WHAT DOES COMMITMENT TO DIVERSITY IN CLINICAL RESEARCH LOOK LIKE IN PRACTICE: PROTOCOL DESIGN, PATIENT, AND STAFFING CONSIDERATIONS

Aisha T. Langford, PhD, MPH
Assistant Professor of Population Health
Co-Director, CTSI Recruitment and Retention Core
aisha.langford@nyulangone.org
Clinical Trials: Diversity in Trial Type, Phase, and Target Populations

Image created by graphic designer Julia Kuhl for Dr. Langford
Fairness and Inclusion in COVID-19 Trials

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

Aisha T. Langford, Alison Bateman-House

JUNE 12, 2020

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

Pages 780-789 | Published online: 13 Mar 2021
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>
</tr>
</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

Know Your Numbers

Key numbers to track in a clinical trial include:

• Number of potentially eligible patients or “pool of patients”
• Number of people invited by different channels (patient portals vs. mailed letters)
• Number of responses by different channels (patient portals, social media, email)
• Number of interested, but not eligible patients
• Number of declines by eligible patients
• Number of enrolled patients
At What Cost to Clinical Trial Enrollment? A Retrospective Study of Patient Travel Burden in Cancer Clinical Trials

Hala T. Borno, Li Zhang, Adam Siegel, Emily Chang, Charles J. Ryan

Department of Medicine, Division of Hematology and Oncology, and Helen Diller Family Comprehensive Cancer Center, University of California San Francisco, San Francisco, California, USA

Disclosures of potential conflicts of interest may be found at the end of this article.

Key Words. Representativeness in clinical trials • Recruitment science • Travel distance • Health care costs • Cancer clinical trial disparities
Context and Setting

• Cancer patients in UC San Francisco Clinical Trial Management System database

• Enrolled in a clinical trial for breast, genitourinary, or gastrointestinal malignancy between 1993 and 2014
Outcome of Interest

• Distance traveled from home to center calculated using a GoogleMaps application programming interface.
Results

• 1,600 patients were enrolled in breast (55.8%), genitourinary (29.4%), or gastrointestinal (14.9%) cancer CTs

• Overall median unidirectional distance traveled from home to study site was 25.8 miles (interquartile range [IQR] 11.5-75.3)
Results Cont.

• Longest distance traveled was for NIH-sponsored trials, with a median of 39.4 miles ($p < .001$).

• Phase I (8.4%) studies had the longest distance traveled, with a median of 41.2 miles ($p = .001$).
Results Cont.

• Patients from lower-income areas ($n = 799$) traveled longer distances compared with patients from higher-income areas ($n = 773$; 58.3 vs. 17.8 miles, respectively; $p < .001$)
Comparison of Racial, Ethnic, and Geographic Location Diversity of Participants Enrolled in Clinic-Based vs 2 Remote COVID-19 Clinical Trials
Question

Were racial, ethnic, and geographic location demographics of participants enrolled in 2 remote clinical trials with online recruitment more diverse compared with those of participants in a clinic-based COVID-19 study?
Context and Setting

• Cohort study

• Secondary analysis of 1410 participants enrolled in 3 COVID-19 studies conducted in 2020 during the early COVID-19
Key Findings and Conclusion

• Remote clinical trials with online recruitment had increased racial, ethnic, and geographic location diversity among study participants.

“These findings suggest that remote clinical trials with online advertising may be considered as a strategy to improve diversity among clinical trial participants.”
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.

Group Question: How would you ensure that all potentially eligible people are invited to consider clinical trials?
Opt Out vs. Opt In Systems
Example of an Opt Out System

NYU Langone Medical Center
Notice of Privacy Practices

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

We may also use or share your information to contact you:

- about health-related benefits or services.
- about your upcoming appointments.
- to see if you would like to take part in research projects.
- about fundraising for NYU Langone.
Screenshot from my own patient record
Example of an Opt In System

What is ResearchMatch?

ResearchMatch is a nonprofit program funded by the National Institutes of Health (NIH). It helps to connect people interested in research studies with researchers from top medical centers across the U.S.

Get connected to research on many different health conditions - through ResearchMatch.

https://www.researchmatch.org/
Example Invitation from ResearchMatch.org

ResearchMatch: You may be a good match for this study!

ResearchMatch <no-reply@mail.researchmatch.org>
Reply-To: info@researchmatch.org
To: aishalangford@gmail.com

A research team with George Washington University in Washington, DC, believes you might be a good match for the following study:

You are invited to participate in a research study that seeks to understand attitudes towards women and the effects on mental health in the United States. The study involves a single survey that will be completed in one sitting, taking approximately 15 minutes. Eligible participants are ciswomen, aged 18 years or older, who are currently living in the United States and who speak English. Participation is voluntary and you will not be compensated; however, your participation in this study will benefit science and humankind to better understand how attitudes toward women impact health.

If you are interested in this study and having the research team contact you directly, please select the "Yes, I'm interested" link below. By clicking the "Yes, I'm interested" link, your contact information will be released to the research team. If you select the "No, thanks." link or do not respond to this study message, your contact information will not be released to the research team.

