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The Clinical Trials Involvement of Latino and White Physicians

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Abstract

Background—Ethnic differences in physicians' attitudes and behaviors related to clinical trials might partially account for disparities in clinical trial participation among Latino patients. Literature regarding Latino physicians' involvement in clinical trials, in comparison to White physicians, could not be found.

Methods—Cross-sectional data from randomly selected physicians (N=695), stratified by ethnicity, were analyzed to test associations of ethnicity with physicians' participation in and attitudes toward referral of patients to clinical trials.

Results—Chi-square analyses showed significant ($p<0.05$) associations of physician race/ethnicity and clinical trials involvement, type of trial for which the physician is likely to recommend a patient, belief in scientific value, and factors that would influence recommendation for a patient to participate. Multivariate analyses resulted in several significant ($p<0.05$) predictors of clinical trials outcomes, including physician race/ethnicity.

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Conclusions—Latino physicians were significantly less involved in clinical trials than White physicians and found less scientific value in them, highlighting areas for future education and intervention.

Keywords

Recruitment; Clinical Trials Participation; Cancer; Latino; Hispanic; Physician Race/Ethnicity; Disparities; Minority Populations

Introduction

Clinical trials provide patients with access to new and state-of-the-art treatments and help with the translation of findings into mainstream clinical practice; however, inclusion of underrepresented groups in clinical trials has proven a significant challenge. Major entities have recognized this challenge, thus the National Institutes of Health (NIH) enacted the Revitalization Act of 1993 (Public Law 103–43) to ensure the inclusion of women and minorities in research, which in 1994 led to Federal Register guidelines governing inclusion of these populations in clinical research. Subsequently, in the report, “The Unequal Burden of Cancer: An Assessment of NIH Research and Programs for Ethnic Minorities and the Medically Underserved,” the Institute of Medicine (IOM) recommended that the National Cancer Institute (NCI) and other entities collaborate to increase clinical trials accrual among underserved groups.¹ Following these guidelines and recommendations, researchers have made an effort to understand the barriers and promoters of underserved populations participating in clinical trials.

Latino (defined as a person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin without regard to race) patients, as well as other ethnic minority, elderly, rural, and low socioeconomic patients, have consistently been underrepresented in clinical trials.^{2–3} A recent analysis of accrual into NCI sponsored trials showed that Latino patients are enrolled at lower rates than White patients of the same age.⁴ For adults aged 30 to 80 years, the overall percentage of Latino patients accrued to clinical trials is less than that of White patients. An Agency for Healthcare Research and Quality (AHRQ) synthesized report of studies evaluating barriers and promoters of underrepresented groups in cancer prevention and treatment trials identified 45 eligible studies, but only seven of those focused on Latinos.³ Cited barriers to the participation of minorities in clinical trials include study design (e.g. protocol length and complexity, patient exclusion criteria) and healthcare system barriers (e.g. lack of cultural competence among staff, lack of minority staff), as well as patient and physician factors.^{3,5} The most frequently reported barriers to Latino patients’ acceptance of clinical trials were mistrust of medical research and the medical system.³ While many studies have highlighted patient barriers, physician barriers have received less focus, although the AHRQ report revealed that provider perceptions and attitudes play a significant role in trial enrollment for underrepresented populations.³

Physicians act as gatekeepers and provide a majority of patient education regarding clinical trials; therefore, they influence recruitment and patient decision-making. Because the role of physicians is so important, understanding their attitudes and practices regarding clinical trials via research is essential. Research has shown that participation and recruitment barriers include the physician’s lack of clinical trial awareness, level of comfort explaining the trial, fear of losing patients, mistrust of medical institutions and researchers, limited resources for data management, perception of simplicity of the study protocol and level of burden, feelings about the patient’s age and comorbid conditions, and awareness of and lack of adequate compensation for involvement.^{6–16}

Physicians may not refer minority patients specifically, because they perceive that these patients face unique barriers, such as mistrust of researchers and lack of awareness/information and resources.^{7–8,17} One study reported that physicians (who were 83.5% nonminority) were also concerned that minority (African American and Latino) patients would be deemed ineligible for trials, and they had concerns that their minority patients would feel like they were receiving inadequate treatment or being treated like “guinea pigs.”¹⁷ A study of mostly White (90%) and male (74%) researchers found that their successful recruitment of minorities into clinical research was related to how valuable the researchers felt it was to recruit minorities.¹⁸

