

## Specific Populations: Pregnant & Breastfeeding Women

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### *Overview of Evidence*

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The following recommendations, and supporting evidence, have been extracted from existing clinical practice guidelines to inform the development of the CAN-ADAPTT Summary Statements.

CAN-ADAPTT worked with the Guidelines Advisory Committee (GAC) to conduct a literature search (years: 2002-2009) to identify existing clinical practice guidelines (CPGs). Five existing clinical practice guidelines were identified as meeting the high quality criteria set out in the [AGREE Instrument](#). The recommendations contained in these high quality CPGs have been used as the evidence base for the CAN-ADAPTT guideline development process. Visit [www.can-adaptt.net](http://www.can-adaptt.net) to view CAN-ADAPTT's [guideline development methodology](#).

### **U.S. Department of Health and Human Services Public Health Service (2008)<sup>1</sup>**

Because of the serious risks of smoking to the pregnant smoker and the fetus, whenever possible pregnant smokers should be offered person-to-person psychosocial interventions that exceed minimal advice to quit. (*Strength of Evidence = A*)

Although abstinence early in pregnancy will produce the greatest benefits to the fetus and expectant mother, quitting at any point in pregnancy can yield benefits. Therefore, clinicians should offer effective tobacco dependence interventions to pregnant smokers at the first prenatal visit as well as throughout the course of pregnancy. (*Strength of Evidence = B*)

### **New Zealand Ministry of Health (2007)<sup>2</sup>**

Offer all pregnant and breastfeeding women who smoke multi-session behavioural smoking cessation interventions from a specialist/dedicated cessation service. (*Grade=A*)

All health care workers should briefly advise pregnant and breastfeeding women who smoke to stop smoking. (*Grade = A*)

NRT can be used in pregnancy and during breastfeeding following a risk-benefit assessment. If NRT is used, oral NRT products (for example, gum, inhalers, microtabs and lozenges) are preferable to nicotine patches. (*Grade=C*)

### **Registered Nurses Association of Ontario (2007)<sup>3</sup>**

Nurses implement, wherever possible, intensive intervention with women who are pregnant and postpartum. (*Strength of Evidence = A*)

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<sup>1</sup> U.S. Department of Health and Human Services Public Health Service. (2008, May). Clinical practice guideline: Treating tobacco use and dependence: 2008 update.

<sup>2</sup> Ministry of Health. (2007, August). New Zealand smoking cessation guidelines. Wellington: Ministry of Health.

<sup>3</sup> Registered Nurses Association of Ontario (RNAO). (2007, March). Integrating smoking cessation into daily nursing practice. Retrieved October 26, 2007 from:

[http://www.rnao.org/bestpractices/PDF/BPG\\_smoking\\_cessation.pdf](http://www.rnao.org/bestpractices/PDF/BPG_smoking_cessation.pdf)

*CAN-ADAPTT Summary Statements*

*Comment on the discussion board*

CAN-ADAPTT's development process reflects a dynamic opportunity to ensure that its guideline is practice informed and addresses issues of applicability in the Canadian context. It has built from the evidence and recommendations contained in existing guidelines. It did not review the primary literature to inform the development of its Summary Statements unless emerging evidence was identified by the Guideline Development Group. The CAN-ADAPTT Guideline Development Group has provided the below Summary Statements for Pregnant and Breastfeeding Women.

**Summary Statement #1 –**

Smoking cessation should be encouraged for all pregnant, breastfeeding and postpartum women.  
GRADE\*: 1A

**Summary Statement #2 –**

During pregnancy and breastfeeding, counselling is recommended as first line treatment for smoking cessation.  
GRADE\*: 1A

**Summary Statement #3 –**

If counselling is found ineffective, intermittent dosing nicotine replacement therapies (such as lozenges, gum) are preferred over continuous dosing of the patch after a risk-benefit analysis.  
GRADE\*: 1C

**Summary Statement #4 –**

Partners, friends and family members should also be offered smoking cessation interventions.  
GRADE\*: 2B

**Summary Statement #5 –**

A smoke-free home environment should be encouraged for pregnant and breastfeeding women to avoid exposure to second-hand smoke.  
GRADE\*: 1B

\*GRADE: See below or click [here](#) for Grade of Recommendation and Level of Evidence Summary Table.

