

Lessons Learned & Practical Applications for the Future

RAISE Public Webinar Workshop 11

Thursday, June 15, 2023, 2 – 4 PM ET

Summary

Overview of RAISE Community Workshop XI

The [webinar slides](#), [recording](#) and transcript are available on the [public meeting website](#).

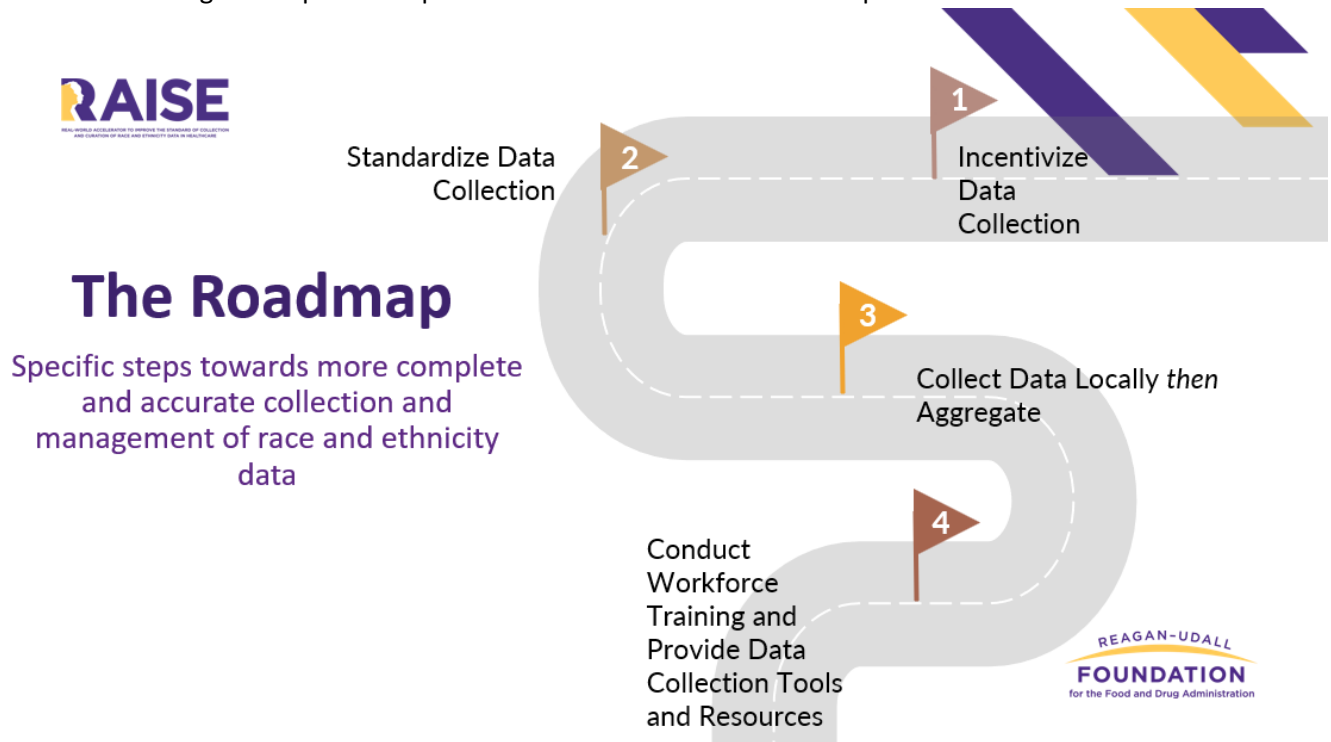
Susan Winckler, CEO of the Reagan-Udall Foundation opened the meeting, followed by remarks by RDML Richardae Araojo, FDA Associate Commissioner for Minority Health and Director of the Office of Minority Health and Health Equity. During the session Dr. Alecia Clary, RAISE Co-Investigator (Evidence to Practice) presented the barrier-facilitator-solutions triads to address missing or misclassified race and ethnicity data in health care. Then, the webinar had two expert panels. The first panel, Considerations for Roadmap Implementation, was moderated by Dr. Carla Rodriguez-Watson and included Dr. Allen Hsiao (Yale School of Medicine and Yale New Haven Health), Dr. Rachele Hendricks-Sturup (National Alliance Against Disparities in Patient Health) and Lenel James, MBA (Blue Cross Blue Shield Association). The second panel, Using the Roadmap to Elevate Race and Ethnicity Data in Health Care and Advance Community-Driven Data Governance and Inclusivity in Medical Product Development, was moderated by Susan Winckler, RPh, Esq. (Reagan-Udall Foundation for the FDA) and included Louis Cabanilla, MSc (Point32 Health), Dr. Bradley Malin (Vanderbilt University), and Dr. Krystal Tsosie (Arizona State University). The webinar closed with a call to action presented by Dr. Carla Rodriguez-Watson.

