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BREAST CANCER SCREENING FOR AVERAGE-RISK WOMEN

RECOMMENDATIONS

Clinical Recommendations

The Women’s Preventive Services Initiative recommends that average-risk women initiate mammography screening no earlier than age 40 and no later than age 50. Screening mammography should occur at least biennially and as frequently as annually. Screening should continue through at least age 74 and age alone should not be the basis to discontinue screening.

These screening recommendations are for women at average risk of breast cancer. Women at increased risk should also undergo periodic mammography screening, however, recommendations for additional services are beyond the scope of this recommendation.

Implementation Considerations

The Women’s Preventive Services Initiative recommends, as a preventive service, that women initiate mammography screening no earlier than age 40 and no later than age 50 and continue through at least age 74. Screening mammography should occur at least biennially and as frequently as annually. Decisions regarding when to initiate screening, how often to screen, and when to stop screening should be based on a periodic shared decision-making process involving the woman and her health care provider. The shared decision-making process assists women in making an informed decision and includes, but is not limited to, a discussion about the benefits and harms of screening, an assessment of the woman’s values and preferences, and consideration of factors such as life expectancy, comorbidities, and health status.
### EVIDENCE MAP

- Average-risk women should initiate mammography screening no earlier than age 40 and no later than age 50.
- Screening should continue through at least age 74 and age alone should not be the basis to discontinue screening.

<table>
<thead>
<tr>
<th>Systematic Reviews</th>
<th>Additional Studies</th>
<th>USPSTF¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>USPSTF 2016 review²:</td>
<td>• Meta-analyses of screening RCTs indicate statistically significant breast cancer mortality reductions with screening for ages 50-59 and 60-69 years; but not 39-49 and 70-74 years. Estimates for age &gt;70 are limited by small sample sizes.</td>
<td>• Age 40-49: Biennial screening mammography should be based on individual factors including the patient's values regarding specific benefits and harms (Level C; 2016).</td>
</tr>
<tr>
<td></td>
<td>Observational studies of screening indicate reduced breast cancer mortality for ages 50-69; studies of younger and older women are lacking or inconsistent.</td>
<td>• Age 50-74: Biennial screening mammography (Level B; 2016).</td>
</tr>
<tr>
<td></td>
<td>• Meta-analysis of screening RCTs indicate no reductions in advanced breast cancer with screening for age 39 to 49 years; but reduced risk with screening for age 50 years and older.</td>
<td>• Age 75 and older: Evidence is insufficient to assess the additional benefits and harms of screening mammography (2016).</td>
</tr>
</tbody>
</table>

Screening mammography should occur at least biennially and as frequently as annually.

<table>
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<tr>
<th>Systematic Reviews</th>
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<th>USPSTF¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>USPSTF 2016 review²:</td>
<td>Screening trials do not compare screening intervals; observational studies are inconsistent and biases limit interpretation.</td>
<td>Age 50-74: Biennial screening mammography (Level B; 2016).</td>
</tr>
<tr>
<td></td>
<td>CISNET modeling study³: Biennial screening intervals provide the most benefit while minimizing potential harms.</td>
<td></td>
</tr>
</tbody>
</table>

Decisions regarding when to initiate screening, how often to screen, and when to stop screening should be based on a periodic shared decision-making process involving the woman and her health care provider.

<table>
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<th>Systematic Reviews</th>
<th>Additional Studies</th>
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</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>None</td>
<td>Suggests informed decision making, however, no studies have evaluated the effectiveness of this approach (2016).</td>
</tr>
</tbody>
</table>

Abbreviations: CISNET=Cancer Intervention and Surveillance Modeling Network; RCTs=randomized controlled trials; USPSTF=U.S. Preventive Services Task Force
SUMMARY OF EVIDENCE

Introduction

Breast cancer commonly includes an asymptomatic phase that can be identified with mammography. The rationale for screening is to improve survival by identifying treatable cancer at localized stages, although screening may not reduce mortality for some aggressive cancer types, and has less impact on slowly progressive types. Screening for women at average risk for breast cancer (i.e., without risk factors indicating high risk) is conducted using periodic mammography. Digital mammography has generally replaced film in the United States, and newer technologies, such as digital tomosynthesis, are rapidly disseminating. Rates of screening mammography in the United States are generally high and have remained relatively stable for the past decade. Mammography screening between 2009 and 2011 was performed by 71% of eligible women covered by commercial plans, 69% for Medicare plans, and 51% for Medicaid plans.

While there is general consensus that mammography screening is beneficial for many women, conflicting screening recommendations have led to practice variability. Issues lacking consensus include the optimal ages to begin and end routine screening; optimal screening intervals; defining and balancing the benefits of screening with potential harms; appropriate use of various imaging modalities including supplemental technologies; values and preferences of women regarding screening; and how all of these considerations vary depending on a woman’s risk for breast cancer.

Current Recommendations and Coverage of Services

The previous Institute of Medicine panel did not address breast cancer screening coverage because a specific clause in the Affordable Care Act indicated that annual mammography screening would be covered for women age 40 years and older without a co-pay or deductible. This coverage applies to the annual screening mammogram only, and subsequent related services are not similarly covered.

In 2016, the U.S. Preventive Services Task Force (USPSTF) updated its recommendation for breast cancer screening for asymptomatic, average-risk women. The new recommendation is similar to the previous recommendation issued in 2009. The USPSTF recommends biennial screening mammography for women ages 50 to 74 years, and determined that the decision to start regular, biennial screening mammography before the age of 50 years should be an individual one and take patient context into account, including the patient's values regarding specific benefits and harms.

The USPSTF concluded that evidence was insufficient to assess the additional benefits and harms of screening mammography in women age 75 years or older. In addition, they determined that evidence was insufficient to support digital breast tomosynthesis (DBT) as a primary screening method, and adjunctive screening for breast cancer using breast ultrasonography,
magnetic resonance imaging (MRI), DBT, or other methods in women identified to have dense breasts on an otherwise negative screening mammogram.

**Background**

Breast cancer is the second most common cancer in women in the United States after non-melanoma skin cancer, and is the second leading cause of cancer death after lung cancer. In 2016, an estimated 246,660 women in the United States will be diagnosed with breast cancer and 40,450 will die, representing 14.6% of all new cancer cases and 6.8% of all cancer deaths. The overall 5-year relative survival rate for breast cancer from 2006 to 2012 was 89.7%, and approximately 3 million women were living with breast cancer in the United States in 2013.

Although many risk factors have been associated with breast cancer in epidemiologic studies, most relationships are weak or inconsistent. Most women who develop breast cancer have no identifiable risk factors beyond sex and age. However, a small number of clinically significant risk factors are associated with high risks for breast cancer and can be used to identify women who may be eligible for screening outside routine screening recommendations. These include women with deleterious BRCA mutations and their untested first-degree relatives; other hereditary genetic syndromes; previously diagnosed high-risk breast lesions; and history of high-dose radiation therapy to the chest between the ages of 10 to 30 years, such as for treatment of Hodgkin lymphoma.

Family history of breast cancer, particularly among first-degree relatives, is also an important risk factor. Approximately 5 to 10% of women with breast cancer have a mother or sister with breast cancer, and up to 20% have either a first-degree or a second-degree relative with breast cancer. The degree of risk associated with family history varies according to familial patterns of disease. Estimates of lifetime risk of breast cancer determined by kindred analysis of over 15 or 20% are considered high.

Breast density is a radiographic measure of breast tissue that is associated with increased risk for breast cancer and reduced mammography sensitivity. Breast density is currently described by four categories: almost entirely fat, scattered fibroglandular densities, heterogeneously dense, and extremely dense. Approximately 37% of women had dense breasts in a recent U.S. study; however, there was a wide variation in density assessment across radiologists. Increased breast density is more common among younger women. Compared with women with scattered fibroglandular densities, hazard ratios for breast cancer are 1.6 for premenopausal women with heterogeneously dense breasts and 2.0 for those with extremely dense breasts.

Models that incorporate several of these risk factors have been developed to predict breast cancer risk for individual women. All of the models include age and number of first-degree relatives with breast cancer into their calculations, but vary in their complexity. Studies of their diagnostic accuracy indicate that the models are poor predictors of an individual’s risk and their effectiveness in selecting candidates for breast cancer screening remains unproven.

Current practice guidelines vary across professional organizations (Table 1).
Table 1. Recommendations of Professional Organizations

<table>
<thead>
<tr>
<th>Organization</th>
<th>Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>American College of Obstetricians and Gynecologists (ACOG)(^{21})</td>
<td>Mammography screening should be offered annually to women beginning at age 40.</td>
</tr>
<tr>
<td>American Academy of Family Physicians (AAFP)(^{22})</td>
<td>The decision to conduct screening mammography prior to age 50 should be individualized and take into consideration the patient’s context and risk factors. For women between ages 50 and 74, the AAFP recommends biennial screening.</td>
</tr>
<tr>
<td>American Cancer Society(^{23})</td>
<td>Women with an average risk of breast cancer should undergo regular screening mammography starting at age 45 years; women aged 45 to 54 years should be screened annually; women 55 years and older should transition to biennial screening or have the opportunity to continue screening annually. Women should have the opportunity to begin annual screening between the ages of 40 and 44 years and should continue screening mammography as long as their overall health is good and they have a life expectancy of 10 years or longer.</td>
</tr>
<tr>
<td>American College of Radiology (ACR)(^{24})</td>
<td>Annual screening mammography for asymptomatic women 40 years of age and older. The decision as to when to stop routine mammography screening should be made on an individual basis by each woman and her physician based on a woman’s overall health.</td>
</tr>
<tr>
<td>National Comprehensive Cancer Network (NCCN)(^{25})</td>
<td>Annual screening mammography, clinical breast exam, and breast awareness for asymptomatic, average risk women age 40 years and older.</td>
</tr>
</tbody>
</table>

**Update of Evidence**

The WPSI update focuses on three issues: optimal ages to begin and discontinue regular screening mammography, and optimal screening intervals for women screened at any age. Several comprehensive evidence reviews on breast cancer screening were recently conducted, including reviews from the Pacific Northwest Evidence-based Practice Center for the USPSTF published in February 2016\(^{2,26}\). Results relevant to the three issues covered in this update are summarized below. Literature searches used for the USPSTF reviews were repeated in August 2016 to identify new evidence, however, no new studies relevant to the update met inclusion criteria.

**Effectiveness of Screening at Different Ages**

**Reducing breast cancer mortality**

Meta-analyses of randomized controlled trials (RCTs) of breast cancer screening with updated data from the Canadian, Swedish Two-County Study, and Age trials indicated statistically significant breast cancer mortality reductions with screening for ages 50 to 59 years and 60 to 69 years, but not for age 39 to 49 years and 70 to 74 years \((Table 2)^{2}\). Estimates for women age 70
and older were limited by low numbers of events from trials that had smaller sample sizes of women in this age group.

Observational studies of the effectiveness of population-based mammography screening on breast cancer mortality reported a wide range of reductions in breast cancer death. Most studies were conducted in Europe or the United Kingdom and included women age 50 to 69 years. Meta-analyses from recent reviews from the EUROSCREEN Working Group indicated 25 to 31% mortality reduction for women invited to screening in the screening programs. This compares to 19 to 22% reduction for women age 50 to 69 years in the USPSTF meta-analysis of screening RCTs.2

Table 2. Age-specific Rates of Breast Cancer Mortality Reduction with Screening2

<table>
<thead>
<tr>
<th>Age, yrs</th>
<th>Number of trials</th>
<th>Mortality rate in the control group per 100,000 person-years (95% CI)*</th>
<th>Breast cancer mortality reduction RR (95% CI)†</th>
<th>Deaths prevented with screening over 10 years (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>39-49</td>
<td>9</td>
<td>34 (26 to 44)</td>
<td>0.88 (0.73 to 1.003)</td>
<td>4.1 (-0.1 to 9.3)</td>
</tr>
<tr>
<td>50-59</td>
<td>7</td>
<td>54 (50 to 58)</td>
<td>0.86 (0.68 to 0.97)</td>
<td>7.7 (1.6 to 17.2)</td>
</tr>
<tr>
<td>60-69</td>
<td>5</td>
<td>65 (52 to 81)</td>
<td>0.67 (0.54 to 0.83)</td>
<td>21.3 (10.7 to 31.7)</td>
</tr>
<tr>
<td>70-74</td>
<td>3</td>
<td>62 (48 to 80)</td>
<td>0.80 (0.51 to 1.28)</td>
<td>12.5 (-17.2 to 32.1)</td>
</tr>
</tbody>
</table>

*Based on trials of screening included in the meta-analysis.
†From meta-analysis of screening trials using the longest follow-up time available.
CI=confidence interval; RR=relative risk.

The only U.S observational study of breast cancer mortality reduction is a record review that indicated no differences in breast cancer deaths between screened versus non-screened women older than age 80 years.27 A large study of the Mammography Screening of Young Women Cohort in Sweden indicated reduced risk for breast cancer deaths for women age 40 to 49 years invited to screening compared with women not invited (RR 0.74; 95% CI, 0.66 to 0.83).28 An observational study of Canadian women age 40 to 79 comparing screening program participants versus nonparticipants indicated 40% reduced breast cancer mortality among participants.29 However, observational studies were susceptible to important methodologic biases limiting these conclusions, particularly regarding important fundamental differences between participants and nonparticipants of screening programs.

Reducing all-cause mortality
All-cause mortality did not differ between randomized groups in meta-analyses of the screening RCTs, regardless of whether trials were analyzed in combined or separate age groups.

Reducing advanced breast cancer
The RCTs of mammography screening provided several measures of intermediate breast cancer outcomes. However, most comparisons between screening and control groups using these categories provided differences between the two groups in relatively early stages of disease, rather than advanced stages. When thresholds were defined by the most severe disease

7
categories available from the trials (Stage III + IV disease, size ≥50 mm, 4+ positive lymph nodes), meta-analysis indicated no reductions in advanced breast cancer with screening for age 39 to 49 years (RR 0.98; 95% CI 0.74 to 1.37); but reduced risk with screening for age 50 years and older (RR, 0.62; 95% CI 0.46 to 0.83). The majority of cases from screening were ductal carcinoma in situ (DCIS) and early stage, and screening resulted in more mastectomies (RR 1.20 [95% CI 1.11 to 1.30]; 5 trials) and radiation (RR 1.32 [95% CI 1.16 to 1.50]; 2 trials).

Several observational studies describe differences between screened and unscreened women, but report various definitions of advanced breast cancer.² Six observational studies compared advanced breast cancer outcomes between women in populations participating in screening versus nonparticipating. Of these, two studies indicated statistically significantly more Stage III and IV breast cancer among unscreened women; three reported more lymph node positive disease; and three reported more tumors greater than 20 mm in size. Four case series studies indicated less extensive surgery, such as fewer total mastectomies and more breast conservation therapies, and less chemotherapy among women who had previously had screening mammography compared with those who did not, but these studies included women with DCIS and early stage cancer as well as advanced cancer.

An analysis of data from the Breast Cancer Surveillance Consortium (BCSC) indicated a lower proportion of Stage III + IV disease among women age 40 to 49 years screened annually versus biennially, but not for women age 50 to 59 years. A second analysis of BCSC data indicated that women age 40 to 49 years with extremely dense breasts had increased risks for advanced stage cancer (IIB+) and large-size tumors (>20 mm) with biennial compared with annual screening. Differences were not significantly different for positive lymph nodes, other density categories, other age groups, or between biennial and triennial screening.

**Effectiveness of Screening Using Different Intervals**

There are no head-to-head trials of the effectiveness of different screening intervals, and existing trials do not provide enough information to determine the specific effects of screening intervals. Two observational studies of screening intervals indicated no breast cancer mortality differences between annual and biennial screening for women 50 years or older, or between annual and triennial screening among women age 40 to 49 years. No RCTs evaluated the incidence of advanced breast cancer outcomes and treatment on the basis of screening intervals.

Because of the lack of studies addressing the effectiveness of different screening intervals, the USPSTF commissioned a modeling study from the CISNET modeling group.³ Results indicated that biennial screening intervals provided the most benefit while minimizing potential harms.

**Harms of Screening**

The USPSTF weighs the benefits of screening against potential harms, including false-positive results leading to additional imaging and biopsies, false-negative results, overdiagnosis, anxiety and distress with screening, pain, and radiation exposure.
False-Positive and False-Negative Mammography Results, Recommendations for Additional Imaging, and Recommendations for Biopsies

Data from the BCSC for regularly screened women using digital mammography based on results from a single screening round indicated that false-positive mammography rates were highest among women age 40 to 49 years (121.2 per 1,000 women; 95% CI 105.6 to 138.7) and declined with age; rates of false-negative results tended to increase with age, but were not statistically significantly different across age groups (Table 3). Rates of recommendations for additional imaging were highest among women age 40 to 49 years (124.9 per 1,000 women; 95% CI 109.3 to 142.3) and decreased with age, while rates of recommendations for biopsy did not differ between age groups. For every case of invasive breast cancer detected by mammography screening in women age 40 to 49 years, 464 women had screening mammography, 58 were recommended for additional imaging, and 10 were recommended for biopsies. These estimates declined with age. These results did not differ by time since last mammography screening regardless of whether broad or narrow estimates of one versus two years were used.

When these outcomes were evaluated by breast cancer risk factors, family history of breast cancer, high breast density, and previous benign breast biopsy were associated with higher rates of false-positive and false-negative results and recommendations for additional imaging and biopsy across most age groups. Premenopausal status, use of menopausal hormone therapy, and lower BMI were associated with some of the outcomes for specific age groups only. Rates for all outcomes were lowest for women with almost entirely fat breasts, and highest for women with heterogeneously dense breasts or for those in the combined category of heterogeneous and extreme density.

Published data from the BCSC using film and digital mammography provided 10-year cumulative rates of false-positive results and biopsies. Rates of false-positive mammography results were 61% for annual and 41% for biennial screening, while rates of false-positive biopsy were 7 to 9% for annual and 5 to 6% for biennial screening. Women older than age 50 years had higher false-positive biopsy rates. Rates of false-positive mammography results and biopsy were highest among women receiving annual mammography, those with heterogeneously dense or extremely dense breasts, and those either 40 to 49 years old or who used combination hormone therapy.

Overdiagnosis

Overdiagnosis refers to breast cancer cases that are detected by screening that would not become clinically important to the patient in the absence of screening. A meta-analysis of three RCTs, a systematic review of 13 observational studies, and 18 individual studies of overdiagnosis were identified for the USPSTF update. Studies of overdiagnosis were primarily based on screening trials, screening programs and registries, or modeled data. Studies differed by their characteristics, methods, and measures. These differences influenced their estimates of overdiagnosis, limited comparisons, and prohibited combined estimates.

Estimates from RCTs indicate overdiagnosis rates of 10.7 to 19.0%. Unadjusted estimates from 13 observational studies included in the EUROSCREEN review indicated overdiagnosis rates ranging from 0 to 54%. For six studies that adjusted overdiagnosis estimates for breast cancer risk and lead time, rates varied from 1 to 10%. Additional observational studies not included in
the EUROSCREEN review reported overdiagnosis estimates of 3 to 50%, with most between 14 to 25%. Although several statistical models of overdiagnosis have been published, these studies have been less acceptable to guideline development groups because of the many assumptions that were used to construct them. Models indicated estimates ranging from 0.4 to 50%.
Table 3. Age-Specific Rates of False-Positive and False-Negative Digital Mammography Results and Recommendations for Additional Imaging and Biopsies From a Single Screening Round in the BCSC\textsuperscript{30}

<table>
<thead>
<tr>
<th></th>
<th>40-49</th>
<th>50-59</th>
<th>Age, y 60-69</th>
<th>70-79</th>
<th>80-89</th>
<th>Difference (P-value)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Women screened, n</td>
<td>113,770</td>
<td>127,958</td>
<td>94,507</td>
<td>50,204</td>
<td>18,752</td>
<td></td>
</tr>
<tr>
<td>Invasive breast cancer cases, n</td>
<td>349</td>
<td>574</td>
<td>651</td>
<td>427</td>
<td>154</td>
<td></td>
</tr>
<tr>
<td>DCIS cases, n</td>
<td>191</td>
<td>246</td>
<td>208</td>
<td>120</td>
<td>43</td>
<td></td>
</tr>
<tr>
<td>Outcomes, n per 1,000 women screened (95% CI)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>False-positive mammography result</td>
<td>121.2 (105.6 to 138.7)</td>
<td>93.2 (82.8 to 104.7)</td>
<td>80.8 (72.9 to 89.4)</td>
<td>69.6 (62.6 to 77.3)</td>
<td>65.2 (58.8 to 72.2)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>False-negative mammography result</td>
<td>1.0 (0.9 to 1.2)</td>
<td>1.1 (0.9 to 1.3)</td>
<td>1.2 (0.9 to 1.5)</td>
<td>1.5 (1.1 to 1.9)</td>
<td>1.3 (0.9 to 1.9)</td>
<td>0.32</td>
</tr>
<tr>
<td>Additional imaging recommended†</td>
<td>124.9 (109.3 to 142.3)</td>
<td>98.5 (88.0 to 110.1)</td>
<td>88.7 (80.6 to 97.4)</td>
<td>79.0 (71.9 to 86.9)</td>
<td>74.4 (67.4 to 82.2)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Biopsy recommended†</td>
<td>16.4 (13.2 to 20.3)</td>
<td>15.9 (12.7 to 19.7)</td>
<td>16.5 (14.3 to 19.1)</td>
<td>17.5 (15.2 to 20.2)</td>
<td>15.6 (13.4 to 18.2)</td>
<td>0.12</td>
</tr>
<tr>
<td>Screen-detected invasive cancer</td>
<td>2.2 (1.8 to 2.6)</td>
<td>3.5 (3.1 to 4.0)</td>
<td>5.8 (5.3 to 6.4)</td>
<td>7.2 (6.4 to 8.1)</td>
<td>7.1 (5.9 to 8.5)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Screen-detected DCIS</td>
<td>1.6 (1.3 to 1.9)</td>
<td>1.8 (1.5 to 2.2)</td>
<td>2.1 (1.7 to 2.5)</td>
<td>2.3 (1.7 to 3.0)</td>
<td>2.1 (1.5 to 3.0)</td>
<td>0.05</td>
</tr>
</tbody>
</table>

*2-sided P-values and 95% confidence intervals from a logistic regression model that accounts for clustering by radiology facility using generalized estimating equations.
†After positive mammography result.
Abbreviations: CI=confidence interval; DCIS=ductal carcinoma in situ.
Anxiety, Distress, and Other Psychological Responses
Systematic reviews including over 100 descriptive studies of anxiety, distress, and other psychological responses to mammography screening have been published, but provide mixed results. In general, women with false-positive results had more anxiety, psychological distress, and breast cancer specific worry after screening compared with those with normal screening results in most studies. Anxiety improved over time for most women, but persisted for over 2 years for some. Two studies reported that women with false-positive results were less likely to return for their next mammogram; two other studies reported no differences; however, when women were given letters tailored to their last screening result they were more likely to re-attend.

Pain during Procedures
A review of 22 descriptive studies indicated that many women experience pain during mammography (1% to 77%), but the proportion of those experiencing pain who do not attend future screening varies (11% to 46%).

Radiation Exposure
Published models calculate the number of deaths due to radiation induced cancer using estimates for digital mammography is between 2 per 100,000 in women age 50 to 59 years screened biennially, and up to 11 per 100,000 in women ages 40 to 59 years screened annually. A new model for the USPSTF reported similar findings. A new model for the USPSTF reported similar findings.

Conclusions
Results of trials comparing mammography screening to no screening indicate reduced breast cancer deaths with screening for women ages 50 to 69 years, but not for women in their 40s or age 70 and older. Individual factors that increase risk for breast cancer, such as family history of breast cancer, previous biopsies, increased breast density, and others, have not been evaluated in screening trials. Models indicate that women with some of these factors may benefit from screening beginning in their 40s. Based on models suggesting that mortality may be reduced and years of life extended by screening women starting at age 40, it may appropriate to begin offering screening starting at age 40 using shared decision-making involving a discussion of the anticipated benefits and adverse consequences. Given that the benefit-to-harm ratio improves with age, women who have not chosen to initiate mammography in their 40s should be recommended to do so at age 50. Estimates for women age 70 and older are limited by the low numbers of older women in the trials. Deaths from all causes are not reduced with screening; while advanced breast cancer is reduced for women age 50 and older, but not younger women. False-positive results are common and are higher with annual screening, for younger women, and for women with dense breasts. Although overdiagnosis, anxiety, pain, and radiation exposure may cause harm, their effects on individual women are difficult to estimate and vary widely. No trials provide information regarding optimal screening intervals. Estimates based on models indicate that biennial screening intervals provide the most benefit while minimizing potential harms. No studies have evaluated the effectiveness of shared decision making in determining whether to undergo mammography screening.
REFERENCES


Clinical Recommendations

The Women’s Preventive Services Initiative recommends comprehensive lactation support services (including counseling, education, and breastfeeding equipment and supplies) during the antenatal, perinatal, and postpartum periods to ensure the successful initiation and maintenance of breastfeeding.

Implementation Considerations

Lactation support services include counseling, education, and breastfeeding equipment and supplies. A lactation care provider should deliver lactation support and provide services across the antenatal, perinatal, and postpartum periods to ensure successful preparation, initiation, and continuation of breastfeeding. Lactation care providers include, but are not limited to, lactation consultants, breastfeeding counselors, certified midwives, certified nurse-midwives, certified professional midwives, nurses, advanced practice providers (e.g., physician assistants and nurse practitioners), and physicians. Breastfeeding equipment and supplies, as agreed upon by the woman and her lactation care provider, include, but are not limited to, double electric breast pumps (including pump parts and maintenance) and breast milk storage supplies. Access to double electric pumps should be based on optimization of breastfeeding, and not predicated on prior failure of a manual pump.
### Comprehensive lactation support services, including counseling, education, and breastfeeding equipment and supplies.

<table>
<thead>
<tr>
<th>Systematic Reviews</th>
<th>Additional Studies</th>
<th>USPSTF¹</th>
</tr>
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<tbody>
<tr>
<td>2016 USPSTF review of 52 studies reported increased rates of any and exclusive breastfeeding at &lt;3 months and at 3-6 months, and exclusive breastfeeding at 6 months for women enrolled in individual-level breastfeeding interventions versus usual care.²</td>
<td>None</td>
<td>For pregnant women, new mothers, and their children, the USPSTF recommends providing interventions during pregnancy and after birth to support breastfeeding (Level B; 2016)</td>
</tr>
</tbody>
</table>

A lactation care provider should deliver lactation support and provide services across the antenatal, perinatal, and postpartum periods to ensure successful preparation, initiation, and continuation of breastfeeding.

<table>
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<tr>
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<th>USPSTF¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016 USPSTF review of studies evaluating the timing of breastfeeding interventions (intervention during only one period [prenatal, perinatal, or postpartum] vs. across multiple periods). Results indicated increased breastfeeding when interventions occurred across multiple periods.²</td>
<td>Two good-quality trials of effective breastfeeding interventions in the U.S. included 5 in-person visits with a lactation consultant (two during prenatal clinic visits, one in the hospital, and one or two voluntary postpartum home visits).³ These were supplemented by phone calls and EHR alerts.</td>
<td>For pregnant women, new mothers, and their children, the USPSTF recommends providing interventions during pregnancy and after birth to support breastfeeding (Level B; 2016)</td>
</tr>
</tbody>
</table>

### Efficiency of double electric pumps.

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<thead>
<tr>
<th>Systematic Reviews</th>
<th>Additional Studies</th>
<th>USPSTF¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compared to other methods, double electric breast pumps more closely mimic the sucking actions of an infant, result in a greater volume of expressed milk, and come the closest to matching the milk removal efficiency of a healthy infant (85% of milk removed in 15 minutes versus 80% of milk removed in 5 minutes).⁴</td>
<td>None</td>
<td>Not addressed</td>
</tr>
</tbody>
</table>

Abbreviations: EHR=electronic health record; USPSTF=U.S. Preventive Services Task Force
SUMMARY OF EVIDENCE

Introduction

Breastfeeding is the process of feeding infants with human milk from a woman’s breast, either directly from the breast or by expressing (pumping) the milk from the breast and bottle-feeding. Breastfeeding counseling and support includes maternity care practices, such as discussions with healthcare professionals about breastfeeding; structured breastfeeding education, such as information and resources provided during the prenatal and intrapartum periods; employee benefits and services, such as designated private space and time for breastfeeding or expressing milk (now included under a provision of the ACA); peer support, such as individual counseling and mother-to-mother support groups; professional support, such as lactation consultations; and marketing initiatives.

Current Recommendations and Coverage of Service

The gap in services provided under the provisions of the Patient Protection and Affordable Health Care Act of 2010 previously identified by the Institute of Medicine (IOM) Committee was that comprehensive prenatal and postnatal lactation support, counseling, and supplies were not included. Health insurance plans are now required to provide breastfeeding support, counseling, and equipment for the duration of breastfeeding including the purchase or rental cost of breast pumps (Table 1). The IOM recommendation includes an explicit description of a more comprehensive set of services than the U.S. Preventive Services Task Force (USPSTF).

Table 1. Summary of Recommendations Currently Covered by the Affordable Care Act

<table>
<thead>
<tr>
<th>IOM Committee(^8)</th>
<th>Comprehensive lactation support and counseling and costs of renting breastfeeding equipment. A trained provider should provide counseling services to all pregnant women and to those in the postpartum period to ensure the successful initiation and duration of breastfeeding</th>
</tr>
</thead>
<tbody>
<tr>
<td>USPSTF(^10)</td>
<td>Provide interventions during pregnancy and after birth to support breastfeeding (Level B; 2016). Interventions may include more than one component and be delivered over prenatal, perinatal, and postpartum periods.</td>
</tr>
</tbody>
</table>

Abbreviations: IOM=Institute of Medicine; USPSTF=U.S. Preventive Services Task Force

Background

Breastfeeding is associated with several health benefits for infants including reduced risk of acute otitis media, non-specific gastroenteritis, severe lower respiratory tract infections, atopic dermatitis, asthma (young children), obesity, type 1 and 2 diabetes, childhood leukemia, sudden infant death syndrome (SIDS), and necrotizing enterocolitis. Breastfeeding is not recommended in specific situations involving mothers who have been infected with human immunodeficiency virus (HIV) or human T-cell lymphotropic virus type I or type II; who are prescribed cancer
chemotherapy agents, taking antiretroviral therapy or drugs, undergoing radiation therapies; using or dependent upon illicit drugs; or have untreated, active tuberculosis. The Surgeon General’s call to action to support breastfeeding identified several barriers to breastfeeding in the United States. These include lack of knowledge, social norms, poor family and social support, embarrassment, lactation problems, employment and child care issues, and lack of access to health services.

The Centers for Disease Control and Prevention (CDC) reported in 2012 that 80.0% of newborn infants started breastfeeding at birth, 51.4% were still breastfeeding at 6 months, and 29.2% at 12 months; 43.3% were exclusively breastfeeding at 3 months and 21.9% exclusively breastfeeding at 6 months. These rates are close to the goals set by Healthy People 2020 (Table 2).

Breastfeeding rates vary greatly and are higher with increasing maternal age, education, and income, and among mothers who do not receive supplemental nutrition assistance (WIC). Rates differ across racial/ethnic groups, with 83.2% of Asian/Pacific Islanders reporting initiating breastfeeding in 2012, 83.0% of whites, 82.4% of Hispanics, 71.5% of American Indian/Alaska Natives, and 66.4% of blacks. These differences are most apparent in the southern United States, with differences between whites and blacks ranging from 9% in Florida to 32% in Alabama.

<table>
<thead>
<tr>
<th>Breastfeeding practice</th>
<th>Prevalence in 2012</th>
<th>Healthy People 2020 goals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initiation</td>
<td>80.0%</td>
<td>81.9%</td>
</tr>
<tr>
<td>At 6 months</td>
<td>51.4%</td>
<td>60.6%</td>
</tr>
<tr>
<td>At 12 months</td>
<td>29.2%</td>
<td>34.1%</td>
</tr>
<tr>
<td>Exclusively at 3 months</td>
<td>43.3%</td>
<td>46.2%</td>
</tr>
<tr>
<td>Exclusively at 6 months</td>
<td>21.9%</td>
<td>25.5%</td>
</tr>
</tbody>
</table>

The American Congress of Obstetricians and Gynecologists (ACOG), the American Academy of Family Physicians (AAFP), the American Academy of Pediatrics (AAP), the American College of Nurse-Midwives (ACNM), and the World Health Organization (WHO) all recommend exclusive breastfeeding for the first 6 months, with continued breastfeeding along with appropriate complementary foods up to age 2 years or beyond. Most groups emphasize breastfeeding through the first year of life and then continuing as long as mutually desired (Table 3).

