Extrinsic Barriers to Clinical Trial Enrollment among Those of Low Socioeconomic Status

by

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Dedication

I dedicate this thesis to the loving memory of my Mother. Her love, encouragement, strength and enthusiasm for life will forever leave an imprint on my soul.

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Abstract

Clinical trial studies are crucial for evaluating the safety and efficacy of a drug, yet a diminutive portion of the participants are minorities or those of low socioeconomic status (SES). An online survey of 5,701 participants was assessed for a correlation between self-reported annual household income and willingness to participate in a clinical trial. Using Spearman's rank correlation coefficient, no association was found between the two variables. Many studies have shown an ongoing deficiency of minority and low SES participation in clinical trials, however, this analysis finds that the willingness is similar across all income levels. This suggests that the disparities among clinical trial enrollees of lower socioeconomic status may be associated with extrinsic barriers that are unrelated to their willingness to participate. These barriers to participation may include indirect costs for patients, lack of awareness and stringent eligibility criteria.

Keywords: disparity, clinical trial, income level, minority, elderly, low socioeconomic status

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Chapter 1: Introduction

The genesis of medical advancements such as chemotherapy, cardiovascular screening, and vaccines are possible because of clinical trials and research. These processes are concise and rigorous research methods that involve many years of pre-clinical studies prior to use in humans. During the phases of clinical research, human volunteers are used to test all investigational drugs, indications, preventions, devices and techniques to evaluate the safety and efficacy of a study agent. Once tested, the study agent may be approved through a governing body such as the United States Food and Drug Administration (FDA). The human volunteers should be fully informed, consented and act in full autonomy. Without the participation of human volunteers, the advancement of medical treatment may not be possible.

The number of volunteers necessary for a clinical trial varies from a few individuals to several thousand, depending on the phase and study design. In general, the clinical trial cohort should resemble the proportionality of the population in areas such as race and ethnicity, gender, and age (Murthy, Krumholz, & Gross, 2004). Currently in the United States, approximately 2% of the general population and 6 % of those with a chronic or severe illness become involved with clinical trials each year (The Center for Information and Study on Clinical Research Participation [CISCRP], 2013). Of those percentages, less than 7% are minority and 33% are elderly (Advani, 2003; CISCRP, 2013; Gross, Fildardo, Mayne, & Krumholz, 2005; U.S. Department of Health & Human Services, 2013).

The importance of this cohort diversity is multifaceted. A diverse population can potentially increase the generalizability of the study findings (Murthy et al., 2004). In some instances, the expression, causation and frequency of a certain disease or drug response may vary among racial and ethnic groups and warrant additional subgroup analyses (Burchard, et al., 2003). Further, diversity among trial participants aids in the assurance that minority groups and those of lower socioeconomic status (SES) have equal access to novel treatments (Unger, et al.,

2013). Unfortunately, many clinical trial populations do not proportionally represent the population (Murthy et al., 2004). The major demographic disproportions in trial populations fall amongst the elderly, minority and ethnic groups and those of low SES (Sateren, 2002; Unger, et al., 2005; Unger, et al., 2013).

Some attribute this disproportion to a dark time in U.S. history when unethical research and scientific experimentation often took place on minority and under-represented groups (Washington, 2007). Although the scientific community and government have attempted to repair the wrong doings made in the name of research, some believe that this grim past is causing an unwillingness to participate amongst minorities in modern day trials (Du, Gadgeel, & Simon, 2006)

Over the last two decades, many studies were conducted to determine the basis and extent of the very low rates of recruitment into clinical trials among minority, elderly and low SES populations (Sateren, 2002; Unger, et al., 2005). More recently, various studies and polls are administered to ascertain the population's perceptions and willingness to participate in clinical trials (CISCRP, 2013; Research!America, 2014). The aggregate conclusions of these studies suggest that researchers should explore beyond the under-represented participant's attitudes and investigate other potential sources. The disparities among clinical trial enrollees of lower socioeconomic status may be associated with extrinsic barriers that are unrelated to their willingness to participate.

