NATIONAL LGBTQIA+ HEALTH EDUCATION CENTER

A PROGRAM OF THE FENWAY INSTITUTE

COVID-19 Webinar Series: Status of clinical trials and the roll out of the vaccine

Kenneth H. Mayer, M.D. and Bisola Ojikutu, M.D., M.P.H.

February 18th, 2021

Our Roots

Fenway Health

- Independent 501(c)(3) FQHC
- Founded 1971
- Mission: To enhance the wellbeing of the LGBTQIA+ community as well as people in our neighborhoods and beyond through access to the highest quality health care, education, research, and advocacy
- Integrated primary care model, including HIV and transgender health services

The Fenway Institute

- Research, Education, Policy

LGBTQIA+ Education and Training

The National LGBTQIA+ Health Education Center offers educational programs, resources, and consultation to health care organizations with the goal of providing affirmative, high quality, cost-effective health care for lesbian, gay, bisexual, transgender, queer, intersex, asexual, and all sexual and gender minority (LGBTQIA+) people.

- Training and Technical Assistance
- Grand Rounds
- Online Learning
  - Webinars, Learning Modules
  - CE, and HEI Credit
- ECHO Programs
- Resources and Publications

www.lgbtqiahealtheducation.org

Technical Questions?

- Please call Zoom Technical Support: 1.888.799.9666 ext 2
- You can contact the webinar host using the chat function in Zoom. Click the “Chat” icon, and type your question.
- Alternatively, e-mail us at education@fenwayhealth.org for less urgent questions.

Sound Issues?

- Ensure your computer speakers are not muted.
- If you cannot hear through your computer speakers: Navigate to the bottom toolbar on your screen, go to the far left, and click the arrow next to the phone icon.
- Choose “I will call in.”
- Dial the phone number and access code.

When the webinar concludes:

- Close the browser, and an evaluation will automatically open for you to complete.
- We very much appreciate receiving feedback from all participants.
- Completing the evaluation is required to obtain a CME/CEU certificates.

CME/CEU Information

This activity has been reviewed and is acceptable for up to 1.0 Prescribed credits by the American Academy of Family Physicians. Participants should claim only the credit commensurate with the extent of their participation in this activity.

Physicians	AAFP Prescribed credit is accepted by the American Medical Association as equivalent to AMA PRA Category 1 Credit™ toward the AMA Physician'sRecognition Award. When applying for the AMA PRA, Prescribed creditearned must be reported as Prescribed, not as Category 1.
Nurse Practitioners,Physician Assistants,Nurses, MedicalAssistants	AAFP Prescribed credit is accepted by the following organizations. Please contact them directly about how participants should report the credit they earned. •American Academy of Physician Assistants (AAPA) •National Commission on Certification of Physician Assistants (NCCPA) •American Nurses Credentialing Center (ANCC) •American Association of Nurse Practitioners (AANP) •American Academy of Nurse Practitioners Certification Program (AANPCP) •American Association of Medical Assistants (AAMA)
Other HealthProfessionals	Confirm equivalency of credits with relevant licensing body.

Learning Objectives:

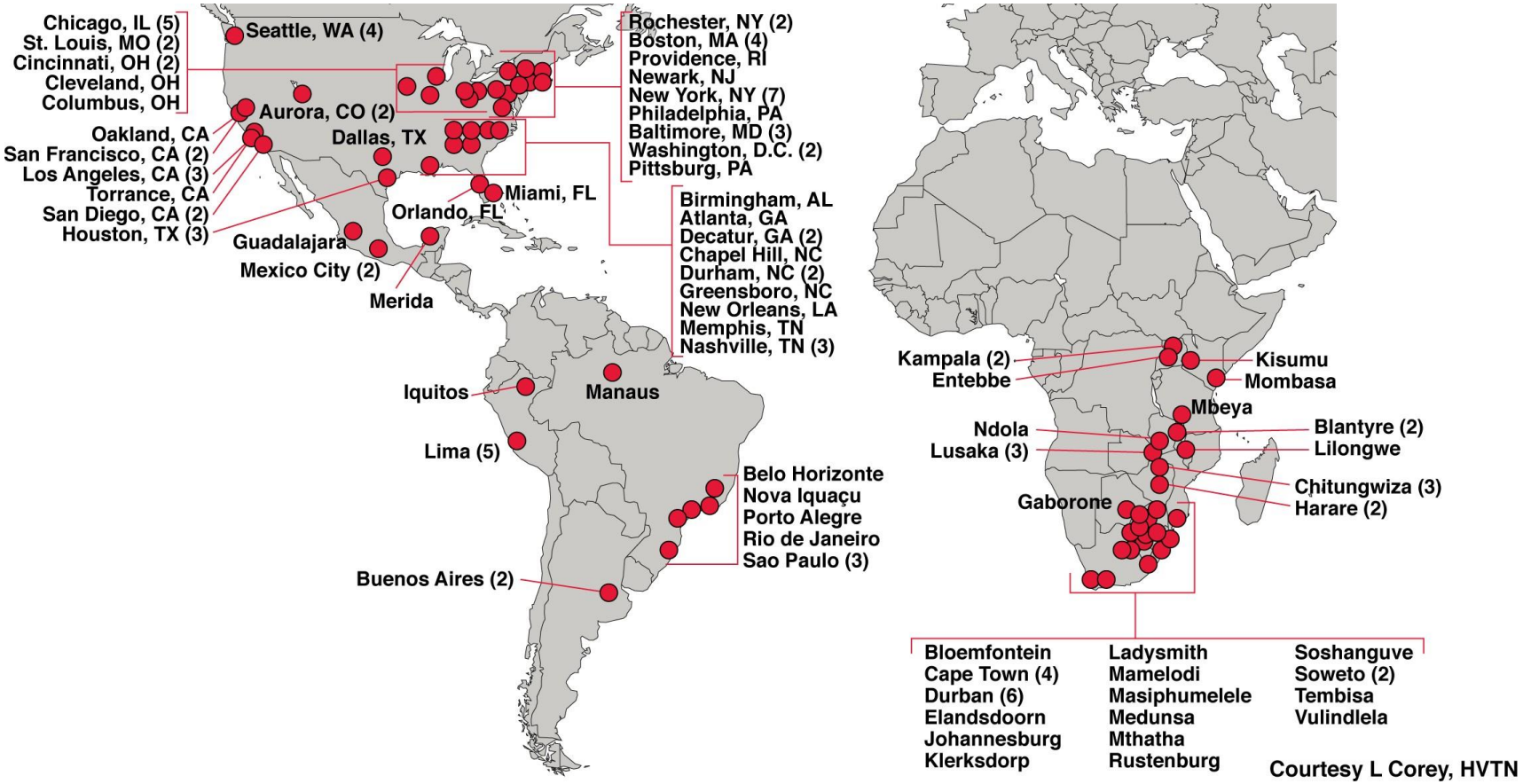
- In this webinar session, participants will:

1. Discuss the state of the COVID-19 vaccine trials and considerations for vaccine distribution.
2. Discover how medical mistrust affects COVID-19 outcomes, particularly for patients in ethnic and racial minority groups.
3. Explore strategies for responding to medical mistrust and engaging in outreach to improve equitable distribution of the COVID-19 vaccine.

