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Different Types of Distrust in Clinical Research Among Whites and African Americans

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Abstract

Background—African Americans are thought to be more distrustful of clinical research compared to elderly whites, but it is unknown whether specific types of distrust in clinical research, such as interpersonal or societal distrust, vary according to race. The primary objective was to identify racial differences in interpersonal or societal distrust in clinical research among African Americans and whites.

Methods—Seven hundred seventy-six older African Americans and whites were surveyed about their interpersonal and societal distrust using a 7-item index of distrust in clinical research. We combined the 2 societal distrust items into a societal distrust subscale. We also assessed trust in primary care physicians, access to care, health/functional status, previous exposure to clinical research, awareness of the Tuskegee Syphilis Study, perceived discrimination in health care, and sociodemographic characteristics.

Results—High societal distrust was more common among African Americans compared to whites (21% vs 7% in the top quartile of the societal distrust, $p < .0001$), but there were no racial differences in responses to the individual interpersonal distrust index items. In sequentially built multivariable analyses, the relationship between African American race and societal distrust (odds ratio, 2.2; 95% CI, 1.2–3.7) was not completely explained by other factors such as trust in one's physician, previous discrimination, or awareness of the Tuskegee Syphilis Study.

Conclusions—Racial differences according to the type of distrust in clinical research may warrant assessing specific types of distrust separately among racially diverse populations in future studies.

Keywords

trust; clinical research

Historically, African Americans and other minority populations have participated in clinical trials in numbers that are disproportionately low when compared to whites. Although the National Institutes of Health (NIH) Revitalization Act of 1993 mandated the inclusion of minorities and women in clinical trials, the representation of African Americans in clinical

trials still continues to be disproportionately low.¹⁻⁴ Investigators have been encouraged to reach out to minority communities and design studies to optimize minority participation.⁵⁻⁷

Despite investigators' efforts, distrust among minority populations may be a persistent barrier to minority research participation.^{5,7,8} Previous studies suggest that African Americans may be more distrustful of clinical research when compared to whites, and distrust is the most frequently cited disincentive for research participation among minority populations.^{5,7,9,10} Corbie-Smith et al discovered higher levels of distrust in clinical research among African Americans compared to whites (24% vs. 6%, $p < .01$) in a nationwide survey among more than 900 individuals.⁵ This increased level of distrust among minorities may be attributable to lower levels of trust in their physicians. Alternatively, skepticism toward research participation, among older African Americans in particular, may also reflect an overall distrust in the health care system, which can be attributed to their awareness of past research abuses such as the US Public Health Service Tuskegee Syphilis Study and their own experiences with the health care system.¹⁰⁻¹³

Though some prior studies have demonstrated that African Americans may be more distrustful of clinical research than whites,^{5,7,8,14-17} fewer studies have focused on different types of distrust, such as societal and interpersonal distrust. Interpersonal distrust in clinical research may be based on personal experiences and interactions of individuals within health care or clinical research settings. In contrast, societal distrust is characterized by a global negative outlook on clinical research based on perceptions of collective research entities or life experiences in society at large. Measures of overall distrust in clinical research may not reflect the potential for an individual to hold contrasting beliefs according to these specific types of distrust. More importantly, potential interventions will differ depending on the type of trust affected. For example, to counteract interpersonal distrust in clinical research, investigators might seek physician referrals to build on the trust already forged in physician-patient relationships. Conversely, to address societal distrust in clinical research, an investigator might channel efforts toward a specific community to increase the awareness of pertinent health care conditions and the vital role of clinical research in advancing health care. Community outreach efforts undertaken outside of the context of trial recruitment also may help to counteract any negative preconceived notions about clinical research among community members. A true understanding of racial disparities in distrust in clinical research may require a more focused exploration of different types of distrust and the myriad factors that may influence each type. Therefore, the primary objective of the study was to examine the relationships between race and both societal and interpersonal distrust in clinical research while accounting for a comprehensive set of potential confounding factors.

METHODS

Survey Sample and Procedures

The sample population was comprised of community-dwelling adults (aged 45 years and over) in the Boston, Massachusetts, metropolitan area who were participating in a voluntary mailing list organized by a local geriatric clinical and research institution. Participants were recruited to be on the list through community outreach efforts, including a quarterly newsletter, community presentations, fliers, and word-of-mouth referrals.

