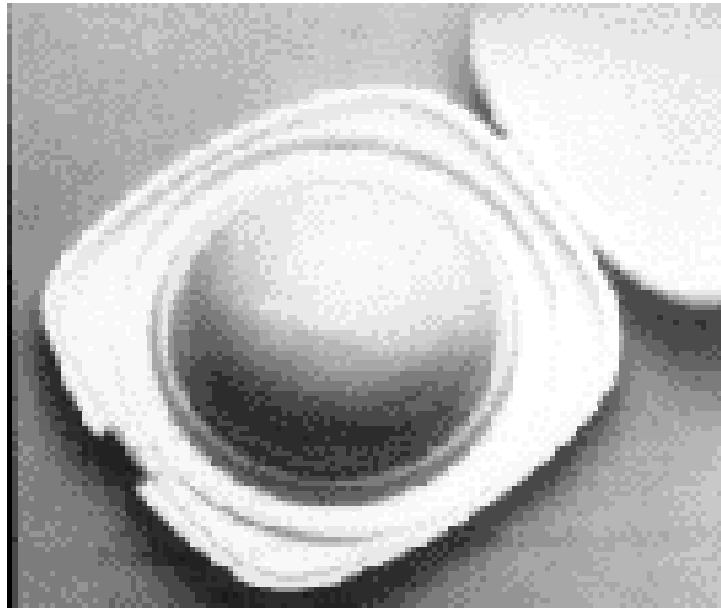


# Use of the Diaphragm for the Prevention of Cervical STD

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# The diaphragm: a brief history



# The diaphragm: a brief history

- Described by Dr. Wilde in 1838 following the vulcanization of rubber
- Use spread rapidly in Europe
- In the early 1900's Margaret Sanger and Emma Goldman saw a variety of diaphragms used in Europe

# The diaphragm: a brief history

- Introduced to US in 1916 by Sanger in her Brooklyn clinic. Clinic was closed after 10 days by NYC Vice Squad.
- Deemed guilty of “maintaining a public nuisance”, Sanger arrested, convicted and jailed for 30 days.
- Sanger re-opened clinic upon release from jail.

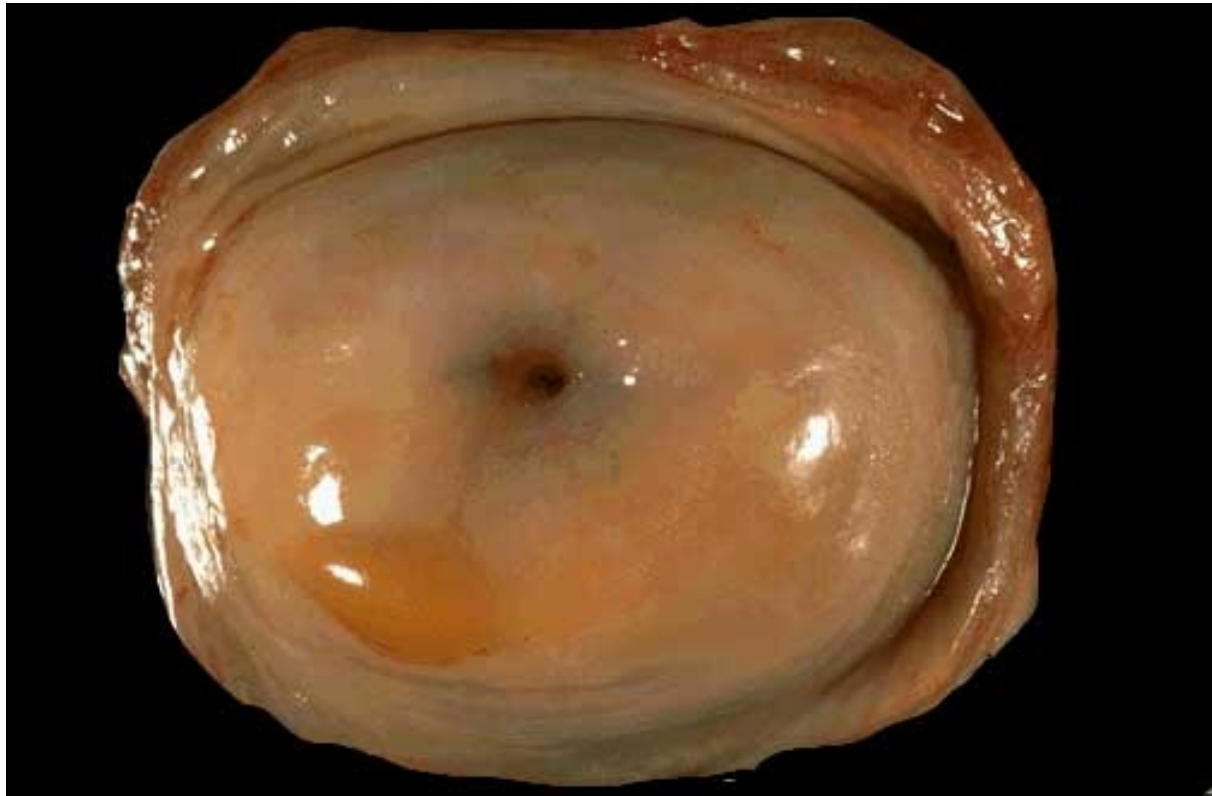
# The diaphragm: a brief history

- In 1925 Sanger's husband established the first US diaphragm manufacturer
- Initial popularity then progressive decline in use; women shift to hormonal contraception.
- Recent increased interest in possible diaphragm use for STD/HIV prevention.

