Workshop Summary:

Scientific Evidence on Condom Effectiveness for Sexually Transmitted Disease (STD) Prevention

June 12-13, 2000

Hyatt Dulles Airport

Herndon, Virginia

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EXECUTIVE SUMMARY

Background

Sexually transmitted diseases (STDs), including HIV, are common, important, and preventable causes of morbidity, mortality, disability, lost-productivity, and health care costs. In the United States, more than 65 million individuals are living with an STD, the majority of which are incurable viral infections. Approximately 15 million new sexually transmitted infections occur annually in the U.S. In the United States, approximately 493,000 individuals have died from AIDS, and 800,000-900,000 people are living with HIV disease. Many sexually transmitted infections can cause adverse pregnancy outcomes including miscarriages, stillbirths, intrauterine growth restriction and perinatal (mother-to-infant) infections. Some STDs can cause infertility or lead to ectopic pregnancy among women and one, the human papillomavirus, can cause cervical and anogenital cancer. Furthermore, other STDs facilitate HIV transmission.

The Problem and the Process

Primary prevention of STD infection is an important health priority. Unfortunately there are no STD vaccines, except for hepatitis B vaccine, and topical microbicides to prevent STDs are not available. Beyond mutual lifelong monogamy among uninfected couples, condom-use is the only method for reducing the risk of HIV infection and STDs available to sexually active individuals.

Recently, a number of Federal agencies sponsored a workshop to answer the following question: "What is the scientific evidence on the effectiveness of latex male condom-use to prevent STD transmission during vaginal intercourse?" This workshop was attended by 180 persons, and the data from numerous peer-reviewed published studies were discussed. Following the workshop, a panel of 28 experts worked to develop this report.

The sessions included review of published information on the properties and user patterns of the male latex condoms for vaginal intercourse and included data from studies on pregnancy prevention. Focused research studies have documented the high effectiveness of condoms for prevention of pregnancy. The data associated with condom use in eight specific STDs were considered in detail, including HIV infection, gonorrhea, chlamydial infection (including gonococcal and chlamydial pelvic inflammatory disease), syphilis, chancroid, trichomoniasis, genital herpes, and genital HPV infection and associated diseases (i.e. cervical dysplasia, cervical cancer and genital warts).

The meeting was not intended to make public health policy recommendations regarding the role of condoms in HIV/STD prevention policy and programs.

Assessment of the Data

In general, the Panel found the published epidemiology literature to be inadequate to definitively answer the question posed to the workshop participants. Most studies reviewed did not employ a prospective design, which is the optimal method to assess the effectiveness of condoms in preventing infection.

Conclusions on STDs Transmitted by Genital Secretions

The published data documenting effectiveness of the male condom were strongest for HIV. The Panel concluded that, based on a meta-analysis of published studies "always" users of the male condom significantly reduced the risk of HIV infection in men and women. These data provided strong evidence for the effectiveness of condoms in preventing HIV transmission in both men and women who engage in vaginal intercourse.

The Panel also concluded that the consistency of findings across four epidemiological studies of gonorrhea indicated that the latex male condom could reduce the risk of gonorrhea for men.

The strongest evidence for potential effectiveness of condoms on other STDs transmitted by genital secretions (i.e. gonorrhea in women, chlamydial infection and trichomoniasis) was the laboratory-based studies on the properties of the male latex condom and the strength of the evidence for condom use reducing the risk of HIV transmission in men and women and gonorrhea in men. The Panel concluded, however, that because of limitations in study designs there was insufficient evidence from the epidemiological studies on these diseases to draw definite conclusions about the effectiveness of the latex male condom in reducing the transmission of these diseases.

Conclusions on Genital Ulcer Diseases

The Panel agreed that the published epidemiologic data were insufficient to draw meaningful conclusions about the effectiveness of the latex male condom to reduce the risk of transmission of genital ulcer diseases (genital herpes, syphilis and chancroid).

Conclusions on HPV

For HPV, the Panel concluded that there was no epidemiologic evidence that condom use reduced the risk of HPV infection, but study results did suggest that condom use might afford some protection in reducing the risk of HPV-associated diseases, including warts in men and cervical neoplasia in women.

Summary

The Panel stressed that the absence of definitive conclusions reflected inadequacies of the evidence available and should not be interpreted as proof of the adequacy or inadequacy of the condom to reduce the risk of STDs other than HIV transmission in men and women and gonorrhea in men. To definitely answer the remaining questions about condom effectiveness for preventing STD infections will require well-designed and ethically sound clinical studies.

