Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

NATIONAL GUIDELINE CLEARINGHOUSE

General

Guideline Title

Screening pelvic examination in adult women: a clinical practice guideline from the American College of Physicians.

Bibliographic Source(s)

Qaseem A, Humphrey LL, Harris R, Starkey M, Denberg TD, Clinical Guidelines Committee of the American College of Physicians. Screening pelvic examination in adult women: a clinical practice guideline from the American College of Physicians. Ann Intern Med. 2014 Jul 1;161(1):67-72. [47 references] PubMed

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

Definitions for the overall quality of evidence (high, moderate, low, insufficient) and the strength of the recommendations (strong, weak) are provided at the end of the "Major Recommendations" field.

Recommendation: The American College of Physicians recommends against performing screening pelvic examination in asymptomatic, nonpregnant, 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, the guideline authors 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 laparoscopies 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.

Definitions:

Grading of Quality of Evidence

High-Quality Evidence: Evidence is considered high quality when it is obtained from 1 or more well-designed and well-executed randomized, controlled trials (RCTs) that yield consistent and directly applicable results. This also means that further research is very unlikely to change confidence in the estimate of effect.

Moderate-Quality Evidence: Evidence is considered moderate quality when it is obtained from RCTs with important limitations—for example, biased assessment of the treatment effect, large loss to follow-up, lack of blinding, unexplained heterogeneity (even if it is generated from rigorous RCTs), indirect evidence originating from similar (but not identical) populations of interest, and RCTs with a very small number of participants or observed events. In addition, evidence from well-designed controlled trials without randomization, well-designed cohort or case-control analytic studies, and multiple time series with or without intervention are in this category. Moderate-quality evidence also means that further research will probably have an important effect on confidence in the estimate of effect and may change the estimate.

Low-Quality Evidence: Evidence obtained from observational studies would typically be rated as low quality because of the risk for bias. Low-quality evidence means that further research is very likely to have an important effect on confidence in the estimate of effect and will probably change the estimate. However, the quality of evidence may be rated as moderate or even high, depending on circumstances under which evidence is obtained from observational studies. Factors that may contribute to upgrading the quality of evidence include a large magnitude of the observed effect, a dose-response association, or the presence of an observed effect when all plausible confounders would decrease the observed effect.

Insufficient Evidence to Determine Net Benefits or Risks: When the evidence is insufficient to determine for or against routinely providing a service, the recommendation was graded as "insufficient evidence to determine net benefits or risks." Evidence may be conflicting, of poor quality, or lacking, and hence the balance of benefits and harms cannot be determined. Any estimate of effect that is very uncertain as evidence is either unavailable or does not permit a conclusion.

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) Working Group.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Cancer (other than cervical), pelvic inflammatory disease, or other benign gynecologic conditions

Guideline Category

Prevention

Screening

Clinical Specialty

Family Practice

Obstetrics and Gynecology

Preventive Medicine

Intended Users

Advanced Practice Nurses

Health Care Providers

Health Plans

Nurses

Physician Assistants

Physicians

Public Health Departments

Guideline Objective(s)

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

Target Population

Asymptomatic, nonpregnant, adult women

Interventions and Practices Considered

Screening pelvic examination was considered but not recommended

Major Outcomes Considered

- Mortality
- Morbidity
- Overdiagnosis
- Overtreatment
- Diagnostic procedure-related harms

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Note from the National Guideline Clearinghouse: A systematic evidence review was prepared by Minneapolis Department of Veterans Affairs Health Care System's Evidence-based Synthesis Program Center (see the "Availability of Companion Documents" field).

Data Sources

The Minneapolis Department of Veterans Affairs Health Care System's Evidence-based Synthesis Program Center's staff searched the Ovid MEDLINE and Cochrane databases for articles published from 1946 through January 2014 to identify studies of any design other than case series or case reports. The staff limited the search to English-language studies involving human participants. Search terms included the following Medical Subject Headings: gynecological examination, women's health, and mass screening. In addition, the staff used the "related citations" feature of PubMed to identify an additional 826 English-language abstracts and obtained articles by hand-searching reference lists of existing systematic reviews and pertinent studies and from suggestions from their technical expert panel and peer reviewers. The full search strategy is presented in the Appendix of the systematic review.

Study Selection

Two investigators independently evaluated each abstract to determine whether it met predefined criteria. The staff included background papers and guidelines (published within the past 5 years), clinical trials, cohort or case-control studies, or cross-sectional survey studies conducted in asymptomatic, nonpregnant, average-risk women seen in outpatient settings that reported outcomes of interest. These outcomes included diagnostic accuracy (sensitivity, specificity, and predictive value), morbidity or mortality from pathologic conditions detected on pelvic examination, and harms directly related to pelvic examination or indirect harms from examination findings (false reassurance, overdiagnosis, overtreatment, or diagnostic procedure-related harms). Full-text reports of studies identified as potentially eligible on abstract review were independently reviewed by 2 investigators. The figure in the systematic review shows the reasons for study exclusion at full-text review.

