

Factors Influencing Participation in Clinical Research: Do Minority and Lower Socioeconomic Status Patients Experience Greater Barriers in Participation?

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Abstract

A disparity exists within the participant population of clinical research trials in the United States. Female, minority, lower socioeconomic status, and lower educational achievement patients are all underrepresented demographics in clinical research trials. After acknowledging this disparity, the next step is to further understand what may be preventing the underrepresented demographics from participating. This study surveyed patients from four family practice clinics in the Lehigh Valley Health Network. One section of this survey gauged patient attitudes towards potential barriers that may inhibit participation in clinical research. The resulting data was used to compare responses between patients of different races and socioeconomic statuses. Caucasian patients reported greater trust in doctors and better understanding of clinical research than Asian, African-American, and Hispanic patients. Patients reporting lower incomes stated greater distrust for doctors and a lesser understanding of clinical research than higher income patients. Understanding these barriers may help develop interventions to change recruitment in order to encourage more minority and lower socioeconomic status patient to participate in clinical research.

Background/Literature Review

The population of clinical trial participants is not representative of the United States' population. Women, minorities and elderly patients are often underrepresented in clinical trials (Ross et al., 1999; Wendler et al., 2005). One of the primary concerns of the existing disparity is that all patients do not respond identically to treatment. Specifically, different demographics may experience different results from identical treatment (Stronks et al., 2013). Therefore, proper representation of all genders, races, and socioeconomic statuses in clinical trials is necessary to develop wide encompassing treatments that are effective for all patients (Buchard et al., 2003). However, achieving this encompassing participant pool is challenging. There have been instances of clinical research trials struggling to build and achieve participant diversity. To overcome this, those studies elected to exclude certain demographics from their protocol without justification in order to meet participant goals (Larson, 1997). Therefore, finding solutions to the clinical research participation disparity is not only a step towards developing better treatment, but also towards health equity. (Stronks et al., 2013).

To further explore this participation disparity, this study surveys patients from four LVHN family practice clinics. The survey's goal is to find the extent to which "distrust of doctors" and "difficulty understanding clinical research" are barriers to the patient's possible participation in clinical research. The resulting data will be analyzed by comparing responses between races and income levels.

It would be expected that higher income level patients would be more likely to participate in clinical research, possibly because this group may have a greater understanding of the research process and medical profession. Furthermore, minorities would be expected to be less likely to participate in clinical research. With research professionals more likely to be

Caucasian males, race, cultural, and language differences may reduce the likelihood of minority participation (Betancourt et al., 2003).

While this study seeks to find the extent of participation barriers minorities and low-income patients may face, it operates on the established under representation of these groups shown through past studies (Purnell et. al, 2005; Sisk et al., 2008). One study shows women accounted for less than 40% of the participant pool in a series of cancer trials (Jasi et al., 2009). Furthermore, studies have found black and Hispanic patients to be less likely to participate in clinical research due to the cultural and language barriers they may face (Betancourt et al., 2003)

In fact, a research team found that as a whole, minorities were less likely to participate in clinical research. More specifically, Hispanic and Black underrepresentation has been linked to poor access to medical care, cultural barriers, and alienation from research professionals (Shavers-Hornaday, 1997). While the literature regarding minority under representation in clinical research is plentiful, there is less research on the participation rates of low-income patients. However, it has been suggested that minority patients may be deterred from participating in clinical research due to financial limitations (Murthy et al, 2004).

Taking the previous works regarding disparities in clinical research participation into account, this study has the opportunity to more specifically find the extent to which the two barriers, mistrust in doctors and difficulty understanding clinical research, affect patients spanning different races and income levels.

Methods

The research team created an IRB approved survey to gather information on patient background, past clinical research participation and demographic information. The survey also asked about patient attitudes towards barriers from participating, motivation for participating, and effectiveness of clinical research promotional resources. The survey utilized a combination of multiple choice and scalar questions. The survey was also translated into Spanish, Simplified Chinese and Traditional Chinese.

