

# Considerations in the Measurement of Race & Ethnicity; Downstream Effects; and Novel Methods to Address the Issue

**RAISE Community Workshop 8**  
Thursday, May 4, 2023, 2 – 3 PM ET

Summary

## **Overview of RAISE Community Workshop VIII**

*Susan C. Winckler, CEO of the Reagan-Udall Foundation opened the meeting, followed by remarks by Dr. Christine Lee, Strategic Research Engagement Lead of the Office of Minority Health and Health Equity at the FDA. During the session we heard three presentations. First, Dr. Carla Rodriguez-Watson, RAISE PI, summarized our previous RAISE workshops and their connection to workshop VIII. Next, Dr. Tegan Boehmer (CDC) discussed how aggregating vs. disaggregating race affects measures of risk. Then, from Drs. Mohanty, Zickmund, and Naranjo (VA IDEAS-Informatics, Decision Enhancement & Analytic Sciences), we learned how the Veterans Health Administration (VHA) collects and updates race and ethnicity data. After the presentations, our citizen voice Rodney Samaco, PhD (Baylor College of Medicine) and Dionna Atkinson (Aetion) joined our speakers on the virtual stage to engage in a discussion led by Dr. Carla Rodriguez-Watson.*

## **Connecting the Dots: More Impact**

*Carla Rodriguez-Watson, PhD, MPH  
Director of Research, Reagan-Udall Foundation for the FDA*

To level set, the RAISE project begins with the assumption that race and ethnicity (R&E) are critical for understanding population health and the real-world utilization and performance and medical products across racialized groups; and thus, the impact that has on the health of those racialized groups.



So, we are focused on the part of the data continuum that includes reporting, collection, curation and integration of R&E data because this is where the corpus of RWD lives. We acknowledge that having R&E in the model doesn't answer all the questions – but it does address some critical questions of importance to the FDA. Which is why, though important, questions of when R&E is not the right variable are not in scope with RAISE. Similarly, the timeline for our discussions does not allow us to delve into issues of access to care.

In workshop seven, we discussed the LATIN-19 project and their work in North Carolina to bridge the insurance enrollment and data gaps due to COVID-19. We also heard from UNC about missing data, and that not being random, and the real consequences that has on the health of missing populations. Today is a continuation of our discussion on impact; particularly how the measures and choices we make impact data inference. We will begin with a talk on how aggregation or disaggregation of racial categories and our choice of whether to use absolute or relative differences affects our interpretation of risk. Then, we'll learn how R&E is ascertained at the VA, along with its accuracy compared to self-report and the imputation approaches of one system. Our discussion will then focus on how this original data collection affects how real-world data researchers might use such secondary data.

### **Methodological Considerations in Measuring Health Disparities by Race and Ethnicity**

*Tegan K Boehmer, PhD, MPH  
Commander, U.S. Public Health Service  
Office of Public Health Data, Surveillance, and Technology  
Centers for Disease Control and Prevention (CDC)*

*Achieving health equity requires focus and ongoing efforts to address injustices, overcome economic, social, and other obstacles, and eliminate health disparities. The CDC recently launched an agency wide strategy that aims to integrate health equity into the fabric of all that is done at the agency. This new strategy challenges the multiple centers at the CDC to incorporate health equity as a foundational element across science, programs, and interventions.*

- To level set, a health disparity is a plausibly avoidable or preventable systematic health difference that adversely affects a socially or economically disadvantaged group.

According to [Keppel et al](#), a health disparity is the quantity that separates the socially or economically disadvantaged group from a specified reference point on a particular measure of health. The choices made on various measurement topics (*shown in the slide below*) can affect the size and the direction of a disparity, and can lead to different conclusions about disparities, both

disparities between groups at a single point in time, as well as changes in disparity over time. Because of this, it's critical to make deliberate choices and then clearly describe and justify these choices. This presentation will focus on the first 3 measurement decisions.

