Reactions to Barriers, Facilitators & Proposed Solutions

RAISE Community Workshop 10

Thursday June 1, 2023, 2 – 3 PM ET

Summary

Overview of RAISE Community Workshop X

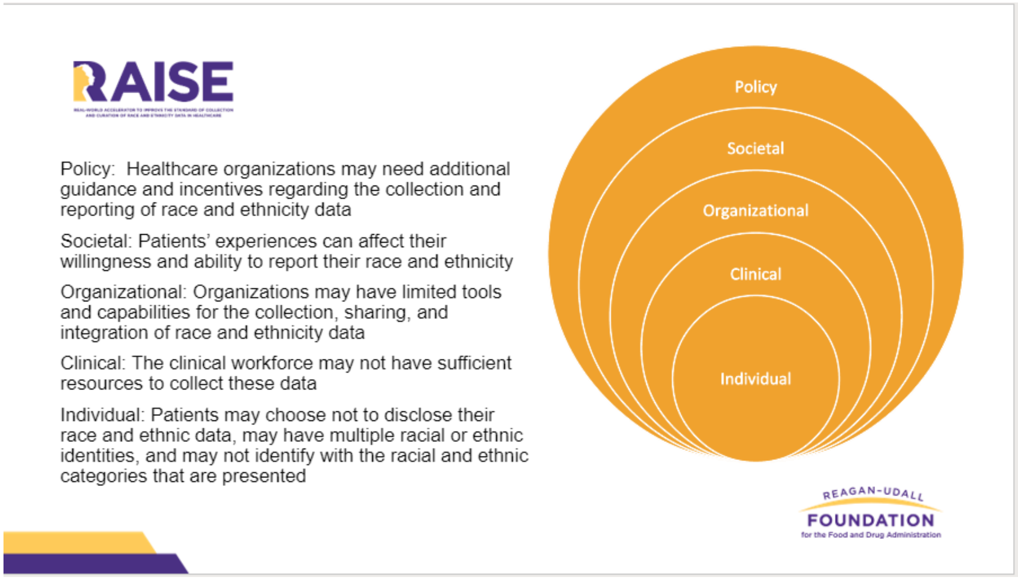
Susan Winckler, CEO of the FDA Foundation opened the meeting, followed by remarks from RDML Richardae Araojo, FDA Associate Commissioner for Minority Health and Director of the Office of Minority Health and Health Equity. During the session, we had one presentation from Dr. Alecia Clary, RAISE Co-Investigator (Evidence to Practice) on RAISE Roadmap: the barriers, facilitators, and solutions, towards the complete and accurate collection of race and ethnicity data. Our expert panel comprised of Sandy Leonard (COTA Healthcare), Dr. Oscar Benavidez (Massachusetts General Hospital), Dr. Elise Berliner (Cerna Enviza), and Dr. Rachele Hendricks-Sturrup (National Alliance Against Disparities in Patient Health) joined our virtual stage to react to the RAISE Roadmap.

The RAISE Roadmap: Barriers to the Complete and Accurate Collection of Race and Ethnicity Data

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

We'd like to acknowledge the contributions of RAISE speakers, panelists, participants, and team members who contributed to the RAISE roadmap.

- As discussed over the last 9 workshops, race and ethnicity (R&E) data are incomplete and inconsistently collected in these health care data sets and that limits the ability to understand the safety and effectiveness of FDA regulated products. RAISE collaborated with a diverse group of leaders to develop a roadmap for actionable solutions and next steps to close the gaps in the collection of R&E data.
- To create the roadmap, data were collected from RAISE workshop transcripts and chats, as well as the literature. Using an inductive approach to coding, the RAISE materials were coded, and barriers, facilitators and solutions were identified via a template analysis, and then summarized into themes. To level-set:
    - A barrier is an obstacle that prevents the collection and management of race and ethnicity data.
    - A solution is the goal, or the approach to address the barrier.
    - A facilitator is the specific task taken to drive us towards the solution.



