

Screening for Ovarian Cancer

US Preventive Services Task Force

Recommendation Statement

US Preventive Services Task Force

IMPORTANCE With approximately 14 000 deaths per year, ovarian cancer is the fifth most common cause of cancer death among US women and the leading cause of death from gynecologic cancer. More than 95% of ovarian cancer deaths occur among women 45 years and older.

OBJECTIVE To update the 2012 US Preventive Services Task Force (USPSTF) recommendation on screening for ovarian cancer.

EVIDENCE REVIEW The USPSTF reviewed the evidence on the benefits and harms of screening for ovarian cancer in asymptomatic women not known to be at high risk for ovarian cancer (ie, high risk includes women with certain hereditary cancer syndromes that increase their risk for ovarian cancer). Outcomes of interest included ovarian cancer mortality, quality of life, false-positive rate, surgery and surgical complication rates, and psychological effects of screening.

FINDINGS The USPSTF found adequate evidence that screening for ovarian cancer does not reduce ovarian cancer mortality. The USPSTF found adequate evidence that the harms from screening for ovarian cancer are at least moderate and may be substantial in some cases, and include unnecessary surgery for women who do not have cancer. Given the lack of mortality benefit of screening, and the moderate to substantial harms that could result from false-positive screening test results and subsequent surgery, the USPSTF concludes with moderate certainty that the harms of screening for ovarian cancer outweigh the benefit, and the net balance of the benefit and harms of screening is negative.

CONCLUSIONS AND RECOMMENDATION The USPSTF recommends against screening for ovarian cancer in asymptomatic women. (D recommendation) This recommendation applies to asymptomatic women who are not known to have a high-risk hereditary cancer syndrome.

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The US Preventive Services Task Force (USPSTF) makes recommendations about the effectiveness of specific preventive care services for patients without obvious related signs or symptoms.

It bases its recommendations on the evidence of both the benefits and harms of the service and an assessment of the balance. The USPSTF does not consider the costs of providing a service in this assessment.

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

Summary of Recommendation and Evidence

The USPSTF recommends against screening for ovarian cancer in asymptomatic women (D recommendation) (Figure 1).

This recommendation applies to asymptomatic women who are not known to have a high-risk hereditary cancer syndrome.

Rationale

Importance

The age-adjusted incidence of ovarian cancer from 2010 to 2014 was 11.4 cases per 100 000 women per year.¹ Ovarian cancer is the fifth

Figure 1. US Preventive Services Task Force (USPSTF) Grades and Levels of Certainty

What the USPSTF Grades Mean and Suggestions for Practice		
Grade	Definition	Suggestions for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer or provide this service.
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate, or there is moderate certainty that the net benefit is moderate to substantial.	Offer or provide this service.
C	The USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small.	Offer or provide this service for selected patients depending on individual circumstances.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.	Read the Clinical Considerations section of the USPSTF Recommendation Statement. If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.

USPSTF Levels of Certainty Regarding Net Benefit	
Level of Certainty	Description
High	The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.
Moderate	The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by such factors as 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. lack of information on important health outcomes. More information may allow estimation of effects on health outcomes.
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.	

USPSTF indicates US Preventive Services Task Force.

most common cause of cancer death among US women and the leading cause of death from gynecologic cancer, despite its low incidence.¹ Approximately 14 000 women die of ovarian cancer each year in the United States. More than 95% of ovarian cancer deaths occur among women 45 years and older.²

Detection

The positive predictive value of screening tests for ovarian cancer is low, and most women with a positive screening test result do not have ovarian cancer (ie, many women without ovarian cancer will have a false-positive result on screening tests).

Benefits of Screening

The USPSTF found adequate evidence that screening with transvaginal ultrasound, testing for the serum tumor marker cancer antigen 125 (CA-125), or a combination of both does not reduce ovarian cancer mortality.

Harms of Screening

The USPSTF found adequate evidence that screening for ovarian cancer can result in important harms, including many false-positive results, which can lead to unnecessary surgical interventions in women who do not have cancer. Depending on the type of screening test

