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## The Effectiveness of Condoms in Reducing Heterosexual Transmission of HIV

By Karen R. Davis and Susan C. Weller

**Context:** It is not established whether the condom is as effective at preventing heterosexual transmission of HIV as it is for preventing conception. An overall estimate of condom effectiveness for HIV prevention is needed.

**Methods:** Information on condom usage and HIV serology was obtained from 25 published studies of serodiscordant heterosexual couples. Condom usage was classified as always (in 100% of acts of intercourse), sometimes (1-99%, 0-99% or 1-100%) or never (0%). Studies were stratified by design, direction of transmission and condom usage group. Condom efficacy was calculated from the HIV transmission rates for always-users and never-users.

**Results:** For always-users, 12 cohort samples yielded a consistent HIV incidence of 0.9 per 100 person-years (95% confidence interval, 0.4-1.8). For 11 cohort samples of never-users, incidence was estimated at 6.8 per 100 person-years (95% confidence interval, 4.4-10.1) for male-to-female transmission, 5.9 per 100 (95% confidence interval, 1.5-15.1) for female-to-male transmission and 6.7 per 100 (95% confidence interval, 4.5-9.6) in samples that specified the direction of transmission. Generally, the condom's effectiveness at preventing HIV transmission is estimated to be 87%, but it may be as low as 60% or as high as 96%.

**Conclusions:** Consistent use of condoms provides protection from HIV. The level of protection approximates 87%, with a range depending upon the incidence among condom nonusers. Thus, the condom's efficacy at reducing heterosexual transmission may be comparable to or slightly lower than its effectiveness at preventing pregnancy.

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- » [article in pdf](#)
- » [table of contents](#)
- » [search the FPP archive](#)
- » [guidelines for authors](#)

When the research described in this article was conducted, Karen R. Davis was research assistant in the Department of Preventive Medicine and Community Health, the University of Texas Medical Branch, Galveston, TX. Susan C. Weller is professor in the Department of Preventive Medicine and Community Health, the University of Texas Medical Branch, Galveston. The authors gratefully acknowledge James Trussell for noting the need to incorporate the length of follow-up time in the analysis, George Papaevangelou for clarifying the condom usage categories in the Roumelioutou-Karayannis A et al. study, Judah Rosenblatt for assistance with the Poisson-based confidence intervals and Mark Vanlandingham for discussion.

Heterosexual intercourse is the primary mode of HIV infection worldwide.<sup>1</sup> In the United States, male homosexual contact and intravenous drug use account for the majority of HIV infections, but transmission via heterosexual contact continues to increase. Heterosexual contact with an infected partner is the greatest risk factor for women and, consequently, for their newborn children. In 1988, 2% of male AIDS cases and 30% of female cases reported in the United States were attributed to heterosexual contact.<sup>2</sup> By 1998, this percentage had risen to 7% for men and 38% for women.<sup>3</sup>

Although new treatments appear promising for retarding the progression of HIV-related disease, prevention remains the most effective weapon against the epidemic.

Recommendations for the prevention of sexually transmitted HIV infection 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.<sup>4</sup> The use of condoms is recommended for individuals who have multiple partners, who have a primary partner who is infected, or who have a partner whose serostatus is unknown,<sup>5</sup> although the absolute amount of protection they provide has not been accurately established.

The effectiveness of the condom as a contraceptive provides insight into its usefulness as a barrier device capable of preventing HIV transmission. Defined as the proportionate reduction in pregnancies caused by use of a contraceptive method, effectiveness is estimated as one minus the ratio of two failure rates. The failure rate ratio is calculated by dividing the pregnancy rate associated with use of a contraceptive method by the rate related to no method use for a given time period.<sup>6</sup> The likelihood of becoming pregnant during the first year of condom use ranges from 2.6% to 15.8%.<sup>7</sup> The likelihood of pregnancy in a population not practicing contraception is estimated from groups such as the Hutterites, and is often assumed to be 85%.<sup>8</sup> These probabilities can be transformed into rates,<sup>\*</sup> providing an estimate of condom effectiveness for preventing pregnancy of 90.7% to 98.6%.

The effectiveness of condoms in reducing HIV may be estimated in the same way as for contraception. For HIV, the failure rate ratio is calculated by dividing the seroconversion rate among couples always using condoms by the rate 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. The best measure of condom efficacy is obtained by comparing monogamous, serodiscordant couples (i.e., those who differ in their HIV infection status) who always use condoms during penetrative vaginal intercourse with those who never do. Since HIV serodiscordant couples cannot ethically be assigned at random to "always" and "never" use condoms, estimates must be obtained from observational studies. Unfortunately, observational studies may be biased by an unequal distribution of HIV risk factors across study categories.

