NATIONAL GUIDELINE CLEARINGHOUSE™ (NGC) GUIDELINE SYNTHESIS

PART I. OVARIAN CANCER: SCREENING

Guidelines

1. **American College of Radiology (ACR)**. Ovarian cancer screening. [online publication]. Reston (VA): American College of Radiology (ACR); 2005. 7 p. [18 references]
2. **Scottish Intercollegiate Guidelines Network (SIGN)**. Epithelial ovarian cancer. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2003 Oct. 36 p. (SIGN publication; no. 75). [182 references]
3. **United States Preventive Services Task Force (USPSTF)**. Screening for ovarian cancer: recommendation statement. Ann Fam Med 2004 May-Jun;2(3):260-2.
4. **University of Michigan Health System (UMHS)**. Adult preventive health care: cancer screening. Ann Arbor (MI): University of Michigan Health System; 2004 May. 12 p. [4 references]

INTRODUCTION

A direct comparison of the American College of Radiology (ACR), Scottish Intercollegiate Guidelines Network (SIGN), United States Preventive Services Task Force (USPSTF), and University of Michigan Health System (UMHS) recommendations for the screening of ovarian cancer is provided in the tables below.

The guidelines differ somewhat in scope. In addition to addressing the screening of ovarian cancer, the SIGN guideline also addresses risk assessment, diagnosis and treatment. UMHS is broader in scope as well, and provides screening recommendations for breast, cervical, colon and prostate cancer. The discussion of ovarian cancer is found in the cervical cancer screening section of the UMHS original guideline document. These topics, however, are beyond the scope of this synthesis.

The tables below provide a side-by-side comparison of key attributes of each guideline, including specific interventions and practices that are addressed. The language used in these tables, particularly that which is used in Tables 4, 5 and 6, is in most cases taken verbatim from the original guidelines:

- Table 1 provides a quick-view glance at the primary interventions considered by each group and which make up the focus of this guideline synthesis.
- Table 2 provides a comparison of the overall scope of both guidelines.

- Table 3 provides a comparison of the methodology employed and documented by the guideline groups in developing their guidelines.
- Table 4 provides a more detailed comparison of the specific recommendations offered by each group for the topics under consideration in this synthesis, including:
  - Screening Recommendations
  - Supporting References
- Table 5 lists the potential benefits and harms associated with the implementation of each guideline as stated in the original guidelines.
- Table 6 presents the rating schemes used by ACR, SIGN, USPSTF, and UMHS to rate the level of evidence and/or the strength of the recommendations.

A summary discussion of the areas of agreement and differences among the guidelines is presented following the content comparison tables.

Abbreviations:

- ACR, American College of Radiology
- SIGN, Scottish Intercollegiate Guidelines Network
- USPSTF, United States Preventive Services Task Force
- UMHS, University of Michigan Health System

TABLE 1: COMPARISON OF INTERVENTIONS AND PRACTICES CONSIDERED
("✓" indicates topic is addressed)

	ACR (2005)	SIGN (2003)	USPSTF (2004)	UMHS (2004)
Screening				
General Population	✓	✓	✓	✓
High-Risk Groups	✓	✓		

TABLE 2: COMPARISON OF SCOPE AND CONTENT

Objective and Scope	
ACR (2005)	To evaluate the appropriateness of radiologic procedures for screening for ovarian cancer
SIGN	To provide evidence-based recommendations for the screening,

(2003)	diagnosis and management of patients with epithelial ovarian cancer
USPSTF (2004)	• To summarize the current U.S. Preventive Services Task Force (USPSTF) recommendation on screening for ovarian cancer and the supporting evidence • To update the 1996 recommendations contained in the *Guide to Clinical Preventive Services*, Second Edition: Periodic Updates.
UMHS (2004)	To implement an evidenced-based strategy for cancer screening in adults
Target Population	
ACR (2005)	• United States • Women at risk for developing ovarian cancer
SIGN (2003)	• Scotland • Women at high risk of ovarian cancer
USPSTF (2004)	• United States • Women seen in primary care settings
UMHS (2004)	• United States • Adults, 18 years and older
Intended Users	
ACR (2005)	Health Plans Hospitals Managed Care Organizations Physicians Utilization Management
SIGN (2003)	Advanced Practice Nurses Allied Health Personnel Clinical Laboratory Personnel

	Nurses Pharmacists Physician Assistants Physicians
USPSTF (2004)	Advanced Practice Nurses Physician Assistants Physicians
UMHS (2004)	Physicians

