Challenging Assumptions About Minority Participation in US Clinical Research

Although extensive research addresses minorities' low participation in clinical research, most focuses almost exclusively on therapeutic trials.

The existing literature might mask important issues concerning minorities' participation in clinical trials, and minorities might actually be overrepresented in phase I safety studies that require the participation of healthy volunteers.

It is critical to consider the entire spectrum of clinical research when discussing the participation of disenfranchised groups; the literature on minorities' distrust, poor access, and other barriers to trial participation needs reexamination. Minority participation in clinical trials is an important topic in public health discussions because this representation touches on issues of equality and the elimination of disparities, which are core values of the field. (*Am J Public Health*. 2011;101:2217–2222. doi:10.2105/AJPH.2011.300279)

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DURING THE PAST 25 YEARS, there have been national efforts in the United States to increase the representation of minorities in clinical trials.[1] Discussions about how to enhance participation have generated an extensive literature that addresses the low participation of minorities, especially African Americans. Significant scholarly interest exists in elucidating why these groups have historically been underrepresented in human participant research. Although current participation rates do not fully represent the overall population of minorities in the United States, progress is being made.

Currently, African Americans and Hispanics make up 12.4% and 15.8% of the US population, respectively.[2] A recent report indicates that minorities represent almost 30% of those enrolled in clinical trials sponsored by the National Institutes of Health (NIH) and that African Americans now make up approximately 15% of those minority participants.[3] There is still room for improvement, however, with significant enrollment issues continuing to affect the representation of Hispanics in clinical trials. One report estimated Hispanic representation in NIH studies at 7.6% of all research participants,[3] and a report on industry-sponsored studies found that only 3% of those participants were Hispanic.[4] Increasing the participation of all minorities in clinical trials is critical for the production of knowledge about new therapies because having diverse research participants can improve the generalizability of medicine. Additionally, minority participation in clinical trials is an important topic in public health discussions because this representation touches on issues of equality and the elimination of disparities, which are core values of the field.

Despite academic interest in the topic, most of the focus has been on the benefits that minority groups can experience from clinical trial participation. There has been little discussion about the involvement of minorities in higher risk or lower benefit research. Currently, there are no databases aggregating demographic data from all clinical trials—neither those sponsored by NIH nor those sponsored by the pharmaceutical industry. Examining the entire spectrum of clinical research is important because the goals of clinical trials—as well as the benefits and risks—differ according to a novel therapy's stage of development.

Clinical trials generally proceed in 3 phases. Phase I studies are safety studies, used to establish appropriate doses for subsequent clinical testing and to generate data on adverse events. These studies are primarily conducted by using healthy volunteers who derive no direct health benefits from their participation. Phase II studies are designed to provide preliminary information about the efficacy of a new treatment as well as further information about its safety, using a few hundred participants with the targeted disease. Participants may derive health benefits from phase II studies, but only about one half of investigational therapies are shown to have promise in phase II trials.[5] Phase III clinical trials require several thousand volunteers with the targeted disease, usually involve the randomization of participants into experimental and placebo arms of the study, and can take from 2 to 4 years to complete. These studies measure the efficacy of an investigational treatment and sometimes a comparative benefit. With an 80% success rate, these trials are believed to offer important health benefits to participants.[5]

Despite the critical differences between study phases—especially between the goals of and types of participants in phase I and phase III studies—discussions about the representation of minorities in clinical trials virtually ignore these distinctions. Most of the literature focuses exclusively on phase III therapeutic trials. As a result, the existing literature may mask important issues concerning minorities' participation in clinical trials. We propose that the representation of minorities in clinical trials changes dramatically when taking a broader view of study participation. Phase I safety studies elicit a different set of findings regarding the representation of minorities in nontherapeutic clinical trials. Most notably, data provided to the authors by industry as part of a larger empirical project suggest that minorities might actually be overrepresented in studies involving healthy volunteers (Table 1).

Because there is currently no comprehensive source of data about industry clinical trials or early phase trials at NIH, we used the phase I participation data provided by representative sources in industry to question the assumptions commonly held about minorities' participation in clinical trials. The literature on distrust, poor access, and other barriers to participation needs to be reexamined. We argue that it is critical to consider the entire spectrum of clinical research when discussing the participation of disenfranchised groups.

