
Risk Made Real: An Evidence-based Approach to Addressing Risk in Contraception

Association of Reproductive Health Professionals www.arhp.org

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Disclosures

Name	Disclosure
Jeffrey T. Jensen, MD (Advisory Committee Chair)	Dr. Jensen serves as a consultant for Bayer, Agile, Merck, HRA Pharma, Population Council, is on the speaker bureau for Bayer, and has contracted research for NICHD, Population Council, Bayer, Medicines360
James Trussell, PhD (Faculty/Advisory Committee Member)	Dr. Trussell is on the Advisory Board for Merck Global Contraception and serves as a consultant for Bayer Economics Health Group Berlin
Anne Moore, DNP, APRN, FAANP (Advisory Committee Member)	Dr. Moore is a trainer for Merck
David Turok, MD, MPH (Advisory Committee Member)	Dr. Turok serves as a consultant for Bayer, Teva, Bioceptive and has contracted research for Medicines360
Carole Chrvala, PhD (Medical Writer) Beth Jordan Mynett, MD (Planner) Rana Suliman, MPH (Planner)	Nothing to Disclose

Learning Objectives

- Assess factors that influence patients' perceptions of risk
 - *Define* absolute risk, attributable risk, relative risk, and odds ratio
 - *Explain* the differences, advantages, and disadvantages of descriptive studies, observational studies, and prospective studies
 - *Demonstrate* effective risk communication strategies
-

Polling Question 1



Communicating the Risks of Hormonal Contraception

Perceptions of
Risk

Definitions of
Risk

Study Design

Communicating
Risk

Section I

Perceptions of Risk

Definition of Risk

“...The probability that a loss or something dangerous or harmful will occur.”

