Screening for Gynecologic Conditions With Pelvic Examination US Preventive Services Task Force Recommendation Statement

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Screening for Gynecologic Conditions With Pelvic Examination

The US Preventive Services Task Force (USPSTF) makes recommendations about the effectiveness of specific preventive care services for patients without obvious related signs or symptoms. It bases its recommendations on the evidence of both the benefits and harms of the service and an assessment of the balance. The USPSTF does not consider the costs of providing a service in this assessment.

The USPSTF recognizes that clinical decisions involve more considerations than evidence alone. Clinicians should understand the evidence but individualize decision making to the specific patient or situation. Similarly, the USPSTF notes that policy and coverage decisions involve considerations in addition to the evidence of clinical benefits and harms.

Rationale

Importance

Many conditions that can affect women's health are often evaluated through pelvic examination. These conditions include but are not limited to malignant diseases, such as ovarian, uterine, vaginal, and cervical cancer; infectious diseases, such as bacterial vaginosis, candidiasis, genital warts, genital herpes, trichomoniasis, and pelvic inflammatory disease; and other benign conditions, such as cervical polyps, endometriosis, ovarian cysts, dysfunction of the pelvic wall and floor, and uterine fibroids. Pelvic examination is a common part of the physical examination; in 2012, an
estimated 44.2 million pelvic examinations were performed in the United States. Although the pelvic examination is a common part of the physical examination, it is unclear whether performing screening pelvic examinations in asymptomatic women reduces morbidity and mortality.

The USPSTF has made separate recommendations on screening for cervical cancer, gonorrhea, and chlamydia using tests that are often performed during a pelvic examination (eg, Pap smear, human papillomavirus test, and nucleic acid amplification tests); in this recommendation statement, the USPSTF seeks to understand the utility of performing screening pelvic examinations for other gynecologic conditions. Although the USPSTF sought evidence on the effectiveness of pelvic examination to screen for all asymptomatic gynecologic conditions other than cervical cancer, chlamydia, and gonorrhea, it was only able to identify limited evidence on its accuracy to detect ovarian cancer, bacterial vaginosis, genital herpes, and trichomoniasis.

Detection

The pelvic examination may include any of the following components, alone or in combination: assessment of the external genitalia, internal speculum examination, bimanual palpation, and rectovaginal examination. The USPSTF found inadequate evidence on the accuracy of pelvic examination to detect a range of gynecologic conditions. Limited evidence from studies evaluating the use of screening pelvic examination alone for ovarian cancer detection generally

<table>
<thead>
<tr>
<th>Grade</th>
<th>Definition</th>
<th>Suggestions for Practice</th>
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<tbody>
<tr>
<td>A</td>
<td>The USPSTF recommends the service. There is high certainty that the net benefit is substantial.</td>
<td>Offer or provide this service.</td>
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<tr>
<td>B</td>
<td>The USPSTF recommends the service. There is high certainty that the net benefit is moderate, or there is moderate certainty that the net benefit is moderate to substantial.</td>
<td>Offer or provide this service.</td>
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<td>C</td>
<td>The USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small.</td>
<td>Offer or provide this service for selected patients depending on individual circumstances.</td>
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<td>D</td>
<td>The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.</td>
<td>Discourage the use of this service.</td>
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Statement

The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined. Read the Clinical Considerations section of the USPSTF Recommendation Statement. If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.
Table 1. Screening for Gynecologic Conditions With Pelvic Examination: Clinical Summary

| Population | Asymptomatic, nonpregnant adult women who are not at increased risk for any specific gynecologic condition |
| Recommendation | No recommendation. Grade: I (insufficient evidence) |
| Note: This statement does not apply to specific disorders for which the USPSTF already recommends screening (ie, screening for cervical cancer with a Pap smear, screening for gonorrhea and chlamydia). |

Table 2. Screening Tests

| Screening Tests | The pelvic examination may include any of the following components, alone or in combination: assessment of the external genitalia, internal speculum examination, bimanual palpation, and rectovaginal examination. |
| Balance of Benefits and Harms | The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of performing screening pelvic examinations in asymptomatic women for the early detection and treatment of a range of gynecologic conditions. |
| Other Relevant USPSTF Recommendations | The USPSTF has made recommendations on screening for cervical cancer, ovarian cancer, gonorrhea, and chlamydia, as well as counseling to prevent sexually transmitted infections. These recommendations are available on the USPSTF website (https://www.uspreventiveservicestaskforce.org). |

For a summary of the evidence systematically reviewed in making this recommendation, the full recommendation statement, and supporting documents, please go to https://www.uspreventiveservicestaskforce.org.

