

Published in final edited form as:

Cancer. 2014 April 1; 120(0 7): 1087–1090. doi:10.1002/cncr.28569.

An Overview of EMPaCT and Fundamental Issues Affecting Minority Participation in Cancer Clinical Trials

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Keywords

Healthcare Disparities; Minority Health

In the United States, health disparities are well documented in minority populations such as African Americans, Native Americans, Asian Americans, and Latinos.¹ When compared to whites, these minority groups experience higher incidence of heart disease, stroke, diabetes, cancer, and other chronic diseases, higher mortality from these diseases, and poorer health outcomes.² There is a significant relationship between **socioeconomic status** and disease, with those most economically disadvantaged being most health disadvantaged as well.³ Several studies have postulated that **poverty is the major factor** that contributes to the widening racial health-disparity divide because it is associated with a lack of resources, information, and knowledge; substandard living conditions; risk-promoting lifestyles; diminished access to health care; and a mistrust of the healthcare system.⁴⁻¹⁰

Health disparities are particularly significant across the cancer continuum. The burden of cancer in racial and ethnic minorities is great. The most recent cancer statistics from ACS confirm that minority populations continue to have poor chances of survival once cancer is diagnosed, suggesting possible influence of disparities in access to and receipt of quality health care and in co-morbid conditions.¹¹ In lieu of a full understanding of the etiology of the disparities, efforts can be directed to provide opportunities for participation in state-of-the-art cancer therapies for those diagnosed with cancer.

Clinical trials provide effective and often improved cancer care in a way that does not tax the health care system, and over the past half century have allowed remarkable progress in the treatment of some cancers. Furthermore, clinical trials provide a valid methodology with which to compare treatments. For ethical, social, and scientific reasons, trials require the

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Conflict of Interest: none

Financial Disclosures: none

recruitment of participants from diverse population groups. However, less than 10% of all patients enrolled in clinical trials are minorities. Recent evidence from a population study examining trial effect in solid organ cancers found that enrollment into cancer trials predicted lower overall and cancer-specific mortality among common cancer sites.¹² Because access to cutting-edge medical treatments and state-of-the-art care that clinical trials provide is not equally available to people in minority communities, this inequity in participation contributes to the ongoing health disparities.

There is long-standing consensus in the scientific community that the enrollment of adult cancer patients in clinical trials is woefully low. For example, enrollment fractions, defined as the number of trial enrollees divided by the population-based estimated cancers diagnosed, in therapeutic non-surgical National Cancer Institute Clinical Trial Cooperative Group studies are below 2%¹³ and are even lower, less than 1%, for surgical trials.¹⁴ When trial eligibility is taken into account, the rates rise but still may be as low as 10%.¹⁵ A recent report by the Institute of Medicine (IOM), commissioned by the National Cancer Institute (NCI), includes as one of its key recommendations that participation of both patients and physicians in cancer clinical trials must be expanded.¹⁶ This report generated extensive media coverage,¹⁷ leading to Congressional attention¹⁸ and a consensus in the medical literature that our system for cancer clinical trials is in crisis.¹⁹

When trials enlist participants from underrepresented populations (i.e., low-income or minority populations) difficulties inherent to the recruitment process are compounded even further.^{20,21} Historically, large teaching hospitals and research institutions have had complicated relationships with the minority communities they serve. While members of the minority community may feel that these institutions provide state-of-the-art care, they are often skeptical of the motives of these organizations. Moreover, common among minority communities are feelings of mistrust, alienation, and lack of ownership in the institutional programs.²² Although these barriers are often systemic in nature, the impact can be felt at the personal level.²³ It is clear that successful recruitment of minority participants to clinical trials needs to begin with efforts to develop trusting relationships between the minority community and the research institution. Mounting evidence²³⁻²⁵ also suggests that efforts to recruit minorities are more labor intensive and need to involve more personal contacts.

For the first time ever, a consortia system national in scope has come together to develop and implement a coordinated approach to address minority accrual into clinical trials on multiple levels.

