

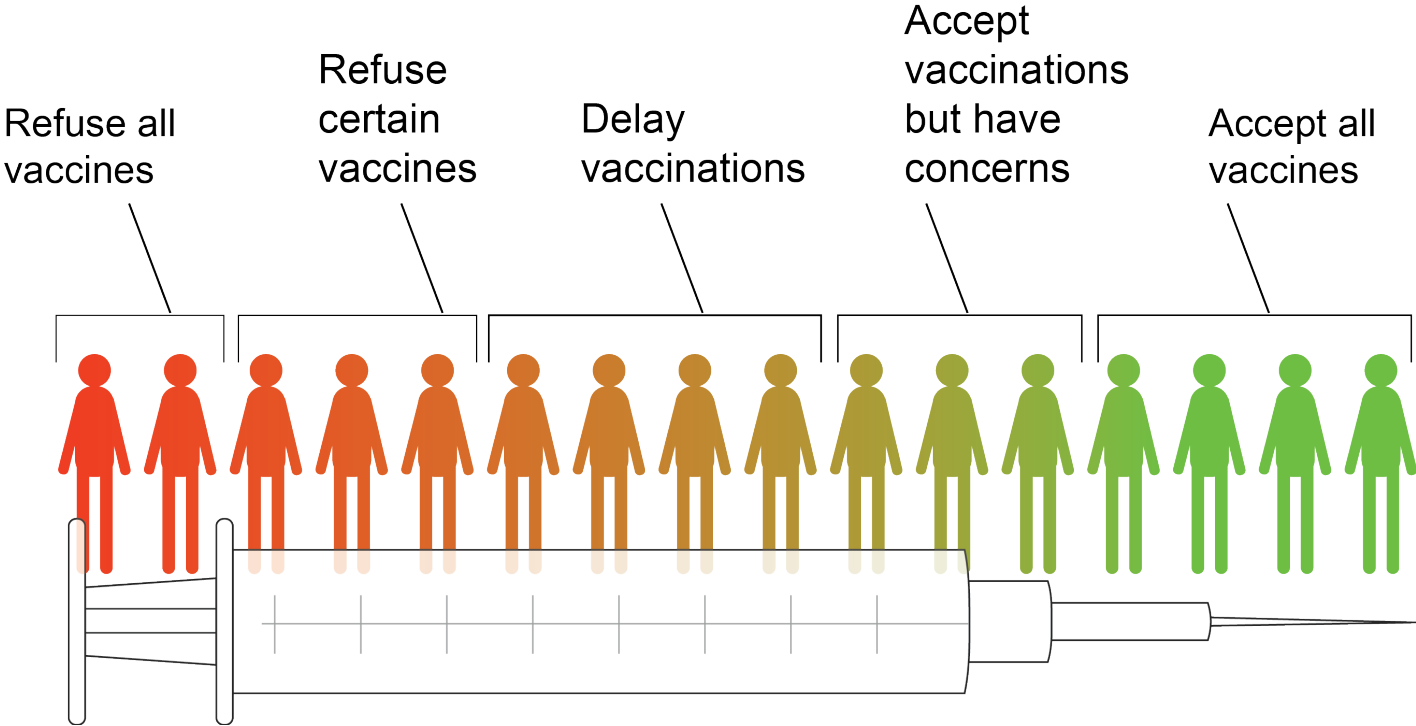


What does equitable inclusion have to do with addressing vaccine hesitancy?

Aisha T. Langford, PhD, MPH
Assistant Professor of Population Health
Co-Director, CTSI Recruitment and Retention Core
aisha.langford@nyulangone.org

