Improving Women’s Health:
Evidence-Based Practice Supporting New Pap Smear Guidelines
Disclosures

• Nothing to Disclose
Introduction

The following presentation is brought to you by:

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At the conclusion of the presentation, participants should be able to:

- Define current recommendations for frequency of Pap smear and HPV co-testing.
- Discuss evidence-based support for the recommended changes to previous guidelines.
Cervical Cancer and History of the Pap Smear

Background
Background

- Papanicolaou (Pap) smear: screening tool for cervical cancer
- Easiest gynecologic cancer to prevent, with regular screening and follow up (CDC, 2016)
- Most successful screening test in entire history of medicine
- Has reduced death from cervical cancer by over 70% in US since it was introduced (Oxford Academic, 2015)
• Half of cervical cancers diagnosed in US are in women who have never been screened
  • Additional 10% of cancers occur in women who have not been screened regularly (within the past five years)

(Oxford Academic, 2015)
Cervical Cancer
Incidence and Mortality

National Statistics
• Healthy People 2020 showed incidence rate of 7.1/100,000 women
• Death rate: 2.2/100,000 women

State of Alabama
• 7.8-10.6/100,000 women diagnosed in 2013
• 2.8-4.0/100,000 women died of cervical cancer

(CDC, 2016)
Cervical Cancer Morbidity and Mortality

Range
- Data not available
- 3.6 to 5.9
- 6.0 to 7.1
- 7.2 to 7.7
- 7.8 to 10.6
History of the Pap Smear

Timeline

George Papanicolaou 1883-1962
History of the Pap Smear

Timeline

- **1928** - Papanicolaou proposed certain cells found in vaginal smear could be indicative of early stages of disease

- **1941** - Published “The Diagnostic Value of Vaginal Smears in Carcinoma of the Uterus”, landmark paper on the subject in the *American Journal of Obstetrics and Gynecology*

(Oxford Academic, 2015)
History of the Pap Smear

Timeline

- **1945**-American Cancer Society (ACS) began promoting Pap smears to encourage early cancer detection
- **Early 1950s**-Became a “standard of care” in practice
- **1952**-Most physicians still not willing to implement Pap smear in practice
- **1961**- ACS found 40% of women had not heard of test

(Oxford Academic, 2015)
History of the Pap Smear
Timeline

- **1980-** ACS *first* changed recommendation for frequency of testing from *yearly* to *every three years* in women with two subsequent negative tests
- **2001-** *Consensus Guidelines for the Management of Women with Cervical Cytological Abnormalities* developed by American Society for Colposcopy and Cervical Pathology (ASCCP)
- **2006-** Consensus Guidelines updated

(Oxford Academic, 2015)
History of the Pap Smear
Timeline

- **2012** - Most current guidelines developed
  - American College of Obstetrics and Gynecology (ACOG) issued statement regarding annual well-woman examination recommendations

- **2016** - “Cervical Cancer Screening” infographic issued by ACOG

(Oxford Academic, 2015)
History of the Pap Smear

Payer Information

Regarding insurance...

• Drastic changes in reimbursement for cervical cancer screening in last 10 years

• Conflicting payer guidelines make it difficult for offices to be consistent in screening
## History of the Pap Smear