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Policy: Healthcare organizations may need additional guidance and incentives regarding the collection and reporting of race and ethnicity data

Societal: Patients' experiences can affect their willingness and ability to report their race and ethnicity

Organizational: Organizations may have limited tools and capabilities for the collection, sharing, and integration of race and ethnicity data

Clinical: The clinical workforce may not have sufficient resources to collect these data

Individual: Patients may choose not to disclose their race and ethnic data, may have multiple racial or ethnic identities, and may not identify with the racial and ethnic categories that are presented

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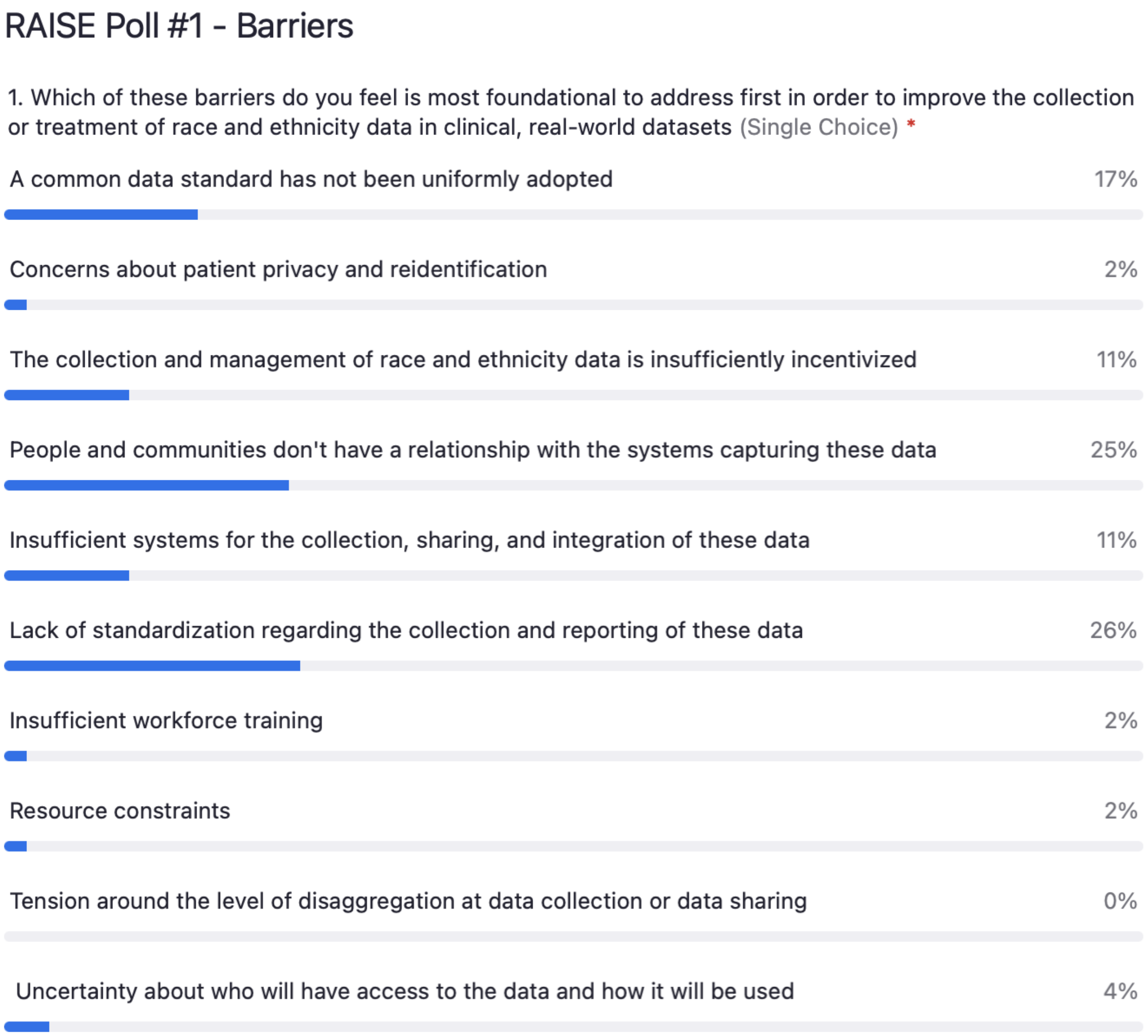
- The barriers (slide above) are represented in an ecological framework. The reasons for R&E incomplete or missingness are listed at the individual, clinical, organizational, societal and policy level.
    - At the policy level, there are no common data standards for R&E, there are concerns about privacy and the collection of R&E data are insufficiently incentivized. "*Putting equity on the back end after [policy] is designed and implemented is where we fail."*
    - At the societal level, the concept of R&E is multifaceted, intersectional, and changes over time. Race and ethnicity aren't the same and can manifest in different combinations. Many people and communities don't have a relationship with the systems capturing this data- from healthcare systems to housing and banking. *"The complexities of assigning categories to a group of people who share physical characteristics and the intersectionality of these."*
    - At the organizational level, there is tension when it comes to disaggregation: from too granular with a risk of re-identification, to not enough options with less utility. There may be insufficient systems for collecting, sharing, and integrating these data, conflicts within and between data sources, and a lack of standardization regarding the collection and reporting of these data. *"The issues of standardization or lack thereof, prevent us from really capturing that information, and, moreover, when we move that data to be integrated with other data and even beyond a single system to a network the failure to transmit …[it's] compounded".*
    - At the clinical level, there is insufficient workforce training and resource restraints including staff time, lack of translations services and lack of tools to facilitate data collection. *"Also, a huge struggle is kind of the economics and the ability to scale for non-English-speaking members."*
    - At the individual level, there is tension around disaggregation of data collection, from too many options are too few. There are also limited resources available in specific languages and uncertainty around the access and use of data collected. *"We also have to be mindful of the fact that there is still some mistrust. Misunderstanding about how this information is being collected and utilized by health care providers that oftentimes is overlooked."*
- Based on the high-level barriers overview, poll one will query which of the barriers that is most foundational to address to improve the collection and treatment of R&E data.

