Inclusion, Diversity, and Equity in Pragmatic Clinical Trials

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Housekeeping

• All participants will be muted

• Enter all questions in the Zoom Q&A or chat box and send to All Panelists and Attendees

• Moderator will review questions from chat box and ask them at the end

• Want to continue the discussion? Look for the associated podcast released about 2 weeks after Grand Rounds.

• Visit impactcollaboratory.org

• Follow us on Twitter: @IMPACTcollab1

• LinkedIn: https://www.linkedin.com/company/65346172 @IMPACT_Collaboratory
Disclosures as of April 15, 2021:

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Dr. Wilkins receives research support from:
- National Institutes of Health
- Patient-Centered Outcomes Research Institute
- Robert Wood Johnson Foundation
- American College of Radiology and Alzheimer’s Association
What is meant by **diversity**?
• **Race:** group a person belongs to (or is perceived to belong to)
  - based on physical attributes – skin color, facial features and hair
  - a socio-political construct; fluid (changes over time)
  - no biological or scientific basis

• **Ethnicity:** group a person belongs to based on culture, language, physical attributes, religion, country of origin

• **Ancestry:** line of descent; usually refers to DNA

• **Culture:** a society’s collective thoughts, actions, customs, beliefs, and values

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Artist Angélica Dass rethinks the concept of race by showing the diversity of human skin colors in her global photographic mosaic. https://www.angelicadass.com/humanae-project
# Current Population

## World Population by Region in 2020

<table>
<thead>
<tr>
<th>Region</th>
<th>Population</th>
<th>World Share</th>
<th>Yearly Change</th>
<th>Median Age</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asia</td>
<td>4,641,054,775</td>
<td>59.5%</td>
<td>0.9%</td>
<td>32</td>
</tr>
<tr>
<td>Africa</td>
<td>1,340,598,147</td>
<td>17.2%</td>
<td>2.5%</td>
<td>20</td>
</tr>
<tr>
<td>Europe</td>
<td>747,636,026</td>
<td>9.6%</td>
<td>0.1%</td>
<td>43</td>
</tr>
<tr>
<td>Latin America &amp; Caribbean</td>
<td>653,962,331</td>
<td>8.4%</td>
<td>0.9%</td>
<td>31</td>
</tr>
<tr>
<td>Northern America</td>
<td>368,869,647</td>
<td>4.7%</td>
<td>0.6%</td>
<td>39</td>
</tr>
<tr>
<td>Oceania</td>
<td>42,677,813</td>
<td>0.5%</td>
<td>1.3%</td>
<td>33</td>
</tr>
</tbody>
</table>

@DrCHWilkins
Changing Population

1950 Population | World Share
-----------------|-------------------
Asia: 1,404,909,021 | 55.4%
Europe: 549,328,883 | 21.7%
Africa: 227,794,136 | 9%
Northern America: 172,602,624 | 6.8%
Latin America & Caribbean: 168,820,620 | 6.8%
Oceania: 12,975,865 | 0.5%

2050 Population | World Share
-----------------|-------------------
Asia: 5,290,263,118 | 54.3%
Africa: 2,489,275,458 | 25.6%
Latin America & Caribbean: 762,432,366 | 7.8%
Europe: 710,486,313 | 7.3%
Northern America: 425,200,368 | 4.4%
Oceania: 57,376,367 | 0.6%
What is meant by inclusivity?
Recruitment Continuum

Awareness Campaign

Tailored Recruitment Materials

Culturally congruent staff

Results to Community & Providers

Awareness

Opportunity

Acceptance

Consent

Enrollment

Retention

Return of Results

Community Partners

Consent forms in multiple languages

MyCap in translated versions

Awareness

Opportunity

Acceptance

Consent

Enrollment

Retention

Return of Results

@DrCHWilkins
Factors contributing to lack of diversity in clinical trials

**System Level**
- Availability of clinical trials
- Supporting infrastructure
- Cost/payer
- Strict eligibility criteria
- Lack of community engagement

**Individual Level**
- **Health Care Professional**
  - Awareness of clinical trials
  - Perception of the hospital/infrastructure
  - Attitude/bias/experience
  - Perception of patient’s race/ethnicity
- **Patient/Family**
  - Awareness of clinical trials
  - Eligibility
  - Personal identity: ethnicity, race, religion
  - Attitude/bias/experience
  - Access (e.g., transportation)

