

Diversity and Inclusion in Clinical Research

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EIDB
EMERGING INFECTIOUS
DISEASES BRANCH



WRAIR
Walter Reed Army
Institute of Research

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- The opinions contained in this presentation are not intended to represent the position of WRAIR, EIDB or MHRP
- I have no personal conflict of interest relevant to this presentation
- Please note Social Work CEU is pending approval, if you request for a certificate, you must complete and submit an evaluation

Outline

- A little about me
- About our institution: WRAIR
- How clinical trials can contribute to public health
- Importance of diversity and inclusion in clinical trials
- Barriers to clinical trials participation for historically underrepresented populations
- Diversity and inclusion in COVID trials
- Role of community/stakeholder engagement in research
- Discussion/Q &A

Pediatrician

**Laboratory
Researcher**



Who am I?

Mom

**Clinical
Researcher**

**Vaccine
Developer**



Community Advocate



Walter Reed Army Institute of Research (WRAIR)

- Established 1893
- Research to address infectious disease threats to Soldier health
- Infectious diseases such as HIV, malaria, Zika, and COVID-19
- Brain and behavioral health



Medical research is critical to protect public health

Research is needed to test vaccines, treatments, and other health interventions that benefit public health

Clinical trials are used to test these various medical interventions

The clinical trial process is long and expensive, but results can have huge impacts



NEW YORK, WEDNESDAY, APRIL 23, 1956. FIVE CENTS

SALK POLIO VACCINE PROVES SUCCESS; MILLIONS WILL BE IMMUNIZED SOON; CITY SCHOOLS BEGIN SHOTS APRIL 25

TRIAL DATA GIVEN
Efficacy of 80 to 90%
Shown—Salk Sees
Further Advance

IN COURT HEARS
WIFE WILL DEFEY
WICK END TO BIAS

Local Approaches Urged
Integration of Schools—
Two Lawyers Opposed

By LAWRENCE A. HOFFMAN
APPROXIMATELY, April 23—
officials for the Salk Institute
in Philadelphia today announced
that the Salk polio vaccine
is now ready to be given
to children in the United States.
The vaccine, which is made
from the bodies of children
who have recovered from
the disease, is now being
given to children in the
United States.

Advertisement of report, summary
of Salk Institute, Page 10.

By WILLIAM L. LUTHERBURN
APRIL 23 (UPI)—Salk Institute
today announced that it
has begun to test an effective
vaccine against polio.

Photo credits:

<https://www.cincinnati.com/story/news/2020/12/10/covid-vaccine-sabin-sunday-polio/3863706001/>

<https://vaxopedia.org/2016/10/12/jonas-salk/>

**History of AIDS research:
clinical trials were essential
in developing HIV treatment
to improve health
outcomes, save lives**

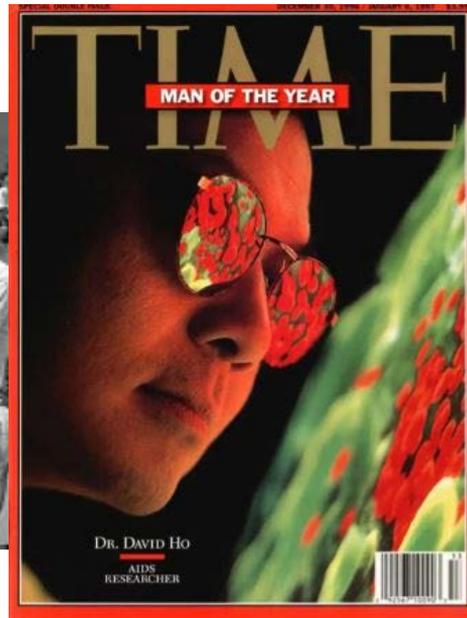
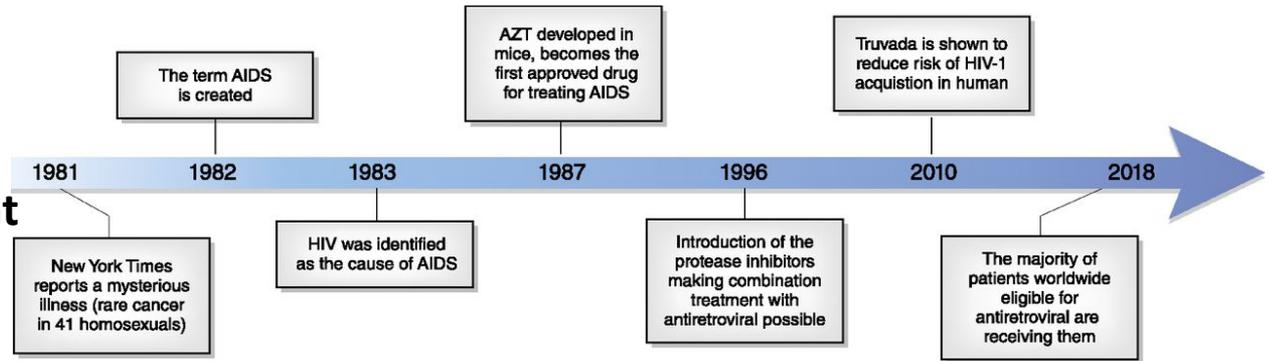


