

**Explaining Effectiveness**  
*... Effectively*

- How effective is this method ?
- How effective would it be *for me ?*

... not easy questions to answer.



# Goal

- Answer these questions accurately, honestly and understandably  
  
..... and help patients use methods as effectively as possible.

# Objectives

- Be familiar with widely-used efficacy estimates.
  - including “typical use” and “perfect use” failure rates
- Be able to interpret results of new research.
  - key factors that influence efficacy rates in studies

## Objectives *(cont)*

- Understand common patient difficulties & preferences in presentation of quantitative information.
- Identify clinician steps that may improve consistent, correct continuing method use.

## Objectives (*cont*)

- Understand why **highly-effective methods** are also highly ***cost*** effective.
- Understand why provision of **emergency contraception** along with a primary method is effective and ***cost*** effective.

# Widely-used Effectiveness Rates

	Typical Use	Perfect Use
<b>Chance</b>	85	85
<b>Spermicides</b>	26	6
<b>Periodic Abstinence</b>	25	
<i>Calendar</i>		9
<i>Ovulation Method</i>		3
<i>Symptothermal</i>		2

# “Typical Use” Rates

- The probability of pregnancy during the first year of *typical* use; *i.e.* effectiveness for the average person who does not always use the method correctly or consistently.
  - Estimated from the National Surveys of Family Growth for spermicides, periodic abstinence, diaphragm, male condom, pill; from clinical trial results for sponge, cervical cap, IUD, sterilization, Depo-Provera and Norplant.



## “Perfect Use” Rates

- The probability of pregnancy during the first year of perfect use of the method; *i.e.*, among those who use the method consistently and according to instructions.
  - Based on clinical studies for all methods; note that information for female condoms, diaphragms, cervical caps and sponges is limited, and that no research is available on perfect use of male condoms, withdrawal, spermicides, or other variants of periodic abstinence.

# Widely-used Effectiveness Rates

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# Widely-used Effectiveness Rates

	Typical Use	Perfect Use
<b>Cap – parous</b>	40	26
<b>– nulliparous</b>	20	9
<b>Sponge – parous</b>	40	20
<b>– nulliparous</b>	20	9
<b>Diaphragm</b>	20	6

# Widely-used Effectiveness Rates

	Typical Use	Perfect Use
<b>Withdrawal</b>	19	4
<b>Condom – female</b>	21	5
<b>Condom – male</b>	14	3
<b>Pill – progestin only</b>	5	0.5
<b>Pill – combined</b>	5	0.1

# Widely-used Effectiveness Rates

	Typical Use	Perfect Use
<b>IUD –</b>	2	1.5
<b>progesterone</b>		
– Cu T	0.8	.06
– LNg	0.1	0.1
<b>Depo-Provera</b>	0.3	0.3
<b>Norplant</b>	0.05	0.05

# Widely-used Effectiveness Rates

	Typical Use	Perfect Use
<b>Female Sterilization</b>	0.5	0.5
<b>Male Sterilization</b>	0.15	0.10

## Warning:

- “Perfect” use has been calculated incorrectly in many published studies . . . .
- Watch for this, especially in older studies.

# Perfect Use / Typical Use

- Method X -- used by 100 women for 1 year
- 2 “perfect” use pregnancies = ~~2 % failure rate~~  
???
- 8 inconsistent use pregnancies = ~~8 % failure~~  
rate ???

Why is this incorrect ? Because we also *need to know the number of cycles of perfect use and of inconsistent use to have the correct denominator for each rate.*



# Perfect Use / Typical Use

- Method X -- used by 100 women for 1 year
- 50 years of perfect use; 50 years of inconsistent use
- 2 / 50 “perfect” use = 4 % failure rate
- 8 / 50 inconsistent use = 16 % failure rate

# Factors That Influence Efficacy Results in Practice & in Research

- Inherent method efficacy [Design of the Study]
- User characteristics
  - Frequency of Intercourse
  - Age
  - Parity
- Influence of the Investigator
- Participation criteria
- Methods for documenting pregnancy outcomes
- Use of additional methods (EC, initial dual methods)
- Study duration

# Factors: Investigator Influence

- Investigator integrity & reliability

... Watch for indirect indicators



# Factors: User Characteristics

- Consistency and correctness of method use

*Fecundity*: key determinants are intercourse frequency, age, parity.

- Fecundity

# Factors: Correct, Consistent Use

	Typical Use	Perfect Use
<b>Cap -- nullip</b>	20	9
<b>Sponge -- nullip</b>	20	9
<b>Diaphragm</b>	20	6
<b>Female Condom</b>	21	5
<b>Withdrawal</b>	19	4**
<b>Male Condom</b>	14	3
<b>Pill – combined</b>	5	0.5

\*\* Often neglected in patient education . . .

# Factors: Intercourse Frequency

<b>Perfect Diaphragm Use</b>	<b>Failure Rate</b>
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Intercourse <b>less than 3x</b> / week	3.4
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Intercourse <b>3x or more</b> / week	9.7
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# Factors: Study Design

- Initial interval of dual method use, or delay in starting the clock on failures
- Provision of emergency contraception
- How emergency contraception use is counted

# Factors: Study Design

- Participant requirements for intercourse frequency
- Participant exclusion that may select for higher fertility
- Pregnancy detected through clinical signs  
*or*  
testing for all subjects



# Factors: Study Duration

- As the study duration increases, those most likely to experience failure are *systematically* removed . . . . So failure rate *improves* over time.
- That's why "1st year" rates are needed for comparability

# Cumulative Pregnancy Risk

*even though effectiveness improves with longer use, the cumulative chance of pregnancy is considerable:*