Number of Source Documents

52 English-language studies, 32 of which included primary data

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Grading of Quality of Evidence

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Moderate-Quality Evidence: Evidence is considered moderate quality when it is obtained from RCTs with important limitations—for example, biased assessment of the treatment effect, large loss to follow-up, lack of blinding, unexplained heterogeneity (even if it is generated from rigorous RCTs), indirect evidence originating from similar (but not identical) populations of interest, and RCTs with a very small number of participants or observed events. In addition, evidence from well-designed controlled trials without randomization, well-designed cohort or case-control analytic studies, and multiple time series with or without intervention are in this category. Moderate-quality evidence also means that further research will

probably have an important effect on confidence in the estimate of effect and may change the estimate.

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Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Note from the National Guideline Clearinghouse: A systematic evidence review was prepared by Minneapolis Department of Veterans Affairs Health Care System's Evidence-based Synthesis Program Center (see the "Availability of Companion Documents" field).

Data Extraction and Quality Assessment

A single investigator extracted details on study design, patient characteristics, and outcomes data onto tables. A second investigator verified the extraction. The Minneapolis Department of Veterans Affairs Health Care System's Evidence-based Synthesis Program Center's staff assessed the quality of diagnostic accuracy studies using a modification of the Quality Assessment of Diagnostic Accuracy Studies (QUADAS) tool. The staff assessed the quality of survey studies using a questionnaire we developed that included these domains: sampling strategy (population-based vs. convenience), incorporation of the sampling structure into the analysis, use of a validated or piloted survey instrument, appropriate method for handling missing data, comparison of responders and nonresponders, and response rates.

Data Synthesis and Analysis

The staff summarized their findings in narrative and tabular form, highlighting relevant characteristics of the study populations, study designs, and methodological limitations.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

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 pelvic 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?

Rating Scheme for the Strength of the Recommendations

The American College of Physicians Guideline Grading System*		
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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) Working Group.

Cost Analysis

Routine pelvic examination in asymptomatic, nonpregnant, adult women add unnecessary costs to the health care system ($2.6 billion in the United States). 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.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

This guideline was approved by the American College of Physicians (ACP) Board of Regents on April 7, 2014.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- Appropriate use of screening pelvic examination of adult women resulting in prevention of possible harms, including fear, anxiety, embarrassment, pain, discomfort, and keeping women from receiving medical care
- Minimization of the risk for false-positive screening results, which can lead to unnecessary laparoscopies or laparotomies

Potential Harms

Not stated

Qualifying Statements

Qualifying Statements

- 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 American College of Physicians (ACP) clinical practice guidelines are considered automatically withdrawn or invalid 5 years after publication, or once an update has been issued.
- The authors of this article are responsible for its contents, including any clinical or treatment recommendations.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Mobile Device Resources

Patient Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Qaseem A, Humphrey LL, Harris R, Starkey M, Denberg TD, Clinical Guidelines Committee of the American College of Physicians. Screening pelvic examination in adult women: a clinical practice guideline from the American College of Physicians. Ann Intern Med. 2014 Jul 1;161(1):67-72. [47 references] PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2014 Jul 1

Guideline Developer(s)

American College of Physicians - Medical Specialty Society

Source(s) of Funding

Financial support for the development of this guideline comes exclusively from the American College of Physicians (ACP) operating budget.

Guideline Committee

Clinical Guidelines Committee of the American College of Physicians

Composition of Group That Authored the Guideline

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Financial Disclosures/Conflicts of Interest

Authors followed the policy regarding conflicts of interest described at www.annals.org/article.aspx?articleid=745942. Disclosures can be viewed at www.acponline.org/authors/icmje/ConflictOfInterestForms.do?msNum=M14-0701.

A record of conflicts of interest is kept for each Clinical Guidelines Committee meeting and conference call and can be viewed at www.acponline.org/clinical_information/guidelines/guidelines/conflicts_cgc.htm.

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Electronic copies: Available from the Annals of Internal Medicine Web site.

Print copies: Available from the American College of Physicians (ACP), 190 N. Independence Mall West, Philadelphia PA 19106-1572.

Availability of Companion Documents

The following are available:

- Qaseem A, Snow V, Owens DK, Shekelle P. The development of clinical practice guidelines and guidance statements of the American College of Physicians: summary of methods. Ann Intern Med. 2010 Aug 3;153(3):194-199. Electronic copies: Available from the Annals of Internal Medicine Web site .
- Bloomfield HE, Olson A, Greer N, Cantor A, MacDonald R, Rutks I, Wilt TJ. Screening pelvic examinations in asymptomatic, average-risk adult women: an evidence report for a clinical practice guideline from the American College of Physicians. Ann Intern Med. 2014 Jul 1;161(1):46-53. Electronic copies: Available from the Annals of Internal Medicine Web site .

A collection of Recommendation Summaries for all current American College of Physicians Clinical Guidelines is available for mobile devices from the American College of Physicians Web site .

Patient Resources

The following is available:

> Summaries for patients. Screening pelvic examination in nonpregnant adult women: recommendations from the American College of Physicians. Ann Intern Med. 2014;161(1):I-24. Electronic copies: Available from the Annals of Internal Medicine Web site .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

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