From 3314 participants in the mailing list, all the African Americans and an equal random sample of whites were recruited for participation in the survey. Each respondent received a cover letter explaining the study along with the survey instrument. A reminder postcard that also offered the option to complete the survey by telephone (completed by 8 respondents) was sent to all nonresponders after 3 weeks. A final mailing, including another cover letter and a second copy of the survey, was sent to all the remaining nonresponders after another 3

weeks. Participants provided verbal informed consent for this study. The study was approved by the institutional review boards at Beth Israel Deaconess Medical Center, Hebrew SeniorLife, and the University of Alabama at Birmingham.

Survey instrument—The survey was administered as part of a larger study to measure respondents' willingness to participate in clinical trials. For these analyses, our main outcome measures were interpersonal and societal distrust in clinical research as measured by the 7-item Corbie-Smith distrust index (Table 1).⁵ Based on the content of the questions, 5 of the index items were categorized as measures of interpersonal distrust (eg, belief that your doctor would explain research fully to you if asking you to participate in a trial). The remaining 2 index items assessed societal distrust (eg, likelihood that you or people like you will be used as guinea pigs without permission). Response options for each index item varied, but those positive responses were coded as expressions of trust and negative or neutral responses as expressions of distrust.

Race was our primary independent variable. The survey instrument also examined other potential confounders or explanatory variables in the following domains: (1) sociodemographic characteristics, (2) trust in one's primary care physician, (3) access to care, (4) health/functional status, (5) previous exposure to clinical research, and (6) prior history of discrimination in health care and/or knowledge of the Tuskegee Syphilis Experiment. Trust in one's primary care physician was assessed using an 8-item trust subscale taken from the Primary Care Assessment Survey (PCAS).¹⁸ The PCAS trust subscale examines trust by inquiring about patients' beliefs, such as their willingness to disclose information to the physician and their confidence in physician transparency in the setting of a medical error. The scale is scored on a continuous scale¹⁸ from 0 to 100, and response data were divided into quartiles of trust in one's primary care physician. To characterize each respondent's access to care, the survey assessed insurance status and whether the respondent had a single physician or nurse primarily responsible for his/her care. The survey also assessed respondents' health and functional status by asking about chronic medical conditions, the number of hospitalizations in the previous 12 months, the number of daily prescription medications that they take, and their ability to complete, independently, basic activities of daily living. Respondents were also asked how many outpatient visits they had with that same provider in the previous 12 months. If a respondent did not have a personal nurse or physician, they were asked to report the number of visits with the provider they had seen most often in the last 12 months.

Exposure to clinical research was assessed by asking respondents whether they had previously participated in a clinical trial. Respondents were asked about their awareness of the Tuskegee Syphilis Study ("Have you ever heard of the Tuskegee Syphilis Experiment?") as well as their own personal history of discrimination in health care and discrimination in general. Finally, respondents were asked about sociodemographic information, including age, gender, race/ethnicity, and education level.

The survey instrument was first tested using cognitive interviews with 5 white and 5 African American subjects over the age of 60 years, and the instrument was modified based on feedback from these interviews.

Analyses

Bivariate analyses were performed using χ^2 or *t* tests as appropriate to identify relationships between distrustful responses to the individual distrust index items. Racial differences in distrust were only evident for the societal distrust items so the remainder of the analysis was focused on these 2 items. Continuous response data on a 5-point Likert scale (eg, 1 = very unlikely to 5 = very likely), used in the 2 societal distrust items, was combined to form a

societal distrust subscale (1 to 10, higher score = more distrust). Based on the cumulative continuous scores on the societal distrust subscale, respondents were then dichotomized into categories of “high societal distrust” (top quartile of subscale scores) and “lower societal distrust” (bottom 3 quartiles of sub-scale scores) to distinguish those with the highest levels of societal distrust from the rest of the respondents. Bivariable analyses were repeated using the dichotomous measure of societal distrust (high vs lower distrust). Those independent variables significantly associated ($p \leq .1$) with high societal distrust on the 2-item subscale were used to sequentially build multivariable logistic models to determine the relationship between race and high societal distrust. The relationship between race and high societal distrust was assessed for changes with the addition of each domain of factors to the model. The analyses also explored interactions between race and other covariates, but these interactions were not significant. Therefore, the final multivariable model shown does not include interaction terms. Data were analyzed¹⁹ using SAS version 9.1.

RESULTS

Respondent Characteristics

Of the 1591 surveys mailed, 67 were returned either because of an invalid address or the intended recipient was deceased (Figure). Of the 846 surveys completed and returned, 70 additional surveys were excluded because the respondent either reported a race other than black or white, reported a combination of black and white race, or did not report any race. Ultimately, the analyses included 776 completed surveys among 1454 eligible respondents, yielding a final response rate of 53%.

