# Practical Strategies for Meaningful Community Engagement in Clinical Trials

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**Manya Magnus, PhD, MPH**
Professor & Interim Chair
Department of Epidemiology
Milken Institute School of Public Health
George Washington University

CTSI Clinical and Translational Science Institute at Children's National
A PARTNERSHIP WITH THE GEORGE WASHINGTON UNIVERSITY

Milken Institute School of Public Health
THE GEORGE WASHINGTON UNIVERSITY

# Disclosures

- No financial conflicts to disclose

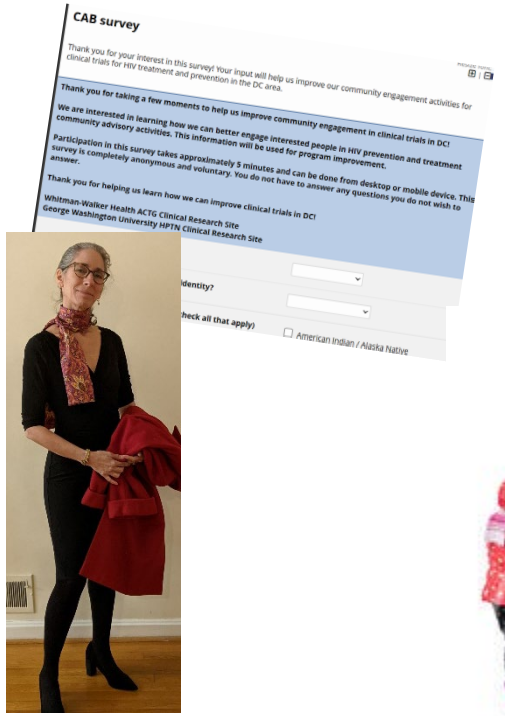
# Outline

- 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

# The Belmont Report (2)

- **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

# The Belmont Report (3)

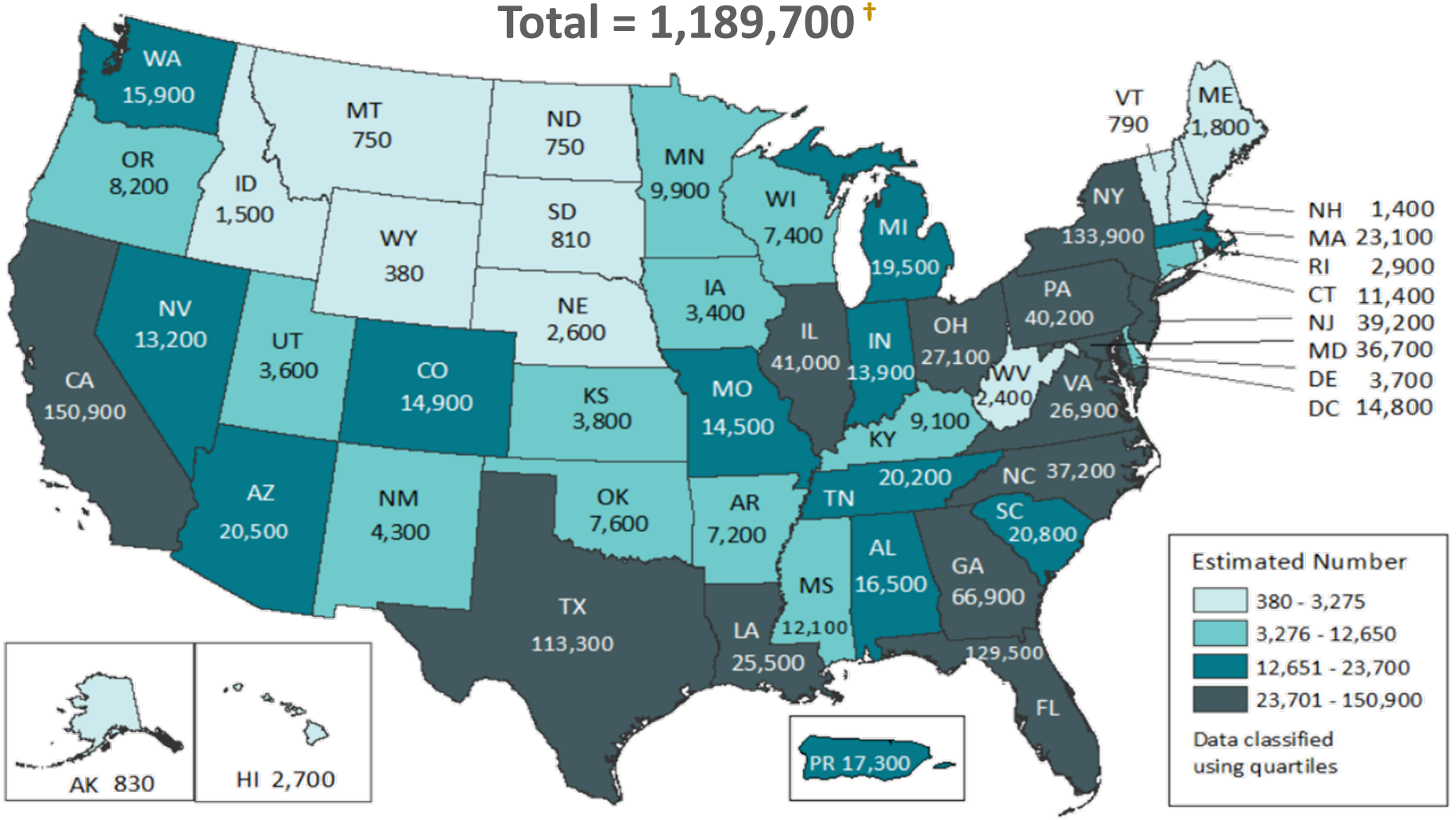
- **Justice**—“Who ought to receive the benefits of research and bear its burdens? This is a question of justice, in the sense of "fairness in distribution" or "what is deserved." An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is 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

