COVID-19 Vaccine Community Leader Mobilization Training

U.S. Public Health Accompaniment Unit
September 2021
Context for these materials

This deck is intended for use in training trusted messengers and community leaders to conduct community-based outreach and education around the COVID-19 vaccine. The goal is to share accurate, science-based evidence that trusted messengers can use to engage in discussion that enables individuals to make informed decisions about their own health. **Supplementing this deck with up-to-date local information (on vaccine availability, eligibility criteria, and registration procedures) is critical.** Please provide trusted messengers with additional information on how to facilitate a community conversation/forum and answer common questions. They may choose to use the Community Conversations Slide Deck in their outreach as well.

The ideas presented in this deck reflect the latest public health thinking and scientific evidence as of September 2021. You are advised that the COVID-19 vaccine landscape remains highly fluid, and it is your responsibility to ensure that decisions are made based on the most up-to-date information available.

Partners In Health does not provide medical advice, diagnosis or treatment in the United States. The information, including but not limited to, text, graphics, images and other material contained in this slide deck, are intended for informational purposes only.
About this training presentation

This training is designed to equip community leaders with the tools and messages needed to be a trusted leader and champion in the COVID-19 vaccine rollout.

The goal is to help you protect your community.

TRAINING AGENDA

Your role as a community leader

Information on COVID-19 vaccine efficacy and access

Vaccine confidence and why it matters

Actions for community leaders
• Share key messages about vaccine safety, efficacy, distribution
• Enable access in your community
• Be an advocate

Next steps in supporting your community
As a community leader, you are uniquely positioned to assist and mobilize others.

**Role of state**
- Provide **guidance, resources, and information**
- Coordinate **allocation, ordering, and distribution**
- Support **municipal coordination**
- Promote **equity**

**Role of community partners**
- Serve as **trusted messengers** for your community
- **Share feedback** from community with state and local leaders
- Tailor outreach and messages to your community's needs
- Connect those in need to social supports and information

**Role of local health & vaccinators**
- **Coordinate and operate** vaccine sites
- Plan with **community needs** in mind – including challenges with scheduling, finding, and attending vaccination appointments.
Your role as a community leader

Information on COVID-19 vaccine efficacy and access

Vaccine confidence

Actions for community leaders
  • Share key messages about vaccine safety, efficacy, distribution
  • Enable access in your community
  • Be an advocate

Next steps in supporting your community
Information on COVID-19 vaccine rollout

• In this section we will provide technical information on COVID-19 vaccines and rollout strategies.
• In your outreach, you will share and explain the same information to members of your community (using the Community Conversations Slide Deck).
• In some cases, we provide greater detail for you so that you will be equipped to answer technical questions.

Please ask questions throughout!

Trusted Messenger Tips:

• Stay informed: we are learning more every day.
• Visit your state and local public health authorities' websites frequently and follow them on social media.
• Work together. Other members in your community can help you improve your outreach and identify new ways to support your community.
Approved COVID-19 vaccines in the U.S.

There are 2 COVID-19 vaccines approved with emergency use authorization (EUA), and 1 COVID-19 vaccine that has received the FDA's full approval.

Named: Comirnaty
Type of Vaccine: mRNA
Efficacy in trials: 91%
Dosing: 2 shots, 21 days apart
Approval status: Fully approved

Type of vaccine: mRNA
Efficacy in trials: 94.1%
Dosing: 2 shots, 28 days apart
Approval status: EUA

Type of vaccine: Viral vector
Efficacy in trials: 72%*
Dosing: 1 shot
Approval status: EUA

*U.S. trial data

ALL 3 vaccines are highly effective at preventing severe illness, hospitalization, and death.

It is hard to compare the vaccines directly, because each trial study was designed slightly differently. Several other vaccines are currently under development.
Who can get the COVID-19 vaccines?

Every adult regardless of allergies, medications, pregnancy, or underlying medical conditions is eligible to receive a COVID-19 vaccine.

The only groups NOT eligible to receive COVID-19 vaccination are:

• Children under 12 years old for Pfizer, and under 18 years old for Moderna and Johnson & Johnson (J&J). No vaccine has yet been authorized for children under 12, but trials are ongoing and authorizations are expected in the coming months.
• Those who experience a severe allergic reaction to the first dose of a two dose COVID-19 vaccine

All vaccines provided through the U.S. government will be free of charge to all individuals, including those without insurance. For those who have insurance, information will be collected so the vaccine provider can bill for administrative costs, but there will be no out of pocket cost to the individual.
How were these vaccines created so quickly while ensuring that they are safe?

