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The Effect of Discrimination on Likelihood of Participation in a Clinical Trial

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Abstract

Objectives: Despite efforts to increase minority enrollment in research, racial disparities still exist and a belief persists that minorities are inherently less likely to enroll in medical research. This lingering view may impact the manner in which studies are presented to minority patients. This study aimed to assess racial differences in reported discrimination while seeking medical care and likelihood to participate in a medical research study.

Methods: 844 residents were enrolled via convenience sampling, and asked to complete a survey designed to examine perceived discrimination while seeking healthcare and likelihood to participate (LoP) in a medical research study.

Results: Participants who reported worse treatment than other races had lower mean LoP scores (53.7 ± 17.6) than participants who reported being treated the same as (61.1 ± 16.1) or better than (64.0 ± 15.0) other races ($p < .001$). There were no significant differences in mean LoP score by race/ethnicity. The interaction of race with discrimination had no significant effect on mean LoP ($p = 0.8$). There was a statistically significant association between race and discrimination ($X^2 = 11.32$, $p = 0.023$), although the majority of participants reported no discrimination.

Conclusion: Patient experiences in the medical arena may have an impact on their willingness to join a medical study. An effective strategy to increase minority participation in research may be to work with investigators and staff on implicit bias with regards to minority patients. Further research should focus on the impact of research staff interactions on an individual's decision-making process.

Keywords

minority; clinical research; discrimination

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Conflict of Interest:

Amie Devlin declares that she has no conflict of interest. Evelyn Gonzalez declares that she has no conflict of interest. Frederick Ramsey declares that he has no conflict of interest. Nester Esnaola declares that he has no conflict of interest. Susan Fisher declares that she has no conflict of interest.

Ethical Approval: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional review committee and with the 1964 Helsinki Declaration and its later amendments.

Informed Consent: Informed consent was obtained from all individual participants included in the study.

INTRODUCTION

It has been 25 years since the National Institutes of Health (NIH) enacted the Revitalization Act which required the inclusion of women and minorities in clinical research (1). In these years, there have been increases in the proportion of minorities participating in clinical research. According to the 2010 US Census, 12.6% of the US population identifies as black or African American (2). For the same year, the NIH reported that blacks made up 11.9% of total domestic enrollment for NIH trials (3). In FDA-approved applications between 2010 and 2012, Eshera et al. (4) found that 77% of study participants were white, which approximates the 2012 US Census estimate that 74.17% of the US population is white (5).

Although the above-mentioned statistics indicate that racial/ethnic participation in medical research studies is beginning to approach population proportions, other data have been mixed. While the rates of Hispanics participating in medical research have been consistently increasing, the gains have lagged behind those for blacks. While Hispanics make up 16.3% of the population (2), they only account for 7.8% total domestic enrollment for NIH trials (3).

Furthermore, though the minority participation percentages are approaching parity with the population percentages, their small absolute size has a negative effect on the statistical ability to analyze trial results separately by race. The small number of participants in each minority group limits the statistical power and restricts the results that can be drawn from such sub-group analyses. The reduced applicability of the results by racial/ethnic subgroups is of particular importance considering that racial/ethnic minorities are disproportionately affected by certain chronic diseases, such as diabetes and heart disease (6, 7).

The purpose of this investigation was to analyze factors which may impact an individual's decision of whether or not to participate in a medical research study. The research had a specific focus on perceived discrimination when seeking medical care as an important predictor of willingness to join a medical research study.

METHODS

Study Population

This cross-sectional study was funded by the National Cancer Institute Population Assessment Supplement. The enrollment goal of that study was to survey 1,000 residents in the Fox Chase Cancer Center (FCCC) catchment area. This area includes six counties in Pennsylvania (including Philadelphia), and nine counties in New Jersey. A secondary enrollment goal of this study was to target medically underserved communities. Participants could meet the criteria of medically underserved either individually—by being uninsured or covered by government subsidized health insurance—or by residing in a ZIP code that met one of the following criteria: Health Resources and Services Administration (HRSA) defined medically underserved area, low education (less than 79% of residents graduated from high school), or low income (median income less than \$38,000). According to these criteria, 76% of study participants were considered medically underserved.