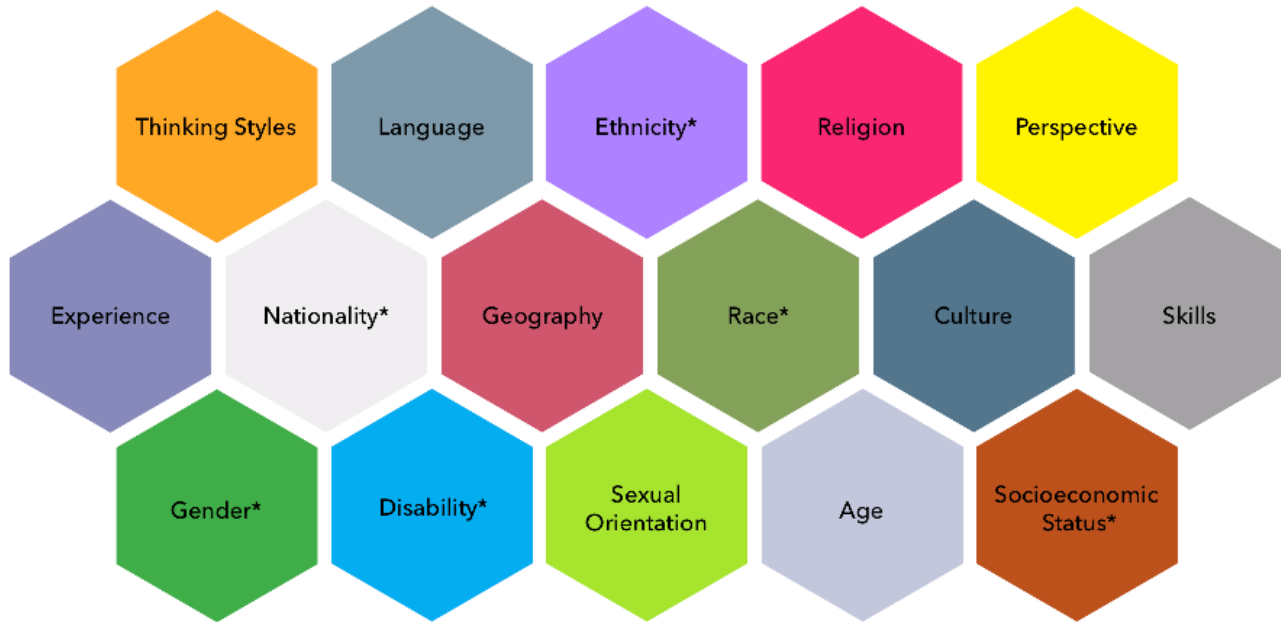


Continuum of Vaccine Acceptance



Conceptualizing diversity, equity, & inclusion in clinical trials and health research

Many Types of Diversity



- A diversity of perspectives and lived experiences is fundamental to achieving research and training excellence.

Equity: One (of many) definitions

- The removal of systemic barriers and biases enabling all individuals to have equal opportunity to access and benefit from the program.

Inclusion: One (of many) definitions

- The practice of ensuring that all individuals are valued and respected for their contributions and are equally supported.

<https://www.sshrc-crsh.gc.ca/funding-financement/nfrf-fnfr/edi-eng.aspx#3>, accessed 10/8/2021

My Participation in Pfizer's Phase 1 COVID Vaccine Clinical Trial

Study #: S20-00515
Version date: 05/20/2020

Page 1 of 20



Research Subject Informed Consent Form (Stage 1)

Title of Study: A Phase 1/2, Placebo-Controlled, Randomized, Observer-Blind, Dose-Finding Study to Describe the Safety, Tolerability, Immunogenicity, and Potential Efficacy of SARS-CoV-2-RNA Vaccine Candidates Against COVID-19 in Healthy Adults S20-00515

Principal Investigator: Mark J. Mulligan, MD
Division of Infectious Diseases and Immunology
430 E. 29th Street, 3rd Floor
New York, NY 10016
212-263-5182

Emergency Contact: Mark J. Mulligan, MD
646-799-0778

1. About volunteering for this research study

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.



