

COVID-19 Vaccine Webinar for Rural Communities

November 15, 2021

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Speakers

- **LaShawn McIver, MD, MPH**
— Director, CMS Office of Minority Health
- **Peter Marks, MD, PhD**
— Director, FDA Center for Biologics Evaluation and Research (CBER)
- **Shannon Chambers, CPC**
— Director of Provider Solutions, South Carolina Office of Rural Health
- **Diane Hall, PhD, MSED**
— Senior Scientist for Policy and Strategy Lead, CDC Rural Health
- **Frances J. Feltner, DNP, MSN, RN**
— Director, University of Kentucky Center of Excellence in Rural Health
- **Darci Graves, MPP, MA, MA**
— Co-Chair, CMS Rural Health Council
— Health Insurance Specialist, CMS Office of Minority Health

Agenda

- CMS Overview
- FDA – Facilitating the Development of COVID-19 Vaccines
- NOSORH – Technical Assistance
- CDC - Building Vaccine Confidence and Demand
- University of Kentucky Center of Excellence in Rural Health – National Rural Health Day
- CMS OMH and HHS Resources

CMS Overview

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Vaccine Eligibility – Updated 11/03/2021

Vaccine Manufacturer	Initial Doses	Eligible Ages and Conditions	Booster Eligibility
Pfizer-BioNTech	<ul style="list-style-type: none"> Two doses Second dose 21 days after first dose 	<ul style="list-style-type: none"> Fully approved for all 16 years and older EUA for 12-15 year olds EUA for 5-11 year olds 	<p>When:</p> <ul style="list-style-type: none"> 6 months after first series <p>Who:</p> <ul style="list-style-type: none"> 65 years+ Age 18+ who live in long-term care settings Age 18+ who have underlying medical conditions Age 18+ who work or live in high-risk settings <p>Which booster:</p> <ul style="list-style-type: none"> You may have a preference, but you can get any booster shot
Moderna	<ul style="list-style-type: none"> Two doses Second dose 28 days after first dose 	<ul style="list-style-type: none"> EUA for 18 years and older 	<ul style="list-style-type: none"> Same eligibility requirements as the Pfizer-BioNTech vaccine
Janssen (Johnson & Johnson)	<ul style="list-style-type: none"> One dose 	<ul style="list-style-type: none"> EUA for 18 years and older 	<p>When:</p> <ul style="list-style-type: none"> At least 2 months after initial J&J shot <p>Who:</p> <ul style="list-style-type: none"> Age 18+ <p>Which booster:</p> <ul style="list-style-type: none"> You may have a preference, but you can get any booster shot

For more information: https://www.cdc.gov/media/releases/2021/p1021-covid-booster.html?fbclid=IwAR24lcG8x5QvoRPJcgKh_ZDnq3g5C8A8MFshrJDyYhh-9ZC2hR8AnC-tI4

Medicare Coverage: Payment for Administering the COVID-19 Vaccine at a Patient's Home

- Effective June 8, 2021, Medicare's additional payment amount for administering the COVID-19 vaccine in the home for certain Medicare patients is **\$35 per dose**. This payment also applies when:
 - Additional doses of the COVID-19 vaccine are administered in the home to certain Medicare patients on or after August 12, 2021.
 - Booster doses are administered in the home to certain Medicare patients on or after September 22, 2021, for the Pfizer-BioNTech vaccine and October 20, 2021, for the Moderna and Johnson & Johnson vaccines.
- Medicare will pay the \$35 amount in addition to the standard administration amount (approx. \$40 per COVID-19 vaccine dose) for a total payment of approx. \$75 for a vaccine dose administered in a patient's home.
- For more information: <https://www.cms.gov/medicare/covid-19/medicare-covid-19-vaccine-shot-payment>

Medicare Coverage: When Can I Get the Additional In-Home Payment for Administering the COVID-19 Vaccine?

- You can get the additional payment when either of these situations applies:
 - The patient has difficulty leaving the home to get the vaccine due to:
 - An illness or injury that restricts their ability to leave home,
 - A condition that makes them more susceptible to contracting a disease, or
 - They are generally unable to leave the home.
 - The patient is hard-to-reach because they have a disability or face clinical, socioeconomic, or geographical barriers to getting a COVID-19 vaccine in settings other than their home.
- Unlike the requirements under the Medicare home health benefit, you or another allowed practitioner don't need to certify that the Medicare patient is homebound, but you must document in the patient's medical record their clinical status or the barriers they face to getting the vaccine outside the home.
- Visit <https://www.cms.gov/medicare/covid-19/medicare-billing-covid-19-vaccine-shot-administration>
- Code Information: <https://www.cms.gov/medicare/covid-19/coding-covid-19-vaccine-shots>

Medicare Coverage: What Locations Qualify for Additional In-Home Payment?

- Many types of locations can qualify as a Medicare patient's home for the additional in-home payment amount, such as:
 - A private residence
 - Temporary lodging
 - An apartment in an apartment complex or a unit in an assisted living facility, group home, or non-Medicaid nursing facility
 - A Medicare patient's home that's made provider-based to a hospital during the COVID-19 PHE
 - Communal spaces of a multi-unit or communal living arrangement
 - Assisted living facilities participating in the CDC's Pharmacy Partnership for Long-Term Care Program when residents are vaccinated through this program
- The following locations do not qualify:
 - Communal spaces of a multi-unit living or communal arrangement (prior to August 24, 2021)
 - Hospitals (except when the Medicare patient's home has been made provider-based to a hospital during the COVID-19 PHE)
 - Medicare skilled nursing facilities and Medicaid nursing facilities

Billing for RHCs & FQHCs

- For Rural Health Clinics (RHCs) and Federally Qualified Health Clinics (FQHCs), Medicare pays for administering COVID-19 vaccines at 100% of reasonable cost through the cost report.
- RHCs and FQHCs should also use the cost report to bill for administering COVID-19 vaccines to patients enrolled in a Medicare Advantage Plan.
- COVID-19 vaccines and their administration will be paid the same way influenza and pneumococcal vaccines and their administration are paid.
 - The COVID-19 vaccine is paid at 100% of reasonable cost through the cost report.
 - The beneficiary coinsurance and deductible are waived.
 - RHCs should include COVID-19 vaccines and their administration costs for patients enrolled in Medicare Advantage on the cost report as well.
- For more location specific information, visit: <https://www.cms.gov/medicare/covid-19/medicare-billing-covid-19-vaccine-shot-administration> and <https://www.cms.gov/Center/Provider-Type/Rural-Health-Clinics-Center>.

Healthcare Workforce Mandate

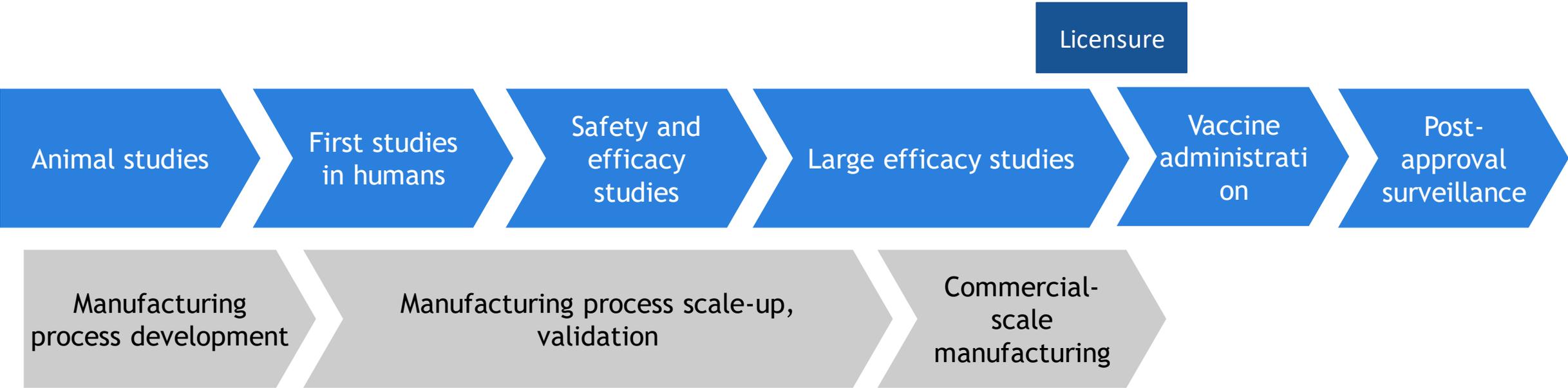
- On September 9, 2021, the Biden-Harris Administration announced that the emergency authorization requiring COVID-19 vaccination for nursing home staff would be expanded to include all Medicare and Medicaid-certified facilities.
- Among the facilities named were:
 - Hospitals
 - Dialysis facilities
 - Ambulatory surgical settings
 - Home health agencies
- On November 5, the CMS Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule went into effect. Under this rule all Medicare and Medicaid-certified facilities must:
 - Ensure all eligible staff have received the first dose of a two-dose COVID-19 vaccine or a one-dose COVID-19 vaccine prior to providing any care, treatment, or other services by December 6, 2021.
 - Ensure all eligible staff have received the necessary shots to be fully vaccinated – either two doses of Pfizer or Moderna or one dose of Johnson & Johnson – by January 4, 2022.
 - Develop a process for exemptions based on recognized medical conditions or religious beliefs, observances, or practices.

Facilitating the Development of COVID-19 Vaccines

Peter Marks, MD, PhD

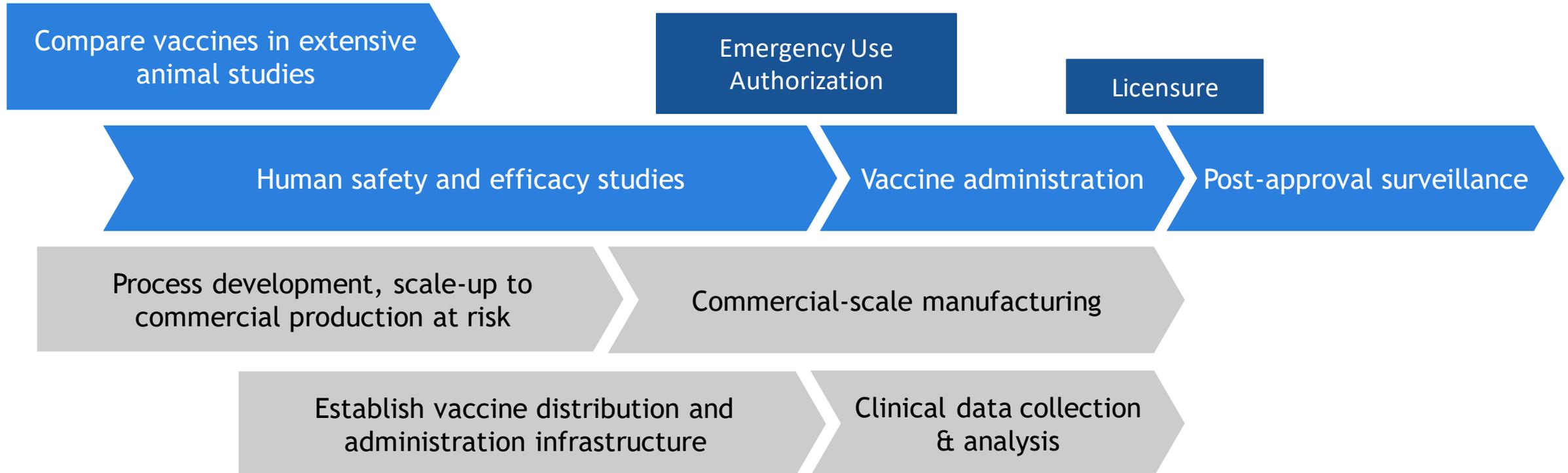


Traditional Vaccine Development





Accelerated Vaccine Development





Safety Monitoring by CDC and FDA

- Passive monitoring through the Vaccine Adverse Event Reporting System (VAERS) and the v-safe text monitoring system for COVID-19 vaccine safety
- Active monitoring through Vaccine Safety Datalink, the Clinical Immunization Safety Assessment, and large databases such as the CMS Medicare Database and Sentinel/BEST covering ≥ 100 million lives
 - Combination of claims data and EHR data
 - Monitoring about 15 safety outcomes of interest