Taber's Cyclopedic Medical
Dictionary

Polling Question 2



Media Influence

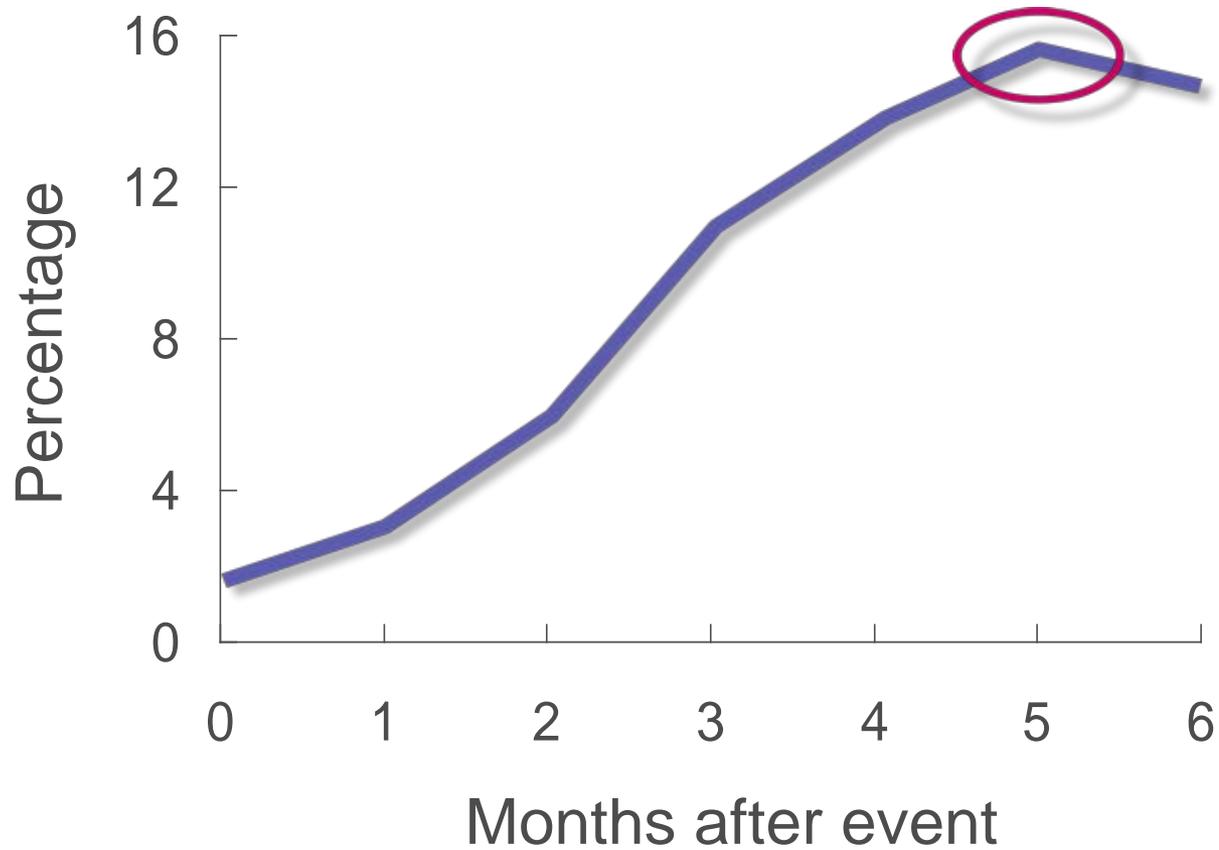


Widespread
dispersion of
reproductive
health
information



Misperception
of
contraceptive
risks

Media Effect on OC Discontinuation



Perception & Interpretation of Risk



Individual



Risk
Presentation



Characteristics
of the Risk

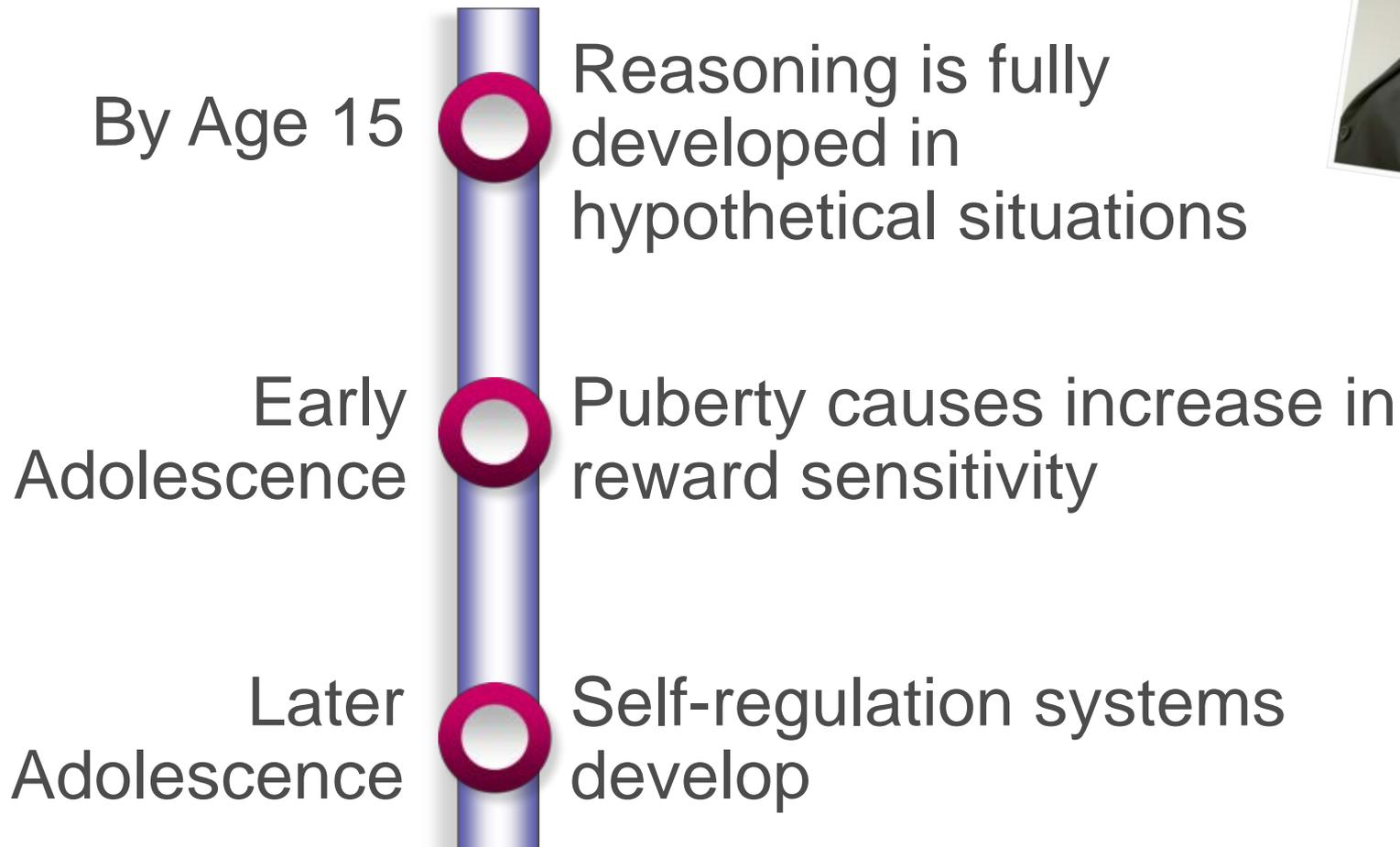
Individual Factors



- Cultural and social factors
- Health literacy
- Level of educational attainment
- Language skills
- Developmental stage
- Preferences for involvement in decision-making
- Human tendencies

more...

