Enrollment of Racial/Ethnic Minorities in NIAID-Funded Networks of HIV Vaccine Trials in the United States, 1988 to 2002

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SYNOPSIS

Objective. The purpose of this study was to analyze enrollment of racial/ethnic minorities in Phase I and Phase II HIV vaccine trials in the U.S. conducted by National Institute of Allergy and Infectious Diseases (NIAID)-funded networks from 1988 to 2002.

Methods. A centralized database was searched for all NIAID-funded networks of HIV vaccine trial enrollment data in the U.S. from 1988 through 2002. The authors reviewed data from Phase I or Phase II preventive HIV vaccine trials that included HIV-1 uninfected participants at low to moderate or high risk for HIV infection based on self-reported risk behaviors. Of 66 identified trials, 55 (52 Phase I, 3 Phase II) met selection criteria and were used for analyses. Investigators extracted data on participant demographics using statistical software.

Results. A total of 3,731 volunteers enrolled in U.S. NIAID-funded network HIV vaccine trials from 1988 to 2002. Racial/ethnic minority participants represented 17% of the overall enrollment. By pooling data across all NIAID-funded networks from 1988 to 2002, the proportion of racial/ethnic minority participants was significantly greater (Fisher's exact test p-value <0.001) in Phase II trials (278/1,061 or 26%) than in Phase I trials (347/2,670 or 13%). By generalized estimating equations, the proportion of minorities in Phase I trials increased over time ($p=0.017$), indicating a significant increase in racial/ethnic minority participants from 1988 to 2002.

Conclusions. There has been a gradual increase in racial/ethnic minority participation in NIAID-funded network HIV vaccine trials in the U.S. since 1988. In the light of recent efficacy trial results, it is essential to continue to increase the enrollment of diverse populations in HIV vaccine research.

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HIV vaccine development is a critical path in developing a long-term strategy to control the worldwide HIV epidemic.[1] The evaluation of candidate preventive HIV vaccines is a priority for the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH), which provides funding and support for preventive HIV vaccine trials both domestically and internationally.[2,3] Testing safety and immunogenicity of candidate preventive HIV vaccines has been in progress since 1987.

In 2003, the Centers for Disease Control and Prevention (CDC) surveillance report indicated that approximately 50% of newly detected HIV infections occurred among African Americans and 19% among Hispanic/Latinos,[4] highlighting a disparity in the infection rates. Because racial/ethnic minorities are disproportionately represented in the HIV epidemic in the U.S.,[4] it is important that HIV vaccine clinical trials be designed and enrolled with adequate representation of these groups, especially African Americans, so that the findings of trials are credible both to scientists and to affected communities. Furthermore, NIH has a mandate, based on the ethical principle of justice,[5] to include more minorities and women in clinical research.[6]

A recent privately-sponsored Phase III HIV vaccine trial including relatively small numbers of participants of color concluded that crude vaccine efficacy rates were higher among black and Asian participants.[7] The significance of this result continues to be debated, as the number of cases and participants were few, and definitive conclusions as to whether racial factors influence transmission are not available. All of these factors highlight the importance of enrolling sufficiently large numbers of racial/ethnic minorities in HIV clinical trials.

In this analysis, we examine the enrollment of racial/ethnic minorities in Phase I and Phase II HIV vaccine trials conducted by NIAID-funded networks in the United States from 1988 to 2002, and analyze enrollment trends. We also discuss strategies for increasing enrollment of racial/ethnic minorities in future HIV vaccine trials.

METHODS

We reviewed all enrollment data in the U.S. on preventive HIV vaccine trials conducted by NIAID-funded networks between 1988 and 2002. We also examined Phase I and II trials evaluating candidate preventive HIV vaccines for safety and immunogenicity in HIV-1–negative participants older than age 18. From 1988 to 2000, such trials were conducted by NIAID's AIDS Vaccine Evaluation Group (AVEG), and one trial was conducted as a collaboration between AVEG and the HIV Network for Prevention Trials (HIVNET). In 2000, when the HIV Vaccine Trials Network (HVTN) replaced AVEG/HIVNET, AVEG completed enrollment for existing trials while HVTN began enrollment for new trials.

