Bias and Structural Inequity in Research

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HCCA’s 2021 Research Compliance Conference
1. Understand the history of bias and structural inequality in clinical research

2. Using data, describe the effects of bias and inequity in clinical research today

3. List four actions organizations can take to reduce bias and inequity
Examining the Issues
As a Compliance Professional, what do you think of when you hear **Bias** in the context of **Research**?

WEB: PollEv.com/nicihardin527  OR

Audience texts **NICIHARDIN527** to **22333** to join the session, then they text a response.
Conflicts

- Of Interest
- Of Commitment
- Institutional
As a Compliance Professional, what does “research ethics” mean to you?

WEB: PollEv.com/nicihardin527 OR

Audience texts NICIHARDIN527 to 22333 to join the session, then they text a response
Research Ethics

• Human Subjects Protections
• HIPAA/Privacy
• Research Billing
Define Structural Inequity

Structural inequities are the personal, interpersonal, institutional, and systemic drivers—such as, racism, sexism, classism, able-ism, xenophobia, and homophobia—that make those identities salient to the fair distribution of health opportunities and outcomes.

Source: The Root Cause of Health Inequities: Communities in Action
Understanding Structural Inequity

Source: YouTube
Understanding Bias

What
What do you see?

We see things differently …

Shaped by our experience, culture, media, awareness…..
Defining Bias

“Unconscious or Implicit” Bias is

- Everyday
- Automatic
- Biologically Hard-wired
- None of us are immune – everyone has biases
- Rapidly sort people into groups that bypass our normal, rational & logical thinking

And most importantly, we don’t know about it
The Diversity Wheel
“The mix” of human similarities and differences

Four Layers of Diversity

- **Thinking Style | Personality** This includes an individual’s likes, dislikes, values, and beliefs. Personality is shaped early in life and is both influenced by, and influences the other three layers throughout one’s lifetime and career choices.

- **Internal Dimensions** These include aspects of diversity over which we have no control (though “physical ability” can change over time due to choices we make to be active or not, or in cases of illness or accidents). This dimension is the layer in which many divisions between and among people exist and which forms the core of a person’s identity. These dimensions include the first things we see in other people, such as race or gender and on which we make many assumptions and base our judgments.

- **External Dimensions** These include life experiences and aspects of our lives which we have some control over, which might change over time and which usually form the basis for decisions on careers and work styles. This layer often determines with whom we develop friendships and social ties. This layer makes each and every one of us different and unique and this makes our society richer.

- **Organizational Dimensions** This layer concerns the aspects of culture found in an organization and/or the work setting. While much attention of diversity efforts is focused on the internal dimensions, organization efforts in valuing diversity and embracing inclusion are impacted by the aspects of this layer.

Source: Gardenswartz & Rowe, Four Layers of Diversity (adapted) | www.gardenswartrowe.com
Unconscious Bias | First Impressions

Snap judgments decide a face’s character, psychologist finds

“We decide very quickly whether a person possesses many of the traits we feel are important, such as likeability and competence, even though we have not exchanged a single word with them. It appears that we are hard-wired to draw these inferences in a fast, unreflective way.”
Dominant narratives about race (family, media, society) coupled with racialized structural arrangements and differential outcomes by race all prime us to believe that people of color are inferior to white people, create and maintain harmful associations, and lead us to make harmful assumptions, consciously and unconsciously, about people of color.

Source: National Equity Project; Implicit Bias and Structural Racism
<table>
<thead>
<tr>
<th>UNETHICAL RESEARCH</th>
<th>RESEARCH REGULATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>1959 - 1962 – Hearings on Thalidomide Disaster</td>
<td>1962 – Kefauver Harris Amendments to the Food Drug and Cosmetic Act</td>
</tr>
<tr>
<td>WWII Nazi Experiments</td>
<td>1947 – Nuremberg Code</td>
</tr>
<tr>
<td>1946 – The Nuremberg Doctors Trial</td>
<td>1964 – Declaration of Helsinki</td>
</tr>
<tr>
<td></td>
<td>1979 – The Belmont Report</td>
</tr>
</tbody>
</table>
Understanding the Impact – Examining the Data & Facts
## COVID-19 is the Number One Cause of Death in the U.S. in Early 2021

Average daily deaths in the U.S. from COVID-19 (Jan. 2021) and other leading causes (2020)