Developmental Stage



Risk Presentation



Framing effects

- Attribute framing
- Goal framing

Uncertainty

Trust

Personal relevance

Clarity of presentation

Characteristics of the Risk



People worry more about risks that:

- The individual cannot control
- Are involuntary
- Are associated with particular dread
- Are novel or unfamiliar
- Result from man-made sources
- Are more easily recalled

Section II

Definitions of Risk

Commonly Used Risk Calculations

Absolute
Risk

Attributable
Risk

Relative
Risk

Odds Ratio

Absolute Risk

The percentage of people in a group who experience a discrete event

Number of events
experienced

Total exposure time
of people at risk

Example of Absolute Risk

Of 100,000 women taking third generation OCs, 30 will develop venous thromboembolism (VTE) per year.

Absolute risk

30 per 100,000
woman-years

Attributable Risk

The difference in risk between those exposed and those not exposed

Risk in exposed — Risk in unexposed

Example of Attributable Risk

Risk from
3rd generation OCs

30 VTE per 100,000
woman-years

—

Risk from
2nd generation OCs

15 VTE per 100,000
woman-years

=

Attributable Risk:

15 more VTE per
100,000 woman-years

Relative Risk

Frequency of the outcome in the exposed group divided by the frequency of the outcome in the unexposed group

X

÷

Y

Frequency
Exposed

Frequency
Unexposed

Example of Relative Risk

Absolute Risk:
3rd Generation OCs

30 per 100,000
woman-years

÷

Absolute Risk:
2nd Generation OCs

15 per 100,000
woman-years

=

Relative Risk:

2

Odds Ratio

Used in case-control studies to identify an association between exposure and outcome

X

Odds in
cases

÷

Y

Odds in
controls

Odds Ratio in the VTE Example

	VTE	No VTE	Total
3 rd Generation	30	99,970	100,000
2 nd Generation	15	99,985	100,000
Total	45	99,955	200,000

$$\text{OR} = (30/99,970)/(15/99,985) = 2.0003$$

$$\text{OR} = (30/15)/(99,970/99,985) = 2.0003$$

Case Control Study of VTE

	Cases (VTE)	Controls (No VTE)	Total
3 rd Generation	30	22	52
2 nd Generation	15	22	37
Total	45	44	89