Chapter 2: Literature Review

History of Research amongst the Under-Represented

African-Americans were subjected to harsh medical treatment and experimentation dating back to colonial America. Due to their enslaved status, they were unwillingly forced to participate in the research and demonstration by physicians and scientists. According to historical physicians' notes, journals and records, these slaves, "bore the worst abuses of these crudely empirical practices, which countenanced a hazardous degree of ad hoc experimentation in medications, dosages, and even spontaneous surgical experiments in the daily practice among slaves" (Washington, 2007). In the publication, *Why African Americans May Not be Participating in Clinical Trials*, Yvonne Harris et al., mention a slave named Fed, who was used to test different medications for heatstroke (1996). The experimental sessions would begin once Fed was administered a certain heatstroke medication. He was then forced into an open pit which was covered and heated until he was no longer able to withstand the heat and would fall unconscious (Harris, Gorelick, Samuels, & Bempong, 1996). This is merely one account of atrocious testing that occurred on human subjects. According to Harris et al., many African-Americans in the Deep South were fearful of the months when medical schools were in session as they were forced to fill hospital beds for medical practice as well as dissection; often they hoped for death during the summer months when school was not in assembly (1996).

At the turn of the twentieth century, the experimental abuses toward African-Americans continued on in plain sight until the 1970s (Reverby, 2008). In 1927, in the small town of Lyles Station, Indiana, healthcare officials contacted the parents of ten young African-American children offering them treatment for dermatophytosis (Leonard, 2010). The young children were subjected to massive experimental doses of radiation to their cranium in an effort to determine the maximum dose needed to remove the fungal infection without impacting the epithelial tissue

(Leonard, 2010). As a result of the experimental treatment, all the children suffered from cranial scarring; however, Vertus Hardiman, a then five year old boy, had the worst side effects, as detailed in the documentary, *A Hole in My Head: A Life Revealed*. Hardiman developed horrific cranial abnormalities from the treatment that led to the slow withdrawing of the bone matter in his skull, leaving a gaping hole at the top of his head (Leonard, 2010).

Radiation experiments continued on for unsuspecting African-Americans. In 1945, Ebb Cabe, an African-American from North Carolina was severely injured in an auto accident leaving him near death with multiple fractures (Washington, 2006). He was taken to the Manhattan Engineer District Hospital, where the physicians were under contract with the U.S. Atomic Energy Commission (AEC), which was part of the Manhattan Project (Washington, 2006). Due to Cabe's dire condition and almost impending death, he was injected with a massive dose of plutonium, a known toxic radioactive substance with the half-life of 24,056 years (Washington, 2006). A few days after he was administered the poisonous chemical and prior to resetting the broken bones of his legs; physicians extracted fifteen of Cabe's teeth and also removed several bone samples (Washington, 2006). The objective was to calibrate the dose of plutonium that will cause leukemia and other such illnesses (Washington, 2006). Cabe escaped from the hospital six months after his initial dose of plutonium and lived on for another eight years. Cabe was not alone, from 1944-1966, the AEC supported over 2,000 experiments using radiation and neither consented nor informed the human subjects, many of which were African-Americans (Washington, 2006).

The most infamous trial of the African-American population is the U.S. Public Health Service's (PHS), *Tuskegee Study of Untreated Syphilis in the Negro Male*. The trial began in 1932 in Macon County Alabama with the intent to observe the natural progression of syphilis in African-American men (Jones, 1993). A total of 600 exclusively African-American men were

enrolled into the trial, of which 399 were infected with syphilis while 201 served as a control group (Jones, 1993). At the time of the trials inception, there was no proven treatment for the disease; however, the men were not fully informed of the trial's objective as the PHS explained to the volunteers that they were being treated for "bad blood", which at the time referred to a host of illnesses including anemia, fatigue and syphilis (Jones, 1993). As an incentive, the men were offered an enticing package of free health care and burial insurance for participating in the study (Center for Disease Control and Prevention, 2011). In 1947, penicillin became the treatment of choice for the disease; however, the men in the trial were never offered the antibiotic. Moreover, the study went on for twenty five years after a proven treatment was available (Center for Disease Control and Prevention, 2011). Meanwhile, numerous men died from the untreated disease and passed it on to their wives and children (Reverby, 2008).

