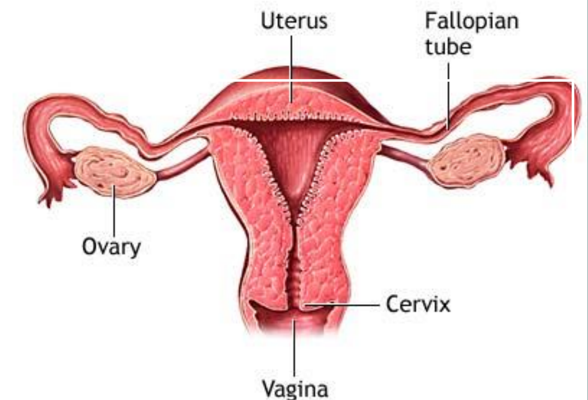
Women's Health Guidelines Update

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

Onset, Massachusetts



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

Speaker:

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

- FNP for 44 years specializing in Women's Health
- National Speaker, Educator, Author, Health Coach
- DNP-2015, Rocky Mountain University, Provo, Utah

- Board of Trustee, Rocky Mountain University

- FELLOW in AANP, AAN

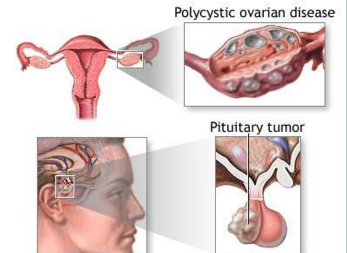
- Coauthor of 2 GYN textbooks, both updated 2018
  - The GYN Exam, Advanced Health Assessment: Skills & Procedures

- Two Health/Fitness books (2017, 2022)
- Passion for helping NPs/PAs become Healthy and Fit

Objectives

Upon completion of the session attendees will be able to:

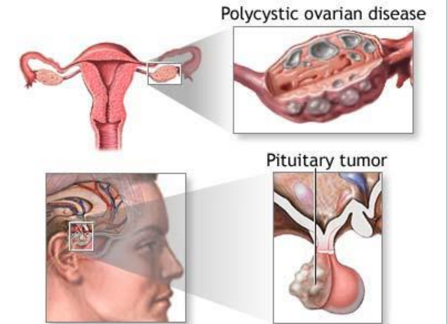
- Discuss the epidemiology of selected conditions* including risk factors 20 min
- Explain key aspects of the most current guidelines and rationale for selected conditions* 20 min
- Describe controversies re: these guidelines 20 min



*Cervical Cancer, Breast Cancer, Osteoporosis, Contraception, STIs, Menopause

Overview

- Gyn Exam: USPSTF 2017 vs ACOG 2017
- Cervical Cancer:
  ACS 2020, ASCCP 2020, USPSTF 2019
- Contraception: CDC 2016
- STIs: ……………CDC 2021
- Menopause: …NAMS 2017
- Osteoporosis: Endocrine Society 2019
- Breast Cancer Screening: USPSTF 2019



Yearly Pelvic Exam: Controversial

- **ACOG - 2017: Yearly Pelvic Exam**
  With or Without a Cervical Cancer Screening

- **USPSTF - 2016:**

- Insufficient Evidence for Pelvic Exams in Asymptomatic Women

- Lack of Research re: Benefits/ Harms of Pelvic Exam in Asymptomatic Women !!!

Sanchez et al. (2019). Well-women examinations: Beyond cervical cancer screening. *JNP, 12*(2), 189-194.

GYN Exam: USPSTF 2016
Justified if Clinical Indication !!!

- **Think Age and Risk of Various Conditions:**
  - STIs, VV, pregnancy, fibroids, AUB, over 50 yr
- “Shared Decision” between Clinician & Patient

Yearly Pelvic Exam: Retrospective, Cohort Study 2019

N = 283

Purpose:

Identify types/ frequency of gynecologic conditions in women ≥ 40 years old, in a large urban county, mostly Hispanic.

