Condom Effectiveness Dossier: A Source Deck for Future Evidence-Based Communications

Table of Contents

Objectives

- Provide a context for understanding the current place of the condoms* in our culture and society
- Describe the manufacturing and quality control processes in place to ensure that condoms are safe and effective
- Present evidence documenting the effectiveness of condoms in preventing STDs and unintended pregnancy
- Review effective models and programs to increase consistent and correct condom use
- Address and counter with scientific evidence misperceptions about condom effectiveness and safety

*Where “condom” is referenced in this slide deck, it refers to latex, polyurethane, or polyisoprene condoms currently marketed in the US, unless otherwise specified.

Overview of Content: Key Messages

Quality Manufacturing

- Condoms are Class II medical devices, regulated by FDA
  - Manufactured to FDA and industry standards
- Most condoms are made of natural rubber latex, a remarkably strong and flexible barrier material
  - Low rates of breakage attest to the superior performance of latex[1,2]
  - Small number of individuals (~3%) have skin sensitivities to latex[1]
  - Alternatives to latex: natural membrane, polyurethane, and synthetic polyisoprene[1]
- Condoms are manufactured to provide a strong barrier that prevents penetration of STD pathogens and sperm
- This section represents an overview of Church & Dwight/Trojan manufacturing process as an industry example, as Church & Dwight Church & Dwight is the largest manufacturer of latex condoms in America and has led the industry in innovations in condom design, with the goal of increasing user pleasure and improving condom compliance
- Church & Dwight manufacturing process is guided by quality management
  - Quality is built into each step in manufacturing process, from compounding, vulcanization, and dipping through final release
  - Consumer protection and satisfaction are the bottom line
  - Long-term stability testing ensures that condoms remain stable through expiration

1. Warner L and Steiner MJ. Male condoms. In: *Contraceptive Technology.* 19th edition. New York, NY: Ardent Media; 2007. 2. Cates W. *Fam Plann Perspect.* 2001;33:231-233.

Overview of Content: Key Messages (cont'd)

Condom Effectiveness and STD Prevention

- STDs constitute a major public health problem in US[1]
  - ~19 million new STD infections occur annually
- Results from laboratory studies show that condoms are effective against STD transmission[2]
- Intact latex, polyurethane, and polyisoprene condoms provide a strong, impermeable barrier to STD pathogens, even the smallest (hepatitis B)
- Epidemiologic studies have shown that, used consistently and correctly, condoms are highly effective in:
  - Preventing transmission of HIV[3]
  - Reducing risk of other STDs, including discharge and genital ulcer disease[3]
  - Preventing some of the most easily transmitted and common STDs: gonorrhea and chlamydia[4]
- Human error can impact condom effectiveness in STD prevention
  - May result in underestimates of effectiveness in studies[5]
  - Breakage and slippage are often attributable to user error[6]

1. CDC. Sexually Transmitted Diseases in the United States, 2008. 2. NIAID Workshop Summary: Scientific Evidence on Condom Effectiveness for Sexually Transmitted Disease (STD) Prevention, 2001. 3. CDC. Male Latex Condoms and Sexually Transmitted Diseases. 4. Cates W, Jr. *Fam Plann Perspect.* 2001;33:231-233. 5. Crosby R, et al. *Int J STD AIDS.* 2008;19:90-93. 6. Steiner M, et al. *Fam Plann Perspect.* 1993;25:220-223, 226.

Overview of Content: Key Messages (cont'd)

Condom Effectiveness and Pregnancy Prevention

- **Rates of unintended pregnancy in US are high**
  - 1 in 20 women (15-44 years) has an unintended pregnancy each year (total 3.1 million in 2001)[1]
  - Risk is highest among teenagers: US rate of teen pregnancy is one of highest among industrialized nations[2,3]
- **In 2006-2008, top 3 methods of contraception in US[2]**
  - Pill (10.7 million)
  - Female sterilization (10.3 million)
  - Condoms (6.2 million; 8.6 million when included as part of dual use)
- **Estimating contraceptive efficacy: perfect use versus typical use[4,5]**
  - With perfect use, condom effectiveness is estimated at 98%
  - With typical use, condom effectiveness is estimated at 83%
- **Challenge of linking efficacy with correct or incorrect use makes method effectiveness difficult to estimate[6,7]**
- **User error, including incorrect or inconsistent use, is single greatest factor contributing to condom failure in preventing pregnancy[8]**
  - Condom education has significant potential to improve effectiveness
- **Condom is the third most popular reversible contraceptive method behind injectables and the pill[2]**
  - Provides a strong barrier impermeable to sperm[8]
  - Advantages over other contraceptive methods: STD/HIV protection, easy accessibility, low cost, portability, minimal side effects, and visual confirmation to both parties[9]

1. Finer LB, Henshaw SK. *Perspect Sex Reprod Health.* 2006;38:90-96. 2. Mosher WD, Jones J. *Vital Health Stat* 23 (29). 2010. 3. Singh S, Darroch JE. *Fam Plann Perspect.* 2000;32:14-23. 4. Trussell J. Contraceptive efficacy. In: *Contraceptive Technology.* 19th edition. 2007. 5. Kost K, et al. *Contraception.* 2008;77:10-21. 6. Fu H, et al. *Fam Plann Perspect.* 1999;31:56-63. 7. Trussell J. *Contraception.* 2004;70:89-96. 8. NIAID Workshop Summary: Scientific Evidence on Condom Effectiveness for Sexually Transmitted Disease (STD) Prevention, 2001. 3. CDC. Male Latex Condoms and Sexually Transmitted Diseases. 9. Warner L and Steiner MJ. Male condoms. In: *Contraceptive Technology.* 19th edition. New York, NY: Ardent Media; 2007.

Overview of Content: Key Messages (cont'd)

Condom Education

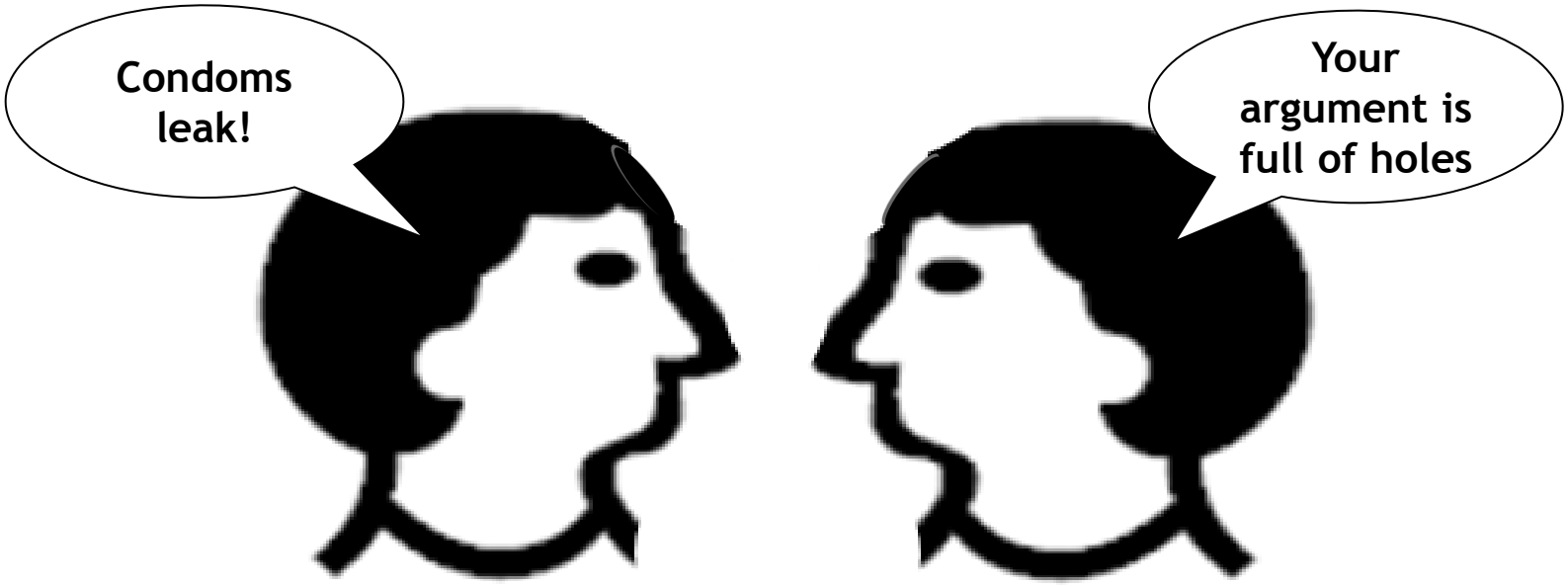
- **Well designed and implemented sex education programs can help counter existing myths and misperceptions about condom use**
- **Abstinence-only programs are ineffective in promoting abstinence, decreasing sexual partners, increasing condom use[1]**
- **Many sex education curricula that emphasized BOTH abstinence and condoms/contraception had a significant positive impact on behavior[2]**
  - Many reduced or delayed sexual activity or increased condom/contraceptive use
  - Did not hasten or increase sexual behavior
- **Condom availability programs are effective in promoting abstinence, delaying initiation of sexual intercourse, and reducing STDs among youth[3]**
- **Condom education deemed an integral part of sex education programs by APA, AMA, APHA, APA, and ACOG[4]**
  - Students in schools where condoms were available had significantly lower rates of lifetime or recent sexual intercourse than students in schools where condoms were not available[5]
- **Condom education and experience may decrease user errors and improve overall effectiveness in preventing STDs and unintended pregnancy[6,7]**
- **Effective sex education curricula should be designed to promote specific behaviors, such as abstinence and condom use, that lead to clear health goals[2]**
  - Address multiple sexual psychosocial risk and protective factors
  - Employ activities, instructional methods, and behavioral messages appropriate to youth culture
  - Employ instructionally sound teaching methods

1. Trenholm C, et al. Impacts of Four Title V, Section 510 Abstinence Education Programs. 2007. 2. Kirby D, Laris BA. *Child Dev Perspect.* 2009;3:21-29. 3. CDC. Condom distribution as a structural level intervention. October 2010. 4. Ott MA, Santelli J. *Curr Opin Obstet Gynecol.* 2007;19:446-452. 5. Blake SM, et al. *Am J Public Health.* 2003;93:955-962. 6. Yarber WL, et al. *Am J Mens Health.* 2007;1:190-196. 7. Albert AE, et al. *Am J Public Health.* 1995;85:1514-1520.

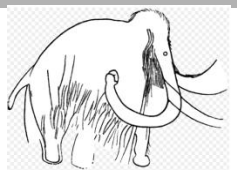
I. Introduction

Why Talk About Condoms?

Because of Conflicting Messages



History of Condom Use



From the first recorded use in the ancient world to development in the modern era

Ancient cave painting at the Grotte des Combarelles in France depicts man and woman having sex, with man's penis covered

Egypt 12th Dynasty (1350-1200 BC) Written descriptions of men wearing *glans condoms*

17th and 18th century innovations in condom design included use of animal intestines and spermicide

Rates of STDs increase dramatically during American Civil War. Comstock laws prohibit distribution of condoms across state lines

In 1916, Trojans introduced by Youngs Rubber. Classified as drug by FDA in 1938

Prehistory | **Ancient Period** | **Modern Period**

1500 BC **0** **1500 AD** **1600** **1700** **1800** **1900** **2000** **2010**

In mythology, King Minos of Crete ejaculated snakes and scorpions and had to use a goat bladder condom to protect his lovers

Sailors returning from voyages to the New World in 15th and 16th centuries spread syphilis, causing an epidemic in Europe

Gabriele Falloppio's treatise on syphilis De Morbo Gallico, published in 1564, describes use of linen condom to protect against syphilis

In 1844, Charles Goodyear patents rubber vulcanization process, leading to first rubber condom in 1855

In 1910s, Julius Schmid pioneers dipping technique. Latex developed in 1920

During WWII, condom use promoted by military. From 1955-1965, 42% of US adults use condoms for contraception

With brands such as Ecstasy™ and Bareskin™, Trojan introduces innovations to increase user sensation and pleasure, with the goal of encouraging condom use

Collier A. The Humble Little Condom. 2007.
Valdiserri RO. *Bull N Y Acad Med.* 1988;64:237-245.

Images from web sources.
Need to check on usage issues with visuals.

Controversy and Condoms Have Gone Hand-in-Hand From the Beginning

- Condoms were in use for STD prevention and birth control by 1600s
  - However, as early as 1605 religious leaders had condemned them as immoral
- By the 1800s, laws discouraging the manufacture of condoms were common
  - Despite this, by the late 1800s, they were the most popular form of birth control in Europe and the US
- During the American Civil War, an epidemic of STDs raged
  - Cited as a contributing factor were the **Comstock Laws**, which banned condoms and other contraceptives and limited education on STD prevention
  - Condoms were not promoted by the medical community for STD prevention
  - STDs were considered punishment for sexual misbehavior

Casanova demonstrates his condom

Collier A. The Humble Little Condom. 2007.

Condoms in the Modern Era: The Struggle for Acceptance

- **Despite a demonstrated protective effect, throughout the modern era, condom use was met with opposition**
  - Religious and social/moral grounds: STDs were considered punishment for sexual misbehavior
  - Opposition was driven by myth that condoms encourage sexual activity
- **Gradually, during 20th century, condom use gained some acceptance**
  - In 1930s, major churches in US and Europe sanctioned use of contraception by married couples
  - During WWII, European and US militaries actively promoted condom use
  - By 1955-1965, 42% of US adults relied on condoms for contraception
  - In 1988, US Surgeon General encouraged condom use
- **Although, condom use is now being promoted more widely as a fundamental public health practice, controversy continues…**

Allen P. *Trigger Issues: Condoms*. London; New Internationalist Publications: 2007.

The Condom Controversy Today: Mixed Messages

Let’s Face it…

- **There will always be disagreement about some things...**

You like tomato and I like tomahto

But Let's Also Face the Facts

- **Condoms are highly effective when used consistently and correctly[1-3]**
  - **They are the only proven contraceptive method that also prevents or significantly reduces risk of STDs**
  - **They provide a flexible and user-friendly option for contraception**
  - **They provide a strong barrier to STD pathogens, especially those transmitted in areas covered by the condom**
- **Condoms are FDA-regulated medical devices[1,3]**
  - **Latex condoms form an impermeable barrier to even the smallest pathogens**
  - **Condoms are manufactured and packaged under high quality assurance standards**

1. Male Latex Condoms and Sexually Transmitted Diseases. Available at: http://www.cdc.gov/nchstp/od/condoms.pdf. Access on: 060310. 2. National Institute of Allergy and Infectious Diseases, Workshop Summary: Scientific Evidence on Condom Effectiveness for Sexually Transmitted Disease (STD) Prevention, July 20, 2001. 3. Warner L and Steiner MJ. Male condoms. In: *Contraceptive Technology.* 19th edition. New York, NY: Ardent Media; 2007. .

Why Talk About Condoms?... Because the Facts Are Important

Facts You Should Know About Condoms

- ✓ **Condoms provide a strong barrier that cannot be penetrated by STD pathogens[1]**
- ✓ **Used consistently and correctly, condoms can reduce the risk of infection with STDs, including HIV, chlamydia, gonorrhea, syphilis, HPV, and herpes[2,3]**
- ✓ **Correctly used, condoms are a highly effective, reliable contraceptive method[1,4]**
- ✓ **Latex condoms are durable, with a long shelf life[5]**
- ✓ **Condoms are made in a variety of sizes and styles to accommodate every user's preferences**
- ✓ **User error, which contributes to most condom failures, is correctable with simple, appropriate educational measures[6-8]**
- ✓ **Correctly used, condoms do not break or slip easily[4,9]**
- ✓ **Teaching young people about condoms and making condoms available to them does not encourage them to have sex[10,11]**

1. NIAID Workshop Summary: Scientific Evidence on Condom Effectiveness for Sexually Transmitted Disease (STD) Prevention, 2001. 2. CDC. Male Latex Condoms and Sexually Transmitted Diseases. Available at: http://www.cdc.gov/nchstp/od/condoms.pdf. Access on: 060310. 3. Winer RL, et al. *N Engl J Med.* 2006;354:2645-2654. 4. Warner L and Steiner MJ. Male condoms. In: *Contraceptive Technology.* 19th edition. New York, NY: Ardent Media; 2007. 5. Source: http://en.wikipedia.org/wiki/Latex. 6. Fu H, et al. *Fam Plann Perspect.* 1999;31:56-63. 7. Yarber WL, et al. *Am J Mens Health.* 2007;1:190-196. 8. Albert AE, et al. *Am J Public Health.* 1995;85:1514-1520. 9. Cates W, Jr. *Fam Plann Perspect.* 2001;33:231-233. 10. Kirby D, Laris BA. *Child Dev Perspect.* 2009;3:21-29. 11. Charania MR, et al. AIDS Behav. 2010.

So, Why Talk About Condoms?

… because healthy lives depend on it

The Humble Condom

Current State of Sexual Health in US: STDs

STD	Statistics
HIV/AIDS[1,2]	• **Prevalence is higher than ever before in US** • In 2008, over 1 million people in the US were living with HIV (increase of >10% from 2003) • Incidence of new cases has stabilized over the past decade at 56,000 new cases annually • Sexual contact is responsible for the majority of infections
Chlamydia[3]	• **Most commonly reported infectious disease in US** • >1.2 million cases reported in 2008 • Prevalence is highest among young and minority women • Rates of infection are higher among minority groups
Gonorrhea[3]	• **Second most commonly reported infectious disease in US** • Prevalence is highest in adolescent girls and young women • In 2008, 70% of cases were seen in black patients • Rates of infection are higher among minority groups
Syphilis[3]	• **On the verge of elimination a decade ago, has re-emerged as public health problem** • In 2008, 13,500 cases were reported: the highest number since 1995 • Majority of cases were among men who have sex with men • Rates of infection were higher among minority groups

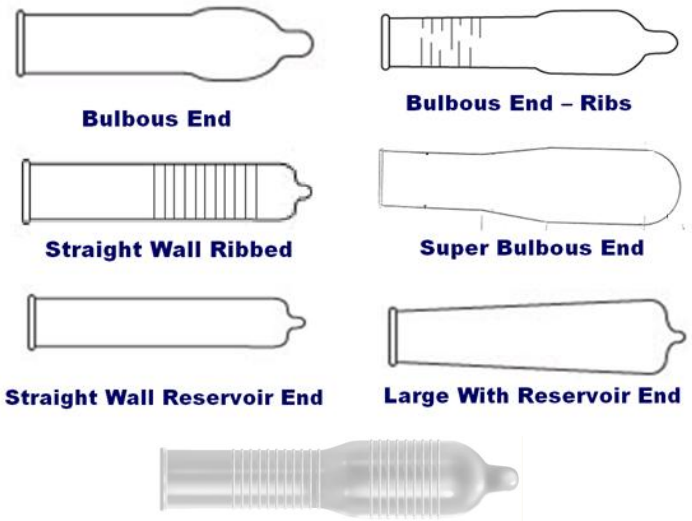
1. CDC. HIV in the United States: An Overview. July, 2010. 2. CDC. HIV Surveillance Report, 2008. 3. CDC. Sexually Transmitted Diseases in the United States, 2008: National Surveillance Data for Chlamydia, Gonorrhea, and Syphilis. November, 2009.

Current State of Sexual Health in US: Pregnancy and Contraception

	Statistics
Contraceptive Use	• **Among women who are sexually active and do not want to become pregnant, 11% are not using any contraceptive method and are at risk for unwanted pregnancy[1]** • The percentage of contraceptive nonusers at risk for unintended pregnancy is highest among teens: 19%[1] • The percentage of women (15–44 years) who currently use a contraceptive method has declined from 64% in 1995 to 62% in 2002 and 2006–2008[1] • A teenage girl who is sexually active and does not use contraception has a 90% chance of getting pregnant within a year[2]
Unintended Pregnancy	• **1 in 20 women (15-44 years) in the US has an unintended pregnancy each year[3]** • Out of 6.4 million pregnancies reported in 2001, 3.1 million were unintended, with 42% of these ending in abortion[3] • Rates of unintended pregnancy are highest among young women, low-income women, and minorities[3] • Risk is highest among teenagers (ages 15-19)[4] • US has one of highest rates of teen pregnancy among industrialized nations[5]

1. Guttmacher Institute. Facts on Contraceptive Use in the United States. June, 2010. 2. Guttmacher Institute. Facts on American Teens' Sexual and Reproductive Health. January, 2010. 3. Finer LB, Henshaw SK. *Perspect Sex Reprod Health.* 2006;38:90-96. 4. Mosher WD, Jones J. Use of Contraception in the United States: 1982-2008. National Center for Health Statistics. Vital Health Stat 23 (29). 2010. 5. Singh S, Darroch JE. *Fam Plann Perspect.* 2000;32:14-23.