Workshop Summary: Scientific Evidence on Condom Effectiveness for STD Prevention

1. Introduction

Sexually transmitted diseases (STDs), including the human immunodeficiency virus (HIV)/AIDS, are important and preventable causes of morbidity, mortality, disability, and associated lost-productivity and health care costs. One in five adults in the United States has an STD (170). In the United States, approximately 450,000 individuals have died from AIDS, and 800,000-900,000 people are living with HIV infection. Approximately 15 million new sexually transmitted infections occur annually in the U.S. Many go undiagnosed, and therefore untreated. The health repercussions of STDs, particularly undiagnosed infections, can be serious. Asymptomatic infections, which can result in unknown transmission of STDs, are important factors in perpetuating STD/HIV infections. Many sexually transmitted infections can cause adverse pregnancy outcomes including, but not limited to, miscarriage, still birth, intrauterine growth restrictions, and perinatal (mother-to-child) infections. Some STDs are associated with infertility among women and one, the human papillomavirus, can cause cervical cancer among women. In addition, studies have shown that both ulcerative and non-ulcerative STDs promote HIV transmission by augmenting HIV infectiousness and HIV susceptibility. Multiple prospective studies have estimated this risk to be between 2 and 5 fold (178).

STDs can be prevented. Current prevention/risk reduction strategies include, abstinence, mutual monogamy with an uninfected partner, use of condoms and engaging in sexual activity that does not result in the transfer of bodily fluids or cell-to-cell transmission. There are no marketed microbicides or vaccines (with the exception of hepatitis B vaccine) for the prevention of STDs, although research to develop them is underway. All STD prevention and risk reduction strategies involve the complex interplay of biological, behavioral, social and structural factors. These issues have been elucidated in the Institute of Medicine report on STDs, *The Hidden Epidemic* (118), and the recent IOM report on HIV prevention, *No Time To Lose* (144).

2. Process: Scope of Workshop

On June 12-13, 2000, four government agencies (U.S. Agency for International Development, Food and Drug Administration, Center for Disease Control and Prevention, National Institutes of Health) responsible for condom research, condom regulation, condom use recommendations, and HIV/AIDS and STD prevention programs, co-sponsored a workshop to evaluate the published

evidence establishing the effectiveness of latex male condoms in preventing HIV/AIDS and other STDS. [1]

Representatives of the sponsoring agencies and outside experts were asked to work as a panel to review and discuss the existing literature and write a report. The expertise of the panel members included STDs, genitourinary tract anatomy, contraception, condoms, behavioral science, epidemiology, medicine, and public health. This report was developed by the panel members. The names and affiliations of the 28 panel members are listed in Appendix A.

The workshop examined only peer-reviewed literature because these studies have been subjected to independent scientific evaluation prior to publication. Based on literature searches and papers identified by the speakers, discussants, meeting attendees and panel members, 138 peer-reviewed papers, published on or before June 2000, were compiled and reviewed. From this selection, the individual presenters determined which papers to consider based on their assessment of the quality of the evidence contained within the papers. Presenters varied in their criteria for inclusion or exclusion and, in general, the Panel's deliberations were focused on the papers deemed sufficient for inclusion by the individual presenters. Because the workshop was structured to examine the level of protection afforded by condom use for individual STD pathogens, presenters responsible for reviewing and summarizing the data for each infection generally excluded studies that presented outcomes for multiple infections in aggregate. The reader is referred to the bibliography for a more complete view of the issues discussed at the workshop. Additionally, for those interested in a broader discussion, a tape recording of the two-day meeting is available and can be ordered[2]. The bibliography appears in Appendix B and includes the reviewed papers (numbered 1- 138) as well as other papers cited in this summary (numbered 139 – 180).

The agenda for the workshop is provided in Appendix C.

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[1] The focus on the latex male condom for the prevention of HIV/AIDS and STDs during penile-vaginal intercourse reflected the predominance of the latex male condom in current condom usage, its FDA labeling for this purpose, and the preponderance of available effectiveness literature. The focus was not intended to diminish the need for research on other forms of male condoms, on female condoms, and on prevention of HIV/AIDS and STDs associated with other forms of sexual activity, such as oral or anal intercourse.

[2] Cassettes can be obtained from:
Audio Transcripts, Ltd.
3660-B Wheeler Avenue,
Alexandria, VA 22304
Conference #1561
June 12-13, 2000
Scientific Evidence on Condom Effectiveness and STD Prevention sponsored by National Institute of Allergy and Infectious Diseases

The scientific scope of the workshop was deliberately limited to three areas:

(1) The device. This workshop examined evidence only for the male condoms made from natural rubber latex. According to sales data, the latex male condom accounts for 97% of all United States condom sales (per unit).
(2) The route of infection. The workshop addressed condom effectiveness in preventing infections transmitted via penile-vaginal intercourse. The U.S. Food and Drug Administration (FDA) permits manufacturers to label latex condoms for use during penile-vaginal intercourse as follows, "If used properly, latex condoms will help reduce the risk of transmission of HIV infection (AIDS) and many other sexually transmitted diseases." Other routes of infection were not evaluated.
(3) The diseases. The workshop examined evidence related to eight STDs: HIV infection, gonorrhea, chlamydial infection, [including gonococcal and chlamydial pelvic inflammatory disease (PID)], syphilis, chancroid, trichomoniasis, genital herpes caused by herpes simplex viruses (HSV) 1 and 2, and genital human papillomavirus (HPV) infection and HPV diseases.

