

---

# Reducing Clinician and Patient Biases Against Vaginal Insert Therapies

Association of Reproductive Health Professionals  
[www.arhp.org](http://www.arhp.org)

---

# Acknowledgment

---

This session is made possible by an educational grant from Teva Pharmaceuticals.

---

# Expert Medical Advisory Committee

Name	Affiliations	Disclosures
Suzan Goodman, MD, MPH (Advisory Chair)	UCSF Associate Clinical Professor Director, TEACH Program Oakland, California	Dr. Goodman has no affiliations to disclose.
Beth Kruse, MS, CNM, ARHP (Planner)	SRH & Family Planning Nurse Practitioner Seattle-King County Public Health Department Seattle, Washington	Ms. Kruse has no affiliations to disclose.
Sheryl A. Kingsberg, PhD (Planner)	University Hospitals Case Medical Center/Case Western Reserve University Cleveland, OH	Dr. Kingsberg receives consulting fees from Pfizer, Shionogi, Trimel, Sprout, BioSante, NovoNordisk, Apricus, Emotional Brain, and Palatin. Dr. Kingsberg has ownership interest and receives consulting fees from Viveve.

# ARHP Consultants and Staff

---

Name	Affiliations	Disclosures
Mary King, PhD (Medical Writer)	Consultant Medical Writer	Nothing to disclose.
Beth Jordan Mynett, MD (Planner)	Medical Director ARHP	Nothing to disclose.
Amy Swann, MA, CAE (Planner)	Director of Education ARHP	Nothing to disclose.
Lanita Williams, MPH (Planner)	Program Manager ARHP	Nothing to disclose.

---

# Learning Objectives

---

- Explain the currently available uses for vaginal insert therapies, including their indications, efficacy, advantages, disadvantages, and adverse effects.
  - Use evidence-based resources to more effectively communicate and to counter common patient misconceptions about the vagina, including myths and fears about female anatomy and vaginal insert therapies from adolescence to menopause and beyond.
- more...*
-

# Learning Objectives (continued)

---

- Apply principles of patient-centered communication when discussing vaginal insert therapies.
-

# Outline

---

- Introduction to vaginal insert therapies
  - Contraception
  - Treatments for vaginitis and other infections
  - Menopausal therapies
  - Pelvic support
  - Case studies
  - Practice Points
-

# Question 1:

---

Terry is 35 years old, single, and a smoker. She does not have a partner at the moment but anticipates needing contraception occasionally during the next few months. She wants to reduce her risk of pregnancy as much as possible while still maintaining personal control over when she uses contraception. Which of these vaginal/intrauterine contraceptive methods would you recommend as a top option?



**C. Diaphragm**

---

## Question 2:

---

Emmy is a 14-year-old who comes to you asking for birth control. She has been having regular intercourse with her boyfriend and is very concerned about becoming pregnant. She has not used any type of contraception before, and after hearing about the different options, just says, “I guess maybe the pill would be best” and shakes her head when you ask her about using a vaginal ring or an IUD. You



**B. Ask specific questions to check her understanding of anatomy and vaginal/uterine contraceptives before ruling them out as options**

---

## Question 3:

---

Maria, age 43, has had 4 vaginal deliveries. She comes to you complaining of constant pressure “down there,” painful voiding, vaginal discharge, and occasional urinary incontinence. You discover she has bacterial vaginitis and poor pelvic tone, with cystocele, rectocele and a mild degree of uterine prolapse. You:



**C. Treat the vaginitis refer her for surgical consultation due to multiple organ involvement**

---

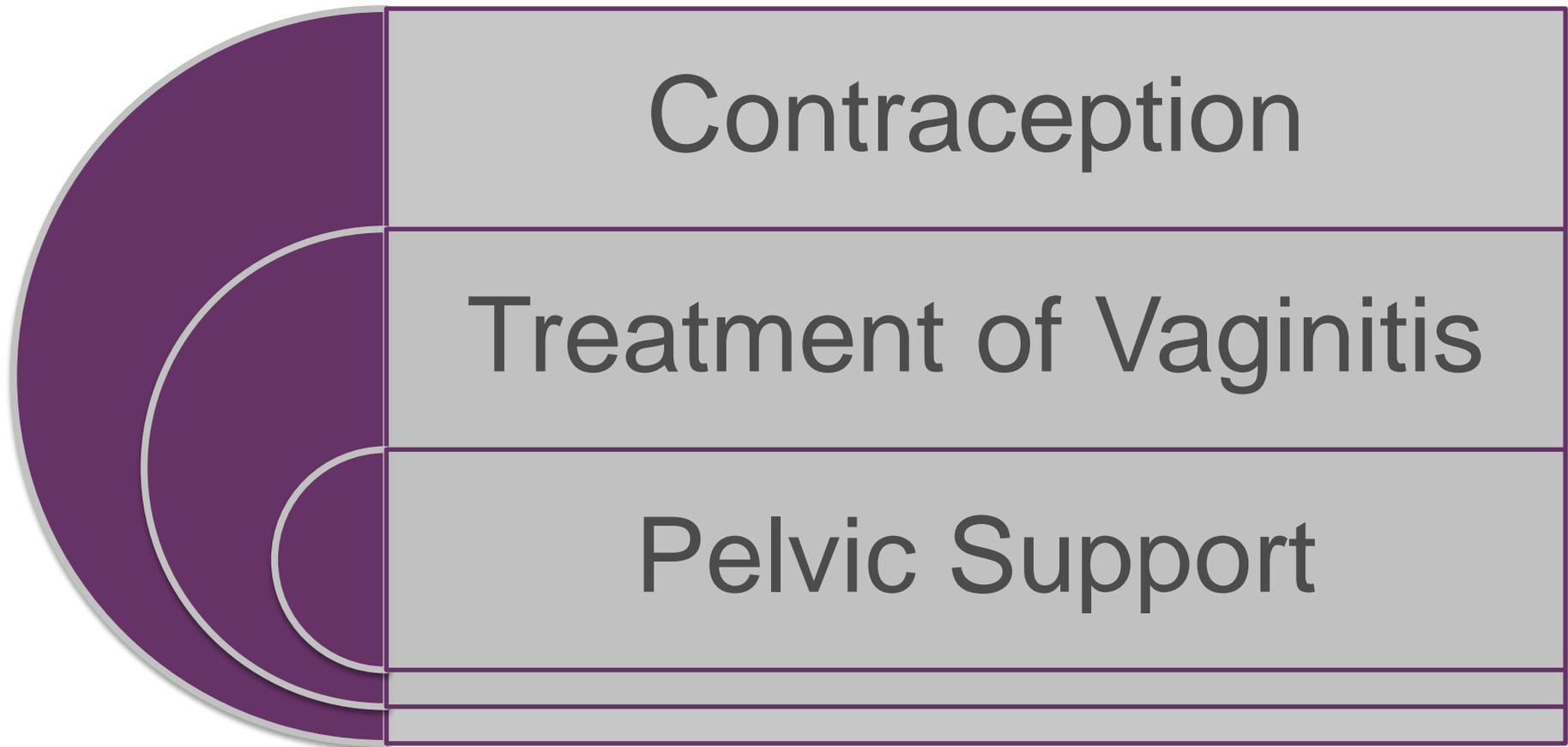
---

# Introduction

---

# Common Uses of Vaginal Insert Therapies

---



# Many Types of Vaginal Insert Therapies Are Available

---

Vaginal Ring

Cervical Cap

Diaphragm

Sponge

Female  
Condom

Gels, creams,  
tablets

Suppositories

Pessaries

---

# Vaginal Insert Therapies Have Advantages Over Oral Dosing

---

- Continuous low dosing
- Less frequent dosing
- Fewer side effects
- More patient control
- Improved patient satisfaction, adherence

# Why Are Vaginal Insert Therapies Underused?

---



# We Still Avoid the Word “Vagina”

---

- “Vagina”
  - Originally meant “sheath” or “scabbard” (a protective covering for a sword)
  - Adopted in 17th century to refer to female genitalia
- 21st century—insufficient clear, accurate info available for public
- Perceptions are slowly changing



# Bias Limits Discussion of Vaginal Issues

---

Clinicians may have difficulty discussing sexuality with patients

<50%

of women comfortable discussing vaginal issues related to **contraceptives**

53%

of postmenopausal women comfortable discussing vaginal **discomfort**

37%

of women would either hesitate to discuss or not mention the subject

# Misinformation About the Vagina Is Common

---

Patients report that they:

- Lack basic knowledge about vaginal health, including during/after menopause
- Have discomfort with touching
- Misunderstand anatomy and/or placement
- Are uncertain whether partner will perceive the presence of a vaginal insert therapy



# Positive, Unbiased Discussion Is Key to Successful Communication

---

- Provide information
- Share decision-making
- Recognize that patient may have biases
- Match communication style to women's preferences and solicited advice
- Be aware that race/ethnicity affects communication

