Male and female condoms

Key points

- Male condoms were the first mass intervention adopted for HIV prevention. Robust evidence gathered over three decades confirms that they remain a highly cost-effective method of preventing HIV. Condoms are an essential component of HIV prevention.
- Despite their effectiveness, condoms do not offer perfect protection. They can be used incorrectly, causing them to slip or tear; they also are used inconsistently, meaning people have unprotected sex. But studies show that the use of male condoms for vaginal sex effectively reduced HIV transmission by 80% (50). For anal sex, there are fewer studies, but the most recent metaanalysis found that male condoms had an efficacy of 70% (51).
- For female condoms, limited evidence suggests that they are 80% effective (52). While their use is low across all groups in developed countries, female condom use has been shown to be more common in certain countries, including Brazil, Ghana, South Africa and Zimbabwe.
- Condom acceptance in key populations rises sharply after media and counselling promote condom use (53). This happens even in populations with strong cultural objections and low historical use. Usage rates may decline in some settings after the initial sharp rise, but they remain significantly higher than historical levels.
- Studies confirm that HIV incidence drops when condoms are combined with other changes (such as frequency of sexual relations) (50). Modelling has shown that condom use was a key factor in containing the spread of the epidemic.
- Programmes that provide access to free or subsidized condoms increase condom use (54). Condoms also protect against unwanted pregnancy and STIs. Where HIV stigma is an issue, the contraceptive benefits can be emphasized to increase usage.
- Promoting condom use through counselling and media interventions has (on average) a neutral impact on incidence, but it is more effective when directed at specific populations. Key populations in which HIV is spread primarily through casual and commercial sex respond well to condom provision and promotion. Compared to the general population, rates of male condom use are higher among gay men and other men who have sex with men, people in casual sexual relationships and people involved in commercial sex.
- The cost per disability-adjusted life year (DALY) averted has been estimated as slightly more than US\$ 100 for male condoms and just less than US\$ 200 for female condoms (55). This compares favourably with the cost of approximately US\$ 550 per DALY averted for first-line antiretroviral therapy.

Male condoms were the first tool adopted for HIV prevention in the early 1980s; the female condom was first launched in the early 1990s. They are inexpensive and cost-effective, and their use does not require the assistance of health-care workers. Together, they remain the most frequently used intervention to prevent HIV infection in many settings.

Condoms have also found a place in combination HIV prevention. Several models have shown that condoms can have a strong impact on disease incidence when used alongside other interventions. For example, modelling in South Africa suggests that from 2000 to 2008, HIV-incidence in adults declined by approximately 31%, with between 23% and 37% of this decline attributed to condom use (*56*). Models from the United Kingdom of Great Britain and Northern Ireland also credit condoms with preventing a quadrupling of cases that would have otherwise occurred (*57*).

What follows is an examination of the effectiveness of condom protection against HIV among heterosexual couples and gay men and other men who have sex with men. Both male and female condoms are covered. After that, a summary of the effectiveness of condom programmes on enhancing the acceptability, availability and accessibility of condoms is presented.

A note on outcome measures for condoms

The specific measurable amount of protection that condoms provide against HIV infection can only be estimated—it is not possible to run randomized controlled trials (51). While efficacy and effectiveness are ideally tested in a randomized controlled trial with strong measures adopted to capture adherence levels, ethical considerations prohibit the exposure of infection-free people to a serious illness like HIV. It is therefore necessary to use observational studies where condom use (or the lack thereof) is examined alongside observed HIV prevalence and incidence rates that are confirmed by serology.

Biological rationale for effectiveness

What does the evidence say about the biological efficacy of condoms?

• Condoms made of latex or polyurethane form an impermeable barrier for HIV.

Condoms are made from latex or polyurethane, and they are required to meet manufacturing standards that make them impermeable to microorganisms *(58)*. WHO and the United Nations Population Fund (UNFPA) operate a prequalification and specification scheme for male condoms. The United States Food and Drug Administration (FDA) and the European Medicines Agency have comparable specifications for female condoms.

