

Condoms, Contraceptives and Nonoxynol-9: Complex Issues Obscured by Ideology

By Heather Boonstra

During the 1990s, as the AIDS crisis worsened and vaccine research faltered, HIV prevention activists increasingly pinned their hopes on nonoxynol-9 (N-9). Widely available in the United States for over 50 years as the active ingredient in spermicides, N-9 was shown to kill the AIDS virus in the laboratory. A number of epidemiologic studies further suggested that N-9 conferred some protection against bacterial sexually transmitted infections (STIs) when used alone or in combination with a diaphragm. Researchers and advocates alike anticipated that it would be shown to prevent HIV in human trials as well, clearing the way for a new and relatively inexpensive preventive option to be made available to people around the world living with or at-risk of HIV.

Those expectations were dashed, however, when in 2000 a study of N-9's effectiveness among sex workers in Benin, Cote d'Ivoire, South Africa and Thailand showed that HIV incidence was actually higher among the women using N-9 than among those using a comparison product. But in addition to being a disappointment for HIV prevention efforts, the results also raised questions about the safety of N-9 when used for the purpose for which it was approved, protection against unwanted pregnancy.

Following the results of this study, experts at the World Health Organization (WHO) and the U.S. Centers for Disease Control and Prevention (CDC) conducted a concerted review of the evidence and made a series of recommendations. Based on those

recommendations, an ad-hoc coalition of individual experts and women's health and AIDS organizations called on manufacturers to stop adding N-9 to condoms and sexual lubricants. In accordance with the available evidence, however, the coalition stopped short of calling for the withdrawal of noncondom contraceptive products containing N-9 from the market. Meanwhile, anti-family planning activists have been using the N-9 issue to further their ongoing campaign to discredit condoms, and contraceptives in general, as a means of promoting abstinence outside of marriage as the only appropriate answer to STIs and unwanted pregnancy.

Expectations Unfulfilled

N-9 spermicides have been available over-the-counter in the United States since the 1960s and are used by approximately half a million women for pregnancy prevention. N-9 is found in a variety of vaginal contraceptive products, including creams, foams, gels and suppositories—used alone or in combination with the diaphragm or cervical cap. Because N-9 was approved for sale before the Food and Drug Administration (FDA) began to require rigorous efficacy studies, knowledge about N-9's effectiveness against pregnancy in various doses and formulations was limited until recently.

In the late 1980s, when researchers saw that N-9 showed in vitro activity against HIV and other STIs, N-9 was also added to condoms and sexual lubricants. In 1988, Surgeon General C. Everett Koop announced that,

based on laboratory tests, condoms with N-9 could provide additional protection against HIV, and public health officials began to advise the use of N-9 for HIV prevention.

In 2001, however, after presentation of the preliminary results of a study testing an N-9 gel in a high-risk population of sex workers, WHO convened a technical consultation—experts from developed and developing countries—to review the available evidence from this and numerous other studies and to make recommendations on the use of N-9. WHO released its summary report on N-9 in October 2001 based on this review, and in May 2002, CDC published its public health guidelines for the use of N-9. The WHO and CDC reports underscore these major conclusions:

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- N-9 is not effective against HIV or other STIs and, when used vaginally multiple times a day, can cause genital lesions—a condition that may increase a woman's risk of acquiring HIV.
- Even at low doses, N-9 can cause massive, short-term damage to the rectal epithelium (lining), thereby increasing an individual's risk of contracting HIV and other STIs during anal intercourse.
- Although noncondom contraceptive products containing N-9 are moderately effective in preventing pregnancy and safe when used infrequently (no more than once a day), condoms lubricated with a small

HPV and the Anticondom Crusade

Social conservatives continue to press their campaign to “warn” Americans that condoms do not protect against HPV, some strains of which cause cervical cancer—despite growing recognition within the public health community both that their facts are wrong and that their focus is misplaced.

HPV is an extremely common STI—so common that it is considered a virtual marker for having had sex. But although most women who are sexually active will acquire HPV at some point, very few will develop cervical cancer. In fact, most HPV infections resolve on their own without treatment: As many as 70% of infections clear within one year, and 91% within two.

