Community Health Centers Engaging in Research: Health Equity at the Center

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June 7, 2024

WHAT IS CLINICAL RESEARCH?

- The study of human health and disease
- Includes clinical trials, observational and interventional studies
- Understand the causes, development, prevention, diagnosis and treatment of diseases and medical conditions
- Goal is to improve patient care and outcomes by advancing medical knowledge and developing new and effective therapies, diagnostic tools, and preventive measures

WHY DO WE NEED CLINICAL RESEARCH?

- Essential for the advancement of medical science and the improvement of patient care
- Identifies effective ways to prevent diseases, leading to healthier populations
- Ensures that new treatments are safe, effective, and accessible, which ultimately leads to better health outcomes and a more equitable healthcare system.
- Provides evidence to inform and shape health policies and guidelines.

HEALTH EQUITY

- Ensuring that **every person**, regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, preferred language, or geographic location, has the opportunity to achieve their full health potential without disadvantages.
- **Integrating health equity** in research and clinical practice applies frameworks that center on **fairness, opportunity, quality, and social justice** to promote well-being and health.
- **Sustainable health equity** often involves changes in laws, policies, processes, norms, values, resource allocation, and power structures (intentional and unintentional) that affect access to healthcare, employment, education, wealth, public safety, housing, safe green spaces, and other social determinants of health.

IMPORTANCE OF DIVERSE PATIENT REPRESENTATION IN CLINICAL RESEARCH

- Representation in clinical research is essential to developing treatments that are effective, safe and equitable for all populations.
- Different populations may have unique genetic variations that affect how diseases manifest and respond to treatments.
- Some diseases disproportionately affect certain racial and ethnic groups. Understanding these patterns can lead to more effective interventions.
- Diverse participation helps in developing treatments that are effective across different populations, avoiding a one-size-fits-all approach.

THE CURRENT LANDSCAPE OF CLINICAL RESEARCH

- Underrepresentation of minority groups

	% of US population	% of clinical trial participants
Black/African Americans	13.4	< 5
Hispanics/LatinX	18.5	< 8
Asians	5.9	1-3
Native Americans	1.3	< 1

CLINICAL RESEARCH DOES NOT BENEFIT ALL GROUPS EQUALLY

- Minority Populations are underrepresented
- Genomic data is not diverse enough: **91%** of genetic material derives from people of European Ancestry
- The common misconception is that minority patients are unwilling to participate, but in reality, they are **not** being **asked** or informed about study opportunities
- More diversity is needed among HCPs, Principal Investigators (PIs), and personnel. Diverse patient enrollment is highly correlated with diversity of site staff

Alzheimer’s Disease (AD)

Alzheimer's disease poses a significant risk to both Hispanic and Black/African American populations, with these groups experiencing higher rates of the disease compared to non-Hispanic whites.

Alzheimer’s Development **Risk**

Black/African American
2x greater chance

Hispanic/Latino
1.5x greater chance

AD **Clinical Trial Participants**

Black/African American	Hispanic/Latino	Non-Hispanic White
7.3%	**3.4%**	**84.7%**