## *Clinical Considerations*

## *Comment on the discussion board*

- There is limited evidence on harms associated with the use of NRT during pregnancy. Two prospective studies found no adverse maternal or fetal effects from the use of nicotine patch during pregnancy; however, one recent study demonstrated potential association between NRT and congenital defects. This data cannot support or exclude an association between first trimester NRT use and an increased risk of congenital defects due to several methodological issues. Therefore, until further information is available, the risks and benefits of smoking versus the use of NRT during pregnancy must be considered when counselling about smoking cessation options.
- There is some evidence from RCTs that NRT may be efficacious in pregnancy in terms of decreasing tobacco use and improving pregnancy outcomes. No safety concerns were identified in these trials. Therefore, benefits of NRT seem to outweigh potential risks; NRT should be considered when counselling has been ineffective.
- Despite preliminary evidence that continued smoking and relapse are more likely among pregnant women who have a smoking partner, there is limited data regarding the benefits of partner involvement in smoking cessation interventions for pregnant smokers. In non-pregnant populations, interventions to increase support did not find increased quitting rates.
- Evidence from a recent systematic review and meta-analysis demonstrated negative perinatal outcomes (e.g. trend towards lower birth weight, smaller head circumference and congenital anomalies) associated with second-hand smoke exposure. Therefore, pregnant and breastfeeding women should avoid this environmental risk.
- Challenges in identification due to stigma associated with smoking during pregnancy.
- Smoking cessation interventions should be considered for the full spectrum of care from preconception visit to 1 year postpartum.
- Smoking cessation counselling and care of pregnant smokers may be conducted by physicians, allied healthcare professionals (e.g. social worker, pharmacist, community health representatives), midwives, doulas, prenatal advisors, postpartum supports, family home visitors, and others.

- Nicotine replacement therapy (NRT) can be considered as a second line option for individuals who cannot quit after counselling interventions.
- Depression during pregnancy is a common occurrence and the use of Zyban (bupropion) may be appropriate to treat both smoking and depression. There is limited evidence on the effectiveness of bupropion for smoking cessation during pregnancy. In addition, there is no evidence of harm related to the use of bupropion during pregnancy and therefore, it may be considered for use as an alternative to NRT for a subpopulation of pregnant smokers (see Table 1 below).
- Including partners, friends, and/or family in a pregnant smoker's quit attempt is essential to increase the likelihood of successful smoking cessation interventions.
- A smoke-free home environment should be encouraged for partners, friends, family members of pregnant and breastfeeding women to ensure safety from second-hand smoke/environmental tobacco smoke.

**Table 1 – Negative Effects Associated with Cigarette Smoking  
During Pregnancy and Breastfeeding**

Cigarette smoking during pregnancy and breastfeeding is associated with numerous negative effects on mother, fetus, infant and adolescent.<sup>4</sup>

<b>Pregnancy Complications</b>	<b>Neonatal Effects</b>	<b>Long-Term Effects</b>
<ul style="list-style-type: none"> <li>• Subfertility (female and male)</li> <li>• Ectopic pregnancy (outside the uterus)</li> <li>• Spontaneous abortion (miscarriage)</li> <li>• Preterm labour</li> <li>• Premature rupture of membranes</li> <li>• Placental problems (previa &amp; abruption)</li> <li>• Growth restriction</li> </ul>	<ul style="list-style-type: none"> <li>• Low birth weight (on average ~200 grams smaller)</li> <li>• Increased perinatal mortality</li> <li>• Increased admission to the neonatal intensive care unit (NICU)</li> <li>• Sudden infant death syndrome (SIDS)</li> <li>• Decreased volume of breast milk and duration of breastfeeding</li> </ul>	<ul style="list-style-type: none"> <li>• Childhood respiratory illnesses (asthma, pneumonia, bronchitis)</li> <li>• Other childhood medical problems (ear infections)</li> <li>• Learning problems (reading, mathematics, general ability)</li> <li>• Behavioral problems</li> <li>• Attention deficit hyperactivity disorder (ADHD)</li> </ul>

<sup>4</sup> Briggs GG, Freeman RK, Yaffe SJ. Drugs in Pregnancy and Lactation, 7<sup>th</sup> edition. Philadelphia: Lippincott Williams & Wilkins, 2005

*Tools/Resources*

*Contribute a Tool/Resource*

Title	Description	Resource
<p><u><a href="#">Couples and Smoking: What you need to know when you are pregnant</a></u></p>	<ul style="list-style-type: none"> <li>This is a self-help booklet for pregnant women who smoke. In this booklet you will learn how routines, habits, and ways of interacting with your partner influence smoking. Understanding how smoking is influenced by others and everyday routines is an important first step in changing smoking behaviours. If you decide to reduce or stop smoking, you can use this booklet along with other resources to support you in reaching your goals.</li> </ul>	<p>Self-help booklet</p>
<p><u><a href="#">Helping Women Quit</a></u></p>	<ul style="list-style-type: none"> <li>A guide giving background on tobacco cessation for women, and step by step instructions to helping women quit smoking. It tells you what questions to ask to identify a cessation approach for each woman, and it points you to resources to address her needs.</li> </ul>	<p>Guide – Alcohol, Drug and Education Service, BC</p>
<p><u><a href="#">PREGNETS</a></u></p>	<ul style="list-style-type: none"> <li>Website with the mission to improve the health of mothers, fetuses, babies and children. Goals: To eliminate smoking in pregnant and postpartum women by increasing the capacity to quit and stay quit using a woman centred model of care.</li> </ul>	<p>Online resource, discussion board</p>
<p><u><a href="#">TEACH training course: Helping Pregnant Smokers Stop Smoking: An Interactive Case Based Course</a></u></p>	<ul style="list-style-type: none"> <li>This specialty course manual will allow clinicians to increase their knowledge about tobacco use, screening, assessment, and interventions with pregnant and postnatal women. The price of this manual reflects only the development and labor costs associated with its production.</li> </ul>	<p>Course manual and in-person training</p>
<p><u><a href="#">Motherisk</a></u></p>	<ul style="list-style-type: none"> <li>Connected to Sick Children’s Hospital in Toronto, Motherisk provides online information on the risks of using substances (including tobacco) while pregnant. It also offers telephone counselling for women, and consultation for service providers.</li> </ul>	<p>Website, telephone counselling 1-877-327-4636</p>
<p><u><a href="#">The Right Time...The Right Reasons...Dads talk about Reducing and Quitting Smoking.</a></u></p>	<ul style="list-style-type: none"> <li>This booklet is based on fathers’ experiences of reducing and quitting smoking. The quotes in the booklet are from expectant and new dads who smoke or have recently reduced or quit and offer their thoughts and ideas. This booklet is for men who identify with the challenges around being an expectant or new dad who smokes.</li> </ul>	<p>Self-help booklet</p>