Although physician attitudes and practices regarding clinical trials influence patient recruitment and accrual, and research is available regarding physician involvement in general, a scarce amount of research has assessed clinical trial participation of ethnic minority physicians. Specifically, through a systematic review of the literature using key terms (clinical trials; cancer; physicians, providers, or doctors; Hispanic, Latino, or Minority) in PubMed, research regarding differences between Latino and White physicians’ clinical trials attitudes and behaviors could not be found. Therefore, the extent to which Latino physicians are involved in clinical trials and find scientific value in them, and which factors influence the likelihood to recommend clinical trials to their patients, as compared to their White counterparts, is unknown. What is known is that Latino physicians tend to see a predominately minority patient population, and physician referral is one of the most important clinical trials recruitment mechanisms.^{19–20} Therefore, ethnic differences among physicians in patterns of patient referral to clinical trials might partially explain ethnic disparities in participation of patients. Research has shown mixed results regarding whether the race/ethnicity of the researcher is related to recruitment success, however, a reported barrier to referral of minorities into clinical trials is a lack of minority researchers.^{18,21–22} Studies of recruitment of African Americans into clinical trials showed recruitment was successful when minorities were on the research team.^{23–24} Communication is clearly paramount to clinical trials decision-making, however, physicians have poorer communication with patients of ethnic and cultural backgrounds different from their own and research shows an ongoing need for cultural sensitivity training.^{25–26} For these reasons it is imperative to have ethnic minority physicians who are knowledgeable about clinical trials, comfortable communicating with their patients regarding opportunities, and understanding of patients’ unique cultures. It follows that in order to adequately increase minority representation in clinical trials, and specifically that of Latinos, it is first necessary to examine Latino physicians’ attitudes and practices regarding clinical trials.

Given that research regarding Latino physicians’ involvement in clinical trials is important to understanding potential barriers and promoters to recruitment of Latino patients, but is none-the-less lacking, the current article addresses this apparent gap in the literature by examining the association of physician race/ethnicity (Latino vs. White) to physician clinical trial attitudes and practices. Because only 13% of all physicians in the U.S. participate in clinical trials as clinical investigators, and Latino physicians may have a unique cultural understanding of what clinical trials represent to patients and thus hesitation about recruiting and referring patients, the authors surmised that Latino physicians would be less involved in clinical trials than their White counterparts.^{7,17,27}

Assessing racial/ethnic differences in physicians’ willingness to participate in clinical trials is crucial for pinpointing appropriate areas for intervention and education designed to promote equity in clinical trial participation.

Materials and Methods

Participants and Data Collection

The study focused specifically on attitudes and practices of Latino and White physicians who care for Latino patients. Physicians were randomly selected from the American Medical Association (AMA) Master file database and eligible for inclusion if they self-identified as Latino/Hispanic or White/Caucasian (hereafter referred to as “Latino” and “White”), were younger than 65 years old, located in one of five geographic regions with large Latino populations (California, Texas, Florida, New York/New Jersey, and Illinois), and categorized as general internist, family physician, gynecologist, or oncologist. The five geographic locations also coincided with the regional offices of *Redes en Acción*, the multi-site NCI initiative to combat cancer among Latinos, which largely funded the study. The sample was stratified to have an equal number of physicians by ethnicity, region, and specialty. A target sample of 200 physicians from each location and the two ethnic groups yielded a total selected sample of 2,000 physicians, which was estimated as an adequate number to allow comparisons of ethnicity with equal representation of each of the five regions. Because physicians were randomly sampled, they should be adequately representative of physicians of similar ethnicity and geographic area.

The 2,000 physicians were mailed surveys in November 2001, and a second mailing was sent in February 2002. Survey packets included five dollars as an incentive. Physicians were informed that the purpose of the study was to learn about their practice needs and priorities; to gather information on their knowledge, attitudes, and practices regarding cancer screening with adult Latino patients; and to assess their communication with Latino patients. Physicians were informed that the collected data would be useful for raising awareness of important general and cancer-specific education and research issues among the medical community and public. The surveys did not contain identifying information, but were linked to identifying information by a Case ID Number. The Project Manager was the only person with access to the Master List containing identifying information.

