This deck is intended to provide guidance for trusted messengers and community leaders to conduct community-based conversations around the COVID-19 vaccines. The goal of this deck is to share accurate, science-based evidence and engage in discussion that enables individuals to make informed decisions about their own health. This slide deck guides a short, 15-minute presentation and is intended to prompt a more comprehensive Q&A session.

Supplementing this deck with up-to-date local information (on vaccine availability, eligibility criteria, and registration procedures) is critical.

Please see additional information on how to facilitate this forum and answer common questions.

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.
AGENDA

Why get Vaccinated?
Available Vaccines in the U.S.
COVID-19 Vaccine Science
Vaccine Safety
Vaccine Frequently Asked Questions
Next Steps: Getting Vaccinated
Annex – Additional FAQs

The goal of today’s session is to share key vaccine information, answer questions about vaccine safety, and engage in honest, non-judgmental conversation.
Why should I consider getting the COVID-19 vaccine?

Getting the COVID-19 vaccine helps prevent severe illness, hospitalization, and death by COVID-19.

To help you:
Even in young, healthy people, COVID-19 can cause very serious illness and death. Older people and persons with health conditions like diabetes are at an even greater risk.

To help your family, friends, and community:
The more people who get the vaccine, the better we can protect our families and communities, and ensure people can go back to their jobs.

To move forward, together:
The best way to achieve normalcy is for all of us to get vaccinated for the coronavirus so we can collectively end this pandemic and provide justice to communities that have been especially impacted.
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.

As of August 23, 2021

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

**CoronaVac**
- **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.
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.

No. Though this is the first mRNA vaccine to be approved for use, 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 FDA approval step. 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 was the first COVID-19 viral vector vaccine authorized under EUA and passed every FDA evaluation step required.

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.

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.

Note: Experiencing side effects does not mean that you have COVID-19. It is your body developing an immune response—which is a good thing. Not everyone has side effects. Both are normal.

Severe reactions are very rare
Your risk of severe illness from COVID-19 infection is much higher than the risk of a severe reaction to the vaccine.
- You will wait for 15 minutes after 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 have epinephrine on site (the medicine stored in an EpiPen) to address the rare possibility of a severe allergic reaction.

Go to your primary care provider, clinic, or alert your vaccination site if:
- Side effects do not go away within 3-4 days
- You received the J&J vaccine and are experiencing symptoms of Thrombosis with Thrombocytopenia Syndrome (TTS)
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.

Continued monitoring & collection of trial data

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
Who participated in the trials?

The vaccine trials included tens of thousands of participants representing a range of demographic groups.

<table>
<thead>
<tr>
<th>Demographic Breakdown of Trial Participants Compared to U.S. Population</th>
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</thead>
<tbody>
<tr>
<td><strong>Breakdown by Race</strong></td>
</tr>
<tr>
<td>White</td>
</tr>
<tr>
<td>Black or African American</td>
</tr>
<tr>
<td>Asian</td>
</tr>
<tr>
<td>Native American or Pacific Islander</td>
</tr>
<tr>
<td><strong>Ethnicity</strong></td>
</tr>
<tr>
<td>Hispanic or Latinx</td>
</tr>
<tr>
<td>Not Hispanic or Latinx</td>
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</tbody>
</table>

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>

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 (Comirnaty), and under 18 years old for Moderna and Johnson & Johnson. 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 change to all, including those without insurance. For those who have insurance, information will be collected, but there will be no out of pocket cost to the individual.
Will the vaccines still work against the variants?

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.

What are the COVID-19 variants?

- **Alpha (B.1.1.7)**: Emerged in September 2020 in UK
- **Beta (B.1.351)**: Emerged in September 2020 in S. Africa
- **Gamma (P.1)**: Emerged in October 2020 in Brazil
- **Delta (B.1.617.2)**: Emerged in September 2020 in India

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.

*Current dominant strain in the U.S. as of August 2021*
The Delta variant of COVID-19 is currently the predominant strain in the U.S. 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**
   Getting vaccinated drastically reduces your chances of catching and spreading COVID-19, severe illness, hospitalization, and death.

4. **Masks and vaccines 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.
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.
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
All individuals 12 and older are eligible for vaccination. Refer to your state or local health department to learn more about how, when, and where vaccines are distributed in your area.

There are a few ways to sign up for appointments – and many sites offer walk-in options.

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
Thank You

We'd love to answer any questions!
Additional Vaccine Questions

➢ Why were the vaccines developed so fast?
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. No standards in the safety evaluations have been changed during this process.

➢ Are the COVID-19 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.

➢ Will the vaccine change my DNA?
No! The Pfizer (Comirnaty) and Moderna vaccines do not contain DNA, they contain mRNA, which does not enter the cell's nucleus, and cannot alter your genes. The J&J vaccine contains modified viral DNA that is only able to create spike proteins.

➢ Will I need a third dose?
Certain immunocompromised individuals are now able to receive a third dose of the Pfizer or Moderna vaccines. This specifically includes solid organ transplant recipients or those diagnosed with conditions with similar levels of immunocompromise. Individuals who are immunocompromised should speak with a health care provider to discuss their eligibility for an additional dose.
Is the vaccine safe for me and my health concerns?

The vaccine is safe and recommended for people with:

- Hypertension, Diabetes (Type I and II), Coronary Artery Disease, Peripheral Artery Disease, history of Stroke
- COPD / Asthma / Emphysema, Pulmonary Fibrosis, Cystic Fibrosis
- Substance Use Disorders (in recovery or active drug use), Alcohol Use Disorders (in recovery or actively drinking)
- Major Depression, Schizophrenia, Bipolar Disease
- Lupus, Rheumatoid Arthritis, Osteoarthritis, Crohn’s Disease, Raynaud’s, Celiac Disease, Multiple Sclerosis, Chronic Kidney Disease (including dialysis)
- HIV / AIDS, other sexually transmitted infections (Gonorrhea, Chlamydia, Syphilis, Herpes), Hepatitis
- Dementia, Alzheimer’s, other developmental or intellectual disabilities
- Sickle Cell Disease, Anemia / Thalassemia, Malnutrition, Obesity
- All cancers in remission + most cancers in treatment: discuss with your healthcare team
- Pregnancy: discuss with your health care team

Not recommended for:

- Children under 12 (Comirnaty-Pfizer) and under 18 (Moderna and J&J)
- Some people with compromised immune systems
- Some people with history of serious allergic reactions

Source: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#underlying-conditions
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.