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RESEARCH, PATIENT CARE, TRANSLATIONAL MEDICINE | NYU LANGONE HEALTH NEWS, NYU LANGONE HEALTH NEWS SUMMER 2021

'I Was One of the First People in the World to Get the Pfizer Vaccine. Here's What I've Learned'



With a master's degree in epidemiology and behavioral science and a doctorate in health education and health behavior, Dr. Aisha Langford has long championed public health. PHOTO: TONY LUONG

RELATED TOPICS:

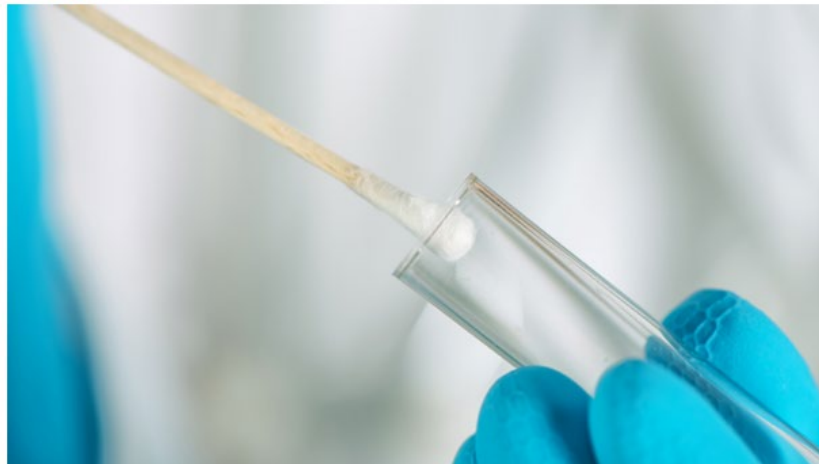
COVID-19 | CLINICAL TRIALS | ACCESS TO CARE | RESEARCHERS | ETHICS

Clinical Trials For COVID-19: Populations Most Vulnerable To COVID-19 Must Be Included

Aisha T. Langford, Alison Bateman-House

JUNE 12, 2020

10.1377/hblog20200609.555007

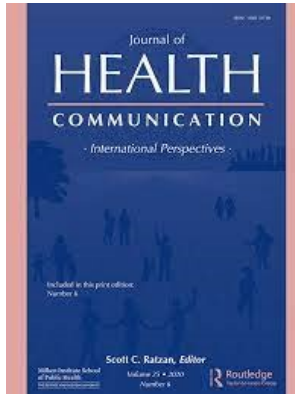


Strategies to Enhance Inclusion of Vulnerable Groups in COVID-19 Trials



- Pay attention to inclusion and exclusion criteria
- Ensure that people are aware of and explicitly invited to participate when eligible
- Conduct trials where people live or get their care
- Minimize participation burden

<https://www.healthaffairs.org/doi/10.1377/hblog20200609.555007/full/>, Accessed 10/16/2020