A young social worker and epidemiologist at the San Francisco Health Department, Peter Buxton, casually heard about the study during a coffee break with a colleague and he was outraged (Jones, 1993). Soon after learning of the trial, Buxton (unsuccessfully) petitioned for the trial to end for over six years (Jones, 1993). It wasn't until 1972, four decades after the trial's inception that Buxton's plight was leaked to the media, and the study finally ended (Jones, 1993). A national public outcry ensued and a class action law suit against PHS and the state of Alabama was immediately filed on behalf of the African-American men and their survivors (Reverby, 2007). Although the study stunned the nation, it was never truly concealed. Throughout the study's duration, over twelve reports were published in medical journals, often with the same statistical conclusion: untreated syphilis shortens lifespans and in many cases, causes death (Reverby, 2007).

Health Disparity Revealed

Soon after the Tuskegee trial was revealed, a pivotal article published in 1973 by Henscke et al., entitled, *Alarming Increase of the Cancer Mortality in the US Black Population (1950 – 1967)*, brought forth evidence of the enormous disparity among the African American population and the importance of using socioeconomic status when explaining disparities in cancer risk and survival (Polednak, 2005). The study's implications stated that the "increase of the black cancer mortality rates has many serious implications," that few African Americans have economic resources for cancer care, the mortality rate is rapidly increasing and that cancer and epidemiological studies must occur (Henschke, et al., 1973). The health disparity among minority groups was becoming increasingly more evident, warranting further research to determine causality; however, the disreputable history of experimentation demanded necessary safeguarding for the under-represented potential participants.

In 1974, after prompting from the maltreatments stemming from the Tuskegee Syphilis Study, the National Research Act was passed into law which created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research which developed and published the Belmont Report in 1979 (U.S. Department of Health & Human Services, 2012).

The Belmont Report laid the foundation for ethical practice in modern research. The first of the three basic principles, respect, states that individuals must be treated as autonomous agents, otherwise, the research subjects are self-governing and not influenced by any outside sources and second that those without autonomy are entitled to certain protections (U.S. Department of Health & Human Services, 2012). The second principle, Beneficence, refers to the obligation of not doing harm and maximizing the benefits while minimizing the possible harms (U.S. Department of Health & Human Services, 2012). The final principle, Justice, refers

to the fairness of distribution; the formulation of just ways to distribute the burdens and benefits "are **(1)** to each person an equal share, **(2)** to each person according to individual need, **(3)** to each person according to individual effort, **(4)** to each person according to societal contribution, and **(5)** to each person according to merit" (U.S. Department of Health & Human Services, 2012). This report was a momentous document that provides the moral framework for present research.

Although policies, such as the National Research Act, were set into place to protect ethnic minorities and the under-represented, there was still an evident disparity in the clinical trial proportion of minority, elderly and low SES populations. The 1993 Revitalization Act of the National Institutes of Health was enacted, mandating that all federal grants for clinical trials and research must include statement specific to the inclusion of women and minorities (U.S. Department of Health & Human Services, 2001). Critics of the act feared that this legislation would create a negative effect on research and that the act was reminiscent of 19th century "race medicine" that was practiced throughout the US and thought to be a precursor to the Tuskegee Syphilis Study (Brawley & Freeman, 1999). Others believed that this Act would close the gap among women and minorities within research (Brawley & Freeman, 1999). Further evidence of the inequality was revealed when a report issued in 1999, by the Institute of Medicine (IOM), *The Unequal Burden of Cancer,* exposed a considerable disparity in the instances of selected cancers and the rate of mortality among those of medically underserved groups (Haynes & Smedley, 1999).