U.S. Candidates – November 2021

- mRNA
 - BNT162b2 (Pfizer-BioNTech) – EUA granted Dec 11, 2020
 - Licensure for individuals 16 years of age and up granted to COMIRNATY on August 23, 2021
 - mRNA-1273 (Moderna) – EUA granted Dec 18, 2020
- Non-Replicating Viral Vector
 - Ad26.COVS.S (Janssen) – EUA granted Feb 27, 2021
 - ChAdOx1 (Astra Zeneca-Oxford)
- Protein Subunit
 - NVX-CoV2373 (Novavax)
 - MRT5500 (Sanofi-Translate Bio)



Pfizer COVID-19 Vaccine Approval

- On August 23, FDA approved the first COVID-19 Vaccine
 - The Pfizer-BioNTech COVID-19 Vaccine will now be marketed as Comirnaty for the prevention of COVID-19 disease in individuals 16 years of age and older
- Included review of updated data on 44,000 participants
 - Overall vaccine efficacy was 91% effective (77 cases of COVID-19 in the vaccine group and 833 COVID-19 cases in the placebo group)
 - 12,000 participants receiving the vaccine followed at least 6 months

Pfizer Adolescent Demographics

30 microgram dose

Characteristic	Age 12-15 Vaccine (N=1131)	Age 16-25 Vaccine (N=537)	Age 12-15 Placebo (N=1129)	Age 16-25 Placebo (N=561)
Female	49.9%	52.5%	48.2%	52.0%
Mean Age (years)	13.6	19.4	13.6	19.6
Median Age	14.0	18.0	14.0	19.0
Black	4.6%	8.8%	5.0%	8.9%
Hispanic/Latino	11.7%	20.9%	11.5%	18.7%
Comorbidity (yes)	21.9%	23.5%	21.3%	25.7%



Pfizer Pediatric Demographics

10 microgram dose

Characteristic	Age 5-11 Vaccine (N=1518)	Age 16-25 Vaccine (N=537)	Age 5-11 Placebo (N=750)	Age 16-25 Placebo (N=561)
Female	47.4%	52.5%	48.9%	52.0%
Mean Age (years)	8.2	19.4	8.1	19.6
Median Age	8.0	18.0	8.0	19.0
Black	5.9%	8.8%	7.7%	8.9%
Hispanic/Latino	21.0%	20.9%	21.2%	18.7%
Comorbidity (yes)	20.6%	23.5%	20.3%	25.7%

Pfizer Adolescent Immune Response

30 microgram dose

Study Group	12-15 Years N=190 GMT (95% CI)	16-25 Years N=170 GMT (95% CI)	GMT Ratio [12-15 Years/ 16-25 Years] (95% CI)	Met Predefined Success Criterion
Vaccine	1239.5 (1095.5, 1402.5)	705.1 (621.4, 800.2)	1.76 (1.47, 2.10)	Yes

Noninferiority is declared if the lower bound of the 2-sided 95% CI for the Geometric Mean Titer (GMT) Ratio is greater than 0.67 and the point estimate of the GMT ratio is ≥ 1.0 .

Pfizer Pediatric Immune Response

10 microgram dose

Study Group	5-11 Years N=264 GMT (95% CI)	16-25 Years N=253 GMT (95% CI)	GMT Ratio [5-11 Years/ 16-25 Years] (95% CI)	Met Predefined Success Criterion
Vaccine	1197.6 (1106.1, 1296.6)	1146.5 (1045.5, 1257.2)	1.04 (0.93, 1.18)	Yes

Noninferiority is declared if the lower bound of the 2-sided 95% CI for the Geometric Mean Titer (GMT) Ratio is greater than 0.67 and the point estimate of the GMT ratio is ≥ 1.0 .

Pfizer Adolescent Efficacy

30 microgram dose

Endpoint	Vaccine 12-15 Years N=1005 Cases	Placebo 12-15 Years N=978 Cases	Vaccine Efficacy % (95% CI)
First COVID-19 occurrence from 7 days after Dose 2 in subjects without prior SARS-CoV-2 infection	0	16	100.0 (75.3, 100.0)

Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period



Pfizer Pediatric Efficacy

10 microgram dose

Endpoint	Vaccine 5-11 Years N=1305 Cases	Placebo 5-11 Years N=663 Cases	Vaccine Efficacy % (95% CI)
First COVID-19 occurrence from 7 days after Dose 2 in subjects without prior SARS-CoV-2 infection	3	16	90.7 (67.7, 98.3)

Note the 2:1 randomization

Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period; no severe cases were observed

Pfizer Adolescent Safety

30 microgram dose

Characteristic	Age 12-15 Placebo Dose 2 (N=1078)	Age 12-15 Vaccine Dose 2 (N=1097)	Age 16-25 Vaccine Dose 2 (N=488)
Injection site pain	17.9%	78.9%	77.5%
Fatigue	24.5%	66.2%	65.6%
Headache	24.4%	64.5%	60.9%
Muscle pain	8.3%	32.4%	40.8%
Chills	6.8%	41.5%	40.0%
Joint pain	4.7%	15.8%	21.9%
Fever	0.6%	19.6%	17.2%



Pfizer Pediatric Safety

10 microgram dose

Characteristic	Age 5-11 Placebo Dose 2 (N=741)	Age 5-11 Vaccine Dose 2 (N=1501)	Age 16-25 Vaccine Dose 2 (N=488)
Injection site pain	29.5%	71.0%	77.5%
Fatigue	24.3%	39.4%	65.6%
Headache	18.6%	28.0%	60.9%
Muscle pain	7.4%	11.7%	40.8%
Chills	4.3%	9.8%	40.0%
Joint pain	3.6%	5.2%	21.9%
Fever	1.2%	6.5%	17.2%

3rd Doses in Immunocompromised

- Third vaccine dose given at least 28 days following the first two doses of this vaccine authorized for administration to individuals at least 12 years of age (Pfizer-BioNTech) or 18 years of age (Moderna) who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise
 - Maintain standard measures to help prevent COVID-19 given that only about half those receiving third doses benefit

Boosters for the General Population

- Evidence from the United States and Israel indicates that immunity to the current vaccines may wane with time, particularly in the setting of the Delta variant
- An additional vaccine dose may provide more durable immunity preventing
 - Hospitalization and death
 - Serious complications of COVID-19 such as long COVID-19
 - Disruption of critical services

Do I qualify for a COVID-19 vaccine booster and which one?



Which primary vaccine series did you complete?	Pfizer-BioNTech	Moderna	Janssen (J&J)
<p>You can get a booster if:</p>	It's been at least 6 months since completing the primary series AND you are:	It's been at least 6 months since completing the primary series AND you are:	It's been at least 2 months since completing the primary series AND you are:
	Age 65+	Age 65+	Age 18+
	OR	OR	
	Ages 18-64 and at high risk of severe COVID-19	Ages 18-64 and at high risk of severe COVID-19	
OR	OR		
Ages 18-64 with frequent institutional or occupational exposure to SARS-CoV-2	Ages 18-64 with frequent institutional or occupational exposure to SARS-CoV-2		
<p>If eligible, you can get a booster of:</p>	Pfizer-BioNTech Moderna Janssen (J&J)	Moderna Pfizer-BioNTech Janssen (J&J)	Janssen (J&J) Pfizer-BioNTech Moderna

For more information, visit www.fda.gov/covid19vaccines.





COVID-19 Vaccines Younger Children

- Special considerations in children under 5 years
 - Determination of appropriate dose
 - Duration and number of children for safety follow-up
 - Benefit-risk considerations
- The various companies are conducting clinical trials
- Expecting data to FDA by early in 2022
- FDA will move quickly when get data

November 18, 2021

#powerofrural

National Rural Health Day TM
Celebrating the Power of Rural!



IT'S NOT JUST A DAY, IT'S A MOVEMENT.

Shannon Chambers, CPC, Director of Provider Solutions, South Carolina Office of Rural Health



National Organization of **State Offices of Rural Health**

Best Practices



National Organization of
State Offices of Rural Health



Best Practices

- Ensuring that vaccine handouts are available in multiple languages.
- Find a physician champion/strong community leader
- Do you have open appointments where anyone can walk in and get the vaccine or do they have to schedule in advance?
- Social Media
- Hashtags, Themed approaches, etc

RHC Vaccine Confidence and Hesitancy Grant



National Organization of
State Offices of Rural Health



RHC Vax Confidence

- NOSORH is the TA provider and will meet with Rural Health Clinics directly to discuss workplans, budget review, and answer any questions.
- Works with the HRSA team on any outstanding issues.
- Period of performance is **July 1st, 2021 to June 30th, 2022**
- Dedicated email address: rhcvoxconfidenceinfo@nosorh.org

[Rural Health Clinic Vaccine
Confidence \(RHCVC\) Program |
Official web site of the U.S. Health
Resources & Services Administration
\(hrsa.gov\)](#)

RHC COVID-19 Vaccine Distribution



National Organization of
State Offices of Rural Health



Direct CDC distribution

- This wonderful opportunity allows RHCs to receive direct shipments to their clinics!
- You can request all 3 vaccines
- Ordering is simple!

[Rural Health Clinic COVID-19 Vaccine Distribution \(RHCVD\) Program | Official web site of the U.S. Health Resources & Services Administration \(hrsa.gov\)](#)



Contact Us

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Building Vaccine Confidence and Demand

Diane M. Hall, Ph.D., MEd.

Senior Health Scientist

Lead, CDC Rural Health

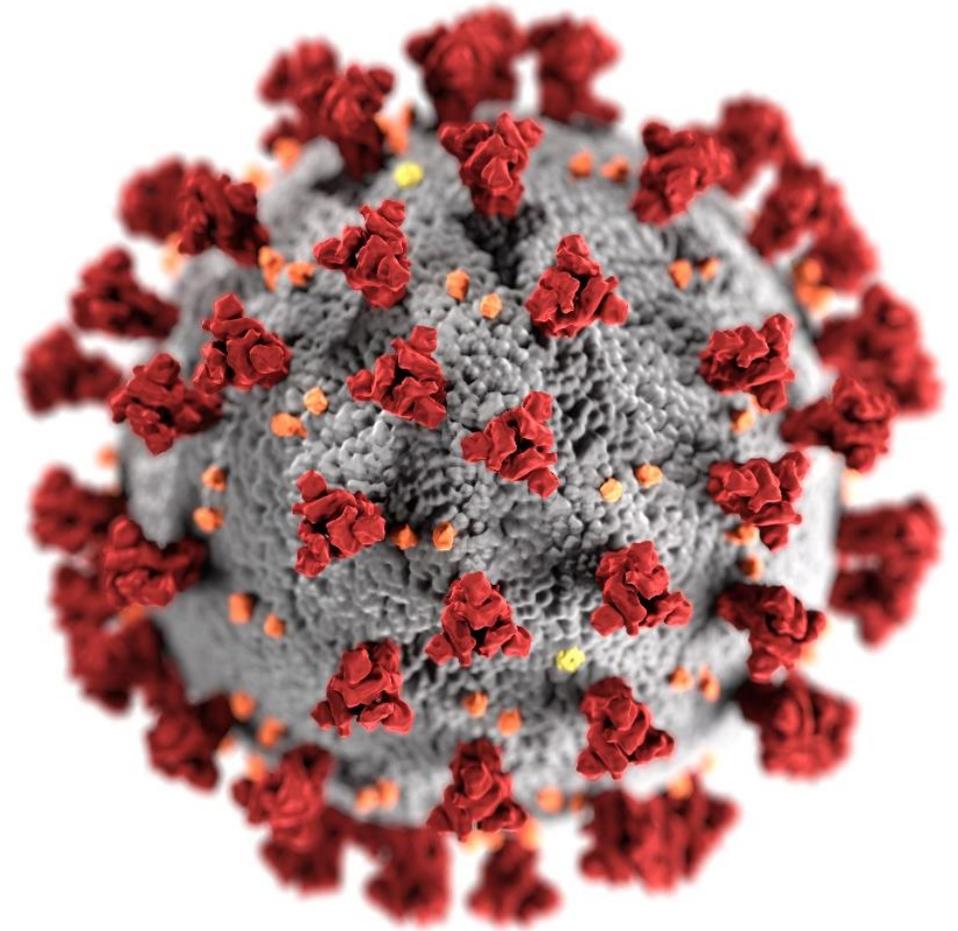
Office of the Associate Director for Policy and Strategy

