UC San Diego Health

Menopause for Primary Care

Update for 2024

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Speaker Disclosures

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Overview

1. Understand treatment options for vasomotor symptoms during menopause, including both hormonal and non-hormonal therapies
2. Review practice pearls on prescribing menopausal hormone therapy, with a focus on individualizing therapy
3. Review diagnosis and management of Genitourinary Syndrome of Menopause (GSM)

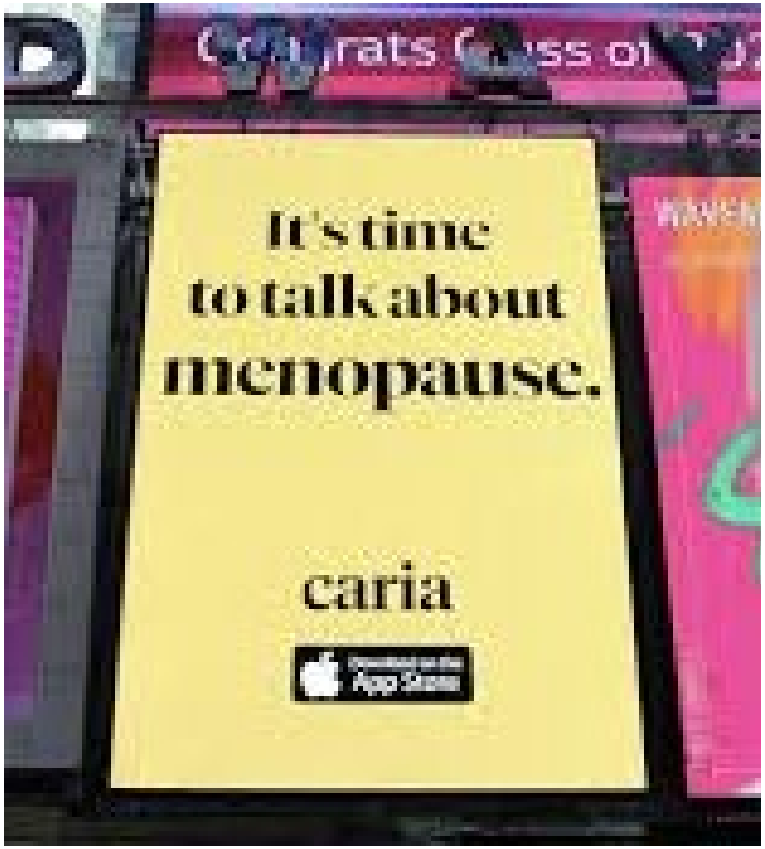
Demographics (US)

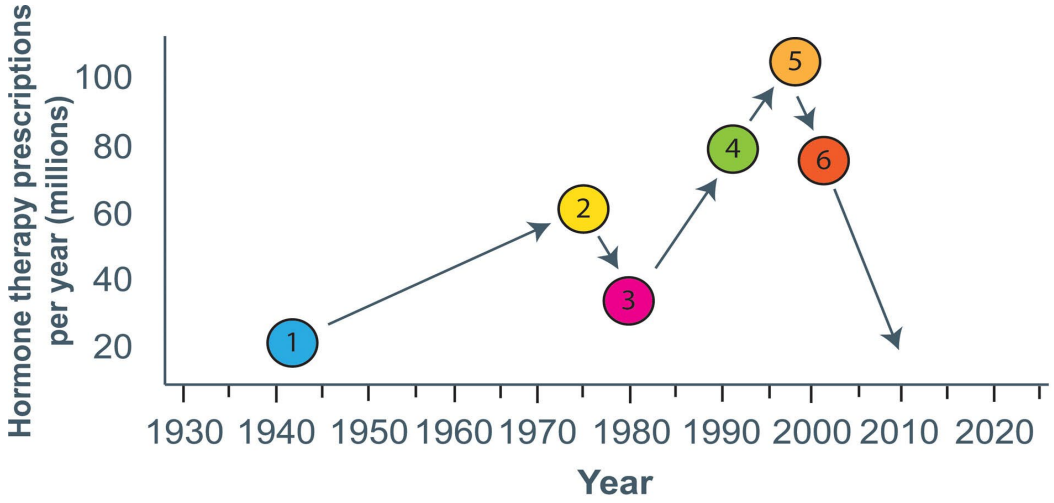
- As of 2022, number of women ≥ age 50 estimated to be *64 million*
- ~ 6,000 US women reach menopause every day (over 2 million per year)
- A woman's life expectancy is estimated at *80.2 years*
- US women who survive to age 50 expected to live average of 33.3 more years
  - *60% of women survive until at least age 80*
- ***Women will spend up to 40% of their lives after menopause transition***