- The first measurement choice is in the *categorization and aggregation of R&E data*. This concept is important as aggregation can potentially mask important differences in health outcomes between subgroups. The example [below](#) illustrates this concept. The example below shows the percentage of COVID-19 patients treated with Paxlovid from January to July of 2022 and highlights the impact of different

#### **Disparities-related Measurement Concepts**

Several methodological issues can affect the measurement of health disparities (both size and direction) between groups in a population.

1. Categorization and Aggregation of Race and Ethnicity
2. Reference Point
3. Absolute vs. Relative Disparity
4. Pairwise vs. Summary Measures
5. Point In Time vs. Changes over Time

**Choices can lead to different conclusions,  
so be deliberate and explain and justify choices**

Source: Keppel et al. Methodological Issues in Measuring Health Disparities Vital Health Stat 2, 2005. PMID: 16032956

categorization choices. As this example shows, disparities can be underestimated when examining race and ethnicity separately. The percent treated is lower when White race includes Hispanic ethnicity (13.5%) than when Hispanic ethnicity is excluded (14.3%). This results in different magnitudes of disparity, for both relative and absolute differences, when comparing minority racial and ethnic groups (e.g., Black, Hispanic) to the “majority” reference group (i.e., White race, non-Hispanic ethnicity, or non-Hispanic White race/ethnicity).

## Example: COVID-19 patients treated with Paxlovid, Jan–Jul 2022 — Combine Race and Ethnicity

Race and Ethnicity separately

Race or Ethnicity	Percent treated	Absolute difference	Relative difference
White	13.5	Ref	Ref
Black	7.0	-6.5	-48.0
Asian	11.9	-1.6	-11.9
AI/AN/NH/OPI	7.9	-5.5	-41.1
Multiple/other	8.5	-5.0	-37.3
Non-Hispanic	12.8	Ref	Ref
Hispanic	6.6	-6.2	-48.4

Race and Ethnicity combined

Race and Ethnicity	Percent treated	Absolute difference	Relative difference
NH, White	14.3	Ref	Ref
NH, Black	7.1	-7.2	-50.4
NH, Asian	12.0	-2.2	-15.8
NH, AI/AN/NH/OPI	8.0	-6.3	-43.9
NH, Multiple/other	10.7	-3.6	-25.1
Hispanic	6.6	-7.7	-53.8

Abbreviation: NH, Non-Hispanic; AI/AN/NH/OPI, American Indian, Alaska Native, Native Hawaiian, Other Pacific Islander

Source: Unpublished data from PCORnet. See Boehmer et al. Racial and ethnic disparities in outpatient treatment of COVID-19. MMWR 2022;71:1359-65.

- The second measurement choice is that of *selecting a reference point*, or the specific quantitative value from which the disparity is measured. This choice of a reference point matters, and it will determine the size and the direction of the disparity. There are several possible options to choose from, including the largest group, the group with the most favorable rate, the total population rate, the average group rate, or the target/goal rate. There are many factors to consider. For example, the largest group will have the most stable rate for comparison. The group with the most favorable rate could be appealing because it represents the highest level attained by a certain racial or ethnic group, but this group could change over time.

### Reference Point

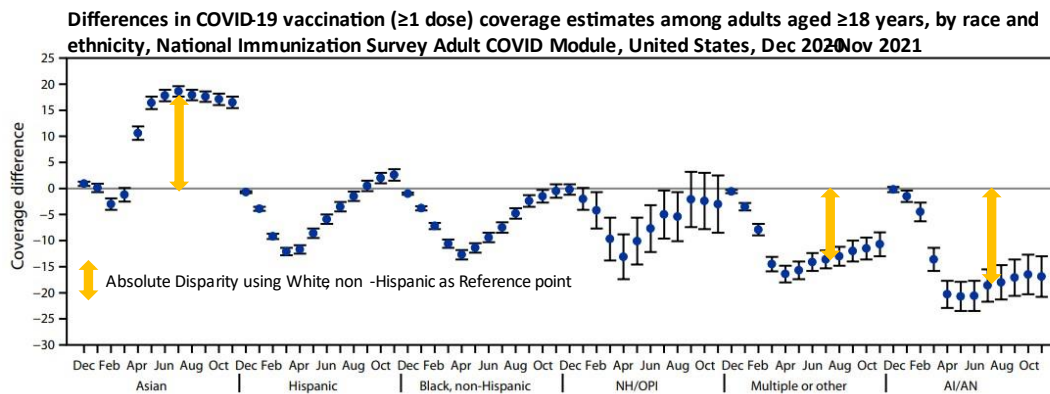
- Reference point:** specific quantitative value from which a disparity is measured
- Choice of reference point will determine the size and direction of the disparity
- Possible options:
  - Largest group
  - Group with the most favorable rate
  - Total population rate
  - Average group rate
  - Target or goal rate



