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Success at last for anti-HIV gel

AIDS patients recently diagnosed have a discussion with health workers from the Centre for Treatment, Activities and Counselling for People living with HIV/AIDS (CESAC), which is the main organisation working with AIDS patients in Mali.

The first successful trial of an HIV gel has shown that it may prevent transmission of the virus to women.

An antiretroviral microbicide gel can cut HIV infection in women by more than 50pc if used consistently.

Worldwide, an estimated 33 million people are living with HIV, roughly half of them women, according to UNAIDS. In South Africa, one in three women aged 20–34 is estimated to be infected with HIV. Because 60pc of all new HIV infections in sub-Saharan Africa are in women, there is a sense of urgency surrounding the development of HIV-prevention tools for this group.

The journey to develop a topical microbicide gel that can kill HIV has been a long and difficult one marked by several public disappointments and no real successes — past clinical trials have shown low efficacy or even increased transmission (see 'Anti-HIV gel trial fails').

Six potential microbicides have been tested in 11 large trials over the past 15 years, but the current trial is the first to use an antiretroviral drug.

Yasmin Halima, the director of the Global Campaign for Microbicides based in Washington DC, says that this type of drug suppresses viral replication. "The other candidates that we've been testing over the past decade were different kinds of agents — they had very different mechanisms of action," she explains. "This is the first time that we've put an antiretroviral into a microbicide. It interferes with a particular part of the viral lifecycle."

Most of the products tested previously as microbicides were either sulphated polysaccharides — which are intended to stop the virus from entering cells — or agents that prevent infection by killing either the virus or cells that carry it.

"It's been a rocky road — many of the strategies that were tested earlier were not especially plausible."

Quarraisha Abdool Karim at the Centre for the AIDS Program of Research in South Africa (Caprisa), Durban, and her colleagues tested a 1 per cent vaginal gel formulation of the antiretroviral drug tenofovir. The drug is manufactured by Gilead Sciences, based in Foster City, California. The study involved 889 women in South Africa aged between 18 and 40 years who were HIV-negative, sexually active and at high risk of HIV infection.

Compared with women who used a placebo, the tenofovir gel cut HIV infection in the group by 39 per cent overall, and by 54 per cent in women who used the gel most consistently.

The US$18-million trial, which was funded primarily by the US Agency for International Development (USAID) and implemented by Caprisa, began enrollment in May 2007 and completed follow-up in December 2009.

"It's been a rocky road — many of the strategies that were tested earlier were not especially plausible," says Michael Lederman, a microbicide expert at Case Western Reserve University in Cleveland, Ohio, who was not involved in the study. "A targeted antiretroviral is a rational approach — these results are very exciting."

Dual action

Unexpectedly, the gel was also shown to reduce Herpes simplex virus 2 (HSV-2) infections by 51 per cent. The formulation is the first to successfully prevent HSV-2.

This is important, because the risk of becoming infected with HIV doubles for women with HSV-2. So the gel prevents HIV transmission both directly and indirectly — by preventing more women from becoming infected with HSV-2, says Salim Abdool Karim, the director of Caprisa.

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However, there is widespread agreement that this victory represents only a first step.

The trial's design had been criticised — particularly the dosage schedule, which required women to apply the gel less than 12 hours before sex and again within 12 hours after sex, rather than daily (see 'HIV trial doomed by design, say critics'). The researchers say they now hope to develop a product that will be easier to use but they say fewer women failed to apply the gel properly than was initially feared.

There is still a lot of work ahead to make sure that the results can be replicated and that the efficacy of the tenofovir gel can be improved. More safety data is needed, says Karim, as well as basic research to help to elucidate why the gel did not protect more women. He anticipates that a tenofovir gel product won't be available to women at clinics in South Africa or anywhere else for at least a year or two. However, the South African Medicines Control Council, which approved the Caprisa trial, could make the decision to start providing the product sooner to women in most need.