Removing Unnecessary Barriers to Contraceptive Services

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No commercial disclosures for this lecture
The best bike team... period
Goals of the Title X Guidance Revision Process

1. Utilize best evidence to design preventive services
2. Prioritize provision of *core* family planning services
   - Allow flexibility for *recommended* services
   - Avoid services where harms exceed benefits
3. Support client decisions re: services received or declined
4. **Remove barriers to care for the client and provider**
5. Improve clinic efficiency
6. Anticipate changes in source of primary care arising from the Affordable Care Act
U.S. Selected Practice Recommendations for Contraceptive Use, 2013

- Removing unnecessary barriers can help patients access and successfully use contraceptive methods

- Several medical barriers to initiating and continuing contraceptive methods might exist, such as
  - Unnecessary screening examinations and tests before starting the method (e.g., a pelvic examination)
  - Inability to receive method on the day of the visit
  - Difficulty obtaining continued contraceptive supplies (e.g., pill packs dispensed at one time)
Clinical Barriers to Contraceptive Services

- Lack of awareness of family planning guidelines
- Unnecessary screening tests
- Limits on same day availability of methods
- Inappropriate restriction on U.S. Medical eligibility criteria Category-3 methods
- Diversion of *limited time* from family planning services to provide non-reproductive primary care
Awareness of Family Planning Guidelines

• No published studies yet on extent of adoption of US 2010 Medical Eligibility Criteria (US-MEC)
• Endorsed by the American College of Obstetricians and Gynecologists (ACOG)
• Anecdotally...
  – Most family planning clinicians use them often
  – Most ObGyns know about them; questionable use
  – Most primary care physicians and APCs don’t know about them or use them routinely
Focus on safety in women with a variety of medical conditions

U.S. Medical Eligibility Criteria for Contraceptive Use, 2010

Adapted from the World Health Organization Medical Eligibility Criteria for Contraceptive Use, 4th edition
U.S. Selected Practice Recommendations for Contraceptive Use, 2013
Adapted from the World Health Organization Selected Practice Recommendations for Contraceptive Use, 2nd Edition
Evidence Based Guidelines for Family Planning

- CDC MEC 2010
- CDC SPR 2013
- CDC STD Treatment Guidelines 2010

Contraceptive Practice

STD Practice

Title X Guidance 2013

F screening
M screening
Preconception
Fertility enhancement
Preg determination
Unnecessary Screening Tests: The “Screening Pelvic Exam”

- Screening pelvic exam started as a
  - Method to obtain cervical specimen for CT/GC
  - Screen for cervical cancer with cytology
  - Screen for ovarian cancer with bimanual exam
- Performed *annually* because of “yearly Pap smear” strategy until 2003
## 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><strong>USPSTF 2012</strong></td>
<td>[D]</td>
<td>Every 3 y</td>
<td>Co-test: Q5</td>
<td>None*</td>
<td>[D]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Cytology: Q3</td>
<td></td>
<td></td>
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<tr>
<td><strong>Triple A 2012</strong></td>
<td>None</td>
<td>Every 3 y</td>
<td>Co-test: Q5</td>
<td>None*</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Cytology: Q3</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>ACOG 2012</strong></td>
<td>“Avoid”</td>
<td>Every 3 y</td>
<td>Co-test: Q5</td>
<td>None*</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Cytology: Q3</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>hrHPV test</strong></td>
<td>Never</td>
<td>Reflex only</td>
<td>Co-test or reflex</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

* If adequate prior screening with negative results

Co-test: cervical cytology plus hrHPV test
Cytology: cervical cytology (Pap smear) alone
Ovarian Cancer Screening

• Options for screening
  – (Bimanual) Pelvic examination
  – Transvaginal pelvic ultrasound (TVS)
  – Serum Tumor Marker: CA-125

• Not recommended for low risk asymptomatic women
  – Low sensitivity, specificity for early disease
  – Low prevalence of disease
  – High cost of evaluation
Ovarian Cancer Screening

USPSTF (2012)

• Screening asymptomatic women with ultrasound, tumor markers, or exam is not recommended [D]

• Insufficient evidence to recommend for or against in asymptomatic women at increased risk [I]
The Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Randomized Controlled Trial

- 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

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

Cases

Deaths

JAMA. 2011;305(22):2295-2303
Pelvic Exam at the Well-Woman Visit
ACOG Committee Opinion 524; August 2012

• 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
Question 30: What examinations or tests should be done routinely before providing a method of contraception?
2004 WHO Selected Practice Recommendations for Contraceptive Use

