General

Guideline Title


Bibliographic Source(s)


Guideline Status

This is the current release of the guideline.


Recommendations

Major Recommendations

The U.S. Preventive Services Task Force (USPSTF) grades its recommendations (A, B, C, D, or I) and the quality of the overall evidence for a service (good, fair, poor). The definitions of these grades can be found at the end of the "Major Recommendations" field.

Summary of Recommendation and Evidence

The USPSTF recommends against screening for ovarian cancer in women (D recommendation). This recommendation applies to asymptomatic women. Women with known genetic mutations that increase their risk for ovarian cancer (for example, BRCA mutations) are not included in this recommendation.

Clinical Considerations

Patient Population

This recommendation applies to asymptomatic women. Women with known genetic mutations that increase their risk for ovarian cancer (for example, BRCA mutations) are not included in this recommendation.

Risk Assessment

Women with BRCA1 and BRCA2 genetic mutations, the Lynch syndrome (hereditary nonpolyposis colon cancer), or a family history of ovarian cancer are at increased risk for ovarian cancer. Although no standardized referral criteria currently exist, women with an increased-risk family
history should be considered for genetic counseling to further evaluate their potential risks. "Increased-risk family history" generally means having two or more first- or second-degree relatives with a history of ovarian cancer or a combination of breast and ovarian cancer; for women of Ashkenazi Jewish descent, it means having a first-degree relative (or two second-degree relatives on the same side of the family) with breast or ovarian cancer.

Women with a family history of ovarian cancer were not excluded from most randomized screening trials. In the only trial reporting ovarian cancer mortality results, women with a family history of ovarian or breast cancer comprised 17% of the participants. The overall trial showed no mortality benefit; outcomes were not separately reported for this subgroup. Although available evidence does not show with absolute certainty whether the balance of benefits and harms of ovarian cancer screening may differ for women with a family history of ovarian cancer, the USPSTF found no reason to believe that such women would necessarily benefit. A higher incidence of cancer may result in more diagnoses and treatments, but the increase may not be accompanied by a reduction in deaths and may actually lead to more associated harms. An ongoing prospective cohort study, the United Kingdom Familial Ovarian Cancer Screening Study, may help to resolve some of these questions.

Factors associated with a reduced risk for ovarian cancer include the use of oral contraceptives, pregnancy and breastfeeding, bilateral tubal ligation, and removal of the ovaries.

Screening Tests

Transvaginal ultrasonography and serum cancer antigen (CA)-125 testing are readily available procedures and commonly suggested screening methods. The bimanual pelvic examination is often conducted (usually annually) in part to screen for ovarian cancer, although its effectiveness and harms are not well-known and were not a focus of this review.

The evaluation of abnormal test results consists of either repeated testing or, frequently, removal of one or both of the ovaries by means of laparoscopy or laparotomy.

Treatment

Treatment of ovarian carcinoma includes surgical treatment (debulking) and intraperitoneal or systemic chemotherapy.

Useful Resources

In its recommendation on genetic risk assessment and BRCA mutation testing for breast and ovarian cancer susceptibility, the USPSTF recommends that women with a family history indicating that they are at risk for a deleterious mutation be referred for genetic counseling and testing. More information on this recommendation can be found at [www.uspreventiveservicestaskforce.org](http://www.uspreventiveservicestaskforce.org).

Definitions:

What the U.S. Preventive Services Task Force (USPSTF) Grades Mean and Suggestions for Practice

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USPSTF Levels of Certainty Regarding Net Benefit

Definition: The USPSTF defines certainty as "likelihood that the USPSTF assessment of the net benefit of a preventive service is correct." The net benefit is defined as benefit minus harm of the preventive service as implemented in a general, primary care population. The USPSTF assigns a certainty level based on the nature of the overall evidence available to assess the net benefit of a preventive service.

