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Awareness and Knowledge of the U.S. Public Health Service Syphilis Study at Tuskegee: Implications for Biomedical Research

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Abstract

The purpose of this review was to collect and interpret the findings of all published qualitative or quantitative research that assessed African Americans' 1) general awareness and/or specific knowledge of the U.S. Public Health Service (USPHS) Syphilis Study at Tuskegee, and 2) attitudes towards and/or willingness to participate in biomedical research. An exhaustive review of the literature produced eight articles that fit the aforementioned selection criteria. All articles that assessed both awareness and knowledge found that familiarity with the USPHS Syphilis Study at Tuskegee did not necessarily ensure accurate knowledge of it Four studies also found that awareness of the USPHS Syphilis Study at Tuskegee did not relate to willingness to participate in biomedical research. In addition to awareness and knowledge of the USPHS Syphilis Study at Tuskegee, published studies suggest that a broad, array of structural and sociocultural factors influence minorities' willingness to participate in biomedical studies.

Keywords

Minority groups; Tuskegee Syphilis Study; research subjects; bioethics; biomedical research

Racial and ethnic minority groups historically have been underrepresented and exploited in biomedical research.[1,2] Years after the National Institutes of Health (NIH) Revitalization Act of 1993, mandating the inclusion of women and minorities in clinical trials, minorities continue to be underrepresented in some types of biomedical/clinical research,[3–7] Such disproportionate representation can undoubtedly limit the reliability, validity, and general inability of research findings.[8–12] In addition, the benefits of research may not reach the most vulnerable groups.

The U.S. Public Health Service Syphilis Study at Tuskegee (USPHS Syphilis Study at Tuskegee), commonly referred to as the Tuskegee Syphilis Study, is often identified as a barrier to participation in biomedical research, particularly within the African American community.[13–15] According to Gamble,[16] this single interpretation can overlook the historical context

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of the beliefs of many African Americans. Mistrust in historically White institutions, such as academia and medicine, is an outgrowth of centuries of racial discrimination and exploitation of the African American community.[16–20] Shavers et al.[19] argue, “The Tuskegee Study is symbolic for the larger problem of African American distrust of the largely white medical establishment which has evolved in the presence of racial discrimination, racial inequalities in quality of care received, and a previous history of medical research misuse” (p. 571). Investigating the natural progression of untreated syphilis among 399 African American sharecroppers from Macon County, Alabama was the focus of the USPHS Syphilis Study at Tuskegee carried out between 1932 and 1972. (For a synopsis of the events of the USPHS Syphilis Study at Tuskegee, see Box 1.)

When details of the study were first reported in a *Washington Star* article by Jean Heller of the Associated Press on July 25, 1972, word spread like wildfire throughout the African American community.[20–23] Subsequently, the story has reverberated, mainly through oral accounts. As with most historical accounts passed down by word of mouth, the stories often become distorted. Fact and fiction are difficult to disentangle and, for many, the stories told have come to represent how African Americans perceive their environment.[24] Incomplete and perhaps even inaccurate accounts of the specific events of the USPHS Syphilis Study at Tuskegee have led to widespread misperceptions in the African American community resulting in a mistrust of medical research in general. This in turn, it is hypothesized, has influenced attitudes towards and willingness to participate in biomedical research.[20]

Numerous conceptual papers, historical literature reviews, and commentaries have been published on the USPHS Syphilis Study at Tuskegee.[16,18,21,24,–30] Few studies, however, have utilized qualitative or quantitative methods to examine the tripartite relationship between individuals’ general awareness of the USPHS Syphilis Study at Tuskegee, their knowledge of specific events of the study, and their willingness to participate in biomedical research.[15,31]

The purpose of this review was to collect and interpret the findings of all published qualitative or quantitative research studies that assessed African Americans’ attitudes towards and/or willingness to participate in biomedical research, as well as their general awareness and/or specific knowledge of the USPHS Syphilis Study at Tuskegee, To the authors’ best knowledge, this is the first review of the literature to be conducted on the effect of awareness and knowledge of the USPHS Syphilis Study at Tuskegee on biomedical research participation.