It is beyond doubt that condoms act as an effective and reliable barrier. Laboratory studies and product testing have shown that condoms from recognized suppliers are completely impermeable to microorganisms as small as viruses when tested in the laboratory *(59)*. The risk of exposure to semen due to condom breakage is 1 per 166 sex acts, a physical reliability of 99.4% *(60)*.

Condoms are therefore highly effective in preventing unintended pregnancy and the transmission of microorganisms. When they fail, it is either because of device failure or user failure. Objections to condom use frequently conflate these two characteristics. User failure takes two forms: either condoms are used inconsistently, which leads to episodes of unprotected sex, or they are used incorrectly, which leads to slippage or breakage. Such device failure is uncommon on its own; it is usually an outcome of user failure. Around 75% of users fail to use condoms for every penetrative sex act, but when they are used consistently and correctly, they are highly effective.

Efficacy of condoms in preventing HIV infection

What does the evidence say about the effectiveness of condoms when they are self-reported to be used consistently?

 Male condoms used consistently for all acts of penetrative sex are 80% effective in preventing HIV transmission through vaginal sex and 70% effective for anal sex.

Considerations in determining condom efficacy

The efficacy of an intervention describes how well it works in a scientific trial or when used as indicated (i.e., consistently). Its effectiveness indicates how well it works to prevent disease or infection in a particular population given actual levels of use.

Studies of condom efficacy have compared HIV incidence or prevalence among people who claim 100% consistent use of condoms against people who use them inconsistently or not at all *(50)*. Because these studies involve private behaviours that investigators cannot observe directly, it is difficult to determine accurately whether an individual is a condom user and whether condoms are used consistently and correctly.

The evidence we have is based on three types of trials, and each has potential weaknesses.

- For the efficacy of condoms against HIV and other chronic STIs, prospective studies of the incidence of HIV—or human papillomavirus (HPV) or herpes simplex (HSV)—in monogamous serodiscordant couples provide the best evidence. Large or long-lasting studies provide more reliable estimates of efficacy.
- Evidence also has been derived from prospective cohort studies that look at the association between self-reported condom use and HIV incidence over time.
- Retrospective cohort studies have correlated levels of reported condom use and other behavioural data with HIV prevalence to determine the association between condom use and HIV infection.

All of these methods are prone to bias due to their reliance on self-reported condom use. Research early in the epidemic showed that 40–70% of men falsely claimed they always use condoms (*61*). Similarly, one study found that 77% of female sex workers reported consistent condom use with clients, but a prostate-specific antigen (PSA) test established that only 52% actually used condoms consistently (*62*). These findings indicate that people overestimate condom usage and find it difficult to sustain 100% use.

Condom efficacy: heterosexuals

The most comprehensive meta-analysis of the efficacy of condoms in heterosexuals was issued as one of the Cochrane Collaboration series of meta-analyses *(50)*. The meta-analysis evaluated 14 longitudinal cohort studies that contained 13 groups of serodiscordant heterosexual couples who said they "always" used condoms and 10 groups who said they "never" used them. There were 587 HIV-negative partners in the "always" group and 276 in the "never" group. The average length of follow-up in the studies was 2.17 years.

The annual incidence of HIV infection in the HIV-negative partners was 6.68% in partners who said they "never" used condoms (40 infections in 276 people) and 1.14% in partners who said they "always" used them (11 HIV infections in 587 people) *(50)*. This represents an 83% reduction in the risk of HIV transmission.

Among the "always" users, the 95% CI for annual HIV incidence was 0.56–2.04%; among those who "never" used condoms, 95% CI for annual incidence was estimated at 3.16–9.66% *(50)*.

Condom efficacy: anal intercourse between men

There have been limited data on the efficacy of condom use in preventing HIV transmission through anal intercourse. A study conducted in 1989 and a meta-analysis of two longitudinal studies published in 2013 each estimated an efficacy of 70% for reported condom use during anal intercourse between gay men and other men who have sex with men: men who said they used condoms 100% of the time were 70% less likely to acquire HIV than men who never used condoms, and they were 68% less likely than men who said they sometimes used them (*51, 63*). This is somewhat lower than the rates seen in studies among heterosexuals, probably because the risk of transmission through anal intercourse is higher than it is through vaginal intercourse, and because there is a higher risk of condom breakage during anal intercourse.