Figure 2. Clinical Summary: Screening for Ovarian Cancer

Population	Asymptomatic women without a known high-risk hereditary cancer syndrome
Recommendation	Do not screen for ovarian cancer in asymptomatic women. Grade: D
Risk Assessment	Women with certain hereditary cancer syndromes are at high risk for ovarian cancer. Women with a family history of ovarian or breast cancer may be at risk for a hereditary cancer syndrome and should discuss their family history with their health care professional. The clinical symptoms of ovarian cancer (eg, abdominal pain or pressure, bloating, constipation, urinary symptoms, back pain, or fatigue) are nonspecific and may be present in both healthy women and women with late-stage ovarian cancer; therefore, use of clinical symptoms for risk stratification for the early detection of disease is difficult.
Screening Tests	The USPSTF does not recommend routine screening for ovarian cancer using any method. Transvaginal ultrasound and serum cancer antigen 125 testing are readily available procedures that are commonly used to evaluate women with signs or symptoms of ovarian cancer and have been evaluated in screening studies. Pelvic examination is also commonly performed to evaluate women with lower abdominal symptoms.
Treatments	Treatment of ovarian cancer typically includes surgical treatment (staging or debulking) and intraperitoneal, intravenous, or combined chemotherapy.
Other Relevant USPSTF Recommendations	The USPSTF recommends that women with a family history indicating they are at risk for a deleterious gene mutation (<i>BRCA1</i> or <i>BRCA2</i>) be referred for genetic counseling and, if indicated, genetic testing. The USPSTF concluded that the current evidence is insufficient to assess the balance of benefits and harms of screening with pelvic examination to detect a range of gynecologic conditions in asymptomatic, nonpregnant women.

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



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used, the magnitude of harm ranges from moderate to substantial and reflects the risk for unnecessary diagnostic surgery. The USPSTF found inadequate evidence on the psychological harms of screening for ovarian cancer.

USPSTF Assessment

The USPSTF concludes that there is at least moderate certainty that the harms of screening for ovarian cancer outweigh the benefits.

Clinical Considerations

Patient Population Under Consideration

This recommendation applies to asymptomatic women who are not known to have a high-risk hereditary cancer syndrome (Figure 2). A hereditary cancer syndrome occurs when a genetic mutation is passed from parent to child that increases risk for developing cancers or can cause earlier onset of cancers. Women who have a hereditary cancer syndrome that puts them at high risk for ovarian cancer are excluded from this recommendation.

Risk Assessment

Women with certain hereditary cancer syndromes are at high risk for ovarian cancer. For example, women with *BRCA1* or *BRCA2* genetic mutations associated with hereditary breast and ovarian cancer syndrome are at high risk for ovarian cancer. Numerous genetic mutations and hereditary cancer syndromes may be associated with

ovarian cancer, each with a different constellation of associated cancers and family history pattern.³⁻⁵ Women with a family history of ovarian or breast cancer may be at risk for a hereditary cancer syndrome and should discuss their family history with their health care professional. Management of a diagnosed hereditary cancer syndrome and prevention of ovarian cancer in these women is beyond the scope of this recommendation statement.

The clinical symptoms of ovarian cancer (eg, abdominal pain or pressure, bloating, constipation, urinary symptoms, back pain, or fatigue) are nonspecific and may be present in both healthy women and women with late-stage ovarian cancer; therefore, use of clinical symptoms for risk stratification for the early detection of disease is difficult.

Screening Tests

The USPSTF does not recommend routine screening for ovarian cancer using any method. Transvaginal ultrasound and serum CA-125 testing are readily available procedures that are commonly used to evaluate women with signs or symptoms of ovarian cancer, and both have been evaluated in screening studies. Pelvic examination is also commonly performed to evaluate women with lower abdominal symptoms, and although many clinicians perceive that pelvic examination with bimanual palpation of the ovaries is useful for screening for ovarian cancer,⁶ there is a lack of evidence to support this.⁷ Furthermore, the Prostate, Lung, Colorectal, and Ovarian (PLCO) Cancer Screening Trial included bimanual palpation of the ovaries in its initial screening protocol, but this screening component was

discontinued 5 years into the study because no cases of ovarian cancer were detected solely with bimanual palpation of the ovaries.^{8,9}

The evaluation of abnormal test results consists of repeat testing with the same or a different test and often surgical removal (by laparoscopy or laparotomy) of 1 or both of the ovaries and fallopian tubes to determine whether a woman has ovarian cancer. Diagnostic guidelines recommend surgical removal of the complete ovary or ovaries, rather than tissue biopsy, to determine whether ovarian cancer is present.

Treatment

Treatment of ovarian cancer typically includes surgical treatment (staging or debulking) and intraperitoneal, intravenous, or combined chemotherapy.

