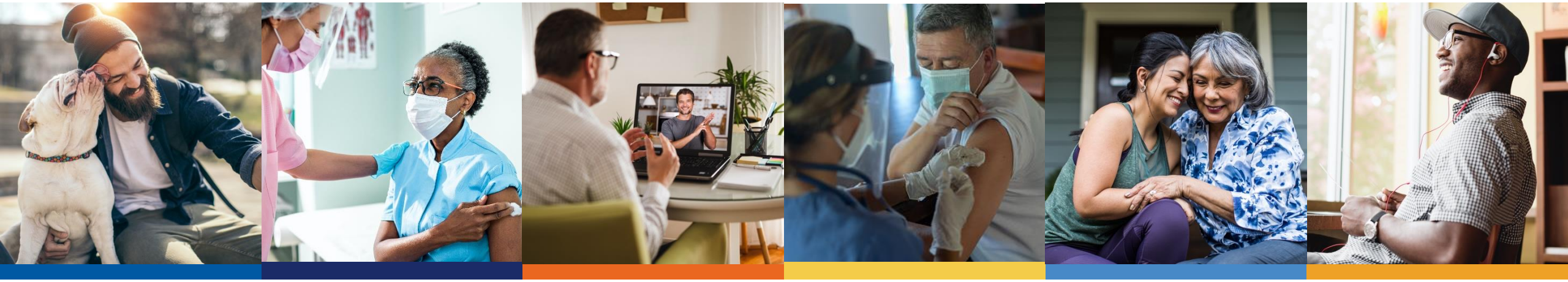
C M S O F F I C E O F M I N O R I T Y H E A L T H



Building COVID-19 Vaccine Confidence

May 13, 2021

Paid for by the US Department of Health and Human Services. Information is considered current at the time of the presentation. The views and opinions expressed outside of this content are those of the presenter and do not reflect views of CMS or the US Department of Health and Human Services.

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OFFICE OF MINORITY HEALTH

Please note, these slides were updated as of the morning of May 13, 2021. Since then, the CDC updated its guidance for fully vaccinated people.

Please visit this site for the latest information.

Reminders

Phone number: (562) 247-8422

Access code: 895-380-069

Please submit questions or comments via the chat box.

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES
OFFICE OF MINORITY HEALTH

Speakers

LaShawn McIver, MD, MPH

Director of CMS Office of Minority Health

Daiva Yee, MPH

State/Jurisdiction Support Lead on CDC COVID-19 Vaccine Confidence Team

Peter Marks, MD, PhD

Director of FDA Center for Biologics Evaluation and Research (CBER)

Agenda

- CMS OMH Overview
- Resources and Funding Opportunities
- Development of COVID-19 Vaccines
- Building Confidence
- Open Discussion
- Contact Us

CMS Office of Minority Health

Mission

To ensure that the voices and needs of the populations we represent are present as the Agency is developing, implementing, and evaluating its programs and policies. These populations include:

- Racial and ethnic minorities
- People with disabilities
- Members of the lesbian, gay, bisexual, and transgender community
- Individuals with limited English proficiency
- Rural populations

Vision

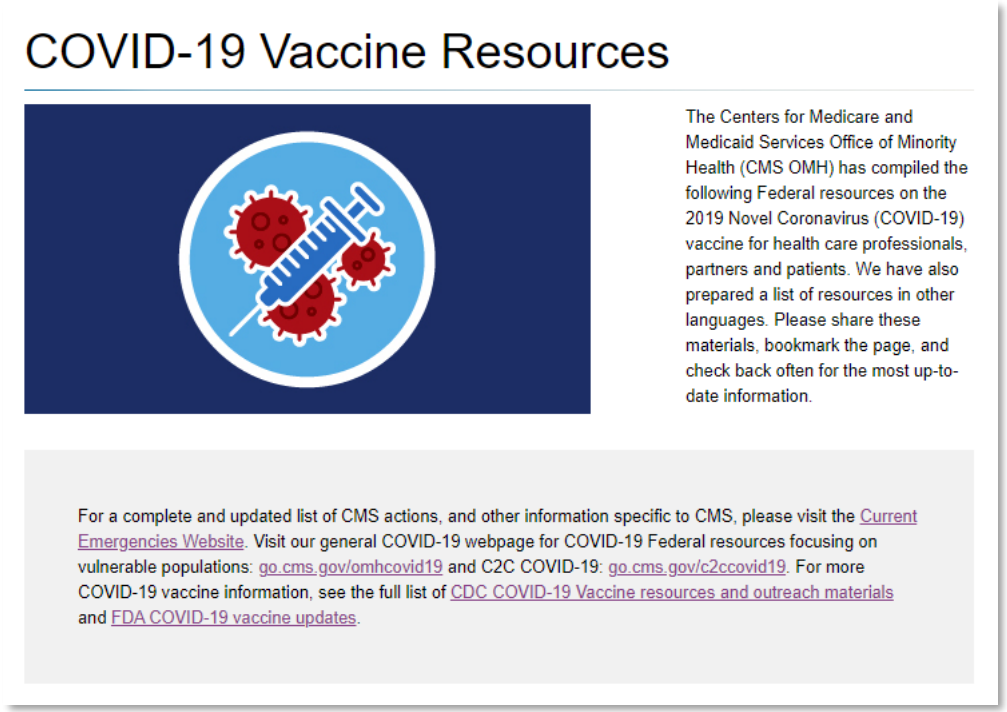
All CMS beneficiaries have achieved their highest level of health, and disparities in health care quality and access have been eliminated.

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



C2C Resources

C2C Coronavirus Health Coverage Resources

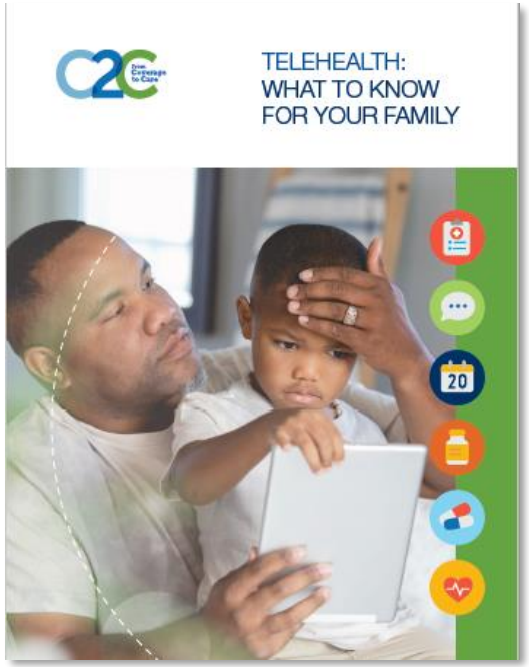
- Coronavirus and Your Health Coverage: Get the Basics – Teaches patients how to protect themselves and their families during COVID-19 with tips for staying healthy and information about what health services are typically covered under Medicare and Marketplace plans.
- Stay Safe: Getting the Care You 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.

