# 2022 Clinical Trials Methodology Course Webinar Series

National Institute of Neurological Disorders and Stroke

## NINDS Health Disparities and Global Health Agenda

**Richard T. Benson, MD/PhD**

NINDS Division of Clinical Research

Office of Global Health and Health Disparities, Director

June 24, 2022

# *Nothing to Disclose*

# Discussion Topics:

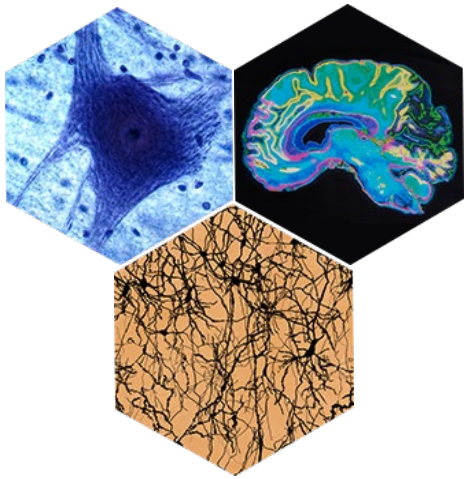
1. NINDS and OGHHD Mission
2. Health Disparities and Health Equity
3. NINDS strategic planning process
4. NINDS Portfolio Analysis and Public request for information (RFI)
5. Inclusion in clinical research
6. Diversity Training and NIH Health Equity Programs
7. Questions???

National Institute of Neurological Disorders and Stroke

***The mission of NINDS is to seek fundamental knowledge about the brain and nervous system and to use that knowledge to reduce the burden of neurological disease for all***

*Strategies:*

- Invest in basic, translational and clinical research
- Identify gaps in research and public health needs
- Train a talented and diverse research workforce
- Support development of tools and resources to enable discoveries
- Communicate and collaborate with all stakeholders, including the public
- Evaluate and continuously improve all NINDS programs



# NINDS Health Disparities Mission Statement

National Institute of Neurological Disorders and Stroke

NINDS Health Disparities Statement:

The NINDS is committed to reducing the disproportionate burden of neurological disease borne by underserved groups of society, including racial and ethnic minority, rural, and socioeconomically disadvantaged populations, by funding a spectrum of research from basic science through clinical studies and training the next generation of health disparities investigators.

MISSION STATEMENT:

- The NINDS Office of Global Health and Health Disparities leads the coordination and development of programs and initiatives that foster national and international research on disparities and inequities in neurological disease.
- Objectives for the Office include:
  - building sustainable capacity in Low and Middle-Income Countries (LMICs) to conduct and apply research to address public health challenges associated with neurological disorders;
  - supporting bilateral partnerships between the U.S. and middle-to high-income countries in research areas that are of mutual interest; and
  - advancing research on tailored prevention and treatment strategies aimed at improving health outcomes in underserved and understudied populations in the US, (including racial and ethnic minority, **rural**, sexual gender minority, and socioeconomically disadvantaged **populations**, through investments in research and training).
  - Congressional Reporting

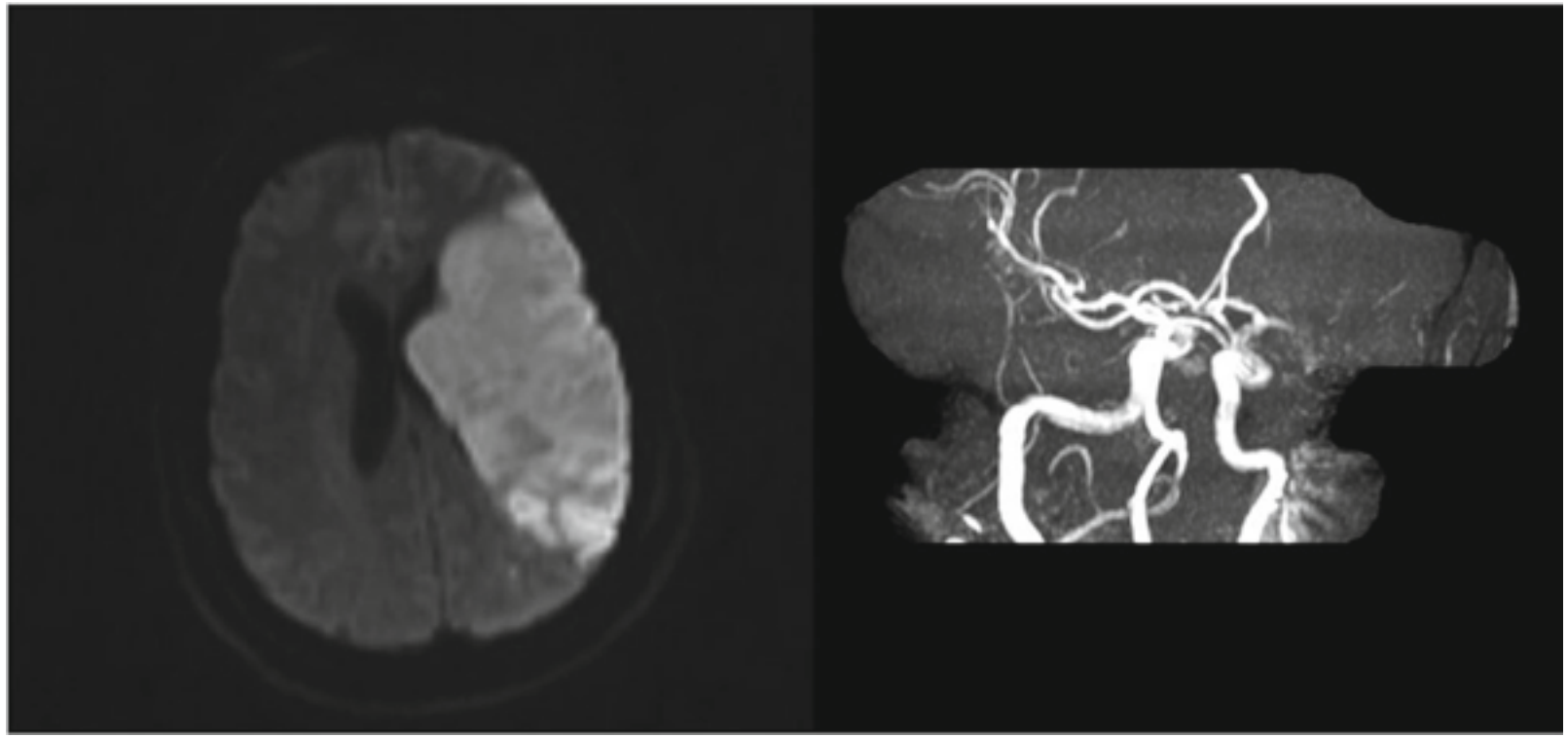
***Strategic Planning for next 5 – 10 years**

Why are we so concerned about disparities?

It's a major problem...!!!

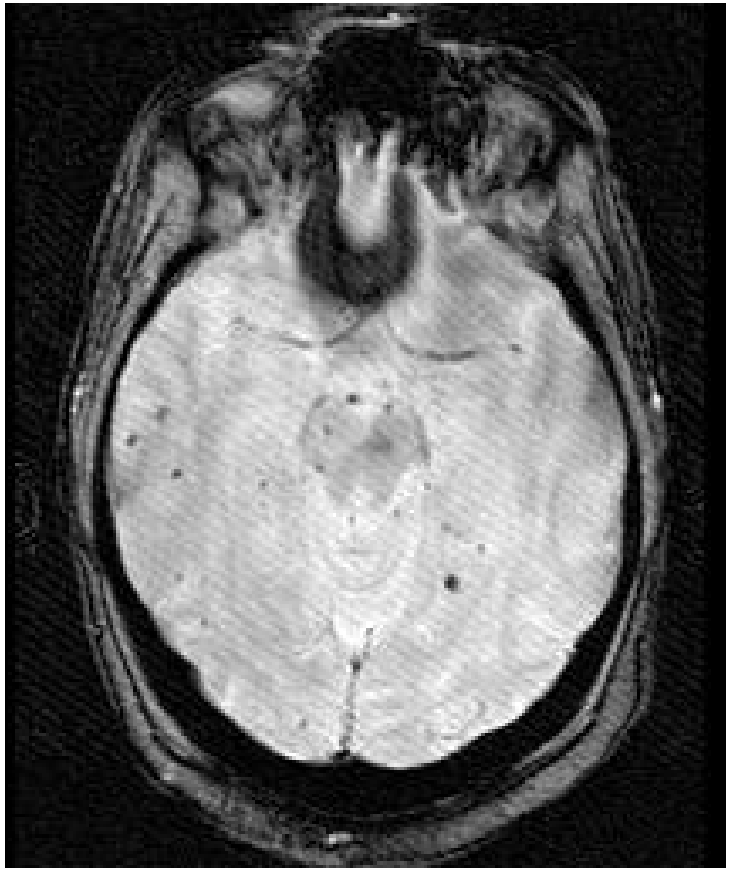
Stroke has the greatest disparity in neurologic mortality!!!

