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# Twenty Years Post-NIH Revitalization Act: Enhancing Minority Participation in Clinical Trials (EMPaCT): Laying the Groundwork for Improving Minority Clinical Trial Accrual

Renewing the Case for Enhancing Minority Participation in Cancer Clinical Trials

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**BACKGROUND:** The National Institutes of Health (NIH) Revitalization Act of 1993 mandated the appropriate inclusion of minorities in all NIH-funded research. Twenty years after this act, the proportion of minority patients enrolled in cancer clinical trials remains persistently low. Clinical trials are vehicles for the development and evaluation of therapeutic and preventive agents under scientifically rigorous conditions. Without representation in trials, it is projected that disparities in the cancer burden for minorities will increase. **METHODS:** For this review article, the authors counted the frequency with which minorities were the primary focus of National Cancer Institute-sponsored clinical trials, examined citations from the PubMed database focusing on the search terms “NIH Revitalization Act of 1993” and “enhancing minority accrual to cancer clinical trials,” and supplemented the review with their expertise in NIH-funded research related to minority accrual in cancer clinical trials. **RESULTS:** The reporting and analyses of data based on minorities in clinical trials remain inadequate. Less than 2% of the National Cancer Institute’s clinical trials focus on any racial/minority population as their primary emphasis. The current review of the literature indicated that the percentage of authors who reported their study sample by race/ethnicity ranged from 1.5% to 58%, and only 20% of the randomized controlled studies published in a high-impact oncology journal reported analyzing results by race/ethnicity. Proportionately greater population increases in minorities, accompanied by their persistent and disproportionate cancer burden, reinforce the need for their greater representation in clinical trials. **CONCLUSIONS:** Renewing the emphasis for minority participation in clinical trials is warranted. Policy changes are recommended. *Cancer* 2014;120(7 suppl):1091-6. © 2014 American Cancer Society.

**KEYWORDS:** cancer clinical trials, National Institutes of Health Revitalization Act, minorities, clinical trial, disparities.

## INTRODUCTION

The National Institutes of Health (NIH) Revitalization Act of 1993 established the Federal legislative mandate that NIH-funded research would be conducted such that “valid analysis of whether the variables being studied in the trial affect. . .members of minority groups.”<sup>1</sup> Although progress for appropriate representation of women and racial/ethnic minorities is evaluated as part of the NIH peer-review process for research studies, 20 years later, the proportion of racial/ethnic minorities participating in cancer clinical trials is persistently lower<sup>2</sup> than the proportion of minorities in the US population at large (36.3%),<sup>3</sup> and minorities remain disproportionately burdened with cancer and underrepresentation in cancer clinical trial enrollments.<sup>4</sup>

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Without appropriate inclusion in cancer clinical trials, health disparities among racial/ethnic minorities are very likely to widen even more. Considered as the gold standard,<sup>5</sup> clinical trials offer scientifically rigorous approaches to develop and evaluate better and/or safer antineoplastic interventions, with the ultimate goal of establishing new practice standards.<sup>6</sup> Consequently, the major advances in cancer treatment have emerged from clinical trials.<sup>7</sup> Participating in most clinical trials offers benefits to patients, such as the provision of state-of-the-art care, with potentially more effective intervention and improved survival.<sup>6,8</sup> Thus, appropriate participation of minorities in cancer clinical trials offers the prospects of generating new hypotheses that affect treatment, exploring differences in responses to risk factors and treatment, and access to potentially life-saving or life-prolonging therapies.<sup>8</sup> The purpose of this article was to review the case for enhancing minority participation in cancer clinical trials. We accomplish this through: 1) counting the number of clinical trials sponsored by the National Cancer Institute (NCI) whose primary focus is on racial/ethnic minority populations, 2) reviewing the published findings and assessments of the status of minority participation in cancer clinical trials since the original 1993 mandate, and 3) summarizing findings and making recommendations for renewing the case for minorities in cancer clinical trials.

