Clinical Guidelines and Recommendations from the American College of Physicians: Their Role in Improving Health Care Value and Reducing Overdiagnosis

Timothy J. Wilt, Amir Qaseem, Mary Ann Forciea and Melissa Starkey
Objectives

- Describe structure, process and products of the American College of Physicians (ACP) Clinical Practice Guideline Committee and their role in improving health care value and reducing overdiagnosis
What does the Clinical Practice Guideline Committee (CGC) do...and...Who are they?

- **Mission:** oversee guideline development to improve medical practice
- Developing guidelines since 1981

- Clinical, evidence synthesis & guideline development experts (physicians) & citizen members
  - 12 internists
  - 2 citizen members
  - Citizen jurors (nonvoting)

- Serve 1-year term, can be renewed (max 4 years)
Products

- Develop several types of recommendations:
  - Clinical Practice Guidelines
  - Clinical Guidance Statements
  - High Value Care Advice
## Impact of ACP Clinical Policy Products 2007-2016

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**Pelvic Exam**
- Media Stories: 1759
- Media Audience: 262,330,351
- Web Hits (Guideline): 94,070

**Insomnia**
- Media Stories: 741
- Media Audience: 101,712,595
- Web Hits (Guideline): 7,881

**CA Screening**
- Media Stories: 563
- Media Audience: 109,087,648
- Web Hits (Guideline): N/A

**Prostate CA**
- Media Stories: 423
- Media Audience: 60,702,901
- Web Hits (Guideline): 74,097

**Sleep apnea**
- Media Stories: 323
- Media Audience: 25,022,186
- Web Hits (Guideline): 121,632

**Cervical CA**
- Media Stories: 232
- Media Audience: 26,037,086
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The Development of Clinical Practice Guidelines and Guidance Statements of the American College of Physicians: Summary of Methods

Amir Qaseem, MD, PhD, MHA; Vincenza Snow, MD; Douglas K. Owens, MD, MS; and Paul Shekelle, MD, PhD, for the Clinical Guidelines Committee of the American College of Physicians

The American College of Physicians (ACP) established its evidence-based clinical practice guidelines program in 1981. The ACP’s Guidelines Committee and the staff of the Clinical Programs and Quality of Care Department develop the clinical recommendations. The ACP develops 2 different types of clinical recommendations: clinical practice guidelines and clinical guidance statements. The ACP clinical practice guidelines and guidance statements follow a multistep development process that includes a systematic review of the evidence, deliberation of the evidence by the committee, summary recommendations, and evidence and recommendation grading. All ACP clinical practice guidelines and clinical guidance statements, if not updated, are considered automatically withdrawn or invalid 5 years after publication or once an update has been issued.

For author affiliations, see end of text.
Guideline Methods Summary

- **Multistep process**
  - Systematic evidence review
  - Deliberation of evidence by committee
    - Disclosures reported & COI addressed
  - Summary recommendations provided
  - Evidence quality determined
  - Strength of recommendation graded
  - Guidelines updated or withdrawn w/in 5 years
## ACP Guideline Grading System

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

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<tr>
<th>Quality of Evidence</th>
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<tr>
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<td>Benefits Clearly Outweigh Risks and Burden or Risks and Burden Clearly Outweigh Benefits</td>
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<tr>
<td>High</td>
<td>Strong</td>
</tr>
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<td>Strong</td>
</tr>
<tr>
<td>Low</td>
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**Insufficient evidence to determine net benefits or risks**

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

High-Value, Cost-Conscious Health Care: Concepts for Clinicians to Evaluate the Benefits, Harms, and Costs of Medical Interventions

• **High-Value care:**
  • Good benefit relative to harms & costs
• **Low value care:**
  • Benefits do not clearly justify harms & costs
Evidence Report for ACP-CPG
Pelvic Examinations

Screening Pelvic Examinations in Asymptomatic, Average-Risk Adult Women: An Evidence Report for a Clinical Practice Guideline From the American College of Physicians

Hanna E. Bloomfield, MD, MPH; Andrew Olson, MD; Nancy Greer, PhD; Amy Cantor, MD, MHS; Roderick MacDonald, MS; Indulis Rutks, BS; and Timothy J. Wilt, MD, MPH

Background: Pelvic examination is often included in well-woman visits even when cervical cancer screening is not required.