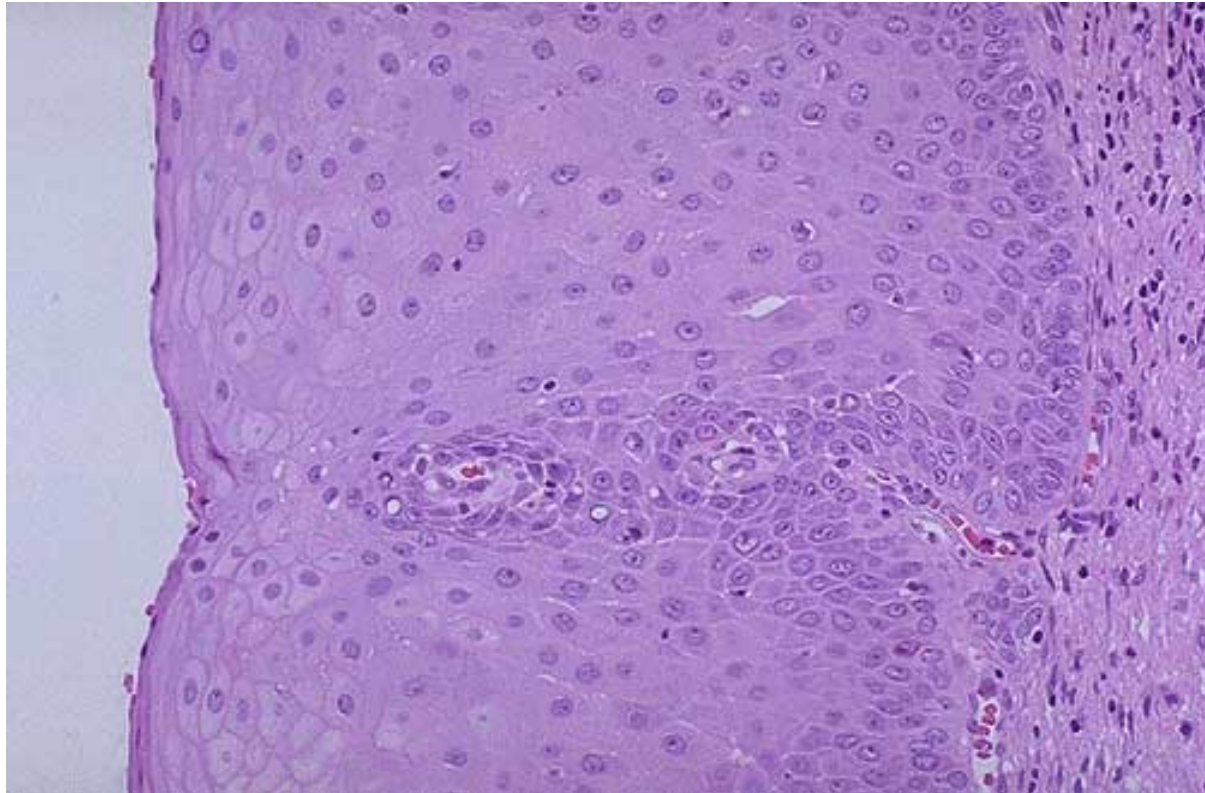
# Diaphragm use for STD prevention

- Biologic plausibility
- Observational studies in humans
- Need for adjunctive microbicide:
  - data from contraceptive efficacy trials
- Potentially deleterious effects of the diaphragm