CoVPN Website

www.coronavirusprevention network.org

CoVPN
Clinical Sites



Courtesy L Corey, HVTN

COVID-19 Vaccine Trials

- Pfizer-BioNtech mRNA, FDA approved

(2 shots/3 weeks apart, very cold storage)-done

- Moderna mRNA, close to FDA approval

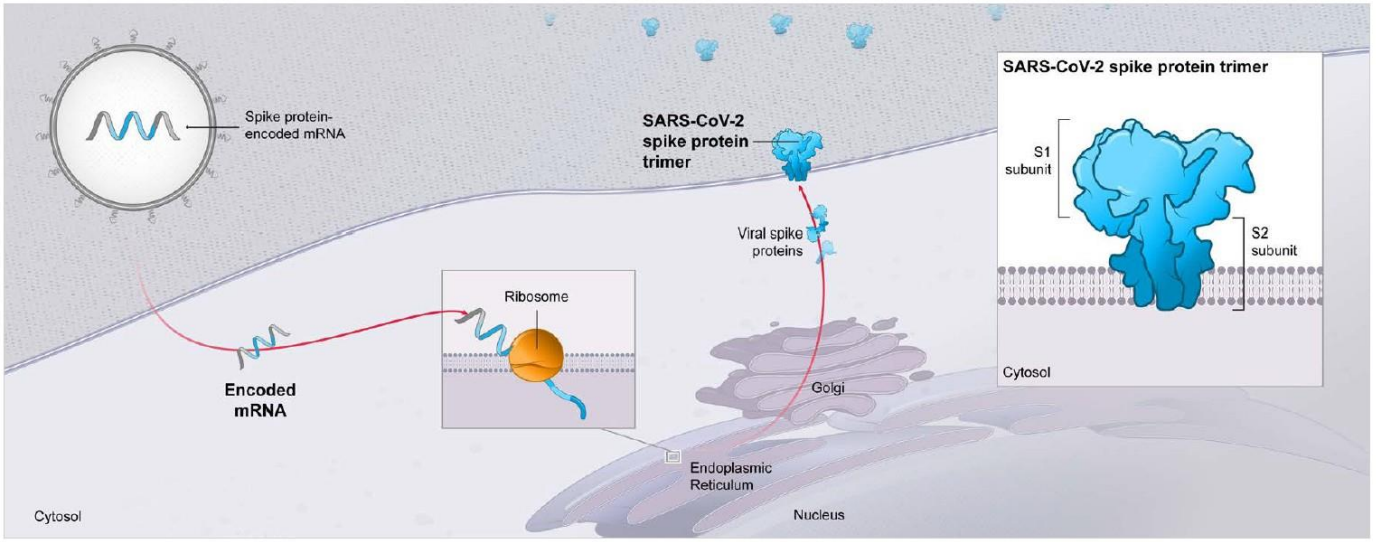
(2 shots/4weeks apart, cold storage)-done

- AstraZeneca Adenovirus, enrolled, data soon

(2 shots/ 4wks apart, easier storage, cheaper)

- Janssen Adenovirus, recently completed (1 shot)
- Novovax protein, enrolling (2 shots/ 4 wks)
- Sanofi-GSK protein, needs to be retooled

mRNA-1273 encodes for the full-length Spike Protein in the Pre-fusion Conformation (S-2P)



moderna

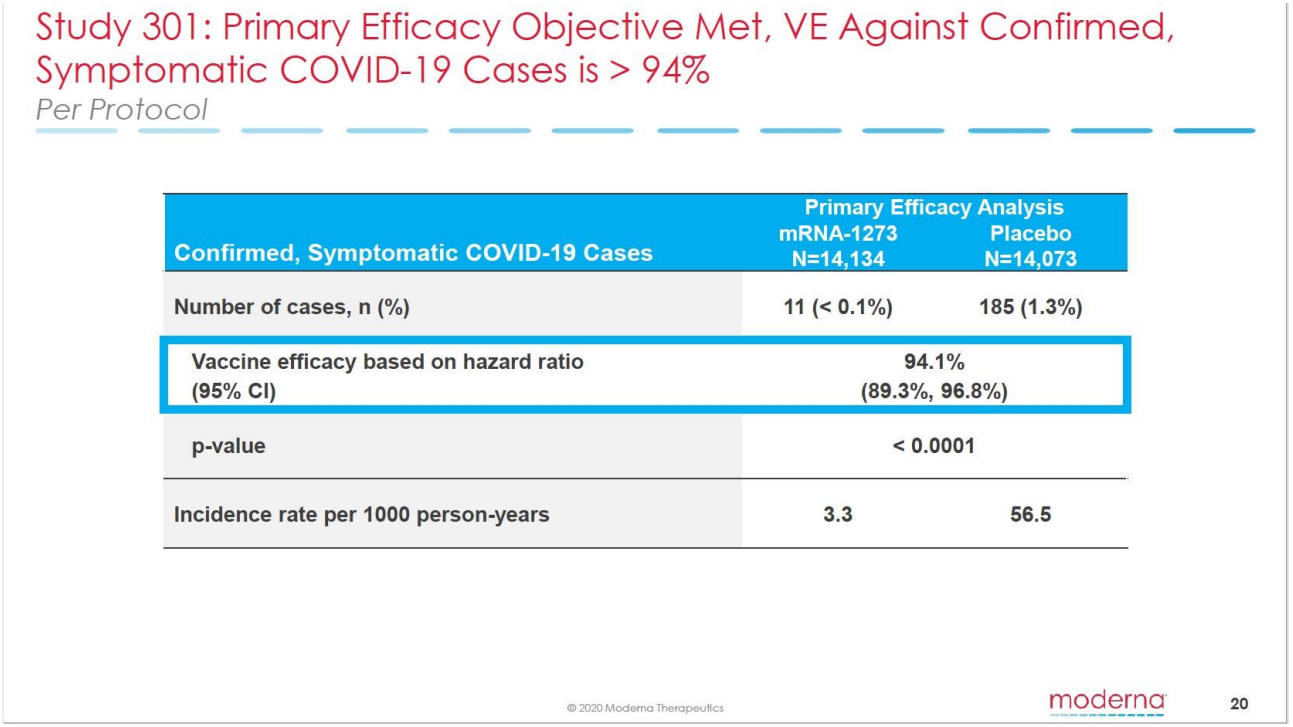
Miller, Jacqueline. Overview of Moderna's COVID-19 Vaccine(mRNA-1273). Available at: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-12/slides-12-19/02-COVID-Miller.pdf

More about the vaccine

- Pfizer clinical trials:
  - 40,000 trial participants
    - 10,000 Latinx/Hispanic
    - 3,500 African- American
    - 1,600 Asian

  - Comorbidities
    - Obesity
    - Diabetes
    - Respiratory
    - Cardiac

Phase 3 Study: Moderna COVID-19 Vaccine



Study 301: Primary Efficacy Objective Met, VE Against Confirmed, Symptomatic COVID-19 Cases is > 94%

Per Protocol

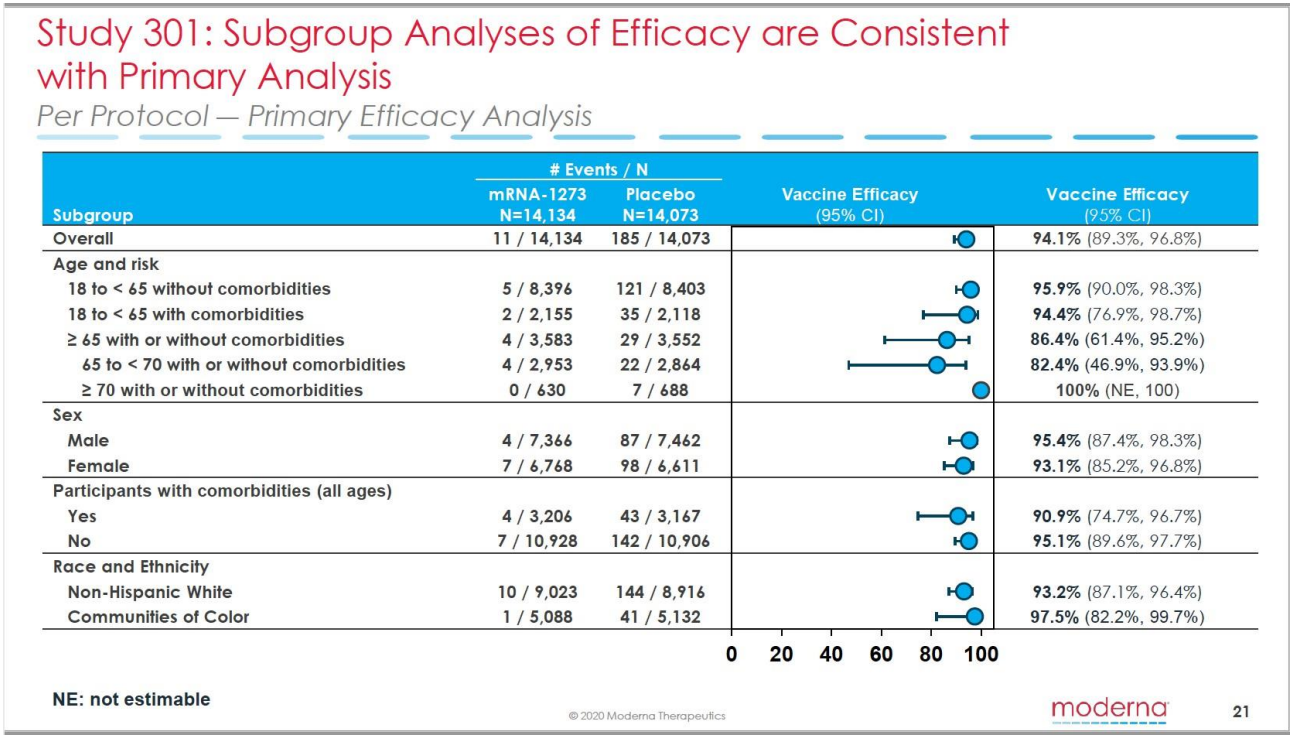
Confirmed, Symptomatic COVID-19 Cases	Primary Efficacy Analysis mRNA-1273 N=14,134	Placebo N=14,073
Number of cases, n (%)	11 (< 0.1%)	185 (1.3%)
Vaccine efficacy based on hazard ratio (95% CI)	94.1% (89.3%, 96.8%)	
p-value	< 0.0001	
Incidence rate per 1000 person-years	3.3	56.5

moderna

20

Miller, Jacqueline. Overview of Moderna's COVID-19 Vaccine(mRNA-1273). Available at: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-12/slides-12-19/02-COVID-Miller.pdf