<table>
<thead>
<tr>
<th>Organization</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>American Academy of Family Physicians (AAFP)</td>
<td>All babies, with rare exceptions, be breastfed and/or receive expressed human milk exclusively for the first 6 months of life. Breastfeeding should continue with the addition of complementary foods throughout the second half of the first year.</td>
</tr>
<tr>
<td>Organization</td>
<td>Recommendation</td>
</tr>
<tr>
<td>--------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>American Congress of Obstetricians and Gynecologists (ACOG)(^{19})</td>
<td>Exclusive breastfeeding is recommended for the first 6 months of a baby’s life. Breastfeeding should continue up to the baby’s first birthday as new foods are introduced. Continue breastfeeding after the baby’s first birthday for as long as mother and baby would like.</td>
</tr>
<tr>
<td>American Academy of Pediatricians (AAP)(^{20})</td>
<td>Exclusive breastfeeding for about 6 months, followed by continued breastfeeding as complementary foods are introduced, with continuation of breastfeeding for 1 year or longer as mutually desired by mother and infant. Medical contraindications to breastfeeding are rare.</td>
</tr>
<tr>
<td>American College of Nurse-Midwives (ACNM)(^{21})</td>
<td>Exclusive breastfeeding for the first 6 months provides complete nutrition for growth and development, and ideally breastfeeding should continue throughout the first year of life.</td>
</tr>
<tr>
<td>The World Health Organization (WHO)(^{22})</td>
<td>Exclusive breastfeeding is recommended up to 6 months of age, with continued breastfeeding along with appropriate complementary foods up to 2 years of age or beyond.</td>
</tr>
</tbody>
</table>

Recommendations provide additional guidance on how to promote and support breastfeeding. Several recommendations suggest the adoption of the WHO/The United Nations Children's Emergency Fund (UNICEF) Ten Steps to Successful Breastfeeding (Table 4).\(^{23}\)

### Table 4. The 10 Steps to Successful Breastfeeding\(^{23}\)

1. Have a written breastfeeding policy that is routinely communicated to all health care staff.
2. Train all health care staff in the skills necessary to implement this policy.
3. Inform all pregnant women about the benefits and management of breastfeeding.
4. Help mothers initiate breastfeeding within one hour of birth.
5. Show mothers how to breastfeed and how to maintain lactation, even if they are separated from their infants.
6. Give infants no food or drink other than breast-milk, unless medically indicated.
7. Practice rooming in, allow mothers and infants to remain together 24 hours a day.
8. Encourage breastfeeding on demand.
9. Give no pacifiers or artificial nipples to breastfeeding infants.
10. Foster the establishment of breastfeeding support groups and refer mothers to them on discharge from the hospital or birth center.

### Update of Evidence

**Interventions to Support Breastfeeding Initiation and Duration**

A systematic review\(^2,24\) was recently published to support the 2016 USPSTF recommendation\(^1\) on breastfeeding. The review is an update of a prior review published in 2008, and includes new studies and re-evaluation of studies included in the prior review.
The review includes 52 studies assessing the effectiveness of breastfeeding support interventions in increasing initiation of breastfeeding and prolonging breastfeeding, either exclusively or with supplementation. The review included only randomized controlled trials (RCTs) for individual-level interventions, and controlled before and after studies and prospective cohort studies for system-level interventions. Studies were conducted in either the prenatal, peripartum, or postpartum phase, or a combination of phases.

Of the 52 studies, 43 provided data about individual level interventions, while the other nine studies provided data on system level interventions. Individual-level interventions include professional support (one-to-one support during hospital stay or outpatient visits, home visits, or telephone support from health professionals); peer support (counseling or social support from peers or lay persons); and formal or structured education (structured education sessions or classes directed at mothers or other family members, typically provided in group sessions). System-level interventions include policies, programs, and staff training (Baby-Friendly Hospital Initiative [BFHI], implementation of a new policy or protocol, or training of health professionals); and other maternity care practices (encouragement of skin-to-skin contact, rooming-in, restricted pacifier use, or distribution of breast pumps).

**Individual-Level Interventions**

Meta-analyses of trials of individual-level interventions to promote and support breastfeeding reported in the 2016 USPSTF review indicate statistically significantly higher rates of any breastfeeding at less than 3 months (RR 1.07; 95% CI, 1.03 to 1.11; 26 trials) and at 3 to 6 months (RR 1.11; 95% CI, 1.04 to 1.18; 23 trials), but not on initiation of breastfeeding or breastfeeding at 6 months (Table 5). The review also reported statistically significantly higher rates of exclusive breastfeeding at less than 3 months (RR 1.21; 95% CI, 1.11 to 1.33; 22 trials), 3 to 6 months (RR 1.20; 95% CI, 1.05 to 1.38; 18 trials), and at 6 months (RR 1.20; 95% CI, 1.05 to 1.38; 17 trials).

<table>
<thead>
<tr>
<th>Breastfeeding practice</th>
<th>Time Point (months)</th>
<th>Studies, n</th>
<th>Mothers, n</th>
<th>RR (95% CI)</th>
<th>I² (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any</td>
<td>Initiation</td>
<td>14</td>
<td>9,428</td>
<td>1.00 (0.99 to 1.02)</td>
<td>22.8</td>
</tr>
<tr>
<td></td>
<td>&lt;3</td>
<td>26</td>
<td>11,588</td>
<td>1.07 (1.03 to 1.11)</td>
<td>72.0</td>
</tr>
<tr>
<td></td>
<td>3 to &lt;6</td>
<td>23</td>
<td>8,942</td>
<td>1.11 (1.04 to 1.18)</td>
<td>46.5</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>20</td>
<td>9,715</td>
<td>1.07 (0.98 to 1.16)</td>
<td>57.5</td>
</tr>
<tr>
<td>Exclusive</td>
<td>&lt;3</td>
<td>22</td>
<td>8,246</td>
<td>1.21 (1.11 to 1.33)</td>
<td>52.4</td>
</tr>
<tr>
<td></td>
<td>3 to &lt;6</td>
<td>18</td>
<td>7,027</td>
<td>1.20 (1.05 to 1.38)</td>
<td>44.6</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>17</td>
<td>7,690</td>
<td>1.16 (1.02 to 1.32)</td>
<td>14.3</td>
</tr>
</tbody>
</table>

**Number of Individual-level Intervention Sessions.** The USPSTF review did not specifically assess the optimal number of sessions required for successful breastfeeding. Results from individual studies are mixed, although higher numbers of professional intervention sessions generally increased breastfeeding rates at less than 3 months, 3 to 6 months, and 6 months. For example, among seven studies of single-session interventions, none showed statistically significant effects on breastfeeding rates at less than 3 months. In comparison, in six studies of 2
to 10 intervention sessions, the intervention was consistently associated with higher rates of breastfeeding, although only three studies reported statistically significant differences. Results were similar for 10 or more intervention sessions, based on 3 studies.

Providing breastfeeding interventions during the prenatal, peri-, and postpartum time points was more effective than interventions provided at one or two time points. Of 10 studies of interventions provided at all three time points, all found higher rates of breastfeeding relative to control at <3, 3 to <6 and 6 month measures, although for three of these studies the risk estimate was not statistically significant.

A best evidence approach that examines the most effective and most relevant studies provides an estimate of the number of intervention visits needed for effective breastfeeding in the United States. Of the eight studies conducted in the U.S., only three studies reported statistically significantly increased breastfeeding rates at any of the follow-up time points, and one reported rates with borderline statistical significance at one time point (Table 6). The Bonuck 2014 studies (two trials reported in one publication) are among the largest studies, and the only U.S. studies with statistically significant results that met criteria for good study quality. Results showed consistently increased rates of breastfeeding at less than 3, 3 to 6, and 6 month follow-up times. Although the interventions in both trials required 20 sessions, only 5 of these sessions were in-person visits with a lactation consultant (two during prenatal clinic visits, one in the hospital, and one or two voluntary postpartum home visits). The prenatal visits averaged 1 hour, hospital visits 40 to 50 minutes, and postpartum contacts greater than 1 hour. The other sessions included prompts in the EMR at prenatal visits or regular phone calls postpartum. In comparison, the fair-quality Bonuck 2006 trial included 4 intervention sessions, and achieved statistically significant rates at <3 and 3 to 6 months, but not at 6 months follow-up.

Table 6. U.S. Based Studies of Individual-level Interventions to Promote and Support Breastfeeding – Effectiveness According to Number of Sessions2

<table>
<thead>
<tr>
<th>Author, year</th>
<th>Number of sessions</th>
<th>Timing of intervention</th>
<th>Intervention type</th>
<th>Risk estimate (RR; 95% CI): Intervention vs. Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bonuck 2014a</td>
<td>20 Pre; Peri; Post</td>
<td>Lactation support and brief education</td>
<td>1.26 (1.03 to 1.54)</td>
<td></td>
</tr>
<tr>
<td>N=666; Good</td>
<td>(3)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bonuck 2014b</td>
<td>20 Pre; Peri; Post</td>
<td>Lactation support and brief education</td>
<td>1.23 (1.08 to 1.40)</td>
<td></td>
</tr>
<tr>
<td>N=275; Good</td>
<td>(3)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bonuck 2006</td>
<td>4 Pre; Peri; Post</td>
<td>Lactation support</td>
<td>1.32 (1.10 to 1.57)</td>
<td></td>
</tr>
<tr>
<td>27 N=382; Fair</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pollard 2011</td>
<td>4 Peri; Post</td>
<td>Self-monitoring</td>
<td>1.21 (0.89 to 1.64)</td>
<td></td>
</tr>
<tr>
<td>N=86; Good</td>
<td>(67)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Paul 2012</td>
<td>2 Peri</td>
<td>Home visits</td>
<td>1.09 (1.00 to 1.18)</td>
<td></td>
</tr>
<tr>
<td>48 N=1154; Fair</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Author, year N: Quality</td>
<td>Number of sessions</td>
<td>Timing of intervention</td>
<td>Intervention type</td>
<td>Risk estimate (RR; 95% CI): Intervention vs. Control</td>
</tr>
<tr>
<td>-------------------------</td>
<td>--------------------</td>
<td>------------------------</td>
<td>-------------------</td>
<td>--------------------------------------------------</td>
</tr>
<tr>
<td><strong>Outcome: any breastfeeding, 3 to 6 months</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hopkinson 2009&lt;sup&gt;60&lt;/sup&gt; N=552; Good</td>
<td>1</td>
<td>Post</td>
<td>Lactation support</td>
<td>0.99 (0.93 to 1.05)</td>
</tr>
<tr>
<td>Edwards 2013&lt;sup&gt;31&lt;/sup&gt; N=248; Fair</td>
<td>23</td>
<td>Pre; Peri; Post</td>
<td>Lactation support</td>
<td>1.88 (0.65 to 1.20)</td>
</tr>
<tr>
<td>Bonuck 2014a&lt;sup&gt;1&lt;/sup&gt; N=666; Good</td>
<td>20</td>
<td>Pre; Peri; Post</td>
<td>Lactation support and brief education</td>
<td>1.49 (1.09 to 2.03)</td>
</tr>
<tr>
<td>Bonuck 2014b&lt;sup&gt;1&lt;/sup&gt; N=275; Good</td>
<td>20</td>
<td>Pre; Peri; Post</td>
<td>Lactation support and brief education</td>
<td>1.37 (1.07 to 1.73)</td>
</tr>
<tr>
<td>Pollard 2011&lt;sup&gt;67&lt;/sup&gt; N=86; Good</td>
<td>4</td>
<td>Peri; Post</td>
<td>Self-monitoring</td>
<td>1.11 (0.65 to 1.90)</td>
</tr>
<tr>
<td><strong>Outcome: any breastfeeding, 6 months</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bonuck 2014a&lt;sup&gt;1&lt;/sup&gt; N=666; Good</td>
<td>20</td>
<td>Pre; Peri; Post</td>
<td>Lactation support and brief education</td>
<td>1.28 (0.85 to 1.94)</td>
</tr>
<tr>
<td>Bonuck 2014b&lt;sup&gt;1&lt;/sup&gt; N=275; Good</td>
<td>20</td>
<td>Pre; Peri; Post</td>
<td>Lactation support and brief education</td>
<td>1.48 (1.01 to 2.17)</td>
</tr>
<tr>
<td>Bonuck 2006&lt;sup&gt;27&lt;/sup&gt; N=382; Fair</td>
<td>4</td>
<td>Pre; Peri; Post</td>
<td>Lactation support</td>
<td>1.34 (0.98 to 1.84)</td>
</tr>
<tr>
<td>Pollard 2011&lt;sup&gt;67&lt;/sup&gt; N=86; Good</td>
<td>4</td>
<td>Peri; Post</td>
<td>Self-monitoring</td>
<td>1.12 (0.62 to 2.03)</td>
</tr>
</tbody>
</table>

**Subgroup Differences.** Seven trials provided direct comparisons of the effect of the intervention based on characteristics of the mother (age, education, insurance status, country of origin, primary language spoken, delivery type, parity, prior breastfeeding experience, and breastfeeding intentions). Maternal country of origin and language spoken were the only significant findings. Breastfeeding rates were lower among women in the U.S.-born control groups than in the U.S.-born intervention group and all foreign-born participants<sup>28</sup> at 13 and 52 weeks; and Spanish-speaking women at 4, 12, and 26 weeks, but not English-speaking women at 4 weeks.<sup>68</sup>

**Adolescents and Young Adults.** Four trials<sup>31,44,49,69</sup> were limited to adolescents or young adults. The three U.S. trials reported statistically significant differences between intervention and usual care groups, while the trial conducted in Australia showed no effect.<sup>49</sup> A U.S. trial<sup>81</sup> provided mothers with support by a community doula during the prenatal, peripartum, and postpartum phases. Mothers in the intervention group were more likely to initiate breastfeeding than the usual care group (63.9% vs. 49.6%; p=0.02) and to breastfeed for at least 6 weeks (28.7% vs. 16.8%; p=0.04), but there was no difference in breastfeeding between groups at 16 weeks (8.3% vs. 4.4%). Another U.S. trial<sup>69</sup> of mothers receiving group prenatal education and given electric breast pumps beginning in the second trimester and through postpartum reported higher rates of breastfeeding initiation compared with usual care (79% vs. 63%) and longer median duration of any breastfeeding (177 days vs. 61 days). The third U.S. trial<sup>44</sup> provided mothers with
postpartum peer telephone support, and reported statistically significant longer durations of exclusive breastfeeding than those receiving usual care (median 35 days vs. 10 days; p=0.004).

System-Level Interventions
Three good-quality studies\(^74,79,80\) reported the effects of hospital policies or BFHI accreditation on breastfeeding rates. One study found that women with lower education (≤12 years) who delivered at a BFHI accredited hospital had higher rates of exclusive breastfeeding at 4 weeks or more by 4.5 percentage points compared with women who delivered at non-BFHI accredited hospitals (effect estimate 0.045; 95% CI, 0.01 to 0.08; p=0.02).\(^79\) No effects were found in other studies.

Three fair-quality trials\(^72,73,78\) of the effects of maintaining mother and baby contact following delivery reported mixed results with only one trial demonstrating an effect. The trial included women scheduled for cesarean section deliveries who were randomized to either a new protocol for minimizing maternal-infant separation following birth or usual peripartum care (infants were removed immediately from the operating room and transferred to the obstetric recovery room with brief or no physical contact with their mother).\(^78\) Women in the intervention group reported higher rates of breastfeeding at hospital discharge (76.0% vs. 52.0%) and at 4 weeks (72.7% vs. 33.3%) compared with usual care (unadjusted RR 2.18; 95% CI, 1.17 to 4.06). Three good-quality trials\(^75-77\) reported no differences in breastfeeding rates between mothers instructed to delay or restrict pacifier use and those not given these instructions.

Efficiency of Different Breast Pumps
Over 80% of mothers need to express breast milk during the first 4 months postpartum.\(^82\) Breast milk can be expressed by hand or through the use of a breast pump. Breast pumps fall into three general categories: manual, battery-operated, and electric. In addition, breast pumps can be single (expressing milk from one breast at a time) or double (expressing milk from both breasts simultaneously) action pumps. Manual and battery-operated breast pumps tend to be single action while electric pumps can be either single or double action.\(^83\)

Reviews of breast milk expression methods have found little direct evidence on which type of breast pump is ideal, and have concluded that the best method of milk expression is likely dependent on individual factors.\(^84,85\) For example, a recent Cochrane review of breast milk expression methods found few differences between breast pump type and maternal satisfaction, adverse events (including milk contamination and breast pain or damage), or volume of milk expressed.\(^85\) The milk expressed by both hand expression and electric pumps had a higher protein content than that expressed by battery-operated pumps, but there were no differences between pump type and other nutrient levels. Only one study included in the review compared electric and manual pumps and the effect on time spent pumping, finding that woman using an electric breast pump spent 20 minutes less per day pumping milk compared to manual pump users.\(^86\) The studies included in the review were heterogeneous in terms of population (both mothers and babies) and the review ultimately concluded that the best method of breast milk expression may be dependent on individual circumstances.

A more recent review evaluated aspects of different methods of breast milk expression.\(^4\) Using the human infant as the “gold standard” for milk expression, electric breast pumps more closely mimicked the sucking actions of an infant and were more efficient at expressing milk when
compared with hand expression. The use of double electric breast pumps, particularly in situations where the breast pump is acting as a replacement for an infant unable to breastfeed, resulted in a greater volume of expressed milk.\(^4\) In addition to volume of breast milk expressed, double electric breast pumps come the closest to matching the milk removal efficiency of a healthy infant (85% of milk removed in 15 minutes versus 80% of milk removed in 5 minutes).\(^4\) The efficiency of milk expression is an important factor in breast pump choice for working mothers who may have limited time to pump or mothers of infants unable to breastfeed (e.g. neonatal intensive care unit infants) who must pump many times a day.

Related to breast pump volume and efficiency, is the mother’s level of dependence on milk expression. For women who are completely dependent on a breast pump to regulate their lactation level, the review concluded that hospital-grade electric pumps are the best choice because of their efficiency and convenience.\(^4\)

For mothers unable to breastfeed during the first days postpartum, electric breast pumps are also important in order to avoid subsequent lactation failure, and their use remains important once lactation has been established.\(^4\) For mothers of healthy breastfeeding infants with established lactation, who are partially or minimally dependent on breast pumps, convenience may be the most important factor in pump choice. Electric pumps may be the best choice for these women.

### Harms of Interventions to Promote or Support Breastfeeding

Two trials\(^{29,33}\) reported harms related to breastfeeding. In one trial,\(^{29}\) mothers in the intervention group expressed feelings of anxiety, decreased confidence, or concerns about confidentiality, while the other trial\(^{33}\) reported no statistically significant differences between the intervention and usual care groups on the State-Trait Anxiety Inventory at 2 weeks.

### Relevant Studies Published Since the USPSTF Draft Systematic Review

#### Other Reviews

A recent systematic review included observational studies as well as trials of interventions to improve breastfeeding outcomes (initiation of breastfeeding, exclusive breastfeeding, continued breastfeeding, and any breastfeeding) and reported similar pooled results as the USPSTF report (Table 7).\(^{87}\)

### Table 7. Meta-analysis of Trials and Observational Studies\(^{87}\)

<table>
<thead>
<tr>
<th>Breastfeeding practice</th>
<th>Studies, n</th>
<th>OR (95% CI)</th>
<th>(I^2) (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initiation</td>
<td>49</td>
<td>1.25 (1.19 to 1.32)</td>
<td>90.6</td>
</tr>
<tr>
<td>Exclusive up to 6 months</td>
<td>130</td>
<td>1.44 (1.38 to 1.51)</td>
<td>91.0</td>
</tr>
<tr>
<td>Continued past 6 months</td>
<td>18</td>
<td>1.61 (1.17 to 2.20)</td>
<td>92.0</td>
</tr>
<tr>
<td>Any breastfeeding</td>
<td>118</td>
<td>1.30 (1.23 to 1.37)</td>
<td>92.1</td>
</tr>
</tbody>
</table>

Abbreviations: CI=confidence interval; OR=odds ratio
Ongoing Studies
Ten randomized controlled trials of interventions to promote or support breastfeeding initiation and prolong breastfeeding are currently in progress. Two trials include telephone support; two focus on earlier versus later (usual care) timing of the intervention; one assesses lay person support; one targets low-income mothers; and another targets populations at risk for childhood obesity. Two Cochrane systematic reviews of interventions for promoting and supporting breastfeeding among overweight or obese women or among women with multiple pregnancies are currently in progress.

Conclusions
Breastfeeding is associated with health benefits, and clinical guidelines encourage women to breastfeed exclusively for 6 months and breastfeed with solid food supplementation up to 1 year. However, multiple barriers discourage breastfeeding including lack of knowledge, inadequate support, lactation problems, constraints of employment, and limited access to appropriate health services and lactation supplies. Randomized controlled trials of individual-level interventions administered by professionals, peers, or lay persons, provided during prenatal, peripartum, or postpartum phases indicate higher rates of breastfeeding initiation and duration than women not receiving interventions. This includes increased rates of any and exclusive breastfeeding at less than 3 months and at 3 to 6 months, and exclusive breastfeeding at 6 months.

Trials evaluating the timing of breastfeeding interventions (intervention during only one period [prenatal, perinatal, or postpartum] versus across multiple periods) indicate increased breastfeeding when interventions occurred across multiple periods. Two good-quality trials of effective breast feeding interventions in the United States included five in-person visits with a lactation consultant (two during prenatal clinic visits, one in the hospital, and one or two voluntary postpartum home visits). These were supplemented by phone calls and alerts in the electronic health record. A review of breast pump methods indicates that double electric breast pumps more closely mimic the sucking actions of an infant, result in a greater volume of expressed milk, and come the closest to matching the milk removal efficiency of a healthy infant.
REFERENCES


88. Soltani H, Fair FJ. Interventions for supporting the initiation and continuation of breastfeeding among women who are overweight or obese. Cochrane Database of Systematic Reviews. 2016(2) PMID: 00075320-100000000-10499.
SCREENING FOR CERVICAL CANCER

Clinical Recommendations

The Women’s Preventive Services Initiative recommends cervical cancer screening for average-risk women aged 21 to 65 years. For women aged 21 to 29 years, the Women’s Preventive Services Initiative recommends cervical cancer screening using cervical cytology (Pap test) every 3 years. Co-testing with cytology and human papillomavirus testing is not recommended for women younger than 30 years. Women aged 30 to 65 years should be screened with cytology and human papillomavirus testing every 5 years or cytology alone every 3 years. Women who are at average risk should not be screened more than once every 3 years.

Implementation Considerations

The Women’s Preventive Services Initiative recommends as a preventive service, cervical cancer screening for average-risk women aged 21 to 65 years. For average-risk women aged 30 to 65 years, informed shared decision-making between the patient and her clinician regarding the preferred screening strategy is recommended.

Women who have received the human papillomavirus vaccine should be screened according to the same guidelines as women who have not received the vaccine.

These recommendations are for routine screening in average-risk women and do not apply to women infected with human immunodeficiency virus, women who are immunocompromised because of another etiology (such as those who have received solid organ transplantation), women exposed to diethylstilbestrol in utero, or women treated for cervical intraepithelial neoplasia grade 2 or higher within the past 20 years. Screening strategies for high-risk women are outside the scope of these recommendations.

Cervical cancer screening is not recommended for women younger than 21 years or those older than 65 years who have had adequate prior screening and are not otherwise at high risk for cervical cancer. Adequate prior negative screening is defined as documentation (or a reliable patient report) of three consecutive negative cytology results or two consecutive negative co-test results within the previous 10 years with the most recent test within the past 5 years. Cervical cancer screening is also not recommended for women who have had a hysterectomy with removal of the cervix and who do not have a history of a high-grade precancerous lesions (e.g., cervical intraepithelial neoplasia grade 2 or grade 3 or cervical cancer within the past 20 years).
EVIDENCE MAP

- Cervical cancer screening for average-risk women aged 21 to 65 years.
- For women aged 21 to 29 years, screening using cervical cytology (Pap test) every 3 years.
- Co-testing with cytology and human papillomavirus testing is not recommended for women younger than 30 years.

<table>
<thead>
<tr>
<th>Systematic Reviews</th>
<th>Additional Studies</th>
<th>USPSTF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cytology alone in younger women supported by:</td>
<td>Co-testing not recommended in younger women supported by:</td>
<td>USPSTF: The USPSTF recommends screening for cervical cancer in women age 21-65 years with cytology (Pap smear) every 3 years or, for women age 30-65 years who want to lengthen the screening interval, screening with a combination of cytology and human papillomavirus (HPV) testing every 5 years.</td>
</tr>
<tr>
<td>- USPSTF review of epidemiologic and observational study data.¹</td>
<td>- One diagnostic accuracy study.³</td>
<td></td>
</tr>
<tr>
<td>- USPSTF modeling study.²</td>
<td>- One RCT.⁴</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- USPSTF modeling study.²</td>
<td></td>
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</tbody>
</table>

Women aged 30 to 65 years should be screened with cytology and human papillomavirus testing every 5 years or cytology alone every 3 years.

<table>
<thead>
<tr>
<th>Systematic Reviews</th>
<th>Additional Studies</th>
<th>USPSTF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Similar or greater detection of CIN2/3+ and cancer for co-testing versus cytology supported by:</td>
<td>Similar or greater detection of CIN2/3+ and cancer for co-testing versus cytology supported by: USPSTF modeling study;² 4 RCTs updated from USPSTF review;⁸ 1 observational study.⁹</td>
<td>USPSTF: see above</td>
</tr>
<tr>
<td>- 2011 USPSTF review of 4 RCTs.¹,⁶</td>
<td>- Improved detection of adenocarcinoma using co-testing versus cytology demonstrated in 4 RCTs updated from USPSTF review.⁸</td>
<td></td>
</tr>
<tr>
<td>- Updated meta-analysis of 4 RCTs from 2014 USPSTF review.⁷</td>
<td>- Negative HPV test is more predictive of normal results in future screening rounds than negative cytology, supporting extended screening intervals with co-testing, supported by follow-up of 1 RCT¹⁰ and 1 observational study.⁹,¹¹</td>
<td></td>
</tr>
</tbody>
</table>

USPSTF: see above
Cervical cancer screening is not recommended for women younger than 21 years or those older than 65 years who have had adequate prior screening and are not otherwise at high risk for cervical cancer.

<table>
<thead>
<tr>
<th>Systematic Reviews</th>
<th>Additional Studies</th>
<th>USPSTF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start and stop ages for cervical cancer screening:</td>
<td>2011 USPSTF review based on SEER and observational study data supports starting age.</td>
<td>USPSTF modeling study.</td>
</tr>
<tr>
<td>Stop age was not systematically reviewed in 2012 USPSTF review, but recommendation was based on 12 observational studies from 2002 USPSTF review and epidemiologic and observational study data identified during the 2012 USPSTF review that supported prior findings.</td>
<td>4 observational studies.</td>
<td>USPSTF: see above</td>
</tr>
<tr>
<td>Screening in women with a hysterectomy: USPSTF recommendation was based on 2 observational studies from the 2002 USPSTF review.</td>
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</table>

Women who have received the HPV vaccine should be screened according to the same guidelines as women who have not been vaccinated.

<table>
<thead>
<tr>
<th>Systematic Reviews</th>
<th>Additional Studies</th>
<th>USPSTF</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>None</td>
<td>USPSTF: Clinical considerations note that current trials do not provide data on long-term efficacy; therefore, the possibility that vaccination might reduce the need for screening with cytology alone or in combination with HPV testing is not established. Given these uncertainties, women who have been vaccinated should continue to be screened.</td>
</tr>
</tbody>
</table>

Abbreviations: ACA=Affordable Care Act, HPV=human papilloma virus, USPSTF=U.S. Preventive Services Task Force.
SUMMARY OF EVIDENCE

Introduction

Invasive cervical neoplasia is caused by persistent infection with high-risk strains of human papilloma virus (HPV) that lead to the development of squamous cell carcinoma and adenocarcinoma of the uterine cervix. Invasive cervical neoplasia is caused by persistent infection with high-risk strains of human papilloma virus (HPV) that lead to the development of squamous cell carcinoma and adenocarcinoma of the uterine cervix. HPV is the most common sexually transmitted infection in the United States with approximately 79 million currently infected individuals. Each year, an estimated 14 million individuals are newly infected. HPV infections are typically self-limited, asymptomatic, and not diagnosed. The 10-year risk for development of cancer precursor lesions ranges from 13% to 17%, while the risk of progression from precancerous lesions to invasive disease is 31% over 30 years.

Periodic screening of sexually active women with cytology-based techniques has long been the standard of care for early cancer detection. In recent years, the introduction of testing for high-risk HPV DNA has allowed the detection of viral strains most commonly associated with the development of cancer even when cytology results are negative.

Current Recommendations and Coverage of Services

The gap in services provided under the provisions of the Patient Protection and Affordable Health Care Act of 2010 (ACA) previously identified by the Institute of Medicine (IOM) Committee was the absence of coverage for co-testing with cytology and high-risk HPV DNA testing among women age 30 years and older. In 2012, the U.S. Preventive Services Task Force (USPSTF) issued new recommendations for women age 30 to 65 years that included screening with a combination of cytology and HPV testing every 5 years. The USPSTF is currently updating this recommendation including an evaluation of the effectiveness and harms of HPV testing with or without cytology as a primary screening strategy.

Table 1. Summary of Recommendations Currently Covered by the Affordable Care Act

| IOM Committee | Addition of high-risk HPV DNA testing to cytology testing in women with normal cytology results. Screening should begin at 30 years of age and should occur no more frequently than every 3 years. |

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Screening for cervical cancer in women age 21 to 65 years with cytology every 3 years or, for women age 30 to 65 years who want to lengthen the screening interval, screening with a combination of cytology and HPV testing every 5 years (Level A 2012).

Recommends against screening for cervical cancer with HPV testing, alone or in combination with cytology, in women age <30 years; screening women age <21 years; screening women age >65 years who have had adequate prior screening and are not otherwise at high risk for cervical cancer; screening women who have had a hysterectomy with removal of the cervix and who do not have a history of a high-grade precancerous lesion (cervical intraepithelial neoplasia [CIN] grade 2 or 3) or cervical cancer (Level D 2012).

Clinical considerations: Current trials do not provide data on long-term efficacy; therefore, the possibility that vaccination might reduce the need for screening with cytology alone or in combination with HPV testing is not established. Given these uncertainties, women who have been vaccinated should continue to be screened.

Abbreviations: CIN=cervical intraepithelial neoplasia; HPV=human papilloma virus; IOM=Institute of Medicine; USPSTF=U.S. Preventive Services Task Force

**Background**

In 2012, cervical cancer was diagnosed in 12,042 women and caused 4,074 deaths in the United States. Cervical cancer diagnosis was most frequent in women age 35 to 44 years (median 49 years) and deaths were most common among those age 45 to 54 years (median 57 years). Although mortality from cervical cancer has generally declined since the introduction of screening programs in the 1950s, women with poor access to care and women of color continue to share a disproportionate burden of incidence and mortality. Among new cervical cancer cases in 2012, black and Hispanic women experienced incidence rates of 9.0 and 9.5 per 100,000, respectively, compared with 7.1 per 100,000 among white women; death rates were 3.7 and 2.7 versus 2.1 per 100,000.

Although deaths from cervical cancer are less common than deaths from other types of cancer, they are mostly preventable through primary prevention, screening, and treatment. In 2010, the overall cervical cancer screening rate among American women was 83%, although rates were lower among Asians (75%), American Indians/Alaska Natives (79%), and Hispanics (79%), as well as women without access to health care (64%). More than half of cervical cancer cases occur among women who had no cytology testing during the months preceding diagnosis, with the remainder attributed to failure of detection and follow-up. Healthy People 2020 contains objectives for increasing the proportion of women in the United States age 21 to 65 years who receive cervical cancer screening by 10% so that 93% of women are screened.

Traditionally, screening used cytology-based methods alone including either conventional dry slide or liquid-based platforms. In the United States, liquid-based cytology accounts for more than 90% of cytology testing, offering improved sample quality compared with conventional cytology, though test characteristics are generally comparable. The most notable advantage
of liquid-based cytology is that it allows both cytology and high-risk HPV testing on a single patient specimen. There are currently two U.S. Food and Drug Administration (FDA) approved liquid-based platforms for cervical cancer screening: the SurePath Pap and the ThinPrep Pap Test.

Co-testing for high-risk HPV types is an option for women between ages 30 and 65 years who wish to extend their screening interval from 3 to 5 years. FDA-approved HPV tests include the Digene HC2, the Cervista, the cobas 4800 HPV test, and the APTIMA HPV Assay. In 2012, a survey by the College of American Pathologists found that 60% of U.S. laboratories were performing co-testing. In 2014, the FDA approved the cobas HPV test to be used as a primary screening tool for cervical cancer in addition to its use in co-testing with cytology. This decision was based on findings from a large U.S. study that found the HPV test to have equivalent or superior effectiveness compared with cytology for primary cervical cancer screening.

