Complete Summary

GUIDELINE TITLE

Ovarian cancer screening.

BIBLIOGRAPHIC SOURCE(S)

Bohm-Velez M, Fleischer AC, Andreotti RF, Fishman EK, Horrow MM, Hricak H, Thurmond A, Zelop C, Expert Panel on Women's Imaging. Ovarian cancer screening. [online publication]. Reston (VA): American College of Radiology (ACR); 2005. 7 p. [18 references]

GUIDELINE STATUS

This is the current release of the guideline.

It updates a previously published version: Bohm-Velez M, Mendelson E, Bree R, Finberg H, Fishman EK, Hricak H, Laing F, Sartoris D, Thurmond A, Goldstein S. Ovarian cancer screening. American College of Radiology. ACR Appropriateness Criteria. Radiology. 2000 Jun;215 Suppl:861-71.

The appropriateness criteria are reviewed annually and updated by the panels as needed, depending on introduction of new and highly significant scientific evidence.

COMPLETE SUMMARY CONTENT

SCOPE
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SCOPE

DISEASE/CONDITION(S)

Ovarian cancer

GUIDELINE CATEGORY

Screening

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Obstetrics and Gynecology
Oncology
Radiology

INTENDED USERS

Health Plans
Hospitals
Managed Care Organizations
Physicians
Utilization Management

GUIDELINE OBJECTIVE(S)

To evaluate the appropriateness of radiologic procedures for screening for ovarian cancer

TARGET POPULATION

Women at risk for developing ovarian cancer

INTERVENTIONS AND PRACTICES CONSIDERED

1. Gynecological evaluation
2. Ultrasound (US)
    - Transabdominal
    - Transvaginal
    - Doppler color
    - Spectral Doppler
3. CA 125 levels
4. Computed tomography (CT)
5. Magnetic resonance imaging (MRI)
6. US follow-up every 3, 6, 12, & 24 months

MAJOR OUTCOMES CONSIDERED

Utility of radiologic examinations in differential diagnosis

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The guideline developer performed literature searches of peer-reviewed medical journals, and the major applicable articles were identified and collected.

NUMBER OF SOURCE DOCUMENTS

The total number of source documents identified as the result of the literature search is not known.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Not Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not stated

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

One or two topic leaders within a panel assume the responsibility of developing an evidence table for each clinical condition, based on analysis of the current literature. These tables serve as a basis for developing a narrative specific to each clinical condition.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Delphi)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Since data available from existing scientific studies are usually insufficient for meta-analysis, broad-based consensus techniques are needed to reach agreement in the formulation of the Appropriateness Criteria. The American College of Radiology (ACR) Appropriateness Criteria panels use a modified Delphi technique to arrive at consensus. Serial surveys are conducted by distributing questionnaires to consolidate expert opinions within each panel. These questionnaires are distributed to the participants along with the evidence table and narrative as developed by the topic leader(s). Questionnaires are completed by the participants in their own professional setting without influence of the other members. Voting is conducted using a scoring system from 1-9, indicating the least to the most appropriate imaging examination or therapeutic procedure. The survey results are collected, tabulated in anonymous fashion, and redistributed after each round. A maximum of three rounds is conducted and opinions are unified to the highest degree possible. Eighty percent agreement is considered a

consensus. This modified Delphi technique enables individual, unbiased expression, is economical, easy to understand, and relatively simple to conduct.

If consensus cannot be reached by this Delphi technique, the panel is convened and group consensus techniques are utilized. The strengths and weaknesses of each test or procedure are discussed and consensus reached whenever possible. If "No consensus" appears in the rating column, reasons for this decision are added to the comment sections.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

In 1996, the cost of an US screening program prompted by an abnormal CA 125 level was estimated to be six times greater in the general population compared to patients with family history. The cost of screening for ovarian cancer is at least 10 times that of screening for breast cancer. Of every 10,000 women participating in an annual screening program with CA 125 for 3 years, 800 would have an ultrasound scan because of an elevated CA 125, 30 would undergo surgery because of an abnormal ultrasound, and 6 would have ovarian cancer detected at surgery (3 will be diagnosed at early-stage disease and have a chance of a cure.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Committee on Appropriateness Criteria.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

ACR Appropriateness Criteria®

Clinical Condition: Ovarian Cancer Screening

Variant 1: Premenopausal or postmenopausal female: low risk.

