MOREHOUSE SCHOOL OF MEDICINE

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Addressing Disparities in Cancer Clinical Trials Summit: Barriers to Participation for Diverse Populations

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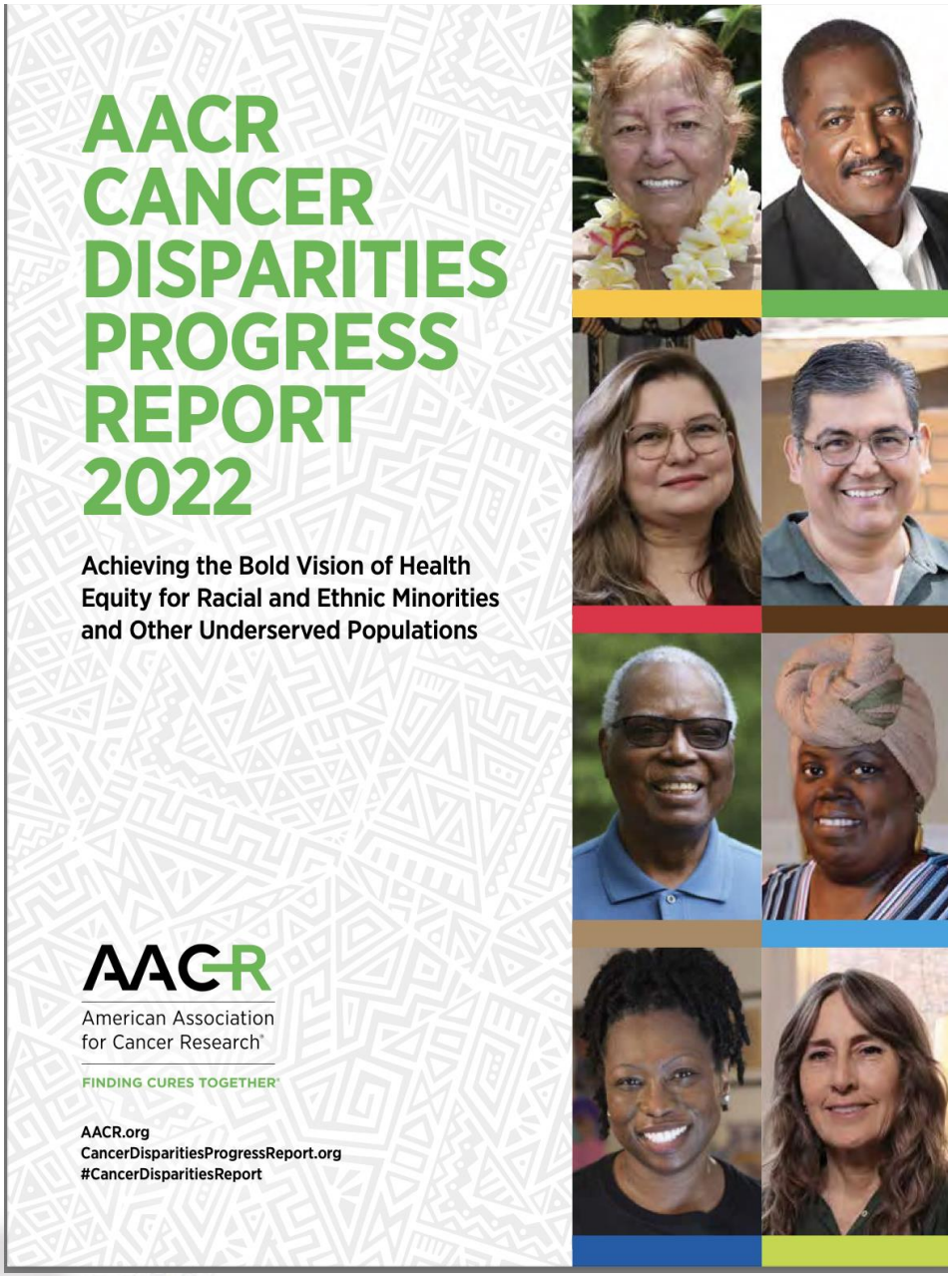
Topic Description

Studies have shown, and the COVID-19 pandemic has clearly demonstrated, that there are barriers to participation in clinical trials. A deficiency of information and access to clinical trials is heightened for Black, Asian, Hispanic, and other ethnic and racial minorities. Rural residents also suffer from diminished access to cutting edge research and treatments. This panel of experts will discuss the impediments they see in their practices and hospitals to increased equity to cancer clinical trials.