Menopause Practice: A Clinician's Guide, 6th ed.
US Census Bureau www.census.gov/data/tables/2022

Menopause in the “mainstream”

- Social media, celebrities, biotech, podcasts
- Telehealth platforms
- **Media publications:**
  - **NYT article- Feb 1, 2023 *“Women have been misled about menopause”* by Susan Dominus**
- Updated review articles:
  - JAMA May 2024, *WHI Randomized Trial and Clinical Practice: A Review* Manson JE, et al





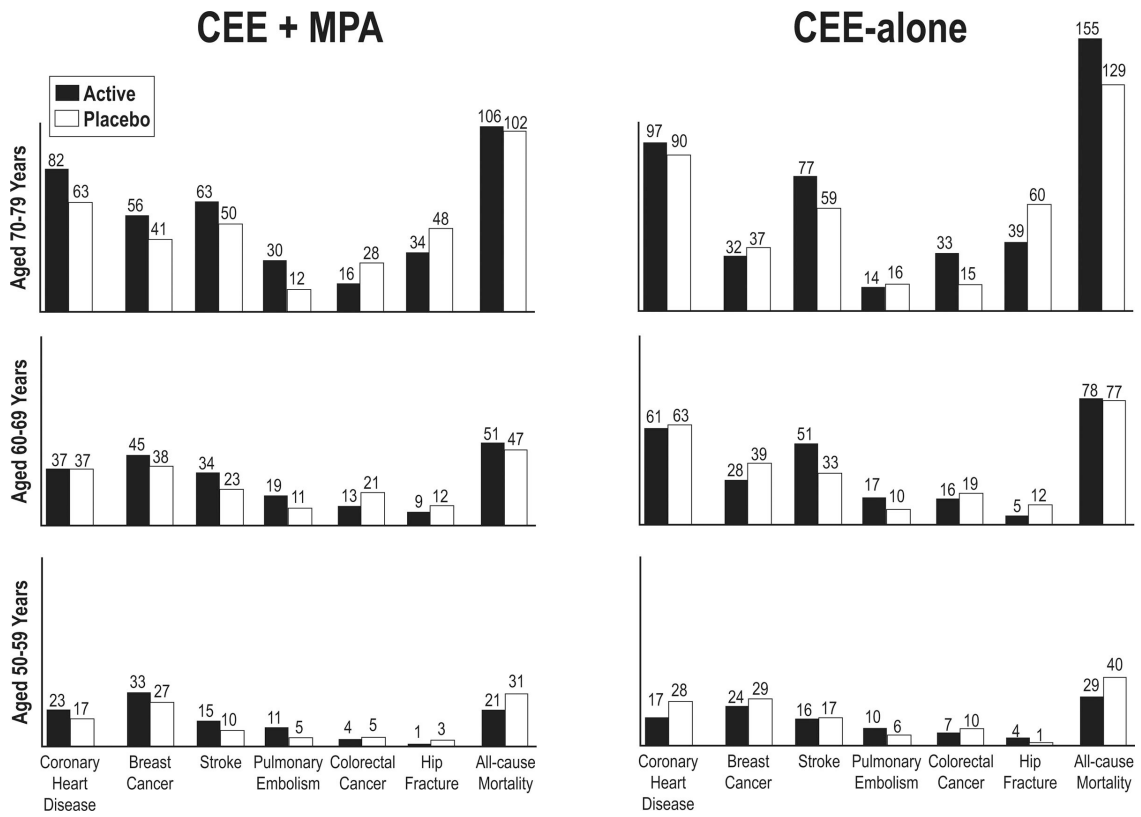
Timeline

1. 1942: Conjugated equine estrogen first introduced
2. 1975: Endometrial cancer risk recognized
3. 1980: Combined estrogen+progestin introduced
4. 1990s: Nurses' Health Study (1991) + PEPI (1995) published
5. 1998: HERS trial published
6. 2002: WHI trial published

Leslie Cho. Circulation. Rethinking Menopausal Hormone Therapy: For Whom, What, When, and How Long?, Volume: 147, Issue: 7, Pages: 597-610, DOI: (10.1161/CIRCULATIONAHA.122.061559)