<table>
<thead>
<tr>
<th>Cause</th>
<th>Deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td>COVID-19</td>
<td>3,049</td>
</tr>
<tr>
<td>Heart Disease</td>
<td>2,068</td>
</tr>
<tr>
<td>Cancer</td>
<td>1,639</td>
</tr>
<tr>
<td>Alzheimer's &amp; Dementia</td>
<td>826</td>
</tr>
<tr>
<td>Stroke</td>
<td>434</td>
</tr>
<tr>
<td>Chronic Lower Respiratory</td>
<td>414</td>
</tr>
<tr>
<td>Diabetes</td>
<td>273</td>
</tr>
<tr>
<td>Other Respiratory Diseases</td>
<td>181</td>
</tr>
<tr>
<td>Influenza &amp; Pneumonia</td>
<td>146</td>
</tr>
<tr>
<td>Renal Failure</td>
<td>140</td>
</tr>
</tbody>
</table>

NOTES: The COVID-19 mortality rate is the daily average for January 2021 through January 26, 2021 using the KFF COVID-19 Tracker data. Mortality rates for causes other than COVID-19 are the average of Morbidity and Mortality Weekly Report (MMWR) weeks 1-52 in 2020 reported by CDC. Heart disease refers to all circulatory diseases except stroke. Accidents are not included in the data source, but typically rank as the 3rd leading cause of death.

SOURCE: KFF analysis of 2020 CDC mortality data

Health Disparities by Race & Ethnicity during the Covid Pandemic

INFECTION RATES

Figure 1: COVID-19 Age-Adjusted Case Rates per 100,000 Persons by Race and Ethnicity, through March 10, 2021

<table>
<thead>
<tr>
<th>Race/Ethnicity</th>
<th>Infection Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Native Hawaiian/Pacific Islander, Non-Hispanic</td>
<td>6,692</td>
</tr>
<tr>
<td>American Indian/Alaska Native, Non-Hispanic</td>
<td>5,711</td>
</tr>
<tr>
<td>Hispanic/Latino</td>
<td>4,145</td>
</tr>
<tr>
<td>Black, Non-Hispanic</td>
<td>3,500</td>
</tr>
<tr>
<td>White, Non-Hispanic</td>
<td>3,267</td>
</tr>
<tr>
<td>Asian, Non-Hispanic</td>
<td>2,217</td>
</tr>
</tbody>
</table>

DEATH RATES

Figure 2: Provisional COVID-19 Age-Adjusted Death Rates per 100,000 Persons by Race and Ethnicity, Reported through March 6, 2021

<table>
<thead>
<tr>
<th>Race/Ethnicity</th>
<th>Death Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Native Hawaiian/Pacific Islander, Non-Hispanic</td>
<td>208</td>
</tr>
<tr>
<td>American Indian/Alaska Native, Non-Hispanic</td>
<td>304</td>
</tr>
<tr>
<td>Hispanic/Latino</td>
<td>288</td>
</tr>
<tr>
<td>Black, Non-Hispanic</td>
<td>236</td>
</tr>
<tr>
<td>White, Non-Hispanic</td>
<td>124</td>
</tr>
<tr>
<td>Asian, Non-Hispanic</td>
<td>127</td>
</tr>
</tbody>
</table>

Percentage of U.S. Medical School Graduates by Race/Ethnicity (alone), Academic year 2018-2019

- American Indian or Alaska Native (38)
- Asian (4,299)
- Black or African American (1,238)
- Hispanic, Latino, or of Spanish Origin (1,063)
- Multiple Race/Ethnicity (1,598)
- Native Hawaiian or Other Pacific Islander (9)
- Non-U.S. Citizen or Nonpermanent Resident (309)
- Other (380)
- Unknown Race/Ethnicity (124)
- White (10,879)

Note: Race/ethnicity "alone" indicates that an individual is reported in only one race/ethnicity category. The "Multiple Race/Ethnicity" category includes individuals who selected more than one race/ethnicity response. The "Non-U.S. Citizen or Nonpermanent Resident" category may include individuals with unknown citizenship.

Source: AAMC Data Warehouse: STUDENT and IND as of Aug. 19,
Historically, minority participation has been low in clinical trials, despite some groups being disproportionately affected by chronic diseases.

According to the Food and Drug Administration (FDA):

- **African-Americans** represent 12% of the U.S. population, but only 5% of clinical trial participants.

- **Hispanics** make up 16% of the population, but only 1% of clinical trial participants.