To target medically underserved populations and to ensure high minority representation, two distinct research teams were utilized for recruitment. Minority enrollment was primarily conducted by Temple Health: Block-by-Block (THB3), a community research program which aims to engage with residents of Temple University Hospital's (TUH) catchment area. TUH's catchment area is comprised of urban, primarily minority neighborhoods; approximately 46% of residents identify as black and 30% are Hispanic or Latino (8). By contrast, the remaining counties in the FCCC catchment area have predominantly white populations similar to that of the U.S. overall(8)

All members of the study population were required to: be at least 18 years of age, be able to speak either English or Spanish, reside within the 15 target counties, and provide their home address. For Spanish speakers, surveys were administered by study team members who were fluent in both English and Spanish. Participants were recruited from October 2017 through April 2018. Study participants were recruited door-to-door, at community venues/events, and by phone. Survey method varied slightly between the THB3 and FCCC research teams. While all 439 surveys collected by the THB3 team were collected in-person and on paper, the 405 surveys collected by the FCCC team were done either in-person utilizing iPads (n = 280) or via telephone (n = 125). The FCCC and THB3 portions of the study were reviewed and approved by the FCCC IRB and the Temple University IRB, respectively.

Measures

Completion of the entire survey took approximately 35 minutes and consisted of previously validated questions on a broad scope of general health and cancer-related topics. The two sections of the survey utilized for this study were the Tuskegee Legacy Project's Likelihood of Participation (9) scale and the Reactions to Race questions from the 2014 Behavioral Risk Factor Surveillance System (BRFSS) Questionnaire.

The goal of the LoP scale is to quantify an individual's willingness to participate in medical research. This 17-item scale asks participants to rank their willingness to participate in a medical research study under a variety of conditions, such as different study procedures and different study funders. Participants are asked to select their response from the following Likert-style scale: *very likely, somewhat likely, not quite sure, somewhat unlikely, very unlikely*. As part of its creation, the LoP Scale was validated among white, black, and Hispanic participants to ensure that it was psychometrically sound in different racial/ethnic groups (10).

The BFRSS Reactions to Race module was first added to the survey in 2002 and has been used periodically since that date (11). The module consists of two questions which captures the respondents' experiences of discrimination in health care settings and in the workplace. Due to the health care focus, this study only utilized the question regarding health care settings. Participants were asked to rate their treatment while seeking health care, and to indicate whether they felt they were treated worse than, the same as, or better than people of other races (12). All study data were entered in a secure, web-based Research Electronic Data Capture (REDCap) database.

Statistical Analysis

For this study, race/ethnicity was separated into three categories: Hispanic, non-Hispanic black, and non-Hispanic white. The decision to categorize Hispanic blacks as Hispanic (rather than as black) was based on the importance of self-identity. This study is focused on an individual's perception of discrimination in medical care. As such, the racial/ethnic category that an individual feels most associated with is the one that they are likely to feel is the basis for any discrimination. According to a Pew Research survey, 67% of Hispanic adults describe their Hispanic background as part of their racial background (9). Additionally, the Census Bureau demonstrated in 2016 that when given the option to select from multiple race/ethnicity categories, 81% of those identifying as Hispanic/Latino marked only the Hispanic box and identified no racial category (13).

Descriptive statistics were used to characterize the survey data. For categorical data, numbers and/or percentages are presented by selected groups. For continuous data, means, standard deviations, and distributional statistics as appropriate are presented. The normality of select continuous variables was assessed using Q-Q plots and histograms. Chi-square tests and t-tests (or ANOVA as appropriate) were conducted to assess the association between groups for categorical and continuous variables, respectively. All analyses were performed using SAS 9.4 (SAS Institute, Cary, NC). A p-value of less than 0.05 was considered statistically significant. All reported p-values are two-sided where applicable and are not adjusted for multiple comparisons.

