NEW AND EVOLVING WOMEN’S HEALTH PRACTICES

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GOALS
• Increase knowledge about contraceptive methods under development
• Review Cytology screening recommendations
• Review follow-up guidelines for abnormal cytology
• Review recommendations for annual visit vs annual exam

PROGESTERONE IMPLANTS
• Nomegestrol Acetate – very potent progesterone – failure rate at 1 year 0.94%
• Nesterone – for breast feeding women
  Combined with lactational amenorrhea
  2 year pregnancy rate 1.7%
  Cannot be taken orally
  Less effective in non-lactating women

IUDs NEWLY AVAILABLE OR IN TRIALS IN US
• Skyla – 13mg Levonorgestrel – 3 year IUD – became available spring 2013
  • 2014 or after
  LNG 19.5 – 5 year
  LNG 20 – 7 year
  smaller devices
  less dosage

OTHER POSSIBLE IUDs
• Intracervical device – Nanopaz – LNG 20 mcg/day
• LNG “16” 5 year IUD
• Ulipristal Acetate IUD
• Copper IUDs with different composites
• Copper IUD with NSAID coating

INJECTIONS
• 25 mg MPA and 5 mg estradiol cypionate – once a month injection – “old Lunelle” – 2013 or 2014
• Levonorgesterol butanoate 50 mg.
  suppresses ovulation 5-6 months
**TRANSDERMAL CONTRACEPTION**

- Twirla – AG200-15 - EE/LNG patch
  - 30 mcg EE
  - minimizes seepage around the patch
  - decreases residue left on the skin
  - expected in 2013
  - each patch for 1 week
  - data to FDA 2012

- EE/Gestodene
  - 20 mcg EE
  - Transparent, smaller size
  - Each patch one week

**TRANSDERMAL CONTRACEPTION**

- Progesterone only patch
  - EE/MPA

**CONTRACEPTIVE RING**

- EE/Nesterone
  - Releases 15 mcg EE and 150 mcg nesterone per day
  - 13 cycles of hormones in one ring
  - 3 weeks in – 1 week out
  - Data at FDA

**CONTRACEPTIVE RINGS UNDER STUDY**

- Nesterone with varying doses – 50, 75, 100 mcg per day
- Progesterone only
- Levonorgestrel – 20 mcg per day used for 3 months
- Ulipristal Acetate – 3 month

**COMBINED ORAL CONTRACEPTIVES**

- NOMAC – 1.5mg 17B estradiol/2.5mg Nomegestrel
- Monophasic 24/4
- 30% - no scheduled bleeding at 12 months
- Application at FDA
COMBINED ORAL CONTRACEPTIVE

• Quartette – 91 days – FDA Approved
  • 42 light pink tablets each containing 0.15 mg of levonorgestrel and 0.02 mg ethinyl estradiol
  • 21 pink tablets: 0.15 mg of levonorgestrel and 0.025 mg ethinyl estradiol
  • 21 purple tablets: 0.15 mg of levonorgestrel and 0.03 mg ethinyl estradiol
  • 7 yellow tablets: 0.01 mg of ethinyl estradiol
  • Better cycle control with the increasing estrogen

COMBINED ORAL CONTRACEPTIVE

• Yaz Flex
  • 20 mcg EE/3mg Drospirenone
  • cyclic 24/4
  • Flexible 1 extended: if 3 days bleeding/spotting days 25-120, stop for 4 days and then restart
  • Flexible 2 extended: stop for 4 days anytime days 25-120
  • Extended: all women to stop for 4 days at day 120

SILCS DIAPHRAGM

• Single use disposable
• Contoured spring and soft pliability
• No fitting needed
• May be available over the counter
• May apply to FDA

CONDOMS – MALE AND FEMALE ALL OVERSEAS

• Male – new sizes
• Female
  • Insertion end packaged like tampon which dissolves and has foam dots that adhere to vaginal walls
  • Condom with sponge at closed end and outer triangular shaped anchoring structure. Pre-lubricated

FEMALE CONDOMS

• Polyurethanne with inner and outer rings but shorter than current version, insertion tool and packaged with waterbased lube
• Rubber latex sheath with sponge at leading edge and octanol frame at outer edge and pre-lube, scented, natural color and pink
• Small silicone cap that has a condom that expands during intercourse

