Reducing Clinician and Patient Biases Against Vaginal Insert Therapies

Association of Reproductive Health Professionals
www.arhp.org
Acknowledgment

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## Expert Medical Advisory Committee

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<th>Affiliations</th>
<th>Disclosures</th>
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<tbody>
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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.
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

- Contraception
- Treatment of Vaginitis
- Pelvic Support
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

Srikrishna S. *Int Urogynecol J.* 2012.
Why Are Vaginal Insert Therapies Underused?

Srikrishna S. *Int Urogynecol J.* 2012.
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

Blackledge C. 2003.
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

More effective
< 1 pregnancy/
100 women in 1 year

6–12 pregnancies/
100 women in 1 year

Less effective
>17 pregnancies/
100 women in 1 year

* IUD and LNG-IUS also included.

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**

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Releases hormones slowly and steadily</td>
<td>• Involves exposure to hormones</td>
</tr>
<tr>
<td>• Requires lower hormone doses than oral contraceptives</td>
<td>• Requires patient to remember special insertion cycle</td>
</tr>
<tr>
<td>• Allows patient to retain control over insertion and removal</td>
<td>• Linked to side effects: vaginitis, leukorrhea, headaches, discomfort</td>
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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

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
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<tbody>
<tr>
<td>• Barrier method; no hormones are introduced</td>
<td>• Requires fitting and periodic refitting</td>
</tr>
<tr>
<td>• Use is controlled by patient</td>
<td>• Requires use with spermicide</td>
</tr>
<tr>
<td></td>
<td>• Requires periodic insertion of additional spermicide</td>
</tr>
<tr>
<td></td>
<td>• Carries risk of toxic shock if left in place &gt; 24 hours</td>
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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

<table>
<thead>
<tr>
<th>Infection</th>
<th>Vaginal Insert Therapy*</th>
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<tbody>
<tr>
<td>Vulvovaginal candidiasis, uncomplicated</td>
<td>Butoconazole 2% cream; 2% sustained-release cream</td>
</tr>
<tr>
<td></td>
<td>Clotrimazole cream (1%, 2%)</td>
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<tr>
<td></td>
<td>Miconazole cream (2%, 4%); suppositories (100 mg, 200 mg, 1,200 mg)</td>
</tr>
<tr>
<td></td>
<td>Nystatin tablet (100,000 unit)</td>
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<tr>
<td></td>
<td>Tioconazole ointment (6.5%)</td>
</tr>
<tr>
<td></td>
<td>Terconazole cream (0.4%, 0.8%); suppository (80 mg)</td>
</tr>
<tr>
<td>Vulvovaginal candidiasis, non-albicans</td>
<td>Non-fluconazole azole, topical</td>
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<tr>
<td></td>
<td>Boric acid gelatin capsule</td>
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Changes in VV Epithelium: Mechanism of Action

- Estrogen production reduced
- Thinning of epithelial cells
- Less exfoliation of vaginal cells
- Less glycogen produced from exfoliated cells
- Less glucose produced
- Less lactic acid produced by action of lactobacilli on glucose
- pH increases
- Overgrowth of other bacteria
- Lactobacilli levels decrease

Non-hormonal Therapies

- **Lubricants**
  - Temporarily moisten

- **Moisturizers**
  - Maintain hydration
  - Can last for 2-3 days

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

<table>
<thead>
<tr>
<th>Composition</th>
<th>Dosing</th>
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<tr>
<td><strong>Vaginal creams</strong></td>
<td><strong>Initial</strong>: 2–4 g/day for 1–2 weeks. <strong>Maintenance</strong>: 1 g/day (0.1 mg of active ingredient per gram)</td>
</tr>
<tr>
<td>• Estradiol</td>
<td><strong>0.5–1.0 g, 3x weekly (0.625 mg of active ingredient per gram)</strong></td>
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<tr>
<td>• Conjugated estrogens</td>
<td></td>
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<tr>
<td><strong>Vaginal ring</strong></td>
<td><strong>Device releases 7.5 μg per day for 90 days</strong></td>
</tr>
<tr>
<td>• Estradiol</td>
<td><strong>Device releases equivalent of 0.05 or 0.10 mg of estradiol per day for 90 days</strong></td>
</tr>
<tr>
<td>• Estradiol acetate (2 strengths)</td>
<td></td>
</tr>
<tr>
<td><strong>Vaginal tablet</strong></td>
<td><strong>Initial</strong>: 1 tablet per day for 2 weeks. <strong>Maintenance</strong>: 1 tablet twice weekly (equivalent to 10 μg of estradiol)</td>
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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

www.mayoclinic.com
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

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

ACOG
The American Congress of Obstetricians and Gynecologists

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 and vaccines as they are used by pregnant women.

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For Women

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Deadline is April 30

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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?

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