Vaccines receive FDA emergency and full approval through a rigorous process:

1. Scientists already knew a lot about vaccine technology and were able to use this knowledge to design vaccines for trial.
2. The companies were able to start manufacturing planning in parallel with trials, with the help of huge $ investments from the government.
3. After strong evidence from 3 phases of trials, the vaccines received Emergency Use Authorization (EUA).
4. Full approval. Pfizer (Comirnaty) received it in August 2021; others expected to follow.

In Summary...

- FDA safety evaluations were not changed or compromised during COVID-19 vaccine development.
- The vaccine process was faster because research and development, clinical trials, manufacturing, and plans for distribution are occurring at the same time, with unprecedented levels of government spending.
- Even after EUA, there is ongoing and rigorous monitoring for adverse events.
- On Aug 23, 2021, the FDA granted full approval of the Pfizer (Comirnaty) vaccine.

Sources:
https://www.fda.gov/media/144412/download
The Pfizer, Moderna, and J & J trials were designed to ensure efficacy was studied across races and ethnicities, to reflect the diversity of the population who will receive the vaccine.

Sources: Johnson & Johnson, EUA Fact Sheet, KFF, Racial Diversity within COVID-19 Vaccine Clinical Trials

Breakdown by Race

<table>
<thead>
<tr>
<th>Race/Origin</th>
<th>US Population</th>
<th>Pfizer</th>
<th>Moderna</th>
<th>Johnson &amp; Johnson</th>
</tr>
</thead>
<tbody>
<tr>
<td>White</td>
<td>74%</td>
<td></td>
<td>82%</td>
<td>79%</td>
</tr>
<tr>
<td>Black or African American</td>
<td>12%</td>
<td>10%</td>
<td>17%</td>
<td></td>
</tr>
<tr>
<td>Asian</td>
<td>6%</td>
<td>4%</td>
<td>5%</td>
<td>4%</td>
</tr>
<tr>
<td>Native American or Pacific Islander</td>
<td>1%</td>
<td>1%</td>
<td>1%</td>
<td>9%</td>
</tr>
</tbody>
</table>

Breakdown by Ethnicity

<table>
<thead>
<tr>
<th>Ethnicity</th>
<th>Hispanic or Latinx</th>
<th>Not Hispanic or Latinx</th>
</tr>
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<tbody>
<tr>
<td>White</td>
<td>18%</td>
<td>82%</td>
</tr>
<tr>
<td>Black or African American</td>
<td>26%</td>
<td>73%</td>
</tr>
<tr>
<td>Asian</td>
<td>45%</td>
<td>79%</td>
</tr>
<tr>
<td>Native American or Pacific Islander</td>
<td>20%</td>
<td>53%</td>
</tr>
</tbody>
</table>

The trials included tens of thousands of participants from varied backgrounds.
Who participated in the trials?

Vaccine trials were performed with many individuals with high-risk conditions. High-risk conditions are those that place an individual at increased risk for severe COVID-19 complications.

<table>
<thead>
<tr>
<th>High-Risk Condition</th>
<th>Pfizer (Comirnaty): % of Trial Participants</th>
<th>Moderna: % of Trial Participants</th>
<th>Johnson &amp; Johnson: % of Trial Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>No high-risk conditions</td>
<td>79.5%</td>
<td>77.9%</td>
<td>60.1%</td>
</tr>
<tr>
<td>Diabetes</td>
<td>8.2%</td>
<td>9.4%</td>
<td>7.2%</td>
</tr>
<tr>
<td>Chronic Lung Disease</td>
<td>8.6%</td>
<td>7.5%</td>
<td>1.3%</td>
</tr>
<tr>
<td>Liver Disease</td>
<td>0.6%</td>
<td>0.7%</td>
<td>&lt; 1%</td>
</tr>
<tr>
<td>Significant Cardiac Disease</td>
<td>1.4%</td>
<td>4.9%</td>
<td>2.4%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>24.4%</td>
<td>6.5%</td>
<td>10.3%</td>
</tr>
<tr>
<td>HIV/AIDS</td>
<td>0%</td>
<td>0.6%</td>
<td>2.5%</td>
</tr>
</tbody>
</table>

Explaining mRNA vaccines: Comirnaty (Pfizer) & Moderna

How does it work?

