Importance of Achieving Racial and Ethnic Equity in Pregnancy Clinical Research

Adetola Louis-Jacques
Objectives

• Discuss current state of representation
• Equity in research
  – Facilitators and barriers
• Strategies for engagement
Disparities in Research

• Critical need for engagement of underrepresented populations
• Underrepresented individuals are willing to participate in research
• Impaired researchers’ ability to engage with underrepresented populations
Underrepresented Populations in Research

- Women
- Pregnant and lactating people
- Racial and ethnic minorities
- Sexual and gender minorities
- Low socioeconomic status
- Individuals with disabilities
- Rural inhabitants

Represented 25%
Historical Antecedents

- Same engagement methods
- Differential treatment

Researchers → Participants

Diverse Participants
Racial and Ethnic Group Underrepresentation in Studies of Adverse Pregnancy Outcomes and Cardiovascular Risk

Sofia E. Gomez MD, Ashish Sarraju MD, and Fatima Rodriguez MD, MPH
Lack of Representation

- Generalizability
- Certain populations do not benefit as much
- Accuracy of race/ethnicity specific subgroup analyses
- Cannot eliminate disparities without representation of those at highest risk

[Graph showing the trend of pregnancy-related mortality ratio from 1987 to 2017]

Data confirms significantly higher pregnancy-related mortality ratios among Black and American Indian/Alaskan Native women. These gaps did not change over time.
Infant Mortality Rates by Race/Ethnicity
U.S., 2000-2017

Source: CDC NCHS 2017 Report
Achieving Health Equity in Maternal Child Health

Equity in Pregnancy Clinical Research
## Barriers

### TABLE 3—Examples of Shared Barriers to Health Research Participation as Observed in the Studies Reviewed From a Search on PubMed and Web of Science From January 2000 to December 2011

<table>
<thead>
<tr>
<th>Barriers</th>
<th>Articles, No. (%)</th>
<th>African American</th>
<th>Asian American</th>
<th>Latino</th>
<th>Pacific Islander</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mistrust</td>
<td>34 (77.3)</td>
<td>Perceive research will benefit Whites or the research institution and not people of color \cite{76}</td>
<td>Concerns related to signing the informed consent \cite{77}</td>
<td>Believe medical experimentation occurs when accessing health care \cite{57}</td>
<td>Negative feelings about the purpose and intent of research \cite{41}</td>
</tr>
<tr>
<td>Competing demands</td>
<td>20 (45.4)</td>
<td>Inconvenience \cite{62}; cost of participation \cite{34}</td>
<td>Lack of time \cite{76} and financial resources \cite{79}</td>
<td>Time conflicts and lack of childcare \cite{67}</td>
<td></td>
</tr>
<tr>
<td>Unintended outcomes</td>
<td>14 (31.8)</td>
<td>Concerns about future long- and short-term side effects \cite{80}</td>
<td>Uncertainty of risks, side effects, and effectiveness of clinical trials \cite{81}</td>
<td>Fear of vaccine-induced HIV infection \cite{82}</td>
<td></td>
</tr>
<tr>
<td>Lack of access to information</td>
<td>14 (31.8)</td>
<td>Misconceptions about research \cite{63}</td>
<td>Limited knowledge about clinical trials \cite{84}, lack of translated materials, including key words or terms; feeling intimidated by English \cite{78}</td>
<td>Unavailable health information in Spanish and lack of access to Spanish-speaking staff \cite{67}, low perceived risk of disease \cite{85,86}</td>
<td>Information about accessing research \cite{87}, language barrier between hospital staff, researchers, and patients \cite{40}</td>
</tr>
<tr>
<td>Stigma</td>
<td>12 (27.3)</td>
<td>Related to genetic or mental illness research \cite{88}</td>
<td>Related to judgment from husband or family for participation in health study \cite{79}</td>
<td>Related to HIV-positive status \cite{89}</td>
<td></td>
</tr>
<tr>
<td>Health insurance coverage</td>
<td>3 (6.8)</td>
<td>Have basic health care or no specific health care needs \cite{90}, fear of discrimination \cite{88}</td>
<td></td>
<td>Lack of information about insurance coverage for clinical trials \cite{77}</td>
<td></td>
</tr>
<tr>
<td>Legal status in United States</td>
<td>2 (4.5)</td>
<td></td>
<td>Concerned immigration status will be affected among immigrants \cite{79}</td>
<td>Fear of deportation among immigrants \cite{57}</td>
<td></td>
</tr>
</tbody>
</table>
## Facilitators