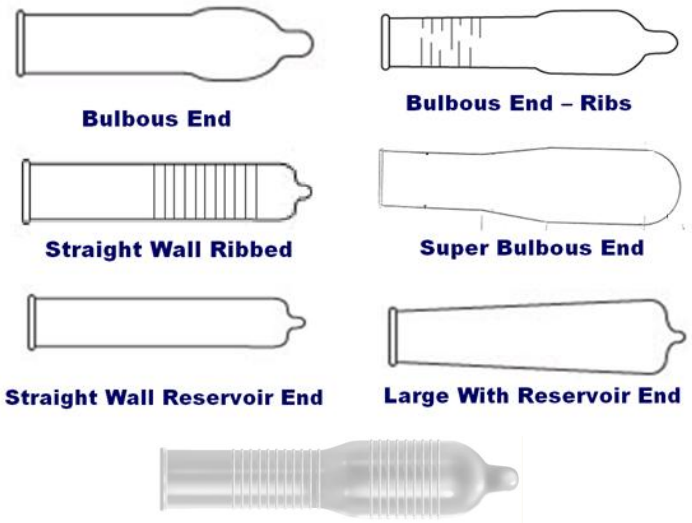
Latex Condoms Are Designed to Achieve the Highest Standards for Protection and Performance



Latex Condoms Are Designed to Achieve the Highest Standards for Protection and Performance

Material

- ✓ **Latex constitutes a barrier impermeable to STD pathogens and sperm, combining strength and elasticity with thinness for protection and optimal sensation.**



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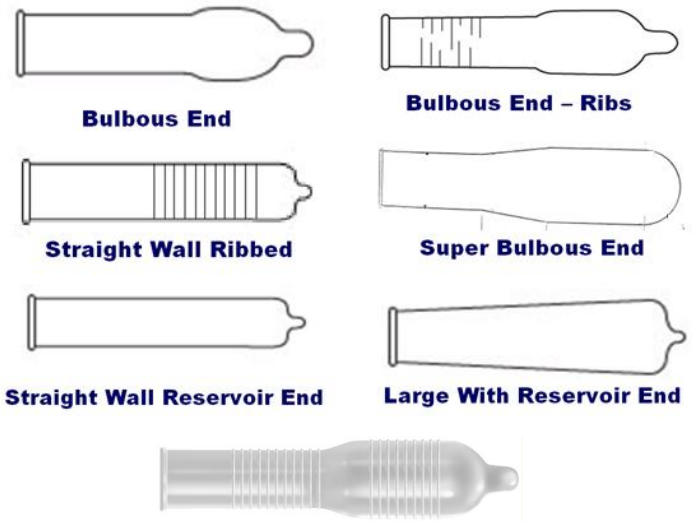

Shape and Feel

- ✓ Condoms are designed with smooth or textured surfaces to satisfy a wide range of user preferences.
- ✓ The latest innovations in condoms are designed to increase pleasure and may increase condom use.

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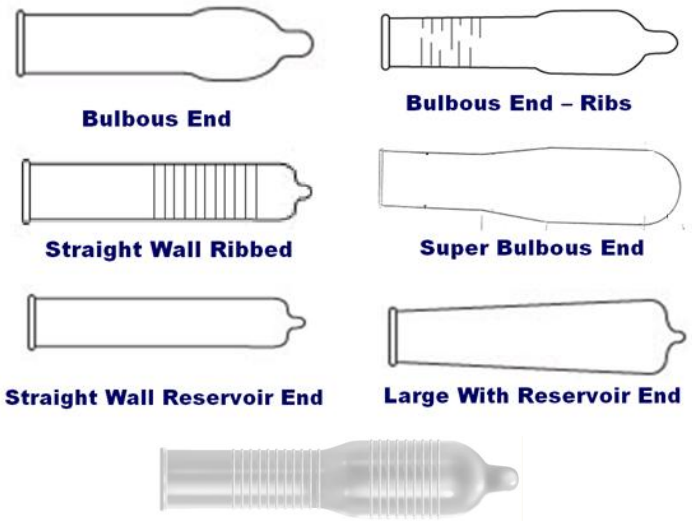

Quality Testing*

- ✓ Throughout the condom manufacturing process, from vulcanization and dipping to packaging and storage, strict QA procedures are in place at every step to ensure that latex and condoms themselves meet the highest standards and exceeds FDA requirements.

*Reflects Church & Dwight/Trojan processes as a representative example.

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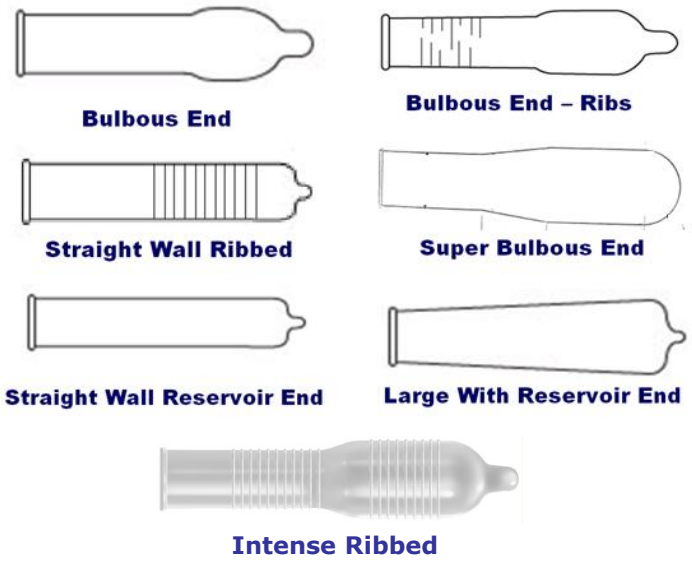

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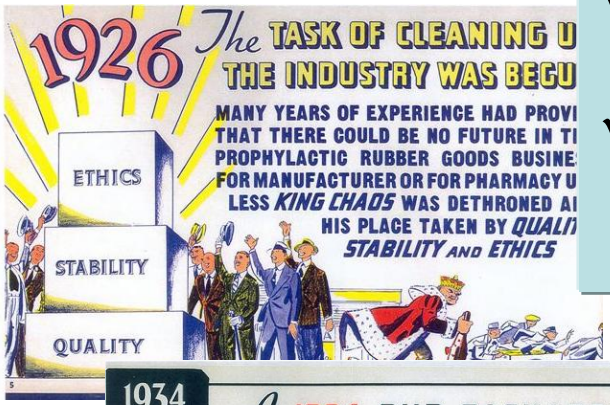
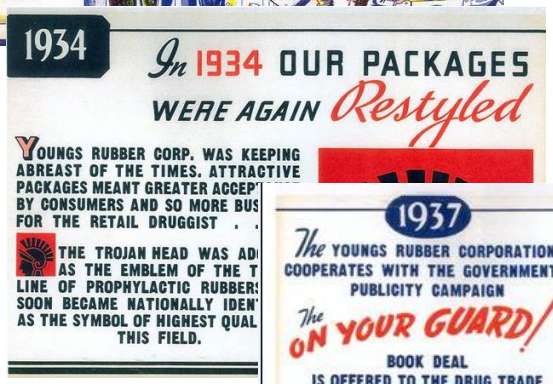
Continuous Improvement

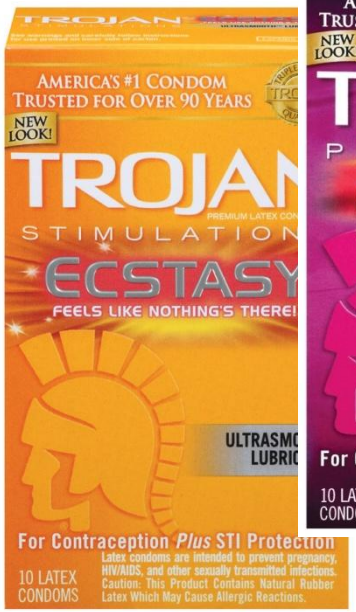
- ✓ Today's condoms perform better than ever in terms of both user pleasure and reliability.

Design Innovations Have Ushered the Condom Into the 21st Century

- ✓ Introduction of ultra-thin, textured, and extra-large condoms
- ✓ Innovative use of spermcides, lubricants, flavors, topical sensitizers







Condom Users Achieved Satisfaction in Terms of Pleasure, Arousal, and Orgasm

- Condom use appeared to have no significant negative effect on ratings of pleasure, arousal, and orgasm, regardless of sex

Reports of Condom Users and Nonusers on Most Recent Vaginal Intercourse Event: NSSHB

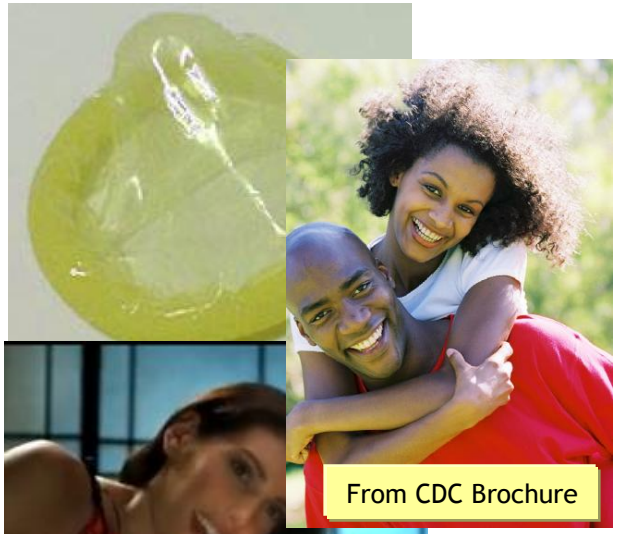
	Men		Women	
	No condom used	Condom used	No condom used	Condom used
Pleasure	(n=696)	(n=241)	(n=640)	(n=180)
Extreme	53.7	43.6	35.5	39.4
Quite a bit to Not at all	46.3	56.4	64.5	60.6
Arousal	(n=692)	(n=238)	(n=638)	(n=180)
Extreme	54.9	42.9	34.2	40.0
Quite a bit to Not at all	45.1	57.1	65.8	60.0
Participant orgasm	(n=686)	(n=241)	(n=620)	(n=171)
Orgasm	95.6	94.6	65.5	64.9
No orgasm	4.4	5.4	34.5	35.1

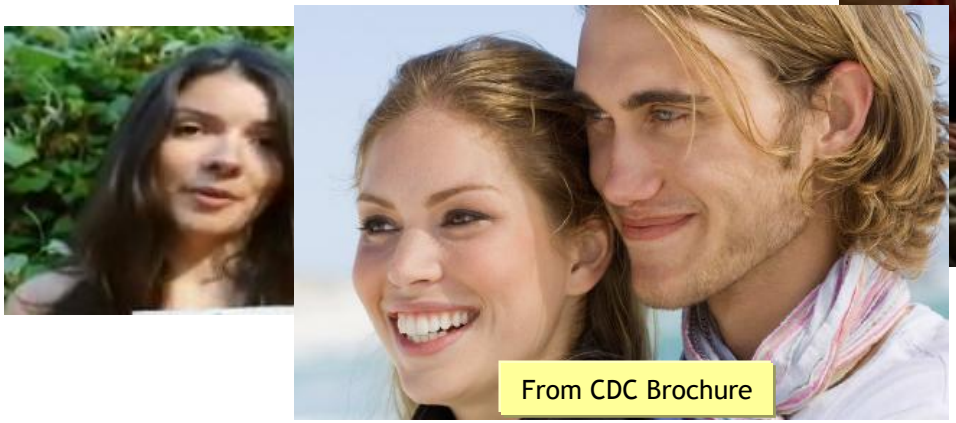
NSSHB, National Survey of Sexual Health and Behavior.

Reece M, et al. *J Sexual Med.* 2010. In press.

The Condom: The First Choice in STD Prevention and Contraception

- The most **MISUNDERSTOOD AND UNDERAPPRECIATED** **proven** method of birth control and STD prevention
  - The **ONLY** proven method of both birth control and STD prevention
  - Strong barrier impermeable to STD pathogens and sperm
  - History of use for > 400 years
  - Inexpensive
  - Easy to use **CONSISTENTLY AND CORRECTLY**
  - Very few, if any, side effects
  - Product features that enhance pleasure





Images other than those from CDC Brochure from Trojan website and sponsored Facebook videos.

The Condom Offers the Most Comprehensive Set of Benefits vs Other Contraceptive Choices

	Contraceptive efficacy	STD Prevention	Easily accessible	Low cost*	Easily reversible	Minimal demand on user	Minimal compliance (dosing, renewal) requirements
Male condom	✓	✓	✓	✓	✓	⊘	✓
Implants	✓	⊘	⊘	⊘	⊘	✓	⊘
Vasectomy	✓	⊘	⊘	⊘	⊘	✓	✓
Female sterilization	✓	⊘	⊘	⊘	⊘	✓	✓
IUD	✓	⊘	⊘	⊘	✓	✓	✓
Injectables	✓	⊘	⊘	⊘	⊘	✓	⊘
Pill	✓	⊘	⊘	⊘	✓	✓	⊘
Patch	✓	⊘	⊘	⊘	✓	✓	⊘
Ring	✓	⊘	⊘	⊘	✓	✓	⊘
Female condom	✓	⊘	✓	✓	✓	⊘	✓
Diaphragm	✓	⊘	⊘	✓	✓	⊘	✓
Fertility awareness	⊘	⊘	✓	✓	NA	⊘	✓
Withdrawal	⊘	⊘	✓	✓	✓	⊘	✓
Spermicide	⊘	⊘	⊘	✓	✓	⊘	✓

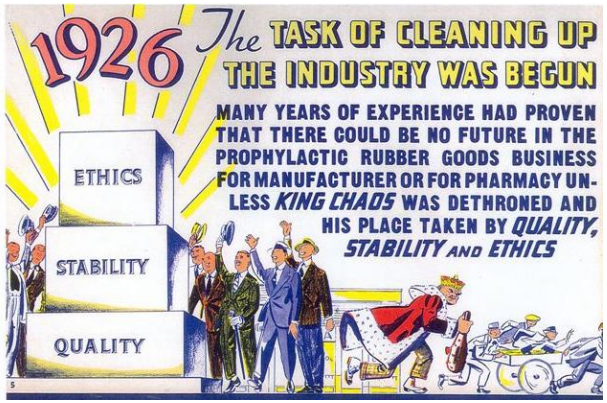
*Determined on a per-unit basis. NA, not applicable.

"Condoms should be the first choice for young people who choose to be sexually active."
–Kaiser Family Foundation

II. Condom Innovation

Building on >400 Years of Trust: Innovations for the 21st Century

- **Condoms have a >400-year history of being trusted for contraception and STD prevention**
- **The condoms that you use today reflect the latest in innovation and design…**



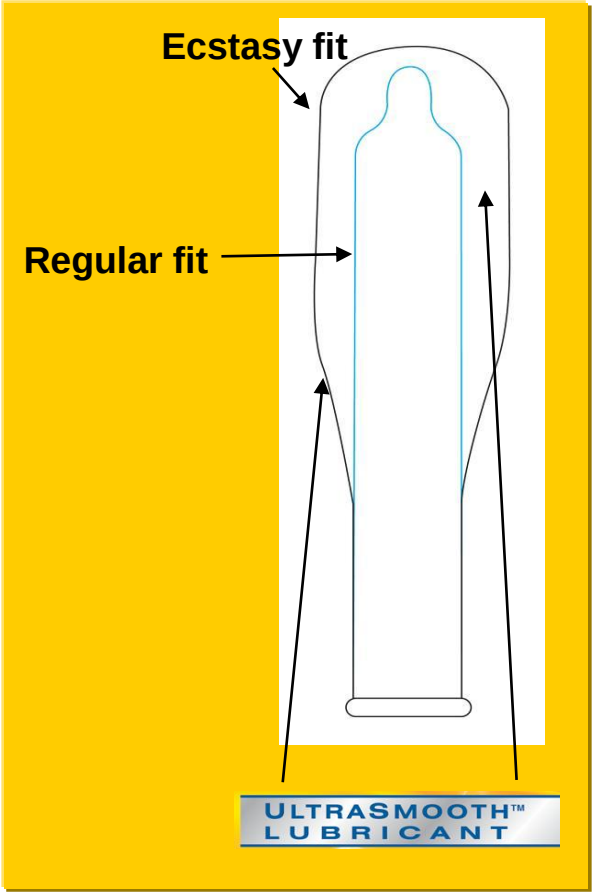
Condom Innovation is Guided by Consumer Feedback

- Church & Dwight values consumer feedback
  - Feedback has allowed Church & Dwight to make consistent improvement in condom design to satisfy consumer needs
  - Better satisfying consumer needs may assist in achieving important public health priorities

Overarching Goals in Condom Improvement

TROJAN Ecstasy Condoms: Superior Innovations to Increase Pleasure

- **Consumer feedback:** Restrictive fit reduces sensitivity for men
- **Ecstasy innovation:** Make the condom bigger around the tip to create a more natural feeling experience
- **Consumer feedback:** Extra lubricant increases sensitivity and pleasure
- **Ecstasy innovation:** Apply premium grade lubricant both *inside* and *out* for enhanced comfort and sensitivity
- *The Ecstasy Equation*
  - *More room + Lubricant Inside and Out = Feels More Natural*



Church & Dwight: Consumer Response to Ecstasy

- **Trojan Ecstasy Ultra-Ribbed Brand condoms users indicated that they intended to increase their use of Ecstasy in the future, and the great majority reported that Ecstasy met or exceed their expectations**

Current vs Future Expected Use of Trojan Ecstasy Ultra-Ribbed Brand condoms*				
	≤2 times per year	3-12 times per year	>1 to 4 times per month	≥2 times per week
Current use	21%	30%	37%	25%
Future use	12%	23%	43%	32%

	Did not meet expectations →			Exceeded expectations
	1-2	3-5	6-7	8-10
Trojan Ecstasy Users†	1%	7%	21%	54%

*Based on a survey of 187 Trojan Ecstasy Ultra-Ribbed Brand condoms users. †Based on a survey of 200 Trojan Ecstasy users who were asked to rate Trojan Ecstasy on a scale of 1-10 according to how it met their expectations (0=Failed To Meet Expectations, 10=Exceeded Expectations).

III. Condom Manufacturing and Quality Control

Condom Manufacturing and Quality Control: Introduction

Objective

- To provide an overview of the manufacturing process and stringent quality control measures in place to ensure that condoms are safe and effective

Note

- This section represents an overview of Church & Dwight/Trojan manufacturing process as an industry example, as Church & Dwight Church & Dwight is the largest manufacturer of latex condoms in America and has led the industry in innovations in condom design.
- While we assume other condom manufacturers follow ASTM and ISO standards, we do not have detailed information on the manufacturing and quality control practices of other condom manufacturers.

ASTM, American Society for Testing and Materials; ISO, **International Organization for Standardization**.

The Condom Manufacturing Process Reflects a Commitment to Quality and Consumer Confidence

- **Condoms are Class II medical devices, regulated by the FDA**
  - Most condoms are made of latex, a remarkably strong and flexible material
- **The Church & Dwight/Trojan condom manufacturing process reflects a commitment to quality and consumer confidence**
  - Quality control measures are built into each step of the manufacturing process
  - Church & Dwight/Trojan standards exceed industry and FDA requirements
  - Internal and third-party audits ensure proper implementation and execution of the quality management system to meet ISO 13485 and Church & Dwight requirements
  - CAPA programs focus on root cause analysis and correction of any issues that arise in the manufacturing process
  - Long-term stability testing assures effectiveness of condoms through their labeled expiration date
- **Trojan condoms undergo extensive toxicology review and evaluation**
  - Meet ISO standards
  - All products are cleared by a board-certified Church & Dwight toxicologist
- **Church & Dwight is committed to continuous improvement**
  - Goal of Church & Dwight design and manufacturing process: to ensure that condoms made today are better than those made before them, in terms of strength, pleasure, design, and quality

CAPA, corrective and preventative action system; ISO, **International Organization for Standardization**.

Condoms Are Strictly Regulated as Class II Medical Device by the US FDA and FDA-Recognized Standards

Condom manufacturing quality standards set by the ASTM
✓ **Standards require that condoms be manufactured from high quality natural rubber latex, conforming to ASTM D 1076-97**
✓ **Manufacturing process must meet criteria that toxic, sensitizing, locally irritating, or otherwise harmful substances are not released or liberated**
✓ **Manufactured to dimensions referenced in ASTM Standards, including length, width, and thickness**
✓ **Latex condoms: ASTM D 3492, *Standard Specification for Rubber Contraceptives (Male Condoms)***
✓ **Polyurethane condoms: ASTM D 6324, *Standard Specification for Male Condoms Made from Polyurethane***
✓ **ASTM Standards require quality control monitoring tests: air burst test pressure, air burst test volume, tensile testing, leakage AQL, and package integrity AQL**

AQL, acceptable quality level; ASTM, American Society for Testing and Materials.