Measures

The entire survey assessed physicians’ general and cancer-specific prevention practices and attitudes, and it emphasized certain areas to evaluate the extent to which physicians were following recommended cancer screening and prevention guidelines (especially controversial or unclear guidelines). The focus of this article is on one section of the survey that was devoted solely to physician involvement in clinical trials, which was not cancer-specific. The items assessed the level of involvement in clinical trials; the type of clinical trial in which the physician was most likely to enroll a patient; the extent to which the physician felt the scientific value of clinical trials outweighed limitations, risks, and ethical concerns; and, assessment of which factors would make a physician more likely to recommend to their patients that they participate in clinical trials. Survey items were developed with input from and review by physicians who participated in clinical trials and by review of the literature.^{7–9,12,14,16,20} All items were used as single item indicators and not as scales.

Physician Race/Ethnicity—Physician self-reported race/ethnicity was the predictor, stratified as Latino or White.

Clinical Trials Involvement—One item read, “In your practice, what has been your involvement in clinical trials? (Check all that apply).” This item included ten “check all that apply” response options: 1) I have had patients inquire about clinical trials; 2) I have referred patients to clinical trials administered by others; 3) I have recruited patients for a clinical trial that I helped administer; 4) I have referred patients to clinical trials who were not accepted; 5)

I have had patients inform me that they have enrolled in a clinical trial without my prior knowledge; 6) I have participated in the design and implementation of a clinical trial; 7) I have administered a clinical trial; 8) I have participated in the evaluation of a clinical trial; 8) I have participated in a clinical trial in other ways; and 10) I have never been involved in a clinical trial. Therefore, if items were checked they indicated a “yes” response to the item, while unchecked items represented a “no” response.

Participation by Type of Clinical Trial—One item read “For which of the following types of clinical trials would you be most likely to enroll patients? (Check all that apply).” The four response options were: 1) Screening/diagnostic trial; 2) Prevention action study (behavior modification); 3) Prevention action agent (chemotherapy); and 4) Treatment. Again, if items were checked they indicated a “yes” response to the item, while unchecked items represented a “no” response.

Clinical Trials Value—The survey contained a 5-point Likert scale item that read, “In general, do you feel that in most clinical trials the scientific value of what can be learned outweighs the limitations, risks, and ethical concerns?” Response options ranged from “strongly disagree” (1) to “strongly agree” (5).

Factors Influencing Recommendations—Lastly, one item assessed factors influencing the likelihood that a physician would recommend a clinical trial: “Which of the following factors would make you more likely to recommend that a patient participate in a clinical trial? (Check as many as apply).” The eight response options were: 1) The trial is likely to improve their medical condition; 2) My familiarity with the protocol or physician leading the study or institution conducting the study; 3) Patient’s lack of other means to pay for health care; 4) Patient’s desire to take a more active role in their health care; 5) Patient’s desire to get regular and careful medical attention; 6) Patient’s desire to advance medical knowledge; 7) Patient’s desire to take advantage of the latest available treatment options; 8) Other. This item subset again indicated a “yes” response to the item if it was checked, while unchecked items represented a “no” response.

Data Analysis

It was important to evaluate whether unchecked responses truly indicated “no” responses or if they were missing values due to failure to respond. Because the nature of the survey items and response options made it difficult to distinguish “no” from missing responses, the first step of data analysis was to determine the extent of missingness among the groups of interest – Latinos and White physicians. A Missing Value Analysis (MVA) was performed to examine the patterns of missingness among the clinical trials items of interest, and any cases missing all clinical trials items of interest were excluded from further analyses, given that all respondents should have been able to answer “yes” to at least one item. The MVA included construction of an indicator variable representing cases that were missing all clinical trials items versus those who had at least one response, and cross-tabulations with chi-square statistics were conducted with that indicator variable to determine the association of physician race/ethnicity to missingness of clinical trials items. This process was also performed for other core items in the survey, but not used in this study, to compare patterns of missingness for clinical trials items to the rest of the survey. Once it was determined that there was not a significant difference in missingness of clinical trials items between Latino and White physicians or between clinical trials items and other pertinent item sets, the authors were confident that bias did not exist due to missingness related to physician race/ethnicity, and subsequent analyses proceeded.