$$\text{OR} = (30/15)/(22/22) = 2.0$$

Section III

Study Design

Overview of Study Designs

Highest Validity



Randomized controlled trial

Clinical trial

Prospective cohort

Retrospective cohort

Case-control

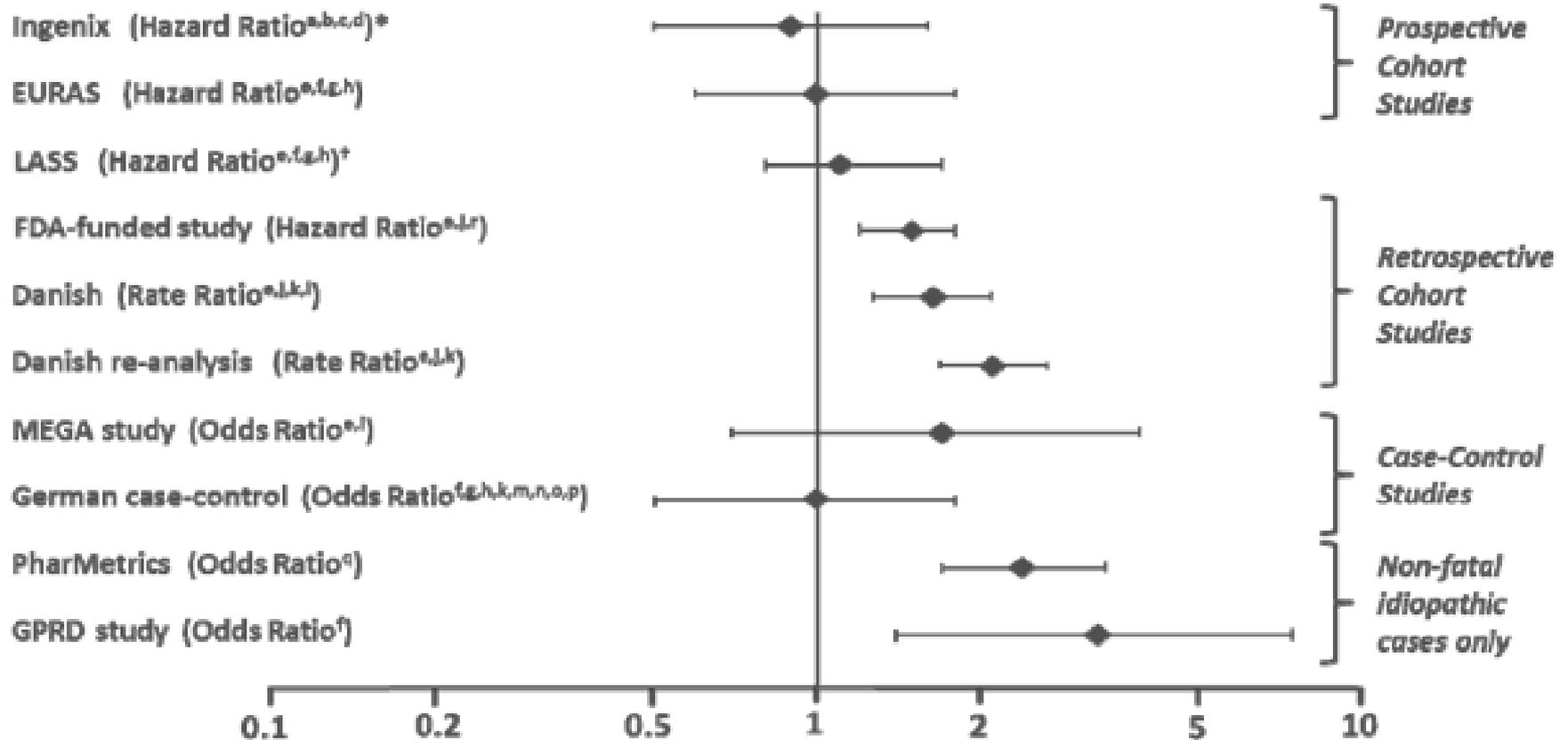
Case series

Lower Validity

VTE Risk Associated with Hormonal Contraceptives

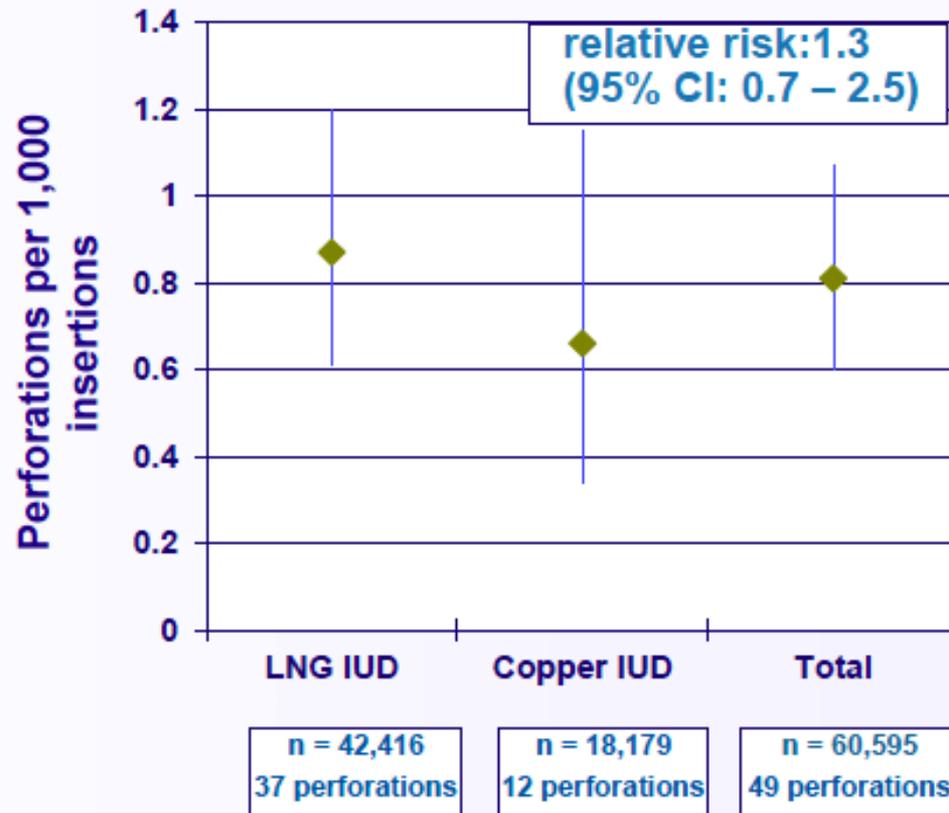
- Information on several factors that are known to affect the risk of VTE is simply not available in the retrospective cohort studies of VTE
 - These factors include:
 - Smoking
 - Body mass index
 - Family history of VTE
 - Precise information on duration of CHC use
-