• Blood pressure measurement before initiation of
  – OCs, POPs, DMPA, and implants
• Not recommended as “contributing substantially to safe and effective use of a hormonal contraceptive method”
  – Breast or genital tract examination
  – Cervical cancer screening
  – STI risk assessment, physical exam, screening tests
  – Hemoglobin determination
  – Other routine lab tests
**U.S. Selected Practice Recommendations for Contraceptive Use, 2013**

<table>
<thead>
<tr>
<th>Examination</th>
<th>Needed for</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood pressure</td>
<td>OC, patch, ring</td>
</tr>
<tr>
<td>Clinical breast examination</td>
<td>None</td>
</tr>
<tr>
<td>Weight (BMI) (weight [kg]/ height [m]²)</td>
<td>Hormonal methods</td>
</tr>
<tr>
<td>Bimanual examination, cervical inspection</td>
<td>IUC, cap, diaphragm</td>
</tr>
<tr>
<td>Glucose, Lipids</td>
<td>None</td>
</tr>
<tr>
<td>Liver enzymes</td>
<td>None</td>
</tr>
<tr>
<td>Thrombogenic mutations</td>
<td>None</td>
</tr>
<tr>
<td>Cervical cytology (Papanicolaou smear)</td>
<td>None</td>
</tr>
<tr>
<td>STD screening with laboratory tests</td>
<td>None</td>
</tr>
<tr>
<td>HIV screening with laboratory tests</td>
<td>None</td>
</tr>
</tbody>
</table>
Choosing Wisely® aims to promote conversations between physicians and patients by helping patients choose care that is:

- Supported by evidence
- Not duplicative of other tests or procedures already received
- Free from harm
- Truly necessary

In response to this challenge, national organizations representing medical specialists have been asked to “choose wisely” by identifying five tests or procedures commonly used in their field, whose necessity should be questioned and discussed. The resulting lists of “Five Things Physicians and Patients Should Question” will spark discussion about the need—or lack thereof—
Don’t perform Pap smears on women younger than 21 or who have had a hysterectomy for non-cancer disease.

Most observed abnormalities in adolescents regress spontaneously, therefore Pap smears for this age group can lead to unnecessary anxiety, additional testing and cost. Pap smears are not helpful in women after hysterectomy (for non-cancer disease) and there is little evidence for improved outcomes.

Don’t screen women older than 65 years of age for cervical cancer who have had adequate prior screening and are not otherwise at high risk for cervical cancer.

There is adequate evidence that screening women older than 65 years of age for cervical cancer who have had adequate prior screening and are not otherwise at high risk provides little to no benefit.

Don’t screen women younger than 30 years of age for cervical cancer with HPV testing, alone or in combination with cytology.

There is adequate evidence that the harms of HPV testing, alone or in combination with cytology, in women younger than 30 years of age are moderate. The harms include more frequent testing and invasive diagnostic procedures such as colposcopy and cervical biopsy. Abnormal screening test results are also associated with psychological harms, anxiety and distress.
Don’t perform routine annual cervical cytology screening (Pap tests) in women 30–65 years of age.

In average risk women, annual cervical cytology screening has been shown to offer no advantage over screening performed at 3-year intervals. However, a well-woman visit should occur annually for patients with their health care practitioner to discuss concerns and problems, and have appropriate screening with consideration of a pelvic examination.

Don’t treat patients who have mild dysplasia of less than two years in duration.

Mild dysplasia (Cervical Intraepithelial Neoplasia [CIN 1]) is associated with the presence of the human papillomavirus (HPV), which does not require treatment in average risk women. Most women with CIN 1 on biopsy have a transient HPV infection that will usually clear in less than 12 months and, therefore, does not require treatment.

Don’t screen for ovarian cancer in asymptomatic women at average risk.

In population studies, there is only fair evidence that screening of asymptomatic women with serum CA-125 level and/or transvaginal ultrasound can detect ovarian cancer at an earlier stage than it can be detected in the absence of screening. Because of the low prevalence of ovarian cancer and the invasive nature of the interventions required after a positive screening test, the potential harms of screening outweigh the potential benefits.
## The “Screening Pelvic Exam” Is Outdated

<table>
<thead>
<tr>
<th>Screen for</th>
<th>Preferred test</th>
</tr>
</thead>
<tbody>
<tr>
<td>GC, Ct</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 hysterectomy for benign disease</td>
</tr>
<tr>
<td>Ovarian cancer</td>
<td>USPSTF rec. against bimanual exam</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>
</tbody>
</table>
Do You Require a Pelvic Exam for OCs?

