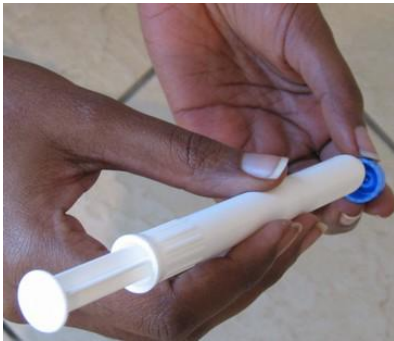


A Unique Approach To Preventing STIs/HIV, Pregnancy, and Mother-To-Child HIV Transmission

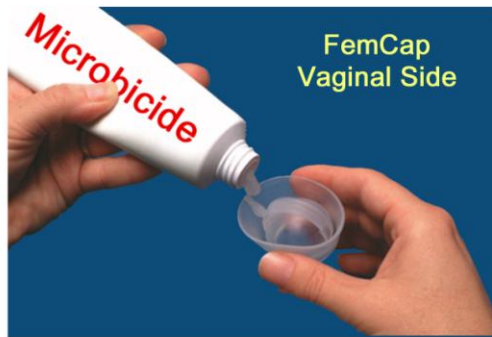
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Objectives: (A) Prevent HIV/STIs by using a cervical barrier to deliver microbicide. (B) Prevent pregnancy and mother-to child HIV transmission. (C) Enhance adherence, retention and efficacy of Tenofovir microbicide..

Traditional Vaginal Applicator



New delivery system for microbicide

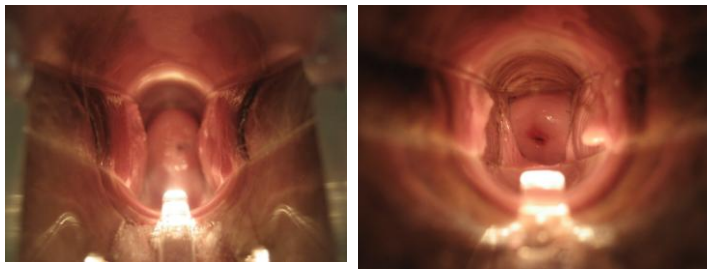


Alternative Delivery System For Tenofovir

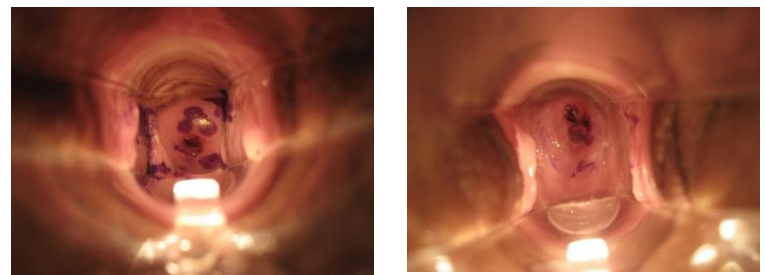
Methods. We investigated the feasibility of the FemCap, an FDA-approved cervical barrier device with a microbicide delivery system on its cervical and vaginal sides, for delivering Tenofovir. We evaluated acceptability, adherence and retention of a stained vaginal lubricant (substituted for Tenofovir) delivered by the FemCap versus delivery with the vaginal applicator utilized in the CAPRISA 004 study. Thirty women compared using a vaginal applicator to deliver a high-viscosity vaginal lubricant stained with Gentian violet before and after intercourse to using the FemCap to deliver the lubricant before intercourse only. We then used colposcopy to study gel retention over the cervix and vagina.

Results: The gel was better retained over the cervix by single application with the FemCap versus two applications with the vaginal applicator.

Stained gel was **absent** 24 hours after application with the applicator



Stained gel was **present** over the cervix 24 hours after application with the FemCap



	The vaginal applicator Vaginal Lubricant applied <u>twice</u> , before and after intercourse with applicator.	The FemCap Lubricant applied with the FemCap <u>once</u> before intercourse
Cervix	Absent after 12 hours	Stained lubricant present after 24 hours
Upper vagina	Absent after 12 hours	Stained lubricant present with many bare spots
Vaginal introitus	Absent after 12 hours	Absent after 24 hours

Conclusions: Study participants preferred one gel application using the FemCap to two applications using the vaginal applicator based on ease of use and elimination of lubricant leakage. We conclude that utilizing the FemCap can prevent pregnancy and mother-to-child HIV transmission, while enhancing compliance and retention of gel over the cervix to potentially prevent STIs and increase the efficacy of Tenofovir