VTE Risk with Yaz Relative to LNG-Containing COCs



EURAS IUD Study

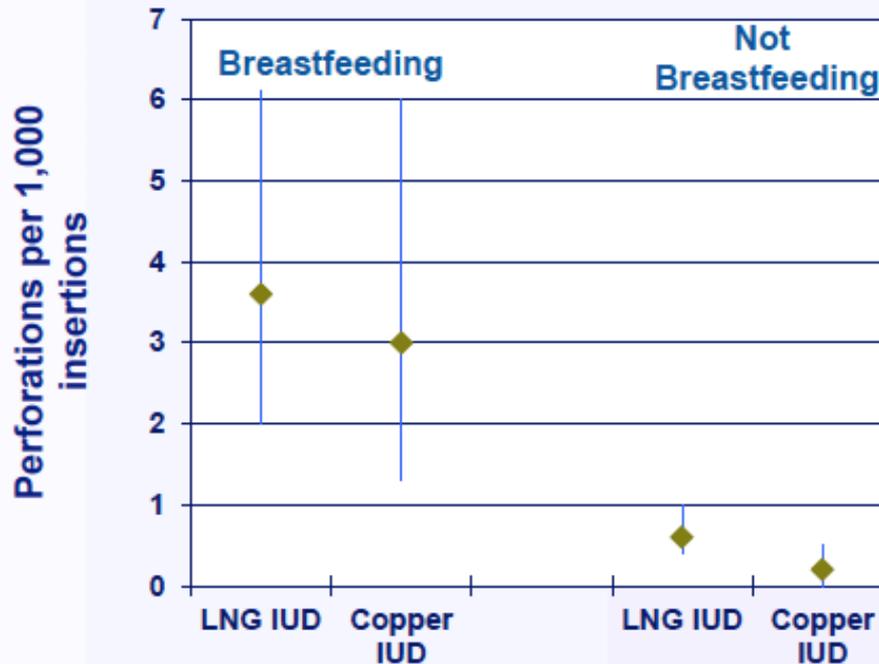
Perforations per 1,000 insertions in LNG IUD and Copper IUD users



EURAS IUD Study

16

Perforations per 1,000 insertions: Breastfeeding vs. non-breastfeeding women



2012 - Barcelona

http://www.pharmacoepi.org/meetings/28ICPE/presentations/OR09_Klaas_Heinemann.pdf

Section IV

Communicating Risk

Comparative Risks

Contraceptive Method/Activity	Chance of Death in 1 Year (per 100,000)
Oral contraceptives	
Nonsmoker aged 35-44	3.0
Smoker aged 35-44	19.2
Diaphragm, condom, or spermicides	0.0
Fertility awareness–based methods	0.0
Tubal sterilization	1.5
Pregnancy (beyond 20 weeks)	14.5
Spontaneous abortion	0.70
Legal induced abortion at 13–15 weeks	1.7
Automobile driving	20

Trussell J. *Contraceptive Technology: Twentieth Revised Edition*. 2011.

Tools: Numerical Data

Try different ways to explain numerical data:



“Three of every 10 women develop nausea.”



“You have a 30% chance of having nausea.”

more...

Tools: Numerical Data (cont' d)

Avoid shifting denominators in proportions:


“Headache developed in
1 of every 333 women.”



“Headache developed in
3 of every 1,000 women.”

more...

Tools: Numerical Data (cont' d)

Use absolute risk:

“OC use increases the risk of heart attack 2.5-fold.”



