Condom effectiveness in reducing heterosexual HIV transmission (Review)

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Status: *Commented*

This record should be cited as:
Weller SC, Davis-Beaty K. Condom effectiveness in reducing heterosexual HIV transmission. *Cochrane Database of Systematic Reviews* 2002, Issue 1. Art. No.: CD003255. DOI: 10.1002/14651858.CD003255.

This version first published online: 21 January 2002 in Issue 1, 2002.
Date of most recent substantive amendment: 19 November 2001

ABSTRACT

Background
The amount of protection that condoms provide for HIV and other sexually transmitted infections is unknown. Cohort studies of sexually active HIV serodiscordant couples with follow-up of the seronegative partner, provide a situation in which a seronegative partner has known exposure to the disease and disease incidence can be estimated. When some individuals use condoms and some do not, namely some individuals use condoms 100% of the time and some never use (0%) condoms, condom effectiveness can be estimated by comparing the two incidence rates. Condom effectiveness is the proportionate reduction in disease due to the use of condoms.

Objectives
The objective of this review is to estimate condom effectiveness in reducing heterosexual transmission of HIV.

Search strategy
Studies were located using electronic databases (AIDSLINE, CINAHL, Embase, and MEDLINE) and handsearched reference lists.

Selection criteria
For inclusion, studies had to have: (1) data concerning sexually active HIV serodiscordant heterosexual couples, (2) a longitudinal study design, (3) HIV status determined by serology, and (4) contain condom usage information on a cohort of always (100%) or never (0%) condom users.

Data collection and analysis
Studies identified through the above search strategy that met the inclusion criteria were reviewed for inclusion in the analysis. Sample sizes, number of seroconversions, and the person-years of disease-free exposure time were recorded for each cohort. If available, the direction of transmission in the cohort (male-to-female, female-to-male), date of study enrollment, source of infection in the index case, and the presence of other STDs was recorded. Duplicate reports on the same cohort and studies with incomplete or nonsepecific information were excluded. HIV incidence was estimated from the cohorts of "always" users and for the cohorts of "never" users. Effectiveness was estimated from these two incidence estimates.

Main results
Of the 4709 references that were initially identified, 14 were included in the final analysis. There were 13 cohorts of "always" users that yielded an homogeneous HIV incidence estimate of 1.14 [95% C.I.: .56, 2.04] per 100 person-years. There were 10 cohorts of "never" users that appeared to be heterogeneous. The studies with the longest follow-up time, consisting mainly of studies of partners of hemophiliac and transfusion patients, yielded an HIV incidence estimate of 5.75 [95% C.I.: 3.16, 9.66] per 100 person-years. Overall effectiveness, the proportionate reduction in HIV seroconversion with condom use, is approximately 80%.

Authors' conclusions

This review indicates that consistent use of condoms results in 80% reduction in HIV incidence. Consistent use is defined as using a condom for all acts of penetrative vaginal intercourse. Because the studies used in this review did not report on the "correctness" of use, namely whether condoms were used correctly and perfectly for each and every act of intercourse, effectiveness and not efficacy is estimated. Also, this estimate refers in general to the male condom and not specifically to the latex condom, since studies also tended not to specify the type of condom that was used. Thus, condom effectiveness is similar to, although lower than, that for contraception.

PLAIN LANGUAGE SUMMARY

Using condoms consistently reduces sexual transmission of HIV infection

Sexual intercourse and contact with contaminated blood products (e.g., intravenous drug use) account for the majority of HIV infections. The wearing of condoms during sexual intercourse has been promoted to reduce the infection and spread of sexually transmitted infections (STIs) such as HIV. The review of studies found that condoms, when used consistently, substantially reduced HIV infection but did not totally eliminate the risk of infection.

BACKGROUND

Heterosexual intercourse is the primary mode of HIV infection worldwide. In the U.S., male homosexual contact and intravenous drug use account for the majority of HIV infections, but transmission via heterosexual contact continues to increase. New treatments appear promising for retarding the progression of HIV-related disease, but prevention remains the most effective weapon against the growing epidemic. Recommendations for the prevention of sexually transmitted HIV include abstinence, long-term monogamy with a seronegative partner, a limited number of lifetime sexual partners, and condom use for each and every act of intercourse (CDC 1988). The use of condoms is recommended for individuals who have multiple partners, who have a primary partner who is infected, or whose partner's serostatus is unknown (CDC 1988; Surgeon General 1993; CDC 1993).

However, the amount of protection condoms provide against HIV and other sexually transmitted infections (STIs) is unknown. Design complexities and ethical considerations make it difficult to study condom effectiveness for STIs. In order to estimate efficacy, infection-free people must be sexually exposed to infection, while some use a condom and some do not. Ideally, individuals should be assigned to use or not use a condom at random (randomized controlled trial). Because it is unethical to expose someone to a possibly serious disease (especially if the disease is uncurable) or to withhold treatment from someone with a treatable disease, studies that might provide clear evidence about efficacy are not possible. Instead, condom efficacy must be estimated from observational studies, where individuals happen to be exposed to infection and happen to use or not use condoms. It is in these naturally occuring, although unfortunate, "experiments" that we are able to obtain information on condom effectiveness for prevention of STIs. In fact, HIV offers an unique opportunity to study condom effectiveness, since it can be sexually transmitted, has no cure, and infection can be confirmed by serology.

Effectiveness of condoms as a contraceptive provides insight into their usefulness as a barrier device capable of preventing HIV transmission. Contraceptive effectiveness is defined as the proportionate reduction in pregnancies caused by use of a contraceptive method. It is estimated as one minus the ratio of the pregnancy rate with a contraceptive method to the rate without any method for a given time period (Trussel personal). The probabilities of contraception with (Vaughan 1981; Schirm 1982; Grady 1986; Glass 1974; Jones 1992; Hatcher 1998) and without (Trussell 1987) condom usage can be transformed into rates (Trussel personal) and provide an estimate of condom effectiveness for preventing pregnancy of 90.7% to 98.6%.