**Interpersonal Level**
- Perception of the institutional infrastructure
- Attitude/perception of each other and care received
- Doctor–patient relationship

**Disparities**

Study-level Barriers to Recruiting Racial and Ethnic Groups Historically Excluded

Investigators
- Limited knowledge/experience recruiting diverse groups
- Few, if any, minority researchers
- Little to no experience working with community orgs
- Ineffective communication strategies
- Lack of cultural humility

Study-level barriers
- budgets inadequate for recruitment
- no expertise to culturally adapt tailor documents
- lack of culturally congruent research staff
- No bilingual staff or access to language services
Barriers to clinical trial participation among African American, Hispanic/Latinx, Asian American, and Pacific Islander groups

Shared Barriers
- Mistrust of research
- Competing demands
- Lack of access to information
- Stigma
- Health insurance
- Unintended outcomes
- Documentation
- Cost of participation

Group-specific Barriers
- Legacy of research abuse
- Racism & discrimination
- Research Integrity
- Fear of randomization
- Lack of social support
- Acculturation
- Misrepresentation of community

Guiding Principles for Successful Trial Recruitment

• Set accrual goals
  • based on evidence of recruitment feasibility, not solely patient counts
• Be transparent about potential risks/adverse events
• Minimize participant burden
• Offer compensation that reflects the true costs of participation (e.g., time-off work, transportation, childcare)
• Set an appropriate budget for recruitment and retention
• Employ a diverse, experienced team
• Share results/return value to participants and community
Strategies to Enhance Minority Recruitment

1. Embed researchers with expertise in minority health and health disparities into research teams
2. Integrate the perspectives of individuals from marginalized groups in the study design and planning
3. Train research teams in cultural humility and effective communications
4. Partner with trusted community organizations
5. Hire individuals with experience working in communities
6. Support an asset-based, community-led approach to recruitment
Hire individuals with experience working in communities

- Specifically, hire individuals with experience working in communities that you want to recruit from
- Preferably individuals from marginalized communities as study coordinators/recruitment staff
- Prioritize individuals who are bilingual and bicultural
Support an asset-based community-led approach to recruitment and retention

- Prepare/support community – emphasize co-learning
- Community capacity building

**TABLE 1 | WAI-Milwaukee Asset-Based Community Development (ABCD) Approach, examples of community activities and current outcomes.**

<table>
<thead>
<tr>
<th>Panel A: Core Aspects of ABCD Approach</th>
<th>Panel B: Examples of Activities</th>
<th>Panel C: Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Community assessment</td>
<td>Outreach &amp; Education</td>
<td>Stigma Reduction</td>
</tr>
<tr>
<td>• Identify the community and their assets</td>
<td>• Breaking the Silence Annual Breakfast and</td>
<td>Increased community awareness of ADRD</td>
</tr>
<tr>
<td>• Identify key community stakeholders</td>
<td>Community Workshops</td>
<td></td>
</tr>
<tr>
<td>• Address the community needs and wants</td>
<td>The “Amazing Grace” Chorus Family Support Program</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Annual Faith-Based ADRD Initiatives</td>
<td></td>
</tr>
<tr>
<td>Community engagement (WAI-Milwaukee becoming part of community “social fabric”)</td>
<td>Coordination of Medical &amp; Social Services</td>
<td>Increased access of community members to comprehensive care and support services</td>
</tr>
<tr>
<td>• Invest time in the community</td>
<td>Milwaukee Health Services Center &amp; Clinic</td>
<td></td>
</tr>
<tr>
<td>• Provide resources identified by the community</td>
<td>Network Development</td>
<td></td>
</tr>
<tr>
<td>• Address barriers through service</td>
<td>Culturally inclusive professional training</td>
<td></td>
</tr>
<tr>
<td>Community involvement</td>
<td>Community Advisory Board development and sustenance</td>
<td>Academic-community partnership in initiatives</td>
</tr>
<tr>
<td>• Recognize community members as experts</td>
<td></td>
<td>Increased community awareness of importance of research</td>
</tr>
<tr>
<td>• Validate community members’ perspectives</td>
<td></td>
<td>Increased African-American participation in research</td>
</tr>
<tr>
<td>• Build relationships between community members, researchers, and health professionals</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Community members provide counsel to WAI-Milwaukee and researchers</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Trial Innovation Network