## MATERIALS AND METHODS

We used 3 general methods to generate the content for this article. One method was to examine relevant websites related to clinical trials and the cancer burden by race and ethnicity. We visited ClinicalTrials.gov, the website that officially lists National Institutes of Health registered clinical trials. On ClinicalTrials.gov, we limited our search to clinical trials sponsored by the NCI as of January 2013 and used the search terms “black,” “African American,” “Hispanic” or “Latino,” “Asian American,” “Native American,” “American Indian,” “Alaska Native,” and “Pacific Islander” to count the number of clinical trials primarily focused on those populations. We then sought to determine the age-adjusted cancer incidence rates for all cancers by race and ethnicity as quantitative measures of the cancer burden.<sup>10</sup> Although age-adjusted cancer prevalence rates would also be desirable, they do not appear to be easily available.

A second method for generating the content for this article was reviewing abstracts and articles from the PubMed database using the search terms: “NIH Revitalization Act of 1993,” “enhancing minority participation in cancer clinical trials,” “minority participation in cancer

clinical trials,” and “increasing minority accrual in clinical trials” based on citations as accessed in January through March of 2013. By using these search terms, we ended up with 42 citations. We then selected the only 5 citations involving studies that explicitly included participation levels by race and ethnicity in their publications. These citations encompassed diverse research studies. A summary of the findings from these 5 citations is presented as Table 1 (see Results, below).

A third method of generating content for this report was through using the “key informant” approach, a qualitative methodology in which experts share their experiences, expertise, and insights based on their involvements in the behaviors being investigated. The content for this approach was selected from presentations made at a June 2012 NIH-sponsored conference by 3 of the authors convened at the University of California, Davis on the “State-of-the-Science of Enhancing Minority Participation in Cancer Clinical Trials.” In addition, the authors included researchers on 3 NIH-funded grants: “Barriers to Accrual in Cancer Trials” (R21 CA101724), “Enhancing Minority Accrual to Clinical Trials” (U24 MD006970), and the NCI-funded National Center to Reduce Asian American Cancer Health Disparities (U54 CA153499). The collective expertise and insights from these key informants also enhanced the content of this article.

## RESULTS

Five key findings related to the state of minority participation in clinical trials emerged from the 3 methods we used. First, *the numbers and percentages of cancer clinical trials that focus primarily on racial/ethnic minority populations are extremely low*. On the basis of a search on ClinicalTrials.gov in January 2013, the NCI sponsored or cosponsored at least 10,000 clinical trials. Those trials included all types of studies and in all stages. However, the actual number of trials that specifically or primarily focused on racial/ethnic minorities such that principal investigators classified their trials as searchable terms (keywords) was less than 150. This does not mean that all of the other clinical trials did not include racial/ethnic minorities but, rather, that their principal investigators did not consider their primary focus to be racial/ethnic minorities. Under those conditions, we observed that, by using the search term “black,” 83 trials were listed, and 81 were listed if the search term was “African American.” Thirty-two studies were listed for “Hispanic” or “Latino,” 5 were listed for “Asian American,” 4 were listed for “Native American,” 2 were listed for “American Indian,” 2 were listed for “Alaska Native,” and 1 was listed for

**TABLE 1.** Reports of Minority Participation in Clinical Trials From 5 Major Reviews of Literature

Topics	No. of Reports Reviewed	Reports by Race/Ethnicity, %	Comments
Clinical trials Ness 1997 <sup>15</sup> Murthy 2004 <sup>11</sup>	65	1.5	Low percentage of race/ethnicity reported Data from NCI Clinical Trials Cooperative Group (breast, colorectal, lung, prostate cancer) 2000–2002; based on N = 75,215 trial participants
NIH K Awards in diabetes and prevention Guevrara 2006 <sup>16</sup>	165	37	No improvement in percentage of studies that focuses on minorities, 1994–2004; improvement in reporting of African Americans but not for Hispanics or Asians; only 7% of awards focused on minorities
Smoking cessation Dickerson 2009 <sup>17</sup>	125	58	Large proportion of studies fail to report race/ethnicity
High-impact journals Geller 2011 <sup>18</sup>	86 High-impact journals, 11 oncology journals	57	Randomized controlled trials in the following high-impact journals were reviewed: <i>New England Journal of Medicine</i> , <i>Journal of the American Medical Association</i> , <i>Journal of Clinical Oncology</i> , <i>Circulation</i> , <i>Clinical Infectious Disease</i> , <i>Obstetrics and Gynecology</i> , and the <i>American Journal of Obstetrics and Gynecology</i>

Abbreviations: NCI, National Cancer Institute; NIH, National Institutes of Health.