The HPV vaccine is an effective method for preventing infection with HPV. Two HPV vaccines are licensed in the United States. HPV4 is a quadrivalent vaccine (HPV 16, 18, 6, 11) licensed for use in males and females and HPV2 (HPV 16, 18) is a bivalent vaccine licensed for use in females. These vaccines are composed of virus-like particles prepared from a capsid protein of targeted HPV strains. Vaccines are prophylactic and do not have any therapeutic effect on HPV-related disease or disease progression in those already infected with HPV. The HPV vaccination is covered in the ACA under a separate recommendation for immunizations. Currently, practice standards recommend screening women who have had an HPV vaccine under the same guidelines as women who have not been vaccinated.

Current practice recommendations from professional organizations are similar to the USPSTF and advise cytology alone or co-testing (Table 2).

Table 2. Recommendations of Professional Organizations

<table>
<thead>
<tr>
<th>Start and Stop</th>
<th>Age 21 to 65 years of age*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cytology</td>
<td>Age 21 to 65 years every 3 years</td>
</tr>
<tr>
<td>Cytology and HPV test together</td>
<td>Age 30 to 65 years every 5 years is preferred (ACP does not specify preference); HPV testing not recommended in women age &lt; 30 years</td>
</tr>
<tr>
<td>Post- hysterectomy</td>
<td>Recommend against screening in women with a hysterectomy for benign disease that included removal of the cervix</td>
</tr>
<tr>
<td>HPV vaccinated women</td>
<td>Follow age-specific recommendations (same as unvaccinated women)</td>
</tr>
</tbody>
</table>

*Discontinuation of screening is based on an adequate screening history in women who are not otherwise at high risk for cervical cancer. Adequate screening history is defined as 3 consecutive negative cytology results or 2 consecutive negative HPV results within 10 years before cessation of screening, with the most recent test occurring within 5 years.

Abbreviations: HPV=human papilloma virus
Expert representatives from multiple advisory groups, including ACOG, ACS, ASCCP, and the ASCP recently convened to provide interim guidance on the use of HPV testing alone for cervical cancer screening. Based on a study that demonstrated equivalent or superior performance of primary HPV screening for detecting lesions compared with cytology alone, the interim advisory panel suggested that HPV alone could be considered as an alternative to current U.S.-based cervical cancer screening methods. However, this option has not been incorporated into current recommendations.

Update of Evidence

The 2012 USPSTF recommendation was based on a systematic review of the evidence of liquid-based cytology and high-risk HPV screening. This review included studies meeting criteria for fair and good-quality and focused on routine screening in populations in developed countries. In addition, the USPSTF commissioned a decision analysis modeling study to evaluate optimal ages at which to begin and end screening, optimal screening intervals, and benefits and harms of different screening strategies.

Ages to Start and Stop Screening; Screening Intervals

USPSTF systematic review and decision analysis

Data are lacking regarding the effectiveness of screening at specific ages and intervals. Indirect evidence includes data on the incidence, prevalence, and mortality of cervical cancer. Based on Surveillance, Epidemiology, and End Results Program (SEER) data from 2009 to 2013, 0.1% of all incident cervical cancer occurred in women younger than age 20 years and there were no reported deaths in this age group. Five observational studies from the United Kingdom, United States, and Iceland suggested that high-risk HPV infections and cytological abnormalities were common and self-limited in women under age 20 years, whereas CIN3+ was less common in this group compared with women older than 25 years. Generally, in these studies, screening in younger women resulted in lower detection rates and higher false positive rates than screening in older women, and did not result in decreased incidence of cervical cancer.

Modeling studies demonstrated no advantage to screening prior to age 21 years, with women in this age group experiencing the largest number of false positive test results (960 at age 20 years to 1003 at age 15 years with annual screening), and the lowest number of expected cancer cases (<3 per 1000 women). With each successive year that screening was delayed beyond age 21 years, the number of false positive test results declined and expected cancer cases increased. In modeling studies, screening every 5 years from age 21 years was associated with a difference in cancer mortality of 2.4 per 1000 women and cancer incidence of 10.2 per 1000 women compared with screening every year. Screening each year was associated with almost four times the number of colposcopies compared with screening every 5 years. Strategies that screen women every 3 to 5 years starting in their 20s were more efficient than annual screening during the teen years. A strategy of screening beginning at age 21 and repeated every 3 years was identified as particularly efficient.

The age to stop screening was not systematically addressed by the 2012 USPSTF review because a prior review undertaken in 2002 found limited evidence based on 12 observational studies.
regarding the benefits of screening women older than age 65 years. In particular, the 2002 systematic review noted that the incidence and prevalence of CIN tends to decrease with age, cervical cancer in older women is not more aggressive or progressive than in younger women, and that rates of high-grade intraepithelial lesions (HSIL) are low among older women who have been screened. Though not systematically addressed, evidence from the 2012 USPSTF systematic review confirmed reduced rates of abnormal cytology and detection of CIN3+ cases as women age and with subsequent screening.

In addition, the recommended age to stop screening was supported by epidemiological data and modeling studies. SEER data from 2009 to 2013 indicate that the median age at diagnosis of cervical cancer was 49 years and incidence declined during the fourth decade. Modelling studies showed that in women with adequate screening histories, changing the age at which to end screening from 65 to 95 years by 5-year intervals resulted in less than 1 life-year improvement after age 65 years, but substantially increased harms related to false positive tests and increased number of colposcopies and cervical biopsies. An adequate screening history was defined as 3 consecutive negative cytology results or 2 consecutive negative HPV results within 10 years prior to stopping screening, with the most recent test being within 5 years. However, in women who have never been screened or have had inadequate screening, screening past age 65 years was shown to have a mortality advantage. In modeling studies, strategies that involved screening women who had never been screened every 2 to 5 years starting at age 65 years and ending at age 70 to 75 years demonstrated a balanced tradeoff between benefits and harms.

Overall, the USPSTF-commissioned modeling study found that a strategy of screening with cytology every 3 years prior to age 30 and then co-testing every 5 years was associated with fewer colposcopies (575 vs. 1083 per 1000), cancers (7.44 vs. 8.50 per 1000), and cancer deaths (1.35 vs. 1.55 per 1000) compared with cytology screening every 3 years from age 21 years. In this model, data were limited to HPV DNA testing using one HPV testing platform (HC2) and the effect of vaccination was not accounted for.

Relevant studies published since the USPSTF systematic review

A large U.S. cohort study of health plan enrollees (Kaiser Permanente Northern California cohort) that estimated the 5-year risk of CIN3+ results in women age 21 to 24 years found very low risks of cervical cancer. In addition, a positive cytology test result predicted low CIN3+ risk except in 0.6% of results that were high grade. The more common HPV positive/ASC-US and low-grade squamous intraepithelial lesion (LSIL) results in women age 21 to 24 years in this study predicted CIN3+ risks similar to ASC-US in women age 30 to 64 years, for which a 6- to 12-month return visit is recommended. Further, the 5-year risk (4.4%) of these women did not reach the 5.2% implicit threshold for colposcopy, supporting repeat testing. In those with HPV-negative/ASC-US and Pap-negative results, CIN3+ risks were similar to cytology alone in women age 30 to 64 years, for which a 3-year return visit is recommended.

Similarly, an observational study used national screening data from England and Wales to compare 3-yearly screening in 100,000 women starting at age 20 versus 25 years. Results indicated that starting at age 20 would lead to an estimated excess of 119,000 screens, 20,000 non-negative test results, over 8,000 referrals to colposcopy, and nearly 3,000 women treated with potentially 1.3 additional cancers detected per 100,000 women. Based on these data,
Studies of screening older women are based on observational studies of screened versus unscreened or inadequately screened women. A review of screening histories of Kaiser Permanente Northern California enrollees aged 65 years and older who were diagnosed with cervical cancer found few cancers in this age group, and most cancers were diagnosed in women who were inadequately screened previously (i.e., not meeting criteria of 3 consecutive negative cytology tests or a single co-test). In a case-control study conducted in the United Kingdom, women with adequate negative screening at age 65 years had the lowest risk of cervical cancer (8 cancers per 10,000 women 20-year risk) compared with those not screened at age 50 to 64 years (49 cancers per 10,000 women 20-year risk). Screening at least every 5.5 years between the ages of 50 to 64 years was associated with a 75% lower risk of cervical cancer between ages 65 to 79 years compared with not screening. In this study, adequate screening was defined as at least three tests at age 50 to 64 years with at least one between ages 60 to 64 years, the last three of which were negative, and no HSIL or worse since age of 50 years. Regular screening was associated with low risk of cervical cancer until age 75 years, and by age 80 years, the risk in adequately screened women was half that of unscreened women.

A case-control study from two U.S. health plans that investigated the screening histories of women age 55 to 79 years who had died from cervical cancer found that cytology screening 5 to 7 years prior to diagnosis was associated with a 74% reduction in cervical cancer death (odds ratio 0.26; 95% CI, 0.10 to 0.63) after adjustment for covariates (smoking, marital status, race/ethnicity). This study estimated that 630 deaths would be averted annually by screening all women age 55 to 79 years in the United States, though estimates were based on small numbers of cases. A second study of the same two U.S. health plans that included women age 55 to 79 years who were diagnosed with invasive cervical cancer found that cytological screening approximately 1 year prior to the occult invasive phase of cervical cancer was associated with a 75% to 77% reduction in the risk of invasive cervical cancer. In this study, incidence remained low for several years following a negative screen, returning to the incidence of unscreened women after 5 to 7 years.

**HPV Testing in Combination with Cytology**

**USPSTF systematic review and decision analysis**

Four fair-quality randomized controlled trials comparing combination HPV (co-testing) versus cytology alone were included in the USPSTF review. Trials included women from national screening programs in Italy (NTCC Phase 1), the United Kingdom (ARTISTIC), Sweden (Swedescreeen), and the Netherlands (POBASCAM) enrolling more than 127,000 women age 20 to 64 years. Colposcopy referral thresholds, follow-up duration, and completeness varied between trials, limiting data on harms and complete ascertainment of outcomes.

Among women age 30 years or older, round-specific screening resulted in relatively more CIN2+ lesions detected with co-testing compared with cytology alone after round 1, less CIN3+ detected after round 2, and fewer cancer cases in the co-testing compared with the cytology group. Cumulative CIN3+ detection was similar between co-testing and cytology alone after two screening rounds in all trials. Cumulative invasive cancer detection was similar, or just slightly
higher, for cytology alone versus co-testing in three of four trials. Only the NTCC trial found a relative increase in any cumulative CIN measure after co-testing, with increased CIN2+ and CIN3+ detection after one screening round and cumulative detection of CIN2+ overall. However, this trial used a lower threshold for colposcopy referral, increasing sensitivity of the primary test.

An observational study of the Kaiser Permanente Northern California cohort compared co-testing to cytology alone among 330,000 women and found that cumulative 5-year incidence of cervical cancer was lower in the HPV-negative and cytology-negative group versus the cytology-negative group alone (3.2 per 100,000 vs. 7.5 per 100,000). Detection of CIN3+ was also higher in earlier screening rounds with co-testing versus cytology alone in this study.

Modeling studies supported similar benefits of co-testing every 5 years or cytology every 3 years (7.44 vs. 8.50 cancer cases and 1.35 vs. 1.55 deaths, respectively), though the preferred strategy would incorporate 3-yearly cytology screening under age 30 and then co-testing after age 30 to limit the number of colposcopies.

In a trial of co-testing (NTCC Phase 1) that included younger women, CIN2+ detection was increased in a substantial number of women under the age of 35 years during the first round and cumulatively. However, younger women who tested positive in this study were not referred to immediate colposcopy like their older counterparts and were instead retested. This difference in testing protocol led to differential loss to follow-up between the study arms. Also, no cumulative data on colposcopy were provided by the study.

Harms of co-testing were difficult to assess because of incomplete reporting of outcomes and varying approaches to abnormal results in studies. However, approaches to management of abnormal screening results in these studies generally differed from U.S. recommendations, limiting their clinical applicability. In four diagnostic accuracy studies, co-testing was generally more sensitive, but less specific than cytology alone, though these data were limited by different thresholds for positivity across studies.

In study of test performance for co-testing in younger women, co-testing (64.0%) was less sensitive for CIN3+ than HPV (92.5%) but not cytology (65.4%) testing alone. Specificity was higher with co-testing (87.6%) than with cytology (81.5%) and HPV testing alone (70.1%).

Relevant studies published since the USPSTF systematic review
A meta-analysis of four European randomized controlled trials included in the USPSTF review that compared co-testing with cytology alone for the detection of high grade CIN lesions and cancer (ARTISTIC, NTCC Phase 1, POBASCAM, Swedescreen) found that co-testing at baseline was associated with significantly higher detection of CIN2+ (RR 1.41, 95% confidence interval [CI] 1.12 to 1.76) and non-significantly higher detection of CIN3+ (RR 1.15, 95% CI 0.99 to 1.33). At the second round, co-testing was associated with significantly lower detection rates of both CIN 2+ and CIN3+ (RR 0.77, 95% CI 0.63 to 0.96; RR 0.68, 95%, CI 0.55 to 0.85; respectively). Overall detection rates did not differ between testing strategies for CIN2+ or CIN3+.
A follow-up study of the four European trials that followed more than 176,000 women age 20 to 64 years over a median of 6.5 years indicated reduced invasive cancer (rate ratio 0.60, 95% CI 0.40 to 0.89). Detection was similar between screening strategies for the first 2.5 years, but was lower among women who had subsequent co-testing (RR 0.45, 95% CI 0.25 to 0.81). Also, the cumulative incidence of invasive cervical cancer was lower with negative entry tests among those who were co-tested compared with cytology alone (4.6 per 100,000 vs. 7.9 at 3.5 years; 8.7 per 100,000 vs. 36.0 at 5.5 years). Rate ratios were generally lower for adenocarcinoma than squamous-cell carcinoma and lowest among women age 30 to 34 years.

An extended follow-up study of the ARTISTIC trial found that a negative HPV test was significantly more predictive of normal results than a negative cytology result over 3 rounds, adding support to extended screening intervals with co-testing. The Kaiser Northern California cohort study reported similar results that indicated the 5-year CIN3+ risk for women with HPV-negative/cytology-negative results was 0.08% (95% CI 0.07% to 0.09%), which is less than the 3-year CIN3+ risk for cytology-negative results of 0.16% in this population.

**HPV Testing Compared with Cytology**

**USPSTF Systematic Review and Decision Analysis**

The USPSTF review included six fair- and good-quality diagnostic accuracy studies that found 1-time HPV testing was more sensitive, but less specific than cytology, with HPV testing sensitivity ranging from 86% to 97% for CIN3+ outcomes and 63% to 98% for CIN2+ outcomes versus 46% to 50% and 38% to 65%, respectively for cytology. Specificity for these outcomes was 3 to 5 percentage points less using HPV testing compared with cytology. One large fair-quality Italian randomized controlled trial (NTCC Phase 2) that compared first round screening with HPV to cytology found increased detection of CIN3+ cancer in women screened with HPV alone compared with cytology, and equivalent numbers of invasive cancers detected in both arms. When invasive cancer cases from HPV testing alone were combined with cases from HPV co-testing strategies from an earlier trial, the cumulative incidence of invasive cancer was lower compared with cytology in women age 35 years and older. However, this finding is based on pooling non-comparable screening strategies.

Assessment of harms from trial data was limited because women with positive HPV results or ASC-US on cytology were immediately referred to colposcopy, resulting in more colposcopies among women screened with the more sensitive HPV test compared with cytology (5.8% vs. 2.5%). This strategy would not be applicable to U.S. women who would have been referred for repeat testing prior to colposcopy. Also, determination of harms was generally limited by incomplete reporting, use of different screening strategies in different rounds of the trial (cytology alone was done in both arms of round 2), and differing referral criteria.

Four fair-quality observational studies found that women who tested positive for HPV had increased immediate anxiety and distress compared with women who tested negative, but this difference had resolved by 6 months.

In women younger than 30 or 35 years, results were similar to those in older women, but they had higher rates of colposcopy referrals after HPV testing. One study that provided test characteristics of HPV and cytology testing in younger women showed that HPV test sensitivity
for CIN3+ and CIN2+ was 23% to 27% higher than cytology, but specificity of HPV testing was reduced to a much greater degree in younger women compared with older women (about 11%).

**Relevant studies published since the USPSTF systematic review**

In April 2014, the FDA approved the cobas HPV test for primary cervical cancer screening on the basis of findings from a large U.S. study (ATHENA) that found it to have equivalent or superior performance for detecting lesions compared with cytology alone. The ATHENA study enrolled 42,000 women age 25 years and older who had cytology and HPV testing. Women without CIN2+ findings were entered into a 3-year follow-up phase to compare three screening strategies: cytology with HPV testing only for ASC-US (cytology); cytology in women under age 30 years followed by co-testing in women 30 years and older (hybrid); and HPV testing in women 25 years and older (HPV primary).

At follow-up, the 3-year cumulative incidence rate of CIN3+ cases in cytology negative women was 0.8% (95% CI, 0.5% to 1.1%) compared with 0.3% (95% CI, 0.1% to 0.7%) in HPV-negative women, and 0.3% (95% CI, 0.1% to 0.6%) in women who were negative for both tests. Cytology was less sensitive (47.8%) for the detection of CIN3+ cases versus HPV primary testing (76.1%) and the hybrid strategy (61.7%), but was more specific (specificity of 97.1%, 94.6%, and 93.5% for cytology, hybrid strategy, and HPV primary testing, respectively). Overall, the HPV primary screening strategy resulted in increased detection of CIN3+ cases compared with other strategies, but also resulted in more colposcopies, though the number of colposcopies needed to detect a single case of CIN3+ was similar to that for the hybrid strategy.

A follow-up study from the Kaiser cohort evaluated the effectiveness of primary HPV testing every 3 years compared with primary Pap testing every 3 years or concurrent Pap and HPV testing (co-testing) every 5 years. This study included data from 1,037,021 women age 30 to 64 who underwent screening at approximately 3-year intervals using co-testing with Pap and high risk HPV testing. Estimation of 3-year risks of cancer and CIN3+ or worse following a negative HPV result were lower than 3-year risks following a negative Pap result (CIN3+=0.069% vs 0.19%, P<0.0001; cancer=0.011% vs 0.020%, P<0.0001) and 5-year risks following an HPV negative/Pap negative co-test (CIN3+=0.069% vs 0.11%, P<0.0001; cancer=0.011% vs 0.014%, P=0.21).

**Conclusions**

Pap tests are effective in identifying abnormal cervical cytology for women age 21 to 29 years, and co-testing with HPV DNA tests in conjunction with cervical cytology are effective for women age 30 to 65. Research supports preferred screening intervals of 3 years for women age 21 to 65 years using cytology alone (Pap test); and every 5 years for women age 30 to 65 years using cytology and HPV DNA testing (co-testing). Data are lacking on the effectiveness of primary HPV testing. Further research is needed to clearly define the optimal screening interval and most effective combination of tests for screening for cervical cancer, as well as the effectiveness of screening using high risk HPV testing alone.
REFERENCES


22. Sawaya G, Kerlikowske K, lee NC. When can cervical cancer screening intervals be lengthened? Outcomes following 1, 2, and 3 or more normal cervical smears. (unpublished data).


41. American Cancer Society. Cancer facts & figures 2016 American Cancer Society. Atlanta:


CONTRACEPTION

RECOMMENDATIONS

Clinical Recommendations

The Women’s Preventive Services Initiative recommends that adolescent and adult women have access to the full range of female-controlled contraceptives to prevent unintended pregnancy and improve birth outcomes. Contraceptive care should include contraceptive counseling, initiation of contraceptive use, and follow-up care (e.g., management, and evaluation as well as changes to and removal or discontinuation of the contraceptive method). The Women’s Preventive Services Initiative recommends that the full range of female-controlled U.S. Food and Drug Administration-approved contraceptive methods, effective family planning practices, and sterilization procedures be available as part of contraceptive care.

The full range of contraceptive methods for women currently identified by the U.S. Food and Drug Administration include: (1) sterilization surgery for women, (2) surgical sterilization via implant for women, (3) implantable rods, (4) copper intrauterine devices, (5) intrauterine devices with progestin (all durations and doses), (6) the shot or injection, (7) oral contraceptives (combined pill), 8) oral contraceptives (progestin only, and), (9) oral contraceptives (extended or continuous use), (10) the contraceptive patch, (11) vaginal contraceptive rings, (12) diaphragms, (13) contraceptive sponges, (14) cervical caps, (15) female condoms, (16) spermicides, and (17) emergency contraception (levonorgestrel); and (18) emergency contraception (ulipristal acetate); and additional methods as identified by the FDA. Additionally, instruction in fertility awareness-based methods, including the lactation amenorrhea method, although less effective, should be provided for women desiring an alternative method.

Implementation Considerations

The Women’s Preventive Services Initiative recommends as a preventive service, access to and provision of the full range of female-controlled U.S. Food and Drug Administration-identified contraceptive methods. This includes access to contraceptive counseling, initiation of contraceptive use, and follow-up care (e.g., management, evaluation, as well as changes to and removal or discontinuation of the contraceptive method) by a health care provider or appropriately trained individual. Additionally, effective family planning practices, and patient-specific services or U.S. Food and Drug Administration-approved methods that may be required based on individual women’s needs are recommended as part of contraceptive preventive services.

The Women’s Preventive Services Initiative recommends accommodation of an alternative form of contraception when a particular drug or device (generic or brand name) is medically inappropriate for a patient as determined by the individual's health care provider. Research indicates that delayed initiation or disruption of contraceptive use increases the risk of
unintended pregnancy; therefore, the Women’s Preventive Services Initiative recommends timely authorization of contraceptives.

The Women’s Preventive Services Initiative also recommends as a preventive service counseling that emphasizes patient-centered decision-making and allows for discussion of the full range of contraceptive options.

For some women, more than one visit may be needed to achieve effective contraception. More than one visit may also be necessary to identify the appropriate contraceptive methods to optimize compliance and effectiveness as determined by a woman and her health care provider, based on shared decision making.
**EVIDENCE MAP**

- Adolescent and adult women should have access to the full range of female-controlled contraceptives to prevent unintended pregnancy and improve birth outcomes.
- The full range of female-controlled U.S. Food and Drug Administration-approved contraceptive methods, effective family planning practices, and sterilization procedures should be available as part of contraceptive care.

<table>
<thead>
<tr>
<th>Systematic Reviews</th>
<th>Additional Studies</th>
<th>USPSTF; Bright Futures</th>
</tr>
</thead>
</table>
| None               | • Contraceptive efficacy is well established and supported in an observational study and review of population data.¹  
• LARC uptake is associated with lower rates of abortion, repeat abortion, and teenage births compared to regional and national rates (p<0.001).²  
• Counseling about and access to the full range of contraceptive methods is associated with increased contraceptive use and decreased unintended pregnancy rates.²,³ | • USPSTF: No recommendation  
• Bright Futures⁴: Recommends a developmentally targeted sexual history, assessment of STI and pregnancy risk, and provision of appropriate screening, counseling, and, if needed, contraceptives. |

Contraceptive care should include contraceptive counseling, initiation of contraceptive use, and follow-up care (e.g., management, and evaluation as well as changes to and removal or discontinuation of the contraceptive method).

<table>
<thead>
<tr>
<th>Systematic Reviews</th>
<th>Additional Studies</th>
<th>USPSTF; Bright Futures</th>
</tr>
</thead>
</table>
| 2013 Cochrane review supports the effectiveness of counseling on contraceptive adherence and continuation for oral contraceptives and injectables.⁵ | • Counseling about and access to the full range of contraceptive methods is associated with increased contraceptive use and decreased unintended pregnancy rates.²,³  
• Higher continuation rates are associated with increased supply of oral contraceptives at initiation (1 RCT)⁶,⁷  
• Providing an increased supply of contraceptive pill packages is associated with decreased unintended pregnancies.⁷,⁸ | • USPSTF: No recommendation  
• Bright Futures: see above. |

Abbreviations: ACA=Affordable Care Act, LARC=long acting reversible contraceptive, USPSTF=U.S. Preventive Services Task Force
SUMMARY OF EVIDENCE

Introduction

The goal of primary prevention of unintended pregnancy is to aid women in the achievement of their pregnancy intentions and to improve maternal, child, and family outcomes by increasing the likelihood that every pregnancy is one that is both desired and planned. Contraceptive methods enable women to actively prevent unintended pregnancy and control the timing of a desired pregnancy. When choosing a contraceptive method, women may consider efficacy, side effects, convenience, prevention of sexually transmitted infections, and non-contraceptive benefits. Most of these methods are female controlled and can be discussed in the context of routine clinical care or with specific counseling.

Contraceptive counseling offers an opportunity to discuss reproductive health goals, educate about the various methods, clarify or dispel myths or misinformation, and facilitate the provision of a method that will be successful for individual women. Comprehensive counseling may facilitate effective use and increase the provision of methods with the highest efficacy, especially in high risk populations, while taking into account the woman's preferences, her time frame for pregnancy, contraceptive efficacy, safety, and side effects.

Current Recommendations and Coverage of Services

The gap in services provided under the provisions of the Patient Protection and Affordable Health Care Act of 2010 (ACA) previously identified by the Institute of Medicine (IOM) Committee was the absence of coverage for contraception (Table 1).

Table 1. Summary of Recommendations Currently Covered by the Affordable Care Act

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td>IOM Committee</td>
<td>Includes the full range of Food and Drug Administration-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity to prevent unintended pregnancy and promote healthy birth spacing.</td>
</tr>
<tr>
<td>USPSTF</td>
<td>Not addressed</td>
</tr>
<tr>
<td>Bright Futures</td>
<td>Recommends a developmentally targeted sexual history, assessment of STI and pregnancy risk, and provide appropriate screening, counseling, and, if needed, contraceptives.</td>
</tr>
</tbody>
</table>

Abbreviations: IOM=Institute of Medicine; STI=sexually transmitted infection; USPSTF=U.S. Preventive Services Task Force

Contraceptive coverage under the ACA requires that all plans in the Health Insurance Marketplace cover contraceptive methods and counseling for all women, as prescribed by a health care provider without charging copayment or coinsurance when provided by an in-network provider regardless of whether the deductible has been met. Private companies are increasingly challenging the contraception provisions in the ACA, and employed women may have plans that are exempt from contraceptive coverage. Nonetheless, as a result of the ACA’s
contraceptive coverage requirement, more than 55 million women currently have access to birth control without copayments.15

Data from a 2016 study evaluating the impact of contraceptive coverage under the ACA demonstrated a 70% decrease in mean total out-of-pocket expenses for U.S. Food and Drug Administration (FDA) approved contraceptives for commercially insured women from 2011 to 2013.16 The study reviewed contraceptive claims for nearly 2.5 million women ages 15 to 44 years in a commercial claims database who were using contraceptives and compared out of pocket costs for pre-implementation versus post-implementation of the ACA contraceptive and family planning mandate.

Title X of the Public Health Service Act, a federal grant program established in 1970 and administered by the Department of Health and Human Services, provides reproductive healthcare and contraceptive services to low-income U.S. women and men.17 Title X serves approximately 1 million teens each year and provides family planning and related preventive health services for low-income persons.

Background

Family planning services are at the cornerstone of effective prevention in reproductive health and include contraception, patient education, and counseling. In the United States, nearly half of the pregnancies that occur annually are unintended.18,19 Unintended pregnancy is defined as a pregnancy that is either mistimed (27% of all pregnancies) or unwanted (18% of all pregnancies).19,20 Between 2008 and 2011, the overall unintended pregnancy rate in the United States decreased substantially among women ages 15 to 44 years from 54 per 1,000 to 45 in 2011, a decline of 18% and the lowest rate of unintended pregnancy in at least 30 years.19,20 Despite the availability of effective forms of contraception, disparities exist in contraceptive use and rates of unintended pregnancy.21 Unintended pregnancies disproportionately occur in women age 18 to 24 years, especially among those with low incomes or from racial/ethnic minorities.22

Long acting reversible contraception (LARC) has been recommended to effectively reduce unintended pregnancy,23 although these methods are less frequently used in the United States compared with other developed countries.24 Access to effective forms of contraception is an important step in preventing unintended pregnancies, but it is not enough to address disparities in unplanned pregnancy. A comprehensive approach includes access to preconception care, fertility planning, health care counseling, and reproductive health education and promotion.25

The Healthy People 202026 goals specify the importance of promoting healthy pregnancy outcomes by preventing unintended conception26,27 and recognize this as a challenge in the United States. These goals are further defined by increasing the proportion of intended pregnancies from 51% to 56%26 because births resulting from unintended or closely spaced pregnancies are associated with adverse maternal and child health outcomes. These include delayed prenatal care, premature birth, and negative physical and mental health effects for children.28-30

Other harms include increased risk of delaying prenatal care, maternal depression, or
experiencing physical violence during pregnancy, in addition to the impact on health behaviors such as breastfeeding and birth outcomes. Secondary benefits of access to contraception include promoting pregnancy spacing, or healthy pregnancy intervals, which is associated with reduction of repeated unintended pregnancy and improved health outcomes for both the mother and the infant. In spite of advances in contraceptive technology and its effectiveness, rates of unintended pregnancy in the United States remain high.

Primary prevention is aimed at preventing the onset of a specific condition. As recently as 2016, a committee assembled by the Centers for Disease Control and Prevention (CDC) released guidelines on health care system measures to advance preconception care and to consider this as a quality metric for prevention. Preconception interventions, such as an evaluation of every woman’s current pregnancy intentions, may be incorporated as an aspect of women’s primary care since data suggest that healthier pregnancies occur in women who are healthy prior to conception. A preconception visit can optimize the chances of a healthy pregnancy by screening for conditions that adversely affect pregnancy, reducing the use of teratogenic medications, and promoting the use of folic acid daily to prevent birth defects.

Contraception as primary prevention enables the routine screening of pregnancy intention. Primary prevention of unintended pregnancy also includes an evaluation of a patient’s satisfaction with her contraceptive method at subsequent visits to reduce discontinued or interrupted use. A recent study found that at subsequent visits after a birth control method was started, providers were less likely to discuss method satisfaction, consistent and correct use, or take a subsequent sexual history than at initial family planning visits. Over a 1-year period, as many as a one fourth of all women experience a gap in contraceptive use and approximately two out of five women may use their oral contraceptives inconsistently, contributing significantly to the risk for unintended pregnancy.

Contraceptive efficacy is well established (Table 2), non-contraceptive benefits of hormonal contraception are recognized, and risk factors for unintended pregnancy are known. Effectiveness is primarily related to contraceptive accessibility and access, especially amongst vulnerable or higher risk populations, including adolescents. Barriers to contraceptive access include policy provisions for privately insured women, immediate access to emergency contraception, and patient protections in the case of provider refusal, including pharmacists, all of which may vary by state.
Table 2. Contraceptive Effectiveness, Proportion Pregnant Over 1 Year of Use

<table>
<thead>
<tr>
<th>Contraceptive method</th>
<th>Perfect use (%)</th>
<th>Typical use (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implant</td>
<td>0.05</td>
<td>0.05</td>
</tr>
<tr>
<td>Vasectomy</td>
<td>0.10</td>
<td>0.15</td>
</tr>
<tr>
<td>IUD, levonorgesterol-releasing</td>
<td>0.2</td>
<td>0.2</td>
</tr>
<tr>
<td>IUD, Copper-T</td>
<td>0.6</td>
<td>0.8</td>
</tr>
<tr>
<td>Tubal sterilization</td>
<td>0.5</td>
<td>0.5</td>
</tr>
<tr>
<td>Injectable</td>
<td>0.2</td>
<td>6</td>
</tr>
<tr>
<td>Pill</td>
<td>0.3</td>
<td>9</td>
</tr>
<tr>
<td>Vaginal ring</td>
<td>0.3</td>
<td>9</td>
</tr>
<tr>
<td>Patch</td>
<td>0.3</td>
<td>9</td>
</tr>
<tr>
<td>Diaphragm</td>
<td>6</td>
<td>12</td>
</tr>
<tr>
<td>Sponge*</td>
<td>9/20</td>
<td>12/24</td>
</tr>
<tr>
<td>Male condom</td>
<td>2</td>
<td>18</td>
</tr>
<tr>
<td>Withdraw</td>
<td>4</td>
<td>22</td>
</tr>
<tr>
<td>Fertility awareness methods†</td>
<td>0.4-5</td>
<td>24</td>
</tr>
<tr>
<td>Spermicides</td>
<td>18</td>
<td>28</td>
</tr>
<tr>
<td>Emergency contraception‡</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>No method</td>
<td>85</td>
<td>85</td>
</tr>
</tbody>
</table>

*For sponge, first figure is for women who have not previously given birth and second is for women who have.
†Includes cervical mucus methods, body temperature methods, and periodic abstinence.
‡Effectiveness of emergency contraception is not measured on a 1-year basis like other methods; it is estimated to reduce the incidence of pregnancy by approximately 90% when used to prevent pregnancy after 1 instance of unprotected sex.
Abbreviations: IUD = intrauterine device

From 2006 to 2010, the National Survey of Family Growth reported that 78.6% of sexually experienced females ages 15 to 44 years received reproductive health services in the previous 12 months. The Healthy people 2020 target for this health indicator is 86.5%. In 2010, 11.5 million visits were made to primary care offices for family planning counseling or contraception. In the same year, 62% of reproductive aged women used contraception. The most frequently used methods of contraception in the United States continue to be oral contraceptives and sterilization (Table 3), despite an increase in the availability of more effective methods.