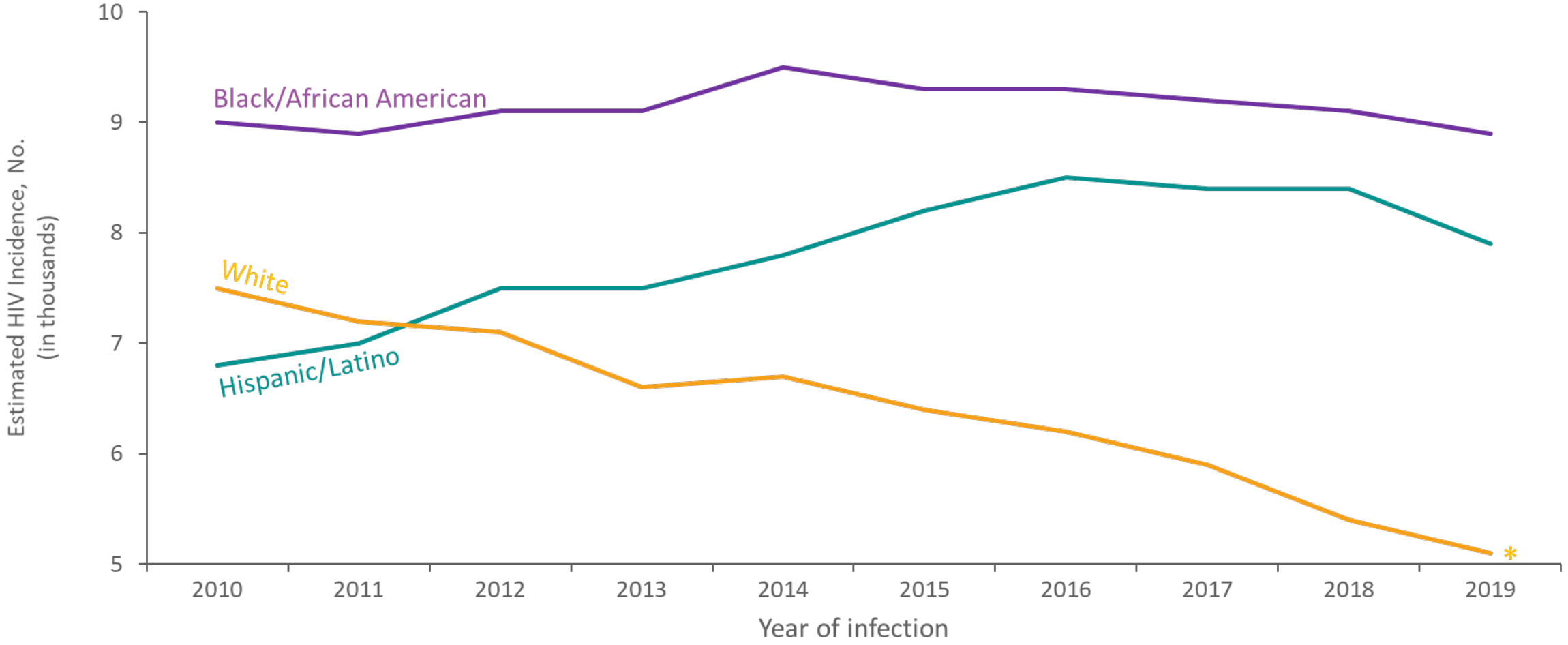
## Total = 1,189,700 †




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.

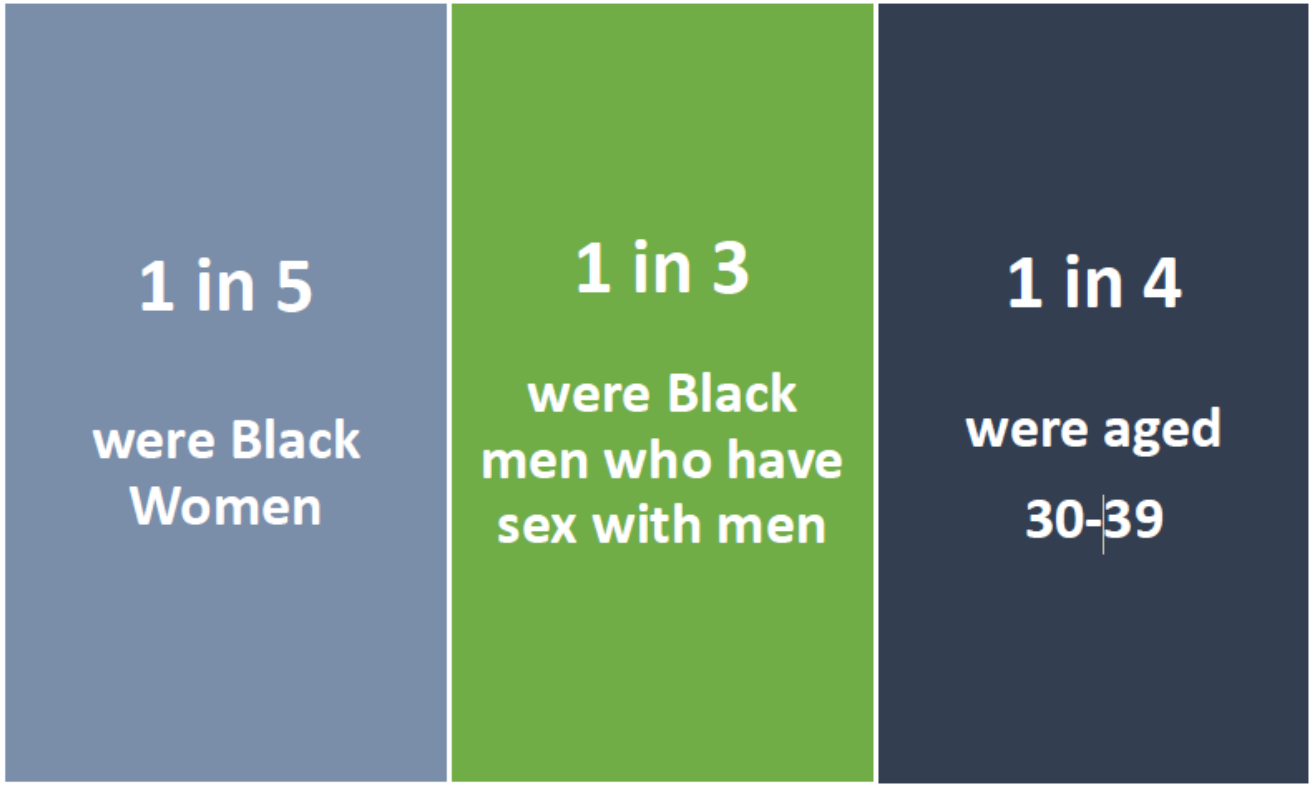
# Estimated HIV Incidence among Men Who Have Sex with Men Aged ≥13 Years by Race/Ethnicity, 2010–2019—United States




