Women's Health Congress
Washington DC, April 5, 2014

Paps & Pelvics: Where Do We Stand?

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Case Study
- 28 year old woman is seen for periodic health screening visit (aka, a “Well Woman” visit)
- Monogamous relationship for the past two years
- Feeling well; no complaint of vaginal discharge, abnormal bleeding, dyspareunia
- Last cervical cytology was 24 months ago: benign result
- Currently using the contraceptive patch
- According to USPSTF guidelines, what should be done?

Check Up Visit (28 Year Old Female)
- Clinical breast exam
- Pap smear
- Bimanual pelvic exam
- Chlamydia NAAT
- Gonorrhea NAAT
- HIV-1 serology
- HSV-2 serology
- Syphilis (VDRL or RPR)
- Hepatitis B serology
- HPV test (Hybrid Capture)

The Health Screening Visit
- Major health objectives
  - Optimize health status through anticipatory guidance and screening for asymptomatic conditions
  - Increase the client’s sense of well-being
  - Promote the clinician-client relationship
  - Positive action toward self-maintenance of health
- In a reproductive health context
  - Clarify the client’s reproductive life plan
  - Support correct and consistent use of her contraceptive, or
  - Counsel regarding fertility and preconception health
  - Advice to protect health and reproductive capacity

USPSTF: Check Up Visit (28 Year Old Female)
- Clinical breast exam
- Pap smear
- Bimanual pelvic exam
- Chlamydia NAAT
- Gonorrhea NAAT
- HIV-1 serology
- HSV-2 serology
- Syphilis (VDRL or RPR)
- Hepatitis B serology
- HPV test (Hybrid Capture)
Who Defines Well Woman Services?

- US Preventive Services Taskforce
  - Primary care specialty societies (ACP, AAFP)
  - Most health plan guidelines
- American College of Obstetricians and Gynecologists
  - “Primary and Preventive Care”
- American Academy of Pediatrics (AAP)
  - “Bright Futures” guidelines
- Advocacy groups
  - ACS, AHA, and ADA joint guideline
- ACA: Women’s Preventive Services
  - Benefits without cost-sharing; not practice guidelines

USPSTF: 25-64 Age Band

- Anticipatory Guidance (counseling)
  - Tobacco cessation; avoid tobacco use
  - Avoid alcohol use while driving, boating, swimming
  - Diet: limit fat and cholesterol; adequate calcium intake
  - Regular physical activity and exercise
  - Injury prevention: seat belts, helmets, smoke detector
  - Sexual behavior: contraception, STD prevention
  - Dental health
    - Regular visits to dental provider
    - Floss, brush with fluoride toothpaste daily
  - Chemoprophylaxis
    - Folic acid (women planning pregnancy)

USPSTF: 25-64 Age Band

- Physical exam, lab, and imaging tests
  - Height and weight
  - Blood pressure
  - Cervical cytology
  - HIV screening (once, individuals 13-65 y.o.)
  - Targeted STD screening (GC, Ct, syphilis, HIV)
  - Mammography (starting at 50 yo)
  - Colorectal cancer screening (starting at 50 yo)
  - Rubella serology or vaccination hx (childbearing age)

ACOG Primary and Preventive Care
ACOG Committee Opinion #483
Obstet Gynecol 2011;117:1008

- More aggressive than other screening guidelines
- Retrogressive, compared to evidence based guidelines
- Assumes that the ObGyn is functioning as primary care provider; no mention of coordination with PCP
- Updated with Opinion #534 (Well Woman Visit) and Practice Bulletin #131 (Screening for Cervical Cancer)

Well Woman Health Screening Visits

- Is a physical exam necessary with every screening visit?
  - As needed for scheduled screening tests
  - Diagnostic exam when symptoms or signs present
  - Some visits will consist solely of counseling and education without an exam beyond a BP check
- Is a yearly health screening visit advised if no tests are due?
  - USPSTF: visits can be every 1-3 years, depending upon health status and risk behaviors of the client
  - ACOG: perform annually