<u>Poll 1: Which of these barriers do you feel is most foundational to address first in order to improve the collection or treatment of race and ethnicity data in clinical, real-world datasets?</u>



RAISE Poll #1 - Barriers

1. Which of these barriers do you feel is most foundational to address first in order to improve the collection or treatment of race and ethnicity data in clinical, real-world datasets (Single Choice) *

A common data standard has not been uniformly adopted	17%
Concerns about patient privacy and reidentification	2%
The collection and management of race and ethnicity data is insufficiently incentivized	11%
People and communities don't have a relationship with the systems capturing these data	25%
Insufficient systems for the collection, sharing, and integration of these data	11%
Lack of standardization regarding the collection and reporting of these data	26%
Insufficient workforce training	2%
Resource constraints	2%
Tension around the level of disaggregation at data collection or data sharing	0%
Uncertainty about who will have access to the data and how it will be used	4%

<u>Panel Reaction to the Barriers</u>

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

Discussants:

- *Alecia Clary, PhD*
- *Sandy Leonard*
- *Oscar Benavidez, MD, MBA, MPP*
- *Elise Berliner, PhD*
- *Louis Cabanilla*
- *Rachele Hendricks-Sturrup, DHSc, MSc, MA*

The expert panel took questions posed by our moderator to further expand on the barrier that is most foundational to improve the treatment of R&E data in clinical, real-world data sets. Our discussion emphasized that the barriers are related, and the priorities discussed reflected the panelists' lens. Highlights from the discussion:

- One of the biggest barriers is policy. Creating a sustainable infrastructure that can be reviewed and adapted as time goes on requires investment. That really does start with a policy to allocate the appropriate resources to create a living and breathing system.
- Incentives are important. The more resources that are put into something leads to prioritization.
- A lot of the barriers are related to each other. We need to have a consensus about what data we need to collect and why. This would help all the other barriers.
- There needs to be a relationship between the communities and the systems collecting the data. By not cultivating that relationship, you run the risk of resources being inappropriately allocated and distributed among communities.
- The communities who are closest to the problem are also closest to the solution.
- We need to always keep how the data will be used at the forefront.
- Individuals are at the core of the data. We need to build trust with the community.

The RAISE Roadmap: Facilitators and Solutions toward the Complete and Accurate Collection of Race and Ethnicity Data