TABLE 3: COMPARISON OF METHODOLOGY	
Methods Used to Collect/Select the Evidence	
ACR (2005)	Searches of Electronic Databases *Described Process*: 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. *Number of References*: 18
SIGN (2003)	Searches of Electronic Databases *Described Process*: Literature searches were initially conducted in Medline, Embase, Cinahl, Cancerlit, and the Cochrane Library using the year range 1993 to 2001. The literature search was updated with new material during the course of the guideline development process. Key Web sites on the Internet were also used, such as the National Guidelines Clearinghouse. These searches were supplemented by the reference lists of relevant papers and group members' own files. The Medline version of the main search strategies can be found on the Scottish Intercollegiate Guidelines

	Network (SIGN) Web site. *Number of Source Documents*: Not stated *Number of References*: 182
USPSTF (2004)	Hand-searches of Published Literature (Primary Sources) Hand-searches of Published Literature (Secondary Sources) Searches of Electronic Databases **Note from the National Guideline Clearinghouse (NGC)**: A systematic evidence review was prepared by the Oregon Health & Science University Evidence-based Practice Center (EPC) for the Agency for Healthcare Research and Quality (AHRQ) for use by the U.S. Preventive Services Task Force (USPSTF) Evidence Review: • Nelson HD, Westhoff C, Piepert J, Berg A. Screening for ovarian cancer: Brief evidence update. Rockville (MD); Agency for Healthcare Research and Quality; 2004 May. 18 p. Electronic copies: Available from the U.S. Preventive Services Task Force (USPSTF) Web site. *Described Process*: **Search Strategy** In conjunction with a medical librarian, EPC staff conducted literature searches using MEDLINE (January 1995-December 2002) and the Cochrane Controlled Trials Register, yielding 685 abstracts. Additional articles were obtained by reviewing reference lists of pertinent studies, reviews, and editorials. EPC staff also reviewed results of a systematic review on screening for ovarian cancer by the Health Technology Assessment (HTA) program in the United Kingdom. **Inclusion and Exclusion Criteria** Studies were included if they addressed the key questions for the target population of asymptomatic women. Studies were excluded if the population was selected according to prior test results. Papers related to genetic testing were also excluded because they are beyond the scope of screening recommendations for the general population.

	Number of Source Documents: Not stated *Number of References*: 23
UMHS (2004)	Searches of Electronic Databases *Described Process*: The literature searches for this project were conducted prospectively on Medline for literature published since 1/1/95. A search was performed using the major key words *adults, humans, English,* plus the terms described below for each topic. (The specific key words associated with a term are detailed in parentheses following the first time a term is used.) The searches were conducted in components each keyed to a specific causal link in a formal problem structure. The searches were supplemented with very recent clinical trials known to expert members of the panel. Negative trials were specifically sought. The searches were single cycle. **Breast cancer screening**. The additional search terms (with specific key words in parentheses) were: breast cancer (breast neoplasms, mammary neoplasms, experimental mammary neoplasms, breast AND cancer), *preventive services (preventive health services, diagnostic services, mass screening, genetic screening, mass chest x-ray, multiphasic screening, neonatal screening, mobile health units, early intervention/education, health education, health fairs, patient education, prevention and control), diagnosis (sensitivity and specificity, predictive value of test, false negative reactions, false positive reactions, likelihood functions), guidelines (clinical protocols, physician's practice patterns, algorithms, outcome and process assessment [health care], consensus development conferences, NIH consensus development conferences, guideline, practice guidelines), research studies (clinical trials - phase IV, randomized clinical trials, controlled clinical trials, multicenter studies, cohort studies).* **Cervical cancer screening**. The additional search terms were: *cervical cancer (cervical neoplasms, cervical intraepithelial neoplasms, cervix dysplasia), preventive services, diagnosis, guidelines, research studies.* **Colon cancer screening**. The additional search terms (with specific key words in parentheses) were: *gastrointestinal cancer (gastrointestinal neoplasms, intestinal neoplasms, stomach neoplasms), preventive services, diagnosis, guidelines, research studies.* **Prostate cancer screening**. The additional search terms were: *prostate cancer (prostatic neoplasms), preventive services, diagnosis, guidelines, research studies.*