Descriptive statistics were calculated for sociodemographic items, practice characteristics, and clinical trials involvement items. Univariate analyses, used to identify significant associations

between physician race/ethnicity and sociodemographic/practice characteristics, included t-tests for continuous variables and Chi-square statistics for categorical variables. Chi-square tests were also used to identify associations between physician race/ethnicity and clinical trials involvement, the type of trial in which the physician was most likely to enroll a patient, feelings toward the scientific value of clinical trials, and factors that would make a physician more likely to recommend that patients participate in clinical trials. The Sequentially Rejective Bonferroni Test was used to control the overall Type I error rate in multiple testing.²⁸

Multivariate analyses were run to test the ability of physician race/ethnicity (independent variable) to predict responses to clinical trials items (outcomes), with the inclusion of potential confounders (covariates). Clinical trials items were modeled as outcomes if they were significantly associated with physician race/ethnicity in univariate analyses at $p < 0.05$. Potential confounders were physician sociodemographic and practice characteristic items that showed significant association to physician race/ethnicity in univariate analyses at $p < 0.05$. A General Linear Models approach was used to model a Likert-scaled outcome assessing clinical trials value. All other models were tested with logistic regression, as the remaining dependent variables were dichotomous (yes/no). Goodness-of-fit was assessed with the Hosmer and Lemeshow Test. Adjusted odds ratios (ORs) with 95% confidence intervals (CI) were reported. The statistical level of significance for all tests was α less than 0.05 for data interpretation. All analyses were conducted using SPSS for Windows.²⁹

Results

Demographic and Practice Characteristics

The physician survey was completed by 742 physicians; the response rate was 37%. Responders differed slightly from the entire sampling frame by physician race/ethnicity; 50% of the sampling frame was reportedly White and 50% was Latino, in contrast to survey responders, whereby 41% were Latino and 55% were White. For statistical analysis, the final sample was 695 after inclusion of only Latinos and Whites (only 3.3% of the original sample were African American, Asian American, or Other) and exclusion of the 14 cases that were missing all clinical trials items.

The mean age of physicians was 45.8 (SD=8.5) years. Nearly 43% of physicians self-reported ethnicity as Latino/Latin American/Hispanic, 71% were male, and the majority (71%) attended medical school in the U.S. Most physicians specialized in Family Medicine (37.6%) and did not have subspecialty training (74.1%). All physicians provided patient care and, on average, spent the majority of their work week in direct care (94.4%). Demographic and practice characteristics are presented in Table 1. Comparisons of characteristics between physicians who were missing all clinical trials items and those who were not revealed that those missing all items were older with a mean age of 50.9 (SD=10.34) years, reportedly treated a greater number of patients less than 40 years old, $t(686) = -2.289$, $p < 0.05$, a lesser number of patients over 65 years old, $t(12.712) = 5.601$, $p < 0.001$, and a lesser number of those using Medicare, $t(12.792) = 4.368$, $p < 0.01$ (data not shown).

Several significant differences were found for demographic and practice characteristics between Latino and White physicians (Table 1). Latino physicians were more likely than White physicians to attend medical school outside of the U.S. ($\chi^2(1) = 72.91$, $p < 0.001$) and were younger than White physicians, $t(689) = -2.104$, $p < 0.05$. They also differed in their type of clinical practice ($\chi^2(7) = 24.89$, $p < 0.01$); White physicians worked more often than Latinos in private offices in a group practice and in university-based settings. Latino and White physicians reported that they saw different patients in regards to ethnicity and insurance status.

Association of Physician Race/Ethnicity and Clinical Trials Participation Items

Clinical Trials Involvement—There were significant associations of physician race/ethnicity and clinical trials involvement for over half of the responses (Table 2). Physician race/ethnicity was significantly associated with patients inquiring about clinical trials ($\chi^2(1)=15.23, p<0.001$), where Latino physicians more often reported that patients did not inquire. Physician race/ethnicity was also significantly associated with referring patients to clinical trials administered by others ($\chi^2(1)=9.29, p<0.01$), where Latino physicians again reported doing so less often than White physicians. Similarly, White physicians reported that they more often recruited patients for clinical trials that they helped administer ($\chi^2(1)=4.78, p<0.05$), referred patients who were subsequently not accepted to clinical trials ($\chi^2(1)=26.97, p<0.001$), and had patients enroll in a clinical trial without their prior knowledge ($\chi^2(1)=15.72, p<0.001$). Finally, Latino physicians more often responded that they had never been involved in a clinical trial in any way ($\chi^2(1)=10.61, p<0.01$).

Participation by Type of Clinical Trial—Physician race/ethnicity was associated with the type of trial into which they were likely to enroll their patients (Table 2). White physicians were more likely to enroll patients in treatment trials than Latino physicians ($\chi^2(1)=6.19, p<0.05$).