Box 1. SYNOPSIS OF THE U.S. PUBLIC HEALTH SERVICE SYPHILIS STUDY AT TUSKEGEE

1932 Tuskegee Study of untreated syphilis began; project involved 399 men with syphilis and 201 without. The men were told they were being treated for “bad blood,” Dr. Dibble and Nurse Rivers, two African American health professionals, are involved in recruiting and retaining the men in the study.

1936 Researchers request that local physicians withhold treatment from study subjects. In addition, the decision is made to follow the men until death.

1940 Researchers keep the men from receiving treatment ordered by the military draft.

1945 Although accepted as the drug of choice for syphilis, USPHS researchers decide not to treat the men with Penicillin.

1968 Peter Buxtun, a venereal disease investigator with the USPHS, voices concern over the study.

1969 The CDC and local chapters of the AMA and NMA reaffirm their support for the study.

1972 Whistle blower Peter Buxtun, informs Associated Press writer Jean Heller about the study. The public learns about the study in local newspapers.

1972 Study ends; participants are offered some monetary and medical reparations.

1973 Congressional hearings begin. A class action law suit filed by the NAACP results in a $9 million dollar settlement.

1997 On May 16th, President Bill Clinton offers a formal apology on behalf of the nation.

Source: Welsh KA, Ballard E, Nash F, et al. Issues affecting minority participation in research studies of Alzheimer Disease. Alzheimer Dis Assoc Disord. 1994;8. (Suppl 4);38–48. The Centers for Disease Control and Prevention (CDC). The Tuskegee timeline. Atlanta: CDC, 2005. Available at: http://www.cdc.gov/nchstp/od/tuskegee/time.htm.

Methods

The authors searched multiple sources to identify eligible articles. In addition to the popular online database *Google Scholar,* the authors searched *Cambridge Scientific Abstracts*' (CSA) natural and social science index using the following keywords: *Tuskegee Syphilis Study* or *Tuskegee, minority and willingness to participate* and *U.S. Public Health Service Syphilis Study*. To acquire as many studies as possible, no limit was put on sample size, year of publication, or study location, *Cambridge Scientific Abstracts* contains over 40 discipline-specific databases, 17 in the natural science index and 23 databases in the social science index. Important electronic sources such as MEDLINE, Sociological Abstracts, and PsycINFO are included in CSA databases. The keywords *Tuskegee Syphilis Study* or *Tuskegee* yielded 45 peer-reviewed journal articles in CSA's social science index and 92 in CSA's natural science index. The keywords *minority* and *willingness to participate* yielded 7 peer-reviewed articles in CSA's social science index and 18 in CSA's natural science index. The keywords *U.S. Public Health Service Syphilis Study at Tuskegee* yielded no results in either CSA index. Although over 150 articles were retrieved using CSA alone, many were conceptual in nature and did not examine any of the aforementioned variables of interest utilizing qualitative or quantitative research methods.

Following the electronic search, the authors examined the bibliographies of retrieved articles to help identify additional studies. A review of the literature produced eight articles that fit the following two selection criteria: 1) the study must have been published in a peer-reviewed journal, and 2) the study must have qualitatively or quantitatively assessed African Americans' attitudes towards and/or willingness to participate in biomedical research, as well as their awareness and/or knowledge of the USPHS Syphilis Study at Tuskegee. Five of the eight articles eligible for review were identified using Cambridge Scientific Abstracts Databases;[19,32–35] one was identified through a secondary bibliographic search[36] and two were identified using *Google Scholar*.[37,38] Four of the eight, retrieved studies utilized a qualitative, focus group design and four studies used a quantitative, cross-sectional survey design. In the following section, the eight studies chosen for review are ordered by their type of study design and year of publication, in ascending order within each design category.

Literature Review Results

Qualitative studies

Between December 1996 and February 1997, Corbie-Smith et al.[34] conducted 5 focus groups with 33 African American adults from an urban public hospital in Atlanta, Georgia. The objective of the study was to explore the reasons for low participation in clinical trials by African Americans. Focus group participants were asked to respond to questions about their health status, past experiences with medical research, awareness of the USPHS Syphilis Study at Tuskegee, knowledge of specific events of the USPHS Syphilis Study at Tuskegee, familiarity with informed consent, and general feelings (attitudes) about medical research.[34] Both positive and negative responses were reported by the participants in response to the question, "What comes to mind when you hear the term *medical research*?" The range of responses indicated a lack of consensus.

