

A Response to Recent Questions about Latex Condom Effectiveness in Preventing Sexual Transmission of the AIDS Virus

The Program for Appropriate Technology in Health (PATH)



FPLM

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Abstract

In a question-and-answer format, this publication addresses concerns regarding the effectiveness of latex condoms in preventing the sexual transmission of HIV, the virus that causes AIDS, and other Sexually Transmitted Diseases (STDs). It draws upon recent studies and surveys to conclude that, if used properly, latex condoms have a great impact on the prevention of HIV transmission.



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Introduction

Seat belts, smoke alarms, and vaccinations are preventative measures intended to reduce health risks. Yet, their use does not eliminate all risk. Similarly, using latex condoms is an effective means of reducing the risk of sexual transmission of the human immunodeficiency virus (HIV), the virus that causes AIDS. But latex condoms do not provide 100-percent protection against sexual transmission of HIV. This fact has caused some in the general public to voice concern about condom effectiveness, and that concern has been exploited by some individuals and groups opposed to condom promotion and to increasing access to condoms for people at risk of contracting AIDS and other sexually transmitted diseases (STDs).

The only totally effective preventive measures against the sexual transmission of diseases are (1) sexual abstinence and (2) sexual intercourse between mutually faithful, uninfected partners. These two concepts need to be promoted in all societies and among all age groups as primary STD prevention strategies. It must be acknowledged, however, that millions of people do not choose abstinence or lifelong fidelity to one uninfected partner. Consequently, public health measures intended to slow the spread of disease must include the promotion and provision of effective protection and education in its proper use.

Although latex condoms are not perfect, their impact in preventing disease transmission, and thus limiting the spread of disease is both measurable and dramatic. When evaluating intervention strategies, the appropriate question from a public health perspective is not whether condoms confer absolute protection, but rather, how can condoms be used most effectively to prevent the spread of disease? To insist upon the former view is to hold condoms to a standard not required of any other public health prevention strategy while worldwide deaths from AIDS continue to mount.

The following is a list of some specific recent questions about condoms and answers based on medical/epidemiological literature and research. The term "condoms" here refers to latex condoms, not natural membrane (skin) condoms, which do not offer the same level of protection against STDs as latex condoms.^{1,2,3}

Questions and Answers

1. Since condoms can break and slip off, can they be relied upon for protection against HIV and other STDs?

Condom breakage and slippage has been analyzed, both through studies in which participants have been surveyed about their condom use and through studies in which participants have been given condoms and asked to report on various aspects of their use.

One U.S. consumer survey of almost 3300 people reported condom breakage rates of less than 1 percent.² In 7 other studies that asked questions about condom use (studies together totaling approximately 2000 people), reported condom breakage rates ranged from less than 1 percent to 7.3 percent.⁴⁻¹⁰ In 9 studies involving over 1000 people whose condom usage was monitored over time, reported condom breakage rates ranged from as low as 0-1 percent in several studies to as high as 12.9 percent in one Caribbean study.¹¹⁻¹⁹

Condom slippage rates are less well documented than breakage rates and "slippage" is also less easily defined (for example, slippage during intercourse versus during withdrawal, and slippage down versus off the penis).

One study attempting to categorize slippage factors reported that fewer than 1 percent of 237 condoms slipped off during coitus or withdrawal; however, 10 percent of the condoms were reported to have slipped *down* (without falling off) during coitus and nearly 16 percent during withdrawal. The authors concluded that these slippage rates testify to a need both for better consumer education and for research to determine whether this type of slippage results in significantly higher risk to either partner.¹⁶ Reported "slippage" or "slip-off" rates in 6 other published studies have ranged from 1.6 percent to 5 percent.^{5,6,7,9,10,20}

Although opponents of condom promotion tend to cite only the high end of breakage and slippage ranges, the ranges show that extremely low rates are achievable, and several facts are worth noting:

- Reports of breakage and slippage must not be confused with condom "failure rates," a term used for condom failure resulting in pregnancy or disease transmission. Condom failure can be caused by a number of factors, including not using a condom during every act of intercourse.
- Breakage or slippage does not inexorably lead to disease transmission. The chances of HIV infection from one unprotected sexual exposure have been estimated to be between 1 in 10 and less than 1 in 1000, depending on a number of factors,²¹ such as the type of intercourse (for example, vaginal or rectal) or the presence of genital ulcers. Consistent condom use, even allowing for occasional breakage or slippage, reduces this risk significantly.
- An undetermined proportion of reported breakage and slippage can be attributed to condom misuse. Misuse includes applying oil-based lubricants (petroleum jelly, shortening, mineral oil, massage oils, body lotions, or cooking oils, etc.) to the condom,²² which can severely damage the condom within a brief period of time.²³⁻²⁵ Other examples of condom misuse include damage from fingernails or other sharp objects, inadequate space in the condom tip, air trapped in the tip, unrolling the condom before donning, inadequate unrolling or lubrication, poor withdrawal technique, improper storage, and condom re-use. Consumer education is essential to bringing about lower rates of breakage and slippage.