- US FDA recognizes the ASTM latex condom standard as the industry standard that all condoms sold in the US should meet
- Church & Dwight quality control measures satisfy or exceed ASTM standards for condom manufacture

The Quality of Condoms is Ensured by Manufacturing Standards and Testing

Condom Manufacturers Must Adhere to Recognized Industry Standards	
These standards are agreed upon by a group made up of	✓ **Industry leaders** ✓ **ISO** ✓ **Regulatory officials (from the US FDA)** ✓ **ASTM-International* (organization that creates standards for a range of products, materials, systems, and services)** ✓ **Testing laboratories** ✓ **Consumer protection groups**
These standards† require	✓ **Stringent testing of condoms before they can be released into the marketplace**
FDA enforces these accepted standards	✓ **Condoms are regulated as medical devices by the US FDA using stringent manufacturing standards**

*ASTM-International is the organization through which industry, regulatory officials (US FDA), testing laboratories, and consumer protection groups participate in formulating manufacturing standards. †Industry specifications are drafted to FDA-recognized standards. ASTM, American Society for Testing and Materials; FDA, Food and Drug Administration; ISO, **International Organization for Standardization.**

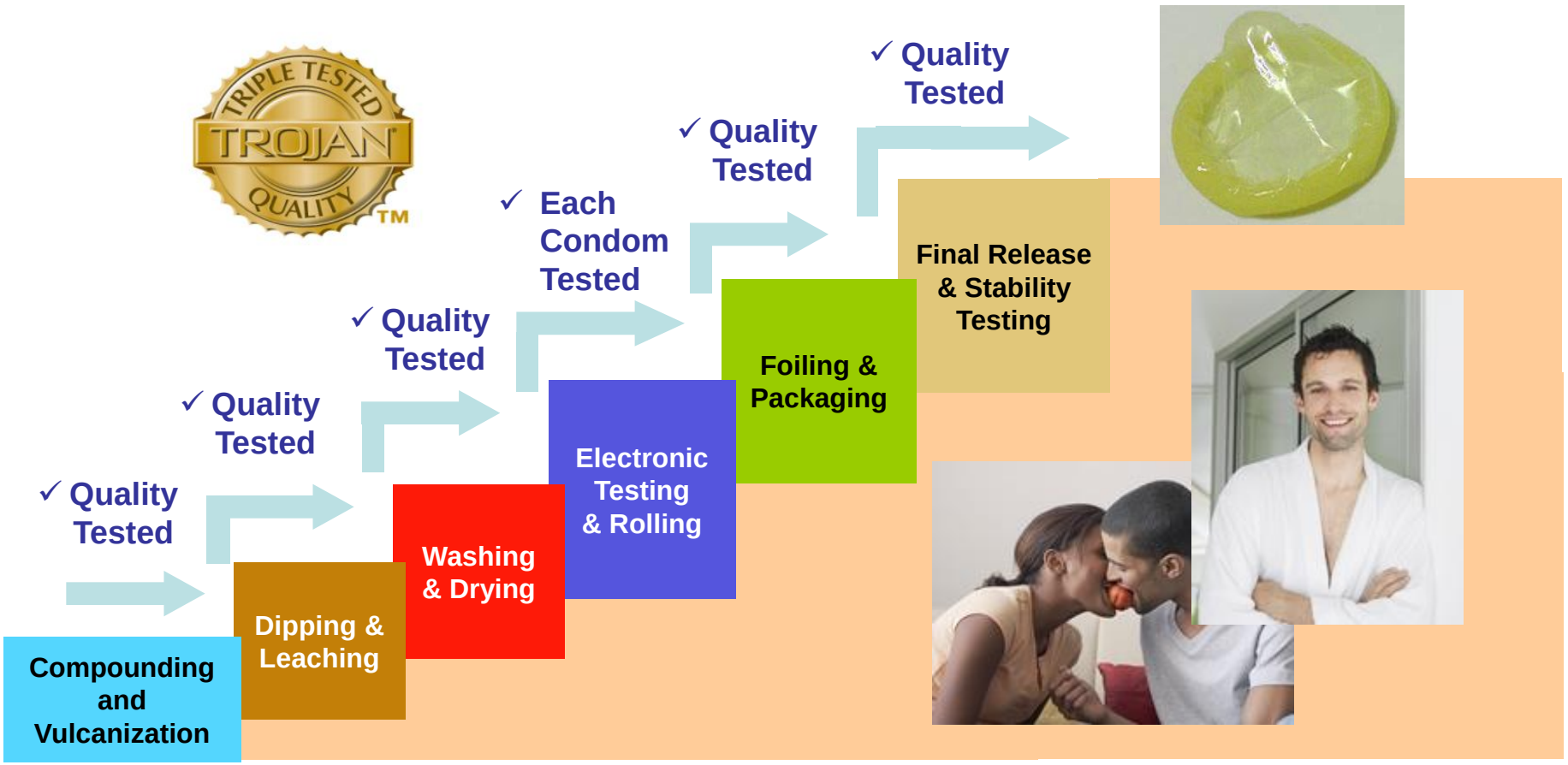
Latex Rubber: The Most Widely Used Material in Condom Manufacture

- Suspension of rubber microparticles in water
- Invented in 1920: eliminated the use of solvents, making condom manufacture safer[1]
  - Performance is superior to rubber: stronger and thinner, with longer shelf-life (5 years vs 3 months for rubber)
- Other uses: medical gloves, diaphragms, catheters, swim caps
- A small number of people have allergic reactions to latex[2]
  - Nonallergenic alternatives to latex include natural lamb skin* and hypoallergenic types of natural latex and synthetic polyurethane

*Condoms made of natural membrane offer no protection from STD pathogens.

1. Collier A. The Humble Little Condom. 2007. 2. Warner L and Steiner MJ. Male condoms. In: *Contraceptive Technology.* 19th edition. New York, NY: Ardent Media; 2007.

Quality Control Measures Are Built Into Every Step of the Church & Dwight Trojan Manufacturing Process



Quality System Oversight

- Condom design, development and production follow the strict standards required of medical devices, as set forth by ASTM and ISO
- Manufacturing complies with the US FDA Quality System Regulation*
- Internal and external third-party audits ensure proper implementation and execution of the quality management system to ISO 13485 standards and Church & Dwight requirements
- Continual QC testing and monitoring at all stages of the manufacturing process deliver quality condoms
- CAPA programs focus on root cause analysis and correction of any issues
- Long-term stability testing assures effectiveness of condoms through their labeled expiration date

*Formerly knows as Current Good Manufacturing Practice for Medical Devices.
ASTM, American Society for Testing and Materials; CAPA, corrective and preventative action system; FDA, Food and Drug Administration; ISO, International Organization for Standardization; QC, quality control.

Snapshot of Quality Manufacturing

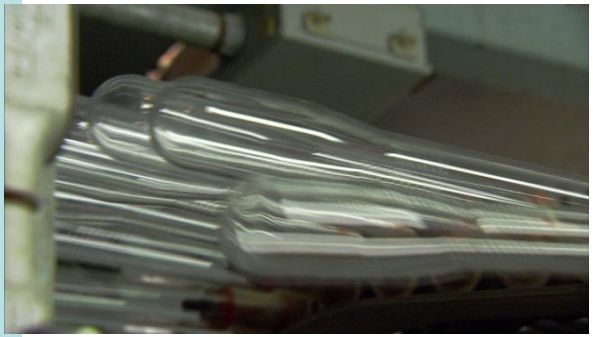
- Partially processed latex is purchased and quality tested
- Latex is vulcanized to increase its elasticity and strength
  - Undergoes quality testing (eg, total solids, pH, viscosity and swollen diameter test)
- Glass molds are dipped into liquid latex and shaped into condoms
  - Monitor for proper condom length, width, and condom wall and ring thickness
  - Water leakage test
- Condoms are washed in a starch slurry and then dried
  - Tensile strength and air burst pressure and volume tests
- 100% of condoms undergo electronic testing before rolling
- Final foiled condom
  - Visual inspection, vacuum testing of foiled condom, and air burst and water leak testing of condom
- Long-term stability testing

The Vulcanization Process Increases the Strength and Elasticity of the Condom

- **Partially processed latex is purchased**
  - Latex is tested to ensure viscosity and mechanical stability are correct before it is deemed appropriate for use by Church & Dwight
- **Latex is vulcanized**
  - Particles of latex (an isoprene monomer) are joined with sulfur to increase elasticity and strength
- **After vulcanization, latex undergoes quality control testing (eg, total solids, pH, viscosity and swollen diameter test) to confirm that it meets standards**

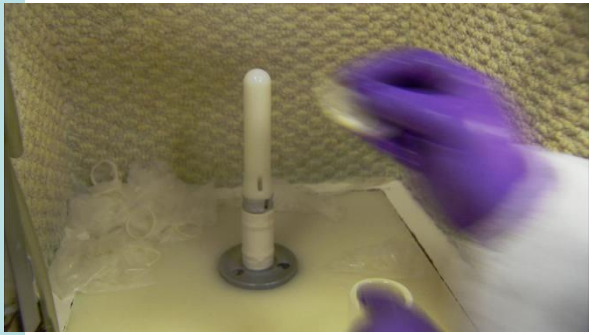
Condoms are Shaped by Dipping Molds Into Liquid Latex, Then Leaching is Used to Remove Residuals

- **Condoms are monitored for proper length and wall and ring thickness during dipping**
- **First water leak quality control test is conducted on manufacturing line**
  - Condoms are hung on a machine and each is filled with 300 mL of water
  - Condoms are then sealed at open end and rolled, squeezed, and visually inspected for evidence of leakage



Condoms are Washed and Dried After Removal From Molds

- **Condoms are washed in a starch slurry then dried in commercial dryers**
- **Quality control measures monitor tensile strength and air burst pressure and volume to ensure condoms meet set standards**
  - Tensile strength: a film sample cut from a condom is stretched on a tensile tester to ensure it has proper strength and elongation
  - Air burst pressure and volume: condom is filled with air and must remain intact up to a determined minimum air pressure and volume



Condoms Undergo Electronic Testing Before Rolling

- **100% of condoms are placed on a stainless steel mandrel for electronic testing**
  - Mandrel is run over a pad that emits >1000 volts of electricity
  - Current flowing through condom signals a hole or defect present and condom is discarded
- **Condoms are rolled to prepare them for foiling and packaging**
- **At least once per shift, a water leak test is conducted to confirm the results of electronic testing**

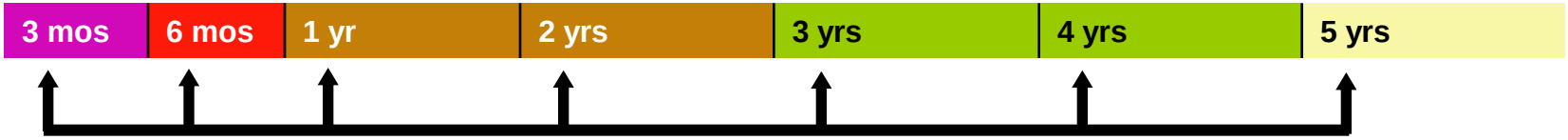
Foiling, Packaging, and Further Quality Control Testing Ensures Product Excellence Prior to Shipment to Market

- **Samples of each lot of condoms undergo final release quality control testing to check for damage, holes, or other weaknesses**
  - Quality control inspectors visually check foils to ensure that condoms have been packaged correctly
  - A sample of foiled condoms is vacuum tested to check that they are properly sealed
  - Additional water leakage testing is performed on a sample of condoms

Condoms Are Designed to Have a Long Shelf Life and Long-term Stability Testing Ensures That Each Condom Meets This Standard

- Each newly developed product goes through accelerated stability testing to set an appropriate expiration date
- Samples of three lots of new product are then placed in a 5-year stability program to confirm real-time shelf life
- Currently marketed products are retested on a maintenance basis

Condom Long-term Stability Testing Schedule



Quality Control Tests

- A sample of packages is tested for weight variation and seal integrity (vacuum test)
- A sample of condoms is tested for appearance, air burst pressure and volume, and tensile strength

Dispelling Common Myths

Myth 1. Latex condoms are not strong or stable

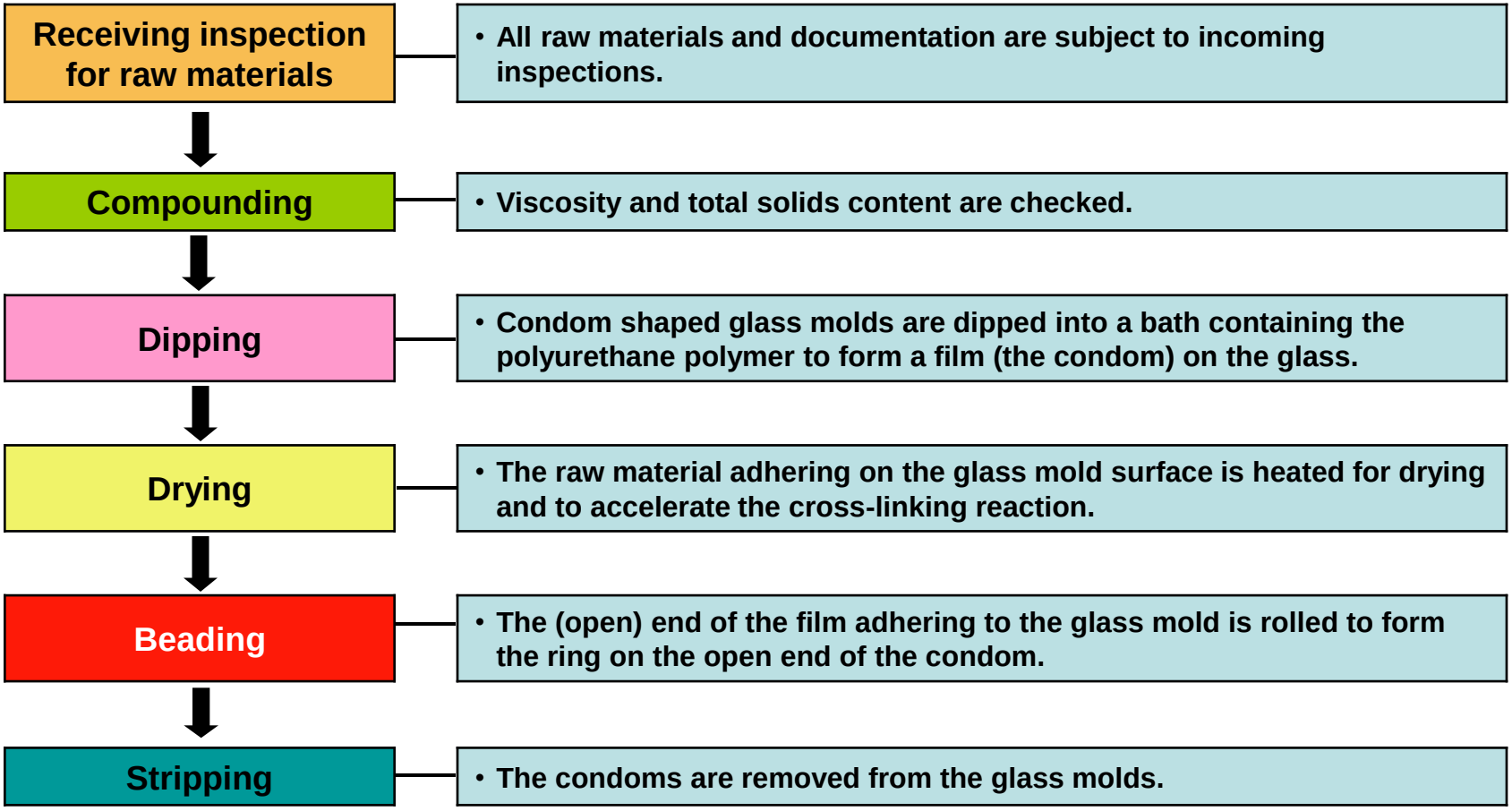
Myth 2. Latex has holes

Facts

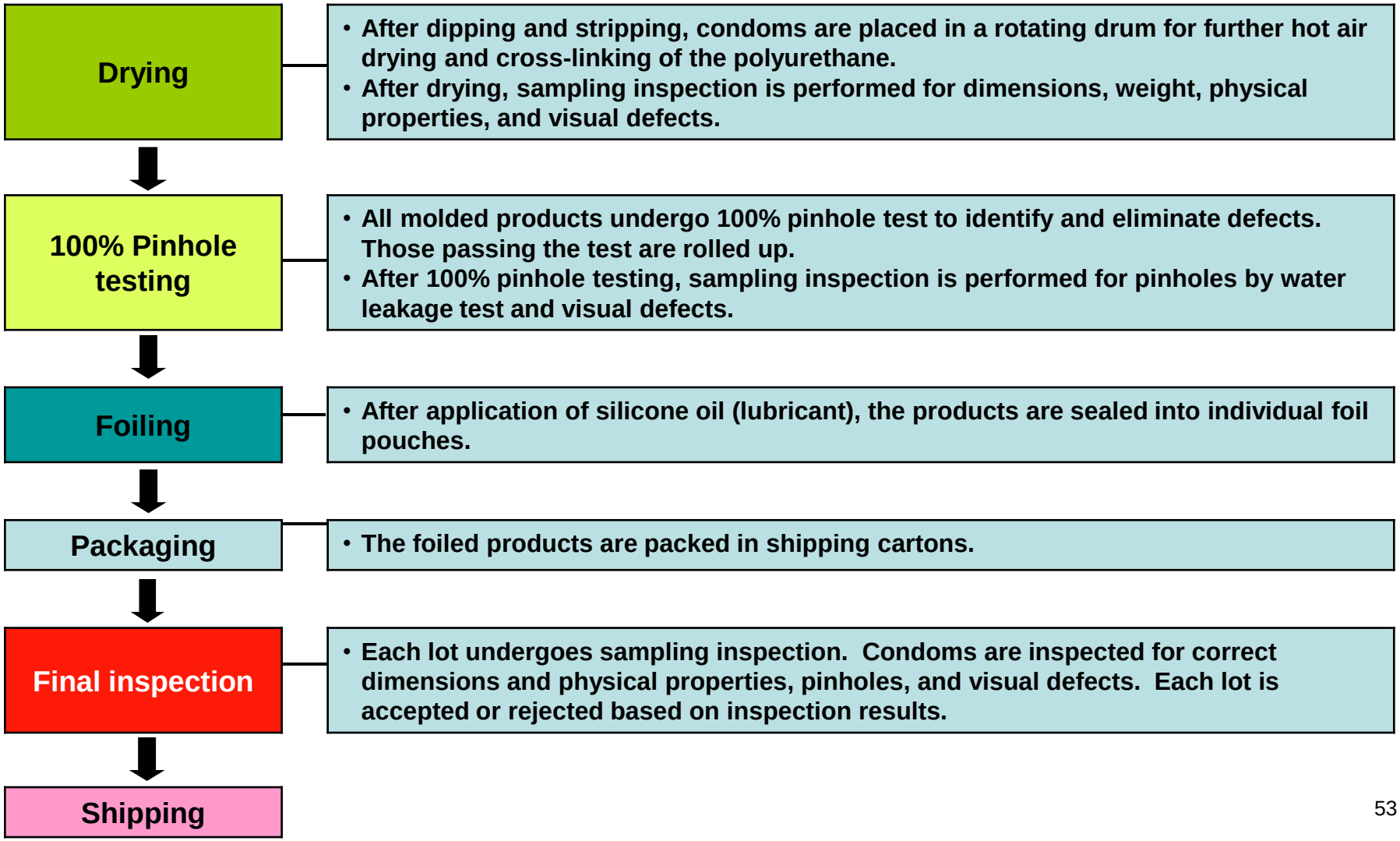
- **Condoms undergo rigorous quality control testing at each step of the manufacturing process to ensure that they are intact, strong, stable, and have no holes**
- **The latex condom is a highly effective barrier to even the smallest STD pathogen**

Polyurethane Condoms Undergo a Similar Manufacturing and Quality Control Process to Latex Condoms

- The manufacturing process for polyurethane condoms is similar to that for natural rubber latex condoms using a dipping process to form the condoms.



Polyurethane Condoms Undergo a Similar Manufacturing and Quality Control Process to Latex Condoms (cont'd)



Church & Dwight Safety Evaluation Program Tests Condom Use Under Normal and Misuse Conditions

- Program goal: to ensure safety of the finished product under normal and reasonably foreseeable misuse conditions
- Testing anticipates all potential routes of human exposure (mucosal [vaginal and penile tissue], dermal, oral, and rectal) and whether exposure is intended or resulting from reasonably foreseeable misuse
- Safety program is multi-dimensional, encompassing evaluation of:
  - Condom and lubricant ingredients
  - Processing and manufacturing
  - Finished product (pre- and post-market)
- Condom (latex or polyurethane), lubricant, and finished product (lubricated condom) undergo extensive safety review and evaluation and are cleared for human use by a board-certified Church & Dwight toxicologist

Church & Dwight Safety Evaluation Program Encompasses All Facets of Condom Manufacture

Ingredient safety evaluation	• All available safety data (literature peer-reviewed, supplier MSDS and certificate of analysis, usage in other similar products, etc) are critically evaluated • Safety profile determined for all ingredients at levels present in the finished product and for all potential routes of exposure • If gaps in ingredient safety data profile are identified, steps are taken to address these and resolve safety concerns
Processing / Manufacturing	• All steps of manufacturing are critically evaluated to ensure that no toxic contaminant or processing by-product is produced in the finished product

Church & Dwight Safety Evaluation Program Encompasses All Facets of Condom Manufacture (cont'd)

Pre-market Considerations	• ISO 10993 testing standards are used to evaluate the safety of new and novel condoms. Testing may include: – Cytotoxicity – Sensitization and irritation – Acute systemic toxicity – Mutagenicity and genotoxicity – Muscle implantation • Condom breakage and slippage are tested when required • All local and federal safety requirements are met (eg, California Proposition-65, FDA 510K submission and consideration)
Post-market Surveillance	• Consumer Relations closely tracks and trends all consumer complaints • Toxicology and regulatory groups review all reports. • All adverse events are reported to the FDA

ISO, International Organization for Standardization.

Prevalence of Latex Allergy in the General Population is Low

- In the general population, prevalence estimates for latex allergy are <1%

Study	Country	N	Test	Prevalence
Turjanmaa et al (1987)	Finland	130	LGSCT	0.8%
Turjanmaa et al (1990)	Finland	1988: 1,051 1988: 1,220 1989: 1,089 1989: 1,342	SPT	1988: 0.8% 1988: 0.7% 1989: 1.1% 1989: 0.8%
Turjanmaa et al (1995)	Finland	300 (Pediatric)	SPT	2%
Turjanmaa et al (1995)	Finland	804	SPT	0.12%
Gautrin et al (1997)	Canada	758	SPT	0.7%
Tarlo et al (1997)	Canada	20	SPT	0%
Ylitalo et al (1997)	Finland	3,269 (Pediatric)	SPT	1.1%

SPT, skin prick test; NRL, natural rubber latex; LGSCT, latex glove scratch chamber test.
Adapted from Liss GM, Sussman GL. *Am J Ind Med.* 1999;35:196-200.

