



COVID-19 Evidence Accelerator Collaborative

Lab Meeting 46

Thursday, December 2nd, 2021, 3 - 4:00 pm ET

Call Summary

Overview of Lab Meeting 46

Lab Meeting 46 focused on the importance of capturing race and ethnicity data in real-world data (RWD). First, we heard from Ryan Argentieri of the Office of the National Coordinator for Health Information Technology (ONC) about their efforts to promote interoperability and accuracy of race and ethnicity data through certification requirements. We then heard from Dr. Gracie Lieberman of TransCelerate about their "Audit Readiness Checklist" initiative which will aim to operationalize a set of best practices for RWD to be used for regulatory decision making. The meeting closed with the data visualization of the week showing just how few states have complete race and ethnicity data related to COVID-19.

Advancing Race & Ethnicity Granular Data Collection and Use to Promote Health Equity: Opportunities for Collaboration

Ryan Argentieri, ONC for Health Information Technology

About ONC

- Coordinates nationwide efforts to implement and use the most advanced health information technology and the electronic exchange of health information.
 - Advance development & use of health IT capabilities
 - Establish expectations for data sharing
- Created in 2004 under HHS, codified into law in 2009, provided new authorities under the 21st Century Cures Act
- Federal Health IT Vision & Mission
 - Vision – A health system that uses information to engage individuals, lower costs, deliver high quality care, and improve individual and population health.
 - Mission – Improve the health and well-being of individuals and communities using technology and health information that is accessible when and where it matters most.

US Core Data for Interoperability (USCDI)

- Core set of data needed to support patient care and facilitate patient access using health IT
- Establishes a consistent baseline of harmonized data elements that can be broadly reused across use cases, including outside of patient care and patient access
- Expands overtime via a transparent, established, and collaborative process, weighing benefits and industry-wide impacts

Technology & Health Equity by Design (HEBD)

- ONC recognizes the further potential of data-driven technologies to impact health equity
- ONC takes an HEBD approach, advancing the use of interoperable, standardized data to represent social needs and conditions in which people live, learn, work, and play
 - Health data, including race/ethnicity data and social determinants of health (SDoH) can help identify health disparities and to inform efforts for research to improve health outcomes at the individual & population levels
- Gaps in available standardized SDoH and other relevant, non-clinical health data make it difficult to leverage available technology (EHRs, portals) to collect, share, and use it for individual and community health.

Opportunities for Industry

- Race & ethnicity data for COVID-19 tests
 - Not available for 40% of people testing positive for COVID-19
 - Similar concerns about race & ethnicity data missingness in Medicaid data and other federal and state programs
 - Medicare data standards varied overtime → concerns about data quality
- COVID pandemic reporting requirements
 - All lab data must be reported through existing public health data reporting methods and include data elements on patient race
- Capabilities for reporting race & ethnicity data exist
 - all certified health IT products have the functional capability to collect granular data on race & ethnicity, but this is not an indication of how the capabilities are used in practice
 - 9 in 10 hospitals have access to certified health IT
 - Still, race/ethnicity (R/E) granular data capture capabilities are under-utilized
- Opportunities
 - Providers & vendors can leverage R/E data capture functionality in their implementation and workflows
 - Built-in standards and functionality for capturing R/E data → precision, accuracy, and equitable treatment for all patients

Leveraging Existing Capabilities for R/E Data

- Certified Health IT modules must be able to capture all of a patient's races and ethnicities in accordance with, at a minimum, CDC's Race and Ethnicity code system (921 race codes, 43 ethnicity codes)
- Certification criteria do not specify how many CDC R/E codes must be available in a system (there is no minimum) or how they are displayed, so it is left to developers in concert with end users in specific care settings
- Recording/exchange of R/E data at a granular level can facilitate accurate identification and analysis of health disparities based on race and ethnicity
- Healthcare providers can and should work with their health IT developer to specify how they would prefer to record race and ethnicity to support the populations they serve

Real World Data Survey Overview

Dr. Gracie Lieberman and Dr. Andre Araujo, TransCelerate

TransCelerate’s RWD Audit Readiness Checklist

- Operationalize thought leadership on the use of RWD in regulatory decision-making
- “Audit Readiness Checklist” – tool targeting data relevance and reliability
 - Leverage Health Authority and Data/Service Provider interactions to develop documentation that supports quality management (QA, QC, and audit) for RWD sources
 - Desired Outcomes: Build trust, reduce barriers, & demonstrate fit-for-purpose use.
 - The Audit Readiness Checklist will help operationalize best practices to aid quality management oversight of RWD, including inspection readiness, in a manner suitable for regulatory decision making.

Data/Service Provider Survey

- Question – what is feasible to include in an “Audit Readiness Checklist” tool targeting data relevance and reliability?
- Target Audience – data/service providers such as market suppliers, EMRs/EHRs, Payers, clinical disease registries, qualified clinical data registry companies
- Benefits
 - May provide benchmarking data in key areas
 - If the Audit Readiness Checklist initiative is successful, it will provide greater clarity on documentation that regulators may require from organizations and sponsors to accept RWD/RWE as a basis to inform a regulatory decision

Data Visualization of the Week

- A lot of gaps in COVID-related race and ethnicity data across states of the US.
- Incomplete picture of what is happening with COVID related to race/ethnicity differences.