# Normal cervix

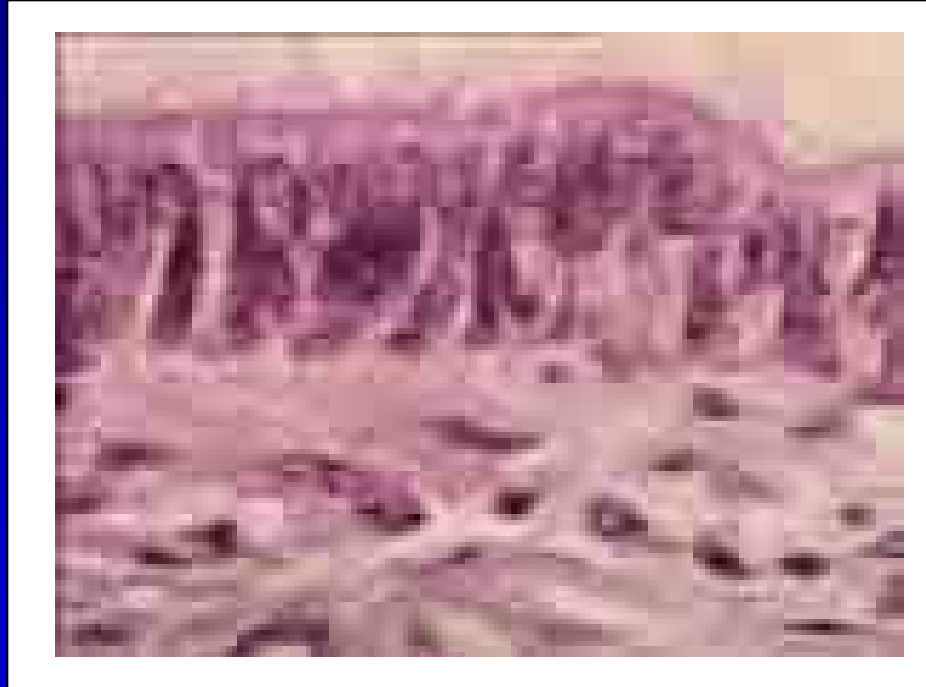


# Normal cervical epithelium





# Columnar epithelium



# OR for Chlamydia: Diaphragm vs. no method

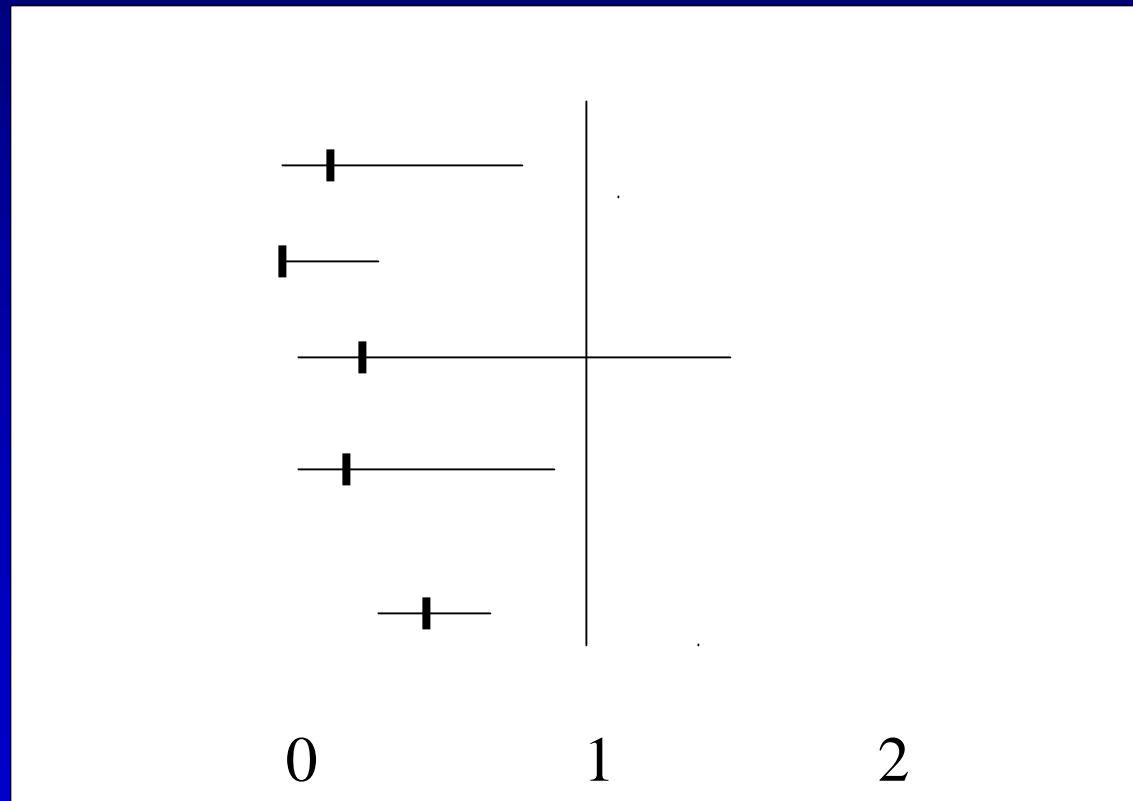
