

February 28, 2008 Thursday

**Rectal Microbide Phase 1 Safety Trial Currently Underway, Phase 2 Threatened by Lack of Funding**

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BBSNews 2008-02-28 -- NEW DELHI (PLUSNEWS) The silence and taboo surrounding anal sex is putting millions of men and women at risk of HIV, delegates attending the fourth international microbicides conference in New Delhi, India, heard this week.

Often thought of as strictly a "gay thing", studies are showing that anal intercourse is also part of heterosexual coupling, and is largely unprotected, said Jim Pickett, chair of International Rectal Microbicide Advocates (IRMA), which released a report on the subject at the conference.

The report, *Less Silence, More Science* warned that researchers could no longer afford to ignore anal sex -- one of the biggest drivers of the epidemic -- and called for more research into the development of a rectal microbicide.

"We must consider the possibility that unprotected anal intercourse, even when practiced rarely, may in fact be a significant source of HIV transmission in many contexts," the report said. Women were also likely to engage in anal sex in cultures and regions where virginity was especially prized and contraception was not easily available.

The danger of unprotected anal sex is that the lining of the rectum is more fragile and contains more susceptible cells than the lining of the vagina and part of the cervix, making it easier to transmit HIV.

"This is a highly vulnerable region for infection -- It's a very easy portal for HIV infection," Dr Ian McGowan, from the Microbicide Trials Network, told delegates.

Although progress has been made in the race towards an effective vaginal microbicide, studies looking at rectal microbicides lag behind. "Within 10 minutes of a vaginal microbicide going on the shelves, it will be going up someone's butt," said Pickett.

Potential microbicides include a range of products -- such as gels, films and sponges -- that could help prevent the transmission of HIV and other sexually transmitted infections. No microbicide has yet been shown to be effective.

Rectal microbicides could offer both primary protection in the absence of condoms and back-up protection if a condom broke or slipped off during anal intercourse.

The only rectal microbicide safety trial so far is currently underway, and two more Phase 1 trials are in the planning stages, the report said. Phase 1 trials are where researchers test a new drug for human safety to determine a safe dosage range and identify side effects.

Pickett attributed the slow pace of research in this field to the scientific challenges in testing products rectally, as well as widespread stigma and homophobia, besides a lack of funding.

The fragile nature of the rectum -- which is just a single cell-layer thick -- could mean that it could be damaged by some of the study-related actions and tests, making it difficult to measure the safety of the product.

### **Stigma, homophobia major barriers**

In Jamaica, a country where homophobia is "deeply embedded" and popular musicians sing about shooting men who have sex with men (MSM) in the head, Jamaican researcher Dr Nesha Haniff has been working with members of a local non-governmental organization (NGO), Jamaica AIDS Support for Life, to advocate for new prevention approaches to protect MSM.

HIV prevalence in the Caribbean country is 2 percent at present, but an estimated 25 percent of the country's MSM are estimated to be living with the virus. Haniff acknowledged that part of the dilemma in calling for rectal microbicides was the act of anal intercourse.

The practice is illegal in many countries, and the strong taboo and homophobia associated with anal sex makes it difficult for both MSM and heterosexual couples to find out about how they can protect themselves from HIV infection.