Effectiveness of condoms in reducing HIV transmission may be estimated in the same way as for contraception. For HIV, the proportionate reduction in HIV due to condom usage is calculated from the seroconversion rate (HIV incidence) among couples always using condoms and the rate (HIV incidence) among couples never using condoms. A comparison group of condom nonusers is essential to determine the reduction in HIV incidence that is due to condom use. Since HIV serodiscordant couples cannot ethically be assigned at random to condom user groups, estimates must be obtained from observational studies. The best measure of condom effectiveness is obtained from a comparison of serodiscordant, always- and never- condom users having penetrative sexual intercourse. When one partner is HIV positive and the other is not (serodiscordant) and they are sexually active, it ensures that the HIV negative partner is exposed to HIV. In order to identify the source of exposure and to link the source of exposure to transmission, the sexual relationship should be of some duration and preferably be monogamous. The seronegative partner should not

have any nonsexual HIV risk factors, such as contact with contaminated blood products or injection drug use (IDU).

The lack of random assignment of individuals to use or not use condoms can result in an unequal distribution of HIV risk factors across those categories and can bias estimates of condom effectiveness. Factors associated with both seroconversion and condom use can bias estimates of condom effectiveness. Differences between "always" and "never" users in duration and frequency of exposure or in infectivity and susceptibility can bias estimates. Because condom use is associated with HIV risk factors, the association between condom use and seroconversion is biased by the self-selection of individuals into the always and never condom usage groups. Notably, condom non-users in recent studies may be more likely to be IDUs (Padian 1997) and may be more likely to engage in other risky behaviors (Skurnick 1998; Kennedy 1993; Pinkerton 1995; Ross 1988). Higher HIV transmission among partners of IDUs (Padian 1997) and a preponderance of partners of IDU index cases among condom nonusers, can inflate incidence estimates for condom nonusers and result in an overestimation of condom effectiveness.

Condom failure can occur because of user failure and/or because of method/device failure. User failure includes incorrect condom usage and other user factors that result in high rates of breakage and slippage. Method failure is the theoretical failure rate of the device, apart from user failure. Method failure is assumed to be constant, although condoms may vary in quality and thus vary in breakage, slippage, and leakage rates. Since method and user failure are inextricably confounded, a study of condom efficacy would attempt to minimize user failure to the extent possible: participants would receive instruction on proper condom use and would be interviewed about if and how condoms were used. Similarly, causes of method failure not related to the outcome (HIV) also would be controlled: all particpants would receive high quality condoms of the same material and the date and quality testing results would be reported by the investigators. Without these guarantees, what is estimated in a study of serodiscordant couples is condom effectiveness and not condom efficacy (e.g., how they perform under good, but not necessarily optimally controlled conditions of use).

Various estimates of condom effectiveness for reducing heterosexual transmission of HIV are available from studies of serodiscordant couples. This review provides a quantitative summary of those studies. An initial meta-analysis (Weller 1993) estimated effectiveness at 69%, but was flawed by aggregation across studies with various definitions of condom use, directions of transmission, study designs, and types of index cases. A subsequent attempt (Pinkerton 1997), controlling for the direction of transmission, estimated effectiveness at 94%, but was also flawed in that the "sometimes" or "occasional" condom users were included with "never" users and the analysis also did not control for study design. A new meta-analysis by Davis and Weller (Davis 1999) estimated condom effectiveness to be approximately 87% and is based upon longitudinal studies of always and never condom users. Davis and Weller also examined seroconversion rates by study date, direction of transmission, and source of infection in the index case. This study re-examines available evidence regarding condom effectiveness for reducing heterosexual transmission of HIV.

OBJECTIVES

The purpose of this review was to estimate condom effectiveness in reducing heterosexual transmission of HIV, based upon available studies of serodiscordant heterosexual couples.

CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

Types of studies

Estimates of HIV incidence for "always" and "never" condom user groups, must be obtained from cohort or longitudinal studies of serodiscordant couples. HIV serology data must be available for two or more points in time: individuals must have demonstrated seronegativity (HIV-) at the beginning of a time period and then must be tested again to determine if seroconversion has occurred. Since incidence is needed to calculate effectiveness, only longitudinal or cohort studies were eligible for inclusion.

Types of participants

Studies of HIV serodiscordant, sexually active heterosexual couples were eligible. Data collection focused on seronegative sexual partners of HIV positive index cases to ensure HIV exposure. Partners had to be seronegative at the beginning of the observation period and be engaging in penetrative sexual intercourse with the HIV positive index case. Studies focusing on commercial sex workers were not considered because of the uncertainty of HIV exposure. (If a commercial sex worker used a condom and was not infected with HIV, it is not clear if the condom provided protection or if the individual was not exposed to HIV.) Sexual relationships of some duration and monogamy between partners clarifies the link between the source of exposure and possible infection. Most studies meeting these latter criteria concern heterosexuals. Thus, this review focused only on serodiscordant heterosexual partner studies. To ensure only sexual exposure, seronegative partners could not have any nonsexual HIV risk factors (IDU or receipt of unscreened blood products).

Types of intervention

To evaluate condom effectiveness, study groups were defined by their reported condom usage. The only available measure of condom use is by self-report, and comparisons of the responses of partners show these data to be reliable (Padian 1990, de Boer 1998). Condom usage was divided into always, sometimes, and never usage groups. Always-use indicates that a condom was used for

100% of vaginal penetrative intercourse acts. Never-use indicates that condoms were not used during any vaginal penetrative acts (0%). Sometimes-use includes all intermediate estimates of usage (1-99%) and combinations of never and sometimes (0-99%) or always and sometimes (1-100%). Since the best measure of condom effectiveness is obtained from a comparison of always- and never- condom users, only the "always" and "never" usage groups were used in this review.

Types of outcome measures

The outcome measures were HIV incidence among always condom users and HIV incidence among never condom users. HIV status was determined by serology and not self-report. HIV incidence was calculated from the number of individuals who seroconverted and the person-years of disease-free exposure time. Thus, the following information was obtained for the seronegative partners in each study: the number of seroconversions and the person-years of disease-free exposure time for those who always used a condom; and the number of seroconversions and the person-years of disease-free exposure time for those who never used a condom. Person-years of disease-free exposure time was calculated from the number of seronegative partners in a condom use group times the average length of disease-free exposure time.

SEARCH METHODS FOR IDENTIFICATION OF STUDIES

See: methods used in reviews.

