Public Health Reviews

Effectiveness of condoms in preventing sexually transmitted infections

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Abstract In June 2000, the United States National Institutes of Health (NIH) organized a review of the scientific evidence on the effectiveness of condoms in preventing sexually transmitted infections (STIs). The review concluded that condoms were effective in protecting against transmission of HIV to women and men and in reducing the risk of men becoming infected with gonorrhoea. Evidence for the effectiveness of condoms in preventing other STIs was considered to be insufficient. We review the findings of prospective studies published after June 2000 that evaluated the effectiveness of condoms in preventing STIs. We searched Medline for publications in English and included other articles, reports, and abstracts of which we were aware. These prospective studies, published since June 2000, show that condom use is associated with statistically significant protection of men and women against several other types of STIs, including chlamydial infection, gonorrhoea, herpes simplex virus type 2, and syphilis. Condoms may also be associated with protecting women against trichomoniasis. While no published prospective study has found protection against genital human papillomavirus (HPV) infection, two studies reported that condom use was associated with higher rates of regression of cervical intraepithelial neoplasia and clearance of cervical HPV infection in women and with regression of HPV-associated penile lesions in men. Research findings available since the NIH review add considerably to the evidence of the effectiveness of condoms against STIs. Although condoms are not 100% effective, partial protection can substantially reduce the spread of STIs within populations.

Keywords Condoms/utilization; Sexually transmitted diseases/prevention and control; Herpes genitalis/prevention and control; Gonorrhea/prevention and control; Chlamydia infections/prevention and control; Trichomonas vaginitis/prevention and control; Syphilis/prevention and control; Papillomavirus, Human; Prospective studies; Review literature (*source: MeSH, NLM*).

Mots clés Condom/utilisation; Maladies sexuellement transmissibles/prévention et contrôle; Herpès génital/prévention et contrôle; Gonococcie/prévention et contrôle; Chlamydia, Infection/prévention et contrôle; Vaginite trichomonas/prévention et contrôle; Syphilis/prévention et contrôle; Papillomavirus humain; Etude prospective; Revue de la littérature (*source: MeSH, INSERM*).

Palabras clave Condones/utilización; Enfermedades sexualmente transmisibles/ prevención y control; Herpes genital/ prevención y control; Gonorrea/ prevención y control; Infecciones por chlamydia/ prevención y control; Vaginitis por trichomonas/ prevención y control; Sífilis/ prevención y control; Papilomavirus humano; Estudios prospectivos; Literatura de revisión (*fuente: DeCS, BIREME*).

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Voir page 459 le résumé en français. En la página 460 figura un resumen en español.

Introduction

In June 2000, the United States National Institutes of Health (NIH), in collaboration with the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration and the United States Agency for International Development (USAID), convened an expert panel to evaluate peer-reviewed published studies on the effectiveness of latex condoms used by men (male latex condoms) in preventing sexually transmitted infections (STIs) during vaginal intercourse (*1*). The NIH defines condom effectiveness as "the level of protection against STDs (sexually transmitted diseases) when condoms are used consistently and correctly" (*1*).

The review looked at HIV infection, gonorrhoea, chlamydial infection, syphilis, chancroid, trichomoniasis, genital herpes and genital human papillomavirus (HPV) infection. The panel of 28 researchers excluded papers with flawed study designs or methods.

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Based on the results of the remaining prospective studies, the panel reached three key conclusions. First, consistent condom use (i.e., using condoms during every act of vaginal intercourse) among heterosexual couples in which one partner was infected with HIV reduced the risk of HIV transmission from men to women and vice versa. This finding was based on a meta-analysis of condom effectiveness studies by Davis & Weller (*2*). They estimated that compared with no condom use, consistent condom use resulted in an overall 87% reduction in risk of HIV transmission, with the best-case and worst-case scenarios ranging from 60% to 96%. In an update of this analysis, Weller & Davis reported a revised estimate of an 80% reduction in risk with a range of 35–94% (*3*).

Second, the NIH report concluded that consistent condom use may reduce the risk of gonorrhoea in men. This finding was based on a 1978 report by Hooper et al. (*4*), which was a prospective study of the risk of transmission of gonorrhoea to men in the United States Navy from a pool of women with a known prevalence of gonorrhoea. A subsequent reanalysis of those data showed that condoms provided a statistically significant level of protection against the combined outcome of gonorrhoea or nongonococcal urethritis in exposed men (*5*).

Third, due to insufficient evidence from prospective studies, the reviewers were unable to determine the effectiveness of condoms in preventing gonorrhoea and chlamydial infection in women, or in preventing syphilis, chancroid, trichomoniasis, genital herpes or genital HPV inf ection in men or women. The panel strongly cautioned the public against misinterpreting the scanty evidence. The small number of well designed prospective studies precluded the panel from making judgments about the effectiveness of condoms in preventing other STIs; the reviews stated that the lack of data were not to be construed as evidence either supporting or denying the effectiveness of condoms.

