



COVID-19 Evidence Accelerator Collaborative

Lab Meeting # 33

Thursday, May 20th, 2021 3 - 4:00 pm ET

Call Summary

Overview of Lab Meeting 33

The focus of the 33rd Therapeutics and Vaccines Lab Meeting was race and ethnicity in real-world data (RWD). First, Dr. Michelle Tarver of the Office of Strategic Partnerships and Innovation in the Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH), presented on how data missingness and other challenges of collecting data on race and ethnicity complicate utilizing these data to evaluate medical devices across diverse populations. Next, Dr. Regina Davis Moss of the American Public Health Association (APHA) presented on how meaningful collection of RWD on race and ethnicity can be improved to address inequities revealed during COVID-19, and beyond. Finally, Dr. Jeff Allen of Friends of Cancer Research and Dr. Carla Rodriguez-Watson of the Reagan-Udall Foundation for FDA presented race and ethnicity data from two studies conducted in the Evidence Accelerator's Therapeutics Parallel Analysis workstream.

Race & Ethnicity in Real-World Data Sources

Dr. Michelle Tarver, Office of Strategic Partnerships and Innovation, FDA/CDRH

Why consider demographic differences?

- COVID-19 revealed worse outcomes and disease trajectories for older populations and people of African and LatinX descent.
- Differences in biology, environment and interactions between them can affect health, disease, and response to medical devices.
- Benefit-risk profile and other aspects of device performance may differ across subgroups.
 - Dermatology devices may have different considerations for use in specific racial or ethnic populations.
 - Orthopedic devices may have different considerations for use in certain age groups.
- These differences underscore the need to consistently and thoroughly collect and examine demographic data, particularly as we develop solutions.

Examples of Race, Ethnicity, and Ancestry Definitions

- **Race** refers to a sociocultural definition recognized in this country (may be different in other countries), not an attempt to define race biologically, anthropologically, or genetically.
- **Ethnicity** refers to the shared social, cultural, and historical experiences stemming from common heritage, nationality, lineage, country, or region of birth.
- **Ancestry** refers to a person's ethnic origin or descent, "roots", heritage, or place of birth of a person, their parents, or ancestors before arrival in the United States. Largely informed by genetic studies.

When is it important to consider demographic groups?

- Clinical trial design, enrollment, retention, and analysis – need representation of demographic groups to ensure study is responsive, respective, and includes people from various backgrounds.
- Collecting and analyzing real-world data – important we collect this data, how it is collected, and how it is linked to other datasets.
- Developing tools to evaluate medical devices – ensure tools are responsive to patients of various backgrounds, use language familiar to various demographic groups and are reflective of what is important to communities.

FDA Guidance

- Real-world evidence is increasingly used in evaluation of medical devices.
- Various guidance documents available to clarify how data on race and ethnicity should be collected, analyzed, and reported.
- Goal to improve gaps in data on demographic subgroups.

Using RWD to Explore Device Experience in Diverse Populations

- Utilized the IRIS registry to evaluate safety and effectiveness outcomes by demographic groups for minimally-invasive glaucoma surgical (MIGS) devices.
- Preliminary analyses found there are differential patterns across demographic groups:
 - African descent, male gender and older age were associated with increased use of MIGS devices.
 - African-descent patients more likely to have better outcomes compared to white patients.
 - Patients of Hispanic ethnicity less likely to have MIGS device implanted despite a higher prevalence of disease in the population (suggesting underutilization).
- Missing data on race within the EHR (12% of patients representing >7.2 million people)

OMB Recommendations

- Ask about ethnicity first (Hispanic/Latino or Non-Hispanic/-Latino) then race (American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, White).
- Self-reporting is recommended with the option to select multiple categories.
- These recommendations may allow for greater consistency in reporting.

Challenges with Race & Ethnicity Variables in Datasets

- Recording in RWD sources varies – Who is reporting? What categories are used? What defines the categories? How is missingness handled in the database?
- Concerns that race reporting impacting care may lead to missing data.
- Inconsistencies in recording or missing data may impair linkage with other data sources.
- Examples of these challenges:
 - EHRs inconsistent recording of race/ethnicity
 - Insurance databases may not be reflective of self-report, laws that complicate collection of race/ethnicity data.

- Patient-Driven Registries have missing data due to discrimination concerns and there is limited inclusion of diverse patients.
- Provider-Led Registries have limited inclusion of diverse patients.
- Literature-reported data challenges
 - Missing data
 - 11-22% of hospital systems don't collect race/ethnicity data
 - 18% of patients in a cancer registry had missing race/ethnicity data
 - 17% of patients are uncomfortable reporting race, and 43% concerned about it being used to discriminate against them
 - Misclassification
 - Certain groups more likely to be misclassified, could impact inferences about outcomes in these groups (Hispanic, Middle Eastern, Native American population often recorded as White race)
 - Race often reported by people other than the patient
 - Unknown/missing race and ethnicity fields resulted in data quality worse than if the data had been generated at random
 - Discordance amongst different health databases inhibiting linkages

Systemic Racism Concerns Impact RWD

- Race and ethnicity are sociocultural constructs that could change with changing country, times, and social pressures. They often have limited relevance to biology and genetics.
- In a survey of Californians, 17.2% reported they were uncomfortable reporting their own race and ethnicity – 46.3% worried this information will be used against them.