Yes, I'm interested!  No, thanks.
Who is in the Biomedical, Clinical, Behavioral and Social Sciences Research Workforce?

- Underrepresented Racial and Ethnic Groups
- Individuals with Disabilities
- Individuals from Disadvantaged Backgrounds
- Women in the Biomedical Workforce

Getting People in the Door: Recruitment
Strategies to Enhance Scientific Workforce Diversity

Mentoring Relationships

Diverse Candidate Pool

Outreach and Networking

Unbiased Talent Searches

Strategies for Promoting Diversity

- **Systematically review** hiring and promotion procedures and policies
- **Be transparent**: collect and publicize aggregate diversity metrics
- **Commit resources** and provide diversity tools to Divisions and Departments
- **Evaluate impact** and adjust strategy if needed

Strategies for Promoting Diversity

• **Review and ensure** equality in salary and resources

• **Ensure** width, breadth, and fairness in talent searches

• **Sponsor** all faculty through promotion for awards and inclusion in professional networks

Strategies for Promoting Diversity

• **Endorse and promote** work-life balance resources for all faculty

• **Conduct anonymous climate surveys** and make changes if necessary

Conducting Unbiased Talent Searches

- Develop **clear criteria** and **standards** for the position before anyone is recruited or contacted
- Create a clear **evaluation system** in advance and avoid global scoring
- Conduct **anonymous voting**, if the size of the pool is large enough
- Ensure that search committees are **diverse**

Unintended Effects of Unpaid Internships

Ryan Ken
@Ryan_Ken_Acts

The t is many unpaid internships are the grooming period for the abuse you will endure as an employee. It's a period of testing your limits. The internship itself can be an assessment of how willing you are accept financial abuse. Pennies sound like a lot after working for free.

8:29 PM · Mar 2, 2021 · Twitter for Android

Ryan Ken
@Ryan_Ken_Acts

Replying to @Ryan_Ken_Acts

Some of my mentors saw me as ungrateful for opportunities, but it was financially impossible for me to devote hours to free labor. These systems were designed for ppl with money and the pressure to "perform" wealth can produce compound financial obstacles for working class ppl.

9:07 PM · Mar 2, 2021 · Twitter for Android
Keeping People in the Door: Retention
Dear Kerry Ann: Can I Mentor African-American Faculty?

02/17/2016

Dear Kerry Ann,

I enjoy reading your columns. I’ll be brief: I don’t know how to mentor scholars of color in my department. I’m a white guy, and I don’t experience the same things minority faculty members do in the classroom or on the campus. Because of that, I feel awkward trying to give them advice. I have a new mentee (a brand-new tenure-track faculty member, who is African-American) and I want to be helpful as her department mentor, but I honestly don’t know how. Can I mentor African-American faculty effectively? Or should I try to connect her with a tenured African-American scholar in another department. (We don’t have any.)

Sincerely,

Unsure How to Mentor

What limiting beliefs are driving your awkward feelings?

Here are a few possible limiting beliefs that may be at work:

• Faculty of color can only be mentored by other faculty of color.
• Faculty of color only need mentoring on issues related to race.
• There are no needs that faculty of color have that can be met by you.
• Mentoring means giving advice to mentees based on your personal experience.

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

Ebony Scott, Bryan McComb, Howard Trachtman, Lois Mannon, Peri Rosenfeld, Rachel Thornton, Nassira Bougrab, Scott Sherman, Aisha Langford
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
Perspectives about the importance of participant-study coordinator concordance

• Respondents were asked to assess the importance of participant-study coordinator concordance regarding:
  – Age
  – Gender
  – Race/ethnicity
  – Language spoken
<table>
<thead>
<tr>
<th>Participant/Study Coordinator Concordance</th>
<th>1 (Not at all important)</th>
<th>2</th>
<th>3 (27.9%)</th>
<th>4 (17.7%)</th>
<th>5 (Very important)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>35 (23.8%)</td>
<td>30 (20.4%)</td>
<td>41 (27.9%)</td>
<td>26 (17.7%)</td>
<td>14 (9.5%)</td>
</tr>
<tr>
<td>Gender</td>
<td>54 (36.7%)</td>
<td>33 (22.4%)</td>
<td>41 (27.9%)</td>
<td>15 (10.2%)</td>
<td>2 (1.4%)</td>
</tr>
<tr>
<td>Race/ethnicity</td>
<td>37 (25.2%)</td>
<td>23 (15.6%)</td>
<td>44 (30%)</td>
<td>28 (19.0%)</td>
<td>14 (9.5%)</td>
</tr>
<tr>
<td>Language</td>
<td>2 (1.4%)</td>
<td>5 (3.4%)</td>
<td>17 (11.6%)</td>
<td>35 (23.8%)</td>
<td>87 (58.2%)</td>
</tr>
</tbody>
</table>
Emerging Questions and Group Discussion

• What aspects of diversity should be prioritized in clinical trials?

• What is the ideal construction of a study team?
Thank You

Aisha T. Langford, PhD, MPH
Assistant Professor of Population Health
Co-Director, CTSI Recruitment & Retention Core
NYU Grossman School of Medicine
E-mail: Aisha.Langford@nyulangone.org