

Intervention Cuts STI Rates Among Black Women

BY SUSAN LONDON
Contributing Writer

MEXICO CITY — African American women who receive an intervention that includes a package of safer-sex options have a large reduction in the incidence of sexually transmitted infections relative to peers who receive general health promotion, researchers reported at the International AIDS Conference.

"Among women in the U.S., marked racial as well as regional disparities [in HIV incidence] exist," said lead author Gina M. Wingood, Sc.D., of Emory University in Atlanta. "Specifically, women in the deep southern U.S. are severely affected." A related issue, she noted, is that HIV interventions for women have focused on the use of condoms and penile-vaginal sex, giving women few preventive options.

To address these issues, Dr. Wingood and her colleagues undertook the STARS (Sisters Talking About Real Solutions) trial. With the database of a health maintenance organization in Georgia, they randomly selected African American women aged 18-29 years and invited those who were sexually active and reported having unprotected vaginal sex in the prior 6

months to participate. Participating women were randomly assigned to an intervention group or a comparison group, Dr. Wingood said. The intervention, delivered in two 4-hour workshops, focused on fostering ethnic and gender pride (to enhance self-esteem, self-awareness, and self-worth), increasing awareness of healthy and unhealthy relationships (to address the link between abuse and sexually transmitted infections [STIs]), and introducing a package of safer-sex options known as AMOUR (Abstain from unsafe sex and douching; Mutual stimulation, meaning nonpenetrative sex; Oral sex with protection; Uninfected partners, referring to ensuring that partners do not have STIs; and Regular condom use and reduction of number of partners). The comparison group received a single 4-hour workshop that focused on general health promotion.

The women enrolled in the trial were a mean age of 24 years; 57% lived with a family member, 89% had completed high school, and 86% were in relationships lasting an average of 23 months. Intention-to-treat analyses were based on 605 women in the intervention group and 243 women in the comparison group. The workshops were completed by 96% and 100%, re-

spectively, and 75% of women in each group completed the trial's 12-month follow-up assessment.

In terms of biologic outcomes at 12 months, women in the intervention group were significantly less likely to have acquired any of four STIs studied (human papillomavirus type 16 or 18, chlamydia, gonorrhea, or trichomoniasis) relative to their counterparts in the comparison group (odds ratio, 0.35). In addition, intervention women were significantly less likely to have acquired human papillomavirus infection individually (O.R. 0.37) and the other, nonviral STIs individually (O.R. 0.62).

Women in the intervention group had significantly more favorable levels of each

of nine risk behaviors than did the comparison group. For example, they were more likely to have asked their main partner to be tested for STIs (O.R. 1.41) and to have had protected oral sex (O.R. 2.05), and they were less likely to have douched (O.R. 0.38) and to have had sex with more than one partner (O.R. 0.73) or with casual partners (O.R. 0.66).

Finally, women in the intervention group had significantly higher scores on tests of knowledge regarding prevention of STIs and HIV, greater self-efficacy regarding condom use, and lower levels of barriers to safer sex.

Dr. Wingood stated that she had no conflicts of interest regarding the study. ■

Researchers Rebound From Latest AIDS Vaccine Failure

BY SUSAN LONDON
Contributing Writer

MEXICO CITY — The development of an AIDS vaccine is likely to take a long time, and research needs to be more selectively focused on the most promising candidate vaccines, given the recent failure of the latest leading candidate to prevent infection in a large international trial, according to the findings of a report aimed at setting priorities for AIDS vaccine research.

Experts at the International AIDS Conference discussed the status of AIDS vaccine efforts at a press conference to unveil the AIDS Vaccine Blueprint 2008. The document, published by the International AIDS Vaccine Initiative (IAVI), is the fifth biennial report of its kind. It comes at a time when optimism in the field is waning, after early closure of the STEP trial of the failed vaccine last year and cancellation of the PAVE 100 trial of a new vaccine this year.

The blueprint delineates the current challenges in developing an AIDS vaccine, and provides interim milestones for each. "This is a way to measure [progress], to hold people accountable," explained Dr. Seth Berkley, president and CEO of IAVI.

The blueprint calls for pruning the vaccine pipeline. "We believe that the majority of the 30-odd candidates that are in the pipeline should be prioritized based on their probability of success," he said. This recommendation is not new, he acknowledged, but the document goes further, detailing how it should be done by requiring vaccine candidates to be superior to ones that have failed in preclinical testing.

In recent years, more stakeholders have rallied behind the blueprint, which will be critical going forward, according to Dr. Peter Piot, executive director of UNAIDS in Geneva. "This [AIDS vaccine development] is not going to be something that can be done by one organization. It requires a coalition," he said.