For both contraception and HIV prevention, condom failure has two sources: user failure and method failure. User failure includes nonuse and incorrect use, and is attributed to the person using the condom. Method failure is the absolute, theoretical failure inherent in the device, and is independent of the user. User failure varies per person and per contact, while method failure is assumed to be constant. It is impossible to measure absolute method failure, since it is confounded with user failure.

Condom failure due to nonuse, incorrect use, breakage and slippage may occur for both HIV prevention and birth control.<sup>9</sup> In several recent in vivo trials measuring failure due to breakage and slippage, rates have varied from 0.5% to 6.7% for breakage and 0.1% to 16.6% for slippage.<sup>10</sup> Quality control standards set by the Food and Drug Administration allow four out of 1,000 condoms in any given batch to leak water.<sup>11</sup> In vitro trials have reported HIV leakage in 0-100% of the condoms tested,<sup>12</sup> with all but one brand<sup>13</sup> between 0.0% and 54%.

Various estimates of the condom's effectiveness at reducing heterosexual transmission of HIV are available from studies of serodiscordant couples. In order to obtain a single

overall estimate of effectiveness, we present a meta-analysis of those results. An initial attempt<sup>14</sup> to do so was flawed because it aggregated studies with varying definitions of condom use, directions of transmission, study designs and types of index cases. A subsequent report<sup>15</sup> controlled for the direction of transmission, but did not remove the sometimes or occasional users of condoms from among the never-users, and also did not control for study design.

An additional source of bias occurs in recent estimates of HIV incidence among condom nonusers. Because condom use is no longer independent of HIV risk factors, as it was prior to the AIDS era, the association between condom use and seroconversion is biased by the self-selection of individuals into the groups always or never using condoms. Notably, there is a potential difficulty with using groups of condom nonusers in recent studies of serodiscordant couples as a control or comparison group: They may not be "equivalent" to the consistent condom users in all aspects except condom use. Thus, in this article, we examine transmission rates by study design, study date, direction of transmission, source of infection in the index case and condom usage group. Condom effectiveness is calculated from two separately estimated transmission rates: the transmission rate among those who always used condoms and the transmission rate among different populations of never-users.

## **METHODS**

We reexamine in vivo evidence of condom efficacy in reducing heterosexually transmitted HIV. Peer-reviewed articles and letters to the editor published prior to July 1999 were located using MEDLINE, AIDSLINE and reference lists. Studies had to meet three criteria for inclusion: They had to have focused on sexual transmission of HIV among serodiscordant heterosexual couples having penetrative sexual intercourse; they had to have determined HIV status by serology; and they had to have inquired about condom usage. Studies focusing on commercial sex workers were not considered because of the uncertainty of exposure.

A meta-analysis is a quantitative summary of results across studies that address the same research question, so it is important that equivalent information is available for analysis. To ensure that comparisons were made across equivalent variables, we classified and combined previous research by study design (cross-sectional or longitudinal), date of subject enrollment and direction of transmission (male-to-female, female-to-male or unknown).

Condom usage was defined as always, sometimes and never. The always-use category indicated that a condom was used for 100% of penetrative acts of vaginal intercourse. The never-use category indicated that condoms were not used during any acts of vaginal intercourse (0%). The sometimes-use category included intermediate estimates of usage (1-99%) and combinations of never-use and sometimes-use (0-99%) or always-use and sometimes-use (1-100%). We based our classification of condom use into these three categories upon published descriptions. Consensus between the authors of this report as to the coding of each study's data was necessary, and we requested clarifications directly from the authors.

Because aggregations are most reliable when made across homogeneous sample estimates, we used a chi-square test to determine homogeneity among the proportions

of HIV seroconversions across different subgroups of studies, and to check for trends across time. Incidence was estimated from the number of seroconversions and the person-years of observation. We obtained an overall estimate of incidence using a weighted average of results from a series of studies (the total number of seroconversions divided by the total person-years of exposure).

Confidence intervals for proportions were constructed with the binomial distribution,<sup>16</sup> and confidence intervals for incidence (with time as the unit of analysis) were determined using the Poisson distribution.<sup>17</sup> Effectiveness was calculated by taking one minus the ratio of HIV incidence among those who always used condoms to that of those who never used condoms. We calculated best-case and worst-case scenarios for effectiveness using upper and lower bounds of the confidence intervals for the two seroconversion rates.

## RESULTS

### The Studies

Thirty-seven studies met the inclusion criteria. Eight studies were excluded because the inquiry on condom usage was not sufficiently detailed, so that neither an always- nor a never-use category could be ascertained.<sup>18</sup> Of the remaining studies, four reports on the same cohort were eliminated from the analysis.<sup>19</sup> In the case of duplicate reports on the same cohort, the report with the most detailed condom usage definition and the largest sample size was selected.