### TABLE 4—Examples of Shared Facilitators to Health Research Participation as Observed in the Studies Reviewed From a Search on PubMed and Web of Science From January 2000 to December 2011

<table>
<thead>
<tr>
<th>Facilitators</th>
<th>Articles, No. (%)</th>
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<th>Asian American</th>
<th>Latino</th>
<th>Pacific Islander</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cultural congruence</td>
<td>27 (61.4)</td>
<td>Community education at fraternities and sororities(^{104}); use of culturally diverse staff(^{45})</td>
<td>Culturally matched research personnel and information in appropriate language(^{41})</td>
<td>Research staff that speak Spanish and can relate to participants(^{103})</td>
<td>Community involvement prerequisite to research for research staff or use of interpreters and translated material(^{41})</td>
</tr>
<tr>
<td>Benefits to participation</td>
<td>27 (61.4)</td>
<td>Money or free medical services(^{104}); access to new, better, or free medicines(^{100}); learn about their own health(^{91}); receive adequate information about the purpose of study(^{105})</td>
<td>No out-of-pocket costs(^{84}); no other effective treatment available(^{84}); more information about clinical trials(^{81})</td>
<td>Monetary compensation(^{82}); access to medical services(^{89}); sufficient or appropriate study information provided(^{82})</td>
<td>Personal need and all medical bills paid(^{41}); improved medical facilities for the community(^{41}); complete disclosure of risks and safeguards(^{41})</td>
</tr>
<tr>
<td>Altruism—helping family or community</td>
<td>24 (54.5)</td>
<td>Contribution to future generations and community(^{91,106}); increase scientific knowledge(^{104}); personal or family history of the disease(^{90,106})</td>
<td>Want to help family member or Asian American community in general(^{78}); care about the purpose of the research(^{107})</td>
<td>Help others(^{86}); advance medical knowledge(^{103}); burden of disease on family or community(^{67})</td>
<td>Clear contribution to future generations and community(^{41})</td>
</tr>
<tr>
<td>Convenience of participation</td>
<td>8 (18.2)</td>
<td>Having workplace support(^{90})</td>
<td>Transportation compensated(^{107})</td>
<td>Childcare provided(^{67})</td>
<td></td>
</tr>
<tr>
<td>Low risk in participation</td>
<td>5 (11.4)</td>
<td>Natural treatment or noninvasive(^{95})</td>
<td>Take medications with known efficacy(^{84})</td>
<td>Low risk of toxicity(^{85})</td>
<td></td>
</tr>
</tbody>
</table>
Eleven community listening sessions (N = 117) representing racial/ethnic minority, economically disadvantaged, and hearing impaired communities.

- Uncertainties of underrepresented populations regarding research participation
- Ineffective communication about research opportunities and research findings
- Research on primary care and prevention are priorities for underrepresented populations
- Research teams need training in cultural competence and humility
Needs, Priorities, and Recommendations for Engaging Underrepresented Populations in Clinical Research: A Community Perspective

Jennifer Cunningham Erves¹ · Tilicia L. Mayo-Gamble² · Alecia Malin-Fair³ · Alaina Boyer⁴ · Yvonne Joosten⁵ · Yolanda C. Vaughn⁶ · Lisa Sherden⁷ · Patrick Luther⁸ · Stephanie Miller⁹ · Consuelo H. Wilkins¹⁰

Research teams need training in cultural competence and humility.