Image credit: Designed by gstudioimagen / Freepik

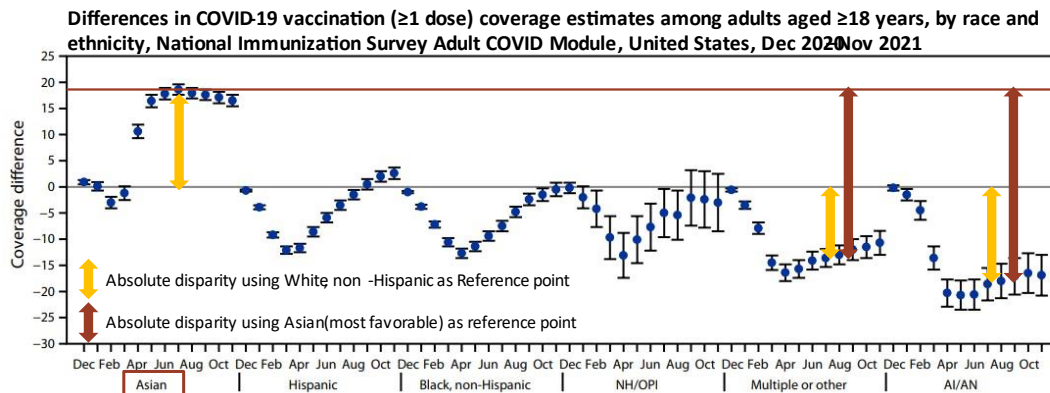
- In the [example](#) of COVID-19 vaccination ( $\geq 1$  dose) coverage estimates, using the largest group as the reference (i.e. non-Hispanic White adults) conveyed that Asian adults had similar vaccination coverage as non-Hispanic White adults for the first 4 months of vaccine availability, and then peaked at 20 percentage points higher than the reference group. Adults of multiple or other race and of American Indian or Alaska Native race had vaccination coverage 15 to 20 percentage points lower than that for the non-Hispanic White reference group. When using this same data and selecting the most favorable group, non-Hispanic Asian adults, as a reference point, the magnitude of this disparity is nearly 2 times larger compared with the largest group for the reference.

### Example: COVID-19 Vaccination Coverage thru Nov '21 — Largest Group as Reference Point



Abbreviations: AI/AN, American Indian or Alaska Native; NH, Non-Hispanic; NH/OPI, Native Hawaiian or other Pacific Islander  
Source: Kriss JL, et al. MMWR 2022;71 <https://www.cdc.gov/mmwr/volumes/71/wr/mm7123a2.htm>