Phase 3 Study: Moderna COVID-19 Vaccine



Study 301: Subgroup Analyses of Efficacy are Consistent with Primary Analysis

Per Protocol — Primary Efficacy Analysis

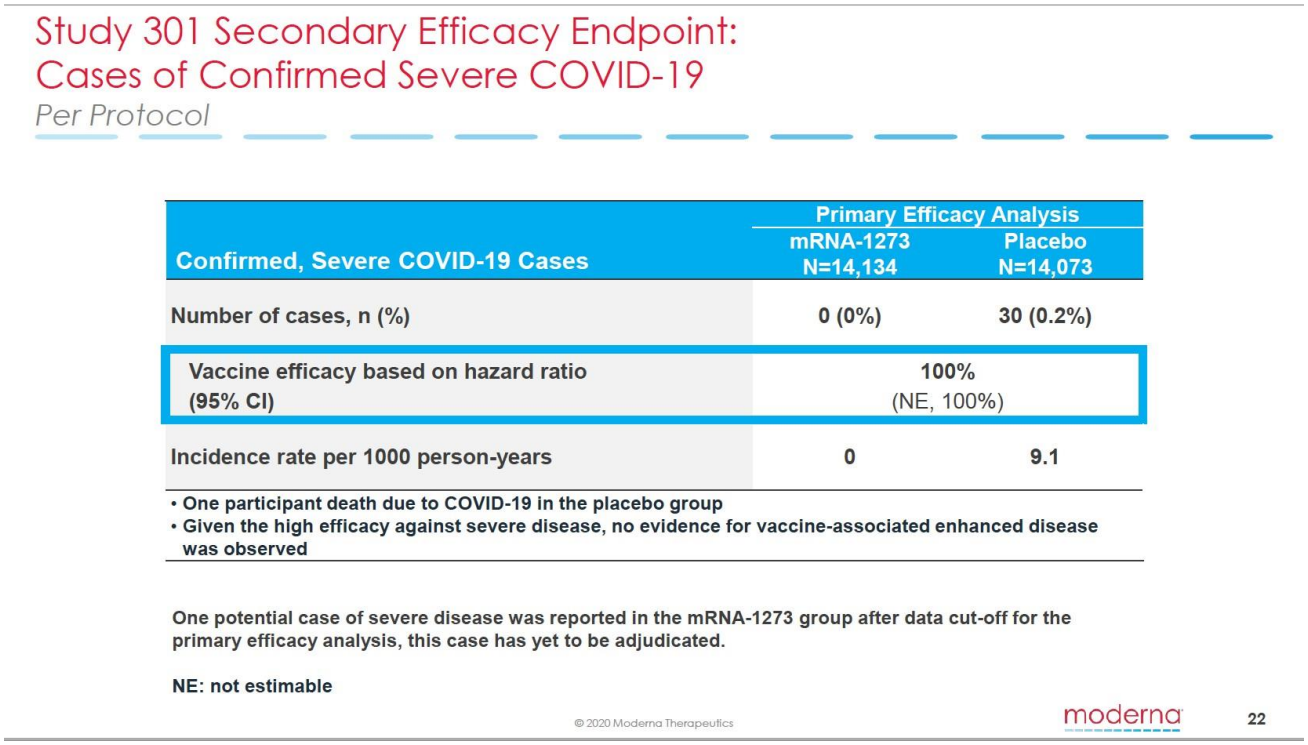
Subgroup	# Events / N mRNA-1273 N=14,134	# Events / N Placebo N=14,073	Vaccine Efficacy (95% CI)
Overall	11 / 14,134	185 / 14,073	**94.1%** (89.3%, 96.8%)
Age and risk			
18 to < 65 without comorbidities	5 / 8,396	121 / 8,403	**95.9%** (90.0%, 98.3%)
18 to < 65 with comorbidities	2 / 2,155	35 / 2,118	**94.4%** (76.9%, 98.7%)
≥ 65 with or without comorbidities	4 / 3,583	29 / 3,552	**86.4%** (61.4%, 95.2%)
65 to < 70 with or without comorbidities	4 / 2,953	22 / 2,864	**82.4%** (46.9%, 93.9%)
≥ 70 with or without comorbidities	0 / 630	7 / 688	**100%** (NE, 100)
Sex			
Male	4 / 7,366	87 / 7,462	**95.4%** (87.4%, 98.3%)
Female	7 / 6,768	98 / 6,611	**93.1%** (85.2%, 96.8%)
Participants with comorbidities (all ages)			
Yes	4 / 3,206	43 / 3,167	**90.9%** (74.7%, 96.7%)
No	7 / 10,928	142 / 10,906	**95.1%** (89.6%, 97.7%)
Race and Ethnicity			
Non-Hispanic White	10 / 9,023	144 / 8,916	**93.2%** (87.1%, 96.4%)
Communities of Color	1 / 5,088	41 / 5,132	**97.5%** (82.2%, 99.7%)

NE: not estimable

moderna

Miller, Jacqueline. Overview of Moderna's COVID-19 Vaccine(mRNA-1273). Available at: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-12/slides-12-19/02-COVID-Miller.pdf

Phase 3 Study: Moderna COVID-19 Vaccine



Study 301 Secondary Efficacy Endpoint:
Cases of Confirmed Severe COVID-19
Per Protocol

Confirmed, Severe COVID-19 Cases	Primary Efficacy Analysis mRNA-1273 N=14,134	Placebo N=14,073
Number of cases, n (%)	0 (0%)	30 (0.2%)
Vaccine efficacy based on hazard ratio (95% CI)	100% (NE, 100%)	
Incidence rate per 1000 person-years	0	9.1

- One participant death due to COVID-19 in the placebo group
- Given the high efficacy against severe disease, no evidence for vaccine-associated enhanced disease was observed

One potential case of severe disease was reported in the mRNA-1273 group after data cut-off for the primary efficacy analysis, this case has yet to be adjudicated.

NE: not estimable

moderna

Miller, Jacqueline. Overview of Moderna's COVID-19 Vaccine(mRNA-1273). Available at: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-12/slides-12-19/02-COVID-Miller.pdf

Phase 3 Study: Moderna COVID-19 Vaccine

Study 301: Summary of COVID-19 Cases Within 6 Weeks After Randomization Based on CDC Case Definition[1]

mITT Population – Interim Analysis

	mRNA-1273 N=14,550 n	Placebo N=14,598 n
From randomization to 14 days post 1st dose	5	11
From 14 days post 1st dose to 2nd dose	3	34
From 2nd dose to 14 days post 2nd dose	0	17
Total	8	62

Data suggest protection may begin prior to dose 2

[1] One clinical symptom from an expanded list and a nasopharyngeal swab positive for SARS-CoV-2 virus

moderna

Miller, Jacqueline. Overview of Moderna's COVID-19 Vaccine(mRNA-1273). Available at: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-12/slides-12-19/02-COVID-Miller.pdf

Phase 3 Study: Moderna COVID-19 Vaccine

Study 301: Summary of Asymptomatic SARS-CoV-2 Infections as Measured by Scheduled NP Swabs Prior to 2nd Dose

Per Protocol — Primary Efficacy Analysis

RT-PCR NP Swab Results	mRNA-1273 N=14,134		Placebo N=14,073	
	n	%	N	%
No documented COVID-19 symptoms between 1st dose and 2nd dose	14	0.1%	38	0.3%