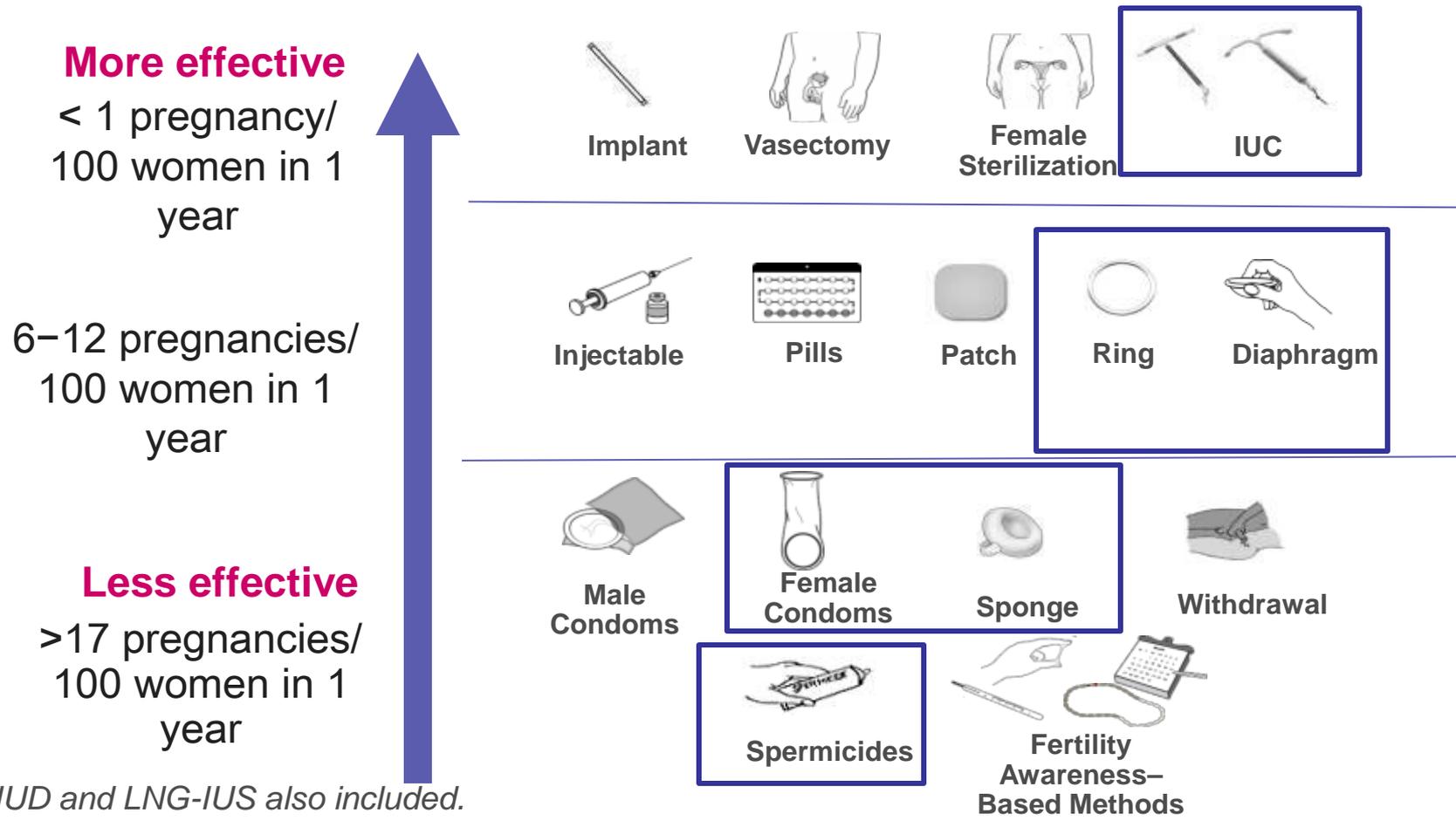


---

# Contraception

---

# Quick Review: Typical Effectiveness of Vaginal\* Insert Contraceptive Methods



Trussell J, et al. In: Hatcher RA, et al., eds. *Contraceptive Technology*. 2011. Chart adapted from WHO 2007.

# Vaginal Rings Were Developed in 1960s for Contraception

---

- Circular devices inserted into the vagina in contact with the vaginal epithelium
- Release a drug in a controlled fashion



# Vaginal Ring: Advantages and Disadvantages

---

## Advantages

- Releases hormones slowly and steadily
- Requires lower hormone doses than oral contraceptives
- Allows patient to retain control over insertion and removal

## Disadvantages

- Involves exposure to hormones
- Requires patient to remember special insertion cycle
- Linked to side effects: vaginitis, leukorrhea, headaches, discomfort

# Vaginal Ring: Contraindications Relate Mostly to Estrogen

---

Contraindications include:

- History of cardiovascular events or thromboembolism
- Advanced hypertension or diabetes, liver disease, headaches w/ neurological manifestations
- Smokers over age 35
- Women with known or suspected breast, endometrial, vaginal, or cervical cancer or undiagnosed abnormal vaginal bleeding



# Diaphragm

---

- A flexible rubber cup that is inserted into the vagina and fits over the cervix
- Used with a spermicide



# Diaphragm: Advantages and Disadvantages



## Advantages

- Barrier method; no hormones are introduced
- Use is controlled by patient

## Disadvantages

- Requires fitting and periodic refitting
- Requires use with spermicide
- Requires periodic insertion of additional spermicide
- Carries risk of toxic shock if left in place > 24 hours

# Other Vaginal Options Include Female Condom, Sponge, Cervical Cap, Spermicide

---

## Selected advantages:

- Woman controls use
- Less expensive options
- No fitting or office visits are required for most
- Female condom offers protection against STIs, HIV/AIDS
- Sponge is effective for up to 24 hours, regardless of the number of times intercourse occurs