Each of the five consortium institutions (University of Minnesota; University of Alabama, Birmingham; Johns Hopkins University, MD Anderson Cancer Center; University of California, Davis) represents a distinct U.S. region and has both a National Cancer Institute (NCI)-funded cancer center and a National Institute for Minority Health and Health Disparities (NIMHD)-funded health disparities program. Combining these two types of NIH-established centers of excellence via a national network of regional consortia provides a unique opportunity to affect minority participation in clinical trials on a national level. Each cancer center serves a patient population with ethnic and racial composition reflective of its geographic region, therefore providing the ability to develop and evaluate recruitment

and retention efforts for each major US ethnic/racial category. These efforts provide the infrastructure that will pay dividends for years to come and potentially be one of the few trans-NIH initiatives to actively transform the clinical trial recruitment and outcomes landscape and reduce health disparities.

In particular, Dr. John Ruffin, Director of the National Institute of Minority Health and Disparities, has been a visionary leader in moving forward the critical issues of health disparities. Dr. Ruffin led the effort to the establishment of the NIMHD Centers of Excellence Program that have made possible significant advances in reducing health disparities through basic research, applied population and community-based research. Since 2002, 88 Centers of Excellence have been established in 31 states, the District of Columbia, Puerto Rico and the U.S. Virgin Islands. He also led the establishment of the NIMHD loan repayment program that has funded more 1,200 doctoral level health researchers in a variety of disciplines. Approximately 70 percent of the recipients are from health disparity populations. Minority accrual in clinical trials which may arguably be one of the greatest disparities in this country where less than 3% of our patients are enrolled in the clinical trials broadly with less than 0.3% of minorities are enrolled in clinical trials.²⁶⁻²⁹ This significantly creates a disparity and burden for those patients to be perpetuated because of the lack of focused and targeted therapies for minority patients.

This supplement provides an overview of the interventional efforts as well as scientific data regarding undertaken by this consortium to document the scope of the problem and the results from multiple methods of interventions for increasing minority accrual in clinical trials. Initially ARRA funded for two years, this consortium continues to rigorously evaluate the efficacy of trial enrollment interventions through a U24 cooperative agreement with the National Institute on Minority Health and Health Disparities. This supplement now provides an insight as well as a number of manuscripts that will hopefully provide the basis for further intervention, clinical trials, as well as enhancement of minority accrual in these efforts for cancer and other chronic illnesses.

Twenty Years Post-NIH Revitalization Act: Renewing the Case for Enhancing Minority Participation in Cancer Clinical Trials

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Twenty years have elapsed since the 1993 NIH Revitalization Act mandated the appropriate inclusion of minorities in all research funded by the National Institutes of Health. Despite this legislation, minority accruals to cancer clinical trials persist at a rate below 5% and the cancer burden has increased; recommendations for amelioration are proposed.

Perspectives on Barriers and Facilitators to Minority Recruitment for Clinical Trials among Cancer Center Leaders, Investigators, Research Staff and Referring Clinics

The authors: Lead Authors: Durant RW, MD, MPH and Martin MY, PhD. Wenzel JA, PhD, RN; Scarinci IC, PHD, MPH; Paterniti DA, Fouad MN, MD, MPH; Hurd T, MD

This paper relates to the overall research work of EMPaCT I with perspectives on barriers of clinical facilitators on minority recruitment in clinical trials among cancer center leaders, investigators, and research staff of referring clinicians. This paper, from the empiric research done as a part of the EMPaCT I, conducted 91 interviews at five cancer centers, identifying underlying barriers that would prevent individuals of minority or ethnic backgrounds from participating in clinical trials through interviews of cancer center leaders, investigators, staff, and referring clinicians. There was a significant amount of distrust, discomfort, and uncertainty in clinical trial participation. There was a negative connotation to overcome related to trials, minorities would often face barriers that preclude them even being offered the opportunity, and barriers that also existed at the individual institutional level that often prohibited them from going forward for trial activity. These factors were significant at multiple levels in preventing and influencing minority individuals from being offered trials as well as enrolling.

