

Screening Pelvic Examination in Adult Women: A Clinical Practice Guideline From the American College of Physicians

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Description: The American College of Physicians (ACP) developed this guideline to present the evidence and provide clinical recommendations on the utility of screening pelvic examination for the detection of pathology in asymptomatic, nonpregnant, adult women.

Methods: This guideline is based on a systematic review of the published literature in the English language from 1946 through January 2014 identified using MEDLINE and hand-searching. Evaluated outcomes include morbidity; mortality; and harms, including overdiagnosis, overtreatment, diagnostic procedure–related harms,

fear, anxiety, embarrassment, pain, and discomfort. The target audience for this guideline includes all clinicians, and the target patient population includes asymptomatic, nonpregnant, adult women. This guideline grades the evidence and recommendations using the ACP’s clinical practice guidelines grading system.

Recommendation: ACP recommends against performing screening pelvic examination in asymptomatic, nonpregnant, adult women (strong recommendation, moderate-quality evidence).

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Pelvic examination is often conducted in asymptomatic women to screen for pathology. The examination consists of inspection of the external genitalia; speculum examination of the vagina and cervix; bimanual examination of the adnexa, uterus, ovaries, and bladder; and sometimes rectal or rectovaginal examination. Performing routine pelvic examination adds both direct costs to the health care system and opportunity costs. The total annual cost of preventive gynecologic examinations and associated laboratory and radiologic services in the United States is estimated to be \$2.6 billion (1). Medicare payments from 2013 were \$38.11 for a screening pelvic examination and \$45.93 for collection of a Papanicolaou (Pap) smear specimen (2). Pathologic conditions that are potentially detectable on the pelvic examination include cancer, infections, and asymptomatic pelvic inflammatory disease.

For the purpose of this article, pelvic examination means the speculum and bimanual examination; it does not include obtaining a Pap smear for cervical cancer screening, which is not considered in this guideline. When screening for cervical cancer, the recommended examination should be limited to visual inspection of the cervix and cervical swabs for cancer and human papillomavirus. However, pelvic examination is often performed in women who are not due for screening for cervical cancer. Many women and clinicians believe that pelvic examination should be part of annual wellness visits for women (1).

The purpose of this American College of Physicians (ACP) guideline is to present the available evidence on

screening for pathology using pelvic examination in adult, asymptomatic, average-risk, nonpregnant women. The target audience for this guideline includes all clinicians, and the target patient population includes asymptomatic, nonpregnant, adult women. These recommendations are based on a background article (3) and a systematic evidence review sponsored by the Minneapolis Department of Veterans Affairs Health Care System’s Evidence-based Synthesis Program Center (4).

METHODS

The evidence review was conducted by the Minneapolis Veterans Affairs Health Care System’s Evidence-based Synthesis Program Center to address the following key questions:

1. How accurate is the screening pelvic examination for detection of cancer (other than cervical), pelvic inflammatory disease, or other benign gynecologic conditions?
2. What are the benefits (reduced mortality and morbidity rates) and harms (overdiagnosis, overtreatment, or diagnostic procedure–related) of the routine screening pel-

See also:

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* This paper, written by Amir Qaseem, MD, PhD; Linda L. Humphrey, MD, MPH; Russell Harris, MD, MPH; Melissa Starkey, PhD; and Thomas D. Denberg, MD, PhD, was developed for the Clinical Guidelines Committee of the American College of Physicians. Individuals who served on the Clinical Guidelines Committee from initiation of the project until its approval were: Thomas D. Denberg, MD, PhD (*Chair*); Michael J. Barry, MD; Molly Cooke, MD; Paul Dallas, MD; Nick Fitterman, MD; Mary Ann Forcica, MD; Russell P. Harris, MD, MPH; Linda L. Humphrey, MD, MPH; Tanveer P. Mir, MD; Holger J. Schünemann, MD, PhD; J. Sanford Schwartz, MD; Paul Shekelle, MD, PhD; and Timothy Wilt, MD, MPH. Approved by the ACP Board of Regents on 7 April 2014.

Table. The American College of Physicians' Guideline Grading System*

| Quality of Evidence | Strength of Recommendation | |
|--|--|--|
| | Benefits Clearly Outweigh Risks and Burden or Risks and Burden Clearly Outweigh Benefits | Benefits Finely Balanced With Risks and Burden |
| High | Strong | Weak |
| Moderate | Strong | Weak |
| Low | Strong | Weak |
| Insufficient evidence to determine net benefits or risks | | |

* Adopted from the classification developed by the GRADE (Grading of Recommendations Assessment, Development, and Evaluation) workgroup.

vic examination performed for the detection of cancer (other than cervical), pelvic inflammatory disease, or other gynecologic conditions?

