Review

Treating nicotine use and dependence of pregnant and parenting smokers: An update

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A growing volume of research since 1975 has demonstrated that clinically proven, effective interventions exist to produce long-term or even permanent abstinence from tobacco for all smokers. Achieving cessation is important for all smokers but especially for pregnant and parenting smokers because their smoking poses risks not only for themselves but also for their pregnancies and children. Treatments for smokers in general apply to parenting smokers, but special considerations regarding treatment need to be made for pregnant women. Due to the harms associated with exposure to environmental tobacco smoke, or second-hand smoke (SHS), parents and caregivers of young children should receive treatment to achieve cessation or counseling on how to eliminate exposure of children to SHS. Despite the availability of these treatments, surveys show that fewer than half of all obstetricians caring for pregnant women in the United States actually provide such treatment. We review the recommendations made in 2000 regarding treatment for pregnant and parenting smokers, summarize recent findings that may affect treatment protocols, and make recommendations regarding further research in treatment approaches for pregnant and parenting smokers. We summarize recommended changes in treatment approaches for clinicians based on this review and describe the factors affecting clinician adoption and use of proven treatments and systems supports found to increase the likelihood of clinician use of these treatments.

Introduction

Despite evidence of increased risk to themselves, their pregnancies, and their families (Cnattingius, 2004), more than 12% of women giving birth in the United States in 2001 continued to smoke throughout pregnancy (U.S. Department of Health and Human Services [USDHHS], 2003). Clinicians providing prenatal care for these women and pediatric care for their newborns and infants are in a unique position to offer clinically proven, effective interventions. The gap between what is known about how to treat pregnant and parenting smokers and what is done in clinical practice is large; fewer than half of all obstetricians surveyed offer treatment recommended in the Treating Tobacco Use and Dependence clinical practice guideline (Fiore et al., 2000; Floyd et al., 2001). Clinicians face many barriers in implementing recommended treatment including sorting out the practice implications of the published literature on cessation for pregnant and parenting smokers.

Even if recommended treatment was available to every pregnant and parenting smoker, its limitations would leave some women, their children, and families without effective treatment. Currently recommended treatments increase cessation in only a minority of pregnant smokers and do not produce higher rates of cessation among women who are more heavily addicted to tobacco. Current best practice does not include routine use of pharmacotherapies known to increase cessation rates among other smokers. Methods for ascertaining smoking status are improved but still do not identify all pregnant smokers. For women...
who are able to quit smoking during pregnancy, effective ways to prevent relapse postpartum have not been identified. Further, counseling and other approaches for helping pregnant women and parents to reduce their and their children’s exposure to SHS are not included in current best practice.

We review here the recommendations made in 2000 regarding treatment for pregnant and parenting smokers, summarize the limitations of these recommendations, present recent findings that may affect treatment protocols, and make recommendations regarding changes in treatment approaches for pregnant and parenting smokers. We identify some areas requiring further research if treatment protocols are to continue to be refined and improved. We conclude by describing factors affecting clinician adoption and use of proven treatments and systems supports found to increase the likelihood of clinician use of these treatments.

**Recommendations for treatment made in 2000**

A growing volume of research since 1975 has demonstrated that clinically proven, effective interventions exist to produce long-term or even permanent abstinence from tobacco for all smokers. Achieving cessation is important for all smokers but especially for pregnant and parenting smokers because their smoking poses risks not only for themselves but also for their pregnancies and children (Cnattingius, 2004). Treatments for smokers generally apply to parenting smokers, but special considerations regarding treatment need to be made for pregnant women (Fiore et al., 2000). Due to the harms associated with exposure to environmental tobacco smoke (ETS), or second-hand smoke (SHS), parents and caregivers of young children should receive treatment to achieve cessation or counseling on how to eliminate exposure of children to SHS.