McCormick '85

Magder '88

Rosenberg '92

Park '95

Cramer '87



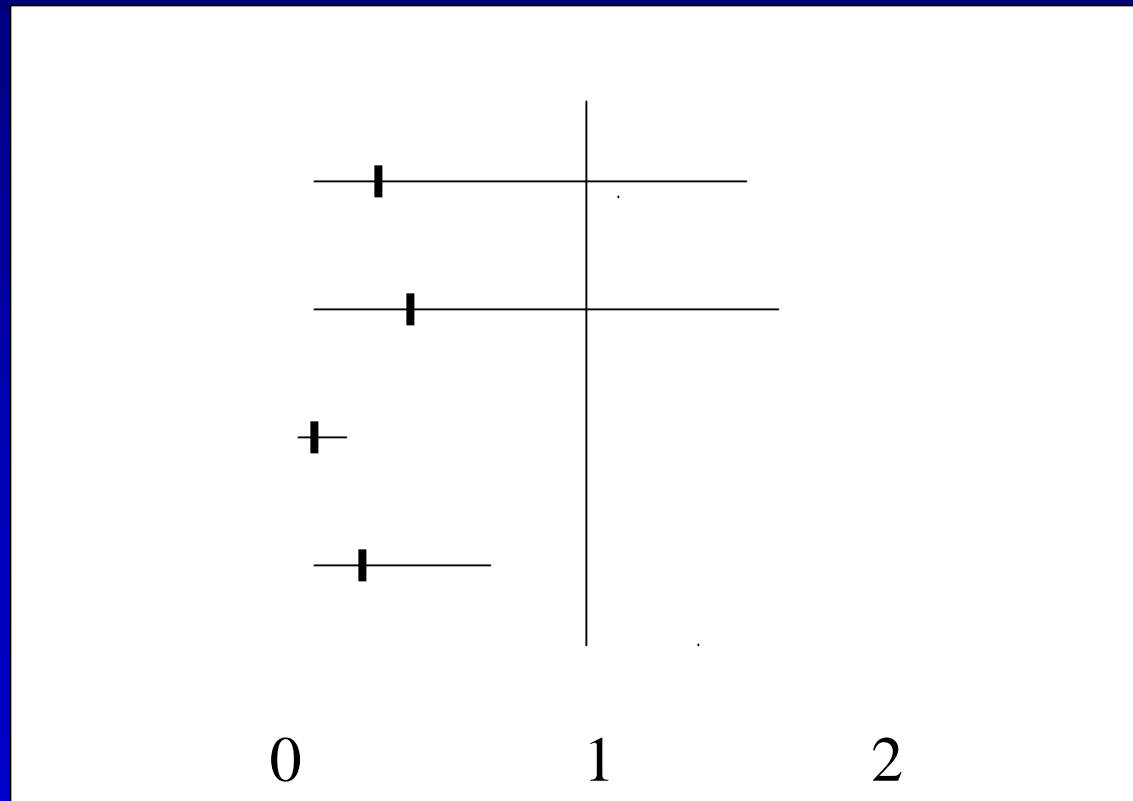
# OR for Gonorrhea: Diaphragm vs. no method