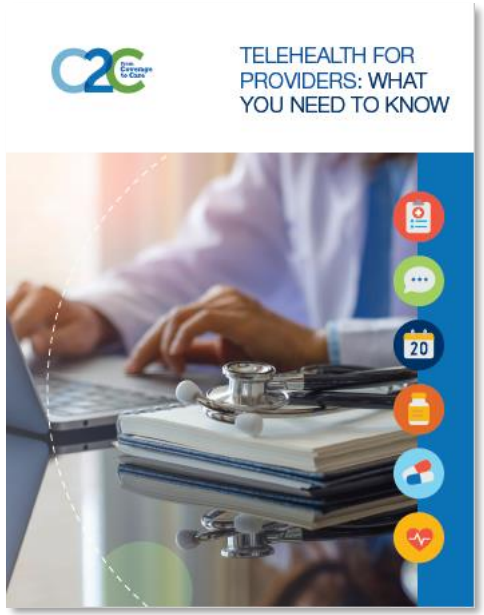
These resources are also available in Arabic, Chinese, Haitian Creole, Korean, Russian, Spanish, and Vietnamese.

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).



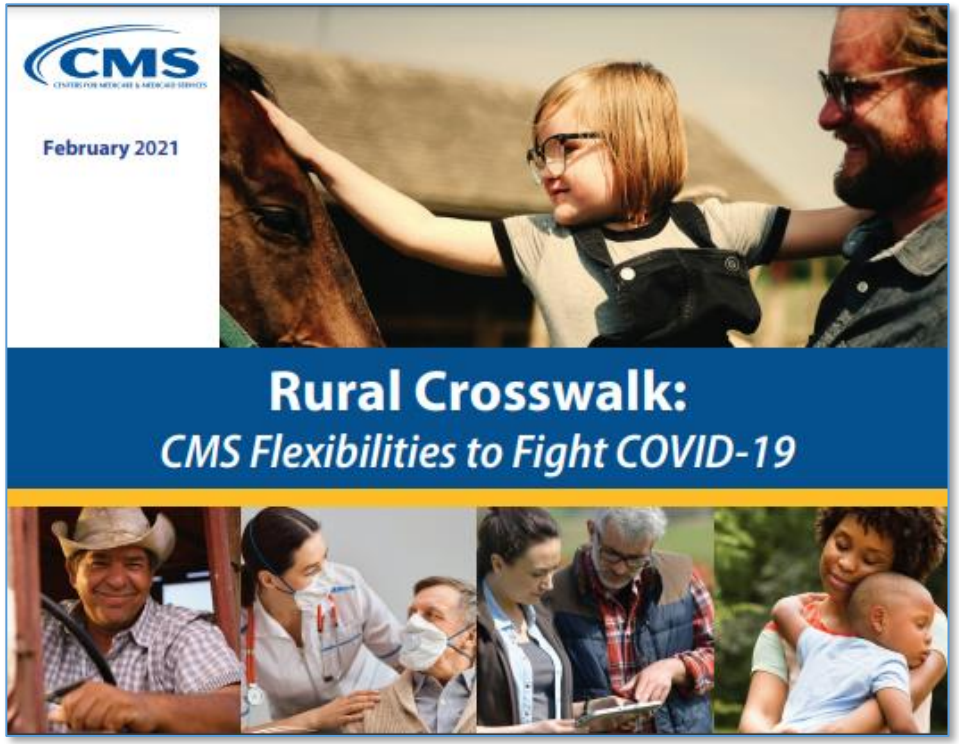


Rural Crosswalk

Rural Crosswalk: CMS Flexibilities to Fight COVID-19

This crosswalk highlights 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



Funding Opportunities

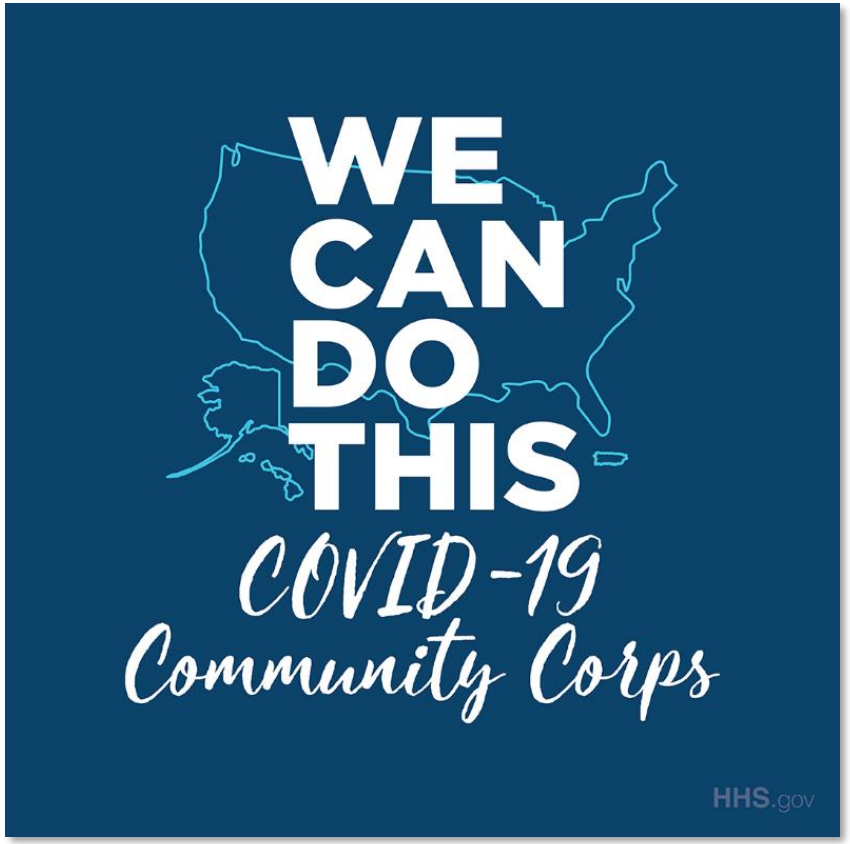
Open

- CDC's Community Health Workers for COVID Response and Resilient Communities (CCR) - Evaluation and Technical Assistance (ETA)
  - The Coronavirus Aid, Relief, and Economic Security (CARES) Act of 2020 allocated funds to the Centers for Disease Control and Prevention (CDC) for states, localities, territories, tribes, tribal organizations, urban Indian health organizations, or health service providers to tribes. CDC announced the availability of funds to achieve the goal of the CARES Act in protecting the American people from the public health impacts of COVID-19. This three-year opportunity provides funds to conduct a national evaluation of the Community Health Workers for COVID Response and Resilient Communities (CCR) program, DP21-2110 and provide training and technical assistance (TA) to CCR recipients. This program has two components: A) conduct a national evaluation of the CCR and B) deliver training and TA to CCR recipients. Applicants may only apply for 1 component.
  - Due: May 24, 2021