The use of LARC among women at risk for unintended pregnancy is increasing in the United States, but was only 8.5% in 2009, compared with much higher rates in other developed countries. National data show that, contrary to the evidence-based CDC recommendations on medical eligibility criteria for contraceptive use, only 38% of physicians providing contraception in the United States offer intrauterine devices (IUDs) to adolescents, 53% to nulliparous women, and 25% immediately after abortion. Women who do not use any form of contraception represent 10% of women at risk for unintended pregnancies, yet account for over half of the unintended pregnancies that occur annually. Notably, the annual risk of pregnancy associated with nonuse of contraception is 85%.
### Table 3. Contraceptive Method Choice, U.S. Women 2012*

<table>
<thead>
<tr>
<th>Method</th>
<th>Users, N</th>
<th>Women age 15-44 years (%)</th>
<th>Women at risk of unintended pregnancy (%)</th>
<th>Contraceptive users (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pill</td>
<td>9,720,000</td>
<td>16.0</td>
<td>23.3</td>
<td>25.9</td>
</tr>
<tr>
<td>Tubal (female) sterilization</td>
<td>9,443,000</td>
<td>15.5</td>
<td>22.6</td>
<td>25.1</td>
</tr>
<tr>
<td>Male condom</td>
<td>5,739,000</td>
<td>9.4</td>
<td>13.7</td>
<td>15.3</td>
</tr>
<tr>
<td>IUD</td>
<td>3,884,000</td>
<td>6.4</td>
<td>9.3</td>
<td>10.3</td>
</tr>
<tr>
<td>Vasectomy</td>
<td>3,084,000</td>
<td>5.1</td>
<td>7.4</td>
<td>8.2</td>
</tr>
<tr>
<td>Withdrawal</td>
<td>1,817,000</td>
<td>3.0</td>
<td>4.4</td>
<td>4.8</td>
</tr>
<tr>
<td>Injectable</td>
<td>1,697,000</td>
<td>2.8</td>
<td>4.1</td>
<td>4.5</td>
</tr>
<tr>
<td>Fertility awareness-based methods</td>
<td>509,000</td>
<td>0.8</td>
<td>1.2</td>
<td>1.4</td>
</tr>
<tr>
<td>Implant</td>
<td>492,000</td>
<td>0.8</td>
<td>1.2</td>
<td>1.3</td>
</tr>
<tr>
<td>Patch</td>
<td>217,000</td>
<td>0.4</td>
<td>0.5</td>
<td>0.6</td>
</tr>
<tr>
<td>Emergency contraception</td>
<td>91,000</td>
<td>0.2</td>
<td>0.2</td>
<td>0.2</td>
</tr>
<tr>
<td>Other methods†</td>
<td>133,000</td>
<td>0.2</td>
<td>0.3</td>
<td>0.4</td>
</tr>
<tr>
<td>No method, at risk of unintended‡ pregnancy</td>
<td>4,175,000</td>
<td>6.9</td>
<td>10.0</td>
<td>NA</td>
</tr>
<tr>
<td>No method, not at risk</td>
<td>19,126,000</td>
<td>31.4</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Total</td>
<td>60,887,000</td>
<td>100.0</td>
<td>100.0</td>
<td>100.0</td>
</tr>
</tbody>
</table>

*Most effective method used in the past month by U.S. women.
†Includes diaphragm, female condom, foam, cervical cap, sponge, suppository, jelly/cream, and other methods.
‡At risk refers to women who are sexually active; not pregnant, seeking to become pregnant, or postpartum; and not non-contraceptive sterile.

Abbreviations: IUD=intruterine device; N=sample size.

Several national and professional organizations have issued recommendations for contraception use (Table 4). The United States Medical Eligibility Criteria for Contraceptive Use, 2016 (US MEC),^49,52 is adapted from the World Health Organization (WHO) medical eligibility criteria (MEC) 5th edition^53 and provides recommendations for contraceptive method safety and efficacy based on updated scientific evidence for women with a wide range of medical conditions.^49 These provide clinicians with comprehensive safety and prescribing guidelines for patients with comorbidities and potential contraindications to particular contraceptive methods.

The U.S. Selected Practice Recommendations for Contraceptive Use 2016 (U.S. SPR),^52 comprises recommendations that address a select group of common, yet sometimes controversial or complex issues regarding initiation and use of specific contraceptive methods, serve as a supplement to the MEC, and are specific to U.S. family planning practices.^54 The document offers guidance related to the use of contraceptives, including initiation, choice of method,
follow-up criteria and testing prior to initiation of methods, with additional guidance on problems that may arise during use such as missed pills or unscheduled bleeding.54

The CDC recommendations for Providing Quality Family Planning Services (QFP) provide additional guidance on contraceptive counseling and provision for the full range of contraceptive methods,55 with specific guidance for offering comprehensive contraceptive services. Some organizations, including the CDC, now recommend increasing access to LARC to reduce unintended pregnancy because of its high level of effectiveness.23 The American Academy of Pediatrics (AAP) updated its policy statement in 2014 to emphasize that the first-line contraceptive choice for adolescents who choose not to be abstinent is a LARC method, specifically an intrauterine device or a subdermal implant.56 In 2015, the American College of Obstetricians and Gynecologists (ACOG) strengthened its LARC recommendations to underscore LARC as the most effective reversible contraceptive option for most women, including nulliparous women and adolescents who are sexually active.57

Table 4. Recommendations of Professional Organizations58

<table>
<thead>
<tr>
<th>Professional Organization</th>
<th>Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>American College of Obstetricians and Gynecologists (ACOG)59</td>
<td>Counseling on contraceptive options to prevent unwanted pregnancy, including emergency contraception, for women 13-39 years.</td>
</tr>
<tr>
<td>American Academy of Family Physicians (AAFP)60</td>
<td>Counseling for men and women to decrease the number of unwanted pregnancies, including abstinence information and prescriptions for routine contraception and emergency contraception.</td>
</tr>
<tr>
<td>American Academy of Pediatrics (AAP)61</td>
<td>Routine contraception and counseling for all adolescents regardless of sexual activity.</td>
</tr>
<tr>
<td>American Medical Association (AMA)62</td>
<td>Reducing unintended pregnancy through family planning and education, and discussing emergency contraception during routine contraceptive counseling.</td>
</tr>
<tr>
<td>Centers for Disease Control, U.S Office of Population affairs (CDC)55</td>
<td>Recommends contraceptive services to delay or prevent pregnancy. These include a full range of FDA-approved contraceptive methods, a brief assessment to identify the methods that are safe for the client, contraceptive counseling to help a client choose a method of contraception and use it correctly and consistently, and provision of one or more selected contraceptive method(s), preferably on site, but by referral if necessary. Education is an integral component of the contraceptive counseling process that helps clients to make informed decisions and obtain the information they need to use contraceptive methods correctly.</td>
</tr>
</tbody>
</table>

Update of Evidence

Contraception is effective in preventing unintended pregnancy1 and LARC methods have the highest efficacy in all patient populations. Data from California demonstrate a 47% reduction in
the rate of adolescent pregnancy between 1992 and 2005, crediting accurate sexual education and increased access to family planning. A statistical model estimating the number of women at risk for unintended pregnancy in Oregon if a similar approach to family planning were adopted determined that numbers would drop from >58,000 to <6,000.

Contraceptive counseling provides an effective opportunity to discuss contraceptive options and emphasize patient-centered decision making. A recent cluster randomized trial evaluating the effectiveness of a “contraceptive vital sign” in primary care demonstrated that primary care providers who routinely incorporated an evaluation of patients’ contraceptive use or pregnancy intentions improved prescribing practices and were more likely to document effective contraceptive use when prescribing potentially teratogenic medication. Contraceptive counseling in primary care may increase the uptake of hormonal methods and LARC, although data on structured counseling in specialized reproductive health settings demonstrated no such effect.

A randomized controlled trial conducted in California demonstrated higher continuation rates of oral contraceptives for patients who received a 7-month supply compared with a 3-month supply of oral pill packs (51% vs. 35%; OR 1.9, 95% CI 1.3 to 2.7). Continuation rates were also higher among participants receiving pill packs compared with those receiving a prescription (OR 1.5, 95% CI 1.1 to 2.4) regardless of age, education, parity, or insurance status. An observational study, also from California, of data from publicly funded reproductive health programs found an association between women receiving a 1-year supply of oral contraceptive pill packages and a decrease in both unintended pregnancies and abortions compared with women who received 3 or 1 cycle of pills. Improved continuation rates are also associated with use of LARC versus oral contraceptives due to ease of use and efficacy.

A 2013 Cochrane review of strategies to improve contraceptive adherence and acceptability identified three trials demonstrating effectiveness of contraceptive adherence and continuation, while six other trials did not. Two of three trials showing counseling effectiveness were conducted in the United States. Studies focused on oral contraceptives or injectables (DMPA), and, while hormonal contraceptives are the most popular forms of reversible contraception, patterns of typical use result in lower effectiveness compared to the high theoretical effectiveness of this method. Effective counseling methods to improve adherence were limited to the trials that combined intensive counseling and multiple contacts or reminders. Limitations of the review included variation in counseling strategies, small sample sizes, high loss to follow-up, and limited contraceptive types, as none examined counseling for users of the vaginal ring, implant, IUD, or levonorgestrel intrauterine system (LNG IUS).

The CHOICE project was a large scale U.S. study aimed at reducing unintended pregnancies by providing no-cost contraception and promoting the use of LARC methods. Notably there was no randomization or control group, but findings demonstrated a teenage birth rate of 6.3 per 1,000 among study participants compared with the national average of 34.3 per 1,000 over the same period. Among 9,256 adolescents and women ages 14 to 45 years at risk for unintended pregnancy who were offered no-cost contraception of any type, there was a significant reduction in the rate of abortion, repeat abortion, and teenage birth rates compared with regional and
national rates (p<0.001).\textsuperscript{2} Population based outcomes of teenage birth and repeat abortion were used as proxies for unintended pregnancies.

A cluster randomized trial across 40 clinics in the United States\textsuperscript{71} investigated whether a clinic-level intervention could improve access to LARCs and reduce pregnancy rates among women age 18 to 25. Results demonstrated a lower pregnancy rate in the family planning intervention group who received counselling on IUDs or implants (565 [71\%] of 797 vs 271 [39\%] of 693, odds ratio 3.8, 95\% CI 2.8 to 5.2) and more selecting LARC methods during the clinic visit (224 [28\%] vs 117 [17\%], 1.9, 1.3 to 2.8). There was a significant intervention effect on pregnancy rates in women attending family planning visits (hazard ratio 0.54, 95\% CI 0.34 to 0.85).

**Conclusions**

The effectiveness of the full range of FDA-approved contraceptive methods for preventing or delaying pregnancy is well established. Effective comprehensive contraceptive care includes counseling, initiation, and follow-up. Contraceptive counseling and access to contraceptive methods is associated with increased contraceptive use and decreased unintended pregnancy rates. Long acting reversible contraceptive (LARC) methods are the most effective reversible contraceptive option for most women, including nulliparous women and adolescents who are sexually active. Counseling on LARC methods is associated with lower pregnancy rates and lower rates of abortion and repeat abortion. Providing an increased supply of oral contraceptives at initiation is associated with higher continuation rates and lower unintended pregnancy rates. Further research is needed to evaluate counseling approaches that promote uptake of the most effective contraceptive methods, reducing costs for women seeking contraception, and reducing barriers to access, especially among those at highest risk for unintended pregnancy.
REFERENCES


SCREENING FOR GESTATIONAL DIABETES MELLITUS

RECOMMENDATIONS

Clinical Recommendations

The Women’s Preventive Services Initiative recommends screening pregnant women for gestational diabetes mellitus after 24 weeks of gestation (preferably between 24 and 28 weeks of gestation) in order to prevent adverse birth outcomes. Screening with a 50-g oral glucose challenge test (followed by a 3-hour 100-g oral glucose tolerance test if results on the initial oral glucose challenge test are abnormal) is preferred because of its high sensitivity and specificity.

The Women’s Preventive Services Initiative suggests that women with risk factors for diabetes mellitus be screened for preexisting diabetes before 24 weeks of gestation—ideally at the first prenatal visit, based on current clinical best practices.

Implementation Considerations

Women’s Preventive Services Initiative recommends screening pregnant women for gestational diabetes mellitus after 24 weeks of gestation to prevent adverse birth outcomes. Risk factors for diabetes mellitus that may help identify women for early screening include, but are not limited to, those identified by the Institutes of Medicine (now National Academy of Medicine). The optimal test for screening prior to 24 weeks of gestation is not known. However, acceptable modalities may include a 50-g oral glucose challenge test, a 2-hour 75-g oral glucose tolerance test, a hemoglobin A1c test, a random plasma glucose test, or a fasting plasma glucose test. If early screening is normal, screening with a 50-g oral glucose challenge test should be conducted at 24 to 28 weeks of gestation as described above.
Screen pregnant women for gestational diabetes mellitus (GDM) after 24 weeks of gestation, preferably between 24 and 28 weeks of gestation, in order to prevent adverse birth outcomes.

<table>
<thead>
<tr>
<th>Systematic Reviews</th>
<th>Additional Studies</th>
<th>USPSTF</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013 USPSTF review of 5 RCTs and 6 cohort studies compared diet modification, glucose monitoring, and insulin as needed with no treatment. Treatment of GDM reduced shoulder dystocia, macrosomia, and preeclampsia.</td>
<td>None</td>
<td>USPSTF: screening for gestational diabetes mellitus (GDM) in asymptomatic pregnant women after 24 weeks of gestation. (Level B; 2014)</td>
</tr>
</tbody>
</table>

Screening with the 50-g oral glucose challenge test (OCT), followed by the 3-hour 100-g oral glucose tolerance test (OGTT) for women with abnormal results on the initial OCT, is preferred because of its high sensitivity and specificity.

<table>
<thead>
<tr>
<th>Systematic Reviews</th>
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<th>USPSTF</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013 USPSTF review of 51 cohort studies of screening tests for GDM (50 g OGCT, fasting glucose, HbA1c) indicated highest sensitivity and specificity for the 50 g OGCT at either the 130 mg/dL or 140 mg/dL threshold.</td>
<td>None</td>
<td>USPSTF: not specifically addressed in recommendation.</td>
</tr>
</tbody>
</table>

Women with risk factors for diabetes mellitus should be screened for preexisting diabetes before 24 weeks of gestation—ideally at the first prenatal visit.

<table>
<thead>
<tr>
<th>Systematic Reviews</th>
<th>Additional Studies</th>
<th>USPSTF</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>None; studies are ongoing.</td>
<td>USPSTF: Current evidence is insufficient to assess the balance of benefits and harms of screening for GDM in asymptomatic pregnant women before 24 weeks of gestation. (Level I; 2014)</td>
</tr>
</tbody>
</table>

The optimal test for screening prior to 24 weeks of gestation is not known; acceptable modalities may include a 50-g oral glucose challenge test, a 2-hour 75-g oral glucose tolerance test, a hemoglobin A1c test, a random plasma glucose test, or a fasting plasma glucose test.

<table>
<thead>
<tr>
<th>Systematic Reviews</th>
<th>Additional Studies</th>
<th>USPSTF</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>None</td>
<td>Not addressed</td>
</tr>
</tbody>
</table>
Appropriate diabetes care (e.g., diet modification, glucose monitoring, counseling, education, and medication) for women diagnosed with diabetes mellitus or gestational diabetes mellitus are necessary to achieve optimal outcomes for both the mother and infant.

<table>
<thead>
<tr>
<th>Systematic Reviews</th>
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<th>USPSTF</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013 USPSTF review of 5 RCTs and 6 cohort studies compared diet modification, glucose monitoring, and insulin as needed with no treatment.¹ Treatment of GDM reduced shoulder dystocia, macrosomia, and preeclampsia.</td>
<td>Postprandial glucose levels are predictive for adverse fetal outcomes.⁴ Adherence with insulin therapy is higher for patients enrolled in insurance plans with reduced or no co-payments for insulin.⁵,⁶</td>
<td>USPSTF: not specifically addressed in recommendation.</td>
</tr>
</tbody>
</table>

Abbreviations: ACA=Affordable Care Act, AAFP=American Academy of Family Physicians, AAP=American Academy of Pediatrics, ADA=American Diabetes Association, ACOG=American College of Obstetricians and Gynecologists, BMI=body mass index, GDM=gestational diabetes mellitus, HbA1c=hemoglobin A1c, IADPSG=International Association of the Diabetes and Pregnancy Study Groups, IOM=Institute of Medicine, OGCT=oral glucose challenge test, OGTT=oral glucose tolerance test, USPSTF=U.S. Preventive Services Task Force.
SUMMARY OF EVIDENCE

Introduction

Gestational diabetes mellitus (GDM) is defined as glucose intolerance detected during pregnancy. GDM increases risk for maternal and fetal complications including preeclampsia,7 fetal macrosomia causing shoulder dystocia and birth injury, and neonatal hypoglycemia.8 Women diagnosed with GDM have increased risk for developing type 2 diabetes mellitus after pregnancy.9 Screening for GDM is a long-established part of prenatal care that typically involves an oral glucose test administered after 24 weeks gestation.10

Current Recommendations and Coverage of Services

The gap in services provided under the provisions of the Patient Protection and Affordable Health Care Act of 2010 previously identified by the Institute of Medicine (IOM) Committee was that screening for GDM was not included.11 In 2014, the U.S. Preventive Services Task Force (USPSTF) issued recommendations for screening for GDM in asymptomatic women after 24 weeks of gestation, but determined that evidence was insufficient to support screening earlier in pregnancy (Table 1).2

Table 1. Summary of Recommendations Currently Covered by the Affordable Care Act

<table>
<thead>
<tr>
<th>IOM Committee11</th>
<th>Screening for gestational diabetes in pregnant women between 24 and 28 weeks of gestation and at the first prenatal visit for pregnant women identified to be at high risk for diabetes.*</th>
</tr>
</thead>
<tbody>
<tr>
<td>USPSTF2</td>
<td>Screening for gestational diabetes mellitus in asymptomatic pregnant women after 24 weeks of gestation (B recommendation; 2014).</td>
</tr>
</tbody>
</table>

*The IOM report described risk factors that have been associated with the development of GDM during pregnancy including history of GDM in a prior pregnancy, previous delivery of a large for gestational age infant, obesity, strong immediate family history of type 2 diabetes or GDM, and a history of unexplained fetal death.11

Abbreviations: IOM=Institute of Medicine; USPSTF=U.S. Preventive Services Task Force

Background

In 2010, the prevalence of GDM in the United States was reported as 4.6% on birth certificates, 8.7% on the Pregnancy Risk Assessment Monitoring System (PRAMS) questionnaire, and 9.2% by either source.12 Prevalence is higher among certain racial/ethnic groups including black, Asian, Hispanic, and Native American women compared with white women. Risk factors for GDM include older maternal age, history of GDM in a prior pregnancy, previous delivery of a large for gestational age infant, obesity, strong immediate family history of type 2 diabetes or GDM, and a history of unexplained fetal death.11

GDM is associated with adverse health effects for pregnant women as well as their infants. GDM increases risk for gestational hypertension, preeclampsia, and cesarean delivery;7 and for
developing diabetes later in life.\textsuperscript{9} Approximately 15\% to 60\% of women with GDM develop type 2 diabetes within 5 to 15 years of delivery.\textsuperscript{13} Effects of GDM on infants include macrosomia causing shoulder dystocia and birth trauma, and neonatal hypoglycemia.\textsuperscript{8}

Screening for GDM has been an established part of prenatal care in the United States since the 1970s and is commonly performed at 24 to 28 weeks gestation. Several professional organizations have issued screening recommendations (Table 2).

\begin{table}[h]
\centering
\begin{tabular}{|l|l|}
\hline
\textbf{Organization} & \textbf{Recommendation} \\
\hline
American College of Obstetricians and Gynecologists (ACOG)\textsuperscript{10} & All pregnant patients should be screened for GDM, whether by the patient's medical history, clinical risk factors, or laboratory screening test results to determine blood glucose levels. Screening is generally performed at 24-28 weeks of gestation. Early pregnancy screening is also suggested in women with risk factors (previous GDM, known impaired glucose metabolism, BMI ≥30); if GDM is not diagnosed, testing should be repeated at 24-28 weeks of gestation. \\
\hline
American Academy of Family Physicians (AAFP)\textsuperscript{14} & Pregnant women without known diabetes mellitus should be screened for GDM after 24 weeks of gestation. \\
\hline
American Diabetes Association (ADA)\textsuperscript{15} & Screening is recommended at 24-28 weeks in women who were not previously diagnosed with overt diabetes. \\
\hline
Endocrine Society\textsuperscript{16} & Recommends universal testing for diabetes with a fasting plasma glucose, HbA1c, or an untimed random plasma glucose at the first prenatal visit (before 13 weeks gestation or as soon as possible thereafter) for women not known to already have diabetes. \\
\hline
\end{tabular}
\caption{Recommendations of Professional Organizations}
\end{table}

Abbreviations: BMI=body mass index; GDM=gestational diabetes mellitus; HbA1c=hemoglobin A1c; USPSTF=U.S. Preventive Services Task Force

The two-step approach to testing is most commonly used and is endorsed by the American College of Obstetricians and Gynecologists (ACOG).\textsuperscript{10} This involves the administration of 50 g of an oral glucose solution followed by a 1-hour venous glucose test. Women meeting or exceeding the screening threshold (130-140 mg/dL) then undergo a 100 g 3-hour diagnostic oral glucose tolerance test. Although the two-step method uses a standard protocol, results are variable because diagnostic thresholds differ. The one-step method proposed by the International Association of the Diabetes and Pregnancy Study Groups (IADPSG) uses a 75 g 2-hour oral glucose tolerance test. The diagnosis of GDM is determined when various threshold values are met.\textsuperscript{17} While this method has been endorsed by the American Diabetes Association, a higher proportion of women are diagnosed with GDM using the one-step compared with the two-step method, and the effectiveness of treatment based on one-step diagnostic criteria is not known.
Treatment for GDM includes nutrition therapy, exercise, and glucose monitoring supplemented by pharmacologic therapy when glucose levels exceed targets. While preprandial glucose levels are monitored in nonpregnant adults with diabetes, postprandial levels are obtained in pregnant women with GDM because they are more predictive for adverse fetal outcomes. Threshold levels of 140 mg/dL at 1 hour postprandial or 120 mg/dL at 2 hours postprandial are recommended. Insulin, which does not cross the placenta, is the standard pharmacologic treatment for GDM. Although oral hypoglycemic medications have demonstrated effective glycemic control in women with GDM, they are not approved by the U.S. Food and Drug Administration (FDA) for this purpose.

Update of Evidence

A systematic review of screening and treatment for GDM was conducted for a National Institutes of Health Consensus Development Conference on Diagnosis of Gestational Diabetes Mellitus in 2013 and was used to update the USPSTF’s clinical recommendations in 2014.

Performance of Screening Tests

Data from 51 cohort studies were used to calculate the performance characteristics of screening tests administered after 24 weeks gestation including the 50 g oral glucose challenge test (OGCT), fasting plasma glucose levels, and hemoglobin A1c (HbA1c). Studies used various screening thresholds for the initial test and various criteria for the diagnostic oral glucose tolerance test. Diagnostic criteria included the American Diabetes Association (ADA), Carpenter-Coustan (CC), Canadian Diabetes Association (CDA), IADPSG, National Diabetes Data Group (NDDG), and World Health Organization (WHO). Results indicated the highest sensitivity and specificity values for the 50 g OGCT at either the 130 mg/dL or 140 mg/dL threshold, which is the current standard of care in the United States (Table 3). Sensitivity and specificity values varied across diagnostic criteria, although the numbers of studies for each set of criteria also varied. Results for the fasting plasma glucose test indicated more variability in sensitivity and specificity than the OGCT, while HbA1c levels had poorer test characteristics than either OGCT or fasting plasma glucose.

Table 3. Summary of Studies of Test Characteristics of Screening Tests for GDM

<table>
<thead>
<tr>
<th>Screening test</th>
<th>Threshold</th>
<th>Diagnostic criteria</th>
<th>Studies, N</th>
<th>Sensitivity; specificity (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>50 g OGCT</td>
<td>130 mg/dL</td>
<td>CC</td>
<td>6</td>
<td>99; 77</td>
</tr>
<tr>
<td></td>
<td></td>
<td>NDDG</td>
<td>3</td>
<td>88; 66</td>
</tr>
<tr>
<td></td>
<td>140 mg/dL</td>
<td>CC</td>
<td>9</td>
<td>85; 86</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ADA</td>
<td>3</td>
<td>88; 84</td>
</tr>
<tr>
<td></td>
<td></td>
<td>NDDG</td>
<td>7</td>
<td>85; 83</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CDA</td>
<td>1</td>
<td>81; 69</td>
</tr>
<tr>
<td></td>
<td></td>
<td>WHO</td>
<td>3</td>
<td>70; 89</td>
</tr>
<tr>
<td>Fasting glucose</td>
<td>85 mg/dL</td>
<td>CC</td>
<td>4</td>
<td>87; 52</td>
</tr>
<tr>
<td></td>
<td>90 mg/dL</td>
<td>CC</td>
<td>4</td>
<td>77; 76</td>
</tr>
<tr>
<td></td>
<td>92 mg/dL</td>
<td>CC</td>
<td>3</td>
<td>76; 92</td>
</tr>
<tr>
<td></td>
<td>95 mg/dL</td>
<td>CC</td>
<td>5</td>
<td>54; 93</td>
</tr>
<tr>
<td>HbA1c</td>
<td>5.0%</td>
<td>CC</td>
<td>1</td>
<td>92; 28</td>
</tr>
<tr>
<td>Screening test</td>
<td>Threshold</td>
<td>Diagnostic criteria</td>
<td>Studies, N</td>
<td>Sensitivity; specificity (%)</td>
</tr>
<tr>
<td>---------------</td>
<td>-----------</td>
<td>---------------------</td>
<td>------------</td>
<td>-----------------------------</td>
</tr>
<tr>
<td></td>
<td>5.3%</td>
<td>IADPSG</td>
<td>1</td>
<td>12; 97</td>
</tr>
<tr>
<td></td>
<td>5.5%</td>
<td>ADA</td>
<td>1</td>
<td>86; 61</td>
</tr>
<tr>
<td></td>
<td>7.5%</td>
<td>ADA</td>
<td>1</td>
<td>82; 21</td>
</tr>
</tbody>
</table>

Abbreviations: ADA=American Diabetes Association; CC=Carpenter-Coustan; CDA=Canadian Diabetes Association; IADPSG=International Association of the Diabetes and Pregnancy Study Groups; HbA1c=hemoglobin A1c; n=sample size; NDDG=National Diabetes Data Group; OGCT=oral glucose challenge test; WHO=World Health Organization

Benefits and Harms of Treating GDM
Five randomized trials and six cohort studies compared diet modification, glucose monitoring, and insulin as needed with no treatment. Only three outcomes associated with GDM were reduced with treatment. These included shoulder dystocia (risk ratio [RR] 0.42, 95% confidence interval [CI] 0.23 to 0.77, 3 trials); macrosomia (birthweight >4000 g) (RR 0.50, 95% CI 0.35 to 0.71, 5 trials); and preeclampsia (RR 0.62, 95% CI 0.43 to 0.89, 3 trials). No differences were found for neonatal hypoglycemia, cesarean delivery, small-for-gestational-age neonates, induction of labor, or admission to a neonatal intensive care unit, although studies were limited for most outcomes. Evidence was insufficient for maternal weight gain, birth injury, and long-term metabolic outcomes among offspring.

Screening in Early Pregnancy
No studies evaluated screening earlier than 24 weeks gestation or among high-risk women specifically. Screening earlier in pregnancy, particularly for women at high risk for diabetes, is based on indirect evidence indicating that diabetes prevalence rates have had the highest increase among reproductive-age women, and the highest perinatal mortality rates of all forms of maternal diabetes have occurred in women with diabetes diagnosed during pregnancy.

Adherence to Treatment
A systematic review of factors affecting adherence to insulin therapy included 17 studies of patients with diabetes mellitus. None of the studies specifically enrolled women with GDM, although treatment is similar regardless of pregnancy status. Results indicated that adherence to insulin therapy is generally poor, especially for women. Adherence was higher for patients using a pen devise rather than vial/syringe method of insulin administration. In two studies conducted in the U.S., adherence improved when patients were enrolled in insurance plans with reduced or no co-payments for insulin. These findings are consistent with results from another review of 66 studies from Canada and the U.S. indicating that increasing the patient share of medication costs for a number of medical conditions was associated with lower adherence.

Conclusions
Gestational diabetes mellitus increases risk for maternal and fetal complications including preeclampsia, fetal macrosomia causing shoulder dystocia and birth injury, and neonatal hypoglycemia. Women with GDM can be identified through screening. A comprehensive review of screening tests for GDM (50 g OGCT, fasting glucose, HbA1c) indicates highest sensitivity and specificity for the 50 g OGCT at either the 130 mg/dL or 140 mg/dL threshold.
Treatment of GDM with diet modification, glucose monitoring, and insulin reduces shoulder dystocia, macrosomia, and preeclampsia compared to no treatment in RCTs and cohort studies. Available studies focus exclusively on screening and treatment for GCM after 24 weeks gestation and the effectiveness of screening earlier in pregnancy is not clear.
REFERENCES


SCREENING FOR HUMAN IMMUNODEFICIENCY VIRUS INFECTION

RECOMMENDATIONS

Clinical Recommendations

The Women’s Preventive Services Initiative recommends prevention education and risk assessment for human immunodeficiency virus (HIV) infection in adolescents and women at least annually throughout the lifespan. All women should be tested for HIV at least once during their lifetime. Additional screening should be based on risk, and screening annually or more often may be appropriate for adolescents and women with an increased risk of HIV infection.

Screening for HIV is recommended for all pregnant women upon initiation of prenatal care with retesting during pregnancy based on risk factors. Rapid HIV testing is recommended for pregnant women who present in active labor with an undocumented HIV status. Screening during pregnancy enables prevention of vertical transmission.

Implementation Considerations

The Women’s Preventive Services Initiative recommends as a preventive service for women, prevention education and risk assessment for HIV infection in adolescents and women at least annually throughout the lifespan. More frequent screening for high-risk women, as determined by clinical judgment, is also recommended as a preventive service. Annual or more frequent HIV testing may be needed and is recommended as a preventive service for women who are identified or self-identify as high risk.

This recommendation refers to routine HIV screening, which is different from incident-based or exposure-based HIV testing. Risk factors for HIV infection in women include, but are not limited to, being an active injection drug user; having unprotected vaginal or anal intercourse; having multiple sexual partners; initiating a new sexual relationship; having sexual partners who are HIV-infected, bisexual, or injection drug users; exchanging sex for drugs or money; being a victim of sex trafficking; being incarcerated (currently or previously); and having other sexually transmitted infections.

Approximately 20–26% of infected patients are not identified by risk-based screening. Early detection and treatment improves outcomes for patients and reduces transmission; therefore, based on clinical best practice, screening annually or more frequently may be reasonable.
**EVIDENCE MAP**

Prevention education and risk assessment for human immunodeficiency virus (HIV) infection in adolescents and women at least annually throughout the lifespan.

