Womens Health Issues

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What’s New in Medicine 2017
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Disclosures

- Member of ACP guidelines and high value care committees
Objectives

- Discuss contraceptive choices
- Discuss vaginal/cervical infections
  - Diagnosis and treatment
- Review current guidelines for cancer screening for average risk person
  - Cervical
  - Colon
  - Breast
  - Lung
Contraception
Why discuss?

- Approx 50% of pregnancies in US are unintended
  - Rate is higher among lower income women
  - This is a preventable health issue
- >90% of women age 15–44 have use some form of contraception in their lifetime
- Improved access to care and education about options may improve contraception use and reduce unintended pregnancies
What to discuss

- Benefits vs risks of each method
  - Contraindications for combined OCP
  - Length of time for LARC
  - Reduction of endometrial cancer

- Efficacy rates of the contraception method

- Prevention of STDs
  - Aside from latex condoms– none of the other options prevents STDs

- Emergency contraception options
Contraception Options

- Hormonal
  - Combined method—OCP, transdermal patch, vaginal ring
  - Progesterone only—oral, injection
  - Long acting reversible contraception— IUD, subdermal implants

- Nonhormonal
  - Condoms
  - Diaphragms
  - Copper IUD
  - Vaginal sponges
  - Sterilization—tubal ligation, vasectomy
  - Abstinence
## Contraception efficacy rates
### unplanned pregnancy in first year %

source: Ann Intern Med In the Clinic 2012

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<th>Method</th>
<th>Typical use</th>
<th>Perfect use</th>
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<tr>
<td>LNG–IUD</td>
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<td>Copper IUD</td>
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<td>Subdermal implant</td>
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<td>Vaginal ring</td>
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<tr>
<td>Transdermal patch</td>
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<td>Combined OCP</td>
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<td>Progesterone only pill</td>
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<tr>
<td>Sterilization</td>
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<td>0.007–0.5</td>
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Long Acting Reversible Contraception

- Intrauterine devices
  - Levonorgestrel – Mirena, Liletta, and Kyleena, Skyla (lower dose) – lasts 3–5 yrs
  - Copper (Paragard) – lasts 10 yrs
- Subdermal implants
  - Etonogestrel (Nexplanon) – last 3 yrs

- Advantages: lowest unintended pregnancy
  - Effective for 3 yr (implant) up to 10 yrs (copper)
  - High satisfaction among women
  - can be used in those where OCP contraindicated
  - Helpful for dysmenorrhea/heavy menses

Disadvantages – abnormal bleeding, expulsion (for IUD), risk of perforation (IUD), cost

Contraindications – distorted uterus (IUD), cervical ca, breast ca, severe liver failure, AIDS
Other hormonal contraception

- Combined estrogen/progesterone
  - Oral birth control pills
  - Transdermal patch (orthoevra)
  - Vaginal ring (nuvaring)

- Progesterone only
  - Oral pills
  - Depo-medroxyprogesterone (given q 3 mo IM inj)

Advantages: effective 90–99% if used correctly
High satisfaction, generics available, cost, help with dysmenorrhea/heavy menses
Disadvantages– more unintended pregnancy, side effects vary depending on type–wt gain, bleeding, liver toxicity, VTE (estrogen containing)

Contraindications: VTE, smoking, h/o stroke, uncontrolled htn, migraine with aura, breast ca, within 30 days of delivery (for combined form),
Case 1

- 22 yo in for RPE wants to discuss birth control. She has one male partner currently using condoms. She does not desire pregnancy for many years. What do you recommend?

- She has no significant past medical history. Mother had breast cancer at age 65
Case 2

- 26 yo wants other options aside from condoms for birth control. She does not want a LARC as she wants to plan pregnancy in next 1–3 years. She has severe cramping with menses and anemia due to heavy bleeding. She has no h/o vte, smoking, htn.

