

# What Do We Want? Increased Hispanic Accrual on Cancer Clinical Trials! When Do We Want It? Now!

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## ABSTRACT

The Hispanic population is one of the fastest growing racial/ethnic group in the United States. Cancer is leading cause of death in this demographic group and have up to 50% higher cancer mortality rates compared to the non-Hispanic white population in the United States. Hispanics face numerous cancer health disparities, including poverty, obesity, and access to health care and insurance. In our previous study, we noted a poor Hispanic accrual rate of 3.9% in all phase II and III cancer clinical trials published in the United States in 2012 and argued for better representation. To assess if a change was made seven years later, we reexamined the clinical trials published in the United States in 2019. We found 48 cancer clinical trials meeting our inclusion criteria. Only 23 (48%) reported information regarding minority accrual. Of these, 8 (17% of all) reported Hispanic accrual. Altogether, of the 2559 patients reported in the 8 clinical trials, 104 (4.1%) were of Hispanic ethnicity, which nearly matches the 3.9% that we reported in 2014. In this manuscript, we highlight the disproportionately low rates of Hispanic accrual in cancer clinical trials and propose processes that will increase representation.

**KEYWORDS:** Hispanic, clinical trials, health disparities, socioeconomic status

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Hispanics constitute the fastest growing demographic group in the United States and represented 18.5% of the US population in 2019 (Census Bureau QuickFacts, 2020). By 2050, the number of Hispanics in the U.S. is expected to triple from 46.7 million to 132.8 million and will represent about 30% of the US population (Haile et al., 2012). Although Hispanics have lower rates of the four most common cancers (breast, colorectal, lung, and prostate cancer) than their non-Hispanic white counterparts, this ethnic group has higher rates of cervical, gallbladder, liver, and gastric cancers. In addition to higher prevalence of these cancers, they have up to 50% higher cancer mortality rates compared to the non-Hispanic white population. Cancer is the leading cause of death among Hispanic/Latinos (Haile et al., 2012).

Hispanics face significant cancer health disparities due to several factors. Poverty, access to care, and obesity play major roles in Hispanic cancer predisposition and higher cancer-mortality rates. Hispanics are the least likely to have health insurance of any racial or ethnic group; among those 18-64 years of age, 25% of Hispanics were uninsured during 2016-2017 compared to 9% of non-Hispanic whites (Hales, 2018). In 2015-2016, 80% of Hispanic adult females and 83% of Hispanic adult males were overweight or obese, compared to 65% and 74% of their non-Hispanic white counterparts. Obesity likely plays a significant role in cancer risk in this population (Hales, 2018).

We have previously highlighted the poor Hispanic accrual rate of 3.9% in cancer clinical trials published in 2012 and raised an alarm urging actions to increase Hispanic accrual (Parra et al., 2014). At that time, we examined Hispanic accrual to phase II or phase III cancer clinical trials in the US published in 2012. We identified 159 clinical trials, only 33 of which presented data regarding patient ethnicity. Only 13 of those 33 studies stated rates of

Hispanic accrual, a mere 8.18% of all phase II or III cancer clinical trials in the US. The problem was clear as was the solution: an increased focus on Hispanic accrual, universal reporting on how representative the trials are of the U.S. population, and the need for improvement.

Seven years later, we have reexamined our national response. We examined all phase II and phase III cancer clinical trials published in 2019 by clinical investigators in the US. We identified studies published in one of the following journals: *The New England Journal of Medicine*, *Journal of Clinical Oncology*, *Journal of the National Cancer Institute*, *Lancet*, and *Blood*. We collected data related to reports of patient ethnicity, patient accrual, and Hispanic enrollment. We found 48 cancer clinical trials that met these inclusion criteria. Of these, only 23 (48%) reported information regarding minority accrual; of this group of 23 reports, 8 (17% of all) reported Hispanic accrual. Ultimately, of the 2559 patients reported in the 8 clinical trials, 104 (4.1%) were of Hispanic ethnicity, almost exactly the same fraction (3.9%) that we reported in 2014.

Although these data demonstrate an increase in the number of clinical trials reporting minority and Hispanic accrual, the proportion of Hispanics participating in clinical trials remains minimal. This plateau in low rates of Hispanic accrual to cancer clinical trials is disconcerting and demands action.

While the need for broad population representation in clinical trials seems self-evident, we should stress the rationale: with significant differences in risk factors, access-to-care, cultural and other variables related to cancer outcomes in the racial and ethnic groups in the U.S., we must be sure that conclusions we reach regarding cancer management can be generalized for all Americans. We do recognize that the challenges to cancer clinical trial accrual are

complex and will require multi-level systemic changes. However, amidst these challenges is an opportunity: As cancer is highly related to age, the absolute number of cancer cases among Hispanics in 2020 is disproportionately lower than their current population. However, while 8.4% of the 65+ U.S. population in 2018 was Hispanic, this group will constitute 21% of the 65+ population in 2060. (Frey, 2018). Every effort to enhance the accrual of Hispanic elderly with cancer will translate into better quality of evidence for treatment decisions in this group. We thus have a unique opportunity to, as Bobby Orr quipped, 'skate to where the puck will be' now and establish how to best provide cancer care for Hispanics rather than react years from now without data.

We propose three simple steps to catalyze this process. First, minority recruitment plans for cancer clinical trials must include specific plans for Hispanic accrual. Second, journals should require data related to Hispanic accrual in demographic tables (classically, 'Table 1'). Finally, an annual 'National Report Card' should provide Hispanic accrual for all trials registered at [clinicaltrials.gov](http://clinicaltrials.gov). Indeed, these are steps that can be applied to enhance clinical trial accrual in all underrepresented minority groups. We are confident that these simple steps will place a bright light on the issue and will ensure that, over time, we will enhance cancer care of this important group of our fellow citizens.

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## Conflicts of interest

There are no conflicts of interest for any authors.

## Authors' contributions

BW, AK, and IT conceptualized the study. BW collected the primary data. BW, AK, and IT conceived analysis and interpretation of the data. BW, AK, and IT wrote and edited final abstract.

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