- **54.8% had GYN conditions !!!**
- Uterine Prolapse 16.2%, Incontinence 12%, Pelvic Masses 11.9%, VVA 11.3%
- Other: Abnormal Uterine Bleeding (AUB), Vaginitis, UTIs

Sanchez et al. (2019). Well-women examinations: Beyond cervical cancer screening. *JNP, 12*(2), 189-194.

HPV 2021 Update: What's New?

- **NEW 2020/ 2018: Primary hrHPV Screening**
- **NEW 2019: "Risk-based" Follow-up of Abnormal Cervical Cancer Screening Guidelines**
- **Vaccine Update: v9 Gardasil**

HPV: Introduction

- Most common STI in US
- Cause of cervical cancer
- Associated with external genital warts, and cancer of the penis, vagina, vulva, anus & oropharynx !

Munoz N. *Vaccine*. 2006; ASCCP Website 2006; Anhang R. *CA Cancer J Clin.* 2004; American Cancer Society. *Cancer Facts and Figures*. 2006; Soper D. *Inf Dis Obstet Gynecol.* 2006; Trottier H. *Vaccine.* 2006.

Epidemiology of Cervical Cancer:

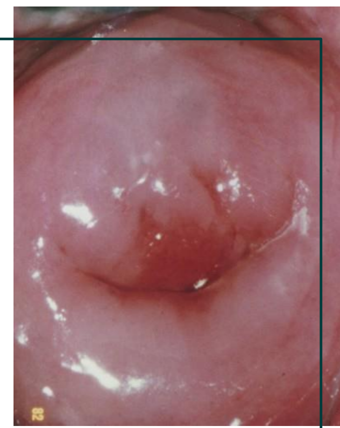
- **~ 12,900 NEW cases invasive cervical cancer**
- **About <u>4,100</u> deaths from cervical cancer**
- **266,000 deaths worldwide (2012)**
- **Hispanic Women: #1 cause of cancer deaths**
- **Most common - in women ≤ 50 years old**

http://www.cancer.org/cancer/cervicalcancer/overviewguide/cervical-cancer-overview-key-statistics#top

HPV Associated Cancers: 2004-2008 CDC, *MMWR* 2012;61(15):258–261.

Cancer site	Average number of cancers per year in sites where HPV is often found (HPV-associated cancers)			Percentage probably caused by HPV	Number probably caused by HPV†		
	Male	Female	Both Sexes		Male	Female	Both Sexes
Anus	1,549	2,821	4,370	91%	1,400	2,600	4,000
Cervix	0	11,422	11,422	91%	0	10,400	10,400
Oropharynx	9,974	2,443	12,417	72%	7,200	1,800	9,000
Penis	1,048	0	1,048	63%	700	0	700
Vagina	0	735	735	75%	0	600	600
Vulva	0	3,168	3,168	69%	0	2,200	2,200
TOTAL	**12,571**	**20,589**	**33,160**		**9,300**	**17,600**	**26,900**

Cervical Cancer: 2020 Screening Guidelines



21-29 years: (To be phased out per ACS)

- Pap = every 3 years (Level A recommendation)
- < 21 = DO NOT SCREEN

>25-65:

- NEW: hrHPV = every 5 years
  - 2020 American Cancer Society recommends (Preferred)
  - Per ACS, “Previous recommendations should be phased out”
  - Per USPSTF and ACOG, (Level A= preferred)

30-65 years: (To be phased out per ACS)

- Pap/ HPV = every 5 years (Level A) Preferred per ACOG
- Pap ONLY = every 3 years (WHY?)