## Cumulative Pregnancy Risk -- 5 years

- Pills (5 % in 1 year) **23 %**
- Diaphragm (20 % in 1 year) **67 %**

# Lifetime Risk

- **1.61** million contraceptive failures per year
- Typical woman: **0.81** contraceptive failures *during her lifetime*

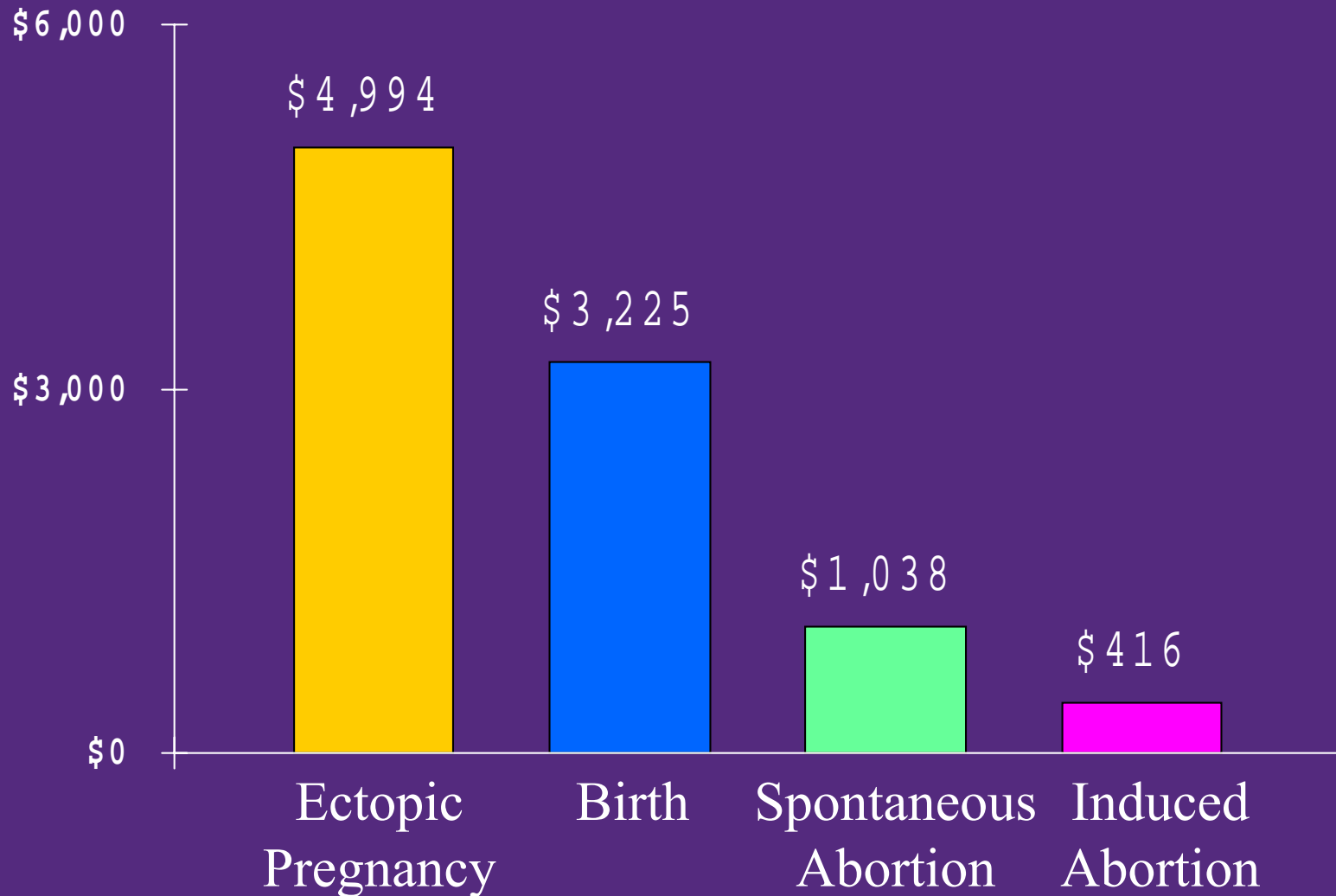
**0.97** if couples protected by sterilization are removed; **1.96** if intervals of “non use” are included