Useful Resources

In a separate recommendation statement, the USPSTF recommends that women with a family history indicating they are at risk for a deleterious gene mutation (*BRCA1* or *BRCA2*) be referred for genetic counseling and, if indicated, genetic testing.¹⁰ The National Cancer Institute provides additional information on ovarian cancer risk and hereditary cancer syndromes.¹¹ The USPSTF also concluded in a separate recommendation statement that the current evidence was insufficient to assess the balance of benefits and harms of screening with pelvic examination to detect a range of gynecologic conditions in asymptomatic, nonpregnant women.⁷

Other Considerations

Research Needs and Gaps

Given that most cases of ovarian cancer are diagnosed at later stages, when associated mortality is high, further research is needed to identify new screening strategies that could accurately detect ovarian cancer early, at a point when outcomes could be improved. There is a need for more sensitive and specific serologic tests, as well as better imaging techniques. Because of the potential for serious harms from diagnostic workup of positive screening results (ie, surgical removal of the ovary to determine whether ovarian cancer is present), new screening strategies should minimize false-positive results and be highly specific. In addition, studies evaluating the benefits and harms of these screening strategies in asymptomatic women not at high risk for ovarian cancer are needed. Study outcomes should include ovarian cancer mortality, quality of life, false-positive rate, surgery rate, surgical complication rate, and psychological harms. Further research is also needed on primary prevention of ovarian cancer.

Discussion

Burden of Disease

Based on United States Cancer Statistics data on invasive cancer rates from 2010 to 2014, the average annual age-adjusted incidence of ovarian cancer was 11.4 cases per 100 000 women per year, with a mortality rate of 7.4 deaths per 100 000 women.¹ In 2017, it is estimated that 22 440 new cases of ovarian cancer will have been diagnosed in the United States and 14 080 deaths will have occurred.¹²

Early stages of the disease are often asymptomatic. Symptoms are usually nonspecific and can include abdominal pain or pressure, bloating, constipation, urinary symptoms, back pain, or fatigue.¹³ The majority of women (88%) diagnosed with ovarian cancer are 45 years and older, with a median age at diagnosis of 63 years.² Most women with ovarian cancer are diagnosed at later stages; approximately 60% of women have distant spread of disease at the time of diagnosis.² From 2010 to 2014, white women had the highest age-adjusted incidence rate (11.8 cases per 100 000 women), followed by Hispanic women (10.3 cases per 100 000 women), black women (9.2 cases per 100 000 women), Asian/Pacific Islander women (9.1 cases per 100 000 women), and American Indian/Alaska Native women (8.3 cases per 100 000 women). White women are most likely to die of ovarian cancer, followed by black, Hispanic, American Indian/Alaska Native women, and Asian/Pacific Islander women.¹

Mortality rates from ovarian cancer vary by stage at diagnosis; 5-year survival rates range from 92.5% for localized cancer to 28.9% for cancer with distant spread.¹⁴

Scope of Review

The USPSTF commissioned a review of the evidence on screening for ovarian cancer to update its 2012 recommendation. The evidence review evaluated the benefits and harms of screening for ovarian cancer in asymptomatic women not known to be at high risk for ovarian cancer. Outcomes of interest included ovarian cancer mortality, quality of life, false-positive rate, surgery and surgical complication rates, and psychological effects of screening. The USPSTF included primary peritoneal cancer in its ascertainment of ovarian cancer outcomes, even if it was not the primary end point of the study, because clinically, both types of cancer are diagnosed and treated as 1 disease. The USPSTF also considered ascertainment of ovarian cancer outcomes that included both incident and prevalent cases of cancer, since screening programs would detect both. The review included any screening approach evaluated by clinical trial design. The USPSTF considered the initial screening test (eg, transvaginal ultrasound or CA-125 testing interpreted using a single cutoff or the risk of ovarian cancer algorithm [ROCA; Abcodia Inc]) as the screening intervention. Further testing that subsequently occurred based on initial screening test results was considered follow-up testing and evaluation, rather than part of screening.

Effectiveness of Screening

The USPSTF reviewed direct evidence evaluating the benefits of screening for ovarian cancer on mortality.³ The USPSTF identified 3 good-quality studies evaluating the effect of annual screening in asymptomatic women not known to be at high risk for ovarian cancer. None of the studies found that screening significantly reduced ovarian cancer mortality. The largest and most recent trial, the UK Collaborative Trial of Ovarian Cancer Screening (UKCTOCS), was a randomized clinical trial of 202 638 postmenopausal women aged 50 to 74 years not known to be at high risk for ovarian cancer.¹⁵ More than 95% of trial participants were white, and 1.6% reported a maternal history of ovarian cancer and 6.4% reported a maternal history of breast cancer; however, women with a family history considered "high risk" for familial ovarian cancer were explicitly excluded.¹⁶ The UKCTOCS trial had 2 intervention groups and a no-screening control group. Women were randomized to screening with CA-125 serum testing, with triage and follow-up determined by ROCA,