<table>
<thead>
<tr>
<th>Systematic Reviews</th>
<th>Additional Studies</th>
<th>USPSTF; Bright Futures</th>
</tr>
</thead>
<tbody>
<tr>
<td>• 2013 USPSTF review on HIV(^1): no studies evaluated the effect of counseling interventions on transmission risk for HIV.</td>
<td>No studies specific to HIV:</td>
<td>• USPSTF(^9): The USPSTF recommends high-intensity behavioral counseling to prevent STIs for all sexually active adolescents and for adults at increased risk for infection. HIV counseling is included in this general recommendation. (Level B; 2013)</td>
</tr>
<tr>
<td>• 2014 USPSTF review of 31 trials(^2): counseling was effective for promoting safer sexual practices and reducing STIs in general.</td>
<td>• Reduced sexual risk taking behaviors after various behavioral interventions in adolescents was reported in 2 RCTs.(^5\text{-}^7)</td>
<td>• Bright Futures(^10): Risk reduction for STIs should be discussed in adolescent visits as part of routine health supervision. Anticipatory guidance should include discussions about sexuality and healthy sexual development and provide an opportunity for risk screening, health promotion, counseling, and sex education.</td>
</tr>
<tr>
<td>• Systematic review of 13 meta-analyses and systematic reviews(^3): behavioral counseling was effective for promoting safer sexual practices and reducing STIs in general.</td>
<td>• A brief sexuality intervention had no effect on safer sexual practices and reducing STIs versus a brief general health intervention in one RCT.(^8)</td>
<td></td>
</tr>
<tr>
<td>• Systematic review of 31 trials(^4): brief sexuality communication showed some effect for promoting safer sexual practices and reducing STIs in general.</td>
<td>No studies on optimal intervals for prevention education and risk assessment for HIV infection.</td>
<td></td>
</tr>
</tbody>
</table>

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\(^1\) USPSTF: The USPSTF recommends high-intensity behavioral counseling to prevent STIs for all sexually active adolescents and for adults at increased risk for infection. HIV counseling is included in this general recommendation. (Level B; 2013)  
\(^2\) Bright Futures: Risk reduction for STIs should be discussed in adolescent visits as part of routine health supervision. Anticipatory guidance should include discussions about sexuality and healthy sexual development and provide an opportunity for risk screening, health promotion, counseling, and sex education.
All women should be tested for HIV at least once during their lifetime.

<table>
<thead>
<tr>
<th><strong>Systematic Reviews</strong></th>
<th><strong>Additional Studies</strong></th>
<th><strong>USPSTF; Bright Futures</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>2013 USPSTF review(^1):</td>
<td>One RCT found initiation of treatment for HIV infection at CD4 counts of (&gt;0.500 \times 10^9) cells/L reduced risk of a composite endpoint that included death and serious AIDS-related and serious non-AIDS-related events (HR 0.43, 95% CI 0.30 to 0.62) compared with initiation of treatment at CD4 counts of (0.350 \times 10^9) cells/L.(^1^1)</td>
<td>• USPSTF(^9): Screen for HIV infection in adolescents and adults aged 15-65 years. Younger adolescents and older adults who are at increased risk should also be screened. (Level A; 2013) • Bright Futures(^1^0): Screen all sexually active high-risk teens for HIV at least once a year. High-risk teens include, but are not limited to, STI clinic patients, youth in detention centers, and injection drug users.</td>
</tr>
</tbody>
</table>

- No studies comparing screening versus no screening reported clinical outcomes.
- No studies compared different screening strategies (e.g. risk-based screening versus routine screening).
- 1 RCT and 6 observational studies found a significant reduction in risk of HIV transmission with early treatment compared with delayed treatment.
- 2 RCTs and 5 observational studies consistently found early treatment of HIV infection significantly reduced risk of death/AIDS-related morbidity compared with delayed treatment.
Additional screening should be based on risk, and screening annually or more often may be appropriate for adolescents and women with an increased risk of HIV infection.

<table>
<thead>
<tr>
<th>Systematic Reviews</th>
<th>Additional Studies</th>
<th>USPSTF; Bright Futures</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013 USPSTF review(^1): no studies compared the yield of repeated HIV screening with one-time screening.</td>
<td>None</td>
<td>USPSTF(^9): Evidence is insufficient to determine optimum time intervals for HIV screening. A reasonable approach may be to rescreen groups at very high risk (e.g., injection drug users) for new HIV infection at least annually and individuals at increased risk at somewhat longer intervals (for example, 3-5 years). Routine rescreening may not be necessary for individuals not at increased risk since they were found to be HIV-negative.</td>
</tr>
</tbody>
</table>

Risk factors for HIV infection in women include, but are not limited to, being an active injection drug user; having unprotected vaginal or anal intercourse; having multiple sexual partners; initiating a new sexual relationship; having sexual partners who are HIV-infected, bisexual, or injection drug users; exchanging sex for drugs or money; being a victim of sex trafficking; being incarcerated (currently or previously); and having other sexually transmitted infections.

<table>
<thead>
<tr>
<th>Systematic Reviews</th>
<th>Additional Studies</th>
<th>USPSTF; Bright Futures</th>
</tr>
</thead>
</table>
| None | Risk factors based on CDC surveillance reports.\(^12\) | • USPSTF\(^9\): High risk includes active injection drug use; having unprotected vaginal or anal intercourse; having sexual partners who are HIV-infected, bisexual, or injection drug users; exchanging sex for drugs or money; acquiring or requesting testing for other sexually transmitted infections (STIs).  
• Bright Futures\(^10\): High-risk teens include, but are not limited to, STI clinic patients, youth in detention centers, and injection drug users. |

Abbreviations: ACA=Affordable Care Act, AIDS=acquired immunodeficiency syndrome, CD4=cluster of differentiation 4 glycoprotein, CDC=Centers for Disease Control and Prevention, CI=confidence interval, HIV=human immunodeficiency virus, HR=hazard ratio, IOM=Institute of Medicine, L=liter, RCT=randomized controlled trial, STI=sexually transmitted infection, USPSTF=U.S. Preventive Services Task Force.
This summary of evidence does not include screening for pregnant women, which is covered under previous recommendations of the U.S. Preventive Services Task Force (USPSTF).

Introduction

Human immunodeficiency virus (HIV) causes infection leading to acquired immunodeficiency syndrome (AIDS) if untreated. AIDS is characterized by progressive failure of the immune system resulting in life-threatening infections and cancer. HIV cannot be cured, but can be controlled with antiretroviral therapy which can prolong life and reduce transmission to others, particularly when used during early stages of infection. Screening for HIV infection detects individuals who are unaware of their infection and would otherwise miss the opportunity to benefit from early therapy.

Current Recommendations and Coverage of Services

The gap in services provided under the provisions of the Patient Protection and Affordable Health Care Act of 2010 (ACA) previously identified by the Institute of Medicine (IOM) Committee was that screening was limited to pregnant women and high-risk adolescents and adults. The IOM Committee recommended expanding this scope to annual counseling and screening for HIV infection for all sexually active women (Table 1).

In 2013, the USPSTF updated its recommendation for HIV screening to include all adolescents and adults aged 15 to 65 years; and younger adolescents and older adults who are at increased risk. Individuals at increased risk include men who have sex with men; active injection drug users; those with sexually transmitted infections; having unprotected vaginal or anal intercourse; having sexual partners who are HIV-infected, bisexual, or injection drug users; and exchanging sex for drugs or money. Screening for pregnant women is also included under this USPSTF recommendation. An update began in late 2016.

Table 1. Summary of Recommendations Currently Covered by the Affordable Care Act

<table>
<thead>
<tr>
<th>Source</th>
<th>Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>IOM Committee</td>
<td>Annual counseling and screening for HIV infection for sexually active women. HIV counseling is also included under a separate recommendation for STI counseling.</td>
</tr>
</tbody>
</table>
| USPSTF                        | • HIV screening for adolescents and adults aged 15 to 65 years and younger adolescents and older adults who are at increased risk (Level A; 2013).  
|                               | • HIV screening for all pregnant women, including those who present in labor who are untested and whose HIV status is unknown (Level A; 2013). |
| Bright Futures                | Screening all sexually active high-risk teens for HIV at least once a year. High-risk teens include, but are not limited to, STI clinic patients, youth in detention centers, men who have sex with men, and injection drug users. |

Abbreviations: HIV=human immunodeficiency virus; IOM=Institute of Medicine; STI=sexually transmitted infection; USPSTF=U.S. Preventive Services Task Force
Background

An estimated 1.2 million individuals age 13 years and older were living with HIV infection in the United States in 2012, including 156,300 (12.8%) whose infections had not been diagnosed.\textsuperscript{14} In 2014, the estimated number of new HIV diagnoses in the United States was 44,073. These included an estimated 35,571 diagnoses among adult and adolescent males (13 years or older), 8,328 among adult and adolescent females, and 174 among children younger than 13 years.\textsuperscript{15} Among women with HIV infection, 74\% of infections are attributed to heterosexual contact and the reminder to injection drug use.\textsuperscript{9,16} Adults age 20 to 29 years accounted for the most new cases of infection (15,738) among different age groups. Blacks accounted for the most (44\%) new cases among racial/ethnic groups, with whites accounting for 27\% and Hispanics 23\%. HIV infection among men who have sex with men accounted for 63\% of new HIV diagnoses.\textsuperscript{12}

Risk factors for HIV infection in women include active injection drug use; unprotected vaginal or anal intercourse; sexual partners who are HIV-infected, bisexual, or injection drug users; exchanging sex for drugs or money; and having other sexually transmitted infections. However, women may not be aware of their sexual partner’s HIV risk. Primary prevention involves behavioral counseling to prevent STIs and condom use.

Several tests are approved for screening including the conventional serum test (reactive immunooassay followed by confirmatory Western blot or immunofluorescent assay); rapid HIV test using blood or oral fluid specimens; combination tests (p24 antigen and HIV antibodies); and qualitative HIV-1 RNA. Tests are highly sensitive and specific. Clinical progression and disease transmission can be reduced with effective combined antiretroviral therapy using three or more antiretroviral agents, immunizations, and prophylaxis for opportunistic infections.

Several professional organizations have issued recommendations for screening (Table 2).

Table 2. Recommendations of Professional Organizations

| American College of Obstetricians and Gynecologists (ACOG)\textsuperscript{17} | Females age 13 to 64 years be tested at least once in their lifetime and annually thereafter based on factors related to risk. Obstetrician–gynecologists should annually review patients’ risk factors for HIV and assess the need for retesting. Repeat HIV testing should be offered at least annually to women who are injection drug users or sex partners of injection-drug users; exchange sex for money or drugs; are sex partners of HIV-infected persons; have had sex with men who have sex with men since the most recent HIV test; have had more than one sex partner since their most recent HIV test. |
| American Academy of Family Physicians (AAFP)\textsuperscript{18} | Screen adolescents and adults ages 18 to 65 years for HIV infection. Younger adolescents and older adults who are at increased risk should also be screened. Screen all pregnant women for HIV, including those who present in labor whose HIV status is unknown. |
American College of Physicians (ACP)\textsuperscript{19}  
Clinicians adopt routine screening for HIV and encourage patients to be tested; clinicians determine the need for repeat screening on an individual basis.

Centers for Disease Control and Prevention (CDC)\textsuperscript{20}  
Diagnostic HIV testing and opt-out HIV screening as a part of routine clinical care in all health-care settings for women age 13 to 64 years, while also preserving the patient's option to decline HIV testing and ensuring a provider-patient relationship conducive to optimal clinical and preventive care. The guidelines address HIV testing in health-care settings only; they do not modify existing guidelines concerning HIV counseling, testing, and referral for persons at high risk for HIV who seek or receive HIV testing in nonclinical settings.

Abbreviations: HIV=human immunodeficiency virus

**Update of Evidence**

A systematic review of screening for HIV was used to update the USPSTF’s clinical recommendations in 2013.\textsuperscript{1,9} This review focused on the effectiveness universal versus targeted HIV screening; the yield of repeated versus one-time screening; the effectiveness of antiretroviral therapy (ART) on clinical outcomes for individuals with early infections and on sexual transmission of HIV; and harms of ART. Clinical outcomes of interest included HIV transmission, AIDS-related events, mortality; and risk of cardiovascular harms associated with long-term (≥2 years) ART use. The updated literature search for the WPSI identified one RCT published since the 2013 USPSTF review that is relevant to screening.\textsuperscript{11} Studies of behavioral counseling to prevent STIs in general (i.e., that are not specific to HIV) are described in the Counseling for Sexually Transmitted Infections Evidence Summary.

**Effectiveness of Screening**
The 2013 USPSTF review found no studies comparing clinical outcomes between adults and adolescents that were screened versus not screened for HIV infection or comparing the yield of repeated HIV screening with one-time screening.

**Effectiveness of Counseling on Transmission Risk**
The 2013 USPSTF review found no studies that evaluated the effects of counseling interventions on transmission risk.

**Effectiveness of ART in Reducing Sexual Transmission**
One RCT (n=1,763 primarily heterosexual, married couples) found that immediate ART in persons with a baseline CD4 count of 0.350 to 0.550 x 10\textsuperscript{9} cells/L was associated with substantially lower risk for HIV transmission than delaying therapy until CD4 count was less than 0.250 x 10\textsuperscript{9} cells/L (hazard ratio [HR] 0.04, 95% CI 0.01 to 0.27).\textsuperscript{21} Pooled results from six observational studies were consistent with the RCT (pooled HR 0.16, 95% CI 0.07 to 0.35.)
Effectiveness of ART in Early Infections

The 2013 USPSTF review included one randomized controlled trial (RCT) and a subgroup analysis from another RCT that found that initiating ART at CD4 counts less than 0.250 x 10^9 cells/L was associated with higher risk for death or AIDS events than initiation at CD4 counts greater than 0.350 x 10^9 cells/L (HR 1.7, 95% CI 1.1 to 2.5 and HR 5.3, 95% CI 1.3 to 9.6.)\(^\text{16}\) Four large observational studies also found that initiating ART at CD4 counts between 0.350 and 0.500 x 10^9 cells/L was associated with significantly lower risk for death than deferred or no ART, and a fifth observational study reported similar results, although the reduction in risk was not statistically significant. Four studies on initiation of ART at CD4 counts greater than 0.500 x 10^9 cells/L did not consistently demonstrate clinical benefits.

One RCT published since the 2013 USPSTF review (n=4,685) compared initiation of ART at CD4 counts greater than 0.500 x 10^9 cells/L with delayed initiation at CD4 counts of 0.350 x 10^9 cells/L.\(^\text{11}\) The study found early initiation with ART significantly reduced risk of serious AIDS-related events (HR 0.28, 95% CI 0.15 to 0.50) and risk of a composite endpoint that included death, serious AIDS-related and serious non-AIDS-related events (HR 0.43, 95% CI 0.30 to 0.62.) All-cause mortality was also reduced, although the number of deaths in both groups was small (0.5% versus 0.9%) and the risk estimate was not statistically significant (HR 0.58, 95% CI 0.28 to 1.17.)

Harms of ART

Additional follow-up from a large cohort study found that some protease inhibitors were associated with increased risk for myocardial infarction (RR 1.1 to 1.2 per year of exposure).\(^\text{22}\) No clear association was shown between other antiretrovirals and increased risk for cardiovascular events, and the newer antiretrovirals are believed to not be associated with the cardiometabolic effects of the older regimens.

Conclusions

Screening for HIV infection detects individuals who are unaware of their infection and would otherwise miss the opportunity to benefit from early therapy. New studies of antiretroviral therapy indicate significantly reduced risks of serious AIDS-related events and death, as well as disease transmission, when treatment is initiated early in the infection. In addition, there are fewer adverse effects with the newer antiretroviral medications. This research strengthens the rationale for population screening.
REFERENCES


SCREENING FOR INTERPERSONAL AND DOMESTIC VIOLENCE

RECOMMENDATIONS

Clinical Recommendations

The Women’s Preventive Services Initiative recommends screening adolescents and women for interpersonal and domestic violence, at least annually, and, when needed, providing or referring for initial intervention services. Interpersonal and domestic violence includes physical violence, sexual violence, stalking and psychological aggression (including coercion), reproductive coercion, neglect, and the threat of violence, abuse, or both. Intervention services include, but are not limited to, counseling, education, harm reduction strategies, and referral to appropriate supportive services.

Implementation Considerations

The Women’s Preventive Services Initiative recommends as a preventive service, screening adolescents and women for interpersonal and domestic violence. There are multiple screening tools that have shown adequate sensitivity and specificity for identifying intimate partner violence and domestic violence in specific populations of women. Minimum screening intervals are unknown; however, based on the prevalence of interpersonal and domestic violence as well as evidence demonstrating that many cases are not reported, it is reasonable to conduct screening at least annually although the frequency and intensity of screening may vary depending on a particular patient’s situation.
**EVIDENCE MAP**

Screen adolescents and women for interpersonal and domestic violence.

<table>
<thead>
<tr>
<th>Systematic Reviews</th>
<th>Additional Studies</th>
<th>USPSTF; Bright Futures (covered by ACA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screening effectiveness (health outcomes):</td>
<td>1 new study of 80 VA women reported accuracy of the HITS instrument(^{16}).</td>
<td>• USPSTF(^{17}): Women of childbearing age: Screen women of childbearing age for intimate partner violence (IPV). (Level B; 2013; update in progress) Elderly or vulnerable adults: Insufficient evidence to assess the balance of benefits and harms of screening all elderly or vulnerable adults (physically or mentally dysfunctional) for abuse and neglect.</td>
</tr>
<tr>
<td>• 2012 USPSTF review(^1): 1 cluster RCT indicated no differences between screened versus non screened women(^2).</td>
<td></td>
<td>• Bright Futures(^{18}): Discuss intimate partner violence at the prenatal, newborn, 1-month, 9-month, and 4-year visits and discuss interpersonal and dating violence at the middle and late adolescence health supervision visits. Consider screening mothers at child health supervision visits when signs or symptoms raise concerns, or if the mother has a new intimate partner. Consider screening adolescents if they have a new intimate partner, when signs or symptoms raise concerns, or during prenatal visits.</td>
</tr>
<tr>
<td>• Cochrane review(^3): included an additional RCT indicating no differences between screened versus non-screened women (^4).</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Screening harms:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• 2013 USPSTF review(^1): included 1 cluster RCT indicating no harms(^2).</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Accuracy of screening instruments:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• 2012 USPSTF review(^1): included 7 studies of 5 instruments(^5)-(^{11}) with fair to high diagnostic accuracy in detecting current or recent IPV; 1 study(^{12}) of the PVS accurately predicted future IPV; 1 study(^{13}) identified past childhood abuse; and 2 studies(^{14},^{15}) of mothers in pediatric settings reported low sensitivity/high specificity in predicting IPV.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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\(^1\) new study of 80 VA women reported accuracy of the HITS instrument\(^{16}\).
When needed, provide or refer for intervention services.

<table>
<thead>
<tr>
<th>Systematic Reviews</th>
<th>Additional Studies</th>
<th>USPSTF; Bright Futures (covered by ACA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Studies of interventions with IPV outcomes:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| • 2012 USPSTF review\(^1\): included 6 RCTs\(^{19-26}\) reporting IPV outcomes; 2 reported reduced recurrent IPV episodes during pregnancy and postpartum for the intervention groups (counseling and mentor support) versus usual care;\(^ {19,20,23,26}\) 1 study of home visitation\(^{21}\) reported lower rates of IPV; 1 study of counseling\(^{25}\) reported decreased pregnancy coercion; use of a wallet-size referral card in 1 study\(^{24}\) showed no differences. | • 1 review of advocacy interventions versus usual care (12 RCTs)\(^{41}\) reported decreased incidence of physical and psychological abuse.  
  • 1 review of counseling techniques (12 RCTs)\(^{41}\) reported mixed results.  
  • 1 review of home visitation versus usual care (6 studies)\(^{42}\) reported mixed results.  
  • 2 reviews of any intervention versus usual care: a review of studies of pregnant women (9 RCTs)\(^{43}\) reported decreased partner abuse; a review of women seen in multiple settings (17 studies)\(^{44}\) indicated that 13 out of 17 studies reported ≥1 benefit.  
  • 3 RCTs,\(^{45-47}\) 2 of motivational interviewing and 1 of case manager versus computer driven interventions, found no differences in outcomes. | • USPSTF\(^{17}\): Women of childbearing age, clinicians provide or refer women who screen positive to intervention services.  
  (Clinical Considerations provide more information on effective interventions.)  
  (Level B; 2013; update in progress)  
  • Bright Futures \(^{18}\): No recommendation regarding intervention services. |
| Cochrane review\(^{27}\) of education or skill-based interventions reported no differences. |                                                                                     |                                                                                                         |
| Cochrane review of advocacy versus usual care (10 RCTs)\(^{28}\) found no differences in incidence of abuse. |                                                                                     |                                                                                                         |
| Cochrane review of any intervention versus usual care in pregnant women (10 RCTs)\(^{29}\) reported decreased partner abuse. |                                                                                     |                                                                                                         |
| Harms:                                                                             |                                                                                     |                                                                                                         |
| • 2012 USPSTF review\(^1\): included 2 RCTs\(^{21,24}\) and 11 descriptive studies\(^{30-40}\) reporting harms; 1 trial reported no harms while another reported increased verbal victimization following home visitations; descriptive studies reported low rates of harms, but some women voiced concerns. |                                                                                     |                                                                                                         |

Abbreviations: ACA=Affordable Care Act, USPSTF=U.S. Preventive Services Task Force, VA=Veteran’s Administration
SUMMARY OF EVIDENCE

Introduction

Interpersonal violence includes domestic violence and, including intimate partner violence (IPV). IPV refers to physical, sexual, or psychological harm by a current or former partner or spouse. Women and adolescents of all ages experience intimate partner violence. It can occur among heterosexual and same-sex couples and does not require sexual intimacy. The Centers for Disease Control and Prevention (CDC) identifies four main types of IPV (Table 1).:

Table 1. Types of IPV

<table>
<thead>
<tr>
<th>IPV Type</th>
<th>CDC Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical violence</td>
<td>The intentional use of physical force with the potential for causing death, disability, injury, or harm. May include (but not limited to): scratching; pushing; shoving; throwing; grabbing; biting; choking; shaking; aggressive hair pulling; slapping; punching; hitting; burning; use of a weapon; and use of restraints or one's body, size, or strength against another person. Also includes coercing other people to commit any of the above acts.</td>
</tr>
<tr>
<td>Sexual violence</td>
<td>Attempted or completed:</td>
</tr>
<tr>
<td></td>
<td>• Rape or penetration of victim</td>
</tr>
<tr>
<td></td>
<td>• Victim was made to penetrate someone else</td>
</tr>
<tr>
<td></td>
<td>• Non-physically pressured unwanted penetration</td>
</tr>
<tr>
<td></td>
<td>• Unwanted sexual contact</td>
</tr>
<tr>
<td></td>
<td>• Non-contact unwanted sexual experiences (unwanted sexual events that are not of a physical nature that occur without the victim’s consent)</td>
</tr>
<tr>
<td></td>
<td>All of these acts occur without the victim’s consent, including cases in which the victim is unable to consent due to being too intoxicated (e.g., incapacitation, lack of consciousness, or lack of awareness) through their voluntary or involuntary use of alcohol or drugs.</td>
</tr>
<tr>
<td>Stalking</td>
<td>A pattern of repeated, unwanted, attention and contact that causes fear or concern for one’s own safety or the safety of someone else (e.g., family member or friend).</td>
</tr>
<tr>
<td>Psychological aggression</td>
<td>The use of verbal and non-verbal communication with the intent to harm another person mentally or emotionally, and/or to exert control over another person.</td>
</tr>
</tbody>
</table>

Current Recommendations and Coverage of Services

The gap in services provided under the provisions of the Patient Protection and Affordable Health Care Act of 2010 previously identified by the Institute of Medicine (IOM) Committee was that interpersonal and domestic violence screening and counseling were not included. In 2013, the U.S. Preventive Services Task Force (USPSTF) issued new recommendations for screening for intimate partner violence and providing or referring women who screen positive to
intervention services\(^\text{17}\) (Table 2). Recommendations regarding screening for violence apply to women and adolescents who do not have signs or symptoms of abuse, and generally involve clinicians asking a series of questions.

**Table 2. Summary of Recommendations Currently Covered under the Affordable Care Act**

<table>
<thead>
<tr>
<th>Source</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>IOM Committee(^{50})</td>
<td>Coverage for screening and counseling for interpersonal and domestic violence. This involves elicitation of information from women and adolescents about current and past violence and abuse in a culturally sensitive and supportive manner to address current health concerns about safety and other current or future health problems.</td>
</tr>
<tr>
<td>USPSTF(^{17})</td>
<td>Screen women of childbearing age for intimate partner violence, such as domestic violence, and provide or refer women who screen positive to intervention services (Level B 2013).</td>
</tr>
<tr>
<td>Bright Futures(^{18})</td>
<td>Discuss intimate partner violence at the prenatal, newborn, 1-month, 9-month, and 4-year visits and discuss interpersonal and dating violence at the middle and late adolescence health supervision visits. Consider screening mothers at child health supervision visits when signs or symptoms raise concerns, or if the mother has a new intimate partner. Consider screening adolescents if they have a new intimate partner, when signs or symptoms raise concerns, or during prenatal visits.</td>
</tr>
</tbody>
</table>

Abbreviations: IOM=Institute of Medicine; USPSTF=U.S. Preventive Services Task Force

**Background**

A survey by the CDC in 2011 indicated that 32% of women experienced physical violence in their lifetimes, and 22% reported severe physical violence by an intimate partner. In addition, 47% experienced psychological aggression, including expressive aggression (i.e., name calling, insults, and/or humiliation) and coercive control (i.e., behaviors intended to monitor, control, or threaten).\(^{51}\) Also, 19% of women experienced rape and 44% experienced sexual violence besides rape. Of those raped, 45% were raped by an intimate partner.

Health effects of intimate partner violence include death and nonfatal traumatic injuries including contusions, fractures, and traumatic brain injury that can result in chronic health conditions.\(^{52}\) Sexual violence may cause sexually transmitted infections, sexual dysfunction, unintended pregnancy, pregnancy complications including preterm delivery, delayed prenatal care, and pelvic inflammatory disease. Chronic health effects include exacerbation of asthma, urinary tract infections, cardiovascular disease, fibromyalgia, irritable bowel syndrome, and chronic pain syndromes including headaches.\(^{53}\)

Associated psychological conditions include anxiety, depression, posttraumatic stress disorder, antisocial behavior, suicidal ideation and behaviors, low self-esteem, fear of intimacy, emotional detachment, sleep disturbances, and inability to trust others.\(^{52,54-57}\) Social repercussions may include restricted access to services, strained relationships with health providers and employers, isolation from social networks, and homelessness.\(^{56-58}\)
Screening methods to identify women exposed to IPV have been developed for administration in a variety of healthcare settings (e.g., obstetrics visits, primary-care settings, emergency department) (Table 3). Some instruments demonstrated high sensitivity (>80%) in accurately detecting IPV in studies, however results differed across studies and populations.

Table 3. Clinical Screening Instruments for IPV Evaluated in Studies\(^1,59\)

<table>
<thead>
<tr>
<th>Measure</th>
<th>Components</th>
<th>Sensitivity; specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>HITS</td>
<td>4 item (hurt, insult, threaten, scream), 5-point Likert scale, self-report or clinician administered survey; score ranges from 4-20 points, ≥11 indicates abuse.</td>
<td>86%; 99%</td>
</tr>
<tr>
<td>PSQ</td>
<td>3 items (physically hurt or threatened, afraid, order for protection), dichotomous scale; score ranges from 0-3.</td>
<td>19%; 93%</td>
</tr>
<tr>
<td>OVAT</td>
<td>4 item (threaten, beaten, would like to kill you, no respect), dichotomous scale; score ranges from 0-4.</td>
<td>86-93%; 83-86%</td>
</tr>
<tr>
<td>SAFE-T</td>
<td>5 items (secure at home, accepted by partner, family likes partner, even disposition of partner, talks with partner to resolve differences), dichotomous scale; score ranges from 0-5.</td>
<td>54%; 81%</td>
</tr>
<tr>
<td>PVS</td>
<td>3 items (past physical violence, perceived personal safety), dichotomous scale, clinician administered; score ranges from 0-3, with ≥1 indicates IPV.</td>
<td>49%; 94%</td>
</tr>
<tr>
<td>WAST</td>
<td>8 item (physical, sexual, and emotional abuse), 3-point response (0=never, 1=sometimes, 2=often) scale; scores range from 0-16; ≥4 indicates exposure to IPV. Short form includes 2 questions about tension in the relationship and how arguments are resolved.</td>
<td>47-88%; 89-96%</td>
</tr>
<tr>
<td>STaT</td>
<td>3 item (pushed or slapped, threatened with violence, partner has thrown, broken, or punched things), dichotomous, self-report scale; score ranges from 0-3.</td>
<td>96%; 75%</td>
</tr>
<tr>
<td>AAS</td>
<td>5 item (sexual coercion, lifetime abuse, current abuse, abuse during pregnancy), dichotomous scale, clinician administered survey; scores range from 0-5, with any positive response considered a positive screen.</td>
<td>32-93%; 55-99%</td>
</tr>
<tr>
<td>HARK</td>
<td>4 item (humiliation, afraid, rape, kick), dichotomous scale, self-report survey, adapted from AAS; scoring ranges from 0-4.</td>
<td>81%; 95%</td>
</tr>
<tr>
<td>Modified CTQ-SF</td>
<td>28 item (abuse and neglect in childhood), 8-point Likert scale, self-report survey; positive response (anything other than never) indicates exposure to IPV.</td>
<td>85%; 88%</td>
</tr>
<tr>
<td>OAS</td>
<td>5 item (threaten, beaten, would like to kill you, no respect), dichotomous scale; scores range from 0-5.</td>
<td>60%; 90%</td>
</tr>
</tbody>
</table>

Abbreviations: AAS=Abuse Assessment Screen; CTQ-SF=Conflict Tactics Scale-Revised Short Form; E-HITS=Extended Hurt/Insult/Threaten/Scream tool; HARK=Humiliation, Afraid, Rape, Kick tool; HITS=Hurt/Insult/Threaten/Scream tool; OAS=Ongoing Abuse Screen; OVAT=Ongoing Violence Assessment Tool; PSQ=Parent Screening Questionnaire;
Women exposed to IPV may benefit from interventions aimed at reducing exposure to IPV and its negative health effects. Interventions generally include advocacy and safety planning, education, and counseling. Several professional organizations recommend screening for IPV (Table 4).

Table 4. Recommendations of Professional Organizations

<table>
<thead>
<tr>
<th>Organization</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>American College of Obstetricians and Gynecologists (ACOG)(^60)</td>
<td>Screen all women for intimate partner violence at periodic intervals, such as annual examinations and new patient visits. Screening during obstetric care should occur at the first prenatal visit, at least once per trimester, and at the postpartum checkup.</td>
</tr>
<tr>
<td>American Medical Association (AMA)(^61)</td>
<td>Questions to assess risk for family violence should be included within the context of taking a routine social history, past medical history, history of present illness, and review of systems as part of emergency, diagnostic, preventive, and chronic care management.</td>
</tr>
<tr>
<td>American Academy of Family Physicians (AAFP)(^62)</td>
<td>Screen women of childbearing age for intimate partner violence, such as domestic violence, and provide or refer women who screen positive to intervention services.</td>
</tr>
<tr>
<td>American College of Emergency Physicians (ACEP)(^63)</td>
<td>Assess patients for family violence in all its forms, including that directed toward children, elders, intimate partners, and other family members.</td>
</tr>
<tr>
<td>Emergency Nurses Association (ENA)(^64)</td>
<td>Routinely screen patients for intimate partner violence.</td>
</tr>
<tr>
<td>American Academy of Pediatricians (AAP)(^65)</td>
<td>Remain alert to the signs and symptoms of exposure to intimate partner violence in caregivers and children and consider attempts to identify evidence of intimate partner violence either by targeted screening of high-risk families or universal screening.</td>
</tr>
</tbody>
</table>

Update of Evidence

The 2013 USPSTF recommendation was based on a systematic review of evidence of effectiveness of IPV screening in reducing subsequent IPV and adverse health outcomes; diagnostic accuracy of screening instruments; and effectiveness of interventions to reduce IVP.\(^1\)

Effectiveness of Screening on Subsequent IPV and Health Outcomes

Trials were limited by heterogeneity, lack of true control groups, high loss to follow-up, self-reported measures, and lack of accepted reference standards.
**USPSTF systematic review**

A large (n=6,743) cluster randomized controlled trial (RCT) in Canada assessed outcomes of abuse and quality of life measures at 18 months for women randomized to either screening or non-screening groups.² Clinicians, at their discretion, discussed positive findings from the screening instrument (Woman Abuse Screening Tool) with patients, and provided them with referrals and/or treatment as they saw necessary. During follow-up, no statistically significant differences were found between screened and non-screened groups in the numbers of women accessing additional health care services; with reduced IPV recurrence, posttraumatic stress disorder symptoms, or alcohol problems; and on scores for quality of life, depression, or mental health.

This trial has several methodological limitations. Women with positive screenings were not offered a specific intervention, and few women who had positive screening results actually participated in discussions about IPV with their clinicians during their clinic visits. Women who were randomly assigned to the nonscreening group were provided with information cards of locally available resources for women with IPV, which constitutes an intervention in other studies. Women in the nonscreening group had extensive questioning about IPV over the 18 months of the trial which could increase their self-awareness of IPV, affect their utilization of services, and influence outcomes of the trial by creating a substantial Hawthorne effect (i.e., the phenomenon that study participants change their behavior as a result of being involved in the study).

