



## Complete Summary

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### GUIDELINE TITLE

The use of progesterone for prevention of preterm birth.

### BIBLIOGRAPHIC SOURCE(S)

Farine D, Dodd J, Basso M, Delisle MF, Farine D, Grabowska K, Hudon L, Menticoglou SM, Mundle WR, Murphy-Kaulbeck LC, Ouellet A, Pressey T, Roggensack A, Maternal Fetal Medicine Committee, Society of Obstetricians and Gynaecologists of Canada. The use of progesterone for prevention of preterm birth. J Obstet Gynaecol Can 2008 Jan;30(1):67-71. [30 references] [PubMed](#)

### GUIDELINE STATUS

This is the current release of the guideline.

## COMPLETE SUMMARY CONTENT

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## SCOPE

### DISEASE/CONDITION(S)

- Preterm labor (PTL)
- Preterm birth

### GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness

Counseling

Prevention

Risk Assessment

### CLINICAL SPECIALTY

Family Practice  
Internal Medicine  
Obstetrics and Gynecology  
Preventive Medicine

## **INTENDED USERS**

Physicians

## **GUIDELINE OBJECTIVE(S)**

- To introduce new information on the use of progesterone to prevent premature labor and to provide guidance to obstetrical caregivers who counsel women on the merits of this choice
- To evaluate the information in these studies and outline the current role for the use of progesterone for this indication

## **TARGET POPULATION**

Pregnant women at risk of preterm labor

## **INTERVENTIONS AND PRACTICES CONSIDERED**

1. Counseling women about benefits and risks of progesterone therapy
2. Progesterone therapy after 20 weeks' gestation
  - 17 alpha-hydroxyprogesterone
  - Progesterone

## **MAJOR OUTCOMES CONSIDERED**

- Relative risk for preterm labor
- Preterm birth rate
- Birth weight
- Infant morbidity: respiratory distress syndrome, need for ventilatory support, intraventricular hemorrhage, necrotizing enterocolitis, patent ductus arteriosus, sepsis, retinopathy
- Perinatal mortality

## **METHODOLOGY**

### **METHODS USED TO COLLECT/SELECT EVIDENCE**

Searches of Electronic Databases

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

A search of both Medline and the Cochrane Library identified the most relevant medical evidence. This document represents an abstraction of the evidence rather than a methodological review.

## **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 obtained from comparisons between times or places with or without the intervention. Dramatic results in 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 the Canadian Task Force on Preventive Health Care.

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

Review of Published Meta-Analyses  
Systematic Review with Evidence Tables

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

Not stated

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

\*Adapted from the Evaluation of Evidence criteria described in the Canadian Task Force on Preventive Health Care.

## **COST ANALYSIS**

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

## **METHOD OF GUIDELINE VALIDATION**

Internal Peer Review

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

This technical update has been reviewed by the Maternal Fetal Medicine Committee and approved by the Executive of the Society of Obstetricians and Gynaecologists of Canada (SOGC).

# **RECOMMENDATIONS**

## **MAJOR RECOMMENDATIONS**

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

1. Women at risk for preterm labour (PTL) should be encouraged to participate in studies on the role of progesterone in reducing the risks of preterm labour. **(I-A)**
2. Women should be informed about the lack of available data for many neonatal outcome variables and about the lack of comparative data on dosing and route of administration. Women with short cervix should be informed of

- the single large randomized controlled trial (RCT) showing the benefit of progesterone in preventing PTL. (**I-A**)
3. Women and their caregivers should be aware that a previous preterm labour and/or short cervix (< 15 mm at 22 to 26 weeks' gestation) on transvaginal ultrasound could be used as an indication for prophylactic progesterone therapy. The therapy should be started after 20 weeks' gestation and stopped when the risk of prematurity is low. (**I-A**)
  4. On the basis of the data from the RCTs and meta-analysis, it is recommended that in cases where the clinician and the patient have opted for the use of progesterone the following dosages should be used:
    - For prevention of PTL in women with history of previous PTL: 17 alpha-hydroxyprogesterone 250 mg intramuscularly (IM) weekly (**I-B**) or progesterone 100 mg daily vaginally. (**I-A**)
    - For prevention of PTL in women with short cervix of <15 mm detected on transvaginal ultrasound at 22 to 26 weeks: progesterone 200 mg daily vaginally. (**I-A**)

### **Definitions:**

#### **Quality of Evidence Assessment\***

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**I.** 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

## **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 use of progesterone for the prevention of preterm labour

### **POTENTIAL HARMS**

A single retrospective study showed that the incidence of gestational diabetes was 12.9% in women treated with 17 alpha-hydroxyprogesterone compared with 4.9% in control subjects.

## **QUALIFYING STATEMENTS**

### **QUALIFYING STATEMENTS**

This technical update reflects emerging clinical and scientific advances as of the date issued and is 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.

## **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

2008 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

Maternal Fetal Medicine Committee

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## **FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST**

Not stated

## **GUIDELINE STATUS**

This is the current release of the guideline.

## **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 February 10, 2009. The information was verified by the guideline developer on March 4, 2009.

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