“Pacific Islander.” Cumulatively, it would appear that the percentage of NCI-sponsored clinical trials in which racial/ethnic minorities represent the major emphasis based on these counts is approximately 100 of 10,000 individuals or, at best, 1%.

Second, *the proportion of minority adults enrolled in cancer clinical trials is not adequate or representative of the US population with cancer.*<sup>6,11,12</sup> The cancer incidence rates indicate that blacks experience the greatest burden (593.7 per 100,000), followed by whites (513 per 100,000), Hispanics (395.2 per 100,000), Asians/Pacific Islanders (309.6 per 100,000), and American Indians/Alaska Natives (294.8 per 100,000).<sup>12</sup> The enrollment fraction in clinical trials by race/ethnicity for all cancers is 1.8% for whites, 1.3% for both blacks and Hispanics, 1.7% for Asians/Pacific Islanders, and 2.5% for American Indians/Alaska Natives.<sup>11</sup> With the possible exception of American Indians/Alaska Natives, all other racial/ethnic groups are under-represented relative to their proportion in the population. Thus, the adequacy for making specific recommendations for any racial/ethnic population is very limited based on enrollment percentages.

By contrast, 60% of patients aged <15 years are enrolled in clinical trials<sup>13</sup> compared with just 3% to 5% of the 10.1 million adults with cancer.<sup>11</sup> Yet, the proportion of minority pediatric patients enrolled in cancer clinical trials (Hispanic, 11.6%; African American, 10.4%; other, 4.7%) is equal to or greater than their representation in the population.<sup>14</sup> The record of participation by racial/ethnic

populations in pediatric clinical trials suggests that a comparable record is potentially achievable in clinical trials for adults.

Third, *the percentages of reports of clinical trials that include usable data about racial/ethnic minority populations are less than optimal.* Our PubMed searches identified 5 publications that reported on their reviews of papers that reported on minority participation in clinical trials (of all types, not restricted to cancer). The findings from these 5 publications are displayed in Table 1.<sup>15–18</sup> These articles reflected a variety of research studies and, thus, a range of participation rates were reported.

The publications included in Table 1 are listed in chronological order, with the earliest (1997) first through the latest (2011). The trend toward increasing the inclusion of reports by race/ethnicity is in the upward direction from 1.5% of the reports that specified race or ethnicity in a 1997 article to 57% in a 2011 article. In the 2011 article, of the 86 articles that published results of randomized controlled trials in 2009, 57% reported sample sizes by racial and ethnic groups, but only 36% provided any analysis by racial or ethnic groups.<sup>18</sup> This trend is encouraging but still less than optimal.

Fourth, our literature review revealed that *barriers for minority participation in cancer clinical trials persist, eg, mistrust,<sup>5,6</sup> costs, transportation, and differences in cultural perspectives.*<sup>2</sup> Other barriers include lack of awareness in available trials or clinical trials as a therapeutic option, physician neglect in inviting patients to consider participation

in a clinical trial, linguistic barriers and (English) language proficiency, differences in culture, and cultural considerations (eg, not exploring preferences for family involvement and culturally defined perspectives on disease). Trial design characteristics, eg, exclusion based on comorbidities or socioeconomic status, especially inhibit minority enrollment in trials.<sup>19</sup> Compared with non-Hispanic whites, the awareness of clinical trials among Asian Americans,<sup>20,21</sup> blacks,<sup>22,23</sup> and Hispanics<sup>22,23</sup> is significantly lower. Although it has been hypothesized that trial awareness might lead to higher rates of trial participation, awareness survey findings have indicated that there is no significant correlation between trial awareness and willingness to participate in a cancer clinical trial among minority subgroups.<sup>24</sup> Even extensive mass media campaigns and internet use do not yield significant increases in minority enrollment.<sup>21</sup> However, the solution is not changing the attitudes of minorities but, rather, ensuring access to health research. On the basis of over 70,000 individuals, African Americans and Hispanics were just as likely to enroll in health research as non-Hispanic whites.<sup>23</sup> Model programs, particularly Minority-Based Community Clinical Oncology Programs, because of their emphasis on minority participation, and supplemental site grants have yielded high proportions of minority participation (range, 44%-56%),<sup>25</sup> especially among African Americans.<sup>26</sup>

Fifth, *evidence is accumulating on the increasing value of participation in cancer clinical trials*. Three examples follow.