Although focus group participants referred to the USPHS Syphilis Study at Tuskegee repeatedly throughout the session, few could recount specific details of the study. Many participants believed the government had injected the men with syphilis and few knew how many men were enrolled in the study. Interestingly, when the focus group moderator began to describe the USPHS Syphilis Study at Tuskegee in detail, several focus group participants challenged her claims, questioning her about where she got her information. One participant stated, "I'm not saying you are lying ... but just like you are telling me one side, there could be a lot of different sides. You may have been misled as to the facts."[34] In general, the focus group participants reported being cautious in interacting with medical institutions and the government. Although conspiracy theories were also mentioned, many participants felt the USPHS Syphilis Study at Tuskegee alone justified their belief that medical research is tainted by deceit.[34] Although participants were asked to discuss the reasons why they might or might not participate in medical research, the researchers did not specifically ask the participants to address the effect of the USPHS Syphilis Study at Tuskegee on their willingness to participate in biomedical research.

In preparation for a National Cancer Institute-funded conference held in Tuskegee, Alabama, 103 African Americans from 9 Alabama counties participated in focus group interviews during March 1997,[38] The objective of the focus group interview was to examine factors related to minority participation and retention in clinical cancer research. During the interview, several topics were discussed, including awareness and knowledge of the USPHS Syphilis Study at Tuskegee, reluctance to participate in clinical trials, and general feelings and beliefs about clinical research. Awareness of the USPHS Syphilis Study at Tuskegee was widespread among the focus group participants, although many expressed inaccurate information about what happened as fact. The belief that the men enrolled in die study were injected with syphilis was prevalent. Most of the focus group participants indicated that the USPHS Syphilis Study at Tuskegee would not affect their decisions to participate in clinical research. In fact, many stated they would participate if asked. Focus group participants had mixed feelings about research; one remarked, "I believe it is good and then again it is bad "[38] During the interviews, participants mentioned several factors they would have to consider before making a commitment to participate in a research study. These included who is conducting the study, trust in the investigator, understanding the associated risks and benefits, and the type of research being done.[36]

Freimuth et al.[32] conducted seven focus groups in Los Angeles, Chicago, Washington, D.C., and Atlanta during the winter of 1997. Sixty African American men and women participated in the focus groups. Issues addressed in the focus groups included knowledge of research terms and procedures, motivations of researchers, past experiences with medical research, beneficiaries of research, awareness of the USPHS Syphilis Study at Tuskegee, specific knowledge of the study's events, willingness to participate in research, and trust in medical research. Although the majority of focus group participants were familiar with the USPHS Syphilis Study at Tuskegee, few had accurate information about the specific events of the study. Many of the participants believed the men in the study were deliberately injected with syphilis, a common finding of similar studies.[19,34,38] Several participants compared the USPHS

Syphilis Study at Tuskegee to other conspiracy theories in the African American community such as the genocidal introduction of HIV/AIDS, the use of Agent Orange, and the Measles Vaccine Study during the 1990s.[32]

> Participants made a direct link between lack of information about real research abuses and the development of rumors and conspiracy theory. Therefore, it is necessary to acknowledge that many African Americans view research within the context of contemporary racism, urban legends and mistrust in healthcare and the larger society, and that their concerns and fears have a legitimate basis in historical reality, (p. 807) 32

Focus group participants were also asked about their willingness to participate in research. Invasiveness of the proposed procedure, confidentiality, and informed consent were identified as factors that would affect one's willingness to participate in research. The USPHS Syphilis Study at Tuskegee was also described as "adequate justification" for many participants' unwillingness to participate.[32] This brief reference to the USPHS Syphilis Study at Tuskegee presumably refers to the influence of general awareness on participants' willingness to participate in research. The relationship between participants' amount of knowledge and willingness to participate was not assessed in this study.