- mRNA is a normal part of human biology. Your body is full of mRNA right now!
- These vaccines work by using mRNA as a "messenger" that contains a blueprint for the COVID-19 spike protein. This tells your body: make this protein.
- You then develop antibodies against COVID-19 spike proteins, creating immunity.
- Once your cells make the protein, the mRNA breaks down and does not stay in your body permanently.
- mRNA does not enter your cell's nucleus and cannot alter your DNA.

Is mRNA new technology?

- No. While the Pfizer vaccine has been FDA approved and both Pfizer & Moderna are EUA recipients, research on mRNA for other diseases, such as Zika, cancer, and the flu, has been underway for 10 years.
- Vaccines based on injecting viral proteins (flu, tetanus, pneumonia) or live virus (oral polio, Chickenpox) take longer to produce.
- Because mRNA vaccines work off a blueprint, they can be created quickly.
- The COVID-19 vaccine passed every regulatory step for authorization. No corners were cut in the creation of these vaccines.

The vaccine cannot give you COVID-19 because it contains no virus.
Explaining viral vector vaccines: Johnson & Johnson

**How does it work?**

- Viral vector vaccines use a common virus ["adenovirus"] to alert your body's immune system. The virus is *weakened and cannot cause disease*.
- Like mRNA, the harmless virus delivers a blueprint, telling your body to make COVID-19 spike proteins.
- Antibodies develop to the spike protein, creating immunity.
- The harmless virus does not stay in your body.

**Are viral vectors new technology?**

- No, Johnson & Johnson has already used this method to develop an approved Ebola vaccine, and the technology has been used for a long time for gene therapy.
- The AstraZeneca vaccine, currently approved for use in other countries, and in final vaccine trials in the U.S., uses the same technology.
- The Johnson & Johnson vaccine is an approved viral vector vaccine under EUA for COVID-19 and **passed every FDA safety step**.

This vaccine cannot give you COVID-19 because it uses a different, harmless virus to create immunity.
For most people, side effects from the vaccine are mild

Side effects are caused by your own body’s immune response to the vaccine.

Minor side effects are common after vaccination. These are short-lived and can include:
- Redness or swelling on the arm where you get the shot
- Weakness, fatigue
- Fever
- Muscle aches
- Headache

Talk to your doctor or vaccine provider about the use of over-the-counter medicine for side effects.

Severe reactions are very rare
- You will be observed for 15 minutes following vaccination to make sure you have no serious reaction. If you have known allergies to an injectable medication, you’ll wait 30 minutes.
- All vaccine sites will have epinephrine on site to address the rare possibility of a severe allergic reaction (the medicine stored in an EpiPen).

Go to your primary care doctor, a clinic, or alert your vaccine provider if:
- Any side effects do not go away within 3-4 days
- You received the J&J vaccine and are experiencing possible symptoms of Thrombosis with Thrombocytopenia Syndrome (TTS) - see appendix
Will the vaccines still work against the variants?

What are the COVID-19 variants?

<table>
<thead>
<tr>
<th>Variant</th>
<th>Description</th>
<th>Date Emerged</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alpha (B.1.1.7)</td>
<td>Emerged in September 2020 in UK</td>
<td></td>
</tr>
<tr>
<td>Beta (B.1.351)</td>
<td>Emerged in September 2020 in S. Africa</td>
<td></td>
</tr>
<tr>
<td>Gamma (P.1)</td>
<td>Emerged in October 2020 in Brazil</td>
<td></td>
</tr>
<tr>
<td>Delta (B.1.617.2)*</td>
<td>Emerged in September 2020 in India</td>
<td></td>
</tr>
</tbody>
</table>

Why do viral variants arise?

- All viruses change naturally as they replicate.
- Sometimes, viruses change in a way that helps them become better at infecting people or faster at replicating.
- These changes allow the virus variants to become better at spreading from person to person.

Experts are confident that current vaccines will provide protection against the current viral variants. Increasing vaccination will help prevent new variants from developing. It is important that you are fully vaccinated to ensure protection against the variants.