Photo credits: <https://electricliterature.com/sarah-schulman-book-let-the-record-show-a-political-history-of-act-up-new-york-1987-1993-aids-crisis/>
<https://time.com/3627996/david-ho-person-of-the-year/>
<https://theconversation.com/it-will-take-more-than-36-billion-every-year-to-end-aids-62382>

Issues with Diversity in Clinical Research

- Historically, participation in clinical trials has not reflected the diversity of the US population
- In prior decades, more research was conducted in men than women
 - Women were thought to have more biological variability
 - Men were considered “the norm” in biomedical research
- Black and brown populations are often under-represented in clinical research, relative to their proportion in the population



Inclusion in clinical research is a matter of justice



- **Ethical review** and protection of research participants is a critical part of the process
- Medical research may provide **direct benefits** to study participants
- Inclusion can facilitate **uptake** of successful interventions in these populations

Diverse and equitable representation in clinical research are critical

Lack of diversity could lead to faulty estimates of treatment outcomes, safety and efficacy of vaccines, drugs or other products in different population groups



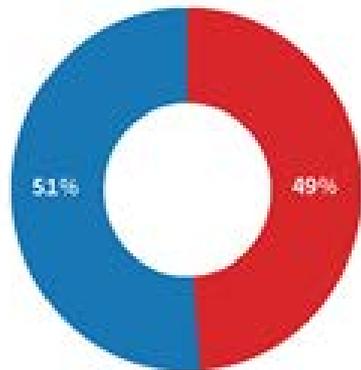
Photo credits: <https://www.fda.gov/consumers/minority-health-and-health-equity/clinical-trial-diversity>

Demographics of Trial Participation

Demographic Categories

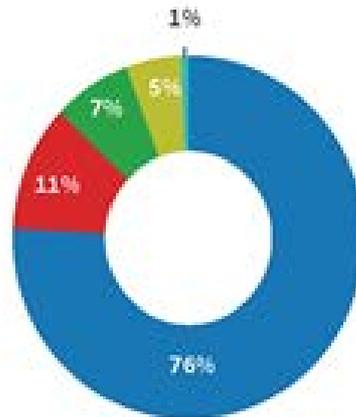
Clinical trial participation is broken down into four categories: sex, race, age, and ethnicity.*

Sex Distribution



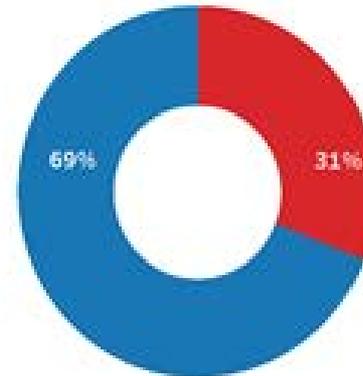
Female ■
Male ■

Race Distribution



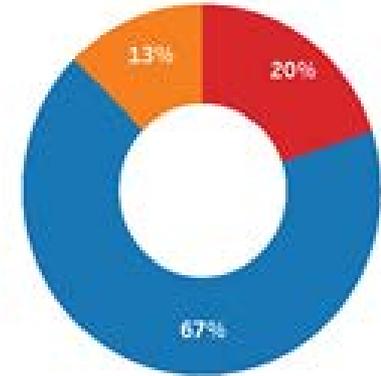
White ■
Asian ■
Black or African American ■
Other ■
American Indian or Alaska Native ■