**Recommended treatment for pregnant smokers in 2000**

The *Treating Tobacco Use and Dependence* clinical practice guideline recommended that pregnant smokers be offered psychosocial interventions exceeding minimal advice to quit, including the provision of pregnancy-specific, self-help materials (Fiore et al., 2000). 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, recommendations specified that clinicians should offer effective smoking cessation interventions to pregnant smokers at the first prenatal visit as well as throughout the course of pregnancy. Given the social pressure and clinician expectation that pregnant women not smoke, some pregnant women are reluctant to disclose their smoking status to their prenatal care providers. The use of a structured question (Figure 1) to improve discernment of smoking status has been tested and found to improve self-report of smoking status by pregnant women. The use of this question was recommended for pregnant smokers (Fiore et al.). The guideline indicated that pharmacotherapies should be considered only when the pregnant woman is otherwise unable to quit and when the likelihood of quitting, with its potential benefits, outweighs the risks of pharmacotherapy and potential continued smoking (Fiore et al.). If nicotine replacement therapies are chosen, the clinician was advised to consider using medication doses at the low end of the effective dose range and to choose delivery systems that yield intermittent, rather than continuous, drug exposure (e.g., nicotine gum rather than the nicotine patch) (Fiore et al.). Because none of these medications had been tested in pregnant women for efficacy in treating tobacco dependence, the relative ratio of risks to benefits was unclear.

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**Figure 1.** Structured question to improve disclosure of smoking status by pregnant women.
A five-step counseling approach (the 5 A’s) was recommended for all smokers in the 2000 clinical practice guideline (Fiore et al., 2000). This recommended best-practice approach was adapted to meet the specific recommendations made for pregnant smokers in the 2000 guideline (Table 1; Melvin, Dolan-Mullen, Windsor, Whiteside, & Goldenberg, 2000). The American College of Obstetricians and Gynecologists (ACOG) issued an educational bulletin outlining this approach (ACOG, 2000). This counseling approach works equally well with women of various ethnic and racial groups but is less effective with pregnant women who smoke heavily (i.e., more than one pack per day). Implementation of brief counseling interventions such as the 5 A’s could be expected to increase cessation rates among pregnant smokers by 30% to 70%, thus preventing several thousand low-birth-weight births and saving several hundred infant lives each year in the United States (Melvin et al., 2000). This and similar counseling approaches for achieving cessation are estimated to save more than US$6 per US$1 spent, more than doubling the overall cost savings attributed to the rest of prenatal care (Marks, Koplan, Hogue, & Dalmat, 1990).

Efforts are under way in the United States to establish brief counseling as described in the 5 A’s approach as a routine part of prenatal care and to promote other research, media, policy, community, and workplace support to facilitate the delivery and use of the 5 A’s (Orleans, Melvin, Marx, Maibach, & Vose, 2004).

**Limitations of recommendations**

Since 2000, a proven, effective approach to help some pregnant smokers quit has been available. However, the approach has limitations. In this section, we describe the limitations and use that discussion as a framework for presenting findings since 2000 and for making recommendations.

**Identifying every pregnant smoker.** Implementation of the best-practice intervention will achieve its maximum potential only if every pregnant woman who smokes is identified and offered assistance. Given the reluctance of some women to disclose their smoking status, ways to increase disclosure or to validate self-reports of smoking status are needed. Although the recommended structured question designed to improve reporting of smoking status (see Figure 1) helped identify a significant number of smokers previously missed, its use did not result in the identification of all pregnant women who smoke. Reliable and valid biochemical testing was available but not routinely recommended because it is more expensive than questioning the patient and introduces a number of ethical issues, including those associated with informed consent.

**Brief counseling intervention.** Although smoking cessation interventions and programs based on these research findings can increase cessation rates among parenting and pregnant smokers, their limitations suggested areas for further research. In 2000, the research showed that brief counseling works best for pregnant women who are light to moderate smokers, leaving us with little information or guidance on how to treat pregnant smokers who are more heavily addicted. Preliminary findings in 2000 also suggested potential benefit associated with at least two enhancements to brief counseling: the use of financial and other reward incentives for pregnant women remaining abstinent from tobacco and the use of biochemical feedback on cotinine levels to motivate reduction or cessation among pregnant smokers. Another major factor affecting the likelihood of pregnant women to undertake quit attempts, to succeed at quitting, and to remain abstinent from tobacco is the smoking behavior and support of the pregnant smoker’s partner or other primary personal support persons. The importance of this support was acknowledged, but we did not have sufficient information on the role of partner involvement or on ways to intervene with partners in support of their own or their partner’s quit attempt. Evidence defining the efficacy of various counseling and behavioral therapies and motivational interventions (e.g., physiological feedback of adverse impacts, quitting benefits) was too sparse to make specific recommendations about how best to use these therapies. Similarly, the efficacy of targeted or individualized interventions in pregnancy needed to be explored.