	Number of Source Documents: Not stated *Number of References*: 4
Methods Used to Assess the Quality and Strength of the Evidence	
ACR (2005)	Weighting According to a Rating Scheme (Scheme Not Given)
SIGN (2003)	Weighting According to a Rating Scheme (Scheme Given - Refer to Table 6)
USPSTF (2004)	Weighting According to a Rating Scheme (Scheme Given - Refer to Table 6)
UMHS (2004)	Weighting According to a Rating Scheme (Scheme Given - Refer to Table 6)
Methods Used to Analyze the Evidence	
ACR (2005)	Systematic Review with Evidence Tables *Described Process*: 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.
SIGN (2003)	Review of Published Meta-Analyses Systematic Review *Described Process*: The Scottish Intercollegiate Guidelines Network (SIGN) carries out comprehensive systematic reviews of the literature using customized search strategies applied to a number of electronic databases and the Internet. This is often an iterative process whereby the guideline development group will carry out a search for existing guidelines and systematic reviews in the first instance and, after the results of this search have been evaluated, the questions driving the search may be redefined and focused before proceeding to identify lower levels of evidence. Once papers have been selected as potential sources of evidence, the methodology used in each study is assessed to ensure its validity. Scottish Intercollegiate Guidelines Network has developed checklists to aid guideline developers to critically evaluate the methodology of different types of study design. The result of this assessment will affect the level of evidence allocated to the paper, which in turn will influence the grade of recommendation it

	supports. Additional details can be found in the companion document titled "An Introduction to the SIGN Methodology for the Development of Evidence-based Clinical Guidelines" (Edinburgh [UK]: Scottish Intercollegiate Guidelines Network. [SIGN publication; no. 50]). Available from the SIGN Web site.
USPSTF (2004)	Systematic Review with Evidence Tables
UMHS (2004)	Systematic Review *Described Process*: Not stated
Methods Used to Formulate the Recommendations	
ACR (2005)	Expert Consensus (Delphi) *Described Process*: 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.
SIGN (2003)	Expert Consensus (Refer to Table 6 for rating scheme) *Described Process*: The process for synthesising the evidence base

to form graded guideline recommendations is illustrated in the companion document titled "An Introduction to the SIGN Methodology for the Development of Evidence-based Clinical Guidelines." (Edinburgh [UK]: Scottish Intercollegiate Guidelines Network. [SIGN publication; no. 50], available from the SIGN Web site.

Evidence tables should be compiled, summarizing all the validated studies identified from the systematic literature review relating to each key question. These evidence tables form an important part of the guideline development record and ensure that the basis of the guideline development group's recommendations is transparent.

In order to address how the guideline developer was able to arrive at their recommendations given the evidence they had to base them on, SIGN has introduced the concept of considered judgement.

Under the heading of considered judgement, guideline development groups are expected to summarise their view of the total body of evidence covered by each evidence table. This summary view is expected to cover the following aspects:

- Quantity, quality, and consistency of evidence
- Generalisability of study findings
- Applicability to the target population of the guideline
- Clinical impact (i.e., the extent of the impact on the target patient population, and the resources need to treat them.)

Guideline development groups are provided with a pro forma in which to record the main points from their considered judgement. Once they have considered these issues, the groups are asked to summarise their view of the evidence and assign a level of evidence to it, before going on to derive a graded recommendation.

The assignment of a level of evidence should involve all those on a particular guideline development group or subgroup involved with reviewing the evidence in relation to each specific question. The allocation of the associated grade of recommendation should involve participation of all members of the guideline development group. Where the guideline development group is unable to agree on a unanimous recommendation, the difference of opinion should be formally recorded and the reason for dissent noted.

The recommendation grading system is intended to place greater weight on the quality of the evidence supporting each recommendation, and to emphasize that the body of evidence should be considered as a whole, and not rely on a single study to support each recommendation. It is also intended to allow more weight to be given to recommendations supported by good quality observational studies where randomised controlled trials (RCTs) are

	not available for practical or ethical reasons. Through the considered judgement process guideline developers are also able to downgrade a recommendation where they think the evidence is not generalisable, not directly applicable to the target population, or for other reasons is perceived as being weaker than a simple evaluation of the methodology would suggest. On occasion, there is an important practical point that the guideline developer may wish to emphasise but for which there is not, nor is there likely to be, any research evidence. This will typically be where some aspect of treatment is regarded as such sound clinical practice that nobody is likely to question it. These are marked in the guideline as "good practice points." It must be emphasized that these are not an alternative to evidence-based recommendations, and should only be used where there is no alternative means of highlighting the issue.
USPSTF (2004)	Balance Sheets Expert Consensus *Described Process*: When the overall quality of the evidence is judged to be good or fair, the U.S. Preventive Services Task Force (USPSTF) proceeds to consider the magnitude of net benefit to be expected from implementation of the preventive service. Determining net benefit requires assessing both the magnitude of benefits and the magnitude of harms and weighing the two. The USPSTF classifies benefits, harms, and net benefits on a 4-point scale: "substantial," "moderate," "small," and "zero/negative." "Outcomes tables" (similar to "balance sheets") are the USPSTF's standard resource for estimating the magnitude of benefit. These tables, prepared by the topic teams for use at USPSTF meetings, compare the condition-specific outcomes expected for a hypothetical primary care population with and without use of the preventive service. These comparisons may be extended to consider only people of specified age or risk groups or other aspects of implementation. Thus, outcomes tables allow the USPSTF to examine directly how the preventive service affects benefits for various groups. When evidence on harms is available, the topic teams assess its quality in a manner like that for benefits and include adverse events in the outcomes tables. When few harms data are available, the USPSTF does not assume that harms are small or nonexistent. It recognizes a responsibility to consider which harms are likely and judge their potential frequency and the severity that might ensue from implementing the service. It uses whatever evidence exists to construct a general confidence interval on the 4-point scale (e.g.,