3. Evaluation Parameters

Efficacy versus Effectiveness

The protection condoms afford against STDs can be examined from three perspectives, including:

(1) The product;
(2) The individual users, who may include those who use the device properly, improperly or intermittently whenever they are at risk for transmitting or becoming infected with an STD; and
(3) The population in which the prevalence of sexual behaviors, including condom use and exposure to different STDs, may vary.

Regarding the product, protection depends on the physical properties of the device, breakage and slippage rates, and the parts of the body it covers. From the perspective of the individual user, protection also depends on whether the device is used properly for every act of intercourse or, in the parlance of condoms and STDs, whether it is used "correctly and consistently." It is important to distinguish between condoms' efficacy, which is the protection that the users would receive under ideal conditions, and their effectiveness, which is the protection they provide under actual conditions of use. Efficacy depends primarily on the properties of the device, whereas effectiveness depends on the

characteristics of the device and the user. Since multiple studies were evaluated, study groups and their condom use behaviors varied. The accuracy with which condom use was defined and measured also varied from study to study. Thus, in all the studies reviewed in this workshop, the observed relationship between reported condom use and STDs reflects both product characteristics and user behaviors that may fall short of ideal and also may not represent "typical" for the population at large. For the purpose of this report, the term "condom effectiveness" will be used to mean the level of protection against STDs when condoms are used consistently and correctly.

Methodological Issues

To make a valid empirical assessment of condom effectiveness for STD prevention, appropriate study design, accurate measurement, and appropriate analyses are necessary. The panel considered the particular methodological challenges posed by condom use studies to determine the quality of the data and to evaluate the strength of the evidence/conclusion. A variety of study designs were used in the literature reviewed and they differed in their ability to provide strong evidence of the relationship between condom use and STDs. The ideal design, a prospective randomized controlled clinical trial, has not been used in evaluating condom effectiveness because of ethical concerns associated with non-use of condoms in high-risk populations. In this design, factors that could bias results are minimized because participants are randomly assigned to treatment and control arms. All published studies reviewed in this document are observational studies, that is, participants were not assigned to use or not use condoms. Instead, the presence or occurrence of infection was compared between those who reported using or not using condoms.

Each observational design carries its own strengths and weaknesses. Prospective cohort studies collect information on events as they occur. A cohort study can provide the strongest evidence among the observational designs. To do so, this design requires following a relatively large number of sexually active participants for an extended period of time and can be quite costly. This design is also vulnerable to attrition of subjects, but errors associated with recall and selection bias can be minimized, as the cohort is assessed in real time. It can also establish the order of events (exposure, infection, disease).

Retrospective case-control studies or cross-sectional prevalence studies can be relatively more economical because individuals who have or had the disease of interest (cases) can be selected and compared with those without the disease (controls), with data collected on possible exposure and use of protective measures during previous intervals. However, these studies are vulnerable to errors in recall and selection bias. These designs also make it difficult to determine the temporal ordering of events because exposure to infection, data on condom use, and outcome are measured at the same time.

The population chosen for study, the incidence and prevalence of disease in the population, and the numbers of subjects also have important implications for a study's ability to detect significant effects and to generalize these effects to other populations. In observational studies, the ability to measure and account for differences in risk between two groups (i.e. condom users versus non-users) is critical. If such "confounders" are not taken into account, the estimate of effectiveness will be biased.

Appropriate measurement of key exposures and infection or disease outcomes is also critical. Ideally, highly specific and sensitive diagnostic techniques for detection of infectious agents should be employed. It is also essential to ascertain whether the condom was used consistently and correctly, including occurrences of slippage or breakage, during the entire period of exposure. Because direct observation and objective measurement of condom use are not possible, all studies must rely on self-reported use, a potential source of error due to recall bias.[3]

The panel's review of the existing literature on condoms and STD transmission revealed that the majority of the studies were not optimally designed to answer the specific questions posed at this workshop; as such, a number of common problems in study design were noted including:

(1) In some STD studies, clinical manifestation of disease rather than the more infection-specific diagnostic tests were used as the outcome measures in evaluating condom effectiveness. Consequently, the study designs were not optimal to ascertain all incident infections and, therefore, to address the objectives of this conference.
(2) Many studies lacked sufficient numbers of subjects to have adequate statistical power to evaluate condom effectiveness.
(3) Many studies were done in special populations, such as commercial sex workers or STD clinic patients, who are at far higher risk for infection than are other sexually active individuals. Therefore, generalizability to other populations is somewhat limited.
(4) Gender differences with respect to infectivity and susceptibility were not taken into account in many studies. For example women are more susceptible than men to gonorrhea and chlamydia.
(5) Insensitive or non-specific methods were often used to detect specific infections.
(6) Most studies did not use the optimal interview methods or questionnaires to elicit complete and accurate information, especially with regard to sexual histories and condom usage.
(7) Factors associated with the outcome disease that are also associated with condom usage can confound and bias estimates of effectiveness. Bias can either over-estimate or under-estimate effectiveness.

[3] New tests using biological markers assessing the presence or absence of seminal fluids in the vagina after intercourse may offer the possibility of better measurements of condom use and/or effectiveness. The use of these biomarkers is promising but remains developmental.