AACR
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2022
Achieving the Bold Vision of Health Equity for Racial and Ethnic Minorities and Other Underserved Populations
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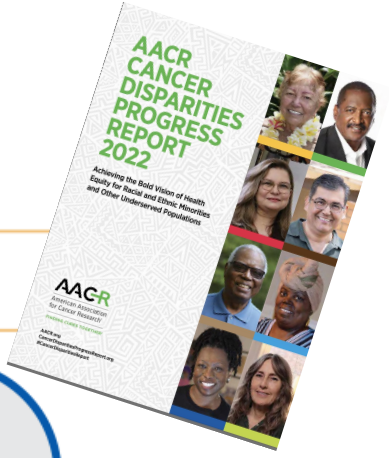


FIGURE 14

The Medical Research Cycle

BENCH BEDSIDE PRACTICE

Therapeutic Development → Clinical Research (Clinical Trials) → Clinical Practice (Standard of Care)

Discovery & Validation

Hypothesis

NEW OBSERVATION

NEW OBSERVATION

NEW OBSERVATION

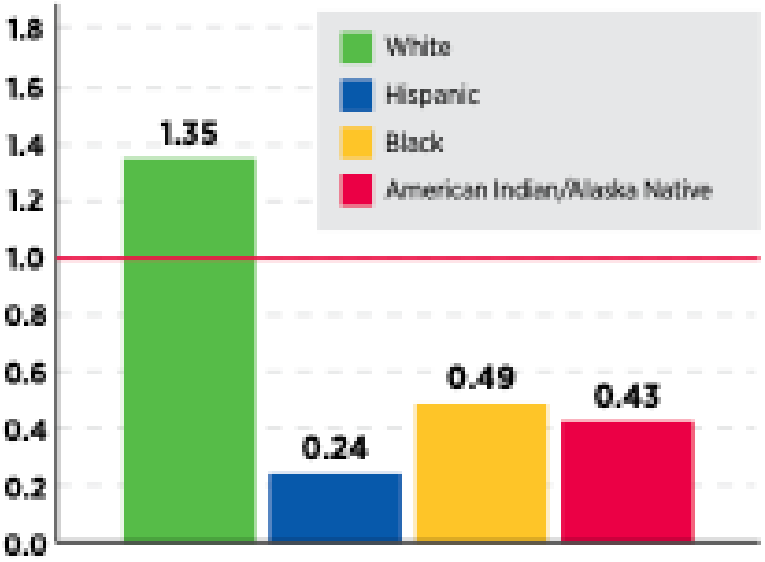
Disparities in Clinical Trial Participation

To fully ensure the safety and efficacy of anticancer therapeutics for everyone who will use them once approved, it is vital that the participants in the clinical trials represent the diversity of the patient population. Unfortunately, several segments of the population continue to be underrepresented in cancer clinical trials relative to their proportion in the overall U.S. population and/or the relevant disease population. Selected examples of these disparities are listed here:

90% vs <25%	According to data from a biopharmaceutical company, 90 percent of their cancer clinical trials achieved **representation of non-Hispanic White participants at or above U.S. census levels** while only **24 percent, 16 percent, 8 percent, and 7 percent of trials achieved proportional representation of Asian, Black, Native Hawaiian or Other Pacific Islander, and Hispanic/Latino** participants, respectively. None achieved census level representation of American Indian or Alaska Native participants (502).
HIGHEST incidence and mortality	Analysis of demographic data from **207 pancreatic cancer clinical trials** reported between 2005 and 2020 indicated that White patients (85 percent) were overrepresented while Black (8 percent), Hispanic (6 percent), American Indian/Alaska Native (0.3 percent), and Asian or Pacific Islander patients (2 percent) were underrepresented compared to their disease incidence in the U.S. population (497). Research has shown that **restrictive eligibility criteria contribute to low participation** of Black patients in pancreatic cancer clinical trials (503). Notably, **Black patients have the highest incidence and mortality from pancreatic cancer** among all U.S. racial and ethnic population groups (504).
>70% vs <3%	Between 2009 and 2019, 81 oral chemotherapeutic agents were approved by the U.S. Food and Drug Administration based on data from 142 clinical trials. **Only 52 percent of these trials reported on race/ethnicity**. Among the participants, **greater than 70 percent were White** while only **2.5 percent and 2.3 percent were Black and Hispanic**, respectively (505).
LOW enrollment	An evaluation of **53 cancer immunotherapy clinical trials** indicated that **enrollment of Black patients** was **32-fold lower** (for ovarian cancer trials), **19-fold lower** (cervical), **15-fold lower** (uterine), and **11-fold lower** (breast) than expected if accrual rates were equal across all races. **Enrollment of Asian patients** was **3-fold lower** (ovarian), **10-fold lower** (cervical), **15-fold lower** (uterine), and **2.5-fold lower** (breast) than expected (506).
>65 YO low enrollment	Fifty-seven percent of **people diagnosed with cancer in the U.S. are 65 years of age or older** (1). Yet, according to a recent analysis of demographic data from a cancer registry in Wisconsin, **patients older than 65 are 43 percent less likely to participate** in clinical trials compared to those who are younger than 65 (507).
AYA low enrollment	Cancer is a leading cause of death among adolescent and young adult (AYA) patients. While evidence suggests that AYA patients were better represented and more diverse than older participants in certain **National Cancer Institute-sponsored clinical trials** conducted over the past two decades (508), **enrollment of Black participants continues to be low** (509).
11% vs 24%	Among patients with blood cancer, **those who reside in rural counties are less likely to enroll in clinical trials** compared to those in urban counties (11 percent versus 24 percent) (510).

It should be noted that U.S. cancer incidence is from SEER data, which are often used as a comparator in studies evaluating racial and ethnic representation in clinical trials, and are collected from regions that overrepresent certain population groups and thus may not be an accurate estimate of the overall U.S. cancer incidence. Given the vital importance of these analyses in evaluating and ensuring racial and ethnic representativeness of past and ongoing clinical studies, researchers are working to identify better datasets for comparison, such as cancer incidence from the geographical areas from which the trial cohort was recruited or data from the North American Association for Central Cancer Registries (NAACR) (511).

In a recent **analysis of 93 precision oncology clinical trials** with 5,867 participants, **representation of racial and ethnic minorities** was calculated using the **ratio of the actual number of enrolled cases to the expected number of cases** based on their corresponding U.S. population (495).



Ratio >1 signifies **overrepresentation**
Ratio <1 signifies **underrepresentation**

Types of Clinical Studies

There are multiple types of clinical studies (also called clinical trials). Although each clinical trial is designed to address specific research questions, many clinical studies can also provide answers to additional questions. For example, treatment trials, which primarily determine clinical outcomes such as efficacy of a drug for treating the cancer type for which the drug has been developed, can also evaluate measures to assess the impact of the treatment being tested on quality of life. In cancer research, the types of clinical trials include:

Prevention Trials
Designed to find out whether healthy people can reduce their risk of cancer by preemptively taking certain actions, such as by smoking cessation; by taking certain therapeutics, vitamins, minerals, or dietary supplements; or by having certain risk-reducing surgeries.

Screening Trials
Designed to evaluate new tests to detect cancer in individuals before symptoms arise, with the goal of determining whether the screening test can reduce deaths from the cancer being screened for.

Diagnostic Trials
Designed to test new ways to diagnose a certain type of cancer.

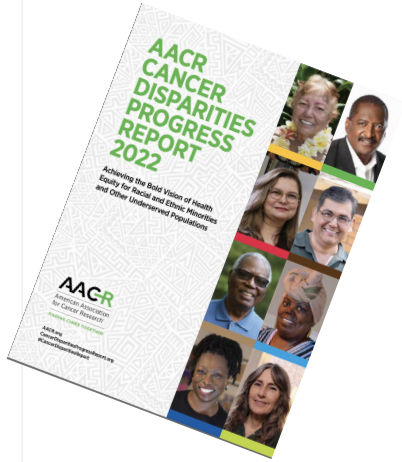
Treatment Trials
Designed to determine whether new treatments or new ways of using existing treatments are safe and effective for people who have cancer. These trials can test any type of treatment, including surgery, radiotherapy, cytotoxic chemotherapy, molecularly targeted therapy, and immunotherapy, alone or in combination with another treatment(s).