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  - The number, size, or quality of individual studies  
  - Inconsistency of findings across individual studies  
  - Limited generalizability of findings to routine primary care practice  
  - Lack of coherence in the chain of evidence  
As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion. |
| Low                | The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of:  
  - The limited number or size of studies  
  - Important flaws in study design or methods  
  - Inconsistency of findings across individual studies  
  - Gaps in the chain of evidence  
  - Findings not generalizable to routine primary care practice  
  - A lack of information on important health outcomes  
More information may allow an estimation of effects on health outcomes. |

Clinical Algorithm(s)
None provided

Scope

Disease/Condition(s)
Ovarian cancer

Guideline Category
Prevention
Screening

Clinical Specialty
Family Practice
Internal Medicine
Obstetrics and Gynecology
Intended Users

Advanced Practice Nurses
Allied Health Personnel
Nurses
Physician Assistants
Physicians

Guideline Objective(s)

- To summarize the current U.S. Preventive Services Task Force (USPSTF) recommendation on screening for ovarian cancer and the supporting evidence
- To update the 2004 USPSTF recommendation statement on screening for ovarian cancer and the supporting evidence

Target Population

Asymptomatic women

Note: This recommendation does not apply to women with known genetic mutations that increase their risk for ovarian cancer (for example, BRCA mutations).

Interventions and Practices Considered

Screening for ovarian cancer using serum cancer antigen (CA)-125 level or transvaginal ultrasound

Major Outcomes Considered

Key Question 1: What are the benefits of screening for ovarian cancer in adult women?
Key Question 2: What are the harms of screening for ovarian cancer?

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 (NGC): An evidence update was prepared by staff at the Agency for Healthcare Research and Quality (AHRQ) for use by the U.S. Preventive Services Task Force (USPSTF). A bridge evidence update was later prepared by the Oregon Evidence-based Practice Center (EPC) for the USPSTF (see the "Availability of Companion Documents" field).
Initial Evidence Update

Data Sources

AHRQ staff performed literature searches of MEDLINE and the Cochrane library. In order to parallel the previous evidence review on this topic, they used the same search terms that had been previously used: ovarian neoplasms, ovarian cancer, mass screening, physical examination, tumor markers, ultrasound imaging, and vaginal smears or pap smear. They included in the searches English-language studies of adult humans (age >18 years) that were published in core clinical journals between July 1, 2002 and January 15, 2008. Core clinical journals, formerly known as the Abridged Index Medicus, are a subset of 120 journals defined by the National Library of Medicine. AHRQ staff also checked reference lists of retrieved articles for possibly relevant studies.

Study Selection

One of two reviewers reviewed the titles and abstracts of retrieved studies; two reviewers independently read and assessed articles for abstraction based on inclusion and exclusion criteria. For the literature on benefits of screening, AHRQ staff included controlled trials as well as systematic reviews and meta-analyses. For harms, they included controlled trials, cohort studies, case-control studies, and case series, as well as systematic reviews and meta-analyses. They excluded editorials and guidelines.

Results

The literature search returned 64 potentially relevant titles that were entered into a reference database. A total of 60 articles were excluded after title and abstract review, and two more were excluded after full article review. AHRQ staff excluded 18 studies not related to ovarian cancer, 34 studies that did not describe screening, two studies that described no relevant outcomes, two studies that described a high-risk or special patient population, and three studies that were an inappropriate study type. One additional report of a prospective screening study that was included in the evidence for harms was identified after a supplemental search of MEDLINE for publications by selected authors.

Limitations

The search strategy employed may have missed some smaller studies on the benefits and harms of screening for ovarian cancer.

Bridge Evidence Update

Methods

PubMed, MEDLINE, and the Cochrane Central Register of Controlled Trials were searched to identify new, substantial evidence on ovarian cancer screening published between October 15, 2007 and July 26, 2011. Searches were restricted to English-language studies in core clinical journals and focused largely on trials following a search strategy developed by AHRQ. The search strategy was modified slightly to include a wider range of studies in more recent years.

The initial literature search yielded 848 titles and/or abstracts. Two individuals reviewed titles and abstracts to identify potentially relevant articles. Thirty articles were identified as potentially eligible and reviewed in full. Of these, articles were excluded for the following (nonmutually exclusive) reasons: not related to ovarian cancer (n=1), not related to screening (n=21), did not include relevant outcomes (n=4), focused on a high-risk or special patient population (n=2), and not an appropriate study type (n=3). Thus, four articles from three studies were identified for inclusion in this report.

Results

Three randomized, controlled trials published results on ovarian cancer screening during the period covered by this review. Only one study—the Prostate, Lung, Colorectal, and Ovarian (PLCO) Cancer Screening Trial—presented information on mortality. The other two studies presented information on screening characteristics and harms related to false-positive screening results.

Limitations

The search strategy employed for the review was designed to identify substantial new studies, particularly randomized trials, published in indexed journals. Thus, this is not a comprehensive review of the literature.

