A Background Information

1) History of Condom Use
   a) Pregnancy prevention possibly dates back to 1350 BC
   b) STD prevention since late 16th century AD (NIH#136)
   c) Modern use of latex condoms to prevent pregnancy and STDs started in 1930’s (Fitch #1)
   d) Use of condoms declined in 1960’s with the introduction of birth control pills
   e) HIV/AIDS epidemic in 1980’s renewed interest in condoms for disease prevention (NIH #98, Fitch #2)

2) Current Manufacturing Standards (Fitch #3)
   a) Improved production and quality control
   b) Improved design modifications
   c) Improved packaging to extend shelf life

3) Types of Condoms
   a) Latex
      (1) This presentation will deal specifically with the male latex condom as used in vaginal intercourse
   b) Polyurethane
      (1) Almost no clinical studies for condom effectiveness against STDs
      (2) Studies seem to indicate greater slippage and breakage compared to latex condoms (NIH #44, 45) (Fitch #16)
   c) Natural Skin (made from animal intestine)
      (1) Recommended for pregnancy prevention only
      (2) Not recommended for STD prevention

B Can Condoms Fail? Yes----Why?

1) Method Failure and User Failure

2) Lab versus Real Life
   a) In the laboratory an intact condom will contain known STDs
      (1) A few studies show some leakage of virus-sized particles through latex but infection due to leakage is highly unlikely (NIH# 12, 67, 76, 77, 78)
   b) In real life clinical settings condoms due to method and user failure, studies show that condoms never 100% prevent STIs; at best they reduce the risk. (NIH # 10, 28, 138) (Fitch #3, 4, 5, 6, 8,14,17,18,21,28,29,30,31,32,33,34,35)

3) Method Failure:
   a) Rupture or breakage of condom during intercourse or withdrawal
   b) Slippage, either partial or complete, during intercourse
   c) Relatively rare manufacturing defects
   d) STDs transmitted “skin to skin” which may occur outside of area protected by a condom (syphilis, HSV, HVP, chancroid)

4) User Failure:
   a) Failure to Use Correctly (Fitch #7)
(1) Genital contact prior to putting on condom
(2) Starting intercourse without condom or talking off during intercourse
(3) Flipping condom over during application
(4) Poking holes in condom with fingernails
(5) Use of oil based lubricants
(6) Not holding on to condom during withdrawal
(7) Not withdrawing while penis erect, etc.

b) Failure to use a condom consistently, every time (100%)

5) What Percent Use Condoms Every Time?
   a) Approximately 10-25% of unmarried adults always use a condom (NIH #4[18.5%], 48[16.9%], 86[15.2%], 110[12%], 138[21%]) (Fitch #4[13%]), Fitch #8[8.3%], Fitch #21[16%], Fitch #23[15.2%], Fitch #30[13.7%], Fitch #31[19-26%]
   b) In HIV serodiscordant couples approximately 50% always use a condom (NIH #29, 108)
   c) In adolescents approximately 12-50% of females (NIH #10) (Fitch #17) and 45% of males (NIH #112) self report as always using a condom.
   d) In female army recruits with medium age of 20.6 years in the past 90 days only 16.4% always used a condom. (Fitch #19)
   e) In studies published in 2004 where half the population was below the age of 25 and half were above, consistent (always) condom was 8.3% (Fitch #8) and 16% (Fitch #21)
   f) In recent study of prostitutes in Uganda 63% always used condoms (Fitch #6) unpublished data show 70-90% condom use in prostitutes in some African countries.

6) What % of Condoms Used Leave the Individual at Risk?
   a) In a study of college males one in ten condoms used exposed the individual to possible risk of disease due to slippage, breakage, and incorrect use (NIH #132)
   b) In the same study 33% of the “always” users were at potential risk during the previous month due to slippage, breakage, or incorrect use (NIH #132)
   c) A study published in September of 2002 by Crosby reported that in a study of college males (Fitch #15)
      (1) 42.8% of the men reported at least one episode in the past 3 months of starting sex without a condom (occurred in 50% of condom uses in this group)
      (2) 15.3% of the men reported at least one episode in the past 3 months of taking condom off before finishing sex. (occurred in 50.6% of condom uses)
      (3) 30.4% of the men reported as least one episode in the past 3 months of putting condom on the wrong side up and had to flip it over. (occurred in 36% of condom uses in this group of 30.4%)
      (4) 35% of the men reported at least one episode in the past 3 months of condom breakage or slippage.

