Menopause Update 2022:

Focus on Hot Flashes, GSM/Atrophic Vaginitis and Libido

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Onset, Massachusetts

Mimi Secor, DNP, FNP-BC, FAANP, FAAN

- FNP for 44 years specializing in Women's Health
- National Speaker, Educator, Entrepreneur, Health Coach
- Senior Faculty, Advanced Practice Education Associates (APEA)

- DNP-2015, Rocky Mountain University, Provo, Utah
- 2020, Outstanding Alumnae Award, Rocky Mountain University

- Coauthor of 2018 (4th ed) Advanced Health Assessment of Women: Skills and Procedures; (2nd ed) Fast Facts about the GYN Exam

- Passion for helping NPs/PAs/people to become healthy and fit

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Presenter Disclosure Information

Menopause Update:
Focus on
Hot Flashes, Atrophic Vaginitis

NONE

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Menopause Update: Objectives

- Describe epidemiology/physiology of menopause, Metabolic changes/Risks, Vasomotor Symptoms (VMS), Vulvovaginal Atrophy (VVA),15 mins
- Discuss diagnosis of VMS and Vulvovaginal Atrophy, 15 mins
- Explain pharm/non pharm options/alternatives for treatment of VMS, VVA, and HSDD*, 30 mins

*HSDD = hypoactive sexual desire disorder

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Menopause Diagnosis
52 Million in 2010: 6,000 day

- Average age 50-52 years
- **12 months since FMP** (final menstrual period)
- NO labs needed
- **FSH over 30** mIU/m
  - I week off CHC*, or 1 month if inconclusive
- Estradiol < 20 pg/ml
- Vasomotor symptoms
- **Contraception x 12 months after FMP!!!**

*CHC/ combination contraceptive contraceptive

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Vasomotor Symptoms (VMS) Epidemiology: COMMON

- **75% of perimenopausal** women experience these
- Caused by fluctuations in hormones
- BUT exact mechanism unclear

- **Duration x 6 months- 2 years, up to 5-12+ years !!!**
- **Average duration 4-7 years**
- **10-25% C/o severe symptoms**
- If severe sx in perimenopause- duration 11+ years
- **May be a marker for subclinical CVD!**
- Ethnic variation: African American 46%, Japanese 18%
- **Surgical menopause = More severe symptoms!!!**

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Early Post-Menopause Complications:

- **If Hot Flashes (VMS) are NOT treated:**
  - **Higher rate of dementia**
  - **Neurocognitive decline**
  - **Parkinson's**
- **VMS assoc. w/ massive blood flow shift in the brain! NOT GOOD FOR Brain Function or Cognition!**
- **Exacerbated by sleep disturbances!!!**

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Vasomotor Symptoms: Worsened by

- **Undiagnosed or Inadequately Treated:**

- **Diabetes**
- **Thyroid disease**

  Hypothyroidism is more common in late peri-menopause and post menopause

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Hot Flashes/VMS and CVD Systematic Review, Meta-Analysis 2016

- **Vasomotor symptoms are generally associated with:**
- **Incr. risk of Cardiovascular disease !!!**
- **Mainly explained by CV risk factors**
- **So requires careful screening!**

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2019: Sex Hormones, Aging and Cardiometabolic Syndrome

- **Obesity or Insulin Resistance (men and women)**
  - **increases risk for Coronary Heart Disease, vascular dysfunction, myocardial infarction, and Stroke**
- **Abdominal Obesity and Insulin Resistance**
  - **are risk factors for Dyslipidemia**

Faulkner, J.L., Belin de Chantemèle, E.J. Sex hormones, aging and cardiometabolic syndrome. *Biol Sex Differ* **10,** 30 (2019). https://doi.org/10.1186/s13293-019-0246-6

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2020: Menopause & Metabolic Effects

- **Decreased Estrogens, Increased Androgens**;
  - leads to metabolic syndromes including:
  - **CVD and Type 2 Diabetes**.
- **Dysregulation of Lipid Metabolism affects**:
  - body fat mass, fat-free mass, fatty acid metabolism,
  - and aspects of energy metabolism including;
  - basal metabolic ratio, **Adiposity & Obesity**.

Ko SH, Kim HS. Menopause-Associated Lipid Metabolic Disorders and Foods Beneficial for Postmenopausal Women. *Nutrients*. 2020;12(1):202. Published 2020 Jan 13. doi:10.3390/nu12010202

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2020: Menopause and Metabolic Effects

- **Alterations in Lipids:**
  - lipoproteins, apolipoproteins, low-density lipoproteins (LDLs), high-density lipoproteins (HDL) and triacylglycerol (TG).
- **Alterations in lipid metabolism and excessive adipose tissue-** play a key role in the synthesis of;
  - excess fatty acids, adipocytokines, proinflammatory cytokines, and reactive oxygen species, which cause lipid peroxidation
- **resulting in Insulin Resistance, Abdominal Adiposity, Dyslipidemia.**

FINDINGS:

- **Vitamin D, omega-3 fatty acids, antioxidants, phytochemicals, help manage abnormal lipid metabolism in post-menopause**

Ko SH, Kim HS. Menopause-Associated Lipid Metabolic Disorders and Foods Beneficial for Postmenopausal Women. *Nutrients*. 2020;12(1):202. Published 2020 Jan 13. doi:10.3390/nu12010202

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2019: Sex Hormones, Aging and Cardiometabolic Syndrome

- **Sex hormones:** play a **significant role in insulin sensitivity** in both lean/ obese, men/ women
- **Estradiol: increases glucose uptake** in skeletal **muscle** and **adipocytes**
- **Low Estrogen: predicted Incr. Visceral FAT** in peri and post-menopause (SWAN study)

Faulkner, J.L., Belin de Chantemèle, E.J. Sex hormones, aging and cardiometabolic syndrome. *Biol Sex Differ* **10,** 30 (2019). https://doi.org/10.1186/s13293-019-0246-6

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VMS: Non-Pharmacologic

- Dress in layers
- Cool bedroom, chilling pillows, sheets
- **Healthy body weight**
- Avoid smoking
  - Incr. estrogen metabolism = incr. VMS
- **Avoid triggers**: (personal)
  - hot drinks, caffeine, spicy foods, ETOH, emotional reactions!