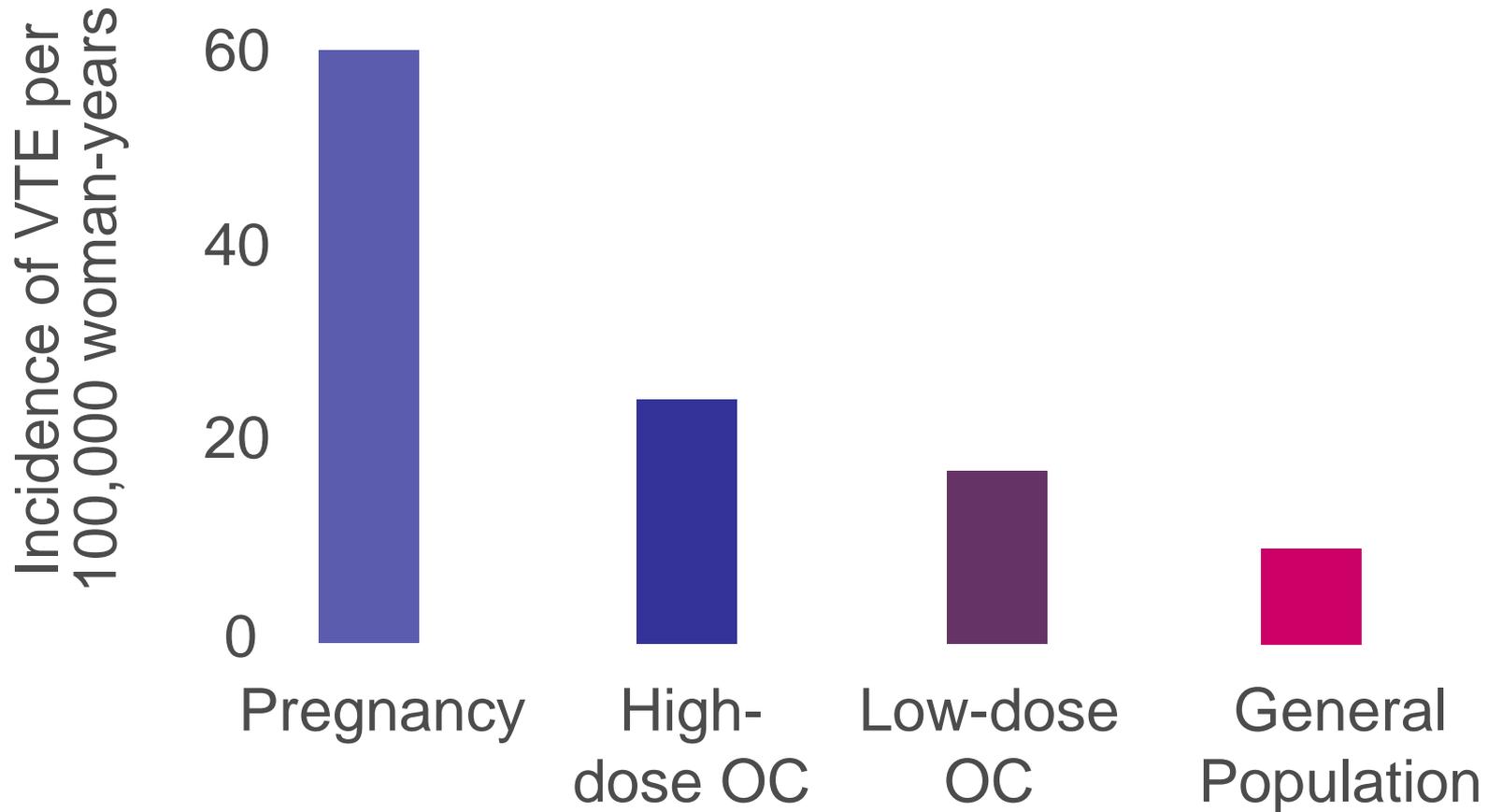
“Heart attacks occur in 4.2 of every 1 million OC users and 1.7 of every 1 million nonusers.”