	substantial, moderate, small, and zero/negative). Value judgments are involved in using the information in an outcomes table to rate either benefits or harms on the USPSTF's 4-point scale. Value judgments are also needed to weigh benefits against harms to arrive at a rating of net benefit. In making its determinations of net benefit, the USPSTF strives to consider what it believes are the general values of most people. It does this with greater confidence for certain outcomes (e.g., death) about which there is little disagreement about undesirability, but it recognizes that the degree of risk people are willing to accept to avert other outcomes (e.g., cataracts) can vary considerably. When the USPSTF perceives that preferences among individuals vary greatly, and that these variations are sufficient to make a trade-off of benefits and harms a "close-call," then it will often assign a C recommendation (see the "Recommendation Rating Scheme" field). This recommendation indicates the decision is likely to be sensitive to individual patient preferences. The USPSTF uses its assessment of the evidence and magnitude of net benefit to make recommendations. The general principles the USPSTF follows in making recommendations are outlined in Table 5 of the companion document cited below. The USPSTF liaisons on the topic team compose the first drafts of the recommendations and rationale statements, which the full panel then reviews and edits. Recommendations are based on formal voting procedures that include explicit rules for determining the views of the majority. From: Harris RP, Helfand M, Woolf SH, Lohr KN, Mulrow, CD, Teutsch SM, Atkins D. Current methods of the U.S. Preventive Services Task Force: a review of the process. Methods Work Group, Third U.S. Preventive Services Task Force. Am J Prev Med 2001 Apr;20(3S):21-35.
UMHS (2004)	Expert Consensus *Described Process*: Consideration of benefits, harms, costs, and patient preferences.
Outcomes	
ACR (2005)	• Utility of radiologic examinations in differential diagnosis
SIGN (2003)	• Accuracy of diagnostic tests • Overall survival rates • Response rates • Progression-free survival rates • Disease-free survival rates • Quality of life

	• Adverse effects of treatment (e.g., toxicity)
USPSTF (2004)	• **Key Question 1**: Does screening for ovarian cancer among asymptomatic women result in early detection and, with effective treatment, reduce premature death and disability? • **Key Question 2**: How well do screening tests or procedures identify women with ovarian cancer? • **Key Question 3**: What are the harms of screening?
UMHS (2004)	• All-cause mortality • Disease specific mortality • Life expectancy • Treatment induced mortality • Progression to metastases • Years of life saved • Radiation induced cancer • Incidence of developing invasive cancers • Predictive value of tests
Financial Disclosures/Conflicts of Interest	
ACR (2005)	Not stated
SIGN (2003)	All members of the Scottish Intercollegiate Guidelines Network (SIGN) guideline development groups are required to complete a declaration of interests, both personal and non-personal. A personal interest involves payment to the individual concerned (e.g., consultancies or other fee-paid work commissioned by or shareholdings in the pharmaceutical industry); a non-personal interest involves payment which benefits any group, unit or department for which the individual is responsible (e.g., endowed fellowships or other pharmaceutical industry support). Details of the declarations of interest of any guideline development group member(s) are available from the Scottish Intercollegiate Guidelines Network executive.
USPSTF (2004)	The U.S. Preventive Services Task Force (USPSTF) has an explicit policy concerning conflict of interest. All members and Evidence-based Practice Center (EPC) staff disclose at each meeting if they have an important financial conflict for each topic being discussed. Task Force members and EPC staff with conflicts can participate in discussions about evidence, but members abstain from voting on recommendations about the topic in question. From: Harris RP, Helfand M, Woolf SH, Lohr KN, Mulrow, CD, Teutsch SM, Atkins D. Current methods of the U.S. Preventive Services Task Force: a review of the process.