CTSA Hubs
>50 major US academic medical centers

Trial Innovation Network Hub Liaison Teams

Trial Innovation Centers (TICs)
Full service coordinating services that can operationalize a clinical trial from study planning, execution, to publication of results

Recruitment Innovation Centers (RIC)
Cohort discovery, systematic and novel engagement, recruitment, and retention and engagement approaches

Key Elements of the Network
3 Central Academic IRBs, Master Contracting, Recruitment System, Infrastructure and Support for Site Based Research

NIH Institutes industry Foundations

Partners Participants Providers Public
Trial Innovation Network

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Key Elements of the Network
3 Central Academic IRBs, Master Contracting, Recruitment System, Infrastructure and Support for Site Based Research
Vision and purpose

Our goal is to positively impact human health by improving participant enrollment and retention in multi-center clinical trials.

Achieving this goal will require sophisticated informatics-based recruitment tools and novel engagement approaches to accelerate recruitment and retention.
Recruitment Continuum: Example COVID Vaccine Trials

- Awareness
- Opportunity
- Acceptance
- Consent
- Enrollment
- Retention
- Return of Results

- National Campaign
- Tailored Recruitment Materials
- Culturally congruent staff
- Results to Community & Providers

- Community Partners
- Consent forms in multiple languages
- MyCap in translated versions

- Trust
- Reliable, Consistent, Competent, Competent
- Hello, Bonjour, Olá

TRIAL INNOVATION NETWORK

CTSA Clinical & Translational Science Awards Program
COVID lifespan progression

- Healthy → Exposed → Infected → Asymptomatic → Symptomatic/Mild → Hospitalized/Moderate → Intensive Care Unit/Severe → Recovering → Recovered

Some remain asymptomatic and/or recover without requiring hospitalization or intensive care

**PROGRESSION**

**OPTIONS**

- Vaccines
- Antivirals
- Host-Targeted Therapies
- Capture correlative biomarkers
- Organ Support

**ACTIVITY**

- Present in environment → Invasion and replication → Viral tissue injury → Inflammatory injury → Organ dysfunction +/- prolonged or irreversible impairment

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TRIAL INNOVATION NETWORK

CTSA Clinical & Translational Science Awards Program
# Comprehensive Approaches to Minority Recruitment

**Goal:** Address study-specific and common barriers

<table>
<thead>
<tr>
<th>Common Barriers</th>
<th>Study-Specific Barriers</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Scientist –level barriers</strong></td>
<td>• Misinformation about COVID-19</td>
</tr>
<tr>
<td>• Limited experience recruiting minorities</td>
<td>• Concerns re safety of COVID-19 tests, treatments, vaccines</td>
</tr>
<tr>
<td>• Lack relationships with community orgs</td>
<td>• Limited access to testing and care</td>
</tr>
<tr>
<td>• Few, if any, minority researchers</td>
<td>• Fears related to government involvement</td>
</tr>
<tr>
<td><strong>Participant-level barriers</strong></td>
<td>• Contact tracing</td>
</tr>
<tr>
<td>• Perceived harms, fear, mistrust</td>
<td>• Information being shared w/ law enforcement</td>
</tr>
<tr>
<td>• Costs, transportation, access, convenience</td>
<td>• Stigma related to COVID-19</td>
</tr>
<tr>
<td>• Info unavailable in preferred language</td>
<td>• Lack of dedicated staff to support recruitment</td>
</tr>
<tr>
<td><strong>Study-level barriers</strong></td>
<td>• No information/resources for family and household members involved in decision making</td>
</tr>
<tr>
<td>• Budgets inadequate for recruitment</td>
<td>• Study materials not available in multiple languages</td>
</tr>
<tr>
<td>• No expertise to culturally tailor documents</td>
<td>• Minimal/no involvement of trusted leaders/community orgs</td>
</tr>
<tr>
<td>• Lack of culturally congruent research staff</td>
<td></td>
</tr>
</tbody>
</table>