Berger '75 \*

Austin '84

Quinn '85 \*

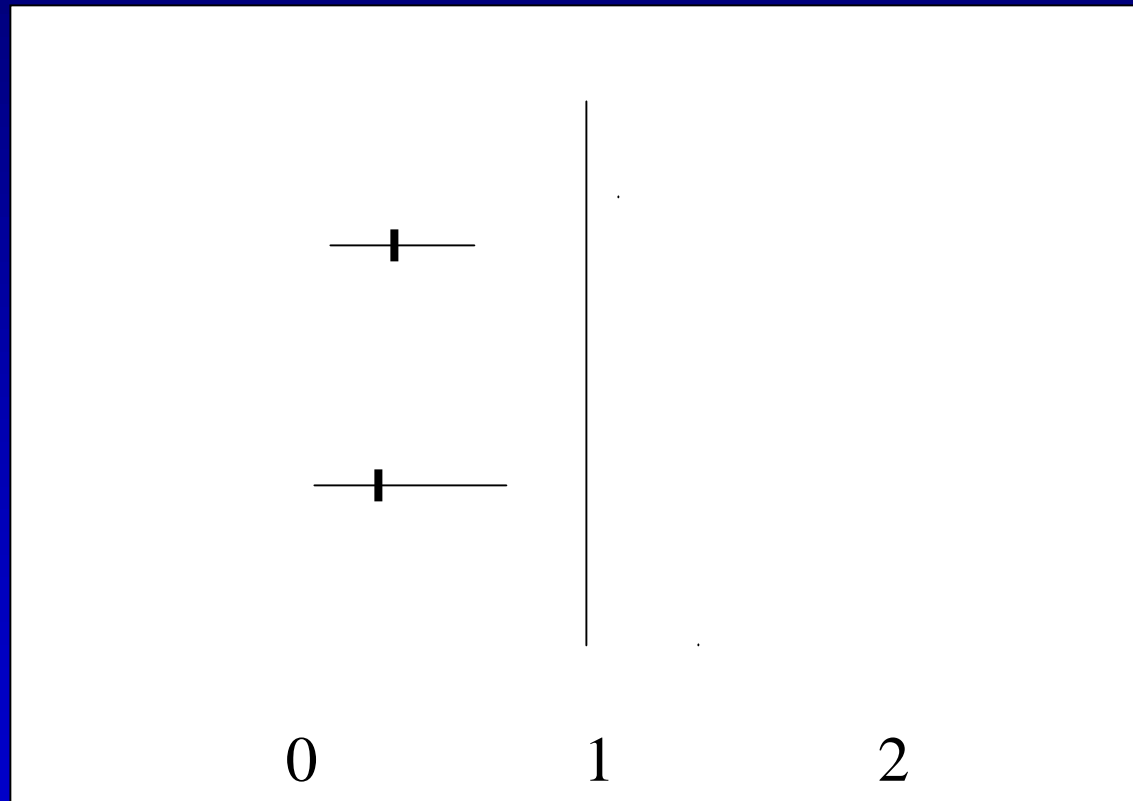
Rosenberg '92



# OR for PID: Diaphragm vs. no method

Kelaghan '82

Wolner-  
Hanssen '90



# OR for Neoplasia: Diaphragm use vs. never use

Hildesheim '90

< 5 yrs

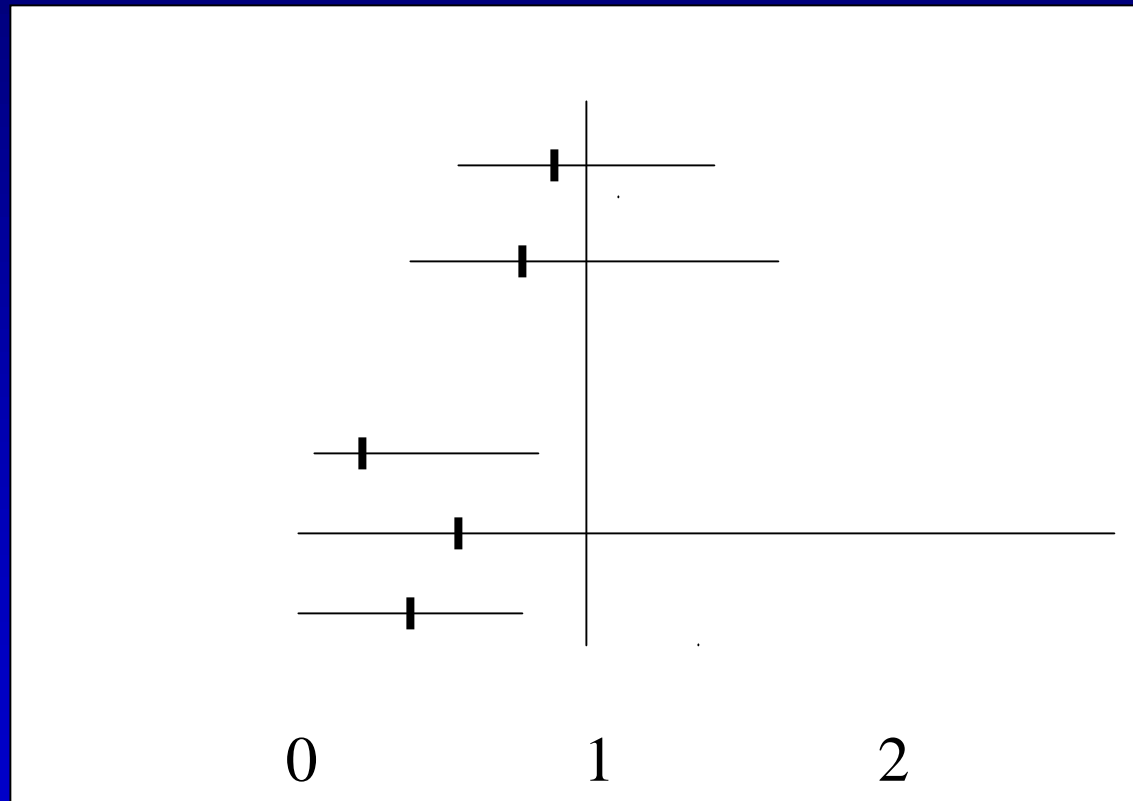
5 + yrs

Becker '94

Ever

Current

Past



# Source of protection

- Women who use the diaphragm are, in general, less likely to have:
  - Chlamydia infection
  - Gonorrhea
  - PID
  - HPV-associated cervical dysplasia
- Does this mean that the diaphragm protects against these infections?