As the NIH prepared to release its report in July 2001, other health agencies responded to the pending report (*6*, *7*). For example, the CDC reviewed its treatment guidelines for STIs that were issued in 2000, and in the same month that the NIH released its report, reasserted the protective value of condoms against STIs (*7*). WHO included condom programmes among the essential components of public health packages for preventing and controlling STIs in the most recent edition of the *Guidelines for the management of sexually transmitted infections* (*8*).

Since the NIH review, reports of several additional prospective studies have further addressed the effectiveness of condoms. A literature review by Hearst & Chen (*9*) considered several lines of evidence for the efficacy of condom use and other behavioural changes in preventing the sexual transmission of HIV; it also discussed related issues about HIV prevention programmes.

We examine findings that have become available since June 2000 from prospective studies of the effectiveness of male condoms in preventing STIs and briefly discuss the limitations of these studies and the effectiveness of programmes to promote condom use.

Methods

We searched Medline for articles published in English after June 2000 with the keyword "effectiveness" and the MeSH heading "condom" and with the following three MeSH terms: "condoms", "evaluation studies", and "sexually transmitted diseases". We reviewed the abstracts of the selected studies to identify prospective cohort studies. We also conducted a limited search for randomized controlled trials using the MeSH heading "condom" and the MeSH term "sexually transmitted diseases". In addition, we identified and reviewed other articles, reports and abstracts that we were aware of having been published, presented, or reported after June 2000.

Findings

Point estimates and confidence intervals of prospective studies on the effectiveness of condom use in preventing STIs are presented in Fig. 1. A summary of the design and participants in those studies can be found in Table 1 (web version only, available at: http://www.who.int/bulletin).

Herpes simplex virus type 2

Genital herpes, usually caused by infection with herpes simplex virus type 2 (HSV-2), is a chronic disease found throughout the world; in sub-Saharan Africa, the seroprevalence of HSV-2 is 70% or higher. Genital HSV infection is transmissible even when partners have no active genital symptoms or lesions.

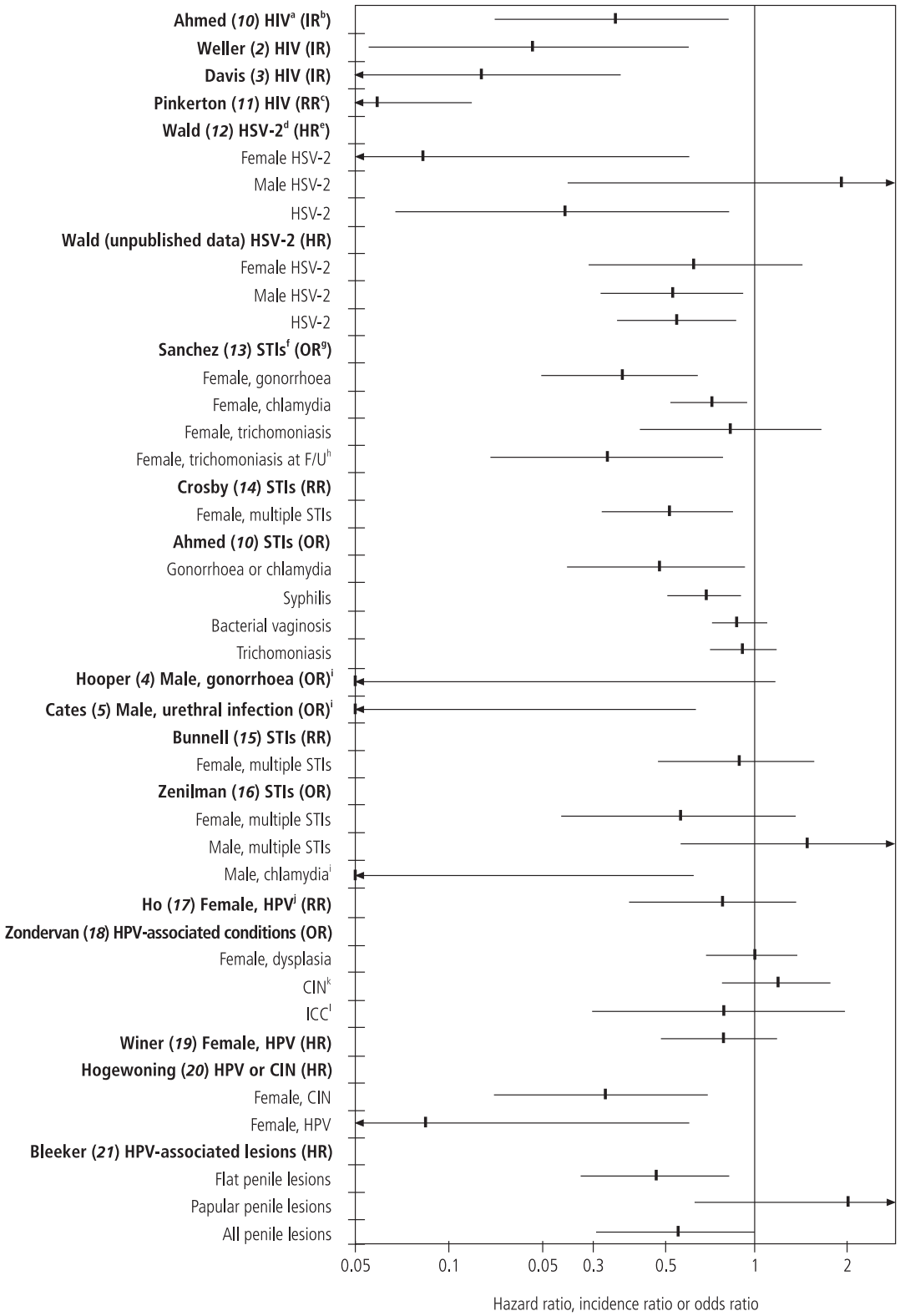
Prospective studies conducted in the United States have shown that condoms partially protect men and women against new infections with HSV-2 (*12*, A. Wald et al., unpublished data presented at the 2002 National STD Prevention Conference in San Diego, CA). In one study (*12*), Wald et al. analysed data from an HSV-2 candidate vaccine trial conducted in the mid-1990s that followed 528 monogamous, HSV-2-discordant couples (one partner was infected with HSV-2, the other was not) for 18 months. The median reported use of condoms was 25% ; it was relatively low because the couples were monogamous. Using condoms during more than 25% of sex acts was associated with a 92% reduction in the risk of women acquiring HSV-2 but was not associated with a protective effect among men.