Menopausal Hormone Therapy and the Women's Health Initiative

- **WHI 2002: CEE/MPA vs placebo[1]**
  - Increased risk of CEE/MPA for breast CA, VTE, stroke, MI
  - Benefit for osteoporotic fracture, colorectal CA
  - Discontinued at 5.6 yrs
  - Age range for enrollment 50-79yrs, median age 63yrs
  - Women with severe VMS excluded
- **WHI 2004: CEE alone vs placebo (s/p hysterectomy)[2]**
  - Increased risk VTE, stroke for CEE
  - Benefit for hip fracture risk
  - Discontinued at 7.2 yrs
  - Trend towards *reduced* breast cancer risk
    - HR 0.77 (CI 0.59-1.01)



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Menopause: where we are now….

- *Not using HT for chronic disease prevention*
- *Not starting women on HT >age 60, >10 yrs from FMP*

- Sub-analysis of WHI and CHD risk: years since menopause, age (2007)[1]
  - Within 10 yrs since menopause, age 50-59 yrs: HR 0.91 (CEE/MPA)

"Timing of initiation" hypothesis- CVD, cognition

- ELITE trial[2]: 5 yr trial, early initiation <6 yrs from menopause
- KEEPS trial[3] – 4 yr trial, within 3 yrs of menopause (avg age 51): neutral effect

- Safer routes of delivery– VTE risk
  - Transdermal vs oral, lower dose

Menopausal HT: Reducing the risks

- **Transdermal ET** associated with lower risk of venous thromboembolism (VTE) than oral ET (observational studies, No RCTs)
  - Avoidance of first pass hepatic metabolism → absent increase of procoagulant factors
  - Rovinski et al. 2018, meta-analysis
    - VTE risk **oral HT: OR 1.66** (1.39-1.98) vs non-oral OR 0.97 (0.9-1.06)
  - Canonico et al 2008, meta-analysis
    - VTE risk **oral estrogen OR 2.5** (CI 1.9-3.4) vs transdermal 1.2 (0.9-1.7)
  - Mohammed et al 2015
    - VTE risk **oral estrogen OR 1.66** (1.42-1.93) vs transdermal
  - Goldstajn et al. 2023 systematic review, 10 studies identified
    - All studies consistent in reporting transdermal estrogen safer than oral for VTE risk

  Some studies also reported on small elevations in VTE risk with addition of progestin vs progesterone

WHI Extended Post-intervention Follow up

- Manson JE et al. 13 yr extended post-intervention follow up of health outcomes from the 2 WHI HT trials
  - CEE/MPA:
    - most risks/benefits seen during intervention dissipated (stroke, VTE)
    - CVD risks remained non-significantly elevated
    - Endometrial CA risk reduction emerged
    - Hip fracture risk remained reduced
    - Breast CA risk persisted, but HRs decreased year-year after stopping HT
  - CEE alone**:**
    - **Breast CA risk reduction became significant (HR 0.79, CI 0.65-0.97)**
    - Hip fracture risk reduction attenuated

The WHI Randomized Trials and Clinical Practice: A Review

Observations for the WHI clinical trial of menopausal HT

- Results do not support hormone therapy with oral CEE/MPA for postmenopausal women or CEE alone for those with prior hysterectomy to prevent cardiovascular disease, dementia, or other chronic diseases.
- Hormone Therapy is effective for treating moderate to severe vasomotor and other menopausal symptoms.
- These benefits of hormone therapy in early menopause, combined with lower rates of adverse effects of hormone therapy in early compared with later menopause, *support initiation of hormone therapy before age 60 years for women* without contraindications to hormone therapy *who have bothersome menopausal symptoms.*

JAMA 2024 May 28;331(20):1748-1760.doi: 10.1001/jama.2024.6542

Vasomotor symptoms (VMS)

- Hot flashes and night sweats: "hallmark" of the menopause transition
- ~75% of women experience VMS during menopause
- Frequency and severity varies among women
- Adverse effects on quality of life[1]
- Primary reason for women to seek treatment during menopause[2]
- Associated with adverse health effects:
  - Depression (perimenopause)[3]
  - Bone health[4]
  - CVD

