

## HIV trial tests fail after participants shun regimen

March 5 2013 at 09:14am  
By LIZ CLARKE  
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The mood at Atlanta is one of disappointment and dismay. Why would thousands of young healthy women in Africa shun the idea of medication that could keep them disease free?

And yet that is precisely what most of the 5 029 participants did in a prevention trial conducted by the US National Institute of Health (NIH)-funded Microbicide Trials Network (MTN) in 15 sites in sub-Saharan Africa over the past three years.

The Voice (Vaginal and Oral Interventions to Control the Epidemic) trials included eight test sites in KZN, the province with the highest burden of disease globally, and three sites in the rest of the country.

The analysis of the data at the Conference on Retroviruses and Opportunistic Infections (CROI) in Atlanta last night, showed that at least 70 percent of those participating were found to have been untruthful about adherence. The evidence was substantiated by detailed analysis, including blood samples. Other trial volunteers simply abandoned the regimen without even starting the prevention measures.

The trial regimen asked of women involved the daily oral intake of one HIV prevention tablet or the daily use of a vaginal gel, which were being tested in hopes of stopping the virus from infecting the body.

Nearly half of the participants were under the age of 25 and most (79 percent) were single.

Even more worrying for researchers was that the women most at risk in the 18-29 age group, appeared to be the least interested in adhering to the trial medication.

In this group of young, single women, HIV incidence was found to be 8.8 percent for unmarried women younger than 25 compared to 0.8 for women older and married.

The highest concentration of HIV was in KZN with a disease ratio in under-25-year-old women currently standing at 10 percent. Again this group was the least likely to use the medication

“These findings are very disappointing,” said lead researcher Jeanne MARRAZZO, MD, MPH, of the University of Washington.

“There are huge barriers to adherence and big gaps in our knowledge of behaviour. The task now is to find out what these gaps and barriers are and how we can overcome them.”

Among the reasons suggested for non-compliance is stigma, the influence of traditional healers and traditional medicine, family and partner intervention, suspicion and cultural beliefs.

It could also be, say some observers, that healthy women believe there is a risk of getting HIV if they take the trial medication.

Of the 5 029 women enrolled in Voice, 312 acquired HIV during the study (another 22 women who were already infected at enrolment were excluded from the analysis), for an overall HIV incidence of 5.7 percent, nearly twice what investigators had expected when they designed the trial.

Adherence to product use was low across all groups, researchers said.



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According to an analysis of blood samples from a subset of 773 participants (including 185 women who acquired HIV), only one quarter (about 25 percent) of the women had used the trial medications, which meant that 75 percent of the gel and tablets had been disposed of.

Adherence, said researchers, was a critical component to the success of any clinical trial.

"If participants fail to follow the study's regimen, it is almost impossible to know the true biological effectiveness of a product or approach," said Marrazzo.

"If these products worked, we have no way of knowing it. Even the most effective product will not provide benefit if it is not used or not used properly."

The 20-year journey to find a successful microbicide and prevention pill has been tougher than many envisaged.

Earlier in the Voice trial two of its "arms" were stopped early by the Data Monitoring and Safety Board because "it was futile to continue".

The two substances that were stopped were the tenofovir tablet and the tenofovir gel, the latter of which in an earlier study by the Durban-based international research group Caprisa was found to be effective in reducing the incidence of HIV in 39 percent of trial participants when used (not daily as in the Voice trial) but before and after sex.

The study, which involved 889 women at two sites in KZN unexpectedly found that tenofovir gel also reduced the risk of HSV-2 by 51 percent.

lizclarke4@gmail.com



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