# Ischemic Stroke



# Hemorrhagic Stroke

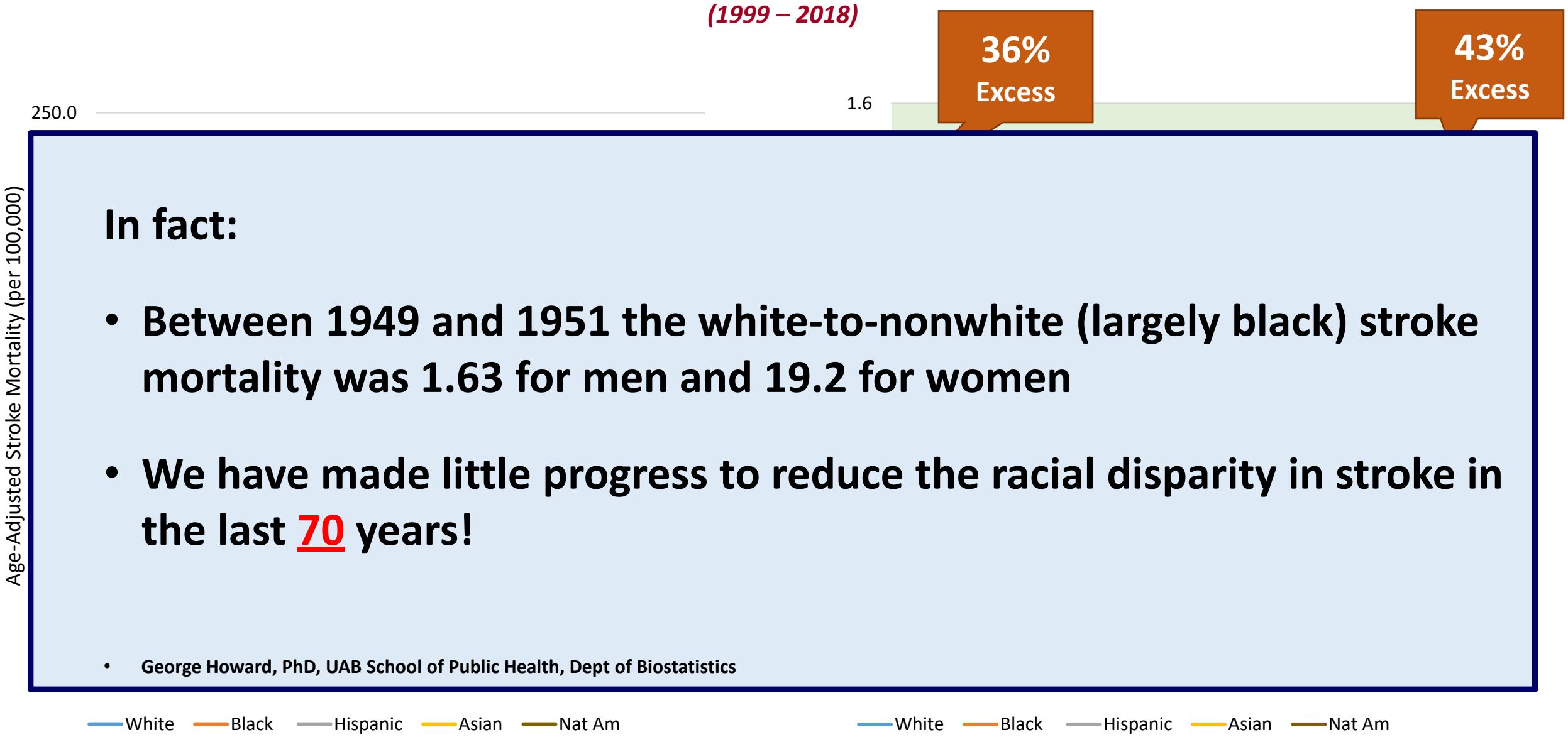
## MRI GRE



## CT

# Recent Pattern of Racial/Ethnic Disparities in Stroke Mortality

*(1999 – 2018)*




**In fact:**

- **Between 1949 and 1951 the white-to-nonwhite (largely black) stroke mortality was 1.63 for men and 19.2 for women**
- **We have made little progress to reduce the racial disparity in stroke in the last 70 years!**

- **George Howard, PhD, UAB School of Public Health, Dept of Biostatistics**

Races are shown for non-Hispanic population, and Hispanic population is shown for all races.

The slave market in Atlanta, Georgia, 1864 (Library of Congress)

Slaves work in Sea Islands, South Carolina. (Library of Congress)

# Geographical stroke disparities

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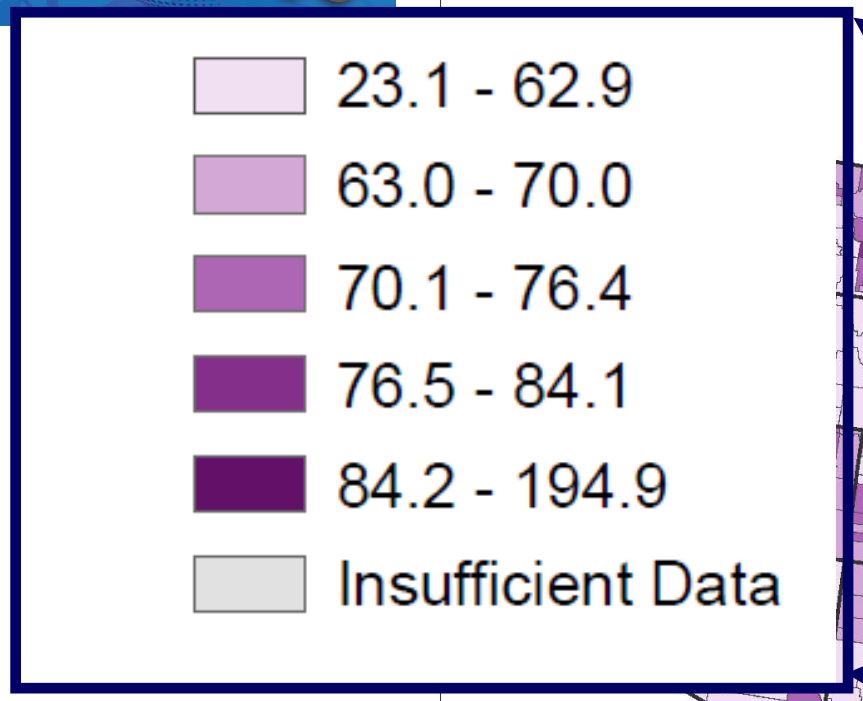
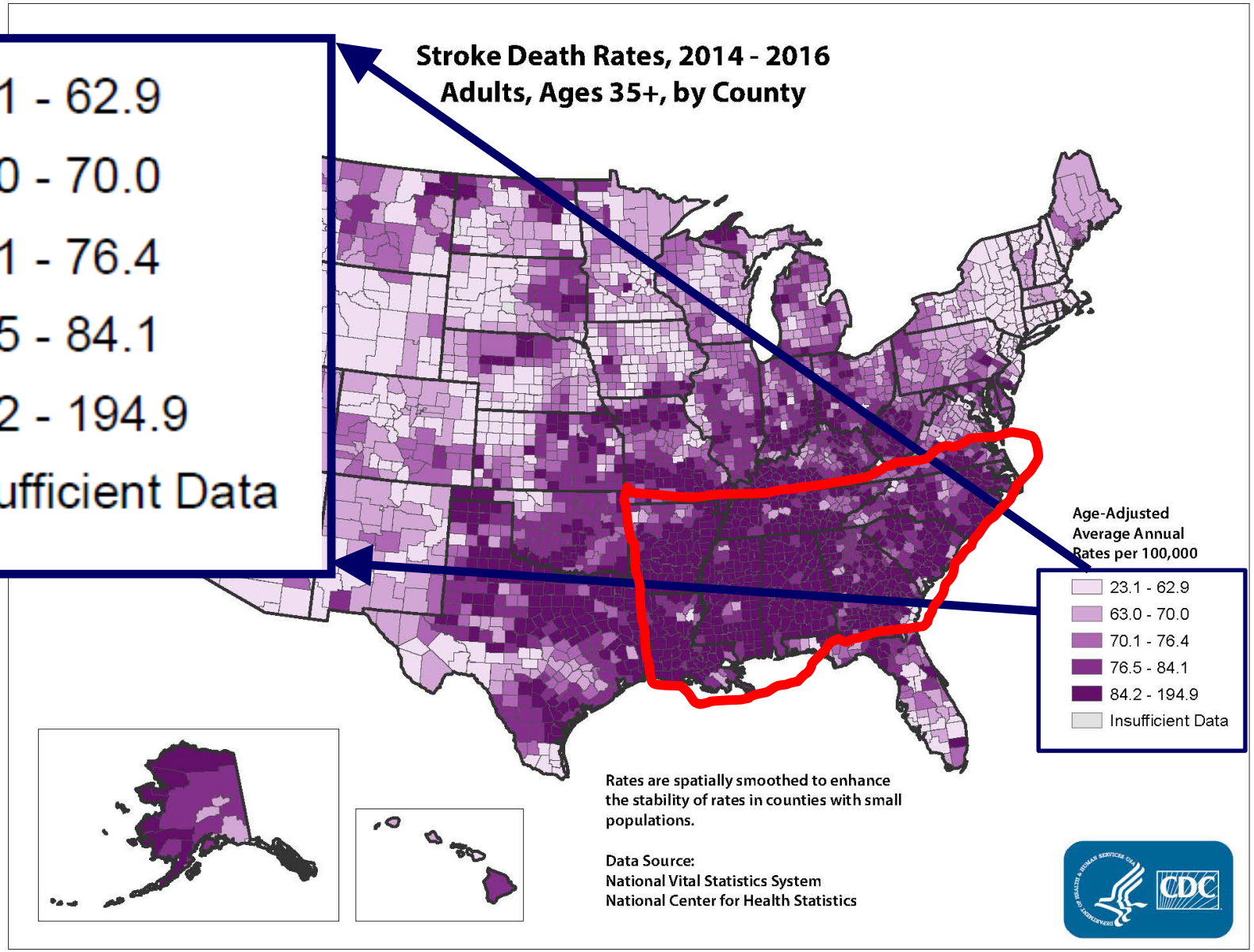



**Stroke Belt**

**Alabama**
**Arkansas**
**Georgia**
**Louisiana**
**Mississippi**
**North Carolina**
**South Carolina**
**Tennessee**

# NINDS Rural Health Disparities

National Institute of Neurological Disorders and Stroke

- Nearly 20% of the U.S. population resides in non-metropolitan areas where they experience many of the same health challenges as their urban counterparts.

- Rural Americans are a population group that experiences significant health disparities.

- Rural risk factors for health disparities include geographic isolation, lower socioeconomic status, higher rates of health risk behaviors, limited access to healthcare specialists and subspecialists, and limited job opportunities.

*Rural Health Information Hub accessed 04-12-2022

**Williams, Olajide and Ovbiagele, Bruce. *"Stroking Out While Black- The Complex Role of Racism." JAMA Neurology*, Aug 2020**

**Major Points:**

a.) NINDS funded REGARDS found that only 40% of Black-White incidence disparity is attributed to prevalence of traditional risk factors.
b.) 60% of the remaining disparity unclear factors.
c.) Some part of this (60%) stroke disparity may be related to the Levels of Racism framework:

1. Structural,
2. Inter-Personal
3. Internalized racism

d.) More research funding in these areas is required with an "equity lens".

- **Goal:** Develop a comprehensive plan to guide research investments over the next 5 – 10 years

- **Components/inputs into the planning process:**
  - NANDS Workgroup led by Drs. Karen Johnston and Edwin Trevathan
  - Health Equity Coordinating Committee (HECC)
  - NINDS Health Equity Workgroup (HEW)
  - Health disparities portfolio analysis
  - Request for Information (RFI)
  - Trans-NIH WG (16 ICs)
  - Literature review
  - Previous recommendations 2011
  - HEADWAY Workshop on September 22-24, 2021 (Capstone of the process)

- **Outputs/products:** Reports of the planning process, findings, and key recommendations (as approved by the NANDS Council) to be widely disseminated to researchers and the public.