You can help by wearing a mask and social distancing, regardless of whether or not you’ve been vaccinated. This will help protect those who cannot yet be vaccinated, including children, and those who are considered high-risk, such as the elderly, or those who are immunocompromised.

*Current dominant strain in the U.S. as of August 2021
The Delta variant of COVID-19 is currently the predominant strain in the US. Not only is Delta more contagious, but it is causing more serious illness, particularly among children and the unvaccinated. Vaccination and wearing your mask is still the best way to protect yourself and your loved ones from severe illness and death.

**Facts about Delta**

1. **Delta is far more contagious than other variants**
   It is 2x more infectious than previous strains.

2. **Delta is impacting children more than previous variants**
   Pediatric COVID-19 cases has drastically increased with Delta, as those under 12 are not yet able to receive a vaccine.

3. **Delta is causing more severe illness than previous strains among unvaccinated people**
   The Delta variant more than doubles the risk of severe illness requiring hospitalization for unvaccinated people.

4. **Vaccines and masks are critical to limit the spread of Delta**
   Getting vaccinated and wearing a mask, regardless of vaccination status, will help prevent COVID-19 spread in communities.

As of August 2021
Breakthrough Cases: Why are fully vaccinated people still getting COVID?

What are breakthrough cases?

- A person who is fully vaccinated and tests positive for COVID-19 is considered a breakthrough case.
- No vaccine can provide full protection from any disease, but this does not mean they are ineffective. The available vaccines provide a high level of protection against catching and transmitting COVID, and especially against severe illness, hospitalization, and death.
- In most breakthrough cases, the symptoms are mild, and do not require hospitalization or result in death.

Why should I get the vaccine if I still can get COVID?

- No vaccine is 100% effective, and some breakthrough cases are expected. The vaccines dramatically lower your chance of infection and transmission, and drastically reduces your risk of severe illness, hospitalization, and death.
- In addition to protecting you, vaccines provide protection for those around you. Full vaccination reduces your chances of catching and transmitting COVID-19. Not everyone is yet eligible for vaccination, such as children under 12. For others, such as those with compromised immune systems, COVID-19 vaccines provide less protection.

Vaccines and masks are our best protection against the COVID-19 Delta variant.
COVID-19 vaccines are highly effective against preventing severe outcomes among the general population. However, some immunocompromised people require an additional layer of protection. Those who have compromised immune systems may now receive a third dose of either mRNA vaccine: Pfizer (Comirnaty) or Moderna.

**Third doses:**
- Are recommended for those who are immunocompromised
- May be referred to as an "immune primer" as it will "prime" immune levels for those whose bodies cannot develop immunity as well as others
- Can be received no sooner than 28 days after a second dose
- Are available immediately
The CDC has recently updated its guidance to better protect people, recommending masking regardless of vaccination status.

This is especially pertinent for those living in areas of substantial or high spread, which currently describes the vast majority of the country.

Those older than 65, with a compromised immune system or a chronic disease, or living with people who fit into one of these categories, may also want to consider masking indoors, regardless of local transmission.

You must still adhere to federal, state, local, tribal, or territorial laws, rules, and regulations, including local business and workplace guidance, which may require masking.

COVID-19 testing and contact tracing remain critically important.

Vaccination is one measure to help stop the pandemic; other personal protection measures remain important.

Source: https://www.cdc.gov/vaccines/covid-19/health-systems-communication-toolkit.html
Many people face challenges in trying to get the vaccine

Populations/communities who may experience more significant challenges – many of whom are already disproportionately impacted by COVID-19 – include the following:

- Low-income
- Non-English speaking or reduced literacy
- The elderly
- Medically frail or disabled (physical, mental, cognitive, and sensory)
- Isolated (due to geography, documentation status)

Potential barriers to accessing the COVID-19 vaccine

**Structural**
- Limited access to health care provider and trusted systems for social support
- Inability to navigate a complex health care system

**Information**
- Inaccessibility of information on vaccine safety, efficacy, available distribution points, and scheduling options

**Logistical**
- Challenges in scheduling (for example, no computer)
- Lack of convenient locations, schedules, and / or available transportation
- Lack of personnel or equipment to administer vaccines

Your role as a community leader

Information on COVID-19 vaccine efficacy and access

Vaccine confidence

Actions for community leaders
- Share key messages about vaccine safety, efficacy, distribution
- Enable access in your community
- Be an advocate

Next steps in supporting your community
"You can’t look at that hesitancy at face value. Centuries of inhumanity — that’s not easily forgotten. Medical professionals have to understand that the fear of Covid-19...does not always outweigh the very clear and well-documented danger of going to a health care system that has proven itself to be as deadly as disease.”