# Cost-effectiveness

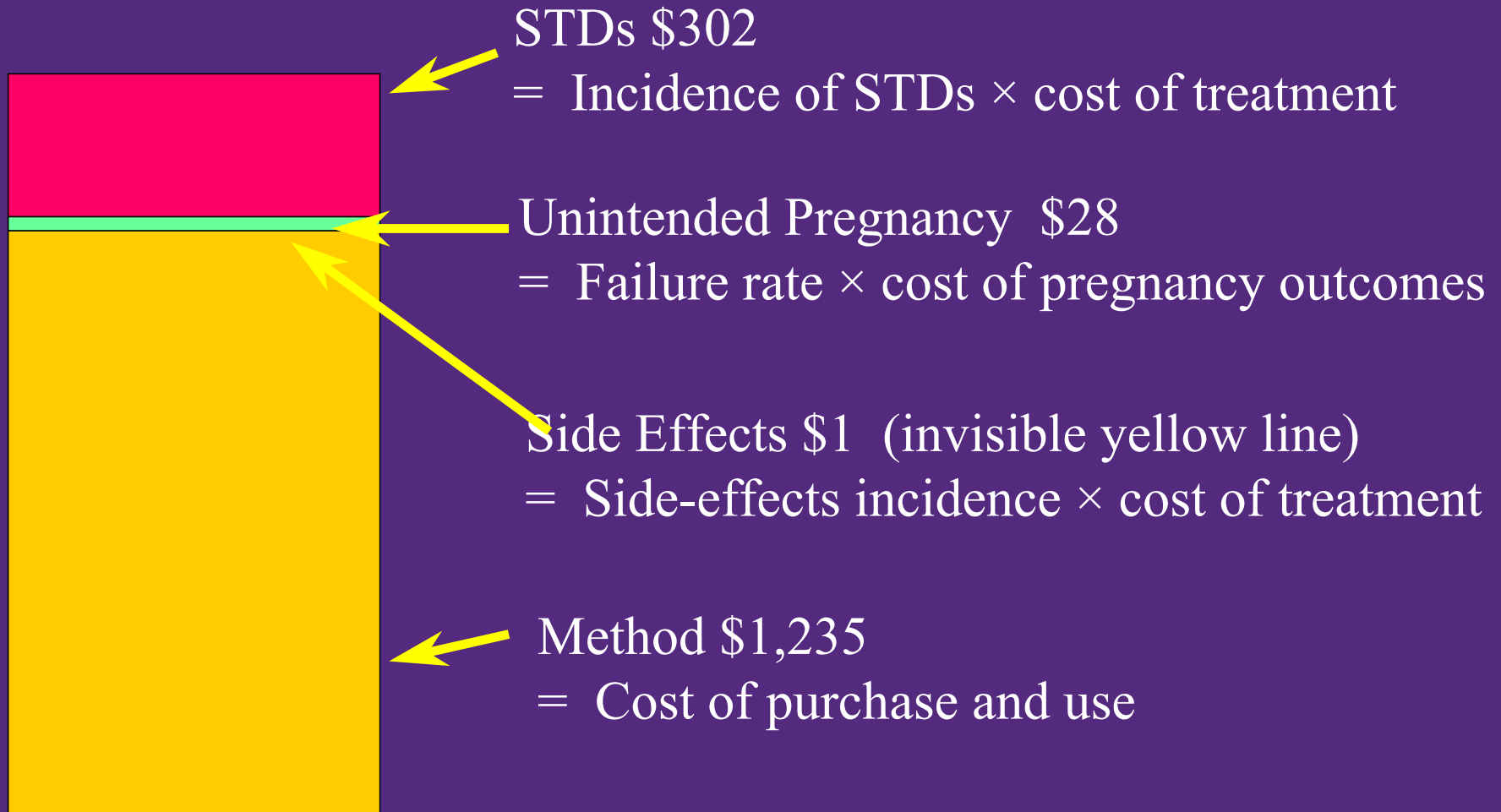
- *Methods with high inherent effectiveness, such as Norplant and IUDs are highly cost effective – despite the initial investment required*