**Table 1.** The 5 A’s for pregnant women who smoke.

<table>
<thead>
<tr>
<th>Action</th>
</tr>
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<tbody>
<tr>
<td>Ask the woman about her smoking status using a multiple-choice question to improve disclosure.</td>
</tr>
<tr>
<td>Advise her to quit using clear, strong and personalized messages about the impact of smoking and the benefits of quitting for her and her fetus.</td>
</tr>
<tr>
<td>Assess her willingness to make a quit attempt within the next 30 days.</td>
</tr>
<tr>
<td>Assist her with ways to quit by suggesting and encouraging the use of problem-solving methods and skills for quitting; providing support as part of the treatment; helping her arrange support among family, friends, and coworkers; and providing pregnancy-specific self-help cessation materials.</td>
</tr>
<tr>
<td>Arrange follow-up contacts with her to assess her smoking status, encourage smoking cessation if she continues to smoke, and refer her to more intensive help if needed.</td>
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</tbody>
</table>
The current guidelines indicate ambiguity around the use of pharmacotherapies for pregnant smokers, leaving practitioners with many questions about the appropriateness of one class of clinical intervention known to double cessation rates among nonpregnant smokers. Trials of either first- or second-line pharmacotherapies in pregnant women had not been conducted, leaving questions about their efficacy and safety for pregnant women and the developing fetus.

Quits achieved during pregnancy are not maintained for most women, and the 2000 review of clinical trials testing interventions to prevent relapse did not yield efficacious approaches for preventing relapse postpartum. Similarly, little success in long-term abstinence has been reported from cessation programs for mothers of young children (Greenberg et al., 1994; USDHHS, 2001; Wall, Severson, Andrews, Lichtenstein, & Zoref, 1995). The lack of effectiveness in these areas means that infants and young children are at continued risk for exposure to SHS and that subsequent pregnancies among these women are likely to be exposed to tobacco smoke.

Spontaneous quitters. Although effective treatments exist to help pregnant smokers quit, many more women quit on their own prior to or just after learning of their pregnancy. The factors affecting the motivation and decisions of these women and their experiences in achieving and maintaining cessation were not well understood nor was the efficacy of relapse prevention for spontaneous self-quitters.

Implementing best practice. As for implementing brief counseling, or the 5 A’s, in practice settings, we did not have sufficient evidence to recommend the most efficacious amount of contact time, number of sessions, and duration of smoking cessation interventions with pregnant women. Although system supports such as reminder systems and registries are known to increase the likelihood of ascertainment and treatment, specific recommendations for providers working with pregnant and parenting smokers were not identified. Additional research was called for to understand how to motivate clinician adoption and compliance with practice guidelines.

Second-hand smoke exposure. Strategies for linking preconception, pregnancy, and postpartum (including pediatric) treatment in support of cessation for pregnant and parenting smokers are key not only to reducing postpartum relapse but also to reducing SHS exposure of infants and children. Primary research needs included mechanisms for the accurate, economical, and noninvasive assessment of SHS exposure; methods for establishing the relationship of SHS to various outcomes while accounting for confounding variables; and ways to intervene with smokers on behalf of infants and children.

Review of findings since 2000

Method

We reviewed the literature published on the major issues identified as limitations of the brief counseling approach for pregnant smokers to determine if the literature supports modifying current best practice. Our review focused on articles published since the cutoff date for materials used for the 2000 clinical practice guideline, January 1, 1999, through March 31, 2003. Searches of the following sources were conducted:

- PubMed, Medline, and PsyCInfo.
- Cochrane Database of Systematic Reviews.
- New Citations, a Web site maintained by the Office on Smoking and Health, part of the Centers for Disease Control and Prevention’s National Center for Chronic Disease Prevention and Health Promotion. The site makes available citations of recently published, tobacco-related articles from behavioral, scientific, and technical literature.

