



**JULY 2005 Special Focus:**  
**Condom Effectiveness**  
**Reviewed, Revised & Reduxed**

This month, the full Senate finally approved the nomination of Lester Crawford for commissioner of the Food and Drug Commission by a 76-16 vote. One of the reasons for the Crawford holdup was that Sen. Tom Coburn (R-OK) had blocked the vote, demanding FDA action on a four-year-old Congressional mandate to revise condom labels. The mandate requires the labels to include scientifically sound information about protection against specific STDs, or lack thereof. Under a compromise announced on July 15, Coburn lifted his objection to the vote on Crawford in return for a promise that the FDA will now actively pursue the condom label issue.

**The re-emergence of the condom labeling issue comes at a time when scientific studies increasingly show that condoms offer more protection against STDs than previously demonstrated.**

One of the most contentious of these diseases is the most common, *human papillomavirus (HPV)*. Some HPV varieties cause genital warts and a few are the source of cervical and anal cancers (see the *June HHSWatch*). Although there has been some evidence that condoms reduce the rate of cervical cancer, Coburn (an MD with a family medicine practice) and other condom critics want a specific warning on condom labels stating they cannot prevent HPV. Their reasoning is that HPV can spread by skin-to-

skin contact outside the genital parts covered by condoms.

**HPV: Very Common... Hard to Study... But New Research Reveals Condom Have Protective Role**

HPV studies have been notoriously difficult to do. "Previous studies had trouble because it is hard to find women who have not been infected by some HPV strain already, and they didn't start out looking specifically at condom use in any case," says Laura Koutsky, an epidemiologist and HPV expert at the University of Washington.

To perform a rigorous evaluation, Koutsky and her colleagues followed 200 female college students who had their first sexual intercourse either during the study period or at most three months before. The women had to complete diaries about their condom use during a two-year observation period. They also underwent regular HPV testing. *When the incidents of HPV infection were tallied, it turned out that the study participants who reported always using condoms during sex had 70% less risk of acquiring HPV than those who never or almost never used condoms.*

The University of Washington study was presented at a July 10-13 conference sponsored by the International Society for Sexually Transmitted Diseases Research.

A University of California San Francisco study at the same conference looked at anal HPV in gay men. It found that consistent condom users' risk of infection was 9.5 times lower than nonusers'. "It's all about risk. If the only exposed area is a small patch outside the anal canal, then your risk of infection and significant disease is much less," commented Peter Chin-Hong, the lead investigator.

### **Finding the right population**

Design problems have troubled nearly all of the previous condom studies, says Lee Warner, an epidemiologist at the Centers for Disease Control and Prevention (CDC). Warner recently published two studies on chlamydia and gonorrhea, showing how poor methodology can greatly reduce estimates of condom effectiveness.

"Gonorrhea and chlamydia are two STIs where condom effectiveness should be high since these infections are all transmitted via the male urethra. They should be prevented with consistent and correct condom use, like HIV," said Warner.

Yet here too, past results have been inconsistent. Warner and his colleagues first looked at a large cohort of women, some of whom contracted one of these diseases and some of whom did not. When the researchers compared the women's condom use records, they could find no significant protection from consistent use. The big problem was that most of the women did not have infected partners. These were the women who tended to use condoms less regularly. Their condom non-use made no difference; they were never exposed to disease. The women more likely to have infected or suspect partners may be more careful about using condoms. They may also be more frequently exposed to gonorrhea and chlamydia on the relatively few occasions when they don't use condoms.

To minimize this effect, Warner looked at a group of women who had partners known to

be infected. Here, the results indicated a high degree of protection for consistent condom use.

Moreover, women with infected partners who reported more than ten unprotected sex acts in the previous three months had nearly *four times* the risk of contracting gonorrhea or chlamydia than those who reported no unprotected sex in this period. The second study evaluated condom use and infection monthly among women who contracted gonorrhea or chlamydia during a six-month observation period. Among these women, non-use of condoms in the month before infection had an effect similar to the first study. Ten or more unprotected incidents of sexual intercourse correlated with a 2.6-fold increase in risk compared to no unprotected incidents.