Currently deployed to CDC's COVID-19

Vaccine Task Force

dmhall@cdc.gov

ruralhealth@cdc.gov



cdc.gov/coronavirus

COVID-19 Vaccine Coverage and Confidence

- **National Immunization Survey–Adult COVID Module**
 - Adults ≥ 18 years
 - Nationally representative sample
 - Random-digit-dialed cell numbers
 - Weighted to represent the non-institutionalized U.S. population
 - Collects data on
 - Vaccination status (≥ 1 dose, fully vaccinated)
 - Vaccination intent
 - Vaccine confidence
 - Behavioral and social drivers of vaccination



Source: <https://www.cdc.gov/vaccines/imz-managers/coverage/covidvaxview/interactive.html>

CDC National Immunization Survey

Vaccination Status and Intent by Demographics - United States

Data Collection Period: October 17 - October 23, 2021 (N= 15,496)

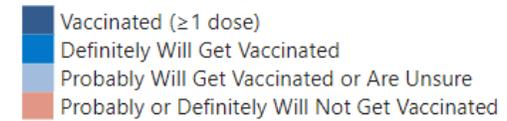
National Jurisdictional

Overall

80.8% are **Vaccinated (78.9%)**
or **Definitely Will Get Vaccinated (1.9%)**

6.6% **Probably Will Get Vaccinated**
or **Are Unsure**

12.6% **Probably or Definitely**
Will Not Get Vaccinated



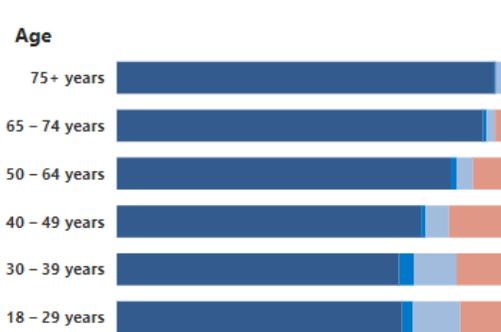
All Adults Age 18+



Sex



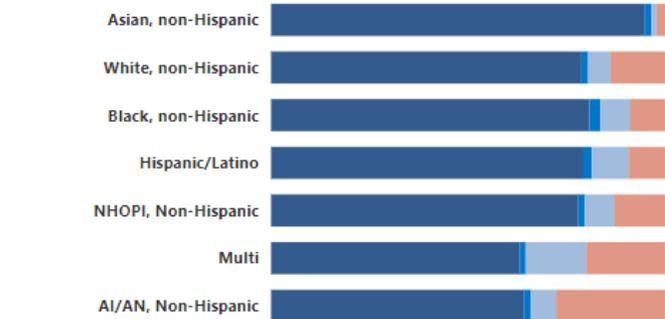
Age



Metropolitan Statistical Area



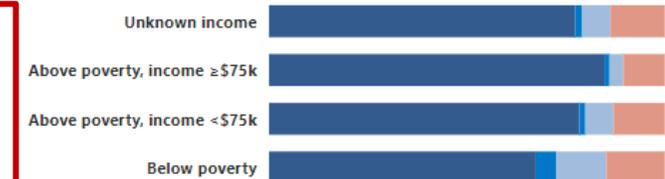
Race/Ethnicity



Health Insurance



Poverty and Income



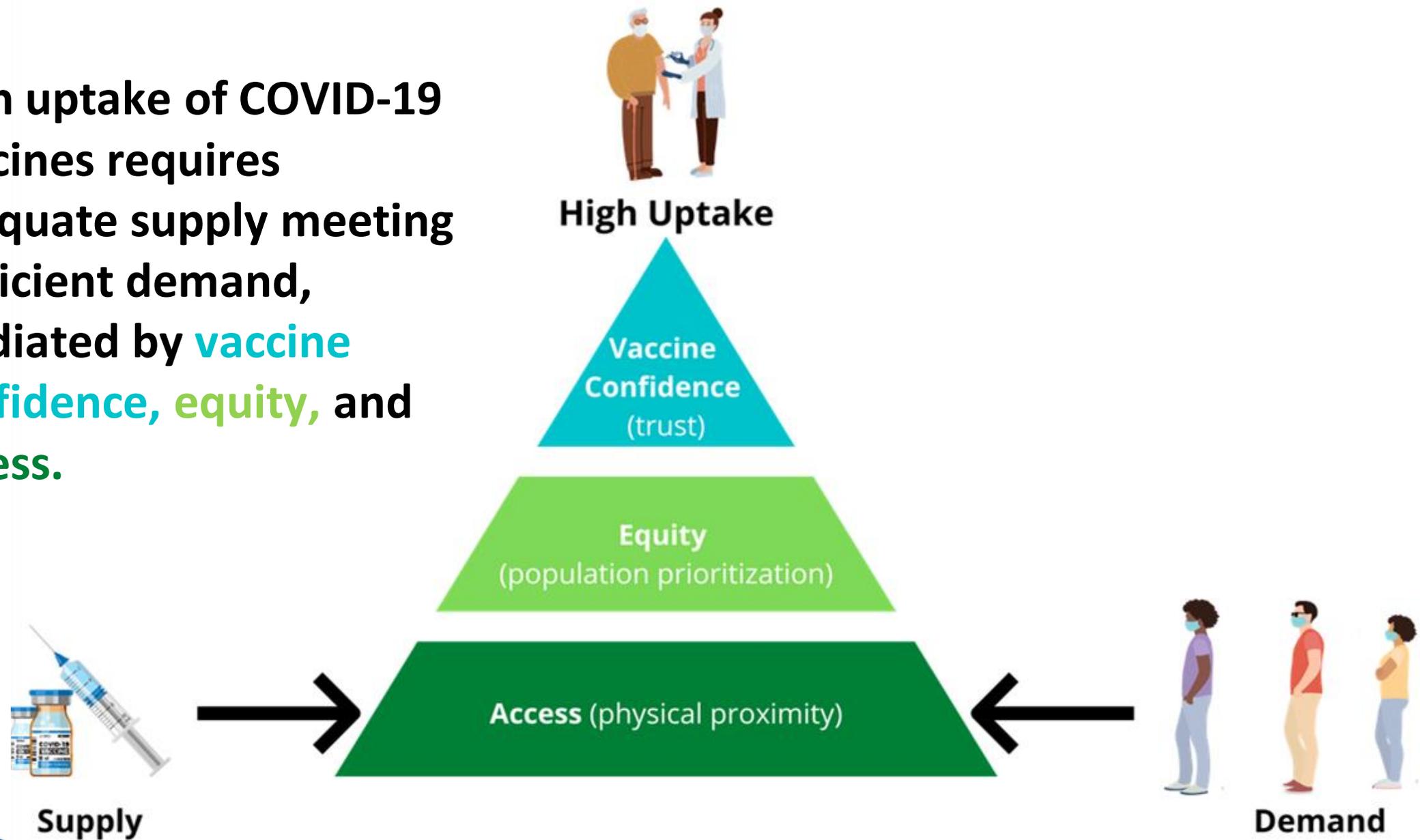
Weighted Percentage (%)

*Due to small sample size results should be interpreted with caution. AI/AN: American Indian/Alaska Native; NH/OPI: Native Hawaiian/Other Pacific Islander; Multi: Multiple races.

Source: CDC National Immunization Survey – <https://covid.cdc.gov/covid-data-tracker/#vaccine-confidence>

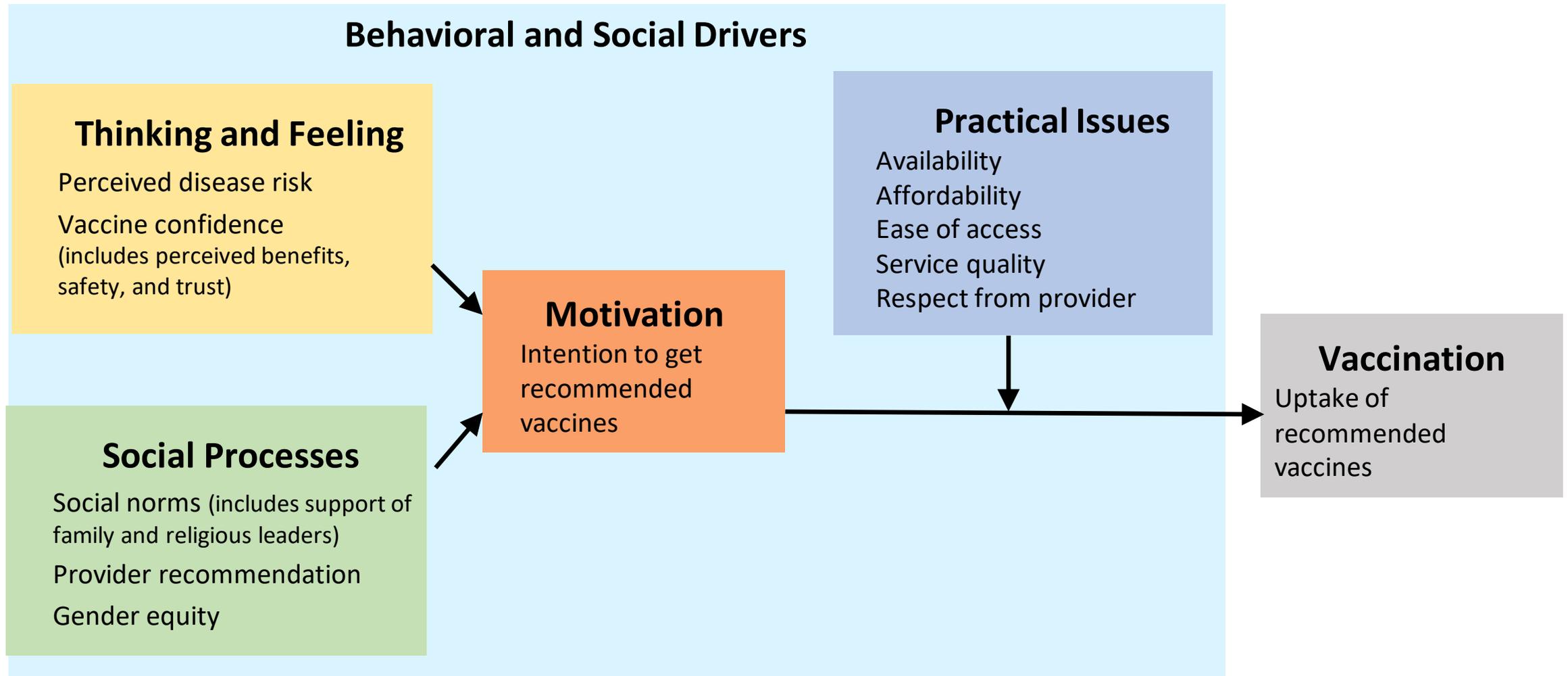


High uptake of COVID-19 vaccines requires adequate supply meeting sufficient demand, mediated by vaccine confidence, equity, and access.



Source: CDC COVID-19 Vaccine Task Force Vaccine Confidence Team

The Behavioral and Social Drivers (BeSD) Framework



Source: The WHO BeSD working group. Based on Increasing Vaccination Model (Brewer et al., 2017)



Vaccinate with **Confidence**

CDC's Strategy to Reinforce Confidence in COVID-19 Vaccines

Build Trust

Objective: Share clear, complete, and accurate messages about COVID-19 vaccines and proactively address mis- and disinformation.