However, in a separate trial of this candidate vaccine among people with more than three sexual partners or at least one STI in the past year, Wald et al. found that the median reported use of condoms was 65%, and that using condoms during more than 65% of acts of vaginal or rectal penetration provided partial protection for men (A. Wald et al., unpublished data, presented at the 2002 National STD Prevention Conference in San Diego, CA). Nonetheless, HSV-2 infection was acquired, although rarely, even by people who reported using condoms during 100% of sexual activity.

Gonorrhoea, chlamydial infection, trichomoniasis and syphilis

For the first time, Sanchez et al. (*13*) demonstrated the statistically significant effectiveness of condoms in preventing not only gonorrhoea, but also chlamydial infection and trichomoniasis in women. A cohort of 917 female sex workers in Lima, Peru, were re-examined monthly for STIs; they were also given condoms. During the observation period of 7908 person-months, the reported rate of consistent condom use rose by 20%. Compared with all others, those women who reported using condoms consistently since the previous examination had a 62% reduction in the risk of acquiring gonorrhoea and a 26% reduction in the risk of acquiring chlamydial infection. There was also evidence of a significant reduction in the risk of acquiring trichomoniasis.

Fig. 1. **Effectiveness of condoms in preventing of sexually transmitted infections**



[a]HIV = human immunodeficiency virus.
[b]IR= incidence ratio.
[c]RR = relative risk.
[d]HSV-2 = herpes simplex virus type 2.
[e]HR = hazard ratio.
[f]STI = sexually transmitted infection.
[g]OR = odds ratio.
[h]F/U = follow-up.
[i]The ORs for these studies were zero, and the lower boundary of the 97.5% CI was 0.
[j]HPV = human papillomavirus.
[k]CIN = cervical intraepithelial neoplasia.
[l]ICC = invasive cervical cancer.

The bold vertical lines correspond to the point estimates, and the horizontal lines to the 95% confidence intervals.

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Macaluso et al. (unpublished report submitted to the US National Institute of Child Health and Human Development, 2000) found that among women considered to be at high-risk for STIs the consistent and correct use of latex male condoms or female condoms was associated with a statistically significant reduction in the combined incidence of gonorrhoea, chlamydial infection or syphilis in high-risk women when compared to rates of use of less than 50%. This prospective study followed female patients at STD clinics in the United States who had monthly STI tests for six months from 1995 to 1998.

Crosby et al.(*14*) reported that using condoms for 100% of sex acts was associated with a significant reduction in the combined incidence of gonorrhoea, chlamydial infection, or trichomoniasis among adolescent African-American females aged 14–18 years. In this study, the researchers tested for all three STIs and treated girls who were infected at baseline. Six months later, the 380 girls who reported penile–vaginal sex were retested and interviewed about condom use. Of the girls who reported using cond oms each time they had had sex since baseline, 17.8% of them had at least one STI compared with 30% of the girls who did not report using condoms consistently (odds ratio (OR) = 1.85; 95% confidence interval (CI) = 1.13–3.04 after adjusting for STI at baseline and having more than one sex partner in the interim).

