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## STI Vaccination: Politics, Policies, & Public Health

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### Disclosures

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- Investigator on HPV-related research grants funded by Merck's Investigator-Initiated Studies Program
- Consultant to Sanofi-Pasteur regarding attitudes about potential HSV-2 vaccination

## Outline

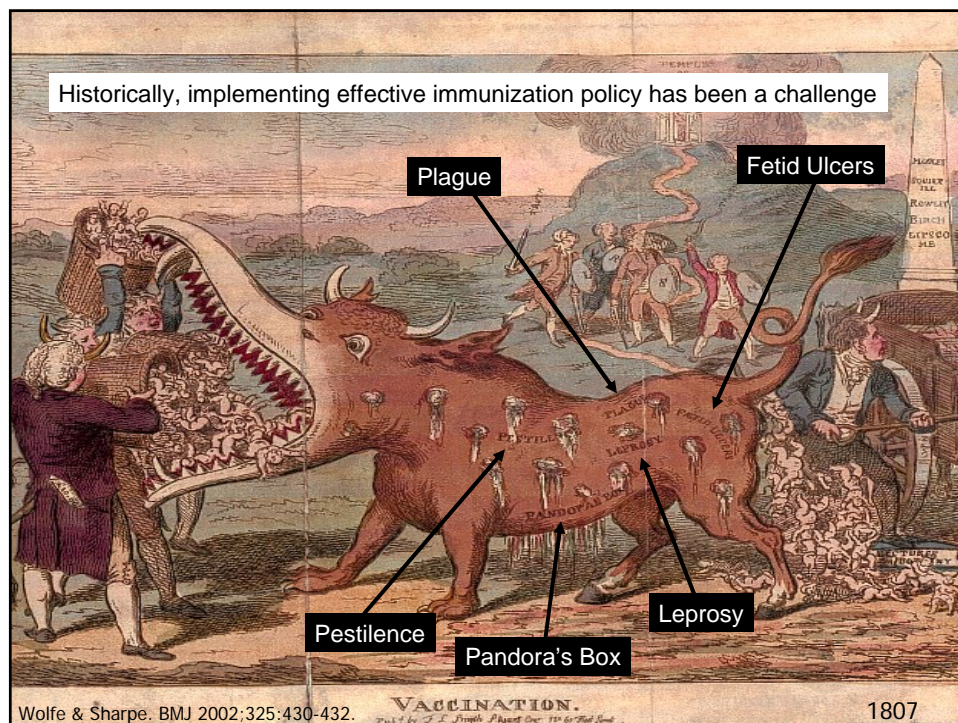
- Historical context
- STI vaccines: Background information
- Acceptance of STI vaccines: Unique issues
- Post-acceptance of STI vaccines: Unique issues