Condom Manufacturing and Quality Control: Summary

- The condom manufacturing process reflects a commitment to quality and consumer confidence
- Condoms are Class II medical devices, regulated by FDA
  - Manufactured to FDA and industry standards
  - Most condoms are made of latex, a remarkably strong and flexible material
  - Low rates of breakage attest to the superior performance of latex
- Church & Dwight manufacturing process is guided by stringent quality control measures
  - Committed to continuous improvement
  - Consumer protection is the bottom line
  - Quality control monitoring is built into each step in the manufacturing process, from vulcanization and dipping through final release
  - Long-term stability testing ensures that condoms remain stable through expiration

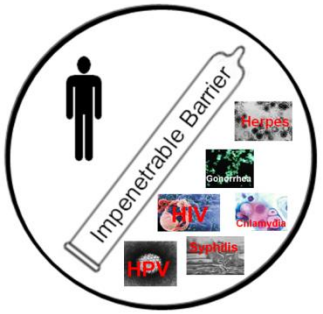
IV. Condom Effectiveness and STD Prevention

Sexually Transmitted Diseases (STDs) Constitute a Major Public Health Challenge

- **STDs constitute a major public health problem[1]**
  - In US, ~19 million new STDs occur annually
  - 50% of these are among young people (ages 15-24 years)
  - Estimated annual cost to US health system: ~$15.9 billion
- **>1.5 million cases of chlamydia and gonorrhea were reported to CDC in 2008, making them the 2 most common infectious diseases reported in US[1]**
  - Largest number of cases were among girls 14-19 years of age
- **Syphilis, once close to being eliminated, has begun to reemerge over the past decade[1]**
- **Prevalence of HIV/AIDS is higher than ever before in US[2,3]**
  - In 2008, >1 million adults and adolescents were living with HIV, an increase of 11% from 2003
- **Each year, STDs lead to infertility in >24,000 women in the US[1]**

1. Sexually Transmitted Diseases in the United States, 2008: National Surveillance Data for Chlamydia, Gonorrhea, and Syphilis. At: http://www.cdc.gov/std/stats08/2008survFactSheet.PDF. Accessed: 06/02/10. 2. CDC. HIV in the United States: An Overview. July, 2010. 3. CDC. HIV Surveillance Report, 2008; vol. 20. Published June 2010. Accessed September 28, 2010.

STDs Are Categorized By Their Mode of Transmission

Mode of Transmission	STD*	Characteristics	Role of Condom in Protection†
Urethral or vaginal secretions	HIV, gonorrhea, chlamydia, trichomoniasis	Pathogens transmitted when secretions come in contact with mucosal surface (vagina, cervix, male urethra)	
Skin-to-skin	Genital herpes, syphilis, chancroid, HPV	Pathogens transmitted through contact with infected skin or mucosal surface	

*Examples of STDs transmitted via the two major modes of transmission.

†The protection condoms give against different STDs varies according to how the STD is transmitted. Condoms provide greater protection against STDs transmitted by urethral or vaginal secretions, because they provide a barrier against those secretions. Condoms may provide less protection against skin-to-skin diseases, because coverage of an entire infected area may not be complete.

CDC. Condoms and STDs: Fact Sheet for Public Health Personnel. July 10, 2010.

Several Factors Impact Condom Effectiveness in Reducing STD Transmission

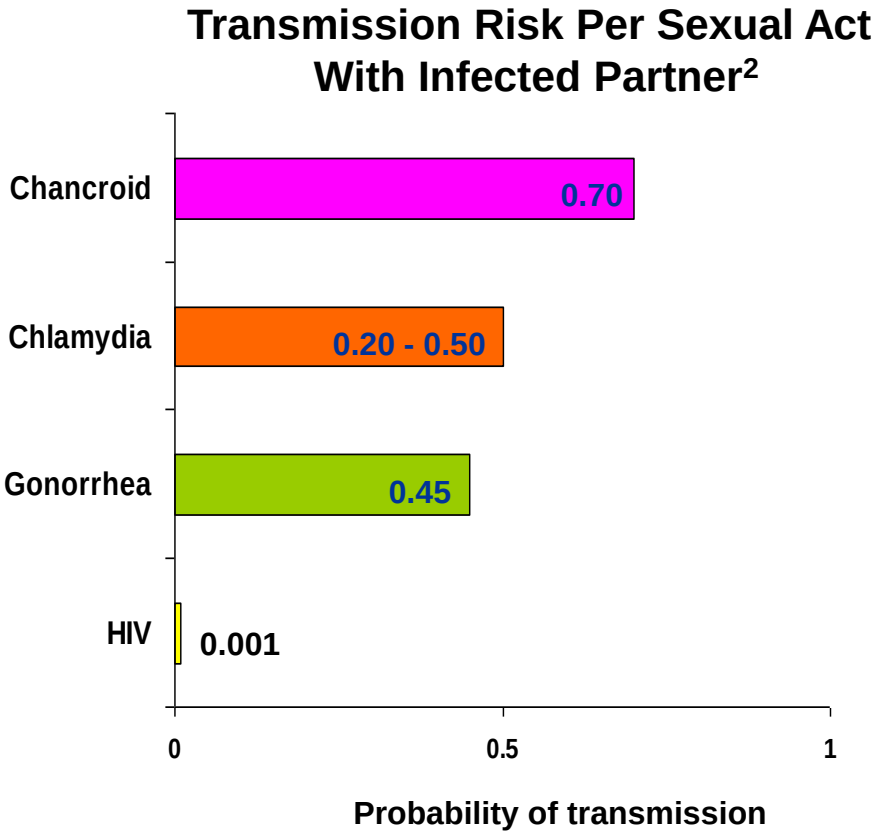
- **Multiple factors influence transmission[1]**
  - Characteristics of infectious microorganism and site(s) of infection
  - Health status of individual
  - Sexual behaviors
  - Prevalence of STDs in community

Factors dependent on STD mode of transmission[2]	
Blood/secretion diseases	Effectiveness dependent on exposure to liquids
Skin-to-skin diseases	Effectiveness dependent on ability of condom to cover lesion

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. CDC. Condoms and STDs: Fact Sheet for Public Health Personnel. July 10, 2010.

Some STDs Are Transmitted More Easily Than Others

- **STD transmissibility is an important factor in condom effectiveness[1]**
  - HIV is less easily transmitted vs gonorrhea
- **However, it is important to be protected from all STD pathogens**
- **With proper use, condoms can provide an effective barrier to STD transmission**



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. Warner L, et al. *Sex Transm Dis.* 2006;33:36-51.

Laboratory and Epidemiologic Studies Are Used to Estimate Condom Effectiveness Against STDs

Type	Specific Tests	Characteristics
Laboratory Studies	✓ Air burst, tensile (strength) property tests ✓ Assay using high concentrations of virus to test for condom leakage	• Test of physical properties of condoms to ensure barrier function
Epidemiologic Studies	✓ Prospective cohort studies: data collected on events as they occur ✓ Retrospective case-control studies or cross-sectional prevalence studies: data from individuals who have had STDs compared with those who have not	• All studies observational: ethical concerns preclude use of randomized, controlled study design • Retrospective studies subject to recall and selection bias

Studies of Condom Effectiveness and STDs Are Limited by Factors Including Ethical Concerns and the Difficulty of Determining Correct Use

- **Ethical concerns associated with nonuse preclude prospective, randomized, controlled trials[1,2]**
  - Studies are limited to observational design[1]
  - Participants must be fully informed of and given access to treatment and preventive services[1]
  - Even prospective cohort studies, which would reduce exposure between users and nonusers, would be unethical for curable STDs[2]
- **Correct and consistent condom use is difficult to measure and often not asked[1,3]**
  - In existing studies, measurement of condom use is often imprecise, not distinguishing between correct and incorrect use[1]
  - Studies that do not adjust for proper use may underestimate condom effectiveness[3]
- **Self-reported data are subject to errors related to event recall: participants may not accurately remember events or may not be entirely truthful[1]**

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. Warner L, et al. *Sex Transm Dis.* 2006;33:36-51. 3. Holmes KK, et al. *Bull World Health Organ.* 2004;82:454-461.

Results From Studies Show That Condoms Are Effective Against STD Transmission

- **Lab studies have demonstrated that intact latex and polyurethane condoms provide an impermeable barrier to STD pathogens[1]**
  - Impermeability includes even the smallest STD virus, hepatitis B
- **Epidemiologic studies have shown that, used consistently and correctly, condoms are highly effective in:**
  - Preventing transmission of HIV[2]
  - Reducing risk of other STDs, including discharge and genital ulcer disease[2]
  - Preventing even the most easily transmitted STDs: gonorrhea and chlamydia[3]
- **Recent prospective studies demonstrate that condom use is associated with a statistically significant protective effect against a range of STDs[4]**

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. Male Latex Condoms and Sexually Transmitted Diseases. Available at: http://www.cdc.gov/nchstp/od/condoms.pdf. Access on: 060310. 3. Cates W, Jr. *Fam Plann Perspect.* 2001;33:231-233. 4. Holmes KK, et al. *Bull World Health Organ.* 2004;82:454-461.

Correct and Consistent Condom Use is Highly Protective Against HIV Transmission

- Lab studies demonstrate that latex condoms provide an impermeable barrier to the HIV virus[1]
- Epidemiologic studies demonstrate conclusively that correct and consistent use of latex condom provides a high degree of protection against HIV transmission[2]
- Methodological strength of condom HIV studies exceeds that of studies of condom use and other STDs[2]
  - Longitudinal studies involving HIV-positive individuals and their HIV-negative partners allow estimates of incidence among condom users and nonusers
- In serodiscordant heterosexual couples, HIV-negative partners ~80% less likely to become infected vs condom nonusers[3]

1. Male Latex Condoms and Sexually Transmitted Diseases. Available at: http://www.cdc.gov/nchstp/od/condoms.pdf. Access on: 060310.
2. National Institute of Allergy and Infectious Diseases, Workshop Summary: Scientific Evidence on Condom Effectiveness for Sexually Transmitted Disease (STD) Prevention, July 20, 2001. 3. CDC. Sexually transmitted diseases: treatment guidelines, 2010. MMWR. 2010;59:1-109.

Consistent Condom Use Is Associated With a Low Risk of HIV Transmission

- **Condom effectiveness in preventing HIV in heterosexual couples is estimated at 82.9%**

Rates of HIV Transmission Among Heterosexual Couples by Condom Usage: Meta-analysis of Cohort Studies

Condom usage cohorts	HIV incidence* (per 100 person-years)	95% CI
Always-users†	1.14	0.56–2.04
Never-users‡	6.68	4.78–8.88

*Incidence estimated from the total number of seroconversions divided by the total person-years of exposure.
†Based on data from 13 cohort samples of serodiscordant heterosexual couples who always used condoms during sex.
‡Based on data from 10 cohort samples of serodiscordant heterosexual couples who never used condoms during sex.

Weller S, Davis K. Cochrane Database Syst Rev. 2002:CD003255.

Condom Use Has the Potential to Significantly Decrease Lifetime Risk of Acquiring HIV

- Results from a model of lifetime risk of HIV infection under different condom use scenarios suggest that condom use has the potential to significantly decrease transmission
- Microsimulation (Monte Carlo) Model*
  - Stochastic, computer-dependent method for simulating a data set according to predetermined probabilistic rules
  - Data set made up of individually simulated records
  - Simulated data analyzed as though derived through prospective observation

*Model inputs on men's sexual activity based on data on sexual activity (eg, propensity to have sex, monthly probability, coital frequency) with casual partners and bar girls taken from the southern region of Malawi in 2001. Model inputs on women's sexual activity based on data on sexual activity (eg, propensity to have sex, monthly probability, coital frequency) with men other than their husbands taken from the southern region of Malawi in 2001.

Bracher M, et al. *Stud Fam Plann.* 2004;35:48-64.

Consistent Condom Use Protects Against Transmission of Gonorrhea

- **Physical properties of latex condom protect against discharge diseases such as gonorrhea[1]**
- **NIH 2001 review of available studies: data demonstrate that, when used consistently and correctly, condoms have a protective effect for male users[2]**
  - Existing studies (at time of review) were limited by retrospective design and small sample sizes
- **Results from systematic reviews of existing studies suggest that condom use reduces risk of gonorrhea transmission[3,4]**
  - 12 of 18 studies demonstrated a protective effect[3]
  - Retrospective analysis of epidemiologic data suggests that methodological limitations of studies may result in underestimates of condom effectiveness[3]
- **Additional studies completed since the NIH 2001 report have demonstrated significant reductions in risk of gonorrhea transmission with condom use[5,6]**
  - Consistent condom usage was associated with a significant decrease in risk (OR: 0.38; $P<0.001$)[6]

1. Male Latex Condoms and Sexually Transmitted Diseases. Available at: http://www.cdc.gov/nchstp/od/condoms.pdf. Access on: 060310. 2. National Institute of Allergy and Infectious Diseases, Workshop Summary: Scientific Evidence on Condom Effectiveness for Sexually Transmitted Disease (STD) Prevention, July 20, 2001. 3. Warner L, et al. *Sex Transm Dis.* 2006;33:36-51. 4. Holmes KK, et al. *Bull World Health Organ.* 2004;82:454-461. 5. Crosby RA, et al. *Am J Public Health.* 2003;93:901-902. 6. Sanchez JMM, et al. *Sex Transm Dis.* 2003;30:273-279.

Condom Use is Associated With Consistent Reduction in Gonorrhea Risk: Meta-analysis Results

- Systematic review of 18 studies conducted between 1966 and 2004 examining the effect of condom use on risk of gonorrhea in males and females
- Majority of studies demonstrate that condom use is associated with reduced risk in both men and women
  - In 3 studies in men and 9 in women, the effect was statistically significant
  - Associations between condom use and reduced risk were demonstrated, even though several studies had methodological limitations contributing to inconsistent results and underestimates of condom effectiveness*

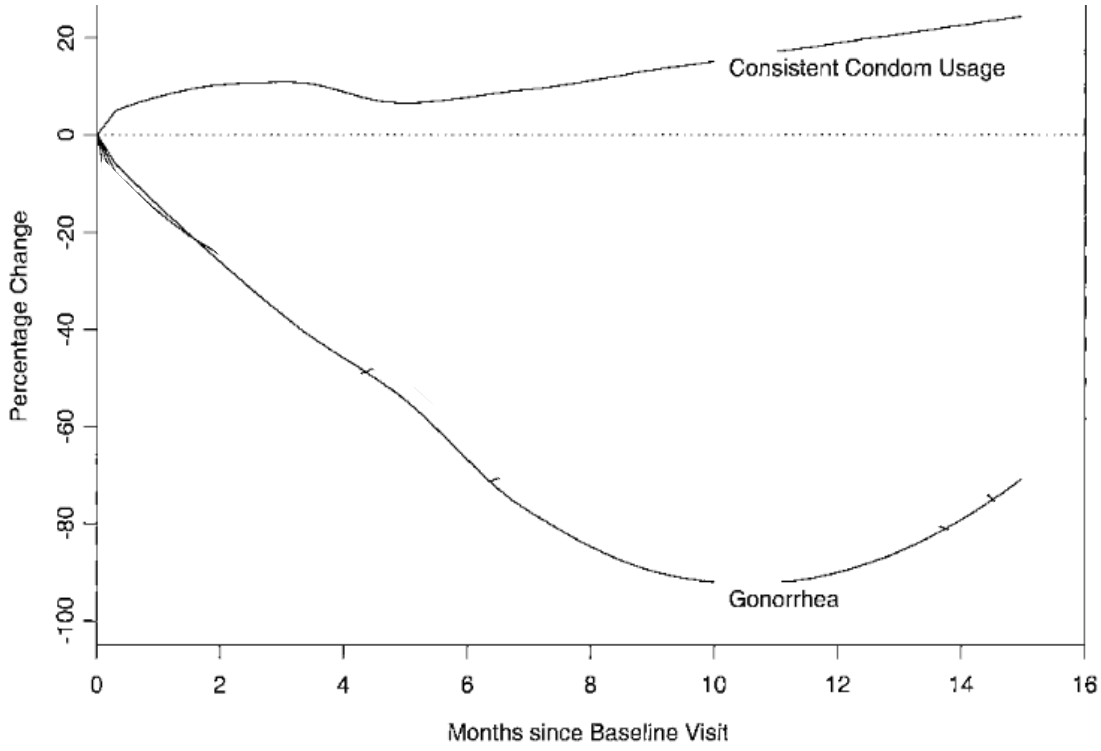
*Common limitations: condom use problems, consistency of use, incidence versus prevalence, lack of documentation of partner exposure to infection during study period.

Warner L, et al. *Sex Transm Dis.* 2006;33:36-51.

Consistent Condom Use is Associated With a Decline in Gonorrhea Prevalence

- Study assessed the impact of consistent condom use on STD prevalence among 917 female sex workers who visited 2 STD clinics in Peru
  - Findings were based on 7908 person-months of observation
- Significant reductions from baseline in gonorrhea prevalence as well as a significant increase in consistent condom usage were reported
- Consistent condom usage over the past month was associated with a significant decrease in risk of gonorrhea (OR: 0.38; *P*<0.001)*

Change From Baseline in Prevalence of Gonorrhea and Condom Use Among 917 Peruvian Sex Workers



*The increase in prevalence after 1 year, resulting from attrition bias, was not significant in the conditional logistic regression model.

Sanchez JMM, et al. *Sex Transm Dis.* 2003;30:273-279.

Consistent Condom Use Protects Against Transmission of Chlamydia

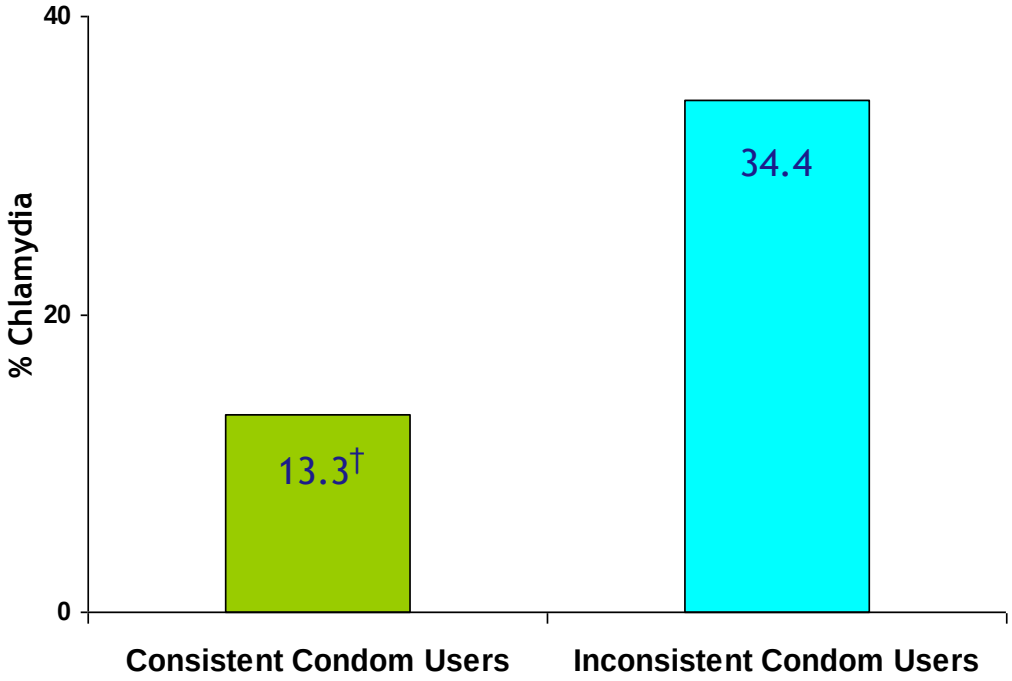
- **Physical properties of latex condom protect against discharge diseases such as chlamydia[1]**
- **NIH 2001 report concluded that existing literature did not allow accurate assessment of protection[2]**
  - Many of the available epidemiological studies were not designed or conducted in ways that allow for accurate measurement of condom effectiveness against discharge diseases[2]
  - Several studies not included in NIH analysis do show a protective effect in both men and women[3]
- **Recent systematic review of existing studies found that condom use reduces risk of chlamydia transmission[4]**
- **Various studies published since 2000 have demonstrated that condoms provide a protective effect[5,6]**

1. Male Latex Condoms and Sexually Transmitted Diseases. Available at: http://www.cdc.gov/nchstp/od/condoms.pdf. Access on: 060310. 2. National Institute of Allergy and Infectious Diseases, Workshop Summary: Scientific Evidence on Condom Effectiveness for Sexually Transmitted Disease (STD) Prevention, July 20, 2001. 3. Cates W, Jr. *Fam Plann Perspect.* 2001;33:231-233. 4. Warner L, et al. *Sex Transm Dis.* 2006;33:36-51. 5. Niccolai LM, et al. *Sex Transm Infect.* 2005;81:323-325. 6. Sanchez JMM, et al. *Sex Transm Dis.* 2003;30:273-279.

Analysis of Records from STD Clinics Demonstrates That Condoms Protect Against Chlamydia Transmission

- Retrospective analysis of medical records database from public STD clinic (N=1455)
- Among subjects with known chlamydia exposure who were consistent condom users, signficantly fewer were diagnosed with chlamyida (*P*=0.02)
- In multivariate analysis, consistent condom use was associated with a 90% reduction in prevalence of chlamyida (adjusted OR: 0.10; 95%CI: 0.01-0.83)

Rates of Chlamydia Among Consistent and Inconsistent Condom Users With Known Chlamydia Exposure*



*N=152. †*P*=0.02, consistent vs inconsistent condom users.

Niccolai LM, et al. *Sex Transm Infect.* 2005;81:323-325.

Condom Use is Associated With Consistent Reduction in Chlamydia Risk

- Systematic review examined the effect of condom use on the risk of chlamydia in males from studies conducted between 1966 and 2004
- In 8 studies of chlamydia in men, 7 reported a protective effect (range: 15-100%)
  - In 3 studies, this effect was statistically significant
- Of 27 studies of chlamydia in women, 21 reported estimates on risk reduction
  - 18 found a protective effect for condoms (range: 10-90%)
  - In 10 of these studies, the effect was statistically significant

Warner L, et al. *Sex Transm Dis.* 2006;33:36-51.