— Gabrielle Perry, clinical epidemiologist

Data Sources:
KFF COVID-19 Vaccine Monitor: July 2021 | KFF
Every person starts at a different point along the path to vaccination. Different engagement, support, and communication strategies are required to meet everyone's needs.

- **“I don’t want or need the vaccine”**

- **“I have heard about the vaccine but have questions”**

- **“I will probably get the vaccine but I want to wait and see”**

- **“I want the vaccine but don’t know where or how to get it”**

- **Mass media campaign on the benefits of vaccination**

- **Q&A session with trusted local doctor**

- **Honest conversation with a community leader**

- **Dedicated scheduling support and free transportation**

You play a critical role in understanding your community’s needs and concerns.

Changing the narrative around "vaccine hesitancy"
Factors influencing Vaccine Confidence

- Racism and inequity
  - Many communities of color and indigenous people have suffered from *generations of racism and inequality*.
  - Policies/structures that have caused harm include those related to *education, economic opportunities, police violence, and housing conditions*.

- Health system discrimination
  - Discrimination against people of color is embodied in *unequal access to care, different health outcomes, and limited resources in poor communities*.
  - It is not just the legacy of experimentation (Tuskegee) but the *lived experiences of limited and unequal access and care*.

For these reasons and more, some people may be reluctant to receive the COVID-19 vaccine.

*It is the responsibility of the public health system and health care providers to be trustworthy: listening to the concerns of everyone, answering questions and providing equitable care.*
You as a community leader can work with providers and local health to improve equitable rollout

**Community Leaders:**
Give people the information they need to decide that the benefits of vaccination outweigh the risks

- Share up-to-date, understandable information with the individuals in your circle
- Launch Trusted Messenger Forums steered by community leaders
- Support multi-lingual education and social media campaigns to boost vaccine confidence

**Local and State Health Authorities:**
Address the significant challenges involved in finding and receiving the vaccine

- Allocate supply to towns, cities, neighborhoods with high proportions of underserved populations
- Set targets and develop strategies in coordination with vaccine providers to ensure vaccines are administered to people living in highest-risk communities in proportion to population
- Stand up pharmacy clinics in high social need towns / cities and underserved rural areas
Your role as a community leader

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Next steps in supporting your community
The way we talk about the COVID-19 vaccine is important

• Lead with the positive – emphasize the importance of the vaccine to protect loved ones and the most vulnerable

• State the facts – Before mentioning a myth, state known facts about the vaccine to ensure this remains in focus

• Mix positive stories about human experience with science and information on the rollout

• Acknowledge people’s hesitancy and reinforce that the choice to get the vaccine is always theirs to make

• Provide scientific and unbiased answers – ensure you are equipped with the latest information

What messaging is particularly important for your community?

What language “do's and don’ts” do you see?
I trust that the vaccine is safe and works to prevent you and your loved ones from becoming seriously ill. Share your own personal story: “I got (or I will get) the vaccine because …”

The vaccine is free, even without insurance. Everyone who is eligible for the current phase can be vaccinated.

People in our community got the vaccine and have had good experiences.

Please reach out to me with questions and share your concerns – I want to hear what is important to you, and I’m here for you.

What else resonates with your community?
Virtual town halls are a useful forum for sharing more in-depth information

**Recommendations for organizing a town hall**

Primary goal to provide participants with the information they need to come to an informed decision on their own.

- Guiding principles:
  - Transparency
  - Local ownership and context
  - Mix of science and data with positive stories
  - Empathy and non-judgment

- Recommended platforms: Virtual meeting platform like Zoom or Facebook Live

- See [Town Hall Facilitation Guide](#) and [Community Conversations Slide Deck](#) for supporting material.

**Organizations hosting virtual town halls**

- Health care providers
- Cities and local health departments
- Community and faith-based organizations and associations

You may also choose to leverage ongoing in-person meetings, (convened by faith-based groups, school boards, etc.) provided they are hosted in accordance with CDC guidelines for community mitigation.
Town Hall Best Practices: Hear concerns and get feedback

Bidirectional communication is key: Have an honest conversation.