Ahmed et al. (*10*) analysed data from a community-based randomized controlled trial of mass treatment for STIs in rural Rakai, Uganda, from 1994 to 1998. HIV prevalence among the study population was 16%; the prevalence of syphilis was 10%, chlamydial infection was 3.1% and gonorrhoea was 1.5%. Of the 17 264 adult participants, only 4.4% reported consistently using condoms in the year prior to the study. During follow-up, for men and women combined, consistent condom use was associated with a significant reduction in the incidence of STIs when compared with the non-use of condoms. There was a significant reduction in the incidence of HIV (relative risk (RR) = 0.37; 95% CI = 0.15–0.88), a significant reduction in syphilis seroprevalence (OR = 0.71; 95% CI = 0.53–0.94) and a significant reduction in the prevalence of gonorrhoea, chlamydial infection, or both (OR = 0.50; 95% CI = 0.25–0.97). The prevalences of trichomoniasis and bacterial vaginosis among women were not reduced.

Human papillomavirus infection

Manhart & Koutsky (*22*) evaluated the effectiveness of condoms in protecting against HPV infection and HPV-related conditions, such as genital warts and cervical cancer. A meta-analysis of 20 studies found no evidence that condoms were effective against genital HPV infection. Neither of the two prospective studies reviewed found that consistent condom use was effective in preventing genital HPV infection or HPV-related conditions. Subsequently, Winer et al. (*19*) followed 444 female students at university as part of a longitudinal study of the cumulative incidence of genital HPV infection. They found that consistently using condoms with a new partner was not associated with significant protection against HPV (hazard ratio (HR) = 0.8; 95% CI = 0.5–1.2). Data on condom breakage or vaginal penetration before condoms were put on were not collected, nor was the analysis adjusted for frequency of intercourse.

Dunne et al. reviewed the methods of 44 studies conducted between 1996 and 2001 that examined condom use, HPV infection, and HPV-related conditions (EF Dunne et al., unpublished data presented at the HPV Clinical Workshop and 20th International Papillomavirus Conference, Paris, 2002). They found that methodological limitations made it difficult to accurately assess condom effectiveness, and they called for studies to consider the consistency and correctness of condom use, incident infections, and the infection status of the partner in the design of studies.

In a unique clinical trial in the Netherlands, Hogewoning et al. (*20*) randomly allocated 135 women not regularly using condoms who had untreated cervical intraepithelial neoplasia (CIN) and their male partners either to use condoms or not use condoms for all instances of vaginal intercourse. Those couples randomized to use condoms had a significantly higher cumulative two-year rate of disease regression (53% versus 35%; HR = 3.1; 95% CI = 1.4–7.1) as well as a higher cumulative two-year rate of HPV clearance (23% versus 4%; HR = 12.1; 95% CI = 1.5–97.2).

Bleeker et al. (*21*) examined the male partners of the women in this study for the presence of penile lesions and for HPV using polymerase chain reaction testing of penile swabs. Consistent condom use over a minimum period of three months was associated with a reduction in the median time until clinical regression of all penile lesions (HR for regression = 1.8; 95% CI = 1.0–3.3; $P = 0.05$ by Cox regression analysis). Interpreting the findings of these two studies is not simple (*20*, *21*). The authors suggest that transmission of HPV back and forth between partners during unprotected sex may prolong the duration of HPV infection, CIN, and penile lesions.

Discussion

This review of prospective studies published since June 2000 has identified evidence that consistent condom use is associated not only with reduced transmission of HIV and with reduced acquisition of urethral infection among men, but also with:

- reduced acquisition of genital HSV-2 infection by men and women;
- reduced acquisition of syphilis by men and women;
- reduced acquisition of chlamydial infection by men and women;
- reduced acquisition of gonorrhoea by women
- possibly reduced acquisition of trichomoniasis infection by women;
- accelerated regression of cervical and penile HPV-associated lesions and accelerated clearance of genital HPV infection by women.

Limitations of studies

Only in prospective studies can the temporal relationship between STIs and condom use be explored. Because many prospective studies have now shown that condom use reduces the transmission of HIV and several other STIs, randomized trials with a high-risk control group that doesn't use condoms have been viewed as unwarranted. Although many studies have randomly allocated people or samples to various prevention interventions that included the enhanced promotion of condom use, we believe the two studies of couples with HPV-related conditions (*20*, *21*) are the only trials in which participants were randomly allocated to condom use or no condom use. The study was strengthened by randomization of couples rather than individuals, randomization to consistent condom use compared with no condom use, and by measurement of outcomes in male and female partners simultaneously.

Two methodological issues in observational studies of condom effectiveness are of particular concern: (1) underestimation of point estimates, and (2) exposure to infected partners.

Underestimates of condom effectiveness could result from over-reporting of condom use by participants in order to satisfy the interviewer (known as social desirability bias). Devine & Aral (*23*) conducted simulation experiments to illustrate that over-reporting of condom use reduced both the point estimate of condom effectiveness and the power of the study to detect a protective effect of condom use.

Studies that do not adjust for the improper use of condoms could also underestimate the effectiveness of proper use. (*24*) For example, in a retrospective study in the United States among 98 male university students selected because they had used condoms during vaginal intercourse at least five or more times, and at least once during the previous month, Warner et al. (*24*) found that in 13% of 270 instances, condoms broke or were used incorrectly; this allowed for direct penile–vaginal contact, and consequently, exposure to STIs.