After these exclusions, 25 studies remained for analysis. Thirteen cross-sectional studies<sup>20</sup> contained 12 samples describing male-to-female transmission and four samples of female-to-male transmission (Table 1). Twelve longitudinal studies<sup>21</sup> contained eight samples describing male-to-female transmission, four samples of female-to-male transmission and four samples that did not state the direction of transmission (Table 2). Average follow-up time in the longitudinal studies was approximately two years, with study averages ranging from 12.5 to 36 months. Some studies provided the number of person-years of follow-up time for the appropriate subgroups;<sup>22</sup> others estimated follow-up time from the overall average<sup>23</sup> or from the average reported for subgroups.<sup>24</sup>

**Table 1. Characteristics of and seroconversion data from cross-sectional studies of HIV transmission, by condom usage category, according to direction of transmission**

Entry date	Study*	Study site	Predominant mode of infection†	Condom usage‡		
				Never	Some	Always
<b>Male-to-male transmission</b>						
1986	Goedert JJ	U.S.	Hemophilic	na	4/18	0/6
1986	Ragni MV	U.S.	Hemophilic	3/13	0/9	na
1987	Padian N	U.S.	Bisexual	11/42	5/31	na
1987	Kim HC	U.S.	Hemophilic	1/7	0/7	na
1987	Roumeliotou-Karayannis A§	Greece	Bisexual and hemophilic	12/16	0/16	0/21
1987	Smiley ML	U.S.	Hemophilic	2/9	0/7	na
1989	Johnson AM	U.K.	Intravenous drug use	na	15/74	0/4
1991	European Study Group	Europe	Intravenous drug use	na	75/388	0/16

1991	Nicolosi A	Italy	Intravenous drug use	136/375	17/109	3/40
1991	Guimaraes MDC	Brazil	Bisexual	49/92	na	7/31
1992	Nagachinta T	Thailand	Heterosexual	na	186/399	1/6
1992	Seidlin M	U.S.	Intravenous drug use	43/72	30/70	na
Total seroconversions				208/534	513/1,484	22/155
Seroconversion rate				39.0%	35.0%	14.2%

#### Female-to-male transmission

1991	Padian N	U.S.	Heterosexual	1/40	0/32	na
1991	European Study Group	Europe	Intravenous drug use	na	16/151	0/8
1991	Nicolosi A	Italy	Intravenous drug use	8/73	8/69	5/64
1992	Seidlin M	U.S.	Intravenous drug use	4/7	3/4	na
Total seroconversions				13/120	27/256	5/72
Seroconversion rate				10.8%	10.5%	6.9%

\*First author. †In index case. ‡Cumulative frequencies of HIV seroconversion, by condom usage category. §Data provided by the author. *Note:* na=not applicable. *Sources:* reference 20.

**Table 2. Characteristics of and seroconversion data from longitudinal and cohort studies of HIV transmission, by condom usage category, according to direction of transmission**

Entry date	Study*	Study site	Predominant mode of infection†	Follow-up (interval)‡	Condom usage§		
					Never	Some	Always
<b>Male-to-female transmission</b>							
1978	Peterman TA	U.S.	Transfusion	34.7	10/51	0/4	na
1984	van der Ende ME	Netherlands	Hemophiliac	36 (3)	0/8	0/3	0/2
1985	Laurian Y	France	Hemophiliac	24 (6)	3/17	na	0/14
1987	Kamenga M	Zaire	Heterosexual	15.4 (6)	na	1/10	1/50
1987	Allen S	Rwanda	Heterosexual	25.3 (3)	4/10	2/16	0/4
1987	Saracco A	Italy	Intravenous drug use	18.5 (6)	8/79	8/55	3/171
1987	Europe	European Study Group	Intravenous drug use	24.5 (6)	na	8/74	0/83
1988	Hira SK	Zambia	Heterosexual	18 (3)	na	5/49	0/30
Total seroconversions					25/165	24/211	4/354
Seroconversion rate					15.2%	11.4%	1.1%
<b>Female-to-male transmission</b>							
1978	Peterman TA	U.S.	Transfusion	31.6	2/23	0/2	na
1987	Kamenga M	Zaire	Heterosexual	15.4 (6)	na	1/1	3/55
1987	Allen S	Rwanda	Heterosexual	27.6 (3)	2/3	0/15	0/5
1987	Europe	European Study Group	Intravenous drug use	24.5 (6)	na	4/47	0/41
Total seroconversions					4/26	5/65	3/101
Seroconversion rate					15.4%	7.7%	3.0%
<b>Transmission direction not stated</b>							
1983	Fischl MA	U.S.	Mixed	24** (6)	12/14	1/10	na
1987	O'Brien TR	U.S.	Transfusion	30 (6)	0/2	0/4	na
1988	Siddiqui NS	U.S.	Intravenous drug	12.5 (3.5)	0/9	0/6	0/7