The 1989 study was part of the Multicenter-AIDS Cohort Study (MACS), the oldest HIV cohort study in the world. The study found that the six-month IR among 2914 initially HIV-negative gay men and other men who have sex with men was 0.7% among those who claimed 100% condom use and 2.9% among those who never used condoms. This also yields a condom efficacy of approximately 70%.

A recent systematic review, published in 2018, found that HIV incidence was 91% lower among gay men and other men who have sex with men who used condoms consistently, contributing to the evidence base of condom effectiveness against HIV (64).

Condom efficacy: anal intercourse in heterosexual couples

The only analysis of condom efficacy for anal intercourse in heterosexuals was a small one published in 1994 *(65)*. There were no seroconversions in 124 couples who always used condoms for vaginal and anal intercourse, compared to 12 in the group of 132 people who used condoms inconsistently.

Anal intercourse was already a minority behaviour among heterosexual couples, and unprotected anal intercourse was even rarer, so the researchers could not directly compare seroconversion rates between women who used condoms for anal sex and those who did not.

Condom efficacy: male and female condoms

Available data reviewed by the CDC in a recent meta-study suggest that female condoms (or an alternating mixture of female and male condoms) may provide degrees of protection against pregnancy and STIs that are similar to those of latex male condoms alone *(51)*. According to the authors, however, this conclusion has not been demonstrated to a level that can lead to an unequivocal recommendation. The uncertainty of this conclusion is reflected in

the FDA labelling for female condoms, which supports their use for disease protection only in mitigating circumstances (i.e., when a latex male condom will not be used). Data from randomized trials designed to quantify the equivalence between the two condom types are not available *(52)*.

The key benefit of the female condom is that it provides women with an option over which they have control. In most settings, uptake of female condoms has been very low, and female condom use globally is less than 1% of male condom use, with notable exceptions (such as Brazil, Ghana, South Africa and Zimbabwe). In light of the uncertainty surrounding their effectiveness and low usage rates, the female condom will be a tool in well-defined settings. Male and female condoms should not be used at the same time. This is because friction between the condoms can increase the likelihood that the condoms will split *(66)*.

Condom failure or misuse: recommended actions and efficacy

In a case of condom failure or misuse where one partner is HIV-positive, the recommendation is to visit a health-care professional, who should prescribe a one-month course of post-exposure prophylaxis (PEP) *(66)*. Where the serostatus of one or both sexual partners is unknown, HIV testing is recommended.

The relationship between consistent use and efficacy

Condoms protect against HIV when used, provided that they do not slip off or break. As soon as attempted condom use falls from 100%, then the degree of protection they offer rapidly declines.

In some studies, inconsistent condom use appears to be even less effective against HIV than not using condoms at all *(68)*. Inconsistent users had 44% more gonorrhoea and chlamydia than non-users, and this was statistically significant and broadly in line with other studies (see below) *(69)*.

The apparent ineffectiveness of intermittent condom use may be due to the fact that such use is associated with settings that have a higher risk of HIV infection: longitudinal studies suggest that intermittent users are likely to have behavioural characteristics that put them at higher risk of HIV infection (such as greater numbers of partners). Researchers also hypothesize that men who never use condoms might be more likely to be in monogamous relationships and therefore generally at less risk of HIV (*69*).

The effectiveness of condoms in key regions and among key populations

What does the evidence say about the effectiveness of condoms when they are delivered as part of prevention packages in different settings?

Condoms are effective alongside other interventions in reducing HIV incidence in different regional and epidemic settings.

Heterosexuals in sub-Saharan Africa

The earliest population-level decline in HIV prevalence in sub-Saharan Africa, which occurred in Uganda, has been attributed to behavioural and epidemiological changes that occurred alongside increases in condom use *(70)*. Evidence from population-level declines in HIV prevalence is derived from population-based surveys, routine HIV testing data and study cohorts. While these types of data are suitable to document trends, they cannot be linked directly to interventions in the same way as experimental studies. Mathematical models and ecological analyses have therefore been used to assess the contributions that programmes such as condom promotion have made to HIV declines.