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VMS: Non-Pharmacologic Self-Care: Variable Efficacy

- **Paced respirations – effective!**
  - **Count: Inhale 1,2,3; Hold 1,2,3; Exhale 1,2,3**
- Exercise
- Yoga
- Acupuncture
  - Avis et al. Feb 2017. Acupuncture for VMS. Menopause: Vol 24(2), 171-179. DOI: 10.1097/GME.0000000000000735
- Massage
- Other self-care options

https://www.nccih.nih.gov/

National Center for Complementary and Integrative Health

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VMS: Over-the-counter? Non-prescription, Herbals, Etc.

- Isoflavones (Soy): modestly effective
- Black Cohosh: NOT effective
  (Remifemin): Studies pending
- **Progesterone cream**: OTC, unclear efficacy, safety, esp. endometrial effects
  (poorly absorbed transdermally)

https://www.nccih.nih.gov/

National Center for Complementary and Integrative Health

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Estrogen for VMS per NAMS

- **Benefits of HT/ET***
- **more likely to outweigh risks**
  - **for symptomatic women**
  - **< 60 years (occult CVD)**
    - **or**
  - **within 10 years since FMP**

*(Hormone Therapy, Estrogen Therapy)
NAMS, 2019

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HT* for VMS: Risk per NAMS

- **Incr. Risk of VTE & Ischemic Stroke w/ Oral HT**
  BUT absolute risk is VERY LOW < 60 years
- **Dose, duration**
  - consistent with treatment goals &
  - safety issues &
  - should be individualized
- **"Shortest period of time and lowest dose !!!!"**

*Hormone therapy = Estrogen, Progesterone/progestin

NAMS, 2019

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2018 Systematic Meta-analysis Systemic Estrogen for VMS by Route

- 9 case-control, 9 cohort, 4 RCT
- Low-moderate quality of evidence

- Oral HT: Increased VTE risk !!!
- Non-oral HT: NO increased VTE risk

Rovinski, D., Ramos, R. B., Fighera, T. M., Casanova, G. K., & Spritzer, P. M. (2018). Risk of venous thromboembolism events in postmenopausal women using oral versus non-oral hormone therapy: A systematic review and meta-analysis. *Thrombosis research*, *168*, 83–95. https://doi.org/10.1016/j.thromres.2018.06.014

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HT for VMS: Risk Breast Cancer

- **Risk >50 years associated with HT is a complex issue!!!**
- **Increased risk** is primarily associated w/ addition of **progestogen (MPA)** to estrogen and **duration** of use
- **Risk is LOW, decreasing after treatment is stopped**
- **No increase** w **Estrogen-only** (CEE) up to 7.1 years
- **Increase w/ (estrogen/progestin) group after 3-5 years**

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VMS Treatment Options

Hormonal

- Estrogen

Non-Hormonal

- Non-estrogen

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VMS: Treatments
Systemic Estrogen for VMS

- Systemic estrogen; Oral, Vaginal, Transdermal
- Estrogen (versus non-estrogen)
- Very effective
- Safer in early post-menopause (within 10 y)
- Less safe age 70 and over
- Less safe as BMI increases
- "Lowest dose for the shortest duration"

NAMS 2019, www.menopause.org

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VMS: Treatments- Estrogen Systemic for VMS (mod-severe)

- **Oral:**
  Estrogen (Premarin, **Estrace**) 0.625-0.4, 0.3 mg
  Progesterone (**Prometrium**) 100-200 mg @hs
  NEW: Estradiol 1 mg, progesterone 100 mg, (Bijuva)
- **Transdermal**: **SAFER per Observational studies!**
  Steady blood levels, lower dose,
  possibly less weight gain AND libido neutral !!!
  Estradiol **Patch** (Vivelle, Climara, etc.)
  Estradiol **Gel** (Estragel, DiviGel (3 doses), etc.)
  Estradiol **Spray** (**Evamist**) 1-3 sprays to forearm in AM
  (biphasic pharmacokinetic curve = 2 doses)
- **Ring:** Estradiol (**FemRing**) every 3 months (for **VVA** too)

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NAMS:
Bioidentical Hormones- What's the Truth?

- Popularized by Suzanne Somers

- Compounded vs FDA Approved:

- **Compounded: Lack of research!**
  Safety, Efficacy: UNCLEAR

- **FDA approved: Robust literature**
  - Estradiol (Estrace)
  - Progesterone (Prometrium)
  (NEW: Bijuva- first oral combo)



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Bioidentical Hormones: FDA Approved Options

Pharmaceutical, FDA approved:

- **Estradiol: Oral, transdermal (preferred), vaginal**
- **Progesterone: Oral**
- **NEW: Estradiol/progesterone (Bijuva)**

Non-Pharmaceutical, NOT FDA approved: CAUTION!!!