BACKGROUND

Significant human participant abuses in medical research have been cited as reasons for low minority participation in contemporary clinical trials. The Tuskegee Syphilis Study, for example, has become infamous as a grievous example of American medical research gone awry. The Tuskegee Syphilis Study was undertaken in 1932 to study the effects of untreated syphilis in 399 African American men from rural Alabama, and the study continued until 1972 although effective treatment of syphilis became available in the 1940s.[6] This unethical experiment has drawn the ire of the research community since it was halted, but there is no consensus about the lasting effect the Tuskegee Syphilis Study has had on the general population, particularly in reference to clinical trial participation. Critics often cite this particular study as the primary reason that African Americans are underrepresented in clinical trials even today; yet, evidence from empirical studies investigating this point is mixed.[7,8]

The Tuskegee Syphilis Study and other examples of unethical clinical research prompted new federal regulations, including the creation of institutional review boards, which are intended to govern the ethical conduct of research.[9] Underpinning US regulations is the Belmont Report (1979), written by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in an effort to highlight the principles needed to guide the ethical conduct of human participant research and to protect against tragedies like the Tuskegee Syphilis Study. One of the ethical principles outlined in the Belmont Report is that of justice, which is concerned with the fair distribution of the benefits and burdens of medical research.

Yet, even with the federal protections of research participants implemented in the years after publication of the Belmont Report in 1979, minority participation in clinical research has remained low. These low enrollment numbers prompted new legislative initiatives, such as the NIH Revitalization Act of 1993, which has a section titled "Inclusion of Women and Minorities" specifically designed to ensure that women and people of color are given appropriate opportunities to participate in clinical trials research.[1]

TABLE 1—Demographics of Phase I Participants at 1 Northeastern and 1 Southwestern US Facility: Minority Participation in Clinical Research, June 2010

Demographic Factor	Phase I Facilities		
	Northeast	Southwest	Total
Total participants	13 612	16 747	30 359
Gender, no. (%)			
Men	9241 (67.9)	9306 (55.6)	18 547 (61.1)
Women	4371 (32.1)	7441 (44.4)	11 812 (38.9)
White, non-Hispanic, no. (%)	4735 (34.8)	6230 (37.2)	10 965 (36.1)
All non-White, no. (%)	8877 (65.2)	10 517 (62.8)	19 394 (63.9)
African American	5755 (42.3)	1027 (6.1)	6782 (22.3)
Asian	423 (3.1)	99 (0.6)	522 (1.7)
Hispanic	1970 (14.5)	9196 (54.9)	11 166 (36.8)
Other	729 (5.4)	195 (1.2)	924 (3.0)

Note. The data are from 2 companies' "active" participant databases as queried in June 2010. The companies' identities are confidential as part of their participation in a broader, ongoing empirical project. We selected them on the basis of their large participant databases and the high volume of studies they conduct for industry, which makes them representative of phase I trials conducted in the United States. Facilities with smaller databases of participants report similar demographic data.

LITERATURE ON BARRIERS TO CLINICAL TRIAL PARTICIPATION

In response to the changes in the NIH guidelines, research has emerged debating the merits of minority representation in clinical trials and the barriers to the participation of these groups.[7,8,10–22] Common barriers include distrust, provider perceptions, and access to care.

Distrust

A substantial group of scholars has proposed that minorities, particularly African Americans, are distrustful of medical research because of a history of exploitation.[10,12,18] Corbie-Smith et al. interviewed African Americans to delineate their feelings about clinical trials participation.[10] They found that interviewees were afraid that physicians would not be honest with them about the risks associated with a study, and many were afraid of being a guinea pig. In a 2002 follow-up study, Corbie-Smith et al. found that African Americans were more likely than were Whites to believe that physicians would not fully explain the details of research participation.[7] The study also identified African Americans' stronger fears that their physicians would allow them to participate in a study even if serious harm was anticipated, and 1 out of 4 African Americans expressed a high level of distrust in physicians.[7] In a more recent study investigating minority participation in clinical research, Paskett et al. concluded that minority populations commonly cite mistrust of medical research to explain their lack of interest in clinical trials participation.[17] Likewise, Freedman interviewed African

American women in an effort to capture and describe their experiences with research and clinical trials and, more generally, the medical establishment.[23] One woman in the study noted,

> We have always had a concern about what white people have done to black people.[23(p945)]

This comment implies that this proposed mistrust extends far beyond medical research to include the effect of slavery and other historical exploitations.[24]