Now closed

- CDC's National Initiative to Address COVID-19 Health Disparities Among Populations at High-Risk and Underserved Communities, Including Racial and Ethnic Minority Populations and Rural Communities
- HHS Office of Minority Health Advancing Health Literacy to Enhance Equitable Community Responses to COVID-19

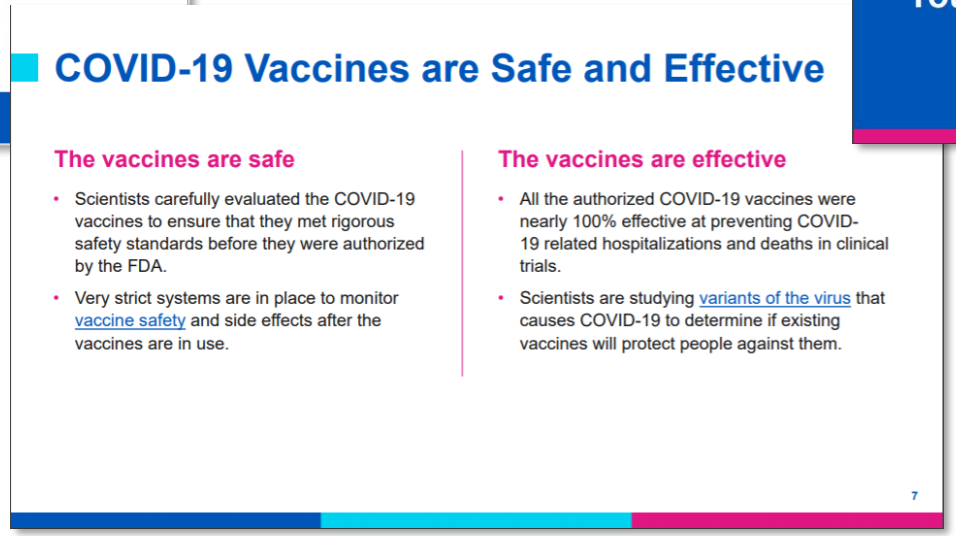
We Can Do This COVID-19 Community Corps



COVID-19 Community Corps is a national volunteer initiative launched by the U.S. Department of Health and Human Services (HHS) to galvanize trusted messengers in the fight against COVID-19.

Learn how you can be a part and find resources, toolkits, and more: hhs.gov/COVIDCommunityCorps

Vaccine Confidence Presentation for Latino Audiences (English and Spanish)



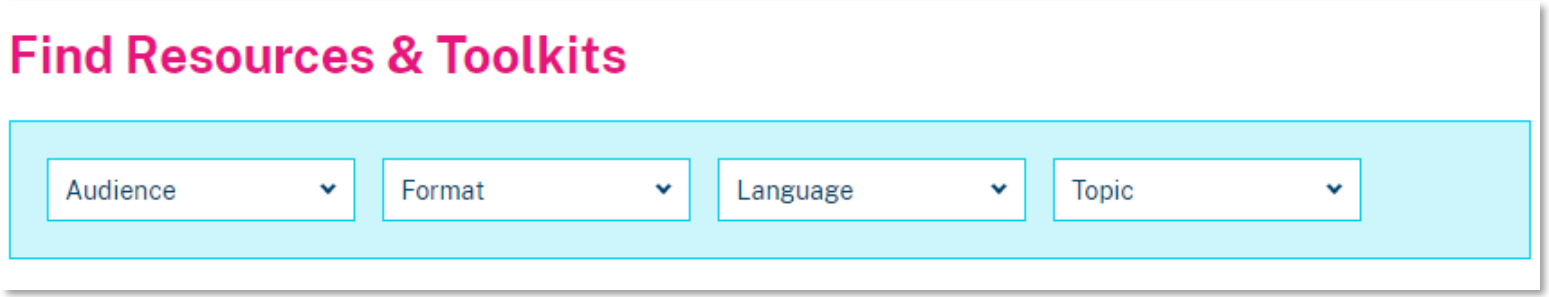
HHS COVID-19 Resources

Updated toolkits for the following groups:

- AIAN
- 65+/older adults
- Community Health Workers / Promotoras
- Agricultural Workers
- Rural
- Nurses
- Puerto Rico
- General Audience

Additional resources:

- Immunity in Our Community podcast
- COVID-19 Vaccine Hesitancy in Your Community map

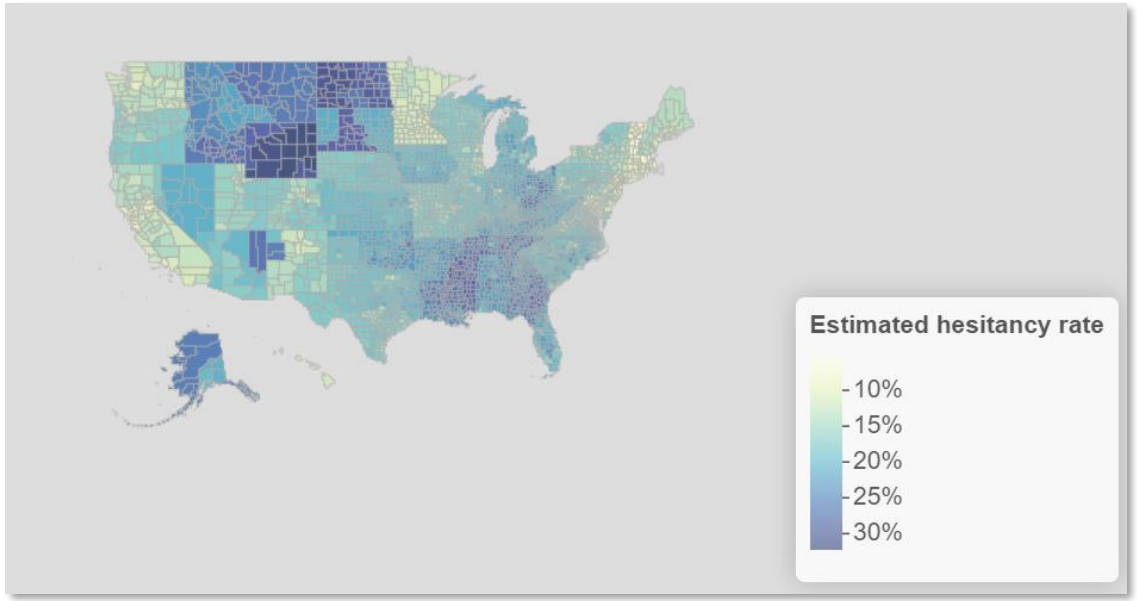


Search for COVID-19 Vaccines Near You

Go to: Vaccines.gov

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:

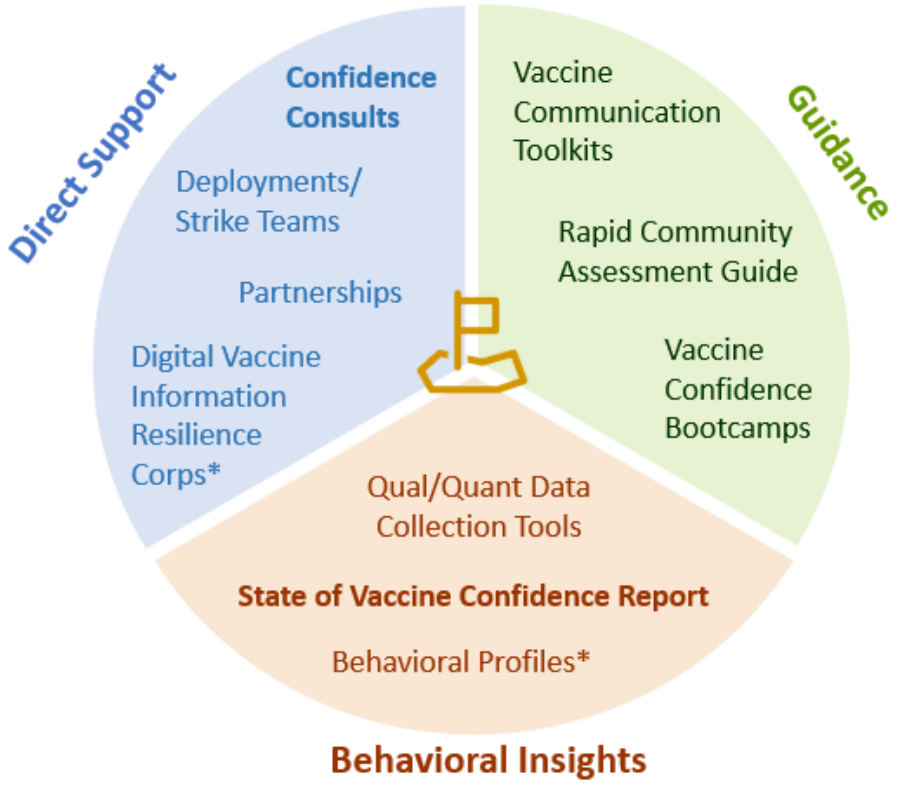
- Vaccinate with Confidence COVID-19 Vaccines Strategy
- Building Confidence in COVID-19 Vaccines

CDC: Six Ways to Help Build COVID-19 Vaccine Confidence

1. Encourage leaders in your family, community, or organizations to be vaccine champions.
2. Have discussions with your friends and family about vaccination to understand their perspective and encourage their decision to vaccinate.
3. Share key messages through multiple channels that people trust and that promote action.
4. Help educate people about COVID-19 vaccines, how they are developed and monitored for safety, and how individuals can talk to others about the vaccines.
5. Learn more about finding credible vaccine information. When you come across COVID-19 information, cross-check with CDC.gov and learn how to respond to misinformation you encounter.
6. When the vaccine is offered to you, make visible your decision to get vaccinated and celebrate it!

Source: CDC Six Ways to Help Build COVID-19 Vaccine Confidence

How the Vaccine Confidence Team is Supporting States and Jurisdictions



*coming soon

- To be added to our distribution list and receive our biweekly state of vaccine confidence insights report, please email: eocevent515@cdc.gov
- To request a confidence consult with our team, please email: confidenceconsults@cdc.gov