C Does the public understand what the following words mean in describing condom effectiveness and are they true statements? If condoms are used consistently and correctly they:
   1) Highly effective? Somewhat effective? Partially effective?
   2) Do they eliminate the risk or at best reduce the risk?
   3) Absolutely protect? Partially protect?
   4) Can help? May help? Should help?
5) Significantly reduce the risk? Moderately reduce the risk? Minimally reduce the risk?

6) Provide safe sex? Provide safer sex?

D Perfect Use versus Typical Use
I) Does the public understand the difference between perfect use and typical use?
2) “Perfect use” is using a condom correctly 100% of the time
3) “Typical Condom Use” is using a condom more often than “never use”, but less often than “always use.” “Typical use” includes consistent and inconsistent use, as well as correct and incorrect use.

4) Efficacy versus Effectiveness (Fitch #9)
   a) Efficacy is the improvement achieved in a desired health outcome in a research setting in expert hands under ideal conditions
   b) Effectiveness of an intervention is the amount of improvement in the health outcome (STDs and their sequela) in the real world with typical implementation (i.e. results that realistically can be expected)

E What Factors Determine Condom Effectiveness?
I) Method Failure (slippage and breakage during intercourse)
2) User Failure (inconsistent and incorrect use)
3) Whether an STD is spread by fluids or skin to skin contact
   a) Condoms are less likely to protect from STDs spread by skin to skin contact since the condom may not cover the affected area or protect from an infected area (HSV, HPV, syphilis, chancroid)

4) Degree of infectivity of the particular STD
   a) 0.1% risk of acquiring HIV with infected partner with one act of vaginal sex with no condom (NIH #29) (Fitch#10)
   b) 20-50% risk of acquiring gonorrhea with infected partner with one act of sex without a condom (NIH #61) (Fitch #11, 12)
   c) HPV may be spread by finger-genital contact (NIH #113)

5) Prevalence of STDs in the community
   a) Method or user failure more likely to result in acquisition of disease if prevalence in community is 50% rather than 1%

6) Prior experience with condoms
   a) Experienced prostitutes had less method failure [slippage & breakage] (1%) (NIH #2)
   b) Couples with more than 5 years condom experience had 0.8% breakage and 0.7% slippage for total method failure of 1.5% (NIH #81)
   c) Couples with less than 5 years condom experience had 6.2% breakage and 1.8% slippage or total method failure of 8.0% (NIH #81)
   d) Recent study of older (average 26 years of age) married or cohabiting males with much condom experience and with a history of an average eight lifetime partners had a 1.3% slippage and breakage rate. (Fitch # 16)
   e) Recent study of mutually monogamous couples over 18 revealed 3.2% slippage and breakage rate (Fitch # 20)
   f) In a large study in England 17,032 married women over the age of 25 were recruited into a study for pregnancy during 1968-1974 (Vessey, Lancet 1982, NIH #127). The lowest pregnancy rate reported in the world literature in a large study is women in the study who had used condoms for over 4 years prior to the start of the study and at the start of the study were over the age of 25. Their failure rate was 3.6%. If they only had 2-4 years of condom experience
prior to the study their pregnancy failure rate was 4.0%. For those married women over 25 years of age with less than 2 years of condom experience at the start of the study had a 6.0% pregnancy failure rate (NIH #126)

7) Age and sex of individual
   a) Adolescents, especially females with ectopy, are more likely to acquire an STD, especially HPV (NIH #118)

8) Presence of other STDs
   a) The presence of another STD, especially an ulcerative disease, can significantly increase the risk of acquiring (or transmitting) HIV (NIH #118) (Fitch #3, 10)
   b) It is unknown whether the presence of a non-HIV STD can increase the risk of acquiring (or transmitting) another non-HIV infection

9) Individual resistance of the individual
   a) Apparently some individuals are immune to HIV infection
   b) Individuals with altered immune system are more likely to acquire an STD

10) Number of acts of intercourse
    a) A method that is 98.5% effective (1.5% risk of condom failure) for a single act of sex can give a cumulative risk of condom failure of 37% with 30 acts over time with an infected partner (NIH #37, Page S89 shows formula, Fitch #18)
    b) Mann et al used a mathematical formula to show that there was a 14% risk of infection for a female over 10 acts of sex with an infected male partner with gonorrhea and 100% condom use but with 3% slippage and breakage. (Fitch #13)
    c) Fitch et al expanded on the mathematical formula of the Mann study to include the work of Warner (NIH #132) which showed one in ten consistent condom users were potentially exposed to disease because of slippage and breakage and incorrect use. If a 10% potential exposure rate is used, then in the same scenario used by Mann above, 40% rather than 14% would be expected to be infected after ten acts of sex with infected partner and it increases to 79% after thirty acts of sex with infected partner. (Fitch # 18)

11) If one wants to know how effective are condoms in preventing STIs for an individual over a number of years then the number of life time partners is very important.