			use				
1988	Deschamps M	Haiti	Heterosexual	25.7 †† (3	13/90	6/45	1/42
Total seroconversions					25/115	7/65	1/49
Seroconversion rate					21.7%	10.8%	2.0%
*First author. †In index case. ‡Mean duration of follow-up (in months), with follow-up interval in parenthesis. §Cumulative frequencies of HIV seroconversion, by condom usage category. **Median. ††24.7 never, 28.9 always †Note: na=not applicable. Sources: M Deschamps, 1996 (reference 1); for all others, reference 21.							

Index cases had been infected by various routes: hemophiliac blood treatment, intravenous drug use, bisexual contact, heterosexual contact, blood transfusion and unknown sources. Some studies used terms such as "regular,"<sup>25</sup> "consistent,"<sup>26</sup> "systematic"<sup>27</sup> and "routine"<sup>28</sup> to describe condom use. If the term could be defined with certainty as always-use, we included it in our always-use category.<sup>29</sup> In some cases, the authors provided clarification.<sup>†</sup> Studies that combined responses to form sometimes/always or never/sometimes groups were included in our sometimes category. Whenever possible, we separated these two imprecise categories into three categories (always, sometimes and never) of condom usage.

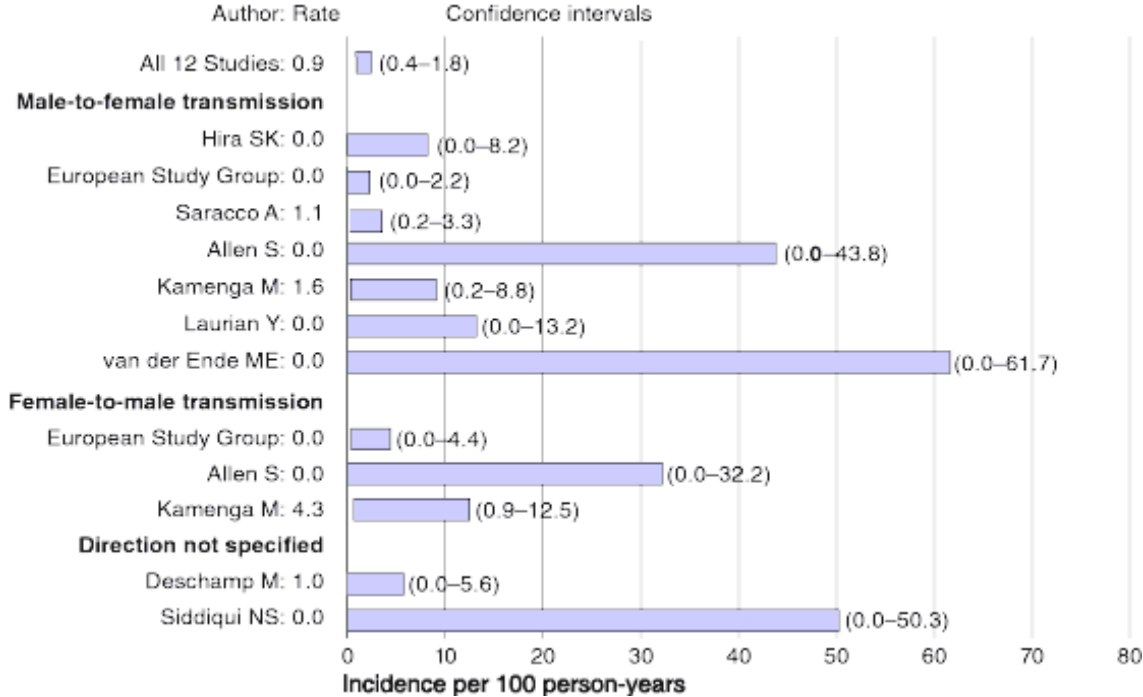
## HIV TRANSMISSION WITH CONDOM USE

Cross-sectional studies (a single blood sample and retrospective reporting of behaviors) indirectly provide information on transmission by indicating the prevalence of HIV infection. Among those who always used condoms and who were heterosexual partners of HIV-positive individuals, the nine cross-sectional samples<sup>30</sup> provided an HIV prevalence estimate of 8.2% (95% confidence interval, 4.9-13.2%); this estimate was homogeneous across studies, regardless of the direction of transmission (p=.079).

Cohort or longitudinal studies of couples who were serodiscordant provide information on the incidence of seroconversion, and thus provide better estimates of the actual transmission rate. Twelve cohort samples contain seroconversion data for those who always use condoms; there are seven samples of male-to-female transmission,<sup>31</sup> three of female-to-male transmission<sup>32</sup> and two that do not specify the direction of transmission<sup>33</sup> (Table 2).