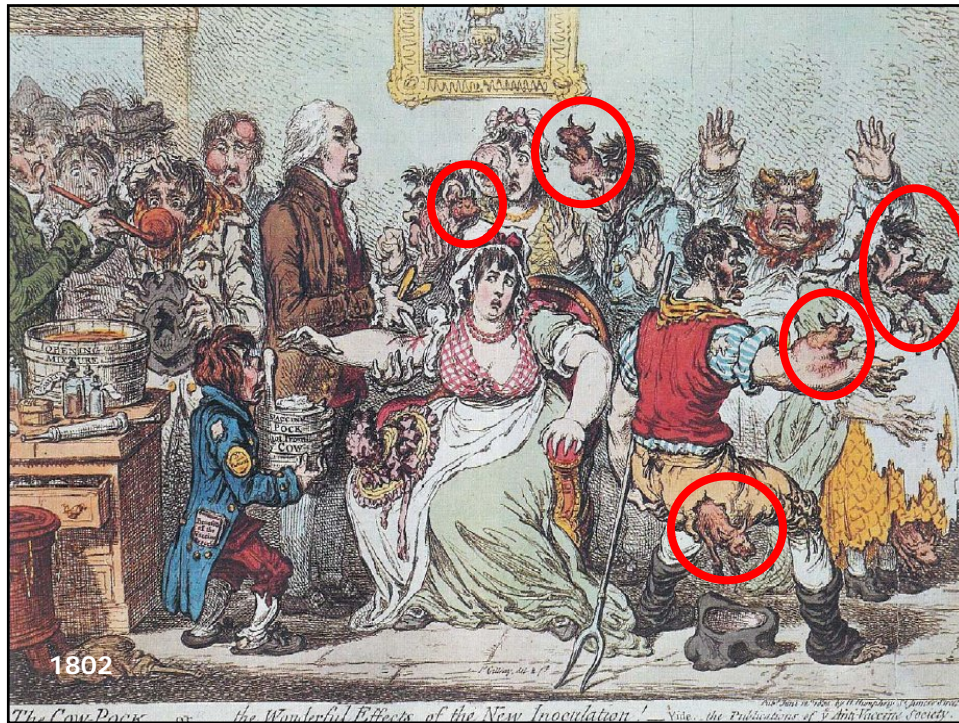
## HISTORICAL CONTEXT

## History of vaccines\*

- Attitudes and policies regarding STI vaccination have to be examined in the broader context of vaccination in general
- Long history of unwarranted & warranted concerns about vaccines
- History of missteps in vaccine policy

\*Arthur Allen. *Vaccine: The Controversial Story of Medicine's Greatest Lifesaver*. 2007





### Cutter Incident: Mid-1950s

- Poor quality control led to incomplete deactivation of the Salk polio vaccine
- Over 100,000 doses contained live polio virus
- Led to many infections, 56 direct cases of paralytic polio, additional secondary cases, and several deaths
- Resulted in new regulations regarding manufacture of vaccines

## Vaccine policy has encouraged fear Precautionary Approaches

- Withdrawal of rotavirus vaccine (1999)
  - Rare cases of intussusception
  - But rotavirus responsible for:
    - Thousands of childhood deaths worldwide
    - Illness, hospitalization, and rare deaths in U.S.
- Removal of thimerosal (2001)
  - Ethyl mercury compound acts as preservative: Stabilizes vaccine & allows for multi-dose vials
  - Incorrect generalization from methyl mercury led to removal, which resulted in:
    - Significantly increased costs & transport difficulties
    - Baseless accusations connecting thimerosal to autism

## STI VACCINES: BACKGROUND INFORMATION

## STI vaccines: Current status

- Vaccines available
  - Hepatitis B (HBV)
  - Hepatitis A
  - Human Papillomavirus (HPV)
- Vaccines in development
  - HIV
  - Genital herpes (HSV-2)
  - Gonorrhea
  - Chlamydia
  - Cytomegalovirus (CMV)