	Methods Work Group, Third U.S. Preventive Services Task Force. Am J Prev Med 2001 Apr;20(3S):21-35.
UMHS (2004)	The University of Michigan Health System endorses the Guidelines of the Association of American Medical Colleges and the Standards of the Accreditation Council for Continuing Medical Education that the individuals who present educational activities disclose significant relationships with commercial companies whose products or services are discussed. Disclosure of a relationship is not intended to suggest bias in the information presented, but is made to provide readers with information that might be of potential importance to their evaluation of the information.

TABLE 4: COMPARISON OF RECOMMENDATIONS FOR THE DIAGNOSIS AND TREATMENT OF CELIAC DISEASE

Screening Recommendations	
ACR (2005)	**Appropriateness Criteria Scale: 1-9. 1 = Least appropriate. 9 = Most appropriate** **<u>Variant 1</u>: Premenopausal or postmenopausal female: low risk.** **Radiologic Procedure and Appropriateness Rating** • Gynecological evaluation = 8 Gynecological evaluation not completely directed for ovarian cancer but for a variety of reasons. • US, pelvis, transabdominal (TA) = 2 • US, pelvis, transvaginal (TV) = 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 **<u>Variant 2</u>: Premenopausal female: high risk.** • Gynecological evaluation = 8 Gynecological evaluation not completely directed for ovarian cancer but for a variety of reasons. • US, pelvis, transvaginal (TV) = 8 • US, pelvis, transabdominal (TA) = 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

<u>Variant 3</u>: Postmenopausal female: high risk.

- Gynecological evaluation = 8
  Gynecological evaluation not completely directed for ovarian cancer but for a variety of reasons.
- CA 125 = 8
- US, pelvis, transvaginal (TV) = 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 (TA) = 6
- CT, pelvis = 2
- MRI, pelvis = 2

<u>Variant 4</u>: Premenopausal female with no mass detected by US: low risk.

- 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, pelvis, follow-up every 3 months = 2
- US, pelvis, follow-up every 6 months = 2
- US, pelvis, follow-up every 12 months = 2
- US, pelvis, follow-up every 24 months = 2
- CT, pelvis = 2
- MRI, pelvis = 2
- CA 125 = 2

<u>Variant 5</u>: Premenopausal female with no mass detected by US: high risk.

- Gynecological evaluation = 8
  Gynecological evaluation not completely directed for ovarian cancer but for a variety of reasons.
- US, pelvis, follow-up every 12 months = 6
- CA 125 = 3
- US, pelvis, Doppler color = 2
- US, pelvis, spectral Doppler = 2
  If there is blood flow with color, spectral waveform will quantify

	the flow. • US, pelvis, follow-up every 3 months = 2 • US, pelvis, follow-up every 6 months = 2 • US, pelvis, follow-up every 24 months = 2 • CT, pelvis = 2 • MRI, pelvis = 2 **<u>Variant 6</u>: Postmenopausal female with no mass detected by US: low risk.** • 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, pelvis, follow-up every 3 months = 2 • US, pelvis, follow-up every 6 months = 2 • US, pelvis, follow-up every 12 months = 2 • US, pelvis, follow-up every 24 months = 2 • CT, pelvis = 2 • MRI, pelvis = 2 • CA 125 = 2 **<u>Variant 7</u>: Postmenopausal female with no mass detected by US: high risk.** • Gynecological evaluation = 8 Gynecological evaluation not completely directed for ovarian cancer but for a variety of reasons. • US, pelvis, 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, pelvis, follow-up every 3 months = 2 • US, pelvis, follow-up every 6 months = 2 • US, pelvis, follow-up every 24 months = 2 • CT, pelvis = 2 • MRI, pelvis = 2 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 alone 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. By placing a high frequency transducer closer to the adnexa, TVS increases resolution and improves the ability to detect abnormalities of the ovary. Combining TVS with color flow Doppler imaging technique has been shown by many authors to further enhance the detection of early stage ovarian cancer. 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 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.
SIGN (2003)	At present the value of general population screening remains uncertain and cannot be recommended. Results from the current UK Collaborative Trial of Ovarian Cancer Screening (UKCTOCS) are not expected until 2011. Screening in the high risk population is discussed below. **Screening in High Risk Groups** **D** - Screening for ovarian cancer in high risk groups should only be offered in the context of a research study designed to gather data on: • sensitivity and specificity of the screening tool • The International Federation of Gynaecology and Obstetrics (FIGO) stages of cancers detected through screening • residual risk of primary peritoneal cancer following prophylactic oophorectomy **D** - Screening programmes for women at increased risk of ovarian cancer should include mechanisms for providing emotional and psychological support. **NGC Note**: Refer to the original guideline document for a discussion of methods to identify high risk groups.
USPSTF (2004)	The U.S. Preventive Services Task Force (USPSTF) recommends against routine screening for ovarian cancer. **D recommendation.** *The USPSTF found fair evidence that screening with serum CA-125 level or transvaginal ultrasound can detect ovarian cancer at an earlier stage than it can be detected in the absence of screening; however, the USPSTF found fair evidence that earlier detection would likely have a small effect, at best, on mortality from ovarian cancer. Because of the low prevalence of ovarian cancer and the invasive nature of diagnostic testing after a positive screening test, there is fair evidence that screening could likely lead to important harms. The USPSTF concluded that the potential harms outweigh the potential benefits.* **Clinical Considerations** • There is no existing evidence that any screening test, including CA-125, ultrasound, or pelvic examination, reduces mortality from ovarian cancer. Furthermore, existing evidence that screening can detect early-stage ovarian cancer is insufficient to indicate that this earlier diagnosis will reduce mortality. • Because there is a low incidence of ovarian cancer in the