A Model of Clinical Trial Decision-making Informed by AA Cancer Patients

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A Model of Clinical Trial Decisional Balance has been developed from focus group discussions among clinical trial-eligible AA cancer patients. Main themes affecting the central concept of decisional balance and decision outcomes include: *Information gathering and processing and Interpersonal influences*; model outcomes include the presence or absence of *decisional regret* and *patient satisfaction* with the decision-making process.

Quantitative Data Collected by EMPaCT Cancer Centers: Current Status and Opportunities for Improvement

The Authors: Lead Author: Hawk ET, MD, MPH. Senior Author: Habermann EB, PhD, MPH. Ford JG, MD; Wenzel J, RN, PhD; Brahmer JR, MD; Chen M, PhD; Jones LA, PhD; Hurd TC, MD; Rogers LM, MS; Nguyen LH, MPH; Ahluwalia JS, MD, MPH; Fouad M, MD, MPH; Vickers SM, MD

This study evaluated the data accrual process and NIH funded comprehensive cancer centers. It sought to understand the process by which cancer centers documented their accrual of minority participation in clinical trials. Cancer centers at John Hopkins, MD Anderson, University of Alabama Birmingham, University of Minnesota, University of California Davis, where a collected status of minority accruals were evaluated as a part of their CCSG competitive renewal. These findings show that proportional accrual of

minorities was less than desired for at least one racial ethnic group at four out of the five cancer centers. Racial and ethnic categories were similar yet defined differently across intuitions. Patient factors reported differently, catchment area definitions were also not necessarily reflective of minority cancer cases.

The challenge found by this paper is that each institution in many ways has allowed an individualized approach to how it collects data on race and ethnicity as well as declarations of catchment areas and definition of minority cancer cases. Improvement on these factors of collection could significantly improve how we understand minority accrual as well as increasing the percentage of overall minority accrual for clinical trials.

State-of-the-Science of Patient Navigation as a Strategy for Enhancing Minority Clinical Trial Accrual

The Authors: Lead author: Ghebre R MD, MPH. Jones LA PhD; Wenzel JA PhD, RN; Martin MY PhD; Durant RW MD, MPH; Ford JG MD

This article does a systematic review of the literature in order to evaluate and identify qualitative and quantitative studies on patient navigation in clinical trials. 212 studies were identified, 12 were eligible for review. The results show that navigators, particularly in the area of African Americans, American Indians, and Native Hawaiians, had a significant reduction in trial refusal (4-6%) compared to our understanding of this significant issue in environments where accrual of trials occurs without navigators. However, there is hypocrisy of clinical trials reporting participation with navigation services, therefore leading for a need for increased research in this area but certainly optimism from their initial investigation, as presented in this paper.

Compliance and Retention in Clinical Trials: A Community-Based Approach

The Authors: Lead author: Fouad MN, MD, MPH. Jonson R, PhD; Nagy C PhD; Person C PhD; Partridge E, MD

The article uses a novel approach for the community health advisors (CHAs) as an interventional tool in a randomized clinical trial, based on the community in Jefferson County, Alabama. This group found that implementation of community health advisors significantly improved compliance for scheduled clinic visits over a reasonably short period of time, demonstrating that there is a significant opportunity for increased clinical trial enrollment by intervention at the community level, by significant individual who have trust and who empower the community to make decisions about their overall healthcare.

We believe this supplement will provide an outstanding overview of the challenges for increasing clinical trial enrollment as well as new strategies for proceeding to increase trial enrollment. But in particular, it provides an overview of the impact of the progress and the importance of the EMPaCT consortium consisting of five leading comprehensive cancer centers as well as five NIMHD funded minority health disparity centers and their combined work effort to change the course of disparities for cancer related treatment for minorities in America.

Acknowledgments

Funding Source: Research reported in this manuscript was supported by the National Institute On Minority Health and Health Disparities of the National Institutes of Health under Award Number RC2MD004797 and U24MD006970.

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