For topics covered in the 2000 clinical practice guideline, searches were done for pregnancy and pregnant smokers for the period January 1, 1999, to March 31, 2003. Searches by keyword were completed for the following topics:

- Improving disclosure of smoking status
- Spontaneous quitting and maintenance of cessation
- Postpartum relapse prevention
- Adjuncts to brief counseling (pharmacotherapies, incentives, biomarker feedback, and approaches for heavily addicted pregnant smokers)

For topics not covered in the 2000 clinical practice guideline, searches were done by keyword for the period January 1, 1994, to March 31, 2003. Searches were completed for the following topics:

- Exposure to SHS during and around the time of pregnancy
- Disclosure of SHS exposure during and around the time of pregnancy
- Increasing compliance with best practice

Each search was reviewed for completeness; each citation and its abstract were reviewed independently by this paper’s authors; areas of disagreement about appropriateness of articles were discussed and resolved; articles were compared with those included in the bibliographies of the papers on these topics in this supplement and with those on appropriate topics included in the clinical practice guideline; articles chosen were read by each of this paper’s...
pregnant women have been recommended at greater levels for passive compared with active smoking for and collected through urine, saliva, or plasma. Cutoff lites of nicotine, is frequently used as a biomarker for cotinine, one of the major proximate metabo-

jects, as well as some cessation programs, have used smoking status, clinical trials and other research pro-

amended by 60% during pregnancy, whereas the clearance of cotinine increased by 140%. These dif-

fications in nonpregnant smokers cannot be used for pregnant smokers. Dempsey, Jacob, and Benowitz (2002) found that the clearance of nicotine increased on average by 60% during pregnancy, whereas the clearance of cotinine increased by 140%. These differences result in a substantial decrease in the half-life of cotinine to a little less than 9 hours for pregnant women, compared with 17 hours for nonpregnant adults (Dempsey et al., 2002). These findings need to be taken into account when considering the use of smoking-related biomarkers to determine smoking status or to confirm self-reported smoking status.

Although incorporating a smoking-related bio-
maker into routine practice would facilitate identi-
fication of pregnant smokers’ exposure to SHS and allow women who do not report smoking to be helped, its use in routine care may be problematic. The tests add to the overall cost of prenatal care; they take time to administer, chart, and discuss; and accurate cutoff values for pregnant women may not be as reliable as once thought. Additionally, trust between the pregnant patient and her clinician is essential to quality health care, and nothing is known about how confronting a smoker with test results indicating that she has not been truthful would affect this relationship. Clinicians have reported anxiety about confronting their patients with this information (Gaffney, Goodrich, & Zens, 2003). Although spec-
ulation abounds regarding why pregnant smokers do not reveal their smoking status, including embarrass-
ment, shame, or not wanting to “hear about it again,” no research has been done to investigate why women are reluctant to admit to smoking.

The structured question currently recommended as a component of best practice by the ACOG and Smoke-Free Families may be somewhat difficult to incorporate into routine practice, especially if screening is done through interview rather than patient completion of a screening form. The question yields improved disclosure in either case. Because it is rather complex and difficult to remember in its entirety,
clinicians choosing to use it in an interview situation may need an aid, such as a pocket guide, to remember the question correctly. Without this prompt, problems may occur with consistent questioning and ascertainment, especially in busy practices. Research on combining some of the responses given in the question to ask it in a more concise way (e.g., “Since you learned you were pregnant have you smoked less, about the same, or stopped?”) have not been tested. The question as written remains our best method for improving disclosure without biochemical testing.

Further research focused on achieving a better understanding of the motivations of pregnant women for not disclosing their smoking status may lead to a strategy that would improve disclosure, avoid the possible negative consequences associated with using smoking-related biomarkers, and replace or enhance the structured question.

**Needs for further research:**
- Establishment of appropriate, empirically based cutoff values for cotinine, expired-air carbon monoxide, and thiocyanate to differentiate between active smoking and passive exposure to tobacco smoke in pregnant women
- Examination of the half-life of cotinine in pregnant smokers, and development of recommendations for testing based on those findings
- Exploration of why women feel unable to truthfully disclose their current tobacco use
- Continued exploration of ways to improve disclosure through structured questions and enhancements to them

**Spontaneous quitting and maintenance of cessation**

Spontaneous quitters are those women who smoked cigarettes prior to conception and who quit smoking shortly after becoming pregnant, on their own and before receiving advice or intervention from prenatal care providers (Solomon & Quinn, 2004). The rates of spontaneous quitting vary according the demographics of the pregnant women and range from 11% to 28% of publicly insured pregnant smokers (Kendrick et al., 1995; Ockene et al., 2002; Secker-Walker, Solomon, Flynn, Skelly, & Mead, 1998; Windsor et al., 1985) and from 40% to 65% of privately insured pregnant smokers (Ershoff et al., 1999; Ershoff, Quinn, & Mullen, 1995; McBride et al., 1999; Saks et al., 2001).