RESULTS

Of the 1,000 participants enrolled, 844 were included in analysis. Participants were excluded from analysis if they were missing data for race/ethnicity, perceived discrimination, or LOP score. Additionally, this study focused on differences between the following racial/ethnic categories: Hispanic, non-Hispanic black, non-Hispanic white. As such, participants were omitted if they were multiracial or did not identify as one of these three racial/ethnic categories. The participants included in analysis were primarily black (57.2%), female (67.7%) and had a mean age of 50.5 years. White participants were older than black or Hispanic participants ($p = <.0001$). Forty-one percent of participants had a household income less than \$20,000 and 13.8% had less than a high school degree (Table 1).

When asked about perceived discrimination in medical settings, most participants (83.41%) indicated that they were treated the same as other races (Table 2). This was seen across all racial/ethnic groups (non-Hispanic White: 82.35%, non-Hispanic Black: 82.82%; Hispanic: 85.58%). However, the percentage of black and Hispanic participants who felt that they were treated worse than other races was more than four times that of white participants (8% vs. 2%; $p = 0.0232$).

For all racial/ethnic groups combined, mean LOP score was 60.88, with minimal variation among Hispanic participants (61.2), non-Hispanic blacks (61.0), and non-Hispanic whites (60.5) ($p=0.9770$; Table 3). As shown in Table 4, differences in LoP scores based on how participants felt that they were treated demonstrated that those who felt that they were treated worse than other races in health care settings had substantially lower LoP scores

(50.67) than those who felt that they were treated the same as (61.01) or better than (64.41) other races. These differences were statistically significant ($p = 0.0013$). A regression model to examine possible interaction of race and discrimination related to LoP demonstrated no significant joint effect of these variables on mean LoP score ($p = 0.8$).

DISCUSSION

In our sample, we found an inverse and statistically significant relationship between perceived discrimination in the medical arena and reported likelihood to participate in clinical research. Conversely, there was no difference in LoP score between the three racial/ethnic groups included in this analysis. This suggests that a reduction in discriminatory treatment in health care settings may result in an increase in minority participation in clinical research. Furthermore, it challenges the notion that low minority enrollment in clinical research can be solely attributed to a reduced willingness of minorities to participate.

This hypothesis is further supported by analogous research showing that perceived discrimination in medical settings has an influence on individuals' care decisions. Casagrande et al. (14) found that increased racial discrimination was associated with higher odds of both delaying medical care and nonadherence to care recommendations. Patients who have experienced past racial discrimination in medical settings have similarly been found to have lower odds of reporting their interactions with medical providers as warm or respectful (15). Additionally, Armstrong et al. (16) found that past experiences of racial discrimination was associated with a 30% increase in odds of health care system distrust. Future research is needed to investigate the association between health care system distrust and likelihood to participate in clinical research.

In our study, we found that, compared to whites, a higher proportion of black and Hispanic participants reported racial discrimination in medical settings (Whites: 1.92%; Hispanics: 7.84%; Blacks: 8.28%). These percentages are consistent with research by Hausmann et al. (15), who found similar discrimination disparities among racial/ethnic minorities (Whites: 2.0%; Hispanics: 5.2%; Blacks: 10.9%). Though these percentages are small on an absolute scale, they show a substantive disparity in how minorities experience healthcare.

While the lasting effect of the Tuskegee Study on the willingness of racial/ethnic minorities to participate in clinical research is an important topic, this relationship has been studied elsewhere (17, 18) and was not included in this analysis. Further, while historical missteps may impact the enrollment of minorities into clinical trials, it is vital to find other, modifiable factors that may influence enrollment. Our results indicate that treatment while seeking healthcare may impact an individual's likelihood to participate in a clinical trial and suggests that this avenue should be explored in order to achieve parity in racial/ethnic enrollment rates. The finding that racial/ethnic minorities report discrimination at higher rates than Whites goes beyond the demonstrated effect on LoP; these results also suggests a need for further research to identify direct and implicit actions which may be causing racial/ethnic minorities to report discrimination at higher rates.

This study is not without limitations. The enrollment goal of this study was to target the medically underserved community. As such, the results of this study may not be generalizable to the larger population. However, clinical trial enrollment rates remain low among medically underserved populations (19). Therefore, the applicability of these findings to the medically underserved may heighten their impact.