Restricting condom effectiveness analyses to participants with known exposure to infected partners reduces confounding and provides a more accurate measurement of the protective effects of condoms against STIs. In a cross-sectional analysis of baseline data from Project RESPECT, Warner et al. (*25*) compared estimates of the effectiveness of condoms in a subsample of people with known exposure (they were referred to the clinic because their partner had gonorrhoea or chlamydial infection) with estimates in a subsample of people who visited the clinic for other reasons. Among the 429 participants with known exposure, the consistent use of condoms was associated with a significant reduction in those STIs (OR = 0.42; 95% CI = 0.18–0.99). Among the 4314 participants for whom exposure information was not known, the consistent use of condoms was less effective (OR = 0.82; 95% CI = 0.66–1.01).

Fitch et al. (*26*) note the importance of differentiating between effectiveness in single-episode use and "period effectiveness". The latter measure takes into account user error, condom failure, the variable infectiousness of particular STIs, and the impact of repeated exposure. Also, it has proven far more feasible to promote condom use during occasional acts of commercial or casual sex than to introduce and sustain consistent condom use during repeated acts of intercourse over years among stable couples (*9*).

Crosby et al. (*27*) identified several potential problems and solutions in condom effectiveness studies.

- An infection-free cohort should be established at baseline through testing and treatment of nonviral STIs.
- It is essential to have sample sizes that are adequate to detect a significant impact of condom use.
- Using the number of unprotected sex acts is preferable to calculating the percentage of times that a condom is used, as the latter does not account for variation in frequency of intercourse.

In view of these issues, it seems remarkable that data from longitudinal studies and the one randomized trial as well as several cross-sectional or case–control studies have nonetheless demonstrated the statistically significant effectiveness of condoms in protecting against HIV and most of the other STIs examined.

Not all earlier prospective observational studies found that consistent condom use was associated with a decreased risk of STIs. For example, Bunnell et al. (*15*) followed 484 adolescents at four clinics over a six-month period and found an incident STI in 21% of 61 participants reporting 100% condom use and in 23% of 423 adolescents reporting inconsistent use or no condom use. Zenilman et al. (*16*) prospectively studied condom use among 598 male and female patients at an STD clinic in Baltimore, Maryland. During follow-up STI incidence was similar for participants reporting 100% condom use and for those reporting that they never used condoms; this was found for both male and female patients. However, when specific STI incidence was examined rather than combined STI incidence, consistent condom use (as compared with sometime use or never use) was associated with a significantly lower rate of chlamydial infection in men (*1*, *16*).

Recommendations for further research

Future research using improved methods for ascertaining the consistency, correctness, and selectivity of condom use may lead to better point estimates of effectiveness. In future trials the accurate assessment of condom use will help delineate the causal pathway linkage of the effectiveness of STI prevention methods that do or do not include the promotion of condom use (*28*).

The general quality of research on condom effectiveness in preventing HIV and other STIs can be readily improved by routinely collecting the partner-specific data in relation to testing for current STIs or incident HIV infection. Questions that should be asked include:

- How many times did you have sex with a particular partner during the past month? How many times were condoms not used with that partner during the past month?
- How many times in the past month were condoms put on after the start of intercourse? How many times were condoms removed before stopping intercourse? How many times did condoms slip off or break before intercourse ended?
- How many times has a particular partner had an STI in the past month? What type(s) of STI(s)?
- Has that particular partner had other partners during the past month?

Condom use is typically more common with partners perceived as likely to be infected than with those not perceived as likely to be infected. Collecting similar data for the past three-month period or longer would also be useful, depending on which STI is being studied. Such information would contribute to research on condom effectiveness and would strengthen monitoring and evaluation processes.

The effectiveness of condom-promotion programmes

The question remains whether programmes designed to increase the frequency of condom use actually achieve increased use and whether they decrease the individual's risk of acquiring HIV and other STIs. Many studies have shown that condom-promotion interventions decrease self-reports of unprotected sex, but fewer have examined the impact of such programmes on the actual incidence of STIs, including HIV infection. Fewer still have done so in randomized controlled trials in which participants were followed prospectively and specifically offered STI testing. Four individual-level or group-level randomized controlled trials that have included condom promotion have reported a reduced risk of STIs (*29–31*) (CB Boyer et al., unpublished data presented at the 15th Biennial Congress of the International Society for Sexually Transmitted Diseases Research, Ottawa, 2003).

Project RESPECT, a multisite, individual-level randomized controlled trial involving 5700 heterosexual, HIV-negative patients at public STI clinics in the United States found that interactive, client-centred HIV and STI risk reduction counselling that emphasized avoiding unprotected sex resulted in more frequent reports of 100% condom use and a statistically significant 20% lower incidence of STIs over 12 months of follow-up when compared with counselling that used only didactic prevention messages (*29*).

