Nonoxynol-9 Spermicide Contraception Use—United States, 1999

MMWR. 2002;51:289-392
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Most women in the United States with human immunodeficiency virus (HIV) become infected through sexual transmission, and a woman’s choice of contraception can affect her risk for HIV transmission during sexual contact with an infected partner. Most contraceptives do not protect against transmission of HIV and other sexually transmitted diseases (STDs), and the use of some contraceptives containing nonoxynol-9 (N-9) might increase the risk for HIV sexual transmission. Three randomized, controlled trials of the use of N-9 contraceptives by commercial sex workers (CSWs) in Africa failed to demonstrate any protection against HIV infection; one trial showed an increased risk. N-9 contraceptives also failed to protect against infection with Neisseria gonorrhoeae and Chlamydia trachomatis in two randomized trials; one among African CSWs and one among U.S. women recruited from an STD clinic. Because most women in the African studies had frequent sexual activity, had high-level exposure to N-9, and probably were exposed to a population of men with a high prevalence of HIV/STDs, the implications of these studies for U.S. women are uncertain. To determine the extent of N-9 contraceptive use among U.S. women, CDC assessed data provided by U.S. family planning clinics for 1999. This report summarizes the results of that assessment, which indicate that some U.S. women are using N-9 contraceptives.

Sexually active women should consider their individual HIV/STD infection risk when choosing a method of contraception. Providers of family planning services should inform women at risk for HIV/STDs that N-9 contraceptives do not protect against these infections.

CDC collected information on types of N-9 contraceptives purchased and family planning program (FPP) guidelines for N-9 contraceptive use. The national FPP, authorized by Title X of the Public Health Service Act, serves approximately 4.5 million predominantly low-income women each year. Program data for 1999 were obtained from all 10 U.S. Department of Health and Human Services regions (HHS) regions on the number of female clients and the number of female clients who reported use of N-9 contraceptives or condoms as their primary method of contraception. CDC obtained limited purchase data for 1999 for specific N-9 contraceptives and program guidelines from eight state/territorial FPPs within six HHS regions. State health departments, family planning grantees, and family planning councils were contacted to request assistance in collecting data on purchasing patterns of the 91 Title X grantees; of the 12 FPPs that responded, eight provided sufficient data for analysis.

In 1999, a total of 7%-18% of women attending Title X clinics reported using condoms as their primary method of contraception. Data on the percentage of condoms lubricated with N-9 were not available. A total of 1%-5% of all women attending Title X clinics reported using N-9 contraceptives (other than condoms) as their primary method of contraception. Among the eight FPPs that provided purchase data, most (87%) condoms were N-9–lubricated. All eight FPPs purchased N-9 contraceptives (i.e., vaginal films and suppositories, jellies, creams, and foams) to be used either alone or in combination with diaphragms or other contraceptive products. Four of the eight clinics had protocols or program guidance stating that N-9–containing foam should be dispensed routinely with condoms; two additional programs reported that despite the absence of a clinic protocol, the practice was common. Data for the other two programs were not available.

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CDC Editorial Note: The findings in this report indicate that in 1999, before the release of recent publications on N-9 and HIV/STDs, Title X family planning clinics in the U.S. purchased and distributed N-9 contraceptives. Among at least eight family planning clinics, most of the condoms purchased were N-9–lubricated; this is consistent with trends in condom purchases among the general public. The 2002 STD treatment guidelines state that condoms lubricated with spermicides are no more effective than other lubricated condoms in protecting against the transmission of HIV infection and other STDs. The 2002 STD treatment guidelines recommend that previously purchased condoms lubricated with N-9 spermicide continue to be distributed provided the condoms have not passed their expiration date. The amount of N-9 on a spermicide-lubricated condom is small relative to the doses tested in the studies in Africa and the use of N-9–lubricated condoms is preferable to using no condom at all. In the future, purchase of condoms lubricated with N-9 is not recommended because of their increased cost, shorter shelf life, association with urinary tract infections in young women, and lack of apparent benefit compared with other lubricated condoms.
Spermicidal gel is used in conjunction with diaphragms; only diaphragms combined with the use of spermicide are approved as contraceptives. The respective contributions of the physical barrier (diaphragm) and chemical barrier (spermicide) are unknown, but the combined use prevents approximately 460,000 pregnancies in the United States each year.