The proportion of seroconversions among those who always used condoms did not differ significantly across the 12 cohort studies, regardless of the direction of transmission (p=.666), the average length of follow-up time (\*<sup>2</sup> for trend, p=.159) or the date when the study started (\*<sup>2</sup> for trend, p=.851). The incidence per 100 person-years was 0.7 per 100 (95% confidence interval, 0.2-1.7) for male-to-female transmission and 1.8 (95% confidence interval, 0.4-5.3) for female-to-male transmission. Across all 12 samples, regardless of the direction of transmission, there were eight seroconversions in 504 people (861.2 person-years), yielding an incidence of 0.9 (95% confidence interval, 0.4-1.8) per 100 person-years. The incidence rates and corresponding 95% confidence intervals from each sample of always-users (from Table 2) are shown in Figure 1.

**Figure 1. HIV incidence rates and confidence intervals for always-users, by study**



Sources: Deschamps M, 1996, reference 1; for all others, reference 21.

Additionally, one may make a simple overall estimate of incidence graphically, by examining the confidence intervals for these studies. Described as the "odd man out" method, it involves constructing a single interval from a small number of samples by finding the confidence region that is common across all but one sample, and thus is likely to contain the true value.<sup>34</sup> Since one outlier may be omitted, this involves identifying the next-to-highest lower confidence limit and the next-to-lowest upper limit (i.e., discarding the highest lower limit and the lowest upper limit). For these data, this method estimates the incidence of HIV for always-users to be between 0.2 and 3.3 seroconversions per 100 person-years. (This is a wider range than the 95% confidence interval calculated for these 12 studies, 0.4-1.8.)

## HIV TRANSMISSION RATE WITHOUT CONDOMS

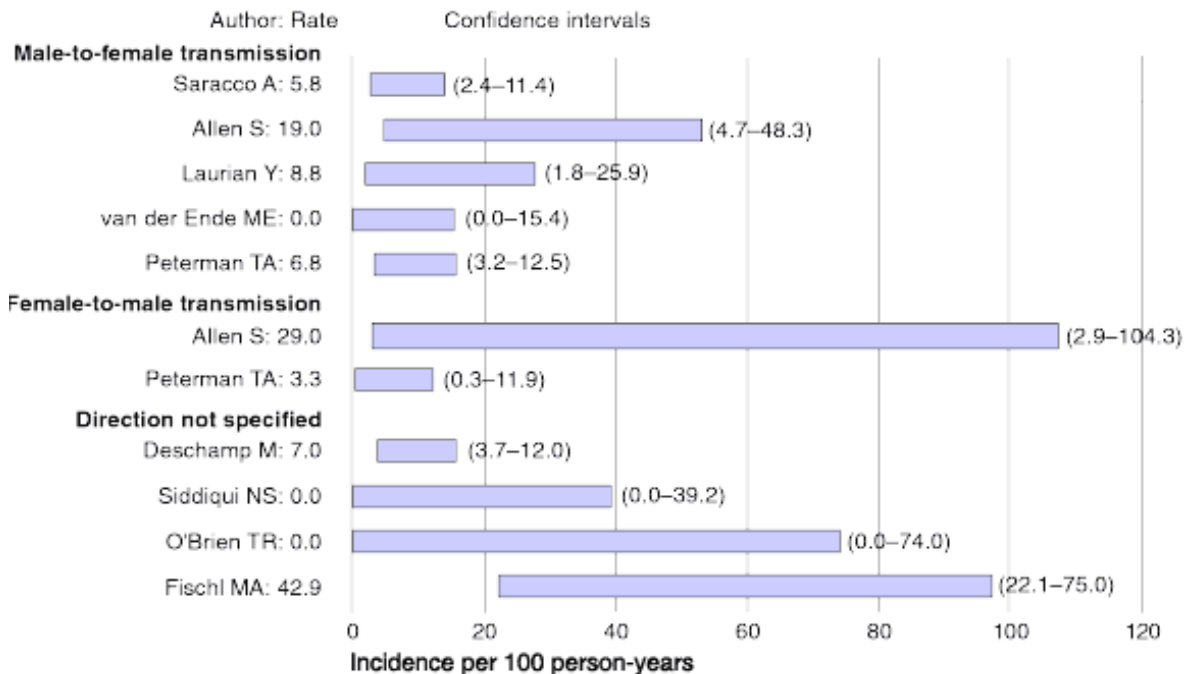
Lack of consistency in prevalence estimates from cross-sectional studies suggests that never-users cannot be compared across populations. The prevalence of HIV among never-users in the eight male-to-female cross-sectional samples<sup>35</sup> is significantly different across samples ( $p=.000008$ ), and increases significantly with the date of data collection ( $*^2$  for trend,  $p=.023$ ). The three female-to-male cross-sectional samples<sup>36</sup> also differ significantly across samples ( $p=.0001$ ) and show an increase by study start date ( $*^2$  for trend,  $p=.00005$ ).