Spontaneous quitters make up the majority of pregnant smokers who successfully quit smoking during pregnancy and are more likely to maintain cessation during pregnancy (Solomon & Quinn, 2004). Despite this success in quitting during pregnancy, spontaneous quitters are likely to relapse postpartum; relapse rates are between 61% and 76% (Hajek et al. 2001; Mullen, Richardson, Quinn, & Ershoff, 1997).

Since 2000, we have learned little about how best to work with spontaneous quitters to maintain cessation postpartum. Relapse prevention counseling featuring mailed self-help interventions only, proactive telephone counseling combined with mailed self-help interventions, face-to-face relapse prevention counseling, or some combination of these components has not increased abstinence rates (Solomon & Quinn, 2004). We have, however, learned more about the characteristics of spontaneous quitters. As a group, they are more likely to have higher education and income, be married or have a partner, have a planned pregnancy, be pregnant with their first child, enter prenatal care early, or experience nausea or sickness during the first trimester, and they more often intend to breast feed (Solomon & Quinn). They tend to be light to moderate smokers, have fewer smokers in their social environment, and believe more strongly that smoking can harm the developing fetus. Perhaps these descriptive findings can guide researchers in developing interventions to maintain spontaneous quitting during and after pregnancy.

**Postpartum relapse prevention**

Although quit rates during pregnancy exceed rates for nonpregnant women, this nonsmoking status is not maintained after the child’s birth. Within 1 year, almost 80% of women who quit smoking during pregnancy become smokers again. Relapse occurs quickly after the birth of the baby, similar to the “classic” relapse curve in which most addicts relapse immediately after the intervention. It is surprising that women who have been abstinent for 5–7 months return to smoking so quickly. Some 45% of smokers who quit while pregnant begin smoking within 3 months of delivery (Mullen et al., 1997).

Efforts to predict factors that maintain postpartum abstinence have produced few answers. A wide range of interventions have been tested and resulted in modest increases of no more than 10%. These interventions include starting messages about relapse
prevention before the birth of the child, involving intimate partners and other members of the smoker’s close social network, and helping maintain motivation and build self-efficacy (Mullen, 2004).

Several factors that seem to predict relapse have not been explored adequately, including concerns about weight gain (Pomerleau, Brouwer, & Jones, 2000; USDHHS, 2001), intention and self-efficacy for maintaining smoke-free status, and the role of breast feeding. Women who breast feed tend to stay quit longer, and starting to smoke postpartum is strongly related to weaning the baby early (Edwards & Sims-Jones, 1998; Mullen et al., 1997; Ratner, Johnson, Bottorff, Dahinten, & Hall, 2000). Smoking behavior of family and friends also affects a woman’s ability to stay quit after delivery. The most consistent single factor associated with postpartum relapse is living with a smoking partner. Women who are married to or live with a smoker are three times more likely to relapse postpartum than women who do not live with a smoker (Mullen, 2004).

Quitting during pregnancy seems to involve different behavioral and cognitive processes for women than does quitting at other times. Concern for the baby’s health and support or disapproval of peers to protect the baby provide unique social-cognitive support, and physical symptoms such as nausea may decrease the physical desire for smoking. Pregnant women use few coping strategies yet have high self-efficacy to abstain during pregnancy (Mullen, 2004). However, when external factors disappeared and other cues such as drinking coffee and alcohol resumed after birth, most women were no longer able to maintain abstinence. Studies argue against relying too heavily on the health of the baby as a motivator to quit smoking because the pregnant quitter does not develop intrinsic motivation and coping skills that will sustain her nonsmoking behavior beyond the birth of the baby (Mullen, 2004).

Pregnant smokers who quit during pregnancy do not always report an intention to quit forever (Bottorff, Johnson, Irwin, & Ratner, 2000; Mullen et al., 1997). Rather they are simply stopping or suspending smoking during the pregnancy, which argues for examination of both pregnancy-specific and general motivations for pregnant smokers (Curry, McBride, Grothaus, Lando, & Pirie, 2001; Mullen, 2004).