Provider Perceptions

There is also literature that suggests that physician bias, false perceptions, and prejudices surrounding medical decision-making dictate the lower number of minority participants in trials. Research has shown that physicians are less likely to prescribe certain treatments to their minority patients. As an example, Smedley et al. speculated that physicians operate on a cognitive heuristic learned in medical school and residency that brings prior expectations to each individual encounter with their patients.[19] The physicians' prior experiences treating persons of similar race, gender, age, and socioeconomic status as themselves enter into their decision-making process. Smedley et al. concluded that physicians' biases do affect actual treatment decisions, although they claim that this does not mean there is a lesser quality of care for minority patients.[19] Nonetheless, a landmark study by Schulman et al. identified the effect of race and gender on patient referral for cardiac catheterization.[25] Findings showed that African American women were least likely to be referred for this important procedure.[25] Moreover, van Ryn and Burke found that physicians are more likely to have negative impressions of their African American patients than of their White patients and are likely to believe that African American patients are less intelligent and educated than are their White patients.[26]

Perhaps most significant in relation to a discussion of clinical trial participation, van Ryn and Burke also found that physicians are biased concerning who they believe will comply with difficult therapeutic regimens.[26] Their study suggests that physicians believe African Americans are two thirds as likely to be adherent as are their White patients. Of course, participation in clinical trials research can be a rigorous and demanding enterprise. Thus, it holds that one possible explanation for the underrepresentation of minorities is that physicians do not believe that their African American patients will adhere to the prescribed protocol.

Access to Care

An additional argument that warrants acknowledgment is that people of color have historically had poor access to medical care. In fact, some studies indicate that the majority of disenfranchised minorities have access only to providers and hospitals that have limited resources.[27–30] Minorities are less likely than are Whites to have health insurance, a prerequisite for gaining access to many medical facilities and for some phase III clinical trials.[21,31] As a consequence, many minorities receive care only in an emergency room setting, where they are seen by a variety of physicians who are likely unfamiliar with them and unconcerned with enrolling them in a clinical trial.[18,32]

Willingness to Participate

Despite these factors, research demonstrates that minorities are, in fact, willing to participate in clinical trials. Wendler et al. found that minorities are as willing to participate as are Whites but that they are not asked to participate.[22] A more recent series of studies by Katz et al. provides evidence that knowledge of the Tuskegee study does not influence minorities' participation rates and that, again, people of color are willing to participate in medical research despite perceptions that they are not.[13–16] There is a paucity of literature comparing the views of minorities with those of Whites, and the few studies that have been conducted imply that minorities' perceptions of clinical trials are similar to those of Whites. For instance, Brown and Topcu found that African Americans were more likely to know about Tuskegee than were Whites but were not significantly less likely to be willing to participate in a clinical trial compared with Whites.[8] Brandon et al.[33] and Katz et al.[16] also found that African Americans are not less likely than are Whites to participate in clinical trials when asked to do so, regardless of prior knowledge of Tuskegee. Brandon et al. did, however, argue that African Americans were more distrusting of medical care in general but concluded that this did not influence trial participation decisions.[33]

MINORITIES' PARTICIPATION IN PHASE I TRIALS

Issues of trust, physician perceptions and biases, and structural issues such as access to health care might factor into the low levels of minority participation in therapeutic clinical trials. However, the literature on minority participation focuses almost exclusively on phase III research. Thus, current investigations ignore the participation of minorities as healthy volunteers in important safety testing performed during phase I work. Although it has been an underreported phenomenon with few high-quality publications on the topic, we propose that minorities might be overrepresented in phase I trials, which has different implications for research.

Participation Rates

It is currently difficult to assess precisely the demographics of phase I participants because of the lack of centralized databases containing this type of information across clinical trials. Moreover, few studies report aggregate information about phase I trial participants, and those that do tend to focus on the underrepresentation of women in these early phase studies.[34–36] However, those who work in the industry claim that a high percentage of African Americans participate at phase I facilities in the northeastern United States and that a high percentage of Hispanics participate in the southwestern United States, meaning that these groups are represented in percentages much greater than their representation in the US population.[37–39] In 2009, the representation of African Americans and Hispanics in the US population was 12.4% and 15.8%, respectively.[2] Yet, anecdotal evidence within the industry has put both of these groups at rates closer to 40% of participants each in phase I trials.[37]

As part of a larger empirical project on phase I clinical trials in the United States, we obtained demographic data on healthy volunteers from 2 of the largest phase I facilities in the country (out of approximately 40 such clinics): 1 in the Northeast and 1 in the