Murthy et al. (2004) argues that the National Research Act didn't hold up to the expectations and excluded the elderly who are grossly under-represented. Their study evaluated the age, sex, racial and ethnicity data of the National Cancer Institute (NCI) sponsored Clinical Trial Cooperative Group's studies among breast, colorectal, lung or prostate cancer enrollees

from 2000 through 2002 (Murthy et al., 2004). The researchers then evaluated these data to determine the degree of disparities among the aforementioned demographics (Murthy et al., 2004). The group went on to evaluate the ethnicity and race data of those enrolled in the same NCI data from 1996 through 1998 and compared these data to the 2000 through 2002 cohort (Murthy et al., 2004). The researchers found that overall, from 1996 through 2002, the enrollment in the NCI sponsored trials increased by nearly 50%; however, the diversity of the non-white participants actually decreased and that the elderly populations of both minorities and whites were extremely under-represented (Murthy et al., 2004).

A study conducted by Sateren et al. (2002) also considered the association between SES factors and accrual rates of NCI sponsored clinical trials. The researchers used several proxies to account for SES including county income level, unemployment rate, poverty and education level (Sateren, 2002) Many other studies were conducted to reaffirm the presence of an under-representation in clinical trials; however, they expanded the research to collect data from patient's perspective.

Willingness to Participate

Willingness to participate in a clinical trial has been studied several times over the past decade and evaluated across several SES factors. Many have speculated that the lack of participation among minorities and those of low SES may stem from the memory of unethical trials and the resulting distrust of research. To test this theory, a phone study compared the difference between the willingness to participate in a clinical trial among African Americans and whites, aged fifty years of age or older (Brown & Topcu, 2003). The concept was that the older African American participants may remember the Tuskegee Syphilis Study and be less likely to participate (Brown & Topcu, 2003). They found very little difference between the two groups (Brown & Topcu, 2003). Katz et al. (2009) also compared the willingness to participate in two separate studies and concluded that African Americans and Hispanics are just as likely as whites

to participate in clinical research.

Little is known about the level of willingness or participation levels among the elderly population. Hutchins et al. analyzed the data of 16,396 patients enrolled in Southwest Oncology Group trials and found the population proportions were similar to that of the U.S. in all areas except enrollees sixty five years of age or older. (Hutchins, Unger, Crowley, & Albain, 1999). Hutchins and his team noted that the elderly were substantially underrepresented (1999).

Few studies analyzed individual income as a single SES proxy in comparison to either actual participation or willingness to participate in clinical trials as many studies utilize area-level surrogates for SES found in the U.S. census (Unger, et al., 2013). A recent breakthrough study found that among 5,499 cancer patients, income was the only SES significantly associated with participation in cancer clinical trials (Unger, et al., 2013). Patients of lower income levels were less likely to participate in clinical trials (Unger, et al., 2013). The study concluded that income levels may be a predictor of participation in a cancer clinical trial (Unger, et al., 2013). This study identifies a need for further analysis of the willingness to participate across income levels.

Chapter 3: Background

In an effort to better understand the general public and patient perceptions of clinical research, The Center for Information and Study on Clinical Research Participation (CISCRP) conducted several international surveys between January and March 2013. CISCRP developed an electronic survey instrument with the input of fourteen pharmaceutical and biotechnology companies. The survey questionnaire was developed as an update to the 2005 Harris Interactive, with revised areas of inquiry. Acurian, a patient recruitment and retention service, supported the global survey distribution.

A total of 5,701 participants, eighteen years of age or older, completed the online survey; 4,286 (75%) of the respondents were North American, while the remaining respondents were South American (5%), European (15%), and Asian-Pacific (5%). The participants responded to several self-reported online survey questions, including the question of interest: *How willing are you to participate in a clinical research study*? Of the North American participants, 4152 (97%) responded to this question. The possible responses to the question were: *I am not sure, not at all willing, not very willing, somewhat willing, very willing*. The responses were further subdivided by annual household income and categorized as defined in Table 1.

Table 1. Number of Respondents within Defined Salary Ranges (from CISCRP).