In Uganda, the incidence and prevalence of HIV started falling in the late 1980s, well before condoms started to be used widely (70). Similarly, the decline in HIV incidence in Zimbabwe after 1991 has been attributed to a combination of factors, including a decline in multiple or concurrent sexual partnerships, a reduction in men paying for sex and changes in social attitudes towards casual sex. Condom use with nonregular partners, which increased during the 1980s and 1990s, has been cited as another plausible contributing factor to HIV prevalence decline in Zimbabwe (71).

Subsequent increases in condom use may have made more direct contributions to reductions in HIV incidence and prevalence in some countries. For example, South Africa experienced a 35% decline in the rate of new HIV infections between 2002 and 2008, and by comparing data from three consecutive national prevalence surveys, researchers were able to estimate changes in incidence and link the improvements to condom use (among other factors) *(56)*.

Heterosexuals in Asia: Cambodia, India and Thailand

National promotion of condom use in brothels in Thailand during the 1990s—the 100% Condom Use Programme—was associated with a rapid and substantial reduction in HIV incidence (72). As part of the programme, police informally licensed brothels and ensured that sex workers had regular health checks to pressure owners to ensure that clients demanding unsafe sex would be turned away. Following the launch of the campaign in 1989, condom use in sex establishments increased from less than 20% in 1990 to above 90% in 1994; it was sustained at that level thereafter. HIV prevalence among male military conscripts fell from 4% in 1993 to 1% in 2004. A similar decline in HIV prevalence was observed in Cambodia, which also used the programme (72).

In India, a decline in HIV prevalence among women especially in southern states, among those aged 15 to 24 years, has been attributed to the widespread adoption of condoms by sex workers and their clients, and to a subsequent reduction in transmission of HIV from male clients to other female partners (73). The researchers also credited a 35% decline in HIV

prevalence among young people to an increase in condom use among commercial sex workers and their clients.

Latin America

While the incidence of HIV (0.4%) is much lower in Latin America than in sub-Saharan Africa or parts of Asia, the total number of people infected is nonetheless substantial (74). Incidence rates are high among key populations such as gay men and other men who have sex with men, sex workers (especially male sex workers) and transgender women. Antiretroviral therapy is widely available across the region, but its uptake is far below 100%, varying between 20% in the Plurinational State of Bolivia and 60% in Argentina. As a result, condoms are a critical intervention.

There is a lack of condom effectiveness studies for this region. One reason for this is that certain key populations often falsely identify themselves as heterosexual or hide their HIV status, because gay men and other men who have sex with men and people living with HIV are highly stigmatized in the region (75).

Key populations

What does the evidence say about the effectiveness of condoms when they are delivered as part of prevention packages for key populations?

 Condoms used alongside other interventions reduce HIV incidence in all key populations, and they need to be part of all programmes reaching those populations.

Gay men and other men who have sex with men

The first instance of a substantial increase in condom use in a key population was among gay men and other men who have sex with men early in the epidemic.

Condom use among gay men and other men who have sex with men in San Francisco quadrupled between 1984 and 1987 *(76)*. Because of this increase—and because of reductions in the number of sexual partners—HIV incidence dropped precipitously in 1983–84 after peaking at 7–8% in 1980–82. It has remained at 0.5–3.0% ever since.

An early survey by Sigma Research in the United Kingdom found that about 90% of gay men and other men who have sex with men consistently did not use condoms for anal intercourse before 1980, but that by 1988, the proportion of "rarely or never" users was down to 22% (77).

Young people

A systematic review of 31 controlled studies conducted in sub-Saharan Africa found that behavioural HIV prevention interventions were associated with an increase in condom use at last sexual episode among males aged 10 to 25 years (78). It also found, however, that intervention and study design were commonly weak. Condom use at last sex was 1.46 times higher among males who received behavioural interventions; any use of condoms also increased in males (RR = 1.32; 95% CI 1.25–1.40). No consistent impact of interventions on condom use was seen in young women, and there was great diversity in the range of behaviour change interventions studied (78).