Though the cohort included some middle-aged persons, the vast majority were elderly with a mean age of 72.9 years. Forty-seven percent of the respondents had a college degree or better and 96% had either public or private health insurance. Compared to whites, African American respondents were younger (mean age, 68 vs 76 years, $p < .0001$) and less well-educated (34% vs 56% with college degree or better, $p < .0001$) (Table 1). African Americans, however, reported having similar rates of health insurance coverage (97.6% of African American respondents vs 98.3% of white respondents, $p = .50$). There were no racial differences in trust in one’s primary care physician (mean PCAS trust scale score 77.1 vs 77.6 for African Americans and whites, respectively, $p = .6$).

Distrust in Clinical Research

Small proportions (<15%) of African Americans and whites expressed negative or distrustful responses on any of the 5 items focused on interpersonal distrust, with no racial differences in the responses (Table 2). There were, however, racial differences in the beliefs expressed in the 2 items focused on societal distrust. African Americans were more likely than whites to think that they could potentially be “used as guinea pigs” without giving their permission (54% vs 28%, $p < .0001$) or to think that health care providers, in general, prescribe medications as a way of “experimenting on people without permission” (60.0% vs 40.6%, $p < .0001$). On the combined societal distrust subscale, African Americans had a higher mean score of societal distrust (5.3 ± 1.8 vs 4.2 ± 1.6 , $p < .0001$) compared to whites. African Americans were also more likely to fall into the top quartile of societal distrust (high distrust) compared to whites (21% vs 7%, $p < .0001$) (Table 3).

Other Respondent Characteristics and Distrust in Clinical Research

In unadjusted analyses, age, education, the number of comorbidities, personal previous clinical trial participation, a history of discrimination in health care, and trust in one’s primary care physician were all associated with high societal distrust on the 2-item subscale (Table 3).

In sequentially built multivariate logistic regression models, the relationship between African American race and societal distrust (odds ratio [OR], 2.2; 95% CI, 1.2–3.7) remained relatively unchanged even after adding groups of potential confounders to the model (Table 4). In the final model, lower levels of trust in one's primary care physician and a history of discrimination in health care were also related to high societal distrust on the 2-item subscale.

DISCUSSION

The study results showed significant differences in societal distrust among African Americans compared with whites, but no differences in interpersonal distrust in clinical research. Lower trust in one's primary care physician and a personal history of perceived discrimination in health care were also associated with high societal distrust, but these did not explain the racial differences in societal distrust we observed. In addition, awareness of the Tuskegee Syphilis Study was not significantly related to high societal distrust among either African Americans or whites.

Previous studies using the same distrust index have found that African Americans were more likely than whites to provide responses reflecting distrust to each index item.^{5,8} These prior studies did not distinguish between those index items assessing interpersonal and societal distrust performed in the current analyses.^{5,8} Furthermore, although many of these previous analyses accounted for sociodemographic differences other than race, none explored whether other factors, such as trust in one's own physician or a history of perceived discrimination, may be related to distrust in clinical research. In this study, racial differences in societal distrust in clinical research persisted despite accounting for other sociodemographic characteristics, trust in one's personal physician, experiences with discrimination, and prior exposure to clinical research. Therefore, these differences in societal distrust may be a reflection of life experiences, distrust in institutions in general (and health care institutions in particular), or other unmeasured factors.^{20–22} One previous study has shown that African Americans have a higher overall distrust in the health care system compared to whites.^{2,23} This racial difference in distrust was related to higher skepticism among African Americans about the adoption of values, such as honesty and altruism, in the health care system.² Conversely, in the same study, there were no racial differences in the perception of competence in the health care system.² Societal distrust in clinical research among African Americans may also be attributable to their similar concerns about certain "values" at the societal level. The absence of racial differences in interpersonal distrust in the current cohort would seem to reinforce a faith in individuals juxtaposed with more skepticism about society at large.