3. What are the examination-related harms and indirect benefits of performing screening pelvic examinations in asymptomatic women? Do these harms vary by patient or provider characteristics?

The literature search included English-language studies published from 1946 to January 2014 identified by using MEDLINE. Additional information came from hand-searching, the “Related Citations” feature of PubMed, and suggestions by members of the technical expert panel and peer reviewers. Assessed outcomes include mortality; morbidity; and harms, including overdiagnosis, overtreatment, diagnostic procedure–related harms, fear, anxiety, embarrassment, pain, and discomfort. Studies were conducted in the outpatient setting. The quality of studies addressing key question 1 was evaluated by using a modification of the QUADAS (Quality Assessment of Diagnostic Accuracy Studies) tool (5, 6). The quality of the survey studies for key question 3 was assessed by evaluating the population, survey instrument, and analysis of findings (4). For additional information, including inclusion and exclusion criteria, refer to the evidence report (4) and article (3).

This guideline rates the evidence and recommendations using the ACP’s guideline grading system (Table). Details of the ACP guideline development process can be found in ACP’s methods paper (7).

DIAGNOSTIC ACCURACY OF PELVIC EXAMINATION

No studies were identified that addressed the diagnostic accuracy of the pelvic examination for asymptomatic pelvic inflammatory disease, gynecologic cancer other than cervical or ovarian cancer, or benign conditions. Evidence for the diagnostic accuracy of the pelvic examination for detecting ovarian cancer and bacterial vaginosis is summarized in the following 2 sections.

Detection of Ovarian Cancer

Three cohort studies (8–10) assessed the diagnostic accuracy of the pelvic examination for detecting ovarian cancer in asymptomatic women (5633 women, mean age 51.0 to 58.1 years). Women at increased genetic risk for ovarian cancer were excluded from these studies. The studies combined found only 4 cases of ovarian cancer over 1 year, with positive predictive values from 0% to 3.6% indicating that 96.7% to 100% of abnormal pelvic examinations did not identify ovarian cancer. In addition, in a large randomized, controlled trial of screening for ovarian cancer with transvaginal ultrasonography and CA-125 involving 78 000 women, the bimanual pelvic examination was dropped after 5 years because no cancer was detected solely by this examination (11).

Detection of Bacterial Vaginosis

One prospective observational study (269 participants) (12) compared the Amsel criteria for screening for bacterial vaginosis with the reference standard of Gram staining. According to the Amsel criteria, a diagnosis of bacterial vaginosis can be made if vaginal secretions obtained by swab during the pelvic examination contain 3 of the 4 following characteristics: thin, homogeneous consistency; pH greater than 4.5; presence of clue cells on microscopic evaluation; and release of amine odor after the addition of a base. The study reported that the Amsel criteria had a sensitivity of 69% and specificity of 93% for detecting bacterial vaginosis. Of note, the study included both symptomatic and asymptomatic women, with a prevalence of bacterial vaginosis that was greater than typically reported.

BENEFITS OF ROUTINE PELVIC EXAMINATION

The clinical benefits that were evaluated included reduced mortality and morbidity rates. No studies evaluated the potential indirect benefit of annual pelvic examination being an incentive for women to access health care and eventually receive recommended gynecologic services, such as contraception, screening for sexually transmitted infections, or other nongynecologic care.

Ovarian Cancer

The PLCO (Prostate, Lung, Colorectal and Ovarian) trial screened with bimanual pelvic examination for 5 years, in addition to CA-125 and transvaginal ultrasonography, and found no reduction in ovarian cancer (or other cancer) mortality rates associated with the pelvic examination or the 3 methods combined (11). No other studies assessed the benefits of pelvic examination for reduction of ovarian cancer morbidity or mortality rates.

Other Cancer

Although no studies explicitly evaluated the effect of the screening pelvic examination on nonovarian and non-cervical cancer morbidity or mortality rates, the PLCO trial did not report any reduction in these outcomes, nor did cohort studies of pelvic examination to detect ovarian

cancer report detection of any nonovarian and noncervical cancer (11). No other studies assessed the benefits of pelvic examination on other cancer.

Pelvic Inflammatory Disease, Bacterial Vaginosis, and Other Benign Conditions

No studies assessed the benefits of pelvic examination for these conditions.