"Science is never a straight line. Failure is part of the game," noted Dr. Alan Bernstein, executive director of the Global HIV Vaccine Enterprise in New York. As

disappointing as the STEP trial's results were, the trial has been a success in the sense that it provided, and continues to provide, a wealth of data that will help inform future trials.

Given the retroviral nature of HIV and the lack of much precedence in developing vaccines against retroviruses, he applauded recent efforts by several organizations to stimulate diverse approaches to the problem.

Putting the AIDS vaccine effort into context, Dr. Berkley noted that the development of a vaccine typically takes decades. Advancing HIV vaccine research will require not only new talent, but also stable, predictable, and flexible financing, he continued. Flexibility is important because "we need to be able to jump on advances and quickly drop things that aren't promising." This ability to be flexible will be critical to maintaining incentives that keep companies engaged in the effort.

In response to calls to end the vaccine research effort, Dr. Piot cited the disease's staggering toll. "If the world can be satisfied with 2.7 million people infected per year—7,500 per day—then I am not so sure where the standards are for declaring something a total disaster," he said.

Shutting down the AIDS vaccine trial sites in Africa would be "a big mistake," agreed Dr. Omu Anzala, chairman of microbiology at the University of Nairobi (Kenya) and director of the Kenya AIDS Vaccine Initiative (KAVI). He noted that these sites not only stand ready for future trials, but also continue to conduct epidemiological and basic HIV research. "It is this information that will then feed into HIV vaccine discovery and also feed into drug discovery," he said.

Dr. Anzala agreed with his colleagues that the failure of a single vaccine is not cause for condemning the entire AIDS vaccine initiative. Noting that he comes from a country known for long-distance running, he likened the search for an effective vaccine to a marathon in which perhaps 100 runners start and many fall by the wayside, but eventually one wins. "We cannot stop now," he concluded. ■

Prescribing Information

FOSTEUM™ Capsules
genistein aglycone (27 MG)
citrated zinc bisglycinate (20 MG)
cholecalciferol (200 IU)

FOSTEUM is a specially formulated prescription medical food product for the clinical dietary management of the metabolic processes of osteopenia and osteoporosis.

FOSTEUM must be administered under physician supervision.

INDICATIONS AND USAGE

Indications

FOSTEUM is indicated for the clinical dietary management of the metabolic processes of osteopenia and osteoporosis.

Usage

FOSTEUM should be taken with sufficient calcium and vitamin D₃ as directed by a physician. In clinical trials of the genistein aglycone in FOSTEUM, patients also received 1,000 mg of calcium carbonate and 800 IU vitamin D₃ per day in two divided doses. See Dosage and Administration for additional information.

Interactions with Food

FOSTEUM can be taken with or without other foods. FOSTEUM may be taken with any beverage desired.

PRECAUTIONS AND CONTRAINDICATIONS

General

Causes of osteopenia or osteoporosis other than menopause or aging should be considered.

Hypersensitivity

FOSTEUM is contraindicated for anyone having a hypersensitivity to any ingredient in the product. See "Other ingredients" for a full list of ingredients.

Patients with Cancer

Since no studies have been done in these populations, as a precaution, FOSTEUM is contraindicated for patients with a history of cancer of the breast or reproductive organs and should be used with caution by women who have a history of breast or reproductive cancer in first degree female relatives.

Vitamin D Deficiency

FOSTEUM is not intended to treat vitamin D deficiency.

Pregnancy

FOSTEUM is contraindicated in pregnant and lactating women. Women capable of becoming pregnant should use appropriate contraception when taking FOSTEUM. The genistein aglycone in FOSTEUM has not been tested in women capable of becoming pregnant.

ADVERSE EVENTS

Study discontinuation in clinical trial subjects was due to gastrointestinal symptoms, including abdominal and epigastric pain, dyspepsia, vomiting and constipation. The incidence of adverse events was statistically higher in the genistein aglycone group. The major adverse events are shown in the table below without attribution of causality.

Adverse Events	Year 1		Year 2	
	Genistein aglycone + Ca/D (n=178)	Ca/D (n=172)	Genistein aglycone + Ca/D (n=150)	Ca/D (n=172)
Abdominal Pain	4 (2.2%)	2 (1.1%)	2 (1.3%)	1 (0.6%)
Dyspepsia	2 (1.1%)	1 (0.6%)	7 (4.7%)	2 (1.3%)
Constipation	5 (2.8%)	2 (1.7%)	8 (5.3%)	3 (1.9%)

Some of these adverse event occurrences may be attributable to the intake of 1,000 mg per day of calcium carbonate by subjects in both groups. Taking FOSTEUM with food may reduce or eliminate some gastrointestinal symptoms.

Regular monitoring of urine and serum calcium may be indicated in this population.

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