Two hundred and fifteen individuals drawn from the southeastern United States participated in focus groups conducted by Bates and Harris from August 2001 to March 2002.[35] Discussion of the USPHS Syphilis Study at Tuskegee was limited to focus groups with African American participants. Bates and Harris found that African American participants' general awareness of the USPHS Syphilis Study at Tuskegee did not necessarily result in unwillingness to participate in biomedical research. In fact, many focus group participants realized the need for improved representation of African Americans in research studies. Bates and Harris's[35] findings both agree with and differ from other studies included in this review. Like the authors of other published studies, Bates and Harris[35] conclude that the USPHS Syphilis Study at Tuskegee made many African American participants suspicious of biomedical research. However, focus group discussions revealed that multiple factors were typically involved in one's decision whether to participate, not simply this one historical event.

Quantitative studies

In a cross-sectional survey of 218 African American and 203 White residents in Jefferson County, Alabama, Green et al.[36] found that awareness of the USPHS Syphilis Study at Tuskegee negatively influenced respondents' interest in participating in health research and promotion activities. The investigators used a random digit dial method to identify eligible participants (household member with the most recent birthday, aged 18 years or older, living in Jefferson County, telephone in the house). Eighty-one percent of eligible respondents completed the survey. In the population sampled, 52% of African Americans had prior knowledge of the USPHS Syphilis Study at Tuskegee, compared with 46% of Whites; this small observed difference between races was not statistically significant ($p > .01$). African American respondents, however, were more than twice as likely to report less interest in participating in health research and health promotion activities due to the USPHS Syphilis Study at Tuskegee as Whites (22% vs. 10% respectively, $p < .01$). This lack of interest was even more pronounced among African American males in comparison with White males (27% vs. 11% respectively, $p < .01$).[36]

Using a convenience sample of 301 African Americans in Durham, North Carolina, Sengupta et al.[37] utilized structural equation modeling to explore distrust and other factors that might influence willingness to participate in AIDS research by means of a cross-sectional survey. Respondents were classified by income level (below poverty vs. lower- to upper-middle class).

The investigators hypothesized that impoverished participants would not be able to answer questions about the USPHS Syphilis Study at Tuskegee due to their lack of knowledge. As a result, Sengupta et al.[37] over sampled from the lower- to upper-middle class subgroup to attain statistical power on questions pertaining to the study. Approximately two-thirds of the sample indicated they had heard of the USPHS Syphilis Study at Tuskegee. Information was not given regarding awareness by income level or any other potential covariates. Amount of knowledge was not assessed, as it was not related to the purpose of the study. Using factor analysis, Sengupta. et al.[37] collapsed multiple indicators (i.e., predictors of willingness to participate) into four variables: distrust, altruism, religiosity, and facilitators/barriers, A comparison between present day AIDS scientists and scientists involved in the USPHS Syphilis Study at Tuskegee was included as an indicator of distrust. Survey participants were asked, “Compared with the Tuskegee Syphilis Study scientists, do you think HIV/AIDS scientists are more, about the same, or less respectful towards blacks participating in their studies?”[37] Given that only 30% of the explanatory power of distrust was attributed to this comparison between modern AIDS scientists and scientists involved in the USPHS Syphilis Study at Tuskegee, Sengupta et al.[37] concluded that the USPHS Syphilis Study at Tuskegee is not the primary reason for African Americans’ distrust in research, but rather that distrust is based upon a general wariness about medical experimentation. Overall, Sengupta et al.[37] reported that distrust, but not necessarily the USPHS Syphilis Study at Tuskegee, was a strong inverse predictor of willingness to participate in AIDS clinical trials.

Shavers et al. “examined the relationship between general awareness of the USPHS Syphilis Study at Tuskegee and specific knowledge of the study’s events, as well as the influence of awareness and knowledge on willingness to participate in medical research. Between 1998 and 1999, a total of 198 residents in the Detroit Primary Metropolitan Statistical Area (Detroit PMSA) participated in the study. This particular analysis, however, was limited to 179 residents who identified themselves as African American or White. Eligible respondents (aged 18 years or older and current resident of household) were identified using a three-stage sampling design, stratified by income and household density, The 1990 U.S. Population Census was used for primary and secondary stratification. Following receipt of an introductory cover letter and postcard, households were sent a long version of the survey instrument. Nonrespondents were then sent a short version; nonrespondents to both versions then received a follow-up telephone interview. Overall, 198 residents completed the survey, for a response rate of 36%.