In a group-level -randomized trial, Shain et al. (*30*) found that enhanced counselling, which included three intensive, small-group sessions for female Hispanic and African-American patients at an STI clinic resulted in a lower incidence of gonorrhoea and chlamydial infection over the following year when compared with standard counselling. The sessions were based on ethnographic research; the sessions for Hispanic women were similar to those for African-American women, but there were some differences in emphasis. The effect of the intervention appeared to be mediated by a number of behavioural changes including increased condom use (*32*). Two other group-level randomized trials involving women also showed efficacy in preventing STIs (*31*, CB Boyer et al. unpublished data).

A randomized trial of voluntary HIV testing and counselling in Kenya, the United Republic of Tanzania and Trinidad between 1995 and 1998 (*33*), which was modelled on the Project RESPECT intervention, compared client-centred counselling with giving health information alone. It found there was a decrease in the incidence of unprotected intercourse with non-regular partners among those who had counselling. There was also a reduction of about 20% in new STIs which was similar to that seen in Project RESPECT but not statistically significant in this underpowered study.

In a field trial in Thailand involving nonrandomized but comparable groups of army conscripts, Celentano et al. (*34*) found that groups participating in a multicomponent HIV and STI prevention intervention that lasted for several months and contained a condom promotion component had 80% fewer incident STIs when compared with the control groups.

Finally, a London-based group-randomized trial of a one-day cognitive behavioural intervention designed to reduce STI incidence among men who have sex with men had different results (*35*). The intervention group reported a modest decrease in the incidence of unprotected anal intercourse but actually experienced a significantly increased risk of new STIs in comparison with the control group. This study illustrates the importance of measuring objective STI outcomes rather than relying only on self-reported changes in behaviour.

Thus, as with prospective studies of condom efficacy, not all harm-reduction interventions that include condom promotion have succeeded in reducing STI morbidity. Success undoubtedly depends on the intervention and the context, among other factors. Nonetheless, adequately powered studies (i.e., those having large enough sample sizes) that examined heterosexual populations have consistently shown a significant impact on subsequent STI outcomes when such outcomes have been measured.

Conclusions

Since 2000 important new evidence (from prospective observational studies, one couple-randomized trial and additional multicomponent STI prevention trials that included condom-promotion components) has come to light to support the effectiveness of condoms in preventing STIs in men and women. In no study has the effectiveness been 100%. Nonetheless, even partially effective interventions can have a major impact on controlling the spread of STIs in the population (*36*). Balanced STI and HIV prevention programmes should include condom promotion along with a complementary combination of prevention strategies targeted towards different age groups, life stages, epidemic levels, and settings (*37*, *38*). Condom promotion represents an important component of comprehensive HIV-prevention and STI-prevention strategies. ■

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Résumé

Efficacité du préservatif pour la prévention des infections sexuellement transmissibles

En juin 2000, les National Institutes of Health (NIH) des Etats-Unis d'Amérique ont organisé une revue des preuves scientifiques de l'efficacité du préservatif pour la prévention des infections sexuellement transmissibles (IST). Cet examen a permis de conclure que le préservatif était efficace pour la prévention de la transmission du VIH chez l'homme comme chez la femme et pour réduire le risque d'infection gonococcique chez l'homme. Les preuves de son efficacité pour la prévention des autres IST ont été jugées insuffisantes. Nous avons examiné les résultats d'études prospectives publiées après juin 2000 et portant sur l'efficacité des préservatifs pour la prévention des IST. Nous avons recherché sur Medline les publications en anglais et y avons ajouté d'autres articles, rapports et sommaires dont nous avions connaissance. Ces études prospectives publiées depuis juin 2000 montrent que l'utilisation du préservatif est associée à une protection statistiquement significative, chez l'homme comme chez la femme, contre plusieurs autres types d'IST, dont les infections à Chlamydia, les gonococcies, les infections par le virus de l'herpès humain type 2 et la syphilis. Elle peut également être associée à une protection contre la trichomonase chez la

femme. Bien qu'aucune étude prospective publiée n'ait montré de protection contre l'infection génitale par le papillomavirus humain (PVH), deux études ont rapporté un taux plus élevé de régression des néoplasies intraépithéliales du col de l'utérus et de disparition des infections cervicales par le PVH chez la femme en cas d'utilisation du préservatif, et une régression des lésions du pénis associées au PVH chez l'homme. Les résultats des travaux effectués depuis la revue des NIH ajoutent considérablement aux preuves de l'efficacité du préservatif contre les IST. Bien que les préservatifs ne soient pas efficaces à 100 %, la protection partielle qu'ils confèrent peut réduire sensiblement la propagation des IST dans les populations.