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 ($P < .05$).

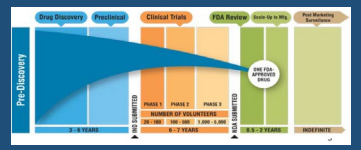
# Characteristics of Newly Diagnosed HIV Cases– District of Columbia, 2016-2020




DC | HEALTH

# PrEP in US as an example

**Pre-2012**




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

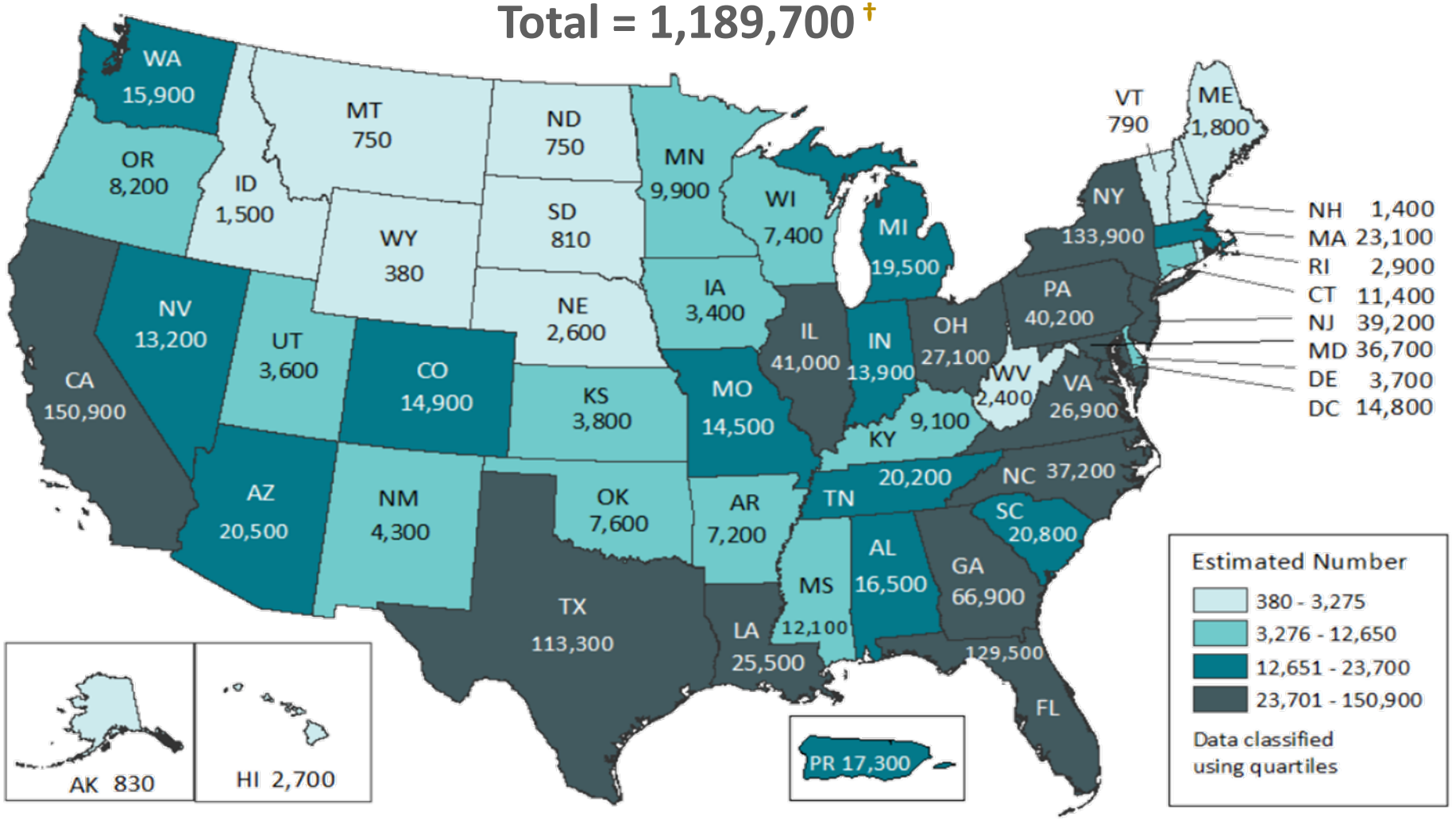
Even[illegible] successful implem[illegible]n and realized outc[illegible]