Similarly, the cohort studies suggest that levels of HIV incidence differ across samples of never-users, although there may be homogeneity within subgroups. The cumulative proportions of seroconversions are consistent across the five male-to-female samples (an overall rate of 15.2%,  $p=.07$ ) and across the two female-to-male samples (15.4%,  $p=.077$ ). The proportions are not similar across those seven samples ( $p=.016$ ), however, or across all 11 longitudinal samples (including samples where the direction is unknown,  $p<.000001$ ).

Because of the differences in incidence across subgroups of index cases, we estimate incidence by subgroup. The incidence and 95% confidence interval for each sample of never-users (from Table 2) appear in Figure 2. The incidence rate for male-to-female

transmission is 6.8 infections per 100 person-years (95% confidence interval, 4.4-10.1). The incidence rate for female-to-male transmission is 5.9 per 100 person-years (95% confidence interval, 1.5-15.1). The subset of samples from early in the AIDS epidemic (hemophiliacs<sup>37</sup> and low-risk transfusion recipients<sup>38</sup>) provide a homogeneous estimate of 5.6 per 100 person-years (95% confidence interval, 3.2-9.3). For the seven studies that specified the direction of transmission, incidence is estimated at 6.7 per 100 (95% confidence interval, 4.5-9.6).

**Figure 2. HIV incidence rates and confidence intervals for never-users, by study**



Sources: Deschamps M, 1996, reference 1; for all others, reference 21

Although the cumulative proportion of seroconversions differed significantly across the seven samples that specified the direction of transmission, the overlapping confidence intervals suggest that the incidence estimates across those samples may be homogeneous. The graphical odd-man-out method<sup>39</sup> estimates incidence to be between 3.2 and 11.9 for those seven studies. Possible heterogeneity among studies becomes evident, however, when we compare interval estimates across all 11 samples of never-users. The odd-man-out method produces an interval estimate across all 11 studies (4.7-11.9) and suggests that the Fischl et al.<sup>40</sup> incidence estimate (95% confidence interval, 22.0-75.0) is very different from the others.

## EFFECTIVENESS ESTIMATES

The failure rate ratio is used to measure condom effectiveness. It is calculated by dividing the HIV incidence for always-users by the incidence for never-users. Effectiveness, then, is one minus the failure rate ratio. The rate for always-users comes from the 12 longitudinal samples that provide a homogeneous estimate of transmission (0.9 per 100 person-years; 95% confidence interval, 0.4-1.8). The rate for never-users is more difficult to determine. Estimates of the never-user rate may be obtained from the five longitudinal male-to-female samples (6.8 per 100), the two female-to-male samples (5.9 per 100), the three hemophiliac/transfusion samples (5.6 per 100) or the seven samples that specified the direction of transmission (6.7 per 100; 95% confidence interval, 4.5-9.6).

Depending upon the incidence estimate chosen for the never-users, condom



effectiveness is estimated at 86.8% with the male-to-female data used as the denominator, 84.7% with the female-to-male data, and 83.9% with the hemophilic or transfusion data. Using all of the never-user samples that specified the direction of transmission produces an overall estimate of 86.6%.

Additionally, best-case and worst-case scenarios may be estimated for effectiveness, using the incidence confidence limits. Using the confidence limits from the aggregate estimates of incidence, a best-case scenario of 95.8% efficacy is obtained from the lower confidence limit on the incidence estimate for always-users (0.4) and the upper limit for never-users (9.6). Similarly, a worst-case scenario of 60.0% is obtained from the upper limit on incidence for always-users (1.8) and the lower limit for never-users (4.5). Thus, the overall estimate of condom effectiveness for HIV prevention is 86.6%, but true effectiveness may be between 60.0 and 95.8%.

## DISCUSSION

Current evidence indicates that the use of condoms for each and every sexual contact reduces the rate of heterosexually transmitted HIV infection. It is difficult, however, to make a single overall estimate of condom effectiveness. Clearly, one should not rely upon the results of a single study or only a few studies when many studies are available. Furthermore, such "effect sizes" are usually estimated through cumulative evidence and examination of consistency across multiple studies.