### Example: COVID-19 Vaccination Coverage thru Nov '21 — Most Favorable Group as Reference Point

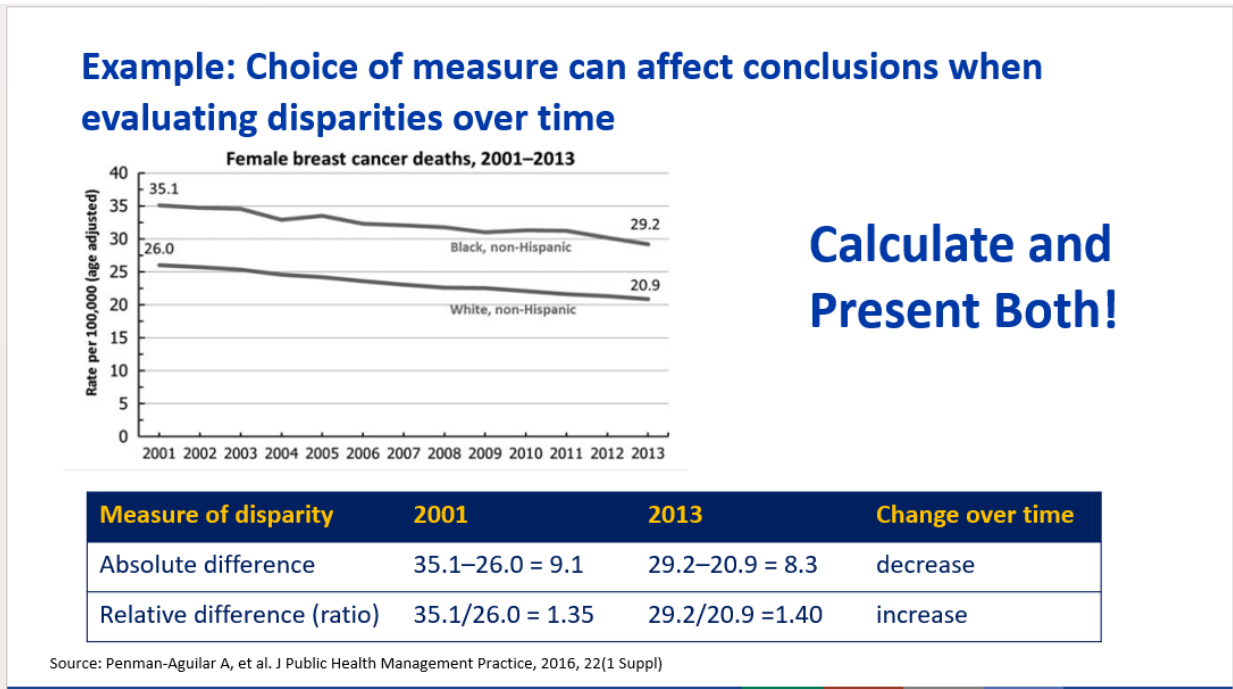


Abbreviations: AI/AN, American Indian or Alaska Native; NH, Non-Hispanic; NH/OPI, Native Hawaiian or other Pacific Islander  
Source: Kriss JL, et al. MMWR 2022;71 <https://www.cdc.gov/mmwr/volumes/71/wr/mm7123a2.htm>

- The third measurement choice is whether to calculate *an absolute or relative disparity* or, ideally, both! An absolute disparity is just a simple difference between a group rate and a reference rate. Absolute measures retain their unit of measurement. Relative disparities are those that are calculated as a percent difference or a ratio between rates and can be used to compare outcomes

across measures with different units. When disparity is measured at a single point in time from the same reference point, the absolute and relative measures will provide similar information about disparities between groups. However, the two types of measures can provide contradictory evidence concerning changes in disparities over time.

- The last [example](#) of the age adjusted breast cancer death rates for non-Hispanic Black and non-Hispanic White women between 2001 and 2013 shows how different disparity measures can lead to different conclusions when evaluating disparities over time. The absolute difference decreased over the 13-year period from 9.1 deaths per 100,000 to 8.3, but the relative difference (ratio) increased over time from 1.35 to 1.40. To be fully transparent and to allow others to draw informed conclusions, it is recommended to always calculate and present both absolute and relative measures of disparity.



- Measurements of disparity can be complex and multi-dimensional, and there's no right or single way to do it.
- Choices to aggregate racial and ethnic groups, select a reference point, and measure on an absolute or relative scale do affect the results and conclusions from analyses of health disparities. As such, it is important that these choices be made deliberately, described clearly, and justified appropriately. This is critical for both the descriptive assessments of health disparities and more sophisticated analysis.