# Health Disparities Definition

National Institute of Neurological Disorders and Stroke

Definition:
Health People 2020 defines health disparities as a particular type of health difference that is closely linked with social, economic, and/or environmental disadvantage.

(May be related to race/ethnicity, socio-economic status, gender, age, geographic region, etc.)

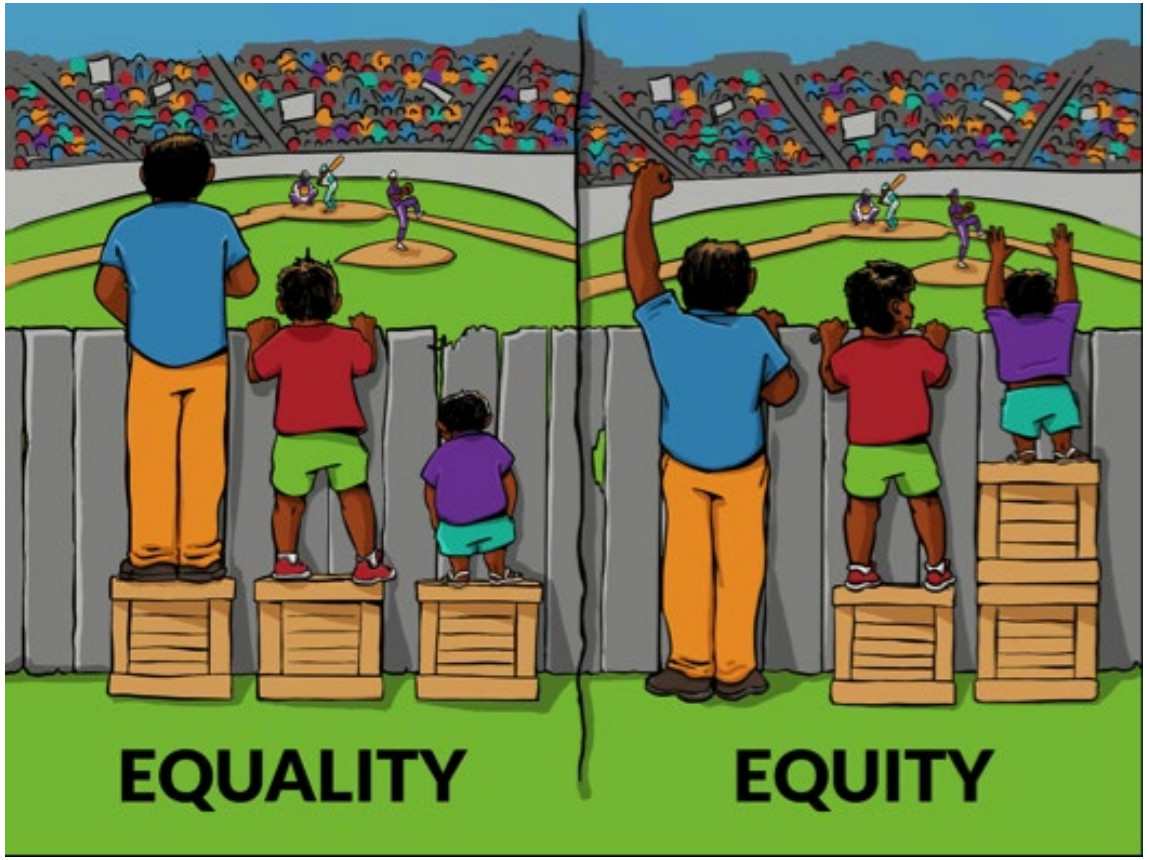
http://www.healthypeople.gov/hp2020/advisory/PhaseI/sec4.htm#_Toc211942917

# NINDS Health Equity Definition

National Institute of Neurological Disorders and Stroke

## Health Equity

Healthy People 2020 defines *health equity* as the "attainment of the highest level of health for all people. Achieving health equity requires valuing everyone equally with focused and ongoing societal efforts to address avoidable inequalities, historical and contemporary injustices, and the elimination of health and health care disparities.



NANDS Steering Committee Orientation and Mission:

- Advise the NINDS on our process and make recommendations
- Develop comprehensive recommendations
- Focus on areas where the NIH/NINDS can have an impact
- Participate in the HEADWAY workshop and present draft recommendations for public input
- Points to Consider:
  1. Leveraging prior neurological research investments
  2. How can we strengthen the science?
  3. Identification of strategies/interventions known to address biologic- and socio-determinants of health
  4. Ensuring sustainability through community participation and other partnerships

# Working Group Sub-Committees

National Institute of Neurological Disorders and Stroke

**Sub-Committees**

**Sub A** – Determine strategies, targets, interventions, type of collaborations needed to optimize interventions that can be implemented and scaled-up.

**Sub B** – Discuss impact of SDOH and ACE and how this impacts HD in neurological disease across the lifespan. How can this be addressed through research interventions that can be scaled-up.

**Sub C** – Discuss and develop an NINDS Health Equity Research framework

**Sub D** – Calculate the excess death from neurological conditions in US (in blacks and other R/E groups compared to whites).

**Sub E** – Develop strategies and best practices to communicate HD-related scientific information and NINDS programs and funding announcements to diverse communities, including investigators, medical providers, and community members.

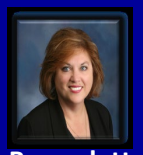
**Sub F-1** – Develop and outline strategies and best practices for training, recruitment, and retention of a diverse health equity research workforce.

**Sub F-2** – Develop and outline strategies and best practices for increased health equity training in the neurosciences/ neurology.

**Deliverables**

**Each subcommittee has incorporated their findings and recommendations into separate manuscripts for publication in a special issue of the journal *Neurology***

Edwin Trevathan, M.D., M.P.H.


Bernadette Boden-Albala, DrPH, M.P.H.

David L. Brody, M.D., Ph.D.

Spero M. Manson, Ph.D. (Pembina Chippewa)

Bruce Ovbiagele, M.D., MSc, MAS

Sameer Sheth, M.D., Ph.D.

Wally R. Smith, M.D.

Christin Veasley, BSc.

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Derek M. Griffith, Ph.D.

Patrick A. Griffith, M.D.

Virginia J. Howard, Ph.D.

Zayd Khaliq, Ph.D.

Daniel Lackland, DrPH.

Geoffrey Ling, M.D., Ph.D.

Girardin Jean-Louis, Ph.D.

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Stephanie Mohl

Susana Ramírez, Ph.D., M.P.H.

Amytis Towfighi, M.D.

Lesli E. Skolarus, M.D., M.S.

Rachel Anne Whitmer, Ph.D.

Carolyn Jenkins, DrPH, MSN, RN

Alexandra M. Sims, M.D., M.P.H.

NANDS Health Disparities Steering Committee

# Mortality Analysis

National Institute of Neurological Disorders and Stroke

How many US deaths from neurological disease would have been averted had NH-Black Americans experienced the same mortality rates as NH-White Americans?

- Methodology
  - Death Counts – NCHS/CDC – 2010-2019
  - Neurological Disease – ICD -10
  - National Institutes of Health Research, Condition, and Disease Categorization (RCDC) system
    - Neurological Disease (e.g. ICH)
    - Potential Neurological Manifestations (e.g. HTN)
  - Non-Hispanic White (NHW) - reference

- **Steven H. Woolf, M.D., M.P.H,**
- Director Emeritus of the Center on Society and Health at Virginia Commonwealth University
- Professor of Family Medicine and Population Health.
- C. Kenneth and Dianne Wright Distinguished Chair in Population Health and Health Equity

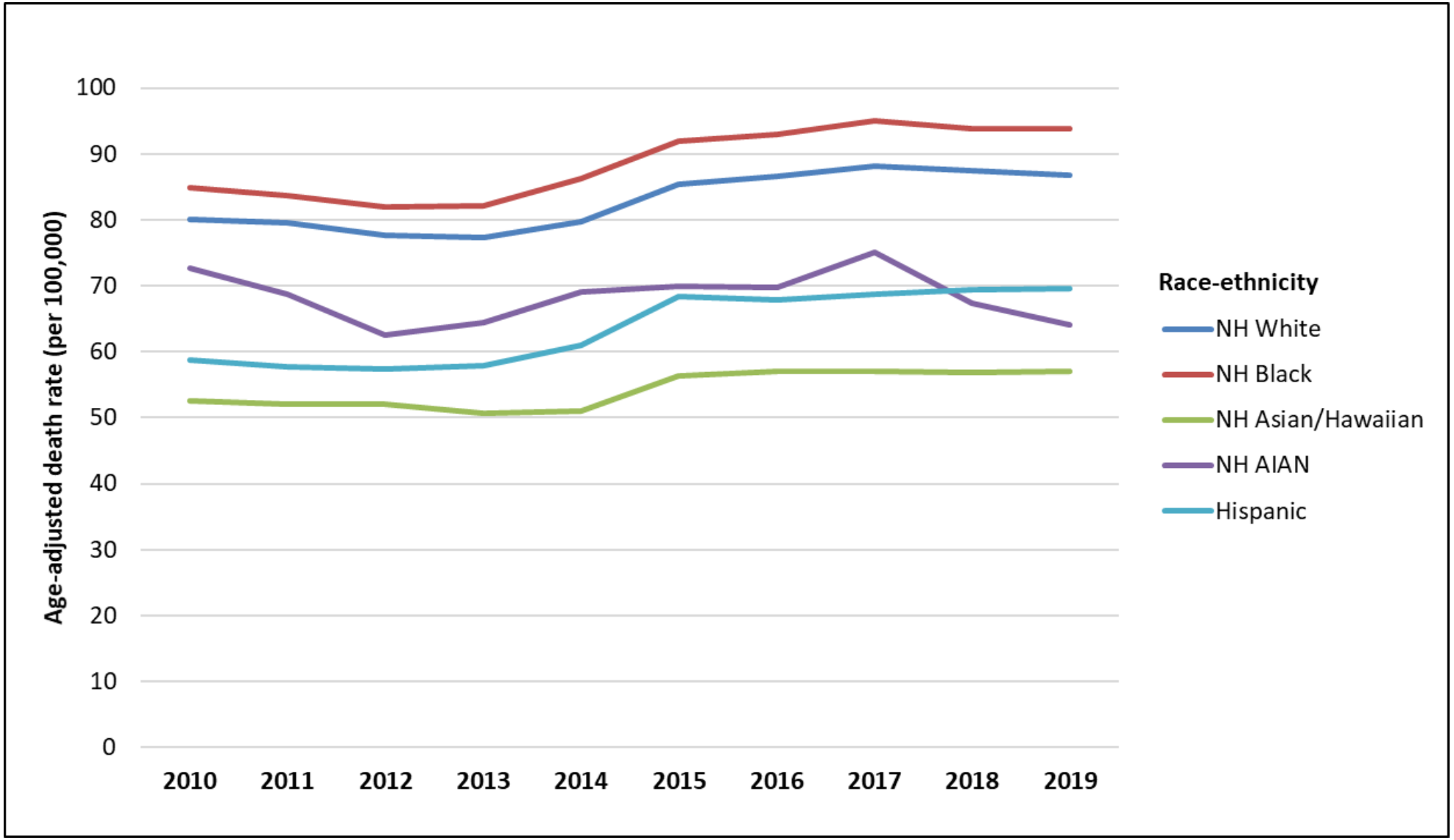
# Age-Adjusted Mortality
# Neurologic Disease by Race and Ethnicity
# (2010-19)