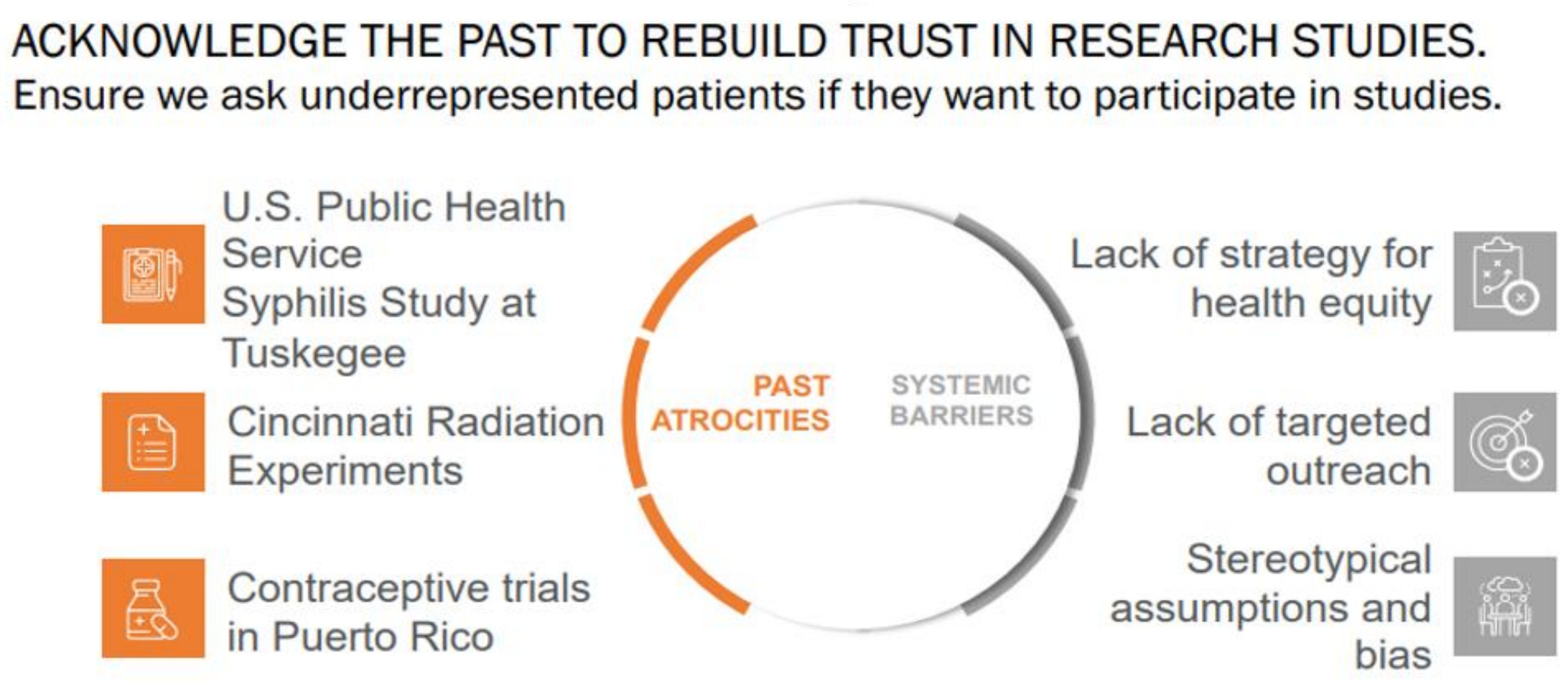
Source: https://www.ncbi.nlm.nih.gov

HCP REFERRALS TO CLINICAL TRIALS IS KEY!

- **68%** doctors did not refer a patient because of lack of information about the protocol
- **48%** Volunteer participants in a clinical trial found out about it from their physician
- **81%** patients indicated they'd be more likely to enroll in a clinical trial if their HCP referred them

Source: https://www.medicaleconomics.com/view/doctors-arent-afraid-refer-patients-clinical-studies

PAST ATROCITIES AND SYSTEMIC BARRIERS



ACKNOWLEDGE THE PAST TO REBUILD TRUST IN RESEARCH STUDIES.

Ensure we ask underrepresented patients if they want to participate in studies.

PAST ATROCITIES

- U.S. Public Health Service Syphilis Study at Tuskegee
- Cincinnati Radiation Experiments
- Contraceptive trials in Puerto Rico

SYSTEMIC BARRIERS

- Lack of strategy for health equity
- Lack of targeted outreach
- Stereotypical assumptions and bias

CONSEQUENCES OF INEQUITY

- Validity of Research Outcomes

- Biased Research Outcomes - Treatments are not effective or safe for all groups

- Health Disparities – Exacerbates existing disparities, prevents equitable healthcare advancements

CHANGE IS NEEDED…..

Efforts to Improve Representation

- Community Engagement – Building trust with community leaders and organizations
- Educational Campaigns – Increasing awareness about clinical research and clinical trials
- Inclusive Study Design – Culturally sensitive and relatable protocols
- Policy and Funding Initiatives – Promoting diversity in clinical research

ADDRESSING THESE DISPARITIES

- FDA introduced the **DEPICT** (**D**iverse and **E**quitable **P**articipation **i**n **C**linical **T**rials) Act

  - Aims to standardize the expectations for diversity in clinical trial recruitment
  - Ensures that clinical trial data better reflects the demographics of the population who will use the medication
  - Emphasizes the need for companies to plan and report on their strategies to recruit a diverse group of study participants