We want this to be a safe space for you to share your concerns with us and others. Is there anything you're worried about when it comes to vaccination? Is there anything that is still unclear?

Please share your feedback after today’s conversation using [insert mechanism and hyperlink which will be emailed to participants]

Thank you!

Follow up with us:

Name (email)
Your role as a community leader

Information on COVID-19 vaccine efficacy and access

Vaccine confidence

Actions for community leaders
  • Share key messages about vaccine safety, efficacy, distribution
  • **Enable access in your community**
  • Be an advocate

Next steps in supporting your community
There are a range of ways to sign up for COVID-19 vaccine appointments in each state. Know your context.

1. Through existing doctors or health care providers
   Individuals may be contacted by their medical provider.

2. Through online or phone scheduling systems
   - Visit vaccines.gov (English) or vacunas.gov (Spanish) to search and find a vaccine near you.
   - Text GETVAX (438829) for English or VACUNA (822862) for Spanish to receive three vaccine sites on your phone within seconds.
   - Call the National COVID-19 Vaccination Assistance Hotline at 1-800-232-0233 for those who prefer to get information via phone call.

3. Most retail pharmacies now offer walk-in vaccines

Identify other resources available within your community

Think back to the barriers to access faced by individuals in your community.

Understand the resources available in your community to overcome such barriers.
• Identify transportation services and scheduling assistance.
• In addition to providing information, can you connect individuals to social supports?

Potential barriers to accessing the COVID-19 vaccine

Structural
• Limited access to health care providers and trusted systems for social support
• Inability to navigate a complex health care system

Information
• Inaccessibility of information on vaccine safety, efficacy, available distribution points, and scheduling options

Logistical
• Challenges in scheduling (for example, no computer)
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Next steps in supporting your community
COVID-19 vaccine rollout requires collaboration

The Roles of Community Partners

• **Spread the word** on the COVID-19 vaccine, providing clear information on safety and efficacy

• **Use information channels that are most useful** to members of your community

• **Share feedback** on the ongoing rollout and attitudes towards the vaccine with state and local health authorities

• **Allow us to benefit from your creativity and reach on potential system improvements** – share your ideas with us and local partners!

The Roles of Local Governments

• **Mobilize range of stakeholders** into action

• **Develop resources** for use by community partners and vaccinators

• **Evaluate ongoing progress** of the rollout with respect to equity

• **Remove roadblocks and address challenges** that impede communities’ access to the vaccine

The role of local government may vary from place to place; best practice is to work shoulder-to-shoulder in vaccine rollout.
Discussion: What are the opportunities to mobilize your community?

- What **work is ongoing** in your organization or community on the COVID-19 vaccine?
- What are you **hearing** from your community members?
- What **opportunities do you see** to increase your community’s awareness of the vaccine and ability to receive it?
- What is your **plan of action** for mobilizing your community?
- What do you need in terms of guidance or information that you don’t have?
- How can you work together with other community members and organizations?
Additional resources for you to use as trusted messengers

Frequently Asked Questions

Community Conversations Presentation Deck

Virtual Town Hall Facilitator’s Guide
Appendix to support further learning for you and your communities
Key information on COVID-19 mRNA vaccine trials (Detail)

<table>
<thead>
<tr>
<th>Study design</th>
<th>Pfizer/BioNTech</th>
<th>Moderna</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Comparison of new cases of COVID-19 between those who received vaccine and those who received a placebo and severity of disease</td>
<td>How effective is vaccine at preventing symptomatic COVID-19?</td>
</tr>
<tr>
<td></td>
<td>• Participants were randomly selected to receive vaccine vs. placebo</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Neither participants nor researchers knew the assignment of vaccine vs. placebo</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Key research question</th>
<th>How effective is vaccine at preventing symptomatic COVID-19?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Efficacy</td>
<td>95%</td>
</tr>
<tr>
<td>Enrolled participants</td>
<td>43,548 total; 49.4% female</td>
</tr>
<tr>
<td>Age range</td>
<td>16 to 91 yrs. old</td>
</tr>
<tr>
<td>Monitoring</td>
<td>Participants were monitored 2 months following injection, as it is unusual for side effects to appear more than 8 weeks after vaccination</td>
</tr>
<tr>
<td>Safety results</td>
<td>Most common adverse reactions were short-term, mild-to-moderate pain at the injection site, fatigue, and headache. Serious adverse events were low and were similar in the vaccine and placebo groups</td>
</tr>
</tbody>
</table>

On August 23, 2021, the FDA granted full approval of the Pfizer-BioNTech vaccine.