(8) Many available studies had limited data regarding condom use in relation to exposure to infectious agents. In many, quantitation of condom use was imprecise and did not distinguish between correct and incorrect use, e.g. timing of donning of the condom during sexual activity and use of the condom during the entire sexual act. Slippage and breakage events were also not quantified and some studies measured only "ever" use and some failed to specify how condom use was measured.
(9) For most studies the ability to document exposure to disease in relationship to condom use was uncertain.

4. Findings: The Device

The Latex Male Condom

Most male condoms are made from natural rubber latex. When used consistently and correctly and without slippage or breakage, male condoms cover the penis and will contain pre-ejaculate emissions as well as semen following ejaculation, thus protecting the female reproductive tract. Condoms also may prevent penile exposure to cervicovaginal secretions and tissues under similar conditions and use. Condom shape, thickness, and other specifications, including the latex formulation itself, have been engineered to produce a product that is placed easily (onto the penis), minimizes slippage and breakage during vaginal intercourse, and contains the collected fluids.

The FDA regulates manufacturers who sell condoms in the U.S., primarily through 510(k) premarket notification (premarket) and compliance with the Quality System Regulation (postmarket). Through premarket notification, FDA can ensure that condoms marketed in the U.S. are designed properly with appropriate specifications. As a postmarket regulatory control, the Quality System Regulation requires manufacturers to:

(1) Employ quality assurance standards for new condom designs;
(2) Employ validated processes in condom manufacture; and
(3) Apply strict product release criteria to condoms.

As a quality assurance step, condom manufacturers sample each lot of finished packaged condoms and visually examine them for holes using a water leak test. FDA recognizes domestic and international standards that specify that the rate of sampled condoms failing the water leak test, for each manufacturing lot of condoms, be less than 1 in 400 (ASTM D3492 and ISO 4074) (http://www.fda.gov/cdrh/ode/oderp399.html). Manufacturers also test lots for physical properties using the air burst test and the tensile (strength) property test. These latter tests provide a measure of consistent condom quality.

The FDA also requires manufacturers to determine condom stability over time and to provide an expiration date of the condom for the labeling. This is done

using accelerated stability tests of packaged condoms at elevated temperatures. In addition, manufacturers must conduct real-time studies to confirm the expiration date (21 CFR 801.435) (http://frwebgate.access.gpo.gov/cgi-bin/get-cfr.cgi). Properly packaged and properly stored, condoms maintain their physical integrity over several years.

FDA researchers have also developed an assay for condom leakage using high concentrations of a laboratory virus (78). The laboratory virus penetration assay is not used routinely as a quality control test, but its sensitivity and relevance are arguably greater than the conventional water leakage test. Using this virus assay, FDA scientists tested many different types of male condoms and showed that condoms are highly effective barriers to virus passage with a very small chance of leakage (76, 77). Intact condoms (i.e., pass the water leak test) are essentially impermeable to particles the size of STD pathogens (including the smallest sexually transmitted virus, hepatitis B). Moreover, these studies show that fluid flow, not virus size, is the most important determinant of viral passage through a hole. Even holes many times larger than the virus impeded fluid flow such that few of the test particles passed through (78).

Applying results from the laboratory tests (12, 76, 77, 78), the hypothetical relative risk of exposure to semen, as a function of semen volume attributable to various independent condom use events, was presented and is shown in the table below. The purpose of this relative risk assessment is to model the expected degree of protection of exposure to semen afforded by condom use, condom non-use, and condom use in the events of breakage or leakage.

Hypothetical Relative Risk Model of Condom Use

Condom Use Event	**Semen Exposure** (Volume, averaged over event probability)	**Relative Risk** Compared to Non-Use
Failure to Use a Condom	3.3 ml	1.0
Condom used, but it breaks	1 ml $\times$ 2/100	0.006
Condom used, No break but has visibly detectable hole (by water leak test)	10^{-2} ml $\times$ 1/400	0.000008
Condom used, No break, No visibly detectable holes, but still passes virus	6×10^{-6} ml $\times$ .023	0.00000004
Condom used, no break, no leak	0.0 ml	0.0

For example, if a condom breaks during intercourse, the associated volume of fluid leaking out of the condom is estimated to be approximately one-third of the total ejaculate, i.e., about 1 ml. Therefore, assuming a 2% breakage or slippage rate during actual use, the relative risk of semen exposure from the infrequent condom breakage (compared to using no condom at all) would be .006 (1 ml $\times$ 2/100 $\div$ 3.3 ml).

Under this risk assessment, failure to use a condom would obviously result in certain exposure (1.0 probability). Conversely, condom use without breakage or slippage would reduce (if not eliminate) exposure dramatically (0.0 probability). However, and perhaps just as importantly, condom use – even in the event of breakage, leakage, or slippage – would also result in greatly reduced exposures.

It should be noted that, for many STDs, risk of infection might not be proportional to exposure to a *volume* of semen. Estimation of risk requires further extrapolation because it depends on additional variables, especially the infectious agent of interest. The concentration, infectivity, and mode of transmission of the specific STDs clearly need to be considered (12).