>65: May continue (NEW 2018)

www.asccp.org, www.acs.org, www.uspstf.org

2019: HPV Testing as Primary Screen for Cervical Cancer

- In U.K. Pilot Program, n= 678,547 women (ages 24-64)

Findings:

- **HPV testing had higher sensitivity than Cytology/PAP for CIN 2-3**
- Lower incidence of subsequent disease

Rebolj, M et al. Primary cervical screening with high risk HPV testing: Observational study. BMJ 2019 Feb 6;364:1240. (https://doi.org/10.1136/bmj.1240)

UPDATE: HPV Vaccine*
9v Gardasil

NEW: FDA approved to PREVENT OROPHARYNGEAL CANCER

- **9-14 years = 2 doses, (6 months apart)**

2019 NEW CDC Recommendations:

- **≥ 15-26 years = 3 doses, (0, 1-2, 6 months)**

- **27-45 years, NOT routinely recommended BUT may benefit if not vaccinated earlier**

NOTE:

Give PRIOR to sexual activity (Coitarche) because Vaccine more effective if Naïve (not exposed to HPV) vs Non-naïve

***2019 CDC/ACIP, ACOG recommendations**

Surveillance for Cervical Precancer in the Era of the HPV Vaccine!

NEW 2019

Decline:

- **21% reduction in CIN2+ (from 2008-2014)!!!**

- **Declines greatest in younger vaccinated women**
- **Declines also in unvaccinated = Herd Immunity!**

Mcclung NM, et al. Trends in HPV types 16 and 18 in cervical precancers, 2008-2014. Cancer Epidemiol Biomarkers Prev 2019 Mar;28:602.

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The HPV Vaccine: Is Making a Difference!

- HPV prevalence has declined steeply !!!

  Even though vaccine coverage remains incomplete

Decline:

- 64% in 14-19 year olds (from 2003-06 vs 2009-12)

  from 11.5% to 4.6%

- 34% in 20-24 year olds

  from 18.5% to 12.1%

- Vaccinated: prevalence declined 91% !!!
- Unvaccinated: decline ONLY 13%
  - (NO herd immunity in US !!)

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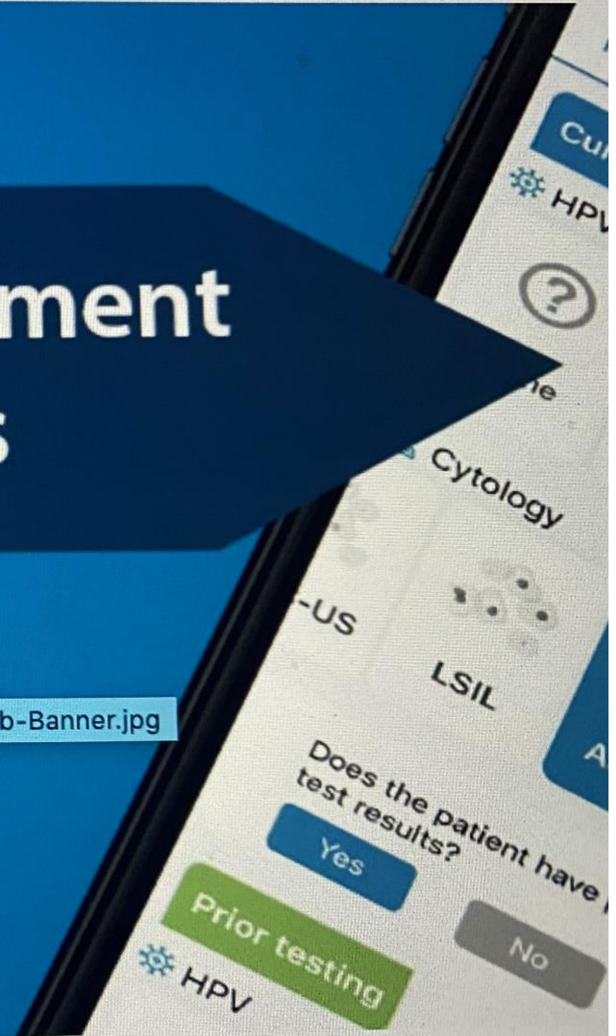
2019 ASCCP: “Risk- Based” Management Consensus Guidelines for Abnormal Cervical Cancer Screening Tests