- **Compounded estrogen, progesterone, testosterone**
- **Progesterone cream: Over-the-counter**
- **Pellets**

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Newer Meds for VMS/VVA: FDA Approved

- **Estradiol/Progesterone (Bijuva)**
- **Estrogen** (**Imvexxy**): PV inserts x2 wk
- **DHEA (Intrarosa)**: 6.5% PV suppositories qd
- **Conjugated Equine Estrogen/Bazedoxifene (DuaVee)**: Combination estrogen/SERM for moderate to severe VMS
- **Ospemifene (Osphena)**: **Oral** Non-estrogen (SERM) for **NEW** for **VVA** and moderate to severe **dyspareunia** due to VVA in menopause

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New 2022: Paroxetine/Emerging Non-estrogen Therapies for VMS

- SSRIs/SNRIs are effective for VMS
- Most Off-label

FDA approved:

- Paroxetine (Brisdelle/Paxil): 7.5 mg Oral daily
- Desvenlafexine (Pristiq): 50-100 mg Oral daily

David, P. S., Smith, T. L., Nordhues, H. C., & Kling, J. M. (2022). A Clinical Review on Paroxetine and Emerging Therapies for the Treatment of Vasomotor Symptoms. *International journal of women's health*, *14*, 353–361. https://doi.org/10.2147/IJWH.S282396

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Paroxitene* (Brisdelle) Low Dose: FDA Approved for VMS

- Dosing 7.5 mg PO daily
- Effective, safe, few side effects
  (dose dependent)
  nausea, fatigue, dizziness
- Alternative: if estrogen contraindicated
- Possible reduced anxiety
- Avoid with Tamoxifen
  Potential for interaction w/ cytochrome P-450 2D6 inhibitors

*Paxil (brand name) 10 mg PO daily

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Non-Hormonal Options for Managing Vasomotor Flushes: (FDA Approved, and Off-Label)

- **Desvenlafexine (Pristiq):** 50-100 mg/day
  - **Studied extensively (FDA approved)**
  - 4 randomized, placebo controlled trials found **significant reduction of VMS at 100 mg daily!**

- **Venlafexine (Effexor XR):** 37.5 mg a day-titrate as needed; Average dose 75 mg/day (**OFF-label)**

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Non-Hormonal Options for VMS: Off-label

- **Clonidine (Transdermal)**: centrally acting, for Rx of HTN.
  - Studied more extensively in 1970s-1990s
  - Reporting mixed results in reducing VMS
  - Trial using clonidine for patients on tamoxifen therapy showed a 38% reduction in hot flushes per day (Pandya et al., 2000)
- **Clonidine (Oral):**
  - Initial oral dose for hot flash treatment is 0.05 mg twice daily, but some women may require at least 0.1 mg twice daily
  - Modest effect on symptoms, adverse side effects (insomnia, dry mouth, constipation, drowsiness.)
- **Hypertension also**: May be a good choice

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Non-Hormonal Options for VMS: Off-label

- **Gabapentin:** indicated in treatment of partial seizures and post herpetic neuralgia; studied in Hot Flash reduction

  - Initiated at a daily dose of 300 mg at HS
  - Can be increased to 300 mg twice daily and then to 3 times daily at 3- to 4-day intervals.
  - Pandya et al., (2005) studied with breast cancer patients (n=420) **hot flush frequency was reduced by 44%**
    - **at 900mg/day.**
  - Studied: titrated to an 1800 mg daily dose, taken orally, 600 mg with the morning meal and 1200 mg with the evening meal.
  - Adverse effects: **dizziness,** somnolence, peripheral edema, **weight gain**

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NEW 2021: Soy Resolved VMS ½ cup of soybeans daily

- Plus Vegan diet
- Vs control group (no change in diet)
- 17 in each group
- 2 episodes VMS daily (very low #)
- Findings: All symptoms resolved in Soy group
- No change in VSM in control group
- VERY SMALL STUDY n=34

Barnard ND, et al. *Menopause*. 2021;doi:10.1097/GME.0000000000001812.

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VMS: Patient Education

- Must be thorough, empathetic, resourceful
- Handouts, websites, etc.