# Other Vaginal Options for Contraception (continued)

---

## **Selected disadvantages:**

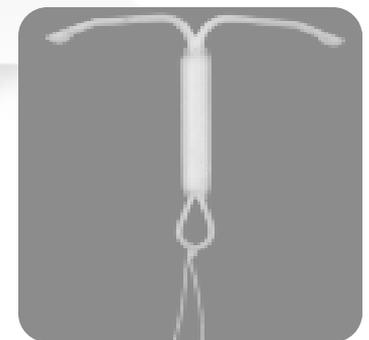
- Less effective than other methods
- Female condom
  - May cause vaginal discomfort, penile irritation
- Films and suppositories
  - Require 10–15 minutes for activation, which may interfere with spontaneity
- Sponge:
  - As with other absorbent products, if left in place for longer than 24–30 hours, the risk of vaginal yeast infection increases



# Intrauterine Contraceptives Suffer from Same Biases as Vaginal Contraceptives

---

- Three IUDs currently available:
  - Copper IUD
  - Two LNG-IUS:
    - 52 mg
    - Newer 13.5 mg
- Not strictly vaginal insert therapies
- However, similar biases exist
- In 2011, 7.7% of US contraceptors used the IUD



# In Brief: Treatment of Vaginal Infections

---

Infection	Vaginal Insert Therapy*
Vulvovaginal candidiasis, uncomplicated	Butoconazole 2% cream; 2% sustained-release cream
	Clotrimazole cream (1%, 2%)
	Miconazole cream (2%, 4%); suppositories (100 mg, 200 mg, 1,200 mg)
	Nystatin tablet (100,000 unit)
	Tioconazole ointment (6.5%)
Vulvovaginal candidiasis, non-albicans	Terconazole cream (0.4%, 0.8%); suppository (80 mg)
	Non-fluconazole azole, topical
	Boric acid gelatin capsule