Cervical Cancer Screening

- Most successful cancer screening program in the US
  - 70% reduction in cervical cancer deaths in past 60 years
  - 2012: 12,000 new cervical cancers; 4,200 deaths per year
- Earlier public health messages have impacted public attitudes and behaviors…but now they need to evolve!
- Advances in cervical cancer prevention since 1940s
  - Liquid-based cytology (LBC)...better test throughput
  - hrHPV-DNA testing...co-testing and triage of test results
  - HPV vaccination...primary prevention of cervical cancer
  - Evidence-based cytology screening guidelines
The BIG Picture
ACOG Practice Bulletin No. 109, Dec 2009

- Of women diagnosed with cervical cancer each year
  - 50% have never had cervical cytology testing
  - 10% had not been screened within 5 years of diagnosis
- **Response**
  - Systemic reminders for those screened infrequently
  - Outreach to women who have never been screened
  - Immigrants from countries where cytology screening is not the norm are an especially high-risk group

ACOG Cervical Cytology Guidelines
ACOG Practice Bulletin #109 (2009)

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Women under 21 yrs old</td>
<td>Avoid screening (regardless of age or other risk factors)</td>
</tr>
<tr>
<td>21-29 years old</td>
<td>Screen every 2 years</td>
</tr>
<tr>
<td>30 to 65 or 70 years old</td>
<td>May screen every 3 years</td>
</tr>
<tr>
<td>65 or 70 years old and older</td>
<td>May discontinue screening</td>
</tr>
<tr>
<td>HIV-positive</td>
<td>Screen annually</td>
</tr>
<tr>
<td>Immunosuppressed</td>
<td></td>
</tr>
<tr>
<td>Exposed in utero to DES</td>
<td></td>
</tr>
</tbody>
</table>

USPSTF Cervical Cytology Guidelines: 3/2012
Meyer VA; Ann Intern Med. 2012; 156(12):880-91

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Grade</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cytology only, 21 to 65 years old</td>
<td>A</td>
<td>Every 3 years</td>
</tr>
<tr>
<td>HPV + cytology co-testing, 30-65 years old</td>
<td>A</td>
<td>Every 5 years</td>
</tr>
<tr>
<td>Women under 21 yrs old</td>
<td>D</td>
<td>Avoid screening</td>
</tr>
<tr>
<td>Age ≥65 with adequate prior screening and not high risk</td>
<td>D</td>
<td>Avoid screening</td>
</tr>
<tr>
<td>Total hysterectomy; benign disease</td>
<td>D</td>
<td>Avoid screening</td>
</tr>
<tr>
<td>HPV testing, alone or in combination, &lt;30 years old</td>
<td>D</td>
<td>Avoid screening</td>
</tr>
</tbody>
</table>

Triple A Guideline: ACS, ASCCP, Am Society for Clinical Pathology
CA CANCER J CLIN March 2012

<table>
<thead>
<tr>
<th>Years of Age</th>
<th>Screening</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;21</td>
<td>No screening</td>
</tr>
<tr>
<td>21-29</td>
<td>Cytology alone every 3 years</td>
</tr>
<tr>
<td>30-65</td>
<td>Preferred: HPV + cytology every 5 years* OR Acceptable: Cytology alone every 3 years*</td>
</tr>
<tr>
<td>&gt;65</td>
<td>No screening, if no history of CIN2+ in the past 20 years or cervical cancer ever</td>
</tr>
</tbody>
</table>

If cytology result is negative or ASCUS + HPV negative

Other Important Messages

- Women at any age should NOT be screened annually by any screening method
- For women 65 and older
  - “Adequate screening” is defined as...
    - 3 consecutively negative results in prior 10 years, or
    - 2 negative co-tests, most recently within 5 years
  - If screening stopped, do not restart for any reason
- Women treated for CIN 2+ or AIS must be regularly screened for 20 years, even if 65 or older
  - With cytology alone Q 3 years or HPV+ cytology Q5 years