What do you recommend?
- A. norethindrone 0.35
- B. ethinyl estradiol/drospirenone (yasmin)
- C ethinly estradiol/norethrindone 30/1.5 (ie junel)
- D. ethinyl estradiol/etonogestrel ring q3wks
- E. ethinyl estradiol/norelgestromin patch
Case 2 considerations

- Progesterone only pill
  - may have higher failure rate
  - needs to be taken same time every day
  - Menstrual irregularity

- Combined OCP/patch/ring
  - All OCP may help acne
  - All have risk of VTE
  - OCP w/drospirenone/desogestrel (Yaz/yasmin) and Patch– 1.5–3 x higher risk of DVT (Lidegaard BMJ 2012)
  - Ring higher risk of DVT than standard OCP– need to weigh risk vs benefit of remembering pill
Other risks/benefits

- Breast tenderness
- Spotting is common in first month
- Nausea

- Decreased risk (by 50%) of endometrial cancer on combined contraception
  - Source: Mueck. Endocr Relat Ca 2010

- Decreased risk of ovarian cancer (by 27%)
  - Source: Crane. J Natl Cancer Inst 2011
Case 3

32 yo had unprotected sex last night and does not want to become pregnant. LMP 3 weeks ago. Wt 170lbs. what do you recommend

A. Do urine preg, if neg reassure
B. Levonoregestrel 1.5 mg (Plan B)
C. Copper IUD
D. Ulipristal 30 mg (Ella/Ella One)
Either copper IUD or Ulipristal are reasonable as first line.

- Copper IUD is most effective form and can remain in place for long term contraception—need to expedite having it placed
- Can be used up to 120 hours after unprotected sex
- Can be used with higher BMI
  - Study using levonorgestrel has higher failure rates in women with Wt > 75 kg (165lbs) 6% vs 2% (<75kg)
    - Source: Kapp N contraception Feb 2015
Prevention of pregnancy is important part of primary care
Discuss with at risk woman for their preference
LARC have highest efficacy and satisfaction
Combined hormonal efficacious
  ◦ Has potential higher risk but also other benefits
Vaginal and Cervical Infections
Bacterial Vaginosis

- Most common vaginal infection 15–44
- Polymicrobial infection w/replacement of normal lactobacilli with other organisms (G.vaginalis, Mycoplasma etc)
- Higher risk with new sex contact, multiple contacts, no condom, douching
- Can increase risk of HIV acquisition and other STD
- Exact mechanism of alteration is not known
Clinical manifestations/Dx

- Thin white or gray discharge
- Fishy odor
- Burning on urination
- Vaginal itching

Diagnosis (3 of 4 needed)
- Thin, white discharge on vaginal wall
- Clue cells on wet mount
- PH >4.5 or
- +whiff test (fish smell after adding KOH)
Bacterial Vaginosis

http://medicalmicro.blogspot.com
Recommended Treatment

- Metronidazole 500 mg bid x 7 days
- Metronidazole gel 0.75% one applicator intravaginally qhs x 5 days
- Clindamycin cream 2% one applicator intravaginally qhs x 7 days
- Not necessary to treat partners
Yeast vaginitis

- Organism—typically *candida albicans*
- 75% of women have had at least one episode
- Higher risk in women with diabetes, HIV/AIDS, immunocompromised

- Clinical: itching, vaginal/vulvar redness
- “cottage cheesy” discharge
Yeast vaginitis: Dx and TX

- Diagnosis – clinical presentation
  - Presence of pseudohyphae or buds on wet prep or KOH

- Treatment
  - Only treat symptomatic women
  - Topical vaginal antifungals (OTC – clotrimazole/miconazole – 3–7 days)
  - Fluconazole 150 mg once
Diagnosis can be difficult

- Vaginal secretion slide less sensitive
- FDA approved PCR for GC/CT can be modified to include trichomonas and sensitivity is higher
- Point of care with Trichomonas rapid test also available
- Rx: metronidazole
- Partner treatment recommended
"Strawberry" cervix due to *T. vaginalis*
Syphilis

- Treponema Pallidum
- Wide clinical presentation “the great imitator”
- Diagnosis: Enzyme immunoassay, Quantitative RPR and treponemal tests
- Treatment: Benzathine PCN
- Test and treat partners
- **LP not recommended unless presence of neurologic symptoms**
  - Consider LP if no improvement in titer post Rx
  - Consider in HIV+: controversial
    - ** new recommendation in 2010 STD guideline**
Cancer Screening
Screening criteria for cancers