AVEG/HIVNET included 15 trial sites: San Francisco, Birmingham, Baltimore (2), Rochester (NY), St. Louis, Nashville, Seattle (2), Philadelphia, Chicago, Boston, New York (2), and Denver. As of 2002, HVTN, serving as an international network to test candidate HIV vaccines, included 13 U.S. trial sites: San Francisco, Birmingham, Baltimore (2), Rochester (NY), St. Louis, Nashville, Seattle, Boston (3), New York (2). Six sites were common to both networks. HVTN also includes 17 non-U.S. trial sites and one trial site in Puerto Rico. Because the focus of this study was minority enrollment in the U.S., for this analysis we included participants enrolled at HVTN sites in the U.S. only.

Study participants

Study participants were recruited by various methods (e.g., person-to-person, media, contact lists) and were eligible for enrollment according to individual study protocol requirements. Generally, participants were eligible if they were in good general health and confirmed to be HIV-1 uninfected. Health history and physical and laboratory exams were used to identify and exclude subjects with pre-existing medical conditions that could affect the safety of the participant or compromise safety or immunogenicity evaluations during the trial. In addition, participants provided informed consent for participation in the vaccine trial. Demographic data, including age, gender, race/ethnicity, and sexual orientation, were collected from each volunteer by interview.

Phase I and Phase II studies enrolled individuals at low to moderate or high risk for HIV infection based on self-reported risk (sex and injecting drug use) behaviors. Most of the Phase I studies enrolled volunteers who met criteria likely to predict a low risk for acquiring HIV-1. Phase II trials included volunteers at higher risk for acquiring HIV-1 to further assess vaccine safety and immunogenicity in a population similar to that needed for efficacy trials.

Data management and statistical methods

All data were collected using a distributed data entry system, with information sent weekly to a central database. Statistical analyses were conducted using SAS version 8.2.[8] We tabulated frequencies for demographic characteristics for all volunteers enrolled in Phase I and Phase II trials. Racial/ethnic categories were defined as "white, non-Hispanic/Latino" and "racial/ethnic minority," because of the low numbers of all racial/ethnic categories other than white. Racial/ethnic minority included African American, Hispanic/Latino (of all races, including white), Asian/Pacific Islander, Native American, multiracial, and other. Race/ethnicity was self-identified. Participants could select only one racial category.

In the AVEG data system prior to March 1993, Hispanic was one of the choices in the race category. After 1993, participants were asked two questions about race and ethnicity: first, a question about Hispanic ethnicity, and then a separate question about race. All participants who had selected Hispanic in the ethnicity category prior to 1993 were mapped to Hispanic in the new ethnicity category, and were re-contacted to obtain their self-reported racial identity. The race designation was then updated in the dataset. The current HVTN data system asks race and ethnicity in the same way as the post-1993 AVEG system, in that race and ethnicity are asked separately. In the HVTN system, the ethnicity category includes "Hispanic or Latino."

To assess trends in enrollment of white, non-Hispanic/Latino participants, we considered AVEG, HIVNET, and HVTN enrollment data. These data included enrollment of 3,731 volunteers at all sites over a 15-year period (1988 to 2002). HVTN Phase I recruitment is ongoing; participants enrolled before May 15, 2002, are included in this analysis.

We excluded Phase II data from the trend analysis because Phase II trials were few in number and conducted with large time lapses between them, making the data temporally disjointed. In addition, Phase II trials enroll participants under different behavioral risk criteria, so trends of racial/ethnic minority enrollment are difficult to compare directly.

We represented the proportion of racial/ethnic minority participants graphically by year of enrollment. Univariate plots, statistics, and summary measures were used as an initial step in the data analysis. To examine time trends more formally, we modeled the log odds of enrolling racial/ethnic minority participants as a function of calendar time. Generalized estimating equations[9] (GEE) were employed to account for possible correlation induced by repeated measurements within particular sites over time. Assessing the significance of time effects was based on the generalized score statistic.[10] A modified version of the Akaike Information Criterion was employed for model selection.[11] We treated time as a continuous covariate with likelihood ratio tests employed to test for trends. All statistical tests were done at the 0.05 significance level.