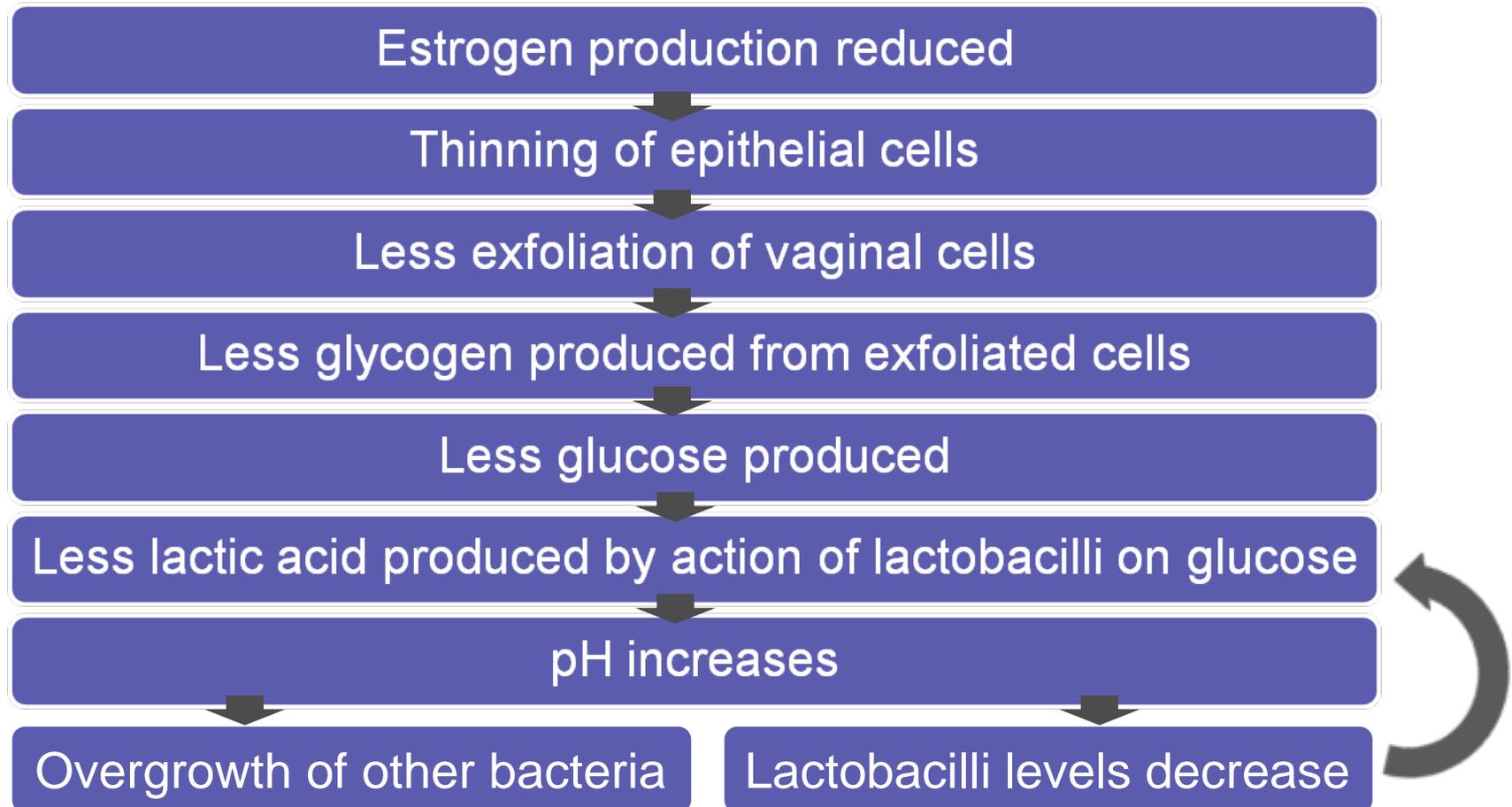
---

# Menopausal Vaginal Therapies

---

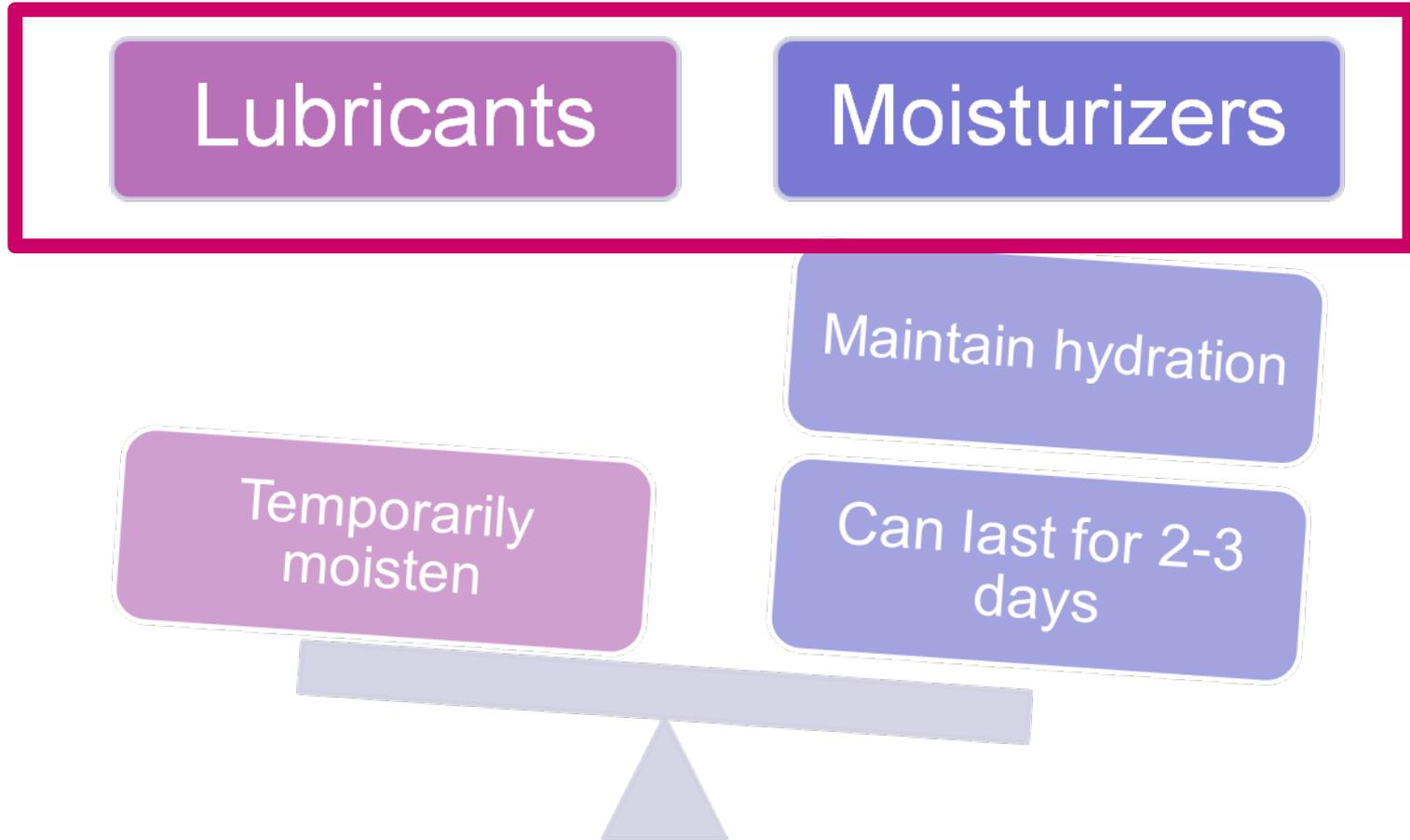
# Changes in VV Epithelium: Mechanism of Action