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

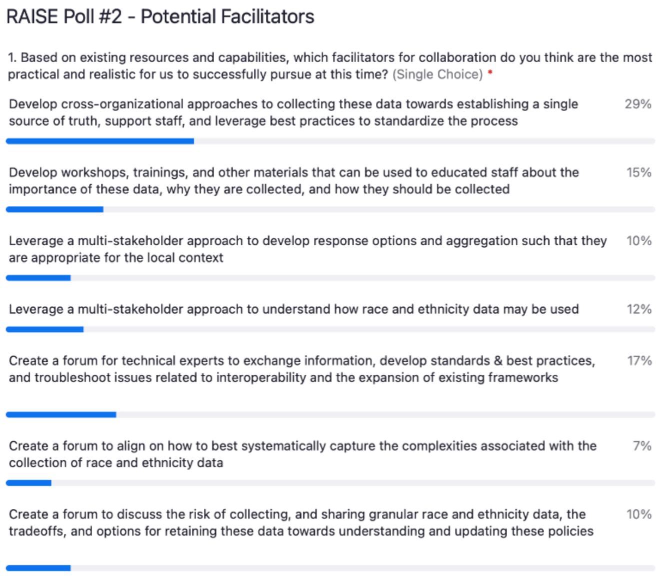
In discussing potential solutions and facilitators towards the complete and accurate capture of R&E data in clinical, real-world datasets, we acknowledge that the factors contributing to the problem are multilevel. The solutions will require a multilevel approach that accounts for the complex interactions between individual, provider, organizational, societal, and policy factors. There is no single stakeholder who is responsible for collecting or managing R&E data. Please note, the potential solutions and facilitators are not listed in order of importance.

1. Insufficient Workforce Training.
    - Potential Solution:
        - Develop workforce training and education.
    - Potential Facilitators:
        - Develop cross-organizational approaches to collecting these data towards establishing a single source of truth, support staff, and leverage best practices to standardize the process.
        - Develop workshops, training, and other materials that can be used to educate staff about the importance of these data, why they are collected, and how they should be collected.
2. Resource Constraints.
    - Potential Solutions:
        - A workflow and patient flow that adequately prioritizes the collection of these data.
        - Data collection tools, scripts, decision aids, and other tools and translation available in the appropriate language.

        - Additional funding to support or incentivize collecting these data.
    - Potential Facilitators:
        - Optimize data collection tools such that it is easier to report these data than to skip it.
        - Assess community needs for language services (including the languages that are needed).
        - Plan to use language services to support staff in the collection of these data.
        - Develop tools that can be used to standardize and routinize the process and the message.
        - Update existing payment models and measures to incentivize the collection of these data.
3. Tensions with data options --simultaneously too few and too many.
    - Potential Solution:
        - Collect data using an approach that aligns with the local context, but can be aggregated, per data standards.
    - Potential Facilitators:
        - Modernize data standards such that more granular categories are collected in a standardized format.
        - Leverage a multi-stakeholder approach to develop response options and aggregation such that they are appropriate for the local context.
4. Lack of transparency regarding intended use of the data.
    - Potential Solution: Collect data using an approach that aligns with the local context, but can be aggregated, per data standards.
    - Potential Facilitators:
        - Use a multi-stakeholder approach to understanding how race and ethnicity data may be used.
        - Develop resources that describe why patients are being asked to provide these data, how the data may be used, the benefits of sharing these data, and who may access these data, incorporating this information into data collection tools and resources.
5. Lack of standardization regarding the collection and reporting of these data.
    - Potential Solutions:
        - Align information, techniques, and strategies to bridge technical stress points.
        - Build interoperable data systems with adequate granularity.
    - Potential Facilitators:
        - Align information, techniques, and strategies to bridge technical stress points.
        - Build interoperable data systems with adequate granularity.
6. The concepts of race and ethnicity are multifaceted, intersectional and change over time.
    - Potential Solution:
        - Collect and verify the data at defined intervals.
    - Potential Facilitators:
        - Facilitate patient access to their demographic data, allowing them to update and verify these data.
        - Create a forum where key stakeholders can align on questions such as:
        - How often should data be collected?

        - How often should people update or confirm existing information?
        - How often should members who declined to answer or did not previously answer be asked again?
        - How should patients access their data?
7. Risk of reidentification associated with the collection of granular race and ethnicity data.
    - Potential Solution:
        - Update practices and policies to accurately assess the risk related to collecting race and ethnicity data.
    - Potential Facilitator:
        - Create a forum for a multi-stakeholder group to discuss the risk associated with collecting, and sharing granular race and ethnicity data, the tradeoffs, and options for retaining these data towards understanding and updating these policies.
8. Race and ethnicity may be suppressed when data are shared.
    - Potential Solution:
        - Update practices and policies to accurately assess the risk related to sharing race and ethnicity data.
    - Potential Facilitator:
        - Create a forum for a multi-stakeholder group to discuss the risk associated with collecting, and sharing granular race and ethnicity data, the tradeoffs, and options for retaining these data towards understanding and updating these policies.
9. No adopted common data standard.
    - Potential Solution:
        - Increase awareness of or require those seeking federal funding to use a common standard.
        - Increase other organizations' (e.g., those not receiving or using federal funding) awareness of the benefits of using a common data standard.
        - When reporting data, use OMB standards along with other reporting types.
    - Potential Facilitator:
        - Understand the barriers and facilitators of implementing a common data standard.
        - Understand the benefits of using a common set of standards, such as OMB.
        - Update OMB standards such that they are reflective of the current climate.

