



The FACTS 001 Study

Prof Helen Rees, Protocol Chair

Prof Glenda Gray, Protocol Co-Chair

CAPRISA 004 Results

- CAPRISA 004 showed that 1% tenofovir gel reduced the risk of vaginally transmitted HIV by 39% when used before and after sex (BAT24)
- Also demonstrated a reduction in the risk of Herpes Simplex Virus 2 (HSV2) by 51%.

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Antiretroviral gel seen as major breakthrough

Microbicide could prevent 1.3m infections over 20 years

KERRY CULLINAN

IN ONE OF the biggest advances in HIV prevention in decades, a vaginal gel containing an antiretroviral drug has been proven to protect about four out of 10 women from HIV.

A study of about 800 HIV-negative women from KwaZulu-Natal found there was a 39 percent lower HIV-incidence rate in the group that used the gel containing tenofovir.

This ARV-containing gel (known as a microbicide) could save more than 800 000 lives and prevent 1.3 million new HIV infections over the next two decades in South Africa alone, according to statistician Brian Williams.

The results were announced at the International Aids Conference in Vienna by the South African husband-and-wife team who led the research, professors Salim and Quarraisha Abdoel Karim, and were published online in the journal Science.

"Of course we were hopeful, but when the statistician came in and gave us the results, we were absolutely stunned. We just looked at each other in disbelief and couldn't speak for a while," said Salim Abdoel Karim, PRO vice-chancellor at the University of KwaZulu-Natal and head of the Centre for the Aids Programme of Research in SA (Caprisa), which conducted the trial.

This is the first prevention method designed specifically for

We need to find a way of getting this into women's hands as fast as possible," said Quarraisha Abdoel Karim, associate professor at Columbia University in New York and Caprisa's associate director.

In the study, half the women were randomly assigned to get tenofovir gel, while the others got plain gel. They had to put gel into their vaginas 12 hours or less before sex and again within 12 hours after sex. All women were counselled on the risks of HIV and encouraged to use condoms at all times.

Koliswa Mthethwa, one of the trial participants, said: "I had no problems with the gel. I mainly put it in in the afternoon. It felt like it wasn't there."

Field workers at the study sites in Vulindlela in the KwaZulu-Natal Midlands and Durban said the only problem they had was when a tumour went around that there was HIV in the gel.

"We had to address community meetings with the traditional leaders to address this myth," said Mike Mthethwa.

Neither the researchers nor the women knew which group they were in until the study ended a few weeks ago.

Sixty of the 464 women who got plain gel became HIV-positive over the 30-month study, whereas only 28 of the 465 women in the tenofovir group got HIV.

The HIV rate was cut by more than half (54 percent) among women who used the tenofovir gel properly at least eight out of

second mechanism whereby the gel may have a bigger impact in preventing HIV," said Salim Abdoel Karim.

The Abdoel Karims have been searching for an effective microbicide for the past 16 years, largely to try to give women who are unable to get their partners to use condoms the chance to protect themselves.

While the results were exciting, Salim Abdoel Karim said another study was urgently needed to verify the results.

"Although the study findings are robust, an independent confirmatory study is needed to see whether the results can be generalised to other settings," he said.

The researchers have ceded all rights to the tenofovir microbicide to the South African government, which plans to set up a plant in Durban via the Technology Innovation Agency to manufacture the gel for further trials and, hopefully, for the mass market.

Michael Warren, executive director of the Aids Vaccine Advocacy Coalition in New York, described the findings as "a true breakthrough for Aids prevention".

However, Warren said further studies were needed to answer a number of questions, including whether the gel could be used by teenagers and in anal sex.

Ambassador Eric Goosby, the US Global Aids Co-ordinator, said: "The results of the Caprisa trial provide new hope and direction for not only HIV prevention, but also broader efforts under the Global Health Initiative. We recognise that microbicides will

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Fast-track anti-HIV gel, says minister

FARANAAZ PARKER | VIENNA, AUSTRIA - Jul 23 2010 11:41

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The South African government would consider fast-tracking a groundbreaking HIV-blocking vaginal gel through regulatory processes to get it into clinics

ARTICLE TOOLS

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BAT 24 regimen used in FACTS 001

Within 12 hours

ASAP and within 12 hours



Women should not use more than **two** gel applicators in a **24-hour period no matter how many times they have sex in a day**

Rationale for confirmatory study

Safety

- Safety of tenofovir gel when used as BAT 24 regimen.