Purpose: To evaluate the diagnostic accuracy, benefits, and harms of pelvic examination in asymptomatic, nonpregnant, average-risk adult women. Cervical cancer screening was not included.

Data Sources: MEDLINE and Cochrane databases through January 2014 and reference lists from identified studies.

Study Selection: 52 English-language studies, 32 of which included primary data.

Data Extraction: Data were extracted on study and sample characteristics, interventions, and outcomes. Quality of the diagnostic accuracy studies was evaluated using a published instrument, and quality of the survey studies was evaluated with metrics assessing population representativeness, instrument development, and response rates.

Data Synthesis: The positive predictive value of pelvic examination for detecting ovarian cancer was less than 4% in the 2 studies that reported this metric. No studies that investigated the morbidity or mortality benefits of screening pelvic examination for any condition were identified. The percentage of women reporting pelvic examination-related pain or discomfort ranged from 11% to 60% (median, 35%; 8 studies [n = 4576]). Corresponding figures for fear, embarrassment, or anxiety ranged from 10% to 80% (median, 34%; 7 studies [n = 10,702]).

Limitation: Only English-language publications were included; the evidence on diagnostic accuracy, morbidity, and mortality was scant, and the studies reporting harms were generally low quality.

Conclusion: No data supporting the use of pelvic examination in asymptomatic, average-risk women were found. Low-quality data suggest that pelvic examinations may cause pain, discomfort, fear, anxiety, or embarrassment in about 30% of women.

Primary Funding Source: Department of Veterans Affairs.

For author affiliations, see end of text.
Screening Pelvic Examination in Adult Women: A Clinical Practice Guideline From the American College of Physicians

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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**Recommendations**

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

- **Strong recommendation, moderate-quality evidence**

**High Value Care**

- No evidence that routine pelvic exam provides benefit
- Exposes women to unnecessary & avoidable harms
- Adds unnecessary costs to health care system
- Additional tests including those of false + screening & med visits
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Summaries for Patients

Screening Pelvic Examination in Nonpregnant Adult Women: Recommendations From the American College of Physicians

Who developed these guidelines?
The American College of Physicians (ACP) developed these recommendations. Members of ACP are internists (specialists in the care of adults).

What is the problem and what is known about it so far?
Pelvic examination is often done to screen for disease in nonpregnant, adult women who do not have symptoms. Screening means looking for a disease in people who do not have any signs or symptoms of that disease. During a pelvic examination, the patient is positioned on an examination table with her feet in stirrups. The doctor examines the external genitalia and then inserts an instrument called a speculum into the vagina to examine the vagina and cervix (speculum examination). Next, the physician places 1 hand in the patient’s vagina and the other on her abdomen to feel for abnormalities in the ovaries, uterus, and other pelvic organs (bimanual examination). Sometimes, the examination includes insertion of a finger into the patient’s rectum to check for abnormalities in the rectum or the space between the rectum and vagina (rectal examination).

What does the ACP recommend that patients and doctors do?
Doctors should not do screening pelvic examinations on nonpregnant, adult women who do not have symptoms of possible pelvic disease.

The ACP reviewed published studies about the potential benefits and harms of screening pelvic examination. “Screening pelvic examination” means speculum and bimanual examination in women who have no pelvic symptoms.

What did the authors find?
Available studies show that the yield of pelvic examination for identifying cancer or other treatable disease in nonpregnant women without symptoms is low and is not associated with improved health outcomes. However, there are many false-positive findings on pelvic examination, and such findings subject patients to unnecessary worry and follow-up. Pelvic examination can cause anxiety, discomfort, pain, and embarrassment, especially in women who have a history of sexual abuse.

What does the ACP recommend that patients and doctors do?
Doctors should not do screening pelvic examinations on nonpregnant, adult women who do not have symptoms of possible pelvic disease.