Poll #2: Based on existing resources and capabilities, which facilitators for collaboration do you think are the most practical and realistic for us to successfully pursue at this time?



RAISE Poll #2 - Potential Facilitators

1. Based on existing resources and capabilities, which facilitators for collaboration do you think are the most practical and realistic for us to successfully pursue at this time? (Single Choice) *

Develop cross-organizational approaches to collecting these data towards establishing a single source of truth, support staff, and leverage best practices to standardize the process	29%
Develop workshops, trainings, and other materials that can be used to educated staff about the importance of these data, why they are collected, and how they should be collected	15%
Leverage a multi-stakeholder approach to develop response options and aggregation such that they are appropriate for the local context	10%
Leverage a multi-stakeholder approach to understand how race and ethnicity data may be used	12%
Create a forum for technical experts to exchange information, develop standards & best practices, and troubleshoot issues related to interoperability and the expansion of existing frameworks	17%
Create a forum to align on how to best systematically capture the complexities associated with the collection of race and ethnicity data	7%
Create a forum to discuss the risk of collecting, and sharing granular race and ethnicity data, the tradeoffs, and options for retaining these data towards understanding and updating these policies	10%

Based on existing resources and capabilities, which facilitators for innovation/engagement do you think are the most practical and realistic for us to successfully pursue at this time?

RAISE Poll #2 - Potential Facilitators

2. Based on existing resources and capabilities, which facilitators for innovation/engagement do you think are the most practical and realistic for us to successfully pursue at this time? (Single Choice) *

Optimize data collection tools such that it is easier to report these data than to skip it	12%
Develop tools that can be used to standardize and routinize the process and the message	15%
Update existing payment models and measures to incentivize the collection of these data	17%
Understand the barriers and facilitators of implementing OMB standards	7%
Understand the benefits of using a common set of standards, such as OMB	5%
Incentivize the adoption of the collection of these data	12%
Assess community and staff needs for language services (including the languages that are needed) to support the collection of these data	7%
Modernize data standards such that more granular categories are collected in a standardized format that reflects the current climate	2%
Develop resources describing why patients are being asked to provide these data, how the data may be used, and who may access these data within data collection tools and resources	15%
Facilitate patient access to their demographic data, allowing them to update and verify these data.	7%

Panel Discussion

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

Discussants:

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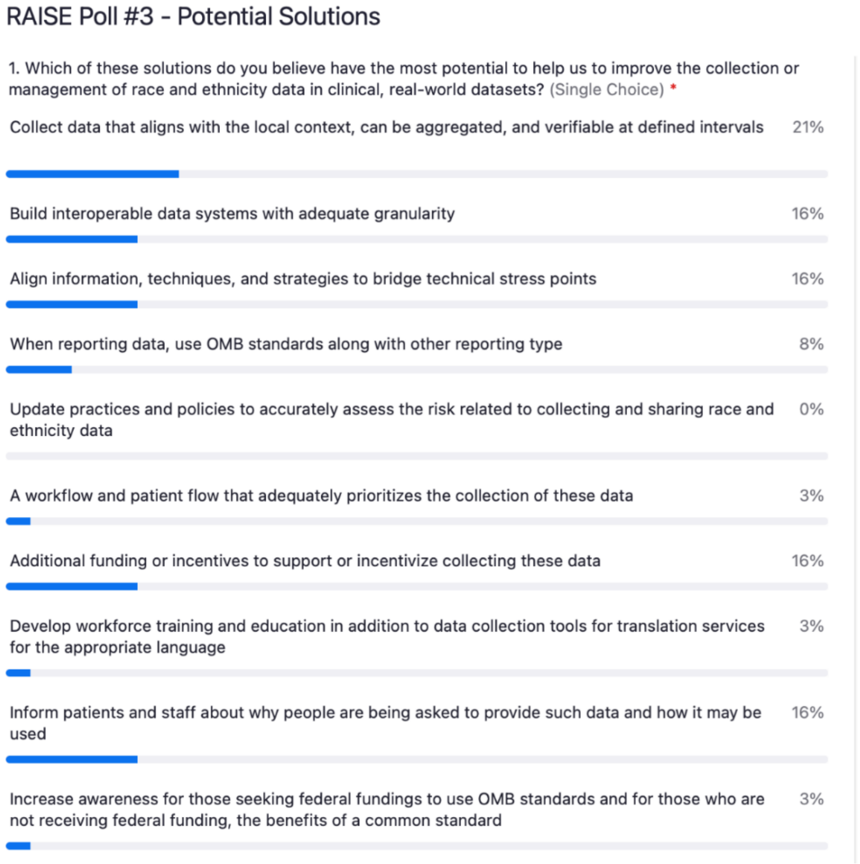
The moderated discussion took questions from the chat as well as those posed by our moderator to further expand on RAISE roadmap potential solutions and facilitators. An emphasis on addressing resource constraints, standardization, and assuring alignment between incentives and community needs emerged. Highlights from the discussion:

- Educating communities about why data collection is occurring and getting their buy in is critical. Many times, communities are asked to provide data and respond to surveys but then they never receive any feedback after. We should allow them to elaborate on how they see themselves culturally in the data with respect to race and ethnicity.
- We need to bring a cross functional group together to really assess risks to protect the patient and patient identity in a thoughtful and respectful way. Who has that that original access in order to make the most use of the data?
- The processes and policies that would incentivize the data collection are key with the current healthcare resource challenges. That might mean having to prioritize or put this ahead of something else.
- The collection of R&E data should be tied to the broader system effort of addressing racialized medicine or addressing health equity. If this becomes a priority, and it becomes incentivized and measured.
- A system needs to be put in place to further facilitate the data collection. We need something on the technical side.
- Simplification standardization with a tiered system where there are levels with groups large enough to do a lot of complex statistical analysis and look at disparities in a meaningful way would be a very helpful facilitator.
- We really need to clarify what data do we need to collect. And why do we need to collect it? What is the value of the data? Who accrues the value and who pays the costs, including the development of the standards, the system updates and integration at the clinical sites and the cost of data collection?
- Race and ethnicity interact with social determinants of health. We really need to consider race and ethnicity to be seen as part of a larger data collection effort.
- We should aim to '*move away from collecting R&E in the doctor's office and more to community-based organizations where there's a greater level of trust.'*, although as discussed in Workshop 4, building trust within the health system is critical.

<u>Poll #3: Which of these solutions do you believe have the most potential to help us to improve the collection or management of race and ethnicity data in clinical, real-world datasets?</u>



RAISE Poll #3 - Potential Solutions

1. Which of these solutions do you believe have the most potential to help us to improve the collection or management of race and ethnicity data in clinical, real-world datasets? (Single Choice) *

Collect data that aligns with the local context, can be aggregated, and verifiable at defined intervals	21%
Build interoperable data systems with adequate granularity	16%
Align information, techniques, and strategies to bridge technical stress points	16%
When reporting data, use OMB standards along with other reporting type	8%
Update practices and policies to accurately assess the risk related to collecting and sharing race and ethnicity data	0%
A workflow and patient flow that adequately prioritizes the collection of these data	3%
Additional funding or incentives to support or incentivize collecting these data	16%
Develop workforce training and education in addition to data collection tools for translation services for the appropriate language	3%
Inform patients and staff about why people are being asked to provide such data and how it may be used	16%
Increase awareness for those seeking federal fundings to use OMB standards and for those who are not receiving federal funding, the benefits of a common standard	3%

<u>Hot Takes and links from the Chat</u>

- The use of standardized race & ethnicity categories is important, but there is still work to do to develop the right standards - I would not necessarily endorse OMB Statistical Policy Directive (SPD) 15 for racial categories as the standard.
- https://www.statnews.com/2023/01/03/better-data-sexual-orientation-gender-identity-improve-lgbtq-health/
- Join us for our final session on Thursday, June 15 from 2-4 pm ET to celebrate and hear about RAISE: Lessons Learned & Practical Applications for the Future! Learn more about the RAISE finale here: https://reaganudall.org/news-and-events/events/raise-lessons-learned-practical-applications-future