Challenges & Opportunities

- Use terminology (race, ethnicity, ancestry) consistently and appropriately
- Create distinct definitions applicable across the globe
- Avoid burdensome and exhaustive categorization
- Integrate collection processes into the delivery of healthcare
- Support data quality through IT infrastructure
- Mitigate against unanticipated consequences of reporting/collection
- Identify and track variability in classification
- Involve patients in the development of these processes

Race, COVID-19, Data and Beyond

Dr. Regina Davis Moss, American Public Health Association (APHA)

Race & Racism Defined

- Race is a social construct that is solely based on physical characteristics, entirely lacks biological basis.
- Racism is the false belief that one race is superior over another race. It unfairly disadvantages some communities and individuals while unfairly advantaging other communities and individuals.

Structural Racism & COVID-19

- Access to testing and care for COVID impacted by structural racism:
 - Testing conveniently located in affluent areas, but not conveniently located in communities of color. (e.g., drive-through vs. walk-up, long lines)
 - Messaging on the need for a gateway provider prevented populations from access primary care.
 - Cost of testing and care for uninsured and underinsured created disparities in access to these services.

Race & COVID Data

- We have antiquated systems for collecting race and ethnicity data.
- Federal race and ethnicity COVID-19 data is not yet comprehensive enough to represent everyone's experience in the US.
- Limited to no federal data on testing, hospitalization, and vaccination that includes information on race and ethnicity.
- Not all states release data on race/ethnicity of vaccine recipients.

Barriers to Obtaining Equity-Oriented Data

- Technology issues – limitations in data systems, data from different sectors incompatible for linking, etc.
- Legal challenges about what information should be shared
- Concerns around data governance/privacy challenges/data standards
- Trust across agencies
- Experiences/hesitation from individual users
- Community and practitioner voices missing when deciding what data matters
- Few incentives to share data

Opportunities for Obtaining Meaningful Data

- Incentivize data system capacity, compatibility, & analytic ability
- Build narratives of shared value
- Promote national data standards development to enable sharing and equity
- Create “federally approved” data sharing agreements
- Leverage experiences from other jurisdictions/sectors and offer technical assistance and guidance
- Win-win partnerships between data holders and researchers
- Partner with funders to incentivize data sharing
- Integrate health data from other sectors
- Integrated/contextual data from community health assessments (CHA)
- Automated sharing of reportable conditions using electronic case reporting (eCR)
- Operate a health information exchange (HIE)

Race & Ethnicity Data from Real-World Studies: Examples from the COVID-19 Accelerator Parallel Analyses Workstreams

Dr. Jeff Allen, Friends of Cancer Research

Dr. Carla Rodriguez-Watson, Reagan-Udall Foundation for the FDA

Case Study 1: The Use of Hydroxychloroquine +/- Azithromycin Among Hospitalized Patients With COVID-19

- 7 research teams developed and conducted a common protocol.
- Analysis period March-June 2020, initial observations shared July 13, 2020
- This research provided the opportunity for initial observations regarding treatment patterns, research methodologies, and experiences with COVID-19 to be shared across multiple different data sets.

Representatives of the Data

- Clinical trials are generally not representative of the overall US population and, in some cases, they are not representative of the patients that use the medical products being studied.

Case Study 1: Observations

- RWD identified treatment patterns and descriptive outcomes (use of mechanical ventilation, discharge rates, in-hospital mortality)
- High-degree of unknown/missing data regarding race/ethnicity from multiple datasets
- 2 of 6 datasets indicated black patients were receiving HCQ-containing regimens at higher rates than white patients
 - Sicker patients generally received HCQ – Greater baseline incidence of cardiovascular disease, obesity, diabetes, kidney disease.
- Data were able to be evaluated from a large proportion of the population than was otherwise available during this period.

Case Study 2: Characterization of serology testing patterns among patients with active SARS-CoV-2 infection (positive molecular test)

- Objective to describe real-world testing patterns by instrument, clinical, and demographic factors.
- N=931,000 patients across 6 partners (2 claims and 4 EHR), national representation
- March 1, 2020 – December 31, 2020 (cohort entry: March 1, 2020 to September 30, 2020)

Case Study 2: Observations

- Even in COVID-19 where we know there are racial disparities in exposure, infection rates, and death – race and ethnicity data are still missing.
- 4 of 6 sites adequately captured race
- Distribution of black population was lower among serotested compared to untested, suggesting lower serotesting in Black population.
- A shorter time to serotesting among Black patients who were tested may point to associations between race, pre-existing conditions, and/or more severe clinical presentation.