Salary Range	Number of Respondents	Percentage of Respondents (%)
< $25,000	1030	25
$25,000 - $34,999	575	14
$35,000 to $49,999	693	17
$50,000 to $74,999	777	19
$75,000 to $99,999	512	12
$100,000 to $149,999	369	9
$150,000 to $199,999	98	2
$200,000 to $249,999	43	1
$250,000 to $299,999	15	<1
$300,000 or more	40	1

The original sample, collected and analyzed by CISCRP (N = 4152), revealed that when asked about the willingness to participate in a clinical trial, 95% of the respondents surveyed were: *very willing* (n=2492; 59%, 62%; 95% [CI]) or *somewhat willing* (n=1448; 33%, 36%; 95% [CI]) to participate in clinical research. The remaining 5% of respondents were: *not very willing* (n=105; 2.5%), *not at all willing* (n=21; <1%), and *I am not sure* (n=86; 2%). See Figure 1.

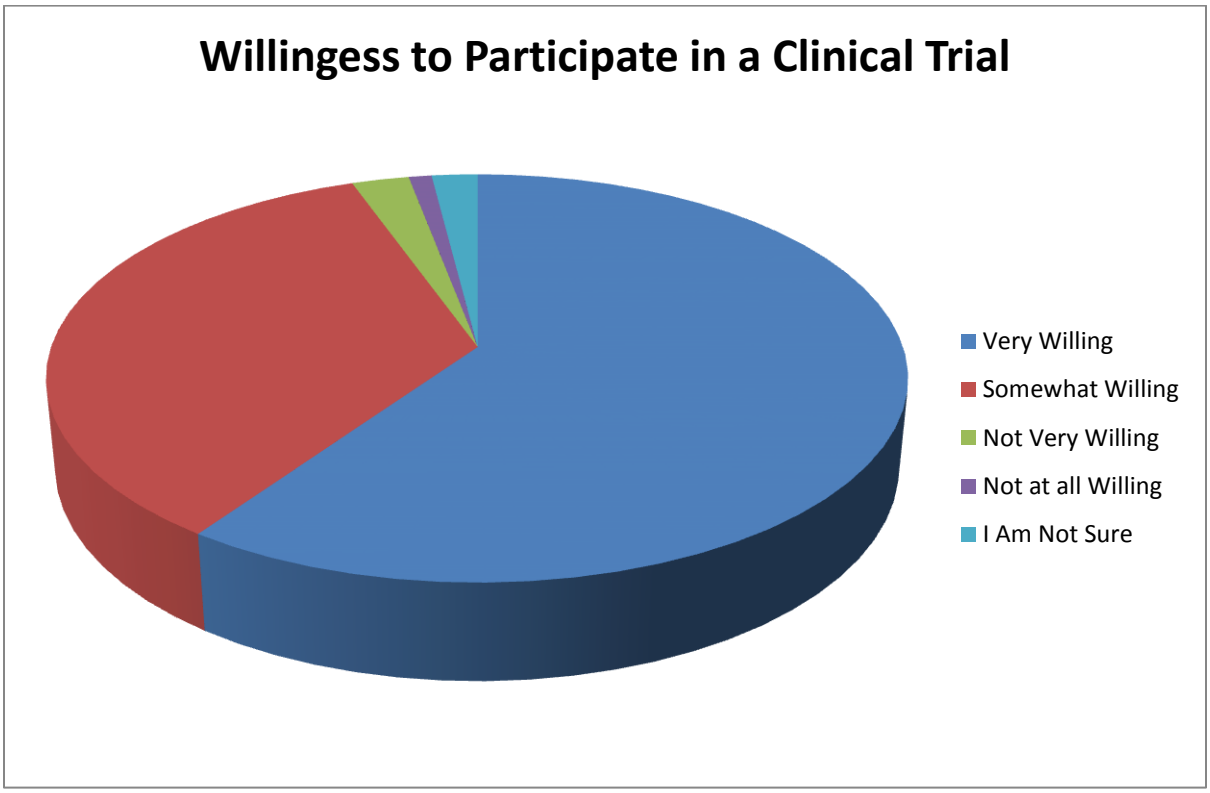

Figure 1. Proportions of Willingness to Participate in a Clinical Trial (from CISCRP).