1. *Avis NE et al Menopause 2009*
2. *Williams RE, et al Maturitas 2007*
3. *Joffe H et al, Menopause 2002*
4. *Crandall CJ, et al. J Bone Mineral Res 2011*

SWAN: Study of Women Across the Nation
Duration of VMS during the menopause transition

- Longitudinal study of 3302 US women followed for 17 years across the menopause transition
- **Median duration of VMS was 7.4 yrs**
- Multi-center, diverse ethnic cohort
  - 5 racial/ethnic groups included (African American, White, Chinese, Hispanic, Japanese)
  - African American women: highest prevalence of VMS, longest total VMS duration (median 10.1 yrs), earlier onset
  - Hispanic women (8.9 yrs), Non-Hispanic white women (6.5 yrs)
  - Japanese/Chinese women: lowest prevalence of VMS, shortest VMS duration (4.8 and 5.4 yrs)

- VMS more prevalent in women with:
  - mood disorders, smoking and low socioeconomic status

Avis et al. JAMA Int Med 2015

Vasomotor symptoms

- Vasomotor symptoms (VMS) may begin during perimenopause, and frequent VMS may persist *on average 7.4 years or longer*

- Hormone therapy remains the gold standard for relief of VMS.
  - Estrogen-alone therapy can be used for symptomatic women without a uterus.
  - For symptomatic women with a uterus, estrogen-progestogen therapy or a tissue-selective estrogen complex protects against endometrial neoplasia.

- ***Shared decision-making*** should be used when considering formulation, route of administration, and dose of hormone therapy for menopause symptom management, with adjustment tailored to symptom relief, adverse events, and patient preferences.

2022 NAMS Hormone Therapy Position Statement

Treatment Options for VMS

Level 1 -- Good and consistent scientific evidence

- Hormone Therapy
- SSRI/SNRIs (paroxetine mesylate 7.5mg FDA approved)
- Gabapentin (off label)
- Fezolinetant
- Cognitive behavioral therapy
- Hypnosis

Level 1-2

- Oxybutynin (off label)

- ***Hormone therapy includes:***
  - Estrogen + progestogen (if uterus)
  - Estrogen + bazedoxefine (SERM) (if uterus)
  - Estrogen only (no uterus)
  - Progesterone

Suggested dosing ranges for nonhormonal therapies

SSRIs		
Paroxetine salt	7.5 mg	Single dose, no titration needed
Paroxetine	10-25 mg/d	Start with 10 mg/d
Citalopram	10-20 mg/d	Start with 10 mg/d
Escitalopram	10-20 mg/d	Start with 10 mg/d (for sensitive or older women, start with 5 mg/d for titration, but this dose has not been evaluated for efficacy)
SNRIs		
Desvenlafaxine	100-150 mg/d	Start with 25-50 mg/d and titrate up by that amount each day
Venlafaxine	37.5-150 mg/d	Start with 37.5 mg/d
Gabapentinoids		
Gabapentin	900-2,400 mg/d	Start with 100-300 mg at night, then add 300 mg at night, then a separate dose of 300 mg in the morning (start 100 mg if concerned about sensitivity)
Neurokinin B antagonists		
Fezolinetant	45 mg/d	Single dose, no titration needed. Monitor liver function tests at baseline and 3, 6 and 9 months

SNRIs, serotonin-norepinephrine reuptake inhibitors; SSRIs, selective serotonin reuptake inhibitors.

Menopausal Hormone Therapy

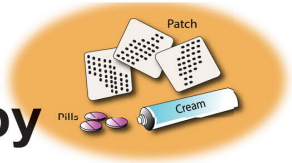
- **Systemic** estrogen +/- progestin/progesterone highly effective for treatment of menopausal VMS
  - PEPI trial, RCT[1]
    - oral CEE alone and CEE + MPA or progesterone effective
  - Cochrane Review, meta-analysis 24 RCTs[2]
    - 75% reduction in VMS frequency and severity
- 4 FDA approved treatment indications:
  - Moderate-severe menopausal VMS
  - Moderate-severe vulvar and vaginal atrophy due to menopause
  - Prevention of postmenopausal osteoporosis
  - Treatment of hypoestrogenism caused by hypogonadism, bilateral oophorectomy, or primary ovarian insufficiency