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- Not all condom breaks are equally risky. Breakage at the condom rim does not usually pose the same risk as breakage at the tip. And when breakage is detected as the condoms is put on, or before ejaculation occurs, the risk of disease transmission is lessened, provided that a replacement condom is available. In one U.S. study, 50 percent of the reported breakage occurred while condoms were being put on or taken off.²⁶

Breakage and slippage are not necessarily events randomly experienced by condom users. Some studies report a relatively small number of people with extremely high breakage or slippage rates.^{9,10,19,27,28} This not only widens the range, but also points to the need for better education on condom use.

2. Are the pores in latex condoms large enough to allow passage of HIV?

- The AIDS virus is miniscule: about 0.1 microns in diameter (the diameter of the head of a human sperm is about 3 microns).²¹ Given that fact, people have questioned whether good quality condoms might prevent the passage of sperm but still allow HIV leakage through naturally occurring pores in latex. In two separate studies, condoms have been examined microscopically for evidence of porosity. A study by the U.S. National Institutes of Health found no condom pores at x2000 magnification.²⁹ Another study, by Consumers Union, used a scanning electron microscope at x30,000 power, a magnification at which HIV-size particles can be observed. This study reported a somewhat bumpy condom surface but no pores, even when the condoms were stretched.²
- Laboratory studies have also been conducted to assess leakage of a variety of microorganisms, including HIV.^{3,30-34} These studies, using test methods designed to simulate the stresses of intercourse on condoms, have demonstrated the ability of intact latex membranes to prevent the passing of HIV, herpes and hepatitis B viruses, cytomegalovirus, and chlamydia trachomatis, even after mechanical stimulation.
- Latex rubber is not naturally porous, but microscopic holes can occur as a result of manufacturing defects or subsequent damage. Researchers of latex rubber contend that holes in condoms are not an intrinsic feature of latex films, but the result of minute foreign particles and air bubbles introduced during manufacture.³⁵ Condoms are manufactured using double- or triple-dipped processes that reduce the possibility of hole defects penetrating through all condom layers.
- A recent laboratory study that found detectable leakage in 29 out of 89 condoms tested³⁶ has been widely quoted by some as "proof" of latex condom porosity. However, this study was conducted using viral-size microspheres in a concentration up to 100 million times the concentration of HIV in semen.²⁹ In addition, the microspheres were subjected to conditions equivalent to 10 minutes of coital thrusting *after* ejaculation. The study authors acknowledged that even the worst case of leakage under these radical conditions allowed less than 0.01 percent of the volume to leak (it is generally believed that the risk of HIV infection decreases significantly with decreasing exposure to the virus). Thus, the authors concluded that even worst-case condom barrier effectiveness had been shown to provide 10,000 times more protection than no condom at all.
- Even assuming that a small percentage of good quality condoms contain microscopic holes, the practical consequences of these holes are open to question. Failure of condoms from holes is a function of "the size and location of the holes, viscosity of semen, size and critical number of disease organisms required for infection, and extent of coital activity following ejaculation."³⁷ In addition, the AIDS virus is non-motile²⁹ and suspended in a viscous medium (semen), in most cases attached to cells that are considerably larger than individual viruses.^{29,38} The presence of a microscopic hole does not equate with a condom failure.

3. Do conventional condom testing measures prevent leaky condoms from reaching the market?

- In recent years, condom testing has brought about a reduction in the number of condom defects resulting in microscopic holes. Increased condom regulation, improvements in the manufacturing process, and compliance testing by public-sector condom purchasers have contributed to quality improvements. As a result of intensive efforts initiated in 1987 by the U.S. Food and Drug Administration (USFDA), overall leakage defects in U.S.-manufactured condoms fell in 1988.³⁹ The number of pinholes per 1000 condoms tested by the USFDA has varied from year to year, but in cases where condom defects exceed acceptable quality levels, products are subject to USFDA recalls or court actions. In addition, although most condom standards throughout the world stipulate an acceptable quality level of 4 pinholes per 1000 condoms, independent tests on behalf of large-scale condom purchasers show that manufacturing improvements have resulted in the consistent achievement by some manufacturers of much lower levels of leakage defects.⁴⁰
- In 1987, in view of the low frequency of leakage defects in latex condoms and the proven effectiveness of latex as a barrier, the USFDA (among the most conservative of national regulatory agencies) issued labeling guidelines for condoms as devices capable of reducing the risk of STDs, including AIDS.⁴¹ In April 1993, new USFDA guidelines recommended that manufacturers place statements on condom efficacy in protecting against STDs on each condom wrapper and the outer packaging.⁴² In its rationale for the new guidelines, the USFDA wrote that "It is imperative to take additional steps to inform the sexually active population about which contraceptives have the potential to protect against STDs and which do not."⁴² Latex condom packaging in the United States should now carry the following statement:

If used properly, latex condoms will help to reduce the risk of transmission of HIV infection (AIDS) and many other sexually transmitted diseases.