Age Distribution



< 65 Years ■
>= 65 Years ■

Ethnicity Distribution



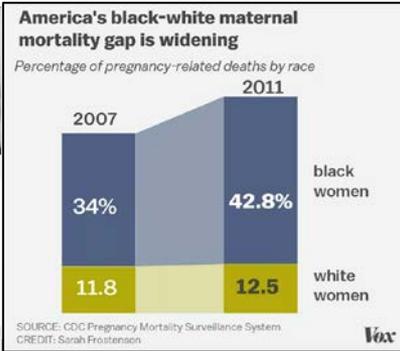
Hispanic or Latino ■
Not Hispanic or Latino ■
Missing ■

*Definitions for race and ethnicity used in the document can be found in the Terminology section.

Example: multiple myeloma trial

- Multiple myeloma (MM) is a cancer affecting white blood cells
- MM disproportionately affects Black Americans:
 - 20% of MM patients are Black
 - Only 13% of the US population is Black
- A promising new drug, Ninlaro, was approved by the FDA in 2015 on the basis of a clinical trial of 722 patients with MM
- The FDA expressed concern that only 1.8% of the trial participants were Black

Barriers to clinical trial participation for historically underrepresented groups



NATURE | NEWS FEATURE

Human experiments: First, do harm

In the 1940s, US doctors deliberately infected thousands of Guatemalans with venereal diseases. The wound is still raw.

Matthew Walter

08 February 2012

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Federico Ramos has suffered excruciating symptoms after US experiments.



Social Determinants of Health

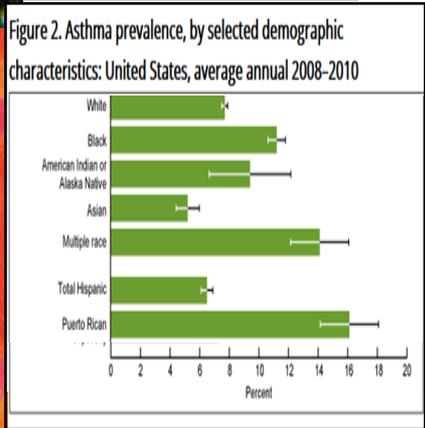
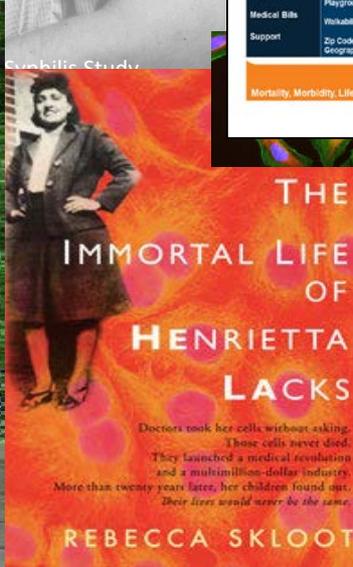
Economic Stability	Neighborhood and Physical Environment	Education	Food	Community and Social Context	Health Care System
Employment	Housing	Literacy	Hunger	Social Integration	Health Coverage
Income	Transportation	Language	Access to Healthy Options	Support Systems	Provider Availability
Expenses	Safety	Early Childhood Education	Community Engagement	Discrimination	Provide Linguistic and Cultural Competency
Debt	Parks	Vocational Training	Stress	Quality of Care	
Medical Bills	Walkability	Higher Education			
Support	Zip Code/Geography				

Health Outcomes
Mortality, Morbidity, Life Expectancy, Health Care Expenditures, Health Status, Functional Limitations

KFF



Statue of Sims in New York's Central Park was removed in April 2018



What are Barriers to Research Participation?