Data suggestive of efficacy for prevention of asymptomatic infection

moderna

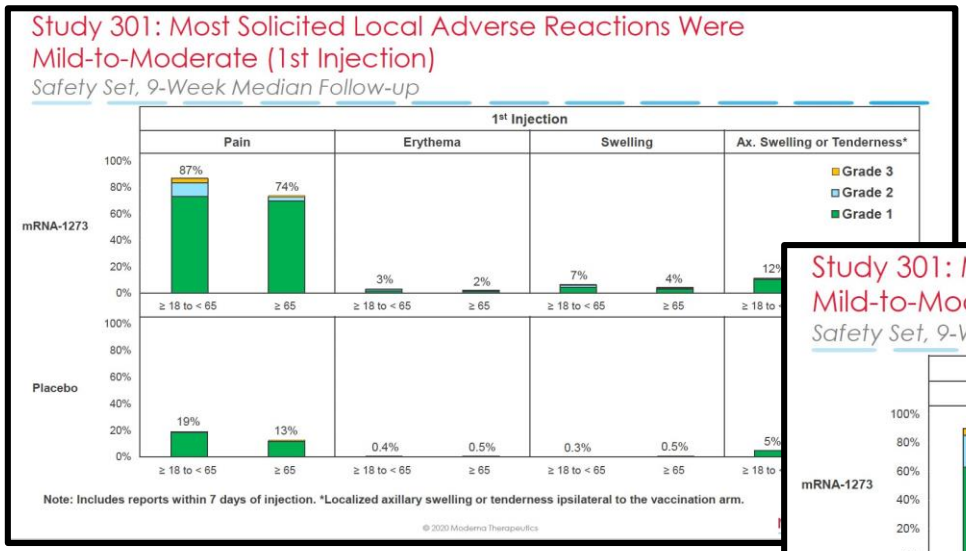
Miller, Jacqueline. Overview of Moderna's COVID-19 Vaccine(mRNA-1273). Available at: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-12/slides-12-19/02-COVID-Miller.pdf

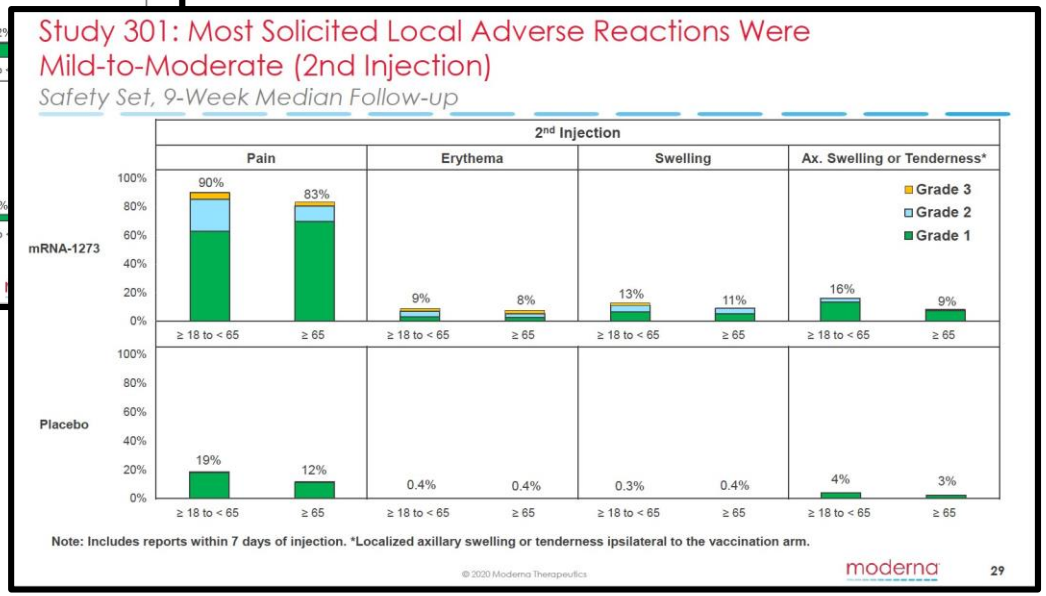
More about the vaccine

- Pfizer side effects
  - 91.6% injection site pain
  - 68.5% fatigue
  - 63.0% headache
  - 59.6% muscle pain

  - No anaphylactic or severe hypersensitivity reactions

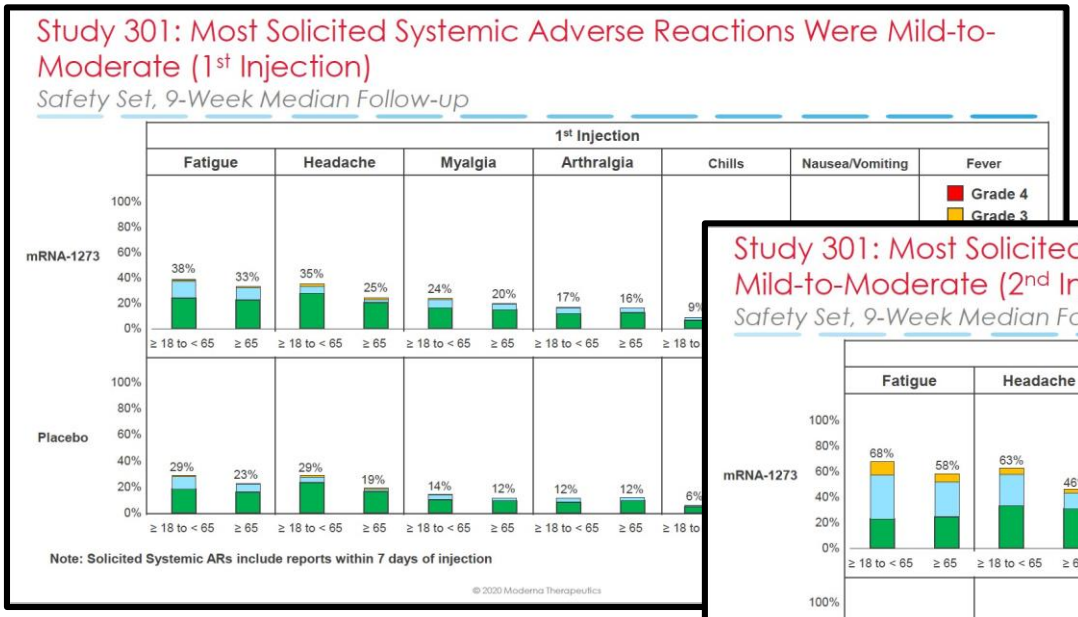
Phase 3 Study: Moderna COVID-19 Vaccine

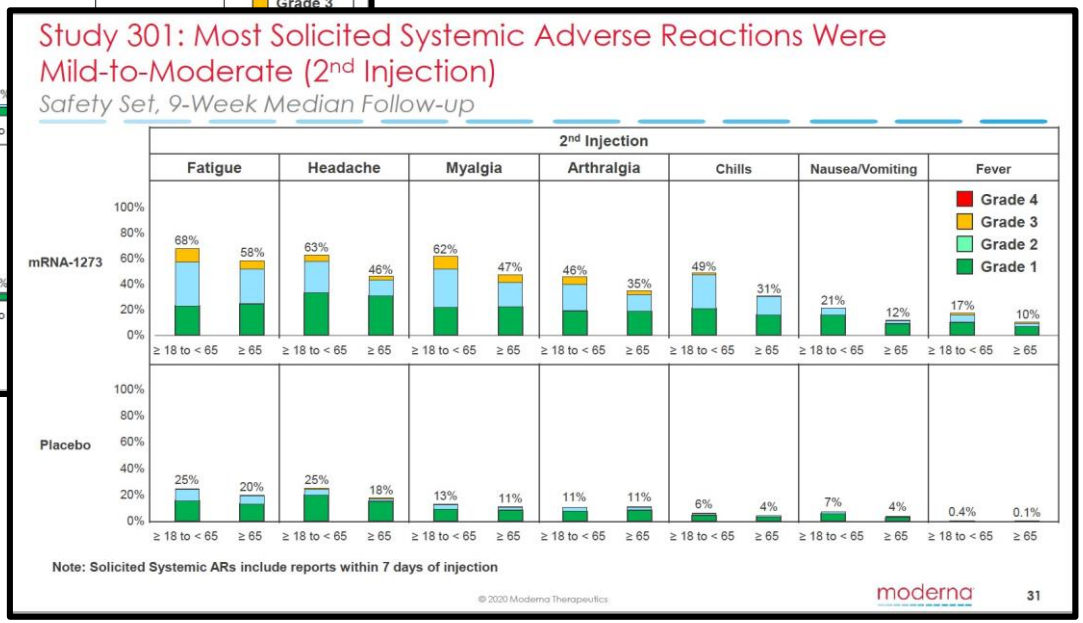




Miller, Jacqueline. Overview of Moderna's COVID-19 Vaccine(mRNA-1273). Available at: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-12/slides-12-19/02-COVID-Miller.pdf