Management of Co-Testing Results

<table>
<thead>
<tr>
<th>Cytology</th>
<th>HPV Positive</th>
<th>HPV Negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative</td>
<td>Co-test in 12 months, or Subtype for HPV 16/18</td>
<td>Co-test in 5 years</td>
</tr>
<tr>
<td>ASC-US</td>
<td>Colposcopy</td>
<td>Co-test in 5 years</td>
</tr>
</tbody>
</table>

ASC-US/HPV-negative is equivalent to cytology negative/HPV negative

ACOG Practice Bulletin #131, Obstet Gynecol 2012;120:1222-38
USPSTF: Co-Testing Caveat

- Co-testing is most appropriate for women who want to extend their screening interval to every 5 years

But...

- “Women choosing co-testing ... should be aware that positive screening results are more likely with HPV-based strategies... and that some women may require prolonged surveillance with additional frequent testing if they have persistently positive HPV results”

Co-testing Strategy as Health Policy

Pros
- Slightly more accurate than cytology alone
- Higher negative predictive value than cytology alone
- Longer screening interval available if desired by patient

Cons
- More false positives, esp. if done too frequently
- High cost/ year of life saved if done too frequently
- Many providers do not have EMRs or other systems to prevent overuse

Summary of Cervical Cancer Guidelines

<table>
<thead>
<tr>
<th></th>
<th>Under 21 years old</th>
<th>21-29 years old</th>
<th>30-65 Years old</th>
<th>&gt;65 years old</th>
<th>Hyst, benign</th>
</tr>
</thead>
<tbody>
<tr>
<td>USPSTF 2012</td>
<td>(D)</td>
<td>Every 3 y</td>
<td>Co-test: Q5</td>
<td>None**</td>
<td>[D]</td>
</tr>
<tr>
<td>Triple A 2012</td>
<td>None</td>
<td>Every 3 y</td>
<td>Co-test: Q5*</td>
<td>None**</td>
<td>None</td>
</tr>
<tr>
<td>ACOG 2012</td>
<td>“Avoid”</td>
<td>Every 3 y</td>
<td>Co-test: Q5*</td>
<td>None**</td>
<td>None</td>
</tr>
<tr>
<td>hrHPV test</td>
<td>Never</td>
<td>Reflex only</td>
<td>Co-test or reflex</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

* Preferred
** If adequate prior screening with negative results
- Co-test: cervical cytology plus hrHPV test
- Cytology: cervical cytology (Pap smear) alone

Common Questions About Cytology Intervals

- Do virginal women need to be screened?
- Are the intervals any different for women
  - With multiple sexual partners?
  - Using hormonal contraceptives, menopausal HT?
  - Who only have female partners?
  - Who are pregnant?
  - Who have been HPV vaccinated?
- If a cytology is not scheduled or necessary, what about the need to perform a screening bimanual pelvic exam?
Pelvic Exam at the Well-Woman Visit

- Women younger than 21 years
  - Pelvic exam only when indicated by medical history
  - Screen for GC, chlamydia with vaginal swab or urine
- Women aged 21 years or older
  - “ACOG recommends an annual pelvic examination”
    - No evidence supports or refutes routine exam if low risk
  - If asymptomatic, pelvic exam should be a “shared decision”
    - Individual risk factors, patient expectations, and medico-legal concerns may influence these decisions
    - If TAH-BSO, decision “left to the patient” if asymptomatic

The Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Randomized Controlled Trial
Buys SS, Partridge E, et al. JAMA. 2011;305(22):2295-2303

- Randomized trial of 78,216 women aged 55-74
- Annual screening with CA-125 for 6 years + transvaginal U/S for 4 years (n=39,105) versus usual care (n=39,111)
- 10 US screening centers
- Followed a median of 12 years
- Bimanual examination originally part of the screening procedures but was discontinued

Ovarian Cancers: PLCO Cancer Screening RCT
JAMA. 2011;305(22):2295-2303

Is The “Screening Pelvic Exam” Outdated?