Tools: Numerical Data (cont' d)

Provide comparisons:

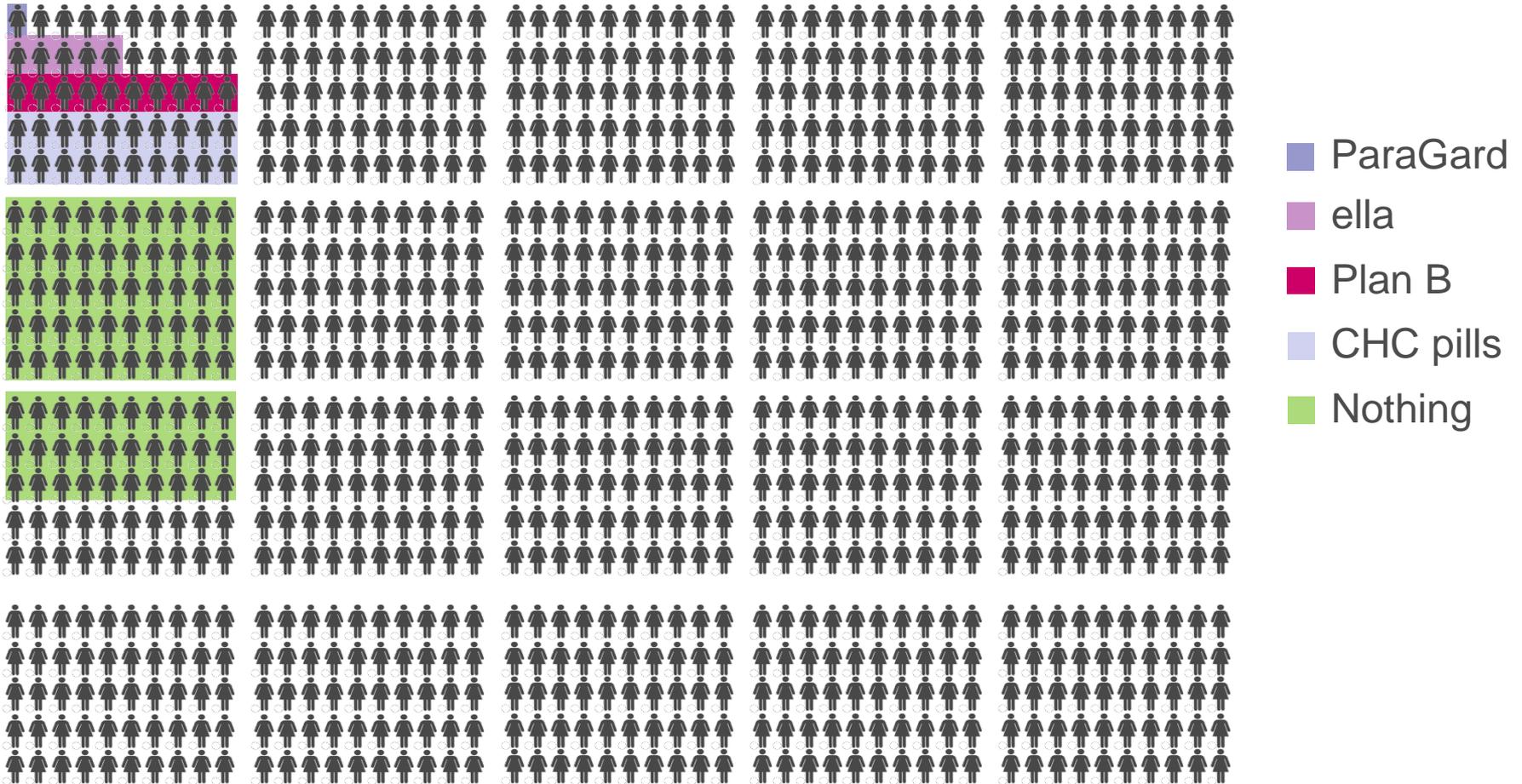
- ✓ “16 of every 100,000 users of low-dose OC have a VTE annually.”
- ✓ “60 of every 100,000 pregnant women have a VTE.”