Another limitation of this study is that enrollment was done via convenience sampling. However, steps were taken to minimize the limitations of this method. Various strategies were used to enroll a diverse group of participants. Much of the enrollment was done during regular business hours via door-to-door canvassing and tabling at community spaces (i.e. libraries, parks, etc.), which had the effect of targeting participants who were home during the day. This could result in a disproportionate number of participants being home due to retirement, disability, or unemployment, thus skewing the sample to be older, sicker or of a lower economic status. However, as previously mentioned, this sampling strategy was used intentionally to ensure that a large percentage of participants qualified as medically underserved. Additionally, efforts were made to offset this bias and enroll participants with more traditional work schedules. The recruitment efforts described above were supplemented with activities conducted in the evenings and on weekends. The research team set-up tables at weekend health fairs, attended community events in the evening, and allowed surveys to be conducted over the phone.

A recruitment strength of this study is the community focused approach. Rather than enrolling at a hospital or medical center, the research team went into the community for recruitment. This enabled enrollment of participants who may be uninsured or do not routinely seek out medical care. Additionally, as this study was conducted by an academic health center, the community-based approach prevented generalizability concerns derived from enrolling only patients who sought care at Temple Hospital and/or Fox Chase Cancer Center.

To our knowledge, this is the first study to examine the association of discrimination and likelihood to participate in medical research studies. This study provides evidence that clinical trial enrollment may be associated with patients' previous personal experiences of racial discrimination and lays the groundwork for future research on this topic. The findings of this study are strengthened by the use of validated survey instruments to assess discrimination and likelihood to participate. As previously mentioned, the development of the LoP scale involved a three prong validation process to ensure that it did not result in significant differences when used in different racial/ethnic groups (10). Therefore, we can be confident that this study's LoP score consistency across the three racial/ethnic groups was not due to a flawed instrument.

CONCLUSION

This study does not attempt to quantify the complex decision-making process an individual uses when considering enrollment into a medical research study. Rather, it seeks to lay the foundation for further research into this topic. Though one of the first studies looking at the role of discrimination on the decision-making process, this study adds to growing literature

which suggests that a person's perceived treatment in a medical setting may influence their health care decisions.

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Table 1.

Demographics by Racial/Ethnic Group

	Total	Non-Hispanic White	Non-Hispanic Black	Hispanic	<i>p-value</i>
No. of Participants	844	208	483	153	
Age in yrs, mean (SD)	50.5 (16.1)	56.4 (17.3)	49.5 (15.3)	46.0 (14.5)	0.6507
Sex, %					<.0001
Female	67.85%	68.27%	68.67%	64.71%	
Male	32.15%	31.73%	31.33%	35.29%	
Education, %					<.0001
Less than 12 years	13.76%	7.21%	13.28%	24.18%	
Completed High School	26.57%	17.79%	30.29%	26.80%	
Post High School	59.67%	75.00%	56.43%	49.02%	
Household Income, %					<.0001
Less than \$20,000	41.15%	17.22%	47.11%	52.90%	
\$20,000 to under \$35,000	13.02%	8.89%	14.67%	13.04%	
\$35,000 to under \$50,000	16.93%	10.00%	14.44%	14.49%	
\$50,000 or more	32.42%	63.89%	23.78%	19.57%	

Table 2.

Perceived Treatment in Medical Settings by Race/Ethnicity, n (%)

	Total	Worse than Other Races	The Same as Other Races	Better than Other Races	<i>p-value</i>
Non-Hispanic White	208	4 (1.92%)	178 (85.58%)	26 (12.50%)	0.0232
Non-Hispanic Black	483	40 (8.28%)	400 (82.82%)	43 (8.90%)	
Hispanic	153	12 (7.84%)	126 (82.35%)	15 (9.80%)	

Table 3.

Mean Likelihood of Participating Score, by Race/Ethnicity

	LoP Score (SD)	<i>p-value</i>
0.9770		
Non-Hispanic White	60.5 (16.2)	
Non-Hispanic Black	61.0 (16.4)	
Hispanic	61.2 (15.8)	

Table 4.

Mean Likelihood of Participating Score, by Perceived Treatment while Seeking Health Care

	LoP Score (SD)	<i>p-value</i>
		0.0007
Worse than other races	53.7 (17.6)	
The same as other races	61.1 (16.1)	
Better than other races	64.0 (15.0)	