Empower Healthcare Personnel

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

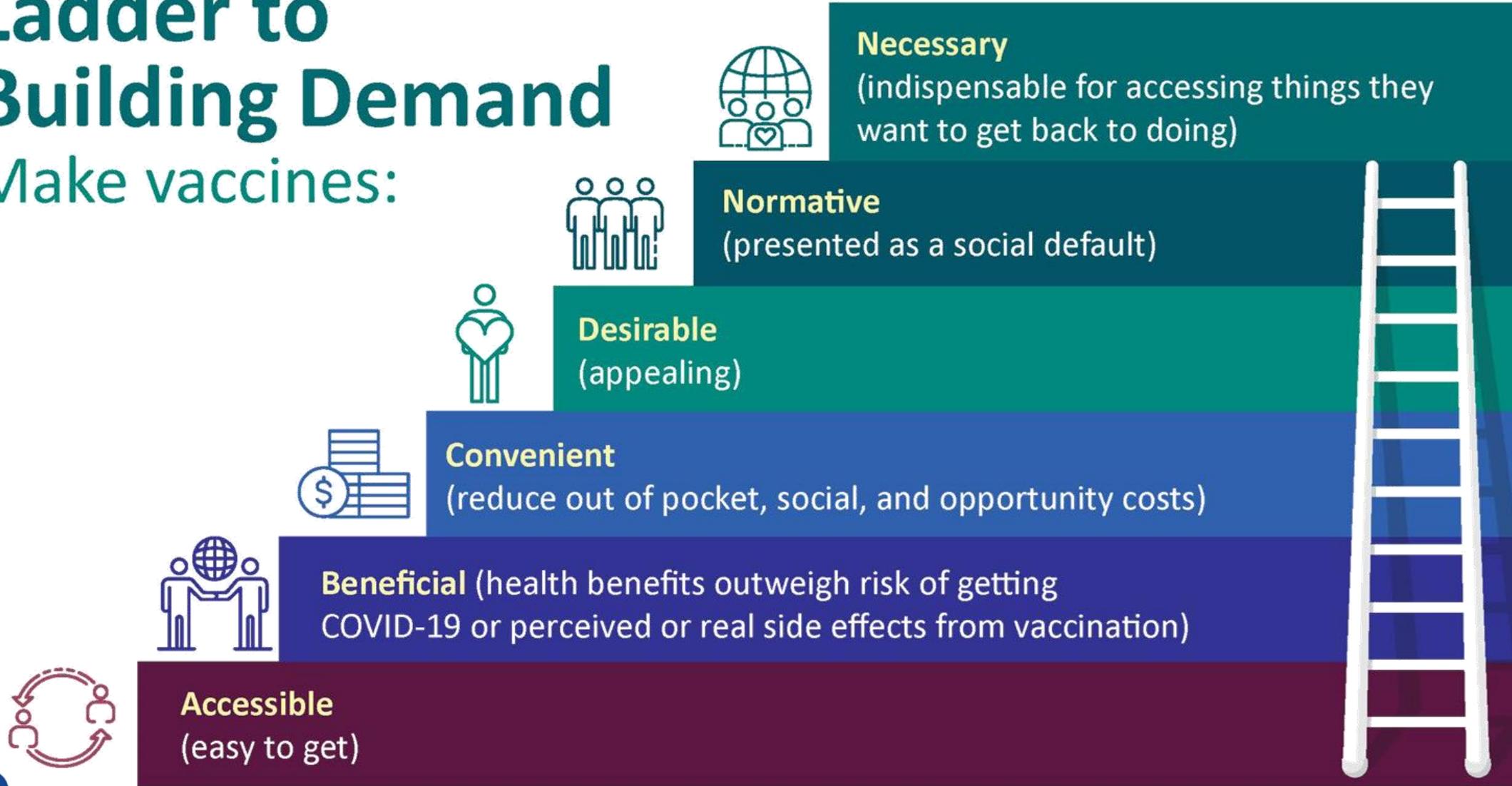
Engage Communities & Individuals

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

*Personnel = All staff working in healthcare settings, including physicians, physician assistants/nurse practitioners, nurses, allied health professionals, pharmacists, social workers, support staff, and community health workers

Ladder to Building Demand

Make vaccines:



Address Misinformation Circulating on Social Media

- Work with your communication staff to take questions on social media, share factual information, and debunk false claims or myths being spread online.
- Post shareable graphics and content, leveraging [CDC](#) and [HHS](#) social media toolkits, [CDC COVID-19 Vaccine Myths and Facts](#), and [CDC's Guide to Finding Credible Vaccine Information](#).
- Link to credible fact checking resources such as [FactCheck.org](#).
- Refer to [CDC's Tips for Addressing Misinformation](#) and [State of Vaccine Confidence Reports](#).



NOTICE: CDC now recommends that certain people are now eligible to receive a COVID-19 booster shot, including those who received Moderna and Johnson & Johnson/Janssen COVID-19 vaccines. Get more information and read [CDC's media statement](#).

Vaccines for COVID-19

COVID-19 vaccines are safe, effective, and free! After you've been fully vaccinated, you can [participate in many of the activities that you did](#) prior to the pandemic. [Key Things to Know](#)

YOUR VACCINATION

WHEN FULLY VACCINATED

BOOSTER SHOT



Getting Your Vaccine

What different vaccines are available?

Are they safe?

What are possible side effects?

Who needs a booster shot?

Should I get vaccinated if I've had COVID-19?

Get Vaccinated



Find a free COVID-19 vaccine near you.

[Find a vaccine near you](#)

Call 1-800-232-0233

Text your zip code to 438829

Message & data rates may apply. [CDC Privacy Policy](#)

COVID-19 Vaccine Data

Total Doses Distributed

503,493,015

Updated Oct 24, 2021 9:00am ET

Total Doses Administered

413,645,478

COVID-19 Data Tracker

View more data on number of vaccines distributed and administered

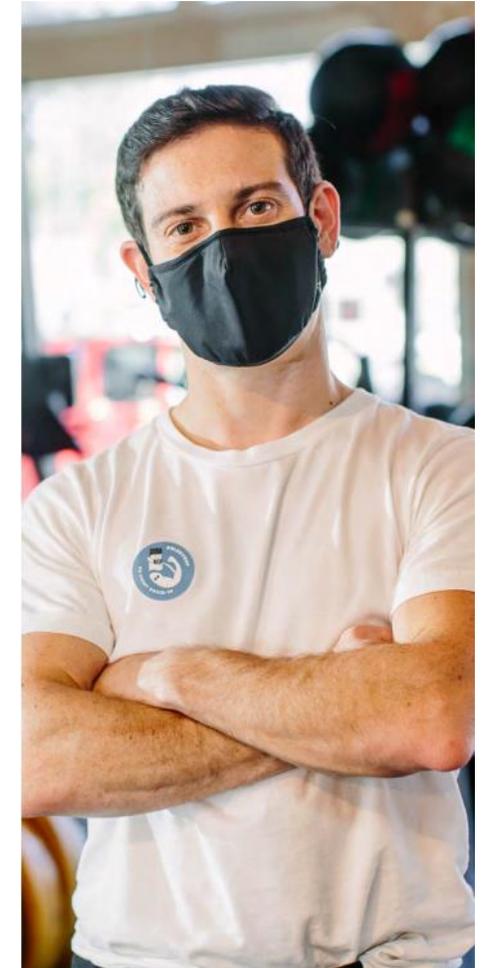
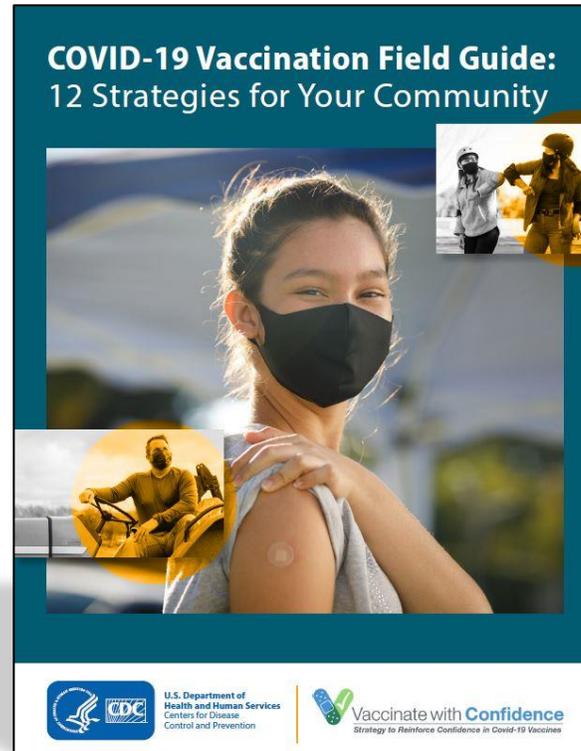
[MORE DATA >](#)



Source: www.cdc.gov/coronavirus/2019-ncov/vaccines/index.html

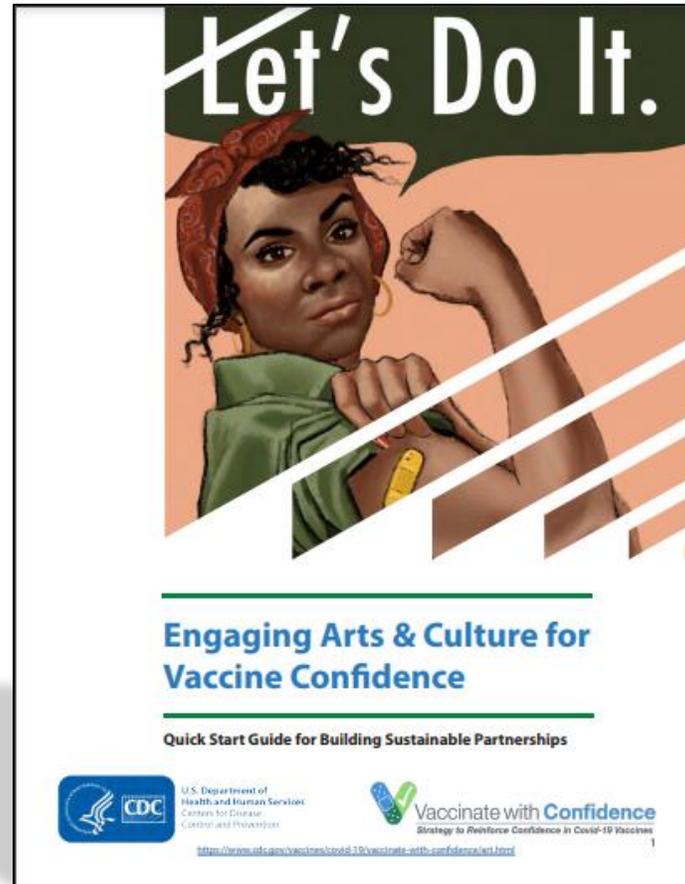
COVID-19 Vaccination Field Guide – **NEW!**

- Strategies are drawn from historical (non–COVID-19) vaccination efforts.
- Strategies are supported by positive outcomes from evaluation research.
- Includes real-world applications.



Source: <https://www.cdc.gov/vaccines/covid-19/vaccinate-with-confidence/community.html>

Engaging the Arts to Build Vaccine Confidence



Source: <https://www.cdc.gov/vaccines/covid-19/vaccinate-with-confidence/art.html>

State of Vaccine Confidence Insights Reports

COVID-19 State of Vaccine Confidence Insights Reports

CDC regularly creates reports about the status of COVID-19 vaccine confidence in the United States, emphasizing major themes that influence vaccine confidence and uptake. The reports include analyses of multiple quantitative and qualitative data sources, ranging from social listening and web metrics to immunization survey data and CDC-INFO inquiries.

Recent Reports

The following reports seek to identify emerging issues of misinformation, disinformation, and places where intervention efforts can positively increase vaccine confidence across the United States.