FOOD AND DRUG OMNIBUS REFORM ACT (FDORA)

NEW OMNIBUS LAW:
CLINICAL TRIAL DIVERSITY STRATEGY CODIFIED INTO LEGISLATION | December 2022

FDA

DIVERSITY ACTION PLANS Sec. 3601

Requires Sponsors to Submit Diversity Action Plan for All **Phase 3 Clinical Trials** of New Drugs, Including:

- Enrollment goals disaggregated by **age group, sex, and racial and ethnic** demographic characteristics
- **Rationale** for enrollment goals
- **Explanation** of how sponsor plans to meet enrollment goals

Plans must be submitted but **no later than submission of protocol for Phase 3 study** (or other pivotal study of the drug)

https://www.congress.gov/bill/117th-congress/house-bill/2617/text
https://www.advi.com/insight/house-and-senate-pass-the-consolidated-appropriations-act-of-2023/

DIVERSITY ACTION PLANS

- FDA’s **DAPs** (**D**iversity **A**ction **P**lans)
  - DAP guidance document was recently submitted to the White House **O**ffice of **I**nformation and **R**egulatory **A**ffairs (OIRA) for final review

DIVERSITY ACTION PLANS **KEY** AREAS EXPECTED TO BE ADDRESSED

- **Specific requirements for DAP content** - Establishing enrollment goals and detailing the methodologies to achieve these goals

- **Processes for requesting waivers** - Guidelines for when and how sponsors can request exceptions from the DAP requirement if applicable

- **Procedures for submitting regular progress reports** – Ensuring ongoing compliance and adjustment to strategies based on real-world data and feedback

COMMUNITY HEALTH CENTERS ARE **KEY** TO BRIDGING THE GAP IN CLINICAL RESEARCH PARTICIPATION

- Trusted entities with the underrepresented patient populations and can effectively recruit diverse participants for clinical trials
- Can leverage patient registries, community events, and collaborations with local organizations to reach potential participants
- Provide culturally competent care and ensure that research protocols are culturally sensitive
- Support services such as transportation, childcare, and flexible scheduling can make participation more feasible for patients
- Embedded in the community

BENEFITS OF COMMUNITY HEALTH CENTERS INVOLVEMENT IN CLINICAL RESEARCH

- Improved health outcomes for diverse patient populations
- Enhanced understanding of how different populations respond to treatments
- Strengthening the trust between healthcare providers and communities

OUTCOMES OF COMMUNITY HEALTH CENTERS INVOLVEMENT IN CLINICAL RESEARCH

- **Participation Rates**
  - Expected increase in diverse participant enrollments

- **Database Growth**
  - Number of individuals willing to join a database to receive information for future studies

- **Community Impact**
  - Increased health awareness and **trust** in clinical research

FDA OMHHE **REACH** (**R**acial and Ethnic Minority **A**cceleration **C**onsortium for Health Equity) Project

- Unique first of its kind consortium of six groups supports community-engaged organizations in developing solutions for representation of minority populations in clinical research

- The NCCHCA project, led by Principal Investigator Dr. Becca Hayes, "Improving Multicultural Engagement in Clinical Research through Partnership with Federally Qualified Health Centers and Community Health Worker Programs" leverages the trust FQHCs and CHWs have in their communities, elevating voices to improve clinical research access and equity.

NCCHCA REACH PROJECT AIMS

- Formed a community engagement administrative core to guide and evaluate efforts.
- To identify barriers, we've conducted focus groups in English and Spanish (in person and virtual) with rural community members, FQHC providers, and CHWs.
- Surveys will follow, leading to new curricula for FQHC care teams and CHWs on clinical trial equity topics. Topics such as the history of clinical trials, understanding informed consent, ethical principles, opportunities to participate, importance of diversity in research participants, and benefits of clinical trial participation. This education aims to increase minority participation in clinical research at FQHCs.

Building Bridges in Communities to address diverse representation in clinical trials

TRUST IS KEY!

A LOT OF EDUCATION & AWARENESS

EMPATHY OF SITE STAFF

STAFF WHO LOOK AND TALK LIKE THE PEOPLE IN THE COMMUNITY

ENROLLMENT SITES THAT ARE IN THE COMMUNITY

QUESTIONS & DISCUSSION

THANK YOU!

¡GRACIAS!

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