This review examined in vivo evidence of condom effectiveness in reducing heterosexually transmitted HIV. For this review, broad search strategies (Appendix A) were developed to identify studies in electronic databases and handsearched reference lists. Abstracts for meetings (unpublished, non-peer-reviewed data) and international journals were included. The following electronic databases were used:
AIDSLINE (1980- June 2000)
CINAHL (1982- March 2000)
Embase (1974- June 2000)
MEDLINE (1966- July Week 4 2000).

METHODS OF THE REVIEW

Inclusion Criteria. Studies had to meet four criteria for inclusion: (1) examination of sexual transmission of HIV among serodiscordant heterosexual couples having penetrative sexual intercourse, (2) longitudinal study design, (3) HIV status determined by serology, and (4) report on condom usage for "always" and/or "never" condom users.

Data Collection. This review examined in vivo evidence of condom effectiveness in reducing heterosexually transmitted HIV. Peer-review articles, letters to the editor, handsearched reference lists, and other sources available in June 2000 were located using computerized databases (MEDLINE, AIDSLINE, Embase, and CINAHL). Sources included abstracts and international journals.

Criteria for Assessing the Quality of Studies. Information regarding condom usage, HIV seroconversion and disease-free exposure time, and possible confounding variables were recorded from published descriptions of each study. Because observational studies may be biased by an unequal distribution of HIV risk factors across study categories, the following variables were recorded when available: direction of transmission (male-to-female or female-to-male), date of study and subject enrollment, source of infection in the index case (IDU, blood product recipient, bisexual, heterosexual), level of infectivity in the index case, type of condom used (latex or other type), the presence or history of another STI in the partner, circumcision in male partners, subtype of HIV, estimates of frequency of sexual intercourse, length of sexual relationship, age, and country (See data collection form in Appendix B). Quality of studies was estimated by the detail and specificity in available data. Specifically, studies that provided actual person-years of disease-free exposure time were assumed to provide a better estimate of disease-free exposure time than those studies that only provided the average length of follow-up time. (Incidence would be underestimated if average follow-up time included disease-free and diseased periods of time.) Also, clear information on condom usage (what was asked and how responses were coded into usage categories) allows for data to be incorporated into the proper categories for analysis. Two people read, coded, and reached consensus about each report. In addition, letters were sent to the senior author of each study with a request to verify the classification of the condom usage data.

Methods of Analysis. Effectiveness was estimated from the HIV incidence among always users and the incidence among never users. Incidence was estimated from the number of seroconversions and the person-years of exposure. Effectiveness could be calculated for studies with both never (0%) and always (100%) condom users and then combined across studies. However, there are few longitudinal studies that contain both categories of users and such studies still would need to control for an unequal proportion of different kinds of index cases (like IDUs) in the two groups. Thus in this review, incidence was estimated separately for the always and never users from the total number of seroconversions divided by the total person-years of exposure across studies. Then, effectiveness was estimated from the two separate incidence estimates: one minus the ratio of incidence among always users to the incidence among never users.

Because aggregations are most reliable when made across homogeneous sample estimates, a chi-square test was used to test for homogeneity across studies in the cumulative proportions of partners who had seroconverted and to check for trends across time. Specifically, the following subgroups were checked

for homogeneity in the cumulative proportion of seroconversions: direction of transmission (M+F-, F+M-) and source of infection in the index case. Possible time trends by study enrollment and publication dates were also checked. Although the chi square test for homogeneity is not very powerful for these comparisons, it can nevertheless serve as a general indicator of the degree of heterogeneity. In the case of heterogeneity across different subgroups of studies, estimates were calculated separately for homogeneous subgroups. Confidence intervals were constructed for proportions with the binomial distribution (Fleiss 1981) and for incidence (with time as the unit of analysis) with the Poisson distribution (Beyer 1966). Effectiveness was calculated by taking one minus the ratio of the HIV incidence among always condom users to that among never condom users. Best- and worst-case scenarios for effectiveness were calculated using the confidence interval upper and lower bounds for the two seroconversion rates.

DESCRIPTION OF STUDIES

See Table for a listing of the studies included in the analysis: their purpose/methods, participants, interventions, and outcomes.

See Additional Tables for a more detailed listing of the incidence information for each study. In that table, the first column contains the first author and publication date for each study, the next four columns provide information on the "always" user cohorts, and the last four columns provide information on the "never" user cohorts. The "Freqs" columns contain the seroconversion information; the number of seroconversions and the cohort size. The "Aver" columns contain the average years of disease-free exposure time per person in the cohort. The "Total p/yrs" column contains the person-years of exposure time (the product of the number in the cohort and the average disease-free observation time). (Note that these tables contain the data used in the analysis.) There are 13 cohorts of "always" users: 7 provide information on male-to-female (M+F-) transmission, 3 on female-to-male (F+M-) transmission, and 3 studies did not specify direction. There are 10 cohorts of "never" users: 5 provide information on male-to-female (M+F-) transmission, 2 on female-to-male (F+M-) transmission, and 3 did not specify the direction of transmission.

METHODOLOGICAL QUALITY

The preferred method for a meta-analysis of these data would be an analysis of the original patient data, controlling for possible confounding variables. The original patient data would contain the disease-free exposure time for each seronegative partner. In the absence of original patient data, this review uses aggregate or average disease-free follow-up time in the calculation of incidence estimates. When those data are explicitly reported in a description of a partner study, it is assumed that they are accurate. For example, a report that provides the incidence and/or person-years of disease-free exposure time would contribute more accurate information to a quantitative summary of studies. A study that does not report that information specifically, and instead reports disease-free follow-up time for all patients studied (and not by the direction of transmission or not by condom usage group) would be less accurate. A study that does not report disease-free exposure time, and instead reports average follow-up time, could potentially be even less accurate if "follow-up time" contains diseased and as well as disease-free observation periods. The quality of the follow-up information is indicated in the Additional Table.