<table>
<thead>
<tr>
<th>Screen for</th>
<th>Preferred test</th>
</tr>
</thead>
<tbody>
<tr>
<td>GC, CI</td>
<td>NAAT: vaginal swab or urine sample</td>
</tr>
<tr>
<td>Cervical cancer</td>
<td>Not recommended until 21 years old</td>
</tr>
<tr>
<td></td>
<td>Cytology every 3-5 yrs afterward</td>
</tr>
<tr>
<td></td>
<td>None, if total hyst for benign disease</td>
</tr>
<tr>
<td>Ovarian cancer</td>
<td>USPSTF rec. against screening</td>
</tr>
<tr>
<td>Vulvar lesions</td>
<td>Unnecessary if asymptomatic</td>
</tr>
<tr>
<td>Vaginal infxn</td>
<td>Unnecessary if asymptomatic</td>
</tr>
<tr>
<td>Myomas</td>
<td>Unnecessary if asymptomatic</td>
</tr>
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How Will These Changes Impact My Practice?

- **The good news**
  - With ACA, first dollar coverage of well woman visits and cervical cytology screening
- **The bad news**
  - Since there is no national population-based educational campaign, we must explain changes to our patients
- **Systems issues**
  - Expect insurance benefit changes based on new guidelines
  - Quality indicators to measure under- and over-utilization
The Affordable Care Act and Cervical Cancer Screening

- Preventive services must be covered by employer-sponsored health insurance plans *without cost-sharing* for all women by January 2014
  - USPSTF [A]: cervical cytology 21-65 yo
  - Women’s Preventive Services
    - Annual well woman visit
    - Co-testing in women 30 and older every 3 years

So What’s The Problem?

- Consumers… either don’t know about the guidelines or believe that they are financially motivated
  - No national level consumer education program
  - Poor understanding that intent is *safety*, not cost savings
- Providers are…
  - Skeptical of abandoning Paps for their “girls” (under 21)
  - Fearful of encountering a patient with an interval cancer
  - Concerned that annual well-woman visits will be skipped

How Can My Practice Prepare?

- Ask every patient if she also sees another provider for screening ….if so, avoid duplication of interventions
- Determine the screening policies for your practice
  - Make sure that *all* staff are aware of your policy
- Inform your patients of changes that apply to them
  - During transition, discuss these decisions with patients
  - Inform patients with a personal letter or newsletter
- Keep track of benefit changes made by your payers
  - Few have changed screening benefits yet…but they will!

ASCCP 2012 Updated Consensus Guidelines for the Management of Abnormal Cervical Cancer Screening Tests and Cancer Precursors

ASCCP guidelines published simultaneously in Obstetrics & Gynecology and the Journal of Lower Genital Tract Disease
  - Obstet Gynecol 2013; 212:829-46
  - Online: www.asccp.org/consensus2012
- Mobile app available with algorithms

Take it Home

<table>
<thead>
<tr>
<th>Michael Pollan: Healthy eating</th>
<th>Healthy Cervical Cancer Screening</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eat food</td>
<td>Start later, end sooner</td>
</tr>
<tr>
<td>Not too much</td>
<td>Not too often</td>
</tr>
<tr>
<td>Mostly plants</td>
<td>Every 3 or 5 years</td>
</tr>
</tbody>
</table>

*What doesn't matter for screening intervals*
- Age of sexual debut
- Prior HPV vaccination
- New sexual partners or practices
- Hormonal contraceptives or hormone therapy

Take It Home

- Over-screening minimally improves lesion detection rates but results in an excess risk of false positive tests
  - Unnecessary colposcopy and biopsies
  - Attendant anxiety and inconvenience
  - Unnecessary costs to the patient and the health system
- Expect quality metrics for cervical cancer screening to evaluate your practice on...
  - Percentage of eligible women who are screened
  - The average interval between tests in women who should be screened routinely every 3 to 5 years
Additional References