Radiologic Exam Procedure	Appropriateness Rating	Comments
Gynecological evaluation	8	Gynecological evaluation not completely directed for ovarian cancer but for a variety of reasons.

Radiologic Exam Procedure	Appropriateness Rating	Comments
US, pelvis, transabdominal	2	
US, pelvis, transvaginal	2	
US, pelvis, Doppler color	2	
US, pelvis, spectral Doppler	2	If there is blood flow with color, spectral waveform will quantify the flow.
CT, pelvis	2	
MRI, pelvis	2	
CA 125	2	
Appropriateness Criteria Scale **1 2 3 4 5 6 7 8 9** **1 = Least appropriate 9 = Most appropriate**		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 2: Premenopausal female: high risk.

Radiologic Exam Procedure	Appropriateness Rating	Comments
Gynecological evaluation	8	Gynecological evaluation not completely directed for ovarian cancer but for a variety of reasons.
US, pelvis, transvaginal	8	
US, pelvis, transabdominal	6	
US, pelvis, Doppler color	6	
US, pelvis, spectral Doppler	4	If there is blood flow with color, spectral waveform will quantify the flow.
CA 125	4	
CT, pelvis	2	
MRI, pelvis	2	

Radiologic Exam Procedure	Appropriateness Rating	Comments
Appropriateness Criteria Scale **1 2 3 4 5 6 7 8 9** **1 = Least appropriate 9 = Most appropriate**		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 3: Postmenopausal female: high risk.

Radiologic Exam Procedure	Appropriateness Rating	Comments
Gynecological evaluation	8	Gynecological evaluation not completely directed for ovarian cancer but for a variety of reasons.
CA 125	8	
US, pelvis, transvaginal	8	
US, pelvis, Doppler color	8	
US, pelvis, spectral Doppler	6	If there is blood flow with color, spectral waveform will quantify the flow.
US, pelvis, transabdominal	6	
CT, pelvis	2	
MRI, pelvis	2	
Appropriateness Criteria Scale **1 2 3 4 5 6 7 8 9** **1 = Least appropriate 9 = Most appropriate**		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 4: Premenopausal female with no mass detected by US: low risk.

Radiologic Exam Procedure	Appropriateness Rating	Comments
Gynecological evaluation	8	Gynecological evaluation not completely directed for ovarian cancer but for a

Radiologic Exam Procedure	Appropriateness Rating	Comments
		variety of reasons.
US, pelvis, Doppler color	2	
US, pelvis, spectral Doppler	2	If there is blood flow with color, spectral waveform will quantify the flow.
US-follow-up every 3 months	2	
US-follow-up every 6 months	2	
US-follow-up every 12 months	2	
US-follow-up every 24 months	2	
CT, pelvis	2	
MRI, pelvis	2	
CA 125	2	
Appropriateness Criteria Scale **1 2 3 4 5 6 7 8 9** **1 = Least appropriate 9 = Most appropriate**		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 5: Premenopausal female with no mass detected by US: high risk.

Radiologic Exam Procedure	Appropriateness Rating	Comments
Gynecological evaluation	8	Gynecological evaluation not completely directed for ovarian cancer but for a variety of reasons.
US-follow-up every 12 months	6	
CA 125	3	
US, pelvis, Doppler color	2	
US, pelvis, spectral	2	If there is blood flow with color, spectral

Radiologic Exam Procedure	Appropriateness Rating	Comments
Doppler		waveform will quantify the flow.
US-follow-up every 3 months	2	
US-follow-up every 6 months	2	
US-follow-up every 24 months	2	
CT, pelvis	2	
MRI, pelvis	2	
Appropriateness Criteria Scale **1 2 3 4 5 6 7 8 9** **1 = Least appropriate 9 = Most appropriate**		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 6: Postmenopausal female with no mass detected by US: low risk.