RESULTS

The electronic searches yielded a total of 4709 references, including duplicates across databases. MEDLINE yielded 1284 studies, AIDSLINE 2215, CINAHL 265, and Embase 945. Once imported into Reference Manager v.8.5, 735 studies were identified as duplicates. An unknown number of additional duplicates were not recognized by Reference Manager and were included in the remaining 3974 references. The title of each of the 3974 references was read to determine relevance to our review; 3596 were excluded. For the remaining 378 references, the abstract was read to determine whether study criteria were met. After reading the abstracts, an additional 203 were eliminated. The full text of the remining 175 studies was reviewed by the authors to determine the presence of study criteria. (Three non-English language studies were reviewed by someone identified by the Cochrane Center.) 52 studies met all four inclusion criteria. In the final stage, 14 were included in the review and 38 were excluded. Those that were duplicate reports on the same cohort or that had incomplete or nonspecific information were excluded from analysis (see Characteristics of Excluded Studies). Studies did not consistently nor completely describe variables that might affect effectiveness estimates, such as level of infectivity, circumcision, subtype of HIV, length of relationship, frequency of sexual relations, correctness of condom usage, and condom type.

There were 13 cohorts of "always" condom users in the studies that met the inclusion criteria. The cumulative proportions of partners that seroconverted were homogeneous across the 7 male-to-female cohorts ($X2[6]=2.76, p=.84$), the 3 female-to-male cohorts ($X2[2]=2.54, p=.28$), across all 13 cohorts regardless of the direction of transmission ($X2[12]=10.49, p=.57$), and across the 10 studies containing those cohorts ($X2[9]=7.77, p=.56$). The cumulative proportions of partners that seroconverted also did not demonstrate a trend across time ($X2[1]$ trend$=2.81$, $p=.09$). Because the studies provided consistent, homogeneous estimates, incidence was estimated across the cohorts. Across all 13 cohorts there were 11 seroconversions among 587 "always" users. There was a total of 964.3 person-years of observation time, approximately 1.6 years per person. The incidence for "always" users es-

timated from these data is 1.14 [95% C.I.: .56, 2.04] seroconversions per 100 person-years.

There were 10 cohorts of "never" users with 40 seroconversions in 276 individuals. Each individual contributed an average of 2.169 years of disease-free observation. In total there were 598.61 person-years of disease-free time. In contrast to the "always" users, the cumulative proportions of partners that seroconverted were significantly different across all 10 cohorts of "never" users (X2[9]= 23.876,p=.005; also significantly different when the case report by Henry is excluded, X2[8]=18.282,p=.019). No time trends were present in the data when cohorts were examined by date of publication (p=.77) or by date of enrollment (p=.78). The cumulative proportions of seroconversions were significantly different across the 5 male-to-female cohorts (X2[4]=13.947, p=.008; and without Henry, X2[3]=8.697,p=.034), but not between the 2 female-to-male cohorts (X2[1]=3.12,p=.078). In fact when studies were categorized by their characteristics (direction of transmission, index case source of infection, continent where the study was located, length of follow-up time), the largest homogeneous category of studies consisted of the group of studies with the longest follow-up time (X2[4]=9.0,p=.06). The follow-up time for these five cohorts was longer than the average follow-up time (2.169 years) for "never" users. Four of the five cohorts are studies of partners of transfusion recipients or hemophiliacs (studies by van der Ende 1988, Peterman 1988, and O'Brien 1994); the fifth is a cohort in the Allen (1992) study. The cumulative proportions of seroconversions in these five cohorts were not significantly different (X2[3]=3.43,p=.33; merging the two cohorts reported in Peterman, X2[2]=1.89,p=.39). The transfusion/hemophiliac studies may also have the fewest confounding variables present (STDs, possible IDU) and may represent the same subtype of HIV. Incidence across all cohorts of "never" users is 6.68 [95% C.I.: 4.78, 9.10] per 100 person-years. In the transfusion/hemophiliac studies there were 12 seroconversions among 84 people (236.4 person-years) with an incidence of 5.08 [95% C.I.: 4.78, 8.88] per 100 person-years. In the transfusion/hemphiliac studies and the Allen F+M- cohort (the five cohorts with the longest follow-up time), there were 14 seroconversions among 87 people (243.3 person-years) with an incidence of 5.75 [95% C.I.: 3.16, 9.66] per 100 person-years for non-condom users.

Condom effectiveness was then estimated from the incidence of HIV among "always" users and the incidence among "never" users. A single, homogeneous estimate of incidence was found for the cohorts of "always" users (1.14), but selection of a "best" estimate for "never" users is more difficult. Effectiveness for reducing sexual transmission of HIV is 82.9% when the overall incidence for "never" users is used (6.68), in spite of the notable heterogeneity among the cohorts. Effectiveness was 77.6% for the subgroup of transfusion/hemophiliac cohorts and 80.2% when incidence among "never" users was estimated with cohorts that had longer than average follow-up time (5.75). A best case and worst case scenario was also estimated using the lower and upper limits of the confidence intervals for the incidence estimates. A best case scenario, using the lower confidence limit for the incidence with always condom use and the upper confidence limit for the non-condom users, estimated effectiveness at 94.2%. A worst case scenario, using the upper confidence limit for the always users and the lower limit for the never users, estimated effectiveness at 35.4%. Thus, effectiveness is approximately 80.2%, but may be as low as 35.4% or as high as 94.2%.

DISCUSSION

This review indicates that consistent use of condoms results in 80% reduction in HIV incidence. Consistent use is defined as using a condom for all acts of penetrative vaginal intercourse. Because the studies used in this review did not report on the "correctness" of use, namely whether condoms were used correctly and perfectly for each and every act of intercourse, nor did they report on the quality of the condoms used, effectiveness and not efficacy is estimated. Also, this estimate refers in general to the male condom and not specifically to the latex condom, since studies also tended not to specify the type of condom that was used.

The set of cohort studies remains essentially the same as in the Davis and Weller (1999) report, with some differences. First, the report by Laurian (1989) was previously coded as providing seroconversion data for 17 "never" users and 14 "always" users (male-to-female transmission). In this report, only the 14 "always" users are included, as the second group was judged to possibly contain sometimes or intermittent users. Second, the Davis and Weller (1999) report used the Saracco (1993) report of the Italian cohorts for male-to-female transmission among always and never users. In this report, the Musicco (1994) report of the always user cohort is used because the sample size is larger. Even though the Musicco cohort of always users contains men on antiretroviral therapy, it is consistent with the other cohorts. Third, in the Davis and Weller (1999) report the Kamenga (1991) female-to-male cohort was reported to have 3/55 seroconversions among the always users. In this report, 3/56 is the number of seroconversions. Fourth, the data in the Fischl (1987) report were coded as 1/10 for sometimes users, 12/14 for never users in the Davis and Weller report. Here those estimates are re-categorized as 1/10 for always users and 12/14 for sometimes users. Finally, a case report (Henry 1991) is included in this report because it met the inclusion criteria. Because case reports may contain bias because of their "unusualness" (why they may warrant publication) and because the case was not included in a scientific study of serodiscordant couples, analyses were performed with and without the case report.