Meta-analysis, or the use of quantitative summarization procedures, facilitates the synthesis and interpretation of a large body of information. The use of meta-analytic techniques is limited in the case of noncomparable studies (those that differ in design, measures and results). Previous attempts at summarizing condom effectiveness did not remove the sometimes-users from among the always-users<sup>41</sup> and never-users,<sup>42</sup> and did not separate results from cross-sectional and longitudinal studies. Only longitudinal or cohort studies can provide estimates of the incidence of HIV. An additional complication is that in new studies (e.g., studies done since it became known that condoms may offer some protection from sexual transmission of HIV), the cohorts of condom nonusers have become cohorts of condom refusers, introducing an unknown amount of selection bias into the estimate of HIV incidence for condom nonusers. Thus, while we can readily obtain a fairly accurate estimate of the transmission rate for consistent condom users, an unconfounded estimate of HIV transmission among nonusers is difficult to obtain.

Usually, condom-use groups are compared within the context of a single study. Such a comparison can control for extraneous confounding variables when those variables are distributed similarly within each category and when the groups are equivalent in all aspects except condom usage. An association between condom use and any other HIV risk factor, however, would confound an estimate of effectiveness. It is now evident that condom use is influenced by many factors. In longitudinal studies, repeated office visits with HIV blood tests, interviewing and counseling cause a significant increase in condom usage<sup>43</sup> and in abstinence.<sup>44</sup> Individuals who knowingly have sex with an HIV-infected partner and, despite continued counseling, refuse to use condoms comprise "condom refusers." Condom nonusers are more likely to use drugs and alcohol.<sup>45</sup> 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

estimating effectiveness.

In this article, we attempted to deal with the difficulty of finding a proper denominator by estimating effectiveness with a variety of possible denominators. One could argue that partners in the early hemophiliac and transfusion studies might serve as the best "historical control" cohorts. These individuals may provide a more accurate estimate of the HIV transmission rate for condom nonusers, since they generally had no additional HIV risk factors,<sup>46</sup> and equally important, data are available from early in the AIDS epidemic. Hemophiliacs have been counseled to use condoms since the mid-1980s, and few hemophiliacs have been infected by blood products since HIV-antibody screening was developed in 1985.<sup>47</sup> Condom effectiveness was estimated to be 84% for the early hemophiliac and transfusion studies.

Condom efficacy for HIV reduction is similar to, although perhaps lower than, that for pregnancy. Condom efficacy for contraception may be best estimated using the lowest observed failure rate (97%).<sup>48</sup> A best-case scenario for prevention of HIV transmission suggests comparable efficacy (96%), whether it is estimated from the overall incidence among condom non-users or from the early hemophiliac and transfusion studies.

While the principle is the same in both HIV and pregnancy prevention, important differences prohibit the simple assumption that condoms will perform as well for HIV. First, there are more routes of transmission for HIV. Pregnancy results only from vaginal sex, but HIV can be transmitted through vaginal, oral<sup>49</sup> and anal routes. Second, conception can only take place during a few days out of a woman's menstrual cycle, while HIV may be transmitted at any time. Third, HIV particles are smaller than sperm cells and may actually leak through condoms.<sup>50</sup> Thus, condom efficacy may be higher for pregnancy than for HIV.

Although our estimate is based upon all published in vivo evidence, it is nevertheless only a crude estimate that does not control for confounding factors. The assumption that condom use is independent of other factors may not be valid and can affect seroconversion rates. Differences between always-users and never-users in the duration and frequency of exposure, infectivity of index cases and susceptibility of their partners can confound results. Some studies included couples who had had only one sexual contact, whereas others had relationships of more than 20 years. Moreover, the index partner's date of seroconversion was rarely known, making his or her partner's duration of exposure to infection difficult to establish.

Differences in infectivity between samples may also affect results. The progression of disease in the index partner increases infectivity,<sup>51</sup> and HIV incidence can be an order of magnitude higher among partners of index cases with advanced HIV than among those with asymptomatic cases.<sup>52</sup> Additionally, effectiveness of the condom would be overestimated if a higher proportion of nonusers has increased infectivity. In fact, one study found a greater proportion of intravenous drug users among nonusers, and also found nonusers to have higher HIV transmission rates.<sup>53</sup> Susceptibility to infection is elevated in partners with a history of sexually transmitted diseases (STDs),<sup>54</sup> and certain (STDs) are more prevalent among groups that do not practice circumcision.<sup>55</sup> The distribution of (STDs) may vary by region, making it difficult to combine rates

across countries and continents. Finally, in some studies participants used spermicides in conjunction with condoms,<sup>56</sup> which may affect estimates of effectiveness.

