Practical Strategies for Meaningful Community Engagement in Clinical Trials

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Disclosures

• No financial conflicts to disclose
Outline

• Goals and objectives
• Thought experiment
• Common approaches that are inadequate
• Need for diversity and inclusion in research
• Practical strategies
  • Proposal development
  • Implementation
  • Dissemination
• Questions/Discussion
Goals and Objectives

• Develop understanding for need for meaningful engagement in research
• Provide examples of strategies for inclusion throughout the research lifecycle
Thought Experiment
Common Approaches that are Inadequate

• We research on communities not with them
• Research designs that do not specify or provide resources for inclusion
• Our priorities are not the same as the community’s
• We are “checking a box”
• We do not partner with members of the community
• We do not invest in the community or share resources
• We drop in and out, with little feedback, continuity, or connection
• Staff does not represent the community we are studying
• Lack of cultural humility
• (To name a few...)
Why we Need Diversity and Inclusion in Research

• Belmont Report
• Generalizability
• Trust
• Access
• Examples
  • PrEP
  • HIV cure studies
The Belmont Report (1)

- **Respect for persons**—“Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection.”

- Allowing engagement in trials as autonomous agents while protecting those with diminished autonomy
• **Beneficence**—“Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being.”

• This has particular impact on our ensuring that we never do any harm to the participants (individually or by virtue of participating in the study) and that we maximize benefits and minimize harms

• Maximizing benefits includes access to research at times, provided we are ensuring safety and voluntariness – access to cutting edge trials

• This is highly relevant when we ensure we link participants into care or aid them in times of emotional crisis
Justice—“Who ought to receive the benefits of research and bear its burdens? This is a question of justice, in the sense of "fairness in distribution" or "what is deserved." An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly”

Who takes the risk and who reaps the benefits
Need for Generalizability

• Heterogeneity in experience, responses to treatments
  • Biological, pharmacokinetic, physiological, metabolic, behavioral, etc.
• Collaborative engagement builds trust
• Strategies to improve implementation and scale up
Estimated HIV Prevalence among Persons Aged ≥13 years, by Area of Residence 2019—United States and Puerto Rico

Total = 1,189,700†

Note. Estimates were derived from a CD4 depletion model using HIV surveillance data. Estimates rounded to the nearest 100 for estimates >1,000 and to the nearest 10 for estimates ≤1,000 to reflect model uncertainty. Estimates for the year 2019 are preliminary and based on deaths reported to CDC through December 2020. Estimates should be interpreted with caution due to incomplete death ascertainment for Kansas, Massachusetts, Mississippi, Nevada, North Dakota, and Vermont.

†Total estimate for the United States does not include data for Puerto Rico.
Estimated HIV Incidence among Men Who Have Sex with Men Aged ≥13 Years by Race/Ethnicity, 2010–2019—United States

Note. Estimates were derived from a CD4 depletion model using HIV surveillance data. Data have been statistically adjusted to account for missing transmission category. Data on men who have sex with men do not include men with HIV infection attributed to male-to-male sexual contact and injection drug use. Hispanic/Latino males can be of any race.

*Difference from the 2010 estimate was deemed statistically significant (P < .05).
Characteristics of Newly Diagnosed HIV Cases—District of Columbia, 2016-2020

1 in 5 were Black Women

1 in 3 were Black men who have sex with men

1 in 4 were aged 30-39
Pre-2012

Success! 2012
TDF/FTC to prevent HIV and is approved for use by FDA

Eventually successful implementation and realized outcomes

PrEP in US as an example

Since 2012:

• Studies to examine populations inadequately included in iPrEX
• Implementation science studies to decrease barriers and increase adherence (e.g., technology)
• Continued poor PrEP delivery to those at highest risk of HIV and payor structures slow to resolve
• Mistrust, stigma, provider barriers, structural barriers to PrEP and other prevention services care
Estimated HIV Prevalence among Persons Aged ≥13 years, by Area of Residence 2019—United States and Puerto Rico

Total = 1,189,700†

Note. Estimates were derived from a CD4 depletion model using HIV surveillance data. Estimates rounded to the nearest 10 for estimates >1,000 and to the nearest 10 for estimates ≤1,000 to reflect model uncertainty. Estimates for the year 2019 are preliminary and based on deaths reported to CDC through December 2020. Estimates should be interpreted with caution due to incomplete death ascertainment for Kansas, Massachusetts, Mississippi, Nevada, North Dakota, and Vermont.

†Total estimate for the United States does not include data for Puerto Rico.
PrEP Coverage among Persons Aged ≥16 Years, by Area of Residence, 2018—United States

Total = 18.1%

Abbreviation: PrEP, preexposure prophylaxis.

Note. PrEP coverage, reported as a percentage, was calculated as the number who have been prescribed PrEP divided by the estimated number of persons who had indications for PrEP. Different data sources were used in the numerator and denominator to calculate PrEP coverage.
PrEP Coverage among Persons Aged ≥16 Years, by Sex at Birth 2018—United States

Abbreviation: PrEP, preexposure prophylaxis.