Perkins, Rebecca B. MD, MSc[1]; Guido, Richard S. MD[2]; Castle, Philip E. PhD[3]; Chelmow, David MD[4]; Einstein, Mark H. MD, MS[5]; Garcia, Francisco MD, MPH[6]; Huh, Warner K. MD[7]; Kim, Jane J. PhD, MSc[8]; Moscicki, Anna-Barbara MD[9]; Nayar, Ritu MD[10]; Saraiya, Mona MD, MPH[11]; Sawaya, George F. MD[12]; Wentzensen, Nicolas MD, PhD, MS[13]; Schiffman, Mark MD, MPH[14]; for the 2019 ASCCP Risk-Based Management Consensus Guidelines Committee 2019 ASCCP Risk-Based Management Consensus **Guidelines for Abnormal Cervical Cancer Screening Tests and Cancer Precursors**, Journal of Lower Genital Tract Disease: April 2020 - Volume 24 - Issue 2 - p 102-131 doi: 10.1097/LGT.0000000000000525

Mobile App

ASCCP Risk Based Management Consensus Guidelines

Mobile-App-Web-Banner.jpg



App ”CDC Contraception 2016” Contraception Guidelines

MEC ≡ Medical Eligibility Criteria

- By condition
- By method

SPR ≡ Selected Practice Recommendations

- Initiation
- Exams and tests
- Routine f/u
- Missed doses
- Bleeding abnormalities

CDC Contraception 2016

MEC by Condition

MEC by Method

SPR

About this App

Full Guidelines

Provider Tools

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CDC MEC App Update May 2021: Selection of 3 Multiple Conditions

- App: “CDC MEC 2016”
- Selection of Multiple Conditions -- Updated US MEC and US SPR Phone App
- CDC has added a new feature to the app for U.S. Medical Eligibility Criteria for Contraceptive Use (US MEC) and U.S. Selected Practice Recommendations for Contraceptive Use (US SPR).
- Providers can now select up to 3 medical conditions or characteristics at once to view recommendations when counseling patients.

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MENU CDC Contraception 2016

Antimicrobial therapy

a. Broad-spectrum antibiotics

Method	Category (Init. / Cont.)	Clarification / Evidence / Comment / SPR Info
Cu-IUD	1	>
LNG-IUD	1	>
Implants	1	>
DMPA	1	>
POP	1	>
CHCs	1	>

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KEY

Antimicrobial therapy

d. Rifampin or rifabutin therapy

Method	Category (Init. / Cont.)	Clarification / Evidence / Comment / SPR Info
CHCs	3†	›

Emergency Contraception

Additional Methods

f. Minor surgery without immobilization

Method	Category (Init. / Cont.)	Clarification / Evidence / Comment / SPR Info
Cu-IUD	1	>
LNG-IUD	1	>
Implants	1	>
DMPA	1	>
POP	1	>
CHCs	1	>

MENU

CDC Contraception 2016

d. Other vascular disease or diabetes of >20 years' duration

Method	Category		Clarification Evidence Comment SPR Info
	Init.	Cont.	
Cu-IUD	1		›
LNG-IUD	2		›
Implants	2		›
DMPA	3		›
POP	2		›
CHCs	3/4[+]		›

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b. Migraine

ii. With aura

Method	Category (Init. / Cont.)	Clarification Evidence Comment SPR Info
Cu-IUD	1	>
LNG-IUD	1	>
Implants	1	>
DMPA	1	>
POP	1	>
CHCs	4†	>

Ischemic heart disease, current or history§

Method	Category		Clarification Evidence Comment SPR Info
	Init.	Cont.	
Cu-IUD	1		>
LNG-IUD	2	3	>
Implants	2	3	>
DMPA	3		>
POP	2	3	>
CHCs	4		>