According to Shavers et al.,[19] African American respondents were significantly more likely than Whites to have heard of the USPHS Syphilis Study at Tuskegee (81% vs. 28%, respectively, $p < .001$). Of those individuals reporting having heard of the study, 41% reported that their awareness of the USPHS Syphilis Study at Tuskegee would affect their decision to participate in future medical research (46% African Americans vs. 34% Whites, $p = .25$). Among those who indicated that the study would affect their decision to participate, 49% of African Americans reported that their awareness of the study would negatively affect their willingness to participate, compared with only 17% of Whites ($p = .05$). Shavers et al.[19] also measured respondents’ knowledge of how the men enrolled in the study contracted syphilis. The majority of respondents were misinformed. While 76% of African Americans familiar with the USPHS Syphilis Study at Tuskegee indicated that the men were deliberately injected with syphilis, 59% of Whites stated this ($p = .26$), signifying the sizable lack of historical accuracy surrounding the study’s events in both, racial groups. Of those who believed that the men in the USPHS Syphilis Study at Tuskegee were injected with syphilis, 65% of African Americans and 100% of Whites indicated they would still be willing to participate in a future medical research study ($p = .01$). Conversely stated, of the respondents who believed that the men were injected with syphilis, slightly over a third of African Americans (35%) and none of the Whites stated they would be unwilling to participate in a future medical research study.

Awareness of the USPHS Syphilis Study at Tuskegee affects minorities' trust in medical researchers in different ways. According to Shavers et al.,[19] 51% of African Americans and 17% of Whites reported that being aware of the "Tuskegee Study" resulted in them trusting medical researchers less than if they were not aware of the study. In contrast, 48% of African Americans and 83% of Whites reported that their trust had not changed as a result of their awareness ($p = .02$). Respondents whose awareness resulted in less trust were significantly less likely than those respondents who experienced no changes in trust to participate in medical research (OR = .19, 95% CI .05, .71). Although not statistically significant, respondents with no awareness of the "Tuskegee Study" were less willing to participate in medical research than respondents who had heard of the study, but experienced no changes in trust as a result (OR = .36, 95% CI .06–2.07), Among African Americans, however, respondents who were not aware of the study were significantly less willing to participate in medical research than their counterparts who were aware of the study and experienced no change in their level of trust (OR = .13, 95% CI. .04–.49). No statistically significant difference in willingness to participate was observed between African Americans without awareness versus African Americans with awareness who reported less trust (OR = .74, 95% CI .18–3.12). Awareness, knowledge, and level of trust did not significantly affect willingness to participate among White respondents. Shavers et al.[19] concluded awareness alone does not appear to be associated with willingness to participate in medical research. Awareness linked with having less trust in medical researchers, however, appears to negatively affect African Americans' willingness to participate. Similar results regarding awareness of the USPHS Syphilis Study at Tuskegee, willingness to participate in medical research, and trust in medical researchers were published in two subsequent publications by Shavers et al.[39,40]

Awareness of the USPHS Syphilis Study at Tuskegee did not appear to be associated with willingness to participate in clinical cancer trials for Blacks or Whites in a telephone survey of 438 respondents conducted by Brown and Topcu.[33] A random digit dial method was utilized to identify eligible participants (over 50 years old, living in the metropolitan Detroit area), with a response rate of 50%. Awareness of the study differed significantly among racial groups, with 55% of African Americans and 38% of Whites reporting they had heard of the USPHS Syphilis Study at Tuskegee ($p < .001$). Using regression to analyze the effects of awareness and fatalistic beliefs on willingness to participate, Brown and Topcu[33] found that neither of these factors were "stronger predictors of behavioral intention" (p. 70) to participate for African Americans than for Whites.[33] Like Shavers et al.,[19] Brown and Topcu[33] suggest that, although the USPHS Syphilis Study at Tuskegee may be symbolic of African Americans' distrust in medical research, it does not appear to affect African Americans' willingness to participate in clinical trials.