Phase 3 Study: Moderna COVID-19 Vaccine





Miller, Jacqueline. Overview of Moderna's COVID-19 Vaccine(mRNA-1273). Available at: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-12/slides-12-19/02-COVID-Miller.pdf

Vaccine Associated Anaphylaxis

- 12/20: 6 case reports of anaphylaxis following Pfizer-BioNTech vaccine
  - One case had a history of anaphylaxis following rabies vaccination
- Overall rate now with both vaccines (1/21): 6.1/100,000
  - 89% within 30 minutes
  - 83% prior allergy
  - More common in women
  - Not sure what is the allergen, many suspect PEG

MODERNA COVID-19 VACCINE

PREGNANT PERSONS

- No data on safety
- mRNA vaccines and pregnancy
  - Not live vaccines
  - Degraded quickly by normal cellular processes and do not enter nucleus of cell
- COVID-19 and pregnancy
  - Increased risk of severe illness
  - May be increased risk of adverse pregnancy outcomes (e.g. preterm birth)
- If a person is a part of a group (e.g., HCP) recommended to receive a COVID-19 vaccine and is pregnant, the individual may choose to be vaccinated
  - Encourage informed decision making in consultation with HC provider

Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States

MODERNA COVID-19 VACCINE

BREASTFEEDING/ LACTATING PERSONS

- No data on safety in lactating women or the effects of mRNA vaccines on breastfed infant or milk production/excretion
- mRNA vaccines not considered live virus vaccines – not thought to be a risk to the breastfeeding infant
- If a lactating person is part of a group (e.g. HCP) recommended to receive a COVID-19 vaccine, they may choose to be vaccinated

Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States

COVID-19 Vaccine Trials in Children

- Pfizer enrolled age 16 and above
- Moderna - 18 and up
- So those are the FDA-approved EUA indications
- Most companies now doing efficacy studies of 12 and up either in US or Europe
- Many are planning studies for <12 years old

SARS-CoV-2 Variants

- In the United Kingdom (UK), a new variant known as 20B/501Y.V1, VOC 202012/01, or B.1.1.7 lineage emerged with a large number of mutations, some affecting the spike protein.
- This variant has since been detected in numerous countries around the world, including the US.
- In South Africa, another variant: 20C/501Y.V2 or B.1.351 lineage emerged independently, but shares some mutations with the B.1.1.7 lineage. Cases attributed to this variant have been detected outside of South Africa.
- Lab experiments suggest that vaccines should work vs. these variants, but at least one monoclonal antibody seemed less effective vs. the South African variant.
- Implications: need enhanced surveillance, continued NPI, and rapid scaling up of vaccinations.

SARS-CoV-2 Variants

Variant	Country Initially Reporting	Features
B.1.1.7		Potential Increased Transmissibility Vaccine Effects May Be Slightly Diminished Convalescent Plasma Diminished Effect Monoclonal Antibody Resistance Present
B.1.351		Potential Increased Transmissibility Vaccine Induced Antibodies May be Moderately Diminished Convalescent Plasma Diminished Effect Monoclonal Antibodies May Be Severely Diminished
P.1		Testing Pending

CDC.gov

Key Resources

- COVID-19 Vaccine Overview/Cheat Sheet on Platforms and Products
  - Pfizer
    - Patient Fact Sheet
    - Provider Fact Sheet
  - Moderna
    - Patient Fact Sheet
    - Provider Fact Sheet
- Advocates Guide to the risks, benefits, and potential opportunities and complications of expedited COVID-19 vaccine research
- Regulatory Approval Primer for Vaccine Advocates

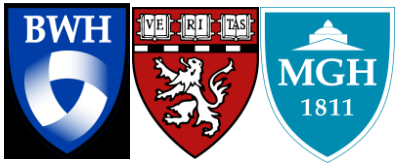
Key Resources

- *New York Times* Coronavirus Vaccine Tracker
- US FDA Guidance Document for Development and Licensure of Vaccines to Prevent COVID-19
- COVID-19 Pipeline
- COVID-19 Mythbusters
- COVID-19 Resources

- More resources at https://www.avac.org/covid

Promoting Uptake of COVID-19 Vaccines among Communities of Color in the US

Bisola Ojikutu MD MPH
Division of Global Health Equity and Division of Infectious Diseases, BWH
Infectious Disease Division, MGH



Racial and Ethnic Disparities and 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]	1.8x	0.6x	1.4x	1.7x
Hospitalization[2]	4.0x	1.2x	3.7x	4.1x
Death[3]	2.6x	1.1x	2.8x	2.8x

https://www.cdc.gov/coronavirus/2019-ncov/covid-data/investigations-discovery/hospitalization-death-by-race-ethnicity.html

Racial and Ethnic Disparities and 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]	1.8x	0.6x	1.4x	1.7x
Hospitalization[2]	4.0x	1.2x	3.7x	4.1x
Death[3]	2.6x	1.1x	2.8x	2.8x

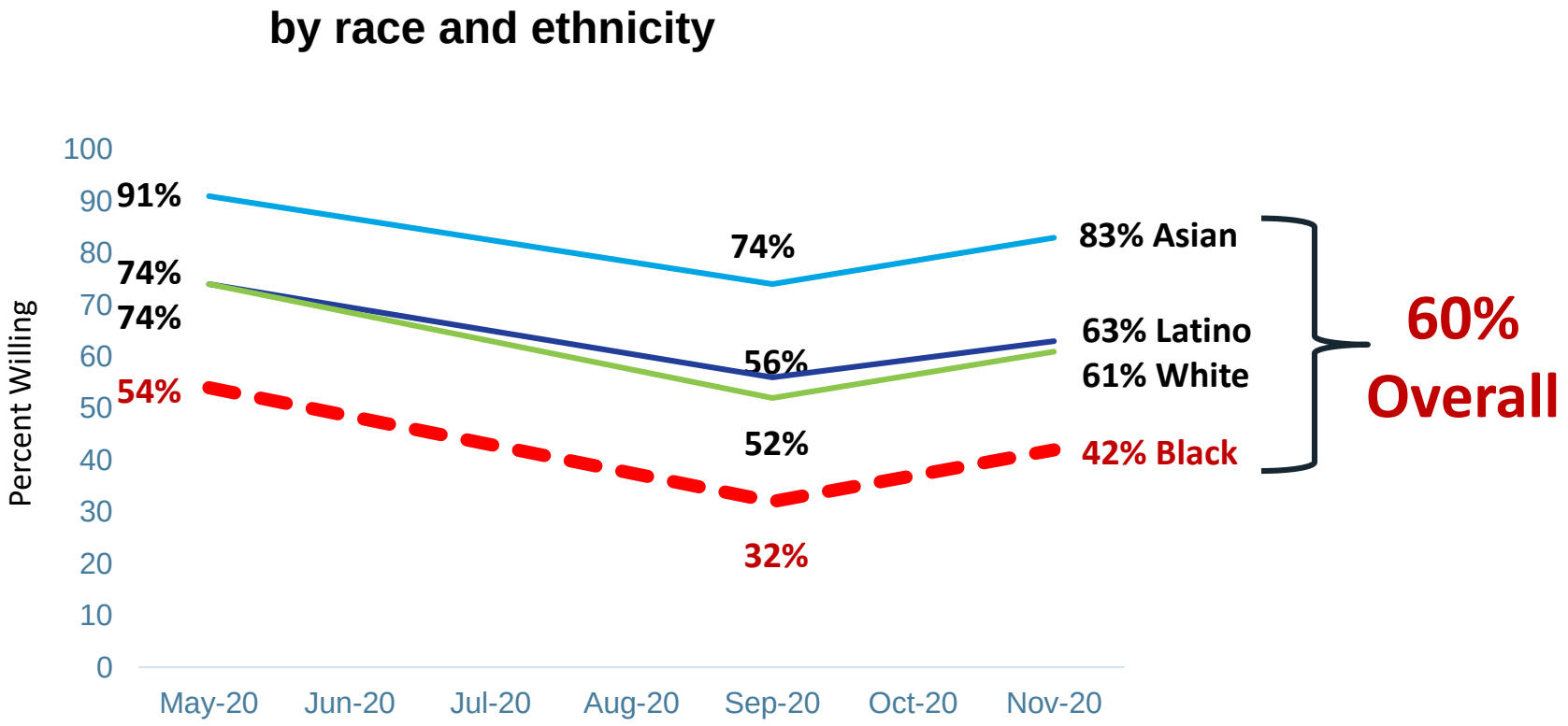
https://www.cdc.gov/coronavirus/2019-ncov/covid-data/investigations-discovery/hospitalization-death-by-race-ethnicity.html