Resumen

Eficacia del preservativo como medio de prevención de las infecciones de transmisión sexual

En junio de 2000, los Institutos Nacionales de Salud (NIH) de los Estados Unidos organizaron una revisión de la evidencia científica disponible sobre la eficacia de los preservativos como medio de prevención de las infecciones de transmisión sexual (ITS). El estudio concluyó que los preservativos protegían eficazmente contra el VIH a hombres y mujeres y reducían el riesgo de que los hombres contrajeran gonorrea. No obstante, se consideró insuficiente la evidencia sobre la eficacia del preservativo como medio de prevención de otras ITS. Hemos examinado aquí los resultados de estudios prospectivos publicados con posterioridad a junio de 2000 en los que se evaluó la eficacia de los preservativos como método de prevención de las ITS. Buscamos en MEDLINE publicaciones en inglés, y añadimos otros artículos, informes y resúmenes que conocíamos. Estos estudios prospectivos, publicados después de junio de 2000, revelan que el uso de preservativos se asocia a una protección estadísticamente significativa de hombres y mujeres frente a otros varios tipos de ITS, incluidas las infecciones por clamidias, la gonorrea, el virus herpes simple tipo 2 y la sífilis. Los preservativos también pueden proteger a las mujeres contra la tricomoniasis. Si bien ninguno de los estudios prospectivos publicados ha revelado un efecto de protección contra la infección por el papilomavirus humano (VPH), en dos estudios se observó que el uso del preservativo se asociaba a mayores tasas de regresión de las neoplasias intraepiteliales cervicouterinas y de desaparición de la infección cervicouterina por VPH en las mujeres, así como de regresión de las lesiones de pene por VPH en los hombres. Los resultados de investigación aparecidos después de la revisión de los NIH refuerzan considerablemente la evidencia acumulada sobre la eficacia de los preservativos contra las ITS. Aunque los preservativos no son eficaces al 100%, la protección parcial conseguida puede reducir sustancialmente la propagación de las ITS en las poblaciones.

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Table 1. **Summary of prospective studies on effectiveness of condom use in preventing sexually transmitted diseases published or presented since June 2000 compared with studies cited in National Institutes of Health review** (*1*)

Study	Design	Participants	Definition of condom use	Notes on estimates
HIV[a] studies				
Ahmed et al. 2001 (*10*)	Community-based randomized trial of mass treatment for STIs in rural Rakai, Uganda, with follow-up every 10 months for 30 months	9536 women and 7728 men aged 15–59 years in 56 communities	Consistent condom use versus never use	Poisson regression model with covariates for demographic characteristics and behavioural risk
Weller & Davis 2004 (*3*)	Meta-analysis of condom effectiveness in reducing heterosexual transmission based on studies in several countries	14 longitudinal studies of serodiscordant couples	Consistent condom use versus never use	Point estimate is the IRR[f] of always-users in 13 studies to never-users in 5 studies that were the largest homogeneous group of studies. Range of estimates is best-case and worst-case scenarios rather than CI[g]s
HIV studies cited in NIH report (*1*)				
Davis & Weller 1999 (*2*)	As Weller & Davis (*3*) above	25 studies of serodiscordant couples, including 13 cross-sectional studies and 12 longitudinal studies	As Weller & Davis above	Point estimate is the IRR[h] of always-users in 12 longitudinal studies to never-users in 7 longitudinal studies that specified direction of transmission. Range of estimates is best-case and worst-case scenarios rather than CIs
Pinkerton and Abramson (*11*)	As Weller & Davis (*3*) above	9 studies of serodiscordant couples	Consistent condom use versus inconsistent use or no use	Point estimate is RR for always-users to inconsistent-users or non-users for all 9 studies
HSV-2[b] studies				
Wald et al. 2001 (*12*)	Randomized, double-blind, placebo-controlled trial of candidate HSV-2 vaccine in USA with 11 follow-up visits over 18 months	528 monogamous couples serodiscordant for HSV-2, including 267 couples with seronegative women and 261 couples with seronegative men	Condom use in more than 25% of sexual acts between follow-up visits	Estimates adjust for covariates
Wald et al., unpublished data, 2002	Candidate HSV-2 vaccine trial in USA with 18 months of follow-up	1862 HSV-2 susceptible people with $\geqslant$ 4 sexual partners or $\geqslant$ 1 STD in the past year	Condom use in more than 65% of sexual acts	Complete data not yet published
Bacterial and parasitic STIs				
Sanchez et al. 2003 (*13*)	Prospective study of condom promotion and improved STI services at two clinics in Lima, Peru, with monthly follow-up for 6 months	917 female sex workers who attended the clinics	Participants who always used condoms with clients during the previous month versus all others	GEE[i] model. Covariates differ across infections Published OR[j] and *P*-values were used to derive 95% CI. For gonorrhoea, the *P*-value (<0.001) was not exact, so the actual CI is shorter than the one reported in Fig.1
Macaluso et al., unpublished data, 2000	Prospective study of a behavioural intervention to promote use of the female condom in USA with follow-up every 4 weeks for 6 months	920 females who attended public STI clinics	Consistent use of male condoms or female condoms between follow-up visits with no problems reported versus condom use in $\leqslant$ 50 % of sex acts	Outcome was incidence of gonorrhoea, chlamydial infection, or syphilis. Complete data not yet published

(Table 1, cont.)

