

Vaccine Trials and Black Americans

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Should Black Americans Participate in Clinical Trials to Develop an HIV Vaccine?

African Americans are disproportionately affected by HIV; they account for 34% of AIDS cases in the United States, but only 11% of the U.S. population. Yet the decision to participate in development of a vaccine against AIDS is not an easy one for most Black Americans. Noted researcher Robert Fullilove once said that “understanding the HIV epidemic among African Americans requires an examination of how factors such as poverty, disease, and the constant theme of racism combine with the virus to kill.”¹

Our question also requires a closer examination of who is at risk. Although African Americans are often viewed as one group, there are, in fact, a number of subpopulations lumped in this category. Upper-class/lower-class, Christian/Muslim, inner-city/suburban, descendants of slaves and recent Caribbean immigrants all are classified as African American but are at very different degrees of risk. In addition, there are Black (and White) Latinos who often must deal with language and immigration issues. Many lack culturally appropriate health care.

For Black Americans, the Tuskegee legacy and other misuses of medical research have become a large barrier and powerful deterrent to participation in any kind of medical research — especially any research that may involve injections. The Tuskegee Study of Untreated Syphilis in the Negro Male² was begun in 1932 to chart the natural history of the disease without treatment. The study became unconscionable in the 1940s,

when these men were not informed that penicillin was available to cure their disease. It wasn't until 1972 that the U.S. Public Health Service was shamed into stopping the "experiment," 1974-75 when reparations began for some of the families, and 1997 when President Clinton finally issued a formal apology. But

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the apology received far less media attention than the HBO movie *Miss Evers' Boys* at about the same time, or James H. Jones book, *Bad Blood*, a more complete account that is used in classrooms from elementary to graduate schools. The president's apology, no matter how well intentioned, will not eliminate the legacy of distrust this blot has placed on all medical research. To make matters worse, many mistakenly believe that the participants were actually injected with syphilis as part of that study.

There is also a persistent belief that AIDS is a form of racial genocide. Such conspiracy

theories of Whites against Blacks abound, ranging from the belief that the government promotes drug abuse in Black communities to the belief that HIV is a manmade weapon of racial warfare. The fact that injection drug use is a major contributor to the spread of HIV in these communities adds to the sense that Black Americans are considered disposable by society and convenient to experiment on.

As far as vaccine trials go, an educator in Harlem noted that many potential participants cannot get past the belief that all vaccines contain the virus they are meant to protect against, and fear only increases when they are advised that they may test positive on an HIV screening test. Reassurances are difficult to hear above the internal alarms this risk sets off. We must probably accept the fact that some people will never be comfortable with the concept of becoming HIV antibody-positive while remaining free from HIV infection.

Take-Home Messages for Blacks About Vaccine Trials

In spite of all this, African Americans must participate if biological and culturally appropriate conclusions will be reached. Potential volunteers need to be educated about HIV prevention, vaccine trials, and biomedical research. At the same time, public health researchers have much to learn about how their activities are perceived in the community. To achieve this, members of communities at risk for HIV infection must play an integral role in setting prevention research priorities and shaping key aspects of studies, including their design, informed consent procedures, and recruitment and retention plans. African American scientists are desperately needed as well for their input and for credibility.

- Fortunately there are systems of protection built into today's government-sponsored research, including independent data and safety monitoring boards, media coverage, access to research results as trials progress, and community advocates who participate in the design and implementation of some studies.
- Federal agencies, such as the National Institutes of Health and the Centers for Disease Control and Prevention, are committed to identifying factors that cause and propagate HIV infections among diverse populations of African Americans. Results of

that research can then be used to develop customized interventions for women, youth, gay men, bisexual and heterosexual men, and substance users, including but not limited to injection drug users.