Racial and Ethnic Disparities and 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]	1.8x	0.6x	1.4x	1.7x
Hospitalization[2]	4.0x	1.2x	3.7x	4.1x
Death[3]	2.6x	1.1x	2.8x	2.8x

https://www.cdc.gov/coronavirus/2019-ncov/covid-data/investigations-discovery/hospitalization-death-by-race-ethnicity.html

Willingness to Take a COVID-19 Vaccine



https://www.pewresearch.org/science/2020/12/03/intent-to-get-a-covid-19-vaccine-rises-to-60-as-confidence-in-research-and-development-process-increases/

Suboptimal Vaccine Uptake by Race and Ethnicity

	Overall	White	Black	Latinx	Indigenous
Seasonal Influenza Vaccination (≥18)	**49%**	**53%**	**41%**	**38%**	**42%**

CDC. Influenza Vaccination Coverage, 2019-2020

Suboptimal Vaccine Uptake by Race and Ethnicity

	Overall	White	Black	Latinx	Indigenous
Seasonal Influenza Vaccination (≥18)	49%	53%	41%	38%	42%
Pneumococcal Vaccination (≥65)	72%	75%	60%	60%	

CDC. Influenza Vaccination Coverage, 2019-2020; CDC. Pneumococcal Vaccination Coverage, 2018

Vaccine Confidence

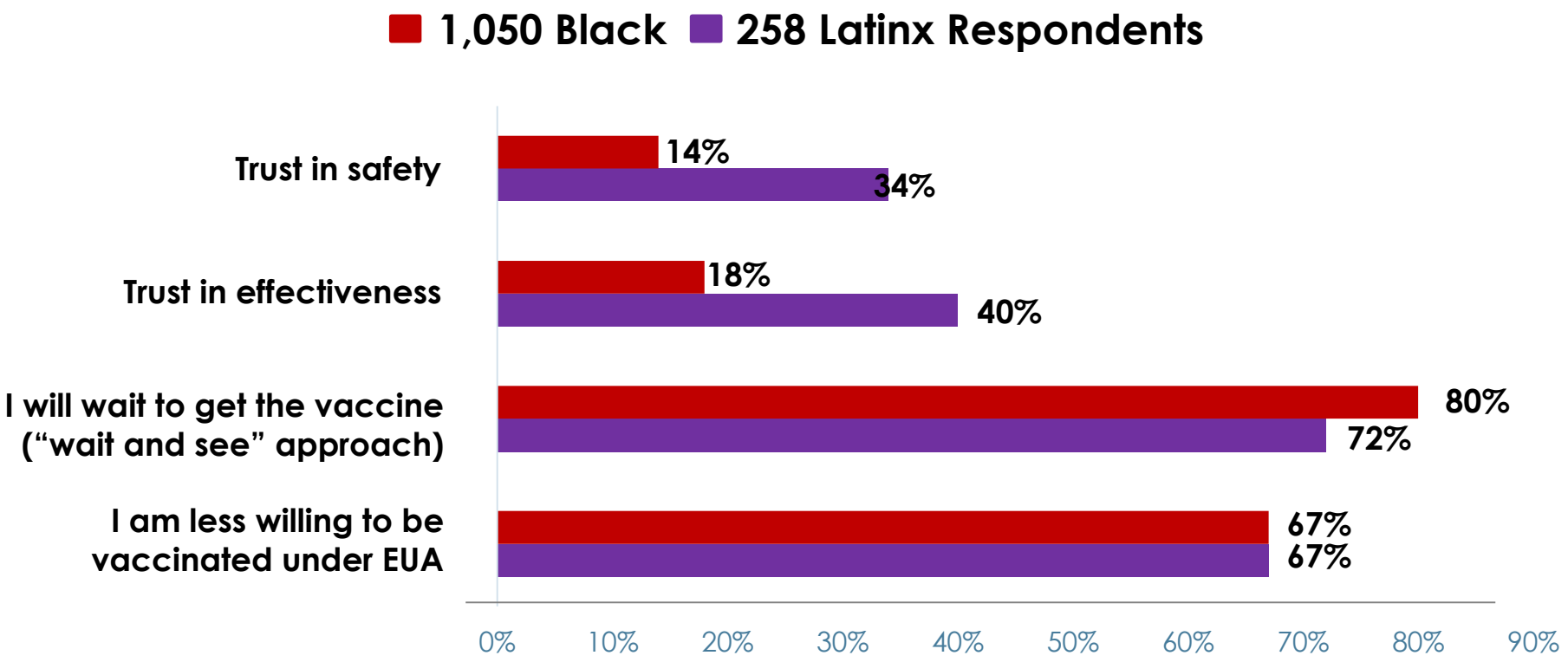
Value

Access
Affordability
Availability

Trust
Effectiveness
Safety
Reliability &
Competence of the
Health System
Motivations of
policymakers

Osterholm MT. *Lancet Infect Dis.* 2012; Quinn SC et al. *Vaccine*. 2019

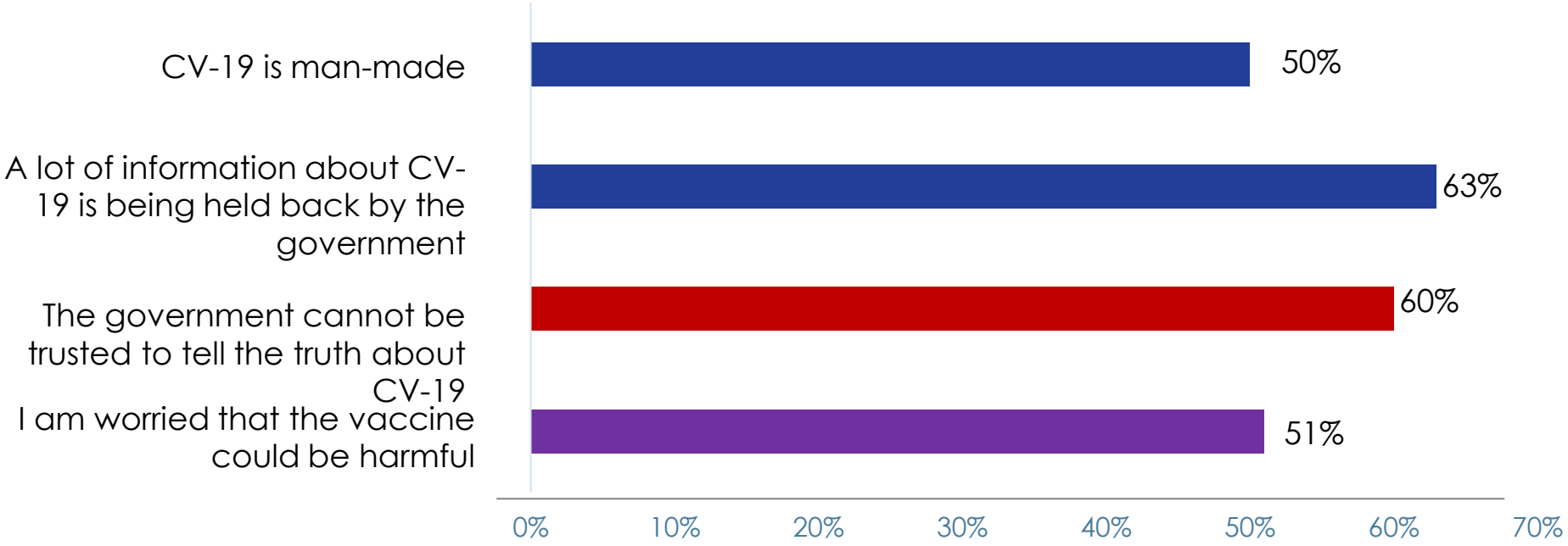
COVID Collaborative Survey Vaccine Confidence



https://www.langerresearch.com/category/our-impact/; https://www.covidcollaborative.us/

COVID-19 Mistrust

Black Adults (90% MSM) living with HIV in Los Angeles County, CA



Note: 97% agreed with at least one mistrust belief (of 10 items)

JAIDS, 2020

How does medical mistrust affect COVID-19 outcomes?