*because the the cost-savings for pregnancies averted is so large*

# Cost of Pregnancy Outcomes

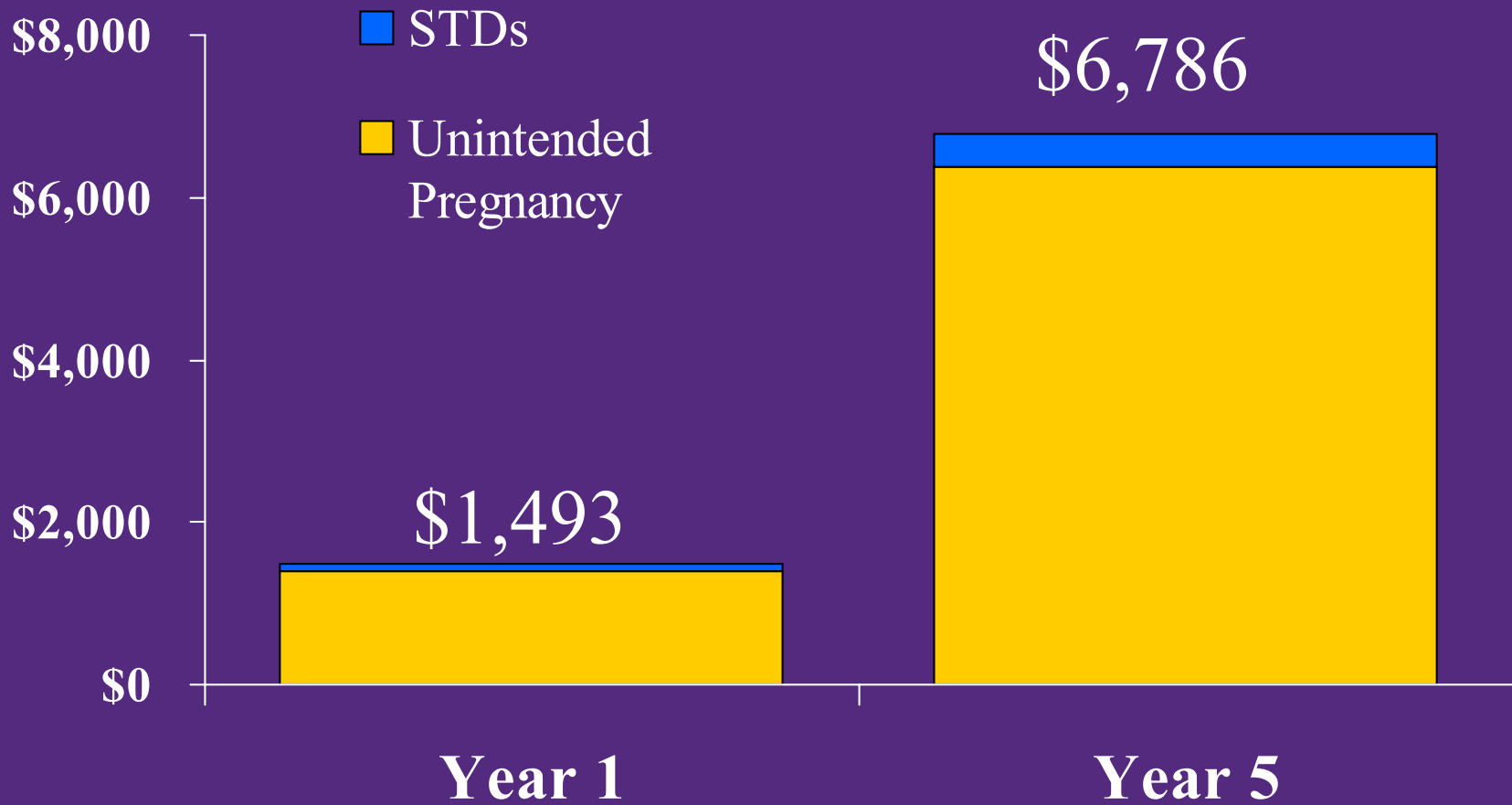


# Cost Components

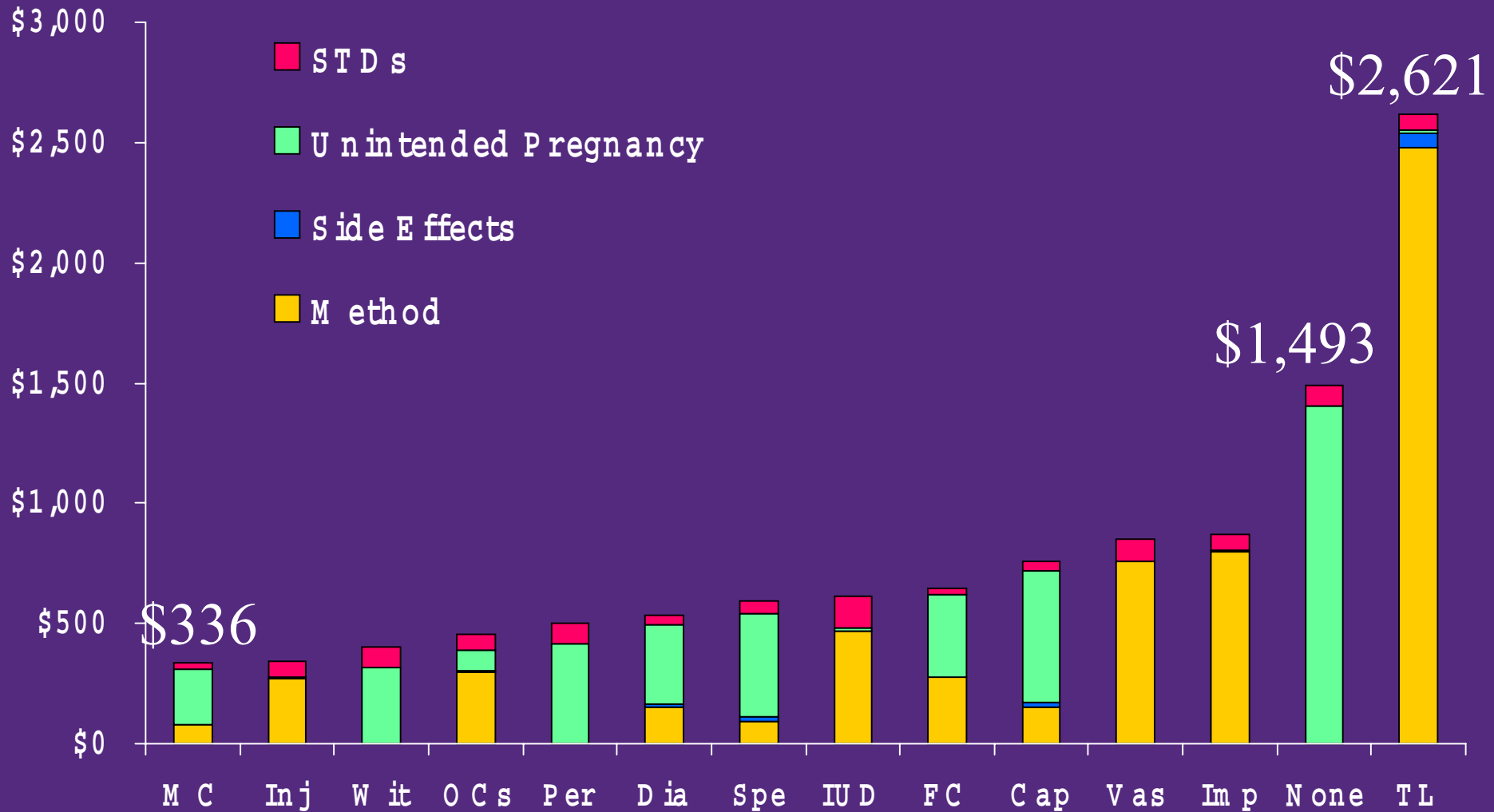


Total Costs for 5 Years of Use of Injectable = \$1,566

# Cost of Using No Method

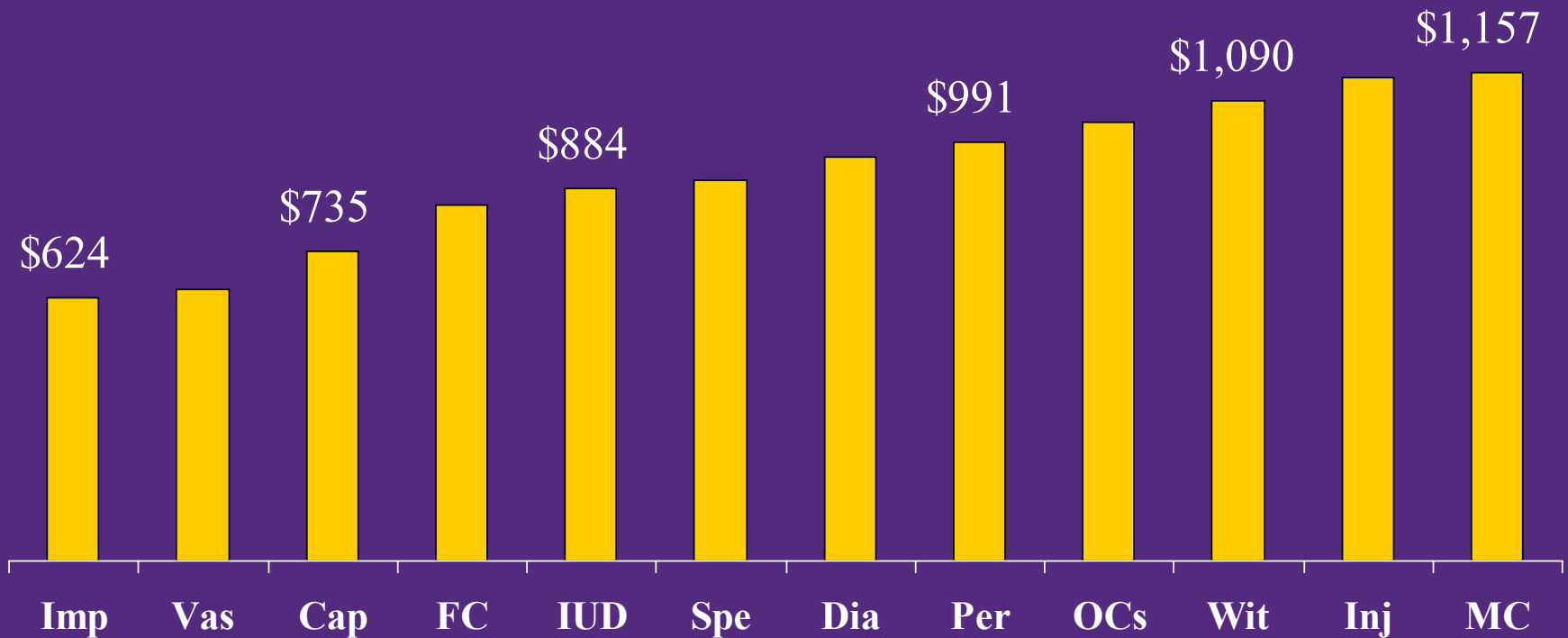


# Total Costs at 1 Year

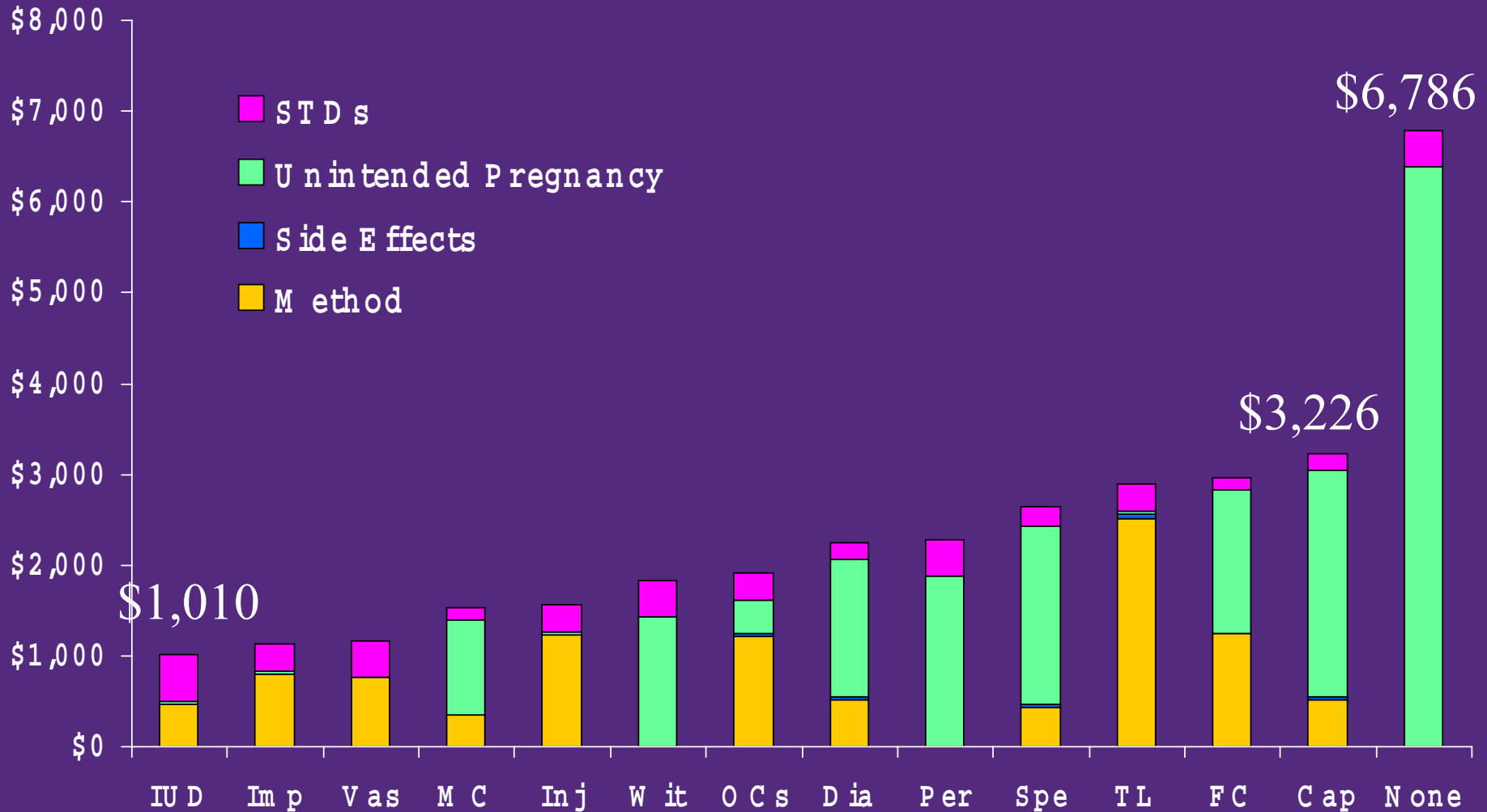




# Savings Over No Method at 1 Year



# Total Costs at 5 Years



# Constructing an Effective Explanation

- Numbers make many people nervous
- Fractions make most people *very* nervous



# Research on Patient Preferences

- Positive percentages / negative percentages
- Positive numbers / negative numbers