- International standards organizations and purchasing authorities have played a crucial role in recent years in tightening and refining condom standards, specifications, and testing procedures, and these activities have served to raise the level of condom quality. Guidelines for condom procurement developed by the World Health Organization Global Programme on AIDS⁴³ include a set of recommended condom specifications that have served as a model for condom purchasing and regulatory efforts in many countries. The U.S. Agency for International Development, the world's largest purchaser of condoms, is committed to rigorous purchase specifications and quality audits of condoms purchased for family planning and AIDS prevention programs in developing countries.

4. Has nonoxynol-9 been proven to prevent HIV infection? Can condom lubricants containing nonoxynol-9 cause irritation that facilitates infection?

- Nonoxynol-9 has been used as an acceptable and effective spermicide for over 30 years, and laboratory evidence suggests that it may be an effective virucide as well, capable of destroying HIV.^{32,44-46} Although no significant *in vivo* research has been conducted to measure the protective effect of nonoxynol-9 in HIV prevention, it has demonstrated a protective effect against gonococcal and chlamydial infections in human-use studies.^{47,48}
- Contraceptive sponges, suppositories, and condoms containing nonoxynol-9 have caused vaginal irritation in some women, especially when used in high concentrations or with high frequency,⁴⁹⁻⁵¹ and resulting genital ulcerations can increase the risk of HIV infection. However, less is known about the effect of nonoxynol-9 at moderate dosage levels in lower frequency use situations. To date, one dosing study of

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nonoxynol-9 has reported that women using nonoxynol-9 suppositories every other day experienced no increase in genital irritation.⁵² This issue needs further investigation, as does the issue of possible nonoxynol-9 effects among men.

- Currently, there is no epidemiological evidence to show that condoms lubricated with nonoxynol-9 are more effective in preventing HIV infection than condoms without nonoxynol-9.^{1,38} No large international public health provider of condoms recommends routine use of nonoxynol-9 as an STD prevention measure nor normally provides condoms lubricated with nonoxynol-9.

5. If condom failure rates are high for contraception, aren't failure rates even higher for HIV prevention? Is seroconversion of an uninfected partner inevitable over time?

- The effectiveness of consistent condom use in preventing HIV transmission is evident in the many epidemiological studies carried out on infected people and their uninfected partners. In 1992 Cates and Stone⁴⁵ tabulated the results of 15 studies measuring condom efficacy in protecting women against HIV transmission. The studies included cross-sectional and prospective studies, many of them conducted among high-risk groups such as prostitutes. Reported study outcomes demonstrated a varied, though consistently strong, protective effect of condom use, even among groups of users where the risk of HIV transmission was extremely high.
- In 1993, two large prospective studies on HIV seroconversion were published. In one of them, 245 discordant heterosexual couples (one partner was HIV positive and the other HIV negative) were followed for a median of 22 months. In this study, none of the 123 male or female partners who consistently used condoms became infected, but 12 of the remaining 122 partners who either did not use condoms or used them inconsistently did.⁵³ A second study monitored the female partners in 305 discordant heterosexual couples for as long as 3 years. This study reported 3 seroconversions among 171 consistent condom users, compared to 16 seroconversions among 134 couples who used condoms either inconsistently or never—a sixfold increase in infection.⁵⁴
- The suggestion that seroconversion of uninfected partners is inevitable over time assumes that the risk of seroconversion is constant and ignores the real probability that condom efficacy will increase over time as users learn more about condoms and gain experience and facility with the method. Two large studies of condom usage have reported marked declines in condom breakage and failure rates among experienced users.^{55,56}
- More data on the frequency of HIV seroconversion over long periods is needed, and continuing research may help to provide this information. In the meantime, what the available data do *not* lead to is the conclusion that condoms are ineffective or that they should be abandoned by people assuming the risk of sexual activity with an infected partner or a partner whose infection status is unknown.

6. Isn't it unrealistic to expect 100 percent user compliance? Total abstinence from sexual intercourse seems more likely to be achieved than use of condoms 100 percent of the time.

- One hundred percent condom compliance among people at risk of STD transmission is as "unrealistic" as 100 percent seat-belt compliance or 100 percent vaccination coverage. Nevertheless, these safety measures are widely promoted because they are vital to good public health. Consistent use of seat belts could reduce motor vehicle fatalities by 40 percent or more, but, like condoms, they require repetitive actions that are frequently inconvenient⁵⁷ and may lead some individuals to abandon their use.