### Payer Information

<table>
<thead>
<tr>
<th>Healthcare Reform Preventive Services</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast Cancer Chemoprevention Counseling</td>
<td>Once in a lifetime</td>
</tr>
<tr>
<td>Breast Cancer Mammography Screenings</td>
<td>Age 35-39, one baseline, 40 and older, one per calendar year</td>
</tr>
<tr>
<td>Breast Cancer Prevention Medication</td>
<td>Effective October 1, 2014</td>
</tr>
<tr>
<td>Breast Feeding Interventions</td>
<td>Age 35 and older, pharmacy only</td>
</tr>
<tr>
<td>Cervical Cancer Screening (Pap Smear)</td>
<td>One per calendar year</td>
</tr>
<tr>
<td>Chlamydia Screening</td>
<td>Age 15 and older, one per calendar year</td>
</tr>
<tr>
<td>Folic Acid Supplements</td>
<td></td>
</tr>
<tr>
<td>Gonorrhea Screening</td>
<td>Age 11 and older, twice per calendar year</td>
</tr>
<tr>
<td>Hepatitis B Screening</td>
<td>One per calendar year for pregnant women</td>
</tr>
<tr>
<td>Iron Deficiency Anemia Screening</td>
<td>One per calendar year for pregnant women</td>
</tr>
<tr>
<td>Osteoporosis Screening</td>
<td>Effective October 1, 2010 - January 31, 2012</td>
</tr>
<tr>
<td></td>
<td>Age 65 and older, 60 and older if at risk, once every 4 years</td>
</tr>
<tr>
<td></td>
<td>Effective February 1, 2012</td>
</tr>
<tr>
<td></td>
<td>Age 65 and older, 65 and younger if at risk, once every 2 years</td>
</tr>
<tr>
<td>Rh Incompatibility Screening (all pregnant women)</td>
<td>Twice per calendar year</td>
</tr>
<tr>
<td>Tobacco Use Screening and Interventions</td>
<td>Effective May 16, 2014 - August 31, 2014</td>
</tr>
<tr>
<td></td>
<td>Women age 10 and older, 8 per calendar year</td>
</tr>
<tr>
<td></td>
<td>Effective September 1, 2014</td>
</tr>
<tr>
<td></td>
<td>Women age 6 and older, 8 per calendar year</td>
</tr>
<tr>
<td>Syphilis Screening (At Risk and All Pregnant Women)</td>
<td></td>
</tr>
<tr>
<td>Human Papillomavirus (HPV)/Screening</td>
<td>Age 30 and older, every 3 years</td>
</tr>
<tr>
<td>Prenatal Conference (Pediatrician only)</td>
<td></td>
</tr>
<tr>
<td>Effective August 1, 2012 - Additional Women’s Preventive Services (Including Pregnant Women)</td>
<td>Age 10 and older, up to two visits per calendar year depending on diagnosis and procedure</td>
</tr>
</tbody>
</table>
### History of the Pap Smear

**Payer Information**

- Coverage same as 35-39 years for those aged 40 and up.

### Healthy You! Wellness Procedures Coding Guidelines

<table>
<thead>
<tr>
<th>Age</th>
<th>Sex</th>
<th>Procedures Recommended/Number of Times Recommended for Age Range</th>
<th>CPT Codes Accepted for Each Procedure</th>
<th>ICD-9-CM Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>18-34 years (continued)</td>
<td>F</td>
<td>- Pelvic exam/1 procedure per calendar year</td>
<td>- 88141, 88143, 88147, 88148, 88150, 88152, 88154, 88164-88167, 88174, 88175, G0123, G0124, G0141, G0143, G0144, G0145, G0147, G0148: Pap smear 87624, 87625: HPV test.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Pap smear/1 procedure every 3 years for ages 21-29</td>
<td>- 80061: Lipid profile</td>
<td>- V72.31: Routine gynecological examination</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Pap smear/1 procedure every 3 years for ages 30-34 or 1 procedure every 5 years with HPV test.</td>
<td>- 82947: Glucose, quantitative 82948: Glucose, blood, reagent strip 82962: Glucose, blood by glucose monitoring device(s)  34615, 34616: Routine venipuncture.</td>
<td>- V76.47: Special screening for malignant neoplasm, vagina</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Lipid profile/1 procedure per calendar year</td>
<td>- 89385: Initial preventive medicine evaluation 99395: Periodic preventive medicine re-evaluation</td>
<td>- V76.2: Special screening for malignant neoplasm, cervix</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Glucose/1 procedure per calendar year (only for high-risk individuals)</td>
<td></td>
<td>- V77.91: Screening for lipid disorders</td>
</tr>
</tbody>
</table>