Radiologic Exam Procedure	Appropriateness Rating	Comments
Gynecological evaluation	8	Gynecological evaluation not completely directed for ovarian cancer but for a variety of reasons.
US, pelvis, Doppler color	2	
US, pelvis, spectral Doppler	2	If there is blood flow with color, spectral waveform will quantify the flow.
US-follow-up every 3 months	2	
US-follow-up every 6 months	2	
US-follow-up every 12 months	2	
US-follow-up every 24 months	2	
CT, pelvis	2	

Radiologic Exam Procedure	Appropriateness Rating	Comments
MRI, pelvis	2	
CA 125	2	
Appropriateness Criteria Scale **1 2 3 4 5 6 7 8 9** **1 = Least appropriate 9 = Most appropriate**		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 7: Postmenopausal female with no mass detected by US: high risk.

Radiologic Exam Procedure	Appropriateness Rating	Comments
Gynecological evaluation	8	Gynecological evaluation not completely directed for ovarian cancer but for a variety of reasons.
US-follow-up every 12 months	8	
CA 125	5	
US, pelvis, Doppler color	4	
US, pelvis, spectral Doppler	4	If there is blood flow with color, spectral waveform will quantify the flow.
US-follow-up every 3 months	2	
US-follow-up every 6 months	2	
US-follow-up every 24 months	2	
CT, pelvis	2	
MRI, pelvis	2	
Appropriateness Criteria Scale **1 2 3 4 5 6 7 8 9** **1 = Least appropriate 9 = Most appropriate**		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Ovarian cancer is the most frequent cause of death from gynecologic malignancy in the United States. Approximately 20,700 new cases are diagnosed each year, and 12,500 of these women will die of their disease. In the United States, one woman in 70 (1.4%) will develop ovarian cancer during her lifetime compared to one in nine for breast cancer. Symptoms usually do not become apparent until the tumor compresses or invades adjacent structures, ascites develops, or metastasis becomes clinically evident. As a result, 70% of women with ovarian cancer have advanced disease at diagnosis with a five year survival rate of 15% to 20% compared to the 5 year survival of 90% in patients with stage I disease. Because of the significant differences in survival rates between early and advanced cancers, a screening method for detecting early ovarian cancer has been sought. Clinical evidence suggests that the preclinical phase for ovarian cancer may be less than two years. This rapid growth pattern may imply difficulty in detecting early, resectable tumors.

Patients at risk include those of low parity, decreased fertility and delayed childbearing. The annual incidence increases with age, from 20 per 100,000 in women age 30 to 50 years of age and 40 per 100,000 in women 50 to 75 years of age. The strongest risk factor for ovarian cancer is familial evidence of ovarian cancer, reported in 7% of women with the disease. A patient with a history of familial ovarian cancer (two or more first-degree relatives-mother, sister, daughter) may have as much as a 50% chance of developing the disease. The presence of a hereditary ovarian cancer syndrome includes occurrence of ovarian, breast, and/or related cancers such as endometrial and gastrointestinal (Lynch II syndrome) in multiple members of two to four generations. These women present with the disease at an earlier age (45 to 52 compared to 59 years in the general population). The risk of ovarian cancer is elevated among women who have a first-degree relative with breast cancer (1.5 times) or colorectal cancer (1.9 times).

Women with a positive family history and a familial tendency for ovarian cancer should be counseled in their early 20s by a gynecologic oncologist or geneticist about their risk, with clinical follow-up in their 30s and possibly preventive surgery (i.e., prophylactic oophorectomy). Patients in the reproductive age group may be counseled on the benefits of oral contraceptives. Studies have demonstrated a decrease in ovarian cancer risks (as high as 50%) in patients taking oral contraceptives, with the protective effect increasing with duration of use.

Current screening tests for detecting ovarian cancer include physical examination, tumor markers (e.g., CA 125) and imaging methods such as US: transabdominal (TAS) and transvaginal (TVS) with color Doppler and power Doppler imaging, CT, and MRI. The pelvic examination, which can detect a variety of gynecological disorders, is not sensitive or specific for detecting ovarian cancer. In general, ovarian malignancies have disseminated by the time they are palpable.