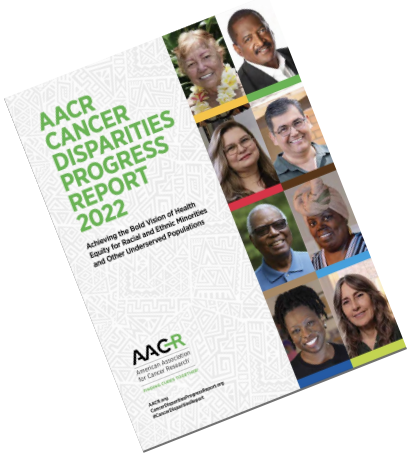
Quality of Life Trials
Designed to examine whether people who have cancer can improve their quality of life by taking certain actions, such as attending support groups or exercising more; or by taking certain therapeutics, such as those to treat depression or nausea. These studies are also known as supportive care or palliative care trials.

Natural History or Observational Studies
Designed to learn more about how cancer develops and progresses by following people who have cancer or people who are at high risk for developing cancer over a long period of time.

Correlative Studies
Designed to examine the relationship between potential efficacy of candidate anticancer therapeutics and positive clinical activity as determined by biomarkers. Correlative studies are an integral part of early-stage clinical trials when the effects of a candidate anticancer therapeutic on key clinical outcomes, such as reduction in tumor size, may not be apparent. Data obtained from correlative studies can provide important guidance on the design and ultimately successful evaluation of anticancer therapeutics in later-stage trials.

Adapted from (2).





A recent **analysis of phase I clinical trials** for anticancer agents developed by biopharmaceutical companies, showed **extremely low participation of patients from racial and ethnic minorities** compared to their proportion in the U.S. population (501).

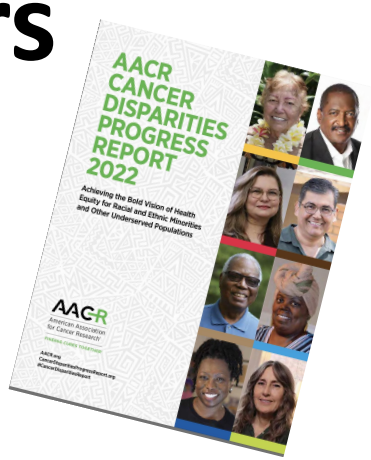
RACE/ ETHNICITY	PERCENTAGE OF PATIENTS	PERCENTAGE OF U.S. POPULATION
White	84.2	76.5
Black	7.3	13.4
Asian	3.4	5.9
Native Hawaiian or Other Pacific Islander	0.1	0.2
American Indian or Alaska Native	0.1	1.3
Hispanic	2.8	18.3

Individual-level Barriers

The individual-level barriers for patients include…

- lack of awareness of clinical trials
- limited health literacy
- mistrust of the health care system
- financial barriers such as costs of cancer treatment and medication
- transportation
- child care
- lost work
- inadequate or complete lack of insurance, among others

Provider-level Barriers



Many barriers exist at the provider level including…

- lack of knowledge of clinical trials
- implicit biases among health care providers
- lack of dedicated staff to serve minority populations
- lack of cultural competence and
- appropriate communication skills

System-level and Structural Barriers

Major system-level and structural barriers include…

- lack of trial availability
- complexity of clinical trials
- time constraints for proper informed consent
- clinical trial paperwork
- patient exclusion due to narrow eligibility criteria
- medical distrust
- lack of facilitators, such as translators or patient navigators, and community engagement in low-resource settings

Panelists

Rodolfo Bordoni, MD
Georgia Cancer Specialists

Jayanthi Srinivasiah, MD,
Georgia Cancer Specialists

Chirag Jani, MD
Phoebe Putney Medical Center

Pooja Mishra, MBA/MHA FACHE,
Grady Health System

Questions

1. What can be done to acknowledge and promote understanding of the challenges faced by the underserved, black, and brown communities?

2. What barrier do you feel impacts Black, Asian, and Hispanic groups most when it comes to participating in clinical trials?

3. What barriers have you seen that are specific to residents of rural areas and what can be done to address those barriers?

4. There is a perception that there is a financial burden associated with participation in clinical trials. How can investigators and staff address financial issues for patients during treatment? What are some steps at the institutional level and study start up level that can be implemented?

5. Do you think access to wireless technology and broadband services are barriers for clinical trial participation?