Clinical Trials Value—Physician race/ethnicity was related to perceptions of scientific value ($\chi^2(4)=14.58, p<0.01$), whereby White physicians more often agreed (63%) or strongly agreed (10.9%) that the value of what can be learned from clinical trials outweighs the limitations, risks, and ethical concerns (Table 2). Latinos were more likely to strongly disagree (4.1%), disagree (13.9%), and be undecided (19.4%) about the value of clinical trials. While White physicians place more value on clinical trials than Latinos, it is noteworthy that 26% still reported being undecided or disagreed that value outweighs risk.

Factors Influencing Recommendations—Significant associations of physician race/ethnicity and factors that would make one more likely to recommend that a patient participate were found for two items (Table 2): the physician's familiarity with the protocol, physician leading the study, or institution conducting the study ($\chi^2(1)=7.90, p<0.01$); and, the patient's desire to advance medical knowledge ($\chi^2(1)=10.23, p<0.01$). In both cases, White physicians more often reported that these two factors would make them more likely to recommend to a patient that they participate (62.8% and 56%, respectively).

Ability of Physician Race/Ethnicity to Predict Clinical Trials Outcomes

There were 10 clinical trials items that were significantly associated with physician race/ethnicity in univariate analyses, therefore, 10 models were constructed for multivariate analyses. Based on the likelihood ratio Chi-square test, three of the overall models were statistically significant ($p<0.05$); results of these models are shown in Table 3. Physician race/ethnicity was a significant predictor ($p<0.05$) in one model ("I've had patients inquire about Clinical Trials" as outcome). Latino physicians were 1.795 (95% CI, 1.023 to 3.149) times more likely to respond "no" than White physicians.

Discussion

Association of Physician Race/Ethnicity and Clinical Trials Participation Items

Overall, less than half of Latino and White physicians reported participating in clinical trials, which is concordant with recent research.²⁷ As expected, this study identified differences in Latino and White physicians' experiences and attitudes related to clinical trials, which could help explain ethnic disparities in clinical trial participation of patients. Race/ethnicity of the physician was significantly associated with clinical trial involvement for six out of ten items,

where Latino physicians reported lower levels of involvement than White physicians in all cases. In addition, nearly one-third of White physicians reported they had never been involved in a clinical trial, while one-half of Latino physicians reported such.

White physicians reported more often than Latino physicians that they referred patients to clinical trials who were subsequently not accepted. This could be due to the fact that White physicians tend to refer more patients to trials in general. Latino physicians referred fewer patients to clinical trials administered by others and recruited less patients to trials that they personally administered. Perhaps Latino physicians in this sample referred their patients to clinical trials administered by others less often because of the aforementioned barriers, including mistrust of researchers, fear the patient would be deemed ineligible, and cultural concerns that their minority patients would feel like they were receiving inadequate treatment or being treated like “guinea pigs.”^{7,17} It also follows that Latino physicians in this sample would report lower levels of recruitment into their own clinical research studies, because so few of them have administered their own trials.

Latino physicians were more likely than White physicians to report that their patients inquired less about clinical trials. One may postulate that the most likely reason for this is that Latino physicians’ patients, of whom the majority is Latino, lack awareness of clinical trials. Also, White physicians had more patients who enrolled in clinical trials without their knowledge, indicating that their patients sought out their own opportunities, regardless of physician input. Again, one may postulate that this is because the majority of the White physicians’ patients were White and have greater awareness of clinical trials options. These assumptions are in line with previous research indicating that ethnic minority patients have low clinical trial awareness when compared to nonminorities.³ With underserved patients lacking awareness, and Latino physicians’ limited exposure to clinical trials, one would expect very little, if any, communication between them regarding clinical trials. Thus, interventions to increase awareness of the benefits of clinical trials need to be directed at both patients and physicians.

This study also identified ethnic differences in physicians’ attitudes toward clinical trials. There was a significant difference between Latino and White physicians in perceptions of the scientific value of clinical trials. Eighteen percent of Latino physicians disagreed or strongly disagreed that the scientific value of clinical research outweighs the risks and ethical concerns, compared to only 9.3% of White physicians. This is an important finding, as it may speak to the reason why Latino physicians showed less involvement in clinical trials. These results offer an opportunity to intervene with Latino physicians, providing education regarding the benefits, limitations, and overall scientific value of clinical trials; informed consent procedures; the role of institutional review boards; and experimental subjects’ bill of rights. Promoting this understanding among Latino physicians would foster opportunities for their Latino and non-Latino patients alike. And while Latino physicians did not perceive the same value in clinical trials that White physicians did, it is noteworthy that 26% of White physicians did not feel that value outweighed risk. This finding indicates that there is still a large amount of physicians overall who do not find value in clinical trials.