Integrating condom promotion into programmes focused on sexual behaviour change is advantageous because decisions around condom use are directly affected by issues such as relationship status, gender-based power disparities and denial of HIV risk. Condom programming, like all behaviour change communication, must be locally relevant and culturally specific in order to be effective.

Linkages that facilitate the integration of condom education, promotion and distribution into existing medical, educational and social services programming can serve to expand their uptake by communities at high risk of HIV, particularly in developing countries.

Sex workers

Interventions to promote condom use among sex workers and their clients are highly effective. A systematic review of interventions to improve condom use in Africa and Asia, for instance, found that of 19 studies that assessed condom use among female sex workers, 15 reported a significant increase in condom use (versus four that did not) *(79)*.

As noted above, Thailand's national 100% Condom Use Programme resulted in a change in reported condom use at sex establishments, with the rate increasing from less than 20% in 1990 to above 90% in 1994, a level that was reportedly sustained thereafter *(72)*.

In India, sex worker outreach projects integrating condom promotion succeeded by using very different techniques (80). In 2004, 70–80% of female sex workers in Karnataka reported using a condom with their last client. This was a sharp increase from prior levels, and it was attributed to the activities of a peer-led female sex worker collective that offered an array of services, including literacy programs, medical care, legal assistance, HIV prevention education and condom promotion. A survey of women and men attending antenatal and STI clinics found a 35% decrease in HIV prevalence (73). The researchers credited these declines to an increase in condom use among commercial sex workers and their clients.

People who inject drugs

Condom promotion can be integrated effectively into harm reduction services for sex workers and people who inject drugs via programmes focused on these key populations. Such integrated programmes are the mainstay of HIV and STI prevention programmes in many countries, and they have been shown to be highly effective in preventing HIV *(73)*.

Prisoners

People in prison settings are another population that is largely deprived of condom access. Most countries still treat condoms as contraband in prisons and jails, despite: (a) clear guidance from the European Court of Human Rights and the UN on the human rights aspect of preventing serious illness; and (b) analysis from WHO, the UN and UNAIDS on the feasibility and benefits of condom provision (84). The political will to reverse these bans is required to create an enabling environment for condom use among people in prison settings.

The overall impact of condom provision and education on HIV risk

What does the evidence say about the effectiveness of condom distribution and promotion?

- Condom distribution and promotion schemes are highly efficacious in increasing condom use, and they deliver additional benefits, such as reductions in STI incidence.
- Condom promotion and use do not increase other high-risk sexual behaviours.

A meta-analysis published in 2011 looked at the impact of condom distribution schemes on condom use and risk behaviours, both in the United States and internationally *(54)*. It covered programmes aiming to increase the following:

- Condom availability through the provision of free or subsidized condoms to individuals practising high-risk behaviours and in high-risk venues.
- Condom accessibility, which uses broader general schemes, such as condom provision at music festivals or to students.
- Condom acceptability through media campaigns, safer-sex posters and information, and peer-group interventions.

The analysis showed that condom distribution and promotion schemes are highly efficacious in getting people to carry and use condoms. It also documented a substantial reduction in STI incidence and delayed sexual debut in young people *(54)*.

The overall effect on condom use in 20 studies was an 81% increase in condom use. In a subset of five youth studies, there was a 43% increase in delayed sexual debut or abstinence, which suggests that condom promotion does not lead to risk compensation in the form of earlier sexual debut. In a subset of five studies that measured STI incidence, there was a 31% decrease in STIs *(54)*.

The increasing integration of condom promotion into services focused on women, couples and young people has also shown success. Women accessing HIV-related services in family planning clinics have demonstrably higher rates of condom use than their peers in the general population *(81)*. Emphasis on the contraceptive value of male and female condoms can also counteract potential stigma by drawing attention away from their association with HIV prevention *(82, 83)*.

Another systematic review found variability between populations and partnership types in the effects of promotion on condom use (79). The review identified 62 studies that had evaluated the effects of condom promotion in Asia or sub-Saharan Africa. Positive impacts were reported for sex workers and serodiscordant couples.