This study involves data from four Family Practice Clinics in LVHN: Lehigh Family Medicine Associates, Bethlehem Family Practice, Community Health and Wellness Center, and Lehigh Valley Family Health Center. The study team approached patients in the clinic's waiting room to determine eligibility and gain consent. Eligibility criterion for this survey included patients 18 years of age or older with the capability of completing the survey in one of the four available languages.

Following eligibility, the study team verbally consented the patient in one of the four languages and provided a survey to be completed before the patient left the clinic. The team maintained a participant log to mark the date, clinic, language of consent, age eligibility, and gender for each patient approached, whether they participated or declined.

The patient survey raw data from the four family practice clinics were coded into a spreadsheet. The observations from the data set were found using simple data analysis of Section K of the survey, potential barriers. Data from this section was further analyzed by independently comparing responses from patients from different races and income levels.

Results

Race/Ethnicity

The two primary barriers this study focuses on are patient distrust of doctors and difficulty of understanding clinical research. Table 1 displays the mean patient response and p-values stating to what extent each of the two aforementioned barriers affected the patient’s decision to participate in clinical research. A value of 0 signifies no barrier to participate and a value of a 4 signifies the greatest barrier to entry.

TABLE 1- EXTENT OF BARRIER TO PARTICIPATION IN CLINICAL RESEARCH (N=177)

Barrier	“My Distrust in Doctors”	“Clinical Studies Are Difficult To Understand”
Mean	1.68	1.30
P-Value	0.80	0.49

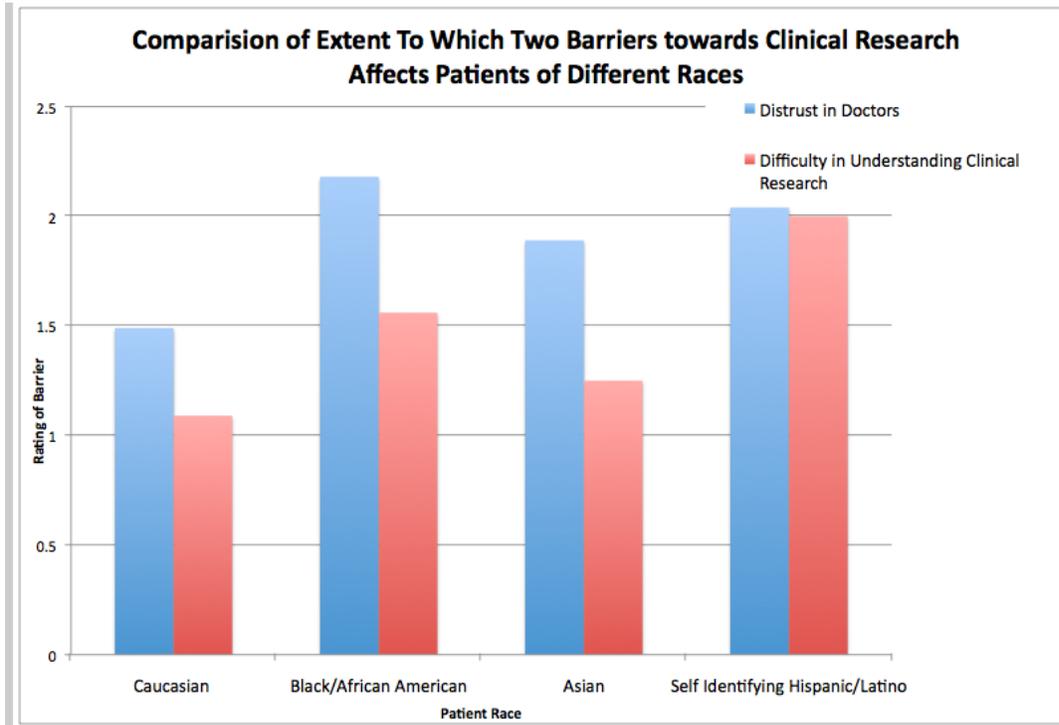
Table 2, displays responses from Caucasian, Black/African American, Asian, and Self-Reporting Latin/Hispanic patients. The table reports the mean response from patients from each race and the p-value of the data set.