RESULTS

Volunteer enrollment

A total of 3,731 volunteers enrolled in U.S. preventive HIV vaccine trials from 1988 to 2002 (see Table): 2,670 enrolled in 52 Phase I trials, and 1,061 enrolled in three Phase II trials. A total of 11 trials were excluded because they enrolled HIV-positive participants. Overall, 3,207 (86%) volunteers enrolled in AVEG trials and the AVEG/HIVNET collaborative trial, and 524 (14%) volunteers enrolled in HVTN trials. Of these, 1,442 (39%) were women. Racial/ethnic minority participants represented 17% of the overall enrollment, comprised of African American (10%), Hispanic/Latino (4%), Asian/Pacific Islander (1%), Native American (0.6%), multiracial (<1%), and other (<1%).

Enrollment trends of racial/ethnic minorities

Pooling data across AVEG, HIVNET, and HVTN from 1988 to 2002, the proportion of racial/ethnic minority participants was significantly greater (Fisher's exact test p-value <0.001) in Phase II trials (278/1,061 or 26%) than in Phase

Table. Enrollment demographics by Phase I and Phase II trials and by AVEG, HIVNET. and HVTN, 1988 to 2002

		N *(percent)*			
		Phase		*Network*	
Characteristic	*Total* N *(percent)*	*I*	*II*	*AVEG, HIVNET*	*HVTN*
Gender					
Female	1,442 (38.6)	1,143 (42.8)	299 (28.2)	1,272 (39.7)	170 (32.4)
Male	2,289 (61.4)	1,527 (57.2)	762 (71.8)	1,935 (60.3)	354 (67.6)
Age (years)					
<20	116 (3.1)	100 (3.7)	16 (1.5)	106 (3.3)	10 (1.9)
20–29	1,198 (32.1)	929 (34.8)	269 (25.4)	1,022 (31.9)	176 (33.6)
30–39	1,263 (33.9)	855 (32.0)	408 (38.5)	1,093 (34.1)	170 (32.4)
40–49	893 (23.9)	603 (22.6)	290 (27.3)	757 (23.6)	136 (26.0)
50+	261 (7.0)	183 (6.9)	78 (7.4)	229 (7.1)	32 (6.1)
Race/ethnicity					
White	3,106 (83.2)	2,323 (87.0)	783 (73.8)	2,697 (84.1)	409 (78.1)
Black	377 (10.1)	192 (7.2)	185 (17.4)	309 (9.6)	68 (13.0)
Hispanic/Latino	157 (4.2)	90 (3.4)	67 (6.3)	134 (4.2)	23 (4.4)
Asian/Pacific Islander	47 (1.3)	37 (1.4)	10 (0.9)	37 (1.2)	10 (1.9)
Native American	23 (0.6)	17 (0.6)	6 (0.6)	17 (0.5)	6 (1.1)
Multiracial	4 (0.1)	4 (0.1)	0 (0.0)	0 (0.0)	4 (0.8)
Other	17 (0.5)	7 (0.3)	10 (0.9)	13 (0.4)	4 (0.8)
Sexual orientation					
Homosexual	1,466 (39.3)	909 (34.0)	557 (52.5)	1,239 (38.6)	227 (43.3)
Heterosexual	2,022 (54.2)	1,602 (60.0)	420 (39.6)	1,769 (55.2)	253 (48.3)
Bisexual	197 (5.3)	143 (5.4)	54 (5.1)	153 (4.8)	44 (8.4)
Missing	46 (1.2)	16 (0.6)	30 (2.8)	46 (1.4)	0 (0.0)
Total	3,731	2,670	1,061	3,207	524

AVEG = AIDS Vaccine Evaluation Group

HIVNET = HIV Network for Prevention Trials

HVTN = HIV Vaccine Trials Network

I trials (347/2,670 or 13%). Given the paucity of Phase II trials from 1988 to 2000, we modeled trends in minority enrollment for Phase I trials and provided descriptive data only for Phase II trials.