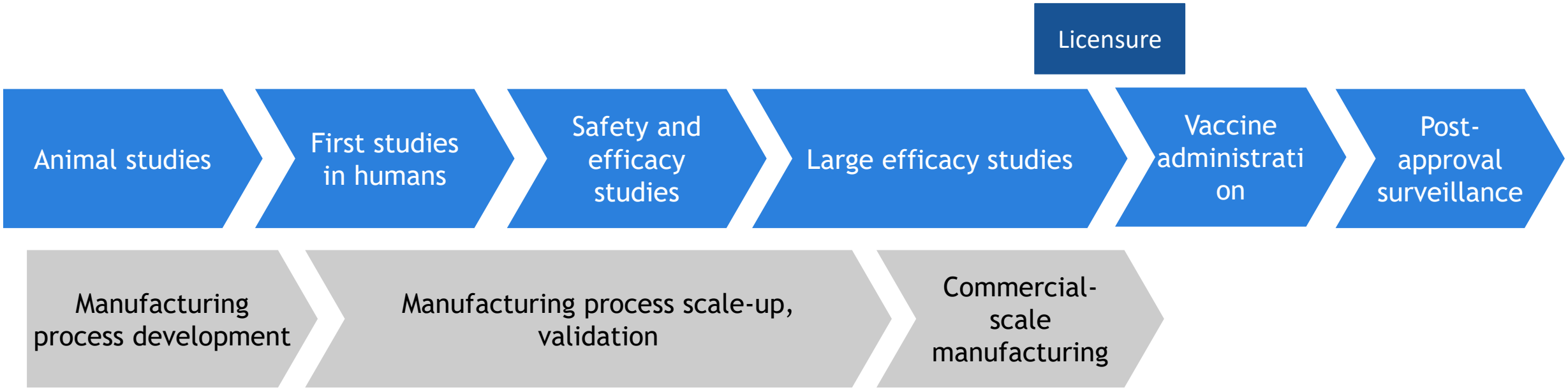
U.S. FOOD & DRUG ADMINISTRATION

The Development of COVID-19 Vaccines

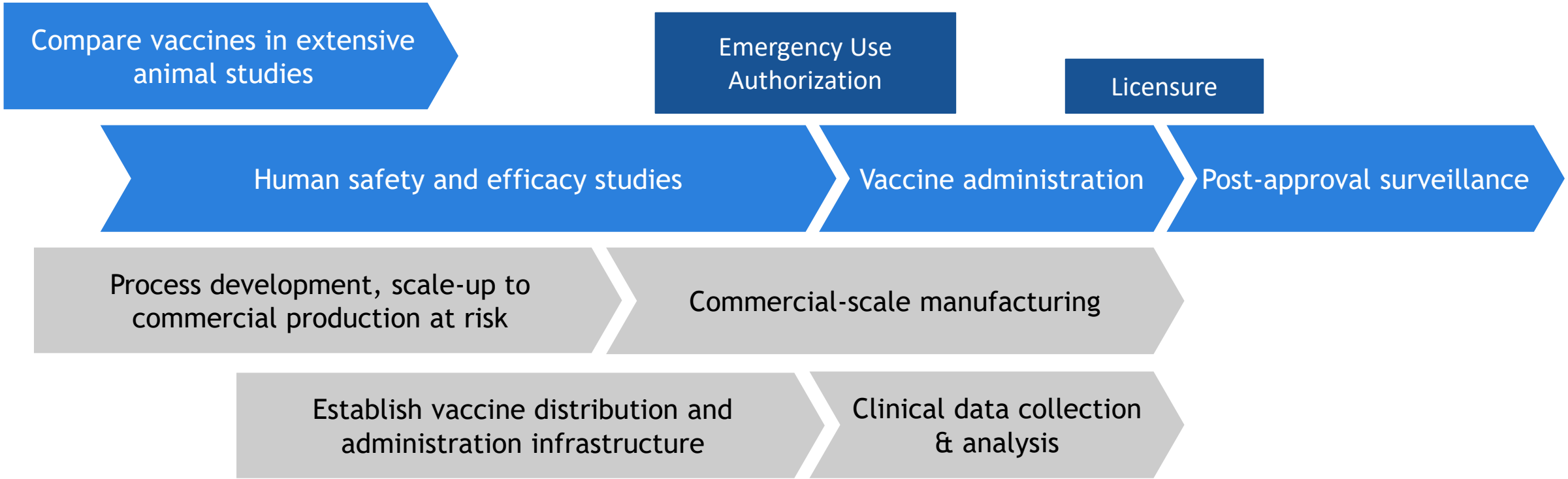
Peter Marks, MD, PhD

May 2021

Traditional Vaccine Development



Accelerated Vaccine Development



Clinical Trials – Key Considerations
Trial Design

- Primary efficacy endpoint point estimate for a placebo-controlled efficacy trials should be ≥ 50%
  - Lower bound of appropriately alpha adjusted 95% confidence interval around the primary efficacy endpoint point estimate should be > 30%
- Need minimum median of 2 months participant follow-up following final vaccination of series

Biologics License Application (BLA)

- Biologics are licensed under both section 351 of the Public Health Service Act and the Federal Food Drug and Cosmetic Act
- Product must be safe, pure, potent, effective
- The standard used is that there is substantial evidence of efficacy from adequate and well-controlled clinical trials

Emergency Use Authorization (EUA)

- Put in place after 9/11 to ensure that potentially lifesaving medical products could be available to people in medical need when there is not an approved and available alternative
- The standard used is that the product “may be effective” and its “known and potential benefits outweigh the known and potential risks”

EUA for a COVID-19 Vaccine

- Must demonstrate clear and compelling efficacy in a large well-designed phase 3 clinical trial
- Careful evaluation of quality, safety, efficacy
- Public advisory committee meeting
- Enhanced post-deployment surveillance

Advanced Candidates – April 2021

- mRNA
  - BNT162b2 (Pfizer-BioNTech) – EUA granted Dec 11, 2020
  - mRNA-1273 (Moderna) – EUA granted Dec 18, 2020
- Non-Replicating Viral Vector
  - Ad26.COV2.S (Janssen) – EUA granted Feb 27, 2021
  - ChAdOx1 (Astra Zeneca-Oxford)
- Protein Subunit
  - NVX-CoV2373 (Novavax)
  - MRT5500 (Sanofi-Translate Bio)

Vaccine Trial Demographics

Vaccine	Pfizer-BioNTech (2 doses 21 d apart)	Moderna (2 doses 28 d apart)	Janssen (1 dose)
Total patients	43,552	30,350	39,321
Receiving vaccine	21,768	15,180	19,630
Receiving placebo	21,784	15,170	19,691
Black/African Amer.	9.8%	9.7%	17.2%
Hispanic/Latino	26.2%	20.0%	45.1%
At least age 65	21.4%	25.3%	20.4%

Vaccine Efficacy in Phase 3

Primary efficacy was determined against moderate and severe/critical COVID-19

Vaccine	Pfizer-BioNTech	Moderna	Janssen
Primary efficacy (vaccinated/placebo)	95% (8/162)	94.1% (11/185)	d14 66.9% (116/348) d28 66.1% (66/193)
Young population	age 16-54 95.6% (5/114)	age 18-64 95.6% (7/156)	age 18-64 d14 63.7% (95/260) d28 66.1% (52/152)
Older population	age 55+ 93.7% (3/48)	age 65+ 86.4% (5/114)	age 65+ d14 76.3% (21/88) d28 66.2% (14/41)
Severe COVID-19	1/9	0*/30	d14 14/60; d28 5/34

*One severe case reported 2 months after vaccination

Vaccine Safety in Phase 3

		Second dose					
		Pfizer-BioNTech		Moderna		Janssen	
Reaction (2nd injection)	Placebo*	<55	55+	<65	65+	<60	60+
Injection site pain	14%	78%	66%	90%	83%	57%	33%
Fatigue	22%	59%	50%	68%	58%	44%	30%
Headache	21%	52%	39%	63%	46%	44%	30%
Muscle pain	10%	38%	29%	61%	47%	39%	24%
Chills	4%	35%	23%	48%	31%	N/A	N/A
Joint pain	8%	21%	19%	45%	35%	N/A	N/A
Fever	0.4%	16%	11%	17%	10%	13%	3%

*Average value across all studies, all doses, all ages

Pfizer Pediatric Demographics

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 Efficacy

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 Safety

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%

FDA
U.S. FOOD & DRUG
ADMINISTRATION

Building Confidence

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES
OFFICE OF MINORITY HEALTH

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 when the time comes.
- And 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 16 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.

Source: CDC Key Things to Know

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 will have the vaccine at no cost.
- For those concerned about undocumented status or undocumented family members, an 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
- 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.

Source: Medicare.gov

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." 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.

Source: Medicare.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.