Source: [http://blackpressusa.com/campaign-launched-to-get-more-blacks-in-clinical-trials/#sthash.0e87gR9V.dpbs](http://blackpressusa.com/campaign-launched-to-get-more-blacks-in-clinical-trials/#sthash.0e87gR9V.dpbs) viewed 05/27/21
## U.S. Cancer Health Disparities

Adverse differences in numerous measures of cancer burden exist among certain U.S. population groups. Examples of disparities in cancer incidence and death rates include:

<table>
<thead>
<tr>
<th>MORE THAN TWICE</th>
<th>African American men have a prostate cancer death rate that is more than twice that for white men.</th>
</tr>
</thead>
<tbody>
<tr>
<td>20% MORE LIKELY</td>
<td>Hispanic children are 20 percent more likely to develop leukemia than non-Hispanic white children.</td>
</tr>
<tr>
<td>TWICE AS LIKELY</td>
<td>Asian/Pacific Islander adults are twice as likely to die from stomach cancer as white adults.</td>
</tr>
<tr>
<td>TWICE AS LIKELY</td>
<td>American Indian/Alaskan Native adults are twice as likely to develop liver and bile duct cancer as white adults.</td>
</tr>
<tr>
<td>51% MORE LIKELY</td>
<td>Adolescents and young adults (ages 15 to 39) with head and neck cancer who have no insurance are 51 percent more likely to die from their disease than those who have private insurance.</td>
</tr>
<tr>
<td>35% HIGHER</td>
<td>Men living in the poorest U.S. counties have a colorectal cancer death rate that is 35 percent higher than that for men living in the most affluent U.S. counties.</td>
</tr>
<tr>
<td>70% MORE LIKELY</td>
<td>Bisexual women are 70 percent more likely to be diagnosed with cancer than heterosexual women.</td>
</tr>
</tbody>
</table>

Adapted from American Association for Cancer Research (AACR) Cancer Disparities Progress Report 2020
Underrepresentation of African Americans in Recent Prostate Cancer Clinical Trials

A striking example of cancer health disparities is that prostate cancer incidence among African American men is nearly 70 percent higher than among white men. Unfortunately, two recent clinical trials testing new therapeutics for the treatment of prostate cancer recruited fewer than 10 percent of patients who were African American.
Summary statistics for the FY 2014-2016 NIH applicant pool.

<table>
<thead>
<tr>
<th>Applicant Race</th>
<th>Applications</th>
<th>PIs</th>
<th>Reviewers</th>
<th>Review Records</th>
</tr>
</thead>
<tbody>
<tr>
<td>Black</td>
<td>1,015</td>
<td>500</td>
<td>2,322</td>
<td>3,064</td>
</tr>
<tr>
<td>White</td>
<td>45,211</td>
<td>19,653</td>
<td>19,100</td>
<td>136,152</td>
</tr>
<tr>
<td>Total</td>
<td>46,226</td>
<td>20,153</td>
<td>19,197</td>
<td>139,216</td>
</tr>
</tbody>
</table>

Source: Advances.sciencemag.org/cgi/content/full/6/23/eaaz4868/DC1; viewed 05/28/21.
Fig. 1 Funding gap between AA/B and WH scientists at each stage of the R01 application and review process.

- **Apps from AA/B investigators**
  - % discussed: 44.0%
  - % of funded if discussed: 24.2%
  - % funded overall: 10.7%

- **Apps from WH investigators**
  - % discussed: 57.4%
  - % of funded if discussed: 30.8%
  - % funded overall: 17.7%

Difference at each step:
- Applications (2.53): 83.7%
- Applications discussed (1.11): 76.6%
- Applications funded (0.27): 78.6%
- Cumulative difference: 50.4% (2.0× disparity)

Travis A. Hoppe et al. Sci Adv 2019;5:eaaw7238

Source: https://advances.sciencemag.org/content/5/10/eaaw7238
Addressing the Impact – Solutions to explore
Strategies for Inclusion of Diversity in Research

A – Assess the environment to identify the ‘multifactorial’ barriers.

B – Bias Mitigation Strategies and design intentional approaches for inclusion

C – Community Trust and engagement, Cultural Competency & Language Access services

D – Diversity Demographics: data and documentation
We are building a research program of 1,000,000+ people.

The All of Us Research Program is an ambitious effort to gather health data from one million or more people living in the United States to accelerate research that may improve health.

OPPORTUNITIES FOR RESEARCHERS

Research focuses on the intersection of three factors

https://allofus.nih.gov/
Questions

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Disclaimer

This slide deck was used to present concepts of Diversity, Equity and Inclusion in a presentation on June 14, 2021 at the HCCA Conference. The information contained in this document were created through research and cited resources from the public domain and is current at the time it was presented, published or shared.

If there are further questions, please contact systemdiversityandinclusion@ssmhealth.com