Racial and Ethnic Minority Inclusion in Clinical Outcome Assessment (COA) Research: A Reflection on Current Practices

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Introduction

- Racial and ethnic minority groups are underrepresented in clinical research, and disparities in health outcomes between ethnic groups are well-documented.
  - For example, despite cancer being the leading cause of death for Asian Americans and the second leading cause of death for African Americans, the Food and Drug Administration (FDA)[1] showed that, in 2020 oncology trials, participants were: 73% White, 14% Asian, 6% Hispanic and 5% Black or African American.
- Lack of diversity in clinical trials can lead to the development of drugs that may not work, or even harm, entire segments of the population.[2]
- The FDA released draft guidance in 2022[3] to improve enrolment from underrepresented groups in clinical trials, and similar issues of representative inclusion exist in patient-centered research, for example the development and evaluation of Clinical Outcome Assessments (COAs).

Objective

- The objective of this conceptual piece is to reflect on barriers and strategies for achieving a racially/ethnically representative sample in COA research as an aspect of clinical research. Focusing specifically on:
  - Recruitment methods;
  - Demographic data collection;
  - Researcher bias; and
  - Reporting in scientific literature.

Recruitment methods

- Individuals from racial or ethnic minorities are typically less engaged with COA research.[4]
- In addition to transportation or technological barriers that exist, typical recruitment methods for COA research are susceptible to participant self-selection bias and may exclude these harder-to-reach individuals.

Recommendations

- Directly engage with members of minority groups or patient advocacy groups to build trusting relationships which can improve willingness to participate.
- Pre-specify recruitment targets/quotas which include representation across all racial and ethnic groups.[5]
- Be flexible in timelines to allow for identification of harder-to-reach populations.

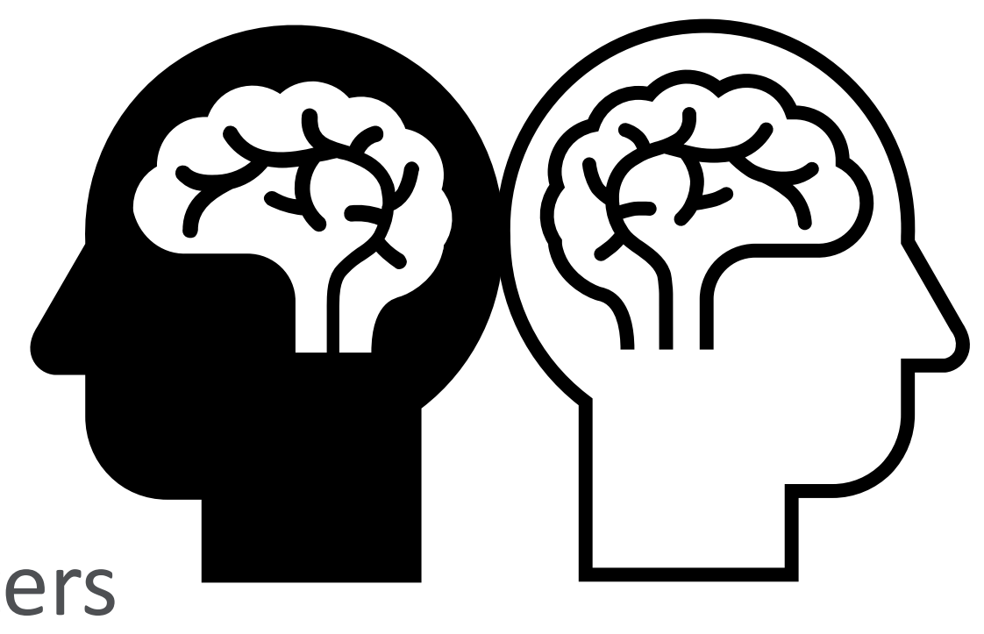
Demographic data collection

- COA researchers should collect comprehensive demographic data, inclusive of race/ethnicity questions, across all research studies, where legal.
- Demographic forms should be used to collect demographic data in a way that is inclusive and accurately captures racial/ethnicity categories.[6] Not only does this ensure samples are demographically diverse but, by using appropriate language, individuals can feel recognised, preventing further barriers to participation.

Recommendations

- Regional guidelines should be used to determine racial/ethnicity categories, for example the United Kingdom census, FDA recommendations, etc.
- Where local guidance is less clear, members of the community should be consulted to ensure appropriate collection of demographic data.

Researcher bias



- Racial bias involves making a personal and often unreasoned judgement based solely on an individual's race.[7]
- Unconscious racial biases can impact medical decision-making as well as the distribution of research funding.[8]
- In COA research, unconscious racial biases may present in recruitment, where researchers/recruiters may be less likely to target certain groups, or during the conduct of research, for example in questions asked/not asked.

Recommendations

- Research teams should undergo trainings on such topics as unconscious biases, to bring recognition to any biases they may have.
- Trainings should also be run with recruitment partners to ensure diverse and inclusive recruitment for all racial and ethnic groups.

Reporting in scientific literature

- Transparency in reporting race and ethnicity of participants in COA research is essential to determine if the COA is applicable across different racial/ethnic groups. However, a review of cancer trials collecting COAs found that only 14 out of 84 (17%) reported ethnicity data.[4]

Recommendations

- Researchers should ensure complete demographic data are reported when disseminating results, without combining racial/ethnic categories.
  - Umbrella terms such as "Non-White" and "Black and Minority Ethnic" should be avoided as this implies a homogenous ethnic identity which does not take into account the diversity across groups.
- Analyses of differences between groups should also be conducted where possible.

~~Non-White~~
~~Black and Minority Ethnic~~

Conclusions

- ✓ Underrepresentation of racial and ethnic groups in COA research inhibits applicability of results to these groups. This can result in COAs being inappropriate measures of clinical effectiveness.
- ✓ A number of barriers to racial and ethnic inclusion in COA research exist. This poster focuses on four aspects of COA research and strategies to overcome these barriers; however, these are not exhaustive.
- ✓ It is important for COA researchers to actively overcome racial and ethnic barriers to inclusion, ensuring intentional efforts are carried out in the journey to achieving inclusivity in health research.

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