For Phase I trials, the proportion of minority participants by year of enrollment is represented in the Figure. The percentage of racial/ethnic minority participants ranged from 0% (0/76 in 1988 and 0/67 in 1990) to 30% (52/172 in 2002). GEE models with constant, linear, quadratic, and cubic time components each indicated a statistically significant increase in the proportion of racial/ethnic minority enrollment in Phase I trials over the time period considered. The modified Akaike Information Criterion indicated that the cubic model with an autoregressive working correlation structure provided the best fit of the models considered. For this model, the generalized score test for a time trend gave a *p*-value of 0.017, indicating a significant increase in racial/ethnic minority participants from 1988 to 2002.

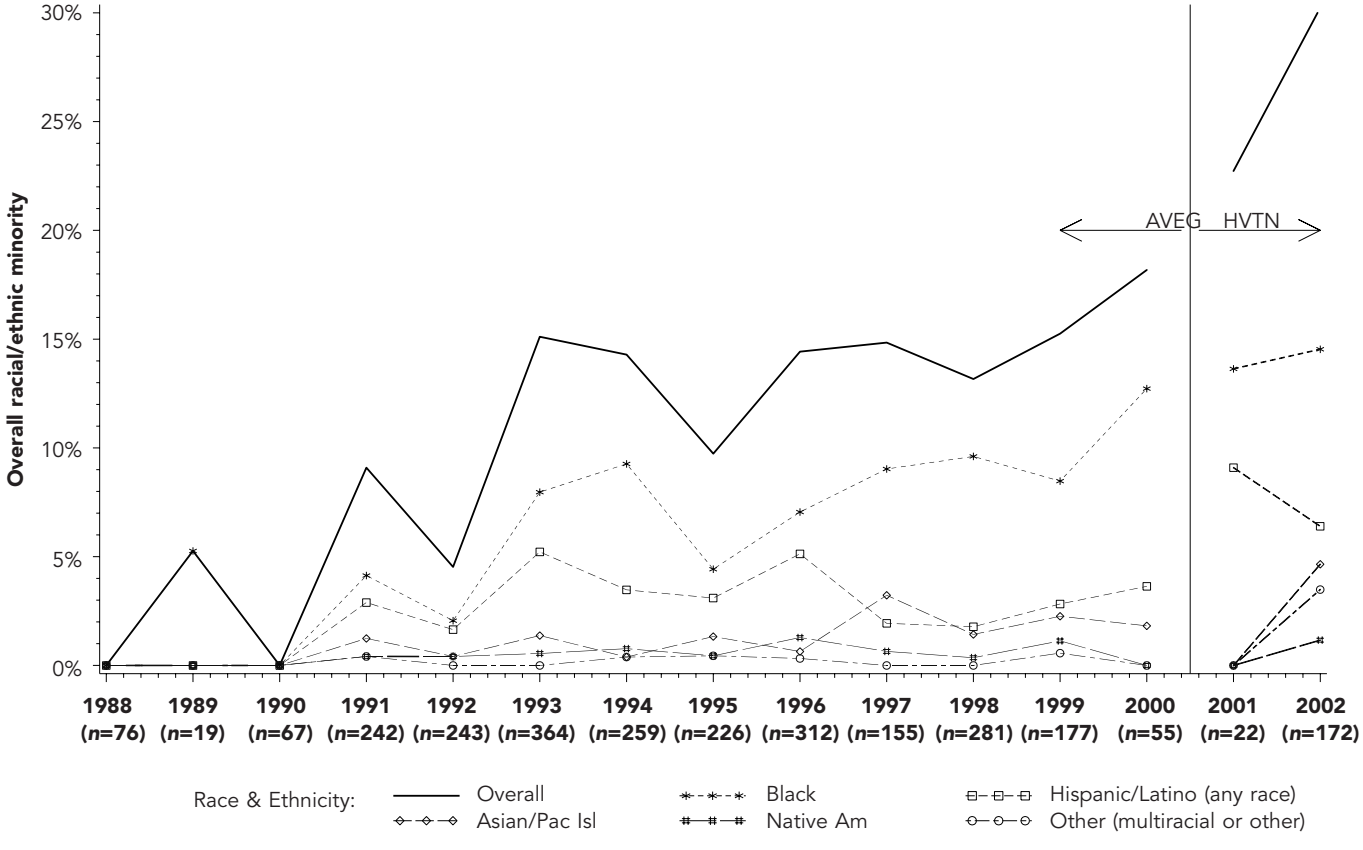
Three protocols were included in the analysis of Phase II trials: AVEG 201, AVEG 202/HIVNET 014, and HVTN 203. Of the 296 participants enrolled in AVEG 201 (1992 and 1993), 78 (26.4%) were categorized as racial/ethnic minority. The greatest proportion of minority enrollment in a Phase II trial occurred from 1997 to 1998, where 142 of 435 (32.6%) of participants in AVEG 202/HIVNET 014 were categorized as racial/ethnic minority. For HVTN 203, 17.6% (58/330) of participants enrolled during 2000 and 2001 were racial/ethnic minority.