Institutional and structural factors:

- History of exploitative relationship between research institutions and minority populations
- Present day racism and marginalization, especially with regard to health care
- Geographic location (research institutions often in major metro areas only)
- Lack of community engagement between the institution and lay communities
- Lack of diverse workforce, lack of professional development to support diversity

Research team and research protocol-related factors:

- Time constraints of investigators to address engagement and outreach needs
- reluctance to increase trial costs to improve diversity
- Researcher biases towards specific minority groups
- Lack of cultural competency, lack of diverse staff

Individual-level barriers

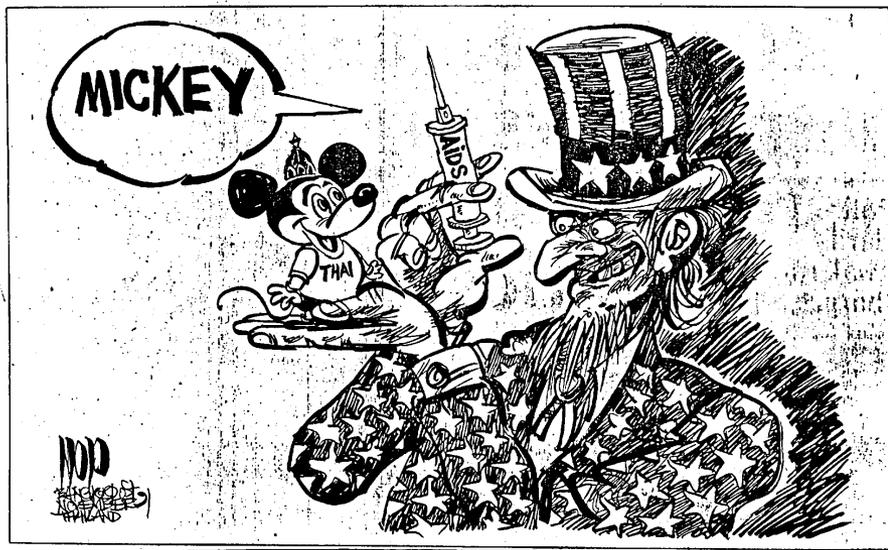
- Experience of ongoing racism and marginalization, including with relation to health care
- Mistrust of medical establishment and medical research
- Lack of awareness of research
- Limited health literacy in some cases
- Income level
- Logistical issues: transportation, childcare
- Language barriers
- ID requirements and tax reporting for clinical trial participation