## 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 †

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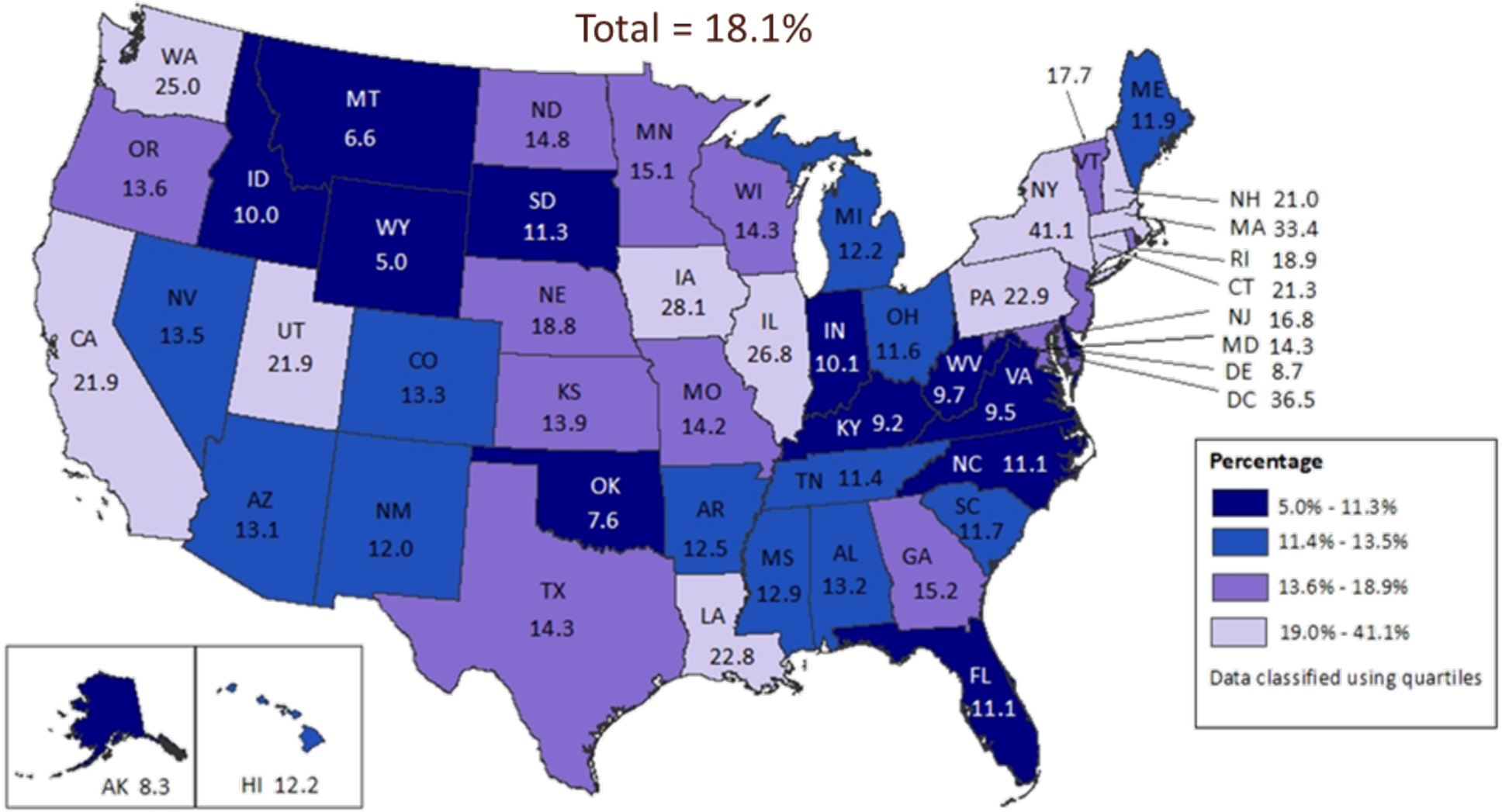
†Total estimate for the United States does not include data for Puerto Rico.