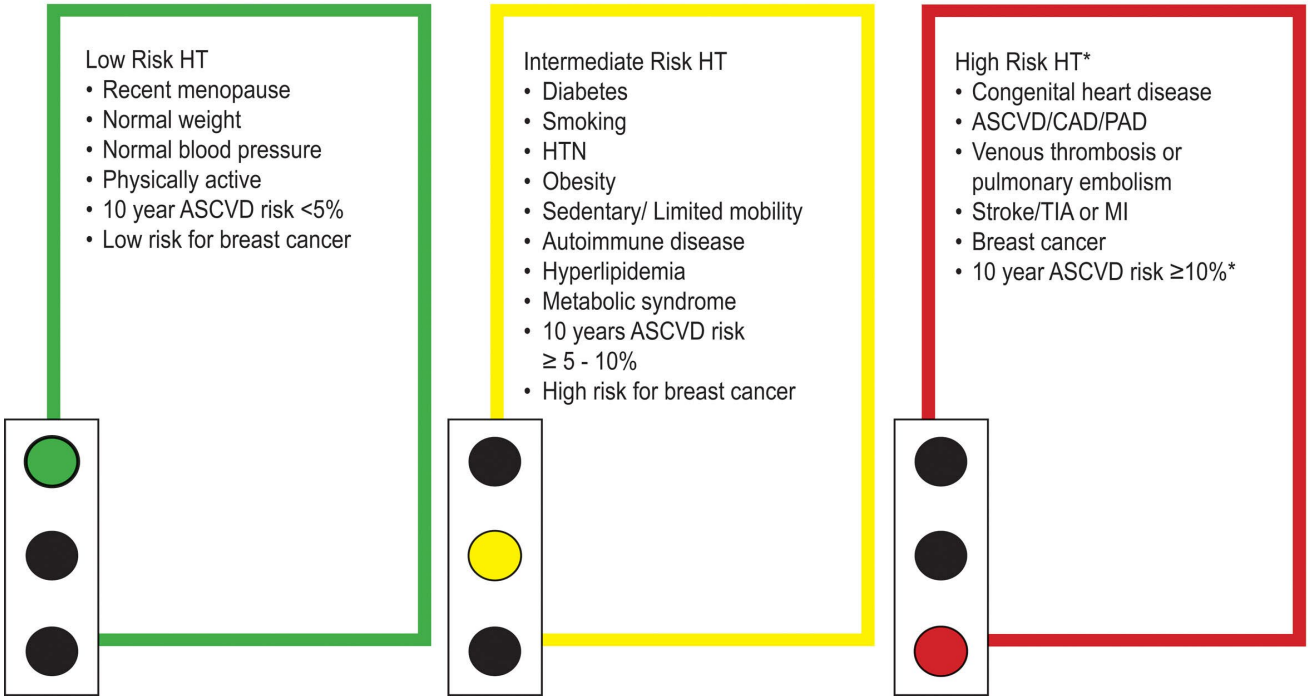
1. Obstest Gynecol 1998;92:982-988. 2. Cochrane Database of Systematic Reviews 2004: issue 4

Menopausal Hormone Therapy: "Ideal Candidate"

- **Recently menopausal (or peri-menopausal)—"younger"**
  - Within 10 yrs of menopause or age <60
- **Bothersome vasomotor symptoms (benefits > risks)**
- **No absolute contraindications to hormone therapy:**
  - Breast cancer, history of venous thrombosis (deep vein thrombosis, pulmonary embolism)
  - Undiagnosed irregular or postmenopausal bleeding
  - Active liver disease
- **No elevated risk for cardiovascular disease, breast cancer**
  - *10 yr ASCVD risk calculator, Breast cancer risk assessment- Tyrer Cuzick*

Menopausal Hormone Therapy





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Estrogen Therapy for menopausal symptoms

- Systemic estrogen therapy—for treatment of hot flashes, night sweats, prevention of osteoporosis*
  - Variety of formulations available in different dosages:
    - Oral pills/tablets
    - Transdermal patches
    - Topical gels, mist
    - Vaginal rings (systemic dosing vs. local)

- Women who have a uterus should add progestogen to systemic estrogen regimen (unless taking estrogen/bazedoxifene combination pill) for prevention of endometrial hyperplasia/cancer

Estrogen formulations: ORAL

- Conjugated (equine estrogens) 0.3-1.25mg
- Synthetic conjugated estrogens, A 0.3-1.25mg
- Synthetic conjugated estrogens, B 0.3-1.25mg
- Esterified estrogens 0.3- 1.25mg
- 17 β estradiol 0.5-2mg