- Just as no lifesaving device or public health strategy can realistically count on perfect use, none can guarantee perfect protection. Cates and Hinman⁵⁷ note that influenza vaccine has often been dismissed because it is "only" 60-80 percent effective; however, many thousands of deaths could be prevented annually through more widespread use of this "imperfect" vaccine. From time to time, debates have arisen over the risks associated with childhood vaccines, but reductions in public health efforts and the resulting low vaccine coverage have invariably led to increased incidence of disease.⁵⁸ Condom efficacy, which can be high with consistent and correct use, constitutes *significant* protection against HIV and other STDs.
 - When condom user compliance has increased, transmission of STDs has decreased. Studies in which condoms are promoted and available and where condom education is provided have shown a substantial impact on the reduction of HIV and STD transmission.⁵⁹⁻⁶³ Education of condom users is critical to increasing the level of condom effectiveness.
 - Given that people at risk of disease transmission fail to use condoms consistently, what level of user compliance can be expected for complete abstinence from sexual intercourse? There appears to be little, if any, published research on the success of abstinence as a means of HIV and STD prevention. However, in the family planning literature, various methods of periodic abstinence (abstinence during the fertile period only--approximately 9 to 14 days per 28-day cycle) have among the highest failure rates of any method of contraception.^{64,65} Failure of this method to prevent pregnancies is no doubt due in part to its incorrect use (e.g., miscalculation of the fertile period), but the inability of some couples to follow a course of abstinence also contributes to failure. It is notable also that the published failure rates represent only those cases of non-use that resulted in pregnancy, suggesting that actual rates of noncompliance are likely to be higher. The inability of people to abstain from intercourse for 9 to 14 days a month raises serious questions about the likely success of complete abstinence as a means of controlling disease transmission. In addition, abstinence, whether periodic or total, requires a degree of motivation and self-control that is often not equally shared between partners, and for many this approach is either unrealistic or undesirable.
 - While abstinence and mutual monogamy between two uninfected partners offer the best protection against sexual transmission of disease and should be advocated, the limitations of these methods need to be recognized--and additional prevention strategies, such as condom education and promotion, employed.
7. **Condoms are perishable. Therefore, can they be relied upon for protection from HIV infection over time?**
- Condoms are made from natural latex rubber, which can deteriorate with prolonged exposure to high heat, humidity, and sunlight. But a large-scale, international study on condom deterioration funded by the USFDA has shown that good quality, well-packaged condoms can be stable even after 4 years of storage in challenging conditions.⁶⁶
 - The USFDA is working with U.S. manufacturers to establish 5-year condom expiration dates based on long-term storage data.
 - Apart from reductions in storage times, environmental damage to condoms can be reduced in at least three ways: (1) by reductions in storage temperature to slow the rate of deterioration, (2) through the introduction of antioxidants into latex formulations, and (3) by eliminating oxygen exposure through impermeable packaging.⁶⁶
 - Widespread efforts are underway--as with vaccines and other life-saving health products--to ensure that condoms are manufactured, regulated, transported, stored, and distributed with attention to the conditions
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that cause damage or accelerate deterioration. Condom purchasing and regulatory authorities play a crucial role in ensuring that the condoms provided to consumers are of high quality. Condom users should avoid exposing condoms to high heat or mechanical damage (for example, by storage in glove compartments or for extended periods in wallets). Condom users should also inspect each condom for signs of broken package seal, discoloration, or stickiness, and report any instances of poor condom quality to appropriate health authorities.

- Condoms made from more stable synthetic materials are being developed and marketed.^{16,67} The new non-latex condoms may have a longer shelf life and they will better accommodate oil-based lubricants. Female condoms already incorporate synthetic materials and condom formulations combining latex and synthetic polymers are likely to emerge in the near future.

Conclusion

Condoms, when used consistently and correctly, effectively reduce the risk of infection from HIV and other STDs. Therefore, efforts focused on improving condom quality, availability, and use represent a critical aspect of public health strategies to contain these diseases. Recent attacks on condom effectiveness, with their implied call for the abandonment of condom use and education, ignore the reality that no disease prevention strategy is ever perfect, and that all strategies, including sexual abstinence, depend to a high degree on consistent and correct use. Promotion of condom use is not incompatible with the promotion of sexual abstinence and mutual monogamy. Both represent a responsible approach to disease prevention. Suggesting that abstinence and mutual monogamy are the only STD-prevention measures that should be advocated ignores the realities of the millions of people in need of the significant protection that condoms afford.

Among the many health authorities that promote condom use for preventing the spread of AIDS and other STDs are the U.S. Surgeon General, the Centers for Disease Control and Prevention, the Food and Drug Administration, the U.S. Agency for International Development, and the World Health Organization Global Programme on AIDS.

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