

<b>NEIGHBORHOOD HEALTH PLAN OF RHODE ISLAND</b>	
<b>Section:</b> Clinical Practice Guideline	<b>Subject:</b> Tobacco Cessation in Pregnancy
<b>Effective:</b> 8/2000	<b>Updated :</b> 8/02, 7/04, 6/06, 6/08, 4/10

**Rationale:**

Cigarette smoking during pregnancy is the greatest modifiable risk factor for pregnancy related morbidity in the United States. Smoking in pregnancy imparts risk to both the woman and the fetus and causes adverse outcomes including stillbirths, spontaneous abortions, decreased fetal growth, premature births, low birth weight, placental abruption, sudden infant death syndrome (SIDS), cleft palates and lips, and childhood cancers and has been linked to cognitive, emotional, and behavioral problems in children. It is estimated that 20 percent or more of low birth weight births could be prevented by eliminating smoking during pregnancy. The odds of a low birth weight infant are about double for women who smoke compared with those who do not.

Many women are motivated to quit smoking during pregnancy, and health care professionals can take advantage of this motivation by reinforcing the knowledge that cessation will reduce health risks to the fetus and that there are postpartum benefits for both the mother and the child.

The goal of a smoking cessation program for pregnant women is to ensure that health care providers fully inform pregnant smokers about smoking-related health risks, motivate pregnant smokers to quit, increase the number of quit smoking attempts, and increase successful cessation among smokers.

The United States Public Health Service-sponsored Clinical Practice Guideline *Treating Tobacco Use and Dependence* (October 2000) and the *Treating Tobacco Use and Dependence: 2008 Update* provide a comprehensive approach to smoking cessation based on current evidence and developed by a panel of experts. Neighborhood endorses these guidelines, which are summarized below.

**Practice Guideline:**  
**Clinical Practice**

**Rationale**

<p>Assess pregnant woman’s tobacco use status using a multiple-choice question to improve disclosure.</p>	<p>Many pregnant women deny smoking, and the multiple-choice question format improves disclosure. For example:</p> <p>Which of the following statements best describes your cigarette smoking?</p> <ul style="list-style-type: none"> <li>• I smoke regularly now—about the same as before finding out I was pregnant.</li> <li>• I smoke regularly now, but I’ve cut down since I found out I was pregnant.</li> <li>• I smoke every once in a while.</li> <li>• I have quit smoking since finding out I was pregnant.</li> </ul>
---	--

	<ul style="list-style-type: none"> <li>I wasn't smoking around the time I found out I was pregnant, and I don't currently smoke cigarettes.</li> </ul>
Congratulate those smokers who have quit on their own.	To encourage continued abstinence.
Motivate quit attempts by providing educational messages about the impact of smoking on both the woman's and the fetus' health.	These are associated with higher quit rates.
Give clear, strong advice to quit as soon as possible.	Quitting early in pregnancy provides the greatest benefit to the fetus.
Suggest the use of problem solving methods and provide social support and pregnancy-specific self-help materials.	Reinforces pregnancy-specific benefits and ways to achieve cessation.
Arrange for follow-up assessments throughout pregnancy, including further encouragement of cessation.	The woman and her fetus will benefit even when quitting occurs late in pregnancy.
In the early postpartum period, assess for relapse and use relapse prevention strategies recognizing that patients may minimize or deny	Postpartum relapse rates are high even if a woman maintains abstinence throughout pregnancy. Relapse prevention may start during pregnancy.

- Although abstinence early in pregnancy will produce the greatest benefits to the fetus and expectant mother, quitting at any point in the 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 the pregnancy.
- Smoking status, # of cigarettes, and type of treatment provided should be recorded at the first visit and tracked over time** to facilitate patient follow-up, program monitoring, and evaluation.
- A brief (5-15 minute) smoking cessation counseling session** should be provided by a trained clinician at the first and subsequent prenatal visits and should be accompanied by pregnancy-specific, self-help materials. 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.

**The counseling session should follow the 5-A's** (more detailed information regarding the 5A's is included in the Tobacco Cessation For Adults, Clinical Practice Guideline)

1. **ASK** patient about smoking status at every prenatal visit.

Even women who have maintained total abstinence from tobacco for 6 or more months during pregnancy have a high rate of relapse in the post partum period. Postpartum relapse may be decreased by continued emphasis on the relationships between maternal smoking and poor health outcomes in infant and children.

2. **ADVISE** client to quit in a clear, strong, and personalized manner.

3. **ASSESS** client's willingness to make a quit attempt.

4. **ASSIST** client in quitting. The pregnant smoker should receive encouragement and assistance in quitting throughout her pregnancy. Pregnant smokers should be encouraged to quit first without pharmacologic therapy.

5. **ARRANGE** for follow-up assessments throughout pregnancy, including further encouragement of cessation.