Figure 2. Screening for Gynecologic Conditions With Pelvic Examination: Clinical Summary

4 Very few studies on screening for other gynecologic conditions with pelvic examination alone have been conducted, and the USPSTF found that these studies have limited generalizability to the current population of asymptomatic women seen in primary care settings in the United States.

Benefits of Screening

The USPSTF found inadequate evidence on the benefits of screening for a range of gynecologic conditions with pelvic examination. No studies were identified that evaluated the benefit of screening with pelvic examination on all-cause mortality, disease-specific morbidity or mortality, or quality of life.

Harms of Screening

The USPSTF found inadequate evidence on the harms of screening for a range of gynecologic conditions with pelvic examination. A few studies reported on false-positive rates for ovarian cancer, ranging from 1.2% to 8.6%, and false-negative rates, ranging from 0% to 100%. Among women who had abnormal findings on pelvic examination, 5% to 36% went on to have surgery. Very few studies reported false-positive and false-negative rates for other gynecologic conditions. No studies quantified the amount of anxiety associated with screening pelvic examinations.

USPSTF Assessment

The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of performing screening pelvic examinations in asymptomatic women for the early detection and treatment of a range of gynecologic conditions. Evidence is lacking and of poor quality, and the balance of benefits and harms cannot be determined.

Clinical Considerations

Patient Population Under Consideration

This recommendation applies to asymptomatic women 18 years and older (Figure 2) who are not at increased risk for any specific gynecologic conditions, such as ovarian or cervical cancer. The recommendation does not apply to pregnant women or adolescents.

Suggestions for Practice Regarding the I Statement

Potential Preventable Burden

Numerous gynecologic conditions may be detected during a screening pelvic examination. These include malignant diseases, such as ovarian, uterine, vaginal, and cervical cancer; infectious diseases, such as bacterial vaginosis, candidiasis, genital warts, genital herpes, trichomoniasis, and pelvic inflammatory disease; and other benign conditions, such as cervical polyps, endometriosis, ovarian cysts, dysfunction of the pelvic wall and floor, and uterine fibroids.

The accuracy of detecting and the benefit of treating some of these conditions early, while women are asymptomatic, is unknown. No studies evaluated the effectiveness of early diagnosis and treatment of screen-detected, asymptomatic gynecologic conditions compared with the diagnosis and treatment of symptomatic gynecologic conditions. It is also unknown whether performing screening pelvic examinations more frequently than every 3 to 5 years (the recommended screening intervals for cervical cancer) is beneficial. Although it is common practice to perform a pelvic examination as part of an annual physical examination, the benefit of performing a pelvic examination at this interval is unclear. The benefit of using pelvic examination alone to screen for gynecologic conditions other than cervical cancer, gonorrhea, and chlamydia is also unknown.

Pap indicates Papanicolaou.
Potential Harms
The USPSTF found limited evidence on the harms of screening with pelvic examination. Harms reported in studies included false-positive and false-negative results. Available evidence reports false-positive rates for ovarian cancer of 1.2% to 8.6% and false-negative rates of 0% to 100%.4 Pelvic examination screening also could result in unnecessary diagnostic workup and treatment. In particular, there is a concern for potential invasive diagnostic procedures and treatment of ovarian cancer (such as surgery) that could result from evaluating abnormal findings on pelvic examination. In the reviewed studies, approximately 5% to 36% of women who had abnormal pelvic examination findings went on to have surgery. The potential association between urinary tract infections and pelvic examinations was explored in a single study, with inconclusive results.5 Additional theoretical harms of pelvic examination include psychological harms (anxiety), pain and discomfort from the examination, and the potential for these harms to serve as a barrier for women to receive medical care.

