

Notice: This Material May Be
Protected by Copyright Law
(Title 17 U.S. Code).

The NIH Condom Report: The Glass is 90% Full

By Willard Cates, Jr.

On July 20, 2001, the National Institutes of Health (NIH) released its long-awaited report on condom effectiveness.¹ This report summarized a workshop held more than 13 months previously, in June 2000, to evaluate the scientific evidence on condom effectiveness for preventing sexually transmitted infections (STIs). While both the workshop and the report were generally modeled on the NIH consensus conference approach, the effort had originated as a result of a congressional request, and thus had both a political and a scientific agenda. This tension between politics and science affected not only the origins of this report, but also its processes along the way and its interpretation after it was released.

The Process

Although NIH was responsible for overseeing the workshop and finalizing the report, three other U.S. agencies participated in organizing the review—the Centers for Disease Control and Prevention (CDC), the U.S. Food and Drug Administration (FDA) and the U.S. Agency for International Development (USAID). Each agency brought its own perspective to the table. The NIH provided its focus on molecular and clinical research, the CDC its expertise in epidemiology and prevention, the FDA its interests in product quality and labeling, and USAID its concerns for preventing the spread of STIs and HIV worldwide. The U.S. government representatives formed a Steering Committee

for the workshop. In addition, a panel of 28 people was chosen from a spectrum of backgrounds and ideologies to help craft the report. The workshop itself was attended by 180 interested individuals.

The ground rules for the report were made clear from the outset. The panel examined only those peer-reviewed, published articles included in the presentations at the workshop. This limitation ensured that the independent scientific evaluation that occurs prior to publication was inherent in all of the data considered. While this approach allowed a certain quality control, it meant that several bodies of data (e.g., those available but unpublished, or those published but deemed unacceptable by the speakers) were not included in the full set of information considered by the panel. Nonetheless, an impressive array of 138 peer-reviewed articles that had been published by the time of the workshop were the basis for the NIH report.

The report was limited to evaluating the effectiveness of male latex condoms used during penile-vaginal intercourse. It examined evidence on eight STIs—HIV, gonorrhea, chlamydia, syphilis, chancroid, trichomoniasis, genital herpes and genital human papillomavirus. The evaluation methodology was extensive, considering both the efficacy (ideal use) and the effectiveness (typical use) of the condom. The quality of the study design, the ascertainment of exposure (e.g., consistent condom use), the laboratory measures of outcome (e.g., STIs) and the adequacy of statistical analytic approaches were examined.

The Report

Several main conclusions emerged from the report:

- *Condom quality.* The available male latex condoms are of high quality. Studies based on viral penetration assays have shown condoms to provide a "highly effective barrier to transmission of particles of sim-

ilar size to those of the smallest [sexually transmitted disease (STD)] viruses."

- *Condom trends.* During the 1980s and 1990s, condom use increased in the United States at the same time that HIV prevention efforts were stepped up. Moreover, the groups in which condom use increased most rapidly are those at greatest risk for STIs—adolescents, young adults and ethnic minorities.

- *Condom failures.* Condom breakage and slippage occurs in an estimated 1.6–3.6% of coital acts. These events are related to user experience with condoms. However, the most important factor affecting condom failure is *nonuse* of the method, rather than breakage or slippage.

- *Condom effectiveness.* Adequate data are available to conclude that consistent and correct condom use prevents unintended pregnancies, HIV infection and gonorrhea in men. Evidence that condom use prevents the other six STIs reviewed by the panel is insufficient, however.

- *Quality of evidence.* The report emphasized 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." All studies reviewed by the panel were observational in nature and carry a variety of methodological limitations well described in the text.

Unfortunately, as the report states, it is not possible to evaluate condom effectiveness using the ideal study design—a prospective, randomized controlled trial. In populations at high risk for STIs, for ethical reasons individuals cannot be randomized to a group that is not to use condoms. In and of itself, this situation speaks to the acceptance of condom effectiveness as the ethical standard of care within the scientific and clinical communities.