F Are Condoms more effective at preventing pregnancy or STDs?
   1) Condoms offer better risk reduction from pregnancy than any STD with the possible exception of HIV
   2) With “perfect use” (100% consistent and correct use) condoms offer an estimated 96% risk reduction for pregnancy during the first year compared to no use
      a) 85% of couples having regular sex and using no contraception get pregnancy during the first year
      b) An estimated 3% will get pregnant with “perfect” condom use during the first year (15% with “typical” condom use)
      c) The relative risk is 3/85=0.04 or a 96% risk reduction
      d) The best risk reduction for “always” condom use for HIV is in serodiscordant couples (approximately 85% risk reduction) (NIH #28)
   3) For pregnancy “typical use” of condoms offers approximately 82% risk reduction (15/85=0.18) for pregnancy during first year compared to no use
      a) The best risk reduction for typical condom use is in HIV sero-discordant couples with an approximate 70% risk reduction (NIH # 28)
A new study from Uganda showed no risk reduction with inconsistent (typical) condom use for HIV, syphilis, and gonorrhea/Chlamydia (Fitch #5).

When quoting studies for condom effectiveness for pregnancy most use “typical use” whereas for STDs “always use” is usually quoted:

- For pregnancy there is minimal difference between perfect use (always use) and typical use (any use).
- For STD prevention there is a significant difference between always use and typical use. Most research indicates that condoms are ineffective or substantially less effective at reducing STD risk if they are not used for every act of intercourse (NIH #8, 28) (Fitch #5).

Condom Effectiveness as of June 2000 (NIH Report) (Fitch# 3):

1. Many of the studies reviewed were old and not well done. Only one study even addressed correct condom use (NIH #8).
2. The panel concluded that “always” use of a condom could significantly reduce the risk of HIV infection in men and women.
3. Consistent use of the condom could reduce the risk of gonorrhea in men and might afford some protection in reducing the risk of HPV-associated diseases, including warts in men and cervical neoplasia in women.
4. There was no evidence that condoms reduced the risk of HPV infection in women.
5. Further the panel concluded that the existing data was insufficient to conclude if condoms reduced the risk or not for chlamydial infection, syphilis, chancroid, trichomoniasis, and genital herpes in both men and women.
6. Lastly there was insufficient data to come to any conclusion for risk reduction or not for gonorrhea in females and HPV in men.

Articles Published Prior to NIH Conference but Not Included and Which Measured Condom Effectiveness for Multiple STDs:

1. Zenilman, 1995 tested participants for acquisition of four STDs over three months (NIH #138)
   - 15% of the men who “always” used a condom had a new infection with at least one of the four STDs compared to 15.3% who “never” used a condom
   - 23.5% of the women who said their partner “always” used a condom had a new infection with one or more of the four STDs compared to 26.8% of women who said their partner “never” used a condom
2. Bunnell, 1999 studied sexually experienced females from 14-19 years of age (NIH# 10)
   - 40% of the girls were infected with one or more of the 6 STDs studied at the beginning of the study, 87% were asymptomatic
   - At the end of the study 23% had a new infection with one or more of the six STDs.
   - Self reported “always” condom use did not significantly reduce one’s risk of having a new STD compared to inconsistent or no condom use. Correct use was not measured
   - Only 12.6% always used a condom over the six month period

Articles Published After the June 2000 cutoff for the NIH Report:

1. Condoms and Genital Herpes [2001] (Fitch #4)
   - A June 2001by Wald study showed risk reduction for women but not men.
   - Unpublished data from the same author which is based on a larger sample of individuals who were not necessarily monogamous indicates risk reduction for
both males and females but significantly less risk reduction for females then previously reported (Fitch #14)

2) Condoms and STDs in Uganda City by Ahmed [2001](Fitch #5)
   a) “Always” condom use reduced the risk of syphilis by 29%, HIV by 63%,
gonorrhea/Chlamydia by 50%. No risk reduction for trichomonas
   b) Inconsistent use did not reduce the risk for any of the above STDs, including
   HIV
   c) Correct use not addressed

3) Condoms and STDs among Kenyan Prostitutes by Baeten [2001](Fitch #6)
   a) “Always condom use reduced the risk of gonorrhea/Chlamydia by 40%,
genital ulcer disease (presumably syphilis and chancroid) by 50% and pelvic
inflammatory disease by 40%
   b) Impact of inconsistent use not addressed nor was incorrect use measured.