Barrier-Facilitator-Solution Triads: A Roadmap to Address Missing/Misclassified Race & Ethnicity Data in Health Care

*Alecia Clary, PhD, MSW
Founder and President
Evidence to Practice*

- The incomplete and inconsistent collection of race and ethnicity (R&E) data within healthcare datasets limits the inclusive medical product development and safety assessment. The barriers to complete an accurate capture of these data lay along the data continuum.
- In RAISE, we seek to understand the barriers from a multi-stakeholder perspective, and to home in on a set of actionable next steps towards solution. During our last workshop, we had an opportunity to present the list of barriers and solutions, asking the community to help us prioritize the barriers that are important to address and solutions that are implementable. Today, we'll discuss the barriers and solutions that the RAISE community helped us to prioritize.
- To start with some of the definitions that we've been using to guide this work:
 - A barrier has been defined as the obstacle that prevents the collection and management of these data.
 - Facilitators are the actions we take the move us towards the solution.
 - Solutions are the goals that we're trying to accomplish.

- The RAISE community recognized that the data must be available to be meaningfully curated, shared, and integrated. Several of the proposed solutions are currently being implemented in healthcare settings. The specific steps are outlined in the 'RAISE Roadmap' below.



- Funding and incentives were highly prioritized by the RAISE community. Incentives and measures point the healthcare community towards priorities for improving patient care and outcomes. The RAISE community suggests that one facilitator towards realigning funding and incentives, is to incentivize health equity. Specific steps towards incentivizing improvements in health equity include:
 - Defining the purpose of updating the payment model or measure, such that the definition specifies where the purpose lies on the continuum between collecting better health equity data and improving health equity outcomes.
 - Convening work groups to understand the availability and the specific opportunities to create or update measures.
 - Monitor use of new payment models/measures, identifying opportunities to improve reporting.
- Next, the community recognized that there continues to be a lack of transparency regarding how the data may be used. This may be particularly salient for populations who may be at increased risk for bias or harm when reporting these data. There's an opportunity to be specific and intentional about why we are collecting these data, how they may be used and who may have access to them for specific purposes. Next steps include:
 - Be specific and intentional about why we are collecting these data, how they may be used and who may have access to them for specific purposes.
 - Use the intentions in the bullet above to develop messaging that can then be piloted in the community and updated based on patients and member feedback.

- Healthcare organizations are really grappling with right-sizing the number of race and ethnicity options that they provide. When there is too much aggregation, people don't see themselves in the options. Conversely, no one is going to search through 900+ options to find the categories that represent them. Therefore, it is suggested to align data collection options with the local context then aggregate per data standards and research the potential options. Specific next steps include:
 - Using the results of that research to facilitate the development of a menu of options from which organizations can select.
 - Developing a tool to help organizations systematically and efficiently prioritize the options based on their community needs.
 - Ensuring that each option is respectful of people and doesn't contain historical language that is harmful.
- Once armed with the most representative options from their community, data collectors need training about best practices towards collecting these data. Specific steps include:
 - Desk research and primary data collection about existing training and training needs, including understanding the barriers and facilitators of consistent collection of these data.
 - Understanding how existing approaches can be improved to better align with the collection of other data, and understanding where data collection might fit best into the workflow.
 - Following such research, there's an opportunity to design or update training tailored for different roles and data collection at different points.
 - Evaluating training effectiveness, and of course, to continue to update training based on evaluation findings.
- Next, there's an opportunity to refine the response options, such that they reflect the community. This includes language appropriate data collection tools, scripts, decision aids, and other tools.
- The next step is to develop tools to facilitate the collection of these data. Specific steps include:
 - Collecting data about existing tools, adopting, or developing new tools, which can be made available in different media and translated into different languages.
 - Testing and validating the tools, training data collectors to use the tools, and monitoring use of them.
- Finally, data standards are key in all real-world data discussions. There are several different organizations and agencies who own data standards, but the RAISE community has identified that there is always room for improvement in terms of adoption and innovation. Of note, OMB is in the process of updating the existing R&E categories and guidance, which leverage several of our proposed next steps, including:
 - Establish a clear goal of wanting to improve the collection of these data to inform existing standards and protocols.
 - Holding listening sessions that inform the development and refinement of the proposed options.
 - Map between the previous standard and updated standards.
- Each of these solutions and next steps suggests that there is a need to fund these efforts, understand why these data are being collected and how they may be used, identify and engage the relevant stakeholders and to disseminate and increase uptake in adoption of new tools and resources.