CA 125 is the antigenic determinant of a glycoprotein expressed by epithelial ovarian tumors and other tissues of müllerian origin. CA 125 is elevated (> 35 U/mL) in more than 80% of patients with epithelial ovarian cancer, however; it is

only 25% sensitive for early disease. It is not specific for ovarian cancers since it can be elevated in other malignant conditions (pancreatic, endocervical, and fallopian tube cancers) and in benign conditions such as pregnancy, endometriosis, leiomyomas, pelvic inflammatory disease, hepatitis, and cirrhosis. CA 125 fluctuates during the menstrual cycle, and in premenopausal women, more than 90% of CA 125 elevations are falsely positive for ovarian carcinoma. Therefore, alone it does not have a sufficiently high sensitivity to be recommended for routine ovarian cancer screening. However, CA 125 levels exceeding 65 U/mL are predictive of malignancy in 75% of postmenopausal women with pelvic masses. The primary usefulness of CA 125 is in the management of patients with documented ovarian cancer. Other tumor markers such as NB/70K, a marker for epithelial mucinous adenocarcinomas of the ovary, may increase the sensitivity of the CA 125 marker when used concurrently.

Data have confirmed that US is a more accurate method of distinguishing normal from abnormal ovaries, especially in the postmenopausal female. The largest study to examine TAS for ovarian cancer was reported in 1989. In this study, premenopausal and postmenopausal women had three annual transabdominal ultrasound examinations; 338 had abnormal screening; five primary ovarian cancers and four metastatic ovarian cancers were detected for an overall specificity of 97.7%. Two of the primary cancers were found at the first screening and three a year after the first screening. One in 50 women with abnormal US had ovarian cancer, which means that of 50 laparotomies one case of primary ovarian cancer would be found with no cancer present in the other 49. The study demonstrated the usefulness of TAS for detecting ovarian abnormalities particularly in postmenopausal women, and its lack of specificity due to its suboptimal resolution of the morphological features. Researchers in another study screened 22,000 asymptomatic postmenopausal women with a combination of both CA 125 and TAS. Their screening program had a specificity of 99.9% with sensitivity of 78.6% at one year and 57.9% at two year follow-up.

By placing a high frequency transducer closer to the adnexa, TVS increases resolution and improves the ability to detect abnormalities of the ovary. In a study of postmenopausal females, researchers found that TVS was able to identify both ovaries in 60% of the cases and at least one ovary in 81% of the cases. Most of the ovaries not visualized were atrophic. These data suggest that not visualizing the postmenopausal ovary with TVS confirms lack of an abnormality. TVS has demonstrated that 17% of postmenopausal ovaries contain simple cysts that are transient and frequently benign. The prevalence of these adnexal cysts or cyst activity is independent of hormone replacement therapy. While scanning 1,300 asymptomatic patients with TVS, researchers in another study identified two early ovarian cancers with normal CA 125 and pelvic examination.

In an attempt to improve the specificity, one study evaluated women with positive family history (one first-degree or second-degree relative) of ovarian cancer with TVS. Three primary stage I ovarian cancers were found, consistent with a false positive rate of 5.5% and a positive predictive value (PPV) of 7.7%. Another study found that 32 surgeries were performed to diagnose ovarian cancer in the low risk population compared to 17 surgeries in the high-risk population.

Combining TVS with color flow Doppler imaging technique has been shown by many authors to further enhance the detection of early stage ovarian cancer. In a

high-risk population, one study found TVS to have a specificity in detecting ovarian tumors of 97.5% and PPV of 25% compared to color flow imaging with a specificity of 99.9% and PPV of 60%. The pulsatility or resistive index (PI or RI) value indicates decrease in resistance to blood flow in the distal vasculature and has been identified in malignant lesions as well as vascular benign masses. The neovascularity identified in malignant masses can also be seen in the formation of the corpus luteum. Therefore, to avoid unnecessary surgery, screening for premenopausal women should be done during days 1 to 12 of the menstrual cycle. In postmenopausal women, low resistance blood vessels are not seen within normal ovaries and when present are considered abnormal. The absence of intraluminal flow or high impedance flow in an ovary can potentially exclude malignancy. However, morphologic characteristics remain the most important criteria in differentiating a normal from an abnormal ovary.