4) [2002] Do Condoms Prevent Genital HPV infection, External Genitalia Warts, or
Cervical Neoplasia? (a meta-analysis by Manhart) (Fitch #22)
   a) Conclusion: available data are too inconsistent to provide precise estimates.
However, they suggest that while condoms may not prevent HPV infection,
they may protect against genital warts, CIN II or III, and ICC.

5) [2003] A Study by Crosby of Multiple STDs in Adolescent Females (age 14-18)
(Fitch #17)
   a) At baseline 28.2% of the girls had at least one of the three STDs
studied.(Chlamydia, Gonorrhea, or Trichomonas vaginalis)
   b) Among adolescents (51% of the group) using a condom 100% of the time
over six months (average 13.5 episodes of sex) 17.8% became reinfected with
at least one of the three STDs studied versus 30.% reinfected with one or more
STDs in those not using a condom every time.

6) [2003] A cohort study of 917 female sex workers were re-examined monthly for
STIs. (Fitch #25)[Sanchez, et al]
   a) Sex Workers who used condoms consistently since the last examination
(approximately one month) had a 62% reduction in the risk of acquiring
gonorrhea, 26% reduction in the risk of acquiring Chlamydia infection and no
statistically significant risk reduction for trichomoniasis.
   b) There was a 66% risk reduction for trichomoniasis at follow up visit. It was
not clear how “follow up visit” was distinguished from “since last
examination”.
   c) This author questions whether or not the results of condom effectiveness in
commercial sex workers can be generalized to the general population where it
is more possible for an individual to have multiple acts of sexual intercourse
with an infected partner over time.

7) [2004] Study of condom effectiveness for individuals exposed to partners known
to be infected with either gonorrhea or Chlamydia by Warner et al. (Fitch #8)
   a) For the 8.3% of the individuals who reported always condom use over the last
three months, there was a 58% reduction in the risk of acquiring either
gonorrhea or Chlamydia compared to those who never used a condom or used
a condom inconsistently
   b) Even in the 8.3% who reported using a condom every time, 30% were
infected with either gonorrhea or Chlamydia.
   c) 2/3 of the study group were less than 25 years of age
8) [2004] A study by Shlay et al of condom effectiveness against gonorrhea, Chlamydia, trichomonas, recent-onset genital warts, first-episode herpes, and molluscum contagiosum by comparing prevalence rates against reported levels of condom use in the past 4 months. (Fitch #21) 
   a) Approximately 45% were under the age of 25. The total population study was 126,000. 
   b) Of the 126,000 patients, 46% reported no condom use, 38% inconsistent condom use and 16% always condom use. 
   c) When any condom use was compared to no condom use the only risk reduction for any of the six STIs was 21% in men against genital herpes and 11% in women against gonorrhea. 
   d) When consistent (always) condom use in women was compared to inconsistent condom use there was 29% risk reduction for gonorrhea, 26% for Chlamydia, 13% for trichomonas and no statistically significant risk reduction for genital warts, genital herpes or molluscum contagiosum. 
   e) When consistent (always) condom use in men was compared to inconsistent condom use there was 13% risk reduction for gonorrhea, 34% for Chlamydia, 27% for genital herpes. There was no statistically significant risk reduction for molluscum contagiosum or genital warts. 
   f) For the 16% men and women who reported always using a condom in the past four months, the risk reduction for gonorrhea and Chlamydia infection varied from 13-34%. 

9) [2004] A short three page research and practice article in the American Journal of Public Health by Ness et al, entitled “Condom Use and the Risk of Recurrent Pelvic Inflammatory Disease, Chronic Pelvic Pain, or Infertility Following an episode of Pelvic Inflammatory Disease”. (Fitch #24) 
   a) When consistent condom users were compared to nonusers there was, after adjustment for covariates, a 50% risk reduction for recurrent PID, 30% risk reduction for chronic pelvic pain, and 60% risk reduction for infertility. 
   b) It was impossible for this reviewer to determine in this limited report (two pages) how the infertility was calculated. The mean follow-up was three years. 

