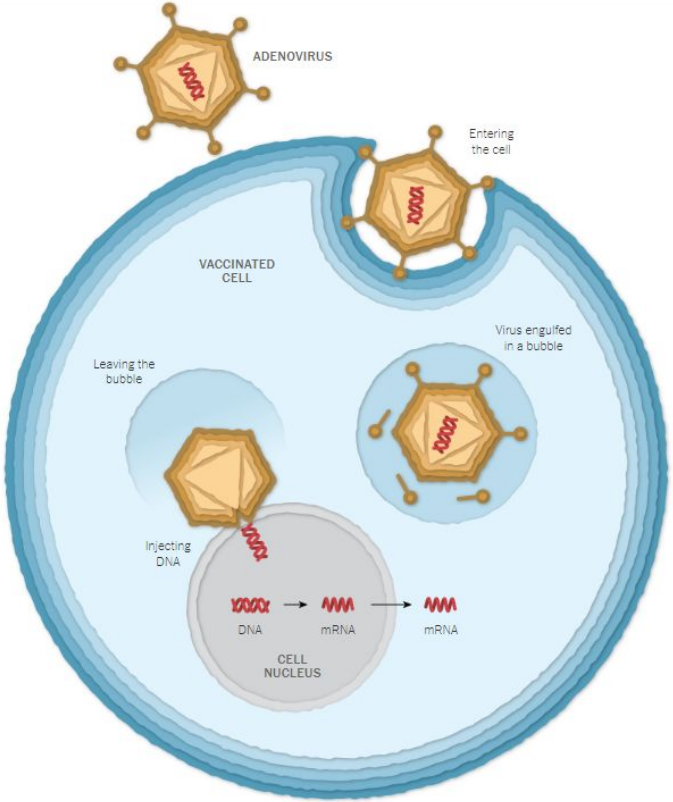


Sources: College of Physicians of Philadelphia. What is an mRNA vaccine? https://historyofvaccines.blog/2020/07/29/what-is-an-mrna-vaccine/
JAMA. COVID-19 and mRNA Vaccines—First Large Test for a New Approach. https://jamanetwork.com/journals/jama/fullarticle/2770485

HOW DOES THE JOHNSON & JOHNSON VACCINE WORK?

Adenovirus vector (adenovirus is a virus such as the common cold) delivering protein instructing the body to manufacture antibodies to the SARS-COV2-spike protein.

Johnson and Johnson made an Ebola vaccine for the Ebola outbreak. Trials for HIV and Zika underway with Johnson and Johnson also.



VACCINE 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

WHO WAS INCLUDED IN THE VACCINE TRIALS?

	Pfizer (BNT162b2)	Moderna (mRNA-1273)	Johnson and Johnson
Number of people enrolled	**Over 40,000**	**Over 25,000**	**43,783**
Race and ethnicity of participants	Total 30% racially diverse 10% Black, 13% Hispanic	37% racially diverse 10% Black, 20% Hispanic/Latino	35% racially diverse 15% Hispanic/Latinx, 13% Black
Older adults	45% were 56-85 years	23% were >65 years	34% were >60

- **Notes**: Courtesy of Dr. Anuj Mehta, Data is accurate as of 11/18/2020. More information is constantly becoming available. Sub-group comparisons (e.g. comparisons about efficacy between races or age groups) may be less accurate due to smaller numbers. Sub-group numbers for the Pfizer vaccine are given for US participants with international percentages in parentheses.
- https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-conclude-phase-3-study-covid-19-vaccine
- https://www.pfizer.com/science/coronavirus/vaccine
- https://investors.modernatx.com/news-releases/news-release-details/modernas-covid-19-vaccine-candidate-meets-its-primary-efficacy
- https://www.modernatx.com/sites/default/files/content_documents/2020-COVE-Study-Enrollment-Completion-10.22.20.pdf

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+

Johnson & Johnson

- **43,783** enrolled
- **8** countries
  - **3** continents
  - 44% in the United States
- Racial/ethnic distribution
  - **74%** - White
  - **15%** - Hispanic
  - **13%** - African American/Blac
  - **6%** - Asian
  - **1%** - Native American
- **34%** ages 60 and older
  - **39%** ages 45-64
  - **25%** ages 65+
- **41%** had comorbidities

For more information, visit www.clinicaltrials.gov

Sources: https://www.pfizer.com/science/coronavirus/vaccine; https://www.modernatx.com/cove-study https://www.jnj.com/johnson-johnson-covid-19-vaccine-authorized-by-u-s-fda-for-emergency-usefirst-single-shot-vaccine-in-fight-against-global-pandemic

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HOW EFFECTIVE ARE THE COVID-19 VACCINES?