Study	Design	Participants	Definition of condom use	Notes on estimates
Crosby et al. 2003 (*14*)	Randomized controlled trial of an HIV prevention programme in USA with follow-up visit after 6 months	380 sexually active African-American females aged 14–18 years recruited from medical clinics and high schools	Consistent condom use versus non-consistent use	Outcome was incidence of gonorrhoea, chlamydial infection, or trichomoniasis. Estimates adjusted for covariates. The OR presented in Fig. 1 is the inverse of the results reported in Crosby et al. (*14*)
Ahmed et al. 2001 (*10*)	See entry under HIV above	See entry under HIV above	See entry under HIV above	GEE model adjusted for covariates
Bacterial and parasitic STIs cited in NIH report (*1*)				
Hooper et al. 1978 (*4*)	Prospective cohort study to estimate the risk of transmission of gonorrhoea from infected females to males at a port in the western Pacific	527 male American sailors who had sexual relations with commercial sex workers during a four-day shore leave	Condom use sometimes or always versus non-use	Published data and *P*-value were used to derive a CI for the OR based on an exact procedure
Cates & Holmes 1996 (*5*)	Reanalysis of Hooper et al.'s 1978 data that estimated the risk of acquisition of gonorrhoea or nongonococcal urethritis	As in Hooper et al. (4) above	As in Hooper et al. above	Published data and *P*-value were used to derive a CI for the OR based on an exact procedure
Bunnell et al. 1999 (*15*)	Prospective cohort study to assess the prevalence and incidence of STIs among adolescents in USA with one follow-up visit after 6 months	484 sexually active African-American females aged 14–19 years recruited from four health clinics	Consistent condom use reported at both baseline and follow-up (i.e. always used condom for birth control and with main partner) versus all others	Outcome was incident STIs, including gonorrhoea, chlamydial infection, trichomoniasis, syphilis, hepatitis B, and HSV-2. Estimates adjusted for covariates
Zenilman et al. 1995 (*16*)	Prospective cohort study to validate self-reported condom use in USA with one follow-up visit after 3 months	275 female patients and 323 male patients at two public STI clinics	Consistent condom use in 30 days before follow-up visit versus never use	Outcome was incident gonorrhoea, chlamydial infection, syphilis, or trichomoniasis. Estimates adjusted for covariates
HPV[c] studies				
Manhart & Koutsky 2002 (*22*)	Meta-analysis of condom effectiveness in preventing HPV or HPV-related conditions (genital warts, CIN[d], ICC[e]) in studies in several countries	20 studies, of which only two were prospective: Ho et al. 1998 (*17*) and Zondervan et al. 1996 (*18*). These are included in Fig. 1	Ho: Consistent use versus never use	Ho: Outcome was cervical HPV DNA. Investigators provided additional data for meta-analysis. Estimates adjusted for covariates
			Zondervan: Ever use condoms for family planning versus never use	Zondervan: Outcomes were dysplasia (which probably refers to mild SIL), carcinoma in situ (which refers to CIN) and ICC. Estimates adjusted for covariates
Winer et al. 2003 (*19*)	Prospective study to estimate cumulative incidence of HPV in USA with follow-up every 4 months for 3 years	444 female university students aged 18–20 years who tested negative for HPV DNA at baseline	Condom use always with new partners versus never use with new partners	Estimates adjusted for covariates

(Table 1, cont.)

Study	Design	Participants	Definition of condom use	Notes on estimates
Hogewoning et al. 2003 (*20*)	Randomized clinical trial of condom effectiveness in the Netherlands with follow-up at 3, 6, 12, 18 and 24 months	135 women with CIN who were not using condoms for birth control at baseline were randomly allocated. Outcomes were assessed for 125 women	Assigned to use condoms or not to use them	Outcomes were clinical regression of CIN and clearance of HPV. Estimates adjusted for covariates. Published HR[k] of the probability of healing was inverted to show the effect of condoms in reducing the probability of not healing
Bleeker et al. 2003 (*21*)	As Hogewoning et al. (*20*) above	100 men who were partners of the women in Hogewoning et al. and who had penile lesions were assessed for outcomes	As Hogewoning et al. above	Estimates adjusted for covariates. Published HR of the probability of regression was inverted to show the effect of condoms in reducing the probability of not regressing

[a] HIV = human immunodeficiency virus; STIs = sexually transmitted infections.
[b] HSV-2 = herpes simplex virus type 2.
[c] HPV = human papillomavirus.
[d] CIN = cervical intraepithelial neoplasia.
[e] ICC = invasive cervical cancer.
[f] IRR = incidence rate ratio.
[g] CI = confidence interval.
[h] RR = relative risk.
[i] GEE = generalized estimating equation.
[j] OR = odds ratio.
[k] HR = hazard ratio.