OTHERS

• Spermicides
• COX 2 inhibitors – delay/prevent follicle rupture
• Alteration of oocyte maturation
• Block embryo implantation
• Vaccines – antisperm, zona pellucida
BACKGROUND: CYTOLOGY/HISTOLOGY
GUIDELINE CHANGES

- Consensus Conference Management of Abnormal Results –
  - 47 experts from 23 organizations and ASCCP
  - met Sept. 2012 to revise 2006 consensus guidelines for managing abnormal cytology, CIN and AIS

DATA compiled over 9 yr period with 1.4 million women cared for at Kaiser Permanente Northern California Medical Care Plan

Prevention strategies identify HPV-related abnormalities likely to progress to invasive cancers
AND avoid destructive treatment of abnormalities not destined to become cancerous

MAIN RATIONALE/STATS FOR 2012
CHANGES

- Oncogenic (high risk HPV) necessary but NOT sufficient factor to develop CIN
- Known cofactors that increase persistence are cig smoking, a compromised immune system, +HIV
- Only persistent HR HPV can progress to high grade lesions and cancer
- Small % of HR HPV are persistent, but when it is persistent at 1 yr and 2 yrs, it strongly predicts subsequent CIN 3 or cancer regardless of age
- HR HPV prevalence decreases with age but risk of persistent infection increases with age

MAIN RATIONALE/STATS FOR 2012
CHANGES (CONTINUED)

- HPV most common in early 20s, decrease in prevalence as women get older
- Most young women have effective immune response that “clears” infection in 8-24 mo. and most CIN will spontaneously resolve in young women
- Newly acquired HPV has same low chance of persistence, regardless of age in women 30+
- BUT, HPV detected in 30+ yrs old is more likely to reflect persistent infection. Correlates with increasing rates HSIL with increasing age.

RATIONALE/STATS FOR CHANGES: HISTOLOGICALLY/TREATMENT

- CIN 1 is acute HPV infection with high rate of regression; expectant management advised
- CIN 3 a significant risk for progression to cancer, if untreated 30% at 30 years progress to invasive cancer
RATIONALE/STATS FOR CHANGES: HISTOLOGICALLY/TREATMENT (CONTINUED)

- Over-treatment with LEEPs and diagnostic tests with colp/bx in young women have adverse consequences-
  - anxiety, cost, reproductive issues and potential preterm labor, premature births
- (challenged now per meta-analysis study BJOG 2011;118:1031-41)
- Most cases of cx cancer occur in unscreened or inadequately screened women and occurs 15-25 years after HPV infection

PRACTICES – CYTOLOGY SCREENING

- No cytology screening before age 21
- Screen every 3 years from age 21-29
- Screen every 5 years from age 30-65 and include High Risk HPV testing
- Stop screening age 65 with appropriate previous screening

PRACTICES – ABNORMAL CYTOLOGY FOLLOW-UP

- American Society for Colposcopy and Cervical Pathology released new guidelines early 2013
- Preferred/ Acceptable language
- New category age 21-24
- Genotyping algorithm for women age 30 and above with a negative cytology but HPV positive

WOMEN 21-24 WITH ASCUS/LSIL

**PREFERRED: 21-24**
- Repeat Pap in 12 months
  - If 12 month Pap NIL, ASC-US or LSIL, then repeat Pap again in 12 mo.
  - If NIL x2 then routine screen (Syn)
- Impact:
  - Decreased # of women referred for immediate colposcopy
- Rationale:
  - ASC-US carries lowest risk of CIN3+ b/c up to 2/3 are not HPV related

**ACCEPTABLE: 21-24**
- Reflex HPV with ASCUS
  - If HPV positive, repeat Pap in 12-24 months
  - If HPV negative, repeat Pap in 3 yrs
  - Note: HPV reflex remains preferred option for women ≥ 25

Main points:
  - PREFER 12 months fu for Ages 21-24 for up to 2 years
  - No direct colpo unless ASC-H, AGC, or HSIL

HOW TO MANAGE ASCUS >25?