	Pfizer (BNT162b2)	Moderna (mRNA-1273)	Johnson and Johnson (Janssen)
Efficacy Overall	95% protection from having an infection	94.1% protection from having an infection	66% moderate to severe disease, 85% from severe infection
Similar efficacy with different race, ethnicity and age			

REACTIONS

- These vaccines produce common reactions after vaccination, especially after the 2nd dose.
- Reactions may include:
    - Fever
    - Headache
    - Muscle aches

} These indicate an immune reaction

Do not worry if you did not experience these. You will still have protection!

- 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.

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

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How could the vaccine be safe if it was developed so quickly?

- Safety is the most important priority in vaccine approval
- Most side effects occur within 6 weeks of vaccination. To be more cautious, the FDA (Food and Drug Administration) requires 8 weeks of safety monitoring of the COVID-19 vaccines
- Monitoring for safety will continue as the vaccine is distributed to the public
- To assess safety FDA typically advises that a minimum of 3,000 participants are included in the trial. The current COVID-19 vaccine trials include 30,000 to 50,000 participants

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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 significant adverse events.

How could the vaccine be safe if it was developed so quickly?

Major reasons we were able to get these vaccines developed more quickly than usual include :

- Global effort with the world's leading scientists focused on a single task
- Nearly unlimited resources (money, knowledge, manpower, technology)
- A large pool of diverse adult volunteer trial participants

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How could the vaccine be safe if it was developed so quickly?

- The FDA is using the same strict standards that it has for decades
- No steps are “skipped”
- Two **independent advisory committees** are reviewing the results. Members and experts of these committees have no conflict of interest and are not associated with any vaccine manufacturers
  - FDA
  - CDC

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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.

CONTRAINDICATIONS

CDC considers a history of the following to be a contraindication to vaccination with COVID-19 vaccines:

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine
- Immediate allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine

People with a contraindication to mRNA COVID-19 vaccines (including due to a known PEG allergy) could consider the Johnson and Johnson vaccine.

    - If someone got their first dose of Pfizer or Moderna and had a severe allergic reaction, they can wait 28 days after their first vaccine dose to receive the Johnson & Johnson vaccine.

https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Contraindications
https://www.who.int/news-room/feature-stories/detail/who-can-take-the-pfizer-biontech-covid-19--vaccine

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CONTRAINDICATIONS

- There are no interactions between the COVID-19 vaccines and:
  - Any antiretrovirals used by People Living with HIV
  - Any medications used to treat Hepatitis C
  - Being on methadone, buprenorphine or other medication for OUD

- If you have the following it is safe to be vaccinated:
  - Hypertension
  - Diabetes,
  - Asthma
  - Pulmonary, liver or kidney disease
  - Chronic infections
  - Allergies (ex: seasonal, to medications or pets)

https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Contraindications
https://www.who.int/news-room/feature-stories/detail/who-can-take-the-pfizer-biontech-covid-19--vaccine

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ARE THE VACCINES SAFE FOR PEOPLE WITH HIV AND OTHER CHRONIC ILLNESSES?

Any currently authorized COVID-19 vaccine can be administered to persons with underlying medical conditions who have no contraindications to vaccination, including:

- Immunocompromised persons
- People with autoimmune conditions
- People with history of Guillain-Barré syndrome, Bell's palsy

Clinical trials demonstrate similar safety and efficacy profiles in persons with underlying medical conditions, including those that place them at increased risk for severe COVID19, compared to persons without comorbidities

https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html

CDC

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ARE THE VACCINES SAFE FOR PEOPLE WITH HIV AND OTHER CHRONIC ILLNESSES?

Persons with HIV infection, other immunocompromising conditions, or who take immunosuppressive medications or therapies might be at increased risk for severe COVID-19

- Immunocompromised persons may receive COVID-19 vaccine unless otherwise contraindicated
  - All currently authorized vaccines are inactivated vaccines
- Individuals should be counseled about:
  - Unknown vaccine safety and efficacy profiles in immunocompromised persons
  - Potential for reduced immune responses
  - Need to continue to follow current guidance to protect themselves against COVID-19

https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html
https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#phrecs

