

Studying volunteers who make vaccine trials possible

by Patricia Kahn, Ph.D.
Special to Q-Notes

Susan Buchbinder is a leading figure in HIV vaccine trials in the US and has followed the epidemic closely from her positions as Director of the HIV Research Section at the San Francisco Department of Public Health and at the University of California, San Francisco. She is also principal investigator of a site within HIVNET, the National Institutes of Health (NIH)-sponsored network that conducts HIV vaccine preparatory research and clinical trials. Buchbinder runs a trial site for the VaxGen Phase III study and serves on the Advisory Council of the Office of AIDS Research (OAR) with NIH and on OAR's Prevention Sciences Working Group.

How did you become involved in AIDS vaccine trial research?

We started in 1993 with vaccine preparedness studies in San Francisco and other US cities, initially as part of a CDC initiative and later within HIVNET. We needed to find-out about high-risk, uninfected gay men — their interest in vaccine trials, baseline level of knowledge about such trials, and the rates of infection in the 1990s.

That work is still continuing. We are also participating in a Phase II vaccine trial that includes both lower- and higher-risk HIV-uninfected people, and are now part of the VaxGen Phase III study. In San Francisco, the predominantly affected population is men who have sex with men; it's the group I have the most direct experience studying. I have also looked at data collected through the HIVNET vaccine preparedness studies, which also involve injection drug users — both men and women — and women whose only risk is heterosexual contact.

What have you learned so far about the reasons why people volunteer for HIV vaccine trials?

Overwhelmingly, for all groups we've enrolled, the leading reason is that they want to help and the belief that their community will benefit from the research. But in Phase III trials there may be something else. The notion of being protected against HIV usually doesn't come up much in Phase I and II trials, but my

sense is that more people may be entering Phase III trials because they hope to gain some degree of protection.

Why do people decline to participate?

The leading reasons are usually logistical — people can't make all the required study visits, or they have difficulty with transportation or the times the clinics are open. People lead very busy lives and sometimes don't have the time to participate in research. Fortunately, some of these things can be changed so that trials are more accessible to more people.

Other concerns relate to safety. These are experimental products and some people are not willing to take on the associated risks.

Some people are also concerned about the possibility of a false positive HIV test — or, more correctly, that they may develop antibodies to HIV which are then wrongly interpreted as meaning they're HIV-infected. That could lead to difficulties in obtaining insurance, jobs, housing, and so on.

Have problems with positive antibody tests actually materialized?

So far we've had very few instances where real issues came up. When they did, the staff at the study site could usually help resolve them. What we don't know is whether the problems will grow when we move into large trials with thousands of participants. Also, as we get into more complex vaccine products, these may be more likely to trigger a positive test result.

We try to educate people up front about the potential problems and to prevent them from arising in the first place. We also offer people a letter stating that they're participating in a vaccine project, if they need to get tested for HIV. That's often helpful. But it's almost always better for them if we do the testing.

Has it been difficult to get women involved in these studies, compared to men?

It has, and I think there are several reasons. The effort to include women stated later, so we're a little further behind in terms of understanding their motivations and the barriers to participation. Women often have competing needs that get in the way of participation; such as childcare or economic issues.

There are also medical barriers. Most vac-

cine trials require women to not be pregnant nor have plans to become pregnant during the course of a trial that could last several years. But women may not want to delay childbearing for so long. We're trying to identify other concerns women may have.

Were there any unexpected findings regarding peoples' willingness to participate?

One of the biggest surprises arose when we were trying to enroll young people — ages 18-25. We found that the parents often didn't want them to participate, and that this can make a big difference. We really hadn't thought about that before. Our educational efforts on HIV vaccine research tend to focus on affected communities, and the parents of these people may not be party to those efforts. We realized that we need a much broader educational program to incorporate families of potential participants.

What knowledge level about vaccines do you encounter in your cohorts?

Baseline knowledge about HIV vaccines is fairly low in general, which is not all that surprising — it's only recently getting more press. Most people have not participated in clinical trials, so don't know how they work. There are often misunderstandings about what a placebo is, what randomization is, what blinding is — all the basic trial concepts.

After putting people through an extensive informed consent process, we give them a quiz to see what they've understood. Usually they do remarkably well.

What are the hardest points to convey?

Many people don't understand that placebos can also cause side effects. That's important because participants need to know that no matter what they get injected with, it can cause some symptoms.

We also tell people that it's possible the vaccine could have harmful effects related to HIV infection or disease. For example, although we obviously hope it will make them less susceptible to infection, it could conceivably do the opposite. Or they could progress to HIV disease more rapidly. That's sometimes a hard concept for people to understand. The assumption is that a vaccine — even a test one — will be

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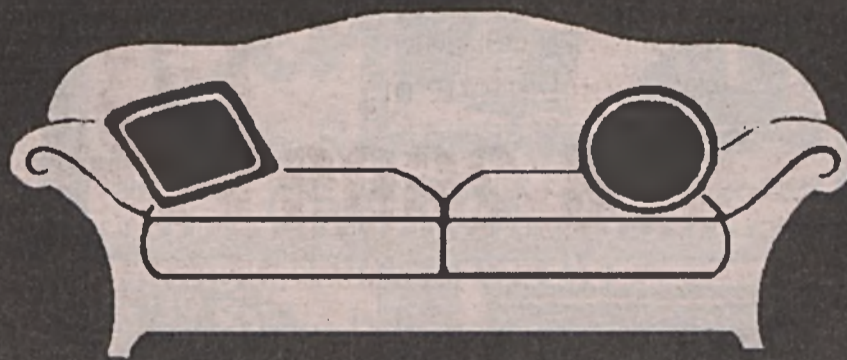


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