### **Prior Studies' Methods Likely to Have Underestimated Condom Protection Rates**

Both of these studies showed a very strong "dose response": *The more unprotected sex with a partner likely to be infected, the greater your chance of getting infected.* This observation underscores a subtle feature of Warner's research. Measuring condom use in percent of sex acts does not reveal how much exposure there actually was. An individual might have sex ten times or 100 times. A 10% rate of unprotected sex in the latter case will lead to ten times the exposure to infection that it would in the former case, if the partners are infected.

The fact that these two differently constructed studies led to similar results further supports the notion that prior studies have underestimated condoms' protection against chlamydia and gonorrhea. Warner says, "The point we were making was that conventional studies were biased to finding no effect for condoms. They were underestimating the condoms' effectiveness. When you see consistency with different methodologies, you have more confidence in the strength of your conclusions."

## **Need for correct use underscores role of education**

Another major issue is poor condom technique, which obviously can make a big difference in condom results. Warner notes, "Several studies have reported large misuse of condoms, but few have related it to STDs." In his second study, Warner's group did take account of occurrences when condoms either slipped off or ruptured. Not surprisingly, even consistent condom users had increased odds of contracting gonorrhea or chlamydia if they reported at least one slippage or breakage incident during a given study month. Their risk was about the same as the women who reported inconsistent condom use. Still, about a third of new chlamydia and gonorrhea infections in the second study occurred during months when participants claimed that they had used condoms for all sex in the past month without slippage or breakage. Aside from false reports – which would reduce apparent condom effectiveness – this observation suggests that there are many other problems that arise when using condoms and underscores the need for more education on correct condom usage.

A final new study, published in June, directly addressed the effects of condom misuse on acquiring chlamydia and gonorrhea. In this study, CDC researchers assessed the condom experiences of sexually active female patients at an adolescent health clinic. In addition to frequency of condom use, slippage, and breakage, the researchers tracked the following typical condom errors: starting to put a condom on upside down and then flipping it over, beginning sex without a condom, and removing the condom before finishing sex. Of the 509 young women who were interviewed, 86% said that they had used a condom at least once in the previous three months. But only 16% said that they had correctly used condoms for all vaginal intercourse. Nearly three-quarters of condom users described some problem, the most frequent being

beginning sex without a condom. Breakage occurred at least once in the prior three months to almost a third of condom users.

The consistent and correct condom users had a greatly reduced risk of current infection compared with non- or irregular users – 60% less risk for chlamydia and 90% less risk for gonorrhea. As with Warner's study, women with a record of consistent but problematic use were not significantly different from those admitting to no or intermittent condom use. These data speak to the role of education, not just on the use of condoms but the *correct* use of condoms, and should provoke additional inquiry into abstinence-only-until-marriage programs that train only on the harmful effects of condom misuse, rather than the methods of correct use.

## **A common thread, and an opportunity to re-assess claims of inconclusiveness**

Taken together, these studies have a constant refrain. *Accurate measure of condom effectiveness requires a careful measurement of exactly how many times you are exposed to an STD.* Less than perfect condom practice with an infected partner still carries a lot of risk, but downright poor behavior with an uninfected partner has no risk at all. In 2001, the National Institutes of Health issued a report on condom effectiveness that dismissed most condom research as inconclusive (except for that relating to HIV). In the coming debate on condom labeling, the advances since then in study design should have great influence so long as the political debate does not overwhelm the scientific one.

## **A call for evaluation of abstinence failure rates**

And to flip the debate over, what about "abstinence failure" – when people rely on abstinence for protection and then have unplanned sex without condoms? As Guttmacher Institute analyst Cynthia Dailard

has argued, "By contrasting the perfect use of abstinence with the typical use of other contraceptive methods... [abstinence-only promoters] are comparing apples to oranges. From a public health perspective, it is important both to subject abstinence to the same scientific standards that apply to other contraceptive methods and to make consistent comparisons across methods."

**David Gilden** researched and wrote this issue.

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