CDC

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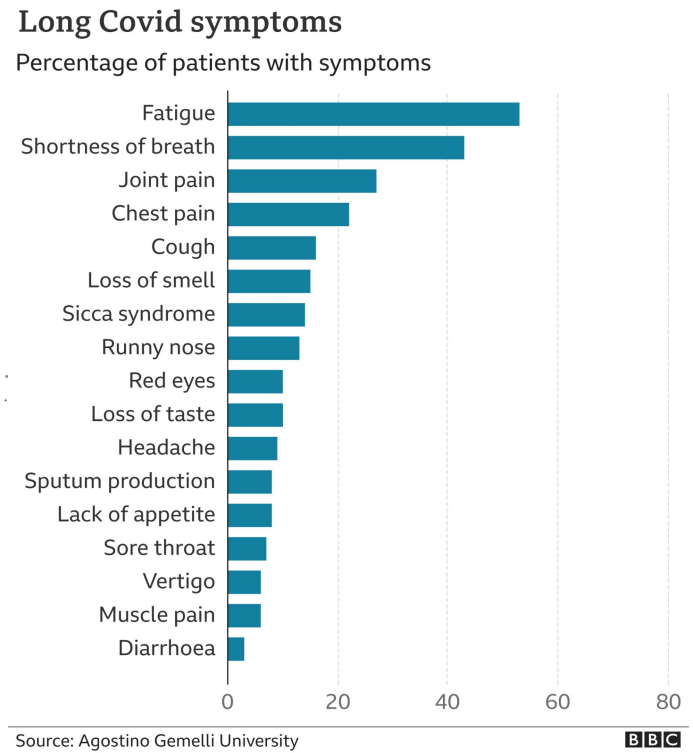
Long Covid/Post-Acute Covid Syndrome



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How this relates to Harm Reduction Community

People who use drugs

People who engage in sex work

People who are experiencing homelessness

People who have HIV/chronic conditions

LGBTC/GNC

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CONCERNS WE HAVE HEARD:

how will it affect my already existing illnesses?

I had covid previously and was worried about harsher side effects.

Concerns around gender, age and race as they can relate to particular issues folks in these sectors may experience and the vaccine trials may not have considered

Every presentation given on the vaccine is full of messages on why we should get it and trying to push the community to take it.

Medical racism: Herd immunity Blankets

Concerns about vaccinating kids

How can they know of possible side effects when the vaccine it is in its infancy.

I am worried about the unknown short and long term side effects.

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Not interested or able to take the COVID Vaccine?

There is much you can do to prevent COVID infection in yourself or loved ones.

- Double masking
  - (CDC recommends: Wear a disposable mask underneath a cloth mask. The cloth mask should push the edges of the disposable mask against your face.)
- Wear a mask with a nose bridge to keep the air
- Physical distancing, small bubble of people
- Frequent COVID-19 testing

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Q&A

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THANK YOU FOR ATTENDING THIS Office Hours

Please fill out the evaluation.

covid19@harmreduction.org

harmreduction.org

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How was the vaccine development timeline accelerated while ensuring safety?

- Researchers used existing clinical trial networks to begin conducting COVID-19 vaccine trials.
- Manufacturing was 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 in large amounts than traditional vaccines.
- FDA and CDC are prioritizing review, authorization, and recommendation of COVID-19 vaccines.

*For more information, visit the COVID-19 Prevention Network: www.coronaviruspreventionnetwork.org/about-covpn

Q: How do we know if COVID-19 vaccines are safe?

- FDA carefully reviews all safety data from clinical trials.
- FDA authorizes emergency vaccine use only when the expected benefits outweigh potential risks.
- ACIP reviews safety data before recommending any vaccine for use.
- FDA and CDC will continue to monitor the safety of COVID-19 vaccines to make sure even very rare side effects are identified.

"COVID-19 vaccines were tested in large clinical trials to make sure they meet safety standards. Many people were recruited to participate in these trials to see how the vaccines offer protection to people of different ages, races, and ethnicities, as well as those with different medical conditions."

Q: Is it safe to get a COVID-19 vaccine if I have allergies?

- Ask what kind of allergies they are concerned about.
- Explain that people should not get vaccinated if they are allergic to any ingredient in COVID-19 vaccines.
- Explain that people with other types of allergies may still be vaccinated, and that you can help determine if it is safe for them.

If you have ever had a severe allergic reaction to any ingredient in a COVID-19 vaccine, you should not get that the vaccine. If you have had an immediate allergic reaction of any severity to other vaccines or injectable therapies, I will help you decide if it is safe for you to get vaccinated. You may still get vaccinated if you have severe allergies to oral medications, food, pets, insect stings, latex, or environmental irritants like pollen or dust.

Q: Is it safe to get a COVID-19 vaccine if I am pregnant or breastfeeding?