- Detect cancer in preclinical phase
  - Cancers that are destined to cause death
- Early treatment more beneficial than waiting until CA is clinically apparent
- Mortality benefit: 10 yr survival impact
- Benefit outweighs harm
- Cost Effective
Cervical cancer

- In 2010, 11,818 diagnosed with cervical CA 3939 died
- Most common occurs in age 35–55
- Population-wide PAP testing has reduced cervical mortality by 80% (Am J Clin Pathol 2012,137:516)

- From 2001–2010
  - Cervical CA incidence decreased by 1.5%–4.2% per yr
  - Mortality decreased by 1.3%–4.6% per yr

Prevention: HPV vaccination of girls and boys

- Source CDC
33 yo female comes in for routine annual exam. Her last PAP was 3 yrs ago and was normal. When should her next PAP test be?

- A. Today
- B. 2 years
- C. 3 years
- D. 5 years
Case 2: cervical

- 68 yo female originally from Somalia presents for routine health care. She has no records and cannot recall her screening previously.
- She is otherwise healthy
- What is the recommendation for cervical cancer screening?
  - A. she no longer needs screening due to age
  - B. she should get PAP test today
  - C. she should go for colposcopy
  - D. do HIV testing and then decide
Cervical CA screening

- Age 21-65 every 3 yrs with NL PAP (no HPV done)
- Age 30-65 every 5 yrs with NL PAP and Neg HPV
- No benefit for PAP in age < 21
- No benefit and potential harm for HPV testing in ages 21-30

Stop screening (for avg risk)
- Age 65 if normal screening PAPs previously- need at least 3 negative PAP (or 2 neg PAP w/ neg HPV) within 10 yrs
- Hysterectomy for benign pathology
- Potential harm of screening higher than benefit
  - No mortality benefit for patient

Recommendations are for average risk women (not HIV+, prior CIN/CA )
Updated guidelines if abnormal PAP  http://www.asccp.org/Guidelines

- Best Practice advice: Ann Intern Med 2015;851–859
Screening: off-target? Cervical CA

FIGURE. Percentage of women who had a recent Papanicolaou (Pap) test (within 3 years), by hysterectomy status and age group — Behavioral Risk Factor Surveillance System, United States, 2000–2010*
< 0.1% of woman > 60yo w/ normal baseline PAP will develop HGSIL or cervical CA

> 80% of women w/ HGSIL or cervical CA have had either no PAP or abnormal PAPs

9610 vaginal PAP smears (s/p benign TAH)
→ 1.1% abnormal PAP smears
→ Zero vaginal CAs

Ref:
- Am Fam Physician 2008;78:1369
- NEJM 1996;335:1559
- Am J Clin Pathol 2012;137:516
Colorectal cancer

- Second leading cause of cancer-related death in men and women

- Incidence 134,000 (2016, approx)
  - Declining by 2–3% over past 15 yrs

- Death approx 51,370 per year
  - Declining by 1.4–3% per year

5% lifetime risk of colorectal CA in US
- 93% occur in pts >50 yo
  - Sources: CDC statistics
Case 1: colorectal

- 50 yo female comes in for annual exam. Which of the following is appropriate for colorectal cancer screening
  - A. FOBT or FIT annually
  - B. Flexible sigmoidoscopy now & every 5 yrs
  - C. Colonoscopy now and every 10 yrs
  - D. All of the above
Case 2: colorectal

- 55 yo female undergoes routine screening colonoscopy. Adenomatous polyps were found and removed. When is her next colonoscopy due?
  - A. 10 yrs
  - B. 5 yrs
  - C. 3 yrs
  - D. 1 yr
Case 3: colorectal

- 75 yo female with h/o CHF and CAD comes in for Medicare wellness visit. She asks about colon ca screening (previous colonoscopy was normal). What is the current recommendation?
  - A. repeat colonoscopy now as last one was 10 yrs ago
  - B. no longer needs colon ca screening
  - C. discuss risk vs benefit before deciding
  - D. depends on his overall health and prognosis
Colon CA screening

- Start age 50 for avg risk
- Start age 40 or 10 yrs before age of dx of 1st degree family member with colon CA

Screening tool
- Optimal colonoscopy for higher risk
- Annual FOBT/FIT (fecal immunochemical test)
- FIT-DNA - few studies, higher cost, ↑ sens, ↓ spec
- Flex-sigmoidoscopy q 5 yrs (debate exists)