DISCUSSION

From 1988 to 2002, the proportion of participants of color in NIAID-network funded Phase I HIV preventive vaccine trials in the U.S. increased.

Since 1994, NIH medical research policies have mandated the inclusion of women and racial/ethnic minorities in clinical trials.[12] While minority enrollment has increased in the trials examined here, barriers still exist that affect adequate recruitment and retention of racial/ethnic minorities into clinical trials. These may include, among others, level of access to health coverage and financial resources; minority-held attitudes, beliefs, and perceptions about clini-

Figure. Minority (non-white, non-Hispanic) enrollment among participants in Phase I HIV vaccine trials represented by year



NOTE: By generalized estimating equations, the proportion of minorities in Phase I trials increased over time (p=0.017).

AVEG = AIDS Vaccine Evaluation Group

HVTN = HIV Vaccine Trials Network

cal research; or level of knowledge regarding clinical research.[13–15] Further assessment on the effectiveness of strategies to increase minority participation in clinical research in the U.S. is needed.[16]

There are important reasons why further efforts to sustain and increase minority enrollment in HIV vaccine trials are needed. First, the NIH has a mandate to increase enrollment of women and minorities in all federal government-supported clinical research. Furthermore, it is important to ensure adequate representation of racial/ethnic minorities in vaccine trials because a licensed vaccine will eventually be offered to some members of these same communities by the public health system. It is important to increase acceptability of efficacy trials as well as an eventually licensed vaccine. Issues of trust in public health institutions and research programs are complex in communities of color in the United States. For example, mistrust among African Americans may be influenced by the federal government's Tuskegee syphilis experiment of the 1930s to 1970s; the history of this program still presents challenges to the provision of prevention services to some communities.[17,18] In addition to mistrust of research, social stigma related to HIV is another barrier to participation in trials that can be especially acute in communities of color.[19–22] The lesson for HIV vaccine development is that early and meaningful involvement of communities of color in HIV vaccine trials is important to building trust with communities, and to ensuring that there is a track record of safety and efficacy of candidate vaccines trials that have included racial/ethnic minorities.

Second, there are important ethical reasons to ensure access of HIV vaccine trials to racial/ethnic minorities, especially since those communities are disproportionately affected by the HIV/AIDS epidemic.[4] Access to vaccine trials may promote the ethical principle of justice and beneficence across communities. In addition, NIH-sponsored vaccine research bears the responsibility to educate, inform, and involve communities in all aspects of vaccine research, which can help to reduce the stigma arising from prejudice about HIV.

From an operational point of view, there may be situations where sufficient statistical power to conduct analyses of vaccine efficacy by racial/ethnic subgroup will be desirable. Results from the first HIV vaccine efficacy trial (conducted by VaxGen, Inc.)[7] suggested that the efficacy rate among black and Asian participants was higher than the efficacy rate among white participants. These findings were very difficult to interpret, however, because (*1*) subgroup analysis was not initially planned, (*2*) a low number of participants of color were enrolled, and (*3*) the number of HIV infections among participants of color was small.