Tools: Risk Comparisons

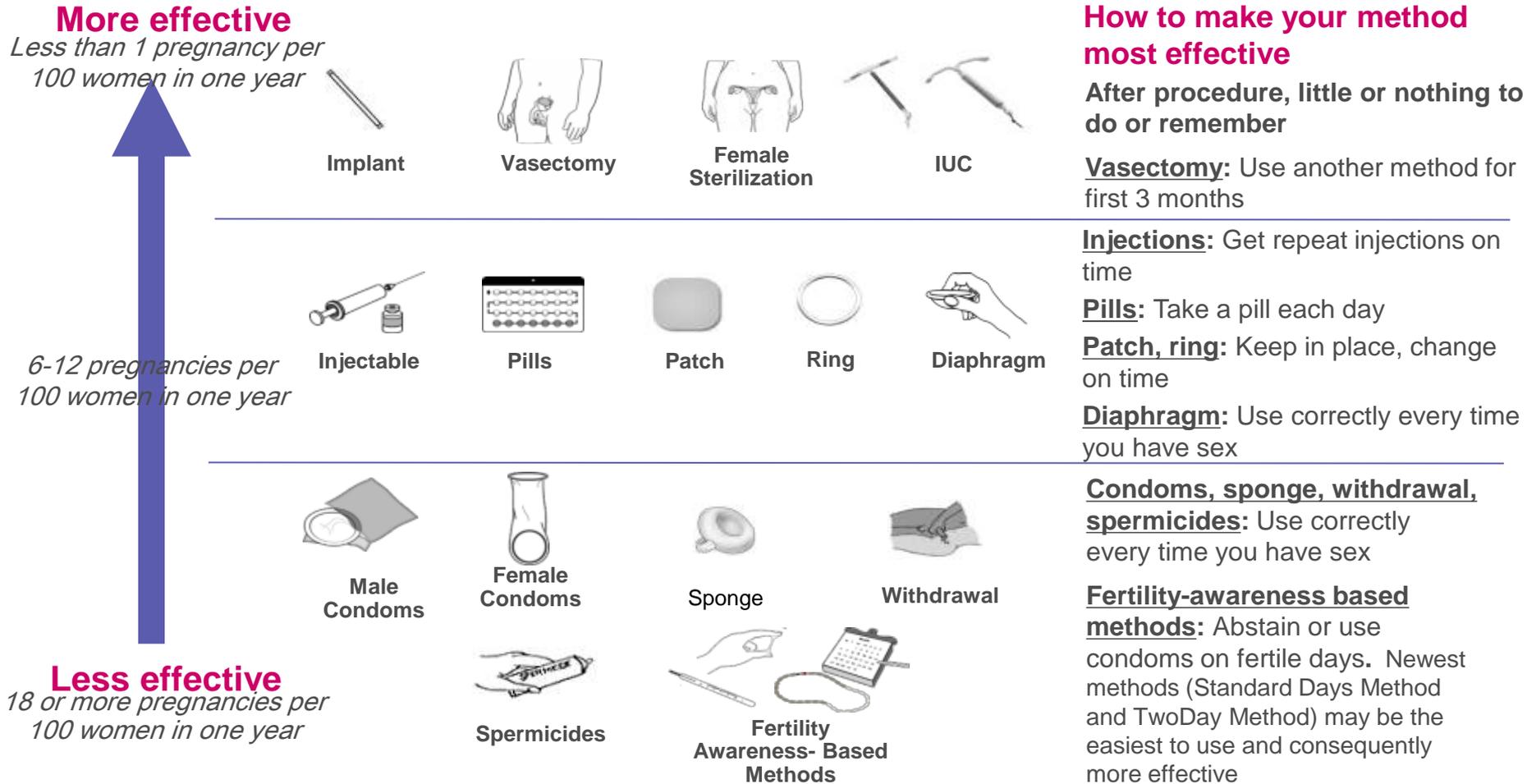


Shulman LP. *J Reprod Med.* 2003. Chang J. In: Surveillance Summaries. 2003.

Tools: Paling Palette: Emergency Contraception Effectiveness



Comparing Typical Effectiveness of Contraceptive Methods



Trussell J, et al. In: Hatcher RA, et al. *Contraceptive Technology*, 20th revised ed. 2011.
Chart adapted from WHO 2007.

Decision Aids for Risk Communication

1

Clarify situation

2

Provide information

3

Clarify patient's values

4

Screen for implementation problems

Tips for Communicating About Alarming Media Reports

- Gather reputable information: ACOG, ARHP, CDC, PPFA.
 - Review relevant editorials in peer-reviewed journals.
 - Help patients gain perspective.
-

Guidance for Risk Communication

- Understand risk and how to communicate it
- Establish a trusting environment conducive to conversation
- Put risks in context
- Remember cultural, literacy, social, and developmental issues
- Remember that discussing risk may make it salient

more...

Guidance for Risk Communication

(cont' d)

- When providing information about risk, discuss risk reduction
- Remember to present absolute risk
- Use numeric, verbal, and visual formats to convey health risk
- Be aware of framing effects
- Use risk comparisons with care
- Have multiple, complementary tools available

Thank You