When asked what types of trials they would enroll their patients in, both Latino and White physicians chose screening/diagnostic trials most often, followed in rank-order by treatment trials, prevention action studies (behavior modification), and prevention agent studies (chemotherapy). Latino physicians reported that they would refer their patients to treatment trials significantly less often than White physicians, but there were no other significant associations of trial type and physician race/ethnicity. This finding is interesting given that the majority of clinical trials are treatment trials. This indicates a mismatch in the type of trials available and in what trials Latino physicians are willing to enroll their patients. This finding also supports the hypothesis that Latino physicians may be more hesitant to refer their Latino

patients due to their own or their patients' perceptions of mistrust and potential experimentation.

Regarding factors that would make the physician more likely to recommend their patient participate in a trial, there were few significant associations between race/ethnicity and individual factors. Specifically, White physicians more often felt that their familiarity with the protocol, physician leading the study, or institution conducting the study would lead to a recommendation for their patient to participate, as well as the patient's desire to advance medical knowledge. Both Latino and White physicians endorsed all items to a large extent. The factor most highly endorsed was that the trial would improve the patient's medical condition. All other factors involved patients' desires, suggesting that perceptions of their patients' desires are leading factors in recommending that patients participate. Physician perceptions of the trial's ability to improve their patients' health, as well as patient desires, may act as either barriers or promoters to patient clinical trial involvement.

In this study, Latino physicians treated a significantly greater number of Latino patients than White physicians, as well as economically disadvantaged patients on Medicaid or those who were uninsured, and patients who are monolingual Spanish speakers. This is probably related to practice setting, as Latino physicians more frequently practiced in private community clinics, HMOs, public hospitals/clinics, and VA hospitals/clinics, while White physicians practiced in a private office/group practice or university-based medical practice. Differences in practice settings may also partially account for clinical trials related experiences and attitudes given that clinical trials often occur in academic settings.

Ability of Physician Race/Ethnicity to Predict Clinical Trials Outcomes

In the three models that were significant overall, physician race/ethnicity was a significant predictor of only one outcome after adjusting for confounding variables: Latino physicians were more likely than White physicians to respond that they have not had patients inquire about clinical trials, perhaps because their patient population is largely Latino and experiences the aforementioned barriers. Physician race/ethnicity showed no significance in the other two regression models indicating there are other factors influencing clinical trials involvement. The conducted analyses suggested that location of medical school, clinical practice type, and perceived insurance status of patients affects clinical trials involvement, regardless of whether the physician is Latino or White. Physicians who attended medical school in the U.S. showed a higher likelihood of patients enrolling in clinical trials without their prior knowledge. Physicians who practiced in University-based medical practices were more likely to have referred patients to clinical trials who were not accepted, and those who practiced in Public Hospitals were more likely to have patients inquire about clinical trials. Also, physicians who reportedly treated more uninsured patients were more likely to have referred patients to trials who were not accepted. Finally, it is important to note that physician age and patient race/ethnicity were not significant predictors of clinical trials participation among physicians, regardless of their ethnicity. The findings of the multivariate analyses highlight important areas for future research.

Strengths and Limitations

There are several caveats to consider when interpreting the results of this study. The data were cross-sectional; thus, causal inferences cannot be made. Since this study was based on self-report data, one must keep in mind the potential for respondent bias. The physicians who responded to the survey may in fact participate in research to a greater degree, which would result in a sample biased toward reporting participation in clinical trials, thus, possibly overestimating the extent to which physicians participate in general. There is also the possibility that physicians responded in a socially desirable manner. Thus, Latino and White physicians'

actual participation in clinical trials may be lower than reported, which would indicate an even greater need for increasing awareness of and opportunities to participate in clinical trials. Also related to self-report limitations, physicians reported their patient population as they perceived it; actual patient-level data were not collected. This limited the ability of this study to examine within- and between-physician differences in treating patients of different ethnicities; for example, whether patients of different ethnicities are treated differently by the same physician, and whether those differences varied by the physician's ethnicity. Lastly, the AMA Master File has inherent qualities that may produce selection bias and affect the validity of the data; for instance, physician specialty is self-reported and there are lags in reporting and updating data.^{30–31} Even so, researchers continue to use the File because it is the most complete and authoritative source for data on U.S. physicians.³²

The study had several important advantages. Comparatively, the sample was large with an almost equal number of Latino and White respondents, represented multiple specialties and practice types, and covered multiple regions of the country. In addition, it appears to be the first study of its kind, specifically examining differences in clinical trial participation between Latino and White physicians. The survey assessed several areas of clinical trials participation, including various types of involvement, feelings about the scientific value of trials, and factors that would influence a recommendation for patients to participate, thus, suggesting several areas in which to intervene should these findings be confirmed in other studies.

