

Kenyatta victory: Defiance to Western affirmation

Warriors remain stagnant

## Voice: When adherence is key

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Women have for long failed to negotiate safe sex. Despite readily available interventions such as the female condom, most women whether educated or uneducated, from urban and rural areas, single or married still somewhat lack the full control and have to seek the approval of their partners.

Others fail to use the female condoms citing religious beliefs. Stories of how women were either labelled to be promiscuous and even beaten up for suggesting the use of or for being found in possession of the female condom have been told.

Most women have been left exposed to sexually transmitted infections that include HIV — the testimonies are endless.

When news of the Vaginal and Oral Interventions to Control the Epidemic research finally broke, women in Zimbabwe, sub-Saharan Africa and other parts of the world were hopeful. At least something they could control had finally come for they had patiently waited for the success of this research.

But last week, the much awaited news finally broke. The trial on the effectiveness of the anti-retroviral drugs, commonly used in treating HIV in preventing sexual transmission of the virus to young unmarried women had shown that the drugs do not work.

According to the report, seven Zimbabweans became infected with HIV during the study.

The Microbicide Trials Network announced that most participants did not use any of the three test products, Tenofovir gel, Oral Tenofovir and Oral Truvada daily as recommended.

The research, Vaginal and Oral Interventions to Control the Epidemic began in September 2009 and its last phase ends in August this year.

It was conducted by the US National Institutes of Health-funded Microbicide Trials Network at 15 trial sites in Uganda, South Africa and Zimbabwe and involves 5 029 participants. Of the 5029 women enrolled in Voice, 4 077 were from South Africa and 322 from Uganda.

In Zimbabwe, centres that include Spilhaus, Seke South and Zengeza clinics enrolled 630 participants. Twenty-two women from the three countries were later identified to have been HIV positive at enrolment and were excluded from the analysis leaving the number of participants at 5 007. From the total participants, 312 women contracted HIV during the study.

While some have suggested that the outcome could be the fault of behaviour than the prevention methods used in the study, more questions remain. How has the ordinary woman received this news? What went wrong? What does this outcome mean for women?

Miss Eva Tande of Harare said it is disappointing that Voice has failed at a time women's expectations were high.

She said failure by the women who participated in the trials to adhere to what they had vowed to leaves a lot to be desired.

"They managed to crush the hopes of millions of sexually oppressed women and young girls. Maybe next time, the importance of such researches should be emphasised to those intending to participate to avoid such kind of discouragements and wastage of resources," she said.

Disappointing, is how Mrs Clara Dzimba of Mabelreign, Harare, aptly put it.

She said she finally thought a new dawn on HIV prevention had finally arrived when the studies begun. Sadly she has to wait longer.

Women and Aids Support Network information officer Ms Evince Magumbate said the shocking results mean that women who might have benefited from these gels are still vulnerable more than two decades after the coming in of HIV/Aids.

"It could have been a celebration if it was successful, especially for those who cannot negotiate for safer sex. It means that if more funds are channelled to these researches then positive results might be yielded. The way forward is for them to use the female condom

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which is the only protection available for them she said.

In a statement, MTN said the drug was detected in less than a third of blood samples from women who were assigned to either Truvada or Oral Tenofovir and in less than a quarter of samples from women designated to use Tenofovir gel.

The Zimbabwean team was led by Professor Mike Chirenje from the University of Zimbabwe, the principal investigator, and Dr Nyaradzo Mgodzi, the project director.

Said Prof Chirenje: "No intervention is going to be effective if it's not used. The point is that the majority of women in Voice did not use any of the study products as recommended.

"So while we are disappointed in these results, we have answered the questions Voice was designed to answer, and what we have learned is critically important."

Dr Mgodzi said it is important to look at a range of different options since one approach is not going to work for all women.

"Women remain most vulnerable to HIV and there is an urgent need for other effective, female controlled HIV prevention methods that women will use. We remain as committed as ever to women in our communities and we are grateful for their participation in Voice. It helps us to better understand what they need to protect themselves against HIV as we continue to fight the epidemic," she said.

Dr Jeanne Marrazzo from the University of Washington in Seattle who led the overall study and reported the results on behalf of the study team said: "Although there may be other explanations for why these products don't always work to prevent HIV, it's hard to ignore the fact that so few women in our study used them.