In the absence of clear evidence on the balance of benefits and harms of using pelvic examination to screen for asymptomatic gynecologic conditions, clinicians are encouraged to consider the patient’s risk factors for various gynecologic conditions and the patient’s values and preferences, and engage in shared decision making with the patient to determine whether to perform a pelvic examination.

Current Practice
According to the National Ambulatory Medical Care Survey, an estimated 44.2 million pelvic examinations were performed in 2012.1 In a 2010-2011 nationally representative survey of obstetricians and gynecologists, almost all surveyed clinicians indicated that they would perform a bimanual examination on asymptomatic patients during routine visits.7 According to another survey performed in 2009, 78% of surveyed clinicians (including obstetricians/gynecologists, family or general practitioners, and internists) believed that pelvic examination is useful for screening for gynecologic cancer in asymptomatic women; approximately 50% to 60% reported believing that pelvic examination is useful for cervical cancer screening, 49% to 70% for ovarian cancer (70% of obstetrician/gynecologists vs 49% to 50% of internists and family practitioners), 39% to 45% for uterine cancer, 57% to 62% for vaginal cancer, and 53% to 62% for vulvar cancer (estimates are based on graphic display of data; exact numbers were not provided).8 Nearly all surveyed clinicians (97%) believed that the pelvic examination included bimanual examination, while most (69%) believed that the pelvic examination included rectovaginal examination.8

Other Considerations
Research Needs and Gaps
The USPSTF recognizes that research on the effectiveness of the screening pelvic examination is difficult, given that multiple conditions could potentially be detected with this single preventive service. However, in reviewing the currently available evidence on the benefits and harms of performing screening pelvic examinations in asymptomatic adult women, the USPSTF identified the following critical evidence gaps. Studies evaluating the accuracy and effectiveness of screening pelvic examination to detect conditions other than ovarian cancer, bacterial vaginosis, genital herpes, and trichomoniasis are lacking. Studies reporting on the harms of screening with pelvic examination (including quantified psychological harms) in asymptomatic women in primary care are also lacking.

Screening Tests
For the purposes of this recommendation, the term “pelvic examination” includes any of the following components, alone or in combination: assessment of the external genitalia, internal speculum examination, bimanual palpation, and rectovaginal examination.

Useful Resources
Screening for cervical cancer, gonorrhea, and chlamydia are not included in this recommendation statement on screening pelvic examinations because they are already addressed in separate USPSTF recommendations.2,3 Screening for ovarian cancer with preventive services other than pelvic examination is addressed in the USPSTF’s recommendation on screening for ovarian cancer9; the USPSTF also has recommendations on counseling to prevent sexually transmitted infections.10 The Women’s Preventive Services Guidelines, supported by the Health Resources & Services Administration, is another resource.11

Discussion
Burden of Disease
Given the range of gynecologic conditions that could be detected with pelvic examination, the burden of disease varies depending on the specific condition. Some conditions, such as vaginal cancer, are rare, with an incidence rate of 0.7 cases per 100,000 women.4 Other conditions, such as candidiasis, are relatively common, with nearly 75% of adult women reporting at least 1 occurrence.4 Associated morbidity and mortality can also vary. Some conditions, such as ovarian cancer, are associated with a high mortality rate (5-year survival rate of 46.2%), while other conditions, such as candidiasis, have no known associated mortality. More information on the burden and epidemiology of the numerous gynecologic conditions potentially detected by pelvic examination is available in Table 1 of the accompanying systematic evidence review.4
Accuracy of Screening Tests

The USPSTF found little evidence on the accuracy of screening pelvic examinations to detect various conditions; 4 studies (n = 26,432) reported on ovarian cancer, 2 studies (n = 930) on bacterial vaginosis, 1 study (n = 779) on genital herpes, and 1 study (n = 779) on trichomoniasis.