Journal of Health Communication >

International Perspectives

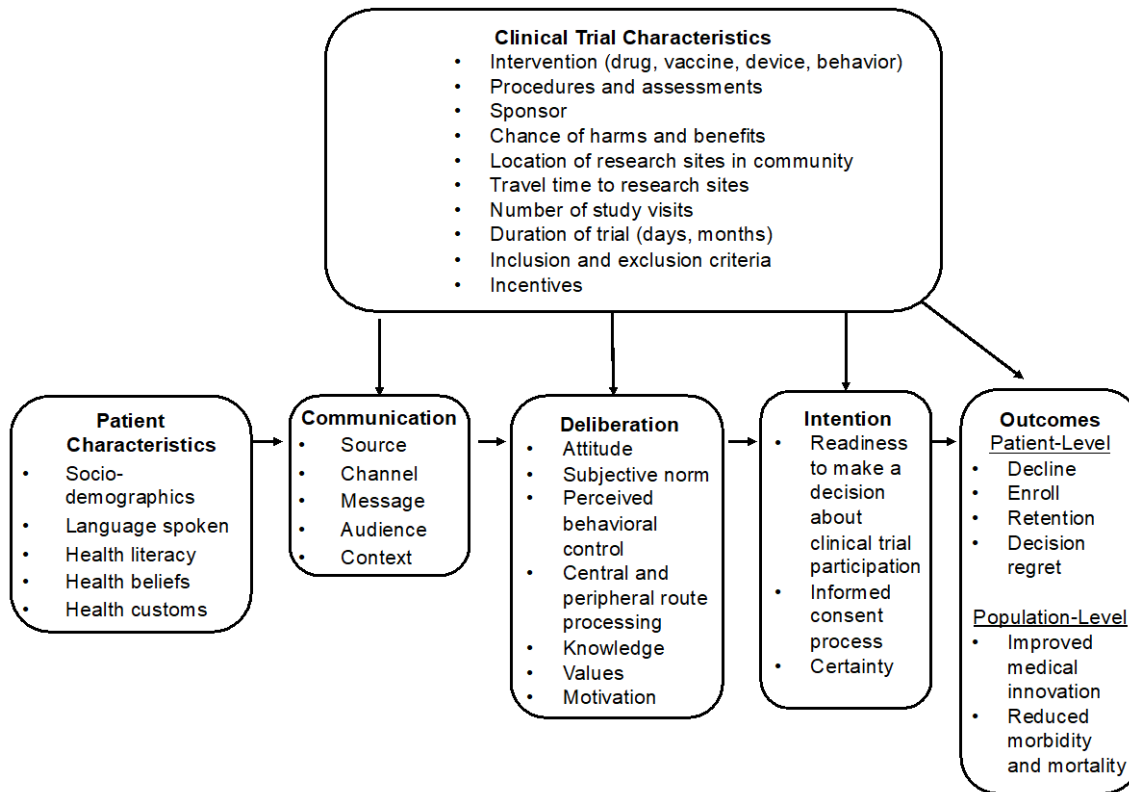
Volume 25, 2020 - Issue 10: Vaccine Communication in a Pandemic: Improving Vaccine Literacy to Reduce Hesitancy, Restore Trust and Immunize Communities

Health Communication and Decision Making about Vaccine Clinical Trials during a Pandemic

Aisha T. Langford  

Pages 780-789 | Published online: 13 Mar 2021

General Model of Clinical Trial Participation: Health Communication and Decision Making Considerations



The ASK Approach to Enhancing Clinical Trial Participation

A	Assume that all patients will want to know their options.
S	Seek the counsel of stakeholders.
K	Know your numbers.

Langford AT (2021). Health communication and decision making about vaccine clinical trials during a pandemic. *Journal of Health Communication*. doi: 10.1080/10810730.2020.1864520.

Stakeholders may include, but not limited to:

- Researchers
- Patients
- Caregivers
- Community health workers
- Community-based organizations
- Faith-based organizations
- Internal clinicians
- External referring clinicians
- Administrators
- Communication and marketing professionals
- Health information technology professionals
- Institutional review board professionals
- Pharmaceutical companies
- Media partners
- Policymakers

Lessons Learned and Emerging Questions

- Managing expectations
- Challenging assumptions
- Validating emotions and concerns
- Consistent, yet adaptive messaging
- Health literacy
- Combating misinformation
- Acknowledging uncertainty

Inclusive Vaccine Trials Are Vital, But Let's Not Boost Biological Views of Race



A registered nurse prepares a shot of the Moderna vaccine at East Boston Neighborhood Health Center in Boston, Massachusetts, on December 21, 2020.

JESSICA RINALDI / THE BOSTON GLOBE VIA GETTY IMAGES

December 27, 2020

By Jill A. Fisher, PhD
Professor of social
medicine in the Center
for Bioethics at the
University of North
Carolina at Chapel Hill

<https://truthout.org/articles/inclusive-vaccine-trials-are-vital-but-lets-not-boost-biological-views-of-race/>,

Accessed 10/8/21

Challenging Assumptions

HEALTH AND SCIENCE

Early coronavirus drug trials tested vaccines mostly on White people; next phase aims for diversity

PUBLISHED FRI, JUL 31 2020-10:40 AM EDT | UPDATED THU, AUG 6 2020-11:04 AM EDT



Meg Tirrell
@MEGTIRRELL

Berkeley Lovelace Jr.
@BERKELEYJR

Harriet Taylor
@HARRIST

Asking is the first step

Goler Blount, of the Black Women's Health Imperative, said plans for inclusion are the first step.