	general population (age-adjusted incidence of 17 per 100,000 women), screening for ovarian cancer is likely to have a relatively low yield. The great majority of women with a positive screening test will not have ovarian cancer (i.e., they will have a false-positive result). In women at average risk, the positive predictive value of an abnormal screening test is, at best, approximately 2% (i.e., 98% of women with positive test results will not have ovarian cancer). • The positive predictive value of an initially positive screening test would be more favorable for women at higher risk. For example, the lifetime probability of ovarian cancer increases from about 1.6% in a 35-year-old woman without a family history of ovarian cancer to about 5% if she has 1 relative and 7% if she has 2 relatives with ovarian cancer. If ongoing clinical trials show that screening has a beneficial effect on mortality rates, then women at higher risk are likely to experience the greatest benefit.
UMHS (2004)	**Role of a screening pelvic exam alone**. The incidence and frequency of ovarian cancer in the general population is relatively low. Although ovarian tumors are occasionally detected on pelvic examination, they are usually at an advanced stage and associated with a poor prognosis. Screening for ovarian cancer with a CA 125 or ultrasound is not recommended for asymptomatic women. The predictive value of either test alone (less than 3 percent) yields an unacceptably high rate of false positive results. Currently no North American expert groups recommend routine screening for ovarian cancer.

SELECTED SUPPORTING REFERENCES

Note from NGC: Bolded references are cited in more than one guideline. Refer to the original for a complete listing of supporting references.

ACR (2005)	**Adonakis GL, Paraskevardis E, Tsiga S, et al. A combined approach for the early cancer in asymptomatic women. *Eur J Obstet, Gynecol Reprod Biol* 1996; 65(2):** Bourne TH, Whitehead MI, Campbell S, et al. Ultrasound screening for familial ovarian ca 1991; 43(2):92-97. Campbell S, Bhan V, Royston P, et al. Transabdominal ultrasound screening for early ova 299(6712):1363-1367. Dorum A, Kustensen GB, Ateler VM, et al. Early detection of familial ovarian cancer. Eur J 32A(10):1645-1651. Fleischer AC, McKee MS, Gordon AN, et al. Transvaginal sonography of postmenopausal o

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UMHS (2004)	Not stated

TABLE 5: BENEFITS AND HARMS	
Benefits	
ACR (2005)	Selection of appropriate radiologic imaging procedures for screening of ovarian cancer

SIGN (2003)	• Improved screening, diagnosis and management of epithelial ovarian cancer
	• Reduced surgical complications
	• Improved response to treatment
	• Improved survival (overall, progression-free, and disease-free)
	• Improved patient quality of life including:
	  • Better symptom control
	  • Structured emotional support

USPSTF (2004)	The U.S. Preventive Services Task Force (USPSTF) found fair evidence that screening with serum CA-125 level or transvaginal ultrasound can detect ovarian cancer at an earlier stage than it can be detected in the absence of screening; however, the USPSTF found fair evidence that earlier detection would likely have a small effect, at best, on mortality from ovarian cancer. Because of the low prevalence of ovarian cancer and the invasive nature of diagnostic testing after a positive screening test, there is fair evidence that screening could likely lead to important harms. The USPSTF concluded that the potential harms outweigh the potential benefits.
UMHS (2004)	Not stated

Harms	
ACR (2005)	Not stated

SIGN (2003)	• False positive results from screening
	• Surgical complications
	• Side effects associated with chemotherapy including:
	  • Anaemia
	  • Deterioration in quality of life