- Explain that there is limited data about the safety of COVID-19 vaccines during pregnancy and breastfeeding, but that experts do not believe it poses a risk.
- Clarify that patients may choose to get vaccinated if they are part of a recommended group.
- Emphasize that vaccination is a personal decision and offer to discuss it in more depth.

There is limited information about the safety of COVID-19 vaccines during pregnancy. However, based on what we know about how these vaccines work, experts believe they are unlikely to pose a risk for pregnant patients. You may choose to get vaccinated if you are part of a group that is recommended for COVID-19 vaccine. We can talk through this decision together.

Q: Have these vaccines been tested in all populations?

- Explain that the clinical trials recruited a diverse mix of participants.
- Be specific and provide the percentages of people from communities of color, people with underlying health conditions, and older adults included in the trials.
- Reiterate that no serious safety concerns were identified.

"The first two mRNA vaccines in line for FDA authorization were tested in a diverse group of people. About 30% of U.S. participants were Hispanic, African American, Asian or Native American. About half were older adults. There were no significant safety concerns identified in these or any other groups."

Q: Is it better to get natural immunity rather than immunity from vaccines?

- Explain the potential serious risk COVID-19 poses to them and their loved ones if they get the illness or spread it to others, adding that the disease can be serious even if they are not in a high-risk group.
- Explain that scientists are still learning more about the virus that causes COVID-19. 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.

"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 sick. Getting a COVID-19 vaccine is a safer choice."

Q: Will the shot hurt? Will it make me sick? What about the side effects?

- Explain that they cannot get COVID-19 from the vaccine.
- Explain what the most common side effects from vaccination are, how severe they may be, and that they typically go away on their own within a week.
  - Make sure patients know that a fever is a potential side effect.
- Provide a comparison if it is appropriate for the patient (for example, pain after receiving the shingles vaccine for older adults who have received it).

"These side effects are signs that your immune system is doing exactly what it is supposed to do. It is working and building up protection to disease."

"Most people do not have serious problems after getting a vaccine. However, your arm may be sore or swollen. These symptoms usually go away on their own within a week. Some people report getting a headache, fever, fatigue, or body aches after getting a vaccine. "

Q: How do we know these vaccines are safe when they are so new? What about long-term side effects?

- Explain how FDA and CDC are continuing to monitor safety.
- Let patients know that ACIP will take action to address any potential safety problems detected.
- Compare the potential serious risk of COVID-19 illness with what is currently known about the safety of COVID-19 vaccines.

"COVID-19 vaccines are being tested in large clinical trials to learn more about their safety and effectiveness. However, it does take time and more people getting vaccinated before we can learn about very rare or long-term side effects. That is why safety monitoring will continue. CDC has an independent group of experts that reviews all the safety data as they come in and provides regular safety updates. Any possible problems will be quickly investigated to find out if the issue is related to the COVID-19 vaccine and determine the best course of action."

Q: How many doses are needed and why?

- Explain that two shots are needed to provide the best protection against COVID-19 for both mRNA vaccines. The first shot primes the immune system, helping it recognize the virus, and the second shot strengthens the immune response.
- Explain that COVID-19 vaccines may differ in the number of doses needed and the spacing between doses.
- When applicable, explain the dosing options available in your office and encourage the patient to set up an appointment before they leave to come back for a second dose.

"Nearly all COVID-19 vaccines being studied in the United States require two shots. The first shot starts building protection, but everyone has to come back a few weeks later for the second one to get the most protection the vaccine can offer."

Q: Do I have to continue to wear a mask and avoid close contact with others after I have been vaccinated?

- Explain that there is not enough information currently available to say if or when CDC will stop recommending that people wear masks and avoid close contact with others. Factors that are being considered include how many people get vaccinated and how the virus is spreading in communities.
- Explain that we don't yet know if the vaccine reduces transmission of SARS-CoV-2.
- Emphasize that these precautions will need to be observed until the vaccine is in widespread use and disease rates start to decline.

Right now, experts don't know how long the vaccine will protect you, so it is important to keep covering your mouth and nose with a mask, washing hands often, and staying at least 6 feet away from others after getting each dose of the vaccine. We also know not everyone will be able to get vaccinated right away, so it's still important to protect yourself and others. Everyone who gets vaccinated should continue taking these precautions until the vaccine is in widespread use and COVID-19 rates have declined.


INTERCONNECTION
IS OUR STRENGTH
SAVES
LIVES!
OVERDOSE
NOW!
NOT ONE MORE
LIFE LOST