National Institute of Neurological Disorders and Stroke

Difference – NHB vs NHW

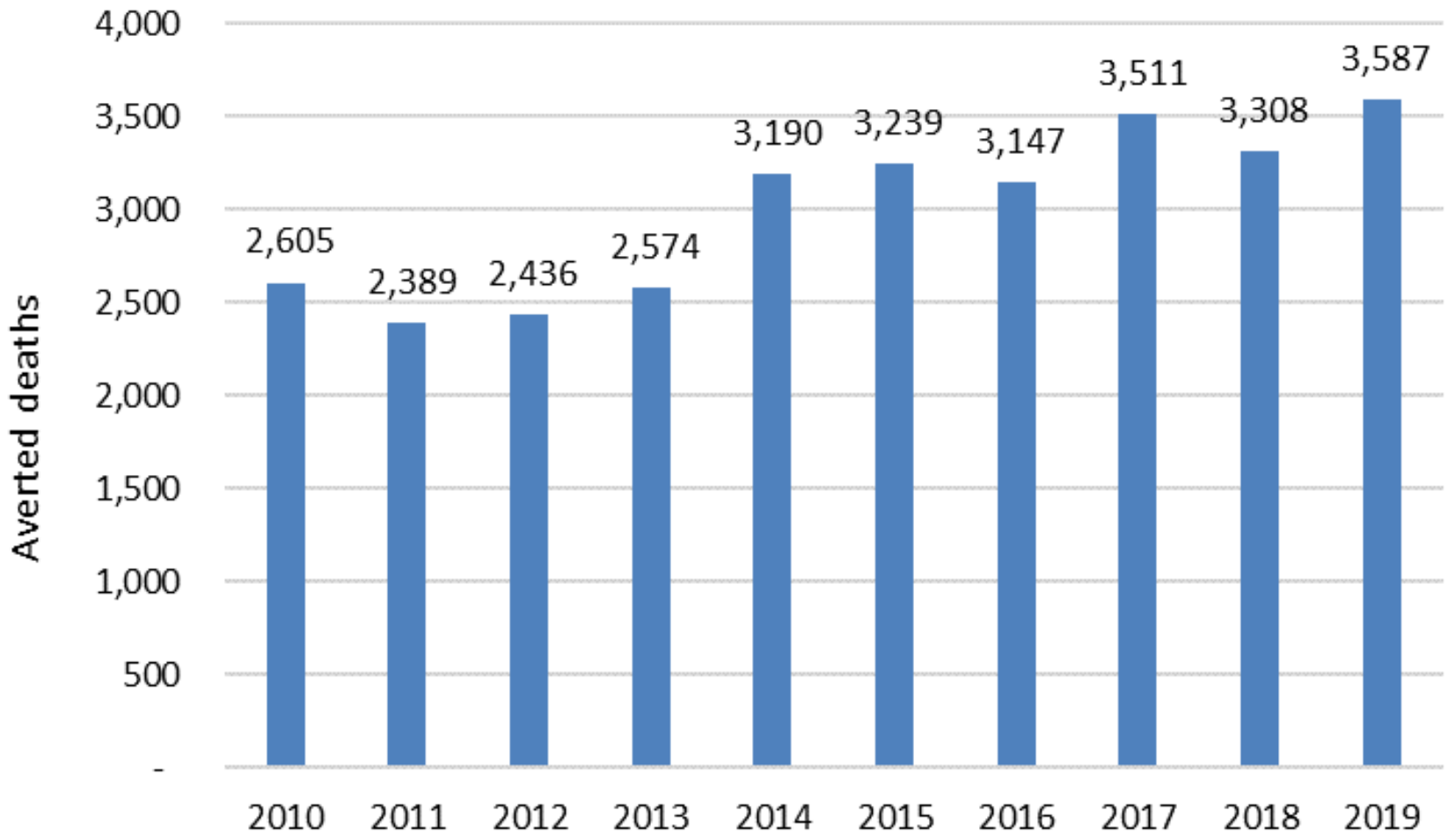
Nadir – 2011
4.2/100,000

Peak – 2019
7.0/100,000



# Avertible Neuro Disease Deaths by Year if NHB Americans had Same Mortality Rate as NHW Americans

National Institute of Neurological Disorders and Stroke




Total N=29,986

National Institute of Neurological Disorders and Stroke

# HEADWAY

## Health Disparities and Inequities in Neurological Disorders Workshop

*Organized by the* NINDS Office of Global Health and Health Disparities

**Save the Date • September 22–24, 2021**

**Available on NIH Video Cast**

**Day 1: https://videocast.nih.gov/watch=43834**

**Day 2: https://videocast.nih.gov/watch=43837**

# RFI: Background and Characteristics

National Institute of Neurological Disorders and Stroke

## A. NIH marketing

- Responses collected through April-July 15, 2020

## B. Direct solicitation

- Non-Profits 376
- Professional societies 92

## C. Format

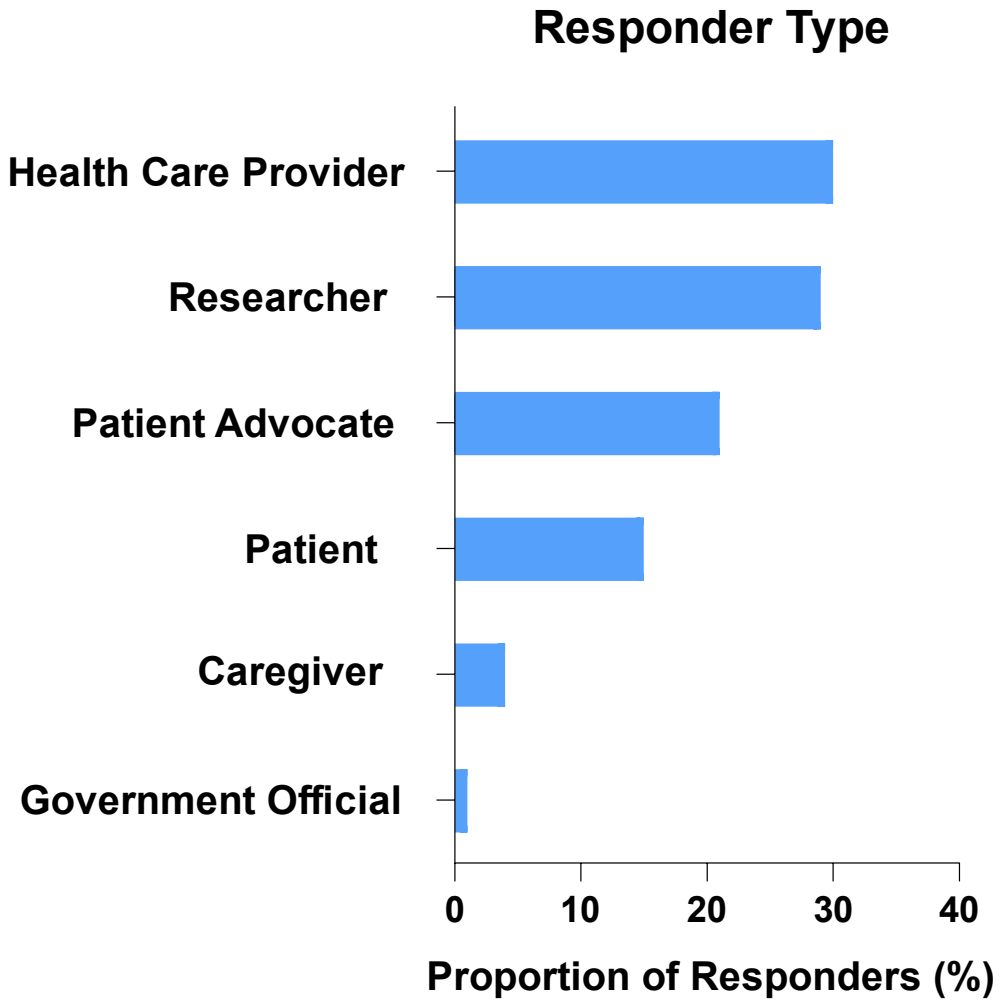
- Multiple choice demographic questions
- Short answer questions

## D. Submissions

- Responses 141

## E. Analysis

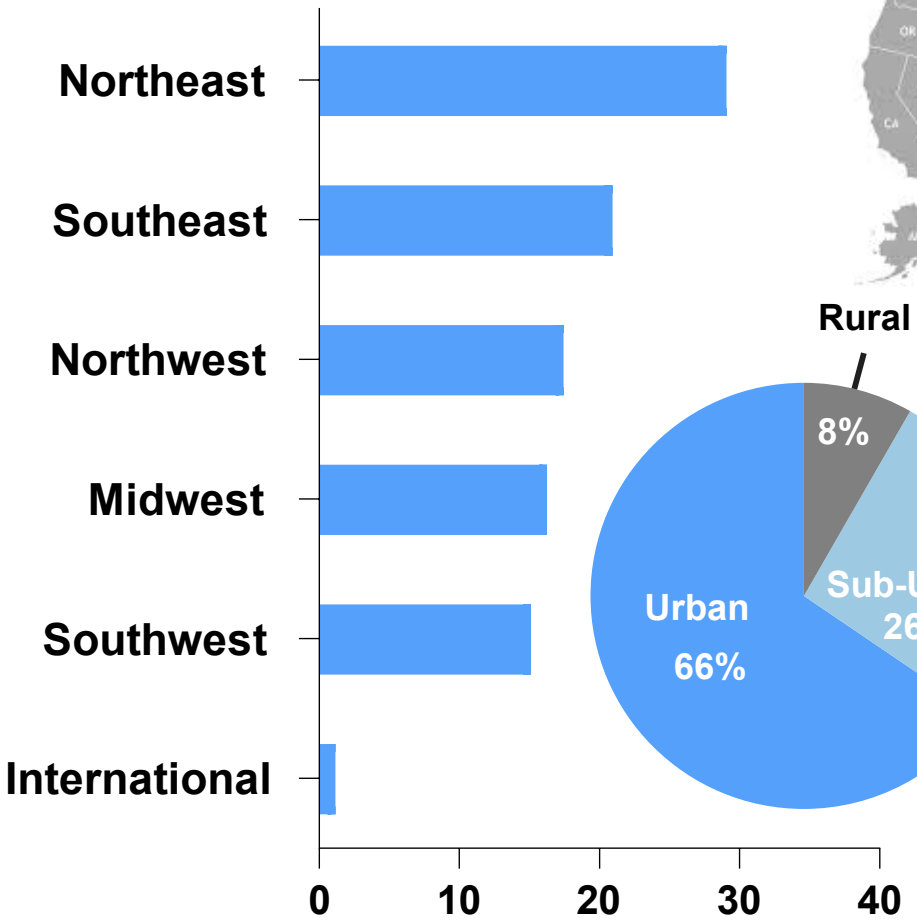
- Qualitative HD Coding
  - HD definitions and categories were developed from HD literature, expert consultation, NIMHD framework, and portfolio analysis collaboration
  - Majority consensus
- Categories coded (combinatorial elements)
  - Neurological Disease Areas
  - Vulnerable Populations
  - Interventions
  - Gaps
- Responder excerpts