or to yearly transvaginal ultrasound. The CA-125 ROCA screening intervention group was described as multimodal screening in the trial publications and included a standard protocol for all additional evaluation. ROCA evaluates changes in CA-125 values over time, following a baseline age-adjusted measurement. Women randomized to the control group received no screening. After a median follow-up of 11.1 years, ovarian cancer mortality (which includes mortality from primary peritoneal and fallopian tube cancer) was not significantly different among the control group and 2 intervention groups (0.35% in the control group, 0.32% in the transvaginal ultrasound group, and 0.32% in the CA-125 ROCA group). There was also no significant difference in mortality risk in the transvaginal ultrasound and CA-125 ROCA groups (hazard ratio, 0.91 [95% CI, 0.76-1.09] and 0.89 [95% CI, 0.74-1.08], respectively).^{3,15} Exploratory analyses of UKCTOCS trial data suggest the potential for emergence of a delayed mortality benefit of screening appearing beyond 10 years from randomization. However, this finding was not statistically significant unless cases of primary peritoneal cancer were excluded. Extended follow-up data may help clarify this potential finding in the future; however, given the aggressive nature (ie, low 5-year survival rate) of ovarian cancer, the mechanism behind a delayed benefit from screening and early detection would be unclear, especially because the trial discontinued screening after 7 to 11 years.

The pilot trial for the UKCTOCS trial, UK Pilot, was much smaller (n = 21 955 randomized). It evaluated the use of a single cutoff value for CA-125 testing and found no significant difference in ovarian cancer mortality (excluding cases of primary peritoneal cancer, which were not reported) between women who were screened vs not screened (0.08% vs 0.16%; relative risk, 0.50 [95% CI, 0.22-1.11]).^{3,17}

The only trial conducted in the United States was the PLCO trial. In that trial, 68 557 women who had at least 1 ovary at baseline were randomized to either annual screening (both CA-125 testing and transvaginal ultrasound for the first 4 rounds of screening, then 2 rounds of CA-125 testing only) or usual care; median follow-up was 12.4 years. Eligible participants were women aged 55 to 74 years without a previous diagnosis of lung, colorectal, or ovarian cancer. Trial recruitment targeted women from the general population; the trial did not actively exclude women based on risk for hereditary ovarian cancer syndromes (based on reported family history), and 17.4% of participants reported a family history of ovarian or breast cancer. Nearly 90% of participants were white. Abnormal test results were managed by the participant's personal health care practitioner. No difference was found in ovarian cancer mortality, which includes primary peritoneal cancer mortality, with 0.34% in the screening group and 0.29% in the usual care group (relative risk, 1.18 [95% CI, 0.82-1.71]).^{3,8} Recent analyses of PLCO trial data that add up to 6 more years of posttrial mortality data also did not find evidence of a longer-term benefit of screening.¹⁸

Potential Harms of Screening

The USPSTF reviewed evidence on harms of screening for ovarian cancer from the 3 studies described above, as well as a fourth study of fair quality reporting on quality of life and psychological harms of screening (Quality of life, Education, and Screening Trial [QUEST]) (n = 549 analyzed).¹⁹ Based on data from the 3 studies, the calculated false-positive rates (ie, the number of women without cancer who had a positive screening test result) were 11.9% in the first screening round in the UKCTOCS transvaginal ultrasound group and

9.0% in the first screening round in the UKCTOCS CA-125 ROCA group.³ These rates exclude cases of primary peritoneal cancer because this information was not reported. Cumulatively, in all subsequent screening rounds (ie, rounds 2 to 11) in the UKCTOCS CA-125 ROCA group, 44.2% of women who did not have ovarian cancer (including primary peritoneal cancer) had a positive CA-125 ROCA result at some point during the trial screening period.³ The false-positive rate for subsequent screening rounds in the UKCTOCS transvaginal ultrasound group was not reported. In the UK Pilot trial, the calculated false-positive rate (excluding cases of primary peritoneal cancer, which were not reported) of CA-125 testing using a single cutoff value was 4.2% across 3 screening rounds. In the PLCO trial, the calculated false-positive rate (including cases of primary peritoneal cancer) of transvaginal ultrasound and CA-125 testing was 9.6% across all 6 screening rounds.³ Surgery to investigate positive screening test results among women who ultimately did not have ovarian cancer occurred in 0.2% of participants in the UK Pilot CA-125 group, 0.97% of participants in the UKCTOCS CA-125 ROCA group, 3.25% of participants in the UKCTOCS ultrasound group, and 3.17% of participants in the PLCO CA-125 plus ultrasound group.³ Up to 15% of these women had major surgical complications.³