10) [2004] A study by Baldwin et al, of condom effectiveness in men against penile (sampled from tip of penis) human papillomavirus detection. (Fitch #23) 
    a) There was a 51% risk reduction for always condom use over three months compared to no condom use in acquiring any type HPV (not significant with a confidence interval of 0.24-1.02) and a 80% risk reduction against oncogenic HPV with a wide confidence interval of 0.05 to 0.89. 
    b) The authors say the following: In this study we sampled only the tip of the penis and therefore cannot draw any conclusion about HPV infection in other areas of the male genitalia, for which condom use may not reduce risk. Because we have not accounted for the presence of virus at other anatomic sites, our analysis may overestimate the protective benefit of condom use.” 

11) [2004] An article by Hearst et al, based on a lengthy review for UNAIDS (www.usp.br/nepaids/condom.pdf) in regards to condom promotion for AIDS prevention and published in the March 04 issue of Studies in Family Planning. (Fitch#26) 
    a) Their review says condoms are 90% effective at reducing the risk of HIV transmission if used consistently.
b) Their review suggests condoms are more effective at the individual level among high risk individuals such as sero-discordant couples, commercial sex workers and casual sex than trying to promote and sustain consistent condom use during repeated acts of intercourse over years among stable couples.

c) “The use of condoms produces minimal benefit if it is not consistent. Many studies find that inconsistent users are at higher risk of HIV transmission than those who never use the method.” (NIH#26, NIH#108, NIH#30, Fitch#5)

d) The authors say the following: “Avoiding harm also means telling the truth: Condoms are safe and effective, but not 100% effective. The common practice of assuring people that they can only acquire HIV through unprotected sex is not accurate. Avoiding overstatements about the effectiveness of condoms may go a long way toward eliminating any possible conflicts between condom promotion and other strategies to reduce sexual risk. Presenting people with accurate information about the advantages of condom use is not impossible. Family planning programs around the world have achieved balance in promoting contraception.”

12) [2004] A review by King Holmes, MD of condom effectiveness in studies since the June 2000 NIH conference. (Fitch#27)
   a) This review is very consistent with the review presented in this Fitch Condom Fact Sheet and our summary is virtually identical.
   b) Dr. Holmes correctly says that condoms are not 100% and says that condoms if used consistently provide reduced acquisition of various STIs rather than stating that condoms “protect” or “prevent”.

13) [2005] A study by Lee Warner using case-crossover design to reduce unmeasured confounding in studies of condom effectiveness in measuring gonorrhea/Chlamydia among female sexually transmitted disease clinic patients. (Fitch#28)
   a) For consistent condom use with no slippage and breakage the case-crossover analysis revealed a risk reduction of 51% (95% confidence interval 0.26 to 0.92) versus a non statistically significant risk reduction in the cohort group of 21% (95% confidence interval of 0.53 to 1.17).
   b) For consistent condom use with breakage or slippage there was no statistically significant risk reduction in either the case-crossover or co-hort design
   c) For inconsistent condom use there was no statistically significant risk reduction in either group.
   d) Only in best of circumstances (case-crossover, consistent condom use with no slippage and breakage) was there any risk reduction and even then it was only approximately 50%.

14) [2005] A study by Gabriela Paz-Bailey of the CDC on the effect of correct and consistent condom use on Chlamydial and Gonococcal Infections among urban youth in Atlanta, Ga. (Fitch 29)
   a) The study was of 13-19 year old sexually active adolescents females (mean age 16.6 years) in regard to condom use for vaginal sex within the past three months. Questions were asked about consistency and correctness of use
   b) **Unfortunately for this author is that incorrect use included condom breakage and slippage in addition to incorrect use such as starting sex without a condom, taking off a condom before sex ended and flipping a condom prior to use.**
   c) General Findings:
Chlamydia prevalence was 21% (25% no use, 23% inconsistent use and 16% consistent use), gonorrhea prevalence was 7% (7% no use, 9% inconsistent use and 4% consistent use).

Condom use errors reported by 71% of those who reported using a condom within the past 3 months.

Consistent condom use was 35%.

Consistent and correct condom use including no slippage and breakage was 16%.