"Clearly, an approach of daily product use is not going to work for the population of women who participated in Voice. Equally important, the women in our study — especially in South Africa — experienced rates of HIV acquisition that were much higher than we expected.

"The bottom line is that this group of young women remains at very high risk of HIV infection and urgently needs safe, effective and practical HIV prevention methods that they will actually use."

Dr Marrazzo added that of the 1002 women in the Oral Tenofovir group, 60 acquired HIV. HIV incidence, however, was calculated to reflect what had occurred up to October 3, 2011, when sites began informing participants that testing of Oral Tenofovir was to stop. At this time, he said, there were 52 infections in the Tenofovir tablet group and 35 in the Oral Placebo group, for HIV incidence rates of 6,3 and 4,2 respectively.

Of the 1 003 women assigned to use Tenofovir gel, 61 women acquired HIV and 70 infections occurred among the 1 000 women in the placebo gel group.

Though the estimates of effectiveness of both Oral Tenofovir and Truvada were less than zero, Tenofovir gel was estimated to reduce the risk of HIV by 7 percent compared to the Placebo gel, he added.

Mitchell Warren, executive director of AVAC, a non-profit HIV/Aids advocacy group, said the results show that clearly, not one prevention method will be right for everyone.

"The Voice results are one more piece of the complex puzzle of providing additional prevention options for women and men. They actually confirm what we already know from previous trials.

"These interventions work when they are used, and they don't work when they are not used and secondly not every woman (or man) can or wants to use a product every day. "Daily PrEP is still a valuable option for many women and men, who recognise their risk and can take PrEP consistently," he said.

He added that the Voice trial actually tells us as much or more about behaviour as it does about the biomedical products that were being studied.

"In fact, HIV prevention is never just biomedical — behaviour is key. What we've learned from this trial is that adherence to the daily dose — the behavioural component — is the variable that determines effectiveness.

"Unfortunately, the women in the trial did not adhere, even though they were clearly at risk and we see again that an urgent public health need for new prevention options does not mean women will automatically demand or use the products.

"We clearly need to better understand women's reproductive and sexual health needs and desires, their perceptions of personal risk for HIV infection and their interest in and ability to use the products offered in those trials," he explained.

According to Warren, there is urgent need for accelerated research and development of additional HIV prevention options that are less dependent on adherence and may be easier and more desirable for women to use.

These, he pointed out, include different delivery mechanisms, such as long-acting rings and injections, and less-than-daily dosing schedules, such as that being tested in the Facts 001 trial, which is looking at 1 percent Tenofovir vaginal gel used around the time of intercourse.

"We also need renewed commitment to develop HIV vaccines, which would overcome many of the issues around adherence, and combined contraceptive and HIV prevention methods, which would address many women's needs more comprehensively.

"But we have to remember that none of these biomedical tools will work in a vacuum, but rather in the complex realities of women's and girls' lives — so there will never be a single






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solution. Instead, we need to give women and men more options — some will prefer gels and pills, some a ring and some an injection. If we have learned anything in Aids and in reproductive health, one size does not fit all," he clarified.

Warren revealed that everyone has a dual responsibility to understand who might benefit from daily PrEP and ensure that they can access it and to accelerate the development of additional options that can meet the urgent needs of others.

"We need to make sure that we get all of the information we can from the Voice participants to help us understand why women were dedicated to the trial and yet were not willing or able to use the products consistently. These women are at such high risk for HIV, we owe it to them to work with them to find the options that they can and will use to protect themselves," he said.

According to MTN, the mean age of the trials was 25,3 (nearly half were younger than 25) and 75 percent of the participants were single.

In South Africa, the mean age was 24,7 although more than half (55 percent) were under 25 and only 8 percent were married. In contrast, the mean age in Uganda and Zimbabwe was 28,3 and 28,1 respectively; 50 percent of the women enrolled in Uganda were married, while in Zimbabwe, 94 percent were married.

Women account 60 percent of adults with HIV in sub-Saharan Africa, where unprotected heterosexual intercourse is primarily to blame for the region's heavy HIV burden. The recent results are further proof that young women are especially vulnerable.

In Zimbabwe, 207 765 women are on anti retroviral drugs according to the National Aids Council.

While efforts to promote abstinence, monogamy and male condom use have not been enough to stop the HIV pandemic nor are these methods feasible in most settings. There is an urgent need for effective strategies that women can control themselves and be willing to use.

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