Colonoscopy every 10 yrs if nl colonoscopy
- Every 5 yrs if adenomatous polyps

Source: USPSTF, ACP, ACS
Screening measures

- Annual FOBT– RCTs show approx 33% lower mortality (NEJM 1993;328:1365)

- Annual FIT testing – may replace FOBT–1 stool, higher sensitivity, French study showed FIT detected 2x more cases of neoplasia than FOBT (Gut 2006)
  - Sens: 62–79% Spec: 87–96%

- Any positive test for either FOBT or FIT warrants colonoscopy

- Flex–sig: large prospective trials show reduction of incidence by 18–23% and mortality 22–31%, better for distal colon ca than proximal
  - NNS to prevent 1 colon CA death: 850 (PLoS Med 2013;9e1001352)
Screening methods

- Colonoscopy
- No RCTs evaluating reducing morbidity/mortality
- Several case-control studies, population based study show benefit
  - 61% reduction in distal colon, 22% in proximal
- Adv: every 10 yrs, can detect and remove polyps, visualize entire colon (if good prep)
- Disadv: 2 days off work, perforation, cost, bleeding, bowel prep, sedation. Operator dependent
- Risks: 4 perf and 8 bleed per 10,000 screened,

New screening techniques

- Fecal DNA testing
- Studies have shown good sensitivity and specificity for detection of CRC and adenoma
  - Studies cite 84–97% sens–lower for adenoma
  - spec 84–85%
- Expensive (compared to FOBT/FIT)–approx $700
- Included on ACS, MSTFCC and ACR guidelines
- Not clear yet on interval testing
- If positive still need colonoscopy

Sources: Ann Intern Med 2014 ITC
NEJM 2014:370:1287
Clin Castroenterol Hepatol 2013;11:1313
Colon CA screening in elderly: benefits

- RCTs for FOBT screening included >40,000 patients age 70–80
  - Reduced colon CA mortality by ~15%
  - Independent of age

- Case–control trials of lower endoscopy included patients age 70–91
  - Reduced colon CA mortality by ~60%
  - Independent of age
Colon CA screening: risks

- Medicare pts age 66–95:
  - Adverse event rate: 14 / 1000 c–scopes
    (Perforation rate: 0.5 / 1000)
  - Serious adverse events increased by:
    - Age
    - Co–morbidity

Ann Intern Med 2009;150:849–857
Benefits and Harms: colorectal
Model estimates per 1000 screened

- Life years gained: 181–270
- Colon ca deaths averted: 17–24
- Complications (GI/cardiac): 9–15

- CA screening strategies comparable

- JAMA 2016;315:2564–90
- Outcomes from CISNET
Colon CA screening: caveats

But... diminishing returns with age?

- Cross-sectional study:

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<tr>
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<th>Age 50-54</th>
<th>Age 75-79</th>
<th>Age ≥ 80</th>
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<tbody>
<tr>
<td>% with advanced neoplasia</td>
<td>3.2%</td>
<td>4.7%</td>
<td>14%</td>
</tr>
<tr>
<td>Years of life expectancy gained</td>
<td>0.85</td>
<td>0.17</td>
<td>0.13</td>
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Colon CA screening: caveats

Diminishing returns: more so with co-morbidity?
Colon CA screening:

- USPSTF:
  - 76–85yo: against routine screening, consider in individual patients (C)
  - >85 yo: against screening (D)
- ACS, ACG: no stop recommendation
- AGS: Life expectancy < 3–5y
- ACP: Age 75, or if life expectancy < 10y
- AAFP: same as USPSTF
Breast Cancer Screening

- Accounts for 23% of all CA in women, cumulative life risk in US 12%
- Mammography remains the primary screening tool
  - Meta-analysis: 15–20% reduction in risk of mortality—all ages but less significant for younger age (ranges 8%–32%)
- Incidence of breast CA in 2015 (US)
  - 231,840 women
- Death from breast CA in 2015 (US)
  - Approx 40,290
- From 2001–2010
  - Incidence is level
  - Mortality decreased by 1.5–2% per year
- Risk Factors: FH, BRCA, alcohol, HRT, obesity, ? breast density, chest radiation