# Possible confounding by sexual behavior

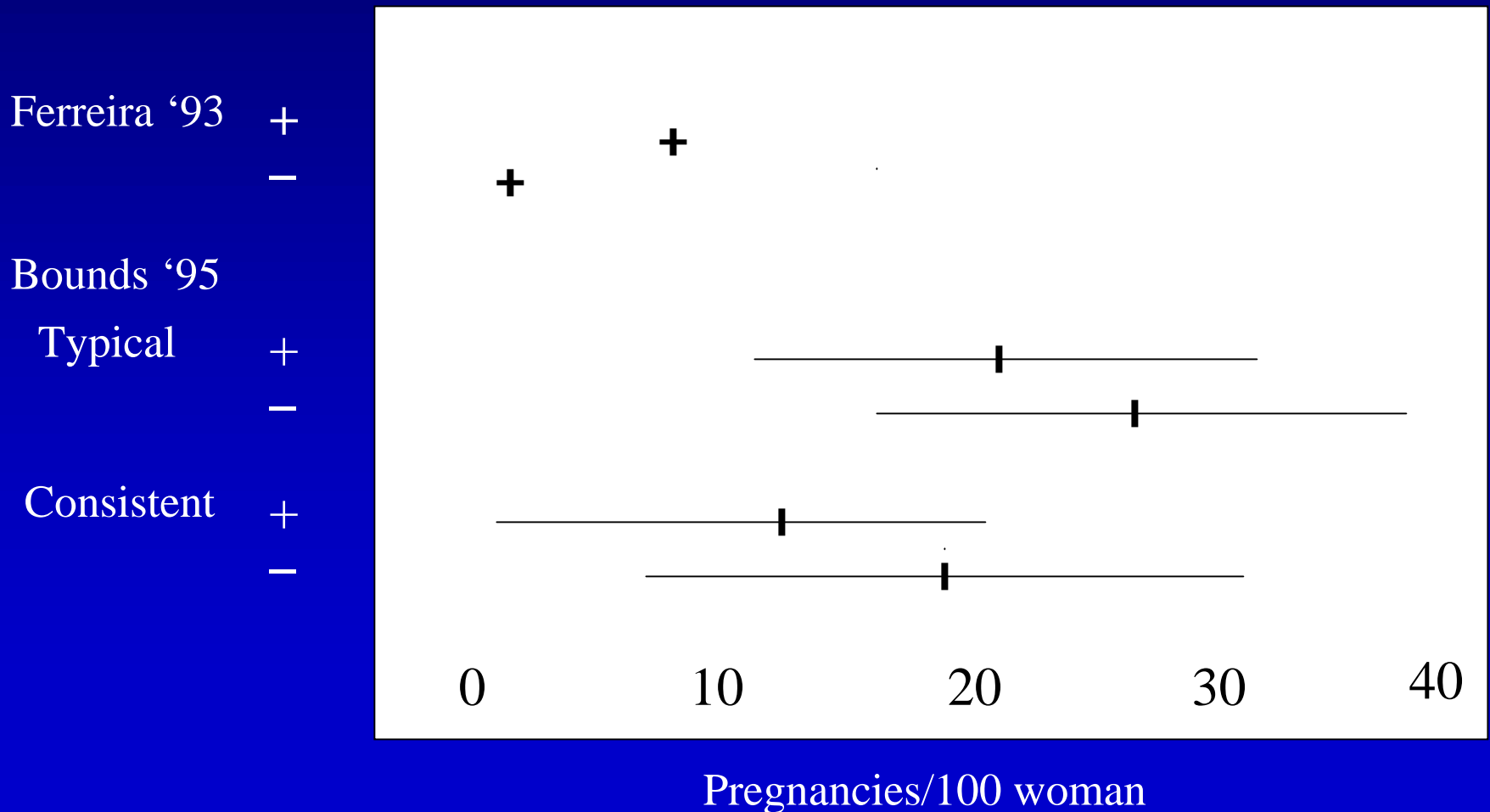
- Studies of the diaphragm do not present high level evidence. All are:
  - Level IIB: cohort or case-control studies;
  - Level III: descriptive studies.
- No randomized clinical trials (Level 1) to date.
- Lower risk of non-cervical STD among diaphragm users suggests differences in behavior.
  - Trichomonas: OR = .29 [.15, .58]

Will use of the diaphragm alone  
be sufficient for STD Prevention?