- ✓ Less adherence to preventive measures (social distancing, mask wearing)
- ✓ Lower acceptability of COVID-19 treatment
- ✓ Lower COVID-19 vaccine confidence

JAIDS, 2020

Mistrust

Healthcare

Providers

Research

Absence of trust that providers/organizations/researchers genuinely care for patients', participants' or their communities' interests, are honest, and transparent

Roots of Mistrust

"Historical and Contemporary Structural Inequity Drives Mistrust"

- Baseline inequity
- Limited access to high quality care
- Adverse environmental exposures
- More illness, worse outcomes, premature deaths
- Stigma, homophobia, xenophobia
- Rational and normal response to adverse circumstances


Transparency
Clear Messages
Trusted Messengers
Community Collaboration & Investment
Equitable Access
Inclusion of Diverse Populations
Trust & Trustworthiness

HEALTH

'Like watching a train wreck': Experts say America is behind on COVID-19 vaccine messaging, call for honest, straight talk

Elizabeth Weise USA TODAY

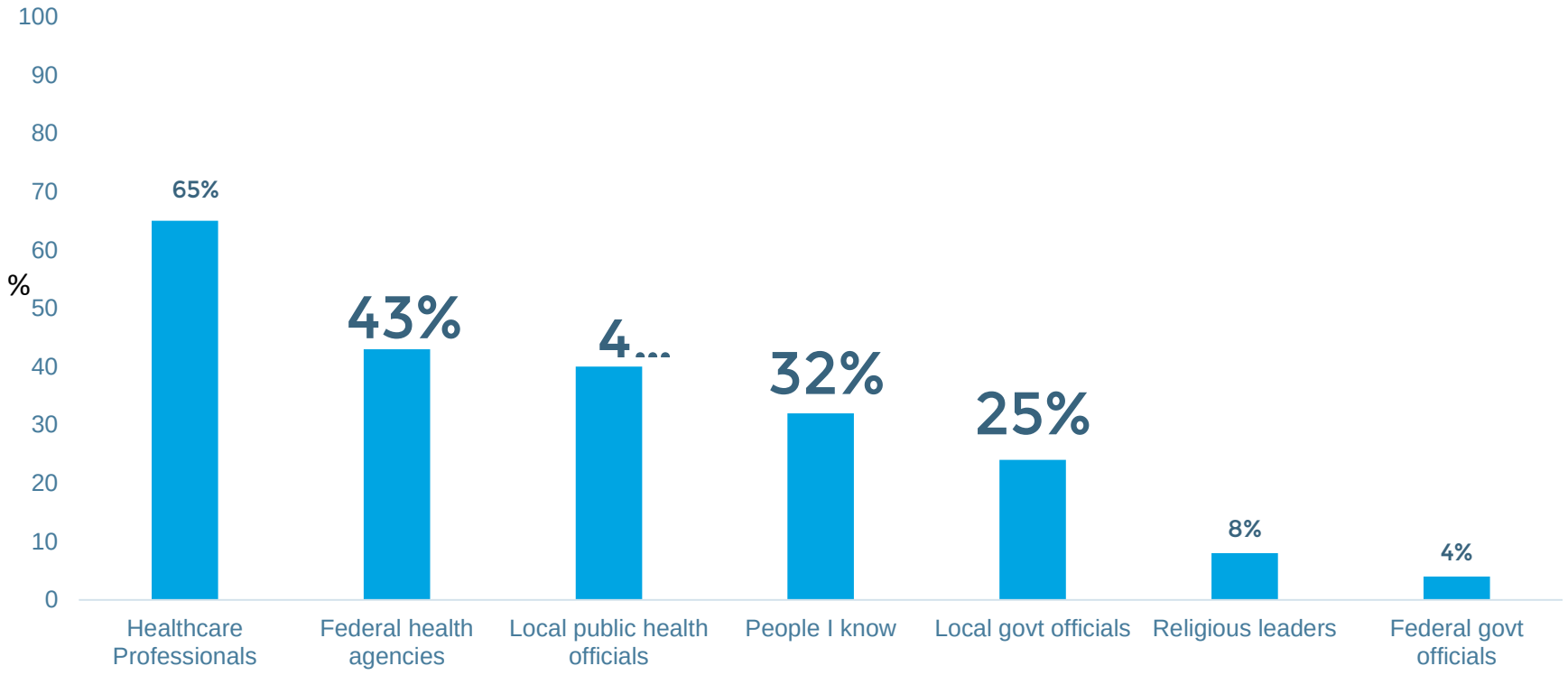
Published 6:00 a.m. ET Nov. 10, 2020 | **Updated 9:47 a.m. ET Nov. 10, 2020**

Potential Messaging Themes:

- Acknowledge systemic inequity and racism as a root causes of mistrust
- Transparency regarding the known and the unknown
- Clearly communicate risks and the unknown
- Social responsibility
- Responsibility to family
- Reframe vaccination as a form of empowerment
- Emphasize choice

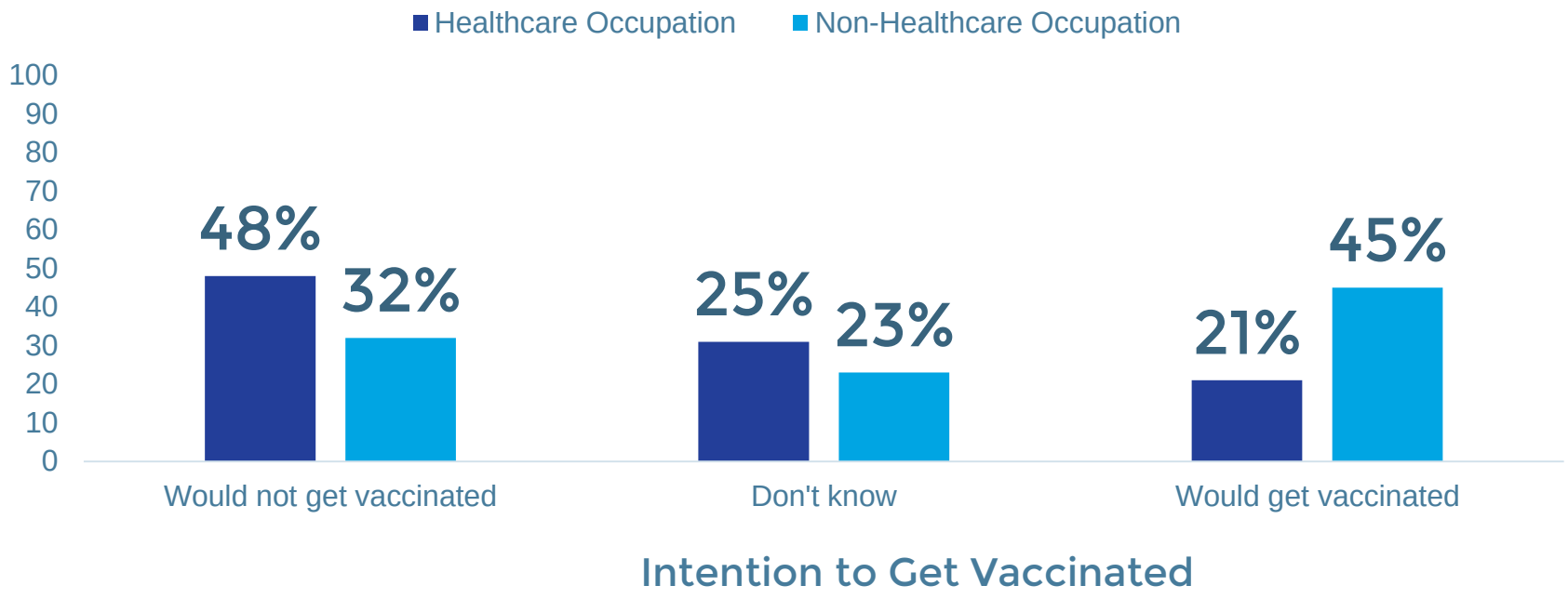
Healthcare Providers are the Most Trusted Source

for
COVID-19 Vaccine Information
(207 Black/African-American Individuals)



Bogart LM, Ojikutu BO, Dong L. RAND Stakeholder Partnership

Vaccine Confidence among Black Individuals
Healthcare Providers vs. Other Professions



Bogart LM, Ojikutu BO, Dong L. RAND Stakeholder Partnership

Racism in healthcare settings were associated with higher vaccine hesitancy

	% Agree / Strongly Agree
Within the healthcare system, people from my racial/ethnic group are treated differently than people from other groups	63%
When it comes to COVID-19, Black people won't receive the same medical care from healthcare providers as people from other groups	64%