"The No. 1 reason Black people and Brown people don't participate in clinical trials is because nobody asks them," she said.

That can be because health providers "make certain assumptions about what patients will and will not do: They won't comply. They don't have the money," Goler Blount said. "So they don't ask."

<https://www.cnbc.com/2020/07/31/early-coronavirus-drug-trials-tested-vaccines-mostly-on-white-people-next-phase-aims-for-diversity.html>, Accessed 3/9/21



Contemporary Clinical Trials Communications

Volume 15, September 2019, 100424



Research paper

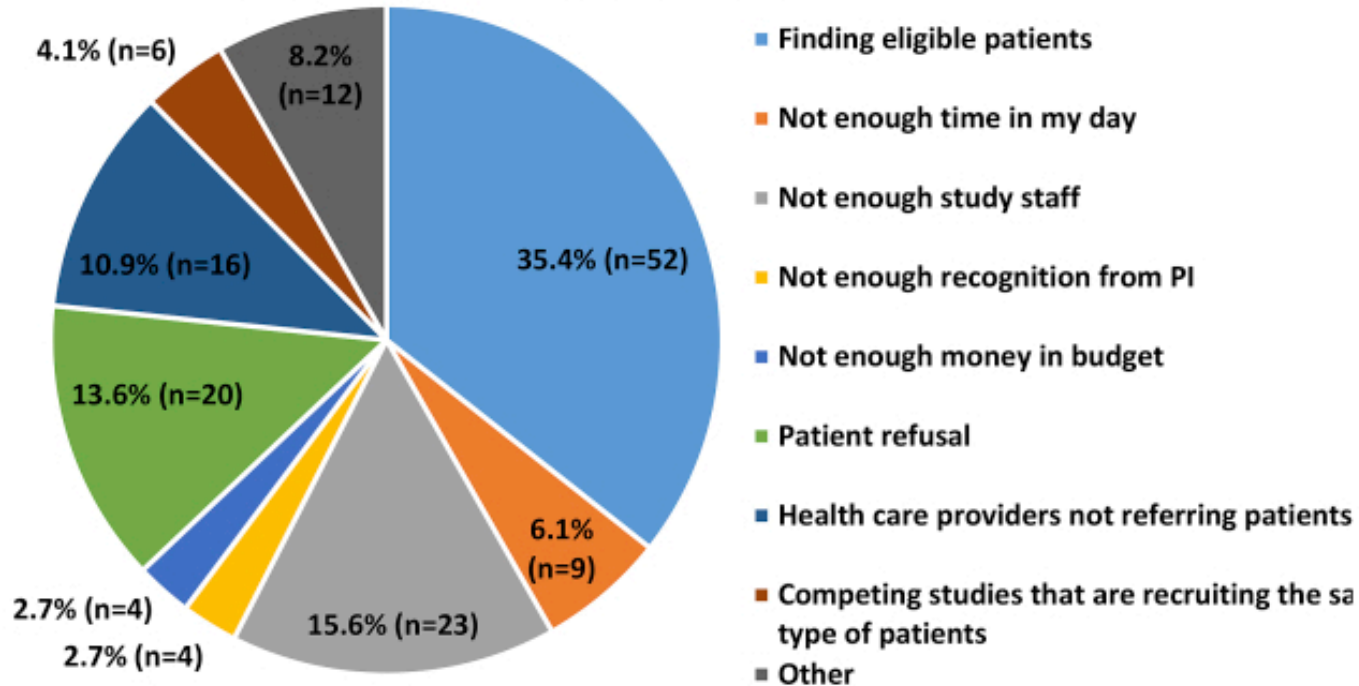
Knowledge and use of recruitment support tools among study coordinators at an academic medical center: The Novel Approaches to Recruitment Planning Study

Ebony Scott ^a  , Bryan McComb ^a , Howard Trachtman ^a , Lois Mannon ^a , Peri Rosenfeld ^b , Rachel Thornton ^a , Nassira Bougrab ^a , Scott Sherman ^{a, c} , Aisha Langford ^a 