Consistent Condom Usage is Associated With Decline in Chlamydia Prevalence

- Study assessed the impact of consistent condom use on STD prevalence among 917 female sex workers who visited 2 STD clinics in Peru
  - Findings were based on 7908 person-months of observation
- Significant reductions from baseline in chlamydia prevalence as well as a significant increase in consistent condom use were reported
- Consistent condom use over the past month was associated with a significant decrease in risk of chlamydia (OR: 0.74; $P<0.05$)

Sanchez JMM, et al. *Sex Transm Dis.* 2003;30:273-279.

Correct and Consistent Condom Use Reduces the Risk of Syphilis Transmission

- **Latex condoms can protect against syphilis transmission when the infected area is covered[1]**
  - Condom must cover the genital area where ulcers or infections are located
- **According to NIH 2001 report, results from 5 of 8 available studies suggest that condoms have a protective effect in syphilis transmission[2]**
  - 2 cross-sectional studies showed 60-70% reduction in prevalence of syphilis among condom users vs nonusers
  - Available studies were limited by methodological problems
- **2009 Meta-analysis found reduced risk of syphilis with consistent condom use[3]**
  - 12 studies included in the analysis had significant methodological limitations: none assessed correct use or condom use problems, nor did any document exposure to the partner with syphilis
  - 2 most rigorous studies suggested reduced risk of syphilis with consistent condom use

1. Male Latex Condoms and Sexually Transmitted Diseases. Available at: http://www.cdc.gov/nchstp/od/condoms.pdf. Access on: 060310. 2. National Institute of Allergy and Infectious Diseases, Workshop Summary: Scientific Evidence on Condom Effectiveness for Sexually Transmitted Disease (STD) Prevention, July 20, 2001. 3. Koss CA, et al. *Sex Transm Dis.* 2009;36:401-405.

Correct and Consistent Condom Use Can Reduce Risk of Transmission of HPV and Associated Diseases

- **Relationship between condom use and HPV is difficult to study because HPV is only intermittently detectable[1]**
  - **Existing studies have methodological differences and have provided conflicting evidence**
  - **Most studies are not designed or conducted in a way to accurately measure condom effectiveness**
- **According to NIH 2001 report, condom use can partially reduce HPV risk[1]**
  - **HPV infection can be transmitted by areas not covered by condoms**
- **Condom use may afford protection from HPV-associated diseases including genital warts, cervical dysplasia, and cervical cancer[1-3]**
- **A more recent studies demonstrate significant reduction in HPV risk with condoms[4,5]**
- **Correct and consistent condom use is recommended for decreasing HPV risk[6]**

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. Male Latex Condoms and Sexually Transmitted Diseases. Available at: http://www.cdc.gov/nchstp/od/condoms.pdf. Access on: 060310. 3. Manhart LE, Koutsky LA. *Sex Transm Dis.* 2002;29:725-735. 4. Winer RL, et al. *N Engl J Med.* 2006;354:2645-265. 5. Nielson CM, et al. *J Infect Dis.* 2010:202:445-451. 6. CDC. Sexually transmitted diseases: treatment guidelines, 2010. MMWR. 2010;59:1-109.

Consistent Condom Use by Male Partners Appears to Reduce Risk of HPV Infection in Young Women

- In women reporting 100 percent condom use by partners, no cervical HPV lesions were detected (32 patient-years at risk)
- In women whose partners did not use condoms or used them less consistently, 14 incident lesions were detected (97 patient-years at risk)

Risk of HPV Infection By Frequency of Condom Use

Risk Factor	HR (95% CI)	*P* Value	Adjusted HR (95% CI)	*P* Value
HPV infection				
Frequency of condom use by partner*				
<5%	**1.0**		**1.0**	
5-49%	**1.8 (0.95-3.4)**	**0.07**	**1.0 (0.5-1.8)**	**0.92**
50-99%	**0.7 (0.3-1.4)**	**0.30**	**0.5 (0.3-0.9)**	**0.02**
100%	**0.4 (0.2-0.95)**	**0.04**	**0.3 (0.1-0.6)**	**0.003**

*Frequency of condom use calculated by dividing number of condoms used for episodes of intercourse by number of instances of intercourse during the previous eight months.

Winer RL, et al. *N Engl J Med.* 2006;354:2645-2654.

Consistent and Correct Condom Use Can Reduce Risk of Herpes Transmission

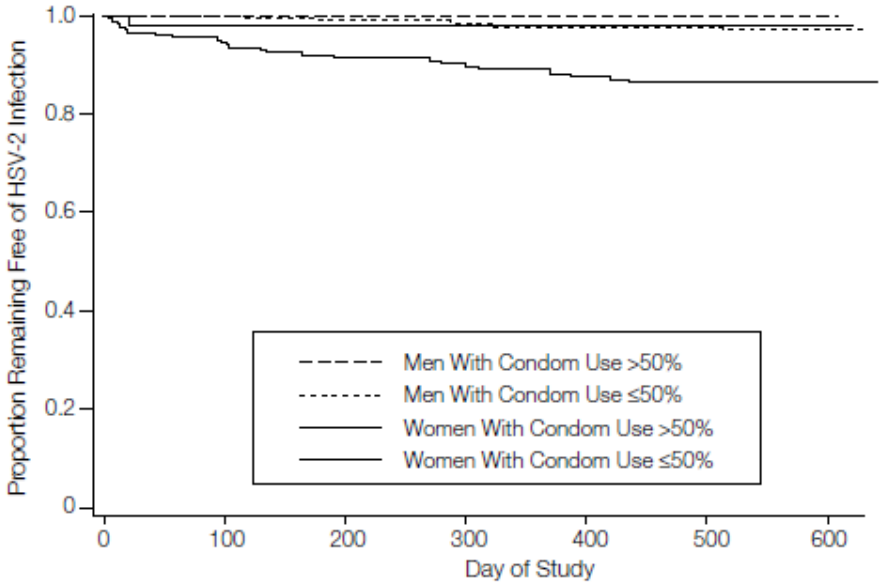
- **Correct and consistent use of latex condoms can reduce the risk of genital herpes transmission only when the infected site or site of exposure is protected[1]**
  - For serodiscordant heterosexual couples, condom use should be part of a strategy to prevent HPV transmission
- **NIH 2001 report found 5 cross-sectional studies that allowed estimates of condom effectiveness in prevention of herpes[2]**
  - None of the studies was designed specifically to measure condom effectiveness
  - Limitations in the design of the studies prevented the panel from forming any conclusions concerning the effectiveness of correct condom use in preventing herpes
- **Results from studies completed since 2001 suggest that condoms are effective against herpes transmission[3,4]**

1. CDC. Sexually transmitted diseases: treatment guidelines, 2010. MMWR. 2010;59:1-109.. 2. National Institute of Allergy and Infectious Diseases, Workshop Summary: Scientific Evidence on Condom Effectiveness for Sexually Transmitted Disease (STD) Prevention, July 20, 2001. 3. Wald A, et al. *JAMA.* 2001;285:3100-3106. 4. Holmes KK, et al. *Bull World Health Organ.* 2004;82:454-461.

Condom Use Was Effective in Reducing the Risk of Women Acquiring Herpes

- Study followed 528 HSV-2 discordant couples who had participated in a failed vaccine trial[1]
- Condoms offered significant protection against acquiring HSV-2 infection in women but not in men[1]
  - Using condoms >25% (median) of the time was associated with a 92% reduction in risk (adjusted HR, 0.085; 95% CI, 0.01-0.67) of women acquiring HSV-2[1,2]

Acquisition of Herpes in Men and Women By Condom Use[1]



1. Wald A, et al. *JAMA.* 2001;285:3100-3106.
2. Holmes KK, et al. *Bull World Health Organ.* 2004;82:454-461.

Human Error Can Impact Condom Effectiveness in Preventing STDs

Multiple types of condom-use errors are highly prevalent among populations at high risk of STDs and may impact the effectiveness of condoms

Prevalence of Condom-Use Errors Among 278 Men Attending an STD Clinic

Type of error	Frequency	Episodes (%)*	N	Men (%)
Placed condom on upside down then turned it over	114	13.7	81	29.1
Removed condom before sex was done	106	12.7	79	28.4
Put condom on after sex had begun	70	8.4	52	18.7
Condom contacted sharp object before or during sex	49	5.9	28	10.0
Used an oil-based lubricant	34	4.1	18	6.5

*Calculated using the total number of condom acts (834) as the denominator.

Crosby R, et al. *Int J STD AIDS.* 2008;19:90-93.

Condom Breakage and Slippage is Often Attributable to User Error

- **In a study of condom use, rates of breakage and slippage were significantly higher among a small group of less experienced users who were prone to user error**
  - **Based on convenience sample of 177 couples, each of whom used 11 condoms**

Condom Breakage and Slippage Rates by Experience in Year Before Study

	Total	Used condom in previous year	Did not use condom in previous year	Broke condom in previous year	Did not break condom in previous year
Breakage					
Rate (95% CI)	**5.3** (4.4-6.4)	**4.5*** (3.6-5.7)	**8.6** (6.0-12.0)	**7.8†** (5.4-11.0)	**3.4** (2.5-4.6)
Slippage					
Rate (95% CI)	**3.5** (2.7-4.4)	**3.0¶** (2.2-4.0)	**5.5** (3.5-8.5)	**5.4§** (3.4-8.3)	**2.2** (1.5-3.3)

*P=0.0029 vs participants who had not used a condom in the previous year. †P=0.0006 vs participants who had not broken condom in previous year. ¶P=0.0256 vs participants who had not used condom in previous year. §P=0.0030 vs participants who had not broken a condom in the previous year.

Steiner M, et al. *Fam Plann Perspect.* 1993;25:220-223, 226.

Summary and Conclusions

- **STDs constitute a major public health problem[1]**
  - **In US, ~19 million new STDs infections occur annually: chlamydia and gonorrhea are the 2 most common infectious diseases reported**
- **STD classified as discharge/genital secretion diseases (HIV, gonorrhea, chlamydia), genital ulcer diseases (genital herpes, syphilis, chancroid), and skin-to-skin (HPV)[2]**
  - **Transmissibility determines how "forgiving" a contraceptive method is to user or device failure**
- **Lab studies have demonstrated that intact latex condoms provide an impermeable barrier to STD pathogens[2]**
- **Latex condoms, used consistently and correctly, are highly effective in[4,5]:**
  - **Preventing transmission of HIV**
  - **Reducing risk of other STDs, including discharge and genital ulcer disease**
  - **Preventing even the most easily transmitted STDs: gonorrhea and chlamydia**
- **Recent prospective studies show condom use is associated with a statistically significant protective effect against a range of STDs[6]**
  - **Studies of condom effectiveness against STDs often have methodological limitations, including observational design, difficulty of accounting for correct and incorrect use, and data subject to recall errors[2,3]**
- **Human error is the most significant factor impacting condom effectiveness in STD prevention[7,8]**

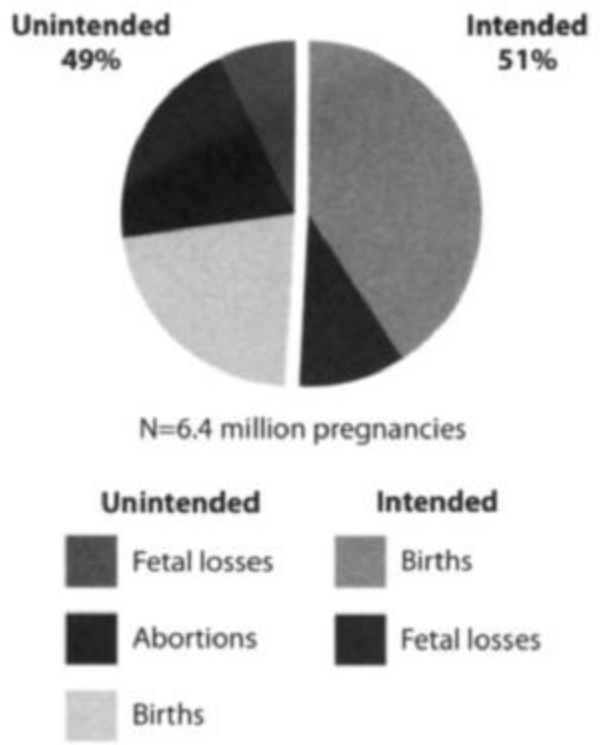
1. CDC. Sexually Transmitted Diseases in the United States, 2008: National Surveillance Data for Chlamydia, Gonorrhea, and Syphilis. 2. NIAID Workshop Summary: Scientific Evidence on Condom Effectiveness for Sexually Transmitted Disease (STD) Prevention. 2001. 3. Warner L, et al. *Sex Transm Dis.* 2006;33:36-51. 4. CDC. Male Latex Condoms and Sexually Transmitted Diseases. 5. Cates W, Jr. *Fam Plann Perspect.* 2001;33:231-233. 6. Holmes KK, et al. *Bull World Health Organ.* 2004;82:454-461. 7. Crosby R, et al. *Int J STD AIDS.* 2008;19:90-93. 8. Steiner M, et al. *Fam Plann Perspect.* 1993;25:220-223, 226.

Section V: Condom Effectiveness and Pregnancy

Unintended Pregnancy Constitutes a Major Public Health Challenge in the US

- 1 in 20 American women (15-44 years) has an unintended pregnancy each year[1]
- Total of 6.4 million pregnancies were reported in the US in 2001[1]
- 3.1 million (49%) were unintended[1]
  - 44% ended in births
  - 42% ended in abortion
  - 14% in fetal loss
- Burden is greatest among certain groups[1,2]
  - Low income
  - 18-24 age group
  - Minorities
- Risk of unintended pregnancy is highest among teenagers (ages 15-19)[2]
- US has one of the highest rates of teen pregnancy among industrialized nations[3]

NSFG 2002 Survey Data: Percentage Distribution of Pregnancies by Intendedness and Outcome[1]



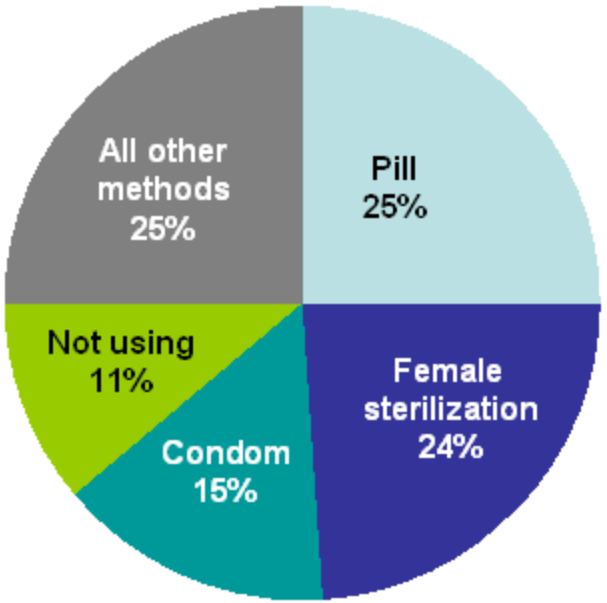
NSFG, National Survey of Family Growth

1. Finer LB, Henshaw SK. *Perspect Sex Reprod Health.* 2006;38:90-96. 2. Mosher WD, Jones J. Use of Contraception in the United States: 1982-2008. National Center for Health Statistics. Vital Health Stat 23 (29). 2010. 3. Singh S, Darroch JE. *Fam Plann Perspect.* 2000;32:14-23.

Some Form of Contraception is Used by a Majority of Women in the US

- **Contraception methods are used by nearly all US women of reproductive age**
  - 99% of all women have used ≥1 contraceptive method
  - 93% have ever had partner who used a condom
  - 82% have ever used the pill
  - 59% have ever had a partner who used withdrawal
- **In 2006-2008, top 3 methods of contraception in US***
  - Pill (10.7 million)
  - Female sterilization (10.3 million)
  - Condoms (6.2 million)†

NSFG 2006-2008 Survey Data: Percentage Distribution of At-Risk Women 15-44 Years of Age By Contraceptive Status



Mosher WD, Jones J. Use of Contraception in the United States: 1982-2008. National Center for Health Statistics. Vital Health Stat 23 (29). 2010.

*Current use among women 15-44 years of age.
†When used as primary method. 8.6 million when included as part of dual use.

The Risk of Unintended Pregnancy During Unprotected Sex Is High

- Likelihood of getting pregnant during unprotected sex[1]
  - 8 out of 100 women who have unprotected sex once during the 2nd or 3rd week of menstrual cycle will become pregnant
- A teen who is sexually active and does not use contraception has a 90% chance of getting pregnant within a year[2]

1. Trussell J. *Contraception.* 2004;70:89-96.
2. Guttmacher Institute. Facts on American Teens' Sexual and Reproductive Health. January, 2010.

Current Contraceptive Use Among Women Shows Acceptance of Condom as a Leading Option for Contraception

Percentages of Current Contraceptive Use by Method: NSFG 1982, 1995, 2002, 2006-2008*

	1982 (N=54,099)	**1995** (N=60,201)	**2002** (N=61,561)	**2006-2008** (N=61,864)
Using any contraception	55.7	64.2	61.9	61.8
Pill	**15.6**	**17.3**	**18.9**	**17.3**
Female sterilization	**12.9**	**17.8**	**16.7**	**16.7**
Condom	**6.7**	**13.1**	**11.1**	**10.0**
Periodic abstinence†	2.1	2.2	2.7	3.3
Withdrawal	1.1	2.0	2.5	3.2
Injectable	--	2.8	4.1	2.7
Diaphragm	4.5	1.2	0.2	--

*Among women ages 15-44 years who have ever had intercourse. †Including calendar rhythm and natural family planning.

Mosher WD, Jones J. *Vital Health Stat* 23 (29). 2010.

Trends in Lifetime Contraceptive Use Among Women Show Acceptance of Condom as a Leading Option for Contraception

Percentages of Lifetime Use of Contraceptive Methods Among US Women: NSFG 1982, 1995, 2002, 2006-2008*

	1982 (N=46.684)	**1995** (N=53,800)	**2002** (N=54,190)	**2006-2008** (N=53,240)
Any method	94.8	98.2	98.2	99.1
Pill	76.3	82.2	82.3	82.3
Female sterilization	22.3	23.4	20.7	19.9
Condom	**51.8**	**82.0**	**89.7**	**93.0**
Periodic abstinence†	19.3	28.5	19.7	24.0
Withdrawal	24.5	40.6	56.1	58.8
Injectable	--	4.5	17.7	24.1
Diaphragm	17.1	15.2	8.5	3.1

*Among women ages 15-44 years who have ever had intercourse. †Including calendar rhythm and natural family planning.

Mosher WD, Jones J. Vital Health Stat 23 (29). 2010.

Condom Use is Higher Among Adolescents and Singles in the US

Results From the NSSHB*

	Condom use during most recent vaginal intercourse event† (%)	Condom use rate during last 10 vaginal intercourse events‡ (%)
Adult males	**24.7**	**21.5**
Adult females	**21.8**	**18.4**
Adolescent males	**79.6**	**79.1**
Adolescent females	**70.2**	**58.1**
Singles	**NA**	**46.7**

*NSSHB, National Survey OF Sexual Health and Behavior, population-based survey of 5,865 individuals. †Among individuals whose last sexual event included vaginal intercourse (n=1966). ‡Among individuals who had had vaginal intercourse during the last year (n=3146).

- **Condom use is significantly higher among adolescence vs categories of adulthood**
- **Other significant associations: Black or Hispanic/Latino race/ethnicity and having sex with a non-relationship partner**
  - **Rates of use with casual partners is 100% higher than among relationship partners**

Reece M, et al. *J Sexual Med.* 2010. In press.

Contraceptive Effectiveness Is Estimated Using Data From Clinical Trials, Surveys, and Other Tests

Data Source	Characteristics
Clinical Trials	• Data are collected prospectively, users closely monitored[1] • Source for best estimates of perfect use[2] • Participants are self-selected, more educated than typical user[1]
Population Surveys	• Major source of contraceptive effectiveness, focused on typical use rates vs inherent efficacy of method[2] • Retrospective survey data may be affected by recall and reporting errors: few checks on accuracy of information[1] • A variety of user-level factors may account for the divergence in typical and perfect use failure rates[1]
Mechanical Tests	• Laboratory models quantify risk of breakage and slippage and are limited in measuring efficacy and effectiveness[3]

1. Fu H, et al. *Fam Plann Perspect.* 1999;31:56-63. 2. Kost K, et al. *Contraception.* 2008;77:10-21

Challenges of Estimating Contraceptive Effectiveness

- Reliance on self-reported data[1]
  - Couples are asked to recall contraceptive use over long periods of time
- Exact risk of pregnancy is different for every couple[2]
  - Depends on factors such as fertility and frequency of intercourse
- Role of user error is difficult to measure
  - Couples are asked what method they use, but often not asked if they used it consistently or correctly[1]
  - There is no way for researchers to verify correct use[1,2]

1. Fu H, et al. *Fam Plann Perspect.* 1999;31:56-63
2. Trussell J. *Contraception.* 2004;70:89-96.

Other Factors Influencing Estimates of Contraceptive Effectiveness

Inherent Efficacy of Method[1]	✓ **Potential for misuse** ✓ **Technical attributes of method that facilitate or interfere with proper use**
Investigator influence[1]	✓ **How well study is designed and executed** ✓ **Analysis of results**
Measurement Issues[2]	✓ **Studies must correct for underreporting of abortion**
Ethical considerations	✓ **Randomized trial designs cannot be used when some couples do not wish to become pregnant**

1. Trussell J. *Contraception.* 2004;70:89-96.
2. Fu H, et al. *Fam Plann Perspect.* 1999;31:56-63.

Understanding Contraceptive Effectiveness

- **Perfect use versus typical use**
  - Perfect use rate refers to how often a method will fail if used consistently and correctly, as in a controlled clinical trial
  - Typical use rate refers to how often a method will fail for a typical couple under real-life conditions

Trussell J. *Contraception.* 2004;70:89-96.