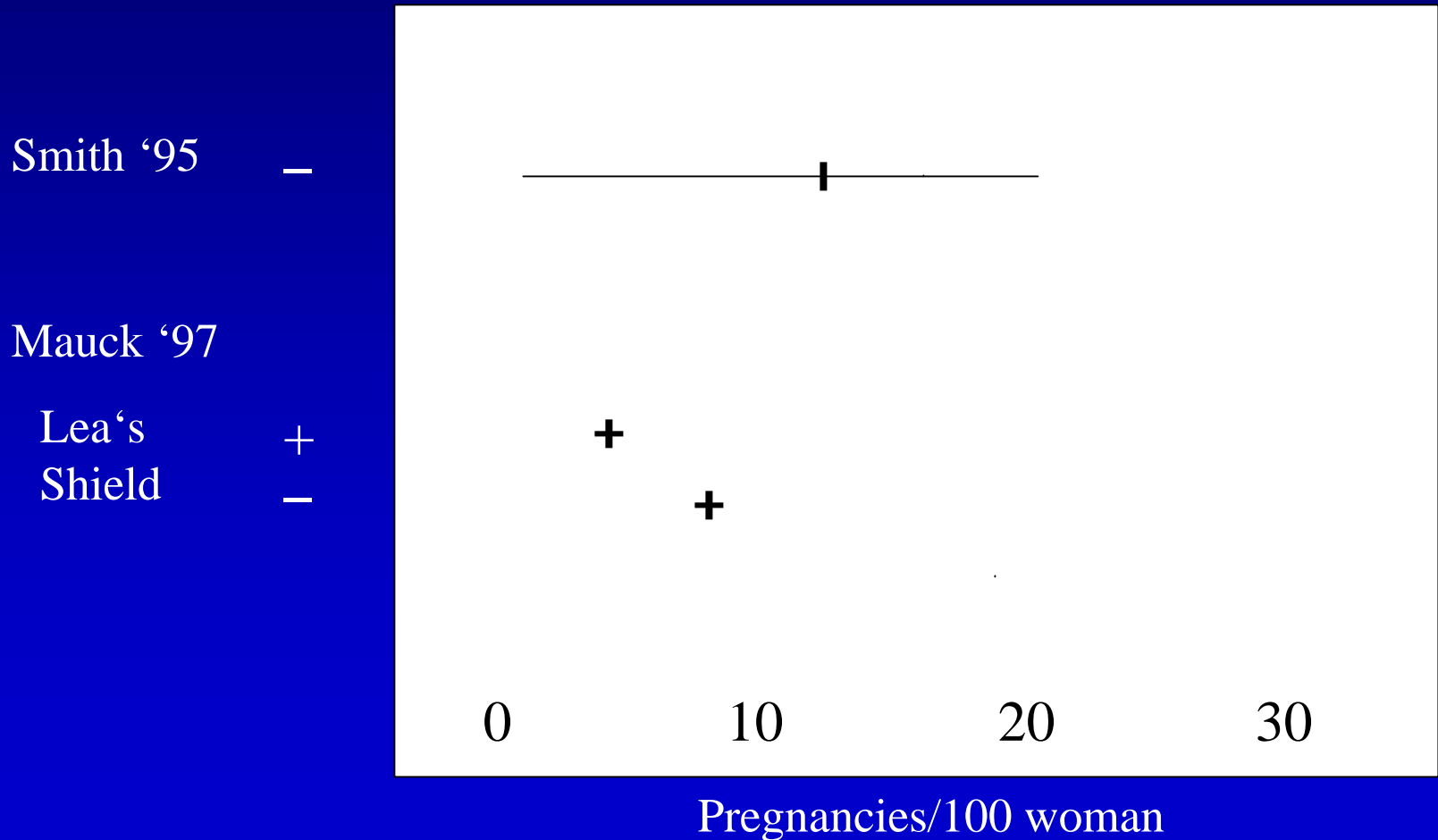
Insights from the contraceptive  
literature about the role of  
adjunctive chemical barriers