- It is equally important to build a relationship between people and the systems collecting these data. A RAISE participant said, *"This work begins with a framework of trust that guarantees that there aren't unintended consequences, harm or bias."*
- Each proposed solution and next step should incorporate patients and community members as key stakeholders. The problem really needs to be taken to the community, instead of expecting the community to come to the healthcare system, and that the results should be disseminated to the community.
- A final quote from a RAISE participant, *"[We need to] enable the community to feel seen, be heard, and be counted. This will generate enthusiasm within the community and lead to increased and deeper engagement. Use data that can be shared back with the community so that the community experiences a return of value."*

Panel 1: Considerations for Roadmap Implementation

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

Discussants:

- *Allen Hsiao, MD, FAAO, FAMIA*
- *Rachele Hendricks-Sturup, DHSc, MSc, MA*
- *Lenel James, MBA*

The expert panel took questions posed by our moderator to further expand on the barrier-facilitator-solution triads presented to improve the treatment of R&E data in clinical, real-world data sets. Our discussion emphasized that community involvement is key. Highlights from the discussion:

- There's a lot of work to be done to raise awareness of the gaps in R&E treatment across all hospitals and health systems; specifically, those that aren't experienced in population health or heavily involved in research. We can raise awareness through workshops (like RAISE), appoint healthcare leaders who consider equity and by leveraging the electronic health record (EHR).
- It's important to understand how persons with lived experience are presenting themselves to the healthcare system (how they are perceiving their race, ethnicity, and culture within that context, within the full scope of possibilities of care options that are even available to them). That includes access to clinical trials and their ability to receive or access novel therapies within their health systems.
- It is important to payors, both locally and nationally, to look to the future and the expectations of NCQA, the federal government and health equity payors. Examples: for NCQA part of their HEDIS says R&E is required for health equity accreditation and that the Office of the National Coordinator requires R&E to certify EHRs.
- We need to engage patients and communities at the table and some of this co-creating data governance and design of what race and ethnicity initiatives look like, especially for their data. This is said with the understanding that engaging persons with lived experience in inequity is not easy. It does require a lot of work, time, and effort.
- Yale has a great program called the Culture Ambassadors Program where they work with minority community leaders; many educated about clinical research. There are opportunities for to get their feedback on how to delicately capture information as patients may feel more comfortable opening

up to a community member or community leader rather than a nurse or a doctor or office staff that they've met for the first time.

- In working with the community engagement from a faith-based perspective, there's multi-million dollars of initiatives that include an expectation of a community component and provide funding.
- It's important to also focus on some of the infrastructure level limitations around R&E data collection. The EHR, for example, may have default mechanisms for collecting R&E data, or had to encounter issues with data migration.
- Hospitals should work with the vendors to educate them to build more useful systems for capturing race and ethnicity data and maybe help us with the mapping so each hospital doesn't have to do it by themselves.
- When considering R&E as a function of health outcomes, we must think about whether it's appropriate to consider R&E alone or are there other proxy indicators that might weigh on our ability to observe or not observe expected treatment outcomes? Geographical location, might have something to do with the amount of stress that they encounter, or lifestyle habits that interact with our ability to predict treatment outcomes or steer those individuals to better treatment.
- On HEDIS measures that are related to R&E: a year and a half ago there were only five measures and two of them were diabetes and hypertension. It used to be, just show me the before and after. Now, a healthcare facility needs to show before and after and the R&E of the patients for better alignment.

Panel 2: Using the Roadmap to Elevate Race and Ethnicity Data in Health Care and Advance Community-Driven Data Governance and Inclusivity in Medical Product Development

*Moderator: Susan C. Winckler, RPh, Esq.
CEO, Reagan-Udall Foundation for the FDA*

Discussants:

- *Louis Cabanilla, MSc*
- *Bradley Malin, PhD*
- *Krystal Tsosie, PhD, MPH, MA*

The expert panel took questions posed by our moderator to further discuss how to elevate R&E data to advance data governance and inclusivity in medical product development. Our discussion emphasized the importance of community sovereignty. Highlights from the discussion:

- We need to acknowledge that the role of incentivization is perhaps misapplied on the path to health equity. Aligning research with market forces is not going to bring health equity because the market itself is inequitable. Ignoring this will mean that change will never happen in a way that truly is equitable.
- We have very few entities that have large enough market forces and power to both equitably benefit from public open data and use of public federal dollars. We also see the use of that market power misapplied to outmaneuver or overbid academic or other entities for the right to claim intellectual property. Operation Warp Speed in response to SARS COV2 is an excellent example of this first point. The antigen was the part of that vaccine that was most novel, but the mRNA vaccine delivery technology was based on established technology. Public funds were utilized for the

centralization of a duopoly who then turned around and used, and quite effectively benefited from that research and then shifted to our market model for the further dissemination of vaccines.