TABLE 2- EXTENT OF BARRIER TO PARTICIPATION IN CLINICAL RESEARCH FOR PATIENTS OF 4 RACES (N=177)

Barrier	“My Distrust in Doctors”	“Clinical Studies Are Difficult To Understand”
Caucasian Patient Mean (P-Value) [n=121]	1.49 (0.29)	1.09 (0.23)
Black/African American Patient Mean (P-Value) [n=18]	2.18(0.76)	1.56(0.71)
Asian Patient Mean (P-Value) [n=10]	1.89 (0.92)	1.25 (1.30)
Self-Identifying Latino/Hispanic Patient Mean (p-value) [n=28]	2.04 (1.32)	2 (1.49)

Figure 1 summarizes the data from Table-2 into a singular chart to more easily compare the differences in how the extent to which the two barriers affected patients from each race.

FIGURE 1- COMPARISON OF PATIENT RESPONSE ACROSS ALL 4 RACES (N=177)



Income/Socioeconomic Status

The same two barriers were studied across patients belonging to one of five income levels. Patients who chose not to disclose their income or failed to complete the question are excluded from the subsequent data analysis.

Table 3 displays responses from patients reporting five different income ranges. The table reports the mean response from patients from each race and the p-value of the data set. Figure-2 displays the same data in a graph.

TABLE 3- EXTENT OF BARRIER TO PARTICIPATION IN CLINICAL RESEARCH FOR PATIENTS IN DIFFERENT INCOME RANGES (N=177)

Barrier	“My Distrust in Doctors”	“Clinical Studies Are Difficult To Understand”
Less than \$30,000 [n=71]	1.93 (0.37)	1.41(0.33)
\$30,001-\$50,000 [n=39]	1.33 (0.46)	1.26 (0.40)
\$50,001, \$75,000 [n=7]	1.89 (0.92)	0.99 (1.30)
\$75,001-\$100,000 [n=9]	1.11 (1.04)	2.00 (1.18)
Greater than \$100,000 [n=11]	0.44 (0.82)	0.67 (0.69)