**PREFERRED**
- Reflex HPV test
  - If HPV+ then colp with ECS
  - (when colp is neg or unsat colp)
  - If HPV – then repeat cotest at 3 yrs

**ACCEPTABLE**
- Repeat Pap in 1 year
  - If Pap is Neg, then return to routine screening
  - 3 years
  - If Pap is ASCUS or greater, then colp

HOW TO MANAGE LSIL >25?

**LSIL and no HPV test OR HPV + test**
- Refer to colpo
  - ECS is preferred if colp neg or unsat colp
- **LSIL with HPV neg test**
  - PREFERRED: Repeat cotest in 1 yr
  - ACCEPTABLE: Colpo
  - If repeat Pap is NIL/HPV neg, then repeat cotest in 3 yrs

**Remember:** Women 21-24 have new preference to follow current adolescent guidelines.
WOMEN ≥30 Y/O: NEG PAP WITH POSITIVE HPV

- Warrants Retesting:
  - Despite neg pap, women with +HR HPV are at higher risk for later CIN 3+ than women with neg HR HPV tests
  - Plan for Retesting (both are acceptable):
    • Cotest in 1 year
    OR
    • Genotyping for HPV 16 and 18 to triage to colp.
      • If 16/18 positive then colp
      • If negative then repeat cotest in 1 year

LINKS/REFERENCES FOR RATIONALE/STATS
- ASCCP guidelines: [www.asccp.org/consensus2012](www.asccp.org/consensus2012)
- USPSTF: [www.uspreventiveservicestaskforce.org/uspservicetoolkit/guidelines](www.uspreventiveservicestaskforce.org/uspservicetoolkit/guidelines)
  - Cervical Cancer Screening: HPV update and Managing Abnormal Results- Patty Cason, MS,FNP-BC, UCLA School of Nursing
  - ACOG Practice Bulletin, Number 131, November 2012
  - The End of the Routine Pap Smear, Charles P. Vega, April 22, 2013

ANNUAL EXAM VS ANNUAL VISIT

WHO IS DEFINING WELL WOMEN SERVICES?
- US Preventative Services Taskforce
- American college of OB/GYN
- American Academy of Pediatrics
- American Academy of Family Physicians
- American Cancer Society
- American Society of Colposcopists and Cervical Pathologists
- Accountable Care Act – Women’s Preventative services
- others

REPRODUCTIVE HEALTH DRIVERS
- Change in cytology screening guidelines
- USPSTF recommendations on clinical breast exam
- Ability to screen for Chlamydia and gonorrhea via urine specimen or self collected vaginal swabs
- Evolution of evidenced based practices

VISIT VS. EXAM
- Is a physical exam (including pelvic exam) necessary with every visit or at every “annual visit”? NO
- As needed for scheduled screening tests – cytology screening
- Diagnostic exam when sign/symptoms present- vaginal discharge
- Some visits will consist solely of counseling and education without exam beyond blood pressure check
### VALUE OF HEALTH SCREENING VISITS

- Carves out a time and place for prevention
- Opportunity for behavioral anticipatory guidance, education and counseling
- Establishes a relationship with the patient
- Increases sense of patient well-being, positive action toward self maintenance of health
- More likely to seek care when a problem occurs

### GENERAL HEALTH SCREENING VISIT

- Optimize health through anticipatory guidance & screening for asymptomatic conditions
- Increase client’s sense of well-being
- Promote relationship with the patient
- Positive action toward self-maintenance of health

### REPRODUCTIVE HEALTH VISIT

- Support correct & consistent use of her chosen contraceptive method
- Clarify reproductive health plan
- Evaluate reproductive health coercion/sabotage
- Optimize reproductive health – STD screenings

### CORE FAMILY PLANNING VISIT FOCUS

- Reproductive Life Plan discussion
- Safe & effective contraceptive use
- Reproductive coercion, birth control sabotage
- Sexual behaviors, STI risk screening and if indicated testing
- Tobacco, alcohol, drug use
- Personal and family history of breast and ovarian cancer

### SCREENING QUESTIONS FOR CORE FAMILY PLANNING VISIT

1. Do you hope to have any (more) children?
2. How many children do you hope to have?
3. How long do you plan to wait until you next become pregnant?
4. How much space do you plan to have between your pregnancies?
5. What do you plan to do until you are ready to become pregnant?
6. What can I do today to help you achieve your plan?
PREGNANCY PLANNING