What are the cautions related to these recommendations?
These recommendations apply only to nonpregnant women with no symptoms. Pelvic examination should be done if symptoms are present or the patient is pregnant.
Guidance Statements

Screening for Prostate Cancer: A Guidance Statement From the Clinical Guidelines Committee of the American College of Physicians

Amir Qaseem, MD, PhD, MHA; Michael J. Barry, MD; Thomas D. Denberg, MD, PhD; Douglas K. Owens, MD, MS; and Paul Shekelle, MD, PhD, for the Clinical Guidelines Committee of the American College of Physicians*

Description: Prostate cancer is an important health problem in men. It rarely causes death in men younger than 50 years; most deaths associated with it occur in men older than 75 years. The benefits of screening with the prostate-specific antigen (PSA) test are outweighed by the harms for most men. Prostate cancer never becomes clinically significant in a patient’s lifetime in a considerable proportion of men with prostate cancer detected with the PSA test. They will receive no benefit and are subject to substantial harms from the treatment of prostate cancer. The American College of Physicians (ACP) developed this guidance statement for clinicians by assessing current prostate cancer screening guidelines developed by other organizations. ACP believes that it is more valuable to provide clinicians with a rigorous review of available guidelines rather than develop a new guideline on the same topic when several guidelines are available on a topic or when existing guidelines conflict. The purpose of this guidance statement is to critically review available guidelines to help guide internists and other clinicians in making decisions about screening for prostate cancer. The target patient population for this guidance statement is all adult men.

Methods: This guidance statement is derived from an appraisal of available guidelines on screening for prostate cancer. Authors searched the National Guideline Clearinghouse to identify prostate cancer screening guidelines in the United States and selected 4 developed by the American College of Preventive Medicine, American Cancer Society, American Urological Association, and U.S. Preventive Services Task Force. The AGREE II (Appraisal of Guidelines, Research and Evaluation in Europe) instrument was used to evaluate the guidelines.

Guidance Statement 1: ACP recommends that clinicians inform men between the age of 50 and 69 years about the limited potential benefits and substantial harms of screening for prostate cancer. ACP recommends that clinicians base the decision to screen for prostate cancer using the prostate-specific antigen test on the risk for prostate cancer, a discussion of the benefits and harms of screening, the patient’s general health and life expectancy, and patient preferences. ACP recommends that clinicians should not screen for prostate cancer using the prostate-specific antigen test in patients who do not express a clear preference for screening.

Guidance Statement 2: ACP recommends that clinicians should not screen for prostate cancer using the prostate-specific antigen test in average-risk men under the age of 50 years, men over the age of 69 years, or men with a life expectancy of less than 10 to 15 years.

For author affiliations, see end of txt.
This article was published at www.annals.org on 9 April 2013.
Best Practice Advice Summary: Prostate Cancer Screening

Talking points with patients

• Most men, screening harms outweigh benefit
• PSA test is not "just a blood test"
• Vast majority grow slow; do not cause death
• Patients choosing testing much more likely to be Dx with CaP
• Small number of CaP serious & cause death
• Most men choosing not to have testing not Dx with CaP; will die of something else
• Small potential benefit of CaP screening
• Prostate biopsy: not free from risk
• If Ca diagnosed: often treated with surgery or radiation, associated with risks
Best Practice Advice Summary: Prostate Cancer Screening

Talking points with patients:

• Most men, screening harms outweigh benefit
• PSA test is not “just a blood test”
• Vast majority grow slow; do not cause death
• Patients choosing testing much more likely than those declining to be Dx with CaP
• Small number CaP serious & cause death
• Most men choosing not to have testing not Dx with CaP; will die of something else
• Small potential benefit of CaP screening
• Prostate biopsy: not free from risk
• If Ca diagnosed: often treated with surgery or radiation, associated with risks
Summaries for Patients

Screening for Prostate Cancer: A Guidance Statement From the Clinical Guidelines Committee of the American College of Physicians

Who developed these recommendations?
The Clinical Guidelines Committee of the American College of Physicians (ACP) developed these guidelines. ACP is a professional organization for internal medicine doctors, who are specialists in adult care.

What is the problem and what is known about it so far?
Prostate cancer is the most commonly diagnosed noncancer among men in the United States. The most common prostate cancer symptoms are difficult or frequent urination, but many men have no symptoms.

A blood test that measures prostate-specific antigen (PSA) levels can find prostate cancer before symptoms develop. If the PSA level is high, a prostate biopsy may be needed.

What does the ACP recommend that patients and doctors do?
Doctors should inform men aged 50 to 69 years about the limited potential benefits and substantial potential harms of prostate cancer screening. Patients and doctors should base screening decisions on the patient’s preferences, prostate cancer risk, health, and life expectancy.

Doctors should not screen for prostate cancer using PSA unless patients express a clear preference for screening after discussion.

Doctors should not screen using PSA in average-risk men younger than 50 years or older than 69 years, or any man with a life expectancy less than 10 to 15 years.