- Describing figures in a sample of 100 or 1000

Social marketing research interviews; 72 female interviewees, including 26 interviewees 16-25.

# Research on Patient Preferences

- Positive: reassuring, encourage contraceptive use
- Negative: “honestly” show the risk of failure (some conclude not worth bothering with contraception)
- Percentages are preferred to numbers (some didn't understand % sign; preferred to imagine a group of 100 women)

# Research on Patient Preferences

- 100 women is easy to understand;  
1000 is difficult to cope with – confusing
- High percentages (95%) *or*  
Low numbers (1 to 10) are easiest to comprehend
- Rates *less than* one percent hard to understand  
[but “almost” suggests imprecision; causes suspicion]

# Research on Patient Preferences

- “ In a year ” vs “ In the first year ”

The word “first” causes worry -- some think method becomes more effective over time, some think less -- so explain or omit the “first.”

# Research on Patient Preferences

- “ higher failure rates if women are less careful in using the method ”

caused confusion & anxiety -- also felt to be *judgmental and blaming* women for failure.

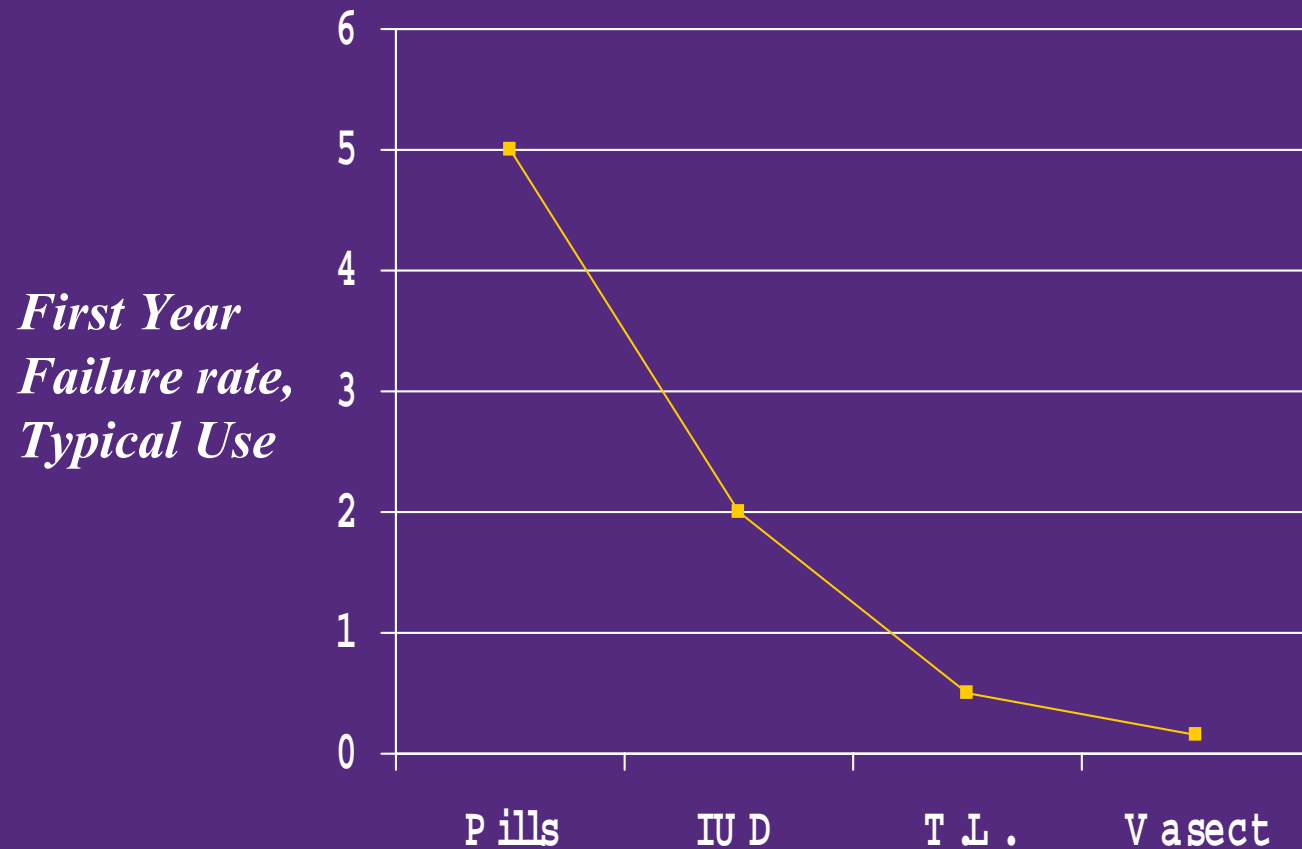


# Research on Patient Preferences

## *Alternative wording*

- “ method X effectiveness is highest for women who are able to use it consistently & correctly.”