- Among homosexually active African American men, even those who self-identify as gay, internalized and societal homophobia and strong attachment to their minority community make it difficult to respond to AIDS as primarily a gay issue. Since the beginning of the epidemic, the absence of national gay leaders and large gay constituencies in the African American population has made it hard to mobilize support.
- For some Blacks, distrust of government may be the main barrier to trial participation; for others, family responsibilities, health risks, and social concerns may cause greater concern. Before signing up for any research study, participants must give informed consent. Researchers must give participants a chance to ask questions and must fully answer those questions. In addition, participants must not be denied other HIV prevention methods that are proven or likely to work while participating in a vaccine trial (*see Consenting Adults: The Challenge of Informed Consent on page 37*).
- Altruism and volunteerism are not words that have high visibility in the African American lexicon. At the same time, helping others without personal reward is a hallmark of minority communities. Blacks have been helping Blacks survive since arriving in America. The Underground Railroad was led and financed by Blacks. Whenever social service systems have not provided food programs, home visitation nurses, and other care, family and friends have provided cost-effective, high-quality information and support that demonstrates community commitment.
- Blacks who volunteer for trials must realize they may be moving science forward only to help future generations. If

experimental vaccines do prove at all effective, one hopes there will be enough African Americans in clinical trials to note statistical differences between their biological responses and those of other participants.

It has been shown that participatory research has important advantages over research where the investigators remain at arm's length and have exclusive control. The people who would be the objects or beneficiaries of the research should help define the questions, control the process, and interpret the findings. This makes the research more relevant to the community, the methods more acceptable, and the results more meaningful, while reducing the chance for improper human experimentation. The challenge is often to get researchers to value and encourage legitimate, active participation throughout the research process.

The National Medical Association, the NAACP, the National Minority AIDS Council, the National Black Lesbian and Gay Leadership Forum, and many other groups have joined the Congressional Black Caucus (CBC) in requesting that Secretary of Health and Human Services Donna Shalala declare a "public health emergency" in their communities. This would increase the types of funds available to address the growing disparity in health outcomes despite major investments in HIV research, prevention, care, and support services. While waiting for action from the Executive Branch, CBC has successfully built the coalitions in Congress that have meanwhile obtained significant additional funds that became available in 1999. This special funding may ensure the development and implementation of an expanded endeavor, but still may not make a difference unless individuals choose to participate in research efforts.

Two-thirds of the HIV/AIDS cases to date have occurred in Africa. African Americans do not realize that Africans who consider participating in a vaccine study in their countries often ask, "How

many Blacks in the United States have been in clinical trials?" The actual number of Black participants may disappoint or discourage people who think of Americans as having many choices and extensive health resources.

Informed consent is usually defined as the point at which an individual understands the risks and benefits of trial participation. For Africans, who often live in settings where a tribal leader makes decisions for everyone, there may also be issues of community consent. Is it the individual who must make informed decisions about participation in research, especially around legal, social, and ethical issues? Or should researchers respect cultural mores and entrust tribal leaders with these choices? Do similar concepts of community consent apply at home to African American churches and other institutions where Blacks seek advice or health care?

So, should Black Americans participate in clinical trials to develop an HIV vaccine?

Yes, if they want to be sure that the scientific response to this epidemic works for Blacks around the world. Protective immunization, the main strategy that has controlled other viral diseases, is the only method that is likely to control HIV/AIDS at home and worldwide. Without Black participation we will not learn about protecting Blacks at the same time we learn about other populations.

Because trust is critical to successful recruitment and retention of Black Americans in vaccine trials, researchers must really *collaborate* with minority communities. As noted by Dr. Barbara Ross-Lee, "advocating for the welfare of all trial participants, mandating exhaustive informed consent processes, and providing thorough patient education place knowledge and power in the hands of potential subjects." Culturally representative research teams would help lessen feelings of vulnerability while increasing the

cultural sensitivity of the research enterprise and increasing community trust. Scientists and community members must be willing to learn from each other in order to trust one another.

The number of HIV/AIDS deaths is down dramatically for white Americans. Blacks have seen the same result when they have access to expensive antiviral drugs. But today's HIV treatments are as accessible to most of the world as a formal black tie dinner. The chef has prepared a sumptuous banquet, her assistants have created flawless presentations, servers are prepared to present an unrivaled dining experience, yet most of the world will not be allowed in the banquet hall. Many cannot even imagine what it is like to watch the guests arrive. Black participation in vaccine clinical trials can create a community, which would assure that we will not only be at the table, but also help determine the menu and service available.

Footnotes:

¹ Fullilove, MT. "Perceptions and Misperceptions of Race and Drug Use (editorial)," *Journal of the American Medical Association*.

² Jones, James H. *Bad Blood: The Tuskegee Syphilis Experiment*, New York, NY, The Free Press, 1993.