---



# Non-hormonal Therapies

---



# Non-hormonal Therapy: Moisturizers

---

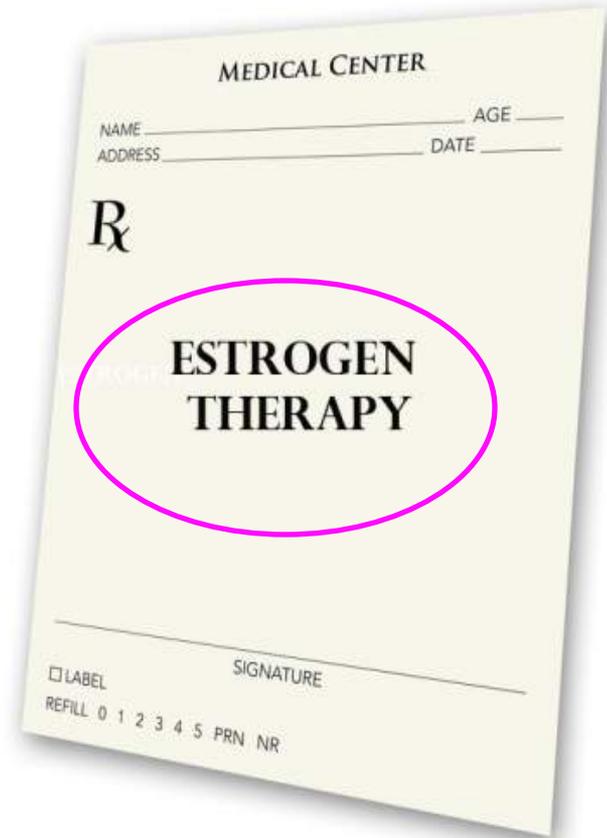
- Gels or creams used regularly to maintain hydration of the vaginal epithelium for long-term relief of vaginal dryness
- Effects last 2–3 days



# Local Estrogen Therapy

---

Low-dose vaginal estrogen therapy is effective for women with symptoms of vaginal dryness and associated pain or discomfort with urination and intercourse



# Local Estrogen Therapies Treat Natural Drop in Vaginal Estrogen

---



Stress incontinence, risk of pelvic organ prolapse, painful sexual intercourse, and/or urination can occur



Local estrogen can improve sexual desire, arousal, orgasmic function

# Low-Dose Vaginal Estrogen Therapies

---

Local estrogen therapies:

- Include creams, tablets, and vaginal rings
- Lead to low levels of circulating estrogen
- Are not associated with endometrial hyperplasia



# In Brief: Vaginal Estrogens

---

Composition	Dosing
<b>Vaginal creams</b> <ul style="list-style-type: none"><li>•Estradiol</li></ul>	- <i>Initial</i> : 2–4 g/day for 1–2 weeks. <i>Maintenance</i> : 1 g/day (0.1 mg of active ingredient per gram)
<ul style="list-style-type: none"><li>•Conjugated estrogens</li></ul>	•0.5–1.0 g, 3x weekly (0.625 mg of active ingredient per gram)
<b>Vaginal ring</b> <ul style="list-style-type: none"><li>•Estradiol</li></ul>	•Device releases 7.5 µg per day for 90 days
<ul style="list-style-type: none"><li>•Estradiol acetate (2 strengths)</li></ul>	•Device releases equivalent of 0.05 or 0.10 mg of estradiol per day for 90 days
<b>Vaginal tablet</b> <ul style="list-style-type: none"><li>•Estradiol acetate</li></ul>	<i>Initial</i> : 1 tablet per day for 2 weeks. <i>Maintenance</i> : 1 tablet twice weekly (equivalent to 10 µg of estradiol)

---

# Pelvic Support: Vaginal Pessaries

A vaginal pessary is a removable device placed into the vagina, usually to help manage pelvic organ prolapse.

---

# Pelvic Prolapse

---

- Symptoms:
  - Pressure
  - Pelvic floor bulging
  - Painful voiding
  - Urinary or fecal incontinence

# Several Factors Increase Risk of Prolapse

---

- One or more pregnancies of vaginal births
- Giving birth to a large baby
- Increasing age
- Frequent heavy lifting
- Chronic coughing
- Prior pelvic surgery
- Frequent straining during bowel movements
- Genetic predisposition
- Being Hispanic or white



# Vaginal Pessaries

---

- Pessaries provide low-risk, inexpensive alternative to surgery
- Success rates 63%–86%
- Several types, shapes, & sizes available

# Vaginal Pessaries (continued)

---

- Proper fitting depends on training and experience of health care provider
- Few nursing or medical programs teach pessary use
- Use with caution in women with
  - Active vaginal infection
  - Persistent vaginal erosion
  - Ulceration or severe vaginal atrophy

# In Brief: Other Vaginal Insert Therapies Under Development

Therapy	Purpose
3-month intravaginal ring with levonorgestrel plus tenofovir	Contraception with HIV prevention
Sponges with antibiotic (e.g., clindamycin)	Treatment of bacterial vaginal infection
Intravaginal ring with microbicides	STI prevention
Vaginal ring with a single antiretroviral, such as dapivirine	HIV prevention
Vaginal ring with combined tenofovir plus acyclovir	HIV and herpes simplex virus prevention

Rossi S, et al. *Pharm Dev Technol.* 2012; Brache V, et al. *Contraception.* 2012; Jensen JT. *Contraception.* 2012; Baum MM, et al. *J Pharm Sci.* 2012; Malcolm RK, et al. *Int J Womens Health.* 2012; Moss JA, et al. *Antimicrob Agents Chemother.* 2012.