Southwest. These preliminary data evince this demographic pattern of high ethnic and racial minority enrollment (Table 1). In both facilities, the percentage of minority participants is much greater than that of White volunteers (63.9% compared with 36.1%, respectively). African Americans make up 42.3% of the healthy volunteers in the Northeast and 6.1% in the Southwest, for an average of 22.3% between the 2 facilities. This figure represents nearly double the proportion of African Americans one would expect on the basis of population alone. Hispanics make up 14.5% of the healthy volunteers in the Northeast and 54.9% in the Southwest, for an average of 36.8% between the 2 facilities. This finding means that Hispanics are represented at more than twice the rate expected on the basis of US population statistics and almost 5 times their representation in NIH-sponsored phase III studies. We acknowledge that these data are not definitive; nonetheless, they illustrate that minority participation in phase I trials is higher than expected on the basis of US demographic data and their representation in therapeutic trials.

Revisiting the Barriers to Participation

The higher than expected participation of minorities as healthy volunteers in phase I studies indicates that it is necessary to revisit and reevaluate the proposed barriers to their participation. Specifically, examining phase I trials puts in doubt the argument about minorities' distrust of medical research. If minorities, especially African Americans, were as distrustful of medical research as the literature suggests, it would not follow that this supposedly underrepresented group would enroll in such high numbers in phase I studies. It would be a paradox for minorities to participate in the riskiest studies and not participate in the studies that could most benefit their medical conditions.

Although the argument that physician bias may contribute to the underrepresentation of minorities in phase III trials is not challenged by the phase I data, there is evidence of an interesting complementary phenomenon that could be occurring. One study found that a phase I facility in the Southwest perceived Hispanic volunteers as more adherent than other groups, and they invested additional resources in hiring Spanish-speaking staff, translating consent forms into Spanish, and recruiting in the Hispanic community to target that group.[37] Moreover, arguments concerning physicians' biases and stereotypes also carry little weight in discussions of phase I trials because of the limited involvement of physician investigators in recruitment. Private sector contract research organizations and pharmaceutical companies' clinical pharmacology units hire large numbers of recruiters and other research staff who recruit, organize, and run most phase I studies. In addition, phase I clinics tend to be located in economically depressed areas of the United States, with a higher concentration of clinics located in the Northeast and in urban areas.[37] These locations tend to facilitate access for racially and ethnically diverse populations.

Financial Incentive to Participate

Additionally, arguments about trust, provider perceptions, and access become more complex when comparing the recruitment of patients for testing the efficacy of a product (phase III) versus the recruitment of healthy volunteers for testing the safety of a product (phase I). A crucial difference between these types of research studies is that volunteers are usually paid large sums for their participation in phase I trials.[39,40] Hence, arguments about altruistic notions that may be relevant to phase III research are much less applicable to phase I volunteers' motivations. This becomes particularly pertinent when considering that many phase I participants use trials as a major source of income. In fact, there are people who have made a career of participating in phase I clinical trials.[41] Critics have commented that the financial remuneration has led to the creation of a profession, that of the guinea pig.[42,43] Whereas phase III trial participants have cited fear of being a guinea pig,[10] phase I participants have welcomed this terminology.[44,45] Because of the loaded nature of the term, however, the US Food and Drug Administration, pharmaceutical companies, and contract research organizations have chosen to refer to these professional volunteers as altruists or independent contractors.[45,46]

ETHICAL CONSIDERATIONS

The ethical issues associated with phase I trials are also different from those of later phase studies given that healthy volunteers do not experience any health benefits from their participation but do bear a considerable burden of risk.[47] Serving as reminders of the potential dangers associated with phase I testing are the deaths of healthy volunteers at Johns Hopkins and Lilly in 2001 and 2004, respectively, and the near fatal TeGenero phase I study in London in 2006 of a humanized monoclonal antibody that caused multiple organ failure in 6 healthy volunteers.[48] Although there is some literature examining the ethics of phase I trials,[46,49–52] current discussions and ethical debates tend to focus on the recruitment of impoverished people, but they often ignore the implications of disenfranchised minorities turning to phase I clinical trials for a primary source of income. The fact remains that we cannot lament, on one hand, the legacy of Tuskegee and the distrust that it might have caused while ignoring, on the other, that minorities as a group might again be assuming much of the risk of biomedical research without sharing the benefit (through either participation in later phase trials or access to pharmaceuticals once they are made available on the market). This would be a violation of the ethical principle of justice outlined in the Belmont Report and may render ineffectual the federal safeguards employed to protect research participants.[9]