[Report 14 | September 13, 2021](#) [8 pages]

[Rapid Report – Announcement of Booster Dose Program of mRNA COVID-19 Vaccines for U.S. Adults | August 26, 2021](#)

[8 pages]

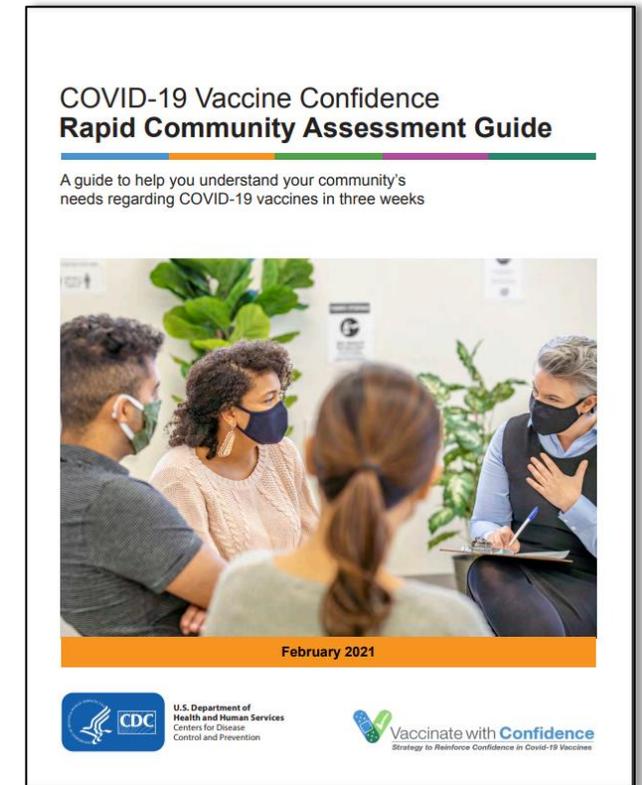
Email eocevent515@cdc.gov to subscribe!



Source: <https://www.cdc.gov/vaccines/covid-19/vaccinate-with-confidence.html#reports>

Rapid Community Assessment Guide

- Can help you:
 - Identify reasons for low vaccination rates in your communities.
 - Understand barriers and facilitators to vaccination.
 - Identify potential strategies for increasing vaccine uptake.
- Include easy-to-use data collection tools that don't require formal research expertise.
 - Can be implemented in 1–3 weeks, depending on resources available.
 - Tools also available in Spanish.

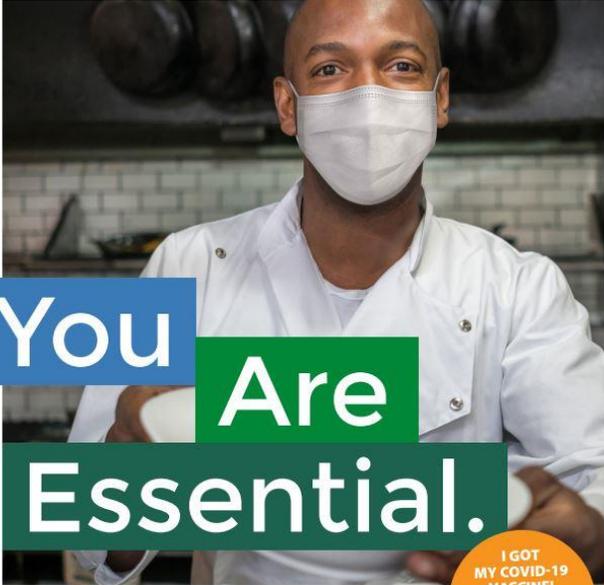


Version 2.0 coming soon!



Source: <https://www.cdc.gov/vaccines/covid-19/vaccinate-with-confidence/rca-guide/index.html>

COVID-19 Vaccine Print Resources



You Are Essential.

I GOT MY COVID-19 VACCINE!

On the job, and at home. Getting a COVID-19 vaccine adds one more layer of protection.

 **Learn how you can get a COVID-19 vaccine.**
[cdc.gov/coronavirus/vaccines](https://www.cdc.gov/coronavirus/vaccines)

Answering Your Questions About the Safety and Effectiveness of COVID-19 Vaccines

Do clinical trial results show whether vaccines are effective?
 Yes, clinical trials provide data and information about how well a vaccine prevents a disease and how safe it is. The Food and Drug Administration (FDA) evaluates these data, along with information from the manufacturers, to assess the safety and effectiveness of the vaccine. FDA then decides whether to approve the vaccine or authorize it for emergency use in the United States.

Why would the effectiveness of vaccines be different after the clinical trials?
 Many factors can affect how well a vaccine works in real-world conditions. These factors can include how a vaccine is transported and stored and how the vaccine is given. Vaccine effectiveness can also be affected by differences in the underlying medical conditions of people vaccinated as compared to those vaccinated in the clinical trials.

CDC is assessing how well COVID-19 vaccines work in real-world conditions. Some real-world assessments observe both people who get vaccinated and those who don't to see how many people in each group become ill with COVID-19. Some assessments look at how COVID-19 vaccine effectiveness differs for people who are partially vaccinated compared to those who are fully vaccinated.

Assessments of vaccine effectiveness can also provide important information about how well a vaccine is working in groups of people who were either not included or were not well represented in clinical trials, and how well vaccines protect against COVID-19 variants.

How are experts evaluating the COVID-19 vaccine effectiveness in real-world conditions?
 Experts are working on many types of assessments to determine vaccine effectiveness in real-world conditions. Each study type uses a different method:

- **Case-control assessments** include cases (people who have COVID-19) and controls (people who do not have COVID-19). People who agree to participate in a case-control assessment provide information on whether they received a COVID-19 vaccine or not. Experts look to see if the cases were less likely to be vaccinated than controls, which would show the vaccine is working.
- **Test-negative design assessments** enroll people who are seeking medical care for symptoms that could be due to COVID-19. In this special type of case-control assessments, experts compare the COVID-19 vaccination status of those who test positive (meaning they have COVID-19) to those who test negative (meaning they do not have COVID-19).



 www.cdc.gov/coronavirus/vaccines

How mRNA COVID-19 Vaccines Work

Understanding the virus that causes COVID-19.
 Coronaviruses like the one that causes COVID-19 are named for the crown-like spikes on their surface, called **spike proteins**. These **spike proteins** are ideal targets for vaccines.

What is mRNA?
 Messenger RNA, or mRNA, is genetic material that tells your body how to make proteins.

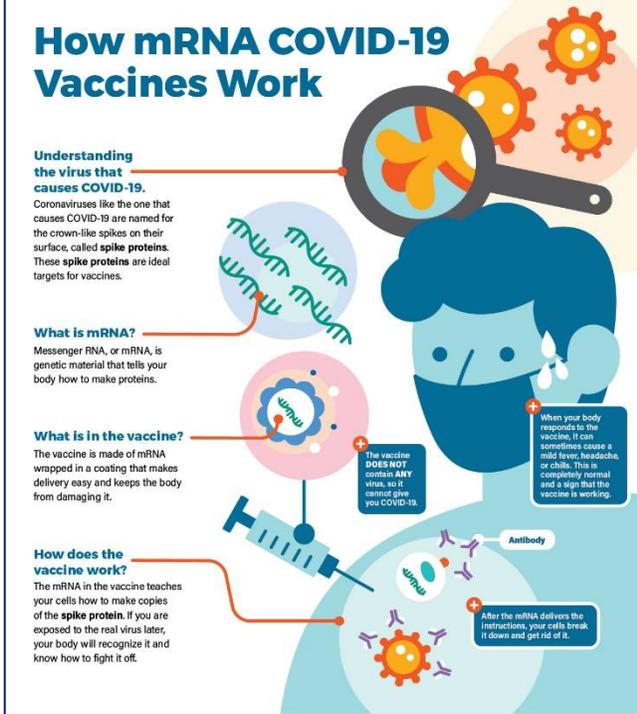
What is in the vaccine?
 The vaccine is made of mRNA wrapped in a coating that makes delivery easy and keeps the body from damaging it.

How does the vaccine work?
 The mRNA in the vaccine teaches your cells how to make copies of the **spike protein**. If you are exposed to the real virus later, your body will recognize it and know how to fight it off.

When your body responds to the vaccine, it can sometimes cause a mild fever, headache, or chills. This is completely normal and a sign that the vaccine is working.

The vaccine DOES NOT contain ANY virus, so it cannot give you COVID-19.

Antibody



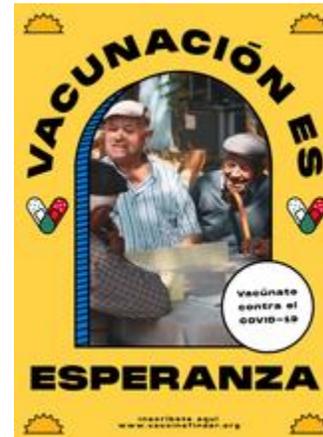
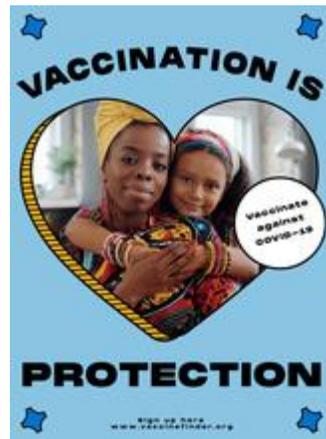
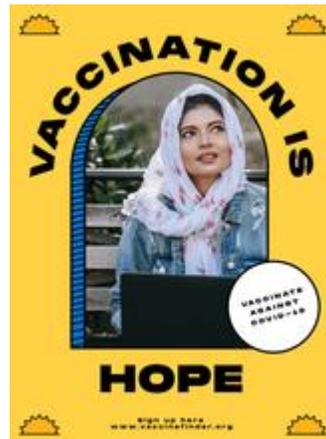
Getting vaccinated?
 For information about COVID-19 vaccine, visit: [cdc.gov/coronavirus/vaccines](https://www.cdc.gov/coronavirus/vaccines)



Source: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/resource-center.html#print-resources>



National Resource Center for Refugees, Immigrants, and Migrants (NRC-RIM)



Source: <https://nrcrim.org/vaccines/vaccine-central>

RCA Conducted To Date

May 24-28, 2021:
Jasper, LaGrange, and Kosciusko
Counties

■ RCA conducted
■ RCA upcoming

August 2021:
Umatilla and Morrow
Counties (Migrant
Farmworkers)

July 2021:
San Mateo County
(Adolescent-focused)

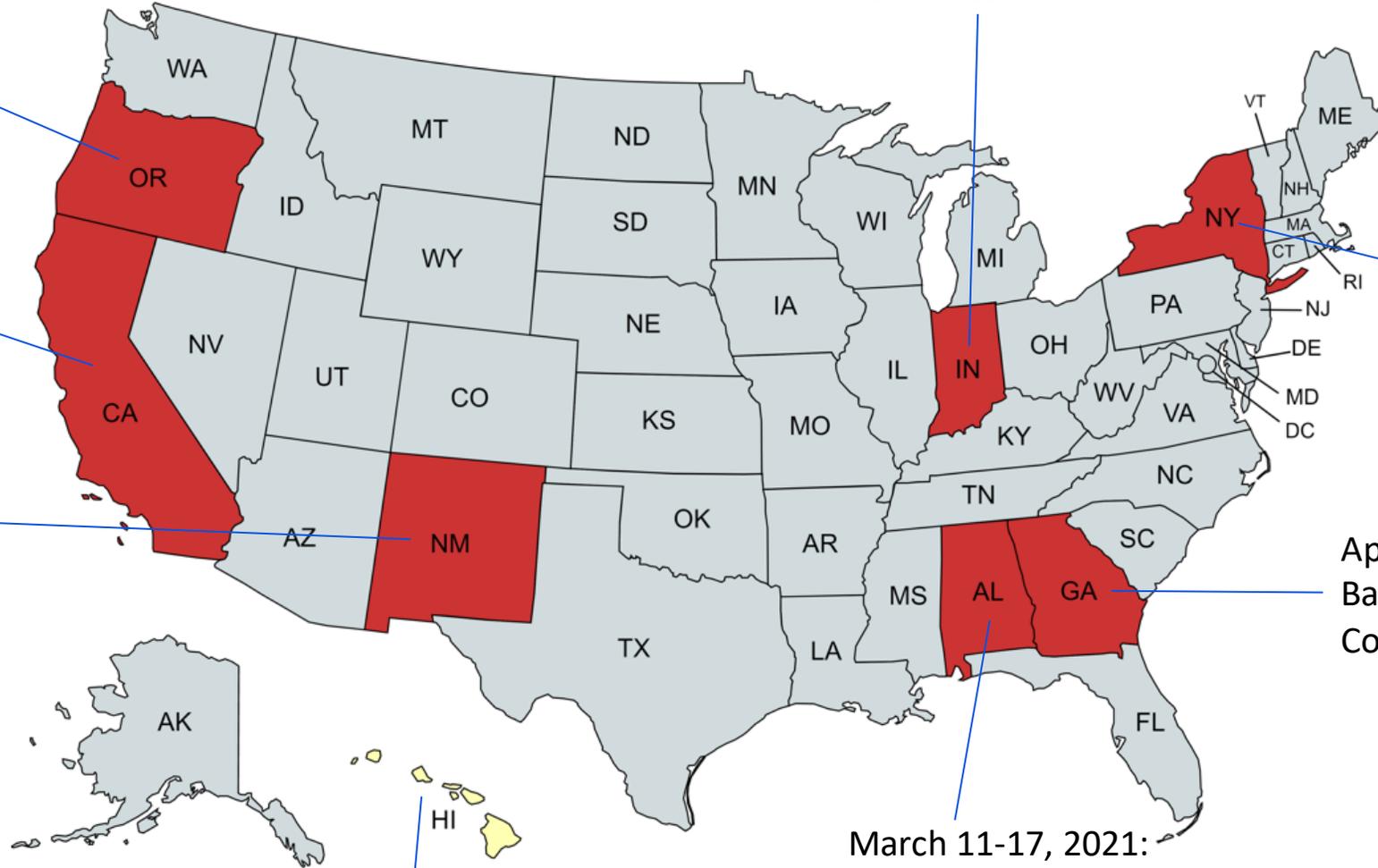
July 2021:
Orange
County

February 2021:
Albuquerque
-Immigrant and refugee
populations
-Essential workers
-Clinic patients
-Mobile populations
-Older adults