Perceptions of discrimination in health care and trust in physicians may be 2 independent factors contributing to societal distrust. In fact, when perceived discrimination was added to the multivariable model, the relationship between race and high societal distrust was partially attenuated. This suggests that the more frequent perception of discrimination in health care among African Americans contributes to the higher societal distrust in this group compared to whites. Given the older age of the cohort, it is possible that the life experiences of many elderly African Americans contribute to a general distrust of society at-large.¹² Conversely, higher trust in one's physician was related to lower odds for high societal distrust among the current respondents. In previous studies, African Americans have frequently been more likely than whites to report discrimination in health care settings while reporting similar trust or confidence in their own physicians.²⁴ This dichotomy suggests that maintaining trust in the patient-physician relationships may be necessary but not sufficient to minimize societal distrust in clinical research. Instead, health care providers and research institutions should ensure fairness in all patient or study participant interactions with all

nonphysician clinic, hospital, or research personnel to guard against the development of societal distrust in clinical research.²⁵

Though the legacy of the Tuskegee Syphilis Study is frequently cited as a major factor underlying distrust among African Americans,¹¹ it did not appear to be related to societal or interpersonal distrust in our analyses. Similar to other studies, the mostly elderly African Americans in this sample were more likely to report having heard of the Tuskegee Syphilis Study. However, this landmark example of research abuse was not related to either type of distrust in clinical research. The legacy of this research abuse could potentially lead to distrust among some African Americans, yet others may actually maintain more confidence in clinical research due to a belief that the discovery of this historic abuse and others has led to the creation of guidelines for the protection of human subjects to prevent similar mistreatment in the future. Therefore, the directionality of any “Tuskegee effect” is uncertain.⁷ Furthermore, investigators should not reflexively view widespread knowledge of the Tuskegee Syphilis Study among elderly African Americans as a contributor to immutable societal or interpersonal distrust within this population.

This study is subject to several limitations. The sample population was a local population of mostly elderly respondents in Boston, and their perspectives on trust in clinical research may not be representative of other age groups or persons living in other cities or regions of the country. In addition, the cohort was both relatively well educated and well insured. Moreover, a substantial portion of them had previous clinical trial experiences as well as good access to care. While those with less-formal education, insurance, or previous exposure to clinical trials might have expressed different feelings of distrust, the cohort is likely more representative of most potential participants who, by virtue of their access to care, are screened for trials through some encounter with the health care system or a research institution. We were also unable to estimate nonresponse bias due to having limited information on the persons not responding to the survey. Finally, institutional distrust in clinical research was not assessed. Certainly, institutional trust may have influenced either general or societal trust among the subjects. Though the impact of institutional distrust could not be quantified using the chosen distrust scale, surrogate constructs, such as trust in one’s primary care physician, were able to be measured.

In this large survey of community-dwelling adults, though no racial differences in interpersonal distrust in clinical research were found, African Americans were more likely to express societal distrust in clinical research. Future work should focus on independently quantifying the different dimensions of trust in clinical research. Because the factors influencing each dimension of distrust vary, societal and interpersonal distrust in clinical research should continue to be assessed separately. Once societal and interpersonal distrust in clinical research can be distinguished and assessed independently, appropriate strategies can be devised specifically to address each type of distrust.

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Figure.
Sampling Scheme and Response Rates

Table 1

Description of the Study Population (N = 776)

Characteristics	African Americans (n = 295)	Whites (n = 481)	P Value
	% or Mean ± Sd	% or Mean ± Sd	
Sociodemographics			
Female gender (n = 772)	81	67	<.001
Age (n = 776)	69 ± 10.0	76.0 ± 9.0	<.001
Education: college graduate or higher (n = 764)	34	56	<.001
Health/functional status			
Excellent or very good health (n = 762)	35	45	.008
Number of medical problems (n = 776)	3.4 ± 2.0	2.9 ± 2.0	.001
Number of daily medications (n = 757)	4.1 ± 3.6	3.4 ± 2.8	.004
Requires help with 1 activity of daily living (n = 776)	9	9	.95
Access to care/health care utilization			
Current health insurance (n = 776)			.5
Yes	98	98	
No	2	2	
Personal doctor or nurse (n = 753)	93	95	.2
No. of visits in last 12 mo (n = 735)	4.2 ± 4.3	3.0 ± 2.5	<.001
No. of hospitalizations in last 12 mo (n = 762)	0.4 ± 0.9	0.5 ± 1.0	.26
Experiential factors			
History of discrimination in health care (n = 776)	43	15	<.001
Awareness of Tuskegee Syphilis Study (n = 776)	64	41	<.001
Previous trial participation (n = 723)	52	59	.07
Trust in physician			
PCAS trust subscale ^a (n = 767)	77.6 ± 14.9	77.1 ± 15.3	.7

^aPrimary Care Assessment Survey trust subscale is scored from 0–100.

