



## Complete Summary

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### GUIDELINE TITLE

Hormone therapy and breast cancer. In: Menopause and osteoporosis update 2009.

### BIBLIOGRAPHIC SOURCE(S)

Hormone therapy and breast cancer. In: Menopause and osteoporosis update 2009. J Obstet Gynaecol Can 2009 Jan;31(1 Suppl 1):S19-26. [83 references]

### GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Belisle S, Reid R, Mills C. Cancer. In: Canadian consensus conference on menopause, 2006 update. J Obstet Gynaecol Can 2006 Feb;28(2 Suppl 1):S87-94. [79 references]

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## SCOPE

### DISEASE/CONDITION(S)

- Menopause
- Breast cancer

### GUIDELINE CATEGORY

Counseling  
Management  
Prevention

Risk Assessment  
Treatment

### **CLINICAL SPECIALTY**

Family Practice  
Internal Medicine  
Obstetrics and Gynecology  
Oncology

### **INTENDED USERS**

Advanced Practice Nurses  
Health Care Providers  
Nurses  
Physician Assistants  
Physicians  
Psychologists/Non-physician Behavioral Health Clinicians

### **GUIDELINE OBJECTIVE(S)**

To provide updated guidelines for health care providers on the management of menopause in asymptomatic healthy women as well as in women presenting with vasomotor symptoms or with urogenital, mood, or memory concerns, and on considerations related to cardiovascular disease, breast cancer, and bone health, including the diagnosis and clinical management of postmenopausal osteoporosis

### **TARGET POPULATION**

- Menopause in asymptomatic healthy women
- Menopause in women presenting with vasomotor symptoms, urogenital, sexual, and mood and memory concerns and specific medical considerations, and cardiovascular and cancer issues

### **INTERVENTIONS AND PRACTICES CONSIDERED**

1. Hormone therapy (HT)
  - Combined estrogen and progestogen therapy (EPT)
  - Estrogen therapy
2. Counseling on risks of HT
3. Appropriate surveillance
4. Raloxifene

### **MAJOR OUTCOMES CONSIDERED**

- Side effects of therapy
- Incidence of breast cancer
- Menopausal symptom relief

## METHODOLOGY

### METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

### DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

MEDLINE was searched up to October 1, 2008, and the Cochrane databases up to issue 1 of 2008 with the use of a controlled vocabulary and appropriate key words. Research-design filters for systematic reviews, randomized and controlled clinical trials, and observational studies were applied to all PubMed searches. Results were limited to publication years 2002 to 2008; there were no language restrictions. Additional information was sought in BMJ Clinical Evidence, in guidelines collections, and from the Web sites of major obstetric and gynaecologic associations worldwide.

### NUMBER OF SOURCE DOCUMENTS

Not stated

### METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

### RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

#### Quality of Evidence Assessment\*

**I:** Evidence obtained from at least one properly randomized controlled trial.

**II-1:** Evidence from well-designed controlled trials without randomization.

**II-2:** Evidence from well-designed cohort (prospective or retrospective) or case-control studies, preferably from more than one centre or research group.

**II-3:** Evidence from comparisons between times or places with or without the intervention. Dramatic results from uncontrolled experiments (such as the results of treatment with penicillin in the 1940s) could also be included in this category.

**III:** Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

\* Adapted from the Evaluation of Evidence criteria described in: Woolf SH, Battista RN, Angerson GM, Logan AG, Eel W. Canadian Task Force on Preventive Health Care. New grades for recommendations from the Canadian Task Force on Preventive Health Care. *Can Med Assoc J* 2003;169(3):207-8.

### METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

## **DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE**

The authors critically reviewed the evidence and developed the recommendations according to the methodology and consensus development process of the Journal of Obstetrics and Gynaecology Canada.

## **METHODS USED TO FORMULATE THE RECOMMENDATIONS**

Expert Consensus

## **DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS**

Not stated

## **RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS**

### **Classification of Recommendations\***

- A.** There is good evidence to recommend the clinical preventive action
- B.** There is fair evidence to recommend the clinical preventive action
- C.** The existing evidence is conflicting and does not allow to make a recommendation for or against use of the clinical preventive action; however, other factors may influence decision-making
- D.** There is fair evidence to recommend against the clinical preventive action
- E.** There is good evidence to recommend against the clinical preventive action
- L.** There is insufficient evidence (in quantity or quality) to make a recommendation; however, other factors may influence decision-making

\*Adapted from the Classification of Recommendations criteria described in: Woolf SH, Battista RN, Angerson GM, Logan AG, Eel W. Canadian Task Force on Preventive Health Care. New grades for recommendations from the Canadian Task Force on Preventive Health Care. Can Med Assoc J 2003;169(3):207-8.

## **COST ANALYSIS**

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

## **METHOD OF GUIDELINE VALIDATION**

Not stated

## **DESCRIPTION OF METHOD OF GUIDELINE VALIDATION**

Not applicable

## RECOMMENDATIONS

### MAJOR RECOMMENDATIONS

The grades of recommendations (A-E and L) and levels of evidence (I, II-1, II-2, II-3, and III) are defined at the end of the "Major Recommendations" field.