Henderson JT et al Obstet Gynecol 2010;116:1257–64
Perceived Problems with Deletion of the Screening Pelvic Exam

- If we miss something, we will be sued
- If women don’t receive a pelvic exam, she will be dissatisfied
- If we don’t do an exam, our clinic will be paid less for these visits
Problem Oriented E/M Visits

Either:
- Composite of 3 key components (Hx + PE + MDM)

Or
- TIME, when greater than 50% of time is spent in counseling
E/M Visit: Time Factor

- Average face-to-face times are listed for each level of E/M code as guideline.
- "Face-to-face Time" supercedes key indicators if:
  - > 50% of total F-to-F time is spent in counseling,
  - Includes time spent with patient and/or family,
  - Excludes pre- and post-encounter time.
- Must document:
  - Total time and face time in minutes or start/stop,
  - Counseled regarding outcome, risks, benefits of…
  - Answered her questions regarding…
E/M: Preventive Services

- Used for periodic health screening (check-up) visits
- **Components**
  - Comprehensive history and physical exam
  - *Counseling, anticipatory guidance, and risk reduction*
  - Order lab, diagnostic procedures
  - Indicate immunizations with separate codes
- If insignificant or trivial problem(s) without extra work to evaluate, do not add separate E/M
- If additional work-up for pre-existing or new problem, may add problem-oriented E/M (-25)
Examinations and Tests Needed Before Initiation of a Cu-IUD or an LNG-IUD

2013 U.S. SPR, page 9-10

• Women should be routinely screened for CT and GC according to national STI screening guidelines
• If a woman has not been screened, testing can be performed at the time of IUD insertion and not delayed
• Women with purulent cervicitis or current GC or CT should not undergo IUD insertion (U.S. MEC 4)
• If a very high individual likelihood of STD exposure generally should not have IUD insertion (U.S. MEC 3)
### Same Day Availability of Methods

**U.S. SPR, Appendix B**

<table>
<thead>
<tr>
<th>Method</th>
<th>When to start</th>
<th>B/U</th>
<th>Exam</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cu-IUC</td>
<td>Anytime</td>
<td>none</td>
<td>pelvic</td>
</tr>
<tr>
<td>LNG-IUS</td>
<td>Anytime</td>
<td>If &gt;7d*</td>
<td>pelvic</td>
</tr>
<tr>
<td>Implant</td>
<td>Anytime</td>
<td>If &gt;5d*</td>
<td>none</td>
</tr>
<tr>
<td>Injection</td>
<td>Anytime</td>
<td>If &gt;7d*</td>
<td>none</td>
</tr>
<tr>
<td>CHC</td>
<td>Anytime</td>
<td>If &gt;5d*</td>
<td>BP</td>
</tr>
<tr>
<td>POP</td>
<td>Anytime</td>
<td>If &gt;5d*</td>
<td>none</td>
</tr>
</tbody>
</table>

* After the first day of menstrual bleeding
<table>
<thead>
<tr>
<th>Categ</th>
<th>Definition</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>No restriction in contraceptive use</td>
<td>Use the method</td>
</tr>
<tr>
<td>2</td>
<td>Advantages generally outweigh theoretical or proven risks</td>
<td>More than usual follow-up needed</td>
</tr>
<tr>
<td>3</td>
<td>Theoretical or proven risks outweigh advantages</td>
<td>Clinical judgment that the patient can use safely</td>
</tr>
<tr>
<td>4</td>
<td>Unacceptable health risk if the method is used</td>
<td>Do not use the method</td>
</tr>
</tbody>
</table>
USMEC-3 *Is Not* Equal to a USMEC-4

- When given the choice, would rather use a Category -1 or -2 than a category-3 method
- There are very few Category -4 conditions; almost always safer alternatives exist
- Clinicians often instructed by medical directors or consultants that Category 3 methods are equally risky as Category-4...not true!!
- Expectation of consultation is reasonable, but not blanket prohibition
Well Woman Preventive Services in Family Planning Clinics

- Comprehensive Well woman services
- Reproductive Preventive Svcs
- Family Planning Preventive Svcs
Well Woman Preventive Services in Family Planning Clinics *Not Acting as PCP*

- Comprehensive Well Woman services
- Reproductive Preventive Svcs
- Family Planning Preventive Svcs

Floor

Ceiling
Well Woman Preventive Services in Family Planning Clinic *Acting as PCP*

- Comprehensive Well Woman services
- Reproductive Preventive Svcs
- Family Planning Preventive Svcs
Well Woman Preventive Services in Family Planning Clinics

- Recommended, but optional, services at any *given visit* are based upon
  - Individual client choice
  - Avoiding duplication of services recently ordered or given by other clinicians, especially
  - Provider attitudes and preferences, as reflected in site-specific policies and protocols
How Are Core Family Planning Preventive Services Different from “Well Woman” Care?