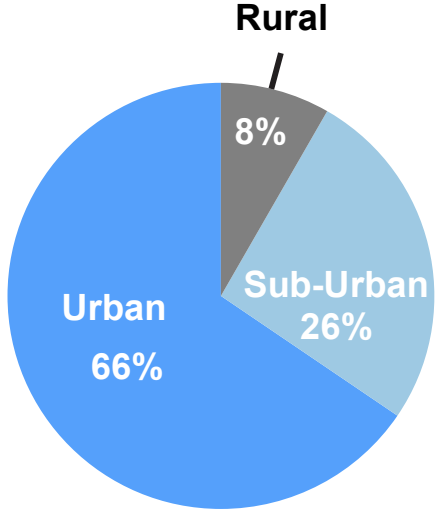


# RFI: Responder Demographics

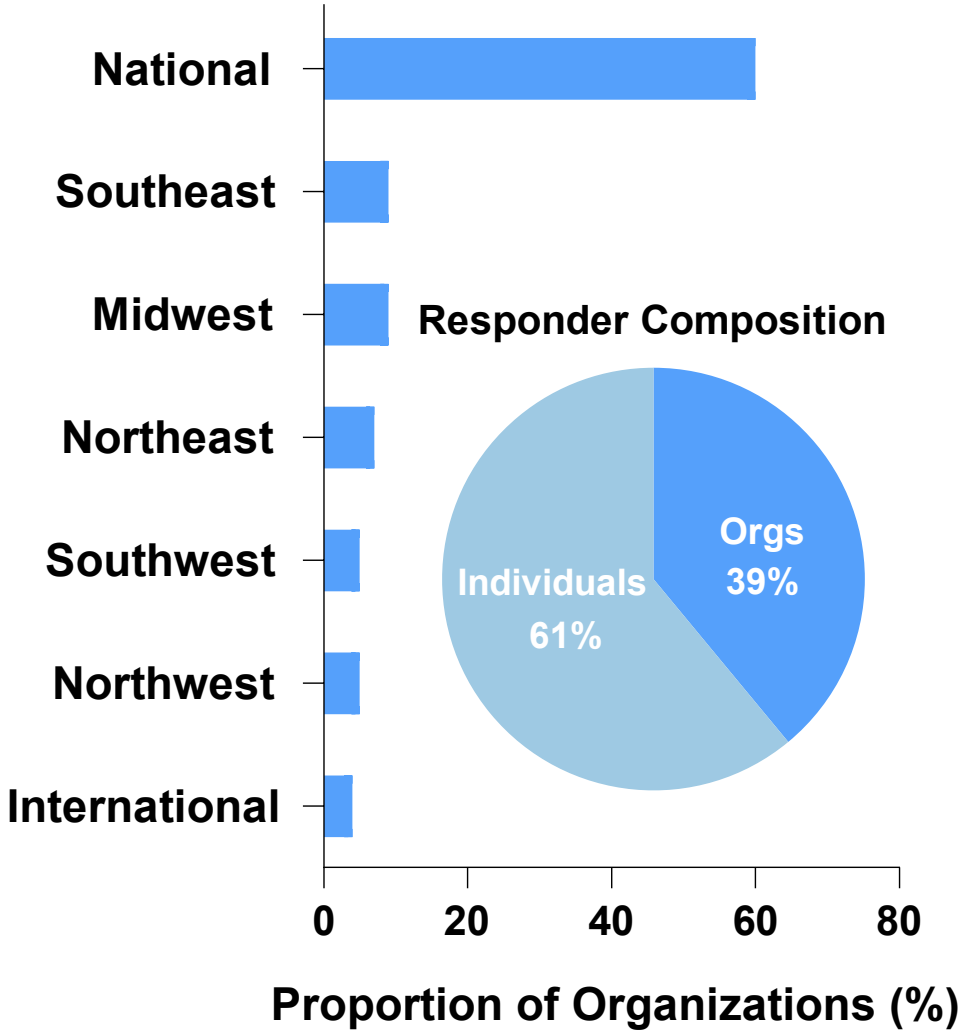
National Institute of Neurological Disorders and Stroke

## Responder Region: Individual



## Responder Region: Organization



# RFI: Organizations

| KEY | | | |
|---|---|---|---|
| Other | Pain | PD | Dementia |
| Brain Injury | Stroke | Epilepsy | Sleep |

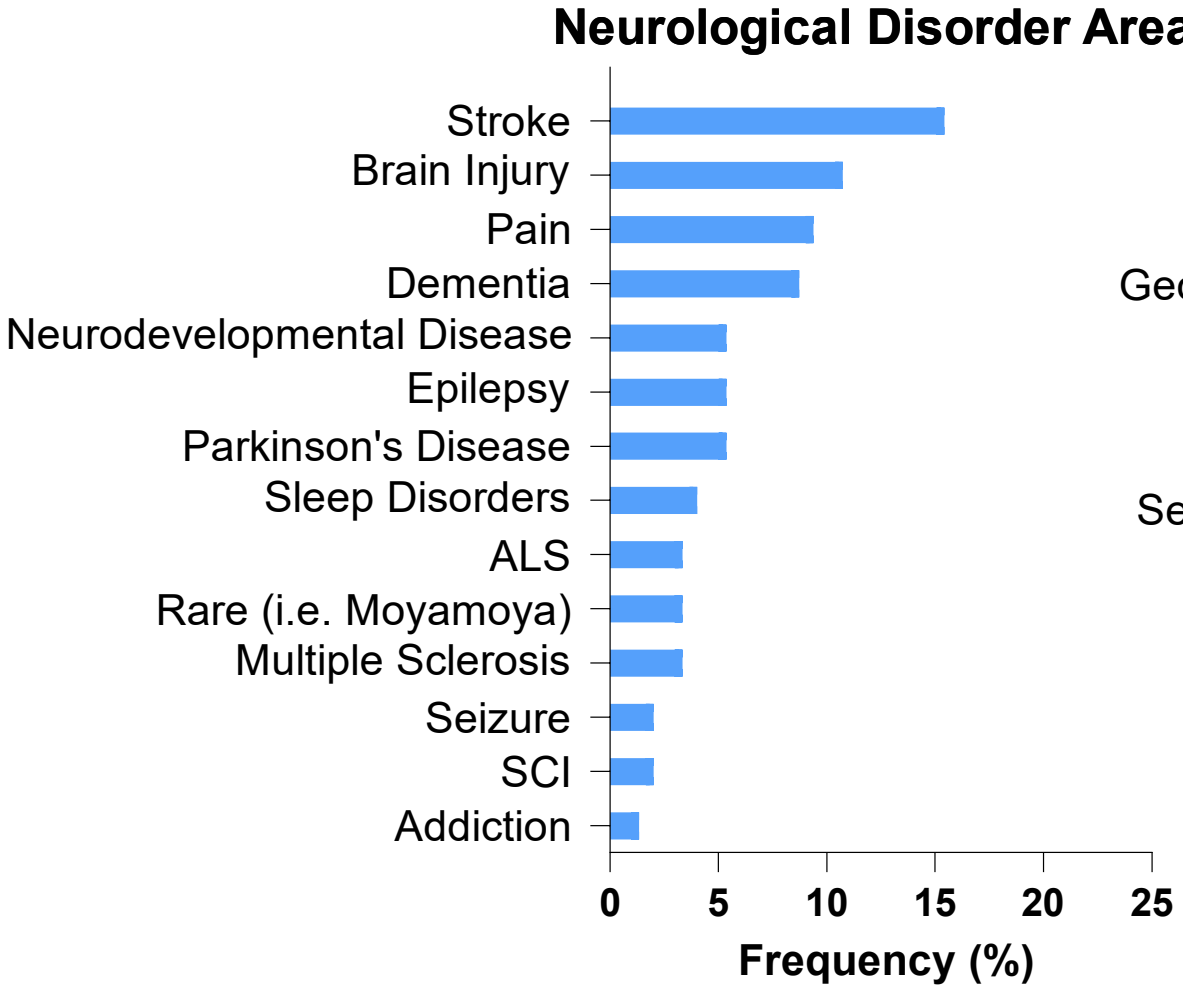
A. Organizations by neurological disease area