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Ineffective communication about research opportunities and research findings.

Research on primary care and prevention are priorities for underrepresented populations.

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Research on primary care and prevention are priorities for underrepresented populations.

Research teams need training in cultural competence and humility.
### Recommendations for engaging underrepresented populations

<table>
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<tbody>
<tr>
<td>Establish a line of communication between researcher and community during all phases of research</td>
</tr>
<tr>
<td>Broadly disseminate research opportunities implementing user-friendly strategies</td>
</tr>
<tr>
<td>Transparency regarding risks of research to participants and community</td>
</tr>
<tr>
<td>Distribution of more comprehensive, up-to-date information on clinical research and researchers</td>
</tr>
<tr>
<td>Recognition of community members as partners in research</td>
</tr>
<tr>
<td>Build trust between community, academicians, and clinicians by teaching these individuals to engage in effective, bi-directional communication among these groups. This will help to gain an understanding of each stakeholders research needs in order to improve research participation of underrepresented groups</td>
</tr>
<tr>
<td>Use of engagement strategies to ensure communications are person-centered</td>
</tr>
</tbody>
</table>
Other Strategies

• Community liaisons
  – to understand the needs of that community

• Representative research workforce
Community Engagement

• Effective, evidence-based
  – interest
  – trust

• Principles
  – Involvement in the research process
  – Community advisory boards
  – Peer-concordant, community based recruiter
Pregnancy Example

Preparation
- Develop collaboration with clinic staff
- Train navigators
- Pilot intervention with target population

Process
- Use existing IT systems to identify eligible participants
- Track participants’ progress through study
- Staff the majority of clinic sessions

Patient-centered
- Create a flexible protocol
- Compensate participants for their time
- Anticipate and be responsive to participants’ needs

Health Equity Training/role play
Representation
Less burdensome
Patient-centered & child friendly


**Successful Strategies for Practice-Based Recruitment of Racial and Ethnic Minority Pregnant Women in a Randomized Controlled Trial: the IDEAS for a Healthy Baby Study**

Sarah L. Goff1,2, Yara Youssef3,4, Penelope S. Pekow2,3, Katharine O. White5, Haley Guhn-Knight1,2, Tara Lagu1,2, Kathleen M. Mazor6,7, and Peter K. Lindenauer1,2
Pregnancy Example

- **Participant level strategies**
  - Respectful, friendly, and reliable
  - Addressed concerns regarding confidentiality
  - Acknowledged competing priorities
  - Matched recruiters by gender and race when feasible

- **Clinical level strategies**
  - Good working relationship with the clinical staff

- **Protocol level strategies**
  - Wide enrollment window
  - Coordinating biospecimen collection with the clinical laboratory tests
  - Collecting survey data on an electronic tablet; text messaging
National Initiatives

• National Institutes of Health
  – NIH Revitalization Act of 1993
  – Amendment in 2001

• Food & Drug Administration (FDA)
  – FDA Year of diversity in clinical trials 2016
FDA — Enhancing Diversity in CT

- Broadening eligibility criteria
- Inclusive trial practices
  - Inclusion of racial and ethnic minorities
  - Analysis of clinical trial data by race and ethnicity
    Differences in response (e.g., pharmacokinetics)
- Trial design
- Enrichment strategies
- Less burdensome trials
- Inclusive enrollment and retention practices

Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs Guidance for Industry

https://www.fda.gov/media/127712/download
https://www.fda.gov/media/157635/download
The U.S. population has become increasingly diverse, and ensuring meaningful representation of racial and ethnic minorities in clinical trials for regulated medical products is fundamental to public health,”...Going forward, achieving greater diversity will be a key focus throughout the FDA to facilitate the development of better treatments and better ways to fight diseases that often disproportionately impact diverse communities.”

FDA Commissioner Robert M. Califf, M.D.