Enabling Minority Recruitment

- Identify sites with capacity to recruit minorities
  - Contact sites with higher % minorities
  - Questions on site selection to determine interest/capacity
    - Prior experience recruiting minorities, bilingual staff

- Support facilities in minority recruitment
  - Training in minority recruitment
  - Culturally tailored recruitment materials
  - Information to address fears related to radiation
Enabling Minority Recruitment (cont)

• Increase pipeline of referrals to COVID-19 research sites
  • Identify primary care and community champions
    • Professional and community-focused orgs, National Med Assoc, Assoc

• Create awareness of study
  • National campaign; using tailored messaging

• Partner with trusted community organizations
  • Engage through trusted community organizations
  • Support families in decision making and study participation
eConsent has addressed the problems of:

- How to continue doing research studies during a pandemic?
- How to do studies with COVID-19+ participants and keep everyone safe, preserve PPE, and reach LARs, parents, translators, etc., when everyone is remote?

YouTube Channel for eConsent education videos: [https://www.youtube.com/playlist?list=PLiMIsWK5xzDsjG_slun3JTDJxlzVWQlR2](https://www.youtube.com/playlist?list=PLiMIsWK5xzDsjG_slun3JTDJxlzVWQlR2)

Recent publication: [REDCap based model for electronic consent](https://www.youtube.com/playlist?list=PLiMlsWK5xzDsjG_slun3JTDJxlzVWQlR2)
MyCap provides the ability to collect valuable data in the outpatient, post-discharge, and recovery contexts such as:

- Medication changes
- New hospitalization
- Symptoms
- Need for follow-up

Soon to be available in Spanish And Portuguese!
ResearchMatch

- Supports recruitment of people that speak English or Spanish
- Matches Spanish recruitment messages with people selecting Spanish language
- Offers Volunteer support, education, and engagement in Spanish
Community Engagement Studios

Guidance from CESs regarding clinical trial recruitment to date:

1. Be aware of exclusion criteria that limits participation.
2. Remove systemic barriers to participation (adding non-traditional times for study visits, transportation/stipends)
3. Develop culturally tailored and translated study materials being carefully not to pander.
4. Partner with respected community (national and local) organizations / contacts
5. Train study staff (e.g. cultural humility and bias) *Hire study staff representative of community.
6. Disseminate results in real time - full transparency to continue to establish and gain trust.
Continuum of Community Engagement in Research

- **Community-Driven Research**: Community stakeholders serve as Principal Investigator (PI) or Co-PI and are leading the research.
- **Research Team Members**: Stakeholders are integral members of the research team and participate in key activities. Often have advanced knowledge, expertise, leadership experience.
- **Governance and Advisory Groups**: Stakeholders serve on boards, councils, committees; provide oversight/guidance.
- **Reviewers, Interviewees, Consultants and Citizen Jurors**: Focus groups, semi-structured interviews, nominal groups techniques, Community Engagement Studios: Stakeholders serve specific, time-limited roles.
- **Knowledge Users and Experiencers**: Surveys, polling, crowdsourcing: Broader community provides brief input.

Faster Together: Training Recruiters to Better Engage Minorities

• Training Recruiters- The Art of Recruitment
  • Course design, syllabus and curriculum created.
  • Course content created.
  • Filming of lessons and supporting materials finalized.
    • Example (3min 40")
• Training in Coursera
FasterTogether: Mass Open Online Course for Enhancing Minority Recruitment in Clinical Trials

https://www.coursera.org/learn/recruitment-minorities-clinical-trials

Course launch: April 1, 2019
LOW PARTICIPATION IN RESEARCH LIMITS:

• Ability to understand differences in effectiveness of treatments across populations
• Discovery of new drugs and devices
• Healthcare delivery
• Scientific knowledge
Interviews with Research Participants

“I used to hear horror stories literally from my grandparents, starting with Tuskegee about what happened, and what was done, and wasn’t told to our community. So there has been mistrust for years.”

“I have never heard back from any of the studies my son has been involved in, and…I would love to see what came of it…That’s also another reason why a lot of minorities don’t want to do the studies is because they never hear the results.”