Mean age of first sex 14.2 years, # lifetime partners 5.8, # sex partners last 3 months 1.8, and # of sex acts past 3 months 16.6.

Of the 509 females reporting sex within the past 3 months:
- 13% used no condom
- 36% had inconsistent use
- 35% had consistent use but included incorrect use
- 16% had consistent and correct use and had no reported slippage & breakage

There was no difference between no condom use and inconsistent use (that is no risk reduction) so these two groups were lumped together.

**d) Condom Effectiveness for Chlamydia:**

1) For consistent but not correct use a 10% risk reduction but not statistically significant

2) For consistent and correct use with no slippage and breakage there was a 60% risk reduction but not statistically significant as the 95% confidence interval was 0.2 to 1.0

**e) Condom Effectiveness for Gonorrhea:**

1) For consistent but not correct use there was a 10% risk reduction but not statistically significant as the 95% confidence interval was 0.3 to 2.3.

2) For consistent and correct use including no slippage and breakage there was 90% risk reduction.

**15) [2005] A study published in the November 15th 2005 issue of the Annals of Internal Medicine by Dr. Wald which showed that consistent condom use reduced the risk of Herpes Simplex type 2 acquisition by 26%. (Fitch #30)**

**16) [2005] A study by Artz in the November 2005 issue of STDs studied gonorrhea, Chlamydia, and syphilis together and found a 70% risk reduction for 100% consistent and correct use and no slippage and breakage. There was no risk reduction for 100% but incorrect and or slippage and breakage.

a) Unfortunately the authors included slippage and breakage in the category of perfect use along with consistent and correct use. Slippage and breakage is a method failure, not an error in usage. (Fitch #31)**

**17) [2008] A study in the June 2006 issue of NEJM by Winer found a 70% risk reduction in HPV in women who always used a condom. (Fitch #32)**

a) The criteria to be in the study at the University of Washington was to be a female age 18-22 who had never had vaginal intercourse or had first had intercourse with one male partner within the previous three months. Out of 24,201 letters mailed out 243 eligible women responded.

b) The study thus was restricted to a very small subset of college women who were virgins and thus might have been motivated and meticulous and thus not representative of the entire college age population.
18) [2008] A study in the *American Journal of Epidemiology* by Warner found 41% of the study group had problems with condom use. *(Fitch #33)*

a) The authors identified five problems with condom use: 1) breakage during intercourse or withdrawal 2) slippage during intercourse or withdrawal 3) applied condom after genital contact 4) removal of condom before completing intercourse 5) Leakage of semen onto the partner’s genital area after withdrawal. One or more of these five “errors” occurred in 41% of the individuals in the group studied over 3 months. The authors omitted the frequent error of “flipping the condom” over.

b) **This author firmly believes that breakage during intercourse, unless an improper lubricant such as vasoline is used and slippage during intercourse is not a user error but rather a method failure. In essence the authors are trying to say what happens when a condom is used every time perfectly and it doesn’t slip or break. This is really a lab study of whether an intact condom protects against STDs spread by fluids. In the real world slippage and breakage (during intercourse) does occur and this is a method failure, not user failure. This author believes the slippage and breakage rate to be between 1-3% depending upon years of experience. Those with more experience tend to have less slippage and breakage.**

c) There were no cases of gonorrhea/chlamydia in the 18 of the 130 participants (13.8%) who reported no condom errors but the numbers were too small to be statistically significant. There was risk reduction in the consistent use but with errors group as well as the inconsistent condom users but the results were not statistically significant.

19) [2010] A study in the *Journal of Infectious Diseases* by Nielson showed consistent condom use is associated with lower prevalence of Human Papillomavirus Infection in Men. *(Fitch #34)*

a) In this study of men there was a 50% risk reduction of HPV in men who always used condoms.