# Case Study 1: Me'shell

---



- 18-year-old G1P1
  - Presents for irregular bleeding and contraceptive management
  - “My period is all over the place – I don’t feel right. I just want my normal period back.”
  - Recent reproductive history:
    - Normal spontaneous vaginal delivery (NSVD) about 9 months ago
    - Depot medroxyprogesterone: immediately PP and every 12-13 weeks thereafter.
    - Stopped breastfeeding at 6 months
-

# Case Study: Me'shell

## (continued)

---



### Medical history:

- 6-week postpartum visit was normal
  - Medications: Ibuprofen for headaches, which have become more frequent and severe since she started Depo.
  - Allergies: Seasonal; no medication or latex allergies
  - Prior to pregnancy and Depo use, menses were typically monthly, with light flow for 2 days, tapering to spotting for 1–2 days, and occasional mild first-day cramping.
  - Last DMPA injection 12 weeks ago (another office)
-

# Case Study: Me'shell (continued)

---



## **Sexual and reproductive history:**

- One sexual partner during the last 6 months (male)
  - Uses condoms consistently; is in a healthy, committed relationship
  - Menarche at age 14; sexual debut at age 15; pregnancy at age 17 concluded in term NSVD without complications of pregnancy or birth
-

# Case Study: Me'shell (continued)

---



## Diagnostic tests:

- Urine pregnancy test
  - Vaginal swab nucleic acid amplification tests (NAATs) for *Chlamydia trachomatis*/*Neisseria gonorrhoeae*
  - HIV and syphilis serologies
-

# Case Study: Me'shell (continued)

---



## What steps would you include in management?

- Reassure
    - Irregular bleeding and amenorrhea are common with the use of any progestin-only method and are not harmful
  - Validate
    - Women's feelings about their own menses are individual as well as cultural
  - Inform and Review
    - Discuss the range of contraceptive methods (using drawings and models) and identify key differences
-

# Case Study: Me'shell (continued)

---



- Ask “What is most important to you about a birth control method?”
- Assess comfort with different types, frequency of participation, potential side effects

**She is interested in learning more about the vaginal ring. What is your next step?**

- Assess basic comfort and familiarity with genital and sexual health in general, and the vagina in particular
-

# Case Study: Me'shell (continued)

---



## Treatment Plan:

- Method-specific counseling:
    - Review mechanism of action, instructions for use, common side effects and anticipatory guidance, troubleshooting, warning signs for estrogen use
  - Provide opportunity for Me'shell to practice insertion of vaginal ring
  - Dispensing:
    - 3 months to start (method is new to her)
-

# Communicating with Adolescents

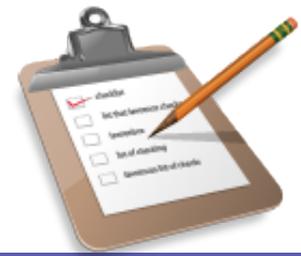
---

- Provide adolescents with individualized discussions
- See patients alone
- Ensure confidentiality
- Demonstrate with pictures or models



# Practice Points

---



## 1. Clinical evaluation

- Engage client in determining her own interests and priorities for birth control selection
- Assess general comfort with genitals/vagina (use of tampons, prior self-exam, etc)
- Appreciate issues that are unique to each patient

## 2. Method-specific counseling

- Offer the patient an opportunity to practice insertion before she leaves the clinic
-

# Case Study 2: Johanna

---

- Johanna, 55 years old, notes “mild irritation down there”
- LMP 3 years ago
- Johanna is reluctant to provide additional details until the health care provider begins a focused interview



# Case Study: Johanna

## (continued)

---



- No vaginal discharge; vaginal dryness x ~3 years
  - Mutually monogamous, healthy relationship with male partner x 8 yrs
  - Libido: “Sex? Well, I’m not that into it lately”
  - Painful sexual intercourse x 1 year
  - Mild urinary symptoms: frequency and stress incontinence x 6 months
  - Smokes: about 5 cigarettes/day x 25 years
-

# Case Study: Johanna

## (continued)

---



### Previous workup:

- Negative urinalysis
  - Negative wet mount
  - Negative *C. trachomatis*/*N. gonorrhoeae*
  - FSH within normal postmenopausal range
-

# Case Study: Johanna

## (continued)

---



### Physical exam:

- Pale, dry skin
  - Thin, friable vaginal epithelium
  - Decreased elasticity of vaginal walls
  - Vaginal dryness
  - Elevated vaginal pH > 4.6
-