April 11-16, 2021:
Bacon County, Dougherty
County

March 11-17, 2021:
Sumter County
March 18-24:
Macon County

<https://www.cdc.gov/vaccines/covid-19/vaccinate-with-confidence/rca-guide/index.html>



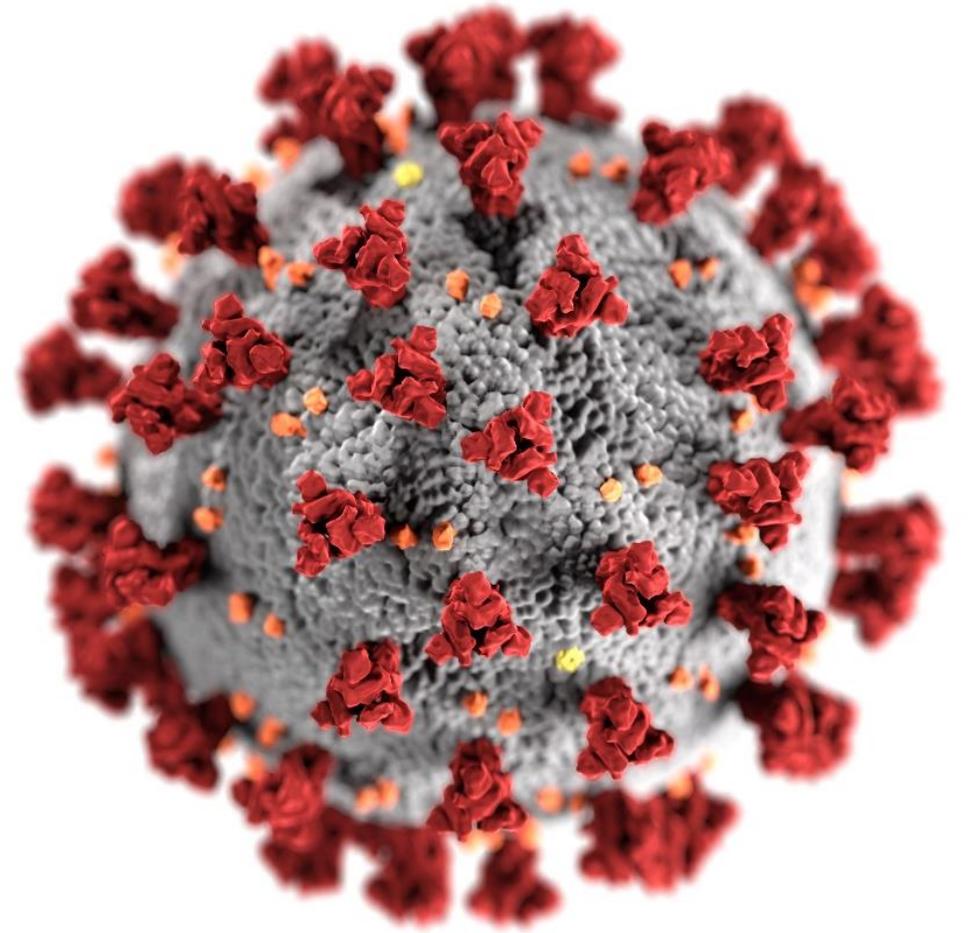
Upcoming: Honolulu
County



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For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.



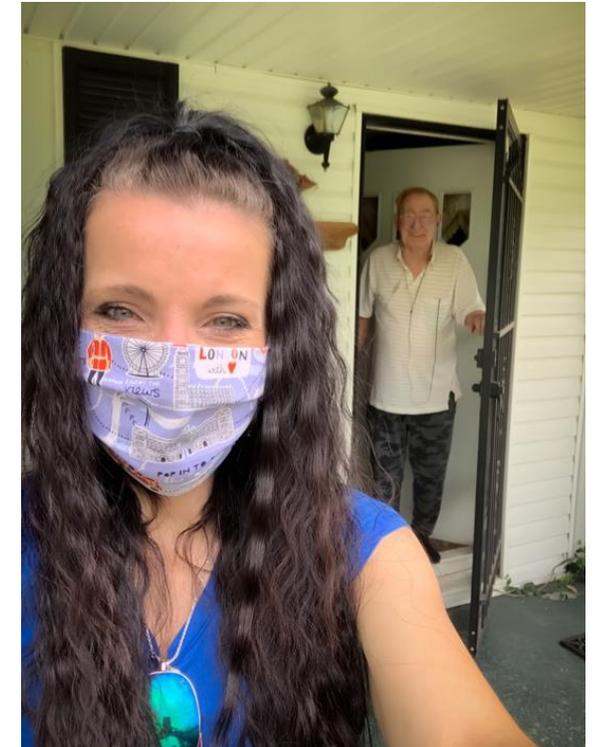
National Rural Health Day

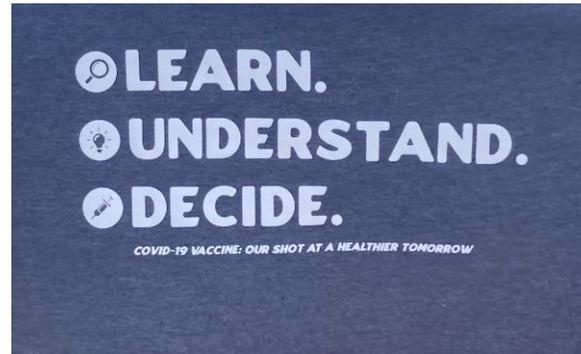
University of Kentucky
Center of Excellence in Rural Health
Frances Feltner, DNP, MSN, RN
UK CERH Director





University of Kentucky Center of Excellence in Rural Health Kentucky Homeplace Community Health Workers





<https://ruralhealth.med.uky.edu/news/appalachian-community-health-days-increase-covid-19-vaccine-efforts-32-county-region>

Goal of Appalachian Community Health Days

Vaccinate

Appalachian

Communities by providing

Community outreach

Increase assess by removing barrier

Needs assessment of individuals, and provide

Education and positive messaging to increase vaccine confidence

Engaging Community Partnerships

- Hospitals and clinics
- Health departments
- Area Development Districts
- Community Agencies
- Community Mental Health Centers
- Public Schools, Colleges and Universities
- Local Government
- Local Businesses
- Faith Based Communities
- Pharmacies
- SUD treatment and recovery centers
- Diabetes Coalitions
- Masonic Lodge
- Christian Social Services
- Extension Offices
- YMCA
- Jails

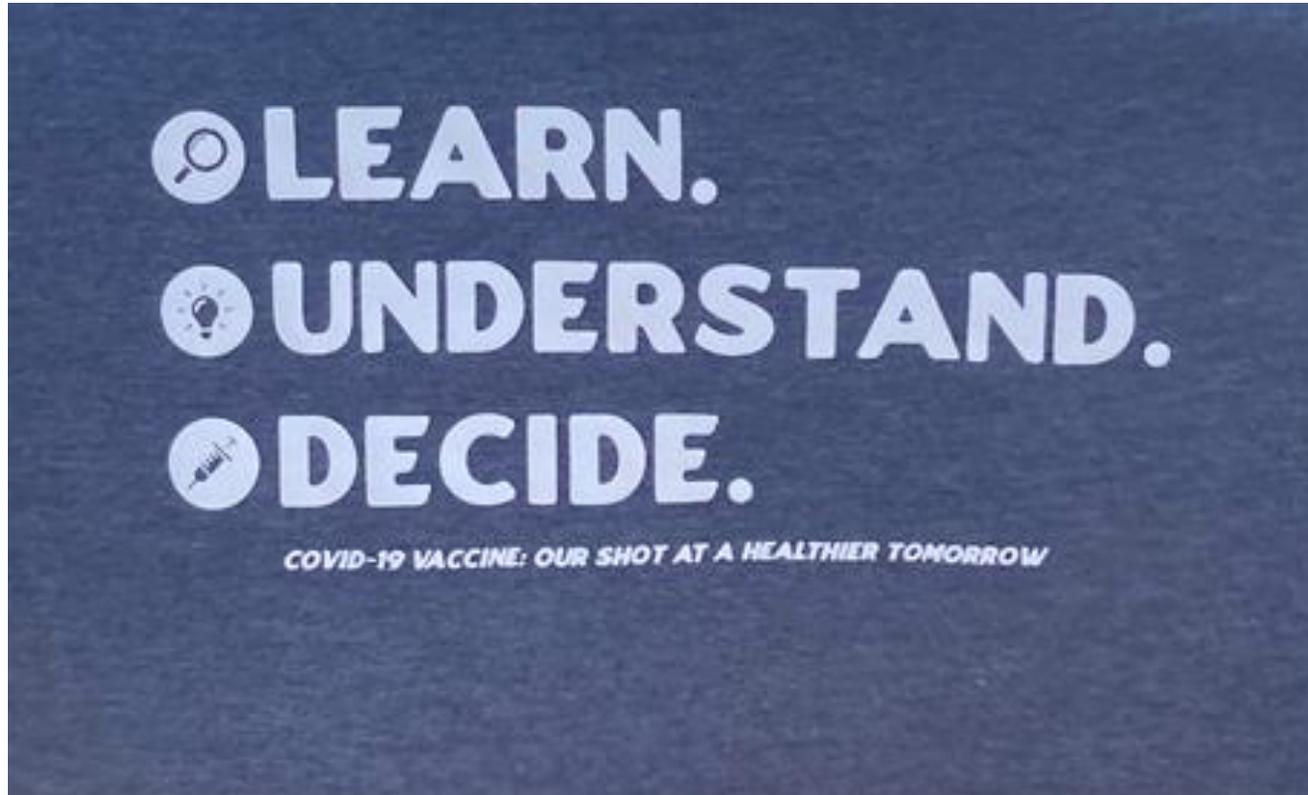
Developed Tracking Tools

<https://ruralhealth.med.uky.edu/news/appalachian-community-health-days-increase-covid-19-vaccine-efforts-32-county-region>



<https://public.tableau.com/views/VaccinationRateTimeline/Dashboard1?:language=en-US&publish=yes&:display count=n&:origin=viz share link>