- **Menopause.org (NAMS)**
- NAMS certification
  As a NCMP



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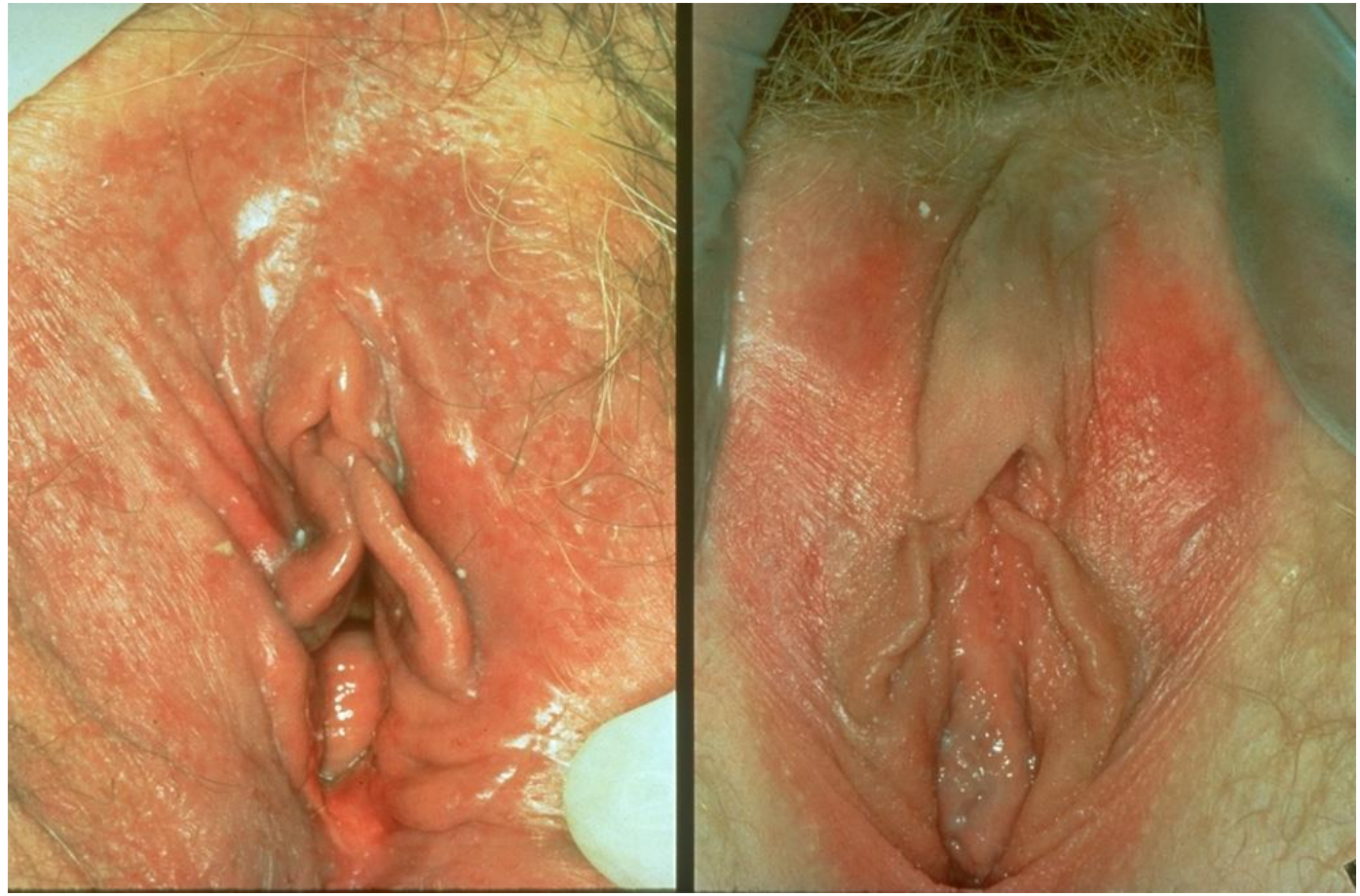
Vulvovaginal Atrophy (VVA) = Atrophic Vaginitis (AV) = "Genitourinary Syndrome of Menopause (GSM)"

1/3 of menopausal women affected

- Irritation
- Dryness
- **Dyspareunia !!! (superficial vs deep?)**
- Discharge- variable
- **Urinary symptoms: Dysuria, urgency, frequency, UTIs, incontinence**

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Vulvitis: Need to Clarify!!!
Vaginal, Cutaneous Yeast, Contact, Allergic, Other



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VVA/GSM

- Vulva
  - ‘Sticky glove sign’
- Erythema, mottling
- Pallor
- Flattening of rugae
- Leukorrhea variable!!!
  - Esp. amount
- Mimics: BV, Trich, HSV
  - other etiologies



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Diagnostic Work up: VVA, GSM

- Vaginal pH elevated ≥ 4.8
  - Proxy test for estrogen levels = maturation index
- Negative Amine KOH "Whiff "test
- Few Lactobacilli
- Mixed bacteria, grainy epithelial cells
- WBCs variable
- Immature epithelial cells, maturation index
- Avoid non-specific vaginal cultures, Pap inaccurate
- STI testing as appropriate!

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NEW:
Vaginal pH Swab Test (VS- SENSE)