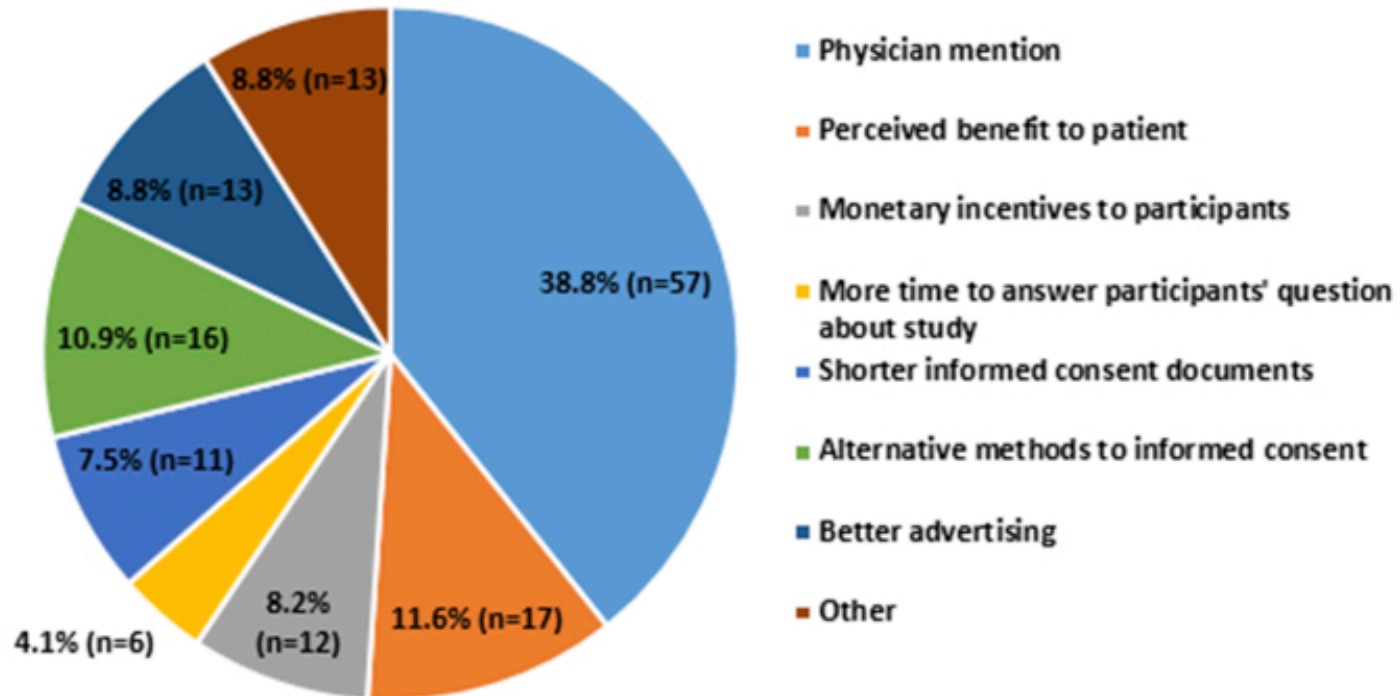
Background & Methods

- Study coordinators play an essential role on study teams; however, there remains a paucity of research on the supports and services they need to effectively recruit and retain study participants.
- A cross-sectional survey was conducted with 147 study coordinators from NYU Langone Health

Number One Barrier to Recruitment



What would make Recruitment Easier?



Additional Results

- Significant associations were found between anxiety about reaching target enrollment numbers and whether the study coordinator was the primary person responsible for developing a recruitment strategy.
- 3 years or more serving as a study coordinator and levels of anxiety for reaching enrollment numbers was also significant.

Conclusion

“More institutional level supports and formal training opportunities are needed to enhance study coordinators’ effectiveness to recruit participants.”

Group Question: How would you ensure that all eligible participants were invited to consider clinical trials?



Group Question: How would you ensure that all eligible participants reasonably understood what they were being asked to do?





THANK YOU

aisha.langford@nyulangone.org