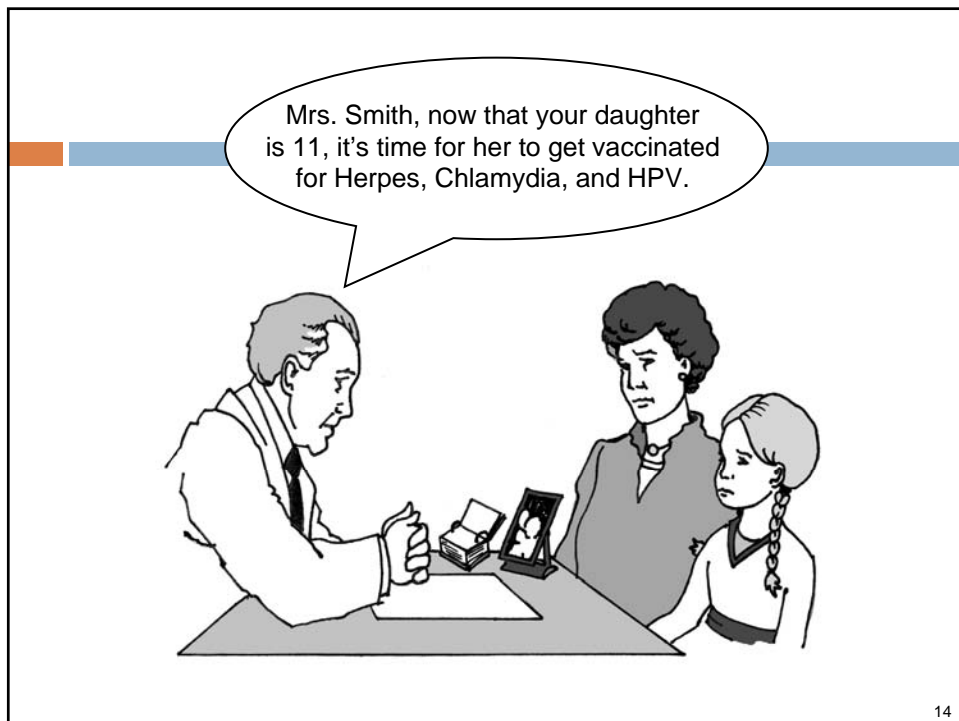
## Benefits of STI vaccination

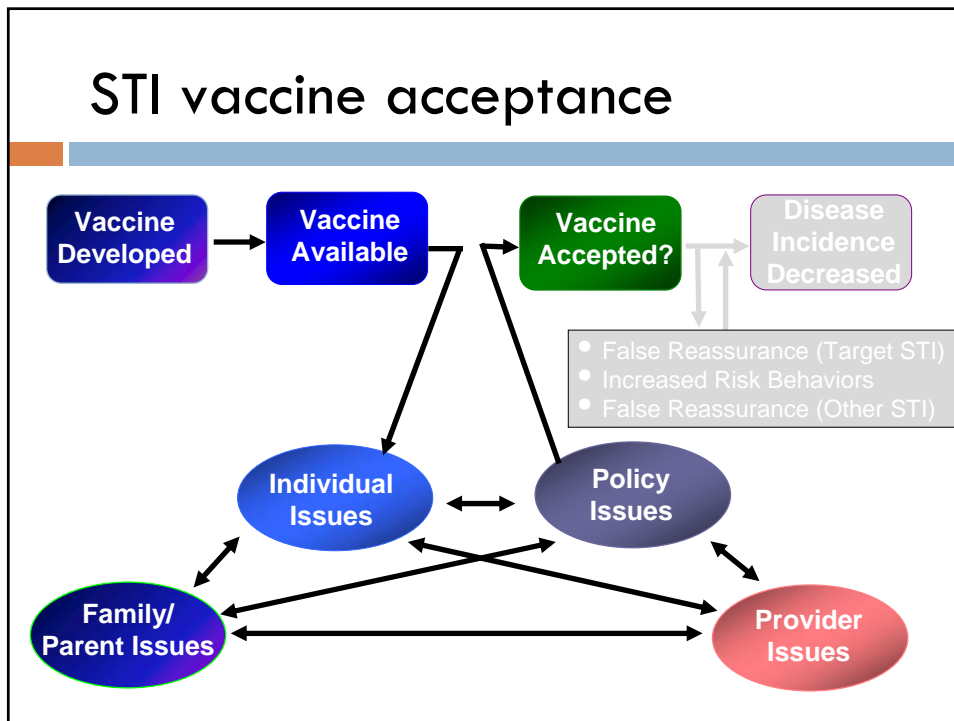
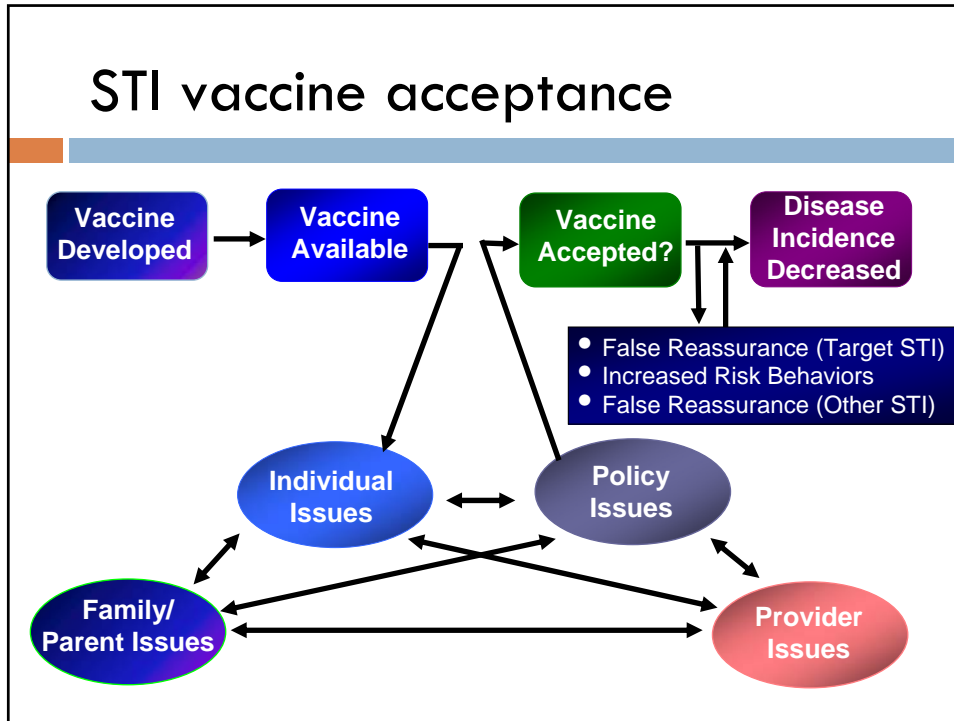
- Huge potential reduction in health-care costs & suffering