**Relevant studies published since the USPSTF systematic review**

A Cochrane review³ identified two RCTs reporting outcomes of reduced IPV after screening including the Canadian trial² and a trial conducted in Japan that also found no statistically significant differences in IPV 3 months after screening.⁴

**Diagnostic Accuracy of Screening Instruments**

**USPSTF systematic review**

Seven studies of five screening instruments⁵-¹¹ demonstrated fair to high diagnostic accuracy in detecting current or recent IPV (summarized in Table 3 above). A study evaluating risk for future IPV reported that positive responses on the Partner Violence Screen predicted verbal aggression (risk ratio [RR] 7.3; 95% confidence interval [CI], 3.2 to 16.2) and violence (RR 11.3; 95% CI 4.8 to 26.3) during the 4 months after screening.¹² A study of the modified Childhood Trauma Questionnaire-Short Form to identify adult women who had past childhood physical or sexual abuse reported high diagnostic accuracy (sensitivity 85%; specificity 88%).¹³ Two studies evaluated mothers in pediatric settings screened with either the Parent Screening Questionnaire¹⁴ or five questions asked by clinicians.¹⁵ Both methods had low sensitivity, but high specificity in predicting IPV (sensitivity: 19% to 29% and 40%, respectively; specificity: 91% to 93% and 91%, respectively).

**Relevant studies published since the USPSTF systematic review**

A study of 80 women veterans compared the diagnostic accuracy of the 4-item Hurt/Insult/Threaten/Scream (HITS) instrument and an extended HITS (E-HITS) version that included a sexual IPV item with the Revised Conflict Tactics Scale (CTS-2), which was the
reference standard. Using a cutoff score of 6 on the HITS and 7 on the E-HITS resulted in the best balance of sensitivity (75% for both) and specificity (83% for HITS and 82% for E-HITS).

**Effectiveness of Interventions**

Studies of the effectiveness of interventions were generally limited by their heterogeneity, lack of true control groups, high loss to follow-up, use of self-reported measures, and lack of accepted reference standards. Results need to be interpreted with these limitations in mind.

**USPSTF systematic review**

Six RCTs reported outcomes after interventions to reduce IPV; three trials targeted pregnant and postpartum women and three trials included primary care patients. Two trials reported statistically significant differences between women receiving interventions (counseling, mentor support) versus usual care for the number of recurrent episodes of IPV during pregnancy and postpartum, birth outcomes (fewer very preterm infants, lower rates of very low birth weight infants, and increased mean gestational age), reduced abuse scores, and odds of experiencing violence at follow-up.

A trial of home visitations for women who recently gave birth to an infant at risk for maltreatment reported lower rates of IPV victimization and IPV perpetration, although results were of borderline statistical significance. A cluster RCT indicated that women receiving counseling who reported IPV at baseline had decreased pregnancy coercion at follow-up, and all women in the intervention group, regardless of recent IPV status, were more likely to discontinue unhealthy or unsafe relationships compared with women receiving usual care. A RCT of a wallet-size referral card compared with a nurse management protocol showed no differences at 2-year follow-up, although both groups had fewer threats of abuse, assaults, danger risks for homicide, and events of work harassment.

**Relevant studies published since the USPSTF systematic review**

Seven reviews of the effectiveness of interventions in reducing exposure to IPV included advocacy, cognitive behavioral therapy (CBT), home visiting, educational or skill-based interventions, or any type of intervention. Many studies included in these reviews did not meet inclusion criteria for the USPSTF review for various reasons including lack of comparison groups, no IPV or health outcomes, and low relevance to clinical settings.

The two reviews comparing the effectiveness of advocacy interventions with usual care included seven of the same trials. One review included ten RCTs in the analysis, but was unable to pool most of the studies due to clinical and methodological heterogeneity. The review found no significant differences between the intervention and usual care groups in the reduction of physical abuse (standard mean difference [SMD] 0.00; 95% CI -0.17 to 0.16; 3 trials) or sexual abuse (SMD -0.12; 95% CI -0.37 to 0.14; 2 trials). The review reported a significantly decreased risk of developing depression for those receiving a brief advocacy intervention compared with usual care (odds ratio [OR] 0.31; 95% CI 0.15 to 0.65; 2 trials). However, there were no differences in reduced depression at 12 months (mean difference -0.14; 95% CI -0.33 to 0.05; 3 trials) or 2 years (SMD -0.12; 95% CI -0.36 to 0.12; 1 trial) after an intensive advocacy intervention compared with usual care. The other review included six RCTs in the analysis and reported decreased incidence of physical abuse (SMD -0.13; 95% CI -0.25 to -0.00; 5 trials) and
psychological abuse (SMD -0.19; 95% CI -0.32 to -0.05; 4 trials) after an advocacy intervention compared with usual care.41 There were no differences in incidence of sexual abuse (SMD -0.20; 95% CI -0.43 to 0.02; 2 trials) or any IPV (SMD -0.32; 95% CI -0.69 to 0.04; 1 trial).

Trials comparing cognitive behavioral therapy with usual care indicated decreased incidence of physical abuse (SMD -0.79; 95% CI -1.26 to -0.33; 2 trials) and psychological abuse (SMD -0.80; 95% CI -1.25 to -0.36; 2 trials), but not sexual abuse (SMD -0.35; 95% CI -1.73 to 1.03; 1 trial) or any type of IPV (SMD 0.09; 95% CI -0.05 to 0.23; 1 trial).41

A review assessed home visitation interventions compared with usual care in six trials and reported mixed results.42 Three trials reported statistically significant reductions in IPV for mothers in the short-term, but the other three trials showed no benefit for the intervention group.

A Cochrane review assessed the effectiveness of education or skill-based interventions aimed at preventing dating or relationship violence in adolescents (12-18 years) or young adults (19-25 years) in any setting.27 The review found no differences between intervention and usual care groups in reducing episodes of relationship violence (RR 0.77; 95% CI 0.53 to 1.13; 8 trials).

Three reviews assessed the effectiveness of any intervention for preventing or reducing IPV; two exclusively in pregnant women29,43 and one in women seen in multiple settings.44 Both reviews of pregnant women included predominantly the same studies and found limited evidence for reduced IPV exposure. One of the reviews included five studies reporting statistically significant decreases in physical, sexual, and/or psychological partner violence (ORs from 0.47 to 0.92).43 The other review reported fewer episodes of partner violence during pregnancy in the intervention group in one trial (RR 0.62; 95% CI 0.43 to 0.88).29 The third review of any type of intervention included 17 trials.44 The review reported that 13 studies demonstrated more than one intervention-related benefit. Six of the 11 studies measuring IPV persistence found reductions in future violence; two of five studies measuring safety-promoting behaviors found increases; and six of ten studies measuring IPV/community resource referrals found enhanced use. Some studies also documented health improvements.

Three RCTs that were not included in the reviews reported effectiveness of interventions to reduce exposure to IPV; two involved motivational interviewing45,46 and one compared a case manager driven intervention with a computerized intervention.47 Neither study of motivational interviewing reported significant differences between groups at either 4 or 12 months follow-up in depressive symptoms, self-efficacy, abuse, or heavy drinking. The study comparing the case manager driven intervention with a computerized intervention also found no differences between groups from baseline to 3-month follow-up for identification of IPV or improvement in receipt of IPV services, social support, IPV self-efficacy, and abstinence from drug use.

**Harms of Screening or Interventions**

**USPSTF systematic review**

Three trials2,21,24 and 11 descriptive studies30-40 reported outcomes related to harms of IVP screening or interventions. Two trials found no harms,2,24 while another trial indicated increased verbal abuse victimization and perpetration over long-term follow-up among women assigned to home visitations because their infants were considered at risk for maltreatment.21 The descriptive
studies generally reported low levels of harms that included discomfort with screening, particularly among those with prior IPV; infringement of privacy; worries about increasing abuse by disclosing IPV; feelings of sadness and depression; and general concerns with IPV screening.\textsuperscript{59} Only a minority of respondents voiced these concerns. No new studies reported adverse effects of IVP screening or interventions.

**Conclusions**

Two trials evaluating screening for IPV in clinical settings and its effects on health outcomes are inconclusive. Several brief screening instruments to identify women exposed to IPV in healthcare settings (obstetrics visits, primary-care settings, emergency department) have high sensitivity (>80%), although results vary across studies and populations. Studies of interventions focus primarily on pregnant women or women seeking obstetric care. Results indicate generally beneficial outcomes, but studies are heterogeneous and most enrolled small numbers of women limiting applicability.
REFERENCES


COUNSELING FOR SEXUALLY TRANSMITTED INFECTIONS

RECOMMENDATIONS

Clinical Recommendations

The Women’s Preventive Services Initiative recommends directed behavioral counseling by a health care provider or other appropriately trained individual for sexually active adolescent and adult women at an increased risk for sexually transmitted infections (STIs).

The Women’s Preventive Services Initiative recommends that health care providers use a woman’s sexual history and risk factors to help identify those at an increased risk of STIs. Risk factors may include age younger than 25, a recent history of an STI, a new sex partner, multiple partners, a partner with concurrent partners, a partner with an STI, and a lack of or inconsistent condom use. For adolescents and women not identified as high risk, counseling to reduce the risk of STIs should be considered, as determined by clinical judgement.

Implementation Considerations

The Women’s Preventive Services Initiative recommends as preventive service for women at increased risk for STIs, directed behavioral counseling that includes, but is not limited to, longer duration or multiple counseling sessions, motivational interviewing techniques, and goal setting.

The Women’s Preventive Services Initiative recommends as a preventive service, STI counseling regardless of whether or not STI screening takes place during the same visit and regardless of the type of sexual activity or the partners’ gender.
Behavioral counseling by a health care provider or other appropriately trained individual for sexually active adolescent and adult women at increased risk for sexually transmitted infections (STIs).

### Systematic Reviews
- 2014 USPSTF review of 31 trials\(^1\): intensive counseling is most effective for promoting safer sexual practices and reducing STIs, although less intense approaches are also effective in some studies.
- Systematic review of 13 meta-analyses and systematic reviews\(^2\): behavioral counseling is effective for promoting safer sexual practices and reducing STIs.
- Systematic review of 31 trials\(^3\): brief sexuality communication showed some effect for promoting safer sexual practices and reducing STIs.

### Additional Studies
- Reduced sexual risk taking behaviors after various behavioral interventions in adolescents reported in 2 RCTs\(^4\)\(^-\)\(^6\).
- A brief sexuality intervention had no effect on safer sexual practices and reducing STIs versus brief general health intervention in one RCT\(^7\).

### USPSTF; Bright Futures
- USPSTF\(^8\): Recommends intensive behavioral counseling for all sexually active adolescents and for adults who are at increased risk for sexually transmitted infections (STIs). At-risk adults include those with current STIs or infections within the past year; have multiple sex partners; or who do not consistently use condoms. Clinicians should also be aware of populations with a high prevalence of STIs. (Level B; 2014)
- Bright Futures\(^9\): Risk reduction for STIs should be discussed in adolescent visits as part of routine health supervision. Anticipatory guidance should include discussions about sexuality and healthy sexual development and provide an opportunity for risk screening, health promotion, counseling, and sex education.

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Abbreviations: RCT=randomized controlled trial, STI=sexually transmitted infection, USPSTF=U.S. Preventive Services Task Force
SUMMARY OF EVIDENCE

Introduction

Sexually transmitted infections (STIs) are a broad category of infectious diseases that are transmitted primarily through sexual activity including chlamydia, gonorrhea, hepatitis B, genital herpes, human immunodeficiency virus (HIV), and syphilis. Counseling to prevent STIs includes any intervention that may reduce the likelihood of an individual acquiring a STI. Interventions range in intensity, delivery, structure, and content, though the focus of this discussion is on interventions that can be delivered by health care providers in a clinical setting.

Current Recommendations and Coverage of Services

The gap in services provided under the provisions of the Patient Protection and Affordable Health Care Act of 2010 (ACA) previously identified by the Institute of Medicine (IOM) Committee was the limitation of STI counseling to adults who have current or recent STIs or who identify as having multiple sex partners.10 The IOM Committee recommended expanding this scope to annual counseling for STIs for all sexually active women (Table 1). The U.S. Preventive Services Task Force (USPSTF) updated its recommendation in 2014, however, the updated recommendation is limited to at-risk adults8 as opposed to all sexually active adults.

Table 1. Summary of Recommendations Currently Covered under the Affordable Care Act

<table>
<thead>
<tr>
<th>IOM Committee10</th>
<th>Annual counseling on STIs for sexually active women. HIV counseling is also included under a separate recommendation for HIV screening.</th>
</tr>
</thead>
<tbody>
<tr>
<td>USPSTF8</td>
<td>Intensive behavioral counseling for all sexually active adolescents and for adults who are at increased risk for STIs. At-risk adults include those with current STIs or infections within the past year; have multiple sex partners; or who do not consistently use condoms. Clinicians should also be aware of populations with a high prevalence of STIs (e.g. African Americans, men who have sex with men, persons with low incomes in urban settings, current or former inmates, military recruits, persons who exchange sex for money or drugs, persons with mental illness or disability, current or former intravenous drug users, persons with a history of sexual abuse, and patients at public STI clinics). Intensive behavioral interventions range in duration from 30 minutes to 2 or more hours. Interventions vary in their components and delivery methods but are intended to be provided by primary care clinicians or through referral to trained counselors. (Level B; 2014)</td>
</tr>
<tr>
<td>Bright Futures9</td>
<td>Risk reduction for STIs should be discussed in adolescent visits as part of routine health supervision. Anticipatory guidance should include discussions about sexuality and healthy sexual development and provide an opportunity for risk screening, health promotion, counseling, and sex education.</td>
</tr>
</tbody>
</table>

Abbreviations: HIV=human immunodeficiency virus; IOM=Institute of Medicine; STIs=sexually transmitted infections; USPSTF=U.S. Preventive Services Task Force
Background

The Centers for Disease Control and Prevention (CDC) provides information about rates and trends of chlamydia, gonorrhea, and syphilis infections in U.S. populations. According to the CDC there were 1,441,789 cases of chlamydia reported in 2014 (546.1 cases per 100,000 population), an increase of 2.8% from previous year. Rates in women as a group increased between 2013 and 2014. However, rates decreased by 4.2% in adolescent women 15 to 19 years, continuing a decline in rates of infection among this group since 2011. Compared with men, the rate of chlamydia infection in women was nearly double (278.4 vs. 672.2 cases per 100,000), reflecting the greater number of women screened for chlamydia. Although overall rates of infection in men are lower than women, they increased by 22% from 2010-2014, compared with a 6% increase for women during the same period. Racial disparities for chlamydia also exist. The highest rates are among blacks, with rates 6 times that of whites, and American Indians/Alaska Natives with infection rates nearly 4 times that of whites.

From 2009 to 2012 the rate of gonorrhea infection increased annually to 106.7 cases per 100,000 population. The increased rate of gonorrhea infection from 2013 to 2014 occurred primarily among men. The burden of infection varied by race with the highest rate of infection among blacks (405.4 cases per 100,000), which was almost 11 times the rate among whites (38.3 cases per 100,000 population). However, while rates of gonorrhea have been declining among blacks since 2010, they have increased in all other racial/ethnic groups. Notably, among American Indian/Alaska Natives, rates have increased 104% over the same period.

Rates of primary and secondary syphilis have increased almost every year since 2000. In 2014, there were a total of 19,999 cases reported to the CDC and the national rate increased to 6.3 cases per 100,000 population, the highest rate reported since 1994. The increased rate of syphilis infection from 2000 to 2014 is largely attributed to an increase among men, specifically, among men who have sex with men. However, during 2013 to 2014, overall rates of infection increased for both women (22.7%) and men (14.4%). In 2014, 91% of all cases of primary and secondary syphilis were in men. During the same period, overall rates of infection increased among men and women in all age categories between 15 and 44, in every region, and in every race/ethnicity other than Native Hawaiians/Pacific Islanders. As with gonorrhea and chlamydia infections, the rate of primary and secondary syphilis infection affect different racial groups disproportionally. The 2014 infection rate among blacks was 5.4 times that of whites and the infection rates among black and American Indian/Alaska Native women were 9 to 10 times higher than that of white women.

STIs in women can result in long term reproductive consequences including pelvic inflammatory disease and subsequent infertility, ectopic pregnancy, and chronic pelvic pain. Perinatal transmission is also a concern. Unfortunately many women are not adequately screened and counselled for STIs. A recent Kaiser Family Foundation survey-based study found that counseling about STIs is not routine among women age 15 to 44 years. Specifically, only 50% of women reported a recent conversation about sexual history with a health provider, 34% reported discussing HIV, and 30% reported discussing STIs. Many women are under the impression that HIV and STI testing are a routine part of the gynecological exam, and about half
of women who reported being tested for HIV/STIs in the past two years mistakenly believed that the testing was done as a routine part of an examination. Consequently, actual screening rates are likely lower than reported rates.

Several professional organizations have issued practice recommendations regarding counseling for STI prevention (Table 2).

### Table 2. Recommendations of Professional Organizations

<table>
<thead>
<tr>
<th>Organization</th>
<th>Recommendation</th>
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<tbody>
<tr>
<td>American College of Obstetricians and Gynecologists (ACOG)</td>
<td>STIs should be discussed at the initial reproductive health visit for adolescent patients and when patients transition from pediatric to adult health care. The annual well-woman visit is an opportunity to counsel women about STI risk and provide information on risk reduction strategies, as well as screening and immunizations for STIs based on age and risk factors.</td>
</tr>
<tr>
<td>American Academy of Family Physicians (AAFP)</td>
<td>Intensive behavioral counseling for all sexually active adolescents and for adults at increased risk for STIs.</td>
</tr>
<tr>
<td>Centers for Disease Control and Prevention (CDC)</td>
<td>All providers should routinely obtain sexual histories from their patients and encourage risk reduction strategies through prevention counseling. Prevention counseling should be provided to all sexually active adolescents and adults with an STD diagnosis, a history of an STD in the past year, or those with multiple sex partners.</td>
</tr>
</tbody>
</table>

**Abbreviations:** STD=sexually transmitted disease; STI=sexually transmitted infection

**Update of Evidence**

**USPSTF systematic review**

A 2014 USPSTF systematic review addressed the effectiveness of behavioral sexual risk-reduction counseling in primary care for prevention of STIs. This review included 31 fair-to good-quality trials. Trials focused on persons at increased risk for STIs based on demographics, risky sexual behavior, or history of an STI; and included mostly women and nonwhite or minority populations.

Although interventions varied, several elements were similar. All interventions aimed to minimize high-risk sexual behaviors and provided basic information about STIs. Interventions often included communication of basic information about STIs, risk assessment, skills training in condom use, safe sex communication, problem solving, and decision making. Some interventions included additional components such as HIV counseling, and many interventions were culturally tailored to a target group. Intervention implementation varied and included face-to-face counseling, videos, computer, and phone support. Most high-intensity (>2 hours) interventions included group sessions with extensive educational and behavioral change components; moderate-intensity programs generally involved one or two individual meetings; and low-intensity programs involved brief individual meetings with providers or were limited to modalities other than face-to-face contact. Interventions were commonly delivered in the setting of a primary care clinic or an STI clinic.
Among adolescents, high intensity interventions significantly reduced STI incidence (odds ratio [OR], 0.38; 95% confidence interval [CI] 0.24 to 0.60, 5 studies). Two moderate intensity intervention groups showed reductions of 33% to 47% in the odds of having an STI, though only one result was statistically significant. One low intensity intervention trial demonstrated non-significant group differences. Four trials conducted in primary care settings reported reductions of 33% or more in the odds of contracting an STI, though not all effects were statistically significant. Six trials that reported sexual behavior outcomes in adolescents found a beneficial effect for some outcomes, most commonly for condom use or unprotected sex.

As with adolescents, high intensity interventions significantly reduced STI incidence among adults (OR 0.70, 95% CI 0.56 to 0.87; 9 studies). Three high-intensity trials conducted in primary care settings had ORs ranged from 0.48 (95% CI 0.24 to 0.97) to 0.82 (95% CI 0.46 to 1.45). The pooled effects for low- and moderate-intensity trials did not demonstrate reductions in the odds of contracting an STI, though some individual low- and moderate-trials demonstrated effectiveness. Nine of twelve high intensity interventions that reported behavioral outcomes found a benefit for at least one outcome. Four trials reported increased use of condoms (reduction in OR 24% to 42%). Studies of moderate intensity interventions had mixed results, with odds ratio for condom use and unprotected sex ranging from 0.98 to 2.2. Low-intensity interventions generally showed no group differences in behavioral outcomes.

Three trials that reported adverse events found no harms related to counseling interventions. No statistically significant increases in STI incidence were noted in any of the studies, and no consistent evidence demonstrated that interventions increased sexual activity in adolescents. Most included trials were conducted in populations with high STI incidence, particularly blacks and/or Hispanic women, and found interventions to be effective in reducing STI incidence. Aside from the increased likelihood of benefit in adolescents compared with adults, there was no clear evidence that any interventions were more or less likely to be effective in any given subgroup evaluated by intervention trials, though some subpopulations were underrepresented in trials. Subgroup results were generally consistent with overall results.

Intervention intensity was the only characteristic that appeared to influence outcomes in trials. There were no clear relationships between other aspects, such as cultural tailoring, group versus individual format, counselor characteristics, setting, or number of sessions and outcomes, although these effects were difficult to isolate.

The results from the USPSTF review were limited in their generalizability since low-risk populations were underrepresented in all studies. Also, there were few studies meeting criteria for good-quality. Methodological shortcomings included high attrition and lack of information on allocation concealment and randomization. The use of self-reported behaviors also affected data reliability.
Relevant studies published since the USPSTF systematic review

Since the USPSTF review, a systematic review that included 31 trials and observational studies (23 in the United States) focused on brief sexuality communication (10 to 60 minute interventions that include some type of communication on sexual health).3 Interventions included audio/visual materials, risk assessment, didactic sessions, skill building/motivational interviewing, and providing resource lists. Overall, results indicated that STIs and HIV were less commonly reported in intervention groups compared with control groups. Condom use was also higher, and numbers of sexual partners and unprotected sexual intercourse were lower in the intervention compared with control groups. This review did not provide data based on age or subpopulations and not all trials showed differences.7

Another systematic review included 13 meta-analyses or systematic reviews (representing 248 studies) of behavioral interventions to promote condom use.2 Results indicated that behavioral interventions were effective in promoting condom use and reducing STIs, as well as delaying intercourse, decreasing the frequency of intercourse and number of partners, increasing STD/HIV knowledge, and reducing unprotected sex. Most interventions were delivered face-to-face, but their components were heterogeneous and included individual counseling, coping strategies, risk reduction counseling, skills training, and provision of resources. This review found that tailoring interventions to the characteristics of the population and including skills building exercises were aspects of successful interventions. The included reviews varied by geography, population, gender, ethnicity, and age sampling, and the primary outcomes were based on self-report.

Two randomized controlled trials of adolescents reported reduced sexual risk taking behaviors after various behavioral interventions. A trial of 738 U.S. urban adolescent females (69% black) randomized participants to a theory-based, sexual risk reduction intervention or a health promotion control group.4 Girls in both groups increased their use of risk reduction strategies post-intervention, but those in the intervention group used risk reduction strategies at a faster rate than those in the control group. Both groups were exposed to motivational interviewing techniques and group and booster sessions.

A trial of 715 African American adolescent females age 15 to 21 years recruited from U.S. clinics providing sexual health services randomized participants to intervention or usual care groups.5 The intervention included two 4-hour group sessions and 4 telephone contacts over 12 months that focused on personal, relational, sociocultural, and structural factors associated with adolescent STI/HIV risk (HORIZONS). The enhanced usual care arm consisted of 1-hour group sessions that included an STI prevention video, question and answer session, and group discussion. Over the 12-month follow-up period, fewer adolescents in the intervention arm had chlamydial infections (42 vs. 67; RR 0.65, 95% CI 0.42 to 0.98) or recurrent chlamydial infections (4 vs. 14; RR 0.25, 95% CI 0.08 to 0.83). Participants in the intervention arm also had higher numbers of condom-protected sex acts (mean difference 10.84, 95% CI 5.57 to 16.42). They were also more likely to report consistent condom use (RR 1.41, 95% CI 1.09 to 1.80) during the 60 days prior to assessment, as well as condom use at last intercourse (RR 1.30, 95% CI 1.09 to 1.54).
To assess persistence of risk reduction behavior following the HORIZONS intervention, a trial of 701 adolescent African American girls from U.S. sexual health clinics compared the HORIZONS intervention that also included a prevention maintenance intervention against a prevention maintenance intervention that focused on general health. The intervention included phone contact every 8 weeks for 36 months to reinforce prevention messages. Results indicated that fewer participants in the prevention specific group had incident chlamydial infection compared with the general health group (94 vs. 105; RR 0.95, 95% CI 0.90 to 1.00) at 36-month follow-up. Participants in the prevention specific group reported more condom use in the 90 days (mean difference 0.08; 95% CI, 0.06 to 0.11) and 6 months (mean difference -0.61, 95% CI -0.98 to -0.24) prior to assessment, fewer episodes of sexual acts while on drugs and/or alcohol, and fewer vaginal sex partners in the prior 6 months.

In addition, a retrospective cohort study based on chart review of 274 sexually active girls aged 15 to 19 years who were seen in an adolescent clinic and diagnosed with gonorrhea, chlamydia, or trichomonas infection found that girls who were had been seen by a health educator for a 20 minute session focused on STI acquisition, treatment adherence, and prevention of future STIs had lower rates of recurrent STIs at 3, 6, and 12 months compared with girls receiving usual care that included standardized counseling by a health care provider or triage nurse (29% vs. 57%, 42% vs. 65%, and 57% vs. 76%, respectively; p< 0.05 for all comparisons), as well as longer time to STI recurrence. Although girls in the control group were more likely to engage in high-risk behaviors including substance use and no-condom use versus girls in the intervention group, the reduced risk among those receiving health education counseling persisted after adjusting for clinical presentation, past history of STIs, drug use, condom use, numbers of retest, age of first intercourse, and numbers of sex partners (hazard ratio 0.38, 95% CI 0.19 to 0.74). Also, in the final multivariate model, health education counseling was found to be protective against subsequent STIs (hazard ratio 0.39, 95% CI 0.22 to 0.72).

Conclusions

Behavioral counseling interventions are effective in reducing high risk STI behaviors for both adolescents and adults. In studies, the effectiveness of interventions generally varies by intensity, with higher intensity interventions more consistently improving outcomes across studies (increased condom use, reduced unprotected sex acts, reduced STI incidence). Interventions targeting adolescents are particularly effective, even at lower intensities. Although a wide variety of counseling interventions have been studied, characteristics defining the most effective methods are not clear. However, most efficacious interventions provide basic STI information, risk assessment, and training in relevant skills such as condom use. Low-risk populations are not well represented in studies, limiting generalizability of conclusions. Also, there is a lack of data regarding the appropriate frequency of interventions, although one study of adolescents demonstrated sustained effects over 36 months with phone contacts every 8 weeks. In the future, new methods of delivery such as text messaging may improve the accessibility, acceptability, and effectiveness of less intense counseling interventions.
REFERENCES


38. Marion LN, Finnegan L, Campbell RT, et al. The well woman program: A community-based randomized trial to prevent sexually transmitted infections in low-income African


WELL-WOMAN PREVENTIVE VISITS

RECOMMENDATIONS

Clinical Recommendations

The Women’s Preventive Services Initiative recommends that women receive at least one preventive care visit per year beginning in adolescence and continuing across the lifespan to ensure that the recommended preventive services including preconception and many services necessary for prenatal and interconception care are obtained. The primary purpose of these visits should be the delivery and coordination of recommended preventive services as determined by age and risk factors.

Implementation Considerations

The Women’s Preventive Services Initiative recommends as a preventive service for women, that women receive at least one preventive care visit per year. Additional well-woman visits may be needed to obtain all necessary services depending on a woman’s age, health status, reproductive health needs, pregnancy status, and risk factors. Visits should allow sufficient time to address and coordinate services, and a team-based approach may be needed. Well-woman preventive services may include, but are not limited to, assessment of physical and psychosocial function, primary and secondary prevention and screening, risk factor assessments, immunizations, counseling, education, and preconception, prenatal, and interconception care. Recommended services are evidence-based items or services that have in effect a rating of ‘A’ or ‘B’ in the current recommendations of the United States Preventive Services Task Force, immunizations that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved, with respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in the comprehensive guidelines supported by the Health Resources and Services Administration, and with respect to women, such additional preventive care and screenings as provided for in comprehensive guidelines supported by the Health Resources and Services Administration.
WPSI recommends that women receive at least one preventive care visit per year beginning in adolescence and continuing across the lifespan to ensure that the recommended preventive services are obtained.

<table>
<thead>
<tr>
<th>Systematic Reviews</th>
<th>Additional Studies</th>
<th>USPSTF; Bright Futures</th>
</tr>
</thead>
</table>
| 2012 Cochrane review\(^1\): no reductions in morbidity or mortality (overall, cardiovascular, or cancer related), but increases in the numbers of new diagnoses with annual health checks. | No studies evaluate the effectiveness of well-woman preventive visits; 3 observational studies of the effectiveness of the periodic health exam concern specific components of the visit rather than the visit itself.\(^1\)-\(^3\) | • USPSTF: No recommendation  
• Bright Futures\(^4\): Preventive pediatric health care visits for children annually from ages 3 through 21 years, including initial/interval medical histories, measurements, sensory screening, developmental/behavioral assessments, physical examination, age-appropriate procedures, oral health, and anticipatory guidance. |

The primary purpose of these visits should be the delivery and coordination of recommended preventive services as determined by age and risk factors.

<table>
<thead>
<tr>
<th>Systematic Reviews</th>
<th>Additional Studies</th>
<th>USPSTF; Bright Futures</th>
</tr>
</thead>
</table>
| None | None | • USPSTF: Individual age-appropriate preventive services are supported by separate USPSTF recommendations.\(^5\)  
• Bright Futures: see above |

Abbreviations: ACA=Affordable Care Act, USPSTF=U.S. Preventive Services Task Force
SUMMARY OF EVIDENCE

Introduction

A well-woman preventive visit is a clinical encounter that addresses issues of general wellness and provides screening, immunizations, counseling, and other prevention services for a variety of health conditions. Visits facilitate access to health care services, identify risk factors, and reduce the likelihood or delay the onset of disease. Well-woman visits apply to women of all ages and stages of life, and are individualized for delivery of appropriate screening recommendations and prevention services.

Current Recommendations and Coverage of Services

The gap in services provided under the provisions of the Patient Protection and Affordable Health Care Act of 2010 (ACA) previously identified by the Institute of Medicine (IOM) was the absence of coverage for well-woman preventive care visits for women ages 21 to 64 years. Support of these visits was based on current policies (Medicaid, Medicare), professional guidelines, and private health plan policies that included mandated coverage for preventive visits for children and adolescents up to age 21 and for some adults age 65 and older. The IOM committee recognized this gap in coverage, further emphasizing a disproportionate burden on women of childbearing age.

The U.S. Department of Health and Human Services (HHS) adopted the IOM Committee’s recommendation for at least one annual well-woman preventive visit (Table 1). These visits include a full evaluation, separate from any other visit for sickness or injury, and focus on preventive care that may include immunizations, screening tests, education, and counseling. In order to obtain all of the recommended services, several visits may be necessary for some women depending on age, health status, health needs, and risk factors. Under the ACA, at least 15 preventive services and one wellness visit are covered on Major Medical Plans sold after 2014 without copays and coinsurance, regardless of meeting deductibles.

Clinical preventive services for adolescents are based on a package of preventive services through the Bright Futures health initiative, a nationally recognized pediatric periodicity schedule that recommends preventive health care visits annually for children ages 3 through 21 years. Federal standards require the provision of prevention services for children under 21 through the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) program, which provides comprehensive and preventive health care services for children under age 21 who are enrolled in Medicaid. Medicare covers annual wellness visits for adults over age 65 years.

Table 1. Summary of Recommendations Currently Covered by the Affordable Care Act

| IOM Committee⁶ | At least one well-woman preventive care visit annually for adult women to obtain the recommended preventive services, including preconception and prenatal care. Several visits may be needed to obtain all necessary recommended preventive services, depending on a woman’s health status, health needs, and other risk factors. |
Preventive pediatric health care visits for children annually from ages 3 through 21 years, including initial/interval medical histories, measurements, sensory screening, developmental/behavioral assessments, physical examination, age-appropriate procedures, oral health, and anticipatory guidance.

