



Centers for Disease Control
and Prevention (CDC)
Atlanta, GA 30333

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Dear Colleague:

At the International AIDS Conference held in Durban, South Africa, from July 9-14, 2000, researchers with the Joint United Nations Programme on AIDS (UNAIDS) presented results of an important study about HIV prevention in women. They studied a product widely used in spermicides, nonoxynol-9 (N-9), to determine if it would be effective in preventing HIV transmission. Products designed to provide a chemical barrier to HIV and STD transmission are called microbicides. This notice summarizes the study results and some implications for use of this product in prevention programs.

From 1996 until May 2000, UNAIDS sponsored a study of the effectiveness of a gel which contained 52.5 milligrams of N-9 (called COL-1492 in the trial and Advantage-S in the United States), compared to an inactive placebo gel. The study was conducted in several locations in Africa. Nearly 1,000 HIV-negative commercial sex workers were enrolled in the trial, and all women were counseled to use condoms consistently and correctly. In addition to condom use, the women were asked to use a vaginal gel each time they had intercourse. Half of the women were provided a placebo gel and half of the women received an N-9 gel. None of the women, or the researchers, knew which product each woman received, and all of the women were informed of the possible risks, benefits, and unknowns involved in the study.

At the end of the trial, researchers found that the women who used N-9 gel had become infected with HIV at about a 50% higher rate than women who used the placebo gel. Further, the more frequently women used only N-9 gel (without a condom) to protect themselves, the higher their risk of becoming infected. Simply stated, N-9 did not protect against HIV infection and may have caused more transmission. Women who used N-9 also had more vaginal lesions, which might have facilitated HIV transmission.

This study was conducted among women at very high risk C commercial sex workers C who used a great deal of the product on a frequent basis. The adverse effects might not be seen at the same level among women who are using spermicides with N-9 less frequently or in different formulations. However, given that N-9 has now been proven ineffective against HIV transmission, the possibility of risk, with no benefit, indicates that **N-9 should not be recommended as an effective means of HIV prevention.**

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With the release of these data, the scientific evidence on N-9 as an HIV prevention strategy is now conclusive and significant. As a result, prevention guidelines must be re-evaluated. UNAIDS and CDC will be holding consultations over the next few months to consider official revisions to public health guidelines for the use of N-9 for HIV prevention and for pregnancy prevention in populations at high risk for HIV. In the interim, these findings have several immediate implications.

First, any community delivering hierarchical prevention messages that counsel individuals who can't use a condom to consider spermicides with N-9 for HIV prevention should immediately revise these messages. This study suggests that the use of N-9 for HIV prevention may be harmful. Second, anyone currently using N-9 as a microbicide to protect themselves from HIV transmission during anal intercourse should be informed of the ineffectiveness of this agent and warned of the potential risk of this practice.

CDC has never recommended N-9 alone for HIV prevention, but current recommendations do emphasize the consistent and correct use of condoms, with or without a spermicide. While the level of N-9 used as a lubricant in condoms is much lower than the level found to be harmful in this study, CDC will re-evaluate this guidance as part of the upcoming consultation. In the interim, while N-9 will not offer any additional protection against HIV, a condom lubricated with N-9 is clearly better than using no condom at all. The protection provided by the condom against HIV far outweighs the potential risk of N-9. If given the choice, condoms without N-9 may be a better option for HIV prevention.

From a research perspective, these findings point to the need for accelerated efforts to identify a safe and effective microbicide. Of the more than 7,000 new HIV infections occurring in the world each day, about 90% are the result of heterosexual transmission. In addition, more than 330 million new cases of other STDs, such as gonorrhea, chlamydia, and syphilis, occur each year.

For those who are unable to access condoms or to negotiate their use, there is an urgent need to identify an effective alternative to prevent HIV and STD transmission. Moving forward with the evaluation of microbicide candidates, which are not likely to cause the same negative effect seen with N-9, should be a public health priority.

We appreciate any assistance you can provide in disseminating this critical public health information and will keep you informed as the consultations are completed.

Sincerely,

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TB Prevention
Centers for Disease Control and Prevention