Repeatability

- Effectiveness in diverse populations with different epidemics

HIV Protection

- Confirm CAPRISA 004 results

Generalizability

- CAPRISA 004 included 899 women in high incidence area of KZN.

HSV-2

- Confirm data on effectiveness for prevention of HSV-2

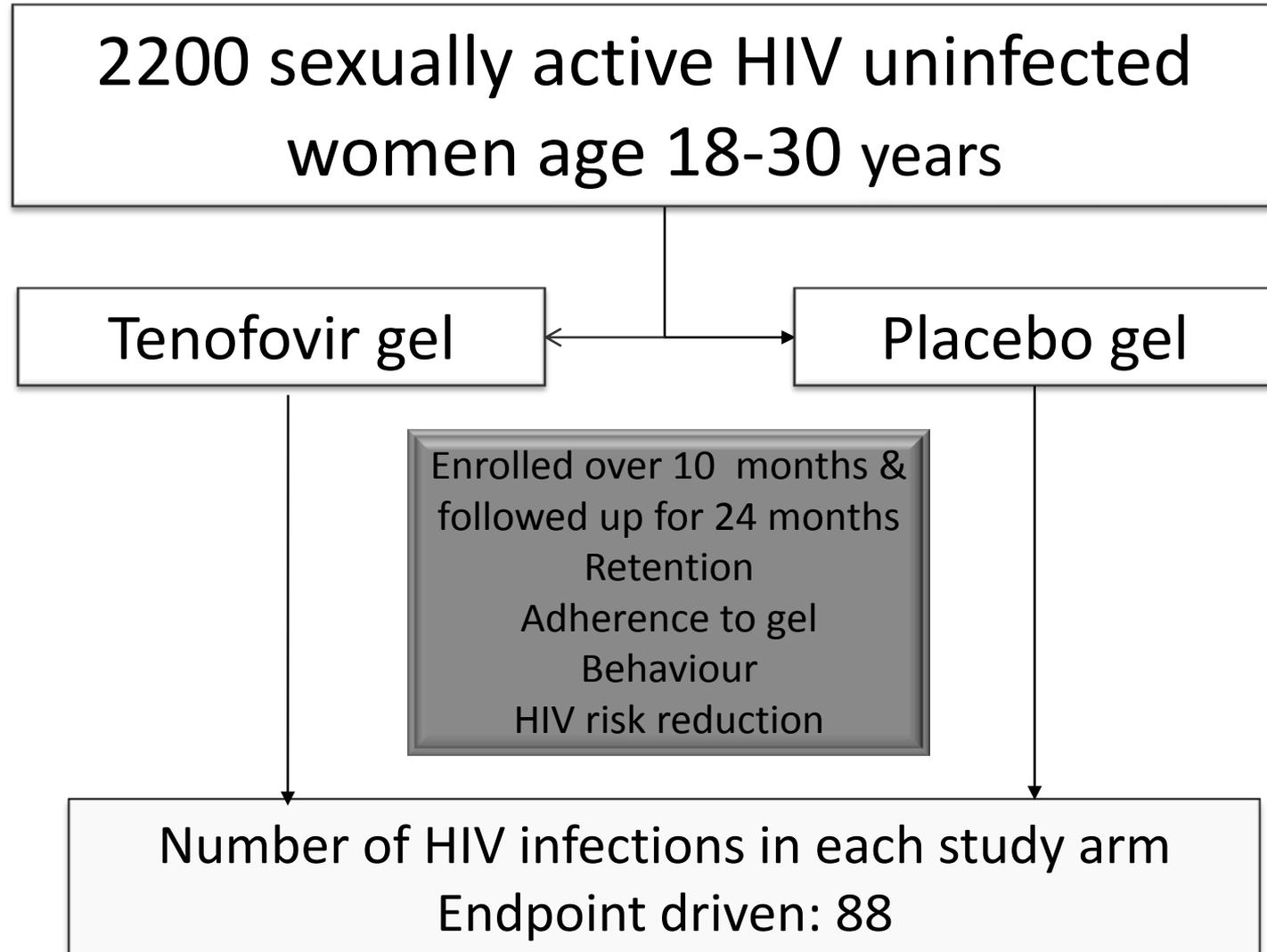
Primary objective

- Evaluate effectiveness and safety of 1% tenofovir gel in preventing sexual transmission of HIV-1 infection in young women