negative positive



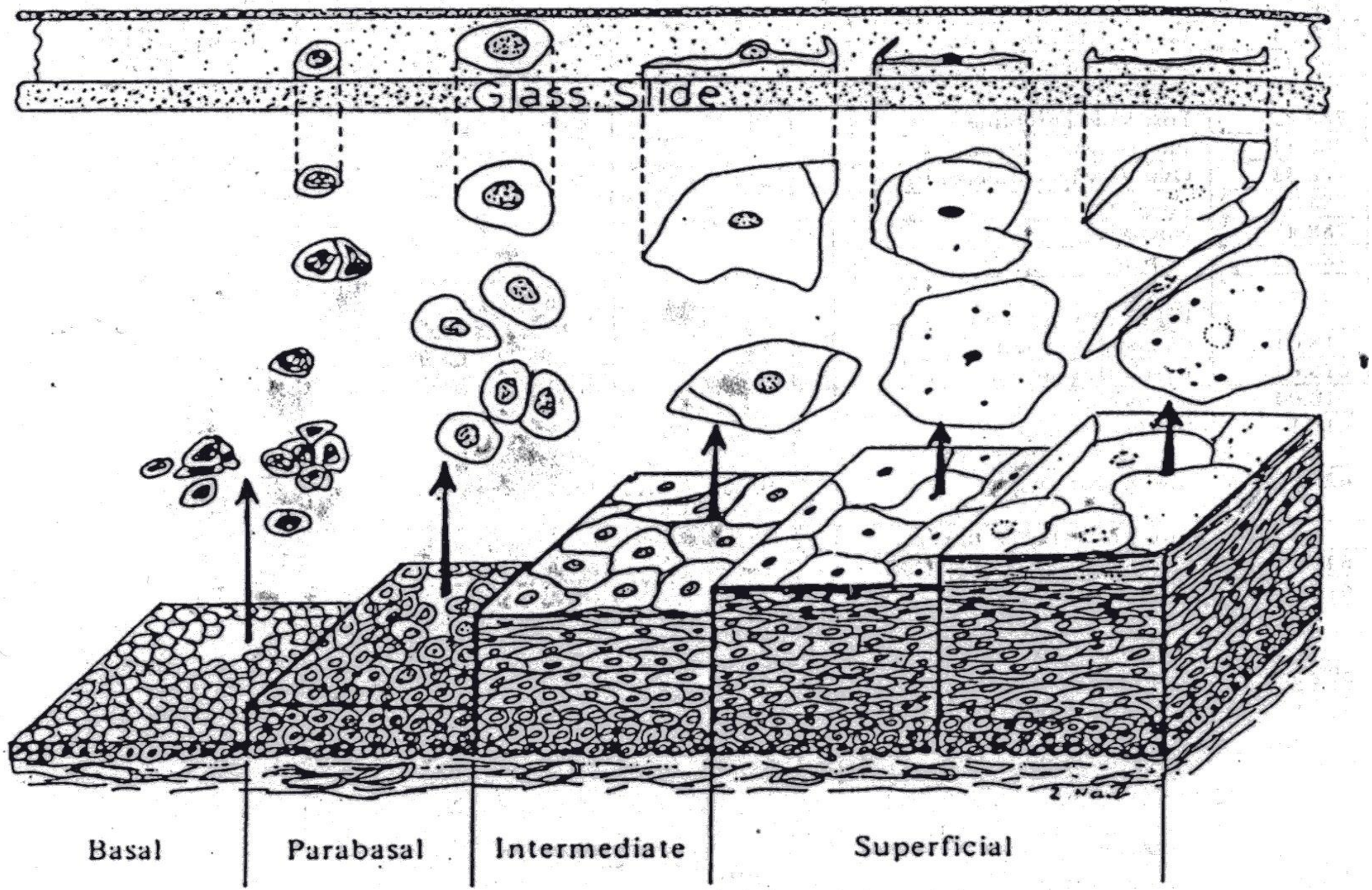
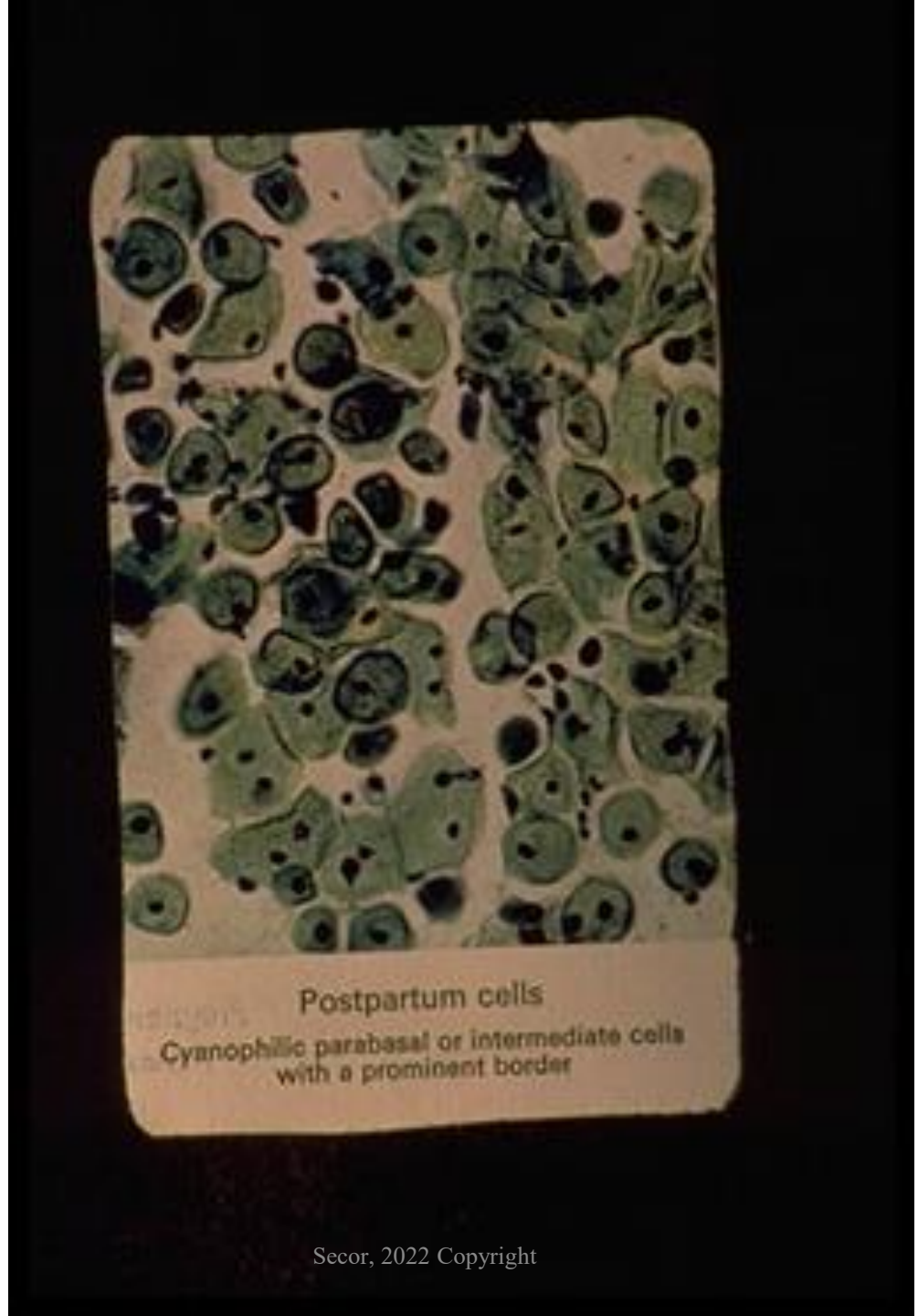
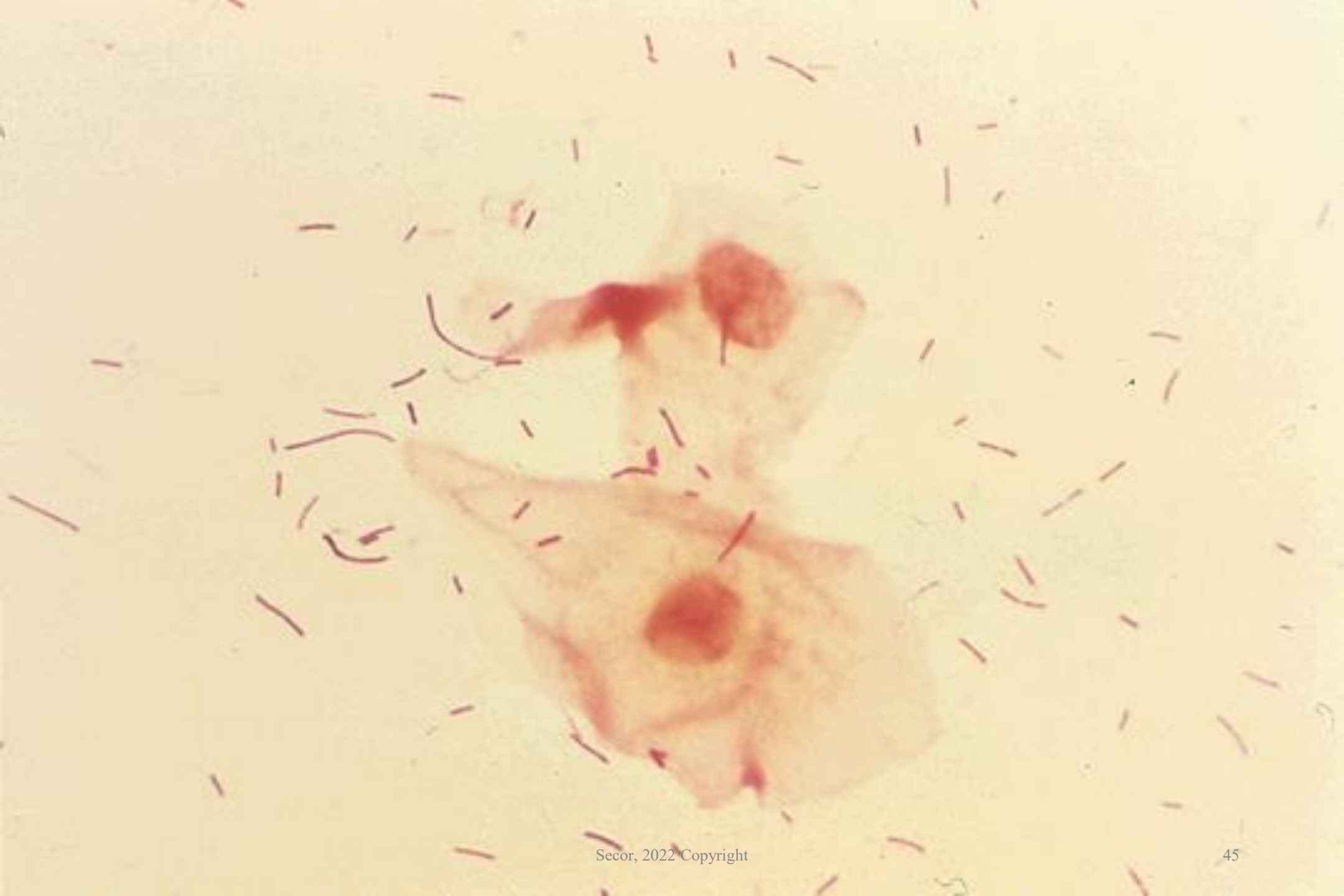