This review used two separately pooled incidence rates to estimate effectiveness rather than pooling relative risks across studies. Comparison of condom usage groups within the context of a single study could control for some extraneous confounding variables, especially if the study used multivariate modeling controlling for

HIV risk factors and reported the adjusted relative risk for condom usage. Four articles reported both always and never user cohorts (Van der Ende 1988, Allen 1992, Siddiqui 1992, Deschamps 1996), but none reported a relative risk controlling for HIV risk factors. A serious problem in estimating effectiveness is the bias that may be present in the two condom usage groups. When condom use is associated with any other HIV risk factor, the groups will be biased and effectiveness may be over- or underestimated. If a true experiment had been conducted (a randomized controlled trial) in which individuals had been randomly assigned to 100% condom use or 0% condom use (and they were instructed to have sexual intercourse with an HIV+ partner), condom usage would be independent of HIV risk factors (because the risk factors would be distributed similarly within each usage category). Such an experiment would not be ethical, but parallel conditions (condom usage should be uncorrelated with HIV risk factors) must exist in an observational study in order to obtain an unbiased estimate of effectiveness and it is clear that condom use is now influenced by many factors. In longitudinal studies, repeated office visits with HIV blood tests, interviewing, and counseling cause a significant increase in condom usage (Deschamps 1996, van der Ende 1988, Kamenga 1991, Allen 1992, Fischl 1987) and abstinence (Deschamps 1996, Kamenga 1991, De Vincenzi 1994, Fischl 1987). The condom non-user group is now a condom refuser group: individuals who knowingly have sex with an HIV-infected partner and, despite continued counseling, refuse to use condoms. Condom non-users are more likely to use drugs and alcohol (Skurnick 1988, Kennedy 1993). The bias inherent in the condom use groups makes it difficult to find an appropriate and minimally-biased comparison group to serve as a denominator for the estimation of effectiveness.

In this study, we attempted to deal with the difficulty of finding a proper denominator by estimating effectiveness from two separate estimates of incidence (with and without condoms) and exploring several possible denominators. It is interesting to note that the 13 cohorts of always users (n=587) provided a homogeneous estimate of incidence, while the 10 never user cohorts (n=276) exhibited significant heterogeneity in spite of the much smaller sample size. The significantly different proportions of seroconversions in the condom nonuser cohorts suggests that there may be different rates of HIV transmission in those cohorts. While the presence of other STIs, different subtypes of HIV, and/or different proportions of IDUs in the cohorts could cause higher transmission rates, overestimation of incidence among nonusers would lead to an overestimation of condom effectiveness. It could be argued that HIV negative partners in the early hemophiliac and transfusion cohort studies might serve as the best "historical control" cohorts, especially for condom nonusers. These groups may provide a more accurate estimate of the HIV transmission rate since they generally had no additional HIV risk factors and condom use in some of the older studies was for contraception and not for HIV prevention. This group of cohorts (van der Ende 1988, Peterman 1988, O'Brien 1994) plus the cohort in Allen (1992) were found to be homogeneous and to have a longer than average follow-up time.

This review is limited by the lack of detail in published reports concerning condom usage information and disease-free exposure time. Although reporting of condom use by individuals appear to be reliable (deBoer 1998, Padian 1990, Upchurch 1991, James 1991), rarely do investigators provide detail on the assessment of condom usage. Most investigators carefully report how HIV status was determined, but do not provide similar detail regarding condom usage. A serious limitation in assessing condom usage in a review of this type lies in the failure of published reports to state what question(s) was asked, how responses were coded, and how responses were recategorized. Terms such as "regular," "consistent," "systematic," and "routine" were used in original reports without a clear defintion.

Another limitation is the availabiity of accurate information on the disease-free exposure time. Use of the average length of follow-up time to calculate incidence rather than the exact number of seronegative person-years underestimates incidence. For example, in the Fischl et al study their reported 24 month median length of follow up time may be 12 months of seronegative time, since half of the sexually active individuals seroconverted at or before 12 months (according to their table). Re-estimation of their incidence and confidence interval with 12 instead of 24 months average follow up, causes the incidence rate to increase and the study becomes even more of an outlier. If incidence is underestimated by different amounts in each condom user group, effectiveness may be over- or underestimated.

To clarify ambiguities in reported information concerning condom usage and disease-free exposure time, letters were sent to the authors of each study. Authors were asked to verify that information taken from their article were coded accurately and if the original data might still be available for analysis. Replies have been received from Feldblum (Hira 1997), Peterman (1988), and Makuch (Siddiqui 1992) confirming the coding of their data. The inquiry to Ryder (Kamenga 1991) was returned unopened and a reply from Lambert (Laurian 1989) indicates Laurian has changed affiliations. No other responses have yet been received, but when and if responses are received the review will be updated.

AUTHORS' CONCLUSIONS

Implications for practice

Consistent condom use is effective in reducing sexual transmssion of HIV, but does not eliminate the risk of HIV transmssion. Consistent use is defined as using a male condom for all acts of penetrative vaginal intercourse. Condom effectiveness is similar to, but somewhat less effective, than for pregnancy.

Implications for research

Estimates of condom effectiveness for reducing HIV transmission can be improved, even though direct estimation of efficacy is impossible to estimate. Design of new studies will not reduce the difficulty of estimating condom efficacy as condom use is now inextricably confounded with HIV risk factors. Individuals who knowingly have unprotected, penetrative sex with an HIV+ partner after being advised to abstain or use protection (condoms) are at-risk for other HIV risk factors. Perhaps a cohort of serodiscordant couples, for example of hemophiliacs, can be located from early in the HIV epidemic (say in the early 1980s) to create an historical control cohort. Detailed analysis of original patient data may also improve estimates of effectiveness. Effort at improving the coding of condom usage and estimation of disease-free exposure time would improve the accuracy of effectiveness estimates. Future couple studies need to be as careful about asking about and reporting condom usage as they are about serological determination of HIV status. Questions should be asked in the most reliable way possible and coding of responses should be reported.