Side Effects of Vaccine vs. Severity of COVID-19

- Many people experience no side effects.
- Common **side effects of the COVID-19 vaccine are normal** and **they resolve within one or two days** of getting the vaccine.
- Side effects could include pain and swelling on the arm where you got the shot. Other possible side effects include:
  - Fever
  - Chills
  - Fatigue
  - Headache
- If you've been exposed to COVID-19 and you develop symptoms more than three days after getting vaccinated or the symptoms last more than two days, self-isolate and get tested.

Johnson & Johnson/Janssen COVID-19 Vaccine

- The FDA and CDC have determined that **the recommended pause regarding the use of the J&J COVID-19 vaccine in the U.S. should be lifted and use of the vaccine should resume**.
- The pause was recommended after 6 cases of a rare and severe type of blood clot were reported following administration of the J&J COVID-19 vaccine.
- The FDA has determined that the available data shows the vaccine's known and potential benefits outweigh its known and potential risks in individuals 18 and older.
- Resources:
  - Janssen COVID-19 Vaccine Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers)
  - Fact Sheet for Recipients and Caregivers

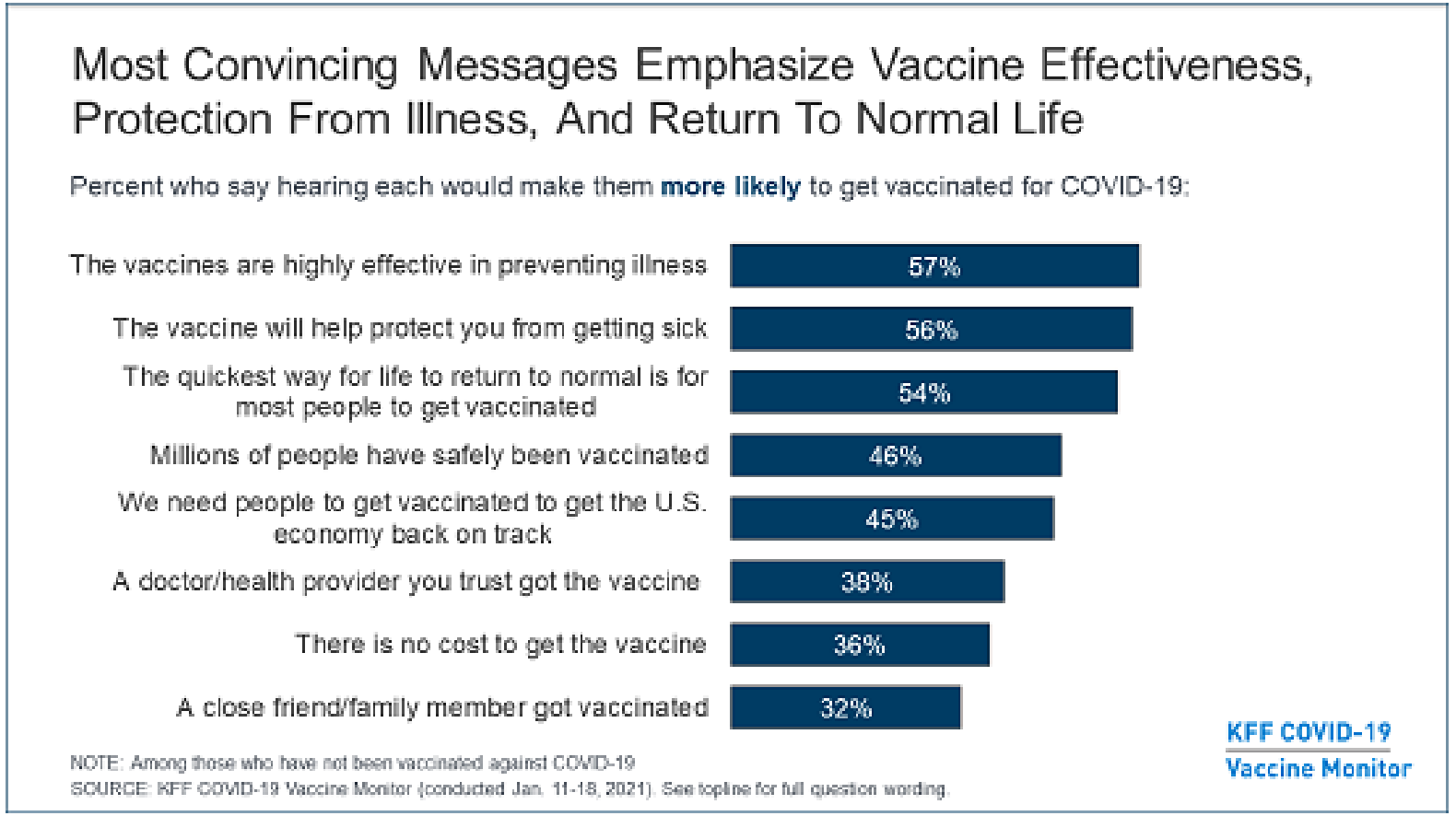
Severity of COVID-19

Rate ratios compared to White, Non-Hispanic persons	American Indian or Alaska Native, Non-Hispanic persons	Asian, Non-Hispanic persons	Black or African American, Non-Hispanic persons	Hispanic or Latino persons
Cases	1.6x	0.7x	1.1x	2.0x
Hospitalization	3.5x	1.0x	2.8x	3.0x
Death	2.4x	1.0x	1.9x	2.3x

Race and ethnicity are risk markers for other underlying conditions that affect health including socioeconomic status, access to health care, and exposure to the virus related to occupation, e.g., frontline, essential, and critical infrastructure workers.

Source: CDC Risk for COVID-19 Infection, Hospitalization, and Death By Race/Ethnicity