Figure 19–11. Different histologic layers of vaginal stratified squamous eipthelium. (From Naib Z. *Exfoliative Cytopathology,* 3rd ed. Boston, Mass: Little, Brown; 1985.)

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Differential Diagnosis

- BV
- STIs: Trichomoniasis, Herpes, etc.
- Precancers

- Vulvar Dermatoses:
  - Lichen sclerosis
  - Lichen simplex chronicus
  - Lichen planus
  - Irritant, allergen, eczema, etc.

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Rule out Dermatoses: LSC, LS, LP



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VVA, GSM Treatments: Low Dose Rx for VVA
Vaginal or Oral (NEWER-Ospemifene)

- Pt preference, symptoms, safety, efficacy, impact decision to treat
- **DO NOT USE: SYSTEMIC ESTROGEN for VVA symptoms only!!!**

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Efficacy, Safety of Vaginal Estrogen for VVA/GSM
2019 Systematic Review, 53 Studies

- **Effective, safe with few adverse effects**
- **Estrogen superior to lubricants**

- **Biehl**, C., Plotsker, O., & Mirkin, S. (2019). A systematic review of the efficacy and safety of vaginal estrogen products for the treatment of genitourinary syndrome of menopause. *Menopause (New York, N.Y.)*, *26*(4), 431–453. doi:10.1097/GME.0000000000001221 (**53 studies**)

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VVA, GSM Treatments: Estrogen Safety?
2018: Nurses Health Study

- Analyzed 18 years of prospective data !!!
- n 900 Vaginal Estrogen users, versus
- n 52,900 non-users
- Compared Users vs Non-users:

  No increased risk of Breast, Uterine Cancer or Cardiovascular Disease!!!