| 35-39 years | F   | - Preventive medicine evaluation, re-evaluation or office visit/1 visit per calendar year (As part of preventive medicine evaluation or re-evaluation, preventive counseling as appropriate for age or stage of development and risk factors present. See counseling recommendations.) | - See immunization codes. Immunizations are set to pay at any age, unless specified by the CPT code. 88141, 88143, 88147, 88148, 88150, 88152, 88154, 88164-88167, 88174, 88175, G0123, G0124, G0141, G0143, G0144, G0145, G0147, G0148: Pap smear 87624, 87625: HPV test. | - V70.0: Routine general medical examination at a health care facility Health checkup |
|             |     | - Blood pressure, height and weight/1 procedure per calendar year | | - V76.19: Other screening breast examination |
|             |     | - Breast exam/1 procedure per calendar year                 | | - V72.31: Routine gynecological examination |
|             |     | - Immunizations                                             | | - V76.47: Special screening for malignant neoplasm, vagina |
|             |     | - Pelvic exam/1 procedure per calendar year                 | | - V76.2: Special screening for malignant neoplasm, cervix |
|             |     | - Pap smear/1 procedure every 3 years or 1 procedure every 5 years with HPV test. | | |
History of the Pap Smear

Payer Information

Adult Medicaid Manual MA-2905- MEDICAID COVERED SERVICES

XII. PREVENTIVE Medical SERVICES

Annual health assessments for individuals over age 21 with the expectation that they will prevent serious illness through early detection and treatment.

Refer to DNA’s website at http://www.dhhs.state.nc.us/dma/mop/mopindex.htm for specific coverage criteria, prior approval requirements, and service limitations.

A. Covered Services

1. Health history
2. Physical examination
3. Laboratory procedures
4. Counseling, education, and limited intervention
5. Pap smear
6. Mammograms

B. Restrictions

1. Medicaid covers only one screening per calendar year
2. Preventive medical services count toward a recipient’s professional services visit limit except as noted in EIA.
3. Medicaid covers only one pap smear per year except when diagnosis supports more frequent testing.

REVISED 08/01/11 – CHANGE NO. 16-11
History of the Pap Smear

Payer Information

Your Medicare Coverage

Is my test, item, or service covered?

Cervical & vaginal cancer screenings

How often is it covered?

Medicare Part B (Medical Insurance) covers Pap tests and pelvic exams to check for cervical and vaginal cancer. As part of the exam, Part B also covers a clinical breast exam to check for breast cancer. Part B covers these screening tests:

- Once every 24 months for all women
- Once every 12 months if you're at high risk for cervical or vaginal cancer, or if you're of childbearing age and have had an abnormal Pap test in the past 36 months

Who's eligible?

All women with Part B are covered.

Your costs in Original Medicare

You pay nothing for the lab Pap test. You also pay nothing for the Pap test specimen collection, pelvic exam, and breast exam if the doctor accepts assignment.

Note

Your doctor or other health care provider may recommend you get services more often than Medicare covers. Or, they may recommend services that Medicare doesn't cover. If this happens, you may have to pay some or all of the costs. It's important to ask questions so you understand why your doctor is recommending certain services and whether Medicare will pay for them.
What is HPV Co-Testing?

Background
What is HPV?

- Human papillomavirus
- Most common sexually transmitted infection
  - Nearly all sexually active men and women infected in their lifetime
  - Around 79 million Americans currently infected with HPV
- More than 100 different HPV subtypes

(CDC, 2017)
• Two different categories:

1. Low Risk HPVs—do not cause cancers; cause skin warts on/around genitals (subtypes 6 and 11 cause 90% of these)

2. High Risk HPVs—types that may cause cancer (subtypes 16 and 18 responsible for most cases)

(National Cancer Institute, 2015)
• What is co-testing?
  • Used in conjunction with Pap smear
  • Screens for HPV DNA in cervical cell sample

• Typically held unless Pap smear results abnormal (called “reflex-testing”)

(CDC, 2016)
HPV Co-Testing

Treatment

- No treatment for HPV
  - Surgical treatment for cancerous changes to the cervix and genital warts
- Most infections suppressed by immune system within 1-2 years without causing cancer

(National Cancer Institute, 2015)
• Vaccination before initiation of sexual activity reduces risk of transmission of high risk subtypes

• Of 12 high risk strains, these vaccinate against 2 most common (16 and 18)
  • Gardasil
  • Gardasil 9
  • Cervarix