- For the above vaccine, the inclusion of minority or indigenous peoples had a controversial effect on the company's relationship with communities and whether the collection of biological material may be superseding some of the moratoria that some tribal nations have in place (attempts to respect tribal sovereignty in name, but then in practice go around it). Entities can fast track their claims to intellectual property and that can disenfranchise academic institutions.
- We must not overpromise when working with indigenous peoples and others. Over-promising things that researchers cannot deliver on is going to conflate people's expectations of the research and when they are not delivered, also deteriorate trust even further for these communities. This leads to telling those communities it's their fault if they don't engage in genomics and precision medicine research they're never going to benefit from. That's victim blaming and coercive.
- When implementing the proposed roadmap solutions, we need to be realistic that there are cost considerations.
- We need to incentivize improvement versus incentivizing a specific outcome at a point in time.
- Everybody is interested and motivated about health equity, but also intimidated about where to start and they feel overwhelmed by the size of the problem. There are barriers and gaps but having a coherent strategy around collecting REL (race, ethnicity, and language) is probably years down the road. There's work that you can do right now to start that journey and start having an impact in your community. The biggest learning is just having a clear strategy for what you can do, what's the easiest point that you can start at where you can have some wins.
- The statistical and the computer science community has become enamored with the notion of algorithmic decision-making to figure out how to de-bias the algorithm to be able to solve health equity issues. There is certainly an algorithmic component that needs to be addressed, but the human element is more important and challenging to address. Organizations should acknowledge that you must build up the relationship to achieve some type of technology that eventually will be equitable.
- If we want to use data to increase health equity, we should also be paying equal attention to ensuring that indigenous peoples and local communities can also be the data collectors, create companies based on their own data, and create innovations/IP based off their own data.
- Most federal agencies recognize tribal sovereignty and language, but don't spell out the ongoing threats and disrespect. They created this single IRB mandate rule to streamline research without guidance on how academic institutions should also respect tribal sovereignty.
- Community-based organizations are the best generators of data and can offer the best solutions for what can be done with the data generated.
- The push toward open data to support reproducibility of studies implies that everybody wants to have data out there and accessible to anyone at any moment for use. That can work with certain populations, but other groups require different types of control. We should rethink the presumption of open access as it may lead to a lack of trust.

Closing Remarks: Takeaways & A Call to Action

Carla Rodriguez-Watson, PhD, MPH

Principal Investigator, RAISE

Director of Research, Reagan-Udall Foundation for the FDA

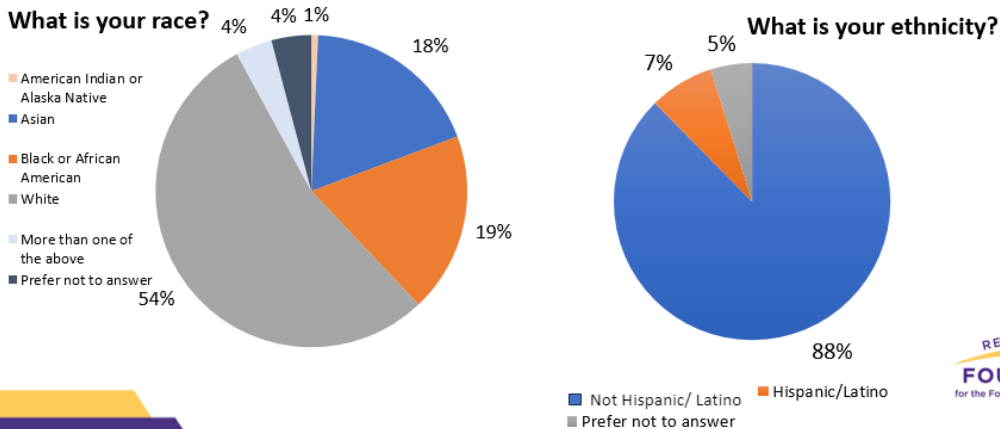
We started RAISE because missing data in real world data sets wasn't only because people opted not to answer the question, but because the question wasn't being asked the right way. It was also that the answer choices don't resonate and are not standardized, which doesn't allow for data to flow, which is needed in the healthcare system that is fragmented by design. Patients and communities have a significant level of distrust in why data are being collected and how it will be used. We also knew that there were many solutions out there.