Willard Cates, Jr., is president of Family Health International, Research Triangle Park, NC. The author thanks Markus Steiner, Lee Warner, Jeff Spieler, JoAnn Lewis and Cynthia Kay for their help in refining the text. The writing of this Viewpoint was supported by funds from Family Health International and by general support from the U.S. Agency for International Development and the National Institutes of Health. The contents do not necessarily reflect the views or policies of these organizations, however.

Additional Developments

Between the workshop of June 2000 and the report of July 2001, several events pertinent to its conclusions occurred. In September 2000, CDC convened an expert panel to review its STD Treatment Guidelines. In February 2001, USAID held an open forum to examine the topic of promoting condoms for dual protection against unintended pregnancy and STIs. Finally, on July 5, 2001, responding to the Public Law 106-554 requirement to provide "medically accurate information regarding the effectiveness or lack of effectiveness of condoms in preventing [STDs]," CDC issued a set of "prevention messages" to state health departments and its other grantees. The conclusions of the documents from all three groups were the same—namely, that "correct and consistent use of latex condoms can reduce the risk of [STIs]."²

These conclusions were supported both by supplementary data not considered by the panel and by additional literature not covered in the report. For example, four studies not included in the chlamydia section of the report demonstrated that condom use has a protective effect against chlamydia among women;³ likewise, two studies implied that condoms protected against chlamydia in men.⁴ For gonorrhea, a similar situation existed regarding the condom's protective effect among women.⁵ Finally, for genital herpes, a recently published study of couples in which one member was infected with herpes simplex virus type 2 and the other was not found that condom use was associated with protection against infection among women.⁶ Therefore, this additional scientific literature supports even stronger statements than those contained in the NIH report about the condom's effectiveness against other STIs.

In addition, on August 16, the United Nations Joint Programme on HIV/AIDS and the World Health Organization issued a statement emphasizing the importance of condoms as "the best defense" in preventing STIs.⁷ These organizations underscored the global imperative to continue promoting condoms for HIV prevention. They also worried that contrasting interpretations could detract from efforts to halt HIV spread.

Finally, Thailand provides a real-world example of the condom's effectiveness in stemming the spread of STIs and HIV.⁸ In 1991, the Thai government implemented a "100% condom program" to encourage widespread condom use in commercial sex facilities. The proportion of commer-

cial sex acts in which condoms were used increased from a reported 25% in 1989 to 94% in 1995. During the same interval, the incidence of curable STIs reported from government clinics decreased dramatically. Moreover, HIV prevalence among Thai military recruits also decreased.

Thus, whether for individual clinicians counseling clients about their personal risks or for policymakers deciding on the relative value of emphasizing condom use as part of an STI and HIV prevention strategy, the data are compelling: Condoms *do* protect against STIs and HIV, and are most effective when used consistently and correctly.

The Interpretations

The response to the report was immediate and polarized. A group of physicians held a press conference to proclaim that the report demonstrated the ineffectiveness of condom use.⁹ These advocates saw themselves as exposing the "fact that condoms are ineffective in preventing transmission of most STDs, thus challenging the notion of 'safe sex' as championed by the CDC." Unfortunately, by inferring that absence of data meant condom ineffectiveness, the group did exactly what the report cautioned readers not to do. The group went even further in calling for the resignation of CDC director Jeffrey Koplan, alleging that his agency had "deliberately misrepresented condom effectiveness." Moreover, they implied the only reason the report had been released was that they had filed a Freedom of Information Act request.

On the other side, some congressional representatives criticized the report for its "misleading statements regarding the effectiveness of condoms."¹⁰ These politicians felt that the report understated the strong epidemiologic evidence supporting the effectiveness of condoms against such infections as chlamydia, gonorrhea, trichomoniasis and genital herpes. Stating that the report was flawed and undermined public confidence in condoms, they feared that this could lead to "decreases in condom use and increases in risky behavior, and the spread of [STIs]." The representatives called for an independent review of the scientific evidence by the Institute of Medicine.

Even press headlines reflected the dichotomy of opinion. CNN, the first news service to break the report, proclaimed "Condom report questions STD protection" on its website. However, the Associated Press declared, "Condoms protect against HIV, gonorrhea." A variety of follow-up articles expressed clinicians' con-

cern about the report's being misinterpreted, although both sides had generated their own spin.