Conclusions

Race/ethnicity of a physician is significantly associated with the level of involvement in clinical trials, the types of clinical trials the physician is likely to enroll a patient in, beliefs about their scientific value, and the factors that would make them more likely to recommend that a patient join a trial. Latino physicians, when compared to White physicians, were significantly less involved in clinical trials and found less scientific value in them, which has implications for whether they recommend them to their patients. Also, Latino physicians have a higher likelihood of saying that their patients have not inquired about clinical trials, and this was true after adjusting for potentially confounding factors. In addition, Latino and White physicians' perceptions of a trial's ability to improve their patients' health was the most frequently cited reason for recommending a trial, followed by the patients' desires. All of these findings are prime areas on which to focus awareness campaigns.

Thus far, ethnic differences in clinical trials attitudes and behaviors have received little attention. Research should identify mechanisms that explain Latino physicians' lower likelihood of participating in and referring their patients to clinical trials, as well as why their patients do not inquire about clinical trials. As analyses in this study have suggested, further study is needed to evaluate the influence that patient and physician characteristics have on the relationship of physician race/ethnicity and clinical trials participation. Future studies should evaluate the specific reasons why Latino physicians find less value in clinical trials than White physicians. Such research would lead to culturally tailored interventions and education that may simultaneously increase opportunities for involvement of patients and physicians in clinical trials, while ensuring that the benefits of participation are equitably distributed to patients. In addition to outreach and education for physicians, to address the barrier of language specific to Latino patients, the formation of bilingual study teams could enhance the ability of Latinos to participate in clinical trials. Language was not assessed as a potential barrier to clinical trials participation in this study, but it poses a challenge to patient-provider communications, attempts to recruit patients into trials, and patient eligibility.^{33–34} Specifically, language factors may make it difficult for provider teams to communicate with patients regarding consent forms and clinical trials documents; hinder recruitment into trials for several reasons, one of which is the cost and effort to translate study materials into Spanish

and back-translate into English, as required by Institutional Review Boards; and, hinder the ability patients to participate, as many U.S. trials require English proficiency. The formation of bilingual teams would help to address the language barrier and increase opportunities for Latino patients, while concurrent educational initiatives might increase opportunities for Latino physician involvement.

The study represents a critical first step in addressing a gap in the literature regarding Latino physicians and clinical trials involvement. It highlights potential areas for focused Latino physician and community-based education to promote communication and clinical trials opportunities among their minority and non-minority patients alike. Given that Latino physicians deal with largely Latino patient populations, such efforts could also serve to address ethnic disparities in clinical trials participation. These disparities will become increasingly important as the Latino population continues to increase.

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Table 1
Sociodemographic and Practice Characteristics of Physicians

Characteristic	Mean (SD) or Percent Distribution		p-value ^f
	Overall	Whites (N=398)	
<i>Age</i>	45.8 (8.5)	46.4 (8.7)	<0.05
<i>Gender</i>			
Female	29.1%	29.6%	0.716
Male	70.9	70.4	
<i>Location of Medical School</i>			<0.001
United States	71.2	83.9	0.922
Other Country	28.8	16.1	
<i>Specialty</i>			
Family Medicine	37.6	36.6	0.616
Internal Medicine	35.6	36.3	
OB/GYN	23.9	24.0	
Other	2.9	3.1	
<i>Subspecialty</i>			
Yes	25.9	24.9	<0.01
No	74.1	75.1	
<i>Clinical Practice Type</i>			
Private Office, Solo Practice	26.7	23.8	<0.01
Private Office, Group Practice	45.4	52.1	
Community Clinic	4.4	3.3	
HMO	4.0	3.1	
University-based Med. Practice	6.2	7.4	
Public Hospital/Clinic	5.0	3.6	
VA Hospital or Clinic	1.0	0.8	
Other	7.2	5.9	
<i>Majority of Work Week Time Spent</i>			N/A
Direct Care	94.4	95.7	0.780
Other Activities	5.6	4.3	
<i>Patient Sociodemographics</i>			
<i>Age</i>			
Under 40 years old	36.9	36.7	0.811
40 – 64 years old	35.6	35.7	
65 or older	29.3	29.5	0.820
<i>Insurance Status</i>			
Medicare	26.1	27.0	0.189
Medicaid	14.4	10.6	<0.001
Private/Fee for Service	21.0	22.1	0.058
HMO/Managed Care	36.5	37.4	0.313
Uninsured/Free Care/Self-Pay	11.7	9.4	<0.01
<i>Ethnicity</i>			
Asian/Asian American	5.2	5.9	<0.001
Black/African American	13.5	13.6	0.796
Latino/Latin Amer./Hispanic	30.5	17.3	<0.001
Native Amer./Amer. Indian/Alaska Native	1.5	1.2	0.296
Pacific Islander/Native Hawaiian	1.4	1.4	0.960