Estrogen formulations: TRANSDERMAL

- Patches: 17 β-estradiol matrix patch
  - Once weekly and twice weekly dosing
  - Wide range of dosages (0.025, 0.0375, 0.05, 0.06, 0.075, 0.1)
  - Very low dose, 0.014 mg/day
    - (approved for osteoporosis prevention only, recent data showing efficacy for hot flashes)
- Dermal:
  - Gel, spray: 17 β-estradiol
    - *Estradiol gel pump* 0.06%
    - *Estradiol gel packets* 0.1%** (0.25mg, 0.5mg, 1.0mg, 1.25mg)
    - *Estradiol spray (titrate 1-3 actuations/day)*

Progesterone and Progestins

- Given for endometrial protection only, in women with a uterus
- ***Progesterone (micronized)***
  - Continuous 100-200mg/day
  - Cyclic 200mg/day x 12-14 days monthly
- ***Synthetic progestins***
  - Medroxyprogesterone acetate (MPA) 2.5mg/day, 5mg days 1-12 monthly
  - Norethindrone acetate
  - Drospirenone
  - Levonorgestrel: combination E/P patch, 52mg progestin releasing IUD (off label)

**side effects: breast tenderness, bloating, fluid retention, headaches*

Estrogen formulations: VAGINAL

- **Creams**
  - Conjugated equine estrogen (0.625mg CE/gram)
  - Estradiol (100mcg E2/gm)
- **Tablets/Suppositories**
  - Estradiol (10 mcg/tablet or 4mcg or 10 mcg insert)
- **Rings:**
  - **Systemic: Estradiol (silastic ring delivers 0.05mg/day, 0.1mg/day)**
  - Local: Estradiol (delivers 7.5mcg E2/day)
    - 2mg E2 ring, 90 day dosing interval

Combination E/P formulations

- **Oral**
  - CEE + MPA
  - CEE + MPA, cyclic
  - Ethinyl estradiol+NETA
  - 17β estradiol + NETA
  - 17 β estradiol +DRSP
  - **Estradiol 1mg+ micronized progesterone 100mg**

MPA medroxyprogesterone acetate

CEE conjugated equine estrogen

NETA norethindrone acetate

DRSP drospirenone

- **Transdermal (patches)**
  - 17 β estradiol + NETA
    - 0.05mg E + 0.14 P
    - 0.05mg E + 0.25mg P
  - 17 β estradiol + levonorgestrel
    - 0.045mg E+ 0.015mg P

FDA-approved “Bioidentical” Hormone Therapy

Active ingredient	Brand (manufacture)[b]	Preparations	Strength	Dosing frequency
17β-estradiol Oral	Estrace (Warner Chilcott, Rockaway, NJ)	Tablet	0.5, 1, or 2 mg	Once daily
17β-estradiol Transdermal	Alora (Watson Pharmaceuticals, Corona, CA)	Patch	0.025, 0.05, 0.075, or 1 mg/d	Twice weekly
	Climara (Bayer HealthCare Pharmaceuticals, Wayne, NJ)	Patch	0.025, 0.0375, 0.05, 0.06, 0.075, or 0.1 mg/d	Once weekly
	Divigel (Upsher-Smith Laboratories, Maple Grove, MN)	Gel (topical)	0.25, 0.5, or 1 mg/packet	Once daily
	Elestrin (BioSante Pharmaceuticals, Lincolnshire, IL)	Gel (topical)	0.87 g/pump	Once daily
	Estrasorb (Novavax, Columbia, MD)	Emulsion (topical)	1.74 g/pouch	Two pouches once daily
	Estrogel (Ascend Therapeutics, Herndon, VA)	Gel (topical)	1.25 g/pump	One pump once daily
	Evamist (VIVUS, Mountain View, CA)	Spray (topical)	1.53 mg/spray	Initially one spray daily; may increase to two to three sprays if needed
	Menostar (Berlex Laboratories, Montville, NJ)	Patch	0.014 mg/d	Once weekly
	Minivelle (Noven Pharmaceuticals, New York, NY)	Patch	0.025, 0.0375, 0.05, 0.075, 0.1 mg/d	Twice weekly
	Vivelle-Dot (Novartis Pharmaceuticals, East Hanover, NJ)	Patch	0.025, 0.0375, 0.05, 0.075, or 0.1 mg/d	Twice weekly
17β-estradiol Vaginal	Estring (Pfizer, New York, NY)	Ring	7.5 mcg/24 h	Once every 90 days
	Femring (Warner Chilcott Laboratories, Rockaway, NJ)[c]	Ring	0.05 or 0.1 mg	Once every 90 days
	Vagifem (Novo Nordisk Pharmaceuticals, Princeton, NJ)	Vaginal Tablet	10 mcg	Once daily for 2 wk, then twice weekly
	Estrace (Warner Chilcott Laboratories, Rockaway, NJ)	Vaginal Cream	0.1 mg/g	Once daily 2-4 g for 1-2 wk followed by 1-2 g for 1-2 wk; 1 g maintenance dose 1-3 times weekly
Progesterone Oral (micronized)	Prometrium (Schering-Plough Research Institute, Kenilworth, NJ; Solvay Pharmaceuticals, Marietta, GA)	Capsules	100 or 200 mg	Once daily
Combined Estradiol and norethindrone acetate[d]	Combipatch (Rhône-Poulenc Rorer, Paris, French)	Patch	0.05/0.14 or 0.05/0.25 mg per day	Twice weekly
Combined Estradiol and levonorgestrel[d]	Climara Pro (Berlex Laboratories, Montville, NJ)	Patch	0.045/0.015 mg per day	Once weekly
Combined Estradiol and norgestimate[d]	Prefest (R.W. Johnson Pharmaceutical Research Institute, Raritan, NJ)	Tablet	1 mg /0 mg ×15 and 1 mg/0.09 mg ×15	Once daily