# Typical 12-month pregnancy rate diaphragm +/- spermicide



# Typical 6-month pregnancy rate barrier +/- spermicide



# Potentially deleterious effects of the diaphragm

Urinary Tract Infection  
Toxic Shock Syndrome

# OR/RR for UTI: Diaphragm vs. oral contraceptives

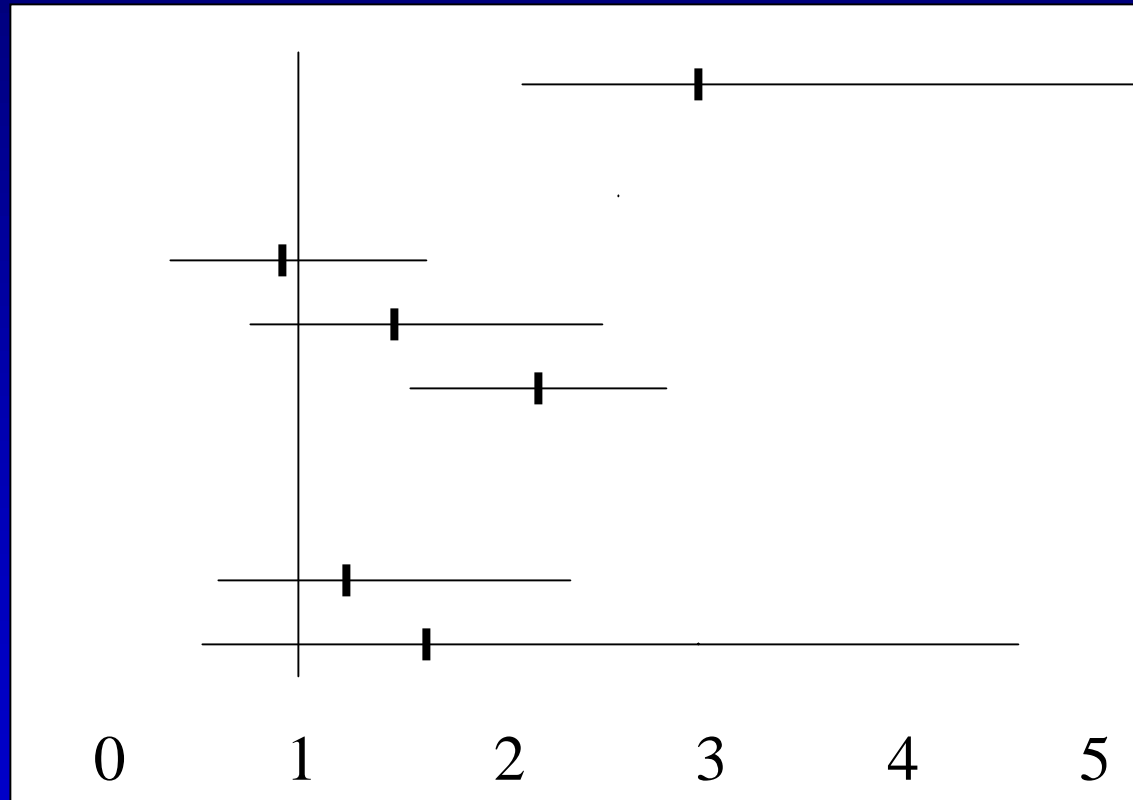
Finn '85

Hooton '96

d/wk 1  
2  
3-7

Scholes '00

Spermicide  
Diaphragm

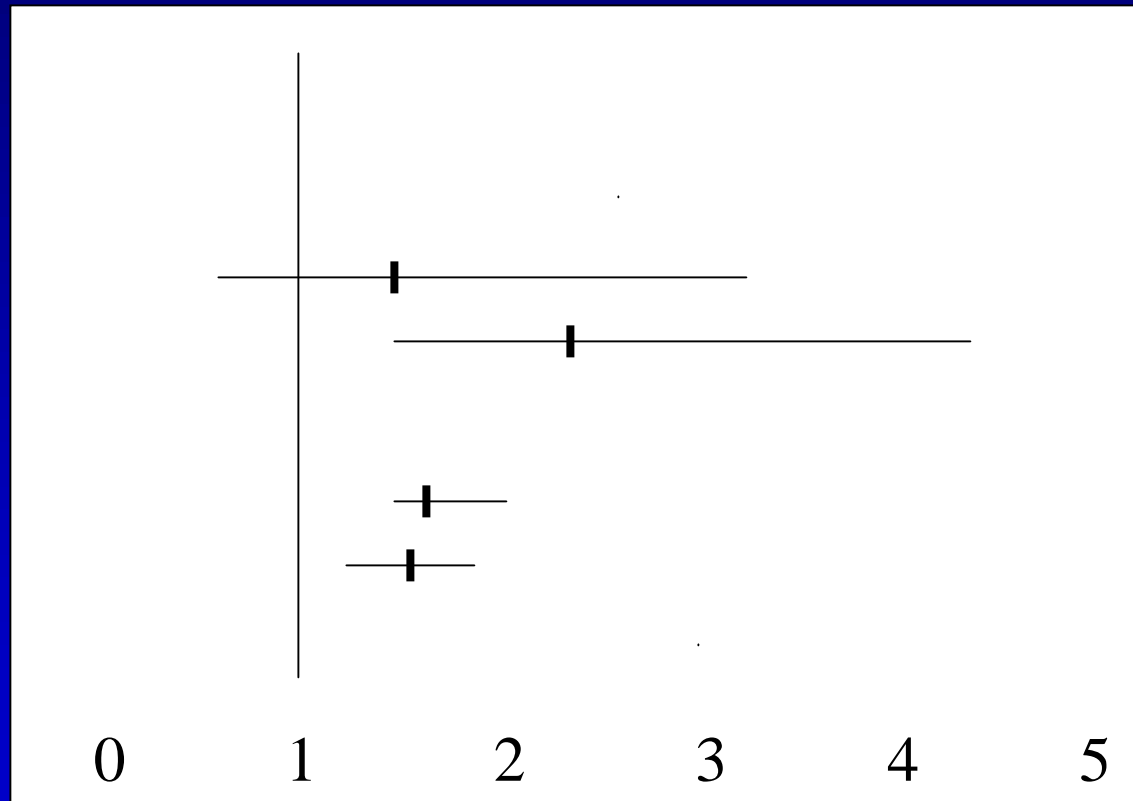


# RR for Bacteriuria: Diaphragm (d/wk)

Hooton '00

Spermicide  
alone

Diaphragm



# Toxic Shock Syndrome

- Case reports of toxic shock syndrome after prolonged & short-term diaphragm use.
- ...cases of nonmenstrual TSS among diaphragm users have been reported previously.... to date, 18 definite and five probable cases associated with diaphragm use have been reported to CDC. (MMWR, 1984)

# Diaphragm Use for STD Prevention

- Ongoing/Planned Trials (CDC/ USAID/ CONRAD)

Acceptability

Efficacy for CT/GC re-infection

Safety with microbicides

Acceptability / Use pattern in CSW

Safety of silicone vs. latex diaphragm?

# Take-Home Messages

- Diaphragms cover the columnar epithelium of the cervix, site of chlamydial & gonococcal infections
- Women who use the diaphragm plus a spermicide (N-9) were less likely to have
  - Chlamydia infection
  - Gonorrhea
  - PID
  - HPV-associated cervical dysplasia



# Take-Home Messages

- The evidence for protection is not strong and the possibility of confounding by sexual behavior has not been ruled out.
- Although not statistically significant, contraceptive studies suggest that adjunctive microbicide use may increase efficacy.

# Take-Home Messages

- Diaphragm is associated with increased risk of symptomatic UTI, recurrent UTI and asymptomatic bacteriuria. Part of risk may be attributable to spermicide.
- Diaphragm use associated with toxic shock syndrome; absolute risk is low. Need to consider implications of prolonged use, poor cleaning.

# Take-Home Messages

Sometimes doing the right thing takes  
great courage.

Margaret Sanger