

Talking Points & Supporting Data: *MMWR* on the Effectiveness of Condoms

1. Latex condoms are highly effective against the sexual transmission of HIV when used consistently and correctly during sexual intercourse.

- New, compelling studies demonstrate that latex condoms are highly effective when used correctly and consistently. (*MMWR*)
- Two studies present the strongest evidence to date that latex condoms are highly effective in preventing HIV. The studies monitored people at extremely high risk by studying couples in which one person was HIV-positive and the other was uninfected. With repeated exposures to HIV, condoms proved to be highly effective for couples using condoms consistently and correctly.
 - Of 123 couples studied from 1987 to 1991, in which one of the partners was HIV-infected and they consistently and correctly used condoms, none of the uninfected partners became infected. However, among 122 couples who inconsistently used condoms, 10 percent (12 of 122) became infected. (DeVincenzi)
 - In an Italian study of uninfected female partners of HIV-infected men, only 2 percent (3 of 171) of the women whose male partners always used condoms during sexual activity became infected. Because couples were followed on average for about 2 years, this results in an infection rate of 1 percent per year. However, 15 percent (8 of 55) of the partners of inconsistent condom users became infected. (Saracco)

2. Latex condoms must be used consistently and correctly in order to be highly effective in preventing the transmission of HIV.

- Consistent use means using a condom from start to finish with every act of intercourse.
- Correct use involves a few simple steps:
 - Use a new condom every time you have sex -- anal, oral, or vaginal.
 - Put the condom on after the penis is erect and before it touches any part of your partner's mouth, anus, or vagina. (If the penis is uncircumcised, pull the foreskin back before putting on the condom.)
 - To put the condom on, pinch the reservoir tip of the condom, then unroll it all the way down the penis. (If the condom does not have a reservoir tip, pinch the tip enough to leave a half-inch space for semen to collect.) Always ensure that no air is trapped in the tip. It can cause the condom to break.
 - If you feel a condom break during sex, stop, and put on a new condom.
 - After ejaculation and while the penis is still erect, hold the rim of the condom and carefully withdraw so no semen is spilled.

- Using lubricants: You may want to apply additional lubrication to reduce the possibility the condom will break. You should use only water-based lubricants, such as glycerin or over-the-counter lubricating ointment.
- Never use oil-based products with condoms, such as cooking or vegetable oils, baby oil, hand lotion, or petroleum jelly. They can weaken the latex and cause the condom to break.
- Storing condoms: Condoms should be stored in a drawer or closet -- somewhere cool, dry, and out of direct sunlight. Changes in temperature, rough handling, or age can make the latex brittle or gummy. Never use condoms that are damaged or discolored, brittle, or sticky. And don't store them for a long time in your wallet or car glove compartment.

3. Latex condoms are excellent quality products.

- Recognizing that latex condoms are highly effective, in April 1993 the FDA announced that labeling for latex condoms should inform the public that, "if used properly, latex condoms will help to reduce the risk of transmission of HIV infection and many other STDs." Other contraceptives are required to carry a statement that they do not protect against HIV infection and other STDs.
- Studies by the FDA Center for Devices and Radiological Health confirm that latex condoms are a highly effective mechanical barrier to HIV-sized particles.
- During the manufacturing process, condoms are double-dipped in latex and undergo stringent quality control procedures.

4. As a medical device, latex condoms are rigorously tested to ensure they meet federal and industry quality assurance standards.

- Every condom manufactured in the United States is tested by manufacturers for defects, including holes or areas of thinning, before it is packaged.
- The FDA randomly tests condoms produced domestically or imported into the United States to ensure they meet quality assurance requirements. The standard test used by the FDA is the water-leak test, in which the condom is filled with 300 ml of water and stretched to as much as four times its original size. If FDA finds that more than 4 per 1000 condoms leak, the lot is not allowed to be sold in the United States.