- Registration statistics are outlined in the slides below. We had over 500 people registered for the series, plus an additional 200 registered today. For R&E, we had only 4% non-response. People of color were represented at 42%. Those who identify as Hispanic or Latino were represented at 7%.

RAISE Meeting Statistics

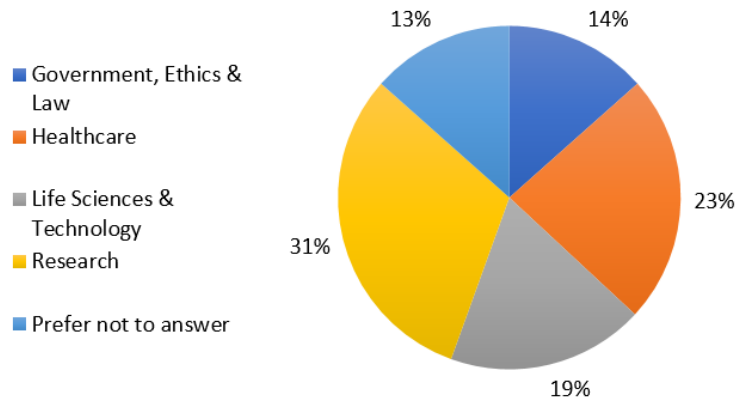
REAL WORLD ACCELERATOR TO IMPROVE THE STANDARD OF COLLECTION AND CURATION OF RACE AND ETHNICITY DATA IN HEALTHCARE

*549 unique persons registered for the series
- plus additional 200+ registered today*



- By stakeholder group, 13% preferred not to answer, or didn't see themselves in the categories that we presented. Research represented 31% of our attendees, 23% are from healthcare (including care delivery and payors) and 19% come from life sciences and technology.

Which of these groups describes your career sector best?



- Over the course of the RAISE series, we have summarized our learnings into a call to action: RISE UP, as illustrated by the letters below.

R Respect for community autonomy, acknowledgment of structural inequity, and cultural humility facilitate a better understanding of the importance of partnership between systems and people.

I Intentionality and transparency in collecting race and ethnicity data can help address mistrust, misinterpretation, misclassification, and missingness.

S Standards that are safe, contextually relevant, and interoperable should be implemented.

E Education is needed to increase awareness of incentives and resources for infrastructure, technical resources, and best practices.

U Understanding and alignment to address the dissonance between:

- why R&E are collected, how R&E questions are answered, and how R&E data are used;
- how communities vs. health systems define health equity

P Payors can collect race & ethnicity data too.

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- R is for respect, for community autonomy, acknowledgement of structural inequity, and cultural humility to facilitate a better understanding of the importance of partnership between systems and people, particularly for community driven data governance, benefit risk sharing, and alignment between the goals of the systems and the people. Partnership needs to be consistent to understand community and health needs that inform relevant programs and opportunities to engage in research that is bidirectional.

- I is for intentionality and transparency in collecting race and ethnicity data that can help address mistrust, misinterpretation, misclassification, and missingness. Systems need to be consistently clear on why race and ethnicity is being collected. Otherwise, distrust festers.
- S is for standards. Standards that are needed should be safe, contextually relevant, and interoperable. Contextual relevancy can be supported by tools such as those from EHR vendors which allow clients to turn on HHS code sets that are relevant to their populations, all of which can still map to the OMB categories. Variables representing social determinants of health can be made interoperable across systems using standard taxonomies and messaging standards developed by HHS and the Office of the National Coordinator through Project Gravity and USCDI, respectively.
- E is for education. Education is needed to increase awareness of incentives and resources for infrastructure, technical resources, and best practice. There are many solutions out there, we just need to socialize them better.
- U is for understanding and alignment to address the dissonance between why race and ethnicity data are collected, how race and ethnicity questions are answered, how race and ethnicity data are used, and how communities versus health systems define health equity. We want to bridge the gaps between lived experience versus the system metrics.
- P is for payors. Payors can collect race and ethnicity data, too. There are only five states where race and ethnicity cannot be collected at enrollment. Two of those states have exceptions for the purposes of measuring quality of care outcomes and performance measurement access, or hospital insurance collecting demographic data.
- While this workshop series has concluded, we'll be busy behind the scenes refining the Barrier Solution facilitator's roadmap and conducting our evaluation of the RAISE program. We at the FDA Foundation are committed to furthering this journey and the Office of Minority Health and Health Equity is committed to continuing this journey with us. We do plan to reach back out to organize work groups, and we hope you'll answer the call.
- We want to give a huge and hearty thank you to all the speakers, workshop champions and the team for their dedication and commitment.