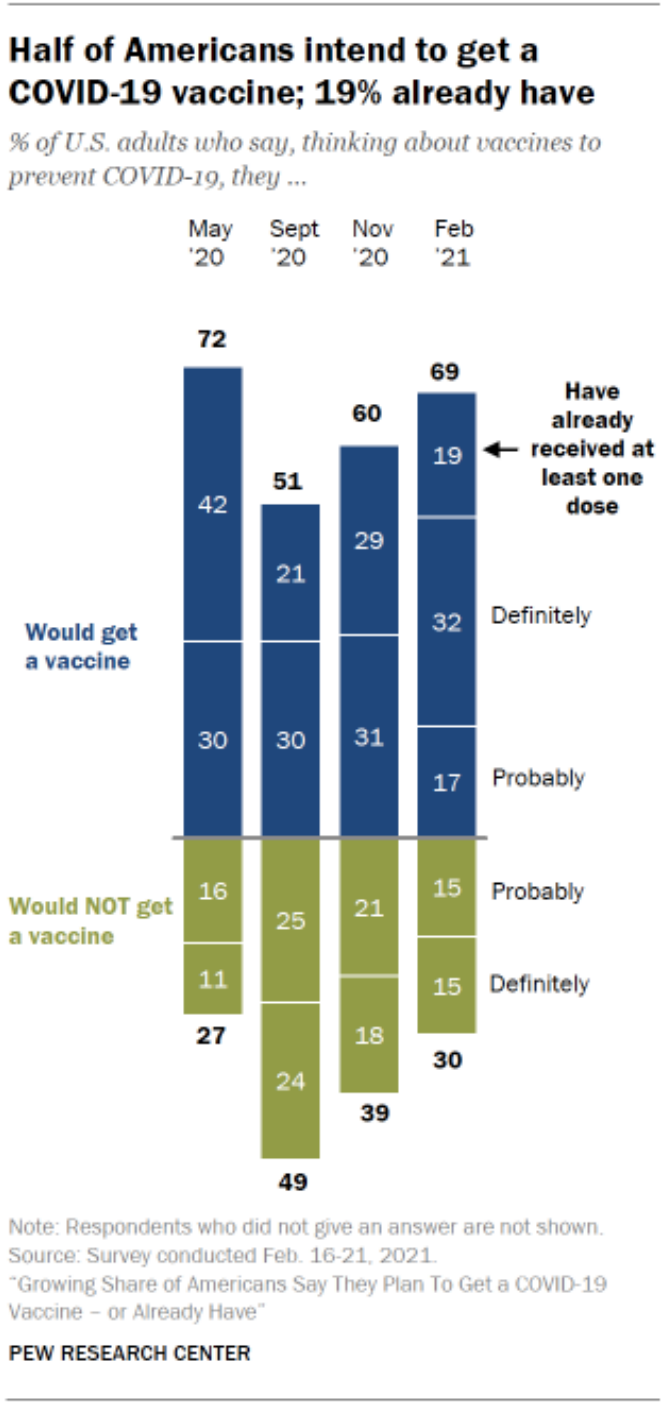
Effective Messaging



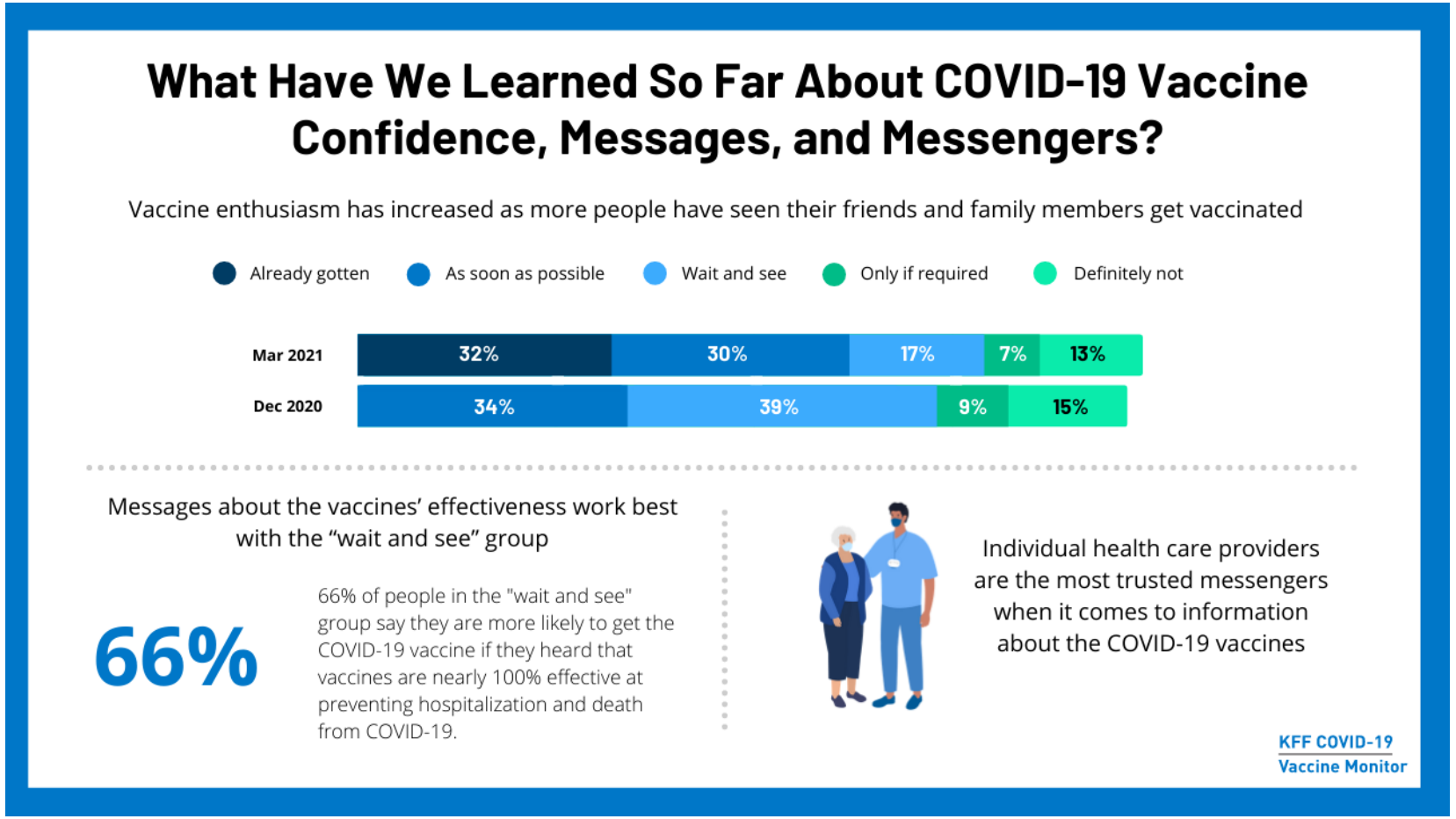
Source: [Kaiser Family Foundation]

Changing Opinions

Source: [Pew Research Center, February 2021]



Changing Opinions



Source: [Kaiser Family Foundation]

CMS Campaign Strategy for People with Medicare

- Paid media to help the “pent-up-demand” to be met
- Work on promoting the “movable middle”
- Leverage the Medicare Voice
- Target hesitant and negatively impacted audiences