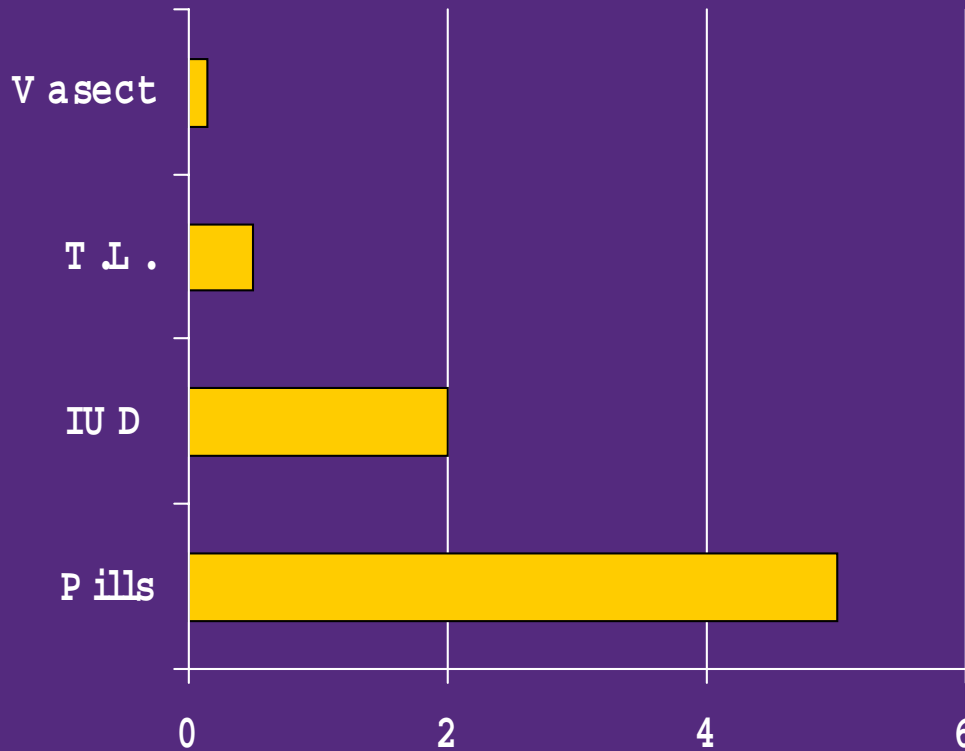
# Research on Patient Preferences



Graphs :

Complete  
***GREEK*** for  
most people.

# Research on Patient Preferences



*First Year Failure rate, Typical Use*

Bar Graphs :

A bit better,  
but still  
confusing.

# Research on Patient Preferences

## Conclusion

- Express efficacy by a positive percentage followed by a negative number statement.
- *i.e.* If women use X according to instructions, it is 99 % effective -- if 100 women use X according to instructions one woman will become pregnant in a year.

# Key Issues in Effectiveness Messages

- Correct and consistent use is *extremely* important.
- Clinician & staff provide accurate and comparable rates for all methods.
- Technology does fail (not always patient's "fault").
- Dual method use dramatically improves effectiveness.
- EC provides a second chance to prevent pregnancy.

# Emergency Contraception

- Options include EC pills (75% - 89% efficacy) or insertion of a copper IUD (99% efficacy).
- EC pill treatment should be initiated within 72 hours after unprotected intercourse.
- Primary action of EC pill treatment is to prevent or delay ovulation; it may also interfere with fertilization and/or implantation; it does not cause abortion.

# Emergency Contraception

- Two products packaged for this use:  
*Plan B* and *Preven*
- Ordinary OCs containing levonorgestrel can also be used.
- Providing a package of emergency contraceptives in advance increases the likelihood that treatment will be used when needed.