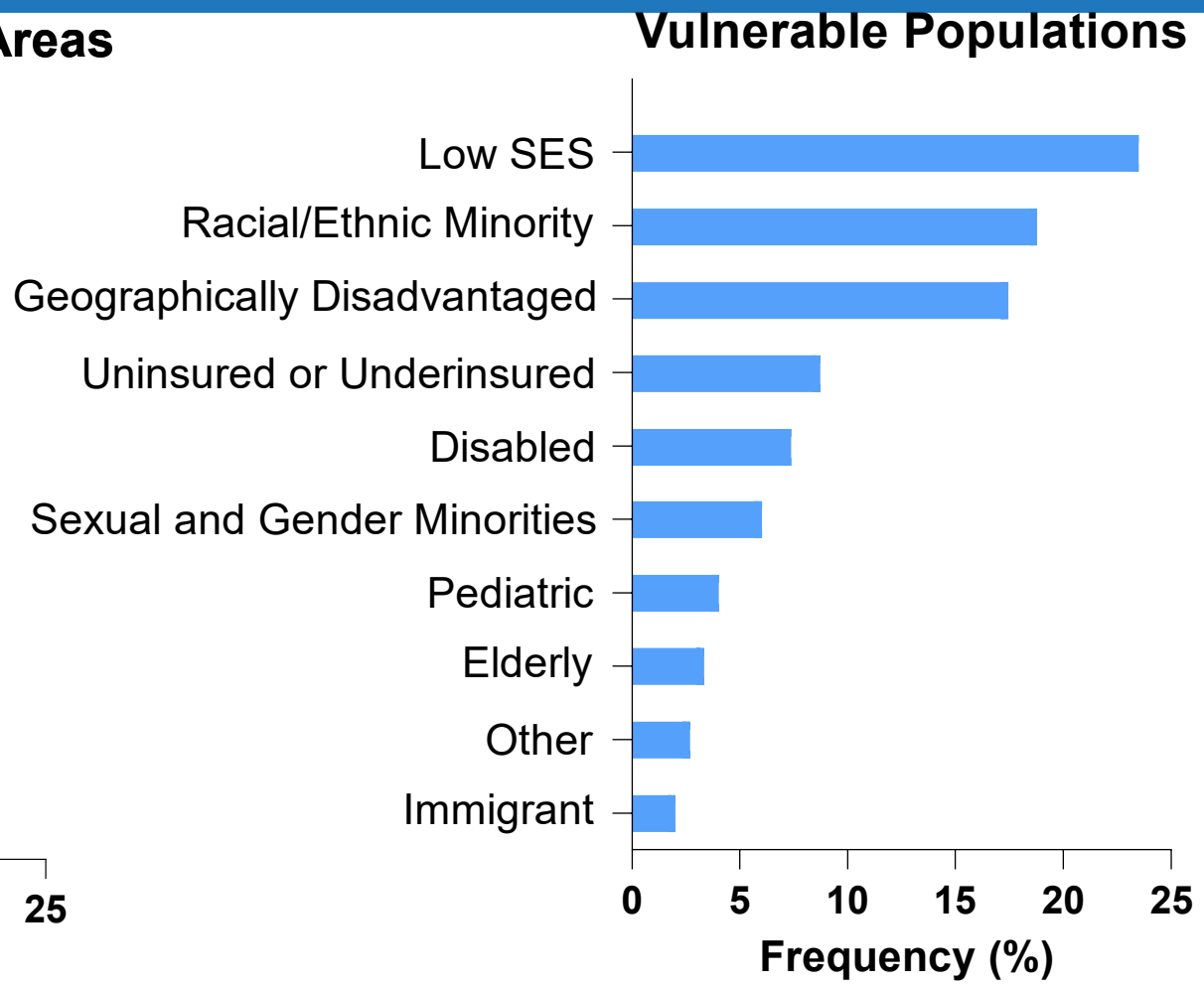
1. TBI, Stroke, Pain well represented

| | | | |
|---|---|---|---|
| 100 Black Men of Greater Washington DC | Rare Advocates Representing Everyone | American Headache Society and American Migraine Foundation | Davis Phinney Foundation |
| AdventHealth | Spastic Paraplegia Foundation | Charleston Health Neurology & Head Pain Consultants, PLLC | Parkinson's Foundation |
| American Academy of Neurology | Team Titin - titin related muscle and heart disorders | Disparities in Headache Advisory Council - A council of the Coalition For Headache And Migraine Patients (CHAMP) | Unified Parkinson's Advocacy Council (UPAC) |
| Center for Dignity in Healthcare for People with Disabilities | Vestibular Disorders Association (VEDA) | Miles for Migraine | American Epilepsy Society (AES) |
| Cognoa (autism) | Brain Injury Association of America | National HeadachevFoundation | Epilepsy Leadership Council |
| Collaborative Working Group from Columbia University, NYU, and St John's University | Harborview Injury Prevention and Research Center | AHA | Pediatric Epilepsy Research Consortium |
| CONSERVATIVE NEUROLOGY SERVICES | Patrick Risha CTE Awareness Foundation | Circle of Rights, Inc. (stroke) | Alzheimer's Association |
| CureDuchenne | Power Of Patients LLC (TBI) | Cleveland Clinic Foundation Cerebrovascular Center Minority Stroke Program | Alzheimer's Los Angeles |
| Hispanic Health Professionals Association,Inc NY | Traumatic Brain Injury Model Systems Cultural Competency Special Interest Group | Hope for HIE | American Academy of Developmental Medicine and Dentistry: National Task Group on Dementia |
| Moebius Syndrome Foundation | United Spinal Association | YoungStroke, Inc. | American Academy of Sleep Medicine |
| National Multiple Sclerosis Society | VA Palo Alto Health care System, Rehabilitation Department | American Parkinson Disease Association | Hypersomnia Foundation |

# RFI: Health Disparity Neurological Disease Areas

National Institute of Neurological Disorders and Stroke

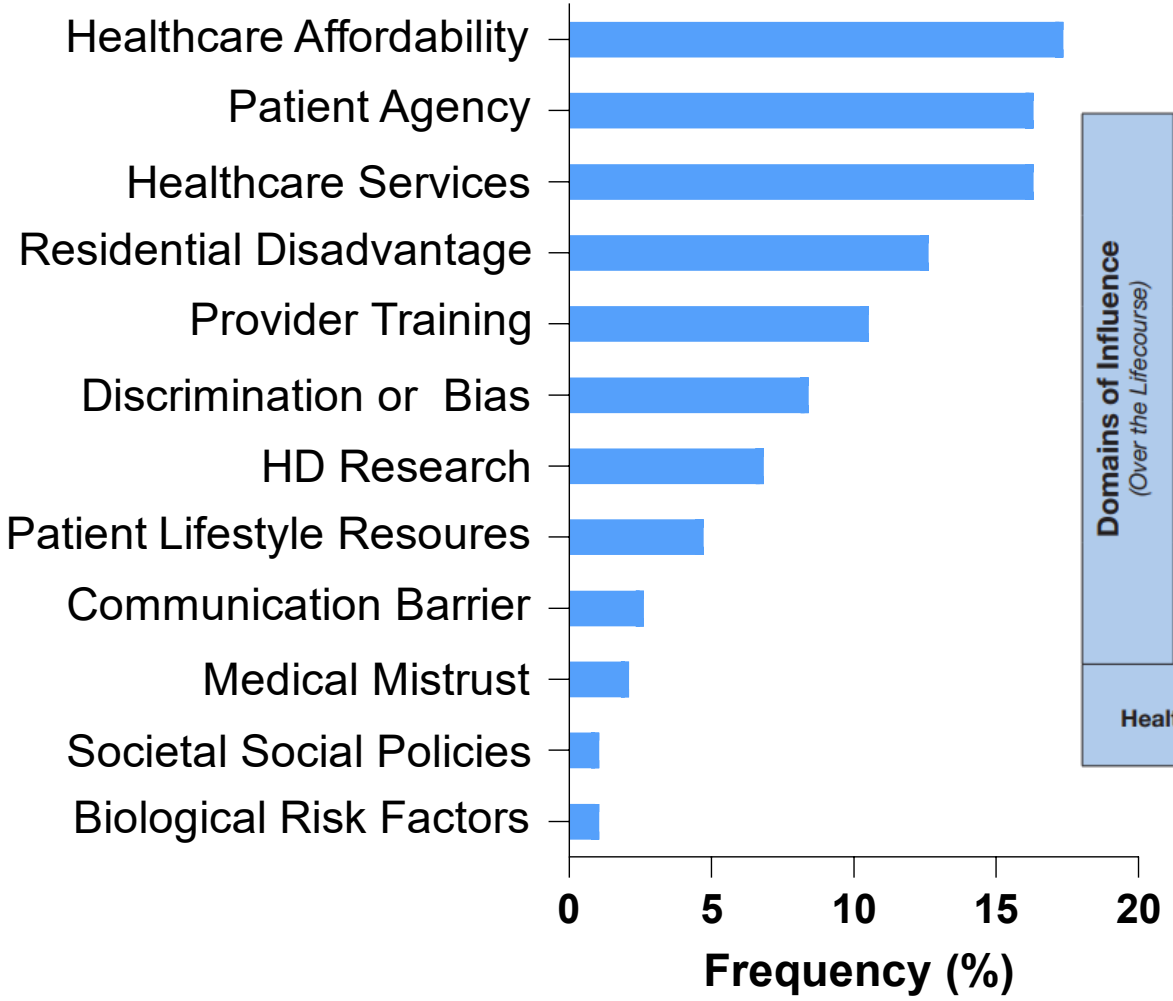


# RFI: HD Determinants

National Institute of Neurological Disorders and Stroke

## HD Determinants




| Domains of Influence (Over the Lifecourse) | Levels of Influence* | | | |
|---|---|---|---|---|
| | Individual | Interpersonal | Community | Societal |
| Biological | Biological Vulnerability and Mechanisms | Caregiver–Child Interaction<br>Family Microbiome | Community Illness Exposure<br>Herd Immunity | Sanitation<br>Immunization<br>Pathogen Exposure |
| Behavioral | Health Behaviors<br>Coping Strategies | Family Functioning<br>School/Work Functioning | Community Functioning | Policies and Laws |
| Physical/Built Environment | Personal Environment | Household Environment<br>School/Work Environment | Community Environment<br>Community Resources | Societal Structure |
| Sociocultural Environment | Sociodemographics<br>Limited English<br>Cultural Identity<br>Response to Discrimination | Social Networks<br>Family/Peer Norms<br>Interpersonal Discrimination | Community Norms<br>Local Structural Discrimination | Social Norms<br>Societal Structural Discrimination |
| Health Care System | Insurance Coverage<br>Health Literacy<br>Treatment Preferences | Patient–Clinician Relationship<br>Medical Decision-Making | Availability of Services<br>Safety Net Services | Quality of Care<br>Health Care Policies |
| Health Outcomes | Individual Health | Family/ Organizational Health | Community Health | Population Health |