Mistrust of Medical Research Crosses Borders



Bangkok Post Wednesday November 6, 1991

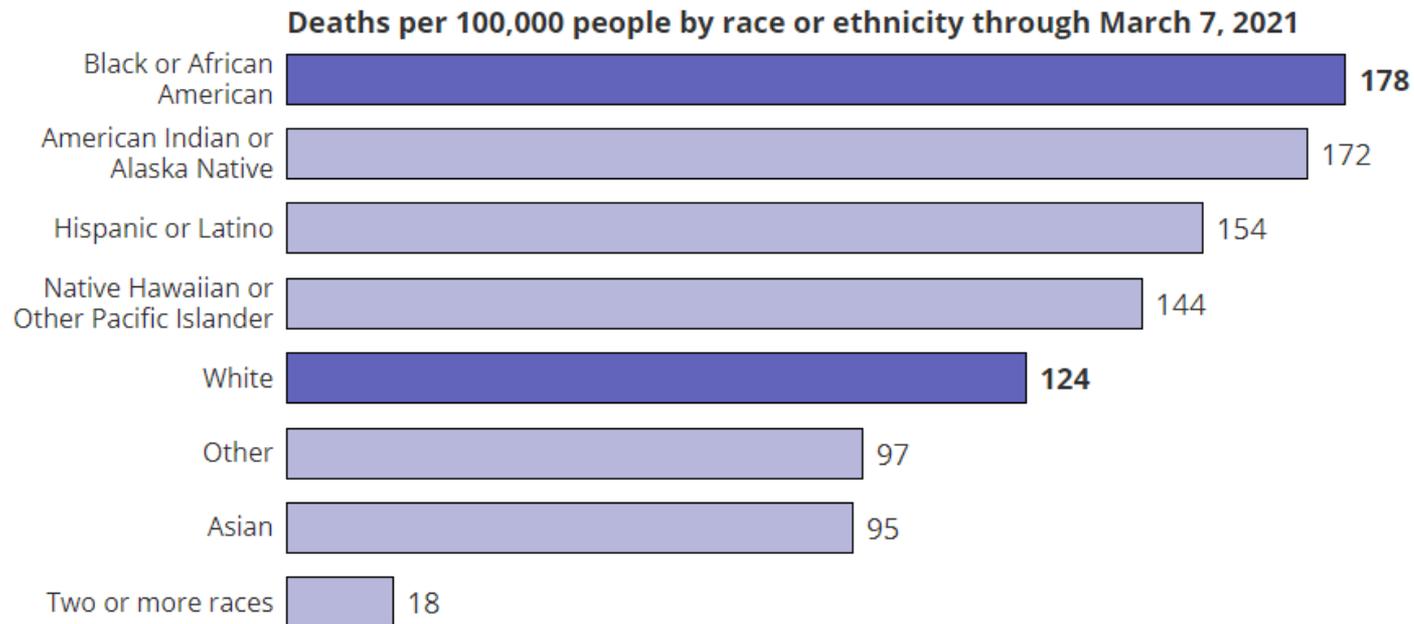
Thailand, 1991



Additional Challenges from COVID

- Need for **rapid** development of new vaccines and treatments
- Need to overcome substantial fear and mistrust among the public about clinical research
- Challenges of outreach in pandemic conditions
- Some minority groups in the US have been hit especially hard by the COVID pandemic, and these same groups may be reluctant to participate in research

COVID outcomes vary among different racial and ethnic groups



<https://covidtracking.com/race>

**These calculations are based on data from The Covid Racial Data Tracker and the U.S. Census Bureau. Race categories may overlap with Hispanic/Latinx ethnicity. Rates are not age-adjusted and some rates are underestimated due to lack of reporting of race and ethnicity categories for COVID-19 deaths.*

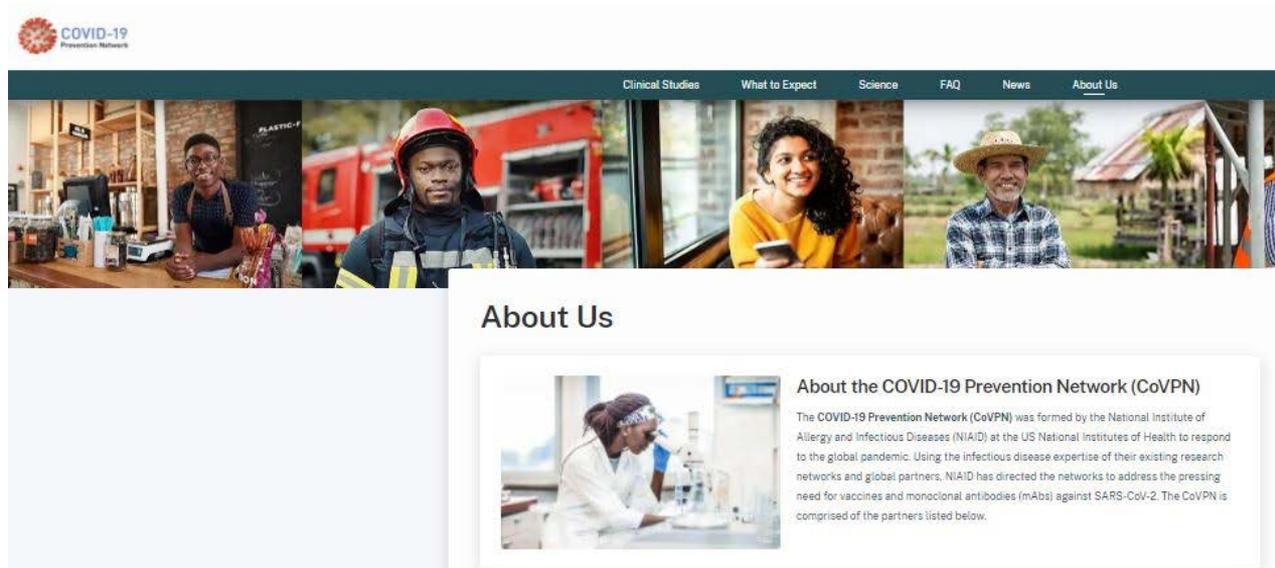
Community and stakeholder engagement can help break down barriers