• One question: “Do you want to become pregnant in the next year?”
  • YES: Folic acid & screen for risk factors that may impact pregnancy
  • NO: birth control to prevent pregnancy, emergency contraception, condoms

CONTRACEPTIVES

• Is the patient using a method
• Is the patient having problem(s) with method
• Does the patient wish to continue the method
• Does the patient need to restart/initiate a method
• Does the patient wish to change her method

COERCION/SABOTAGE

• Is your partner supportive of your contraceptive choice
• Will your partner use condoms when asked
• Is your partner supportive of your desires regarding pregnancy
• Has your partner hidden or destroyed your birth control method
• Has your partner pressured you to become pregnant
• Has your partner threatened you to continue or terminate a pregnancy
• Has your partner pressured you to have sex

STDs

• Screen for high risk behaviors
• Test as indicated
• Treat as needed using CDC Treatment Guidelines
• Rescreen following treatment for positive CT/GC per CDC guidelines
• Test of Cure following GC treatment if not using ceftriaxone/azithromycin

TOBACCO USE – SMOKE/CHEW

• Men and Women
• Tobacco users have increase in cancers and heart disease
• Increase in bone loss
• Teen smokers 2x’s more likely to die early than non-smokers
• 3% smokers quit every year – repeated discussions on quitting have an impact on smokers stopping

ALCOHOL USE

• Risky drinking habits
  • Men – max 4 drinks on one occasion or 14 drinks per week
  • Women – max 3 drinks on one occasion or 7 drinks per week
• Simple Question – Have you had 5 or more drinks on one occasion in the past year?
**BREAST/OVARIAN CANCER**

- Have you had breast or ovarian cancer?
- Do you have a blood relative that has had breast or ovarian cancer?
- NO to both then routine screening
- YES to #1 see U.S.MEC for guidance regarding contraceptive methods
- YES to #2 then……..

**POTENTIALLY HIGH RISK BREAST/OVARIAN CANCER**

- 3 or more breast cancer or 2 or more ovarian cancers on the same side of the family (maternal or paternal)
- blood relative under 45 with breast cancer?
- blood relative 50 or under with ovarian cancer
- 2 or more breast or pancreatic cancer on the same side of the family
- male relative with breast cancer
- BRCA gene present in the family

**BREAST CANCER SCREENING GUIDELINES**

<table>
<thead>
<tr>
<th>Previous Guideline</th>
<th>ACS 2003</th>
<th>USPSTF 2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast Self Exam (BSE)</td>
<td>Monthly</td>
<td>Optional</td>
</tr>
</tbody>
</table>
| Mammogram | • Baseline @ 35
• 40-49: Q2 yrs
• ≥ 50: yearly | ≥ 40: annually | 40-49: [C]
50-74: [B], every 2 years
≥ 75: [I] |

**BREAST SCREENING**

**ACS**

- BSE – optional
- CBE – 20-39 q 3 years
- Mammogram – annually starting at age 40

**USPSTF**

- BSE – data level D – harms outweigh benefits
- CBE – insufficient data
- Mammogram – 40-49 individualize
- 50-74 every 2 years
- 75 + insufficient data

**BREAST SELF-AWARENESS (BSA)**

- Defined as women’s awareness of the normal appearance and feel of their breasts
- Endorsed by ACOG, ACS, PPFA, and the National Comprehensive Cancer Network
- Effect of BSA education has not been studied
- Rationale:
  - ½ of breast cancer cases ≥50 y.o. and 70% of cases in younger women detected incidentally by themselves
  - New cases can arise during screening intervals—BSA may prompt women not to delay reporting changes even if recent negative screening result

ACOG Practice Bulletin No. 122. 2011

**SCREENING MAMMOGRAPHY GUIDELINES –USPSTF 2009**

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>25-39</td>
<td>Screen if specified high risk factors</td>
</tr>
<tr>
<td>40-49</td>
<td>Discuss pros and cons of screening*</td>
</tr>
<tr>
<td>50-59</td>
<td>Encourage screening*</td>
</tr>
<tr>
<td>60-69</td>
<td>Strongly encourage screening*</td>
</tr>
<tr>
<td>70-74</td>
<td>Discuss pros and cons of screening*</td>
</tr>
<tr>
<td>&gt;75</td>
<td>Little data</td>
</tr>
</tbody>
</table>