5. When condoms fail, it is usually due to user error.

- Most condom breakage is due to incorrect usage rather than poor condom quality. Common reasons for breakage include teeth or fingernail tears, using oil-based lubricants, using old condoms, exposure to heat, reusing condoms, unrolling the condom before putting it on, or leaving air in the tip

- Many Americans don't know that latex condoms provide better protection from HIV than natural membrane condoms, and don't understand that they should be used from start to finish or that only water-based lubricant should be used. It is vital to step up our efforts in educating the public about correct condom use.
- 6. Both refraining from intercourse with infected partners and consistently and correctly using condoms are effective prevention strategies.**
- A two-pronged AIDS prevention approach is needed in this country -- with messages encouraging both abstinence *and* the correct and consistent use of condoms. Both strategies can be highly effective if practiced all the time.
 - We know that one of the key determinants of condom use is the belief that condoms work. Stated another way, sexually active individuals will be less motivated to use condoms if they don't believe that condoms will be effective barriers. Therefore, it is important that sexually active individuals get the message that latex condoms provide effective protection from HIV if they are used correctly and consistently. We have a responsibility to let the public know that a compelling case now exists for condom use as a prevention strategy -- if condoms are used consistently and correctly.
 - A clear message about condoms is not incompatible with the message to young people that initiation of sexual activities at an early age carries health risks. In fact, recent data from Switzerland demonstrate that a public education campaign promoting condom use can be effective without increasing the proportion of adolescents who are sexually active.
(Hausser)

Kantor LM. Scared Chaste? Fear-Based Educational Curricula. SIECIUS Report Dec.1992/ Jan.1993;1-15.

Kirby D. Sexuality Education: It Can Reduce Unprotected Intercourse. SIECIUS Report Dec.199 Jan.1993;19-25.

Ku LC, Sonenstein FL, Pleck JH. The Association of AIDS Education and Sex Education with Sexual Behavior and Condom Use Among Teenage Men. Fam Plann Pers 1992;24:PP.

The World Health Organization (WHO). Does Sex Education Lead to Earlier or Increased Sexual Activity in Youth? A Review of 19 Studies Presented at the 9th International Conference on AIDS/ Berlin, Germany, 1993.

On Americans' Desire for Strong HIV Prevention Messages

Center for Population Options. Finding Common Ground: A Proposal for a Public-Private Partnership to Use the Media to Promote Condom Use Among Sexually Active Adolescents. New York Center for Population Options, 1993.

The Roper Organization, Inc. AIDS: Public Attitudes and Education Needs. New York: Gay Men Health Crisis, 1991.

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T93-45
Oct. 12, 1993

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LATEX CONDOM STUDY FLAWED

We are receiving inquiries about a Mariposa Foundation study that ranks the quality of various brands of condoms. Media reports of the studies suggest that some brands leak and therefore may not provide protection against AIDS and other sexually transmitted diseases. The following can be used to answer questions.

FDA believes that the study is flawed and therefore cannot be relied upon to judge the relative quality of various brands of condoms. The agency is concerned that some people may stop using condoms as a result of this study.

FDA's position continues to be that latex condoms, if used consistently and correctly, provide highly effective protection against sexually transmitted diseases, including AIDS.

In 1988, the Mariposa Foundation, a private research group in Topanga, Calif., conducted a laboratory study of 31 condom brands to select condoms to be used in a clinical trial that would have evaluated their protection against HIV, the virus that causes AIDS. The clinical trial was never conducted.

One part of Mariposa's laboratory study measured the ability of condoms to serve as a physical barrier to HIV. Test results indicated that at least eight brands offered excellent protection against the virus while at least five allowed some leakage.

FDA does not believe these test results should be relied on, however, because the study was flawed for several reasons:

1. Too few batches were sampled to generalize about any brand as a whole. Mariposa sampled three batches for most brands. A sample of a few hundred condoms from a batch of a million might provide adequate information about that particular batch if the sample is taken in a scientifically random fashion, but it cannot establish the performance of the entire brand. Environmental and manufacturing conditions vary too much from one batch to another to allow conclusions about the efficacy of a particular brand on the basis of a small study sample.

FDA regularly inspects condom manufacturers and tests samples of their products. When a faulty batch is found, the agency prevents the sale of that batch. This applies both to domestic and imported condoms.

2. Some brands include condoms made by different manufacturers. Some batches from a single brand in the Mariposa study could have come from a different manufacturer than the majority of condoms sold under that brand name.

3. The Mariposa Foundation did not consider possible deterioration due to improper storage conditions or age. Condoms deteriorate rapidly when subjected to extremes of temperature, and latex also deteriorates as it ages.

FDA is establishing expiration dating for all latex condoms. Most domestic condoms already display an expiration date on the packaging. New regulations will require expiration dates for both domestic and imported latex condoms.