A subsequent systematic review and meta-analysis of studies published between 1990 and 2006 on behavioural interventions for people living with HIV in developing countries found those interventions had a very strong effect on condom use in serodiscordant couples (85). The study found that counselling couples together had a significant and substantial effect, whereas individual counselling alone had no impact. This is in keeping with the findings

discussed in the previous section on the effectiveness of HIV testing of couples (see "The effect of voluntary HIV counselling and testing on sexual behaviour").

A large 2006 meta-analysis of 174 studies published between 1989 and 2003 of any interpersonal (individual or group) sexual risk reduction intervention (not just condoms or condom promotion) found no evidence that, taken as a whole, those interventions increased sexual risk behaviour or the amount of sexual activity *(86)*. These findings contradict assertions that condom promotion encourages risk behaviour, and they support the inclusion of focused condom promotion in all HIV prevention programmes.

Operational considerations

The UNFPA publication *Comprehensive condom programming: a guide for resource mobilization and country programming* has guidance that applies to both male and female condoms (*87*). It outlines a 10-step strategic approach:

- 1. Establish a national condom support team.
- 2. Undertake a situation analysis.
- 3. Develop a comprehensive and integrated national strategy for male and female condoms.
- 4. Develop a multi-year operational plan and budget.
- 5. Link the multi-year operational plan with the national commodity security plan.
- 6. Mobilize financial resources.
- 7. Strengthen human resources and institutional capacity.
- 8. Create and sustain demand for condoms.
- 9. Strengthen advocacy and engage the media.
- 10. Monitor the programme routinely, conduct research and evaluate outcomes (87).

Acceptability and effectiveness

While there may be many reasons why people do not use condoms, two main themes stand out when people are asked why they do not use them: intimacy and pleasure. Condoms are sometimes equated with a lack of trust or with relationships that have not yet been firmly established. They can even be taken as proof of unfaithfulness.

Surveys such as those based on the Demographic and Health Surveys (DHS) programme almost invariably find that condom use in long-term relationships is much lower than in casual sex. This applies to both heterosexual men and gay men and other men who have sex with men: men in steady relationships, irrespective of the serostatus of their partner, are far less likely to use condoms.

Condom breakage and slippage

What has been called "fit" and "feel" may be crucial when it comes to the decisions that men make about whether or not to continue to use condoms. Failure to supply condoms that fit varying sizes of penis, for instance, may make a difference, as might lubrication and smell. One study, for instance, found that although most men do not have problems with condom fit and feel, men with shorter or larger penile dimensions (length or circumference) were more likely to have negative attitudes and perceptions of condom fit and feel *(88)*.

Unsatisfactory fit and feel also were associated with condom breakage. In one study, condom breakage was twice as likely to be reported by men who felt their condoms did not fit properly *(89)*. Other predictors of condom breakage were, unsurprisingly, letting sharp objects near the condom and previous experiences of condom slippage. STIs were significantly higher with condom breakage, suggesting a similar risk for HIV.

In resource-rich countries, condom manufacturers offer a range of condoms in different sizes and fits. However, the choice of condoms tends to be much more limited when they are supplied free of charge in developing countries. More work is needed to identify what range of condoms must be supplied in different settings in order to increase men's comfort and satisfaction when using them.

In 2013, the Bill & Melinda Gates Foundation identified the development of new and easier-touse condoms for resource-poor countries as one of its development priorities (90).

The role of lubricants in condom breakage, slippage, reliability and safety

A woman produces natural lubricating fluids during vaginal sex, but these may not be enough for safer condom use. Women also may need additional lubrication for comfort. A survey of women's lubricating practices in nine countries in Asia, Africa and Latin America found that the use of substances that increased vaginal lubrication was widespread *(91)*. Lubricants also are used by the majority of gay men and other men who have sex with men and by female sex workers *(92)*.

A more recent survey covered lubricant use during anal sex among both men and women (93). In this international survey of 6124 individuals who reported anal sex in the last six months, only 35% used condoms consistently, but 59% always used lubricants. It is recommended that condoms be used with silicone- or water-based lubricant for anal sex. Use of water-based lubricant is associated with a lower male condom failure rate during anal intercourse. In one study, condom breakage was significantly less frequent when used with water-based lubricant compared to no lubricant (3.0% vs 21.4%) (94).