FIGURE 2- COMPARISON OF PATIENT RESPONSE ACROSS FIVE INCOME RANGES

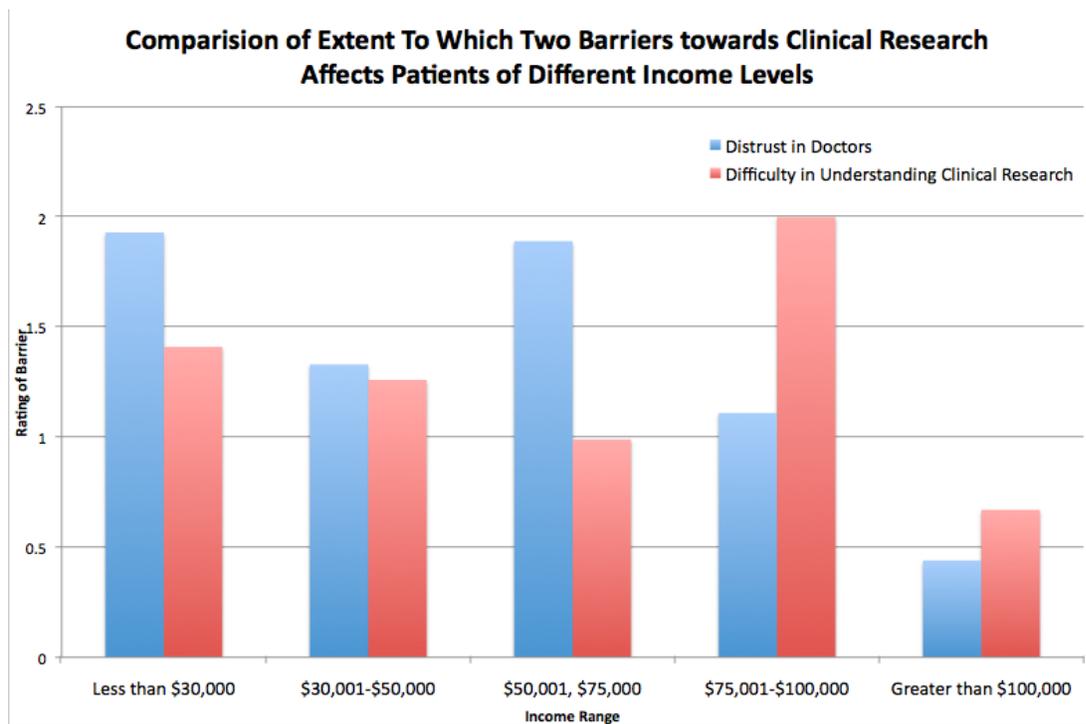
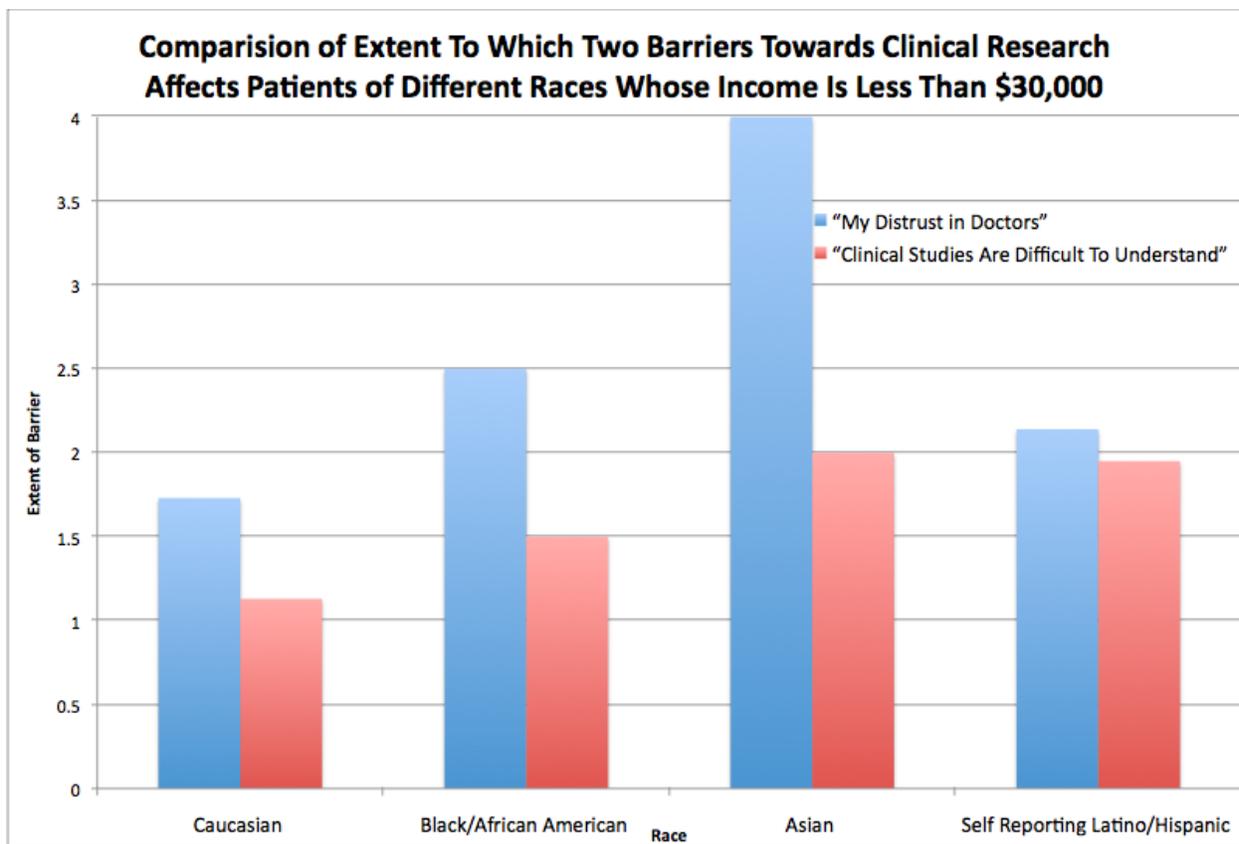


Table 4 combines race and income level data to study the responses for patients whose income is less than \$30,000 from different races. Figure-3 displays the same data using a chart.

