



MICROBICIDES DEVELOPMENT PROGRAMME

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Microbicides could be available in 2014, but will we know how to use them?

An estimated 7,400 new HIV infections occurred EVERY DAY in 2008, the majority in women of child bearing age.

The South African CAPRISA 004 microbicide trial reported:

- 39% reduction in HIV in women using tenofovir vaginal gel compared to placebo gel
- 51% reduction in genital herpes (HSV2)
- 54% reduction in HIV when gel was used as instructed for 80% or more of the sex acts

The instructions were complicated requiring TWO doses per sex act, but NO MORE THAN TWO in one day.

CAPRISA 004 was a good result for HIV prevention, and a good result for microbicides as a method of delivery, but did not answer the following questions:

- will tenofovir gel prevent HIV in broader study populations and younger women aged 16-17?
- will ONE dose of gel prior to sex provide protection (it protects 100% of monkeys)?
- will a dose of gel EVERY DAY provide better protection (a regime that might tolerate missed doses)?
- how does tenofovir gel compare to tenofovir tablets as prevention?
- could other methods of delivery such as rings and depo injections provide greater protection?

In 2013 the VOICE trial will report on the safety and effectiveness of using tenofovir gel EVERY DAY in broader populations, and the relative benefits of gel and tablets. The US Food and Drug Administration (FDA) have stated that this trial should be sufficient to support a licensure application for tenofovir gel.

The FACTS trial will repeat the TWO dose strategy used in CAPRISA 004, which informally the South African Medicine Controls Council (MCC) have indicated a preference for, in order to support licensure in South Africa.

The International Partnership for Microbicides plans to test the dapivirine ring which releases constant drug against placebo in two trials 2011-14. This will appeal to many women, but may not suit women having infrequent sex.

In 2014, we will not know if ONE dose of gel per sex act will protect women

ONE dose would be simpler and cheaper to implement, but it may not work well enough to justify roll-out.

The quickest and most accurate way to assess ONE dose per sex act is to compare it to placebo gel.

The proposed MDP302 trial

- Will explore ONE dose per sex act compared to placebo
- Will include TWO doses per sex act as a 'positive' standard
- Will include 16-17yr olds and women from Mozambique, Uganda, Tanzania and Zambia as well as South Africa – 3 of these countries have no current experience of tenofovir gel
- Will reduce the intensity of the clinic visits and tests to get closer to a roll-out schedule
- Is good VALUE FOR MONEY because it is built on established clinic, laboratory and community infrastructure and trained personnel have a TRACK RECORD of completing a microbicide trial
- Communities are already engaged in microbicide research as they are supporting a study with placebo gel that is completing in 2010 and therefore all the trial sites are ready to start MDP 302

CAPRISA 004 has broken new ground, opening the door to a new technology that women can use to protect themselves against HIV, and still have children.

ONE dose per sex act with less frequent clinic visits and tests would allow accelerated uptake, and increase the number of women that can be given a choice in 2014.

Europe invested €202M in microbicide research in the last decade - €22M more over the next 4 years would build on this investment and tell us whether ONE dose per sex act protects in time to inform implementation once the gel is licensed.

This is a small additional investment for a large return – millions of women and their children would benefit.