Pelvic CT is not indicated for screening due to its inability to image small lesions, poor soft tissue discrimination in the pelvis, high cost and need for contrast material. The cost of MRI, in addition to the lack of resolution in the pelvis precludes its use in screening for small ovarian abnormalities.

In 1996, the cost of an US screening program prompted by an abnormal CA 125 level was estimated to be six times greater in the general population compared to patients with family history. The cost of screening for ovarian cancer is at least 10 times that of screening for breast cancer. Of every 10,000 women participating in an annual screening program with CA 125 for 3 years, 800 would have an ultrasound scan because of an elevated CA 125, 30 would undergo surgery because of an abnormal ultrasound, and 6 would have ovarian cancer detected at surgery (3 will be diagnosed at early-stage disease and have a chance of a cure.

In postmenopausal women, surgical evaluation may be recommended when the ovarian volume is enlarged (> 8 cc) with an elevated CA 125 or a normal CA 125 with abnormal morphologic characteristics of the ovary (i.e., complex or solid mass). If an ovarian simple cyst measures > 5 cm in diameter or < 5 cm with an elevated CA 125 and/or low impedance flow, surgical intervention may be considered.

Since there is a low prevalence of the disease in the general population, there are no statistically significant data to show that screening reduces mortality. Additionally, a screening test with high sensitivity is needed. Therefore, routine screening for ovarian cancer cannot be recommended. The results from a large clinical trial comparing long-term mortality from ovarian cancer between screened and nonscreened cohorts are needed. Future developments in serum proteomes may offer exciting opportunities for identifying novel biomarkers or patterns of markers that will have a greater sensitivity and lead time for preclinical disease.

Abbreviations

- CT, computed tomography
- MRI, magnetic resonance imaging
- US, ultrasound

CLINICAL ALGORITHM(S)

Algorithms were not developed from criteria guidelines.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations are based on analysis of the current literature and expert panel consensus.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Selection of appropriate radiologic imaging procedures for screening of ovarian cancer

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

An American College of Radiology (ACR) Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists, and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those exams generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the U.S. Food and Drug Administration (FDA) have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Personal Digital Assistant (PDA) Downloads

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

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Bohm-Velez M, Fleischer AC, Andreotti RF, Fishman EK, Horrow MM, Hricak H, Thurmond A, Zelop C, Expert Panel on Women's Imaging. Ovarian cancer screening. [online publication]. Reston (VA): American College of Radiology (ACR); 2005. 7 p. [18 references]

ADAPTATION

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

DATE RELEASED

1996 (revised 2005)

GUIDELINE DEVELOPER(S)

American College of Radiology - Medical Specialty Society

SOURCE(S) OF FUNDING

The American College of Radiology (ACR) provided the funding and the resources for these ACR Appropriateness Criteria®.

GUIDELINE COMMITTEE

Committee on Appropriateness Criteria, Expert Panel on Women's Imaging

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Panel Members: Marcela Böhm-Vélez, MD; Arthur C. Fleischer, MD; Rochelle F. Andreotti, MD; Elliot K. Fishman, MD; Mindy M. Horrow, MD; Hedvig Hricak, MD, PhD; Amy Thurmond, MD; Carolyn Zelop, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

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The appropriateness criteria are reviewed annually and updated by the panels as needed, depending on introduction of new and highly significant scientific evidence.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the American College of Radiology (ACR) Web site.

ACR Appropriateness Criteria® *Anytime*, *Anywhere*™ (PDA application). Available from the ACR Web site.

Print copies: Available from the American College of Radiology, 1891 Preston White Drive, Reston, VA 20191. Telephone: (703) 648-8900.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- ACR Appropriateness Criteria®. Background and development. Reston (VA): American College of Radiology; 2 p. Electronic copies: Available in Portable Document Format (PDF) from the American College of Radiology (ACR) Web site.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on February 10, 2006.

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