The USPSTF identified limited evidence on the psychological harms of screening for ovarian cancer from the UKCTOCS and QUEST trials.^{3,19,20} The UKCTOCS trial measured anxiety in a subgroup of participants. Although no significant differences were found between the intervention and control groups, there was a greater odds of psychological morbidity among women who were referred to higher levels of screening.²⁰ The QUEST trial evaluated the effect of screening for ovarian cancer on cancer worry and quality of life among average-risk US women 30 years and older. Cancer screening consisted of alternating CA-125 testing and transvaginal ultrasound every 6 months, for a maximum of 4 screening rounds. Although no statistically significant difference in cancer worry was found between study groups, the trial found that women with abnormal test results were more likely to report cancer worry at 2 years of follow-up (odds ratio, 2.8 [95% CI, 1.1-7.2]) than women without abnormal results.¹⁹

Estimate of Magnitude of Net Benefit

The USPSTF found adequate evidence that screening for ovarian cancer does not reduce ovarian cancer mortality. Three large good-quality studies all found no benefit in ovarian cancer mortality from annual screening in asymptomatic women not known to be at high risk for ovarian cancer. The USPSTF also found adequate evidence from these 3 studies that the harms from screening for ovarian cancer are at least moderate and may be substantial in some cases. Harms from screening for ovarian cancer include false-positive results, which may lead to unnecessary diagnostic surgery to determine whether ovarian cancer is present, often resulting in removal of 1 or both of the ovaries and fallopian tubes. Serious surgical complications can also result. The USPSTF found the evidence on psychological harms of screening to be inadequate and could not draw any definitive conclusion on whether ovarian cancer screening causes psychological harms. Given the lack of mortality benefit of screening, and the moderate to substantial harms that could result from false-positive screening test results and subsequent surgery, the USPSTF concludes with moderate certainty that the harms of screening for ovarian cancer with CA-125 testing (using a single cutoff value or the ROCA), transvaginal

ultrasound, or both outweigh the benefit, and the net balance of the benefit and harms of screening is negative.

Response to Public Comment

A draft version of this recommendation statement was posted for public comment on the USPSTF website from July 18, 2017, to August 14, 2017. Many comments voiced concern that given the aggressive nature of ovarian cancer and that symptoms often only appear at later stages, any screening test that can detect ovarian cancer early should be recommended. The USPSTF agrees that screening tests are needed that can accurately detect ovarian cancer earlier to prevent deaths from ovarian cancer; however, the evidence shows that currently available tests are not able to do so and can lead to harm by causing healthy women to undergo surgical removal of their ovaries when no cancer is present. The USPSTF issued its recommendation against screening based on this evidence, not on the costs of screening. Additional comments sought clarification on which women are at high risk for ovarian cancer and to whom the recommendation applies. The USPSTF revised the recommendation statement to clarify the role of family history in ovarian cancer risk and to describe symptoms of ovarian cancer. Women with a family history of ovarian or breast cancer or symptoms should discuss this with their health care provider. The USPSTF also provided more information on how it considered evidence from specific studies. The USPSTF considered study results that included cases of primary peritoneal cancer in the ascertainment of ovarian cancer because clinically, both types of cancer are diagnosed and treated as 1 disease. Similarly, the USPSTF considered study results that included reporting of both prevalent and incident cases of ovarian cancer, because screening would detect both.

Update of Previous USPSTF Recommendation

This recommendation statement is consistent with the 2012 USPSTF recommendation.²¹ Since 2012, the large UKCTOCS trial was published, and much like the PLCO trial, it did not find that screening for ovarian cancer reduces ovarian cancer mortality in asymptomatic women not known to be at high risk for ovarian cancer.

Recommendations of Others

There is consensus among major medical and public health organizations that screening for ovarian cancer in the general population is not recommended. The American College of Obstetricians and Gynecologists does not recommend screening for ovarian cancer in low-risk, asymptomatic women; evaluation of high-risk women may include transvaginal ultrasound and CA-125 testing, in addition to physical examination.²² The American Cancer Society states that there is no screening test proven to be effective and sufficiently accurate in the early detection of ovarian cancer and does not recommend screening for ovarian cancer in average-risk women.²³ The American College of Radiology does not recommend screening for ovarian cancer in average-risk women.²⁴ Consistent with the USPSTF, the American Academy of Family Physicians recommends against screening for ovarian cancer in asymptomatic women.²⁵ Although it is beyond the scope of the USPSTF recommendation, other organizations, such as the National Comprehensive Cancer Network, have issued guidelines for the prevention of ovarian cancer in women with hereditary cancer syndromes.²⁶

ARTICLE INFORMATION

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