

Anti-HIV vaginal gel promising protection in Africa, SE asia

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A new vaginal microbicide gel and drug formulation looks promising for empowering women in developing countries to protect themselves from HIV during intercourse, without having to inform their partners, according to research published in the April 2011 issue of the journal *Antimicrobial Agents and Chemotherapy*.

HIV infection remains a major risk for women in sub-Saharan Africa and Southeast Asia, and one over which women often have little control due to unequal gender status over much of those regions. Investigators say the gel, the subject of the current research, will be cost-effective for such women, and laboratory studies suggest the gel-drug combination will be safe and effective. ImQuest BioSciences, Inc., the drug's developer, hopes to have the gel-drug combination in human clinical trials in 2012.

One of the drug's most important attributes is that it has two distinct mechanisms of action. IQP-0528, as the drug is known, inhibits the virus' ability to enter human cells, as well as the reverse transcription of the virus' genome into the host genome, "which is required for productive infection of the cell," says Robert Buckheit, of ImQuest BioSciences, of Frederick, MD. In that sense, IQP-0528 is like two drugs in one. Laboratory studies suggest that the product will work very effectively.

The investigators assayed a number of candidate drugs before choosing IQP-0528. Some of the other drugs were chemically unstable, or

unstable at pH values to which they would be exposed, or otherwise unstable, says corresponding author Patrick F. Kiser of the University of Utah, Salt Lake City. It was critical for the formulation to be stable at ambient temperatures of sub-Saharan Africa, as refrigeration is not widely available in much of that region.

ImQuest continues to investigate a variety of options for drug, gel, and device formulations. “At present we have gels, intravaginal ring, and biofilm formulations of IQP-0528, in addition to the gel described in the paper, and products developed, which include combinations of IQP-0528 with tenofovir, which was recently found to inhibit the sexual transmission of [HIV](#),” says Buckheit. All this is in the interest of developing a product which women can use most easily and comfortably.

Kiser is particularly proud of the “symphony of tools and techniques used in the study. We had virology, human explant studies, chemical and physical stability studies, transport studies, and permeability studies of the drug,” he says. “Putting all those things together is not trivial.”

More information: A. Mahalingam, et al. 2011. Vaginal microbicide gel for delivery of IQP-0528, a pyrimidinedione analog with a dual mechanism of action against HIV-1. *Antim. Agents Chemother.* 55:1650-1660.

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