Understanding How Perfect Use is Calculated

- **Perfect rates estimate how often a method will fail with consistent and correct use**
- **Calculated on the following basis:**
  - **Out of 100 couples who use the method consistently and correctly, a given percentage will experience an unintended pregnancy in the first 12 months of use**
- **Perfect use shows how effective a method can be under ideal circumstances**

Trussell J. *Contraception.* 2004;70:89-96.

Consistent Condom Use* in Clinical Trials Results in Low Probability of Pregnancy

- 2% failure rate was extrapolated using results from these studies[1]
- Condoms rarely broke or slipped off during intercourse and provided high contraceptive efficacy[1,2]

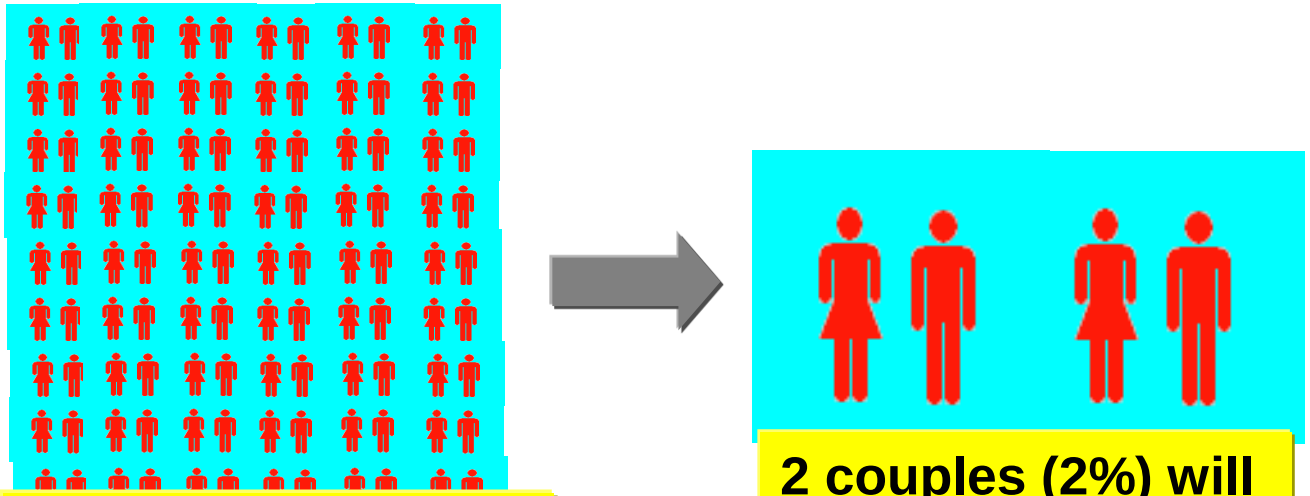
Study	N	6-month probability of pregnancy (%)	Characteristics of sample	LFU (%)
Frezieres et al (1999)[3]	767	**1.0, Ramses** **2.1, Avanti**	Mean age of subjects: 27 years	<5
Walsh et al (2003)[4]	830	**0.7, Trojan-Enz or LifeStyles** **5.1, Tacrylon**	74% > high school education	0.7
Steiner et al (2003)[5]	901	**6.5, eZ-on** **2.1, Kimono Select**	73% living with partner	~5

*All 3 studies estimated efficacy during consistent use. However, only one study (Walsh et al, 2003) estimated efficacy during perfect use. LFU, loss to follow-up

1. Trussell J. Contraceptive efficacy. In: *Contraceptive Technology.* 19th edition. New York, NY: Ardent Media; 2007. 2. Walsh TL, et al. *Contraception.* 2004;70:407-413. 3. Frezieres RG, et al. *Fam Plann Perspect.* 1999;31:81-87. 4. Walsh TL, et al. *Perspect Sex Reprod Health.* 2003;35:79-86. 5. Steiner MJ, et al. *Obstet Gynecol.* 2003;101:539-547.

Condom Effectiveness and Pregnancy: Perfect Use

Accepted Standard Estimate



Using condoms consistently and correctly over a 12-month period

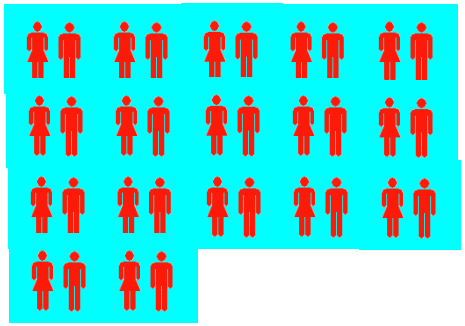
*Based on the mean of estimates of the 6-month probability of pregnancy from 3 clinical trials. These estimates were extrapolated to a 12-month period and adjusted according to perfect use estimates from one of the studies as 2 of the studies reported estimates only for consistent use.

Trussell J. Contraceptive efficacy. In: *Contraceptive Technology.* 19th edition. New York, NY: Ardent Media; 2007.

Condom Effectiveness and Pregnancy: Typical Use

Accepted Standard Estimate

Out of 100 couples



17 couples (17%) will become pregnant

Based on 2002 NSFG estimates of condom effectiveness in typical use.

Kost K, et al. *Contraception.* 2008;77:10-21.

Understanding How Typical Use is Calculated

- **Typical rates estimate how often a method will fail under typical circumstances**
- **Calculated on the following basis:**
  - **Out of 100 couples who use condoms as their primary birth control method, a given percentage will experience an unintended pregnancy in the first 12 months of use**
  - **Couples may have been using the method incorrectly or not using the method at all at the time they experienced an unintended pregnancy**
- **Typical use shows how effective a method can be under real-life conditions**

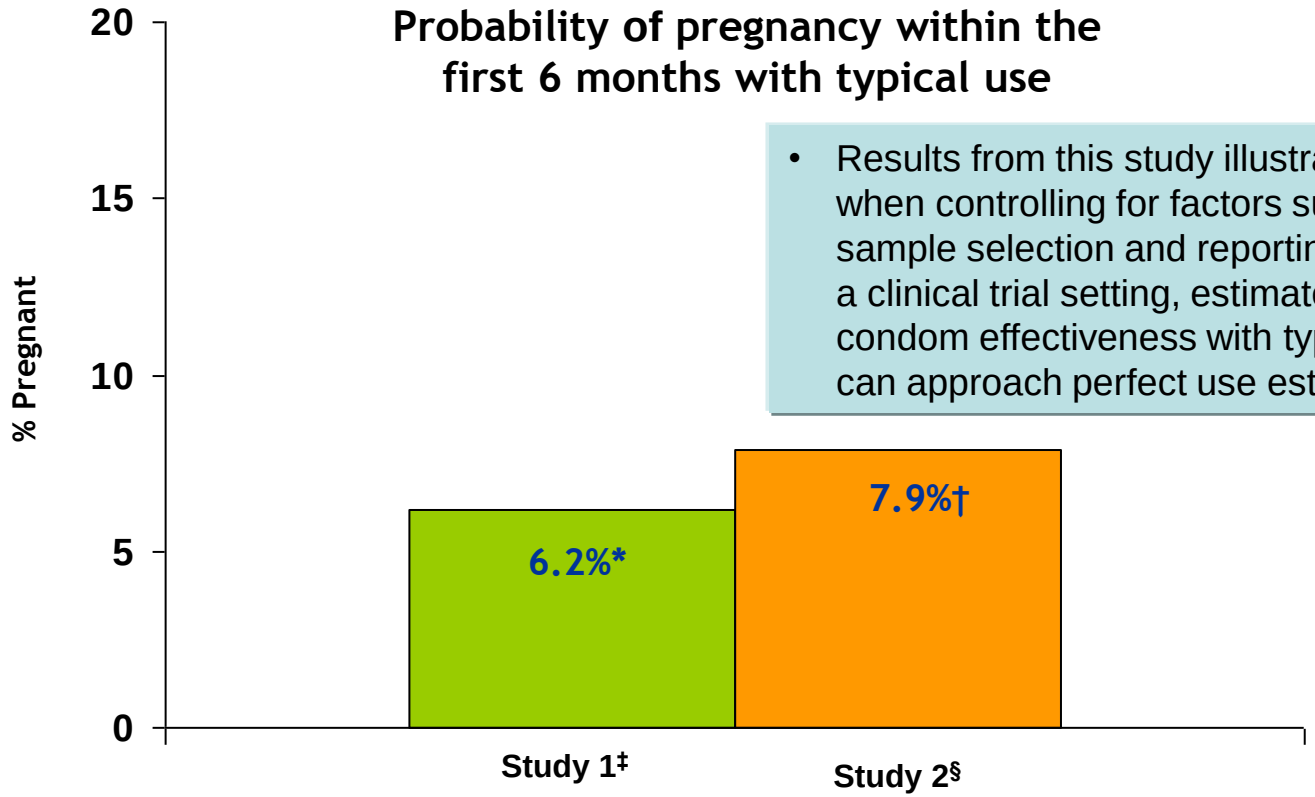
Trussell J. *Contraception.* 2004;70:89-96.

NSFG Survey Data Help Us Estimate Condom Effectiveness and Pregnancy With Typical Use

- NSFG estimates the probability of pregnancy within the first 12 months of condom use[1]
  - 1995 estimate: 17.8%
  - 2002 estimate: 17.4%
- What do these estimates mean?
  - Out of 100 couple who report using condoms over the course of a year, 17 will become pregnant
- How NSFG calculates typical use rates[2]
  - If you are considered a condom user, your pregnancy is counted as a failure even if you were not using a condom when the pregnancy occurred

1. Kost K, et al. *Contraception.* 2008;77:10-21.
2. Trussell J. *Contraception.* 2004;70:89-96.

Data From Clinical Trials Also Help Us Estimate Condom Effectiveness and Pregnancy With Typical Use

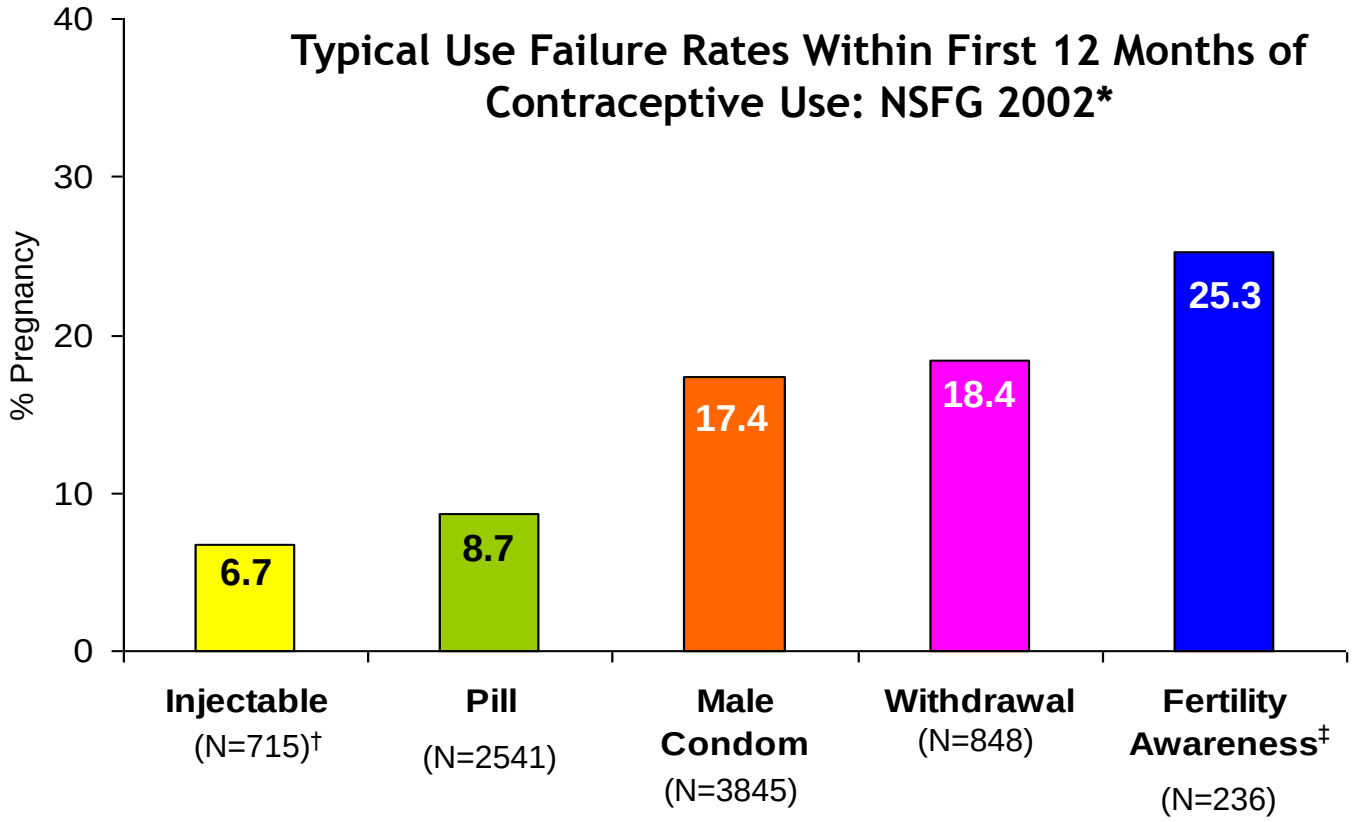


- Results from this study illustrate that, when controlling for factors such as sample selection and reporting errors in a clinical trial setting, estimates of condom effectiveness with typical use can approach perfect use estimates

*Based on 20 pregnancies over a total of 1952 calendar months.†Based on 24 pregnancies over a total of 1818 calendar months. ‡404 couples used Ramses Sensitol as part of a randomized, controlled contraceptive efficacy trial. §415 couples used Trojan Enz (n=208) and Lifestyle (n=207) as part of a randomized, controlled contraceptive efficacy trial.

Walsh TL, et al. *Contraception.* 2004;70:407-413.

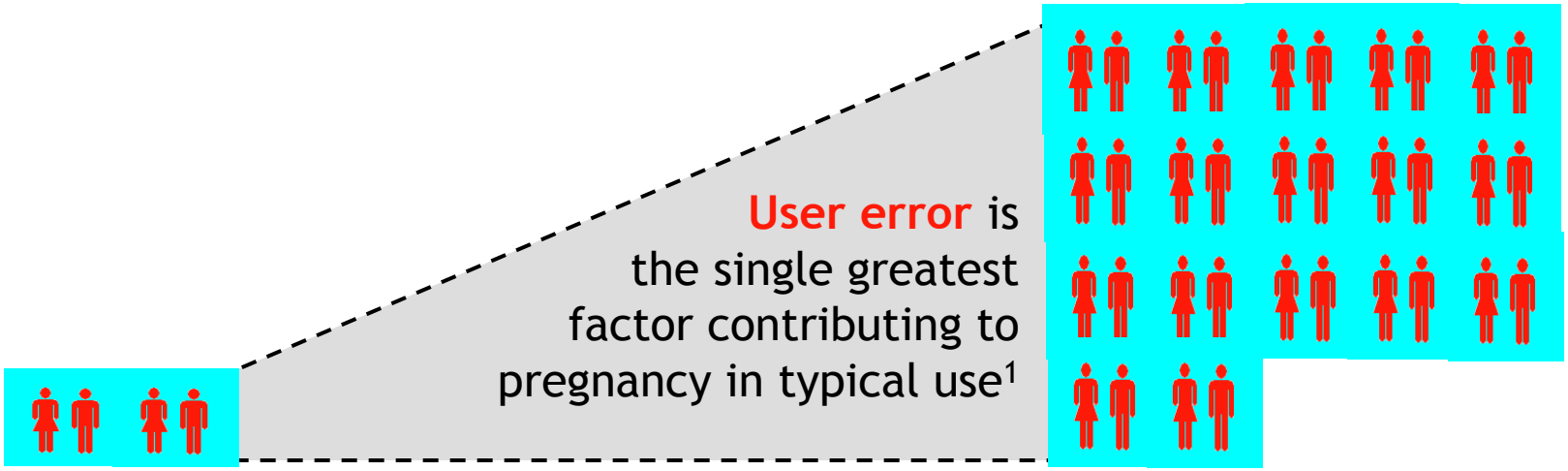
NSFG Results Allow Comparisons of Contraceptive Effectiveness With Typical Use Among Different Methods



*Weighted data corrected for underreporting of abortion. †Segments of contraceptive use. ‡Fertility-awareness-based methods include “rhythm-”, “calendar-”, “mucus-”, and “temperature-” methods, “periodic abstinence” or “natural family planning.”

Kost K, et al. *Contraception.* 2008;77:10-21.

Condom Effectiveness and Pregnancy: User Error Explains the Gap Between Perfect and Typical Use



Perfect Use[2]: 2%*

Typical Use[3]: 17%†

***Based on the mean of estimates of the 6-month probability of pregnancy from 3 clinical trials.**
†Based on 2002 NSFG estimates of condom effectiveness in typical use.

Condom education has the potential for correcting user error and bridging the gap

1. Fu H, et al. *Fam Plann Perspect.* 1999;31:56-63.
2. Trussell J. Contraceptive efficacy. In: *Contraceptive Technology.* 19th edition. New York, NY: Ardent Media; 2007.
3. Kost K, et al. *Contraception.* 2008;77:10-21.

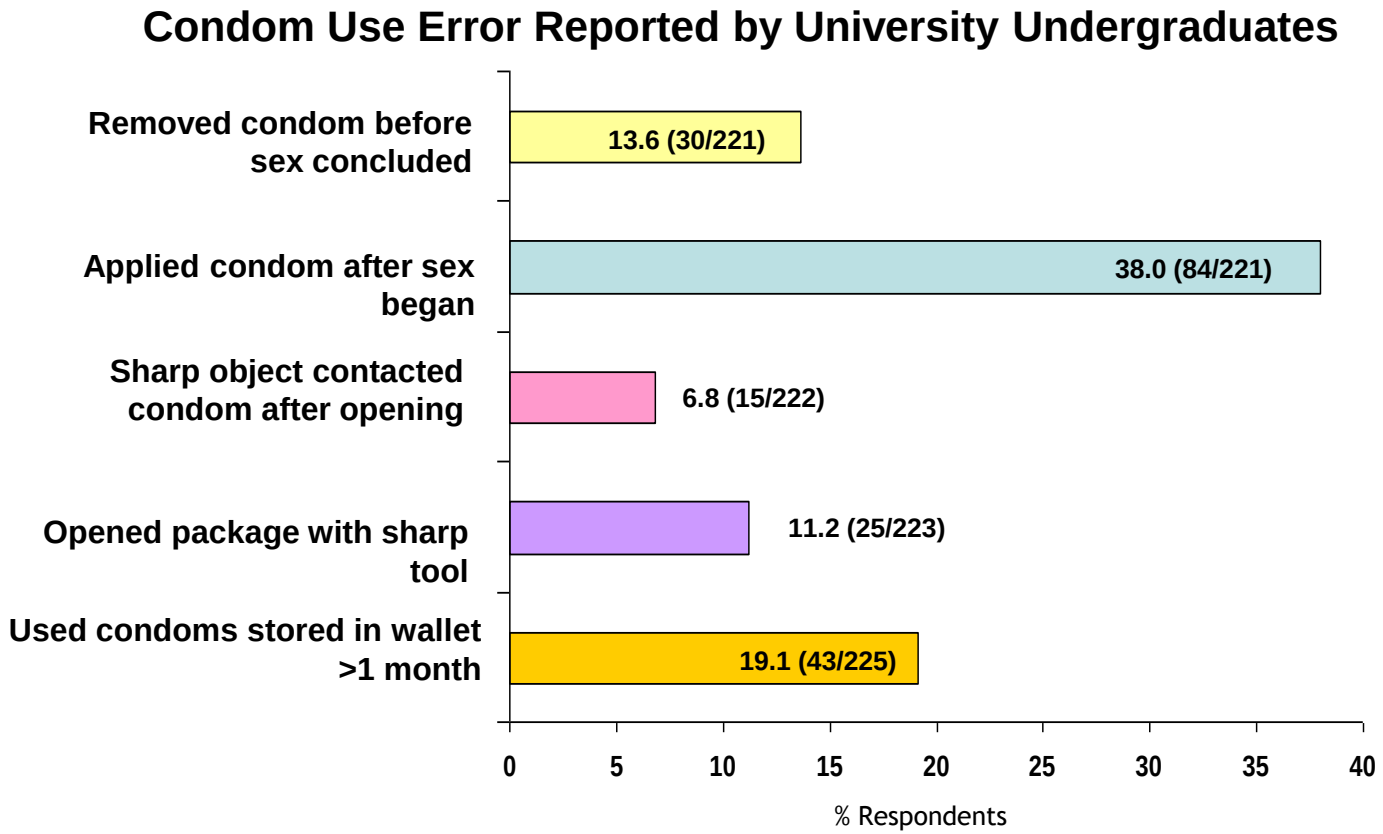
User Error Accounts for Most Contraceptive Failures With Condoms

- **Majority of pregnancies during contraceptive use result from incorrect or inconsistent use[1]**
  - **Rates of breakage and slippage vary but are generally low (occur in estimated 1.6–3.6% of coital acts)[2,3]**
- **High rates of user error may indicate that condom effectiveness is underestimated[4]**
  - **Failure rates reflect inconsistent or incorrect use[1]**

1. Fu H, et al. *Fam Plann Perspect.* 1999;31:56-63. 2. Warner L and Steiner MJ. Male condoms. In: *Contraceptive Technology.* 19th edition. New York, NY: Ardent Media; 2007. 3. Cates W. *Fam Plann Perspect.* 2001;33:231-233. 4. Crosby R, et al. *Am J Prev Med.* 2003;24:367-370.