Using oil-based substances, cooking oil and other oily substances as lubricant with latex condoms is not regarded as safe. Oils and greases weaken condoms within minutes: one study found that a condom's resistance to being punctured decreased by 47% and 59%, respectively, after 15 and 30 minutes of exposure to mineral oil *(95)*.

Lubricants are manufactured to a range of specifications according to market requirements. As a result, they differ in their chemical constituents and safety profile. Lubricants may cause harm to the vaginal or anal mucosa, or they may cause damage to male or female condoms *(96)*. In either instance, they would increase the risk of HIV infection.

Lubricants are not subject to uniform regulation; in some cases, they are not regulated. There is an advisory note on lubricants from WHO, UNFPA and FHI 360, but additional evidence on the effects of lubricants is required *(97)*. If no local regulation exists or if regulation is weak, then it is advisable to recommend products that have already been approved in highly regulated markets, such as Europe (products with the "CE" marking) and other developed markets.

Since condom use in many settings is increased by making condoms available for free or at highly subsidized prices, it is advisable to make lubricants available in a similar manner. In these contexts, it should be emphasized that there is no evidence to suggest that lubricants on their own are protective against HIV.

Structural-level condom interventions

Programmes exist that distribute condoms free of charge on a large scale to individuals and communities at high risk of HIV infection. These structural-level condom interventions often are combined with individual or group behaviour change interventions, and they often are supported by community-based social marketing activities. A systematic review and meta-analysis published in 2011 reviewed 21 studies of structural-level interventions in which HIV-related risk behaviours and STIs were measured as relevant outcomes (*54*). The overall effect of the interventions was an 81% increase in condom use, and in a subset of five youth studies, investigators found a 43% increase in abstinence or delayed sexual debut. In another subset of five studies—this time measuring STI incidence—researchers documented a 31% decrease in STIs (*54*).

The meta-analysis found that interventions addressing any one of the three parameters acceptability, accessibility or availability—had a similar magnitude of effect. Interventions to improve availability, such as requiring saunas or sex work premises to make condoms available, had the greatest impact when combined with measures to improve accessibility (such as large-scale condom distribution). Interventions that combined structural-level condom distribution with individual, small group or community interpersonal communication components had significantly greater efficacy than interventions that solely implemented a structural-level component (54).

Social marketing

Condom social marketing (not to be confused with communication that uses social media, such as Facebook) refers to activities that seek to build demand for condoms that are made available at a subsidized price. It was first initiated in the 1980s by international family planning organizations, and it broadened in the 1990s as epidemic rates of HIV highlighted the urgent need to increase condom use.

Social marketing may be combined with free access to condoms through health facilities, family planning clinics or community outreach. It applies the tools and concepts of commercial marketing to noncommercial goals, such as promoting healthy behaviours, and it is generally used to address issues affecting low-income populations that have high morbidity and mortality rates.

In 2012, a systematic review and meta-analysis by Sweat et al. examined six studies of social marketing interventions to increase condom use in developing countries (98). Five of the six studies were conducted in sub-Saharan Africa. The review found that exposure to a social marketing intervention approximately doubled the likelihood that respondents reported condom use at their last sexual encounter. It also confirmed that social marketing only has a moderately positive effect on increasing condom use. Among those exposed to social marketing, overall condom use was slightly more likely among men than women; the effect of social marketing remained significant only for men when the analysis was restricted to casual partners.

Condom social marketers sometimes pave the way for governmental HIV prevention efforts by introducing new condoms and creating public demand for them. That introduction then facilitates the wider distribution of condoms by public health services. In Brazil, for example, DKT (a private-sector social marketer) introduced female condoms in 1997 at a subsidized price. The government subsequently joined the effort by making the condoms available for free for those unable to buy them. By 2004, four million female condoms were being distributed annually through a mix of public and private (social marketing) channels, a figure that the government estimated as one fifth of the actual number needed (*100, 101*).

The total market approach

The term "total market approach" was first applied to social marketing in 2004 (102). Since then, it has come to be applied to a framework that harmonizes social, private and public market forces to address public health needs. Under such an approach, all sectors (public sector, private sector and social marketing) are integrated within one market that is segmented by willingness to pay (103).