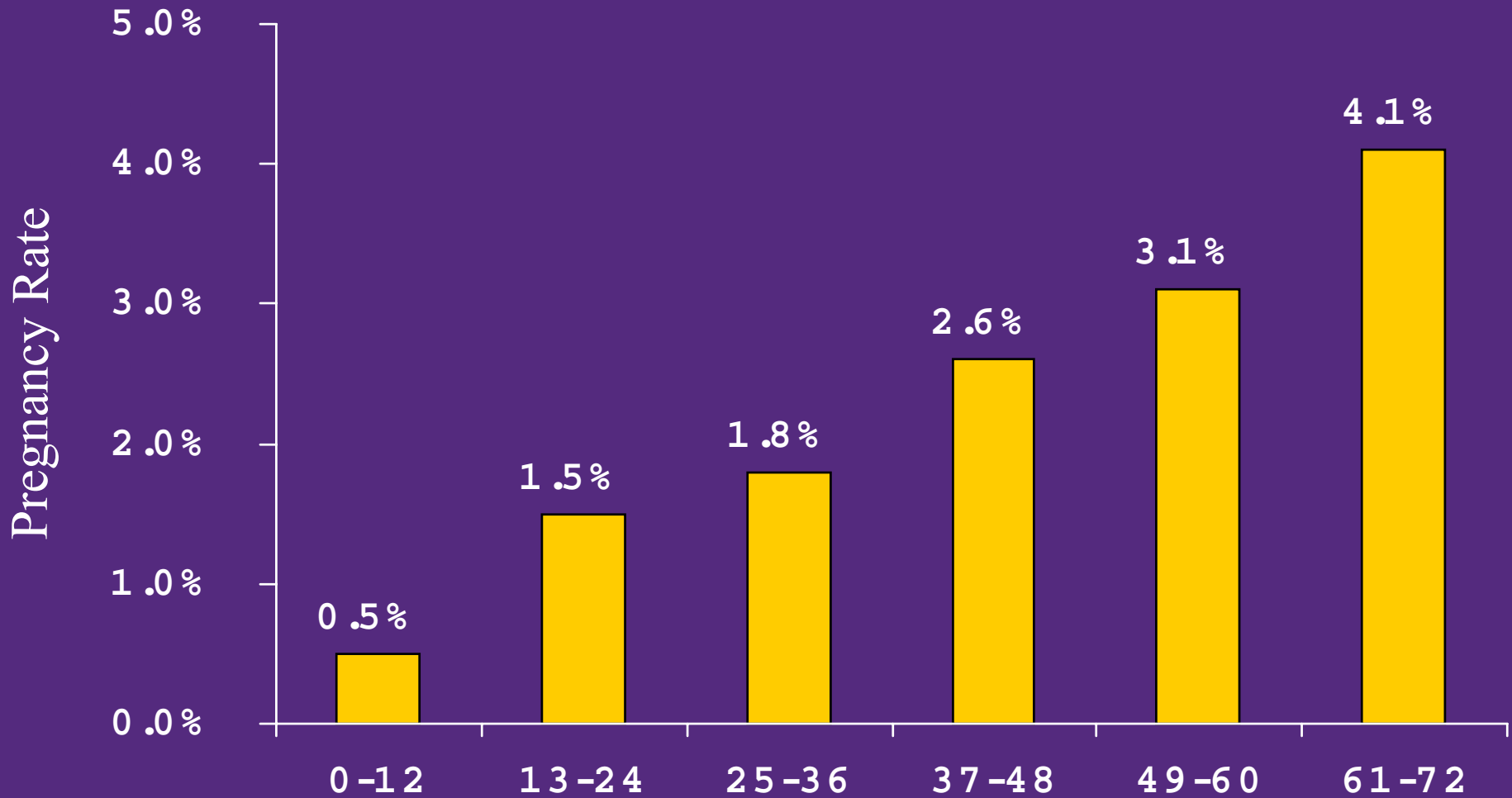
# Emergency Contraception

- Emergency treatment is most effective when initiated in the first 12 hours after exposure.
- Levonorgestrel only emergency treatment such as ***Plan B*** is more effective than use of combined estrogen/progestin options such as Preven.



# How Long After the Morning After?

*WHO Pooled Data (Yuzpe and LNg), 1998*



*Lancet, 1999*

# Dual Method Efficacy

- Perfect use of male condoms 3 %
- Perfect use of spermicide 6 %
- Perfect use of both together 0.1 % \*\*

**\*\* *as good as OC . . .***

**“ Method ” failures do happen**

It's not fair -- or honest -- to assume  
that the woman is to blame.

# Honesty: Provide accurate & fair rates

- Compare “Column A” to “Column A”

*perfect rate vs perfect rate*

*typical rate vs typical rate*

. . . Reinforce with a chart

# Honesty

Intellectual honesty & scholarly precision  
are not always the same thing

“*X* is twice as likely to fail as *Y*”

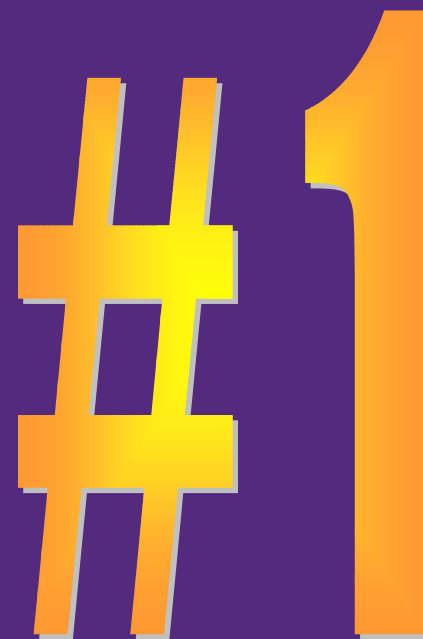
May be true but nevertheless a dishonest way  
to present information –  
the difference between  
0.00001 and 0.00002 may not be clinically  
meaningful.

# Encouraging Success

- Can successful adherence be predicted with certainty ?
  - NO
- Factors associated with success:
  - Intention to prevent pregnancy rather than delay
  - Older age
- Appropriate clinician roles
  - Clear instructions
  - Information about side effects and what to do if they occur
  - Encouragement to return if the method is not working out
  - Helping patient plan for adherence

# Encouraging Success: Continuation

- Many, many unintended pregnancies occur because a method has been discontinued, and an alternative method not yet initiated.



# Continuation

## % Continuing Use at 1 Year

Copper T IUD	78
Depo Provera	70
Oral Contraceptives **	71
Male Condom	61
Diaphragm	56

**\*\* lower for teens**



# Encouraging Success: Consistent, Correct Use

- The difference between a method's typical use and perfect use rate shows how important perfect use is for that method

for many methods, this is **extremely** important



# Consistent, Correct Use: Questions to Discuss With Patients

- Will daily pill taking (monthly shots . . . ) work for you ?
  - What time will you take them each day ? Where ?
  - What might help you remember ?
  - How have you remembered other things (vitamins . . . )
- Is ambivalence a factor in your situation ?
- What would you plan to do if your schedule is interrupted or you forget one or more pills ?

# Encouraging Success: Promote Use of Condoms

- When STI risk is a consideration, condom use is potentially life-saving.
- Condoms used along with any other method\* provides extremely high contraceptive efficacy.  
*\*male and female condoms should not be used together*



# Encouraging Success: Provide Emergency Contraception

- Women provided with a package of emergency contraceptive pills are more likely to use them when needed than are women merely instructed to call for a prescription if the need arises,