Of the 4 studies reporting on detection of ovarian cancer, the largest was the Prostate, Lung, Colorectal, and Ovarian (PLCO) Cancer Screening Trial, conducted in the United States. The PLCO trial, a good-quality population-based, randomized trial, recruited women aged 55 to 74 years (mean age, 62.9 years) without a history of cancer. It evaluated screening for ovarian cancer with ultrasonography and blood testing for the tumor marker cancer antigen 125 but originally included palpation of the ovaries in its screening protocol. The ovarian palpation component was discontinued 5 years into the study because no cases of ovarian cancer were detected solely by bimanual palpation of the ovaries. In a subanalysis that evaluated 20,872 participants who underwent ovarian palpation at least once, the yield of screening was 23 cancer cases (0.1%) detected over 1 year of follow-up and 72 cancer cases (0.3%) detected over 1 to 5 years of follow-up (Paul Pinsky, PhD, National Cancer Institute, written communication, May 2, 2016). Over multiple rounds of screening (mean number, 2.4 [range, 1-4]), 96.7% of the ovarian cancer cases identified during the trial were not detected by palpation. The reported sensitivity and specificity for detection of ovarian cancer over 1 to 5 years of follow-up in the PLCO trial was 2.8% (95% CI, 0.6%-8.6%) and 98.8% (95% CI, 98.7%-99.0%), respectively. The other 3 fair-quality studies were conducted in Greece, Australia, and the United Kingdom and were generally much smaller (n = 1010 to 2550). Outcomes were reported at 1 year of follow-up, and the range of sensitivity and specificity was 0% to 100% and 91.4% to 98.4%, respectively.

The 4 studies that reported on the accuracy of pelvic examination to detect various infectious diseases (bacterial vaginosis, genital herpes, and trichomoniasis) were all fair-quality and conducted in the United States. One study was conducted in a hospital setting, while the other 3 were conducted in sexually transmitted infection clinics. It is important to note that given the settings of these studies, participants were more likely to represent higher-risk, symptomatic populations compared with women generally seen in primary care. The reported yield of screening was 38.7% to 47.0% of bacterial vaginosis cases, 47.8% of genital herpes cases, and 15.2% of trichomoniasis cases. Depending on the specific clinical sign used in screening, reported sensitivity ranged from 2.3% to 78.8% for bacterial vaginosis, from 14.2% to 19.6% for genital herpes, and from 1.7% to 59.2% for trichomoniasis. Specificity ranged from 48.4% to 100% for bacterial vaginosis, from 97.1% to 97.5% for genital herpes, and from 72.0% to 100% for trichomoniasis.

Effectiveness of Early Detection

No good- or fair-quality studies directly evaluated the effectiveness of screening pelvic examinations in asymptomatic, nonpregnant adult women to improve quality of life, reduce disease-specific morbidity, or reduce disease-specific or all-cause mortality.

Potential Harms of Screening

The USPSTF found little evidence on the potential harms of screening pelvic examination. Studies reporting on the accuracy of screening pelvic examination to detect various gynecologic conditions also reported on false-positive and false-negative rates, which could lead to important harms due to missed diagnoses or unnecessary and potentially harmful procedures and treatment. The false-positive and false-negative rates at 1 year of follow-up in the PLCO trial subanalyses were 1.2% (95% CI, 1.0%-1.3%) and 95.7% (95% CI, 81.4%-99.5%), respectively. False-positive and false-negative rates in the other 3 ovarian cancer studies ranged from 1.6% to 8.6% and 0% to 100%, respectively. The 4 studies reporting on the accuracy of screening with pelvic examination for ovarian cancer also reported the percentage of patients with positive results who subsequently underwent surgery, which overall ranged from 5% to 36%. Based on the PLCO trial subanalyses, 11.2% of women who had a positive finding on palpation examination over up to 4 rounds of annual screening but did not ultimately receive an ovarian cancer diagnosis underwent surgery (Paul Pinsky, PhD, National Cancer Institute, written communication, May 2, 2016). Depending on the specific clinical sign used to detect various infectious diseases, the false-positive rate ranged from 0% to 46.1% for bacterial vaginosis, from 2.5% to 2.9% for genital herpes, and from 0% to 28.0% for trichomoniasis. The false-negative rate ranged from 21.2% to 97.7% for bacterial vaginosis, from 80.4% to 85.8% for genital herpes, and from 40.8% to 98.3% for trichomoniasis. Given the uncertainty regarding the accuracy of performing screening pelvic examinations to detect a range of gynecologic conditions, there is the potential for false-positive findings to cause harms by leading to unnecessary and invasive evaluations, including surgery; there is also the potential for false-negative findings to cause harms by providing false reassurance when clinically important conditions are actually present. One exploratory study (n = 150) reported on urinary tract infections in patients undergoing pelvic examination; however, the study was underpowered to detect any significant difference. The USPSTF searched for but did not find any studies that quantified harms of anxiety or other psychological harms associated with screening pelvic examination.
Estimate of Magnitude of Net Benefit