The first is an example of how participation in trials may result in lower mortality. In a study based on the California Cancer Registry, 1846 patients who enrolled in cancer clinical trials experienced a lower hazard of death from lung, colon, and breast cancers.<sup>8</sup>

The second example is one that exemplified how participation in trials led to vital new scientific discoveries about specific populations. This is illustrated by the role for epidermal growth factor receptor (EGFR) tyrosine kinase inhibitors, such as gefitinib, in the treatment of lung cancer. Molecular characterization of tumors from patients who received treatment with gefitinib revealed that tumors harboring EGFR mutations were exquisitely sensitive to gefitinib and that the proportion of patients with EGFR-mutant tumors was higher in Asian populations than in other racial groups. For example, in 1 analysis, 15 of 58 Japanese patients (26%), versus 1 of 61 American patients (1.6%), had an EGFR-mutated tumor.<sup>27</sup> These data suggest that ethnic and geographic differences play a significant role in cancer pathogenesis, promoting the benefit of ethnic diversity in therapeutic

trials. Furthermore, this observation allowed for the timely conduct of the IRESSA Pan-Asia Study trial, which demonstrated the benefit of gefitinib over that of standard doublet chemotherapy for patients with advanced lung cancer harboring an EGFR mutation.<sup>28</sup> Data from that study have revolutionized how we treat lung cancer worldwide and have provided evidence that racial/ethnic molecular profiling is the key to improving outcomes for patients with lung cancer. It is noteworthy that those findings created the momentum to explore treatment outcomes by molecular and clinical features in minority subsets.

A third example of how research area is strongly influenced by racial and ethnic diversity is pharmacogenomics (ie, the study of how genetic factors contribute to drug effectiveness and toxicity). This research is particularly important in oncology, in which efficacious doses of drugs are narrow and their toxicities may be life-threatening. For instance, the pharmacogenetics of irinotecan, a commonly administered drug for the treatment of colon cancer, has been implicated in the drug's therapeutic-toxic effects. It has been demonstrated that polymorphisms in the promoter region of uridine diphosphate glucuronosyltransferase 1 family, polypeptide A1\*28 (*UGT1A1\*28*) influence the risk of grade 4 neutropenia after irinotecan therapy.<sup>29</sup> The frequency of the *UGT1A1\*28* genotype is significantly higher in Caucasian patients (12%) compared with Japanese patients (3%). Consequently, the US Food and Drug Administration approved pharmacogenomics-based prescribing of irinotecan in 2004 that allows for a lower starting dose for cancer patients with this genetic polymorphism. More recently, pharmacogenomics have become center stage because of the controversy over cytochrome P450, family 2, subfamily D, polypeptide 6 (*CYP2D6*) polymorphism and tamoxifen efficacy. *CYP2D6* is important in metabolizing tamoxifen to its active form, and it was hypothesized that poor metabolizers of *CYP2D6* might have an inferior benefit from tamoxifen. Two independent studies reported no impact of tamoxifen metabolism on its efficacy in postmenopausal women with breast cancer.<sup>30,31</sup> A re-evaluation of the data suggests that *CYP2D6* testing may be warranted. A thorough reanalysis of the data has been recommended. This has significant clinical implications given that the frequency of poor metabolizers is approximately 7% to 10% in Caucasians, 1.9% to 7.3% in African Americans, and 1% in Asians.

Given the accumulating empirical evidence of the value added for appropriate minority inclusion in cancer clinical trials, the issue of how to do so looms. Certainly,

increased research on the determinants of clinical trial participation is needed. However, a systematic policy decision should also be considered when the types of NCI-funded clinical trials are examined.

## DISCUSSION

The purpose of this article is to renew the case for enhancing minority participation in cancer clinical trials. Twenty years have elapsed since the legislative mandate embodied in the NIH Revitalization Act of 1993 required the appropriate inclusion of minorities in NIH-funded research. Yet the participation rate of minority adults in cancer clinical trials continues to be inadequately low.