HARMS OF PELVIC EXAMINATION

Examination-Related Harms

The evaluated harms included fear, anxiety, embarrassment, pain, and discomfort. Physical harms may include urinary tract infections and symptoms, such as dysuria and frequent urination. Fourteen surveys (13–26) and 1 longitudinal cohort study (27) assessed women's attitudes about, and experiences with, pelvic examination (13 000 participants from 6 countries). Most studies included only women in their reproductive years. The overall quality of the studies was low. Women who reported pain or discomfort during the pelvic examination ranged from 11% to 60% (median, 35%; 8 studies including 4576 participants), and 10% to 80% reported fear, embarrassment, or anxiety (median, 34%; 7 studies including 10 702 participants). Women who experienced pain or discomfort during their examination were less likely to have a return visit than those who did not (5 out of 5 studies reporting this relationship) (14, 16, 20, 21, 27).

Procedure-Related Harms

The evaluated harms included false reassurance, overdiagnosis, overtreatment, and diagnostic procedure-related harms. The evidence review identified no studies that addressed these harms in asymptomatic, nonpregnant women. Indirect evidence from 1 study on the use of pelvic examination to detect ovarian cancer (10) showed that pelvic examination led to unnecessary surgery in 1.5% of women screened (29 out of 2000).

Variation in Harms According to Patient Characteristics

The evidence review evaluated data on how patient factors, including demographic characteristics, physical traits, history of sexual trauma or posttraumatic stress disorder (PTSD), and veteran status, influenced distress or harms.

Obesity

The evidence review identified 2 low-quality studies that evaluated body weight (28, 29), finding that very overweight women may receive fewer pelvic examinations because of embarrassment than moderately overweight or normal-weight women (28). Overweight women were more likely than nonoverweight women to feel embarrassment and disrespect during a gynecology visit (28).

History of Sexual Violence

Evidence from 9 low-quality studies was mixed on use of gynecologic services among women with a history of sexual violence (30–32). Two (30, 33) studies reported that fear, anxiety, or embarrassment were greater among women with a history of sexual abuse, whereas 2 studies (33, 34) showed a greater rate of pain and discomfort during the examination among women with a history of sexual abuse. Two studies (34, 35) showed that women with a history of sexual violence who were also diagnosed with PTSD experienced more distress, fear, and embarrassment than women without PTSD, regardless of sexual violence history.

Variation in Harms According to Provider Characteristics

The evidence review identified no studies that evaluated the relationship between provider characteristics and harms associated with the pelvic examination.

SUMMARY

Pelvic examination is commonly used in asymptomatic, nonpregnant, adult women to screen for pathology. Evidence shows that the diagnostic accuracy of pelvic examination for detecting ovarian cancer or bacterial vaginosis is low. The PLCO trial and cohort studies suggest that the screening pelvic examination rarely detects noncervical cancer or other treatable conditions and was not associated with improved health outcomes. The PLCO trial found no reduction of ovarian cancer mortality rates by screening with pelvic examination or by screening with CA-125 or transvaginal ultrasonography, both of which are more sensitive for detecting ovarian cancer than the pelvic examination itself. Thus, there is indirect evidence that pelvic examination (as distinct from cervical cancer screening) in asymptomatic, adult women does not reduce morbidity or mortality rates. No studies were identified that addressed the diagnostic accuracy of the pelvic examination for other gynecologic conditions, such as asymptomatic pelvic inflammatory disease, benign conditions, or gynecologic cancer other than cervical or ovarian cancer. Many false-positive findings are associated with pelvic examination, with attendant psychological and physical harms, as well as harms associated with the examination itself. Harms of pelvic examination include unnecessary laparoscopies or laparotomies, fear, anxiety, embarrassment, pain, and discomfort. Women with a history of sexual violence, and particularly those with PTSD, may experience more pain, discomfort, fear, anxiety, or embarrassment during pelvic examination. See the **Figure** for a summary of the recommendations and clinical considerations.

RECOMMENDATIONS

Recommendation: ACP recommends against performing screening pelvic examination in asymptomatic, nonpregnant,

Figure. Summary of the American College of Physicians guideline on screening pelvic examination in adult women.