Obesity

a. BMI ≥30 kg/m²

Method	Category Init.	Category Cont.	Clarification Evidence Comment SPR Info
Cu-IUD	1		›
LNG-IUD	1		›
Implants	1		›
DMPA	1		›
POP	1		›
CHCs	2		›

a. History of DVT/PE, not receiving anticoagulant therapy

i. Higher risk for recurrent DVT/PE (one or more risk factors)

- History of estrogen-associated DVT/PE
- Pregnancy-associated DVT/PE
- Idiopathic DVT/PE
- Known thrombophilia, including antiphospholipid syndrome
- Active cancer (metastatic, on therapy, or within 6 months after clinical remission), excluding non-melanoma skin cancer
- History of recurrent DVT/PE

Method	Category		Clarification Evidence Comment SPR Info
	Init.	Cont.	
CHCs	4		›

NEW: FDA Approved 1-Year, Vaginal Ring

- **Ethinyl estradiol (EE), Segesterone acetate (SA) (Annovera)**
- **3 weeks in, 1 week out**
- **Refrigeration not required**
- **Same CHC contraindications/warnings**
- **FDA requiring post-marketing studies to further study safety, effects of tampons, etc.**

FDA.gov

New: Transdermal Patch Estrogen/Progestin (Twirla)

- Estrogen and Progestin 120 mcg (Levonorgestrel)
- Weekly Patch (7 days Patch free)
- Safe, effective, adherent (well tolerated)
- Lower dose than previous Patch
- Contraindication: BMI $\geq$30 (incr VTE)
- If estrogen is contraindicated (Migraine w aura)

NEW 2021 CDC Update: DMPA-SC
Self-administration of Subcutaneous Depot Medroxyprogesterone Acetate

Curtis KM, Nguyen A, Reeves JA, Clark EA, Folger SG, Whiteman MK. Update to U.S. Selected Practice Recommendations for Contraceptive Use: Self-Administration of Subcutaneous Depot Medroxyprogesterone Acetate. MMWR Morb Mortal Wkly Rep 2021;70:739–743. DOI: http://dx.doi.org/10.15585/mmwr.mm7020a2external icon.

New 2021 CDC: STI Treatment Guidelines

- Workowski KA, Bachmann LH, Chan PA, et al. Sexually Transmitted Infections Treatment Guidelines, 2021. MMWR Recomm Rep 2021;70(No. RR-4):1–187. DOI: http://dx.doi.org/10.15585/mmwr.rr7004a1external icon.

- CDC.gov/STI treatment guidelines

CDC STIs 2021: Updates

- GC: DO NOT GIVE AZITHROMYCIN

  CHLAMYDIA?: DOXY 100 MG PO BID X 7
  - Cervicitis: Rx = Chlamydia
  - HIV - Universal screening
  - HSV - IGG serology (No Universal screening)
  - Chlamydia, GC: NAAT
  - Trich -Teens and > 40 yr, (7 days for men, HIV+)
  - BV - x 7 days Rx, Pregnancy- Oral or Vaginal

    NEW: Secnidazole (Solosec) Oral Single Dose
  - PID - Low threshold for diagnosis
  - Sexual Assault – STI testing update
  - Syphilis- Increasing esp. in WOMEN

NEW: Gonorrhea Treatment 2020 CDC

- If $<$ 330 lbs - Ceftriaxone 500 mg IM
- If $\geq$ 330 lbs - Ceftriaxone 1 gm IM
- DO NOT GIVE Azithromycin!