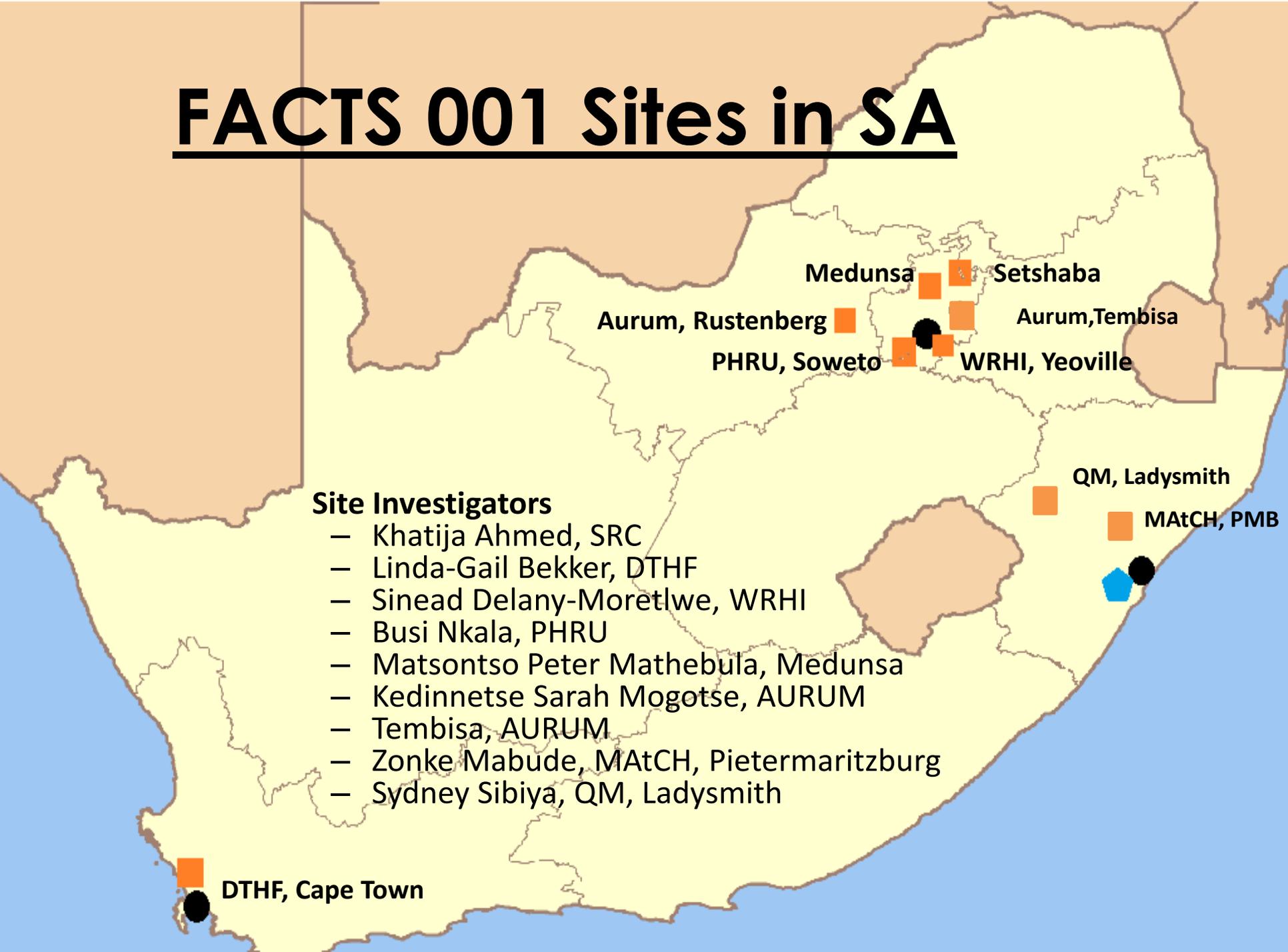
Secondary objectives

- Effectiveness against HSV-2
- Impact on pregnancy outcomes
- Effectiveness of gel according to levels of condom use
- In women that become HIV infected during trial:
 - Effect of tenofovir gel on viral load set point
 - Tenofovir resistance

Study design of FACTS



FACTS 001 Sites in SA



Medunsa Setshaba
Aurum, Rustenberg Aurum, Tembisa
PHRU, Soweto WRHI, Yeoville

QM, Ladysmith
MATCh, PMB

DTHF, Cape Town

CAPRISA 002

- Safety and acceptability of use of 1% tenofovir gel in 16 and 17 year old girls in South Africa
- Submitted to MCC, S Africa
- Ongoing design considerations
 - How often to expose young girls noting this is BAT-24 regimen?
 - Daily versus BAT 24 ?
 - Combination of both?