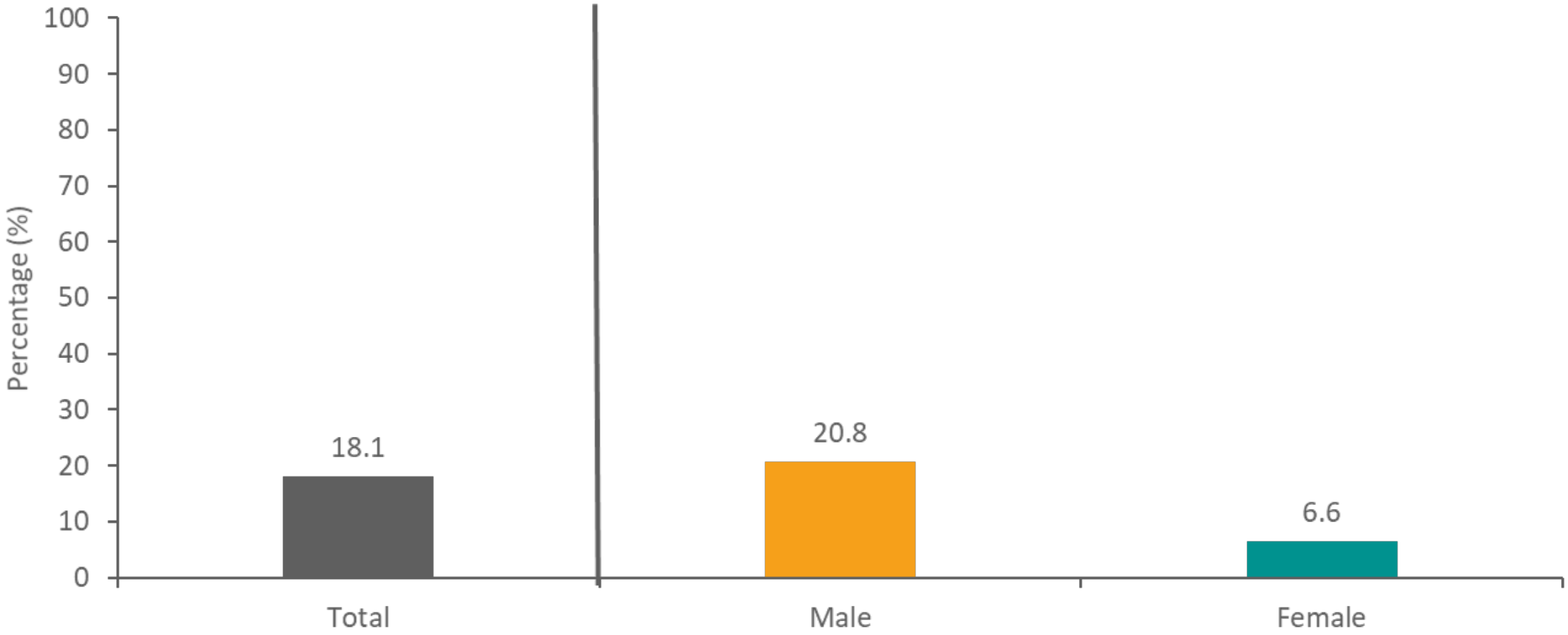
# PrEP Coverage among Persons Aged ≥16 Years, by Area of Residence, 2018—United States




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.

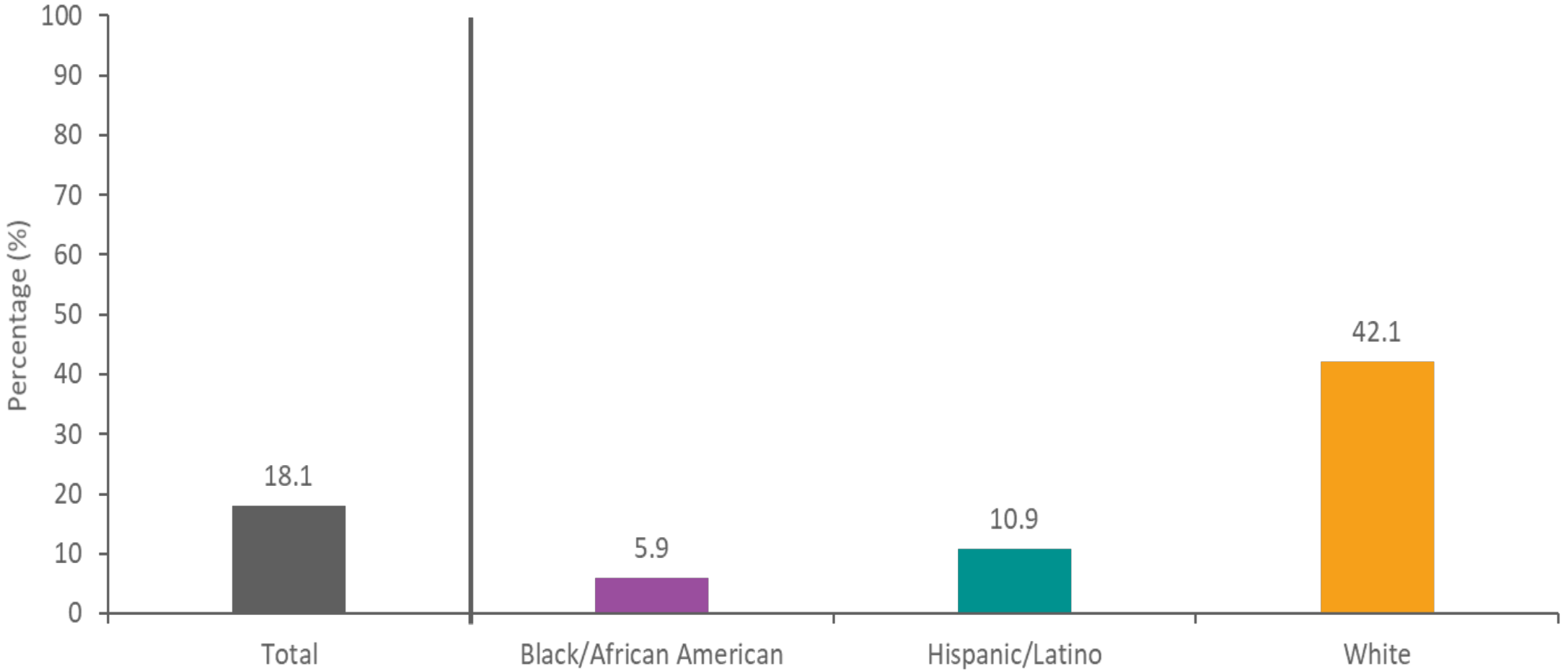
# PrEP Coverage among Persons Aged ≥16 Years, by Sex at Birth 2018—United States




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



ents

**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 35kg 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."

AIDS RESEARCH AND HUMAN RETROVIRUSES
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# Population Representation in HIV Cure Research: A Review of Diversity Within HIV Cure Studies Based in the United States