  (high rate of resistance)
- If Chlamydia can NOT be ruled out,
- Give Doxycycline 100 mg PO bid x7d

NEW Antifungal:
Ibrexafungerp (Brexafemme)

- FDA approved June, 2021 based on
- Two Phase 3 trials (VANISH-303, VANISH 306)
- Novel oral "glucan synthase inhibitor"
  - Fungicidal
- Dosing: 150 mg BID x 2 days
- Effective, well tolerated
- Side Effects: Nausea, Vomiting, Diarrhea, etc.
- $350+
- Safety in pregnancy NOT known

Davis, M. R., Donnelley, M. A., & Thompson, G. R. (2020). Ibrexafungerp: A novel oral glucan synthase inhibitor. *Medical mycology*, *58*(5), 579–592. https://doi.org/10.1093/mmy/myz083

2018/2022 Menopause Guidelines: North American Menopause Society- NAMS, "Menopro" App

Within 10 years of LMP (FMP)

- **Vasomotor Symptoms (VMS)- Systemic Estrogen**
- **Vulvovaginal Atrophy (VVA) - Local Estrogen***

= Genitourinary Syndrome of Menopause (GSM) !!

- **Estrogen*: cream, tablets, ring, "Imvexxy"**
- **Ospemifene (Osphena) SERM, DHEA (Intrarosa)**
- **LASER: AVOID- per FDA Warning**

Lack long-term safety data !!!

*Bhupathiraju, S. N., Grodstein, F., Stampfer, M. J., Willett, W. C., Crandall, C. J., Shifren, J. L., & Manson, J. E. (2018). Vaginal estrogen use and chronic disease risk in the Nurses' Health Study. Menopause (New York, N.Y.), 26(6), 603–610. doi:10.1097/GME.0000000000001284 (**Vaginal Estrogen/ no incr risk. of breast, uterine cancer or CVD)**

Osteoporosis

- Disease of **low bone mass** with microarchitectural disruption

T-score:

- -1.0 to -2.5 (Osteopenia)
- -2.5 and below (Osteoporosis)

Osteoporosis: Risk Factors

- Caucasian, Asian
- Advanced age
- Previous fracture!!!
- Long-term glucocorticoid therapy
- Low body weight (< 127 lbs)
- Cigarette smoking
- Excess alcohol intake

Osteoporosis Screening: Guidelines

- DXA scan: dual x-ray absorptiometry
- Age 65: START screening !!!
- NO Pre-menopausal Screening unless risk factors

Osteoporosis

T-score:

- -1.0 to -2.5 (Osteopenia)
  - Possibly Treat if Risk Factors

- -2.5 or lower (Osteoporosis)

“FRAX” Calculator:
(No App Currently)

- Determines if treatment is necessary
- 10 year estimate of fracture risk
- Easy, Step by step process

Treatment based on RISK Estimates:

- Hip fracture risk >3% in 10 years
- All fracture risk >30% in 10 years

Osteoporosis Management

- Weight bearing exercise
- Resistance training!!! (wt lifting)
  Twice weekly (recommended)
- Stop cigarette smoking
- Avoid excess alcohol
- Avoid corticosteroids, anticonvulsants

Osteoporosis Management

- Calcium: Daily intake 600-1500 mg/day
- Preferred calcium source: FOOD !!!

- Vitamin D deficient: *Vitamin D3*
  - 800 - 1000 iu daily
  - varies per reference

- National Osteoporosis Foundation
  www. NOF.org

Osteoporosis: Medications

Inhibits Osteoclasts:

- Bisphosphonates: Alendronate (Fosamax 70 mg q d), Ibandronate (Boniva), Risedronate (Actonel):

    Take w 8 oz water, sit 60 mins, ~5 yr max duration

  Zoledronic acid (Reclast): 5 mg IV x 1 yearly

- Denosumab (Prolia): 60 mg SC q 6 months (forever)
- Calcitonin (Miacalcin): 200 iu spray altern. nostrils q d

Stimulates Osteoblasts:

- Teriparatide (Forteo): 20 mcg SC daily x 2 y

    Builds bone, used > 5 yrs postmenopause

- Raloxifene (Evista): 60 mg oral daily, hx DVT !
  - SERM estrogen-like effects on bone, protects breast, uterus