Because of major advances in detection and prevention, notably the Pap test, cervical cancer has become relatively uncommon in the United States. (The American Cancer Society estimates that 12,200 cases will occur to American women this year, resulting in 4,100 deaths.) According to CDC, regular screening to detect precancerous lesions, which can then be treated, remains the key strategy for preventing cervical cancer. Indeed, the majority of cervical cancer cases in this country occur to women who have not had a Pap test in the last three years (“HPV in the United States and Developing Nations: A Problem of Public Health or Politics?” TGR, August 2003, page 4).

Admittedly, genital HPV cannot be entirely prevented by condom use, because HPV is spread through skin-to-skin contact, not through the exchange of bodily fluids (like HIV). Still, due to the partial protection that can be provided, correct and consistent condom use has been shown to lower the incidence of cervical cancer.

In any event, the debate over condom effectiveness against HPV could be largely made moot by the advent of a vaccine that prevents HPV in the first place. Two such vaccines are in the final stages of testing and could be available within two years. The drug makers, Merck and GlaxoSmithKline, hope the vaccine can be folded into routine medical care for young women.

“The best way to prevent infection is to vaccinate the population just before they become sexually active, which is when they’re young,” Eliav Barr, Merck’s senior director of biologics clinical research, told the Newark Star-Ledger. But the anticipated rollout is already facing opposition from those who fear the vaccine will have a “disinhibiting effect” on young women, giving them a green light to have sex (see related story, page 11). “The best way to prevent HPV is through abstinence,” said Bridget Maher of the Family Research Council to The Star-Ledger. “I see potential harm in giving this vaccine to young women.”

amount of N-9 are no more effective in preventing pregnancy than are lubricated condoms without N-9.

A Call to Action

In 2002, within months of the CDC report on N-9, HIV and women’s health advocates in the United States launched a campaign to caution the public about the appropriate use of N-9 and to encourage responsible behavior by industry. Led by the Global Campaign for Microbicides and endorsed by more than 80 scientists and public health organizations, the open letter makes the following key points:

- Couples engaging in vaginal intercourse should not use products containing N-9 for the prevention of HIV or other STIs, and in no case should these products be used during anal intercourse.

- Manufacturers should remove N-9 from condoms and lubricants, because the small amount of N-9 they contain is dangerous if used rectally and offers no demonstrated contraceptive benefit.

- N-9 contraceptive products designed exclusively for vaginal use remain an important option for pregnancy prevention for women who have sex infrequently and are at low risk of HIV infection; removing these products from the market is unwarranted.

Since the launch of the call to action, nine condom and lubricant manufacturers—including Johnson & Johnson, Mayer Laboratories and the makers of Durex condoms—have discontinued production of N-9 condoms and lubricants. Planned Parenthood Federation of America (PPFA), which joined the call to action, immediately stopped produc-

ing N-9 condoms and stopped recommending N-9 as a way to protect against HIV or other STIs. The Office of Population Affairs (OPA) at the U.S. Department of Health and Human Services, which oversees family planning service delivery under the Title X program, sent a copy of CDC’s report on N-9 to its regional offices and encouraged them to share the information with grantees. And the New York-based Gay Men’s Health Crisis, one of the largest AIDS service organizations in the United States, initiated a public education campaign targeted at men who have sex with men to inform them not to use N-9 condoms and lubricants.

Right-Wing Reactions

To be sure, the controversy over N-9 did not fail to capture the attention of social conservatives in Congress,

who have sought to turn the issue to their advantage in their ongoing campaign against the condom (see box). That campaign started in 1999 when, as a member in the U.S. House of Representatives, now-Senator Tom Coburn (R-OK) pushed legislation mandating that condom packages carry a cigarette-type warning that condoms do not protect against human papillomavirus (HPV). Although his directive was never enacted, he was successful in imposing a requirement that FDA reexamine condom labels to determine whether they are medically accurate with respect to condoms' "effectiveness or lack of effectiveness" in preventing STIs, including HPV.

Meanwhile, Coburn and his allies, Reps. Mark Souder (R-IN), Joseph Pitts (R-PA) and David Weldon (R-FL), were quick to respond to the findings of the N-9 sex-worker study upon their release in 2000. Immediately, they called for an investigation by the Government Accountability Office (GAO) into the federal government's actions related to N-9. And before GAO had the chance to respond, Souder's Subcommittee on Criminal Justice, Drug Policy and Human Resources twice called on FDA to pull all N-9 products from the market—the consequences of which would have been serious, especially for those women who, for pregnancy prevention, rely on the diaphragm or cervical cap, which are labeled for use with a spermicide. (Because N-9 is the only spermicide available in the United States, eliminating N-9 products without a substitute would effectively preclude diaphragm and cervical cap use as intended.)