Bogart LM, Ojikutu BO, Dong L. RAND Stakeholder Partnership

Community Investment and Engagement

Financial Investment: Government and Industry

Community Engagement & Investment

Research Investment

AJPH, December 2020

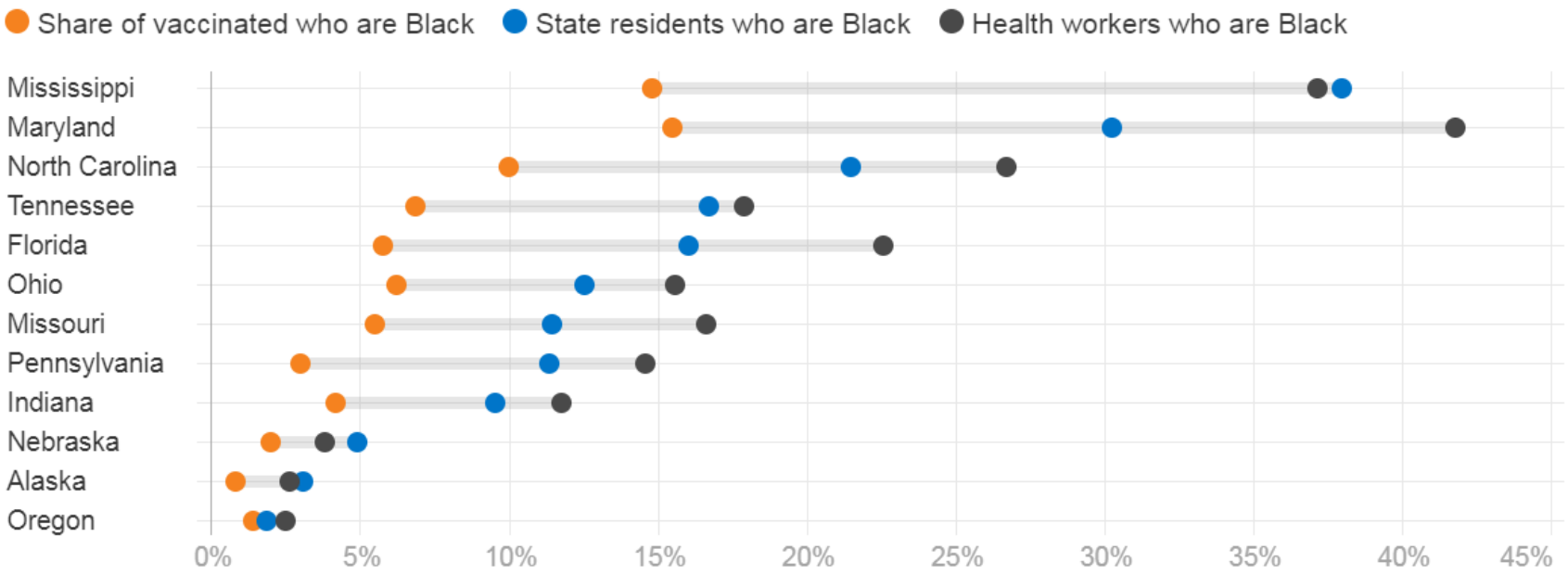
Selected Investment Strategies to Support Diversity and Engagement in Research (Build Trust)

Invest in Community Based-Organizations and Institutions	• Provide in-kind resources including technical expertise, mentoring, clinical and non-clinical resources to help to strengthen and build capacity in community organizations
Invest in Building Trust	• Require government/industry establish contracts with minority-owned businesses in proportion to the public dollars invested
Invest in Future Research Leadership	• Increase funding to support the development of careers of racial and ethnic minority investigators • Support programming to increase community research literacy

AJPH, December 2020

Black Americans Significantly Trail in Covid Vaccinations

The percentage of those vaccinated who are Black is far lower than their share of both the general population and the health care workforce. Most people who have been vaccinated are health workers.



NOTE: The 12 states shown are those that report race separately from ethnicity; four other states with incomparable data were excluded. Covid vaccinations for which the race of the recipient is unknown were excluded.

CREDIT: Hannah Recht/KHN

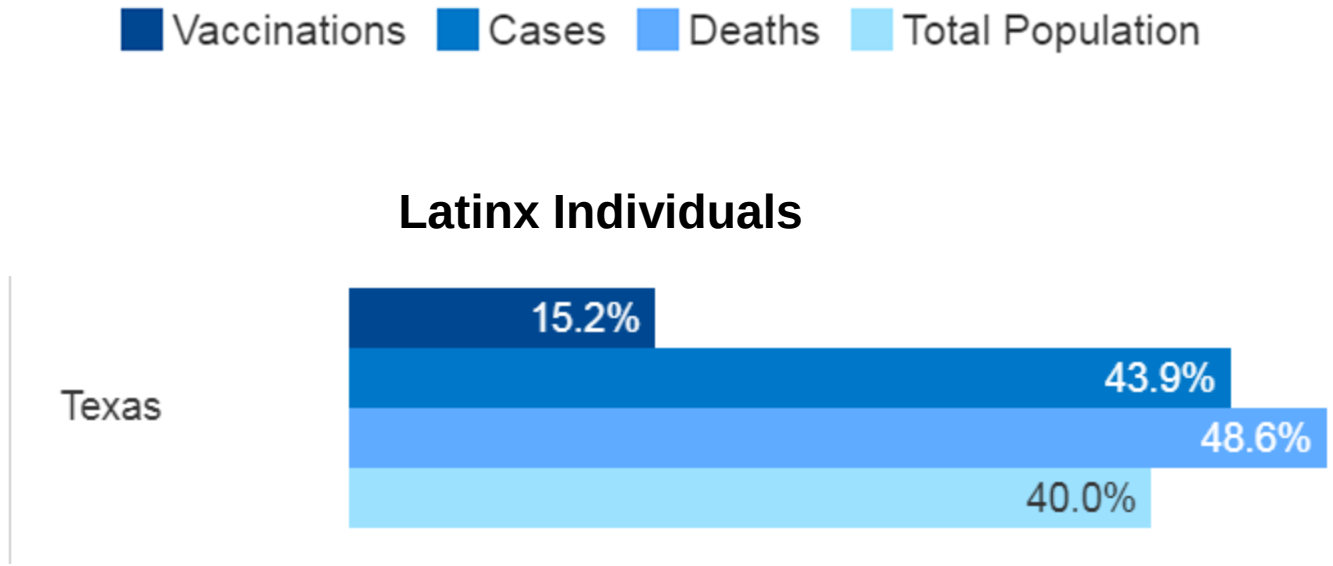
SOURCE: Data from state health departments as of Jan. 14, 2021; American Community Survey 2019; Integrated Public Use Microdata Series • Download PNG

KHN

Early State Vaccination Data Raise Warning Flags for Racial Equity

Nambi Ndugga, Olivia Pham, Latoya Hill, Samantha Artiga, and Salem Mengistu

Jan 21, 2021



Achieving COVID-19 Vaccine Equity

1. Prioritize (open sites in) the hardest hit neighborhoods
2. *Prioritize the people in those neighborhoods*
3. Collect and release good data
4. Simplify access
5. Utilize resources that are already in the highly impacted communities
6. Build long term capacity and sustainable infrastructure
7. Create partnerships with communities
8. **Communities should be leading the way**

Recommendations for Providers

- Respond to patient concerns in an understanding manner, while conveying accurate information
    - Validate mistrust and skepticism
    - Be non-judgmental and non-confrontational
    - Ask open-ended questions
    - Use reflection/reflective listening

Recommendations for Providers: Motivational Interviewing

- Open communication
  - Show you care about them holistically
  - Fully hear their concerns
- Reflect/roll with resistance: Leave room for patients to state concerns in their own words (why they do not want to do something), and reflect their concerns back to them
  - Hold back your "righting reflex"
  - Give them accurate information about the vaccines
  - **Then allow patients to make their own decision**

Conclusions

- Low COVID-19 vaccine confidence within communities of color is rooted in structural racism and systemic inequity
- To address low vaccine confidence no one approach is most effective; a multi-faceted strategy tailored to specific communities is needed
- COVID-19 vaccine distribution must be focused on equity
- If we hope to promote sustainable change, communities that are most impacted must lead the way

NATIONAL LGBTQIA+ HEALTH EDUCATION CENTER

A PROGRAM OF THE FENWAY INSTITUTE

The National LGBTQIA+ Health Education Center provides educational programs, resources, and consultation to health care organizations with the goal of optimizing quality, cost-effective health care for lesbian, gay, bisexual, transgender, queer, intersex, asexual, and all sexual and gender minority (LGBTQIA+) people.

The Education Center is part of The Fenway Institute, the research, training, and health policy division of Fenway Health, a Federally Qualified Health Center, and one of the world's largest LGBTQIA+ focused health centers.

☎ 617.927.6354

✉ education@fenwayhealth.org

www.lgbtqiahealtheducation.org

www.acponline.org/fenway

TRANSTALKS

TRANSGENDER TRAINING FOR HEALTHCARE PROVIDERS