Bhupathiraju, SN, Grodstein, F, Stampfer, MJ et al. (2018) Vaginal estrogen use and chronic disease risk in the Nurses Health Study. Menopause, 26(6), 603-610. doi:10.1097/GME.0000000000001284

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Estrogen- Local Vaginal Options: Minimal Systemic Absorption so NO Progestagen NEEDED !!!

Daily for 2-4 weeks, then twice weekly PRN

- **Vaginal estrogen creams**: 0.5-2 gms pv at bedtime
  - Conjugated Equine Estrogen /CEE (Premarin)
  - Estradiol (Estrace)
- **Estradiol vaginal tablets** (Vagifem): 10 mcg dose
  - If dry atrophy, or introital dyspareunia, less effective?
- **Vaginal estradiol ring** (Estring): every 3 months
  Effective, convenient, may help OAB as pessary
- **NEWER: Vaginal estrogen inserts: (Imvexxy)**
- **Risk of secondary yeast, approx. 50% !!!**

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NEW: Ospemifene (Osphena)

- Non-estrogen, SERM, agonist to vulvar/vagina
- NEW 2018: Indicated for VVA/ GSM !!!
- and Mod-Severe Dyspareunia assoc w VVA
- Oral 60 mg tablet
- Daily with food
- Similar efficacy to estrogen, over 4-12 weeks
- Avoid: Current cancer, CVD, stroke
- Side effects: Hot flashes, > vaginal discharge
- Breast (unclear, no human studies yet)
- Bone effects (appears protective)

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NEW: Laser for VVA, GSM?

- "Mona Lisa Touch" and others
- 3 procedures, yearly. **NOT FDA APPROVED**
- Re-epithelializes vaginal epithelium
- Expensive $$$
- Insurance coverage- plan specific
- Long term safety: UNCLEAR?
- **NEW 2018 FDA WARNING:**
- **DO NOT RECOMMEND**
- https://www.breastcancer.org/research-news/fda-issues-warning-on-vagina-laser-tx

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NEW: DHEA (Intrarosa, Prasterone) for Post-Menopausal VVA, GSM

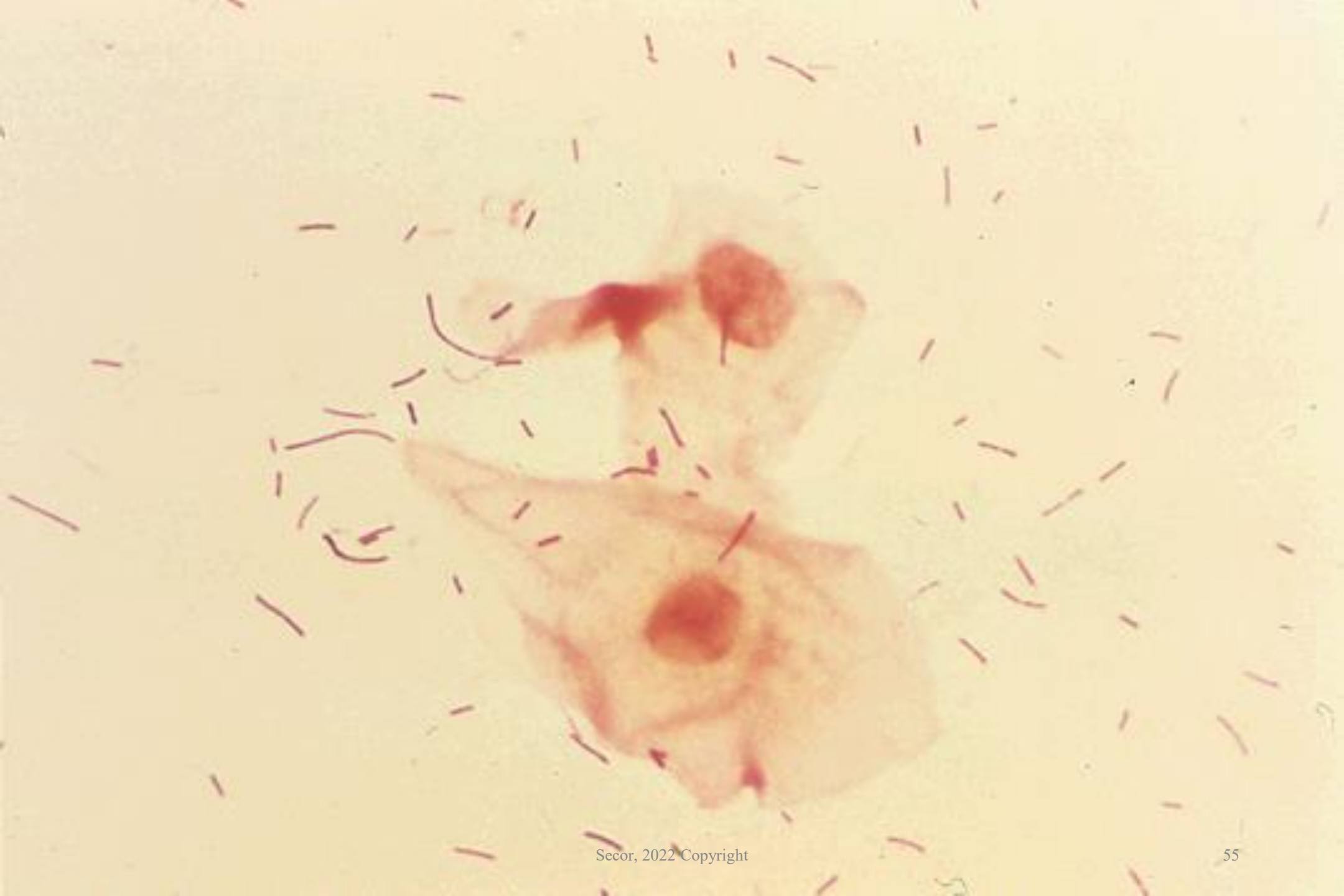
- **Daily use**
- **Dosing 0.05% (6.5% ovules) vaginal at bedtime**
- **Converted intracellularly into estrogen!**
- **BUT: Little to no rise in estradiol serum levels**
- **May be safer if history of breast cancer**
- **Studies underway**