SUMMARY OF THE AMERICAN COLLEGE OF PHYSICIANS GUIDELINE ON SCREENING PELVIC EXAMINATION IN ADULT WOMEN

| | |
|----------------------------------|---|
| Disease/Condition | Cancer, pelvic inflammatory disease, other benign gynecologic conditions |
| Target Audience | Internists, family physicians, other clinicians |
| Target Patient Population | Asymptomatic, nonpregnant, adult women |
| Interventions | Pelvic examination |
| Outcomes | Mortality; morbidity; harms, including overdiagnosis, overtreatment, and diagnostic procedure-related harms |
| Benefits of Screening | None identified |
| Harms of Screening | Unnecessary laparoscopies or laparotomies, fear, embarrassment, anxiety, pain or discomfort, avoidance of necessary care |
| Recommendations | <i>Recommendation: ACP recommends against performing screening pelvic examination in asymptomatic, nonpregnant, adult women (strong recommendation, moderate-quality evidence).</i> |
| High-Value Care | ACP found no evidence that routine pelvic examination in asymptomatic, nonpregnant, adult women provides any benefit. With the current evidence, we conclude that performing pelvic examination exposes women to unnecessary and avoidable harms with no benefit. In addition, these examinations add unnecessary costs to the health care system. These costs may be compounded by expenses incurred by additional follow-up tests, including follow-up tests as a result of false-positive screening results, increased medical visits, and costs of keeping or obtaining health insurance. |
| Clinical Considerations | Clinicians do not need to perform pelvic examination before prescribing oral contraceptives. Screening for sexually transmitted disease can be performed with urine testing or vaginal swabs and does not require a pelvic examination. Evaluation is often indicated in women with such symptoms as vaginal discharge, abnormal bleeding, pain, urinary problems, and sexual dysfunction. When screening for cervical cancer, examination should be limited to visual inspection of the cervix and cervical swabs for cancer and HPV. |

HPV = human papillomavirus.

adult women (strong recommendation, moderate-quality evidence).

The current evidence shows that harms outweigh any demonstrated benefits associated with the screening pelvic examination. Indirect evidence showed that screening pelvic examination does not reduce mortality or morbidity rates in asymptomatic adult women, as 1 trial showed that screening for ovarian cancer with more sensitive tests (transvaginal ultrasonography and CA-125) also did not reduce mortality or morbidity rates. Because CA-125 and transvaginal ultrasonography found all cancer detected by the screening pelvic examination as well as additional cancer and this earlier detection did not lead to a reduction in morbidity or mortality rates, we conclude that the screening pelvic examination alone would also not reduce morbidity or mortality rates. No studies assessed the benefit of pelvic examination for other gynecologic conditions, such as asymptomatic pelvic inflammatory disease, benign conditions, or gynecologic cancer other than cervical or ovarian cancer. Also, there is low-quality evidence that screening pelvic examination leads to harms, including fear, anxiety, embarrassment, pain, and discomfort, and possibly prevents women from receiving medical care. In addition, false-positive screening results can lead to unnecessary lapa-

roscopies or laparotomies. Note that this guideline is focused on screening asymptomatic women; full pelvic examination with bimanual examinations is indicated in some nonscreening clinical situations. This guideline does not address women who are due for cervical cancer screening. However, the recommended cervical cancer screening examination should be limited to visual inspection of the cervix and cervical swabs for cancer and human papillomavirus and should not entail a full pelvic examination.

HIGH-VALUE CARE

Although screening for chlamydia and gonorrhea traditionally required a speculum examination, nucleic acid amplification tests on self-collected vaginal swabs or urine have been shown to be highly specific and sensitive, and this technique is supported by several organizations (36–40). ACP found no evidence that screening pelvic examination in asymptomatic, nonpregnant, adult women provides any benefit and indirect evidence that it does not reduce morbidity or mortality rates. However, many clinicians include pelvic examination as part of the well-woman visit (41–43), and because pelvic examination is low-value care, it should be omitted from the well-woman visit.

Many clinicians also require pelvic examination before prescribing oral contraceptives (44), although this practice is low-value care and not supported by evidence. Many organizations also advise against screening pelvic examination before prescribing hormonal contraception for healthy asymptomatic women (45, 46).

With the available evidence, we conclude that screening pelvic examination exposes women to unnecessary and avoidable harms with no benefit (reduced mortality or morbidity rates). In addition, these examinations add unnecessary costs to the health care system (\$2.6 billion in the United States) (47). These costs may be amplified by expenses incurred by additional follow-up tests, including follow-up tests as a result of false-positive screening results; increased medical visits; and costs of keeping or obtaining health insurance.

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Note: Clinical practice guidelines are “guides” only and may not apply to all patients and all clinical situations. Thus, they are not intended to override clinicians’ judgment. All ACP clinical practice guidelines are considered automatically withdrawn or invalid 5 years after publication, or once an update has been issued.

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