Summary of findings

Multiple topics were assessed in the eight studies reviewed. Table 1 provides a checklist of the topics assessed by each study included in the literature review. For example, Green et al.[36] addressed general awareness of the USPHS Syphilis Study at Tuskegee, as well as the relationship between awareness and willingness to participate in biomedical research. Topic areas not addressed by the study included amount of knowledge of the USPHS Syphilis Study at Tuskegee, the relationship between awareness or amount of knowledge and attitudes towards biomedical research, and the relationship between amount of knowledge and willingness to participate in biomedical research.

In addition to the checklist provided in Table 1, a full description of each study's sample population, objectives, main findings, and limitations is provided in Table 2. Following the format outlined in the review, articles are ordered chronologically within each design category (qualitative and quantitative). Only those limitations specified in the articles reviewed are listed.

Although differing objectives, hypotheses, and nuance (e.g., willingness to participate vs. interest in participating, and clinical trials vs. biomedical research) made it difficult to make comparisons across studies, at least one common theme emerged from the literature. All the articles that assessed both awareness and knowledge found that familiarity with the USPHS Syphilis Study at Tuskegee did not necessarily correspond to entirely accurate knowledge about the study.[19,32,34,38]

In general, the studies lacked consensus on key issues such as racial differences in awareness and willingness to participate in biomedical research, as well as determinants of medical mistrust. Shavers et al.[19] and Brown and Topcu[33] found that awareness of the USPHS Syphilis Study at Tuskegee differed between racial groups, while Green et al.[36] found no significant difference in awareness between African Americans and Whites. Freimuth et al.[32] and Green et al.[36] reported that awareness of the USPHS Syphilis Study at Tuskegee had a negative impact on African Americans' willingness to participate in biomedical research; Brown and Topcu,[33] Shavers et al.[19] Green et al.,[38] and Bates and Harris,[35] on the other hand, found that awareness of the study was not independently related to willingness to participate among racially diverse groups. Bates and Harris,[35] Freimuth et al.,[32] and Corbie-Smith et al.[34] found that African Americans' negative attitudes towards biomedical research were often attributed to the USPHS Syphilis Study at Tuskegee. In contrast, Sengupta et al.[37] found that the USPHS Syphilis Study at Tuskegee was not the primary basis of distrust, but rather an indication of general suspicion towards medical research. Shavers et al.[19] was the only study to examine the relationship between amount of knowledge of the USPHS Syphilis Study at Tuskegee and willingness to participate in biomedical research. They discovered that inaccurate knowledge of how the men enrolled in the USPHS Syphilis Study at Tuskegee were infected with syphilis did not generate unwillingness to participate in biomedical research, particularly among Whites.[19]

Discussion

The USPHS Syphilis Study at Tuskegee has long been the subject of scholarly debate and research, yet empirical evidence that directly links awareness or knowledge of the USPHS Syphilis Study at Tuskegee to individuals' willingness to participate in biomedical research is scarce. Few studies have utilized data to determine if awareness corresponds to accurate knowledge of the USPHS Syphilis Study at Tuskegee, whether awareness and amount of knowledge differs by race, or how awareness and amount of knowledge affects individuals' willingness to participate in biomedical research. Although many investigators have studied African Americans' perceptions of the USPHS Syphilis Study at Tuskegee, most of the published literature is conceptual. Such a narrow research focus has resulted in significant gaps in the existing literature. To state conclusively what factors affect African Americans' attitudes towards and willingness to participate in biomedical research, investigators must quantity the contribution of other salient factors such as personal experiences with racial discrimination and access to culturally-competent, high-quality health care as well.