Number of Source Documents

Initial Evidence Update
Key Question 1: 0 studies
Key Question 2: 3 studies

Bridge Evidence Update

Four articles from three studies were identified for inclusion.

Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus

Rating Scheme for the Strength of the Evidence

Not applicable

Methods Used to Analyze the Evidence

Systematic Review

Description of the Methods Used to Analyze the Evidence

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Initial Evidence Update

Data Extraction

No studies were included for data abstraction on the benefits of screening for ovarian cancer. For data on the harms of screening, one reviewer abstracted information on sample size, number of patients with abnormal test results, and follow-up evaluation of abnormal tests, including surgical biopsy and cancer outcomes.

Data Synthesis and Analysis

Data from the included studies were not able to be synthesized due to heterogeneity in patient populations and study design, but are summarized qualitatively in narrative format.

Bridge Evidence Update

Findings from the three trials included in the review were summarized.

Methods Used to Formulate the Recommendations

Balance Sheets

Expert Consensus

Description of Methods Used to Formulate the Recommendations

The U.S. Preventive Services Task Force (USPSTF) systematically reviews the evidence concerning both the benefits and harms of widespread implementation of a preventive service. It then assesses the certainty of the evidence and the magnitude of the benefits and harms. On the basis of this assessment, the USPSTF assigns a letter grade to each preventive service signifying its recommendation about provision of the service (see Table below). An important, but often challenging, step is determining the balance between benefits and harms to estimate "net benefit" (that is,
benefits minus harms).

Table 1. U.S. Preventive Services Task Force Recommendation Grid*

<table>
<thead>
<tr>
<th>Certainty of Net Benefit</th>
<th>Magnitude of Net Benefit</th>
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<tbody>
<tr>
<td></td>
<td>Substantial</td>
</tr>
<tr>
<td>High</td>
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</tr>
<tr>
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</tr>
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<td>Low</td>
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*A, B, C, D, and I (Insufficient) represent the letter grades of recommendation or statement of insufficient evidence assigned by the U.S. Preventive Services Task Force after assessing certainty and magnitude of net benefit of the service (see the "Rating Scheme for the Strength of the Recommendations" field).

The overarching question that the Task Force seeks to answer for every preventive service is whether evidence suggests that provision of the service would improve health outcomes if implemented in a general primary care population. For screening topics, this standard could be met by a large randomized, controlled trial (RCT) in a representative asymptomatic population with follow-up of all members of both the group "invited for screening" and the group "not invited for screening."

Direct RCT evidence about screening is often unavailable, so the Task Force considers indirect evidence. To guide its selection of indirect evidence, the Task Force constructs a "chain of evidence" within an analytic framework. For each key question, the body of pertinent literature is critically appraised, focusing on the following 6 questions:

1. Do the studies have the appropriate research design to answer the key question(s)?
2. To what extent are the existing studies of high quality? (i.e., what is the internal validity?)
3. To what extent are the results of the studies generalizable to the general U.S. primary care population and situation? (i.e., what is the external validity?)
4. How many studies have been conducted that address the key question(s)? How large are the studies? (i.e., what is the precision of the evidence?)
5. How consistent are the results of the studies?
6. Are there additional factors that assist the USPSTF in drawing conclusions (e.g., presence or absence of dose–response effects, fit within a biologic model)?

The next step in the Task Force process is to use the evidence from the key questions to assess whether there would be net benefit if the service were implemented. In 2001, the USPSTF published an article that documented its systematic processes of evidence evaluation and recommendation development. At that time, the Task Force's overall assessment of evidence was described as good, fair, or poor. The Task Force realized that this rating seemed to apply only to how well studies were conducted and did not fully capture all of the issues that go into an overall assessment of the evidence about net benefit. To avoid confusion, the Task Force has changed its terminology. Whereas individual study quality will continue to be characterized as good, fair, or poor, the term certainty will now be used to describe the Task Force's assessment of the overall body of evidence about net benefit of a preventive service and the likelihood that the assessment is correct. Certainty will be determined by considering all 6 questions listed above; the judgment about certainty will be described as high, moderate, or low.

In making its assessment of certainty about net benefit, the evaluation of the evidence from each key question plays a primary role. It is important to note that the Task Force makes recommendations for real-world medical practice in the United States and must determine to what extent the evidence for each key question—even evidence from screening RCTs or treatment RCTs—can be applied to the general primary care population. Frequently, studies are conducted in highly selected populations under special conditions. The Task Force must consider differences between the general primary care population and the populations studied in RCTs and make judgments about the likelihood of observing the same effect in actual practice.