The Take-Home Messages

First, the report itself was a quality effort. The NIH and the other federal agencies did their assigned job by reviewing and summarizing the available scientific evidence. The main problem was timeliness, caused in part by multiple reviews to accommodate sensitivities to political misinterpretation.

Second, from a public health perspective, the data clearly show that the glass is 90% full (that condoms are relatively effective) and only 10% empty (that data are inadequate). Male condom mechanics and quality assurance are good; moreover, levels of condom breakage and slippage are low and are not a major public health problem. At both the individual and the population levels, nonuse of male condoms is the predominant factor affecting condom failure.¹¹ Because trends in condom use among the highest-risk populations have been encouraging,¹² interpretations of the data that would discourage condom use might enhance the spread of STIs.

Third, existing studies demonstrate that the effectiveness of male condoms varies by the particular STI. In part, this is what I call the condom's "forgiveness factor"—namely, its ability to withstand certain levels of inconsistent use without allowing transmission of an infection (or permitting a pregnancy). This forgiveness measure is directly related to the organism's "beta"—its ability to be transmitted during a single act of unprotected intercourse.¹³ In general, the lower the beta, the higher the forgiveness with imperfect use. HIV is less easily transmitted and gonorrhea is more easily transmitted during unprotected coitus; thus, the condom is more forgiving of imperfect use when it comes to HIV prevention than it is for gonorrhea prevention.

Fourth, the inadequacy of the data should not be interpreted as indicating the inadequacy of condoms. Deliberate attempts to characterize the evidence as demonstrating the "ineffectiveness of condoms" constitute a misunderstanding of what the report states. Moreover, such misrepresentation can undermine the public's confidence in condoms, thereby leading to nonuse and to further spread of STIs and HIV.

Conclusions—The Next Steps

The data presented in the report, as well as subsequent evidence available since the workshop, are clear. Male latex condoms

are effective in preventing the most serious STI (HIV), the most easily transmitted STIs (gonorrhea and chlamydia) and another important sexually transmitted condition (unplanned pregnancy). A crucial qualifier to this statement is that condoms work best when they are used consistently and correctly.¹⁴ All public health messages must reinforce the notion of condom effectiveness. The goal is to increase levels of consistent and correct male condom use in sexually active populations with a high prevalence of STIs and HIV.

Having emphasized that condoms work, we must also realize they do not work perfectly. But nothing in medicine (or in life, for that matter) always works.¹⁵ A full decade before the hoopla generated by this report, absolutist approaches to HIV prevention were being demanded: In 1991, an article in a national periodical was entitled "There is no safe sex."¹⁶ The author argued that because condoms were not foolproof in preventing HIV infection, the combination of abstaining from sex until marriage and practicing monogamy thereafter provided our only hope against the further spread of HIV. This is the same recommendation being made today by the physician advocacy group.

We must not, in Voltaire's terms, let "the best be the enemy of the good." Our prevention approaches—not only to HIV, but to other conditions as well—recognize that incremental, partially effective steps are necessary to mount collectively effective (but imperfect) prevention programs.¹⁷ The aggregation of these combination prevention strategies can have a dramatic effect on HIV spread.¹⁸

The STI and HIV epidemics are not monolithic events that happen in the same way or at the same rate in all groups. They are not uniformly susceptible to claims of

panacea-prone advocates. Controlling the spread of STIs will require different, mutually reinforcing techniques to reach the myriad of groups in our pluralistic society. The NIH condom report shows that male latex condoms are effective interventions that help to prevent the spread of STIs and unintended pregnancy. They must be the mainstay of our dual protection strategies both in the United States and globally.¹⁹ Any attempt to undermine their use will have a negative and long-lasting public health impact.