Note. PrEP coverage, reported as a percentage, was calculated as the number who have been prescribed PrEP divided by the estimated number of persons who had indications for PrEP. Different data sources were used in the numerator and denominator to calculate PrEP coverage.
PrEP Coverage among Persons Aged ≥16 Years, by Race/ethnicity
2018—United States

Abbreviation: PrEP, preexposure prophylaxis.
Note. PrEP coverage, reported as a percentage, was calculated as the number who have been prescribed PrEP divided by the estimated number of persons who had indications for PrEP. Race/ethnicity data were only available for 35% of persons prescribed PrEP in 2018. Number prescribed PrEP and PrEP coverage for race/ethnicity reported in the table were adjusted applying the distribution of records with known race/ethnicity to records with missing race/ethnicity. Different data sources were used in the numerator and denominator to calculate PrEP coverage.
FDA NEWS RELEASE

FDA approves second drug to prevent HIV infection as part of ongoing efforts to end the HIV epidemic

For Immediate Release: October 03, 2019

The U.S. Food and Drug Administration today approved Descovy (emtricitabine 200 mg and tenofovir alafenamide 25 mg) in at-risk adults and adolescents weighing at least 35 kg for HIV-1 pre-exposure prophylaxis (PrEP) to reduce the risk of HIV-1 infection from sex, excluding those who have receptive vaginal sex. Descovy is not indicated in individuals at risk of HIV-1 infection from receptive vaginal sex because the effectiveness in this population has not been evaluated.

“PrEP drugs are highly effective when taken as indicated in the drug labeling and can prevent HIV infection,” said Jeffrey Murray, M.D., M.P.H., deputy director of the Division of Antiviral Products in the FDA’s Center for Drug Evaluation and Research. “This approval provides more prevention options for certain patients at-risk for acquiring HIV and helps further efforts by the FDA and the U.S. Department of Health and Human Services to facilitate the development of HIV treatment and prevention options to reduce new HIV infections.”
Population Representation in HIV Cure Research:  
A Review of Diversity Within HIV Cure Studies Based in the United States

Carly Roberts,1,4 Emma Creamer,2,4 Cheriko A. Boone,3,5 A. Toni Young,2,4 and Manya Magnus1,1

Abstract

HIV is experienced across diverse populations, with gender and racial/ethnic minority populations bearing a significant proportion of disease. With National Institutes of Health (NIH) placing a priority on the enrollment of women and racial/ethnic minorities into studies, it is important to understand the diversity of participants in research. We sought to characterize how HIV cure research studies report data on diversity. A sampling frame of publications with funding provided by the Martin Delaney Collaboratories for HIV Research in 2019 was reviewed for reporting of demographic data. Of 55 publications that included research on humans/human specimens, only 51% provided any demographic description. There often is insufficient consideration of diversity of populations in HIV cure research. Ameliorating gaps in this regard will require recruitment of diverse populations/specimens and specifications to report demographic data in articles. This will ensure inclusion of diverse participants in HIV cure research from earliest laboratory to eventual phase III studies.

Keywords: diversity, generalizability, representativeness, HIV cure research
Practical Strategies

In the immortal words of Anthony Rawls...

Expect nothing and appreciate everything!
Think of inclusivity on all fronts:

- Abilities
- Age
- Ethnicity
- Mental health
- Physical conditions
- Race
- Risk groups
- Sex, gender identity
- Sexual orientation
- Socioeconomic status
- Etc.
Proposal Phase (1)

- Allow enough time for conversations with community prior to writing
- Build team during proposal phase
- Provide resources

<table>
<thead>
<tr>
<th>Who does the work</th>
<th>Who supports the work</th>
<th>Who should benefit from the work</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI</td>
<td>Leaders in the field, mentors, administrative leadership</td>
<td>Stakeholders</td>
</tr>
<tr>
<td>Project Director</td>
<td>Co-Investigators</td>
<td>CAB members, community</td>
</tr>
<tr>
<td>Research Associate(s) (field, analysis, lab, etc.)</td>
<td>Experts, consultants</td>
<td>Peers</td>
</tr>
<tr>
<td>Field team</td>
<td>External advisors, SACs</td>
<td>Local public health community, clinical stakeholders, government</td>
</tr>
<tr>
<td>Administrative supports</td>
<td></td>
<td></td>
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</tbody>
</table>
Proposal Phase (2)

- Require diversity by design
Implementation Phase (1)

- Invest in staff from the community
  - Train and pay them
- Partner with community based organizations and leaders
  - Provide resources
- Make a meaningful CAB
- Monitor inclusion
- Invite feedback on tools, instruments, protocols
- Listen and learn from community experts
Implementation Phase (2)

- When you make mistakes, be honest about them
- Change course if needed
Dissemination Phase

• Include community members in dissemination as authors, at conferences
• Find out what resources the community needs to get the word out – and create them with them and for them
• Provide access to data
• Stay in touch even when the study is over
Questions and Discussion
thank you