Conclusion

Natural rubber latex condoms for men are manufactured to conform to limits specified within consensus standards, including water leakage. Laboratory studies show that manufactured condoms meet these specifications. Other studies, based on viral penetration assays, have demonstrated that condoms provide a highly effective barrier to transmission of particles of similar size to those of the smallest STD viruses. These data also provide a strong probability of condom effectiveness when used correctly, where the etiology of STD transmission is linked to containment of pre-ejaculate and seminal fluids or barrier coverage of lesions on the penis and there is no slippage or breakage.

Condom Use Data

Condom use patterns

National surveys that monitor contraceptive behaviors among Americans have documented increases in condom use throughout the 1980s and 1990s, coincident with increased awareness of AIDS and increased prevention efforts. The largest increases in condom use have occurred among adolescents and young adults, the age groups most at risk for infection with HIV and other STDs. The National Survey of Family Growth reported that condom use among American women 15-44 years of age increased from 12% in 1982 to 15% in 1988, and to 20% in 1995 (98). Reported condom use in women is higher among those who are unmarried and younger. The trends in National Survey of Family Growth data are corroborated by data from national representative sample surveys of youths. Two surveys of young men, completed in 1988 and 1995 document that in 1988, 33% of youth ages 15-19 report always using a

condom when having sex, and in 1995 that proportion increased to 45%. In 1988 the proportion of those who had sex and never used condoms was 18.4%, while in 1995, only 9.5% reported never using condoms (112). The Youth Risk Behavior Survey (youth in grades 9-12) also documents significant increases in reported condom use between 1991 and 1997, from 55% to 62% for males and from 38% to 51% for females (180). That study reports use at the last act of coitus, but does not address correct or consistent use nor slippage and breakage. A 1990 re-interview of participants in the 1988 National Survey of Family Growth assessed the reasons for condom usage in a representative sample of 932 sexually experienced unmarried women (aged 17-44). In this group 41% reported using condoms for protection, at least some of the time, against STDs; 18.5% reported "every time" use (4).

Condom Slippage and Breakage during Use

For a condom to be fully effective, it must stay on the penis during sexual intercourse, and it must not break. However, condoms sometimes do slip or break during use. Many studies have looked at condom slippage and breakage, but most were conducted ten or more years ago and, therefore, do not represent higher quality condoms being manufactured today. Moreover, most employed methodologies led to questionable relevance or reliability of reported rates. Such methodological drawbacks included inexact definition of terminology, selection bias, study size (e.g., <100 couples; <1000 uses), populations that are less generalizeable (e.g., commercial sex workers, low STD risk, etc.), and reporting methods (e.g., retrospective surveys relying on memory of events six months earlier). None of the studies considered by the panel evaluated condom slippage and breakage rates in sexually active teenagers less than 18 years of age. Only three published articles report results from recent prospective sizeable trials of latex condoms in the U.S. and provide reliable slippage and breakage rates (44, 45, 80). Estimates of condom breakage from these studies range from 0.4-2.3%. Slippage rates from these three studies ranged from 0.6% to 1.3%. Slippage rates include both slippage during intercourse and slippage during withdrawal. The combined method failure (slippage plus breakage) is estimated at 1.6% – 3.6%.

These and other studies show that factors affecting slippage and breakage are related to user familiarity and knowledge, including user experience, selection of condom size (width), and proper use of additional (exogenous) lubricant (2, 51, 81, 123). With increased education and improved experience, one can expect condom slippage and breakage rates to decrease.

One additional drawback of all these studies is reliance on self-reports for tallying the events themselves, i.e., slippage, breakage, and use. More recently, study methodologies have provided for improved logs of coital activity to be used by study participants, as well as careful study monitoring techniques to encourage their consistent use. It is believed that this has added to the reliability of slippage and breakage rates numbers. Still, these studies may inherently be hindered by

relying on the self-assessment of study participants. Over the past 2-3 years, researchers have begun to use biological markers and postcoital testing of the vaginal pool as a potentially more objective measure of method failure. The eventual success of these efforts remains to be seen (75, 79, 129).

Overall, results from clinical slippage and breakage studies, when coupled with results from laboratory studies, suggest that condoms provide a reliable barrier for the areas covered (the penis) and touched (vaginal and cervical mucosa) and that the level of protection is greatest when used correctly.

Lessons from Pregnancy Studies

Information on consistent and correct condom use for the prevention of pregnancy has also provided valuable insights on the importance of consistent use. Approximately 3% of couples who reported using condoms consistently and correctly (considered "perfect use") are estimated to experience an unintended pregnancy during the first year of use (123), based on results of one rigorous controlled trial as well as modeling based on rates of condom breakage and slippage. In a recent well-controlled randomized clinical trial of monogamous couples using latex male condoms for contraception over six months, the pregnancy rate during “typical use” was reported at 6.3%, with a 1.1% pregnancy rate during “consistent use” (45). Most of these couples had experience using condoms. However, based on estimates from National Surveys of Family Growth (123), 14% of couples are estimated to experience an unintended pregnancy during the first year of “typical” use, a failure rate that includes both inconsistent (non-use) and incorrect use, as well as breakage and slippage. Failure rates in the second year of typical use are about 50% lower (167).