References

1. National Institute of Allergy and Infectious Diseases. *Workshop Summary: Scientific Evidence on Condom Effectiveness for Sexually Transmitted Disease (STD) Prevention*. July 20, 2001.
2. Gayle H. Prevention messages in response to PL 106-554, letter dated July 5, 2001.
3. Ramstedt K et al., Risk factors for Chlamydia trachomatis infection in 6810 young women attending family planning clinics, *International Journal of STD and AIDS*, 1992, 3(2):117-122; Fennema JSA et al., Clinical sexually transmitted diseases among human immunodeficiency virus-infected and noninfected drug-using prostitutes, *Sexually Transmitted Diseases*, 1997, 24(6):363-371; Holmes KK. Condoms, chemicals and STIs, paper presented at the International Congress of Sexually Transmitted Infections, Berlin, Germany, June 27, 2001; and Ahmed S et al., HIV and STD incidence association with condom use: a population study in Rakai, Uganda, *Journal of Acquired Immune Deficiency Syndromes*, in press.
4. Cates WC, Jr., and Holmes KK. Re: condom efficacy against gonorrhea and nongonococcal urethritis, *American Journal of Epidemiology*, 1996, 143(8):843-844; and Zenilman JM et al., Condom use to prevent incident STDs: the validity of self-reported condom use, *Sexually Transmitted Diseases*, 1995, 22(1):15-21.
5. Fennema JSA et al., 1997, op. cit. (see reference 3); Holmes KK, 2001, op. cit. (see reference 3); Levine WC et al., Decline in sexually transmitted disease prevalence in female Bolivian sex workers: impact of an HIV prevention project, *AIDS*, 1998, 12(14):1899-1906; Upchurch DM et al., Behavioral contributions to acquisition of gonorrhea in patients attending an inner-city sexually transmitted disease clinic, *Journal of Infectious Diseases*, 1990, 161(5):938-941; and Joesoef MR et al., Patterns of sexu-

ally transmitted diseases in female sex workers in Surabaya, Indonesia, *International Journal of STD and AIDS*, 1997, 8(9):576-580.

6. Wald A et al., Effect of condoms on reducing the transmission of herpes simplex virus type 2 from men to women, *Journal of the American Medical Association*, 2001, 285(24):3100-3106.
7. UN News Service. Condoms still best defence against sexually transmitted diseases: UNAIDS, Aug. 16, 2001, accessed at <http://www.un.org/cgi-bin/dh.pl#54>.
8. Rojanapithayakorn W and Hanenberg R, The 100% condom program in Thailand, *AIDS*, 1996, 10(1):1-7.
9. Coburn T et al., Condoms ineffective against STDs, press release, Washington, DC, July 24, 2001.
10. Pelosi N et al., Pelosi and House colleagues criticize administration report for undermining condom effectiveness: members request study guided by science not ideology, press release, Washington, DC, July 24, 2001.
11. Steiner MJ, Cates W, Jr., and Warner L, The real problem with male condoms is nonuse, editorial, *Sexually Transmitted Diseases*, 1999, 26(8):459-462.
12. Catania JA et al., National trends in condom use among at-risk heterosexuals in the United States, *Journal of Acquired Immune Deficiency Syndromes*, 2001, 27(2):176-182.
13. Anderson RM, Transmission dynamics of sexually transmitted infections, in: Holmes KK et al., eds., *Sexually Transmitted Diseases, 3rd ed.*, New York: McGraw Hill, 1999, pp. 25-37.
14. Cates W, Jr., How much do condoms protect against sexually transmitted diseases? *IPPF Medical Bulletin*, 1997, 31(1):2-3.
15. Cates W, Jr., and Hinman AR, AIDS and absolutism—the demand for perfection in prevention, *New England Journal of Medicine*, 1992, 327(7):492-494.
16. Noble RC, There is no safe sex, *Newsweek*, Apr. 1, 1991, p. 8.
17. Cates W, Jr., and Hinman AR, 1992, op. cit. (see reference 15).
18. Garnett GP and Anderson RM, Strategies for limiting the spread of HIV in developing countries: conclusions based on studies of the transmission dynamics of the virus, *Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology*, 1994, 9(5):500-513.
19. Cates W, Jr., and Steiner MJ, Dual protection against unintended pregnancy and sexually transmitted infections: what is the best contraceptive approach? *Sexually Transmitted Diseases*, 2001 (in press).