Endocrine Society: NEW 2019 Osteoporosis Guidelines

- Postmenopausal Women at High Risk,
  TREAT w/ Bisphosphonates (NOT Boniva)
- Reassess Risk after 3- 5 years,
  if NOW LOW RISK, consider Drug Holiday
- Denosumab: Alternative But NEW concern
  Rapid bone loss when STOP….so…
  Start NEW Med when stop Denosumab

Full guideline in the Journal of Clinical Endocrinology & Metabolism (Free PDF) http://response.jwatch.org/t?ctl=5207C:293E88F1177CBE119E197495A878D422D2B71D9A95FA21D3&
List of guideline recommendations (Free) http://response.jwatch.org/t?ctl=5207D:293E88F1177CBE119E197495A878D422D2B71D9A95FA21D3&

Oral Bisphosphonates:

First line for most patients

- Inhibits bone resorption:

  Remains active in bone for weeks, months, maybe years !!!

- Increases bone mass:
- Reduces risk of fracture:

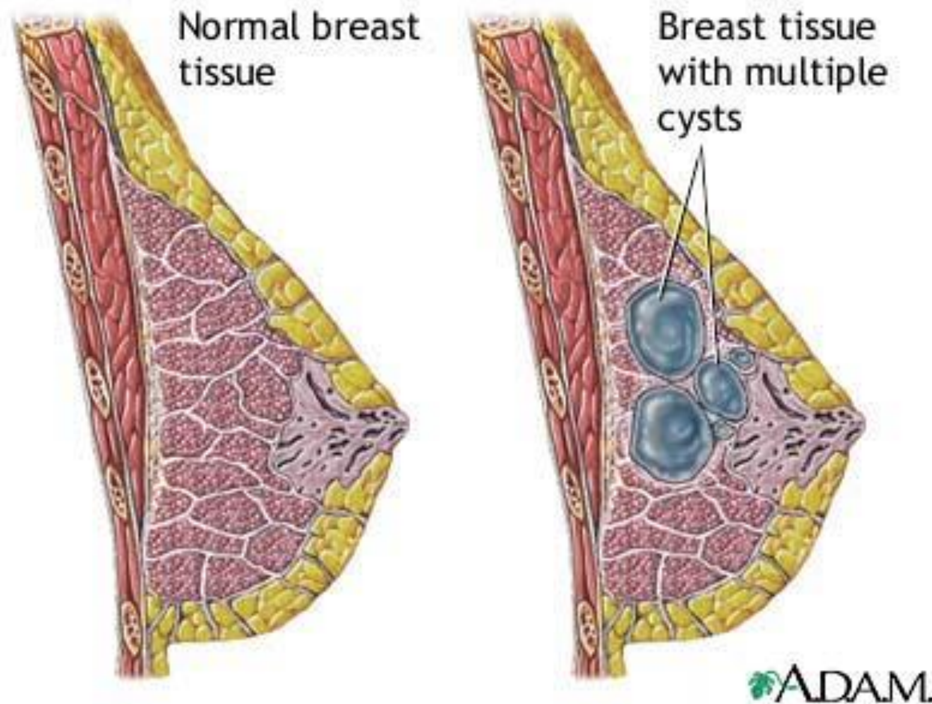
  Alendronate (Fosamax®) weekly
  Risedronate (Actonel®) weekly

- AVOID: Ibandronate (Boniva®) monthly

  No data re: reduced hip Fx risk!