Video



<https://youtu.be/uAWyqMLNVXU>



kyruralhealth.org

CMS OMH and HHS Resources

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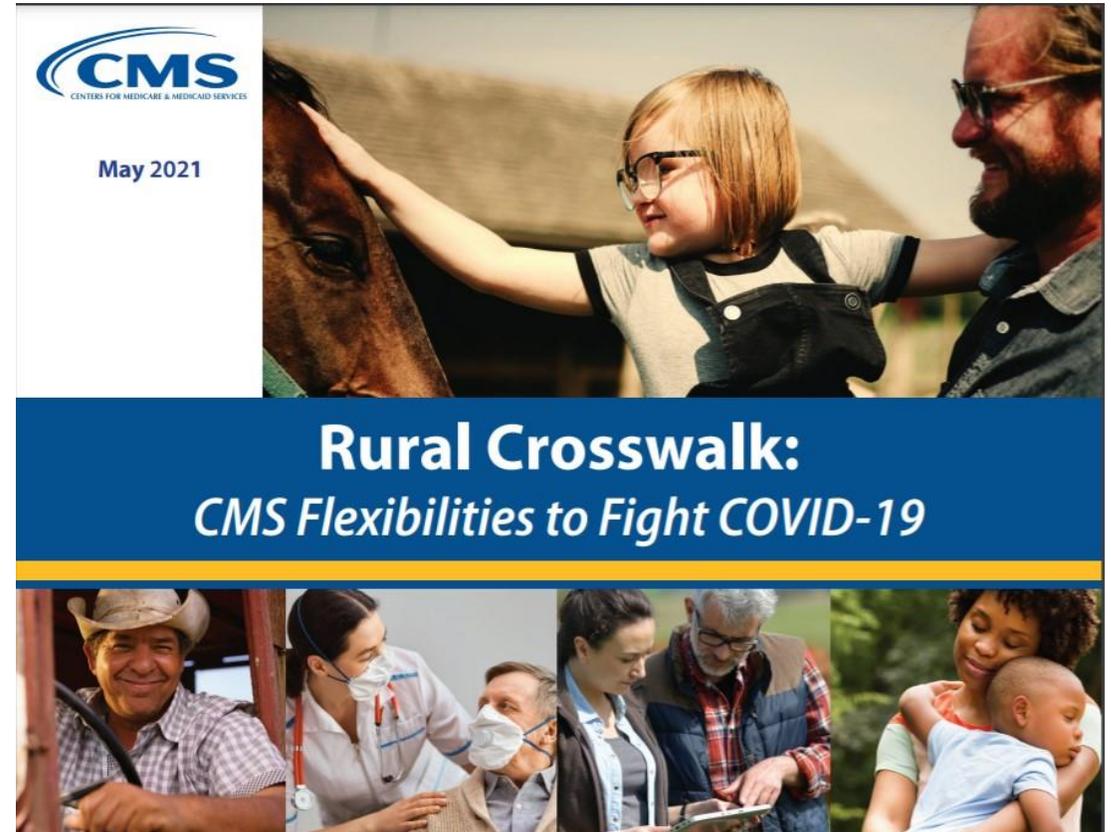


Rural Health Resources

- CMS is committed to improving the quality of health care that rural Americans receive and reducing the barriers that impact their ability to access care.
- Our rural health resources include:
 - [Rural Health Strategy](#)
 - [Rural Maternal Health Care](#)
 - [Rural Crosswalk: CMS Flexibilities to Fight COVID-19](#)
 - [Connected Care: The Chronic Care Management Resource](#)
 - [Rural Health Data and Reports](#)
 - [Rural Health Clinics Center](#)
 - [Federally Qualified Health Centers](#)

Rural Crosswalk: CMS Flexibilities to Fight COVID-19

- The [Rural Crosswalk: CMS Flexibilities to Fight COVID-19](#) highlights the COVID-19 related provisions that CMS has issued by regulation or waiver that impact these rural providers:
 - Rural Health Clinics
 - Federally Qualified Health Centers
 - Critical Access Hospitals
 - Rural Acute Care
 - PPS Hospitals
 - Skilled Nursing Facilities



Diabetes Awareness

- The prevalence of diabetes is shown to be greater in rural communities, with 12.6% of the population in non-metropolitan counties being diagnosed with diabetes as compared to 9.9% in metropolitan counties.
- Those living with diabetes who contract COVID-19 are at increased risk of serious illness, adding to the importance of vaccinating this population.
- Diabetes Resources:
 - [Diabetes Disparities in Medicare Fee-for-Service Beneficiaries](#)
 - [Managing Diabetes: Medicare Coverage and Resources](#)
 - [Diabetes Management: Directory of Provider Resources](#)
 - [A Culturally and Linguistically Tailored Type 2 Diabetes Prevention Resources Inventory](#)
 - [Racial and Ethnic Disparities in Diabetes Prevalence, Self-Management, and Health Outcomes among Medicare Beneficiaries](#)



CMS OMH COVID-19 Webpages

COVID-19 Resources on Vulnerable Populations & COVID-19 Vaccine Resources

- Resources organized for:
 - Health care professionals
 - Consumers and patients
 - Non-English speakers
 - Partners educating COVID-19 vaccine recipients
 - Long-term care facilities
 - Health plans and programs

COVID-19 Vaccine Resources



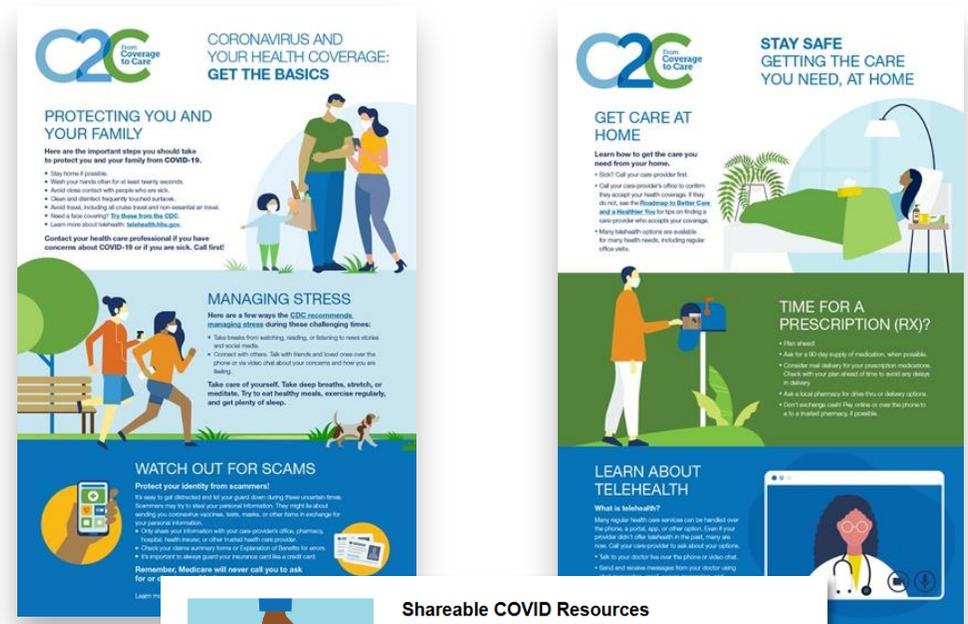
The Centers for Medicare and Medicaid Services Office of Minority Health (CMS OMH) has compiled the following Federal resources on the 2019 Novel Coronavirus (COVID-19) vaccine for health care professionals, partners and patients. We have also prepared a list of resources in other languages. Please share these materials, bookmark the page, and check back often for the most up-to-date information.

For a complete and updated list of CMS actions, and other information specific to CMS, please visit the [Current Emergencies Website](#). Visit our general COVID-19 webpage for COVID-19 Federal resources focusing on vulnerable populations: go.cms.gov/omhccovid19 and C2C COVID-19: go.cms.gov/c2ccovid19. For more COVID-19 vaccine information, see the full list of [CDC COVID-19 Vaccine resources and outreach materials](#) and [FDA COVID-19 vaccine updates](#).

C2C Resources

C2C Coronavirus Health Coverage Resources

- [Coronavirus and Your Health Coverage: Get the Basics](#) – Teaches patients how to protect themselves and their families during COVID-19 with tips for staying healthy and information about what health services are typically covered under Medicare and Marketplace plans.
- [Stay Safe: Getting the Care You Need, at Home](#) – Provides tips to patients on how to stay healthy during COVID-19 with information about scheduling health appointments from home and planning ahead for prescriptions.
- These resources are also available in Arabic, Chinese, Haitian Creole, Korean, Russian, Spanish, and Vietnamese.



Shareable COVID Resources

Partners and organizations are encouraged to download and share C2C COVID-19 resources to help everyone remain healthy and safe during this public health emergency. Use these social media graphics on your own channels to share information about ways to stay healthy during COVID-19. For more C2C materials, please visit to the [Partner Resources](#) web page.

Social Graphic 1 / English

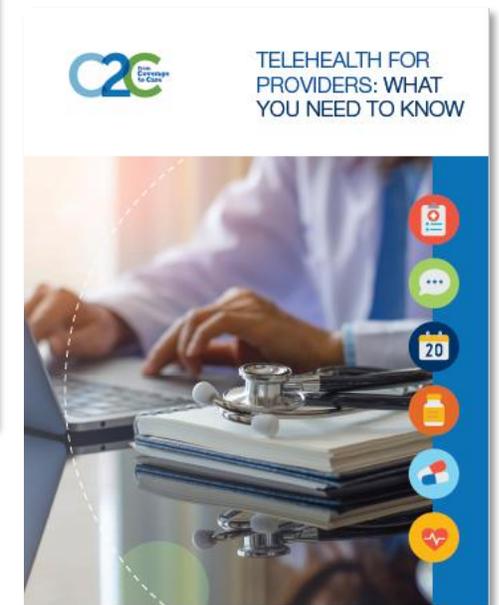
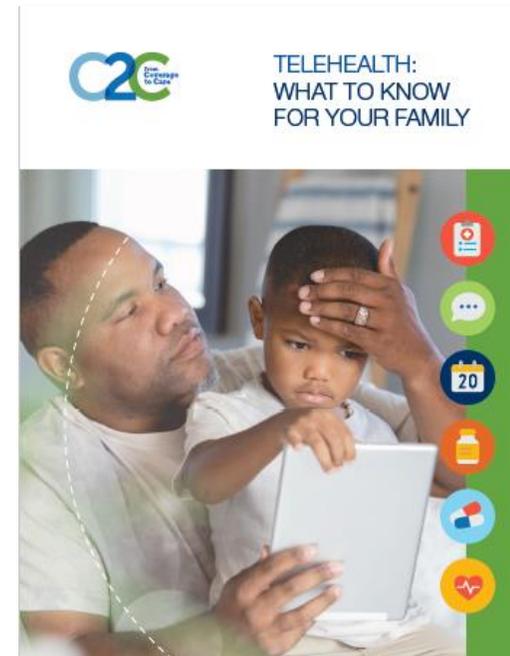
Social Graphic 2 / English

Social Graphic 3 / English

C2C Resources

C2C Telehealth Resources

- [Telehealth: What to Know for Your Family](#) – Patients can find out the types of care they can receive through telehealth, how to prepare for an appointment, what to expect during a visit, and more. This resource is also available in Spanish.
- [Telehealth for Providers: What You Need to Know](#) – Providers can learn how and when to use telehealth, including how to set up telehealth services, how to conduct a successful visit, and how to keep up to date on telehealth payment (particularly for Medicare and Medicaid).