Conclusions

Condom use in the U.S. has increased over the past 20 years. Recent studies conducted in the U.S. show condom breakage rates during use to be in the range of 0.4% to 2.3%, with comparable rates for slippage. Use factors such as experience, condom size, and use of lubricant can affect condom slippage and breakage.

Information on condom use for pregnancy prevention indicates that, at least in the population described above, as condom experience and facility in use of condoms increases in couples using condoms as their primary method of birth control, unintended pregnancies decrease.

5. Findings: The Diseases

The eight STDs addressed in this report are HIV infection, gonorrhea, chlamydial infection, (including PID caused by gonococcal and chlamydial infections), syphilis, chancroid, trichomoniasis, genital herpes caused by HSV 1 and 2, genital HPV infection and HPV diseases including genital warts, cervical dysplasia and cervical cancer. These infections span the spectrum of medical microbiology, including viral, bacterial, and parasitic infections. Each of these infectious diseases is unique; variation in transmissibility, duration of infectivity, co-morbidity, and clinical manifestations are well described. Variations in the modes of transmission and the transmissibility of the different infections will affect the level of protection that condoms can be expected to provide.

Seven of the eight STDs fall into two categories: discharge diseases and ulcerative diseases. The discharge diseases include HIV infection, gonorrhea, chlamydial infection and trichomoniasis. The infectious agents of discharge diseases are present in genital secretions (i.e., semen and cervical-vaginal fluid). In genital ulcer diseases (genital herpes, syphilis, and chancroid), the infectious agents are present in sores or ulcers; however, the infectious agents may also be released or "shed" into secretions. HPV infection cannot be classified in either category; this virus is probably transmitted via contact with infected cell surfaces in the presence or absence of fluid or tissue exchange. Organism-related factors that influence transmission include infectiousness of virus, bacterium or parasite, duration of infectiousness, and variation in infectiousness based on stage of disease.

In addition to causing symptomatic disease, most of these infections cause diseases with no symptoms (asymptomatic) or with very mild symptoms; these infections are called "silent." People who have silent infections do not seek health care and consequently, most remain undiagnosed and untreated. Not all STDs respond to treatment. The curable diseases include four bacterial infections (gonorrhea, chlamydial infection, syphilis, and chancroid) and the one parasitic infection (trichomoniasis). Appropriate treatment eliminates these infections. In contrast, the viral infections (HSV, HIV, and HPV) either persist for life (HSV and HIV) or are cleared spontaneously (approximately 90% of HPV infections). However, HSV and HIV infections may be controlled or ameliorated with anti-viral therapies.

The likelihood of spreading these infections during sexual intercourse varies. Multiple factors influence transmission, including characteristics of the infectious organism and the site(s) of infection, the health of the infected individual and the uninfected partner, the couple's sexual behaviors, and the prevalence of STDs in different populations will affect the likelihood of exposure to STDs.

A number of biologic factors, specific to the infected individual and his or her partner influence transmission rates including age, sex, and nutritional status.

Based on genetic make-up and history of previous infections, individuals may vary in non-specific defenses and specific (immune-mediated) defenses. These defenses will alter susceptibility to infection if exposed. If the person is infected, host defenses may alter that person's infectiousness by reducing the frequency of shedding of the infectious agent, the concentration of the infectious agent in secretions or lesions, and the duration of infection. Whether or not a host becomes symptomatic during infection may influence health care seeking behaviors that would also influence infectiousness.

A couple's sexual behavior is important; specifically foreplay, the types of sexual intercourse (e.g. anal and/or penile-vaginal), abrasions, the number of acts of intercourse and intercourse during menses may influence exposure and transmission rates. Importantly, the duration and perceived seriousness of the relationship and the gender roles and empowerment, will affect the use of condoms, choices of contraceptive, and choices regarding sexual monogamy.

General population factors that influence transmission rates include prevalence of infection and access to health care. The risk of transmission of infection can vary widely in observed populations because actual exposure depends upon the choice of individual sex partner and that person's risk characteristics.

To complicate matters, a change in one factor may lead to other changes that counter-act the anticipated change in risk of transmission. For example, anti-herpes therapies (e.g., acyclovir) reduce the amount of genital herpes virus that is shed in the genital tract fluids. The expectation is that the person is less infectious since these secretions may not contain much virus. However, if infected individuals do not use condoms during intercourse because they believe that they are not infectious, the rate of HSV transmission may not be reduced. In aggregate, both biomedical and behavioral factors determine whether or not infection is transmitted.

Measurement of condom effectiveness is affected by transmissibility; the relative ease of transmission in part determines how "forgiving" the method is if user- or device-failure occurs. If infection is transmitted easily, for example gonorrhea, failure to use a condom or incorrect use even one time may result in exposure and infection. In contrast, if an infection is hard to transmit, for example HIV, failure to use a condom or incorrect use may not result in infection because the probability of transmission is lower per exposure.