Meanwhile, the 2010 US Census documented the increased numbers and proportions of racial/ethnic minorities—African Americans; American Indians and Alaska Natives; Asian Americans; Hispanics or Latinos; and Native Hawaiians and other Pacific Islanders. In at least 5 jurisdictions (California, Texas, Hawaii, New Mexico, and the District of Columbia), these minority populations already comprise the majority of residents.<sup>3</sup> Although cancer mortality rates are declining for the majority of organ sites for all groups, racial/ethnic minorities continue to experience the highest cancer incidence and mortality rates. African Americans continue to endure the highest incidence and the highest mortality for all cancer sites for both genders. Specifically, African Americans experience both the highest incidence and the highest mortality rates for cancers of the prostate, lung, colon and rectum, pancreas, esophagus, and kidney. Although African Americans do not experience the highest incidence of breast cancer, they experience the highest mortality for breast cancer. American Indians experience the highest incidence of kidney cancer and the highest mortality rates for lung cancer. The leading cause of cancer incidence and mortality for Hispanics is cervical cancer and lung cancer, respectively. Asian Americans experience both the highest incidence and the highest mortality rates for liver and stomach cancers. In fact, cancer has been the leading cause of death for Asian Americans since 2000<sup>32</sup> and, in 2012, became the leading cause of death for Latinos.<sup>33</sup>

Between 2010 and 2030, the projected increase in cancer incidence rate is 99% for minorities, compared with 45% for the population at large. It is anticipated that individuals of mixed race, Latinos, Asian Americans, and Pacific Islanders will experience the greatest increases in the immediate future.<sup>17</sup> Failure to adequately enroll minorities into clinical trials that can help to customize therapeutic and prevention interventions for racial/ethnic minority subgroups will mean even greater economic and

social burdens for the nation from increased morbidity and mortality because of cancer.

In light of the compelling demographic changes affecting the US population, minority participation in cancer clinical trials not only can enhance the health of minorities but also can contribute to the broader understanding of determinants to improve health for all. The value added for minority participation in clinical trials continues to accumulate. Yet participation by minorities remains less than optimal.

Our analyses suggest that the focus should now turn to policy. Less than 2% of the NCI-sponsored clinical trials indicate that their primary focus is on any racial/ethnic minority population. In other words, 98% were trials that focused on cancer types rather than trials in which the driving force was to assure appropriate and adequate representation of one or more minority groups disproportionately affected by cancer. Just as the impetus to appropriately assure representation and applicability of research findings to women, the emphasis should now be placed on renewing the emphasis on each of the racial/ethnic minority populations. For example, on ClinicalTrials.gov, we identified 6497 cancer trials that emphasized females and 3029 cancer trials that emphasized males; however, cumulatively, less than 150 cancer trials were focused on minorities, race, or ethnicity in the aggregate, and even fewer emphasized a specific race grouping, eg, only 83 studies emphasized “blacks,” the largest number for any minority group. Data from the NCI Clinical Trial Cooperative Group that included 75,215 trial participants in studies of breast, colorectal, lung, and prostate cancer from 2000 to 2002 indicated that the reports by race/ethnicity remain low, with little improvement in the reporting of participants by race/ethnicity or analyses by race/ethnicity. Although trial enrollment numbers and rates increased by almost 50% between 1996 and 2002, the proportion of nonwhite trial participants declined from 3.7% to 3% among blacks and from 11% to 7.9% among Hispanics.<sup>11</sup>

Other incentives or measures should be attempted to achieve greater representation by race/ethnicity. Although not a new recommendation, we believe that journal editors should require appropriate representation and analyses of NIH-funded research by race/ethnicity.<sup>17</sup> Another recommendation is for the NCI to prioritize new clinical trials based on adequacy of sampling specific individual groups rather than organ sites.<sup>12</sup> By focusing on individual groups and specifically indicating which race/ethnicity will be the focus rather than the disease and to assure impact on the individuals affected, we believe the participation of minorities in cancer clinical trials will increase.

## Conclusions

Despite 20 years of a legislative mandate to increase the appropriate inclusion of minorities in NIH-funded research, the representation of adults enrolled in cancer clinical trials remains woefully inadequate. The case for enhancing minority participation in cancer clinical trials is being buttressed by the increasing proportions of the US population from racial/ethnic minorities, the projected increased cancer burden in the nation, and the mounting evidence on the empirical value of clinical trial participation. Seeking policy changes through the peer-reviewed literature and priorities for new cancer clinical trials from an organ-specific approach to an individual-centered approach, in which particular groups are explicitly targeted for involvement in the clinical trial, are recommended for clinical trials to impact the cancer burden.

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## CONFLICT OF INTEREST DISCLOSURES

The authors made no disclosures.

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