Chapter 4: Methods

Further analysis of the above CISCRP data was conducted by the author to explore a possible correlation, or lack thereof, between the annual household income level and willingness to participate in a clinical research study. Race or ethnicity data were not available from the CISCRP surveys; therefore, SES was used as a surrogate.

Two minor modifications were made to the original dataset. The response, *I am not sure*, was omitted and those respondents (86; 2%) were removed from the analysis. The revised sample (N=4066) was subdivided into an alternate range of annual household income levels as categorized in Table 2.

Table 2. Number of Respondents within Alternate Salary Range.

Salary Range	Number of Respondents	Percentage of Respondents (%)
< $25,000	1030	25
$25,000 - $49,999	1268	31
$50,000 to $74,999	777	19
$75,000 to $99,999	512	12
$100,000 or more	565	13

Chapter 5: Results

The Spearman's rank correlation coefficient between annual household income level and willingness to participate in a clinical research study, was a slightly negative coefficient (r_s=-0.04), meaning that as one variable increases, the other variable decreases. Although this is statistically significant (p = 0.012) due to the large sample size, the magnitude of the coefficient is slight. The willingness to participate across the alternate range of annual household income level is shown in Figure 2.

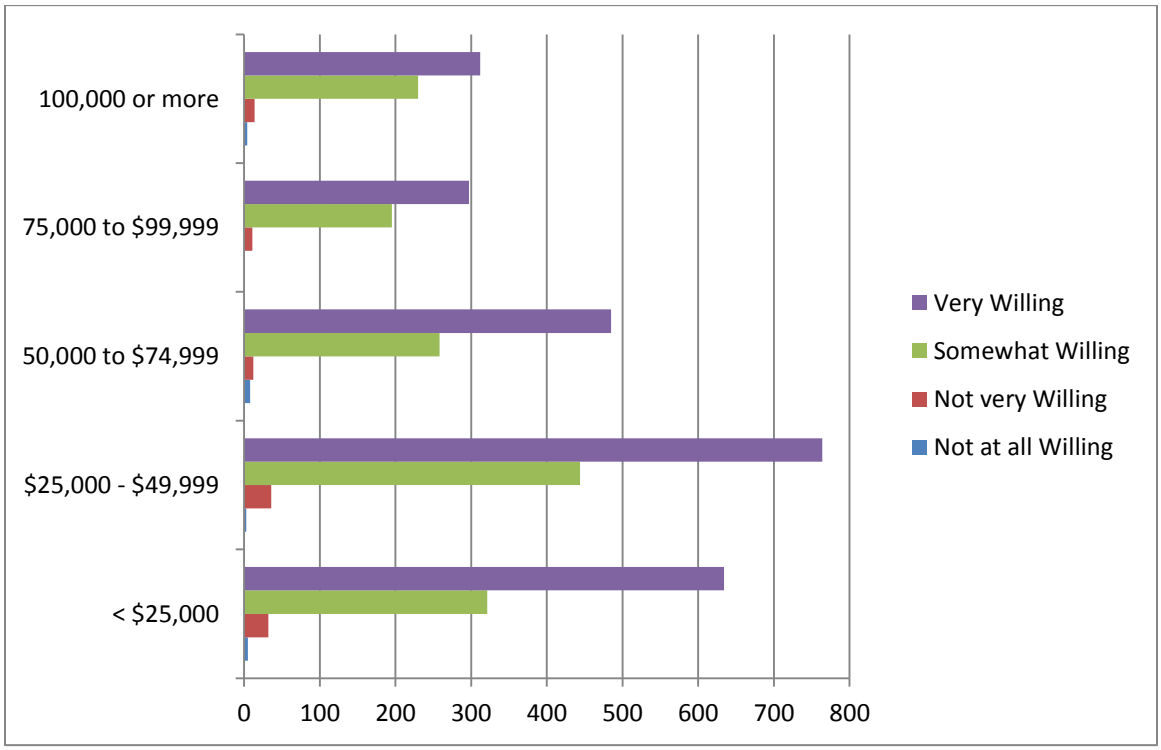

Figure 2. Willingness to Participate by Salary Range.