Infection	Morbidity
Chlamydia	PID; infertility
Gonorrhea	PID; infertility
HSV-2	Recurrent outbreaks & pain; Increased susceptibility to HIV
HPV	Genital warts & cancers; Increased susceptibility to HIV
HIV	Chronic, often fatal, infection; Increased susceptibility to other infections



Given the clear health and money-saving benefits of STI vaccination, what's the issue?







## ACCEPTANCE OF STI VACCINES: UNIQUE ISSUES

### Vaccine acceptance: Are there unique issues with STI vaccines?

- STI stigma & fear of sex influence:
  - Advertising & public health messages
  - Media attention
  - Public health discussion & approach
- Mandate controversy
- But, what does the research tell us?

STI stigma & fear of sex :

## Advertising – HBV vaccine brochure

**What,  
my kids?  
Yes...**



**How can hepatitis B  
be transmitted  
among school-aged  
adolescents?**

Unfortunately, there are many ways hepatitis B can be transmitted among adolescents. Many adolescents get tattoos or have their ears pierced. Friends sometimes share earrings, razors or toothbrushes. And many adolescents are starting to become sexually active. Close contact is common in certain sports or games, and minor cuts and scrapes often happen. Each of these activities listed above has the potential of transmitting the hepatitis B virus from an infected individual.

STI stigma & fear of sex :

## Media sensationalism & distortion

HPV Vaccine Coverage

### **Cancer Vaccine Will Be a Hard Sell Parents Balk at Idea of STD Drug for Kids**

by Ed Silverman, Star-Ledger Staff

April 03, 2005

At first blush, a vaccine that prevents a deadly form of cancer would seem like a no-brainer for parents.

But as two major drug makers prepare to introduce such a product, sides are already being drawn in what promises to be an all-out culture clash.