TABLE 4- EXTENT OF BARRIER TO PARTICIPATION IN CLINICAL RESEARCH FOR PATIENTS OF DIFFERENT RACES WHOSE INCOME IS LESS THAN \$30,000

Barrier	“My Distrust in Doctors”	“Clinical Studies Are Difficult To Understand”
Caucasian [n=44]	1.73	1.13
Black/African American [n=7]	2.50	1.50
Asian [n=1]	4.00	2.00
Self Reporting Latino/Hispanic [n=16]	2.14	1.95

FIGURE 3- COMPARISON OF PATIENT RESPONSE FOR PATIENTS OF DIFFERENT RACES EARNING LESS THAN \$30,000



Discussion/Conclusion

Data analysis for patient responses across the four races suggested two similar patterns. The population of Caucasian patients reported “distrust of doctor” as a lower barrier than Black/African American, Asian, and self-reporting Hispanic/Latino patients. This same pattern was seen with Caucasian patients reporting “difficulty in understanding clinical research” as lesser barrier than Black/African American, Asian, and self-reporting Hispanic/Latino patients.

The data suggests that Caucasian patients are deterred to a lesser extent by the two studied barriers than patients of the other three races. The notion that Caucasian patients face fewer barriers has been seen in previous research. Conversely, research has also attributed to the lower participation rates for minorities in clinical research to the greater barriers minorities face (Lara et al., 2001; Murthy et al., 2004). This study adds value by finding two specific barriers that minorities face to a greater extent than Caucasian patients.

When viewing the data using income level as the separating criterion, two general trends emerged. As the patient’s income level increased, the patient’s level of distrust towards doctors decreased. Similarly, patients marked “difficulty understanding clinical research” as less of a barrier as income increased.

Conclusions from the race-based section, the primary findings from the income-level section have also been insinuated in a previous study that had linked lower income to a minority patient’s barrier to participation. Low-income itself might be a barrier that prevents participation in clinical research due to travel and time costs.

Table 4 and Figure 3 show a combination of the data from the previous two sets. When using race as the separating criterion for patients reporting annual incomes less than \$30,000, the same trend seen without the fixed income range is seen. Minority patients still reported distrust

in doctors and difficulty understanding clinical research as greater barriers. This suggests minority low-income patients face the greatest barrier towards participating in clinical research.

This study did have limitations and ways to improve the validity of its conclusions. The study had a total of 177 patients, but each demographic within the dataset was not equally represented. 68.3% of all participants were Caucasian and 41% of participants reported incomes less than \$30,000. There was limited data on Asian patients and patients earning between \$50,001-\$75,000 and \$75,001-\$100,000 per year. There was only one Asian patient represented in Table 4 and Figure 3. There were also a limited number of participants in the two aforementioned income ranges. The resulting high p-values in Table-3 suggest the possibility of those values being outliers. Continuing to survey patients in order to increase the number of participants, especially from minority patients and incomes greater than \$50,000 will help generate more significant conclusions.

The primary findings of this paper are that minority and low-income patients face greater barriers to participation in clinical research than Caucasian and high-income patients. There are many opportunities for future endeavors directions for research. Using the knowledge of two specific barriers lower income and minority patients face may help develop interventions to encourage greater patient participation.

Previous research has suggested major roots of mistrust towards doctors. This distinction may stem from the doctor speaking a different language, being the opposite gender, and being a different race than the patient. An intervention could focus on the possible impact of participation rates with research professionals with similar backgrounds to the patients providing consent. This intervention could also involve the consenting research professional to explain the

research study and provide all paperwork in the patient's primary language. This may reduce difficulty in understanding clinical research as a barrier.

An intervention to overcome the barriers preventing lower income patients from participating in clinical research may include recruiting and advertising to patients differently at clinics with lower average patient income. To overcome the greater distrust in doctors, research professionals may offer greater opportunity to ask questions about the research. To combat the difficulty in understanding clinical research, clinics in lower income areas may offer simplified literature regarding clinical research.

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