20) [2012] A study by Crosby et al, in *Sexually Transmitted Diseases* studied condom effectiveness against non-viral sexually transmitted infections (Chlamydia, Gonorrhea, & Trachomatis) using electronic daily diaries. *(Fitch #35)*

a) This is probably one of the best studies to date because they used daily electronic diaries and they measured not only consistent use but also tried to measure correct use.

b) The problem I have with this article is that the authors lumped together human error with what I consider method failure. In the opinion of this author breakage which occurs during intercourse is not an error but rather method failure unless an improper lubricant has been used such as Vaseline which may increase breakage. The authors also included slippage during intercourse as error and I consider that to be method failure. Slippage during withdrawal would be in my opinion be a user error.

c) The five errors which were measured were 1) slippage 2) breakage 3) leaking 4) early removal & 5) late application. It is surprising that Crosby and other authors left out the errors of poking holes in condoms with fingernails and flipping the condom over during application, especially since in a 2002 article by the same author he reported on condom flipping. In the 2002 study by Crosby 30.4% of the study population reported at least one occurrence of flipping a condom and in this 30.4%, 36% of condoms used in this group were
flipped. A condom can only be unrolled in one direction. If it is applied incorrectly and has to be flipped in order to be unrolled onto the penis then any discharge that happens to be on the tip of the male penis and urethra is now on the outside of the condom which is about to be inserted into the female vagina where any bacteria such as Gonorrhea or chlamydia can then easily make its way through the cervix and into the uterus and fallopian tubes and possible later infertility.

d) Yes there is less slippage and breakage with experience but both slippage and breakage during intercourse is in the eyes of this author a method failure, not human error. Slippage during withdrawal is a user error. Other words what the authors are saying is what happens if a condom is used perfectly every time and it does not suffer slippage and breakage. I believe we can say that in the lab an intact condom should prevent STI infection spread by fluids 100% of the time.

e) In this study if a condom was used 100% of the time and it was used properly with no slippage and breakage according to the author’s guidelines there was a 59% lower odds of acquiring an STI. In the opinion of this author the results should have been 100% lower odds of infection according to their guidelines (If a condom is used perfectly every time and there is no slippage or breakage for a STI spread by fluids there should be no risk or infection or zero chance of infection]. Obviously errors occurred which were not reported or appreciated by the individuals studied.

f) In the same study if a condom was used every time but suffered one or more “human errors” there was a 25% less odds of infection but the results were not statistically significant.

g) In this study only 17.9% used a condom every time and suffered no errors according to their criteria and thus had a 59% lower odds of acquiring an STI or 3.35% incident infections among this group. What about the other 82.1%? This group had 8.75% incident infections. What is missed in this article is that all were at risk of infection and thus all are in need of being tested for an STI.

h) In conclusion the authors consider a 59% lower odds of infection to be considered “excellent protection”.

\section*{J Summary of Condom Effectiveness as of 2013}

1) \textbf{Consistent condom use (always or 100\%)}

\begin{enumerate}
\item \textit{Consistent condom use} appears to offer the best risk reduction for HIV in both males and females (approximately 85\% risk reduction for 100\% consistent use in sero discordant couples)
\item The next best risk reductions (considerably less than for HIV) appears to be for gonorrhea in males.
\item Additionally recent studies, (both published and unpublished), suggest risk reduction for gonorrhea in females, and Chlamydia, syphilis and herpes simplex type 2 in both males and females, but the precise degree of risk reduction remains unclear. No clear evidence of risk reduction has been found for trichomonas or bacterial vaginosis.
\item There appears to be no consistent risk reduction for HPV infection in women (one study showed risk reduction in prostitutes and one recent study (Fitch #32) in a small subset of college age women who were virgins at the start of the study showed 70\% risk reduction) but condoms might afford some protection
\end{enumerate}
in reducing the risk of HPV-associated diseases, including warts in men and cervical neoplasia in women. A 2010 study in men reported a 50% risk reduction in HPV with consistent condom use.

e) **In summary with consistent (100%) condom use there is about 85% risk reduction for HIV in sero discordant couples.** For gonorrhea, Chlamydia, herpes simplex and syphilis there appears to be approximately 50% or less risk reduction although the data is limited for some of the STDs. For HPV there appears to be minimal, if any, risk reduction in most studies but the most recent study in men showed a 50% risk reduction for consistent use (Fitch #34). For trichomonas and bacterial vaginosis infection we simply have inadequate data to state whether or not condoms offer any risk reduction.