With regard to condoms, the division of labour is generally as follows:

- Commercial businesses sell a range of brands to buyers who can pay retail prices.
- Non-profit, community-based organizations provide branded and unbranded condoms at subsidized prices.
- Public sector workers (e.g., clinics, hospitals and health educators) distribute free condoms.

A 2012 evaluation of work in African countries found that social marketing using a total market approach resulted in significantly increased condom use by women in nonmarital, non-cohabiting relationships in seven countries, and by their male peers in five countries *(104)*.

Cost-effectiveness

Are condoms cost-effective?

 Condoms are likely among the most cost-effective HIV prevention interventions available in most settings.

Evidence of the cost-effectiveness of condom distribution and marketing is necessary to sustain political support for its continuation. While it is intuitively apparent that investment in preventing new HIV infections is less expensive than lifelong treatment costs and other expenses associated with HIV acquisition, cost-effectiveness studies have not evaluated male condom promotion as a stand-alone intervention. Instead, it is evaluated as part of an intervention package that also includes HIV education, support and STI prevention. For instance, mathematical modelling to estimate the cost-effectiveness of various HIV prevention interventions in sub-Saharan Africa suggests that male condom provision (with its appropriate ancillary programming) costs only US\$ 181 per HIV infection prevented, making it "the most economically efficient of HIV prevention strategies in sub-Saharan Africa" (*105*).

A 2014 analysis of the cost-effectiveness of female condoms showed that, despite a higher price, female condoms are nevertheless highly cost-effective compared to other HIV prevention tools when measured by DALY averted *(55)*. As the only dual prevention method (i.e., it blocks STIs and HIV and acts as a contraceptive) that women can initiate when male condom use has been rejected, female condoms are an important complement to the larger HIV prevention intervention package.

Risk compensation: the potential for a decline in condom use

What is the role of condoms in the age of antiretroviral therapy?

- When antiretroviral therapy is available, condoms are still needed to prevent rising HIV incidence.
- In the majority of countries, less than half of people living with HIV had a suppressed viral load in 2016. Even if the 90–90–90 targets are achieved, more than a quarter of people living with HIV would not be virally suppressed, and people who are virally suppressed at the time of a viral load test may not be constantly virally suppressed.

It has been questioned whether condom use in resource-rich countries has declined since the advent of antiretroviral therapy in the mid-1990s. The evidence is conflicting, varies between countries and depends on what measures are taken of risk behaviour. Potential different factors include whether condom use and unprotected sex (including unprotected sex between definitely or possibly serodiscordant partners) is counted, and whether the question is asked positively (e.g., "Have you always used a condom during intercourse in the last year?") or negatively (e.g., "Have you had intercourse without a condom over the last year?").

Following the advent of antiretroviral therapy in 1996, the proportion of gay men and other men who have sex with men who sometimes did not use condoms started to increase. A survey in San Francisco, for instance, found that the proportion of gay men and other men who have sex with men who reported that they did not always use condoms increased from 31% in 1994 to 47% in 1999 (106).

In the United States, the proportion of gay men and other men who have sex with men who had anal sex without a condom at least once in the previous year increased by nearly 20% between 2005 and 2011 (107). Among men in 2011 who tested HIV-positive but did not know their status, a third had high-risk sex the last time they had sex; this rate had not changed from 2008. This does not imply that not knowing one's status leads to high-risk sex; rather, it shows that people living HIV who don't know their status are more likely to have taken sexual risks recently and are more likely to have been recently infected.

Limited data on increasing trends in some STIs may suggest reduced condom use with increased availability of antiretroviral therapy. Despite that, there is not enough evidence to make a definitive statement to that effect.

Conclusion: male and female condoms

Condoms were the first successful mass intervention to prevent the spread of HIV. Their role in containing and reducing HIV incidence alongside other interventions is well-documented, even though the exact level of their effectiveness remains unknown. High effectiveness depends on consistent and correct use, which is not easy to reach, but evidence confirms that increased and sustained condom usage can be achieved following a process such as that outlined in the UNFPA guide, Comprehensive condom programming (87).

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