It is also important to note that one of the key questions in the analytic framework refers to the potential harms of the preventive service. The Task Force considers the evidence about the benefits and harms of preventive services separately and equally. Data about harms are often obtained from observational studies because harms observed in RCTs may not be representative of those found in usual practice and because some harms are not completely measured and reported in RCTs.

Putting the body of evidence for all key questions together as a chain, the Task Force assesses the certainty of net benefit of a preventive service
by asking the 6 major questions listed above. The Task Force would rate a body of convincing evidence about the benefits of a service that, for example, derives from several RCTs of screening in which the estimate of benefits can be generalized to the general primary care population as "high" certainty (see the "Rating Scheme for the Strength of Recommendations" field). The Task Force would rate a body of evidence that was not clearly applicable to general practice or has other defects in quality, research design, or consistency of studies as "moderate" certainty. Certainty is "low" when, for example, there are gaps in the evidence linking parts of the analytic framework, when evidence to determine the harms of treatment is unavailable, or when evidence about the benefits of treatment is insufficient. Table 4 in the methodology document listed below (see the "Availability of Companion Documents" field) summarizes the current terminology used by the Task Force to describe the critical assessment of evidence at all 3 levels: individual studies, key questions, and overall certainty of net benefit of the preventive service.


Rating Scheme for the Strength of the Recommendations

What the U.S. Preventive Services Task Force (USPSTF) Grades Mean and Suggestions for Practice

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  * Lack of coherence in the chain of evidence |


As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.

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More information may allow an estimation of effects on health outcomes.

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Comparison with Guidelines from Other Groups

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Peer Review. Before the U.S. Preventive Services Task Force (USPSTF) makes its final determinations about recommendations on a given preventive service, the Evidence-based Practice Center and the Agency for Healthcare Research and Quality send a draft evidence review to 4 to 6 external experts and to Federal agencies and professional and disease-based health organizations with interests in the topic. The experts are asked to examine the review critically for accuracy and completeness and to respond to a series of specific questions about the document. After assembling these external review comments and documenting the proposed response to key comments, the topic team presents this information to the USPSTF in memo form. In this way, the USPSTF can consider these external comments before it votes on its recommendations about the service. Draft recommendation statements are then circulated for comment among reviewers representing professional societies, voluntary organizations, and Federal agencies, as well as posted on the Task Force Web site for public comment. These comments are discussed before the final recommendations are confirmed.

Response to Public Comment. A draft version of this recommendation statement was posted for public comment on the USPSTF Web site from 10 April to 8 May 2012. In response to comments, the USPSTF clarified language describing what is meant by increased risk for ovarian cancer, what is known about ovarian cancer screening in women with a family history of the disease, and the diagnostic pathway for abnormal screening results.

Commenters also asked about other potential screening methods and about the potential role of symptoms in the earlier detection of ovarian cancer. The USPSTF noted that the OvaDx test for is not currently approved by the U.S. Food and Drug Administration for clinical use in ovarian cancer screening and there is currently limited evidence to assess the ultimate health effects of other potential screening tests for ovarian cancer. The USPSTF also noted that a search for data on potential role of symptoms to guide earlier detection of ovarian cancer was outside the scope of the commissioned systematic evidence review used to inform this recommendation statement. However, a literature search reveals that there may be important inherent challenges related to the reliability of incorporating these nonspecific symptoms into ovarian cancer screening and diagnostic testing decisions (see the "Response to Public Comments" section in the original guideline document for additional detail).

Comparison with Guidelines from Other Groups. Recommendations for screening from the following groups were discussed: the American Congress of Obstetricians and Gynecologists and the American Cancer Society.

Evidence Supporting the Recommendations
Type of Evidence Supporting the Recommendations

The type of supporting evidence is not specifically stated for each recommendation.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Benefits of Detection and Early Intervention and Treatment

The U.S. Preventive Services Task Force found adequate evidence that annual screening with transvaginal ultrasonography and testing for a serum tumor marker, cancer antigen (CA)-125, in women does not reduce the number of ovarian cancer deaths.

Potential Harms

Harms of Detection and Early Intervention and Treatment

Adequate evidence shows that screening for ovarian cancer can lead to important harms, including major surgical interventions in women who do not have cancer.