Underlying the discussion of results from the VaxGen efficacy trial was the possibility that a vaccine might be variably efficacious in different racial/ethnic groups for a genetic reason. Although it seems most likely that there would not be a biologic basis for variations in vaccine efficacy among different racial/ethnic groups, it is plausible that differences in response to a vaccine could occur based on variations in Human Leukocyte Antigen (HLA) or antibody response profiles associated with race/ethnicity.[23–25] There are, however, behaviorally mediated reasons that preventive HIV vaccine efficacy may vary among racial/ethnic groups. Recent data illustrating a stark difference in HIV incidence rates among young gay men in urban areas by race/ethnicity[27] suggest that there may be important differences by race/ethnicity in patterns of exposure or density of exposure to HIV among men who have sex with men, who will be an important pool of volunteers in future U.S. efficacy trials. Although HVTN trials typically collect risk behavior information on all trial participants, it is important to ensure that these highest-risk people are well represented in the trials. Overall vaccine effectiveness may also depend upon the degree to which vaccine recipients engage in high-risk behaviors because they believe that vaccination protects them, although recent Phase III trial results do not show this to be the case.[7,26] Monitoring changes in risk behaviors during the conduct of an efficacy trial will be important, and we must measure whether changes in risk behavior after vaccination vary among racial/ethnic groups.

The data and our analyses have important limitations. We did not attempt to associate increased proportions of participants of color in HIV vaccine trials with underlying changes in the demographic characteristics of the populations in the areas where the trials were conducted. Therefore, it is possible that some portion of the increased representation of participants of color simply reflects an increasing awareness of HIV and research among people of color in communities where trials were conducted. The increase in minority participation in HVTN trials as of 2000 may also be due to the fact that such participation was aggressively sought. However, the rate of increase in enrollment of people of color over time suggests other factors may have played a role.

While this paper did not focus on the effectiveness of past enrollment approaches, HVTN is pursuing multiple strategies to sustain and increase the enrollment of greater racial/ethnic diversity in HIV vaccine trials in the future. HVTN investigators at U.S. sites are developing plans to increase recruitment of volunteers for HIV vaccine trials by beginning or increasing advertising in media that reach large numbers of potential participants of color. The HVTN has made educational and consent materials available in languages other than English, employed racially/ethnically diverse staff, and involved community leaders from minority communities in HIV Vaccine Community Advisory Boards. Furthermore, in recognition of future needs, HVTN leadership committed additional funding in 2003 to fighting the legacy of the Tuskegee trial and to increasing minority enrollment in HVTN trials.

Globally, HVTN has developed HIV vaccine trial units in Asia, Africa, South America, and the Caribbean, and is in the process of expanding in those areas. This expansion will result in larger numbers of participants of color, involvement in the vaccine development process of communities most affected by HIV, and greater experience with HIV vaccines in populations with varied HLA constitutions. Although increased enrollment of racial/ethnic minorities at international sites may help address concerns about biologic factors related to vaccine efficacy, issues of trust between the African American community and the public health system in the United States call for a sustained effort to engage diverse communities in vaccine clinical trials in the U.S.