The findings in this report are subject to at least two limitations. First, data on specific products and patterns of contraceptive use were limited; CDC used a nonrepresentative sample of regions and states that voluntarily provided data, and specific use patterns of the contraceptives could not be extrapolated from these data. Second, data correlating use of N-9 contraceptives with individual HIV risk were not available.

Prevention of both unintended pregnancy and HIV/STD infection among U.S. women is needed. In 1994, a total of 49% of all pregnancies were unintended. Furthermore, 26% of women experience an unintended pregnancy during the first year of typical use of spermicide products. In 1999, a total of 10,780 AIDS cases, 537,003 chlamydia cases, and 179,534 gonorrhea cases were reported among U.S. women. Contraceptive options should provide both effective fertility control and protection from HIV/STDs; however, the optimal choice is probably not the same for every woman.

N-9 alone is not an effective means to prevent infection with HIV or cervical gonorrhea and chlamydia. Sexually active women and their health-care providers should consider risk for infection with HIV and other STDs and risk for unintended pregnancy when considering contraceptive options. Providers of family planning services should inform women at risk for HIV/STDs that N-9 contraceptives do not protect against these infections. In addition, women seeking a family planning method should be informed that latex condoms, when used consistently and correctly, are effective in preventing transmission of HIV and can reduce the risk for other STDs.

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Fixed Obstructive Lung Disease in Workers at a Microwave Popcorn Factory—Missouri, 2000-2002

MMWR. 2002;51:345-347
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IN MAY 2000, AN OCCUPATIONAL MEDICINE physician contacted the Missouri Department of Health and Senior Services (MoDHSS) to report eight cases of fixed obstructive lung disease in former workers of a microwave popcorn factory. Four of the patients were on lung transplant lists. All eight had a respiratory illness resembling bronchiolitis obliterans with symptoms of cough and dyspnea on exertion, had worked at the same popcorn factory (factory A) at some time during 1992-2000, and had spirometric test results that were lower than normal for both FEV1 (forced expiratory volume in 1 second) and FEV1/FVC (forced vital capacity) ratio. Employment durations ranged from 8 months to 9 years. MoDHSS requested assistance from CDC’s National Institute for Occupational Safety and Health in evaluating factory A for respiratory hazards to workers. This report summarizes the epidemiologic findings motivating the technical assistance request and preliminary results. The findings of this investigation indicate that workers exposed to flavorings at microwave popcorn factories are at risk for developing fixed obstructive lung disease. Public health authorities, employers, and health-care providers are collaborating to prevent obstructive lung disease in popcorn factory workers.

At factory A, soybean oil, salt, and flavorings are mixed into a large heated tank in a process that produces visible dust, aerosols, and vapors with a strong buttery odor. To determine whether exposure to inhaled mixing-tank substances was associated with disease, MoDHSS analyzed patients according to job categories determined by work proximity to the mixing tank: workers who were mixers of oil, salt, and flavorings and who had direct contact with the tank; microwave-packaging workers who worked 5-30 meters from the tank; and workers in other areas of the factory who were >30 meters from the tank.

During 1992-2000, factory A employed approximately 560 workers; 425 no longer worked at the factory as of May 2000. Of the eight patients reported, four were mixers and four were microwave-packaging workers. No microwave-packaging workers had ever worked as mixers. Discussions with workers and management staff at factory A indicated that an estimated 13 (3%) of the 425 former workers had been mixers, 276 (65%) had worked in microwave packaging, and 136 (32%) had worked in other areas of the factory. On the basis of this estimated distribution, the crude incidence of illness was highest in mixers (four of 13 [31%]) and microwave-packaging workers (four of 276 [1%]); no cases were reported in the estimated
136 workers in other areas of the factory (Chi square for trend = 19.0, p = 0.00001).