Infections Transmitted by Genital Secretions

With penile-vaginal intercourse, HIV/AIDS, gonorrhea, chlamydia and trichomoniasis are transmitted from infected males to uninfected females via exposure of the cervix and vaginal epithelium to semen and from infected females to uninfected males via exposure of the male urethra to female genital secretions. The effectiveness of the latex male condom in reducing the risk of infection is, in large part, dependent upon preventing exposure to fluids that may

be infectious. If used correctly and without slippage or breakage, the latex male condom contains the male pre-ejaculate and ejaculate and thus reduces the risk that the female will be exposed to these secretions. Likewise, if used correctly and without slippage or breakage, the latex male condom should adequately cover the male urethra and protect the penis from exposure to female genital secretions.

HIV (Human Immunodeficiency Virus)/AIDS

Background

In 1999, an estimated 6 million adults and children around the world were newly infected with HIV. Approximately 40,000 of these infections occurred in the U.S; 70 percent of new infections were diagnosed among men and 30 percent among women. Notably, more than 80 percent of all adult HIV infections throughout the world have been transmitted during heterosexual intercourse.

HIV is found in the blood and virtually all other body tissues and fluids. Stage of disease as well as co-infection with other STDs can increase HIV shedding in genital secretions and thereby increase risk of transmission. HIV/AIDS can be sexually transmitted by anal, penile-vaginal, and oral intercourse. The highest rate of transmission is through anal exposure. In addition, secretions from ulcerative lesions (associated with other STDs) on the penis may also be a source of infected male-to-uninfected female transmission of HIV/AIDS, and ulcerative lesions may be sites for uninfected male exposure to HIV/AIDS from infectious female secretions.

Key Research Findings on Effectiveness

HIV infection is the only STD for which formal meta-analyses have been published (28, 166). The most recent analysis by Davis and Weller (28) was evaluated. This analysis, in which only longitudinal or cohort studies were included, used the following criteria to select studies related to condom use and HIV/AIDS prevention:

(1) Sample included serodiscordant, sexually active, heterosexual couples;
(2) HIV status was determined by serology (so that exposure to HIV was known);
(3) Data collection included self report about condom use; and
(4) Study design afforded longitudinal follow-up of HIV uninfected partner.

Studies with insufficient condom use information and/or duplicate or interim reports on the same cohort were excluded.

Davis and Weller found twelve studies, which met these criteria (139, 29, 30, 150, 155, 158, 160, 161, 165, 108, 171, 173). The meta-analysis noted the direction of transmission (male-to-female, female-to-male, and unstated) and

date of study enrollment. Condom usage was classified into the following three categories: always (100% use), sometimes, and never.

Among participants who reported always using condoms, the summary estimate of HIV/AIDS incidence from the twelve studies was 0.9 seroconversion per 100 person years. Among those who reported never using condoms, the summary estimate of HIV/AIDS incidence from the seven studies was 6.7 seroconversions per 100 person years. Overall, Davis and Weller estimated that condoms provided an 85% reduction in HIV/AIDS transmission risk when infection rates were compared in always versus never users.

Conclusions

The methodological strength of the studies on condoms to reduce the risk of HIV/AIDS transmission far exceeds that for other STDs. There is demonstrated exposure to HIV/AIDS through sexual intercourse with a regular partner (with an absence of other HIV/AIDS risk factors). Longitudinal studies of HIV- sexual partners of HIV+ infected cases allow for the estimation of HIV/AIDS incidence among condom users and condom non-users. From the two incidence estimates, consistent condom use decreased the risk of HIV/AIDS transmission by approximately 85%. These data provide strong evidence for the effectiveness of condoms for reducing sexually transmitted HIV.

Gonorrhea (Neisseria gonorrhoeae)

Background

Gonorrhea causes significant morbidity in the U.S. and around the world. Every year an estimated 650,000 cases occur in the United States and 62 million cases occur worldwide. Gonorrhea is one of two major causes of pelvic inflammatory disease (PID); the other cause is chlamydial infection. Although PID is often silent and therefore difficult to diagnose, PID is a serious disease in the upper reproductive tract of women. PID causes tubal scarring and can result in ectopic or tubal pregnancy, tubal infertility, and chronic pelvic pain. Like most other STDs, gonorrhea may cause adverse pregnancy outcomes, such as neonatal ophthalmia, with loss of vision.

Infection results from exposure to *Neisseria gonorrhoeae* in infectious cervical/vaginal secretions or ejaculate during oral, vaginal, or anal intercourse. Although the infectious dose is unknown, one ejaculate from an infected man contains approximately 6 million live bacteria (157). Although limited, data suggest an average transmission of 1 infection for every two exposures. Transmission efficiency is gender dependent. Females are at greater risk of acquisition, with 0.6 to 0.8 infections following a single exposure with an infected male. Males are at less risk (0.2) from a single act of vaginal intercourse, with cumulative risk increasing from 0.6 to 0.8 with four or more exposures (61, 172).