# Case Study: Johanna

## (continued)

---



- Probable cause: postmenopausal epithelial changes with associated urinary symptoms, and decreased libido (multifactorial) – consistent with reduction in estrogen production
  - Treatment options:
    - Vaginal moisturizers and lubricants (nonhormonal)
    - Lifestyle changes
    - Vaginal estrogen
-

# Case Study: Johanna

## (continued)

---



### Treatment plan:

1. Discuss options with Johanna, requesting her input
2. Recommend:
  - Lifestyle changes
  - Regular use of vaginal moisturizer
  - Vaginal lubricant with intercourse
  - Low-dose vaginal estrogen

# Communicating with Peri- and Postmenopausal Women

---

- >50% want to discuss sexual concerns, but health care providers initiate conversation only 19% of time
- Postmenopausal women want more information about actual risks of hormone therapy *from their provider*



# Practice Points

---

- Uncomfortable vulvovaginal symptoms are a common postmenopausal issue
- Patients may hesitate to raise this topic but often wish they had more information
- Health care providers should ask specific questions and provide full information



# Resources



Association of Reproductive Health Professionals

ARHP

Reproductive Health Topics | Publications & Resources | Professional Education | Newsroom | Membership | Policy & Advocacy | About Us

PATIENT RESOURCES

**Method Match**

You are unique and so are your birth control needs. Use this tool to compare methods on the criteria that matter most to you. Find the method that matches your lifestyle by sorting, filtering, and comparing up to 4 methods side-by-side by clicking the [X] under each method.

Extremely Effective

Very Effective

Narrow Results

- Does not contain hormones
- Protects against STDs
- Does not require testosterone or other drugs
- No on-again, off-again required
- Quickly reversible
- May decrease sexually transmitted and STIs
- Private/Not detectable
- Works after sex

ACOG

THE AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS

Member Login | My ACOG | About ACOG

Enter Search Keyword

Home | Resources & Publications | Practice Management | Education & Events | Advocacy | For Patients | About ACOG

Resources & Publications

Home / Resources & Publications

Find an Ob-G

ACOG Today Newsletters

Articles & Resources

Clinical Review

Committee Opinions

Department Publications

Episiotomy

Green Journal

Guidelines for Adolescent Health Care

**Featured Committee Opinion**

**Ethical Issues in Pandemic Influenza Planning Concerning Pregnant Women**

Pregnant women traditionally have been assigned priority in the allocation of prevention and treatment resources during outbreaks of influenza because of their increased risk of morbidity and mortality. The Committee on Ethics of the American College of Obstetricians and Gynecologists explores ethical justifications for assigning priority for prevention and treatment resources to pregnant women during an influenza pandemic, makes recommendations to incorporate ethical issues in pandemic influenza planning concerning pregnant women, and calls for pandemic preparedness efforts to include clinical research specifically designed to address safety and efficacy of treatment interventions or prevention strategies used by pregnant women.

PROLOG eModule

PROLOG are a brief concept the best of PROLOG PRECIS if online m format. [www.acog.org/e](http://www.acog.org/e)

Subscribe Today

Clinical Women's Care is for practicing primary care to [www.clinicalpdp](http://www.clinicalpdp)

Neonatal or Infant

Ovarian Cancer

www.menopause.org

Member Log In | Join | Donate | Store | About NAMS

THE NORTH AMERICAN MENOPAUSE SOCIETY

Promoting women's health at midlife and beyond

For Professionals | Annual Meetings | Publications | For Women | Commercial Supporters | Press Room

**For Professionals**

Submit your abstract for the NAMS Annual Meeting **Deadline is April 30**

[Learn More](#)

**For Women**

Explore the very latest on peer-reviewed research, menopause symptoms, tools, treatments, and more...

[Learn More](#)

**Clinician's Textbook**

- Login
- Sample
- Purchase Online
- Purchase Using Order Form

**MenoPause: the blog**

Reporting and interpreting new menopause research & midlife health news for you

# Question 1:

---

Terry is 35 years old, single, and a smoker. She does not have a partner at the moment but anticipates needing contraception occasionally during the next few months. She wants to reduce her risk of pregnancy as much as possible while still maintaining personal control over when she uses contraception. Which of these vaginal/intrauterine contraceptive methods would you recommend as a top option?



**C. Diaphragm**

---

## Question 2:

---

Emmy is a 14-year-old who comes to you asking for birth control. She has been having regular intercourse with her boyfriend and is very concerned about becoming pregnant. She has not used any type of contraception before, and after hearing about the different options, just says, “I guess maybe the pill would be best” and shakes her head when you ask her about using a vaginal ring or an IUD. You



**B. Ask specific questions to check her understanding of anatomy and vaginal/uterine contraceptives before ruling them out as options**

---

## Question 3:

---

Maria, age 43, has had 4 vaginal deliveries. She comes to you complaining of constant pressure “down there,” painful voiding, vaginal discharge, and occasional urinary incontinence. You discover she has bacterial vaginitis and poor pelvic tone, with cystocele, rectocele and a mild degree of uterine prolapse. You:



**C. Treat the vaginitis refer her for surgical consultation due to multiple organ involvement**

---