Qualifying Statements

Qualifying Statements

- The U.S. Preventive Services Task Force (USPSTF) makes recommendations about the effectiveness of specific clinical preventive services for patients without 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.
- Recommendations made by the USPSTF are independent of the U.S. government. They should not be construed as an official position of the Agency for Healthcare Research and Quality or the U.S. Department of Health and Human Services.

Implementation of the Guideline

Description of Implementation Strategy

The experiences of the first and second U.S. Preventive Services Task Force (USPSTF), as well as that of other evidence-based guideline efforts, have highlighted the importance of identifying effective ways to implement clinical recommendations. Practice guidelines are relatively weak tools for changing clinical practice when used in isolation. To effect change, guidelines must be coupled with strategies to improve their acceptance and feasibility. Such strategies include enlisting the support of local opinion leaders, using reminder systems for clinicians and patients, adopting standing orders, and audit and feedback of information to clinicians about their compliance with recommended practice.

In the case of preventive services guidelines, implementation needs to go beyond traditional dissemination and promotion efforts to recognize the added patient and clinician barriers that affect preventive care. These include clinicians’ ambivalence about whether preventive medicine is part of their job, the psychological and practical challenges that patients face in changing behaviors, lack of access to health care or of insurance coverage for preventive services for some patients, competing pressures within the context of shorter office visits, and the lack of organized systems in most practices to ensure the delivery of recommended preventive care.
Dissemination strategies have changed dramatically in this age of electronic information. While recognizing the continuing value of journals and other print formats for dissemination, the USPSTF will make all its products available through its Web site. The combination of electronic access and extensive material in the public domain should make it easier for a broad audience of users to access USPSTF materials and adapt them for their local needs. Online access to USPSTF products also opens up new possibilities for the appearance of the annual, pocket-size Guide to Clinical Preventive Services.

To be successful, approaches for implementing prevention have to be tailored to the local level and deal with the specific barriers at a given site, typically requiring the redesign of systems of care. Such a systems approach to prevention has had notable success in established staff-model health maintenance organizations, by addressing organization of care, emphasizing a philosophy of prevention, and altering the training and incentives for clinicians. Staff-model plans also benefit from integrated information systems that can track the use of needed services and generate automatic reminders aimed at patients and clinicians, some of the most consistently successful interventions. Information systems remain a major challenge for individual clinicians' offices, however, as well as for looser affiliations of practices in network-model managed care and independent practice associations, where data on patient visits, referrals, and test results are not always centralized.

Implementation Tools
- Foreign Language Translations
- Mobile Device Resources
- Patient Resources
- Pocket Guide/Reference Cards

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)


Adaptation

Not applicable: The guideline was not adapted from another source.
Date Released
1996 (revised 2012 Dec 18)

Guideline Developer(s)
U.S. Preventive Services Task Force - Independent Expert Panel

Guideline Developer Comment
The U.S. Preventive Services Task Force (USPSTF) is a federally-appointed panel of independent experts. Conclusions of the USPSTF do not necessarily reflect policy of the U.S. Department of Health and Human Services (DHHS) or its agencies.

Source(s) of Funding
The U.S. Preventive Services Task Force (USPSTF) is an independent, voluntary body. The U.S. Congress mandates that the Agency for Healthcare Research and Quality support the operations of the USPSTF.

Guideline Committee
U.S. Preventive Services Task Force (USPSTF)

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Guideline Status
This is the current release of the guideline.


Guideline Availability

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

Availability of Companion Documents

The following are available:

Evidence Reviews:


Background Articles:


Electronic copies: Available from the USPSTF Web site.

The following are also available:


See the related QualityTool summary on the Health Care Innovations Exchange Web site.

The Electronic Preventive Services Selector (ePSS), available as a PDA application and a web-based tool, is a quick hands-on tool designed to help primary care clinicians identify the screening, counseling, and preventive medication services that are appropriate for their patients. It is based on current recommendations of the USPSTF and can be searched by specific patient characteristics such as age, sex, and selected behavioral risk factors.

Patient Resources

The following are available:


Print copies: Available in English and Spanish from the Agency for Healthcare Research and Quality (AHRQ) Publications Clearinghouse. For more information, go to http://www.ahrq.gov/research/publications/index.html or call 1-800-358-9295 (U.S. only).

Myhealthfinder is a new tool that provides personalized recommendations for clinical preventive services specific to the user's age, gender, and pregnancy status. It features evidence-based recommendations from the USPSTF and is available at www.healthfinder.gov.

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.

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