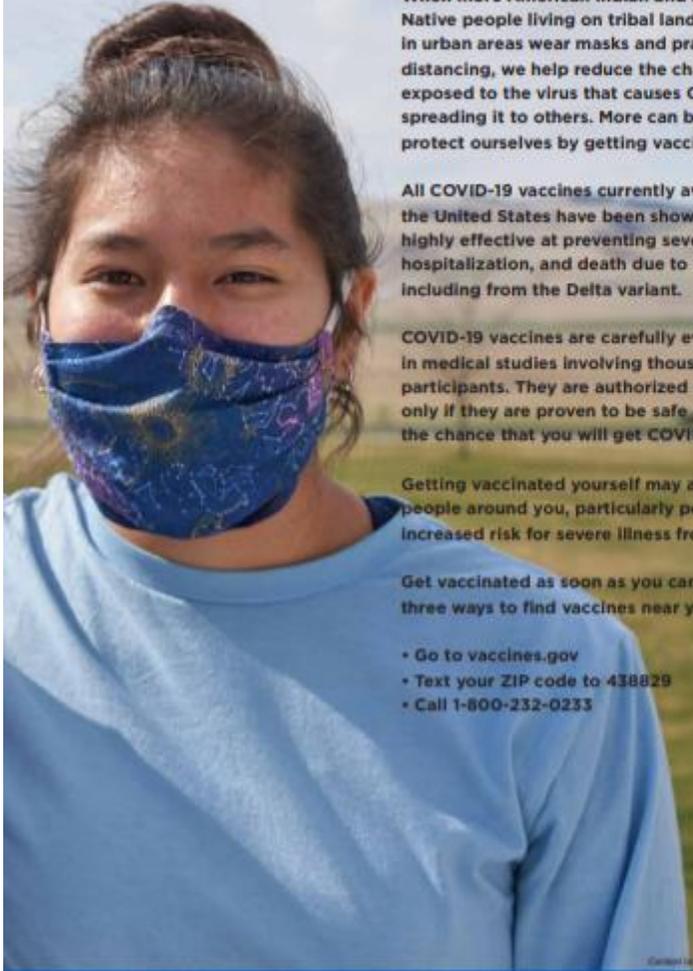
We Can Do This Toolkits

- The We Can Do This public education campaign includes multiple resources designed to help various vulnerable populations:
 - [General Audience Toolkit](#) – Information and materials about COVID-19 vaccines for partners to share in their community.
 - [Toolkit for Rural Communities](#) – Resources for how to build vaccine confidence and promote preventive measures with rural communities.
 - [Essential Workers in Agriculture Toolkit](#) – Complete resources to build vaccine confidence and promote preventive measures with agricultural workers. (Also available in [Spanish](#))
- For additional resources, visit <https://wecandothis.hhs.gov/>



Tribal Resources

- We Can Do This Resources
 - [American Indian/Alaska Native Tribal Leaders Toolkit](#)
 - [Together We Can Do This Fact Sheets for NE, NW, Plains, SW and All Regions](#)
 - [Social Media Post for American Indians / Alaska Natives](#)
- [Indian Health Services \(IHS\) COVID-19 Webpage](#)
- [CDC What Tribal Communities Need to Know About COVID-19 Vaccines](#)
- [COVID-19 Children's Eagle Book Coloring Storybook](#)



WE CAN DO THIS
Indian Country

Replace this box with your organization's logo here

Let's Do Our Part

When more American Indian and Alaska Native people living on tribal lands and living in urban areas wear masks and practice physical distancing, we help reduce the chance of being exposed to the virus that causes COVID-19 and spreading it to others. More can be done to protect ourselves by getting vaccinated.

All COVID-19 vaccines currently available in the United States have been shown to be highly effective at preventing severe illness, hospitalization, and death due to COVID-19, including from the Delta variant.

COVID-19 vaccines are carefully evaluated in medical studies involving thousands of participants. They are authorized or approved only if they are proven to be safe and decrease the chance that you will get COVID-19.

Getting vaccinated yourself may also protect people around you, particularly people at increased risk for severe illness from COVID-19.

Get vaccinated as soon as you can. You have three ways to find vaccines near you:

- Go to [vaccines.gov](https://www.vaccines.gov)
- Text your ZIP code to 438829
- Call 1-800-232-0233

Content last reviewed September 8, 2021



Find COVID-19 Vaccines and More

Go to: [Vaccines.gov](https://vaccines.gov)

Find a COVID-19 vaccine near you

Use Vaccines.gov to find a location near you, then call or visit their website to make an appointment.

[Find COVID-19 Vaccines](#)

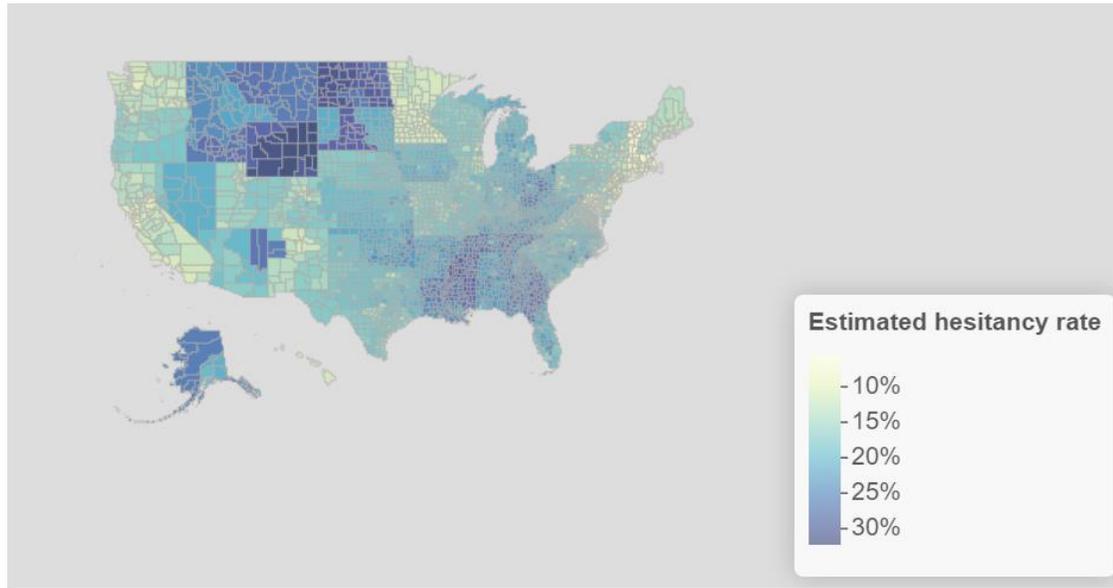
[I'm looking for flu vaccines](#) →

Powered by **VaccineFinder**



CDC Vaccinate with Confidence

- CDC's website offers tips on how to encourage confidence.
- Resources are available for community partners, including tip sheets, guides, checklists, conversation starters, and more.



Visit these CDC pages:

- [Vaccinate with Confidence COVID-19 Vaccines Strategy](#)
- [Building Confidence in COVID-19 Vaccines](#)

Protect Yourself and Your Family

- To stop this pandemic, we need to use every tool available.
- For yourself, your family, and your community: Get vaccinated.
- We must continue to follow the CDC's recommendations to continue protecting ourselves and others.
- No matter when you get your vaccine and even after, it's still important to:
 - Wear a mask.
 - Watch your distance.
 - Wash your hands.
- We can't let our guard down.

CDC: Key Things to Know About COVID-19 Vaccines

- COVID-19 vaccines are [safe and effective](#).
- You may have [side effects](#) after vaccination, but these are normal.
- It typically takes two weeks after vaccination for the body to build protection (immunity) against the virus that causes COVID-19. You are not fully vaccinated until 2 weeks after the 2nd dose of a two-dose vaccine or two weeks after a one-dose vaccine.
- COVID-19 vaccines are more widely accessible. Everyone 5 years and older is now eligible for a COVID-19 vaccination. [Find a COVID-19 vaccine](#).
- People [who have been fully vaccinated](#) can start to do some things that they had stopped doing because of the pandemic.
- Boosters are now available. Timing varies based on initial vaccination:
 - Pfizer-BioNTech and Moderna – 6 months after completion of primary series
 - Johnson & Johnson – 2 months after primary dose is received

Cost of Vaccines

- The vaccine is available to all people at no cost, regardless of insurance or immigration status.
- The Health Resources and Services Administration (HRSA) COVID-19 Vaccine Administration Assistance Fund (VAAF) ensures that even uninsured individuals can get the vaccine at no cost.
- For those concerned about undocumented status or undocumented family members, identification does not have to be shown and cannot be used for other purposes.
- Coverage of COVID-19 vaccine administration is mandatory for most Medicaid and CHIP beneficiaries, without cost sharing, during any quarter for which the state or territory claims the temporary FMAP increase under FFCRA section 6008.

Reminders:

- For Medicare beneficiaries, bring your red, white, and blue Medicare card.
 - You should bring your Medicare card even if you're enrolled in a Medicare Advantage Plan.
- If you have other insurance, bring your insurance card so the insurance can be billed.

Cost of Vaccines

Sources:

- [Medicare.gov](https://www.medicare.gov)
- [HRSA FAQs for COVID-19 Claims Reimbursement to Health Care Providers and Facilities for Testing, Treatment and Vaccine Administration](#)
- [Coverage and Reimbursement of COVID-19 Vaccines, Vaccine Administration, and Cost Sharing under Medicaid, the Children's Health Insurance Program, and Basic Health Program](#)

Note on Fraud and Scams

- The vaccine is covered at no cost to you, so if anyone asks you for your Medicare Number to get early access to the vaccine, you can bet it's a scam.
- **Here's what to know:**
 - You can't pay to put your name on a list to get the vaccine.
 - You can't pay to get early access to a vaccine.
 - Don't share your personal or financial information if someone calls, texts, or emails you promising access to the vaccine for a fee.

Note on Fraud and Scams

- **If you paid a fee or got a bill for a COVID-19 vaccine**, check this list to see if your provider should have charged you:
 - Check the receipts and statements you get from your provider for any mistakes.
 - Call your provider’s office to ask about any charges you think are incorrect.
 - If you have Original Medicare, review your “Medicare Summary Notice” for errors. Report anything suspicious to Medicare by calling 1-800-MEDICARE (1-800-633-4227).
 - If you have other coverage like a Medicare Advantage Plan, review your “Explanation of Benefits” and report anything suspicious to your insurer.
- **If you think your provider incorrectly charged you for the COVID-19 vaccine**, ask them for a refund.
- **If you think your provider charged you for an office visit or other fee, but the only service you got was a COVID-19 vaccine**, report them to the Office of the Inspector General, U.S. Department of Health and Human Services by calling 1-800-HHS-TIPS or visiting [TIPS.HHS.GOV](https://www.tips.hhs.gov).

Turning Hesitancy to Confidence

- Resistance to vaccines, for any reason, can occur and may vary across demographics including race, age, urban vs. rural, etc.
- Some reasons may include:
 - Belief that the risks of COVID-19 are overstated.
 - Belief that getting vaccinated is a personal choice rather than a public health responsibility.
 - Use of a “wait and see” approach“ due to concerns about safety, effectiveness, or equitable distribution.
 - Mistrust of and previous poor experience with the health care system.

Turning Hesitancy to Confidence

- [Vaccine confidence](#) is the **trust that parents, patients, or providers have** in:
 - Recommended vaccines.
 - Providers who administer vaccines.
 - Processes and policies that lead to vaccine development, licensure, manufacturing, and recommendations for use.
- Confidence in the vaccines, the vaccinator, and the system all **support the decision to get vaccinated.**
- [Strong confidence in the vaccines](#) within communities leads to **more people getting vaccinated, which leads to fewer COVID-19 illnesses, hospitalizations, and deaths.**

Strategies to Build Confidence

Common strategies include:

- **Trust in public health messengers**, across all communities.
- **Seek out peers with positive experiences** to encourage peer-to-peer messaging.
- **Target vaccine information** to specific populations.
 - Media and social media
 - Resources in accessible languages
- **Remove functional barriers.**
 - Access
 - Cost (reinforce the message that people will pay nothing for the COVID-19 vaccine)
- **Share accurate information and messaging.**

Messages to Build Confidence

- According to the [Kaiser Family Foundation](#), individual health care providers are the most trusted messengers when it comes to information about the COVID-19 vaccines.
- In the messages KFF has tested, emphasizing the [effectiveness of the vaccine at preventing serious illness and death](#) is the most effective across groups.
- The “wait and see” group is an important target for outreach and messaging, since they express some concerns about getting vaccinated, but will likely be much easier to convert from vaccine-hesitant to vaccine-acceptant.
- Other messages/information that are effective at persuading many in the “wait and see group” include:
 - Scientists have been working on the technology used in the new COVID-19 vaccines for 20 years.
 - More than 100,000 people from diverse backgrounds took part in the vaccine trials.
 - The vast majority of doctors who have been offered the vaccine have taken it.
 - There is no cost to get the vaccine.

Connect with CMS OMH

Contact Us

OMH@cms.hhs.gov

Visit Our Website

go.cms.gov/omh

Rural Health

RuralHealth@cms.hhs.gov

Coverage to Care

CoverageToCare@cms.hhs.gov

Health Equity Technical

Assistance Program

HealthEquityTA@cms.hhs.gov

Listserv Signup

bit.ly/CMSOMH

Q&A Session

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