• Core FP preventive services focus upon
  – Avoiding pregnancy or becoming pregnant
  – Safe and effective contraceptive use
  – Protection of reproductive health

• Additional preventive services may be performed by
  – The patient’s primary care provider (PCP), or
  – Her family planning clinic, in the absence of a PCP

• Given limitations of time and resources, provision of core family planning services is our top priority!
Appendix
# Routine Cancer Screening in Women

<table>
<thead>
<tr>
<th>Age</th>
<th>18-20</th>
<th>21-25</th>
<th>26-29</th>
<th>30-39</th>
<th>40-49</th>
<th>50-59</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cervix CA</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Cytology</td>
<td>None</td>
<td>None</td>
<td>Q 3 yrs</td>
<td></td>
<td></td>
<td>Q5 yrs</td>
</tr>
<tr>
<td>• Co-testing</td>
<td>None</td>
<td>None</td>
<td>Q 3 yrs</td>
<td></td>
<td>Annual</td>
<td></td>
</tr>
<tr>
<td><strong>CBE</strong></td>
<td>None</td>
<td>Q 3 yrs</td>
<td></td>
<td></td>
<td>Annual</td>
<td></td>
</tr>
<tr>
<td>• ACS</td>
<td>None</td>
<td>Q 3 yrs</td>
<td></td>
<td></td>
<td>with MG</td>
<td></td>
</tr>
<tr>
<td><strong>Mammogram</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• ACS</td>
<td>None</td>
<td>Hi Risk</td>
<td></td>
<td>Annual</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• USPSTF</td>
<td></td>
<td></td>
<td>[I]</td>
<td>Q2y [C]</td>
<td></td>
<td>Q2y [B]</td>
</tr>
<tr>
<td><strong>Colorectal cancer</strong></td>
<td>None</td>
<td>Hi Risk</td>
<td></td>
<td></td>
<td></td>
<td>[A]</td>
</tr>
</tbody>
</table>

**ACOG:** Am College of Ob-Gyn  
**ACS:** American Cancer Society  
**CBE:** Clinical breast exam  
**CDC:** Centers for Disease Control  
**USPSTF:** US Prev Services Task Force
## Routine STI Screening

<table>
<thead>
<tr>
<th>Age</th>
<th>18-20</th>
<th>21-25</th>
<th>26-29</th>
<th>30-39</th>
<th>40-49</th>
<th>50-59</th>
</tr>
</thead>
<tbody>
<tr>
<td>CT (Both)</td>
<td>Annually</td>
<td></td>
<td>Targeted</td>
<td></td>
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<td></td>
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<tr>
<td>GC (Both)</td>
<td>Targeted</td>
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</tr>
<tr>
<td>HIV</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Both</td>
<td>Once, then Hi risk only</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Syphilis</td>
<td>Hi Risk</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Both</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vag trich</td>
<td>Hi Risk</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- CDC 2010</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hepatitis C</td>
<td>Once, then Hi risk only</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- CDC 2012</td>
<td></td>
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</tbody>
</table>

Both: CDC+USPSTF

CDC: Centers for Disease Control
USPSTF: US Prev Services Task Force
## Routine Metabolic Screening

<table>
<thead>
<tr>
<th>Age</th>
<th>18-19</th>
<th>20-25</th>
<th>26-29</th>
<th>30-39</th>
<th>40-49</th>
<th>50-59</th>
</tr>
</thead>
<tbody>
<tr>
<td>BP</td>
<td>≤Q2 yrs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BMI</td>
<td>≤Q2 yrs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>T2DM</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• ADA</td>
<td>Hi Risk</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• USPSTF</td>
<td>HTN [B]</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lipids</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• ATP</td>
<td>Q5 yrs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• USPSTF</td>
<td>Hi Risk</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Definitions:**
- **BP:** Blood Pressure
- **BMI:** Body Mass Index
- **T2DM:** Type 2 Diabetes Mellitus
- **HTN:** Hypertension
- **Lipids:** Lipid Profiling
- **ATP:** Adult Treatment Panel
- **USPSTF:** US Preventive Services Task Force

**Abbreviations:**
- **CHD:** Coronary Heart Disease
- **T2DM:** Type 2 Diabetes Mellitus
- **USPSTF:** US Preventive Services Task Force

**Notes:**
- **Hi Risk** indicates a high-risk status.
- **Q2 yrs** indicates a frequency of every 2 years.
- **Q3y** indicates a frequency of every 3 years.
- **HTN[A]** indicates a specific guideline or protocol for hypertension management.

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**ATP:** Adult Treatment Panel  
**CHD:** coronary heart disease  
**HTN:** hypertension  
**T2DM:** Type 2 diabetes mellitus  
**USPSTF:** US Prev Services Task Force