Table 2

Responses to Individual Distrust Index Items Stratified by Race

	African Americans (n = 295)	Whites (n = 481)
Interpersonal distrust Items	%	%
1. Belief that your doctor would explain research fully to you if asking you to participate in a trial (disagree or don't know) ^a	12.5	14.6
2. Believe that you can freely ask your health care provider any questions (no or don't know) ^a	4.9	7.3
3. Belief that your doctor would not ask you to participate in harmful medical research (disagree or don't know) ^a	13.5	14.9
4. Feeling that your doctor always protects from unnecessary risks with certain treatments? (no) ^a	4.4	6.0
5. Belief that you have received medication from any doctor as part of an experiment without your permission (yes or don't know) ^a	2.5	1.5
Societal distrust Items		
6. Likelihood that you or people like you will be used as guinea pigs without permission (very/somewhat likely) ^{a,b}	54.2	27.7
7. Frequency that doctors, in general, prescribe medications to experiment on people without their knowledge (very/fairly often or don't know) ^{a,b}	60.0	40.6

^aResponse options indicating distrust for each of the distrust index items.

^bComparisons between African Americans and whites (χ^2) with $p \leq .05$.

Table 3

Relationship Between Respondent Characteristics and High Societal Distrust

Respondent Characteristics	High Societal Distrust, ^a %	p Value
Gender		.4
Male	11	
Female	13	
Race		<.001
White	7	
African American	21	
Age		.002
<65	21	
65–80	10	
>80	10	
Education		.008
Some college or less	15	
College graduate or higher	9	
Current health insurance		.5
Yes	12	
No	7	
Do you have a personal physician or nurse?		.1
Yes	12	
No	19	
No. of clinic visits in the last 12 mo		.3
0	16	
1–3	11	
≥4	13	
Health status		.6
Excellent, very good, good	11	
Fair or poor	13	
No. of comorbidities		.08
0–1	8	
2–3	12	
≥4	15	
No. of medications		.1
0	12	
1–2	9	
≥3	14	
No. of hospitalizations in the last 12 mo		.6
0	11	
≥1	13	
Needs help with ≥1 activity of daily living		.4
Yes	9	

Respondent Characteristics	High Societal Distrust, ^a %	p Value
No	13	
Previous trial participation		.08
Yes	10	
No	15	
Awareness of Tuskegee Syphilis Study		.2
Yes	14	
No	11	
History of discrimination in health care		<.001
Yes	23	
No	9	
Trust in primary care physician		.004
1st quartile (most trust)	8	
2nd quartile	8	
3rd quartile	14	
4th quartile (least trust)	18	

^aHigh societal distrust defined as top quartile of distrust measured by 2-item societal distrust subscale.

Table 4

Odds Ratio of High Societal Distrust Using Sequential Model Building^{a,b}

Characteristics	Model 1	Model 2	Model 3	Model 4	Model 5
	OR (95% CI)				
Race					
Whites (reference)					
African Americans	3.5 (2.2–5.5)	2.8 (1.7–4.6)	2.7 (1.7–4.5)	1.9 (1.1–3.3)	2.2 (1.2–3.7)
Other sociodemographics					
Age					
<65 (reference)					
65–80		0.8 (0.3–0.9)	0.5 (0.3–0.9)	0.5 (0.3–0.9)	0.5 (0.3–0.9)
>80		0.6 (0.3–1.2)	0.6 (0.3–1.2)	0.6 (0.3–1.2)	0.6 (0.3–1.2)
Education					
Some college or less (reference)					
College graduate or higher		0.7 (0.4–1.1)	0.7 (0.4–1.1)	0.6 (0.3–0.95)	0.6 (0.4–0.96)
Health status					
No. of comorbidities					
0–1 (reference)					
2–3			1.2 (0.6–2.2)	1.4 (0.7–2.8)	1.4 (0.7–2.9)
≥4			1.5 (0.8–2.9)	1.6 (0.8–1.1)	1.7 (0.8–3.6)
Experiential factors					
Previous trial participation (reference: no previous participation)				0.7 (0.4–1.1)	0.7 (0.4–1.1)
Discrimination in health care (reference: no discrimination)				2.3 (1.4–3.8)	1.8 (1.1–3.1)
Trust in physicians					
1st quartile (highest) (reference)					
2nd quartile					1.0 (0.4–2.2)
3rd quartile					2.0 (1.0–4.3)
4th quartile (lowest)					3.0 (1.4–6.3)

^a Model 1 = race alone, model 2 = race + other sociodemographics, model 3 = race + other sociodemographics + health status, model 4 = race + other sociodemographics + health status + experiential factors, model 5 = race + other sociodemographics + health status + experiential factors + trust in physicians.

^b Bold figures represent statistically significant ($p < .05$) odds ratios.