USPSTF (2004)	There is a significant potential for harms associated with screening for ovarian cancer, although there are few data to assess the magnitude of harms from screening, such as needless surgery or increased anxiety.
UMHS (2004)	Not stated

TABLE 6: EVIDENCE RATING SCHEMES AND REFERENCES	
ACR (2005)	The recommendations are based on analysis of the current literature and expert panel consensus.
SIGN (2003)	**Levels of Evidence** **1++**: High quality meta-analyses, systematic reviews of randomised controlled trials (RCTs), or RCTs with a very low risk of bias **1+**: Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias **1-**: Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias **2++**: High quality systematic reviews of case control or cohort or studies; high quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal **2+**: Well conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal **2-**: Case control or cohort studies with a high risk of confounding or

	bias and a significant risk that the relationship is not causal **3**: Non-analytic studies, e.g. case reports, case series **4**: Expert opinion **Grade of Recommendation** The grade of recommendation relates to the strength of the evidence on which the recommendation is based. It does not reflect the clinical importance of the recommendation. **A**: At least one meta-analysis, systematic review of randomised controlled trials (RCTs), or RCT rated as 1++ and directly applicable to the target population; *or* A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results **B**: A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; *or* Extrapolated evidence from studies rated as 1++ or 1+ **C**: A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; *or* Extrapolated evidence from studies rated as 2++ **D**: Evidence level 3 or 4; *or* Extrapolated evidence from studies rated as 2+ **Good Practice Point**: Recommended best practice based on the clinical experience of the guideline development group
USPSTF (2004)	**<u>Definitions</u>**: **Strength of Recommendations** The USPSTF grades its **recommendations** according to one of five classifications (A, B, C, D, I) reflecting the strength of evidence and magnitude of net benefit (benefits minus harms): **A**

	The USPSTF strongly recommends that clinicians provide [the service] to eligible patients. The USPSTF found good evidence that [the service] improves important health outcomes and concludes that benefits substantially outweigh harms. **B** The USPSTF recommends that clinicians provide [this service] to eligible patients. The USPSTF found at least fair evidence that [the service] improves important health outcomes and concludes that benefits outweigh harms. **C** The USPSTF makes no recommendation for or against routine provision of [the service]. The USPSTF found at least fair evidence that [the service] can improve health outcomes but concludes that the balance of benefits and harms is too close to justify a general recommendation. **D** The USPSTF recommends against routinely providing [the service] to asymptomatic patients. The USPSTF found at least fair evidence that [the service] is ineffective or that harms outweigh benefits. **I** The USPSTF concludes that the evidence is insufficient to recommend for or against routinely providing [the service]. Evidence that the [service] is effective is lacking, of poor quality, or conflicting and the balance of benefits and harms cannot be determined. **Strength of Evidence** The USPSTF grades the **quality of the overall evidence** for a service on a 3-point scale (good, fair, poor): **Good** Evidence includes consistent results from well-designed, well-conducted studies in representative populations that directly assess effects on health outcomes. **Fair** Evidence is sufficient to determine effects on health outcomes, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies, generalizability to routine

	practice, or indirect nature of the evidence on health outcomes. **Poor** Evidence is insufficient to assess the effects on health outcomes because of limited number or power of studies, important flaws in their design or conduct, gaps in the chain of evidence, or lack of information on important health outcomes.
UMHS (2004)	**Definitions**: **Levels of Evidence** A. Randomized controlled trials B. Controlled trials, no randomization C. Observational trials D. Opinion of expert panel

GUIDELINE CONTENT COMPARISON

The American College of Radiology (ACR), Scottish Intercollegiate Guidelines Network (SIGN), United States Preventive Services Task Force (USPSTF), and University of Michigan Health System (UMHS) present recommendations for the screening of ovarian cancer and provide explicit reasoning behind their judgments.

The guidelines differ somewhat in scope. In addition to addressing the screening of ovarian cancer, the SIGN guideline also addresses its diagnosis and treatment. UMHS is broad in scope as well, and provides screening recommendations for breast, cervical, colon and prostate cancer. The discussion of ovarian cancer is found in the cervical cancer screening section of the UMHS guideline.

Guideline Methodology

To collect and select the evidence, all four guideline groups performed searches of electronic databases, with SIGN, USPSTF and UMHS providing the names of the databases searched, the date range over which they searched, and the search strategy. USPSTF also performed hand-searches of published literature (primary and secondary sources). USPSTF based their guideline statements on a separately-prepared, systematic evidence review that included applying quality criteria to published studies to select those suitable for evidence review and guideline formulation (see "Availability of Companion Documents" in the NGC summary of this guideline).