FEEDBACK

Condom effectiveness in reducing heterosexual HIV

Summary

Why aren't the data presented as time to event? Is this a limitation of the
way the results were presented?

Even if considering the outcome as binary rather than time to event is
justified could you explain why the numerators and denominators have been
simply summed across trials, which is
considered wrong for RCTs? It is usual to apply a weighting scheme such
that the trials containing the most information receive the most weight.

Author's reply

The data are indeed presented as the average length of disease-free followup
time. That is necessary to estimate incidence. For each study the following are reported: the cohort size, the number of subjects who
seroconverted, and the average disease-free follow-up time. This information is reported for those who used and for those who did not use
condoms. A limitation is that this information is available only in the
aggregate for each study and not for individual subjects. Cohort results
are combined relative to their sample sizes and are not weighted equally.

Contributors

S. Weller.

POTENTIAL CONFLICT OF INTEREST

None. (No other private or federal funding related to condoms or condom use.)

ACKNOWLEDGEMENTS

This review is based in part upon the article by Davis and Weller that appeared in Family Planning Perspectives (1999, 31:272-279).

SOURCES OF SUPPORT

External sources of support

- The Population Council, Horizons Project USA

Internal sources of support

- No sources of support supplied

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TABLES

Characteristics of included studies

Study	**Allen 1992**
Methods	Prospective study of sexually active HIV discordant heterosexual couples (incidence estimation and associated risk factors)
Participants	- Kigali, Rwanda, prenatal & pediatric outpatient clinics - enrolled in 1988 - M+F- couples (n=30) - F+M- couples (n=23) - IC type: heterosexual - partner exclusions: none
Interventions	- counselling (educational video about AIDS & discussion group led by a social worker) - free latex condoms & spermicidal suppositories - free health care - @ 3mo sex practices, HIV serotest - @ 6mo medical history - @ 12mo physical exam
Outcomes	Vaginal condom usage - every time (100%) - sometimes (1-99%) - never (0%) HIV serotesting by ELISA, confirmed by Western blot
Notes	- some male partners not monogamous - some male partners circumcised, some not - spermicide use
Allocation concealment	D – Not used

Study	**Deschamps 1996**
Methods	Prospective study of sexually active HIV discordant heterosexual couples (incidence estimation and associated risk factors)
Participants	- Port-au-Prince, Haiti, National Institute for Laboratory Research (sole source of free testing for HIV in Haiti) - enrolled 1/88- 7/92 - M+F- couples (n=143) - F+M- couples (n=34) - IC type: heterosexual - partner exclusions: homosexuals, bisexuals, IVDU, blood transfusion in past 5 years
Interventions	- counselling about HIV and safe sex - free latex condoms - @ 3mo HIV serotest

Characteristics of included studies (*Continued*)

Outcomes	Vaginal (and possibly anal) condom usage - "used for every sexual act" (100%) - occasionally (1-99%) - never (0%) HIV serotesting by ELISA, confirmed by Western blot
Notes	- STDs in partners
Allocation concealment	D – Not used

Study	**Fischl 1987**
Methods	Prospective study of HIV transmission to household members (including sex partners)
Participants	- United States, university medical center in FL - enrolled 1/83- 6/85 - M+F- couples (n=18) - F+M- couples (n=6) - IC type: IVDU, heterosexual, bisexual, transfusion, hemophiliac, unknown - partner exclusions: those with "an independent risk factor"
Interventions	- @ 4-6 mo medical history, sexual practices, physical exam, lab tests (inc. serotest for HTLV-III/LAV)
Outcomes	Vaginal condom usage - routine use (100%) - intermittent/ never (0-99%) HIV serotesting by radioimmunoprecipitation and enzyme immunoassay, confirmed by Western blot
Notes	- all of the index cases had AIDS
Allocation concealment	D – Not used

Study	**Henry 1991**
Methods	Case report (n=1) of male-to- female HIV transmission
Participants	- U.S., Minnesota - 1990 - M+F- couple (n=1) - IC type: IVDU bisexual
Interventions	- HIV test results available for 1988- 1990
Outcomes	HIV serotesting by EIA, confirmed by Western blot
Notes	- because this is a case report, it may be an unusual observation
Allocation concealment	D – Not used

Study	**Hira 1997**
Methods	Prospective study of sexually active HIV discordant heterosexual couples (incidence estimation and associated risk factors)
Participants	- Lusaka, Zambia, STD clinic - enrolled 1988- 1992 - M+F- couples (n=80) - F+M- couples (n=30) - IC type: heterosexuals attending an STD clinic - partner exclusions: 1 F who seroconverted by first f/u but reported no sex
Interventions	- counselling to use condom and spermicide together - free latex condoms and spermicidal products - @ 3mo contraceptive counselling, physical exam, STD tests, HIV test, coital log

Characteristics of included studies (*Continued*)

Outcomes	Vaginal condom usage - always (100%) - sometimes/ never (0-99%) HIV serotesting by ELISA, confirmed by Western blot
Notes	- spermicide (N-9) use - STDs in partners - majority of men not circumcised - each sex act considered independently
Allocation concealment	D – Not used

Study	**Kamenga 1991**
Methods	Prospective study of sexually active HIV discordant heterosexual couples (incidence estimation and associated risk factors)
Participants	- Zaire, HIV counselling center - enrolled 1987- 1988 - M+F- couples (n= 79) - F+M- couples (n=69) - IC type: heterosexual factory and bank employees - partner exclusions: none
Interventions	- "intensive" counselling about STDs, HIV, and condoms use - free condoms w/ spermicidal lubricant - @ 1mo coital log, counselling - @ 6mo physical exam, venipuncture, GYN exam
Outcomes	Vaginal (and possibly anal) condom usage - always (100%) - some/never (0-99%) HIV serotesting by ELISA, confirmed by Western blot
Notes	- some male partners uncircumcised - STDs in partners (low prevalence) - index cases are not IVDUs - suspected improper use among some seroconverters, but not reported for all
Allocation concealment	D – Not used