**Data Collection, Sources, and Algorithms for Race and Ethnicity Determination in VHA**

*April F. Mohanty, MPH, PhD*

*Research Health Scientist*

*VA Informatics, Decision Enhancement, & Analytic Sciences Center, Salt Lake City VAMC*

*University of Utah, Department of Internal Medicine*

*Susan Zickmund, PhD*

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- The VA is committed to adhering to best practices for collecting patient R&E data, and over the years has made strides to improve R&E data completeness, accuracy, and consistency over time and across sites. The electronic health record has the most up to date data for VA patient R&E and is the most frequently used for research. Information is intended to be collected at VA facilities during patient enrollment, or during in or outpatient visit encounters.
- Since 2003, patient R&E are stored as two separate variables and veterans may select multiple values for race using OMB categories. If a patient's demographic files are updated, new information will overwrite previously stored values, though in rare instances when a patient is enrolled at more than one VA facility, there can be multiple demographic records per patient identifier.
- From 2016-2019, the racial and ethnic distribution of the VHA population was 67% non-Hispanic White, 16% African American and 6.4% Hispanic. Seven and a half percent of the population have unknown, declined, or missing race or ethnicity. Additionally, the prevalence of non-Hispanic White veterans is projected to decline by 13% from 2019 to 2045.
- Over the years, many researchers have sought to address missing R&E data and to validate the VHA data by combining it with other external and internal data sources. An [example](#) study by Peltzman et al linked VA patient data from 2000 to 2018 with R&E data from VA Medical SAS files (MedSAS), Corporate Data Warehouse (CDW), VA Centers for Medicare extracts (CMS), and VA Defense Identity Repository Data (VADIR) to assess the accuracy of each data source. Generally, agreement was high for data sources, especially for the Black or African American and White race categories. Recommendations from this study and others include prioritization of self-reported race, treatment of R&E as a social construct with other social determinants of health data and to apply potential algorithms to include multiple data sources such as those described by Peltzman et al, noting the strengths and weaknesses of each of the data sources and fit based on the research question at hand.
- As part of our interagency agreement with the FDA, an ancillary project to assess the benefit of adding USVETS data which combines VA, DOD and commercial data for all veterans along with VA the OMOP (Observational Medical Outcomes Partnership) a Common Data Model algorithm to define R&E. Combining data reduced missing R&E in our study from 4% to less than 1%. We applied two methods, an agreement approach across R&E data sources and a hierarchical approach that prioritized Hispanic or non-White R&E documentation when there was disagreement across the data sources. As expected, the agreement approach resulted in a higher prevalence of non-Hispanic White race when compared to the hierarchical approach.
- To understand the impact of COVID-19 on racial and ethnic minority Veterans of color requires complete R&E data in the electronic health record (EHR). An internal VA report identified that there

can be variation in the completeness and accuracy of VHA R&E data. The report suggested identification of best practices from high performing sites and the development of recommended practices to be shared with all VA sites.

- Our FDA OMHHE R&E project follows up on the internal VA report and proposes to use qualitative methods to explore barriers and facilitators of receiving accurate VA R&E data for use in the EHR and reasons for site variation to help develop best practice recommendations.
- The results from interviews of individuals (e.g., Clerks who help enroll Veterans in VHA) at sites across VHA where there is variation in the completeness and/or accuracy of R&D data will be used to communicate a learned understanding of the data procurement life cycle.
- *A special acknowledgement to the collaborators and partners who contributed to this work, including the partnership with the FDA- OMHHE, the University of Utah including the IDEAS Center and the larger VA/FDA Interagency Agreement collaboration team.*

### **Moderated Discussion**

*Moderator: Carla Watson-Rodriguez, PhD  
Director of Research, Reagan-Udall Foundation for the FDA  
Principal Investigator, RAISE*

*Discussants:*

- *Citizen Voice: Rodney C. Samaco, PhD*
- *Dionna Atkinson, MPH*
- *Tegan K. Boehmer, PhD, MPH*
- *Diana Naranjo, PhD, MPH*
- *April F. Mohanty, MPH, PhD*
- *Susan Zickmund, PhD*

The moderated discussion took questions from the chat as well as those posed by our moderator to further expand on the workshop's presentations. Our discussion emphasized that R&E data need to be captured deliberately, accurately, and transparently to make meaningful progress in identifying and addressing disparities in health and health care. Highlights from the discussion:

- In developing potentially life changing therapies that are based on genetics or correcting at the genome level, it is important to be deliberate when capturing R&E data, noting the rationale and collection method.
- To generate real-world evidence, the real-world data (RWD) needs to be both valid and transparent. Each type of real-world data has different key information captured which helps to determine what data source is a good fit for each individual research question. However, R&E is often recorded inconsistently over data sources, many lacking reliable information or a risk for misclassification. Within the given clinical and regulatory context, there should be assurances that RWD is of sufficient quality, relevant, robust, and representative. Making the efforts to accurately capture these important data will lead to meaningful progress in identifying and addressing disparities in health and health care using RWD.
- VA data is generally collected for clinical reasons and not for research purposes during patient enrollment, and over the course of inpatient or outpatient treatment. The original purpose was patient care (outside of research studies, such as the Million Veteran Program). The R&E deep dive project our team is leading should help with understanding how R&E is collected across VA

nationally and lead toward a future with a clearer understanding of how to improve R&E data collection and analysis.

- Ethnicity is distinct from race.
- With the desire to protect patient confidentiality and protective health information, it can be difficult to acquire a HIPAA compliant data set with granularity on the multiple factors and variables that are needed to understand public health or clinical question. R&E data are often aggregated into larger categories. There can be a tradeoff to stay compliant with HIPAA that trades granular R&E data for either geography, age, specific dates of service or some combination with patient privacy. The best bet is to try to balance the desire for granularity with what is truly needed to inform public health action and interventions.

### Hot Takes and links from the Chat

- The agenda and other materials for Workshop 8 can be found on the FDA Foundation website: <https://reaganudall.org/news-and-events/events/considerations-measurement-race-and-ethnicity-downstream-effects-and-novel>
- Website references from Dr. Boehmer:
  - Healthy People 2020 Disparities Data: <https://wayback.archive-it.org/5774/20220413165531/https://www.healthypeople.gov/2020/data-search/health-disparities-data>
  - Healthy People 2020 Final Review Overview of Health Disparities: [https://www.cdc.gov/nchs/healthy\\_people/hp2020/health-disparities.htm](https://www.cdc.gov/nchs/healthy_people/hp2020/health-disparities.htm)
  - Health Disparities Calculator (NCI): <https://seer.cancer.gov/hdcalc/>
- CDR Tegan Boehmer recommends these articles as additional reading:
  - 1. Keppel, 2005: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3681823/>
  - 2. Penman-Aguilar, 2016: <https://pubmed.ncbi.nlm.nih.gov/26599027/>
  - 3. Huang, 2022: <https://pubmed.ncbi.nlm.nih.gov/36409518/>
- Peltzman paper I discussed can be accessed here: <https://pubmed.ncbi.nlm.nih.gov/35323934/>

*Please join us for future RAISE Workshops:*



**RAISE** Community Workshop Series

1<sup>st</sup> & 3<sup>rd</sup> Thursday of the month at 2 pm ET

#	Date / Time (ET)	Key Theme
1	Jan 26 / 2-4 pm	Opportunities to Improve Race & Ethnicity Data in Health Care
2	Feb 2 / 2-3 pm	Collecting Better Data I: Incentives, Framework, Mission
3	Feb 16 / 2-3 pm	Collecting Better Data II: System Infrastructure
4	Mar 2 / 2-3 pm	Creating Safe Space I: Reporting Race 101
5	Mar 16 / 2-3 pm	Creating Safe Space II: Capturing Race and Ethnicity Data
6	Apr 6 / 2-3 pm	Technical challenges in the transfer of information
7	Apr 20 / 2-3 pm	Factors & Impact of Missingness, Misclassification, and Measurement Bias
8	May 4 / 2-3 pm	Advanced Analytics – Novel Ways to Apply Existing Race & Ethnicity Data
9	May 18 / 2-3 pm	Advanced Analytics - Interim Solutions When Race & Ethnicity are Missing
10	Jun 1 / 2-3 pm	Reactions to Barriers, Opportunities & Proposed Solutions
11	Jun 15 / 2-4 pm	Summary - Visioning & Next Steps