# RFI: Interventions

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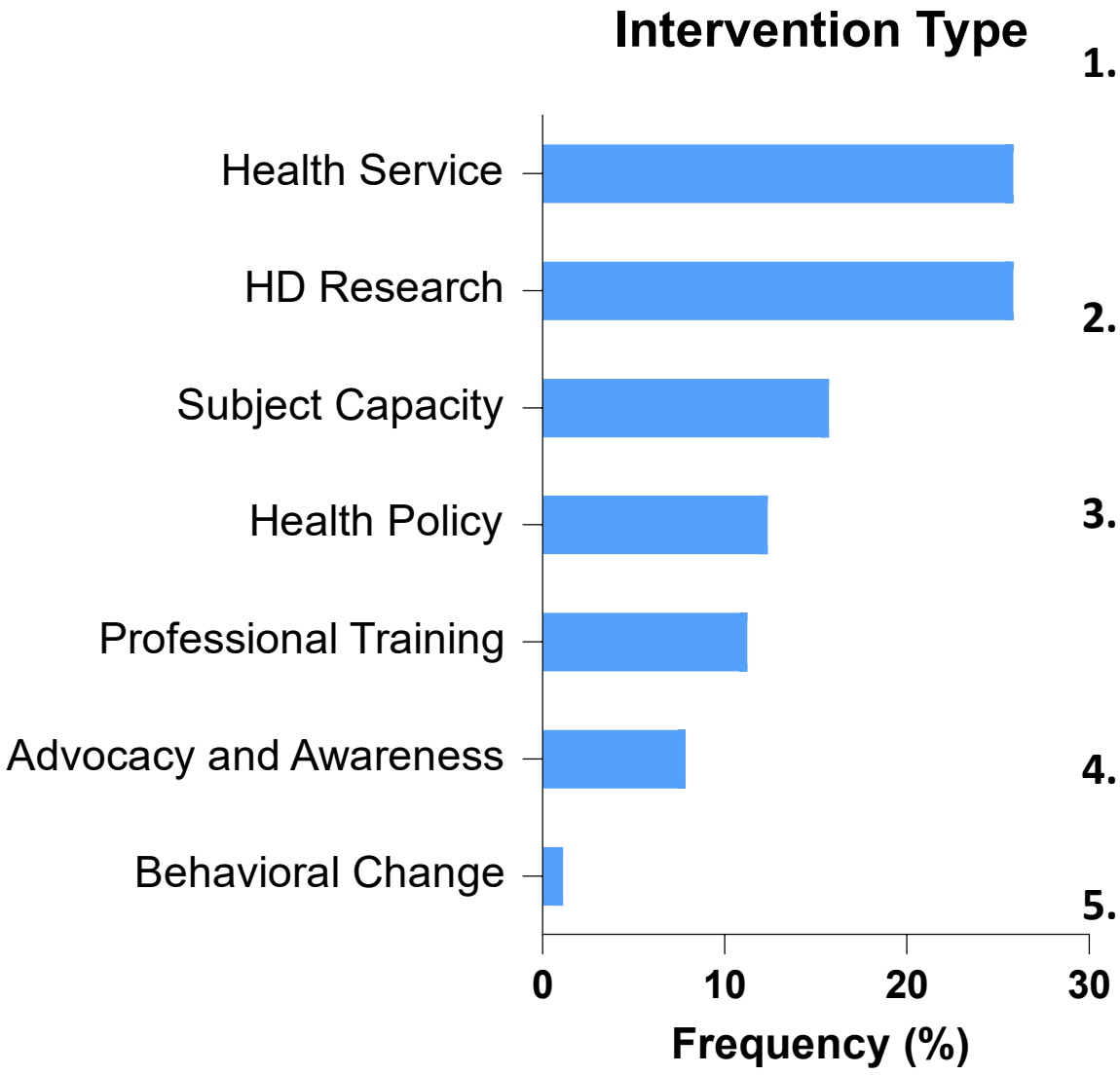


1. **Health service** – describes measures to increase health services, care, or HCP capacity (providers/interpersonal ) (i.e bias training; HC system/community; more nurses or increase in Spanish speaking staff; hire more primary care physicians)
2. **HD Research or Research strategy** - Describes measures to increase HD research capacity, funding, prioritization, or knowledge ( i.e. more research; adding CHWs, increasing trial inclusion)
3. **Subject Capacity** - describes increasing patient/individual level resources (i.e health literacy increase or snap benefits or employment opportunity, food access, housing access, supply population with blood pressure monitors)
4. **Health Policy** - Describes structural healthcare management l i.e. ACA/expand acceptable insurance in health system)
5. **Advocacy and awareness** - describes social campaign at any level (not research strategy) (i.e Using social Pressure to Invoke Change, develop or empower community or to promote structural change like food security, or transportation)

# Type of Research

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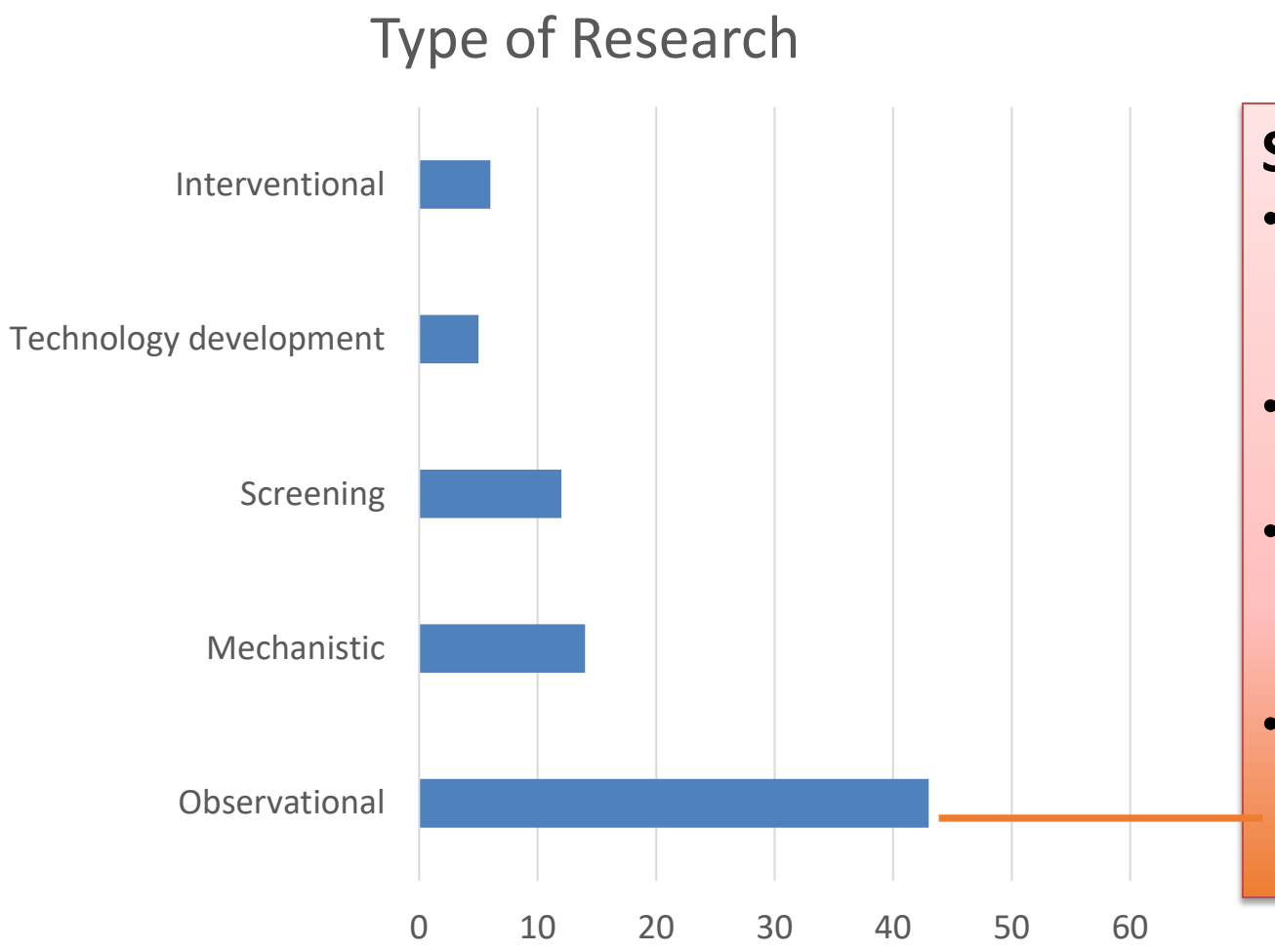


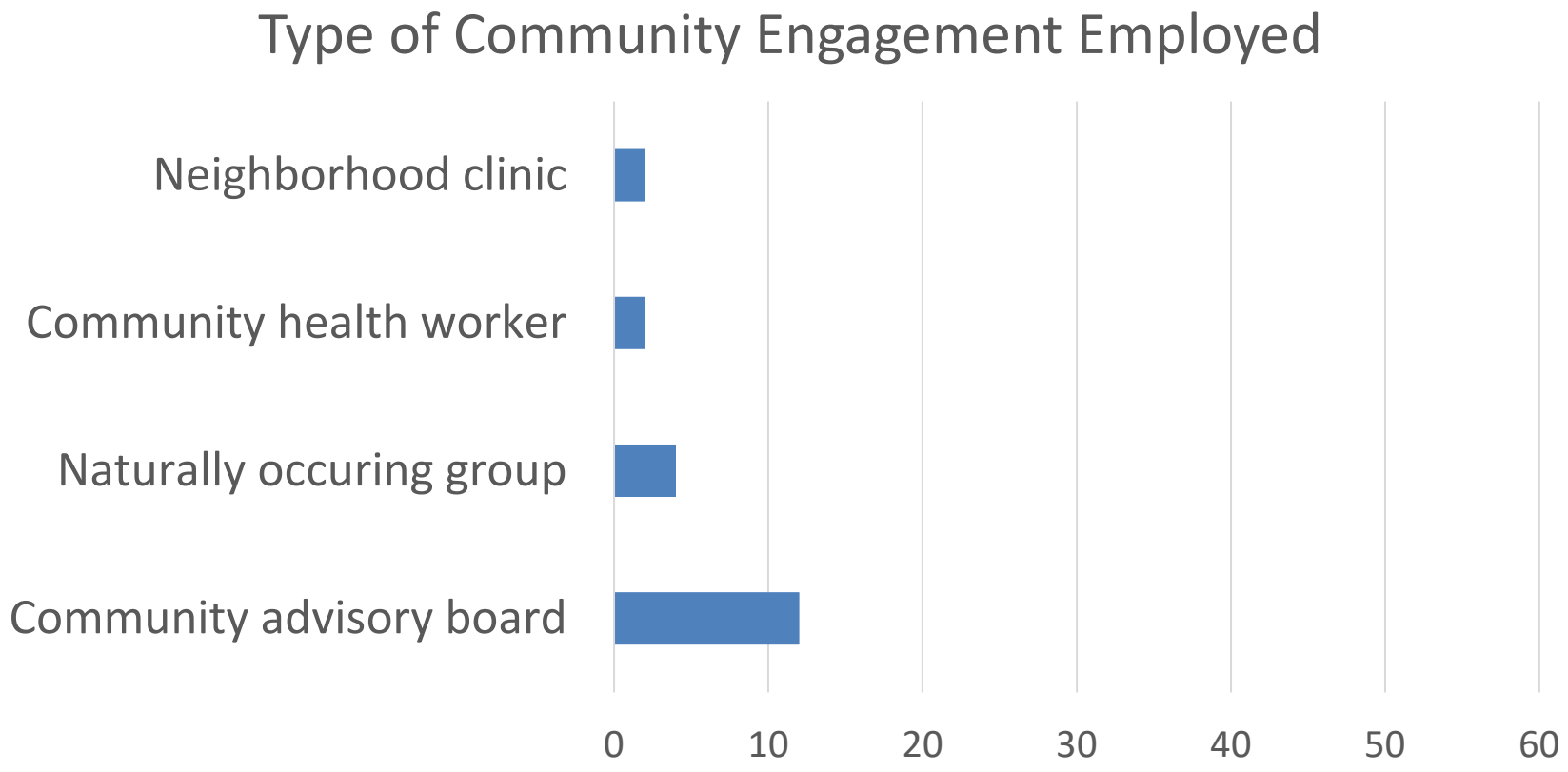

**Selected Examples:**

- Reasons for Geographic and Racial Disparities in Stroke/VCID in a Biracial Cohort (REGARDS), 2001-Present; VCID added in 2018
- Brain Attack Surveillance in Corpus Christi (BASIC) Study 1999-Present
- The Northern Manhattan Study (NOMAS), 2003-2020; Cognitive component added in 2015
- Atherosclerosis Risk in Communities (ARIC) Neurocognitive Study, 2010-present