Breast Cancer

Malignant tumor of the breast



ALERT: 85% of breast cancer occurs in women > 50 years

Breast Cancer: Risk Factors

- **Age, Gender: (Women > Men)**
- **Obesity:**
- **NEW - Dense Breasts: 3D = Tomosynthesis**
- **Family History/ Genetic risk: NEW: Ontario Tool**
  - **BRCA 1, 2 genetic mutations REFER**
- **Reproductive History: (low parity)**
- **Estrogen Exposure:**
  - **Early menarche <12 years**
  - **Late menopause >55 years**
- **Estrogen Meds: (vaginal estrogen NO incr. risk)**
  - **Combo OC- very low risk**

Incidence

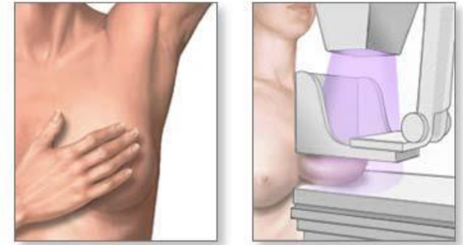
Age of woman	Risk of Breast Cancer
By age 30	1 in 2,212
By age 40	1 in 235
By age 50	1 in 54
By age 60	1 in 23
By age 70	1 in 14
By age 80	1 in 10
Ever	1 in 8

Breast Masses

- Most common:
  Fibroadenomas, Cysts
- Benign complaints:
  CAN *mimic* breast cancer
  and vice versa!
- DON'T assume "low risk" due to AGE

Diagnostic Studies

- **US: < 30 years**
  - for female/male < 30 years, w focal mass, or symptom
  - first line in pregnancy, or < 30 years
  - to assess mass identified on mammography



All breast lumps should be checked 3 ways: by self-exam, by health care provider exam and by mammography

ADAM.

- **Mammography: > 30 years**
  - for any female/male > 30 yr w/ breast complaint
  - **3D = Tomosynthesis:** If DENSE BREASTS

    Takes multiple views in an "arc"

Screening: Average or High Risk

- Average Risk Women – Mammogram* (3D best): CONTROVERSIAL
  - ACS:
    - 45-54 = every year (may screen 40-44)
    - 55+ = every 2 years* (yearly may be offered)
    - 75+ = If ~10 year survival =>> May continue screening
  - USPSTF 2016/2018: (12,070 studies, 5 systemic rev of 62 studies)!
    - 50-74 = every 2 years (may start earlier!!!)
- Clinical Breast Exam/ Self-breast Exam: NOT Recommended (ACS)
  - BUT consider performing and teaching SBE: WHY?
- High Risk Women: (USPSTF 2019 (JAMA)
  - Personal OR Family History Breast /Ovarian/ Tubal cancer
  - Ontario Family History Assessment tool (in Primary Care)!!
  - REFER: if Positive for Genetic testing (BRCAPRO, etc.)
  - Consider Annual MRI Screening AND Clinical Breast Exam

https://www.cdc.gov/cancer/breast/pdf/BreastCancerScreeningGuidelines.pdf

https://www.breastcancer.org/research-news/risk-assessment-tool-accurate-for-19-yrs

https://www.timeofcare.com/ontario-family-history-assessment-tool/

https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/brca-related-cancer-risk-assessment-genetic-counseling-and-genetic-testing

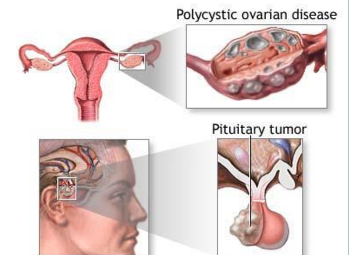
Resources and "Apps"

- "CDC Contraception 2016"
- Medications/contraceptives: "MPR"
- NEW: "ASCCP mobile, risk based f/u for abnormal cervical cancer screening tests"
- NEW: "CDC STD 2021"
- Menopause: Menopause.org
- Osteoporosis: "FRAX", NOF.org
- Breast Cancer: ACS.org
- ARHP. Org, NPWH.org, ACOG.org

Summary of Objectives

Upon completion of the session attendees will be able to:

- Discuss the epidemiology of selected conditions* including risk factors
- Explain key aspects of the most current guidelines/rationale for selected conditions* (Pharm 25%)
- Describe controversies re: these guidelines



*Cervical Cancer, Breast Cancer, Osteoporosis, Contraception, STIs, Menopause

Thank you and Questions

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MimiSecor.com