*When done, perform routine mammography biennially
SUPPLIES
• Emergency Contraception in advance of need
• Male and female condoms for Dual Protection

EC OVER THE COUNTER
• Plan B One-Step over the counter to any age
• FDA granted exclusive rights to Teva Pharmaceuticals for 3 years
• Other companies can apply for Over the Counter but it will not be allowed for 3 years

GENERAL HEALTH VISIT
• Domestic/intimate partner violence
• Bone Health – calcium & Vit D intake
• Preconception – Folic Acid
• Nutrition – fruits, vegetables, grains, protein, dairy
• Physical Activity – get up and move
• Immunizations – current?
• Injury prevention

DOMESTIC/INTIMATE PARTNER VIOLENCE
• Have you been pushed, hit, kicked, slapped, choked, or physically hurt in any way?
• Are you afraid of your partner or anyone else?
• Have you been humiliated, shamed, or put down in any way?
• Are you kept from seeing your friends, or doing things you want to do?
• Are you worried about your safety or the safety of your child(ren)?

BONE HEALTH
• Risk factors for bone loss: age, BMI, history of fractures, alcohol use
• Teens – ACOG recommends all teens receive information on bone health at their annual visit
• Assess calcium intake with all women
• Calcium needs 1000-1300 mg/day with at least 600 mg of Vitamin D for absorption

NUTRITION, ACTIVITY
• Assess intake of fruits, vegetables, grains, protein, and dairy
• Get up and move
### IMMUNIZATIONS
- Tetanus – q 10 years
- Pertussis/diphtheria – booster one time with tetanus included
- HPV – male and female 3 doses – new info on prevention for oral cancer also
- Meningococcol
- Hepatitis A and B

### SELECTED PRACTICE GUIDELINES
- Released June 14, 2013
- Exams and tests needed before initiation of the method
- Most women need no or very few exams or tests before initiating a method

### RATING SYSTEM FOR EXAM AND/OR TEST
- Class A – mandated exam and/or test
- Class B – exam and/or test contribute substantially
- Class C – exam and/or test do not contribute substantially
- Safe initiation of a contraceptive method

### EXAMS/TESTS CATEGORIES
- BMI, Blood Pressure, Weight
- Bimanual exam and cervical inspection
- Glucose
- Liver enzymes
- Clinical Breast exam
- Lipids
- Cytology Screening
- STD screening
- Hemoglobin

### MANDATED EXAM AND/OR TEST
- Bimanual exam and cervical inspection before and IUD insertion
- Blood Pressure before initiation of combined hormonal contraception

### REIMBURSEMENT
- How to get paid for a visit that does not include and exam
- Evaluation and Management code using the 50% rule
BY TIME

- If “coding” office visit (E&M) by time then the 50% rule **RULES**
- More than 50% of the visit time MUST be spent in education and counseling.
- MUST document total face to face time and time spent in education/ counseling/ coordination of care and the content summary of the ed/counseling

THANK YOU

Questions?
RESOURCES: New and Evolving Women’s Health Practices

September 10, 2013

Contraceptive Technology 20th edition, Chapter 22, pages 621 – 649

The American College of Obstetricians and Gynecologists, www.acog.org

Committee opinions: Reproductive and Sexual Coercion

- Intimate Partner Violence
- Sexual Assault
- Access to Emergency contraception
- Well-Woman Visit
- Primary and Preventive Care: Periodic Assessments

Institute of Medicine, Preventative Services for Women,
www.iom.edu/Activities/Women/PreventiveServicesWomen.aspx

www.hrsa.gov/womensguideliens/

Contraceptive Technology Update, Nov 2012, Vol. 33, No. 11

CDC MMWR April 21, 2006 Vol. 55/No.RR-6, Recommendations to Improve Preconception Health and Health Care

CDC “Taking a Sexual Health History”, www.cdc.gov/std/treatment/SexualHistory.pdf

Futures Without Violence, www.futureswithoutviolence.org


Anals of Internal Medicine, June 19, 2012, Volume 156, No.12, Screening for Cervical Cancer: U.S. Preventive Services Task Force Recommendation Statement

Managing Contraception, www.managingcontraception.com