Needs for further research:
- Interventions that begin in late pregnancy and involve smoking partners
- Interventions that engender intrinsic motives and skills that can be maintained postpartum in the face of loss of external support and the stresses of a new baby
- Examination of how to handle weight loss and concern for weight loss
- Determination of the role of breast feeding as a motivator

Adjuncts to brief counseling
Pharmacotherapies to aid smoking cessation. The use of first-line pharmacotherapies to aid smoking cessation for pregnant women remains a controversial topic. Current classifications of these therapies for pregnancy are contained in Table 2, and definitions of the classifications are given in Table 3. Questions about the safety and efficacy of pharmacotherapies for pregnant women remain unanswered, especially given the small number of clinical trials and the small numbers of women enrolled in those trials. Reviews (Benowitz & Dempsey, 2004; Dempsey & Benowitz, 2001; Windsor, Oncken, Henningfield, Hartmann, & Edwards, 2000) have focused on the risks of continuing to smoke during pregnancy compared with the risk of using medications, particularly nicotine replacement therapy (NRT), that might result in a woman quitting (Benowitz & Dempsey). These reviews concluded that the use of NRT during pregnancy, while not without risk, poses less risk to the fetus than continued exposure to maternal smoking and the harmful carcinogens and toxins, principally carbon monoxide, associated with smoking cigarettes.

Benowitz and Dempsey (2004) acknowledged that definitive work on the safety of nicotine in humans still needs to be done, and they concluded, based on animal studies, that the main fetal health concern about nicotine administered during pregnancy is fetal neuroteratogenicity. Other researchers have suggested additional consequences of prenatal nicotine exposure. A review of the evidence for the neurodevelopmental effects of in utero exposure to nicotine found that prenatal exposure to nicotine may lead to dysregulation in neurodevelopment and can indicate higher risk for psychiatric problems, including substance abuse (Ernst, Moolchan, & Robinson, 2001). A number of primate and other animal studies suggested a variety of effects of prenatal nicotine exposure on neonatal lung: decreased lung size and volume, increased number of alveolar type II cells, increased size and number of neuroendocrine bodies, increased type I and III collagens, decreased elastin in lung parenchyma, increased mean linear intercept, decreased radial alveolar counts, increased alveolar volume, and increased airway wall area (Pierce & Nguyen, 2002). Studies in rats have suggested a link between nicotine exposure during the neonatal brain growth spurt and hyperactivity later in life, particularly during adolescence (Thomas, Garrison, Slawecki, Ehlers, & Riley, 2000).
Conclusions about potential maternal harm associated with nicotine are less clear and include possible pregnancy effects such as uteroplacental insufficiency, increased maternal blood pressure and heart rate, platelet activation, and lower plasma levels of estrogen (Benowitz & Dempsey, 2004). Although the nature and magnitude of risk to mother and fetus of exposure to pure nicotine remains unknown, it is likely far less than the risk of cigarette smoking during pregnancy (Benowitz & Dempsey, 2004; Okuyemi, Ahluwalia, & Harris, 2000; Windsor et al., 2000). Given this rationale, the use of NRT to reduce harm during pregnancy, it is argued, may be reasonable. This evidence does not however answer another question regarding NRT—whether its use during pregnancy helps a pregnant woman quit smoking. Only two clinical trials of nicotine patch use with pregnant smokers have been conducted, and neither showed an increase in cessation with NRT use during pregnancy (Kapur, Selby, Klein, & Koren, 2001; Wisborg, Henriksen, Jespersen, & Secher, 2000). A study that looked at heavy smokers found that

### Table 2. Pregnancy categories for nicotine replacement therapy and bupropion.

<table>
<thead>
<tr>
<th>Type</th>
<th>Product</th>
<th>Characteristics</th>
<th>Pregnancy category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nicotine replacement therapy</td>
<td>Nicotine gum (Nicorette)</td>
<td>Packaged in 2-mg and 4-mg doses, sold over the counter (OTC)</td>
<td>C</td>
</tr>
<tr>
<td></td>
<td>Transdermal nicotine patch (Habitrol, Nicoderm, Nicotrol, Prostep)</td>
<td>Doses range from 5 mg to 22 mg, sold by prescription and OTC</td>
<td>D</td>
</tr>
<tr>
<td></td>
<td>Nicotine inhaler</td>
<td>Packaged in 10-mg cartridges, with 13 mg delivered with each puff, sold by prescription</td>
<td>D</td>
</tr>
<tr>
<td></td>
<td>Nicotine nasal spray</td>
<td>Each spray releases 0.5 mg of nicotine, sold by prescription</td>
<td>D</td>
</tr>
<tr>
<td></td>
<td>Nicotine lozenge</td>
<td>Packaged in 2-mg and 4-mg doses, sold OTC</td>
<td>D</td>
</tr>
<tr>
<td>Bupropion</td>
<td></td>
<td>Available in 150-mg tablets, sold by prescription</td>
<td>B</td>
</tr>
</tbody>
</table>

*See Table 3 for explanation of pregnancy categories.