Abbreviations: IOM=Institute of Medicine; USPSTF=U.S. Preventive Services Task Force

**Background**

Preventive health care improves health and is a major component of medical practice in the United States.\(^1\) Well-woman preventive visits are important to women of all ages, including adolescents, and its goals vary by age, risk factors, and comorbidities.\(^4,6,16\)

There are no standard definitions for the well-woman preventive visit, and various other terms have been used to describe these types of visits including the periodic health exam, annual physical, and health maintenance visit. Few studies have been done to determine the effectiveness of the visit in improving health outcomes,\(^3\) although the effectiveness of many services that would be delivered in this setting is well supported, including A and B Level recommendations from the USPSTF.\(^5\) Routine visits have been associated with subsequent use of increased preventive care and cancer screening.\(^3\) They may serve as entry points to additional prevention care, as well as opportunities to reach marginalized individuals who would not otherwise seek regular health care.\(^17\)

A well-woman preventive visit consists of various components that often vary among medical specialties.\(^18,19\) In addition, the scope of services may vary by provider,\(^20,21\) as well as by the perceived value of routine exams by both physicians\(^22-24\) and the public.\(^25\) In a survey of primary care physicians, 65% agreed that a periodic health exam was necessary for asymptomatic adults.\(^22\) Despite variation, several professional groups recommend periodic preventive health visits (Table 2).

Several models of care may improve delivery of these services. The concept of the patient centered medical home has been proposed as a model for streamlining women’s health care as it emphasizes care coordination, continuity, evidence-based practice, enhanced access, and payment reform.\(^26\) In early 2008, the National Committee for Quality Assurance (NCQA), in collaboration with four medical specialty societies (AAFP, ACP, AAP, and the AOA) and the Patient Centered Primary Care Collaborative, further refined the concept of the patient centered medical home by defining specific practice standards and reporting measures.\(^27\) Another potential model of focused preventive visits is the Medicare Annual Wellness visit, which is a tailored, evidence-based approach to an annual exam that includes a medical history, recommended immunizations and screenings with further tests depending on health and medical history. In this case, compliance with the visit may affect coverage or reimbursement.
Table 2. Recommendations of Professional Organizations

<table>
<thead>
<tr>
<th>Organization</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>American College of Obstetricians and Gynecologists (ACOG)(^{18})</td>
<td>Annual health assessments and routine annual exams for women ages 13 and above as an opportunity to counsel patients about preventive care and to provide or refer for recommended services. These assessments should include screening, laboratory and other tests, counseling, and immunizations based on age and risk factors. The interval for individual services varies.</td>
</tr>
<tr>
<td>American Academy of Family Physicians (AAFP)(^{28})</td>
<td>Policy recommendations for a number of clinical preventive services for general and specific populations, but no specific recommendation for or against a well-woman exam or routine physical.</td>
</tr>
<tr>
<td>Centers for Disease Control and Prevention (CDC)(^{29})</td>
<td>See a doctor or nurse for a well-woman visit every year. These visits include a full checkup, separate from any other visit for sickness or injury, and focus on preventive care for women. Recommended for women under 65.</td>
</tr>
</tbody>
</table>

Based on 2015 data from the DHHS, 137 million Americans now have insurance coverage for preventive services without cost sharing under the ACA, including over 55 million women.\(^{30}\) A study of the impact of coverage for young adults, age 18 to 26 years, after the implementation of the ACA demonstrated higher rates for receiving routine examinations (47.8% vs 44.1%, \(P<0.05\)) and preventive services from 2009 to 2011.\(^{31}\) While implementation of the ACA has provided women access to well-woman preventive visits, many women are unaware of the benefit and providers may not be sure what is covered despite consumer and provider oriented materials\(^{32}\) to help them understand and access services.

**Update of Evidence**

Most studies of the effectiveness of the periodic health exam concern specific components of the visit rather than the visit itself.\(^{1-3,33}\)

A 2012 Cochrane systematic review quantified the benefits and harms of general health checks, or preventive health exams, focusing on morbidity and mortality outcomes. Data from 14 randomized trials comparing health checks versus no health checks (182,880 patients) found no reduction in morbidity or mortality (overall, cardiovascular, or cancer related), but an increase in the number of new diagnoses. Harmful outcomes were infrequently studied or reported.\(^1\) However, the clinical applicability of these studies to U.S. population is low. Eleven of the studies included in the Cochrane review were conducted in Europe, where health care delivery and coverage differ greatly from the United States. In addition, most patients in the Cochrane studies had regular contact with primary care physicians. The three U.S. studies were conducted between 1964 and 1980, before the wide-spread implementation of routine, evidence-based screening.

The effectiveness of routine well-woman physical exams has not been supported by studies. Traditionally, these exams were tied to screening, such as for cervical and breast cancer, that are
themselves effective health services. However, more recent studies\textsuperscript{34} demonstrate the limited utility of routine pelvic exams outside of cervical cancer screening\textsuperscript{35}.

**Conclusions**

A well-woman preventive visit is a clinical encounter that addresses issues of general wellness and provides screening, immunizations, counseling, and other prevention services for a variety of health conditions. These visits also serve to facilitate access to health care services. Few studies have been done to determine the effectiveness of the visit in improving health outcomes, although the effectiveness of many services that would be delivered in this setting is well supported. These include A and B Level recommendations from the USPSTF such as screening for different types of cancer (e.g. cervical, breast, colon) and sexually transmitted infections, risk assessment for chronic diseases (e.g., cardiovascular disease, osteoporosis), and counseling for healthy behavior changes (e.g., smoking cessation).
REFERENCES


16. The American College of Obstetricians and Gynecologists. Annual Well-Woman examination. Top reasons why you should have an annual well-woman examination.


30. Department of Health & Human Services. The Affordable Care Act is improving access to preventive services for millions of Americans.


APPENDIX: EVIDENCE SUMMARY METHODS

Introduction

Focused updates of evidence reviewed for the nine topics considered for revision under the Women’s Prevention Services Initiative were conducted by the Pacific Northwest Evidence-based Practice Center at Oregon Health & Science University beginning in March 2016 (Table 1). Summaries for each topic provide overviews of recent systematic reviews for the U.S. Preventive Services Task Force (USPSTF) published since the last recommendations were issued by the Institute of Medicine (IOM) Committee in 2011,1 as well as summaries of additional relevant studies published since the systematic reviews.

Literature Search Strategy

A research librarian conducted searches in Ovid MEDLINE, the Cochrane Central Register of Controlled Trials, and the Cochrane Database of Systematic Reviews through August 2016 for all topics. For topics on counseling for sexual transmitted infections (STIs), interpersonal and domestic violence, and well-woman visits, searches were also conducted in PsycINFO through March 2016. Search strategies are provided below. Investigators also manually reviewed reference lists of relevant systematic reviews and articles.

Study Selection

A best evidence approach was applied when reviewing abstracts and selecting studies to include for this review that involves using the most relevant studies with the strongest methodologies.2-4 The results of searches are described in Table 2. For most topics, systematic reviews and key studies published since the most recent systematic review for the USPSTF were included. For well-woman visits and contraceptive methods and counseling, there are no USPSTF reviews or recommendations, therefore, other systematic reviews and studies published since the 2011 IOM recommendations for these topics were included.

Randomized controlled trials and large (>100) prospective cohort studies were included if they provided relevant information for a specific topic. Other study designs, such as case-control and modeling studies, were included when evidence was lacking or when they demonstrated new findings. Studies conducted in settings applicable to the United States were particularly applicable. Findings related to population subgroups were specifically included when available. The focus of each review was on gaps identified in the 2011 IOM recommendations and any new evidence that could change or additionally inform the recommendations where evidence was not previously available. Selection criteria specific to each topic include the following:

Breast Cancer Screening for Average-risk Women

Comprehensive evidence reviews on breast cancer screening were recently conducted by the EPC for the USPSTF and published in February 2016. These reviews served as the main source documents for the evidence summary. Literature searches used for the USPSTF reviews were
repeated to identify new evidence relevant to optimal ages to start and stop screening and screening intervals. However, no new studies met inclusion criteria.

**Breastfeeding Services and Supplies**
Abstracts that described interventions to promote or support breastfeeding in developed countries were reviewed. The population of interest was pregnant women or women who recently gave birth. Studies that focused on effectiveness of interventions and included outcomes related to breastfeeding practices (initiation and duration of breastfeeding) were included. A systematic review of breastfeeding support published in 2016 that was used to update the USPSTF’s clinical recommendations served as the main source document.

**Screening for Cervical Cancer**
Abstracts that described screening for cervical cancer in average-risk women in developed countries were reviewed. Studies that focused on the efficacy of screening or addressed screening intervals, age to start screening, and age to stop screening were targeted. Since most cytological screening in the U.S. is done with liquid-based techniques, the comparison between conventional and liquid-based platforms was not reviewed. Studies that evaluated screening with a combination of cytology and high-risk HPV testing (co-testing) were included. An in-depth review of the performance of screening tests was not undertaken and different triage protocols were not evaluated. Modeling and case-control studies were included when information was lacking or when new findings were presented.

**Contraception**
Abstracts that described the effectiveness of providing contraception were reviewed, including counseling interventions and access. Studies that focused on counseling, health disparities, contraceptive access, and provision of contraception were targeted. Studies of contraceptive efficacy and risks for unintended pregnancy were not reviewed because contraceptive efficacy is well established and risk factors for unintended pregnancy are known. Non-contraceptive benefits of hormonal contraception were outside the scope of this report and not included. Studies that addressed the impact of coverage and contraceptive access and reproductive planning were included. Modeling and observational studies were included when randomized trials were lacking or when relevant population data were provided.

**Screening for Gestational Diabetes Mellitus**
Abstracts of studies of the benefits and harms of screening for gestational diabetes mellitus (GDM) among average-risk or high-risk women that were applicable to U.S. medical practice were reviewed. Studies addressing evidence gaps, such as screening at early or later stages of pregnancy; risk-based screening; comparisons of screening and diagnostic strategies; and comparisons of treatment effects were particularly targeted. A systematic review of screening and treatment for GDM for a National Institutes of Health Consensus Development Conference on Diagnosis of Gestational Diabetes Mellitus in 2013, and used to update the USPSTF’s clinical recommendations in 2014, served as the main source document.

**Screening for Human Immunodeficiency Virus Infection (HIV)**
Abstracts of studies of the benefits and harms of screening and counseling for HIV among average-risk or high-risk women that were applicable to U.S. medical practice were reviewed. Studies addressing evidence gaps, such as screening at early versus later stages of infection; risk-
based screening; comparisons between universal versus selective strategies, including screening intervals; and comparisons of treatment effects on health outcomes and transmission were particularly targeted. A systematic review of screening and treatment for HIV that was used to update the USPSTF’s clinical recommendations in 2013 served as the main source document.

Screening for Interpersonal and Domestic Violence
Abstracts that described screening and interventions for interpersonal and domestic violence were reviewed. The population of interest was asymptomatic women presenting to settings applicable to the U.S. Studies that focused on diagnostic accuracy of screening instruments or trials of interventions aimed at reducing exposure to intimate partner violence were targeted. Studies that reported infant or maternal health outcomes from screening, accuracy of screening instruments, and reduced exposure to interpersonal and domestic violence were included.

Counseling for Sexually Transmitted Infections (STI)
Abstracts that described counseling interventions applicable to clinical settings intended to prevent any type of STI were reviewed. Studies about interventions that focused on reducing STIs in general or chlamydia, gonorrhea, and syphilis specifically were targeted. Articles that described outcomes of STI incidence or behavioral changes such as condom use were included.

Well-Woman Visit
Currently there is not a standard definition for the well-woman exam or the periodic health exam. A conceptual framework was developed to define this visit and its potential benefits and harms, and searches were based on key terms that could be used to describe a well-woman visit. Abstracts that described annual, well woman, or routine physical exam or visit were reviewed. Existing guidelines were reviewed and studies were included using a best evidence approach, prioritizing systematic reviews and clinical best practices to identify which services or group of services may promote well-being.

Data Management and Synthesis
No new or revised statistical meta-analyses were conducted. Studies were qualitatively synthesized according to interventions, populations, and outcomes measured. Studies and their findings are described in a narrative, descriptive format to provide an overview of the new evidence for each topic.

Assessing Applicability
Applicability is defined as the extent to which the effects observed in published studies are likely to reflect the expected results when a specific intervention is applied to the population of interest under “real-world” conditions. It is an indicator of the extent to which research included in a review might be useful for informing clinical decisions in specific situations. Factors important for understanding the applicability of studies were considered including differences in the interventions, comparators, populations, and settings.
References


<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>Breast cancer screening was not addressed</td>
<td></td>
<td>C age 40-49; B age 50-75; I age &gt;75</td>
<td>C age 40-49; B age 50-75; I age &gt;75 (average risk; 2016)</td>
<td>Screening for women who determine that benefits outweigh harms at an individual level</td>
<td>What is the new evidence of optimal screening ages and intervals?</td>
</tr>
<tr>
<td>Breastfeeding, support, supplies, and counseling (comprehensive lactation support and counseling and costs of renting equipment)</td>
<td></td>
<td>B (counseling only)</td>
<td>B (breastfeeding interventions during pregnancy and after birth; 2016)</td>
<td>Inclusion of comprehensive lactation support, counseling, and costs (not limited to renting)</td>
<td>What is the new evidence of the effectiveness of counseling and support for breastfeeding?</td>
</tr>
<tr>
<td>Cervical cancer screening: HPV testing (addition of HPV testing to cytology testing beginning at age 30 and no more frequently than every 3 years)</td>
<td>I</td>
<td>A (cytology and HPV combination age 30-65 every 5 years; 2012). Review in progress on HPV testing alone +/- cytology (2018)</td>
<td>• Ending screening age &gt;65 • 3-year versus 5-year screening intervals for co-testing</td>
<td>What is the new evidence of the effectiveness of cervical cancer screening, including ages to end screening and screening intervals?</td>
<td></td>
</tr>
<tr>
<td>Contraceptive methods and counseling</td>
<td>Not addressed</td>
<td>Not addressed</td>
<td>Not covered by USPSTF</td>
<td></td>
<td>What is the new evidence of the effectiveness of contraceptives and access to them?</td>
</tr>
<tr>
<td>Gestational diabetes screening (24-26 weeks gestation and first prenatal visit for women at high risk for diabetes)</td>
<td>I</td>
<td>B (asymptomatic women after 24 weeks gestation; 2012)</td>
<td>• Earlier screening for women at high risk for diabetes • Screening between 24 to 26 weeks versus after 24 weeks</td>
<td>What is the new evidence of the effectiveness of screening for gestational diabetes in average-risk and high-risk women?</td>
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</tr>
</tbody>
</table>
| HIV counseling and testing (annual counseling and testing for sexually active nonpregnant women) | C | A (age 15-65; pregnant women; others at increased risk; 2013) | • Screening all sexually active women versus all women  
• Inclusion of adolescents  
• Annual coverage versus non-specified screening intervals | What is the new evidence of the effectiveness of HIV counseling and screening? |
| Interpersonal and domestic violence screening and counseling (includes current and past violence) | I | B (screen women of childbearing age; 2013) | • All ages versus child bearing age  
• Effects of past as well as current violence  
• Includes counseling | What is the new evidence of the effectiveness of screening and counseling for interpersonal and domestic violence? |
| STI counseling (annual counseling for sexually active nonpregnant women) | I | B (all sexually active adolescents; adults at increased risk; 2014) | • Screening all sexually active women versus women at increased risk  
• Annual versus non-specified screening intervals | What is the new evidence of the effectiveness of counseling for STIs in average versus high-risk women? |
| Well-woman visits | Not addressed | Not addressed | Not covered by USPSTF | What is the new evidence of the effectiveness of well-woman visits to improve health? |

Key to USPSTF codes:  
A=Recommend; substantial net benefit  
B=Recommend; at least moderate net benefit  
C=Provide selectively  
D=Do not recommend  
I=Insufficient evidence

Current USPSTF recommendations: http://www.uspreventiveservicestaskforce.org/BrowseRec/Search?s

Abbreviations: HIV=human immunodeficiency virus; HPV= human papilloma virus; IOM=Institute of Medicine; STI=sexually transmitted infection; USPSTF=U.S. Preventive Services Task Force
<table>
<thead>
<tr>
<th>Topic</th>
<th>Databases searched Dates searched</th>
<th>Citations reviewed</th>
<th>Full-text reviewed</th>
<th>Included</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast Cancer Screening</td>
<td>Medline, CDSR, CCRCT 2015-2016</td>
<td>1,116</td>
<td>107</td>
<td>Four USPSTF reviews (97 studies)</td>
</tr>
<tr>
<td>Breastfeeding Support and Counseling</td>
<td>Medline, CDSR, CCRCT 2015-2016</td>
<td>1,238</td>
<td>59</td>
<td>USPSTF review (52 studies); 6 other reviews</td>
</tr>
<tr>
<td>Gestational Diabetes Screening</td>
<td>Medline, CDSR, CCRCT 2011-2016</td>
<td>307</td>
<td>52</td>
<td>USPSTF review (62 studies); 4 other studies</td>
</tr>
<tr>
<td>HIV Screening and Counseling</td>
<td>Medline, CDSR, CCRCT 2012-2016</td>
<td>1,474</td>
<td>101</td>
<td>USPSTF review (22 studies)</td>
</tr>
<tr>
<td>Cervical Cancer Screening</td>
<td>Medline, CDSR, CCRCT 2010-2016</td>
<td>1,763</td>
<td>189</td>
<td>USPSTF review (35 studies); 1 modeling study; 11 other studies</td>
</tr>
<tr>
<td>Interpersonal Domestic Violence Screening and Counseling</td>
<td>Medline, CDSR, CCRCT, PsycINFO 2012-2016</td>
<td>1,011</td>
<td>122</td>
<td>USPSTF review (35 studies); 4 Cochrane reviews of 74 trials;* 4 SRs of 51 studies;* 4 other studies</td>
</tr>
<tr>
<td>Contraceptive Methods and Counseling</td>
<td>Medline, CDSR, CCRCT 2009-2016</td>
<td>1,642</td>
<td>258</td>
<td>Cochrane review of 9 trials; 11 other studies</td>
</tr>
<tr>
<td>STI Counseling</td>
<td>Medline, CDSR, CCRCT, PsycINFO 2010-2016</td>
<td>1,181</td>
<td>72</td>
<td>USPSTF review (31 studies); 1 SR of 31 studies; 1 SR of 13 SRs or meta-analyses; 3 other studies</td>
</tr>
<tr>
<td>Well-Woman Visit</td>
<td>Medline, CDSR, CCRCT, PsycINFO 2011-2016</td>
<td>562</td>
<td>55</td>
<td>Cochrane review of 14 trials; 3 other studies</td>
</tr>
</tbody>
</table>

*Studies may overlap between systematic reviews

Abbreviations: CDSR=Cochrane Database of Systematic Reviews; CCRCT=Cochrane Central Register of Controlled Trials; HIV=human immunodeficiency virus; SR=systematic review; STI=sexually transmitted infection; USPSTF=U.S. Preventive Services Task Force
Table 3. Abbreviations List

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>AAFP</td>
<td>American Academy of Family Physicians</td>
</tr>
<tr>
<td>AAP</td>
<td>American Academy ofPediatricians</td>
</tr>
<tr>
<td>AAS</td>
<td>Abuse Assessment Screen</td>
</tr>
<tr>
<td>ACA</td>
<td>Patient Protection and Affordable Care Act of 2010</td>
</tr>
<tr>
<td>ACEP</td>
<td>American College of Emergency Physicians</td>
</tr>
<tr>
<td>ACOG</td>
<td>American College of Obstetricians and Gynecologists</td>
</tr>
<tr>
<td>ACS</td>
<td>American Cancer Society</td>
</tr>
<tr>
<td>ADA</td>
<td>American Diabetes Association</td>
</tr>
<tr>
<td>AMA</td>
<td>American Medical Association</td>
</tr>
<tr>
<td>ART</td>
<td>antiretroviral therapy</td>
</tr>
<tr>
<td>ARTISTIC</td>
<td>A Randomized Trial in Screening to Improve Cytology</td>
</tr>
<tr>
<td>ASCCP</td>
<td>American Society for Colposcopy and Cervical Pathology</td>
</tr>
<tr>
<td>ASCP</td>
<td>American Society for Clinical Pathology</td>
</tr>
<tr>
<td>ASC-US</td>
<td>atypical cells of undetermined significance</td>
</tr>
<tr>
<td>ATHENA</td>
<td>Addressing the Need for Advanced HPV Diagnostics study</td>
</tr>
<tr>
<td>CBT</td>
<td>cognitive behavioral therapy</td>
</tr>
<tr>
<td>CC</td>
<td>Carpenter-Coustan</td>
</tr>
<tr>
<td>CCRCT</td>
<td>Cochrane Central Register of Controlled Trials</td>
</tr>
<tr>
<td>CDA</td>
<td>Canadian Diabetes Association</td>
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<td>CDC</td>
<td>Centers for Disease Control and Prevention</td>
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<tr>
<td>CDSR</td>
<td>Cochrane Database of Systematic Reviews</td>
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<tr>
<td>CI</td>
<td>confidence interval</td>
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<tr>
<td>CIN</td>
<td>cervical intraepithelial neoplasia</td>
</tr>
<tr>
<td>CTS-2</td>
<td>Revised Conflict Tactics Scale</td>
</tr>
<tr>
<td>DMPA</td>
<td>depot medroxyprogesterone acetate</td>
</tr>
<tr>
<td>DNA</td>
<td>deoxyribonucleic acid</td>
</tr>
<tr>
<td>E-HITS</td>
<td>Extended Hurt/Insult/Threaten/Scream tool</td>
</tr>
<tr>
<td>ENA</td>
<td>Emergency Nurses Association</td>
</tr>
<tr>
<td>EPSDT</td>
<td>Early and Periodic Screening, Diagnostic, and Treatment</td>
</tr>
<tr>
<td>FDA</td>
<td>U.S. Food and Drug Administration</td>
</tr>
<tr>
<td>GDM</td>
<td>gestational diabetes mellitus</td>
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<tr>
<td>HARK</td>
<td>Humiliation, Afraid, Rape, Kick tool</td>
</tr>
<tr>
<td>HbA1c</td>
<td>hemoglobin A1c</td>
</tr>
<tr>
<td>HHS</td>
<td>U.S. Department of Health and Human Services</td>
</tr>
<tr>
<td>HITS</td>
<td>Hurt/Insult/Threaten/Scream tool</td>
</tr>
<tr>
<td>HIV</td>
<td>human immunodeficiency virus</td>
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<tr>
<td>HOM</td>
<td>human immunodeficiency virus</td>
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<tr>
<td>HPV</td>
<td>human papilloma virus</td>
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<tr>
<td>HR</td>
<td>hazard ratio</td>
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<tr>
<td>HSIL</td>
<td>high-grade squamous intraepithelial lesion</td>
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<tr>
<td>IADPSG</td>
<td>International Association of the Diabetes and Pregnancy Study Groups</td>
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<tr>
<td>IOM</td>
<td>Institute of Medicine</td>
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<tr>
<td>Abbreviation</td>
<td>Definition</td>
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<tr>
<td>IPV</td>
<td>intimate partner violence</td>
</tr>
<tr>
<td>LARC</td>
<td>Long acting reversible contraception</td>
</tr>
<tr>
<td>LNG IUS</td>
<td>levonorgestrel intrauterine system</td>
</tr>
<tr>
<td>LSIL</td>
<td>low-grade squamous intraepithelial lesion</td>
</tr>
<tr>
<td>MEC</td>
<td>medical eligibility criteria</td>
</tr>
<tr>
<td>Modified CTQ-SF</td>
<td>Conflict Tactics Scale-Revised Short Form</td>
</tr>
<tr>
<td>N</td>
<td>sample size</td>
</tr>
<tr>
<td>NCQA</td>
<td>National Committee for Quality Assurance</td>
</tr>
<tr>
<td>NDDG</td>
<td>National Diabetes Data Group</td>
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<tr>
<td>NTCC</td>
<td>New Technologies for Cervical Cancer screening study</td>
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<tr>
<td>OAS</td>
<td>Ongoing Abuse Screen</td>
</tr>
<tr>
<td>OGCT</td>
<td>oral glucose challenge test</td>
</tr>
<tr>
<td>OR</td>
<td>odds ratio</td>
</tr>
<tr>
<td>OVAT</td>
<td>Ongoing Violence Assessment Tool</td>
</tr>
<tr>
<td>POBASCAM</td>
<td>Population Based Screening Study Amsterdam Program</td>
</tr>
<tr>
<td>PRAMS</td>
<td>Pregnancy Risk Assessment Monitoring System</td>
</tr>
<tr>
<td>PSQ</td>
<td>Parent Screening Questionnaire</td>
</tr>
<tr>
<td>PVS</td>
<td>Partner Violence Screen</td>
</tr>
<tr>
<td>RCT</td>
<td>randomized controlled trial</td>
</tr>
<tr>
<td>RR</td>
<td>risk ratio</td>
</tr>
<tr>
<td>SAFE-T</td>
<td>Secure, Accepted, Family, Even, Talk measure</td>
</tr>
<tr>
<td>SEER</td>
<td>Surveillance, Epidemiology, and End Results Program</td>
</tr>
<tr>
<td>SGIM</td>
<td>Society of General Internal Medicine</td>
</tr>
<tr>
<td>SIDs</td>
<td>sudden infant death syndrome</td>
</tr>
<tr>
<td>SMD</td>
<td>standard mean difference</td>
</tr>
<tr>
<td>STaT</td>
<td>Slapped, Threatened, and Throw measure</td>
</tr>
<tr>
<td>STD</td>
<td>sexually transmitted disease</td>
</tr>
<tr>
<td>STI</td>
<td>sexually transmitted infection</td>
</tr>
<tr>
<td>U.S. SPR</td>
<td>US Selected Practice Recommendations for Contraceptive Use 2013</td>
</tr>
<tr>
<td>U.K.</td>
<td>United Kingdom</td>
</tr>
<tr>
<td>UNICEF</td>
<td>United Nations Children’s Emergency Fund</td>
</tr>
<tr>
<td>U.S.</td>
<td>United States</td>
</tr>
<tr>
<td>USPSTF</td>
<td>U.S. Preventive Services Task Force</td>
</tr>
<tr>
<td>vs.</td>
<td>versus</td>
</tr>
<tr>
<td>WAST</td>
<td>Woman Abuse Screening Tool</td>
</tr>
<tr>
<td>WIC</td>
<td>Special Supplemental Nutrition Program for Women, Infants, and Children</td>
</tr>
</tbody>
</table>
Search Strategies

Breast Cancer Screening
Database: Ovid MEDLINE(R) without Revisions
Search Strategy:

1 exp breast neoplasms/
2 exp Mass Screening/
3 1 and 2
4 (screen* or ((earl* or routin*) adj2 (diagnos* or detect* or discover* or identif*))).mp.
5 exp biomarkers/
6 mammogra*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
7 4 or 5 or 6
8 exp breast neoplasms/di
9 exp mammography/
10 7 and 8
11 3 or 9 or 10
12 (predict* adj3 ((breast* or mammar*) adj2 (cancer* or tumor* or tumour* or malig* or neoplas*))).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
13 11 or 12
14 limit 13 to (english language and humans)
15 exp "Sensitivity and Specificity"/
16 exp Diagnostic Errors/
17 exp Diagnosis, Differential/
18 exp "Outcome and Process Assessment (Health Care)"
19 exp "Costs and Cost Analysis"
20 15 or 16 or 17 or 18 or 19
21 14 and 20
22 limit 21 to yr="2015 -Current"
23 limit 14 to yr="2015 -Current"
24 limit 23 to (comparative study or controlled clinical trial or guideline or meta analysis or randomized controlled trial or systematic reviews)
25 exp Epidemiologic Studies/
26 23 and 25
27 26 not (22 or 24)

Database: Ovid MEDLINE(R) without Revisions
Search Strategy:
1 exp breast neoplasms/
2 exp Mass Screening/
3 1 and 2
4 (screen* or ((earl* or routin*) adj2 (diagnos* or detect* or discover* or identif*))).mp.
[mp=title, abstract, original title, name of substance word, subject heading word, keyword
heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
5 exp biomarkers/
6 mammogra*.mp. [mp=title, abstract, original title, name of substance word, subject heading
word, keyword heading word, protocol supplementary concept word, rare disease supplementary
concept word, unique identifier]
7 4 or 5 or 6
8 exp breast neoplasms/di
9 exp mammography/
10 7 and 8
11 3 or 9 or 10
12 (predict* adj3 ((breast* or mammar*) adj2 (cancer* or tumor* or tumour* or malig* or
neoplas*)�).mp. [mp=title, abstract, original title, name of substance word, subject heading word,
keyword heading word, protocol supplementary concept word, rare disease supplementary
concept word, unique identifier]
13 11 or 12
14 limit 13 to (english language and humans)
15 exp "Sensitivity and Specificity"/
16 exp Diagnostic Errors/
17 exp Diagnosis, Differential/
18 exp "Outcome and Process Assessment (Health Care)"
19 exp "Costs and Cost Analysis"
20 15 or 16 or 17 or 18 or 19
21 14 and 20
22 limit 21 to yr="2015 -Current"
23 limit 14 to yr="2015 -Current"
24 limit 23 to (comparative study or controlled clinical trial or guideline or meta analysis or
randomized controlled trial or systematic reviews)
25 exp Epidemiologic Studies/
26 23 and 25
27 26 not (22 or 24)
28 22 not 24
Database: Ovid MEDLINE(R) without Revisions
Search Strategy:
heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier
5 exp biomarkers/
6 mammogra*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
7 4 or 5 or 6
8 exp breast neoplasms/di
9 exp mammography/
10 7 and 8
11 3 or 9 or 10
12 (predict* adj3 ((breast* or mammar*) adj2 (cancer* or tumor* or tumour* or malig* or neoplas*))).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
13 11 or 12
14 limit 13 to (english language and humans)
15 exp "Sensitivity and Specificity"/
16 exp Diagnostic Errors/
17 exp Diagnosis, Differential/
18 exp "Outcome and Process Assessment (Health Care)"
19 exp "Costs and Cost Analysis"/
20 15 or 16 or 17 or 18 or 19
21 14 and 20
22 limit 21 to yr="2015 -Current"
23 limit 14 to yr="2015 -Current"
24 limit 23 to (comparative study or controlled clinical trial or guideline or meta analysis or randomized controlled trial or systematic reviews)
25 exp Epidemiologic Studies/
26 23 and 25
27 26 not (22 or 24)
28 22 not 24

Database: EBM Reviews - Cochrane Central Register of Controlled Trials

Search Strategy:

--------------------------------------------------------------------------------
1 (predict* adj3 ((breast* or mammar*) adj2 (cancer* or tumor* or tumour* or malig* or neoplas*))).mp. [mp=title, original title, abstract, mesh headings, heading words, keyword]
2 ((sensitiv* or specific*) adj3 (diagnos* or detect* or test*) adj7 ((breast* or mammar*) adj3 (cancer* or carcinom* or neoplas* or tumor* or tumour* or malig*)).mp. [mp=title, original title, abstract, mesh headings, heading words, keyword]
3 ((Diagnos* or detect* or mammogra*) adj5 (accura* or error* or erroneous* or mistak* or miss* or wrong* or fals*) adj7 ((breast* or mammar*) adj3 (cancer* or carcinom* or neoplas* or tumor* or tumour* or malig*)).mp. [mp=title, original title, abstract, mesh headings, heading words, keyword]

139
(((breast* or mammar*) adj3 (cancer* or carcinom* or neoplas* or tumor* or tumour* or malig*) adj7 (biomarker* or screen* or ((earl* or routin*) adj2 (diagnos* or detect* or discover* or identif*))))) or mammogra*) adj7 (death* or dead or mortal* or surviv*)).mp. [mp=title, original title, abstract, mesh headings, heading words, keyword]

((((breast* or mammar*) adj3 (cancer* or carcinom* or neoplas* or tumor* or tumour* or malig*) adj7 (biomarker* or screen* or ((earl* or routin*) adj2 (diagnos* or detect* or discover* or identif*))))) or mammogra*) adj7 ((outcom* or success* or fail* or impact* or treat* or therap* or effect* or regimen* or interven* or chemother* or pharmcother* or radiother*) adj5 (measur* or judg* or assess* or quantif* or determin* or compar* or estimat* or calculat*))).mp.