In March 2005, GAO issued its long-awaited report on the federal government's efforts to research and inform the public about N-9 and HIV. By and large, the report recited the succession of research trials that raised concerns about N-9 and the federal

government's response. It described how the National Institutes of Health and CDC subsequently stopped conducting and funding research on N-9 and how CDC changed its guidance. In addition, the report gently rebuked FDA for taking so long to inform the public about evidence related to N-9 and HIV transmission. "Since FDA is still in the process of completing warning label changes for N-9 vaginal contraceptive products and condoms, the public may be left in doubt about the appropriate uses of these products until FDA finalizes these warnings," the GAO report concluded. "Further, the public may be at risk if these products are used inappropriately."

Once again, Coburn and his allies were ready to pounce, and they used the GAO report's release as a springboard to promote abstinence as the only certain way to protect against pregnancy and STIs. In a joint press release, issued with Weldon, Pitts and Souder in April 2005, Coburn spoke about the "shortcomings" of condoms with regard to both HPV and HIV: "Condoms do not protect

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against the most common STD—human papillomavirus (HPV), which causes nearly all cases of cervical cancer—and contraceptives with N-9 increase HIV risk." For his part, Weldon took the opportunity to take a swipe at federally funded family planning programs. Ignoring the actions take by PPFA and OPA following the report from WHO and guidance issued by CDC in 2002, Weldon cited the findings of the GAO report on N-9 as "just another example of how Planned Parenthood,

Title X clinics and federal agencies have distorted science to promote a social policy that has the exact opposite impact of the stated goal. We may never know the toll in terms of new HIV cases that have resulted from the promotion and distribution—with taxpayer dollars—of N-9 containing condoms."

Outlook

Looking ahead, FDA is soon expected to propose new labeling for condoms as required by law, and officials have announced that the guidance will include the N-9 issue. And on its own initiative, FDA is looking more broadly at N-9 vaginal contraceptive products. In January 2003, the agency proposed adding a warning to alert consumers that vaginal contraceptives containing N-9 do not prevent the transmission of HIV and other STIs, and that frequent vaginal use (more than once a day) can increase vaginal irritation, which may increase the risk of infection. FDA is expected to finalize the rule for the new warning sometime this fall.

Meanwhile, HIV and women's health advocates are concerned that the admittedly nuanced and complex messaging that should be taking place around N-9 may not be getting through. They remain concerned that N-9 is still being used for lubrication and, mistakenly, for protection against disease, especially during anal intercourse. At the same time, they worry that some women for whom N-9 contraceptives may be appropriate are being scared off.

The work by these advocates to inform the public about N-9 is complicated by the decision of some companies to continue selling N-9 condoms. (Approximately one in five condoms sold in the United States is still lubricated with N-9, accounting for a significant share of the \$295 million U.S. market.) Church &

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Condoms...

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Dwight, manufacturer of the top-selling Trojan brand, stands by its decision, arguing that N-9 condoms “remain an important family planning option for couples whose primary concern is pregnancy prevention and who prefer the extra measure of pregnancy prevention that spermicidally lubricated condoms provide”—even though no evidence of extra protection has been demonstrated. (Trojan’s label says that “the extent of decreased risk [of pregnancy] has not been established.”) Company representatives have also expressed concern that removing N-9 condoms from the market might only further confuse the issue, which they fear would play into the hands of family planning foes and jeopardize the availability of other N-9 contraceptive products. The company notes that it

has “proactively revised labeling on all Trojan condoms lubricated with N-9 to help ensure these condoms are used appropriately.”

But the Global Campaign’s Lori Heise, who initiated the 2002 call to action, says she remains disappointed that companies continue to produce N-9 condoms. “I appreciate the companies’ concern about the continued availability of other N-9 contraceptive products, but there is simply no evidence that adding N-9 to condoms provides backup pregnancy protection in case of condom failure. Moreover, in my view, if N-9 condoms were taken off the market, it would do a lot to clarify the issue and take the steam out of the social conservatives’ drive to use the issue of N-9 condoms to bash *all* condoms and promote their morally-based agenda of abstinence outside of marriage.” ☉



May 2005

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