STI stigma & fear of sex :  
Public health discussion & approach

- Medline searches
  - (Cost-effectiveness OR cost-benefit analysis) AND:
    - HPV vaccines = 176 articles
    - Meningococcal vaccines = 48 articles
  - (Attitude OR attitudes) AND:
    - HPV vaccines = 251 articles
    - Meningococcal vaccines = 12 articles

STI stigma & fear of sex :  
Public health discussion & approach

Male HPV Vaccination

- Evidence of quadrivalent vaccine efficacy in males has been demonstrated for prevention of warts and AIN
- Questions about cost-effectiveness
  - Including males less cost-effective than female-only vaccination
  - But, cost-effectiveness of gender-neutral approach better with lower female vaccination rates
- Questions about limited resources
  - Particularly a concern for developing countries
  - Also an issue with rising health costs everywhere

### But...

- What about protecting MSM?
- Vaccinating males ensures greatest protection for women
- Gender-neutral approach is more equitable
- Genital warts & HPV-related cancers in males very costly
- In U.S. relatively poor coverage of females suggests male vaccination would be helpful
- Vaccination policy & health policies in general are not always driven by cost-effectiveness research (e.g., MCV4)
- From a public health perspective, isn't the goal of vaccination to work toward herd immunity as quickly as possible?

Zimet & Rosenthal. *Gynecol Oncol* (suppl. 1) 2010

### STI vaccine acceptance

#### Mandate controversy: HPV vaccine

- Controversy sparked by early push for mandates
  - Backlash against both mandates & HPV vaccine
  - Gave publicity to anti-vaccine movement
- Arguments against mandates
  - Vaccine for a non-casually-transmitted infection should not be mandated
  - Public health benefit is not enough to warrant intrusion on parental autonomy
  - Limited health care dollars should not be directed to cervical cancer prevention

## STI vaccine acceptance

### Mandate controversy: Counter arguments\*

- Vaccine for a non-casually-transmitted infection should not be mandated
  - Tetanus and Hepatitis B vaccines
  - Automobile child-restraint laws
- Public health benefit is not enough to warrant intrusion on parental autonomy
  - 12,200 new cases of cervical cancer in 2010
  - Over 4,000 deaths in 2010
- Limited health care dollars should not be directed to cervical cancer prevention
  - Prevention almost always preferable to treatment
  - Vaccine is cost-effective
  - What about other expenditures (e.g., 9/11)

\*Haber et al. *J Pediatr Adolesc Gynecol* 2007

## STI vaccine acceptance: Summary

- Introduction of STI vaccines characterized by:
  - Avoidance of sex & STI in advertising & public health education (HBV vaccine)
  - Tremendous and often distorted media attention (HPV vaccine)
  - An unusual amount of cost-effectiveness & acceptability research (HPV vaccine)
  - More intense controversy than usual around school-entry requirements (HPV vaccine)

## But, what does the research tell us?

- HPV pre-licensure studies of parents: 70%-80% intend to vaccinate\*
  - Relatively few express concern about sexual disinhibition
- Studies on attitudes about HIV & HSV-2 vaccination show relatively high acceptability\*\*
- National surveillance data (ages 13-17)\*\*\*
  - 2009 HPV vaccination rate: 44.3% for  $\geq 1$  dose
  - 2008 Meningococcal vaccination rate: 41.8%

\*Zimet et al. *Ann Rev Med* 2008.

\*\*Newman & Logie. *AIDS* 2010.  
Liddon et al. *J Adolesc Health* 2005.