Characteristic	Mean (SD) or Percent Distribution		p-value ^f
	Overall	Whites (N=398)	
White/European Amer./Caucasian	48.6	60.3	<0.001
Multieethnic/Mixed Ethnicity	6.5	6.1	

^fTwo-sided *p*-value from Fisher's exact tests and Chi-square for comparison of proportions and independent t-test for comparison of means.

Table 2
Association of Physician Race/Ethnicity and Clinical Trials Participation

Item	Percent Distribution		p-value ¹
	Overall	Latino (N=297)	
Clinical Trials Involvement			
Patients inquired about clinical trials (CT)	29.4%	21.5%	35.2%
I referred patients, CT administered by other	48.8	42.1	53.8
I recruited patients, CT administered by self	20.0	16.2	22.9
I referred patient, patient not accepted	17.0	8.4	23.4
Patient enrolled without my knowledge	39.1	30.6	45.5
I participated in design and implementation	9.2	9.4	9.0
I administered a CT	14.1	12.5	15.3
I participated in evaluation	9.6	8.4	10.6
I participated in other ways	19.0	16.8	20.6
I have never been involved	36.5	43.4	31.4
Types of Clinical Trials			
Screening/Diagnostic Trial	68.9	72.1	66.6
Prevention Action Study	48.6	48.8	48.5
Prevention Agent Study	31.7	29.0	33.7
Treatment	61.9	56.6	65.8
Clinical Trials Value			
Strongly Disagree	3.5	4.1	3.0
Disagree	9.6	13.9	6.3
Undecided	17.9	19.4	16.7
Agree	59.1	53.7	63.0
Strongly Agree	10.0	8.8	10.9
Factors Influencing Recommendations			
Will improve medical condition	85.0	84.2	85.7
My familiarity with protocol, physician, or institution	58.3	52.2	62.8
Patient's lack of means to pay	49.5	45.8	52.3
Patient's desire to take active role	50.4	47.8	52.3
Patient's desire to get medical attention	39.7	37.7	41.2
Patient's desire to advance medical knowledge	50.8	43.8	56.0
Patient's desire for latest treatment options	67.3	65.3	68.8
Other	2.2	2.0	2.3

¹Two-sided p-value from Chi-square tests for comparison of proportions.

Table 3

Multivariate statistics for significant logistic regression models

Model: I have had patients inquire about clinical trials (outcome)				
Independent Variables	Regression Coefficient	Standard Error	Significance, <i>p</i>	Odds Ratio (95% CI)
Physician Race/Ethnicity, Latino	0.585	0.287	0.042	1.795 (1.023,3.149)
Physician Clinical Practice Type, Public Hospital or Clinic	−1.325	0.642	0.039	0.266 (0.076,0.935)
Model: I have referred patients to clinical trials who were not accepted (outcome)				
Independent Variables	Regression Coefficient	Standard Error	Significance, <i>p</i> Value	Odds Ratio (95% CI)
Physician Clinical Practice Type, University-Based Medical	−1.777	0.811	0.028	0.169 (0.035,0.829)
Patient Insurance Status, Uninsured	−0.021	0.010	0.027	0.979 (0.961,0.998)
Model: I have had patients inform me that they have enrolled in a clinical trial without my prior knowledge (outcome)				
Independent Variables	Regression Coefficient	Standard Error	Significance, <i>p</i> Value	Odds Ratio (95% CI)
Physician Medical School Location	−0.772	0.270	0.004	0.462 (0.272,0.784)

Note: Only significant results are reported in the table.