Wendler et al.[41] and Freedman[42] suggest that recruitment, a key component of participation in research, is largely responsible for minorities' lack of participation in biomedical research. It appears that although minorities may generally mistrust medical research, are aware of the USPHS Syphilis Study at Tuskegee, and express an unwillingness to participate in medical research, they may participate at the same rates as Whites if recruited to participate. Efforts to increase participation of minorities, therefore, should focus on improving recruitment practices and lessening physical barriers to participation, such as lack of child care, cost, and transportation.[33,41]

Other investigators have proposed that the foundation of mistrust in biomedical research predates the USPHS Syphilis Study at Tuskegee.[16] Historical events, such as Dr. Marion Sims's experimental gynecological treatments on slaves and tales of night doctors stealing bodies from African Americans' gravesites, have undoubtedly influenced African Americans' attitudes towards the medical community.[16] Collective memory, characterized by shared beliefs and experiences within a community, may also contribute to African Americans' mistrust in medical research.[24] Open, honest dialogue between clinicians or researchers and minority communities about these historical and sociocultural factors may help ease individuals' apprehension regarding biomedical research studies.

No single factor has been identified conclusively as bringing about low participation among minorities, and it is likely that there are multiple factors affecting the phenomenon. Perceptions of the USPHS Syphilis Study at Tuskegee are reinforced by many of the structural barriers and exclusionary processes that many minorities, especially African Americans, face in their everyday lives.[30] Additionally, there is the issue of recruitment as discussed by Wendler et al.[41] and Freedman[42] (i.e., the low rates at which minorities are contacted to be part of medical research may itself explain much of the low participation rates).

Two important lines of research remain to be carried out to fully understand the legacy of the USPHS Syphilis Study at Tuskegee for future efforts to recruit minority populations into biomedical research. First, the combined effects of awareness and amount of knowledge of the USPHS Syphilis Study at Tuskegee must be assessed. Second, in order to put the USPHS Syphilis Study at Tuskegee properly in context, investigators should evaluate the independent and interactive effects of other salient factors such as sociocultural dynamics and matters of contact and consent. Examining these factors in combination would fill gaps in the literature and improve current efforts to increase minority participation in biomedical research.

Conclusion

Minority participation rates in biomedical research continue to be low. Efforts are underway to understand the factors underlying the low rates of participation alongside concerted efforts to increase participation rates. The critical analysis of the literature presented here indicates that a majority of studies focus on the effects of either awareness or knowledge of the USPHS Syphilis Study at Tuskegee on participation rates. To date, efforts to examine the combined effects of both awareness and knowledge of the USPHS Syphilis Study at Tuskegee on likelihood of participation in biomedical research are missing. In addition, sociocultural factors and recruitment practices, influencing mistrust of and apprehension about medical research, must be examined to understand factors underlying underrepresentation. Research along these lines is especially important to inform recruitment efforts to increase minority participation rates in biomedical research.

Notes

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Table 1

SUMMARY OF TOPICS ASSESSED BY THE EIGHT STUDIES REVIEWED

Authors	Awareness	Amount of knowledge	Awareness & attitudes	Amount of knowledge & attitudes towards B. research	Awareness & willingness to participate In B. research	Amount of knowledge & willingness to participate in B. research
Corbie-Smith et al., 1999	✓	✓	✓	✓		
Green et al, 2000	✓	✓			✓	
Freimuth et al., 2001	✓	✓	✓	✓	✓	
Bates & Harris., 2004	✓		✓		✓	
Green et al., 1997	✓				✓	
Sengupta et al., 2000	✓		✓			
Shavers et al, 2000	✓	✓	✓		✓	✓
Brown & Topcu, 2003	✓				✓	