Overall, the USPSTF found inadequate evidence on screening pelvic examinations for the early detection and treatment of a range of gynecologic conditions in asymptomatic, nonpregnant adult women. No studies directly evaluated the effectiveness of screening pelvic examinations to improve health outcomes such as quality of life, morbidity, or mortality. Few studies reported on the accuracy of screening pelvic examination; among the range of possible gynecologic conditions that could be detected with pelvic examination, only 4 were evaluated in published studies, often in only a single study. Although studies on detection of ovarian cancer often recruited participants from the community, participants in studies evaluating detection of infectious diseases came from sexually transmitted infection clinics, whose populations are likely more symptomatic and at higher risk for disease than the typical primary care population, thus making the applicability of this evidence to primary care populations unclear. Overall, the current available evidence is insufficient for the USPSTF to determine the net balance of benefits and harms of screening pelvic examinations, and the USPSTF cannot recommend for or against performing screening pelvic examinations in asymptomatic, nonpregnant adult women.

Response to Public Comment

A draft version of this recommendation statement was posted for public comment on the USPSTF website from June 28, 2016, to July 25, 2016. One concern expressed in the comments was the perception that the USPSTF was recommending against performing screening pelvic examinations and therefore against screening for cervical cancer. The USPSTF has clarified that it is recommending neither for nor against screening with pelvic examination for gynecologic conditions other than cervical cancer, gonorrhea, or chlamydia. The evidence on performing pelvic examinations to screen for conditions other than cervical cancer, gonorrhea, or chlamydia is currently lacking, and the USPSTF is unable to determine the overall balance of benefits and harms. However, as it has previously, the USPSTF continues to recommend screening for cervical cancer, gonorrhea, and chlamydia in separate recommendations. Some comments also expressed concern that the USPSTF based its recommendation on costs. The USPSTF has clarified that it does not consider the costs of a preventive service when determining a recommendation grade; it bases its recommendations on the quality and strength of the available evidence about the potential benefit and harms of a preventive service. Comments also expressed concern that the USPSTF did not sufficiently consider the harms of performing pelvic examinations and that the USPSTF should have recommended against performing them. The USPSTF reviewed all available relevant studies that reported on harms of pelvic examinations. Too few studies were available for the USPSTF to determine the net benefit or harm of performing screening pelvic examinations.

Recommendations of Others

Across various organizations, guidelines range from recommending against performing screening pelvic examinations to recommending that they be performed annually. The American College of Physicians recommends against performing screening pelvic examinations in asymptomatic, nonpregnant adult women.22 Based on the American College of Physicians’ review and recommendation, the American Academy of Family Physicians also concluded that performing screening pelvic examinations in asymptomatic, nonpregnant adult women is not recommended.23 The American College of Obstetricians and Gynecologists recommends performing pelvic examinations annually in all patients 21 years and older.24 While it found no evidence to support or refute the benefit of annual pelvic examination or speculum and bimanual examination in asymptomatic, low-risk patients, it concluded that the decision to perform a complete examination at the time of the periodic health examination should be a shared decision between the patient and clinician. The Well-Woman Task Force, convened by the American College of Obstetricians and Gynecologists in 2013, recommends that for women 21 years and older, external examination may be performed annually and that inclusion of speculum examination, bimanual examination, or both in otherwise healthy women should be a shared, informed decision between patient and clinician. The Well-Woman Task Force also recommends speculum examination, bimanual examination, or both for asymptomatic patients with specific indications (eg, intrauterine device placement or cervical cancer screening).25

Author Contributions: Dr Bibbins-Domingo had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. The USPSTF members contributed equally to the recommendation statement.

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REFERENCES