• Regular Pap smears and co-testing still recommended in those vaccinated

(National Cancer Institute, 2015)
Adoption of Evidence-Based Practice

Barriers to Care
Barriers to Care Provider

- A study of gynecologists from 2004 revealed lack of agreement on how routine screening should be provided
  - How often smears should be taken
  - Who should do the screening
  - Whether efforts should be made to persuade women to be screened
  - How test results should be conveyed

(Sarkadi, Widmark, Tornberg, & Tishelman)
Table 1. Emerging themes in qualitative analysis

5. Recommendations versus practice
- To say no (when women demand a smear)
- Three ways—follow new guidelines, do as always have, and integrate guidelines in practicable way
- Screening recommendations imposed from ‘above’

14. Not to miss out
- The fear of leaving a cancer or atypia unrecognized
- Notable cases where things went wrong
Barriers to Care

Provider

On economics...

- “...If you calculate—that this is not worth it, we have to sacrifice this woman because we can’t afford a 100 million”
- “I’ll sit down and explain all this... It sounds complicated and of course I sometimes think... I’ll just take that smear, but it is important...you accept the screening intervals and don’t just take smears because women want it done and waste a lot of money on that”
Barriers to Care Provider

Regarding patient autonomy...

• “...If the patient pays herself then she has to have the right to decide what she wants to have done...So then if they say ‘I want to have this smear because it makes me feel more secure’, well then I think you have to be allowed to do it”
On “at-risk” screening...

• “...If you have a person who is a risk-group...make the judgment that she has had that kind of a sex-life...that she is a risk population...if that gynecologist says ‘I want to check her and take a smear monthly’, that's almost wild screening, because screening is normally population-based”
Barriers to Care Provider

Regarding learned health behaviors
- “For most of them going privately, it's a bit too much with three years between each visit, you loose the continuity, so there's psychology to it”
- “We’ve come so far with educating women about the need for annual health screenings. We need to be very careful, very measured, in our attempts to undo that learned health behavior.”- Dr. Martin Mahoney, Family Physician and Associate Professor of Oncology, Roswell Park Cancer Institute, NY
A study from 2003 examined women’s attitudes, beliefs, and barriers to risk-based cervical cancer screening.

- Agreed regular screening is important
- Not open to idea of reducing frequency of Pap smears
- Have concerns about test accuracy
- Were distrustful of rationales for reducing frequency
- Previous bad experiences reinforced need for self-advocacy

(Smith, French, & Barry)
On lessening frequency of testing:

- “Well, I know that I have to have one, you know, if it is the difference between life and death ...”
- “You cannot tell me one reason that would be good enough to not have one.”
In regards to pap smear accuracy and value:

• “Because, sometimes they’re right and sometimes they’re wrong. You can go in and get a wrong one, and then you’re all scared, then like 2 days later...you can go in and get a right one...”

• “I think they are very effective... I mean, us women can have yeast infections, and different kinds of things, and those Pap smears, when they check you, they will let you know whatever’s wrong with your body...”
In regards to distrust for new guidelines:

- “I don’t think HMOs are looking for quality. They’re looking to save their pocket, and that’s a fact.”
On self-advocacy:

• “...You have to be able to do research on your own. That’s the key to me for having good health because you cannot just depend on the doctor to give you all the information.”

• “I don’t take what my doctor says as gospel because I’ve had breast cancer and I firmly believe that if I had followed my original doctor’s recommendations, I’d be dead now...you have to take control, do the research and find what’s going on.”
Bridging the Gap

Teaching Points
If the patient is younger than 21 years of age…

**SCREENING IS NOT RECOMMENDED.**

Based on very low incidence of cancer and lack of data that screening is effective in this age group. Only 0.1% of cases of cervical cancer occur before age 20 years.

If the patient is aged 21-29 years...

...they should have a Pap test every THREE years.

3-year testing intervals associated with similar reductions in risk of cancer as annual testing and require less additional testing with invasive procedures.