Besides differences in stage of disease and presence of STDs, HIV subtypes may also differ in infectivity. One study noted that female commercial sex workers in Thailand tend to be infected with HIV1-E while male homosexuals and intravenous drug users in North America and Europe tend to be infected with HIV1-B.<sup>57</sup> The authors suggest that HIV1-E may be sexually transmitted more readily than HIV1-B, and this may help explain the contradictory results concerning male-to-female and female-to-male transmission rates. Larger studies from North America<sup>58</sup> and Europe<sup>59</sup> found male-to-female transmission to be greater than female-to-male transmission, while smaller studies from Africa<sup>60</sup> and Asia<sup>61</sup> have found the opposite. This article found only a slight asymmetry in transmission by gender of the index case, with male-to-female transmission being slightly higher than female-to-male transmission among nonusers of condoms.

The source of infection in the index cases also may affect transmission rates, because of group-specific behaviors. Intravenous drug users may have intravenous drug-using partners who could acquire the virus via unreported needle-sharing rather than through sexual contact, thereby confounding estimates of heterosexual transmission. Anal sex may occur more often among female partners of bisexual men.<sup>62</sup> Most studies, however, did not include nonvaginal intercourse in their definition of condom usage. If unreported HIV risk behaviors, such as intravenous drug use and anal sex, were distributed similarly among always-users and never-users, then estimates of effectiveness should not be affected. One can assume, though, that those consistently using condoms also may be more likely to practice other safe behaviors. Conversely, those refusing to use condoms may be more likely to engage in other risky behaviors,<sup>63</sup> increasing the transmission rate for nonusers and inflating estimates of condom effectiveness.

Misclassification of individuals according to their condom use also can affect results. Cross-sectional studies relying on a single interview and blood sample with a retrospective sexual history are seriously limited by the accuracy of reported behaviors recalled over long periods of time. Prospective studies with multiple interviews, blood tests and counseling may report sexual behaviors more accurately than retrospective studies, but active intervention (counseling) introduces bias by intentionally trying to increase condom use. Study participants may provide more socially desirable responses and may overreport condom usage, especially after being counseled to use condoms. However, studies comparing the responses of partners have found fairly good reliability in the reporting of sexual behaviors.<sup>64</sup>

Use of the average length of follow-up time rather than the exact number of seronegative person-years to calculate incidence can also result in the underestimation of incidence. In one study, for example, the 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).<sup>65</sup> Reestimation of the incidence and confidence interval using 12 months instead of 24 months follow-up raises the incidence rate, and the study becomes even more extreme. If incidence is underestimated by different amounts in each condom-use group,

effectiveness may be overestimated or underestimated.

In this article, we have attempted to present all available data from in vivo studies and to estimate the effectiveness of

condoms in reducing heterosexually transmitted HIV. When condoms were used for each and every sexual contact, they provide a reduction in risk similar to that for pregnancy prevention. Nevertheless, these estimates may reflect optimal condom performance. Both user failure and method failure are present in scientific studies of condoms and HIV-related behaviors, but these effects would be expected to be minimized by the promotion of proper condom use, the self-selection effect of volunteering for study participation and quality control measures for condoms.

In a study setting, individuals are instructed in the proper use of condoms and may be more motivated; condom effectiveness may be lower outside of the research setting. For example, the condom's effectiveness in reducing pregnancy is lower among younger and less-educated users, because user failure increases.<sup>66</sup> Similarly, method failure may increase outside of the context of a scientific study, where there is less quality control on condoms. Quality control standards for condom manufacture are not consistent around the world, and condoms may be subjected to extremes in temperature or stored for long periods of time in some settings. All of these factors contribute to higher failure rates and potentially lower effectiveness in real-life settings.

In future research, the collection of new cohort data may provide more accurate estimates of HIV transmission among condom users, but not necessarily for nonusers. In fact, future efforts might be directed toward a careful reconstruction of an appropriate cohort of historical controls (e.g., studies done before condom use was actively promoted). It is clear that a variety of factors increase transmission and affect estimates of condom efficacy. Condoms are not 100% efficacious, and it is not likely that efficacy is as high as 95-99%, as some individual studies might suggest. Minimization of bias is necessary to approach an accurate estimate, but because of the need to rely on observational studies, an exact estimate may never be obtained. It is reasonable to assume, however, that estimates obtained for contraception are the upper limits of the condom's efficacy for prevention of HIV transmission.

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\*The likelihood of pregnancy with or without condoms is actually a probability and must be transformed into a rate. Thus, effectiveness is:  $1 - (-\ln(1-f_c)) / (-\ln(1-f_o))$ , where  $f_c$  indicates the likelihood of pregnancy with a condom and  $f_o$  is the likelihood without a condom. (Trussell J, personal communication, July 1999).

†For this study, authors provided detailed classification of data for Roumelioutou-Karayannis A et al. (reference 20). In addition, for an earlier analysis (reference 14), authors of Ragni MV et al., Padian N et al., and Kim HC et al. (reference 20) provided detailed data.