JAMA 2015;314
Ann Intern Med 2016;164
NEJM 2007: 356
Case: breast ca screening

- 45 yo woman comes in for routine health maintenance exam. No FH of breast CA. she is confused about whether she should get mammogram screening. What is the recommendation?
  - A. Screen now and then annually
  - B. delay screening to age 50 and do annually
  - C. Screen now and then delay to age 50
  - B. Delay screening to age 50 and do every 2 yrs
Breast CA screening

- ACS: variable
  - 40-44 discuss, 45-54 annual, 55+ q 1-2 yrs
- USPSTF: age 50-74; every 2 yrs
  - Age 40-49-individual decision- every 2 yr
  - Consider stopping age 75
- ACOG: age 40+ annual
  - Consider stopping or discussion age 75
- Canadian PSTF: age 50-74- annual
- ACR: age 40+ annual
  - JAMA 2014;311:1327
  - JAMA 2015; 314:1599-1614
Why the controversy?

- 40–49: RRR 15%: approx 2400 women screened to prevent 1 death
  - Higher rate of false positive (60%)
- 50–59: RRR 15%: 1500 screened to prevent 1 death
- 60–69: RRR 32%: 377 screened to prevent 1 death
- Over 10 yrs of mammogram at least 50% will have one false alarm

  - Source: Ann Intern Med  april 2010 ITC (USPSTF)
  - JAMA 2015; 314 :1615–31 (USFSTF/CISNET)
Why every 2 yrs and age 50?

- 2009 USPSTF update on breast ca screening
- Gain for screening age 40–49 is small (C rec)
- New data shows little difference in mortality with biennial screening vs annual for age 50–74 (B rec)
- Insufficient evidence for screening > 75yo

Why every 2 yrs and age 50?

- Mandelblatt et al: Mammogram screening: model estimates of potential benefits and harms
- Evaluate screening strategies using 6 models
- Results:
  - Biennial screening maintained avg 81% (67–99) of annual screening benefit
  - 50% reduction of false-positive results
  - Mortality reduction (age 50–69) 16.5%, age 40–49 additional 3% reduction but more false positives
- Take home: Biennial screening achieves most of benefit with less harm than annual

25 yo follow up for breast ca incidence & mortality
Randomized screening trial
Results: 89835 women followed
1190 breast ca found (666 in mammo/524 control)
351 deaths (of 1190 during screening period)
Conclusion: similar cumulative mortality between screened and control in both age groups (40–49 and 50–59)
SEER data 1976–2008

Results: increase number of cases of early breast ca (112 to 234/100,000)

Decrease of late stage presentation (102 to 94)

Only 8 of the 122 early ca were predicted to progress to advance disease

Estimate that in 2008–overdx of breast ca in 70,000 women (31% of all breast ca dx)

Decrease in death – 28% (ages 40+) – study claims this is more from improved RX than screening
UK/Swedish studies

J Med Screen 2010;17:25–30

- Analysis of Swedish two-county randomized trial and UK breast screening program
- Ages: 50–69, screening every 24–33 mo
- Result of Swedish study: 8.8 breast cancer deaths prevented per 1000 screened
  - Overdx: 4.3 per 1000
- Result of UK study: 5.7 deaths prevented per 1000 screened
  - Overdx 2.3 per 1000

Conclusion: for every 2 cancer deaths prevented, 1 overdx
Risks of mammogram

- Overdiagnosis of breast ca (ca that will not become clinically problematic or cause death)
- False positive—leading to biopsy, scarring, anxiety
- Radiation risks over time
What about dense breasts?

- Friedewald et al: retrospective study
- Compared digital mammogram vs digital mammogram with tomosynthesis
- Main outcomes:
  - 1207 CA in mammogram
  - 950 CA in mammo plus tomo
  - Overall increase in CA detection of 1.2 (0.8–1.6) in mammo/tomo
  - PPV 4.3% (mammo) vs 6.4% mammo/tomo
- Take home: mammo/tomo less recall and slight increase CA detection. Did not have data on harm or mortality benefit
- Risks: mammo/tomo – 2x radiation of digital mammo

- JAMA 2014;311:2499–2507
- JAMA Intern Med 2013;173:807–16
So what do I do?