Conjugated Estrogens/Bazedoxifene (CE/BZD)

- BZD is a Selective Estrogen Receptor Modulator (SERM) or estrogen receptor agonist/antagonist with addition of conjugated estrogen (TSEC, tissue selective estrogen complex) – brand name Duavee
- "Progestin-free" HT option for VMS (BZD is estrogen receptor antagonist in endometrium)
- FDA approved Sept 2013
- CE 0.45mg/20mg Bazedoxifene, once daily oral therapy
- Novel therapy for indication of:
  - treatment of mod-severe hot flashes associated with menopause
  - prevention of postmenopausal osteoporosis
  - *In women with a uterus*

Conjugated Estrogens/Bazedoxifene (CE/BZA)

- 75% reduction in HF frequency vs 50% placebo (by 12 weeks)
- Provides endometrial protection with *higher amenorrhea rates* vs. standard HT
  - (87% CE 0.45mg/BZA 20mg vs. 54% CE 0.45/MPA 1.5mg)
- Lower incidence of breast pain and tenderness
- Does not appear to increase mammographic breast density
- May be good option for women intolerant to progesterone or with breast tenderness
- Similar efficacy for treating hot flashes, preserving BMD across different ethnic groups (non-Hispanic white, African American and Hispanic)[3]

Fertil Steril 2009, Menopause 2016

Genitourinary Syndrome of Menopause (GSM)

- Intended to more fully describe effects of estrogen loss on genital and urinary systems in menopausal women
  - Vulvovaginal atrophy (VVA) is a component of GSM
- Includes vulvar and urinary symptoms and physical changes, not just vaginal
- Most commonly reported symptoms: *vulvar irritation, inadequate lubrication, burning, dysuria, dyspareunia, vaginal discharge*
- Clinical exam findings: *labial and clitoral atrophy, pallor of vaginal epithelium with lack of rugae, introital stenosis, vaginal dryness, urethral prolapse, erythema of urethral meatus*

Menopause 2014; 21: 1063-65

GSM- Treatment options

- OTC vaginal lubricants and moisturizers
- Vaginal estrogen (minimal systemic absorption, no need to oppose with progestin)
  - Cream
    - Estradiol 0.01%, conjugated equine estrogen 0.625mg/gm
  - Tablet
    - Estradiol 10 mcg, preloaded in applicator, 2x/week
  - Insert
    - Estradiol 10 mcg or 4 mcg, no applicator 2x/week
  - Ring
    - Estradiol 2mg ring (delivers 7.5mcg estradiol/day), change q3 months

- Vaginal DHEA (prasterone 6.5mg, ovule, daily)
- Oral SERM (estrogen agonist/antagonist): ospemiphene 60 mg oral tablet daily

Case Presentation

CC: “*I want to try estrogen*”

52 yo F with Type 2 DM, hyperlipidemia presents with c/o worsening hot flashes, night sweats, and disrupted sleep over past year.