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REFERENCES

1. Klausner RD, Fauci AS, Corey L, Nabel GJ, Gayle H, Berkley S, et al. The need for a global HIV vaccine enterprise. Science 2003 Jun 27;300:2036-9.
2. An HIV vaccine: how long must we wait? [Editorial] Lancet 1998; 352(9137):1323.
3. NIAID's HIV Vaccine Trials Network (HVTN) [cited 2004 Dec 22]. National Institute of Allergy and Infectious Diseases. Available from: URL: http://www.niaid.nih.gov/factsheets/hvtn.htm
4. Centers for Disease Control and Prevention. HIV/AIDS surveillance report, 2003 (Vol. 15). Atlanta: Department of Health and Human Services (US), CDC; 2004.
5. Protection of human subjects; Belmont Report: notice of report for public comment. Fed Regist 1979;44(76):23191-7.
6. NIH guidelines on the inclusion of women and minorities as subjects in clinical research [cited 2004 Dec 22]. Available from: URL: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-048.html
7. Flynn NM, Forthal DN, Harro CD, Judson FN, Mayer KH, Para MF, et al. Placebo-controlled trial of a recombinant glycoprotein 120 vaccine to prevent HIV infection. J Infect Dis 2005;191:647-9.
8. SAS OnlineDoc. Version 8. Cary (NC): SAS Institute Inc; 1999.
9. Liang K-Y, Zeger SL. Longitudinal data analysis using generalized linear models. Biometrika 1986;73:13-22.
10. Rotnitzky A, Jewell NP. Hypothesis testing of regression parameters in semiparametric generalized linear models for cluster correlated data. Biometrika 1990;77:485-97.
11. Pan W. Akaike's information criterion in generalized estimating equations. Biometrics 2001;57:120-5.
12. Baird KL. The new NIH and FDA medical research policies: targeting gender, promoting justice. J Health Polit Policy Law 1999;24:531-65.
13. Giuliano AR, Mokuau N, Hughes C, Tortolero-Luna G, Risendal B, Ho RCS, et al. Participation of minorities in cancer research: the influence of structural, cultural, and linguistic factors. Ann Epidemiol 2000;10(8 Suppl):S22-34.
14. Corbie-Smith G, Thomas SB, Williams MV, Moody-Ayers S. Attitudes and beliefs of African Americans toward participation in medical research. J Gen Intern Med 1999;14:537-46.
15. Mills E, Cooper C, Guyatt G, Gilchrist A, Rachlis B, Sulway C, Wilson K. Barriers to participating in an HIV vaccine trial: a systematic review. AIDS 2004;18:2235-42.
16. Shavers VL, Lynch CF, Burmeister LF. Knowledge of the Tuskegee study and its impact on the willingness to participate in medical research studies. J Natl Med Assoc 2000;92:563-72.
17. Sengupta S, Strauss RP, DeVellis R, Quinn SC, DeVellis B, Ware WB. Factors affecting African-American participation in AIDS research. J Acquir Immune Defic Syndr 2000;24:275-84.
18. Corbie-Smith G, Thomas SB, St George DM. Distrust, race, and research. Arch Intern Med 2002;162:2458-63.
19. Koblin BA, Avrett S, Taylor PE, Stevens CE. Willingness to participate in HIV-1 vaccine efficacy trials and the effect of media events among gay and bisexual men in New York City: Project ACHIEVE. J Acquir Immune Defic Syndr Hum Retrovirol 1997;15:165-71.
20. Sheon AR, Wagner L, McElrath MJ, Keefer MC, Zimmerman E, Israel H, et al. Preventing discrimination against volunteers in prophylactic HIV vaccine trials: lessons from a phase II trial. J Acquir Immune Defic Syndr Hum Retrovirol 1998;19:519-26.
21. Strauss RP, Sengupta S, Kegeles S, McLellan E, Metzger D, Eyre S, et al. Willingness to volunteer in future preventive HIV vaccine trials: issues and perspectives from three U.S. communities. J Acquir Immune Defic Syndr 2001;26:63-71.
22. Novitsky V, Flores-Villanueva PO, Chigwedere P, Gaolekwe S, Bussman H, Sebetso G, et al. Identification of most frequent HLA class I antigen specificities in Botswana: relevance for HIV vaccine design. Hum Immunol 2001;62:146-56.
23. Gilbert P, Popovic V, Gurwith M, Heyward W, Francis D, Sinangil F, et al. Immunologic responses to rgp-120 vaccine and correlation with the risk of HIV infection: results from the world's first HIV vaccine efficacy trial. AIDS Vaccine 2003. 2003 Sep 21; New York.
24. Montefiori D, Metch B, McElrath MJ, Self S, Weinhold K, Corey L. Conditional influence of race and gender on the neutralizing antibody response to candidate HIV-1 vaccines. AIDS Vaccine 2003. 2003 Sep 20; New York.
25. HIV incidence among young men who have sex with men—seven U.S. cities, 1994–2000. MMWR Morb Mortal Wkly Rep 2001;50(21):440-4.
26. Bartholow BN, Buchbinder S, Goli V, Celum C, Koblin B, Marmor M, et al. HIV risk behavior change over 24 months of follow-up in a phase-III HIV vaccine efficacy trial. XIV International AIDS Conference. 2002 Sep 7–10; Barcelona, Spain.