Carly Roberts,[1,*] Emma Creamer,[2,*] Cheriko A. Boone,[3] A. Toni Young,[2,†] and Manya Magnus[1,†]

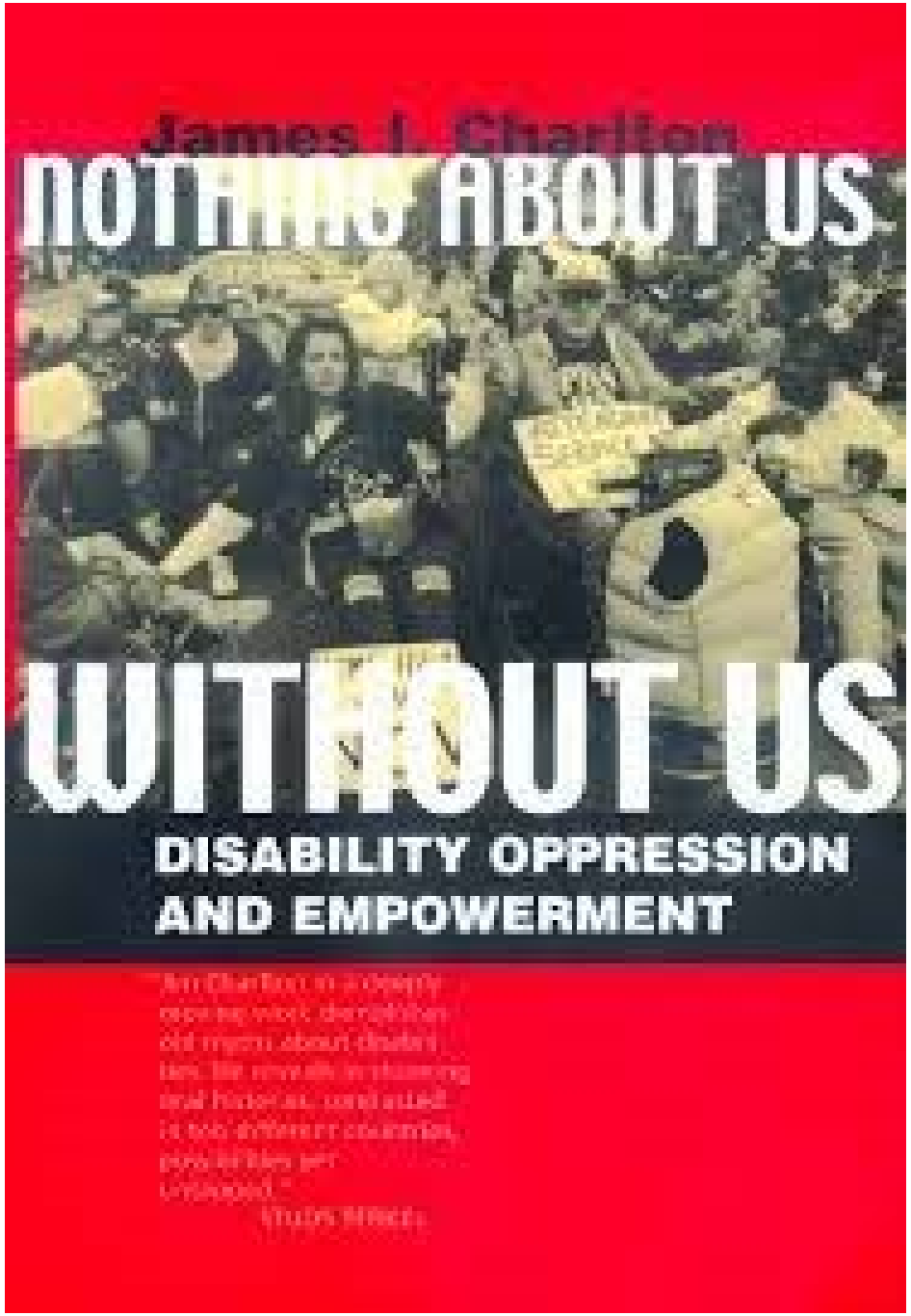
**Abstract**

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…




## Think of inclusivity on all fronts:

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

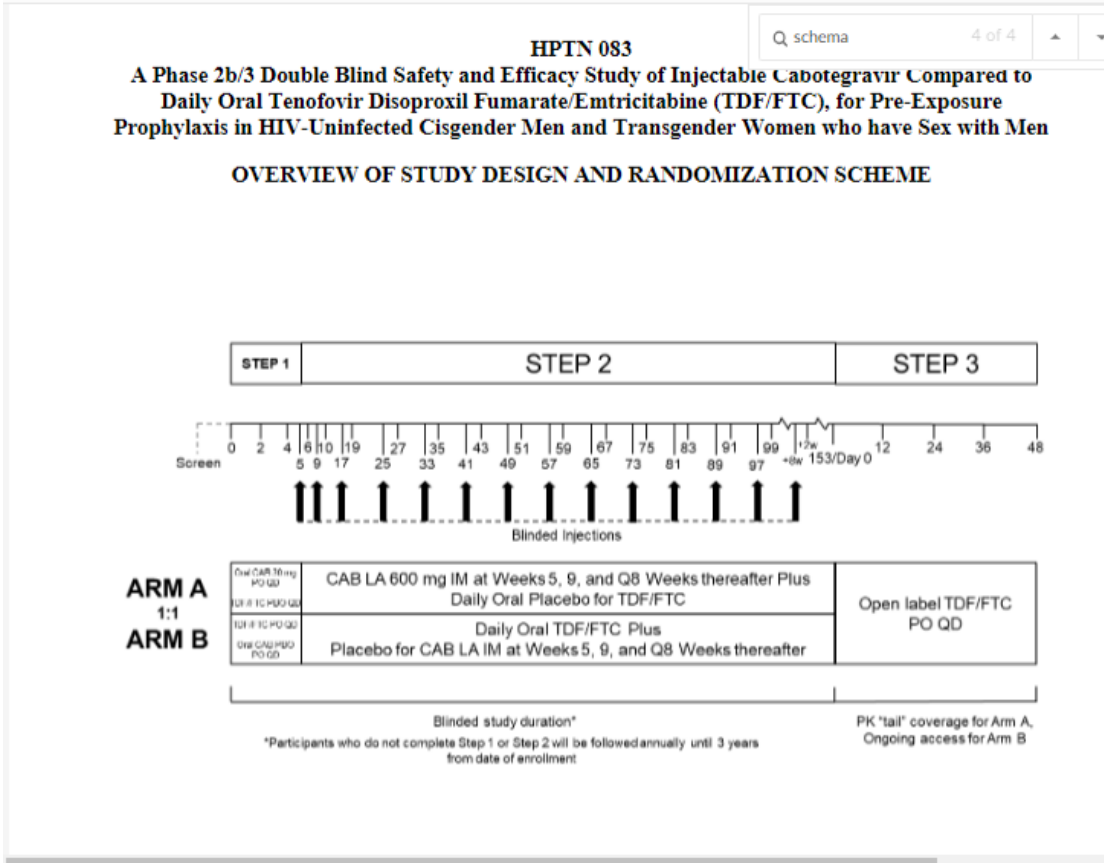
# Proposal Phase (1)

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

| Who does the work | Who supports the work | Who should benefit from the work |
|---|---|---|
| PI | Leaders in the field, mentors, administrative leadership | Stakeholders |
| Project Director | Co-Investigators | CAB members, community |
| Research Associate(s) (field, analysis, lab, etc.) | Experts, consultants | Peers |
| Field team | External advisors, SACs | Local public health community, clinical stakeholders, government |
| Administrative supports | | |

# Proposal Phase (2)

- Require diversity by design



HPTN 083

**A Phase 2b/3 Double Blind Safety and Efficacy Study of Injectable Cabotegravir Compared to Daily Oral Tenofovir Disoproxil Fumarate/Emtricitabine (TDF/FTC), for Pre-Exposure Prophylaxis in HIV-Uninfected Cisgender Men and Transgender Women who have Sex with Men**

**OVERVIEW OF STUDY DESIGN AND RANDOMIZATION SCHEME**



The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