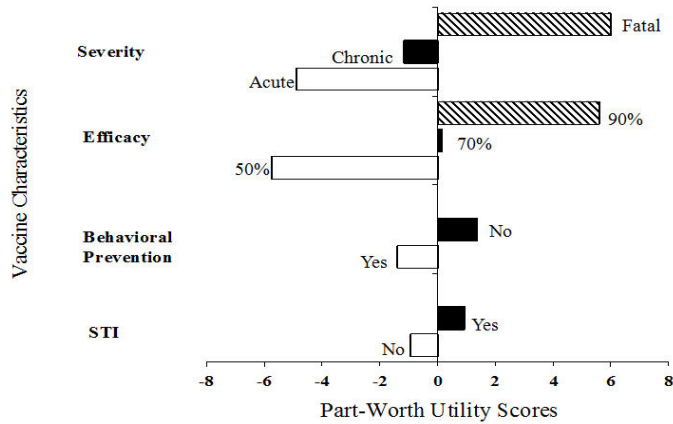
\*\*\*CDC. *MMWR* 2010.

## HPV vaccination: Post-licensure\*

- Main reasons for non-vaccination of adolescent girls
  - Desire for more information
  - Concern about “newness” of vaccine
  - Lack of physician recommendation/missed opportunities
- Worries about sexual disinhibition not identified as a major barrier to vaccination

\*Yeganeh et al. *Vaccine* 2010.  
Dempsey et al. *Vaccine* 2010.  
Gerend et al. *J Adolesc Health* 2009.  
Gottlieb et al. *J Adolesc Health* 2009.

## What Do Parents Want From Vaccines?\*



\*Adapted from: Zimet et al. *Arch Pediatr Adolesc Med.* 2005.

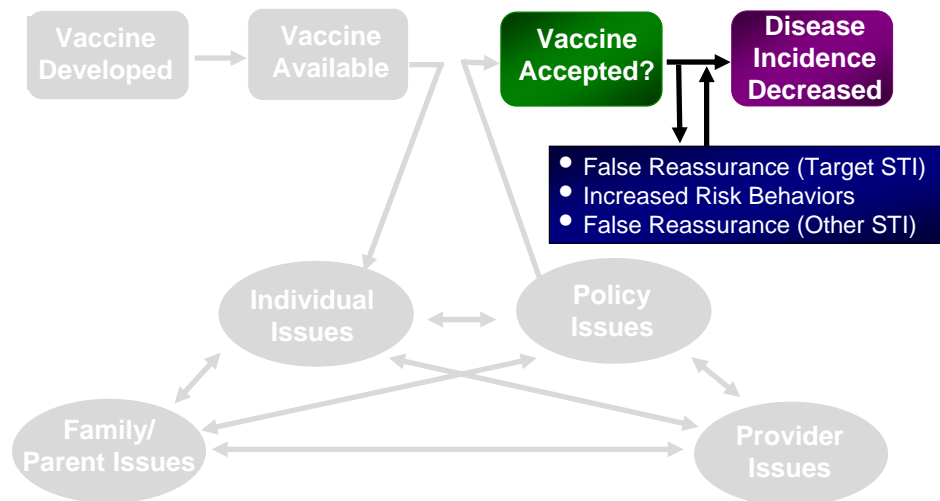
## Acceptance of STI vaccines

- When it comes to vaccines for prevention of STI:
  - Conventional wisdom, the scientific/public health community, the political world, media, & advertisers may be out of step with the attitudes & behaviors of parents
  - But, these groups, particularly the political and media worlds, may adversely influence consumer attitudes & behaviors



## POST-ACCEPTANCE OF STI VACCINES: UNIQUE ISSUES

### Post-acceptance issues



### Post-Acceptance Issues

- Risk-compensation: Will vaccination lead to initiation of sex at an early age and/or decrease rates of condom use?
  - Could lead to increased infection with targeted pathogen with low efficacy vaccine
  - Could lead to increases in other STI & pregnancy with high efficacy vaccine
  - With HPV vaccine might lead to decreased screening
- Likely dependent on:
  - Specific vaccine
  - Individual's personality

### Risk-compensation: HIV vaccine

- May be more issues with risk-compensation because HIV/AIDS has been a central element of sex education interventions for many years
- If fear of AIDS is reduced through availability of an effective HIV vaccine, what will the result be?
- 77% of adolescents surveyed said that increased sexual risk behavior would occur after getting immunized with a 90% efficacious HIV vaccine\*

\*Webb et al. *J Adolesc Health* 1999.