Study	**Laurian 1989**
Methods	Prospective study of sexually active HIV discordant heterosexual couples (and associated risk factors)
Participants	- France, hospital - enrolled 10/85- 10/87 - M+F- couples (n=31) - IC type: hemophilia - partner exclusions: ?
Interventions	- counselling - @ 6mo counselling, HIV antibody and antigen tests
Outcomes	Vaginal (and possibly anal) condom usage - always (100%) - some/never (0-99%) HIV antibody and antigen tested by ?
Notes	
Allocation concealment	D – Not used

Characteristics of included studies (*Continued*)

Study	**Musicco (ISG) 1994**
Methods	Prospective study of sexually active HIV discordant heterosexual couples (incidence estimation and associated risk factors)
Participants	- Italy, hospitals, IVDU outpatient clinics, HIV surveillance centers - enrolled 2/87- 5/92 - M+F- couples (n=436) - IC type: IVDU (predom.) - partner exclusions: IVDU, prositutes, recipients of blood products
Interventions	- counselling about HIV prevention, condom use, GYN exams - @ 6mo sexual history, STD history, contraceptive history, HIV test
Outcomes	Vaginal (and possibly anal) condom usage - always (100%) - not always/ never (0-99%) HIV serotesting by immunoenzymatic method, confirmed by Western blot
Notes	- some ICs underwent zidovudine treatment (and had lower transmission) - each time exposure considered independent (each person mihgt contribute to each category of condom use/ exposure time)
Allocation concealment	D – Not used

Study	**O'Brien 1994**
Methods	Retrospective cohort study of HIV discordant heterosexual couples (incidence estimation and associated risk factors)
Participants	- U.S., HIV+ transfusion recipients in CA, NJ, NY contacted through physician or health department - enrolled 1987- 1992 - M+F- & F+M- couples (n= 36 in prospective portion, includes abstainers) - IC type: transfusion after 1978 - partner exclusions: none necessary (no other risk factors present)
Interventions	- counselling about HIV - @ 6mo medical history, sexual history, counselling, HIV serotest
Outcomes	Vaginal condom usage - all (100%) - most but not all (1-99%) - never (0%) HIV serotesting by enzyme immunoassay (EIA), confirmed by Western blot
Notes	- date of transfusion known
Allocation concealment	D – Not used

Study	**Peterman 1988**
Methods	Retrospective cohort study of sexually active HIV discordant heterosexual couples (incidence estimation and associated risk factors)
Participants	- U.S., HIV+ transfusion recipients contacted through physician or health department - enrolled 1987 - M+F- couples (n=55) - F+M- couples (n=25) - IC type: transfusion after 1978 - partner exclusions: those with other HIV risk factors
Interventions	- none (look-back study)

Characteristics of included studies (*Continued*)

Outcomes	Vaginal (and possibly anal) condom usage - ever used (1-99%) - never (0%) HIV serotesting by enzyme- linked immunosorbent assay, confirmed by Western blot
Notes	- date of transfusion known - follow-up reported for IC transfusion to IC HIV-diagnosis
Allocation concealment	D – Not used

Study	**Saracco (ISG)1993**
Methods	Prospective study of sexually active HIV discordant heterosexual couples (incidence estimation and associated risk factors)
Participants	- Italy, hospitals, IVDU outpatient clinics, HIV surveillance centers - enrolled 2/87- 5/91 - M+F- couples (n=305) - IC case: IVDU (predom.) - partner exclusions: those with other HIV risk factors
Interventions	- counselling about HIV, condom use, advise to remove IUDs - @ 6mo sexual & medical history, HIV serotest
Outcomes	Vaginal (and possibly anal) condom usage - always (100%) - not always (1-99%) - never (0%) HIV serotesting by ELISA, confirmed by Western blot
Notes	
Allocation concealment	D – Not used

Study	**Siddiqui 1992**
Methods	Prospective study of sexually active HIV discordant heterosexual couples (incidence estimation and associated risk factors)
Participants	- U.S., methadone maintenance clinics - enrolled 12/88- 10/91 - M+F- couples (n=16) - F+M- couples (n=6) - IC case: IVDU (only) on methadone maintenance - partner exclusions: IVDU
Interventions	- counselling - @ 3-4mo sexual & medical history, HIV serotest
Outcomes	Vaginal condom usage - every time (100%) - intermittent (1-99%) - none (0%) HIV serotesting by ?
Notes	- 3 partners had STDs - 2 couples had anal sex 1.9 times/mo
Allocation concealment	D – Not used

Study	deVincenzi (ESG)1994
Methods	Prospective study of sexually active HIV discordant heterosexual couples (incidence estimation and associated risk factors)
Participants	- 8 countries in European Community, hospital wards, outpatient clinics, STD clinics, public health departments - enrolled from 3/87- 3/91 - M+F- couples (n=157) - F+M- couples (n=88) - IC type: IVDU (predom.), transfusion, bisexual, heterosexual - partner exclusions: IVDU, male homosexuals, recipients of unscreened blood products, multiple sexual partners, one or more sexual partners from sub-Saharan Africa or w/ above risk factor
Interventions	- counselling about HIV and safe sex - @ 6mo counselling, HIV serotest, sexual history
Outcomes	Vaginal and anal condom usage - always (100%) - inconsistent (0-99%) HIV serotesting by ELISA, confirmed by Western blot or radioimmunoprecipitation
Notes	- "always" users were those who used condoms for all vaginal AND anal contacts - STDs in partners
Allocation concealment	D – Not used

Study	van der Ende 1988
Methods	Prospective study of heterosexual hemophiliacs and their partners
Participants	- Netherlands - enrolled 1984 - M+F- couples (n=13) - IC case: hemophilia - partner exclusions: none (no other risk factors present)
Interventions	- @ 3mo blood screened for cell counts, liver enzyme activity, cytomegalovirus, Epstein-Barr virus, and HIV - @ 6mo lymphocyte counts and lymphocyte stimulation tests
Outcomes	Vaginal condom usage - always (100%) - sometimes (1-99%) - never (0%) HIV antibody confirmed by immunoblotting
Notes	- 7/13 had Walter Reed stages IV or V, "progressive disease"
Allocation concealment	D – Not used

Characteristics of excluded studies

Study	Reason for exclusion
Andes 1989	insufficient condom usage information
Cameron 1989 ab	insufficient information on the entire sample
Feldblum 1992 ab	insufficient information (see Hira 1997)
Feldblum ab	insufficient information on condom use and seroconversions
Flepp	not received

Characteristics of excluded studies (*Continued*)