CONCLUSIONS

Research that promotes a more accurate understanding of minority participation in clinical trials has significant public health implications because it relates to efforts to eliminate disparities and achieve equality through clinical research. Currently, there seems to be an unequivocal belief that participation in clinical studies is both necessary and beneficial for minority populations. We assert that this is an overly simplistic view. Instead, the participation of minorities in clinical trials should be framed in 2 ways. First, individuals of diverse ethnic and racial backgrounds should have the

opportunity to participate in clinical trials. This is important from the perspective of fairness, and diversifying participants in clinical trials leads to better science and creates the potential to reduce health disparities in medicine. Second, medical research must not unduly burden or exploit particular groups in society. Regardless of the reasons for the overrepresentation of minorities in phase I trials and the continued underrepresentation of minorities in phase III trials, we need to consider these phenomena from an ethical standpoint. Minorities share a disproportionately greater risk and enjoy disproportionately fewer benefits (from a health and disease standpoint) from participating in clinical trials. If we as a research community are genuinely concerned about the legacies of exploiting minorities for the sake of medical progress, we should question the current system of phase I testing that could lead marginalized communities to believe even more that the research community treats their members as human guinea pigs that fill a particular need in the global economy.[53,54] ■

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Eye Disease Resulting From Increased Use of Fluorescent Lighting as a Climate Change Mitigation Strategy

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Increased use of fluorescent lighting as a climate change mitigation strategy may increase eye disease. The safe range of light to avoid exposing the eye to potentially damaging ultraviolet (UV) radiation is 2000 to 3500K and greater than 500 nanometers. Some fluorescent lights fall outside this safe range.

Fluorescent lighting may increase UV-related eye diseases by up to 12% and, according to our calculations, may cause an additional 3000 cases of cataracts and 7500 cases of pterygia annually in Australia.

Greater control of UV exposure from fluorescent lights is required. This may be of particular concern for aging populations in developed countries and countries in northern latitudes where there is a greater dependence on artificial lighting. (*Am J Public Health.* 2011;101:2222–2225. doi: 10.2105/AJPH.2011.300246)

CLIMATE CHANGE MITIGATION will involve numerous changes in the use of technology. Many people worldwide are exposed to artificial light sources both in the home and in the workplace. Until recently, this mainly entailed exposure to incandescent lights and, less frequently, to fluorescent lighting. Moves to sustainability and a low-carbon economy have involved the phasing out of incandescent lights and a shift toward more energy-efficient lighting in a number of countries, including Australia and the countries of the European Union.[1,2] In the United States, federal law stipulates that incandescent lights be phased out by 2014.[3]

Globally, increasing numbers of workers spend their work time in buildings rather than in fields or other outside locations and are thus, regularly and for extended periods, exposed to ultraviolet (UV) radiation via fluorescent lighting. This increase is partly due to rapid urbanization and the increasingly knowledge-based society (attracting workers into offices) in which we live. Although fluorescent lighting has been used in schools and offices for many years, only in recent years has it dominated UV exposure in the home, and it will continue to do so in future years.

The types of energy-efficient lighting with which incandescent lights are being replaced are high-intensity discharge (HID) lamps, light-emitting diodes (LEDs), and fluorescent lighting, including the popular compact fluorescent lamps (CFLs). All of these light sources are more efficient than the incandescent lamp, which electrically heats a tungsten filament so that it glows but loses much energy as heat.[4] CFLs, for example, use 75% less energy than do incandescent lamps.[5]

HID lamps produce intense light in a small area, and although they are less energy efficient than fluorescent lights, they are used widely for lighting large areas such as streets and sports facilities.[6] LEDs are energy efficient but not as bright, stable, or cheap as fluorescent lights. Fluorescent lighting, with its minimal energy demands, is considered to provide the most efficient form of light, one that most closely resembles daylight and provides the visual acuity necessary for task performance. Consequently, as a result of the popularity of fluorescent lighting a large number of people are now exposed to artificial sources of UV radiation emitted from these lights. Could this be a precursor to a substantial increase in future eye disease? We examine the potential for such an increase.

FLUORESCENT LIGHTING AND ULTRAVIOLET RADIATION

A fluorescent lamp or tube is a gas-discharge device that uses electricity to excite mercury vapor. The excited mercury atoms produce UV radiation, which causes the phosphorescent coating inside