## *Research Gaps*

## *Contribute a Research Gap*

- Relationship between smoking and infertility
- Use of Bupropion and Varenicline as a smoking cessation aid – need more research on the effectiveness and safety
- Need more evidence of risk/benefit analysis of various smoking cessation aids

## *Overview of CAN-ADAPTT's Practice-Informed Guideline*

The full text guideline is available online at [www.can-adaptt.net](http://www.can-adaptt.net). The Guideline includes the following sections:

- Counselling and Psychosocial Approaches
- Pharmacotherapy (*in development*)
- Aboriginal Peoples
- Hospital-Based Populations
- Mental Health and/or Other Addiction(s)
- Pregnant and Breastfeeding Women
- Youth (Children and Adolescents)

**We invite you to comment on the applicability and usability of this section, suggest additional tools and resources, and help to identify any gaps in knowledge.**

**Table 2. Grade of Recommendation & Level of Evidence Summary Table\*\***

<b>GR/LOE*</b>	<b>Clarity of risk/benefit</b>	<b>Quality of supporting evidence</b>	<b>Implications</b>
<b>1A.</b> Strong recommendation. High quality evidence.	Benefits clearly outweigh risk and burdens, or vice versa	Consistent evidence from well performed randomized, controlled trials or overwhelming evidence of some other form. Further research is unlikely to change our confidence in the estimate of benefit and risk.	Strong recommendations, can apply to most patients in most circumstances without reservation. Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
<b>1B.</b> Strong recommendation. Moderate quality evidence.	Benefits clearly outweigh risk and burdens, or vice versa	Evidence from randomized, controlled trials with important limitations (inconsistent results, methodologic flaws, indirect or imprecise), or very strong evidence of some other research design. Further research (if performed) is likely to have an impact on our confidence in the estimate of benefit and risk and may change the estimate.	Strong recommendation and applies to most patients. Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
<b>1C.</b> Strong recommendation. Low quality evidence.	Benefits appear to outweigh risk and burdens, or vice versa	Evidence from observational studies, unsystematic clinical experience, or from randomized, controlled trials with serious flaws. Any estimate of effect is uncertain.	Strong recommendation, and applies to most patients. Some of the evidence base supporting the recommendation is, however, of low quality.
<b>2A.</b> Weak recommendation. High quality evidence.	Benefits closely balanced with risks and burdens	Consistent evidence from well performed randomized, controlled trials or overwhelming evidence of some other form. Further research is unlikely to change our confidence in the estimate of benefit and risk.	Weak recommendation, best action may differ depending on circumstances or patients or societal values
<b>2B.</b> Weak recommendation. Moderate quality evidence.	Benefits closely balanced with risks and burdens, some uncertainty in the estimates of benefits, risks and burdens	Evidence from randomized, controlled trials with important limitations (inconsistent results, methodologic flaws, indirect or imprecise), or very strong evidence of some other research design. Further research (if performed) is likely to have an impact on our confidence in the estimate of benefit and risk and may change the estimate.	Weak recommendation, alternative approaches likely to be better for some patients under some circumstances
<b>2C.</b> Weak recommendation. Low quality evidence.	Uncertainty in the estimates of benefits, risks, and burdens; benefits may be closely balanced with risks and burdens	Evidence from observational studies, unsystematic clinical experience, or from randomized, controlled trials with serious flaws. Any estimate of effect is uncertain.	Very weak recommendation; other alternatives may be equally reasonable.

\*GR- Grade of Recommendation, LOE – Level of Evidence

\*\*Adapted from: UpToDate. Grading guide. No date. Available from: <http://www.uptodate.com/home/about/policies/grade.html>; and Guyatt G, Gutterman D, Baumann MH, Addrizzo-Harris D, Hylek EM, Phillips B, Raskob G, Lewis SZ, Schönemann H. Grading strength of recommendations and quality of evidence in clinical guidelines: Report from an American College of Chest Physicians task force. Chest. 2006 Jan;129(1):174-81, originally adapted from the GRADE Working Group.