- Highest value is for women age 50–69
- Discuss screening for ages 40–49 (shared decision making)
- Reasonable to start age 50+ with 2 yr screening—no change in mortality and less false positive
- Dense breasts—? Unknown if annual vs biennial better or mammo/tomo vs mammo
- No benefit after age 80
- If healthy female—likely benefit ages 70–79
Lung Cancer

- Leading cause of CA death in the US
- Most imprt risk factor: smoking—contributes to 85% of lung CA cases
- In 2010: 201,144 dxed with lung CA
  - 158,248 diet from disease
  - From 2001–2010
  - Incidence in men decreased 2.3–2.7% per yr (women 0.6–1%)…..stable for AA, AI, NA, Asian
  - Mortality in men decreased 1.6–3.3% per yr) women 0.9–1.1%)….level for AI, Asian
Case 1: Lung ca

- 60 yo female former smoker. 15pk yrs. Quit 10 yrs ago. FH + for CAD but no CA.
- What is the appropriate screening?
  - A. Transvaginal US for ovarian CA
  - B. Colon CA
  - C. CT chest for lung CA
  - D. Abdominal Aortic Aneurysm
65 yo current smoker with 35 pk yrs. Has no desire to quit. Just heard about lung cancer screening and wants your opinion. What do the guidelines say?

A. should not have screening as still smokes
B. Lung CA screening may be beneficial
C. should have CXR instead
D. Screening reduced lung ca mortality by 50%
LUNG CA Screening

- USPSTF guidelines
- Annual screening with low-dose CT
- Criteria: min 30 pk yr smoking hx
- Current smoker or quit within 15 yrs
- Age 44–80
- Life expectancy > 10 yrs
- Willing to undergo lung surgery

What’s the data

- **DANTE trial**: Am J Respir Crit Care Med 2009;180:445
- Men age 60–75, 20 pk yr smokers
- Compared annual LDCT x 4 yr vs control (one cxr)
- 1276 in LDCT vs 1196 in control
- Results
  - 60 lung ca in LDCT vs 34 in control
  - More stage 1 in LDCT
  - No difference in death rates (20 in each grp)
  - Harm more invasive procedures for benign disease in LDCT
What’s the data

- Nat’l Lung Screening Trial (NLST)
- Randomized to annual LDCT vs CXR
- Age 55–74, 30 pk yr smoking, quit <15 yr or current smoker
- Incidence of lung ca 645/100,000 person yrs (LDCT) vs 572/100,000 (CXR)
- Death 247/100,000 vs 309/100,000
- Outcome: 20% relative reduction of mortality
- 18% overdiagnosis
- NNS to prevent one lung ca death: 320
- Higher complications in LDCT screening
- Conclusions: LDCT might be beneficial but have to weigh risks/benefits
  - Source: NEJM 2011;365:395–409
What’s the data

source: NEJM 2011;365:395-409

Diagram: Death from Lung Cancer

- Cumulative No. of Lung-Cancer Deaths vs. Years since Randomization
  - Chest radiography
  - Low-dose CT
What’s the data

- 3 reviews (incl NLST)
- Findings: only NLST showed benefit, the other 2 smaller studies showed no benefit (DANTE/DLST)
- Harms: 20% of LDCT in each round had positive results requiring some f/u. only 1% had lung ca
- Conclusions: one RCT showed benefit, consider screening high risk pts but need to do risk/benefit discussion
Lung CA screening

- New study showing relative risk reduction of 20%
- Annual screen ages 55-74 with
  - 30+pk yr smoking hx
  - Still smoking or quit within 15 yrs
- Use low dose chest CT scan with no contrast

Potential harms
- high false positive rate-leading to procedure risk
- radiation exposure
- does not address root cause….TOBACCO

source: NEJM 2011;365:295-409
Take Home Points

- Cancer screening can save lives if used appropriately
  - Cervical ages 21–65 (q3–5yrs)
  - Colon ages 50–75 (consider older if healthy)
  - Breast ages 50–75 (consider older if healthy)
  - Lung – ages 55–80 (only at risk)

- Know when to stop screening for elderly, co–morbid or when necessity is gone (ie TAH)