

Public health official proposes 'open' AIDS clinical trials

Plan would expand access to treatments, but the role of participants in process is unclear

By Simpson Garfinkel

SAN FRANCISCO — Only one out of nine people diagnosed with AIDS or AIDS-related complex (ARC) is enrolled in a clinical trial designed to test a new therapy or treatment for the syndrome or its associated diseases. Often slots in testing programs are limited to people in certain stages of the disease or to people in a certain geographic area.

A professor at Harvard University's School of Public Health, Marvin Zelen, wants to change that. Under a new plan advanced by Zelen at the annual meeting of the American Association for the Advancement of Science (AAAS) here early in January, every person with AIDS or ARC (PWA, PWARC) or who is HIV-antibody-positive who wishes to take part in a clinical trial could have that option.

Zelen, an expert in evaluating clinical trials and chair of Harvard's Department of Biostatistics, proposed a new "open protocol system" for conducting future AIDS clinical trials. Experiments would be conducted on a nation-wide basis, and any physician in the country who signed up could enroll any PWA, PWARC, or HIV antibody-positive individual in an ongoing experiment. Drugs would be provided for free.

The "closed" nature of most AIDS trials — meaning the strict limits on enrollment — has persuaded many PWAs to prescribe drugs for themselves that have not been approved and which have unknown effectiveness and toxicity, according to Zelen. Closed trials have also drastically limited the number of people who could participate in research, he said, at a time when the number of scientific questions [regarding AIDS] is large and requires many more clinical trials than are currently in process.

Properly conducted clinical trials are vitally important, said Daniel F. Hoth, director of the AIDS program of the National Institute of Allergy and Infectious Diseases, because "there is simply no other way to determine which drug works, which does not, which is safe, and which is not."

In addition, the standard of care that people receive in clinical trials — which includes constant monitoring and treatment for accompanying diseases — is much higher than the standard they would otherwise enjoy. "Clinical trials, well designed and carefully applied, ought to be the treatment of choice for people with AIDS," says another panelist, Richard D. Gelber, an associate professor of Biostatistics at Harvard University.

Zelen argues that current AIDS trials are

flawed in part because they have been based on the National Cancer Institute's "cooperative cancer group" strategy for conducting tests of new cancer treatments. "But there are many differences between AIDS and cancer," he said, which necessitate a different approach.

Zelen's "open protocol system" would consist of a number of physicians around the country who would be pre-approved to take part in the trials. New physicians could sign up by filling out a questionnaire and attending a training session. The roster of approved physicians would be published. Zelen did not specify whether an existing government agency or other organization would administer his proposed system.

Those interested in participating in trials would contact a physician on the roster who would inform participants of the terms of current protocols. The physician could then register the patient by telephone or computer; drugs, detailed experimental protocol and forms for data collection would arrive at the physician's office within 24 hours. Zelen did not indicate whether his plan would include substantial input by those seeking treatment over which treatments they would receive.

The physician would monitor the progress of the PWA and periodically report on the patient's status to a national data collection center. Zelen's system would include a national telephone hot line for the use of those involved in the study, a quality control auditing system to assure the reliability of the findings, and an electronic mail system to allow medical consultation and the sharing of toxicity information.

"Everything that I have discussed is feasible right now," he said, estimating that a pilot program with 1,000 participants might cost as much as \$30 million. Such a pilot program would increase the number of people in AIDS-related drug trials by 25 percent.

"It is very important that we double, triple, or quadruple the number of patients in national AIDS clinical trials," he said. "Otherwise, we will be provoking human misery. As a country, we have to accelerate the whole process."

In his presentation of his proposal, Zelen did not mention Community-based Research Initiatives (CRIs), which are cooperative efforts developed by PWAs and their doctors to make treatments accessible and to gather data using ethical and humane methods. An assistant in Zelen's office told GCN that Zelen developed his proposal

Continued on page 6

Continued from page 3

"based on scientific experience, not in consultation with any AIDS activists."

Several physicians at the AAAS symposium expressed skepticism that such a large-scale study could maintain contact with its patients. For example, in a recent study of people with AIDS who sought help in clinics designed for low-income groups, researchers lost touch with nearly 20 percent of the subjects within 11 months, says Dr. David W. Barry, vice president of research at Burroughs-Wellcome. That dropout rate remained high despite a substantial effort on the part of researchers to recontact the study's participants, according to Barry. Nevertheless, participants at the symposium gave Zelen's proposal an enthusiastic review and expressed hope that a pilot project could be started quickly. □

Lesbian valentines smooch for gay rights

Mass. gay rights public support

BOSTON — The ongoing State House-front vigil in support of a holiday theme Feb. 14, as 30 lesbian and gay activists celebrated in. The public rally and displays of affection were intended to focus attention on the Gay and Lesbian Civil Rights Bill and to focus attention on the House Feb. 15. Several passing Beacon Hill motorists cheered reading, "Honk if you support lesbian and gay rights," and "away," and took turns kissing (and posing) in front a ten-foot Love."

On Feb. 16, after the public testimony was presented, the bill passed the Commerce and Labor Committee by a slim margin. The actual vote was 10-7. Three legislators "reserving their rights" to vote. According to the Massachusetts Gay and Lesbian Political Caucus, Rep. Marilyn S. Glickman, said she was opposed to the bill but agreed to support it.

Opponents to the bill killed the legislation in the previous session in 1987 and 1988, the bill was held up in the Committee on Bill and checked to ensure they are written in accordance with Sen. Lewis (D-Jamaica Plain), the chair of that committee during the bill's passage.

Sen. William MacLean, the new chair of the Committee on Commerce and Labor, would not use his power as chair of the Committee on Bills and Resolutions, could not be reached for comment after the bill passed. If the bill passes, it will be the second statewide lesbian/gay

Michael Hirsch, activist, dies

By Andrew Miller

NEW YORK — Michael Hirsch, a prominent and outspoken AIDS activist, died on Feb. 3 from AIDS-related complications at St. Vincent's Hospital in Greenwich Village. He was 34 years old.

Hirsch was both a founding member and first executive director of the New York People with AIDS Coalition, the first organization run both by and for people with AIDS. The Coalition, which was formed in 1985, has subsequently become the largest group of its kind in the country. Similarly run organizations have sprung up in other cities. In 1987, Hirsch went on to

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Thomas Stehling