## Risk-compensation: Other STI vaccines

- Likely less of an issue than with HIV vaccination
- With HPV vaccine, implies that threat of HPV infection historically inhibited sexual behavior, which is very unlikely
- Are vaccines administered to pre-adolescents/early adolescents likely to impact behavior initiated one or more years later?
- Only 36 of 66 adolescents (54%) who had received HPV vaccine reported getting vaccinated\*
  - If they cannot remember it, is it really going to affect behavior?

\*Stupiansky et al. SAHM meeting. 2011

## Risk-Compensation?

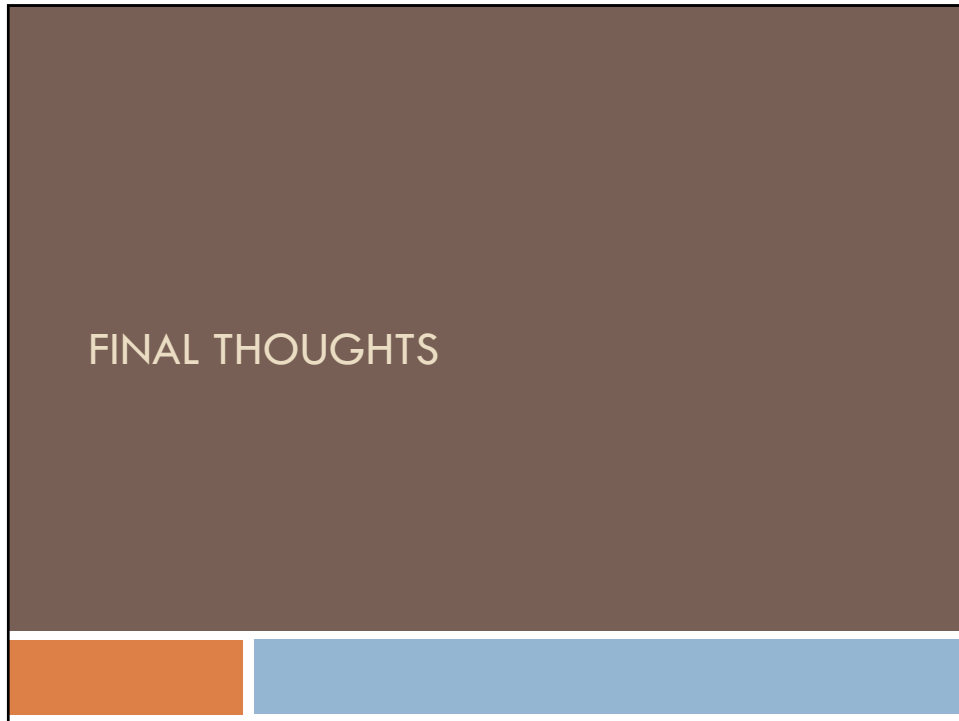


### Arguments against risk-compensation as a significant issue for STI vaccination

- Underestimates parental influence
- No compelling evidence from other research
  - Emergency contraception
  - School-based sex education programs
  - Condom availability programs
  - HAART treatment
    - Mixed evidence regarding disinhibition

### But, the take home message is:

- **Failure to administer STI vaccination due to *fears* about risk-compensation is unethical**
- **If risk-compensation is shown to be an issue, it should be addressed through research and clinical practice**



STI vaccination:  
Final thoughts

- STI vaccines have to be understood in the context of vaccines in general
- The “unique” issues associated with STI vaccines may be more of an issue for the media, public health, scientific, advertising, and political worlds than for consumers
- Risk-compensation, if it is a concern at all, should have no bearing on availability of STI vaccination