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ACOG, 2016
# Cervical Cancer Screening Guidelines

<table>
<thead>
<tr>
<th>Patient Demographic</th>
<th>Guideline Recommendation</th>
<th>EBP Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>If the patient is aged 30-65 years...</td>
<td>...they should have a Pap test + HPV co-testing every FIVE years (preferred) or a Pap test alone every 3 years.</td>
<td>Women 30 years or older with negative cervical cytology screening result and negative high-risk HPV test result shown to be at extremely low risk of developing CIN 2 or CIN 3 in next 4–6 years.</td>
</tr>
<tr>
<td>If the patient is 65 years or older...</td>
<td>...SCREENING IS NO LONGER RECOMMENDED.</td>
<td>Cervical cancer occurs a median of 15–25 years after HPV infection, so screening women in this age group would prevent very few cases of cancer.</td>
</tr>
</tbody>
</table>

*With no history of cervical changes and either 3 negative pap tests in a row or two co-tests within the past 10 years, with the most recent test performed in the past 5 years.

*Note: Use of cotesting in women younger than 30 largely would detect transient HPV infection without carcinogenic potential.

(ACOG, 2016)
Teaching Points:
ACOG Committee Opinion

• Patients still need screening when vaccinated
  • Rationale: vaccines cover only most common high-risk HPV subtypes (National Cancer Institute, 2015)

• Still need screening if hysterectomy performed, but cervix not removed
  • Rationale: supracervical hysterectomy accounts for 3-28% of all hysterectomies worldwide and risk of cancer still present (Lethaby, Mukhopadhyay, & Naik, 2012)
### Teaching Points

#### Exception to Screening Guidelines

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</tr>
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<tbody>
<tr>
<td>If patient had a hysterectomy in which cervix was removed and: They have a history of cervical cancer or moderate to severe cervical changes...</td>
<td>...the patient should continue to have screening for 20 years after surgery.</td>
<td>Women with high-grade cervical intraepithelial lesions before total hysterectomy can develop recurrent intraepithelial neoplasia/carcinoma at vaginal cuff years after the procedure.</td>
</tr>
<tr>
<td>If patient had a hysterectomy in which cervix was removed and: They have no history of cervical changes...</td>
<td>...SCREENING IS NOT RECOMMENDED.</td>
<td>Cytology screening in this group has small chance of detecting abnormality, and test has a very low positive predictive value.</td>
</tr>
</tbody>
</table>

(ACOG, 2016)
### Teaching Points

**Patient Demographic**

- If patient was exposed to DES before birth or has HIV, a weakened immune system, or a history of cervical cancer...

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**Guideline Recommendation**

- ...they may need more frequent screening.

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**EBP Rationale**

- Certain risk factors associated with CIN in observational studies. Routine screening guidelines are intended for average-risk women.

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*(ACOG, 2016)*
Teaching Points:
ACOG Committee Opinion

Remember...

- Patients should continue to see OBGYN annually, even if not due for Pap smear
  - Birth control counseling
  - Vaccinations
  - Health screenings
  - Preconception care
  - Latest information about reproductive health

(ACOG, 2016)
Teaching Points: Abnormal Results

- **Dysplasia**: abnormal cells on cervix caused by HPV
- Mild dysplasia usually goes away without treatment
- Some moderate and most cases of severe dysplasia do not
  - Cells are considered "pre-cancerous"
  - If not found and treated, could develop into cervical cancer
- Abnormal results typically followed up with Pap smear in one year or additional testing such as colposcopy, based on severity

(ASCCP, 2016)
What is the Take Home?

Conclusion
Conclusion

- Cervical cancer slow growing; easy to treat and prevent with routine screening
- Pap smear developed 89 years ago and considered standard practice for more than 50 years
- Alabama among several states with highest cervical cancer morbidity and mortality
- Barriers to implementation of current EBP guidelines include provider attitude, patient knowledge, and conflicting insurance coverage
• Patients younger than 21, regardless of sexual activity, older than 65, and status-post hysterectomy generally do NOT need screening
  • Exceptions include those with history of cervical changes in last 5 years or hysterectomy due to cervical cancer
• Patients 21-29 should have pap test every 3 years
• Patients 30-65 should have pap test every 3 years OR a Pap with HPV co-testing every 5 years
  • More frequent screening done for patients with immunodeficiency or abnormal results
Conclusion

Key Points

• Most recent guidelines for less aggressive testing supported by evidence that cervical cancer takes years to develop

• Important...Still recommended that patients have well-woman exam annually for other important examinations and services