User Error Has a Significant Impact on Condom Effectiveness

- Incorrect condom use, rather than product failure, appears to be more important in determining condom effectiveness



Crosby R, et al. *Am J Prev Med.* 2003;24:367-370.

Certain Subgroups Have a Greater Risk of Contraceptive Failure With Condoms

- Socioeconomic factors, including race/ethnicity and poverty, played a major role in risk of contraceptive failure with the condom
- By contrast, duration of use had no effect on risk

Relative Risk of Contraceptive Failure With Condom by Socioeconomic Characteristics, 2002 NSFG*

Characteristic	Relative Risk†	P-value	95% CI
Age <30	1.55	0.0093	(1.11-2.16)
Cohabiting	1.61	0.0009	(1.22-2.13)
1 or more births	2.54	<0.0001	(1.88-3.43)
Race/ethnicity: non-Hispanic black	1.63	0.0001	(1.27-2.09)
Poverty status: <200%	1.91	<0.0001	(1.46-2.49)

*Unweighted data corrected for underreporting of abortion in the 2002 NSFG. †Risk relative to that for the reference group, indicated in parentheses.

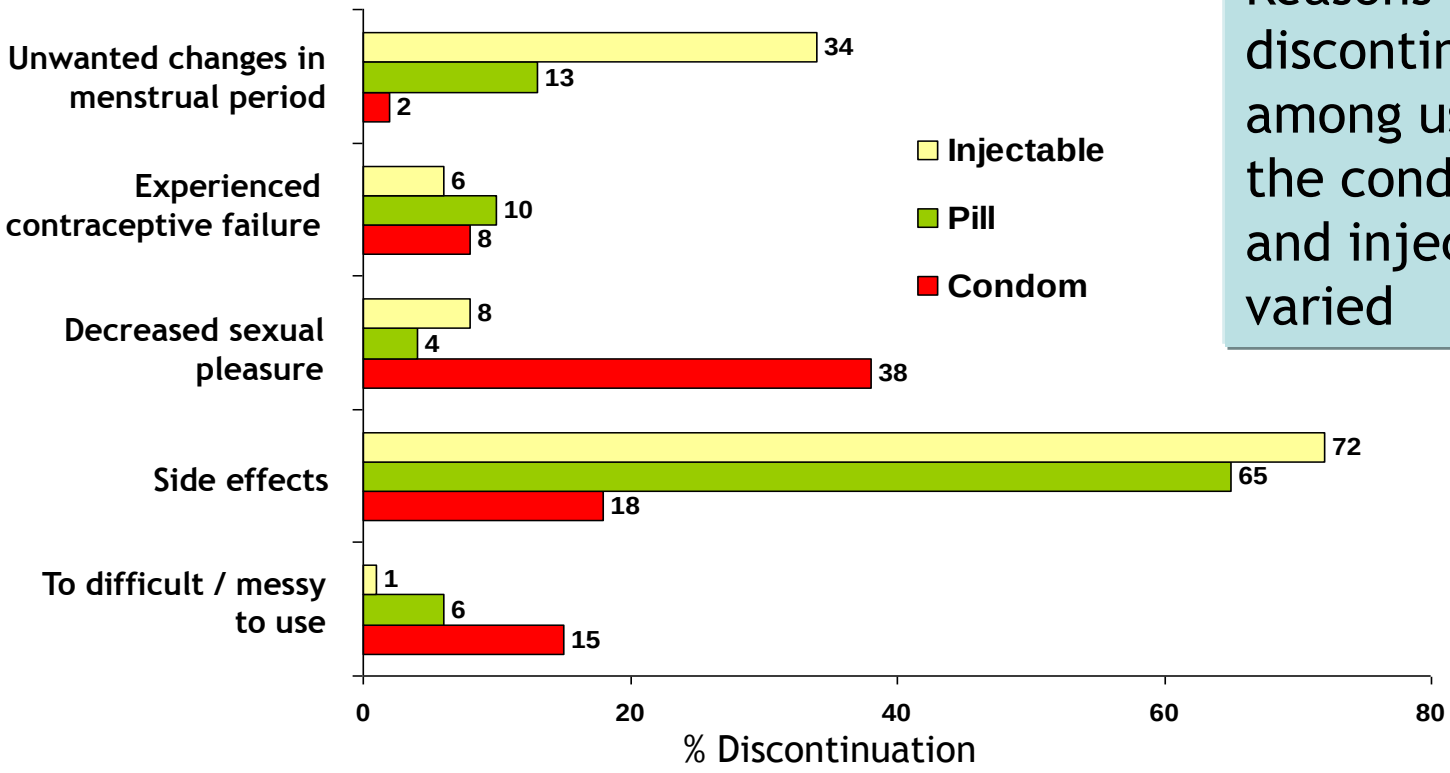
Kost K, et al. *Contraception.* 2008;77:10-21.

Condoms Provide Advantages Over Other Birth Control Methods

STD protection	✓ Only method that provides a barrier that minimizes risk of STD transmission
Easily accessible	✓ No prescription required, readily available
Low cost	✓ Among the most inexpensive contraceptive methods
Portable	✓ Can be easily and safely stored and carried
Minimal side effects	✓ Nonhormonal, rarely causes medical problems ✓ Latex sensitivity affects ~3%
Reversible	✓ Compared with sterilization and other methods, condoms are easily reversible

Warner L and Steiner MJ. Male condoms. In: *Contraceptive Technology.* 19th edition. New York, NY: Ardent Media; 2007.

Reasons for Dissatisfaction With Contraceptive Method Leading to Discontinuation



Reasons for discontinuation among users of the condom, pill, and injectables varied

Moreau C, et al. *Contraception.* 2007;76:267-272.

Combining Condoms With Other Contraceptive Methods in Perfect Use Diminishes Risk of Pregnancy

Probability of Pregnancy With Perfect Use of a Condom Combined With Other Methods for One Year*

	Diaphragm	Spermicide	Pill	IUD	Injectable
Condom, % risk	0.00959	0.03058	0.00047	0.00093	0.00047

*Under perfect use conditions.

Referencing to be determined.

Summary and Conclusions

- 1 in 20 American women experience an unintended pregnancy each year
- Contraception use is nearly universal among US women of reproductive age[1]
  - Top 3 methods: the pill, female sterilization, condoms[2]
- Contraceptive effectiveness: perfect vs typical use[3]
  - Perfect use: how well a method works if used consistently and correctly
  - Typical use: how well a method works in practice
- Condom effectiveness estimate with perfect use: 98%[3]
- Condom effectiveness estimate with typical use (2002 NSFG): 83%[4]
  - User error accounts for most contraceptive failures and may lead to underestimates of condom effectiveness[5]
  - Socioeconomic factors (race/ethinicity, poverty) play a major role in risk of contraceptive failure with condoms[4]
- Condom is the third most popular reversible contraceptive method behind injectables and the pill[2]
  - Advantages over other contraceptive methods include STD/HIV protection, easy accessibility, low cost, portability, and minimal side effects[6]

1. Finer LB, Henshaw SK. *Perspect Sex Reprod Health.* 2006;38:90-96. 2. Mosher WD, Jones J. *Vital Health Stat* 23 (29). 2010. 3. Trussell J. Contraceptive efficacy. In: *Contraceptive Technology.* 19th edition. 2007. 4. Kost K, et al. *Contraception.* 2008;77:10-21. 5. Fu H, et al. *Fam Plann Perspect.* 1999;31:56-63. 6. Warner L and Steiner MJ. Male condoms. In: *Contraceptive Technology.* 19th edition. New York, NY: Ardent Media; 2007.

Section VI: Condom Education

Common Myths About Condom Use

"Condoms have holes big enough to allow HIV through"

"Men have a hard time finding condoms that fit properly"

"Condoms break and slip easily"

"Using condoms for contraception is like playing Russian Roulette"

"The latex in condoms can degrade during storage"

"Condoms provide no protection against HPV or herpes"

"Making condoms available to youth encourages them to have sex"

"Condoms do not feel good"

"Teaching youth about condoms encourages them to have sex"

DHHS-Sponsored Randomized Study Evaluated Abstinence-Only Sex Education Programs

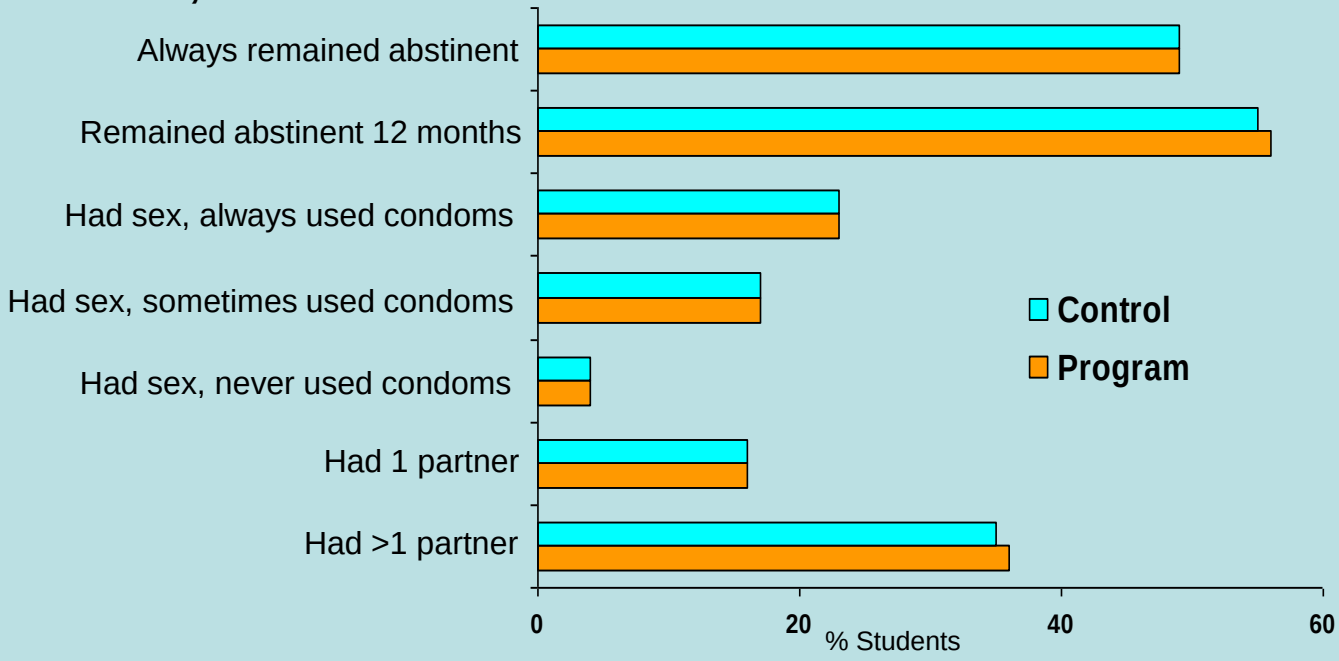
- Under a DHHS contract, a randomized study was conducted to evaluate the effectiveness of 4 federally funded, abstinence-only-until-marriage sex education programs being implemented in public schools
  - Students were randomly assigned to an abstinence-only curriculum (n=1209) or control group (n=848) in which no services were offered
  - 4 chosen programs were considered among the best abstinence-only curricula
  - Outcomes measured included sexual behaviors and knowledge of risks involved in having sex

DHHS, US Department of Health and Human Services.

Trenholm C, Devaney B, K. F, Quay L, Wheeler J, Clark M. Impacts of Four Title V, Section 510 Abstinence Education Programs. Final Report. HHS 100-98-0010. 2007.

Abstinence-Only Programs Are Not Effective

Randomized, Controlled Assessment of School-Based Abstinence-Only Programs



- **No significant differences were shown between programs and controls for abstinence, rates of unprotected sex, and number of partners**
- **Program participants were more likely to believe that condoms were ineffective in preventing STDs**

Trenholm C, et al. Impacts of Four Title V, Section 510 Abstinence Education Programs. Final Report. HHS 100-98-0010. 2007.

Abstinence-Only Sex Education Programs Withhold Information That Can Make a Difference

"Although abstinence is a healthy behavioral option for teens, abstinence as a sole option for adolescents is scientifically and ethically problematic."

John Santelli, MD, MPH of Columbia University and colleagues[1]

- To reduce teen pregnancy, sex education programs must[2]
  - Decrease sexual activity or increase contraceptive use
- Recent declines in teen pregnancy rates have been associated more with increased contraceptive use than with decreased sexual activity[3]
- Sex education programs that combine abstinence and contraceptive education have been shown to result in durable increases in contraception use among teens[2]
  - By not including contraception education, abstinence-only programs withhold the information that has the greatest potential to decrease pregnancy rates

1. Santelli J, et al. *J Adolesc Health.* 2006;38:72-81. 2. Bennett SE, Assefi NP. *J Adolesc Health.* 2005;36:72-81.
3. Santelli JS, et al. *Am J Public Health.* 2007;97:150-156.

Comprehensive Sexuality Education Includes Information on All Effective Methods for STD and Pregnancy Prevention

Comprehensive Sexuality Education

- ✓ Programs begin in kindergarten and continue through 12th grade
- ✓ Provide students with opportunities for developing skills as well as learning information
- ✓ Include age-appropriate, medically accurate information on a broad set of topics related to sexuality
  - **Human development**
  - **Relationships**
  - **Decision-making**
  - **Abstinence**
  - **Contraception**
  - **Disease prevention**

Sexuality Information and Education Council of the United States (SIECUS).

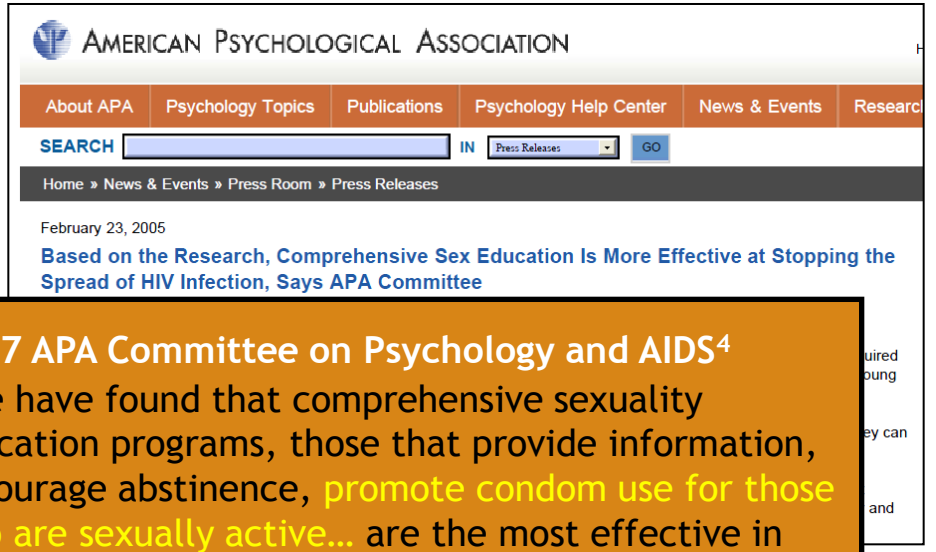
Dual Emphasis on Abstinence and Condom Use Has Been Shown to be Realistic and Effective Against Pregnancy and STDs

- Two-thirds of sex education curricula studied in which both abstinence and condoms/contraception were emphasized reported a significant positive impact on behavior
  - Many reduced or delayed sexual activity or increased condom/contraceptive use
  - Evidence is also strong that such programs did not hasten or increase sexual behavior
- Results suggest that the same program can both delay sex and increase use of condoms or other forms of contraception
- There is some evidence that comprehensive programs result in durable, long-term effects

Kirby D, Laris BA. *Child Dev Perspect.* 2009;3:21-29.

Condom Education is Recognized as an Integral Part of Sex Education Programs

- Comprehensive sexuality education is endorsed by a range of mainstream health organizations[1]
  - ACOG, AMA, APA, AAP, and APHA
- Peer-reviewed studies of abstinence-only and comprehensive sexuality ed programs concluded[1,2]:
  - Comprehensive sexuality ed programs are effective in delaying initiation of intercourse and promoting protective behaviors such as condom use
  - There is no evidence that abstinence only is effective
- There were similar rates of STDs found among youth who have pledged abstinence and those who have not[3]



2007 APA Committee on Psychology and AIDS[4]

"We have found that comprehensive sexuality education programs, those that provide information, encourage abstinence, promote condom use for those who are sexually active… are the most effective in keeping sexually active adolescents disease free."

Mary Jane Rotheram, PhD
University of California, Los Angeles

ACOG, American College of Obstetricians and Gynecologists; AAP, American Academy of Pediatrics; AMA, American Medical Association; APHA, American Public Health Association; APA, American Psychological Association.

1. Ott MA, et al. *Curr Opin Obstet Gynecol.* 2007;19:446-452. 2. Kirby DB, et al. *J Adolesc Health.* 2007;40:206-217. 3. Bruckner H, Bearman P. *J Adolesc Health.* 2005;36:271-278. 4. APA Committee on Psychology and AIDS. Available at: http://www.apa.org/news/press/releases/2005/02/sex-education.aspx. Accessed on: 6/9/2010.

Making Condoms Available in Schools Does Not Encourage Sexual Intercourse

- **Sample of 4,166 adolescents in Massachusetts high schools[1]**
  - Comparison of students in schools with and without condom availability programs
  - Students in schools where condoms were available had significantly lower rates of lifetime or recent sexual intercourse[1]
- **Other studies have produced similar results[2,3]**

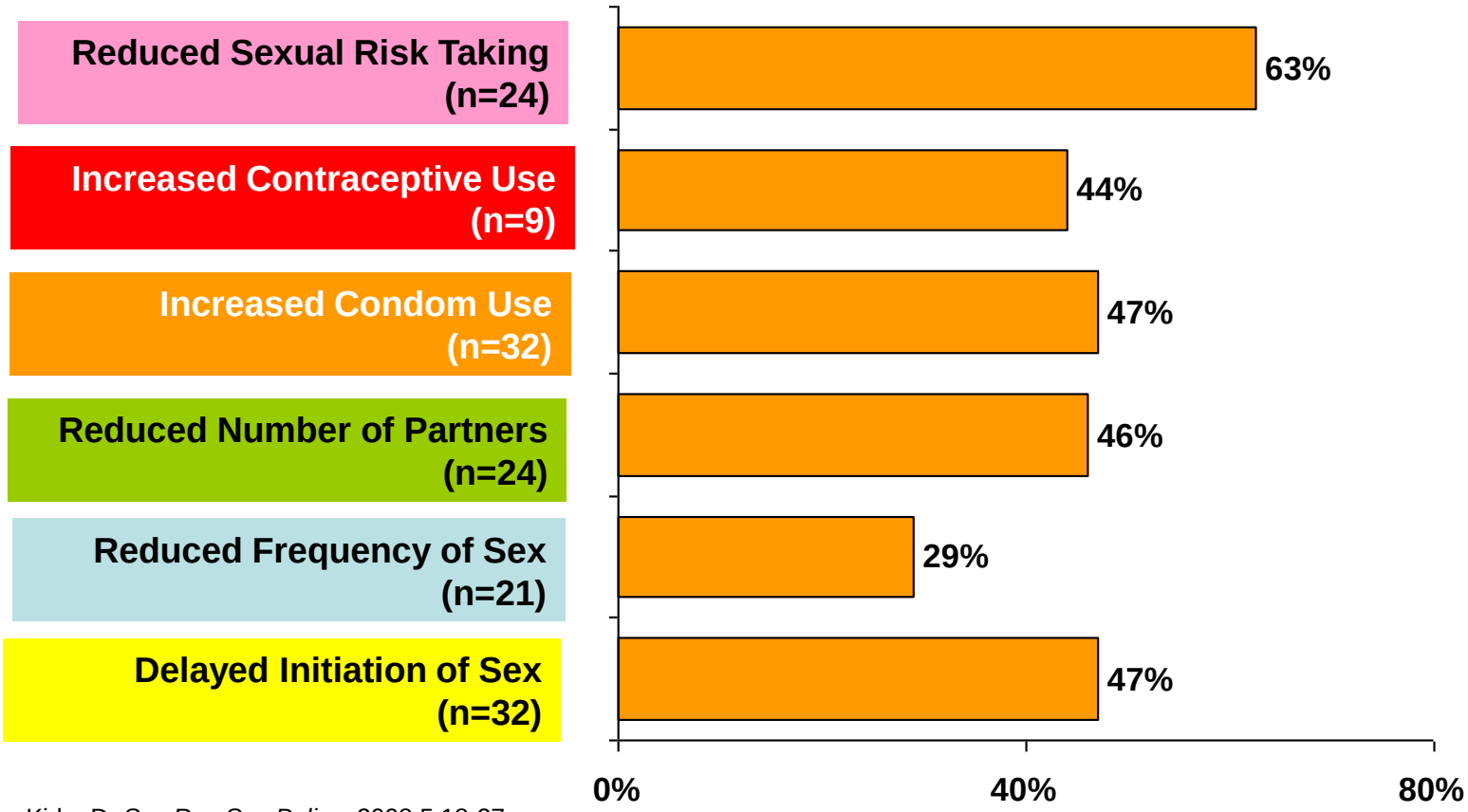
Associations Between School-Based Condom Availability Programs and Adolescent Sexual Practices[1]

	Condoms not available (n=3301)	Condoms available (n=865)
Ever had sexual intercourse (%)	49	42
Mean age at first intercourse (y)	14.3	14.4
Mean time since first sexual intercourse (y)	2.6	2.5
Mean lifetime sexual partners	2.8	2.8

1. Blake SM, et al. *Am J Public Health.* 2003;93:955-962. 2. Schuster MA, et al. *Fam Plann Perspect.* 1998;30:67-72, 88. 3. Guttmacher S, et al. *Am J Public Health.* 1997;87:1427-1433.