2) **Consistent and Correct Use (which means no slippage or breakage according to recent condom studies)**

   a) Only one study in the NIH report (NIH #8) measured both consistent and correct use.

   b) The June 2005 study by Paz-Bailey (Fitch#28) measured both consistent and correct use but unfortunately to this writer the correct use mandated no slippage and breakage which this author considers a method failure (except for slippage on withdrawal). **Unfortunately Warner 2005 (Fitch #28) and Artz 2005 (Fitch #31), Warner 2008 (Fitch #33), & Crosby 2012 (Fitch #35) also defined correct use as no slippage and breakage. This author believes slippage and breakage during intercourse is method failure, not human error.**

   c) As one might suspect risk reduction was greater for both consistent and correct use [including no slippage & breakage] (NIH #8, Fitch #28, Fitch #33 & #35) compared to only consistent use with no measure of correct use (NIH # 10, 138, Fitch #28) In the Crosby 2012 study of Gonorrhea, Chlamydia, & Trachomatis there was a 59% less odds of acquiring one or more of these three STIs if a condom was used 100% of the time and correctly 100% of the time with no slippage and breakage.

3) **Typical Condom Use** (includes inconsistent and or incorrect use)

   a) Typical condom use appears to offer no risk reduction or significantly less risk reduction. (NIH #8) (Fitch #5)

   b) With the exception of HIV and HSV there is lacking conclusive evidence that inconsistent use provides any risk reduction.

4) **Fitch Thoughts As Of 2013:**

   a) It is clear now that not only do condoms have to be used every time but correctly every time in order to achieve any measure of risk reduction. Condoms in the opinion of this author do not “protect” but can offer significant risk reduction if used every time and correctly every time. Risk remains however because condoms can and do occasionally slip and break even when used correctly so the number of episodes of sex with an infected partner is critical.

   b) Current condom studies include all slippage and breakage as user errors whereas this scientist considers slippage and breakage during intercourse as method failure. Even in the most recent and probably the best condom study to date by Crosby in 2012 there was only a 59% less odds of infection in
the group which suffered “no errors” according to the authors. This less chance of infection was achieved in only 17.9% of the population group.

c) It is obvious to this scientist that there is significant risk reduction for the 15-25% of the population who can actually achieve both consistent and correct use over just a few months. Even then some risk remains because of slippage and breakage due to method failure 1-3% of the time. In general you would expect experienced condom users to have less slippage and breakage and beginners to condom use to have greater slippage and breakage percentages.

d) Finally it appears to this scientist that condoms appear to offer the best hope of reducing risk for “casual sex” or for “one night stands”. This hope is primarily for the 15-25% of individuals who can successfully over a few months use a condom both consistently and correctly for every act of sex. Even then risk remains so---------

e) So while consistent and correct condom use should be encouraged, testing for STIs must be increased if we are to dramatically decrease the number of new STIs yearly.

f) The CDC recommends that all women under the age of 25 be screened annually for Chlamydia. Less than half of women in this age group achieve this goal. There is no recommendation for men but this author believes all men under the age of 25 should also be screened for the common STIs.

g) For “casual sex” or “one night stands” the only tool in the arsenal is a condom used perfectly. For couples who start cohabitation (typically seen in men and women in their 20’s and 30’s) this authors suggestion is to use a condom perfectly every single time while both partners are being tested and treated as necessary. If both partners are found to be negative or become negative after being treated then condom use can be discontinued and contraception of choice can be used. Of course discontinuing condom use is based on a mutually faithful monogamous relationship.

h) Perhaps we need to distinguish the value of condoms for reducing the acquisition of STI infection at the individual level versus the population level. For the approximately 20% of the population who seem to be able to use a condom consistently and correctly there is potential risk reduction from acquiring an STI. For the 80% of the population who do not use a condom both consistently and correctly there appears to be minimal or no risk reduction.

i) In summary the public needs to understand what condoms can and cannot do and under what circumstances so that each couple can make an informed decision.

j) If you have sex with a partner who you do not know for certain is uninfected (never had sex before or is sexually experienced but has been tested for all known STIs and has been found to be free of infection) you are at potential risk of infection and should be screened on a periodic basis for an STI regardless of reported condom use (i.e. both “protected” and “unprotected” sex). Yes your risk is less if you use a condom every time, even less risk if a condom if used every time correctly but even if a condom has been used perfectly every time you are still as risk for an STI spread by fluids because of slippage and breakage and thus your need to be tested for a STI on a periodic basis. For STIs spread by skin to skin contact you are at potential greater risk even if a condom is used perfectly every time and has not slipped or broken
because a condom may not always cover the infected STI lesion.

Bibliography

The articles designated as NIH can be found by going to the following web address: www.niaid.nih.gov/dmid/stds/condomreport.pdf for the entire bibliography for the entire NIH Workshop Summary on Condom Effectiveness. Bibliography not included in the NIH report is listed below. In the report they are referenced as Fitch #XX.