CMS Office of Communications COVID Message Testing

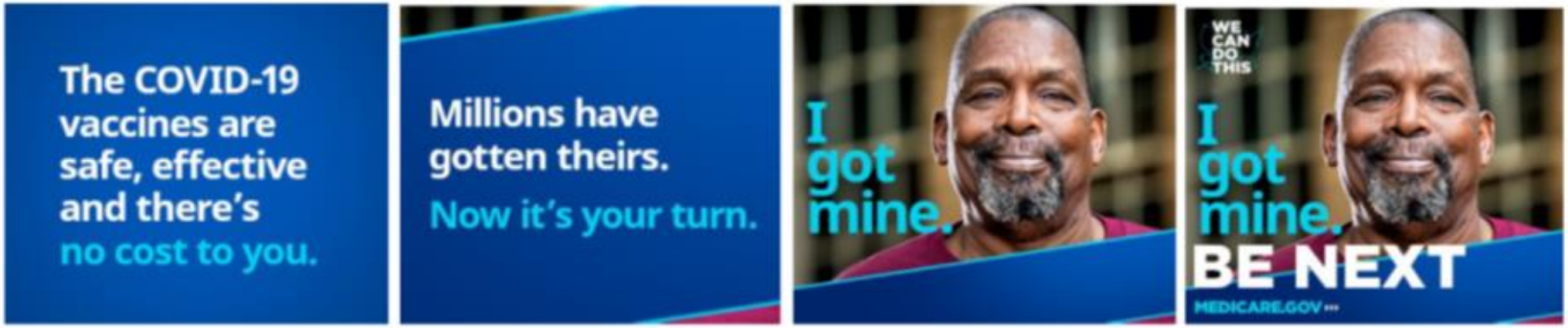
- Messages were tested with Medicare beneficiaries who are hesitant about getting the vaccine. In general, skepticism in the effectiveness of the vaccine was the main reason for hesitancy, but messaging pointing to vaccine effectiveness isn't as compelling to every audience.
- Of the seven messages tested, the top three were:
  1. ***I will get the vaccine to help protect the people I love, myself, and others around me.***
     - Protecting loved ones and helping to slow the spread of infections resonated.
  2. ***Getting an appointment for the vaccine might be a hassle, but it's worth it, so I can get back to my normal life.***
     - Reflects what they cautiously hope for: a return to normal; but some are not convinced this will happen, even with the vaccine.
  3. ***Getting COVID can be deadly. Thousands of Americans have died from COVID. Get the COVID vaccine to protect yourself and others.***
     - This is a compelling concept if the vaccine really is effective in providing protection against COVID.
- Less compelling messages included ones that suggested that odds are better with the vaccine than with getting COVID; a message that the vaccine limits the likelihood that you will get COVID (seen as proof that it may not be effective); focus on the idea that the vaccine is safe and effective (they do not believe this); and the idea that vaccine side effects are worth the protection (they are concerned with the potential for adverse events due to the vaccine).

Tactics

- **To Date:**
  - Emails, direct to consumer (32 sent to a list of 13 million)
  - Medicare.gov COVID page
  - Social media
  - Partnership outreach
- **Began May 10:**
  - Paid advertising to reach target African American, Latino, and low-income audiences
  - Earned media promoting vaccine
  - Use customer voice as often as possible
  - Partnership reach into local populations

Example of Ad That Started May 10

- COVID-19 vaccines are safe, effective and no cost to you.
- Millions have gotten theirs, now it’s your turn.
- I got mine. Be Next.



Discussion

CMS
ICARE & MEDICAID SERVICES
MINORITY HEALTH

Thank You

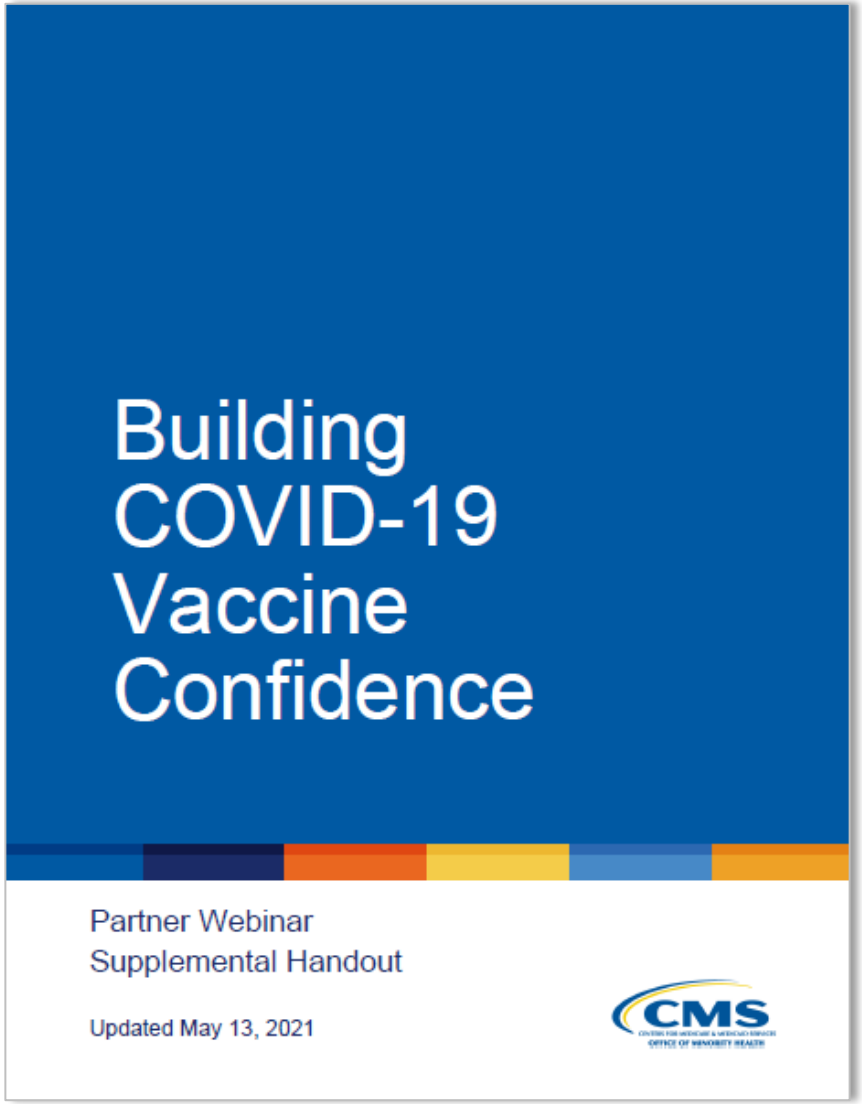
Contact:

omh@cms.hhs.gov

Quick Links:

go.cms.gov/omhcovid19vaccine

cms.gov/covidvax

wecandothis.hhs.gov

cdc.gov/vaccines/covid-19/vaccinate-with-confidence.html