## Cabotegravir for HIV Prevention in Cisgender Men and Transgender Women

R.J. Landovitz, D. Donnell, M.E. Clement, B. Hanscom, L. Cottle, L. Coelho, R. Cabello, S. Chariyalertsak, E.F. Dunne, I. Frank, J.A. Gallardo-Cartagena, A.H. Gaur, P. Gonzales, H.V. Tran, J.C. Hinojosa, E.G. Kallas, C.F. Kelley, M.H. Losso, J.V. Madruga, K. Middelkoop, N. Phanuphak, B. Santos, O. Sued, J. Valencia Huamaní, E.T. Overton, S. Swaminathan, C. del Rio, R.M. Gulick, P. Richardson, P. Sullivan, E. Piwowar-Manning, M. Marzinke, C. Hendrix, M. Li, Z. Wang, J. Marrazzo, E. Daar, A. Asmelash, T.T. Brown, P. Anderson, S.H. Eshleman, M. Bryan, C. Blanchette, J. Lucas, C. Psaros, S. Safren, J. Sugarman, H. Scott, J.J. Eron, S.D. Fields, N.D. Sista, K. Gomez-Feliciano, A. Jennings, R.M. Kofron, T.H. Holtz, K. Shin, J.F. Rooney, K.Y. Smith, W. Spreen, D. Margolis, A. Rinehart, A. Adeyeye, M.S. Cohen, M. McCauley, and B. Grinsztejn, for the HPTN 083 Study Team*

ABSTRACT

**BACKGROUND**

Safe and effective long-acting injectable agents for preexposure prophylaxis (PrEP) for human immunodeficiency virus (HIV) infection are needed to increase the options for preventing HIV infection.

**METHODS**

We conducted a randomized, double-blind, double-dummy, noninferiority trial to compare long-acting injectable cabotegravir (CAB-LA, an integrase strand-transfer inhibitor [INSTI]) at a dose of 600 mg, given intramuscularly every 8 weeks, with

The authors' grees, and al Appendix. Ad Landovitz at t Research and California, Los Ste. 200, Los rlandovitz@n