Chapter 6: Discussion

The correlation between annual household income and willingness to participate in clinical trials is miniscule across all income levels (r_s=-0.04). Because this coefficient is slight and the sample size large, the data might better be interpreted as implying little or no association between the annual household income level and willingness to participate. The willingness to participate in clinical trials, defined as "somewhat willing" and "very willing", across all income levels is 95%. These analyses suggest that an income level is not a predictor of the willingness to participate in a clinical trial. Additionally, the percentage of respondents' willingness is extremely high among all income levels indicating that the vast majority of the population is somewhat or very willing to participate in clinical trials. While many studies evaluate aggregate SES factors as opposed to individual annual household income, the outcomes are similar in that the majority of individuals are willing to participate (Sateren, 2002). There is a great disconnect when the number of participants in clinical trials amongst minority, elderly and low SES groups are paralleled to the willingness to participate. Furthermore, the Unger et al. (2013) study suggested that income is a predictor for the participation in clinical trials, finding that those of lower income are much less likely to participate. If this disproportion is not due to the patient's willingness, the disparities among clinical trial enrollees of lower socioeconomic status may be associated with extrinsic barriers.

Limitations

The paper has several limitations. Questioning about one's willingness to participate in a hypothetical situation may not necessarily reflect the willingness if the situation actually occurred. CISCRP was unable to collect race and ethnicity data due to a technical malfunction in the survey and this demographic was not available for analyses; therefore, SES was used as a surrogate for race and ethnicity. When CISCRP surveyed participants, the specific type of clinical trial was not collected, whereas many comparison studies cited throughout the paper

refer to cancer specific trials. Moving forward, it would be useful to collect data from all varieties of clinical trials and not exclusively cancer trials. Also, additional demographics, such as race, ethnicity and education levels are fundamental variables that may generate more profound multivariate analyses. For example, the willingness to participate among African Americans would provide a glimpse of the current perceptions of modern day clinical trials and whether unethical research from decades ago could still be affecting present attitudes .

Significance of Diversity and Research

If diverse populations are willing to participate, this may further pharmacogenetics research, which is the study of genetic variations from inherited distinctions in drug metabolism and targets (Burroughs, Maxey, & Levy, 2002). In recent years, scientists have discovered variances among different races in drug metabolism, efficacy and adverse events. Additionally, clinical trials offer access to novel and innovative treatment options that may provide better outcomes (Du, et al., 2006). If minorities and those of low SES are not provided the opportunity to participate in potentially promising clinical trials for reasons beyond their willingness, they are being denied treatment opportunities.

Extrinsic Barriers and Feasible Solutions

Much research has been done to explore the possible extrinsic factors that affect clinical trial enrollment for minorities and those of low SES. Although low SES patients are just as willing to participate in a clinical trial as those of higher SES, certain reasons may contribute to the low enrollment. For instance, those of lower income SES may be more susceptible to indirect costs such as transportation, childcare and time taken from work (Unger, et al., 2013). Lack of insurance or the concern of additional copays, etc., may also be a deterrent for participation (Unger, et al., 2013). According to the study conducted by Unger, et al., there was a strong association between income level and concern with trial related costs (2013). Nearly

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53% of those with income < $20,000 were concerned with possible costs related to participation while 24% of those with income ≥ $100,000 were concerned with such expenses (Unger, et al., 2013). Kilgore, et al. (2008) compared expenses related to clinical trial participants with a matched cohort of patients receiving treatment for the same cancers from the same providers. They concluded that prescription drug costs were higher for clinical trial participants on an average $131 over six months when compared to non-participants; however, there was no significant difference between the two groups with respect to out-of-pocket cost (Kilgore & Goldman, 2008). Physicians' communication with potential participants regarding the modest or absence of out-of-pocket costs related to trial participation could possibly reduce this concern among those of lower income levels. Moreover, if trial sponsors reimbursed the participants for out-of-pocket expenses, additional prescription costs, and the other indirect costs discussed previously, perhaps the patients of lower income levels would be more likely to participate in clinical trials; however, care must be taken to not impose undue influence on those of low SES.