What does full approval mean?

- Pfizer's approval builds on the extensive data and information previously submitted that supported the EUA
- Additional safety testing was conducted and hundreds of thousands of pages of research reviewed
- The vaccine can be distributed after the public health emergency ends
- Approval reaffirms evidence showing that the COVID-19 vaccines are safe and saving lives

It is important that we continue to recommend that people get whichever vaccine is most accessible to them.

Moderna has applied for full FDA approval, and Johnson & Johnson is expected to apply soon as well. Medical experts expect that both vaccines will receive full FDA approval given extensive data already available on both. In the meantime, they remain available under EUA.

Sources:
Why should I get the COVID-19 vaccine?

Getting the COVID-19 vaccine helps prevent you from getting sick with COVID-19. COVID-19 can cause very serious illness and death. Older adults and persons with health conditions like diabetes or obesity are at an even greater risk. The more people who get the vaccine, the better we can protect our families and communities, including those yet eligible for vaccination.

Are the vaccines safe?

Medical and public health experts trust the very serious and thorough FDA approval process for the vaccines, as well as the ongoing public health regulatory system that constantly monitors ongoing vaccine safety and effectiveness. Results from both clinical trials and real-world experiences reveal that the vaccines are very safe and work very well at preventing illness.

What side effects will the vaccine have? Are there going to be long-term side effects?

Side effects can include pain at the injection site, fatigue, headache, chills, muscle pain, fever, nausea, and joint pain. These side effects are usually mild and last 1-3 days. Generally, side effects are more common in younger vs. older patients, and the 2nd dose associated with more side effects than the 1st. Talk to your doctor or vaccine provider about taking over-the-counter medicines for managing any discomfort you may experience after getting vaccinated. Historically, long-term effects from vaccines are very rare. But just to reassure you, the CDC will continue to watch very closely as this is rolled out more widely.
Do I still need to wear a mask and follow social distancing protocols after I take the vaccine?

Mostly, yes. The CDC has recently updated its guidance to better protect people, recommending masking regardless of vaccination status. The CDC now recommends masking indoors for anyone—regardless of vaccination status—living in areas of substantial or high spread, which currently describes the vast majority of the country. Country transmission levels can be found here. Those older than 65, with a compromised immune system or a chronic disease, or living with people who fit into one of these categories, may also want to consider masking indoors, regardless of local transmission. Getting COVID-19 while outdoors is very unlikely in most scenarios, but if in crowded spaces, people may want to consider wearing a mask.

Why were the vaccines developed so fast? I’m concerned that these vaccines did not undergo enough testing as other vaccines.

The speed of COVID-19 vaccine development is not a result of compromised safety or quality. The vaccine process is happening faster because research and development, clinical trials, manufacturing, and plans for distribution are occurring at the same time, with unprecedented levels of government spending. This method removes delays that occur when these processes are carried out sequentially. No standards in the safety evaluations have been changed during this process.
For all vaccines, the FDA oversees rigorous monitoring for safety and adverse events. A recent pause and resumption in the administration of the J&J vaccine is an example of the regulatory system working as it is intended to prioritize public safety and transparency.

Feb. 27, 2021
Johnson & Johnson receives Emergency Use Authorization (EUA) from FDA

April 13, 2021
Out of an abundance of caution, the CDC & FDA recommend a pause in states' administration of J&J after reports of 6 cases of a rare and severe type of blood clotting disorder.

April 14-22, 2021
During the pause, regulators gathered additional evidence on the frequency of the event. Of the 7.9 million doses of J&J administered, there were 15 cases of the disorder. The risk of serious complications of COVID-19 are far more common.

April 23, 2021
Regulators and medical experts determined that the benefits of the Johnson & Johnson vaccine outweigh potential risks. After 10 days, states resumed use of the vaccine.

Ongoing
Authorities will continue to diligently monitor the safety of the J&J vaccine and all others.
US Public Health Accompaniment Unit

For more information please contact LearningCollab@pih.org

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