((breast* or mammar*) adj3 (cancer* or carcinom* or neoplas* or tumor* or tumour* or malig*) adj7 (biomarker* or screen* or ((earl* or routin*) adj2 (diagnos* or detect* or discover* or identif*)))).mp. [mp=title, original title, abstract, mesh headings, heading words, keyword] (1327)

mammogra*.mp. [mp=title, original title, abstract, mesh headings, heading words, keyword] (1327)

1 or 2 or 3 or 4 or 5 or 6 or 7

limit 8 to yr="2015 -Current"

Database: EBM Reviews - Cochrane Database of Systematic Reviews

----------------------------------------

1  (predict* adj3 ((breast* or mammar*) adj2 (cancer* or tumor* or tumour* or malig* or neoplas*))).mp. [mp=title, abstract, full text, keywords, caption text]

2  ((sensitiv* or specific*) adj3 (diagnos* or detect* or test*) adj7 ((breast* or mammar*) adj3 (cancer* or carcinom* or neoplas* or tumor* or tumour* or malig*))).mp. [mp=title, abstract, full text, keywords, caption text]

3  ((Diagnos* or detect* or mammogra*) adj5 (accura* or error* or erroneous* or mistak* or miss* or wrong* or fals*) adj7 ((breast* or mammar*) adj3 (cancer* or carcinom* or neoplas* or tumor* or tumour* or malig*))).mp. [mp=title, abstract, full text, keywords, caption text]

4  ((((breast* or mammar*) adj3 (cancer* or carcinom* or neoplas* or tumor* or tumour* or malig*) adj7 (biomarker* or screen* or ((earl* or routin*) adj2 (diagnos* or detect* or discover* or identif*))))) or mammogra*) adj7 (death* or dead or mortal* or surviv*)).mp. [mp=title, abstract, full text, keywords, caption text]

5  (((((breast* or mammar*) adj3 (cancer* or carcinom* or neoplas* or tumor* or tumour* or malig*) adj7 (biomarker* or screen* or ((earl* or routin*) adj2 (diagnos* or detect* or discover* or identif*))))) or mammogra*) adj7 ((outcom* or success* or fail* or impact* or treat* or therap* or effect* or regimen* or interven* or chemother* or pharmcother* or radiother*) adj5 (measur* or judg* or assess* or quantif* or determin* or compar* or estimat* or calculat*))).mp.

6  ((breast* or mammar*) adj3 (cancer* or carcinom* or neoplas* or tumor* or tumour* or malig*) adj7 (biomarker* or screen* or ((earl* or routin*) adj2 (diagnos* or detect* or discover* or identif*)))).mp. [mp=title, abstract, full text, keywords, caption text]

7  mammogra*.mp. [mp=title, abstract, full text, keywords, caption text]

8  1 or 2 or 3 or 4 or 5 or 6 or 7

9  (2015* or 2016*).up.

10 8 and 9
Breastfeeding Support, Supplies, and Counseling
Database: Ovid MEDLINE(R) without Revisions
Search Strategy:
--------------------------------------------------------------------------------
1    exp Breast Feeding/
2    exp Counseling/
3    exp Health Promotion/
4    exp Health Education/
5    exp Physician-Patient Relations/
6    exp Attitude to Health/
7    (counsel* or guid* or promot* or instruct* or teach* or learn* or taught).mp.
8    6 and 7
9    2 or 3 or 4 or 5 or 8
10   1 and 9
11   limit 10 to english language
12   limit 11 to yr="2008 -Current"
13   limit 12 to (comparative study or controlled clinical trial or guideline or meta analysis or randomized controlled trial or systematic reviews)
14   exp "Quality of Life"/
15   exp "Quality of Health Care"/
16   exp "Costs and Cost Analysis"/
17   14 or 15 or 16
18   12 and 17
19   18 not 13
20   exp Epidemiologic Studies/
21   12 and 20
22   21 not (13 or 18)
--------------------------------------------------------------------------------
Database: EBM Reviews - Cochrane Central Register of Controlled Trials
Search Strategy:
--------------------------------------------------------------------------------
1    ((counsel* or guid* or promot* or instruct* or teach* or learn* or taught) adj7 (breastfeed* or breastfed or (breast* adj2 (feed or fed))).mp. [mp=title, original title, abstract, mesh headings, heading words, keyword]
--------------------------------------------------------------------------------
Database: EBM Reviews - Cochrane Database of Systematic Reviews
Search Strategy:
--------------------------------------------------------------------------------
1    ((counsel* or guid* or promot* or instruct* or teach* or learn* or taught) adj7 (breastfeed* or breastfed or (breast* adj2 (feed or fed))).mp. [mp=title, abstract, full text, keywords, caption text]
Cervical Cancer Screening: Human Papillomavirus DNA Testing
Database: Ovid MEDLINE(R) without Revisions
Search Strategy:

1  exp cervical neoplasms/
2  exp Papillomavirus Infections/
3  exp Mass Screening/
4  1 and 3
5  (screen* or ((earl* or routin*) adj2 (diagnos* or detect* or discover* or identif*))).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
6  exp biomarkers/
7  5 or 6
8  exp cervical neoplasms/di
9  7 and 8
10  4 or 9
11  (predict* adj3 ((cervical or cervix) adj2 (cancer* or tumor* or tumour* or malig* or neoplas*)�).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
12  10 or 11
13  limit 12 to (english language and humans)
14  exp "Sensitivity and Specificity"/
15  exp Diagnostic Errors/
16  exp Diagnosis, Differential/
17  exp "Outcome and Process Assessment (Health Care)"
18  exp "Costs and Cost Analysis"
19  14 or 15 or 16 or 17 or 18
20  13 and 19
21  limit 20 to yr="2010 -Current" (635)
22  limit 13 to yr="2010 -Current" (2642)
23  limit 22 to (comparative study or controlled clinical trial or guideline or meta analysis or randomized controlled trial or systematic reviews)
24  exp Epidemiologic Studies/
25  22 and 24
26  25 not (21 or 23)

Database: Ovid MEDLINE(R) without Revisions
Search Strategy:

1  exp cervical neoplasms/
2  exp Papillomavirus Infections/
3  exp Mass Screening/
4  1 and 3
5  (screen* or ((earl* or routin*) adj2 (diagnos* or detect* or discover* or identif*))).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
6  exp biomarkers/
7  5 or 6
8  exp cervical neoplasms/di
9  7 and 8
10  4 or 9
11  (predict* adj3 ((cervical or cervix) adj2 (cancer* or tumor* or tumour* or malig* or neoplas*))).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
12  10 or 11
13  limit 12 to (english language and humans)
14  exp "Sensitivity and Specificity"/
15  exp Diagnostic Errors/
16  exp Diagnosis, Differential/
17  exp "Outcome and Process Assessment (Health Care)"/
18  exp "Costs and Cost Analysis"/
19  14 or 15 or 16 or 17 or 18
20  13 and 19
21  limit 20 to yr="2010 -Current"
22  limit 13 to yr="2010 -Current"
23  limit 22 to (comparative study or controlled clinical trial or guideline or meta analysis or randomized controlled trial or systematic reviews)
24  exp Epidemiologic Studies/
25  22 and 24
26  21 not 23

Database: EBM Reviews - Cochrane Database of Systematic Reviews
Search Strategy:
--------------------------------------------------------------------------------
1  ((screen* or biomarker* or (gene* adj3 (risk* or predispos*)) or ((earl* or routin*) adj2 (diagnos* or detect* or discover* or test* or assay* or identi*)) adj7 (hpv or human papilloma virus* or human papillomavir* or ((cervical or cervix) adj3 (cancer* or neoplas* or tumor* or tumour* or malig* or carcino*)))).mp.

Database: EBM Reviews - Cochrane Central Register of Controlled Trials
Search Strategy:
--------------------------------------------------------------------------------
1  ((screen* or biomarker* or (gene* adj3 (risk* or predispos*)) or ((earl* or routin*) adj2 (diagnos* or detect* or discover* or test* or assay* or identi*)) adj7 (hpv or human papilloma virus* or human papillomavir* or ((cervical or cervix) adj3 (cancer* or neoplas* or tumor* or tumour* or malig* or carcino*)))).mp.
Contraceptive Methods and Counseling
Database: Ovid MEDLINE(R) without Revisions
Search Strategy:
--------------------------------------------------------------------------------
1 exp Contraception/
2 exp Contraceptive Devices/
3 exp Contraception Behavior/
4 exp Family Planning Services/
5 exp preconception care/
6 1 or 2 or 3 or 4
7 limit 6 to female
8 limit 6 to male
9 8 not 7
10 6 not 9
11 limit 10 to english language
12 exp Primary Health Care/
13 women's health services/
14 exp women's health/
15 Physicians, Family/
16 exp General Practice/
17 exp General Practitioners/
18 exp Counseling/
19 12 or 13 or 14 or 15 or 16 or 17 or 18
20 11 and 19
21 limit 20 to english language
22 limit 21 to "review articles"
23 limit 21 to (meta analysis or systematic reviews)
24 22 or 23
25 limit 24 to yr="2011 -Current"
26 exp "Outcome and Process Assessment (Health Care)"
27 exp "Sensitivity and Specificity"
28 mo.fs.
29 exp vital statistics/
30 28 or 29
31 exp "Quality of Life"
32 exp Attitude to Health/
33 exp health behavior/
34 (aca or affordable care act).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
35 exp health services accessibility/
36 26 or 27 or 30 or 31 or 32 or 33 or 34 or 35
37 21 and 36
38 limit 37 to yr="2011 -Current"
39 limit 11 to (meta analysis or systematic reviews)
40 limit 11 to "review articles"
41 39 or 40
42 exp united states/
43 41 and 42
44 limit 43 to humans
45 44 not 25
46 11 and 36
47 limit 46 to yr="2011 -Current"
48 42 and 47
49 48 not 38

Database: Ovid MEDLINE(R) without Revisions
Search Strategy:
--------------------------------------------------------------------------------
1 exp Contraception/
2 exp Contraceptive Devices/
3 exp Contraception Behavior/
4 exp Family Planning Services/
5 exp preconception care/
6 1 or 2 or 3 or 4
7 limit 6 to female
8 limit 6 to male
9 8 not 7
10 6 not 9
11 limit 10 to english language
12 exp Primary Health Care/
13 women's health services/
14 exp women's health/
15 Physicians, Family/
16 exp General Practice/
17 exp General Practitioners/
18 exp Counseling/
19 12 or 13 or 14 or 15 or 16 or 17 or 18
20 11 and 19
21 limit 20 to english language
22 limit 21 to "review articles"
23 limit 21 to (meta analysis or systematic reviews)
24 22 or 23
25 limit 24 to yr="2011 -Current"
26 exp "Outcome and Process Assessment (Health Care)"/
27 exp "Sensitivity and Specificity"/
28 mo.fs.
29 exp vital statistics/
30 28 or 29
31 exp "Quality of Life"/
32 exp Attitude to Health/
33 exp health behavior/
(aca or affordable care act).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]

exp health services accessibility/

26 or 27 or 30 or 31 or 32 or 33 or 34 or 35

21 and 36

limit 37 to yr="2011 -Current"

limit 11 to (meta analysis or systematic reviews)

limit 11 to "review articles"

39 or 40

exp united states/

41 and 42

limit 43 to humans

44 not 25

46 11 and 36

limit 46 to yr="2011 -Current"

48 42 and 47

49 48 not 38

Database: Ovid MEDLINE(R) without Revisions
Search Strategy:

1 exp Contraception/
2 exp Contraceptive Devices/
3 exp Contraception Behavior/
4 exp Family Planning Services/
5 exp preconception care/
6 1 or 2 or 3 or 4
7 limit 6 to female
8 limit 6 to male
9 8 not 7
10 6 not 9
11 limit 10 to english language
12 exp Primary Health Care/
13 women's health services/
14 exp women's health/
15 Physicians, Family/
16 exp General Practice/
17 exp General Practitioners/
18 exp Counseling/
19 12 or 13 or 14 or 15 or 16 or 17 or 18
20 11 and 19
21 limit 20 to english language
22 limit 21 to "review articles"
23 limit 21 to (meta analysis or systematic reviews)
24 22 or 23
limit 24 to yr="2011 -Current"
exp "Outcome and Process Assessment (Health Care)"
exp "Sensitivity and Specificity"
mo.fs.
exp vital statistics/
28 or 29
exp "Quality of Life"
exp Attitude to Health/
exp health behavior/
(aca or affordable care act).mp.
exp health services accessibility/
26 or 27 or 30 or 31 or 32 or 33 or 34 or 35
21 and 36
limit 37 to yr="2011 -Current"
limit 6 to english language
limit 11 to (meta analysis or systematic reviews)
limit 11 to "review articles"
40 or 41
exp united states/
42 and 43
limit 44 to humans
45 not 25
11 and 36
limit 47 to yr="2011 -Current"
49 not 38

Database: Ovid MEDLINE(R) without Revisions
Search Strategy:

--------------------------------------------------------------------------------
1 exp Contraception/
2 exp Contraceptive Devices/
3 exp Contraception Behavior/
4 exp Family Planning Services/
5 exp preconception care/
6 1 or 2 or 3 or 4
7 limit 6 to female
8 limit 6 to male
9 8 not 7
10 6 not 9
11 limit 10 to english language
12 exp Primary Health Care/
13 exp women's health services/
14 exp women's health/
Physicians, Family/
exp General Practice/
exp General Practitioners/
exp Counseling/
12 or 13 or 14 or 15 or 16 or 17 or 18
11 and 19
limit 20 to english language
limit 21 to "review articles"
limit 21 to (meta analysis or systematic reviews)
22 or 23
limit 24 to yr="2011 -Current"
exp "Outcome and Process Assessment (Health Care)"
exp "Sensitivity and Specificity"
mo.fs.
exp vital statistics/
28 or 29
exp "Quality of Life"
exp Attitude to Health/
exp health behavior/
(aca or affordable care act).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
exp health services accessibility/
26 or 27 or 30 or 31 or 32 or 33 or 34 or 35
21 and 36
limit 37 to yr="2011 -Current"
limit 11 to (meta analysis or systematic reviews)
limit 11 to "review articles"
39 or 40
exp united states/
41 and 42
limit 43 to humans
44 not 25
11 and 36
limit 46 to yr="2011 -Current"
48 and 47
48 not 38

Database: EBM Reviews - Cochrane Central Register of Controlled Trials
Search Strategy:
--------------------------------------------------------------------------------
1 ((counsel* or advis* or advice or advocat*) adj7 (contracept* or (birth* adj control*) or condom* or iud* or (intrauterin* adj devic*) or (family adj plan*) or vasectom* or (tub* adj2 (ligat* or tie or tied))).mp. [mp=title, original title, abstract, mesh headings, heading words, keyword]
Database: EBM Reviews - Cochrane Database of Systematic Reviews
Search Strategy:
--------------------------------------------------------------------------------
1  ((counsel* or advis* or advice or advocat*) adj7 (contracept* or (birth* adj control*) or condom* or iud* or (intrauterin* adj devic*) or (family adj plan*) or vasectom* or (tub* adj2 (ligat* or tie or tied))).ti,ab,kw.
2  ((effectiv* or strateg* or interven* or outcom* or success* or ((primar* or family) adj2 (physician* or care)) or (general adj practi*) or (family adj medicin*)) adj10 ((counsel* or advis* or advice or advocat* or educat* or instruct*) adj7 (contracept* or (birth* adj control*) or condom* or iud* or (intrauterin* adj devic*) or (family adj plan*) or vasectom* or (tub* adj2 (ligat* or tie or tied))))).mp.
3  1 or 2

Gestational Diabetes Screening
Database: Ovid MEDLINE(R) without Revisions
Search Strategy:
--------------------------------------------------------------------------------
1  exp Diabetes, Gestational/
2  exp Mass Screening/
3  1 and 2
4  (screen* or ((earl* or routin*) adj2 (diagnos* or detect* or discover* or identif*)
5  exp biomarkers/
6  4 or 5
7  exp Diabetes, Gestational/di
8  6 and 7
9  3 or 8
10  (predict* adj3 (gestation* adj2 diabet*)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
11  9 or 10
12  limit 11 to (english language and humans)
13  exp "Sensitivity and Specificity"/
14  exp Diagnostic Errors/
15  exp Diagnosis, Differential/
16  exp "Outcome and Process Assessment (Health Care)"/
17  exp "Costs and Cost Analysis"/
18  13 or 14 or 15 or 16 or 17
19  12 and 18
20  limit 19 to yr="2012 -Current"
21  limit 12 to yr="2012 -Current"
22  limit 21 to (comparative study or controlled clinical trial or guideline or meta analysis or randomized controlled trial or systematic reviews)
23  exp Epidemiologic Studies/
24  21 and 23
25  22 or 24
26  20 or 25
**Database: EBM Reviews - Cochrane Database of Systematic Reviews**

Search Strategy:

```
1  ((screen* or biomarker* or (gene* adj3 (risk* or predispos*)) or ((earl* or routin*) adj2 (diagnos* or detect* or discover* or test* or assay* or identif*)) or predict*) adj7 (gestat* adj3 diabet*)).mp.
```

**Database: EBM Reviews - Cochrane Central Register of Controlled Trials**

Search Strategy:

```
1  ((screen* or biomarker* or (gene* adj3 (risk* or predispos*)) or ((earl* or routin*) adj2 (diagnos* or detect* or discover* or test* or assay* or identif*)) or predict*) adj7 (gestat* adj3 diabet*)).mp.
```

**Human Immunodeficiency Virus Screening and Counseling**

Database: Ovid MEDLINE(R) without Revisions

Search Strategy:

```
1  exp hiv/
2  exp hiv Infections/
3  exp Mass Screening/
4  1 and 3
5  (screen* or ((earl* or routin*) adj2 (diagnos* or detect* or discover* or identif*))).mp.
   [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
6  exp biomarkers/
7  5 or 6
8  exp hiv infections/di
9  7 and 8
10 4 or 9
11  limit 10 to (english language and humans)
12  exp "Sensitivity and Specificity"/
13  exp Diagnostic Errors/
14  exp Diagnosis, Differential/
15  exp "Outcome and Process Assessment (Health Care)"/
16  exp "Costs and Cost Analysis"/
17  12 or 13 or 14 or 15 or 16
18  11 and 17
19  limit 18 to yr="2012 -Current"
20  limit 11 to yr="2012 -Current"
21  limit 20 to (comparative study or controlled clinical trial or guideline or meta analysis or randomized controlled trial or systematic reviews)
22  exp Epidemiologic Studies/
23  20 and 22
```
24  23 not (19 or 21)

Database: Ovid MEDLINE(R) without Revisions
Search Strategy:
--------------------------------------------------------------------------------
1  exp hiv/
2  exp hiv Infections/
3  exp Mass Screening/
4  1 and 3
5  (screen* or ((earl* or routin*) adj2 (diagnos* or detect* or discover* or identif*))).mp.
   [mp=title, abstract, original title, name of substance word, subject heading word, keyword
    heading word, protocol supplementary concept word, rare disease supplementary concept word,
    unique identifier]
6  exp biomarkers/
7  5 or 6
8  exp hiv infections/di
9  7 and 8
10  4 or 9
11  limit 10 to (english language and humans)
12  exp "Sensitivity and Specificity"/
13  exp Diagnostic Errors/
14  exp Diagnosis, Differential/
15  exp "Outcome and Process Assessment (Health Care)"
16  exp "Costs and Cost Analysis"/
17  12 or 13 or 14 or 15 or 16
18  11 and 17
19  limit 18 to yr="2012 -Current"
20  limit 11 to yr="2012 -Current"
21  limit 20 to (comparative study or controlled clinical trial or guideline or meta analysis or
    randomized controlled trial or systematic reviews)
22  exp Epidemiologic Studies/
23  20 and 22
24  23 not (19 or 21)
25  19 not 21

Database: EBM Reviews - Cochrane Database of Systematic Reviews
Search Strategy:
--------------------------------------------------------------------------------
1  ((effectiv* or strateg* or interven* or outcom* or success* or ((primar* or family) adj2
    (physician* or care)) or (general adj practi*) or (family adj medicin*)) adj10 ((screen* or
    (routin* or periodic*)) adj3 (test* or detect* or diagnos* or assay*)) adj7 (aids or hiv or acquired
    immunodefic*)).mp.
2  ((screen* or ((routin* or periodic*) adj3 (test* or detect* or diagnos* or assay*)) adj7 (hiv
    or acquired immunodefic*)).mp.

151
Database: EBM Reviews - Cochrane Central Register of Controlled Trials
Search Strategy:

3  ((effectiv* or strateg* or interven* or outcom* or success* or ((primar* or family) adj2 (physician* or care)) or (general adj practi*) or (family adj medicin*)) adj10 ((counsel* or advis* or advice or advocat* or educat* or instruct*) adj7 (hiv or acquired immunodefic*)).mp.
4  (counsel* adj7 (hiv or acquired immunodefic*)).mp.
5  1 or 2 or 3 or 4

Interpersonal and Domestic Violence Screening and Counseling
Database: Ovid MEDLINE(R) without Revisions
Search Strategy:

1  exp intimate partner violence/
2  ((((intimat* or domestic* or romantic* or dating) adj3 partner*) or spous* or husband* or wife or wives or common law) adj5 (violen* or abus* or assault* or attack* or intimidat* or harass* or crime* or criminal)).mp.
3  1 or 2
4  exp Counseling/
5  exp Health Promotion/
6  exp Health Education/
7  exp Physician-Patient Relations/
8  exp Attitude to Health/
9  ((counsel* or guid* or promot* or instruct* or persuad*) adj3 (test* or screen*)).mp.
[mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
10  8 and 9
11  4 or 5 or 6 or 10
12  3 and 11
13  limit 12 to english language
14  limit 13 to female
15  limit 14 to yr="2012 -Current"
16  limit 15 to (comparative study or controlled clinical trial or guideline or meta analysis or randomized controlled trial or systematic reviews)
17  limit 3 to yr="2012 -Current"
18  limit 17 to (comparative study or controlled clinical trial or guideline or meta analysis or randomized controlled trial or systematic reviews)
19  limit 18 to female
20  limit 18 to male
21  20 not 19
22  18 not 21
23  19 or 22
24  15 or 23

Database: EBM Reviews - Cochrane Central Register of Controlled Trials
Search Strategy:
--------------------------------------------------------------------------------
1  exp intimate partner violence/
2  (((intimat* or domestic* or romantic* or dating) adj3 partner*) or spous* or husband* or wife or wives or common law) adj5 (violen* or abus* or assault* or attack* or intimidat* or harass* or crime* or criminal)).mp.
3  1 or 2
4  exp Counseling/
5  exp Health Promotion/
6  exp Health Education/
7  exp Physician-Patient Relations/
8  exp Attitude to Health/
9  ((counsel* or guid* or promot* or instruct* or persuad*) adj3 (test* or screen*)).mp.
[mp=title, original title, abstract, mesh headings, heading words, keyword] (1936)
10  8 and 9
11  4 or 5 or 6 or 10
12  3 and 11
13  limit 12 to english language
14  ((counsel* or screen* or detect* or measur* or disclos* or interview* or survey* or questionnair* or assess* or advis* or advocat* or diagnos* or determin* or identif* or interven* or prevent* or reduc*) adj7 (((intimat* or domestic* or romantic* or dating) adj3 partner*) or spous* or husband* or wife or wives or common law) adj5 (violen* or abus* or assault* or attack* or intimidat* or harass* or crime* or criminal))).mp.
15  12 or 14

Database: EBM Reviews - Cochrane Database of Systematic Reviews
Search Strategy:
--------------------------------------------------------------------------------
1  ((((intimat* or domestic* or romantic* or dating) adj3 partner*) or spous* or husband* or wife or wives or common law) adj5 (violen* or abus* or assault* or attack* or intimidat* or harass* or crime* or criminal)).ti,ab,kw.
2  ((counsel* or screen* or detect* or measur* or disclos* or interview* or survey* or questionnair* or assess* or advis* or advocat* or diagnos* or determin* or identif* or interven*
or prevent* or reduc*) adj7 (((intimat* or domestic* or romantic* or dating) adj3 partner*) or spous* or husband* or wife or wives or common law) adj5 (violen* or abus* or assault* or attack* or intimidat* or harass* or crime* or criminal))).mp.
3    1 or 2

Database: PsycINFO
Search Strategy:
--------------------------------------------------------------------------------
1   exp intimate partner violence/
2   exp domestic violence/
3   (((intimat* or domestic* or romantic* or dating) adj3 partner*) or spous* or husband* or wife or wives or common law) adj5 (violen* or abus* or assault* or attack* or intimidat* or harass* or crime* or criminal)).mp.
4        1 or 2 or 3
5   exp screening/
6   exp screening tests/
7   screen*.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
8              5 or 6 or 7
9       4 and 8
10  exp Counseling/
11  exp Health Promotion/
12  exp Health Education/
13  exp health attitudes/
14       ((counsel* or guid* or promot* or instruct* or persuad*) adj3 (test* or screen*)).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
15             13 and 14
16             10 or 11 or 12 or 15
17             4 and 16
18             9 or 17
19  limit 18 to english language
20  limit 19 to female

Sexually Transmitted Infection Counseling
Database: Ovid MEDLINE(R) without Revisions
Search Strategy:
--------------------------------------------------------------------------------
1   exp sexually transmitted infections/di, pc
2   exp sexually transmitted infections/
3   exp hiv/
4   exp Treponema pallidum/
5   exp Neisseria gonorrhoeae/
6   exp Chlamydia trachomatis/
7        2 or 3 or 4 or 5 or 6
8   exp mass screening/ or screen*.mp. or test*.mp.
exp Counseling/
exp Health Promotion/
exp Health Education/
exp Physician-Patient Relations/
exp Attitude to Health/
((counsel* or guid* or promot* or instruct* or persuad*) adj3 (test* or screen*)).mp.
[mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
15 and 16
11 or 12 or 13 or 17
10 and 18
limit 19 to english language
limit 20 to female
limit 21 to yr="2013 -Current"
limit 22 to (comparative study or controlled clinical trial or guideline or meta analysis or randomized controlled trial or systematic reviews)
24 exp "Quality of Life"/
25 exp "Quality of Health Care"/
26 exp "Costs and Cost Analysis"/
27 24 or 25 or 26
28 22 and 27
29 28 not 23
30 exp Epidemiologic Studies/
31 22 and 30

Database: EBM Reviews - Cochrane Database of Systematic Reviews
Search Strategy:
--------------------------------------------------------------------------------
1 ((counsel* or advis* or advice or advocat*) adj7 (sti or stis or syphilli* or gonorrh* or chlamyd* or (genital* adj2 herp*) or (sex* adj2 transmi* adj5 (infect* or diseas*))).mp.

Database: EBM Reviews - Cochrane Central Register of Controlled Trials
Search Strategy:
--------------------------------------------------------------------------------
1 ((counsel* or advis* or advice or advocat*) adj7 (sti or stis or syphilli* or gonorrh* or chlamyd* or (genital* adj2 herp*) or (sex* adj2 transmi* adj5 (infect* or diseas*))).mp. (130)
2 limit 1 to yr="2011 -Current"

Database: PsycINFO
Search Strategy:
--------------------------------------------------------------------------------
1 exp sexually transmitted diseases/
Well-Woman Visits
Database: Ovid MEDLINE(R)
Search Strategy:

1  (well* adj2 (woman or women) adj5 (visit* or appointment* or check-up or checkup)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
2  (wellness adj2 (physical or exam* or appointment* or visit*)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
3  (((regular* adj2 schedul*) or routine* or periodic* or annual* or yearly or year) adj5 ((doctor* or physician* or practitioner* or health* or medical* or wellness or prevent* or screen*) adj3 (assess* or checkup* or check-up* or physical or physicals or exam* or appointment* or visit*)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
4  ((routine* or annual* or yearly or (health* adj maint*)) adj2 (physical or exam* or appointment* or visit*)).mp.
5  3 or 4
6  1 or 2 or 5
7  Female/
1  (well* adj2 (woman or women) adj5 (visit* or appointment* or check-up or checkup)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
2  (wellness adj2 (physical or exam* or appointment* or visit*)）。mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
3  (((regular* adj2 schedul*) or routine* or periodic* or annual* or yearly or year) adj5 ((doctor* or physician* or practitioner* or health* or medical* or wellness or prevent* or screen*) adj3 (assess* or checkup* or check-up* or physical or physicals or exam* or appointment* or visit*)））。mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
4  ((routine* or annual* or yearly or (health* adj maint*)) adj2 (physical or exam* or appointment* or visit*)）。mp.
5  3 or 4
6  1 or 2 or 5
7  Female/
8  Male/

Database: Ovid MEDLINE(R)
Search Strategy:  
--------------------------------------------------------------------------------
1  (well* adj2 (woman or women) adj5 (visit* or appointment* or check-up or checkup)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
2  (wellness adj2 (physical or exam* or appointment* or visit*)）。mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
3  (((regular* adj2 schedul*) or routine* or periodic* or annual* or yearly or year) adj5 ((doctor* or physician* or practitioner* or health* or medical* or wellness or prevent* or screen*) adj3 (assess* or checkup* or check-up* or physical or physicals or exam* or appointment* or visit*)））。mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
4  ((routine* or annual* or yearly or (health* adj maint*)) adj2 (physical or exam* or appointment* or visit*)）。mp.
5  3 or 4
6  1 or 2 or 5
7  Female/
8  Male/
9 8 not 7
10 6 not 9
11 limit 10 to English language
12 limit 11 to (meta analysis or "review" or systematic reviews)
13 limit 12 to yr="2011 -Current"
14 exp "Outcome and Process Assessment (Health Care)"
15 exp "Sensitivity and Specificity"
16 mo.fs.
17 exp vital statistics/
18 16 or 17
19 exp "Quality of Life"
20 exp Attitude to Health/
21 exp health behavior/
22 14 or 15 or 18 or 19 or 20 or 21
23 11 and 22
24 limit 23 to yr="2011 -Current"
25 limit 24 to English language
26 (aca or affordable care act).mp. [mp=title, abstract, original title, name of substance word,
subject heading word, keyword heading word, protocol supplementary concept word, rare
disease supplementary concept word, unique identifier]
27 10 and 26
28 13 and 22
29 1 or 2 or 24 or 27
30 limit 29 to English language
31 limit 30 to yr="2011 -Current"
32 31 not 28
33 exp United States/
34 32 and 33

Database: EBM Reviews - Cochrane Database of Systematic Reviews
Search Strategy:
-----------------------------------------------------------------------------------------------
1  (well* adj2 (woman or women) adj5 (visit* or appointment* or check-up or checkup)).mp. [mp=title, abstract, full text, keywords, caption text]
2  (wellness adj2 (physical or exam* or appointment* or visit*) adj5 (woman or women or
female* or mother*)).mp.
3  1 or 2
4  ((woman or women or female* or mother*) adj7 (((regular* adj2 schedul*) or routine* or periodic* or annual* or yearly or year) adj5 ((doctor* or physician* or practitioner* or health* or medical* or wellness or prevent* or screen*) adj3 (assess* or checkup* or check-up* or physical or physicals or exam* or appointment* or visit*)))).mp.
5  ((woman or women or female* or mother*) adj5 ((routine* or annual* or yearly or (health*
adj maint*))) adj2 (physical or exam* or appointment* or visit*))).mp.
6  4 or 5
7  6 not 3
Database: EBM Reviews - Cochrane Central Register of Controlled Trials
Search Strategy:
--------------------------------------------------------------------------------
1  (well* adj2 (woman or women) adj5 (visit* or appointment* or check-up or checkup)).mp. [mp=title, original title, abstract, mesh headings, heading words, keyword]
2  (wellness adj2 (physical or exam* or appointment* or visit*) adj5 (woman or women or female* or mother*)).mp.
3  1 or 2
4  ((woman or women or female* or mother*) adj7 (((regular* adj2 schedul*) or routine* or periodic* or annual* or yearly or year) adj5 ((doctor* or physician* or practitioner* or health* or medical* or wellness or prevent* or screen*) adj3 (assess* or checkup* or check-up* or physical or physicals or exam* or appointment* or visit*)))).mp.
5  ((woman or women or female* or mother*) adj5 ((routine* or annual* or yearly or (health* adj maint*)) adj2 (physical or exam* or appointment* or visit*)�).mp.
6  4 or 5
7  6 not 3

Database: PsycINFO
Search Strategy:
--------------------------------------------------------------------------------
1  (well* adj2 (woman or women) adj5 (visit* or appointment* or check-up or checkup)).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
2  (wellness adj2 (physical or exam* or appointment* or visit*) adj5 (woman or women or female* or mother*)).mp.
3  1 or 2
4  (((regular* adj2 schedul*) or routine* or periodic* or annual* or yearly or year) adj5 ((doctor* or physician* or practitioner* or health* or medical* or wellness or prevent* or screen*) adj3 (assess* or checkup* or check-up* or physical or physicals or exam* or appointment* or visit*)))).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
5  ((routine* or annual* or yearly or (health* adj maint*)) adj2 (physical or exam* or appointment* or visit*)�).mp.
6  4 or 5
7  exp Human Females/
8  6 and 7
9  ((woman or women or female* or mother*) adj7 (((regular* adj2 schedul*) or routine* or periodic* or annual* or yearly or year) adj5 ((doctor* or physician* or practitioner* or health* or medical* or wellness or prevent* or screen*) adj3 (assess* or checkup* or check-up* or physical or physicals or exam* or appointment* or visit*)))).mp.
10  ((woman or women or female* or mother*) adj5 ((routine* or annual* or yearly or (health* adv maint*)) adj2 (physical or exam* or appointment* or visit*)�).mp.
11  9 or 10
12  8 or 11
13  12 not 3
14  exp health promotion/
15 exp prevention/
16 exp Early Intervention/
17 exp Public Health/
18 14 or 15 or 16 or 17
19 13 and 18