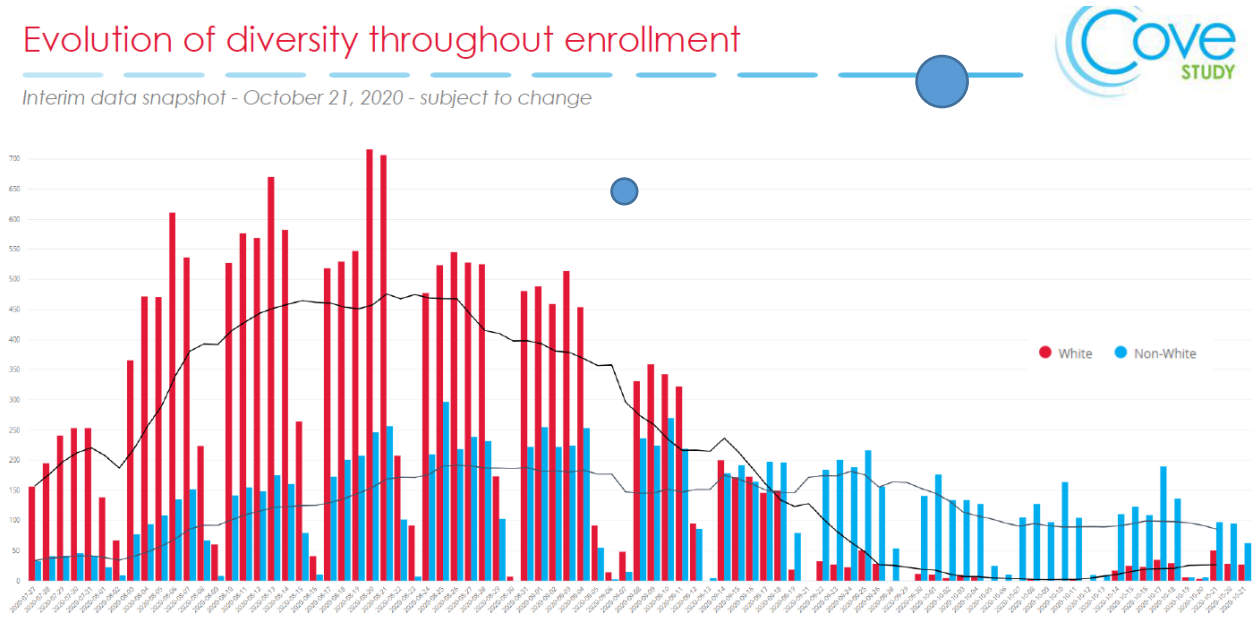
# Implementation Phase (1)

- 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)

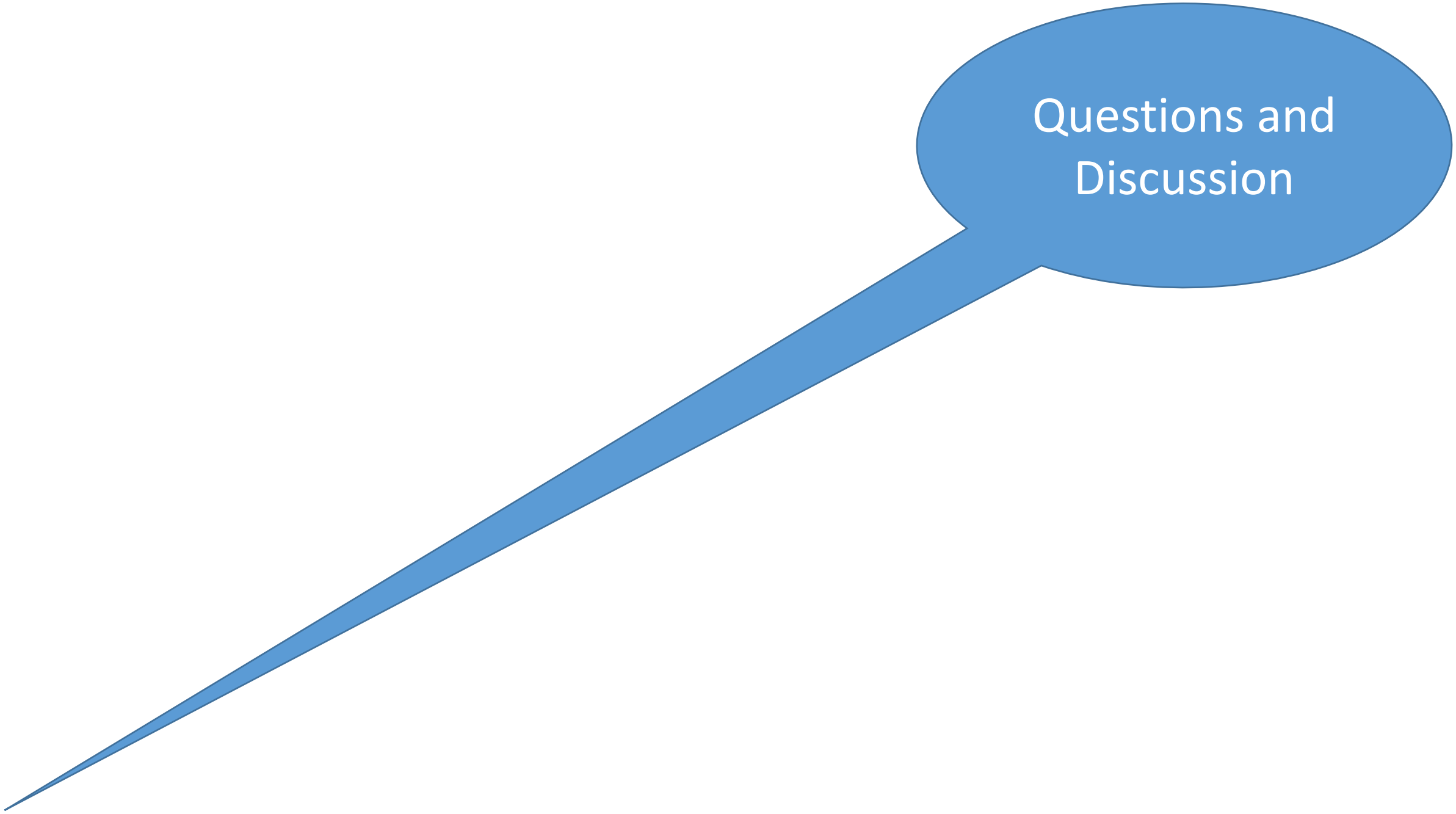
At GW,
n=349,
~50% BIPOC

- 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


Contact information
Manya Magnus, PhD, MPH
manyadm@gwu.edu
202-994-3024