With regard to methods used to analyze the evidence, ACR , SIGN, and USPSTF performed a systematic review with evidence tables. Note that these are available

on demand from SIGN and are not published in the guideline. UMHS performed a systematic review, and SIGN also performed a review of published meta-analyses. All four groups used expert consensus to formulate their recommendations, while USPSTF also used balance sheets. SIGN, USPSTF and UMHS rank the level of evidence supporting each major recommendation, and SIGN and USPSTF also grade the strength of the recommendations.

SIGN and USPSTF provide their guidance through explicit graded recommendation statements (note that only 1 recommendation is provided by USPSTF in this particular guideline), supplemented by narrative discussion. In the narrative discussion they link the supporting evidence directly to their recommendation statement(s). ACR provides its appropriateness criteria ratings, followed by a discussion with in-text references directing the reader to the corresponding resource in the reference list. Like SIGN and USPSTF, UMHS also provides its guidance in the form of recommendation statements for which the supporting evidence is graded, followed by narrative discussion. They do not, however, provide in-text references to supporting evidence. Instead, they provide a list of annotated references used to support major recommendations.

All four guideline groups provide reference lists (18 for ACR, 182 for SIGN, 23 for USPSTF, 4 for UMHS).

Screening and Prevention of Ovarian Cancer: Comparison of Key Recommendations Between the ACR, SIGN, USPSTF and UMHS Guidelines	
ACR (2005)	• Routine screening for ovarian cancer cannot be recommended. • Assigns appropriateness ratings for various radiologic interventions in low- and high-risk populations
SIGN (2003)	• At present the value of general population screening remains uncertain and cannot be recommended. • Screening for ovarian cancer in high risk groups should only be offered in the context of a research study designed to gather data.
USPSTF (2004)	• The USPSTF recommends against routine screening for ovarian cancer.
UMHS (2004)	• Screening for ovarian cancer with a CA 125 or ultrasound is not recommended for asymptomatic women.

Areas of Agreement

Screening

All four guideline groups found that there is insufficient evidence to support a recommendation for routine screening of the general population for ovarian cancer, citing reasons such as its low prevalence (ACR, UMHS and USPSTF), a lack of evidence that screening reduces mortality (ACR, USPSTF), evidence that harms of screening outweigh potential benefits (USPSTF), and a high rate of false-positive screening results (USPSTF, UMHS). SIGN states that the value of general population screening remains uncertain and cannot be recommended. They add that results from the current UK Collaborative Trial of Ovarian Cancer Screening (UKCTOCS) are not expected until 2011. Note that while ACR, SIGN and UMHS note that there is insufficient evidence to recommend screening, USPSTF goes a step further and recommends against screening, concluding that the potential harms of genetic screening do, in fact, outweigh the potential benefits.

ACR differs from the other groups in that it stratifies its recommendations for individual radiologic interventions by menopausal status, risk level, and presence of an ultrasound-detected mass, and further rates the appropriateness of each radiologic procedure on a level of 1 (least appropriate) to 9 (most appropriate). In line with their conclusion that there is insufficient evidence to recommend screening the general public for ovarian cancer, they accord an appropriateness rating of "2" to all of the radiological procedures for low-risk populations. They assign an appropriateness rating of "8" to a gynecological evaluation not completely directed for ovarian cancer but for a variety of reasons.

Two of the guideline groups, ACR and SIGN, address screening in high-risk groups, with SIGN recommending that screening in this population be offered only in the context of a research study designed to gather data. ACR provides higher appropriateness ratings for radiologic interventions in high-risk populations than for low-risk.

Areas of Differences

There are no significant areas of difference between the guideline groups.

Conclusion

There is general agreement across the ACR, SIGN, USPSTF and UMHS guidelines concerning the lack of evidence to recommend screening for ovarian cancer in the general public. SIGN notes that screening in high-risk populations should only be conducted in the context of a research study to gather data. ACR assigns Appropriateness Criteria to radiologic procedures for both low-risk and high-risk populations, and assigns higher ratings to interventions for high-risk populations.

This Synthesis was prepared by ECRI on October 2, 2007. It was reviewed by SIGN on October 10, 2007, UMHS on October 25, 2007, and ACR on November 2, 2007.

Internet citation: National Guideline Clearinghouse (NGC). Guideline synthesis: Part I. Ovarian cancer: screening. In: National Guideline Clearinghouse (NGC) [website]. Rockville (MD): 2007 Nov. [cited YYYY Mon DD]. Available: http://www.guideline.gov.

Date Modified: 6/9/2008