Doctors should not screen for prostate cancer using PSA unless patients express a clear preference for screening after discussion.

What are the cautions related to these recommendations?
These recommendations apply to men at average risk for prostate cancer who do not have symptoms that could be caused by prostate cancer. The authors did not consider non-U.S. guidelines.
A Value Framework for Cancer Screening: Advice for High-Value Care From the American College of Physicians

Russell P. Harris, MD, MPH; Timothy J. Wilt, MD, MPH; and Amir Qaseem, MD, PhD, MHA, for the High Value Care Task Force of the American College of Physicians*

Experts, professional societies, and consumer groups often recommend different strategies for cancer screening. These strategies vary in the intensity of their search for asymptomatic lesions and in their value. This article outlines a framework for thinking about the value of varying intensities of cancer screening. The authors conclude that increasing intensity beyond an optimal level leads to low-value screening and speculate about pressures that encourage overly intensive, low-value screening.

For author affiliations, see end of text.
Screening Value Framework
Screening Value Framework

[Diagram showing the relationship between screening intensity and value, with sections for low and high value, benefits, harms, and costs.]
Screening for Cancer: Advice for High-Value Care From the American College of Physicians

Timothy J. Wilt, MD, MPH; Russell P. Harris, MD, MPH; and Amir Qaseem, MD, PhD, MHA, for the High Value Care Task Force of the American College of Physicians*

Background: Cancer screening is one approach to reducing cancer-related morbidity and mortality rates. Screening strategies vary in intensity. Higher-intensity strategies are not necessarily higher value. High-value strategies provide a degree of benefits that clearly justifies the harms and costs incurred; low-value screening provides limited or no benefits to justify the harms and costs. When cancer screening leads to benefits, an optimal intensity of screening maximizes value. Some aspects of screening practices, especially overuse and underuse, are low value.

Methods: Screening strategies for asymptomatic, average-risk adults for 5 common types of cancer were evaluated by reviewing clinical guidelines and evidence syntheses from the American College of Physicians (ACP), U.S. Preventive Services Task Force, American Academy of Family Physicians, American Cancer Society, American Congress of Obstetricians and Gynecologists, American Gastroenterological Association, and American Urological Association. “High value” was defined as the lowest screening intensity threshold at which organizations agree about screening recommendations for each type of cancer and “low value” as agreement about not recommending overly intensive screening strategies. This information is supplemented with additional findings from randomized, controlled trials; modeling studies; and studies of costs or resource use, including information found in the National Cancer Institute's Physician Data Query and UpToDate.

The ACP provides high-value care screening advice for 5 common types of cancer; the specifics are outlined in this article. The ACP strongly encourages clinicians to adopt a cancer screening strategy that focuses on reaching all eligible persons with these high-value screening options while reducing overly intensive, low-value screening.

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**Breast Women ages 40 - 49:** Discuss benefits and harms with women in good health and order screening if individual woman requests: Mammography every 2 years

**Women Ages 50 - 74 in good health:** Encourage mammography every 2 years

**Women aged < 40 or > age 75; women of any age not in good health and with life expectancy less than 10 years:** Any screening

**Any group:** Annual Mammography; MRI; tomosynthesis

**Any group:** Regular systematic breast self-exam
## High and Low Value Breast Cancer Screening

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## High and Low Value Breast Cancer Screening

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**Women Ages 50-74 in good health:** Encourage mammography every 2 years | **Women aged < 40 or ≥ age 75; women of any age not in good health and with life expectancy less than 10 years:** Any screening  
**Any group:** Annual Mammography; MRI; tomosynthesis  
**Any group:** Regular systematic breast self-exam |
Future Directions to Enhance Screening Value & Reduce Overdiagnosis by Reducing Screening Intensity

- Screen less frequently
- DC screening after prior negative screens
- Screen with less sensitive tests
- Use higher thresholds for defining + screening test
Conclusion

- ACP strives to improve health care value and reduce overdiagnosis harms through development and communication of clinical recommendations
- Uses Value Framework for Developing CPG
- Incorporating value → less intensive tests/treatments
  - Maintains vast majority of benefit
  - Reduces harms & costs
  - Decreases overdiagnosis and overtreatment
  - Targets resources where greatest net benefit
- Public involvement will take an increasingly important role in these processes & products