Among men, symptoms typically appear within 2-5 days following infection. Estimates from screening studies suggest that asymptomatic disease occurs in approximately 10% of infected men. Among symptomatic women, incubation periods vary. Asymptomatic disease occurs in 20 to 80 percent of infected women.

Three methods are generally used to diagnose gonorrhea – gram stain, nucleic acid amplification tests, and culture. However, since gram staining is not sensitive for detecting infections in women nucleic acid amplification tests, or laboratory culture are usually used to diagnose gonorrhea. The sensitivity and specificity of these two tests are extremely high (approaching 98%) (147). Gonorrhea is curable with single-dose therapy; currently cephalosporin or fluoroquinolone antibiotics are used.

Key Research Findings on Effectiveness

Key Research Findings on Effectiveness

The panel reviewed thirteen studies on gonorrhea and condom effectiveness. Four studies in men and two studies in women were deemed acceptable for assessing gonorrhea transmission. The single prospective study, among U.S. sailors having sex with commercial sex workers, demonstrated that 0% (0/29) of men who sometimes or always used condoms acquired gonorrhea compared to10.2% (51/498) of non-users; however this difference was not statistically significant (61). Two cross-sectional studies and one case-control study found between a 49-75% reduction in risk of gonorrhea among men reporting condom use compared to non-users (8, 96, 110**).** Only one of these studies (8) reported measuring consistent and correct condom use. In this study, a 71% reduction in relative risk for gonorrhea was observed in men who reported correct condom use (4/106) compared to men reporting incorrect use (20/153). One case-control study found no significant risk reduction in gonorrhea cases when women who had ever used condoms without other methods (98/706) were compared to women who had never used condoms (126/889) during the previous three months (O.R 0.90) (6). Another cross-sectional study found a 39% relative risk reduction in gonorrhea infection comparing women attending an STD clinic who reported using condoms as a method of contraception (93/984) to those who did not use condoms, sponges, or diaphragms as a birth control method (521/4068) (105).

Two case control studies that used either pelvic inflammatory disease (PID) or tubal infertility as outcome measures were also evaluated. Although the PID study did not distinguish between PID due to gonorrhea or chlamydia, a 55% relative reduction in the risk of PID was observed among women who had ever used a condom in the previous three months; 32/279 of women with PID reported condom use in the previous 3 months compared to 213/959 who did not have PID (absolute risk reduction 13.7%, relative risk reduction 55%) (69). The second study found a statistically insignificant effect on the risk of tubal infertility

Appendix A

Scientific Evidence on Condom Effectiveness for STD Prevention

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Appendix B

Scientific Evidence on Condom Effectiveness for STD Prevention

June 12-14, 2000

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Appendix C

Scientific Evidence on Condom Effectiveness and STD Prevention

Hyatt Dulles Airport
Herndon, Virginia

June 12-13, 2000

Agenda

Monday, June 12, 2000

7:30a.m.	Registration
8:15 a.m.	Chair: ***Colin Pollard*** Overview and Charge to the Group – ***Penny Hitchcock***
9:00 a.m.	The Male Condom – ***John Gerofi, Speaker; David Lytle, Discussant***
10:00a.m.	Break
10:30 a.m.	Methodological Issues – ***David Kanouse,Speaker; Freya Sonenstein, Discussant***
11:30 a.m.	Chair: ***Susan Newcomer*** Panel Discussion
12:30 p.m.	Lunch (no-host buffet)
1:30 p.m.	Chairs: ***Judith Auerbach*** & ***James Buehler*** Overview of STDs – ***Allen Ronald***, ***Speaker***
2:30 p.m.	HIV Infection – ***Timothy Schacker*** & ***Susan Weller***, ***Speakers***
3:30p.m.	Break
4:00 p.m.	Gonorrhea – ***Donald Orr, speaker; Jonathan Ellen, Discussant***
5:00p.m.	Adjournment

Tuesday, June 13, 2000

8:00 a.m.	Chairs: ***JoAnn Luoto*** & ***John Santelli*** Chlamydial Infection – ***Edward Hook, Speaker; Richard Stephens, Discussant***
9:00 a.m.	Trichomoniasis – ***Jane Schwebke, Speaker; John Krieger, Discussant***
10:00a.m.	Break
10:30 a.m.	Genital Herpes – ***Lawrence Stanberry, Speaker; Timothy Schacker, Discussant***
11:30 a.m.	Other Genital Ulcer Diseases (Syphilis and Chancroid) – ***George Wendel, Speaker; Stanley Spinola, Discussant***
12:30 p.m.	Lunch (no-host buffet)
1:30 p.m.	Chair: ***Jeff Spieler*** HPV infection – ***Robert Burk, Speaker; Laura Koutsky, Discussant***
2:30 p.m.	Chair: ***Heather Miller*** Open Discussion: The Condom; the Methods; the Diseases.
3:30p.m.	Break
4:00 p.m.	Chair: ***Allan Hildesheim*** Answered and Unanswered Questions; Research Needs.
5:00p.m.	Adjournment