Provide practical counseling (problem solving/skills training)

- Review previous quit attempts, what helped and what hurt
- Stress total abstinence is essential
- Anticipate triggers or challenges in upcoming quit attempt and discuss ways to successfully overcome them.
- Plan for dealing with other smokers living in the home

Provide intra-treatment social support

Provide a supportive clinical environment while encouraging the quit attempt

Help obtain extra-treatment social support

Ask spouse/partner, friends, coworkers to support smoker in quit attempt

<u>Nicotine Pharmacotherapy's</u>	<u>Category in Pregnancy</u>
• Bupropion SR	Category B
• Nicotine Patch	Category D
• Nicotine Gum	Category C
• Nicotine Lozenge	
• Nicotine Nasal Spray	Category D
• Nicotine Inhaler	Category D
• Chantix (Varenicline)	Category C

Safety is not categorical. A designation of “safe” reflects a conclusion that a drug’s benefits outweigh its risks. Nicotine most likely does have adverse effects on the fetus during pregnancy. Although the use of NRT exposes pregnant women to nicotine, smoking exposes them to nicotine plus numerous other chemicals that are injurious to the woman and fetus. These concerns must be considered in the context of inconclusive evidence that cessation medications boost abstinence rates in pregnant smokers.

**\*Chantix:** FDA ALERT [2/1/2008]: FDA is issuing this Alert to highlight important revisions to the WARNINGS and PRECAUTIONS sections of the full prescribing information for Chantix regarding serious neuropsychiatric symptoms.

**\*Chantix and Bupropion:** FDA ALERT [7/1/2009]:  
**FDA has required the manufacturers of the smoking cessation aids Varenicline (Chantix) and Bupropion marketed as (Zyban and generics) to add new *Boxed Warnings* and develop patient Medication Guides highlighting the risk of serious neuropsychiatric symptoms in patients using these products. These symptoms include changes in behavior, hostility, agitation, depressed mood, suicidal thoughts and behavior, and attempted suicide.**

ACOG says “The use of nicotine replacement products or other pharmaceuticals as smoking cessation aids during pregnancy has not been sufficiently evaluated to determine its efficacy or safety. Nicotine gum and patches should be considered for use during pregnancy only when non-pharmacologic treatments (eg, counseling) have failed, and if the increased likelihood of smoking cessation, with its potential benefits, outweighs the unknown risk of nicotine replacement and concomitant smoking.”

Other reputable sources say that while the FDA, because of possible risk to the fetus does not approve the use of NRT during pregnancy, some experts recommend NRT use during this time because of the even higher risks of continued smoking. Nicotine is classified by the FDA as a Pregnancy Category D drug. When used during pregnancy, lower and intermittent, short acting dosing methods should be used, such as nicotine gum, nasal spray, or inhaler.

Clinicians who choose to consider pharmacotherapy for pregnant smokers who have been unable to quit using behavior modification and other non – pharmacologic interventions should consider obtaining written informed consent from the patient prior to the prescribing of NRT.

Behavioral intervention is first-line treatment in pregnant women. Pharmacotherapy has not been sufficiently tested for efficacy or safety in pregnant patients. It may be necessary for heavy smokers (>1 pack/day)

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.

**Resources:**

- Neighborhood’s “Quit for Life” telephonic tobacco cessation services
- QUITWORKS-RI
- [ahrq.gov](http://ahrq.gov)
- [cdc.gov](http://cdc.gov)

Clinicians should ask all pregnant women about tobacco use and provide augmented, pregnancy-tailored counseling for those who smoke.

1. The American College of Obstetrics and Gynecology, Educational Bulletin, Smoking Cessation During Pregnancy, Number 260, September 2000.
2. Barker DC, Windsor RA, Quinn VP, Wall M, McPhillips-Tangum C. Maternal smoking cessation: a cost effective strategy for managed care. *Tobacco Control* 2000;9(Suppl I):160-164.
3. Fiore MC, Bailey WC, Cohen SJ, et. al. Treating Tobacco Use and Dependence. Quick Reference Guide for Clinicians. Rockville, MD: U.S. Department of Health and Human Services. Public Health Service. October 2000.
4. Treating Tobacco Use And Dependence: 2008 update. Rockville (MD): U.S. Department of Health and Human Services, Public Health Service; 2008 May. 257 p.
5. A Clinician's Guide to Helping Pregnant Women Quit Smoking, The American College of Obstetricians and Gynecologists, 2002.
6. The Tobacco Use and Dependence Clinical Practice Guideline Panel, Staff, and Consortium Representatives. A Clinical Practice Guideline for Treating Tobacco Use and Dependence. *JAMA*, 2000;283:24:3244-3254.
7. Windsor RA, Woodby LL, Miller TM, Hardin JM, Crawford MA, DiClemente CC. Effectiveness of Agency for Health Care Policy and Research clinical practice guideline and patient education methods for pregnant smokers in Medicaid maternity care. *Am J Obstet Gynecol* 2000;182:68-75.
8. U.S. Preventive Services Task Force. Counseling and interventions to prevent tobacco use and tobacco-caused disease in adults and pregnant women: U.S. Preventive Services Task Force reaffirmation recommendation statement. *Ann Intern Med* 2009 Apr 21;150(8):551-5. [7 references]