LMP age 45, at time of hysterectomy for fibroids (ovaries retained)

Current medications: gabapentin, venlafaxine, metformin, lovastatin

Family history: mother-HTN, no h/o breast CA

Exam: BP 121/84, BMI 34

LABS: recent lipid panel WNL, A1c 6.9%

Mammogram up to date, negative “scattered fibroglandular densities” (no h/o abnormal mammogram or breast biopsy),

Gyn evaluation

- Labs ordered:
  - FSH 57, Estradiol 25
- Pt counseled on risks of Estrogen therapy (ET), concern for CVD risk factors (DM, HLD, obesity), already using non-hormonal treatment options for VMS (gabapentin, SNRI):

  "*Safest option would be to avoid hormones, but pt understands risks and really feels that she needs relief of VMS with estrogen*"
- ***Should we allow patient trial of estradiol therapy?***
  - ***10 yr ASCVD risk 3.5%***
- ***If so, what formulation? Dose?***

Treatment plan and follow up visit

- Rx estradiol transdermal patch at lowest dose 0.025mg, change every 3-4 days
- Call to office 1 month later "*this patch is not working; I'm still having hot flashes*"
- Estradiol patch dose increased to 0.05mg with improvement in symptoms at 3 month follow up visit

6 month follow up visit

- c/o hot flashes increasing again by day 2-3 of the patch (patch is changed every 3-4 days), c/o having more mood changes
- Discussed changing route of delivery → Rx oral estradiol 0.5mg/day
- Follow up with PCP, changed from venlafaxine to sertraline
- Interval hx:
  - 4 months- pt called office with c/o continued HFs on oral estradiol- advised to increase estradiol to 0.5mg BID and if effective, change to 1mg/d dosing
  - 6 months later- calls with c/o continued HFs, additional 0.5mg oral estradiol recommended (1mg + 0.5mg daily)
- Maintained on oral estradiol for 5 years, symptoms well controlled

Follow up

- F/U with endocrinologist, started on insulin therapy and recommended to change back to transdermal estradiol (less risk of VTE vs oral estrogen)
- Oral estradiol discontinued → Estradiol patch 0.075mg
- 3 month follow up- symptoms initially improved, problems with the patch, hot flashes gradually returned

  ”*patient is overlapping patches, using band-aids to keep the patch from falling off”*
- Estradiol level 69
- Rx changed to estradiol vaginal ring 0.1mg/24hr (changed every 3 months) – Femring
- 4 month f/u: *”Hot flashes are resolved! Pt is happy with the ring”*

Flash forward 5 years……

- Interval hx:
  - Pt is now 66 yo, reports recently discontinued Femring due to persistent vaginal discharge which resolved after removing the ring
    - VMS were well controlled on the ring– but now having them again, not as severe as initial (but bothersome)
    - Annual mammograms have been normal
    - DM, HLD well controlled on medication, BP normal
    - Baseline DEXA at age 65, normal BMD
    - Continues to take gabapentin, sertraline

WHAT NEXT????

Fezolinetant

- 45 mg oral pill, once daily
- Contraindications:
  - Known cirrhosis, severe renal impairment or ESRD, concomitant use of CYP1A2 inhibitors
- Precautions: elevated serum transaminases
  - Check baseline LFTs, do not start if >2x upper limit normal or if total bilirubin elevated
  - Repeat transaminases at 3, 6 and 9 months after initiation of therapy
  - Most common adverse reactions: (>2%)
    - abdominal pain (4.3% vs 2%), diarrhea (3.9% vs 2.6%), insomnia (3.9% vs 1.8%),

      hot flush (2.5% vs 1.6%) , hepatic transaminase elevation (2.3% vs 0.8%)

3 month follow -up

- Success!
  - "*HFs are much better during the day, took ~4 weeks for the medication to start working, still hot at night, sometimes room is too warm, satisfied with results*"
  - 3 month f/u LFTs in normal range

Thank you!

- **UC San Diego Health**
- **Women's Health Services**
  - **La Jolla (VLJ, Genesee)**
  - **Encinitas**
  - **Carmel Valley (PHR)**
  - **Kearny Mesa (Convoy)**
  - **Rancho Bernardo**
  - **Hillcrest (MOS)**
  - **Carlsbad- *coming soon!***