Guimaraes ab	insufficient information on condom use and seroconversions
Hira 1989 ab	Hira 1997 has a larger cohort
Jingu 1993 ab	insufficient information
Jingu ab	insufficient information on condom use and seroconversions
Kamenga 1989 ab	Kamenga 1991 more recent
Kamps 1989 ab	insufficient information on follow-up time
Lawrence 1985	insufficient information on condom usage
Laye 1998 ab	insufficient information on condom usage
Lo 1992 ab	insufficient information on condom use and seroconversions
Mandelbrot 1997	Insufficient information on exposure time
Massimo 1992 ab	More information in Musicco 1994
Moss 1992 ab	insufficient information on condom use and seroconversions
Musicco 1992 ab	More detail in Saracco 1993; Musicco 1994
Musicco 1993 ab	More detail in Saracco 1993; Musicco 1994
Nagachinta ab	insufficient information on condom use and seroconversions
Nastiff 1998 ab	insufficient information on condom use and seroconversions
O'Brien 1993	insufficient information on condom usage
O'Brien 1993 ab	insufficient information on condom usage
Operskalski 1997	insufficient information on condom usage
Padian	insufficient information on condom usage
Padian 1989 ab	insufficient information on condom usage and seroconversion
Padian 1997	insufficient information on condom usage
Papetti	insufficient information on condom usage
Papetti 1992 ab	insufficient information on condom use and seroconversions
Papetti ab	insufficient information on seronegative partners (see Papetti 1992)
Saracco 1989 ab	insufficient information
Serwadda 1995	insufficient information on condom usage
Sion	insufficient information on total exposure time to index case
Sion 1992 ab	insufficient information on condom usage
Skurnick 1995 ab	insufficient information on seroconversions
Tice ab	insufficient information on condom use and seroconversions
Tor 1992 ab	insufficient information on condom usage
al Nozha	not received

ADDITIONAL TABLES

Table 01. Incidence rate information by study

Study	(A) Freqs	(A) Aver. Exposure	(A) Total p/yrs	(A) Notes	(N) Freqs	(N) Aver. Exposure	(N) Total p/yrs	(N) Notes
M+F-								
Allen 1992	0/4	2.107*	8.4	*estimated from total reported M+ F- exposure	4/10	2.107*	21.1	*estimated from total reported M+ F- exposure
deVincenzi (ESG) 1994	0/83	2.038*, 2.013**	169.2*, 167.1*	*estimated from total reported M+ F- and F+ M- exposure **calculated by subtracting total reported f/u for some/ never from reported total f/u				
Hira 1997	0/30	1.506*	45.2	*estimated from total reported M+ F- exposure				
Kamenga 1991	1/50	1.258*	62.9	*estimated from total reported M+ F- exposure				
Laurian 1989	0/14	2.000	28.0					
Musicco (ISG) 1994	5/243*	1.492*	362.5	*the total count (243) includes abstainers				
Peterman 1988					10/51	2.883*	147.0	*weighted mean time from IC's transfusion to IC's diagnosis (Table 1)
Saracco (ISG) 1993					8/79	1.763	139.3	
van der Ende	0/2*	3.000	6.0		0/8*	3.000	24.0	*frequencies

Table 01. Incidence rate information by study (*Continued*)

Study	(A) Freqs	(A) Aver. Exposure	(A) Total p/yrs	(A) Notes	(N) Freqs	(N) Aver. Exposure	(N) Total p/yrs	(N) Notes
1988								from table
Henry					1/1	0.006	0.006	
F+M-								
Allen 1992	0/5	2.304*	11.5	*estimated from total reported F+ M- exposure	2/3	2.304	6.9	*estimated from total reported F+ M- exposure
deVincenzi (ESG) 1994	0/41	2.038*, 2.013**	83.6*, 82.5**	*estimated from total reported M+ F- and F+ M- exposure **calculated by subtracting total reported f/u for some/ never from reported total f/u				
Kamenga 1991	3/56	1.308 R	73.2	*estimated from total reported F+ M- exposure				
Peterman 1988					2/23	2.625*	60.4	*weighted mean time from IC's transfusion to IC's diagnosis (Table 1)
DIR UNKNOWN								
Deschamps 1996	1/42	2.405	101		13/90	2.059*	185.3	*calculated from total p/yrs for sometimes & never users
Fischl 1987	1/10	0.854*	8.54	*calculated by adding total exposure time for sexually				

Table 01. Incidence rate information by study (*Continued*)

Study	(A) Freqs	(A) Aver. Exposure	(A) Total p/yrs	(A) Notes	(N) Freqs	(N) Aver. Exposure	(N) Total p/yrs	(N) Notes
				active partners, from Table1				
O'Brien 1994					0/2	2.5*	5.0	
Siddiqui 1992	0/7	1.065*	7.5	*estimated from total reported M+ F- and F+M- exposure	0/9	1.065*	9.6	*estimated from total reported M+ F- and F+M- exposure

GRAPHS AND OTHER TABLES

This review has no analyses.

INDEX TERMS

Medical Subject Headings (MeSH)

Cohort Studies; Condoms [*standards; utilization]; Disease Transmission, Horizontal; Evaluation Studies; *Heterosexuality; HIV Infections [*prevention & control; transmission]; HIV Seronegativity; HIV Seropositivity

MeSH check words

Female; Humans; Male

COVER SHEET

Title	Condom effectiveness in reducing heterosexual HIV transmission
Authors	Weller SC, Davis-Beaty K
Contribution of author(s)	Karen R. Davis: search for and identify studies, read and abstract information from studies, table information from studies, write-up description of methods. Susan C. Weller: read and abstract information from studies, analyse information from studies, write-up findings and discussion, send letters to PIs of original studies.
Issue protocol first published	/
Review first published	/
Date of most recent amendment	23 May 2006
Date of most recent SUBSTANTIVE amendment	19 November 2001
What's New	Information not supplied by author
Date new studies sought but none found	Information not supplied by author

Date new studies found but not yet included/excluded	Information not supplied by author
Date new studies found and included/excluded	Information not supplied by author
Date authors' conclusions section amended	Information not supplied by author
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DOI	10.1002/14651858.CD003255
Cochrane Library number	CD003255
Editorial group	Cochrane HIV/AIDS Group
Editorial group code	HM-HIV