B. research = biomedical research

Table 2

DETAILED DESCRIPTIONS OF EIGHT STUDIES INCLUDED IN THE LITERATURE REVIEW

Authors	Sample	Population	Objectives	Outcomes	Limitations
Corbie-Smith, Thomas, Williams, and Moody-Ayers, 1999	N=33 Location: Atlanta, GA	M=10 F=23 AA=33	Explore the reasons for low participation in clinical trials among AAs (attitudes and beliefs towards informed consent, knowledge of the USPHSSST, real/perceived examples of medical abuse, risks and benefits of participation)	• Few participants could recount specific details of the USPHSSST • Participants were cautious about trusting government sponsored research	Focus group results are intended to generate, rather than test hypotheses. Participants were interviewed at only 1 location; results may not be generalizable to other locations.
Green, Partridge, Fouad, Kohler, Crayton, & Alexander, 2000	N=103 Location: Jefferson, Greene, Macon, Cherokee, Barbour, Dallas, Madison, Mobile, & Montgomery County, AL	M=31 F=72 AA=103	Examine factors related to minority participation and retention in clinical cancer trials	• All participants were aware of the USPHSSST. • Inaccurate information about the study was prevalent among the focus group participants. • Most participants indicated their awareness would not affect their decision to participate in clinical trial.	A convenience sample was utilized for the study; results may not generalize to all African Americans. The majority of the sample was female. The focus groups were conducted with different moderators, which may have influenced responses.
Freimuth, Quinn, Thomas, Cole, Zook, & Duncan, 2001	N=60 Location: Los Angeles, Chicago, Washington, and Atlanta	M=20 F=40 AA=60	Examine knowledge and attitudes toward medical research, knowledge of the USPHSSST, and reactions to Miss Ever's Boys	• The majority of participants were aware of the USPHSSST. • Participants lacked specific details of the study events. • Respondents' negative attitudes towards participation were often contributed to the USPHSSST.	One of the focus groups in Chicago did not take place. Finding a representative sample was not the goal of recruitment.
Bates & Harris, 2004	N=215 Location: Southeastern states	M=127 F=86 Ref=2 AA=118 W=71 H=15 O=l1	Investigate the use of the USPHSSST as an emergent theme in public discussion	• Only AA participants mentioned the USPHSSST. • Awareness did not always result in unwillingness to participate. • The USPHSSST did make AA participants suspicious of research	Results may not be generalizable. Income of the group differs from the median for the state.
Green, Maisiak, Wang, Britt, & Ebeling, 1997	N=421 Location: Jefferson County, AL	M=206 F=215 AA=218 W=208	To report the effects of the USPHSSST on participation in health promotion activities and research studies.	• AAs reported significantly less interest in participating in health research due to the USPHSSST than Whites. • Slightly more AAs were aware of the study than Whites.	Results may not be generalizable. Respondents' knowledge may be influenced by their location, Knowledge of the USPHSSST was not assessed.
Sengupta, Strauss, DeVillis, Quinn, Devillis, & Ware, 2000	N=301 Location: Durham, NC	M=83 F=218 AA=301	Examine a multidimensional construct of institutional distrust and other factors that may influence willingness to participate in AIDS research	• The majority of the sample was aware of the USPHSSST. • The USPHSSST was one of several contributing factors to distrust. • Distrust was a strong predictor of unwillingness to participate in AIDS research.	Random sampling was not utilized. Results may not be generalizable outside of Durham, NC. Causation cannot be implied from cross-sectional data. The SEM model did not have an excellent fit to the data. The model used is one of several plausible models.
Shavers, Lynch, & Burmeister, 2000[2]	N=198 Location: Detroit, MI	M=83 F=96 (includes AA and Whites) AA=91 W=88	Examine racial differences, knowledge of the USPHSSST and the influence of this knowledge on willingness to participate in medical research	• Awareness was significantly higher in AAs than Whites.	The census data used for sampling was 10 years old; newly built homes may be overlooked. Low response rates inhibit ability to generalize data.

Authors	Sample	Population	Objectives	Outcomes	Limitations
		H=8 O=6 Ref=5		• The majority of respondents were misinformed about how the study subjects got syphilis. • Awareness linked to distrust negatively impacts AA’s willingness to participate.	
Brown & Topcu, 2003	N=438 Location: Detroit, MI	M=143 F=295 AA=216 W=222	Determine if older AAs are less likely than Whites to express willingness to participate, given knowledge of the USPHSSST and fatalistic beliefs	• AAs were significantly more aware of the USPHSSST than Whites. • Awareness of the study influenced AA's and White's "behavioral intention" of participation equally.	Behavioral intention does not necessarily equate to actual participation.

[2] Two subsequent publications using the Detroit PMSA database were published by Shavers et al. in 2001 and 2002.

M = male

F = female

USPHSSST = U.S. Public Health Service Syphilis Study at Tuskegee

AA = African American