FDA. FDA approves Intrarosa for postmenopausal women experiencing pain during sex. 2016 Nov 17; (epub:. http://www.fda.gov/NewsEvents/Newsroom/PressAnnoucements/ucm529641.htm

J Steroid Biochem Mol Biol. 2016;159:142.

Archer DF. DHEA vaginal for VVA .J Steroid Biochem Mol Biol. 2015 Jan;145:139-43. doi: 10.1016/j.jsbmb.2014.09.003. Epub 2014 Sep 6. Review.

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Abnormal Vaginal Bleeding: Post-menopausal

- **ANY Vaginal bleeding 12 months after FMP***
  Spotting, 1 time, or 1 drop blood!
  NEW: 9% have endometrial cancer !!!

- **REFER, Mandatory Workup:**
- Transvaginal ultrasound (Must do with EMB)
- Endometrial biopsy (EMB): > 5 mm Endom. stripe

*LMP = FMP = final menstrual period

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Sexual Counseling: FUN
Complex, Individual, Time-consuming



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Sexual Counseling: Complex, Individualized

- Regular SEX, Sleep, Lifestyle!
- Lubricants: (Low osmolarity is less drying)
- Pelvic Physical Therapy (PT)
  APTA.org
- Vibrators
- Dilators
- Romance!
- Orgasm before intercourse

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How Effective and Safe is Testosterone in Women? 2019 Systematic Review and Meta-analysis

- 36 trials, n= 8480 participants, 12-24 weeks, longest 2 years

- **"Confirms EFFICACY for women w/ bothersome low sexual desire, but long term safety is unknown."**
- T patches releasing 300 ug daily resulting in T levels in upper range of premenopausal range

- T significantly enhanced sexual outcomes, event frequency, desire, pleasure, arousal, orgasm, self image in post-menopausal women
- **RISKS: Incr. LDL**, reduced HDL/trigs, **weight gain**, acne, hair growth
- Did NOT appear to cause serious adverse events

Islam, RM et al. (2019, July 25). Safety and efficacy of testosterone for women: A systematic review and metaanalysis of randomized controlled trials data. *Lancet Diabetes Endocrinology,* (19) 30189-5 ; epub. https://doi.org/10.1016/s2213-8587=[

Bupropion (Welbutrin)
Off Label for HSDD (Low libido)

- NDRI:
- **Studied in pre-menopausal women**
- **Significantly MORE Effective than placebo**
- Contraindications include: HTN, seizures
- Side effects: can be significant
  - agitation, insomnia, anxiety, weight loss, etc.

Safarinejad MH, Hosseini SY, Asgari MA et al. (2010). A randomized, double blind, placebo controlled study of the efficacy and safety of bupropion for treating HSDD in ovulatory women. *BJU Int, 106*(6), 832-839.

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Flibanserin (Addyi) for HSDD: 2015 FDA approved for Premenopause

- Centrally mediating on serotonin receptors in the brain
- Oral: 100 mg at hs
- Greater sexual desire than placebo, and decreased distress (4-12 weeks before sx relief)

- NEW: 2 hours between Medication and ETOH
- Side effects: Dizziness, fatigue, nausea, etc.

Katz M, Derogatis LR, Ackerman R, et al. (2013). Efficacy of Flibanserin in women with HSDD: Results from the Begonia trial. *J Sex Med. 10*(7), 1807-1815.

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Bremelonatide acetate (Vyleesi)
2019 FDA approved for Premenopause

- "Melanocortin receptor agonist" = centrally acting peptide (in brain)
- Efficacy: Significantly incr. arousal, desire, #events, less distress, p <0.5
- Indication: Acquired generalized hypoactive sexual desire disorder (HSDD) (Not due to other causes) Premenopausal Women

- SC: 1.75 mg (abd or thigh), 45 min before sex, once daily !!!!
- DC if no effect in 8 weeks!
- Contraindications: CV disease, uncontrolled hypertension, pregnancy, nursing
- Warnings: hyperpigmentation at injection site, hepatic/ renal conditions

- Side effects: Nausea (40%), vomiting, flushing, headache, injection site reactions, cough, fatigue, hot flushes, parasthesias, dizziness, transient incr BP, decreased HR
- Interactions: Naltrexone, NSAIDS, antibiotics

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Resources: from NAMS
"Menopro" App

2017 Clinical Practice Guidelines for the Management of Menopausal Women

North American Menopause Society (NAMS)

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Menopause Update: Objectives

- **Describe epidemiology/physiology of menopause, Metabolic changes/Risks, Vasomotor Symptoms (VMS), Vulvovaginal Atrophy (VVA),15 mins**
- **Discuss diagnosis of VMS and Vulvovaginal Atrophy, 15 mins**
- **Explain pharm/non pharm options/alternatives for treatment of VMS, VVA, and HSDD*, 30 mins**

*HSDD = hypoactive sexual desire disorder

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Thank You and Good Luck!
Questions Welcome

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