# Clinical Research: Community Engagement

National Institute of Neurological Disorders and Stroke

*Only 16 of 58 applications described community engagement strategies*



# NINDS Health Disparities Mission Statement

National Institute of Neurological Disorders and Stroke

Why are recruitment and inclusion of diverse populations (e.g. race, ethnic, gender, age) important for clinical trials :

1. Diversity of clinical trial participants is needed to help ensure that the trial population is representative of the patients who will use the medicine, medicinal product or intervention and ensure that the results are generalizable. (Rigor)
2. Participants in research should reflect the diversity of our culture and conditions, taking into account race, ethnicity, gender, age, etc.
3. The lack of diversity among research participants has serious ethical and research consequences.

Why are recruitment and inclusion of diverse populations (e.g. race, ethnic, gender, age) important for clinical trials :

# IT'S THE LAW...!!!!

The NIH is mandated by the Public Health Service Act sec. 492B, 42 U.S.C. sec. 289a-2 to ensure the inclusion of women and minority groups in all NIH-funded clinical research in a manner that is appropriate to the scientific question under study. The primary goal of this law is to ensure that research findings can be generalizable to the entire population. Additionally, the statute requires clinical trials to be designed to provide information about differences by sex/gender, race and/or ethnicity.

# Why Diversity matters to NINDS?

- Recruitment of the most talented researchers from all groups;
- Creates Improvement in the quality of the educational training environment;
- Balanced perspective in setting research priorities;
- Improves capacity to recruit subjects from diverse backgrounds into clinical research protocols;
- Improved capacity to address health disparities.

# NIH Definition of "Diversity"

National Institute of Neurological Disorders and Stroke

Individuals from **underrepresented racial and ethnic groups**

Individuals with **disabilities**, who are defined as those with a physical or mental impairment

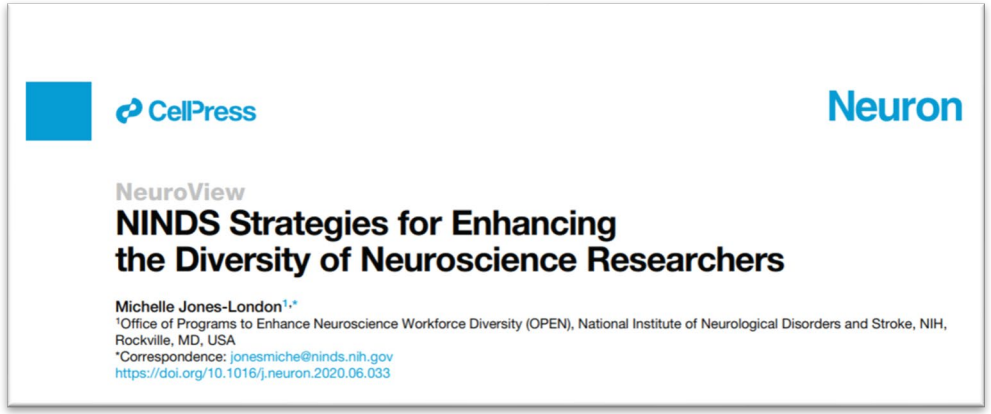
Individuals from **disadvantaged** backgrounds (socially, culturally, economically, or educationally)

Only applicable to high school and undergraduate candidates

# Enhancing Diversity of NINDS-funded Grantees

National Institute of Neurological Disorders and Stroke

**From Potential to Action: NINDS Trainees Navigate Diverse Paths to Success**



CellPress Neuron

NeuroView

**NINDS Strategies for Enhancing the Diversity of Neuroscience Researchers**

Michelle Jones-London[1,*]
[1]Office of Programs to Enhance Neuroscience Workforce Diversity (OPEN), National Institute of Neurological Disorders and Stroke, NIH, Rockville, MD, USA
*Correspondence: jonesmiche@ninds.nih.gov
https://doi.org/10.1016/j.neuron.2020.06.033

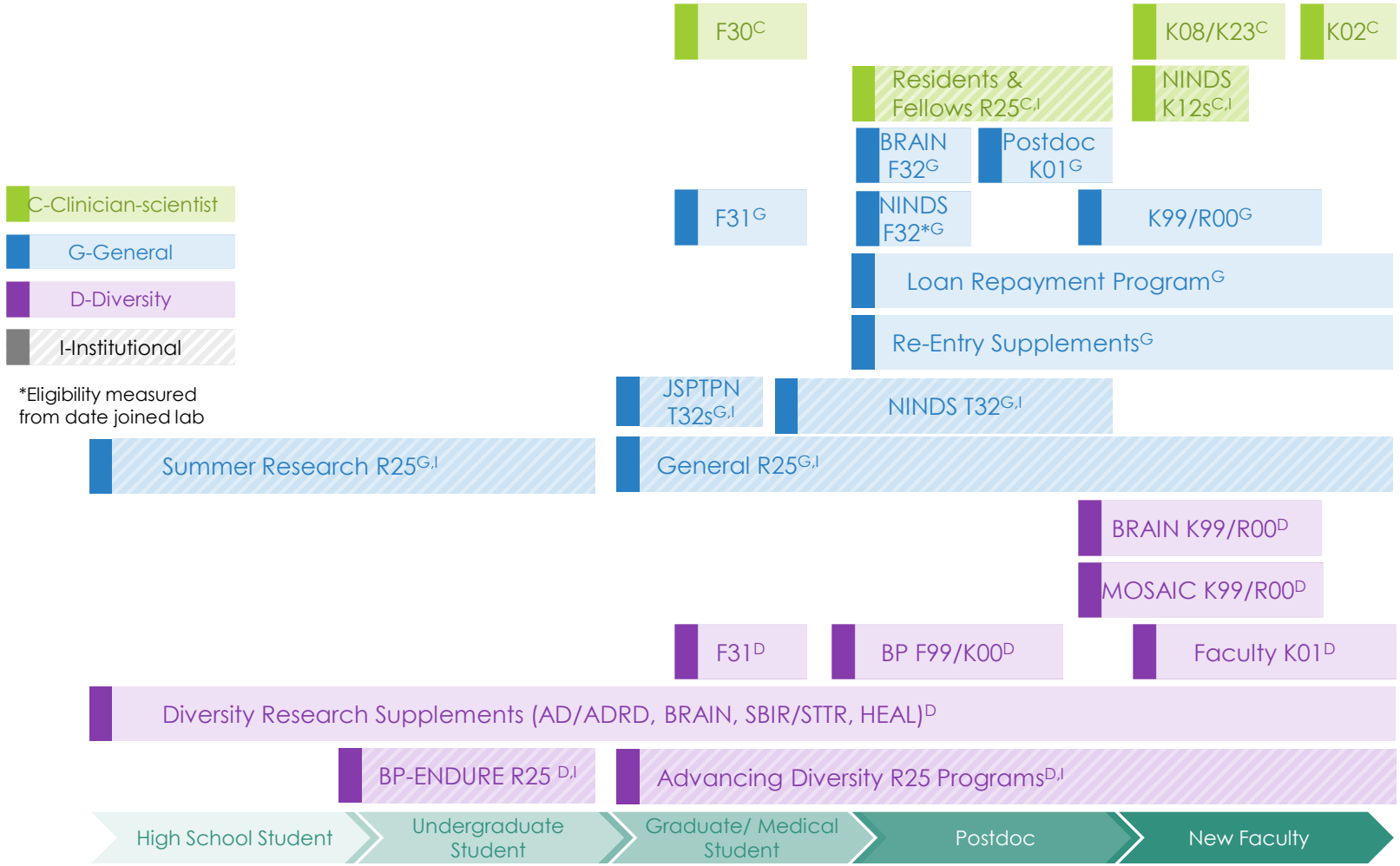
The **Office of Programs to Enhance Neuroscience Workforce Diversity (OPEN – WD)** coordinates NINDS's diversity activities

Goals include:

- Increase applications from underrepresented groups
  - Enhance outreach and attract investigators to neuroscience/NINDS
  - Support training and capacity building
- Identify and root out bias in peer review and all other aspects of funding decisions
  - Include contributions to a research environment of inclusive excellence in the mix of factors in the choosing high program priority grants for "select pay" decisions
- Develop and track metrics openly

# NINDS Extramural Training and Career Development Programs

National Institute of Neurological Disorders and Stroke



# NIH Commitment to Ending Structural Racism

National Institute of Neurological Disorders and Stroke

- NIH is committed to instituting new ways to support diversity, equity, and inclusion, and identifying and dismantling any policies and practices that may harm our workforce and our science.
- NIH established the **UNITE** initiative to address structural racism in biomedical research with the goal of ending racial inequity.

**nih.gov/ending-structural-racism**

- Primary goals of the initiative are:

**U** Understanding stakeholder experiences through listening and learning
**N** New research on reducing health disparities and promoting health equity
**I** Improving the NIH culture and structure for equity, inclusion, and excellence
**T** Transparency, communication, and accountability with our internal and external stakeholders
**E** Extramural research ecosystem: changing policy, culture and structure to promote workforce diversity

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National Institute of Neurological Disorders and Stroke

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Thank you
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Asante
Děka
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# NINDS Office of Global Health & Health Disparities (OGHHD)

National Institute of Neurological Disorders and Stroke

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