Assuming exposure to factory work contributed to reported occupational lung disease, former workers had 1,448-2,819 person-years at risk, depending on assumptions about whether risk for disease continues after employment ceases. On the basis of the eight cases reported during this period, the calculated rate of illness was 28-70 cases per 10,000 person-years. Assuming that all eight reported patients represented cases of occupational lung disease, this represents a five- to 11-fold excess over the expected number of reported occupational respiratory conditions attributed to toxins.1

MoDHSS and CDC investigated the worksite for possible exposures to airborne respiratory toxins, but found no known substance that could explain the illnesses. The focus shifted to assessing risk for current workers and a possible new cause of occupational airways obstruction. Because of the apparent high risk to mixers and microwave-packaging workers, CDC recommended that all workers in both groups wear respirators while the investigation proceeded, with the minimum recommended respirator being a half-face, nonpowered respirator equipped with P-100 filters and organic vapor cartridges.

In November 2000, CDC conducted a cross-sectional survey of 117 current workers that included interviews, pulmonary-function testing, and air sampling for volatile organic compounds (VOCs) and dusts at factory A. On the basis of national data adjusted for smoking and age, current workers had two to three times the expected rates of respiratory symptoms and self-reports of physician diagnoses of asthma or chronic bronchitis; the rate of obstruction on spirometry was 3.3 times higher than expected.2

Industrial hygiene sampling conducted during the November 2000 survey detected approximately 100 VOCs in the plant air. Diacetyl, a ketone with butter-flavor characteristics, was measured as a marker for exposure to flavoring vapors. The geometric mean air concentration of diacetyl was 18 parts per million parts air (ppm) in the room where the mixing tank was located, 1.3 ppm in the microwave-packaging area, and 0.02 ppm in other areas of the plant. Rates of obstructive abnormalities on spirometry increased with increasing cumulative exposure to airborne flavoring chemicals. Concentrations of total and respirable dust were below SHA-permissible exposure limits (PELs) for particulates not otherwise regulated. No OSHA-PELs or NIOSH-recommended exposure levels exist for diacetyl. To reduce exposures, CDC investigators recommended engineering controls including increased ventilation and isolation of VOC sources.

CDC is conducting repeated air sampling and medical surveillance at 4-month intervals to monitor response to interventions. To date, serial pulmonary function testing has documented excessive declines in FEV₁ and additional persons with airways obstruction among those working in the plant before engineering controls lowered exposures by several orders of magnitude. The adequacy of controls in protecting workers hired since exposures were lowered is being assessed by interval changes in FEV₁.

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CDC Editorial Note: Bronchiolitis obliterans, a rare, severe lung disease characterized by cough, dyspnea on exertion, and airways obstruction that does not respond to bronchodilators, can occur after certain occupational exposures. Inhalation exposure to agents such as nitrogen dioxide, sulfur dioxide, anhydrous ammonia, chlorine, phosphine, and certain mineral and organic dusts can cause irreversible damage to small airways without affecting chest radiograph and diffusing capacity.3

This investigation initiated by MoDHSS identified a large cluster of conditions resembling bronchiolitis obliterans associated with occupation at a microwave popcorn factory. The results of this investigation raise concern about possible risk for workers in other flavoring and food production industries. Recent reports to CDC document bronchiolitis obliterans cases in the settings of flavoring manufacture and a case of fixed-airways obstruction in a worker at a microwave popcorn factory in Nebraska (CDC, unpublished data, 2001).

Preliminary animal studies at CDC suggest severe damage to airway epithelium after inhalation exposure to high air concentrations of a butter flavoring used in factory A. Further animal studies are planned to determine the causal ingredients in the complex butter-flavoring mixture.

The Food and Drug Administration regulates flavorings based on the safety of the amounts consumed, not the safety of prolonged worker inhalation of high concentrations. CDC has no evidence to suggest risk for consumers in the preparation and consumption of microwave popcorn.

CDC is investigating whether other cases of fixed obstructive lung disease have occurred in workers at other microwave popcorn factories. Healthcare providers should report to state health authorities and CDC any cases of suspected occupational respiratory disease in workers exposed to food flavorings.

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