1. Health care providers should periodically review the risks and benefits of prescribing Hormone Therapy (HT) to a menopausal woman in light of the association between duration of use and breast cancer risk. **(IA)**
2. Health care providers may prescribe HT for menopausal symptoms in women at increased risk of breast cancer with appropriate counselling and surveillance. **(IA)**
3. Health care providers should clearly discuss the uncertainty of risks associated with HT after a diagnosis of breast cancer in women seeking treatment for distressing symptoms. **(IB)**

#### Definitions:

#### Quality of Evidence Assessment\*

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#### Classification of Recommendations\*\*

**A.** There is good evidence to recommend the clinical preventive action

**B.** There is fair evidence to recommend the clinical preventive action

**C.** The existing evidence is conflicting and does not allow to make a recommendation for or against use of the clinical preventive action; however, other factors may influence decision-making

**D.** There is fair evidence to recommend against the clinical preventive action

**E.** There is good evidence to recommend against the clinical preventive action

**L.** There is insufficient evidence (in quantity or quality) to make a recommendation; however, other factors may influence decision-making

\*The quality of evidence reported in these guidelines has been adapted from the Evaluation of Evidence criteria described in the Canadian Task Force on Preventive Health Care.\*\*\*

\*\*Recommendations included in these guidelines have been adapted from the Classification of Recommendations criteria described in the Canadian Task Force on Preventive Health Care.\*\*

\*\*\*Woolf SH, Battista RN, Angerson GM, Logan AG, Eel W. Canadian Task Force on Preventive Health Care. New grades for recommendations from the Canadian Task Force on Preventive Health Care. Can Med Assoc J 2003;169(3):207-8.

## **CLINICAL ALGORITHM(S)**

None provided

## **EVIDENCE SUPPORTING THE RECOMMENDATIONS**

### **TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS**

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

## **BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS**

### **POTENTIAL BENEFITS**

Appropriate management and prevention of breast cancer in post menopausal women

### **POTENTIAL HARMS**

- The risk of breast cancer appears to be greater with estrogen and progestogen therapy (EPT) than with estrogen alone. Women using EPT had an 11% greater risk of an abnormal mammogram after 5 years.
- One study showed that there is an elevated risk of breast cancers with a lobular component (these account for about 16% of invasive carcinomas in the United States) after 3 years of combined hormone therapy (HT). The authors hypothesized that EPT use may stimulate the growth of foci of lobular carcinoma that would have remained small or perhaps clinically undetectable in the absence of EPT exposure.
- Women receiving postmenopausal HT in one study were found to have increased breast density and a greater frequency of abnormal mammograms compared with those receiving placebo. Even though breast density can be increased by the use of estrogen with a progestin, it has never been shown that an acquired increase in density, as in hormone treatment, increases breast cancer risk.
- Another study found that women who used HT after a diagnosis of breast cancer had a higher recurrence risk than did women assigned to placebo.

- Raloxifene is associated with a higher, though not statistically significant, risk of noninvasive breast cancer.

## QUALIFYING STATEMENTS

### QUALIFYING STATEMENTS

This guideline reflects emerging clinical and scientific advances as of the date issued and are subject to change. The information should not be construed as dictating an exclusive course of treatment or procedure to be followed. Local institutions can dictate amendments to these opinions. They should be well documented if modified at the local level. None of these contents may be reproduced in any form without prior written permission of the Society of Obstetricians and Gynaecologists of Canada (SOGC).

## IMPLEMENTATION OF THE GUIDELINE

### DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

## INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

### IOM CARE NEED

Staying Healthy

### IOM DOMAIN

Effectiveness  
Patient-centeredness

## IDENTIFYING INFORMATION AND AVAILABILITY

### BIBLIOGRAPHIC SOURCE(S)

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### ADAPTATION

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

### DATE RELEASED

2006 Feb (revised 2009 Jan)

**GUIDELINE DEVELOPER(S)**

Society of Obstetricians and Gynaecologists of Canada - Medical Specialty Society

**SOURCE(S) OF FUNDING**

Society of Obstetricians and Gynaecologists of Canada

**GUIDELINE COMMITTEE**

Not stated

**COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE**

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**FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST**

The following conflicts of interest have been disclosed by the authors.

Dr Reid: Speaker or consultant to Wyeth, Bayer, Organon, Proctor and Gamble, Novo Nordisk; advisory boards: Paladin, Wyeth; research support: Organon, Bayer.

Dr Blake: Speaker or consultant to Wyeth, Merck, Glaxo Smith Kline, Bayer; advisory boards: Bayer, Wyeth and Lilly, Novo Nordisk.

Dr Abramson: Speaker or consultant to Abbott, Astra Zeneca, Boehringer Ingelheim, Bristol Myer Squibb, Dupont, Eli Lilly, Lifespeak, Novartis, Fournier, Merck Frosst, Pfizer, Servier, Schering, Sanofi-Aventis; advisory boards: Astra Zeneca, Boehringer-Ingelheim, Novartis, Pfizer, Sanofi-Aventis; research support: Astra Zeneca, Boehringer Ingelheim, Merck.

Dr Khan: Speaker or consultant to Amgen, Merck, Lilly, Novartis, Servier, Proctor and Gamble; research support: Merck, Lilly, Novartis, Alliance for Better Bone Health.

Dr Senikas: None declared.

Dr Fortier: Speaker or consultant to Proctor and Gamble, Merck; advisory boards: Amgen, Bayer, Novo Nordisk, Novartis, GlaxoSmith Kline, Lilly, Paladin; research support: Wyeth, Sanofi.

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## **GUIDELINE AVAILABILITY**

Electronic copies: Available in Portable Document Format (PDF) from the [Society of Obstetricians and Gynaecologists of Canada Web site](#).

Print copies: Available from the Society of Obstetricians and Gynaecologists of Canada, La société des obstétriciens et gynécologues du Canada (SOGC) 780 promenade Echo Drive Ottawa, ON K1S 5R7 (Canada); Phone: 1-800-561-2416

## **AVAILABILITY OF COMPANION DOCUMENTS**

None available

## **PATIENT RESOURCES**

None available

## **NGC STATUS**

This NGC summary was completed by ECRI Institute on May 4, 2009. The information was verified by the guideline developer on May 21, 2009.

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