Randomization is another deterrent for participant enrollment as some patients are apprehensive of receiving placebo and find the blinded treatment worrisome (Comis, Miller, Aldige, Krebs, & Stoval, 2003). One study found that among several thousand surveyed cancer patients (N=5,499), those who were offered participation in a clinical trial and declined (n=482), chose *Dislike of Randomization* as the most prevalent reason for non-participation (68%); however, those of lower income levels were less concerned with randomization and more concerned with monetary issues associated with participation than those of higher income levels (Unger, et al., 2013).

Although few studies are conducted to understand the disproportion of research amongst the elderly populations, in previous years an obvious deterrent was the unwillingness of third party payers to cover the expenses of "experimental" clinical trials. In September 2000, an executive order mandated that the National Institutes of Health sponsored trials will be covered

by Medicare and Medicaid (Sateren, 2002). Another hurdle for the aging patients to overcome when attempting enrollment into research is meeting the often stringent eligibility criteria of a given trial. According to Sateren et al., comorbidities often exclude the elderly population from enrolling (2002). Perhaps loosening the eligibility criteria would decrease the exclusion of the elderly demographic as well as other under-represented populations. Several oncology cooperative groups have begun to relax the eligibility criteria in an effort to include a more proportionate population of patients (Lara, et al., 2001).

Physician advocacy is a critical part of successful enrollment; however, not all physicians are fully engaged in research (Avis, Smith, Link, Hortobagyi, & Riviera, 2006). In a prospective study at the University of California Davis (UCD) Cancer Center, physicians recorded enrollment consideration, available protocols, and eligibility status of their cancer patients. The study found that physicians excluded up to one-third of patients eligible for clinical trials due to a biased conception of an eligible patient (Lara, et al., 2001). Often times, physicians are unaware of trials or do not communicate available trials to their patients. Overcoming this barrier is crucial, as it has been demonstrated that physician endorsement can increase trial accrual (Umutyan, et al., 2008). In some cases, physicians are not likely to participate in clinical trials as they fear losing their autonomy and, ultimately, risking the relationship with their patient (Umutyan, et al., 2008).

Randomization can also pose challenges to physicians. It may be perceived as a balancing act between safeguarding the patient's safety and furthering scientific research and potential medical advancement (Ellis, Butow, Tattersal, Dunn, & Joussami, 2001; Lilford & Jackson, 1995). Equipoise is not always attainable and some physicians fear that this could damage the trust of the patient (Lilford & Jackson, 1995). More studies should be conducted to detect an inherent bias amongst researchers toward minorities, elderly and those of low socioeconomic status. Perhaps physicians assume that minorities are not interested in research

because of previous maladies. Are physicians attempting to protect the once exploited or fragile groups?

Urging community leaders, patient advocates, church and community groups to become involved with clinical trial communication and education may increase participation among those of low SES (Advani, 2003). Offering clinical trials at outreach clinics may extend enrollment to the disparate groups; however, care must be taken to protect the vulnerable populations. Endorsements from well know organizations may educate and promote trust of the clinical trial process and engage with the under-represented groups. Perhaps getting minority physicians more involved with clinical trials would increase trust among minority patients (Advani, 2003). A variety of involvement at the community level and increased awareness for both patients and physicians may increase access for those of low income levels who are just as willing to participate in clinical trials as their higher income level counterparts.

Chapter 7: Conclusion

Annual household income cannot be a predictor for the willingness to participate in a clinical trial; however, income level is a predictor of clinical trial participation (Unger, et al., 2013). This strongly suggests that extrinsic factors, unrelated to the patients' willingness to participate, may be a major force in the disparity among those of lower income levels. These findings indicate that further research to identify the barriers as well as possible solutions is warranted. Presently, there is not a distinct causation of or solution to this disparity; however, a combination of community outreach, physician endorsement and patient awareness may aid in bridging this gap in clinical research.

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