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

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Continuum of Vaccine Acceptance

- Refuse all vaccines
- Refuse certain vaccines
- Delay vaccinations
- Accept vaccinations but have concerns
- Accept all vaccines
Conceptualizing diversity, equity, & inclusion in clinical trials and health research
Many Types of Diversity

- Thinking Styles
- Language
- Ethnicity*
- Religion
- Perspective
- Experience
- Nationality*
- Geography
- Race*
- Culture
- Skills
- Gender*
- Disability*
- Sexual Orientation
- Age
- Socioeconomic Status*

• 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.

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

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  
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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.
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

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

Aisha T. Langford
General Model of Clinical Trial Participation: Health Communication and Decision Making Considerations

Clinical Trial Characteristics
- Intervention (drug, vaccine, device, behavior)
- Procedures and assessments
- Sponsor
- Chance of harms and benefits
- Location of research sites in community
- Travel time to research sites
- Number of study visits
- Duration of trial (days, months)
- Inclusion and exclusion criteria
- Incentives

Patient Characteristics
- Socio-demographics
- Language spoken
- Health literacy
- Health beliefs
- Health customs

Communication
- Source
- Channel
- Message
- Audience
- Context

Deliberation
- Attitude
- Subjective norm
- Perceived behavioral control
- Central and peripheral route processing
- Knowledge
- Values
- Motivation

Intention
- Readiness to make a decision about clinical trial participation
- Informed consent process
- Certainty

Outcomes
- Patient-Level
  - Decline
  - Enroll
  - Retention
  - Decision regret
- Population-Level
  - Improved medical innovation
  - Reduced morbidity and mortality

The ASK Approach to Enhancing Clinical Trial Participation

<table>
<thead>
<tr>
<th>A</th>
<th>Assume that all patients will want to know their options.</th>
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</thead>
<tbody>
<tr>
<td>S</td>
<td>Seek the counsel of stakeholders.</td>
</tr>
<tr>
<td>K</td>
<td>Know your numbers.</td>
</tr>
</tbody>
</table>

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

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

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

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.”

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

- Finding eligible patients: 35.4% (n=52)
- Not enough time in my day: 10.9% (n=16)
- Not enough study staff: 13.6% (n=20)
- Not enough recognition from PI: 6.1% (n=9)
- Patient refusal: 15.6% (n=23)
- Health care providers not referring patients: 4.1% (n=6)
- Competing studies that are recruiting the same type of patients: 2.7% (n=4)
- Other: 2.7% (n=4)
What would make Recruitment Easier?

- Physician mention: 38.8% (n=57)
- Perceived benefit to patient: 8.8% (n=13)
- Monetary incentives to participants: 8.8% (n=13)
- More time to answer participants' question about study: 10.9% (n=16)
- Shorter informed consent documents: 7.5% (n=11)
- Alternative methods to informed consent: 8.2% (n=12)
- Better advertising: 11.6% (n=17)
- Other: 4.1% (n=6)
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
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