Community engagement brings communities into **dialogue** with researchers and research institutions



Involves working with community-based organizations and representatives to elicit their views and to understand community perspectives and values

Research on COVID -19 vaccines and treatments



- Medical research on COVID-19 vaccines and treatments was heavily coordinated and funded by the US Government
- Vaccine trials used a network of clinical sites across the US and around the world to accomplish historic feat of rapid vaccine testing and authorization - CoVPN

NIH Community Engagement Alliance Against COVID-19 Disparities

U.S. Department of Health & Human Services | National Institutes of Health

NIH National Institutes of Health
Community Engagement Alliance

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NIH Community Engagement Alliance (CEAL)

The Community Engagement Alliance (CEAL) Against COVID-19 Disparities **works closely with the communities hit hardest by COVID-19.**

Find FAQs, fact sheets, and other resources you can share to provide accurate information and encourage people to get informed and take steps to overcome COVID-19.

[Explore Our Resources](#)

Explore CEAL Topics

- [Vaccines](#)
- [Diversity & Inclusion](#)
- [Clinical Trials](#)
- [COVID-19 Basics](#)

Get the Latest CEAL News

Sign up for the CEAL eNewsletter now to ensure you get our newest COVID-19 resources.

[Sign Up Now](#)

<https://covid19community.nih.gov/>

Community engagement can provide vital information about research and help build trust.

- Researchers also bring information about the research and address questions, misperceptions, and concerns
- Community perspectives can be incorporated into research design, procedures, recruitment, and advertising

Image: Infographic produced by COVPN

<https://www.coronaviruspreventionnetwork.org/>



Messenger RNA (mRNA) Vaccines

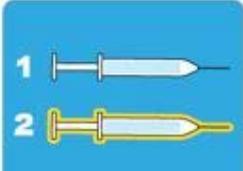
ARE THEY SAFE?

? Are the mRNA vaccines safe?

YES! Long-term safety is still being studied. The Moderna vaccine has been tested in approximately 30,000 people 18 years and older in the USA. The Pfizer vaccine was tested in approximately 43,000 people 16 years and older in the USA, Argentina, Brazil, and South Africa.



Most side effects happen within 7 days of vaccination and last 1-3 days



More people reported side effects following the second dose

Commonly reported side effects were **mild to moderate** and include:



Injection site soreness



Fatigue



Headaches



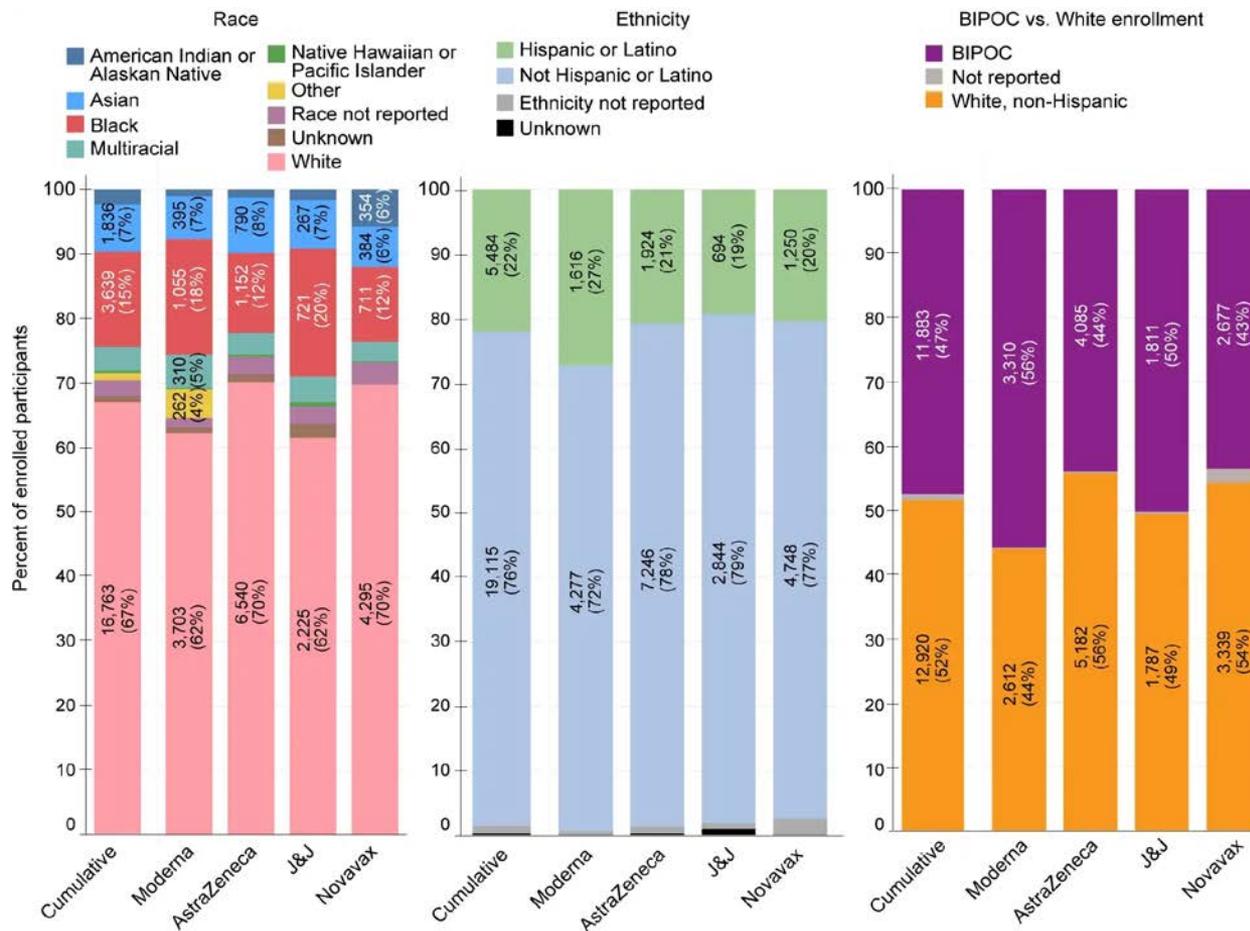
Body aches

Rarely reported side effects include: swollen lymph nodes*, appendicitis, and Bell's Palsy* (temporary weakness or paralysis of muscles in face).

*A note about Bell's Palsy and swollen lymph nodes: The rate of both Bell's Palsy and swollen lymph nodes seen in study participants is similar to the rate seen in the general population. These conditions were not determined to be associated with the vaccine.

Help end the uncertainty.  COVID-19 Prevention Network [PreventCOVID.org](https://www.PreventCOVID.org)

Community engagement to increase diversity in COVID-19 vaccine trials



reference: Andrasik et al, PLoSOne

<https://journals.plos.org/plosone/article/comments?id=10.1371/journal.pone.0258858>

WRAIR Community Engagement Project

Began October 2020

Goals

- Bringing community perspectives into our research plans and activities
- Increasing diversity in research
- Informing communities about the importance of community participation

Activities to Date

- established a Community Advisory Board
- developed new partnerships with local organizations
- gathering information about community perspectives and needs
- organizing educational activities



Conclusions-1

- Diversity and inclusion are critical to realize the full benefits of research in a just manner, so that all populations and communities can achieve better health outcomes
- Marginalized groups are underrepresented in research because they lack access to research, information about research, and trust in researchers and research institutions, among many other factors
- A concerted effort is needed by research institutions, regulators, and community-based organizations to work together to address this challenge

Conclusions-2

Critical role of community engagement



Community engagement can help address current health needs and preparedness for future pandemics



Having robust community engagement structures in place makes research more nimble, responsive, and inclusive



CE processes take time to build and depend on solid relationships—cannot wait for the next pandemic to arrive to start this work



Continuous engagement is necessary to maintain relationships and trust

Discussion / Q&A

Questions? Comments?

Want more information?

Connect with a WRAIR Community Engagement Team member by sending us an email at

Community@eidresearch.org

Call: (301)-204-5511