Comprehensive Sex Education Including Condom Use is Effective in Decreasing Risky Sexual Behavior

Analysis of 48 Comprehensive Sex and STD/HIV Education Programs: Percentage of Studies Reporting Effects on Different Sexual Behaviors



Kirby D. *Sex Res Soc Policy.* 2008;5:18-27.

Comprehensive Sex Education Does Not Encourage Young People to Have Sex

- **Sex education for young people covering both abstinence and contraception, including condom use, has benefits[1]**
  - Does not lead teens to have sex earlier, more frequently, or with more sexual partners
- **In fact, studies have shown that the opposite is true[2]**
  - Comprehensive sex education helps delay intercourse, reduce the frequency of intercourse, and decrease the number of partners
- **Additionally, teaching young people about condoms will increase the likelihood that they will[1,2]:**
  - Use condoms and other contraceptive methods when they become sexually active
  - Benefit from the protection from unintended pregnancies and STDs that condoms provide

1. Kirby D. Emerging Answers: Research Findings on Programs to Reduce Teen Pregnancy (National Campaign to Prevent Teen Pregnancy, Washington, DC, 2007. 2. Kirby DB, et al. *J Adolesc Health.* 2007;40:206-217.

Condom Educational Efforts Appear to Lead to Increased Condom Use

- Findings from the NSSHB documented higher rates of condom use among young people and minority groups
  - These results suggest the success of public health condom education efforts in highlighting the potential risks of HIV and other STD infections and the efficacy of condoms in protecting against them

NSSHB, National Survey OF Sexual Health and Behavior.

Reece M, et al. *J Sexual Med.* 2010. In press.

Condom Education and Experience May Decrease User Errors and Improve Overall Effectiveness

- Study examined factors associated with condom breakage and slippage among 428 single college males and females[1]
- Significant associations were demonstrated between breakage and slippage and
  - Lack of education on condom use
  - Being less motivated to use condoms
- Findings from other studies suggest that education in proper condom use as well as increased experience may be key factors in decreasing condom use errors and increasing condom effectiveness[2,3]

1. Yarber WL, et al. *Int J STD AIDS.* 2004;15:467-472. 2. Yarber WL, et al. *Am J Mens Health.* 2007;1:190-196. 3. Albert AE, et al. *Am J Public Health.* 1995;85:1514-1520.

Condom Education Interventions Appear to Decrease Risk for STDs

- Several researchers have assessed the effect of educational interventions including correct condom use on STD risk
- In one study in Rawanda, HIV serotesting and counseling on safe sex (including condom use) resulted in increased condom use and decreased incidence of HIV[1]
  - Test intervention included a video on correct condom use
  - 53 discordant couples were followed for average of 2.2 years
  - Condom use increased greatly after serotesting and counseling
  - Infection rate among women was half that of nonintervention comparison group
- Randomized, controlled study in minority women found that an educational intervention including condom use instruction resulted in decrease in STD infection rates[2]
  - 598 African American and Mexican American women were randomized to intervention (n=285) and control (n=264) groups
  - Behavioral-cognitive intervention included instruction in correct and consistent condom use
  - Rates of STD infection (chlamydia, gonorrhea) over 12-month period were significantly lower in intervention vs control groups

1. Allen S et al. *BMJ.* 1992;304:1605-1609.2. Shain RN et al. *N Engl J Med.* 1999;340:93-100.

American Social Health Association: Teaching Correct Condom Use via Animation

- In 2008, ASHA developed a virtual condom demonstration (***click on ASHA logo***)
  - Targeted to people of all ages, genders, nationalities, literacy levels
- Designed to decrease user error
- Demonstrated 6 key components of correct condom use
  - Condom packages have an expiration date
  - Should be stored in a cool dry place
  - Should be opened with fingers rather than scissors
  - Should be unrolled partially before touching penis
  - Should be put on when the penis is erect
  - Should be lubricated only with water-based products

ASHA Condom Use Animation Is Effective in Improving Knowledge About Correct Condom Use

- **Animation was evaluated through user testing and expert review**
- **2009 survey (N=858) tested changes in condom use knowledge**
  - Significant improvements in knowledge were seen in 5 of 6 concepts
  - Format and content were well received

Component	Before Demo (%)	After Demo (%)	*P*-value
Expiration date	89	95	<.01
Storage	86	94	<.01
How to open	85	94	<.01
When to use	75	87	<.01
Unrolling	66	64	NS
Lubricants	82	93	<.01

Condom Education: Summary

- Well designed and implemented sex education programs can help counter existing myths and misperceptions about condom use
- Abstinence-only programs are ineffective in promoting abstinence, decreasing sexual partners, and promoting condom use[1]
- Many sex education curricula emphasizing both abstinence and condoms/contraception have been shown to have a significant positive impact on behavior[2]
  - Many reduce or delay sexual activity or increased condom/contraceptive use
  - Do not hasten or increase sexual behavior
- Condom education is deemed an integral part of sex education programs by APA, AMA, APHA[3]
  - Students in schools where condoms were made available were less likely to report lifetime or recent sexual intercourse[4]
- Condom education and experience may decrease user errors and improve overall effectiveness in preventing STDs and unintended pregnancy[5,6]
- Effective sex education curricula should be designed to promote specific behaviors, such as abstinence and condom use, that lead to clear health goals[2]

1. Trenholm C, et al. Impacts of Four Title V, Section 510 Abstinence Education Programs. 2007. 2. Kirby D, Laris BA. *Child Dev Perspect.* 2009;3:21-29. 3. Ott MA, Santelli JSb. *Curr Opin Obstet Gynecol.* 2007;19:446-452. 4. Blake SM, et al. *Am J Public Health.* 2003;93:955-962. 5. Yarber WL, et al. *Am J Mens Health.* 2007;1:190-196. 6. Albert AE, et al. *Am J Public Health.* 1995;85:1514-1520.

VII. Conclusions

Summary and Conclusions

- **Condoms are a proven method of contraception and STD prevention with a >400 year history of use[1]**
- **Unintended pregnancy is a significant problem in the US and worldwide[2]**
- **Condom effectiveness with typical use is generally estimated at 83% and with perfect use at 98%[3,4]**
  - Third most popular means of reversible contraception[5]
  - User error accounts for the majority of condom failure and may lead to underestimates of effectiveness[6]
  - Condoms provide important advantages vs other methods of birth control, including STD/HIV protection, portability, and affordability[1]
- **STD prevention constitutes a major public health challenge[7]**
- **Condoms play a central role in STD prevention[7,8]**
  - Lab studies show that condoms provide a strong barrier impermeable to STD pathogens—even the smallest (hepatitis B)[9]
  - Used consistently and correctly, condoms are highly effective vs HIV, gonorrhea, chlamydia, and reduce risk vs other STDs[7,8]
  - Recent prospective studies have demonstrated that condom use is associated with significant protective effect vs range of STDs[10]

1. Warner L and Steiner MJ. Male condoms. In: *Contraceptive Technology.* 19th edition. 2007. 2. Finer LB, Henshaw SK. *Perspect Sex Reprod Health.* 2006;38:90-96. 3. Trussell J. Contraceptive efficacy. In: *Contraceptive Technology.* 19th edition. 2007. 4. Kost K, et al. *Contraception.* 2008;77:10-21. 5. Mosher WD, Jones J. *Vital Health Stat* 23 (29). 2010. 6. Fu H, et al. *Fam Plann Perspect.* 1999;31:56-63. 7. CDC. Sexually Transmitted Diseases in the United States, 2008. 8. Cates W, Jr. *Fam Plann Perspect.* 2001;33:231-233. 9. NIAID Workshop Summary: Scientific Evidence on Condom Effectiveness for Sexually Transmitted Disease (STD) Prevention, 2001. 10. Holmes KK, et al. *Bull World Health Organ.* 2004;82:454-461.

Summary and Conclusions (cont'd)

- **A range of myths concerning condom use shape our expectations and confidence in condom effectiveness**
  - Scientific data documenting condom effectiveness and safety must be used to dispel these myths
- **Condom manufacturing and testing process is regulated by FDA and other agencies**
  - Ensures that condoms meet the highest standards for safety and effectiveness
- **Since user error accounts for most instances of condom failure in contraception and STD prevention,[1-3] education in proper use is crucial**
  - Studies have demonstrated that comprehensive sex education in young people including correct condom use can help protect against unintended pregnancy and STD transmission[4]
  - Education in correct condom use for adults may also play an important role in reducing user error and improving condom effectiveness[5,6]

1. Crosby R, et al. *Int J STD AIDS.* 2008;19:90-93. 2. Steiner M, et al. *Fam Plann Perspect.* 1993;25:220-223, 226. 3. Fu H, et al. *Fam Plann Perspect.* 1999;31:56-63. 4. Kirby D, Laris BA. *Child Dev Perspect.* 2009;3:21-29. 5. Yarber WL, et al. *Am J Mens Health.* 2007;1:190-196. 6. Albert AE, et al. *Am J Public Health.* 1995;85:1514-1520.

VIII. Appendices

A Large Proportion of Condom Users Report Satisfaction With Condom Fit and Comfort

- **Some research indicates that condom fit may be an issue for some individuals[1-3]**
- **However, 2 recent studies reported that ≥50% of participants felt that condoms were either comfortable or fit well[1,3]**
  - **Of those who complained about fit, size was most often the issue**
- **Condom manufacturers are committed to providing condoms in a variety of sizes and styles to suit the range of users**

1. Crosby RA, et al. *Sex Transm Infect.* 2004;80:306-309. 2. Crosby RA, et al. *Sex Transm Infect.* 2010;86:36-38. 3. Reece M, et al. *Sex Transm Infect.* 2009;85:127-131.

Condom Are Available in Latex, Natural Membrane, and Synthetic Polyurethane or Polyisoprene

Approximately 97% of male condoms available in the US are made of latex

Characteristics of Latex, Natural Membrane, and Synthetic Condoms			
Type	**Latex**	**Natural Membrane**	**Synthetic**
Material	Natural rubber	Lamb caecum	Polyurethane, polyisoprene*
Lubricant use	Water-based only	Any	Any†
Cost	Low	Moderate	Moderate/high
Recommended as contraception	Yes	Yes	Yes‡
Recommended for prevention of STDs	Yes	No	Yes‡

*Most synthetic condoms are made from polyurethane. †Provided use of a particular lubricant is not disclaimed in product labeling.
‡Polyurethane condoms are an alternative for those persons that are sensitive or allergic to natural rubber latex.

Reproduced from Warner L and Steiner MJ. Male condoms. In: *Contraceptive Technology.* 19th edition. New York, NY: Ardent Media; 2007

Low Rates of Breakage and Slippage Attest to the Quality of Condom Design and Manufacturing

- Fear that condom will break or slip off during use is common
  - However, studies have shown that these events are rare with proper use[2]
- Breakage and slippage tends to occur among small proportion of users[3]

Rates of Breakage and Slippage Across 2 Randomized Trials of Condom Efficacy for Contraception[1]

	First 5 uses (%) (n=3,715)	6 Months (%) (n=40,223)
Clinical Failure	**1.4**	**0.8**
Breakage	**0.4**	**0.3**
Slippage	**1.1**	**0.5**

- Majority of studies show:
  - During vaginal intercourse, condom breakage and slippage each occur at rates of about 2%[1,4,5]

1. Walsh TL, et al. *Contraception.* 2004;70:407-413. 2. Warner L and Steiner MJ. Male condoms. In: *Contraceptive Technology.* 19th edition. New York, NY: Ardent Media; 2007 3. Steiner M, et al. *Fam Plann Perspect.* 1993;25:220-223, 226. 4. Albert AE, et al. *Am J Public Health.* 1995;85:1514-1520. 5. Cook L, et al. *Contraception.* 2001;63:25-31.

Rates of Contraceptive Use: An International Perspective

Percentages of Married Couples Using Different Contraceptive Methods in Select Countries*

	Any method	Pill	Condom	Female sterilization
US, 2006-2008	79	16	12	24
France, 2000	82	44	5	NA
Netherlands, 2003	67	41	8	4
Norway, 2005	88	31	13	8
Spain, 2006	66	17	25	6
Portugal, 2005-2006	67	45	9	0
United Kingdom, 2007-2008	82	22	27	9
Australia, 2001-2002	71	24	15	14

NA, not available. *Data on contraceptive use in selected countries from UN Population Division, "Contraceptive Prevalence, 2007," available at: http://www.un.org/esa/population/publications/WCU2009/Main.html.

Mosher WD, Jones J. Vital Health Stat 23 (29). 2010.

Elements of Effective Curriculum-Based Sex and STD/HIV Education Programs

Effective sex education curricula promote specific behaviors, such as abstinence and condom use, that lead to clear health goals

Curriculum Development

- ✓ **Involved multiple people with diverse backgrounds** in theory, research, and sex ed in development
- ✓ **Assessed relevant needs** and assets of target group
- ✓ **Used a logic model approach** to develop the curriculum*
- ✓ **Designed activities consistent with community values and resources**
- ✓ **Pilot test program**

*Model that specifies health goals, behaviors affecting those goals, risk and protective factors affecting those behaviors, and activities addressing those risk and protective factors.

Curriculum Goals and Objectives

- ✓ **Focus on clear health goals**: prevention of STD/HIV and/or pregnancy
- ✓ **Focus narrowly on specific behaviors** leading to goals (eg, abstinence or using condoms)
- ✓ **Give clear messages about these behaviors**, and address situations that might lead to them and how to avoid them
- ✓ **Address multiple sexual psychosocial risk and protective factors** affecting sexual behavior (eg, knowledge, perceived risks, values, attitudes)

Kirby D, Laris BA. *Child Dev Perspect.* 2009;3:21-29.

Elements of Effective Curriculum-Based Sex and STD/HIV Education Programs (cont'd)

Activities and Teaching Methodologies

- ✓ **Create safe social environment** for youth to participate
- ✓ **Include multiple activities** to change each of the targeted risk and protective factors
- ✓ **Employ instructionally sound teaching methods** that actively involve the participants and help them personalize information
- ✓ **Employ activities, instructional methods, and behavioral messages appropriate to the youth's culture**, developmental age, and sexual experience
- ✓ **Cover topics in a logical sequence**

Curriculum Implementation

- ✓ **Secure at least minimal support** from appropriate authorities (eg, departments of health or education, school districts)
- ✓ **Select educators with desired characteristics** (whenever possible), train them, and provide monitoring, supervision, and support
- ✓ **Implement activities (as needed) to recruit and retain youth** and overcome barriers to involvement (eg, publicized program, offer food, obtained consent)
- ✓ **Implement virtually all activities with reasonable fidelity**

Kirby D, Laris BA. *Child Dev Perspect.* 2009;3:21-29.

Most Studies Show That Condom Use Can Protect Against Syphilis Transmission

Study	Design	N	Measure of Effect	
			Univariate	Multivariate
Studies of condom use and syphilis in females				
Mejia et al (2007)	Cross-sectional	514	**0.52** (0.30-0.93)* (vaginal sex) **0.38** (0.09-1.61)* (anal sex)	**0.72** (0.38-1.35)* (vaginal sex) **0.43** (0.10-1.85)* (anal sex)
Xueref et al (2003)	Cross-sectional	316	**2.4** (1.2-5.1)	**1.89** (0.98-3.70)*
van den Hock et al (2001)	Cross-sectional	966		**0.26** (0.11-0.59)*
Levine et al (1998)	Prospective cohort	508		**0.39** (0.23-0.64)
Sanchez et al (1998)	Cross-sectional	400	**0.3**	**0.3** (0.1-1.2)
Joesoef et al (1997)	Cross-sectional	1873	**0.53** (0.34-0.79)*†	
Taha et al (1996)	Prospective cohort	807	**0.59** (0.03-4.02)†‡ (HIV-infected) **0.0** (0-6.44)†‡ (non-HIV-infected)	

*Measure of effect and confidence interval are reciprocals of those provided in article. †Confidence interval calculated by Koss et al.
‡Measure of effect calculated by Koss et al from data in article.

Koss CA, et al. *Sex Transm Dis.* 2009;36:401-405.

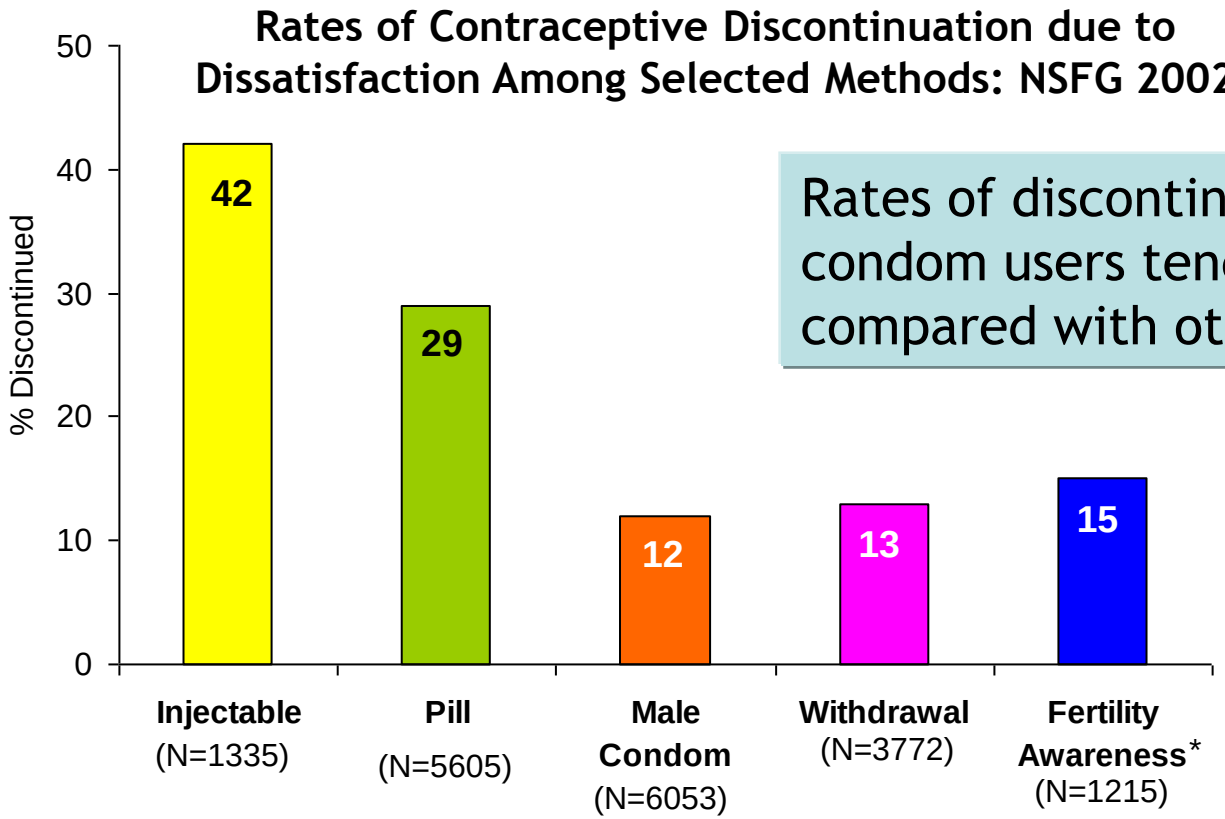
Most Studies Show That Condom Use Can Protect Against Syphilis Transmission (cont'd)

Study	Design	N	Measure of Effect	
			Univariate	Multivariate
Studies of condom use and syphilis in males				
Ruan et al (2007)	Cross-sectional	526	**0.60** (0.22-1.61)†‡	
Joesoef et al (2003)	Cross-sectional	296		**0.77** (0.43-1.25)‖
Gattari et al (1994)	Cross-sectional	77	**0.0** (0-1.51)†‡ [SPHA-IgM] **0.59** (0.17-2.26)†‡ [TPHA]	
Studies of condom use and syphilis in males and females				
Ahmed et al (2001)	Cross-sectional	17,264	**0.46** (0.35-0.60)	**0.71** (0.53-0.94)
Finelli et al (1993)	Case-control	144	**0.24** (0.08-0.67) [Male] **0.89** (0.25-3.22) [Female]	

*Measure of effect and confidence interval are reciprocals of those provided in article. †Confidence interval calculated by Koss et al. ‡Measure of effect calculated by Koss et al from data in article. ‖Measure of effect and confidence interval are reciprocals of those provided in article. SPHA-IgM, solid phase hemadsorption; TPHA, *T. pallidum* hemagglutination assay.

Koss CA, et al. *Sex Transm Dis.* 2009;36:401-405.

User Satisfaction Is an Important Factor in Contraceptive Use and Effectiveness



Rates of discontinuation among condom users tended to be low compared with other methods

*Fertitlity-awareness-based methods include “rhythm”, “calendar”, “mucus”, and “temperature” methods, “periodic abstinence,” or “natural family planning.”

Moreau C, et al. *Contraception.* 2007;76:267-272.

Dual Method Use: Adding Condoms to Other Highly Effective Contraceptive Methods

- Using NSFG 2002 data, projections of reductions in unplanned pregnancies and abortions were based on usage of condoms in combination with other highly effective methods of contractions
  - Dual usage practiced by half of women would result in a 40% decrease in unplanned pregnancies and abortions
  - Dual usage practiced by all women would result in an 80% decrease in unplanned pregnancies and abortions

Rates of dual usage among women	Annual Reduction in Unplanned Pregnancies	Annual Reduction in Abortions
40%	393,000	76,000
80%	786,000	152,000

Pazol K, et al. *Public Health Rep.* 125:208-217.