### Table 3. U.S. Food and Drug Administration pregnancy categories for drugs.

**Pregnancy category A.** Studies in pregnant women have not shown that (name of drug) increases the risk of fetal abnormalities if administered during the first (second, third or all) trimester(s) of pregnancy. If this drug is used during pregnancy, the possibility of fetal harm appears remote. Because studies cannot rule out the possibility of harm, however, (name of drug) should be used during pregnancy only if clearly needed.

**Pregnancy category B.** Reproduction studies have been performed in (kind(s) of animal(s)) at doses up to (x) times the human dose and have revealed no evidence of impaired fertility or harm to the fetus due to (name of drug). There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used in pregnancy only if clearly needed.

**Pregnancy category C.** If animal studies have shown an adverse effect (other than decrease in fertility), but adequate and well-controlled studies in pregnant women have failed to demonstrate a risk to the fetus during the first trimester of pregnancy (and there is no evidence of a risk in later trimesters), (name of drug) should be used during pregnancy only if clearly needed.

**Pregnancy category D.** Reproduction studies in (kind(s) of animal(s)) have shown (describe findings) at (x) times the human dose. Studies in pregnant women, however, have not shown that (name of drug) increases the risk of abnormalities when administered during the first (second, third, or all) trimester(s) of pregnancy. Despite the animal findings, it would appear that the possibility of fetal harm is remote, if the drug is used during pregnancy. Nevertheless, because the studies in humans cannot rule out the possibility of harm, (name of drug) should be used during pregnancy only if clearly needed.

**Pregnancy category X.** See Contraindications section. Under Contraindications, the labeling states: (Name of drug) may (can) cause fetal harm when administered to a pregnant woman. (Describe the human data and any pertinent animal data.) If this drug is used during pregnancy, or if this patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus.


women who continued to smoke during pregnancy may be predisposed to a high rate of nicotine metabolism (Selby, Hackman, Kapur, Klein, & Koren, 2001).

To reduce harm associated with tobacco smoke by pregnant women, Benowitz and Dempsey (2004) suggested the consideration of NRT for pregnant smokers who are moderately or highly addicted and who have participated in behavioral counseling without success in quitting smoking. Windsor and colleagues (2000) suggested that the decision to use NRT be an individual decision between a patient and her clinician, the same conclusion reached in the clinical practice guideline (Fiore et al., 2000). Benowitz and Dempsey suggested that NRT be used in combination with behavioral therapy, that selection of the dose of nicotine be guided primarily by evidence on what is effective to achieve cessation, that the nicotine delivery system be individualized according to the patient’s symptoms, that nicotine patches be used for 16 hours rather than 24 hours, that NRT be started as early in pregnancy as possible, and that a national registry for nicotine therapy use during pregnancy be established. In addition to these recommendations, Benowitz and Dempsey, as well as others (Fiore et al.; Peters & Morgan, 2002), have suggested that nicotine administration be supervised closely by monitoring urinary cotinine levels and use of non-continuous treatment, for example, gum, spray, and 18-hour rather than 24-hour patches. Windsor et al. (2000) recommended five questions that clinicians should ask pregnant smokers before suggesting the use of NRT:

- Has the patient indicated that she wants to quit?
- Has the patient received effective counseling procedures and not been able to quit?
- Has the patient reported smoking 10 cigarettes per day or more?
- Are there coexisting medical problems that need to be addressed, such as other drug dependence or depression?
- Is NRT acceptable to the patient? If so, which method does she prefer?

Although these questions raise important points, treatment decisions based on the answers are not defined, and, depending on the answers, clinicians could be left in a quandary about how to proceed. For example, if medical problems such as drug dependence or depression are present, what should the clinician do in response? These questions also do not help the clinician gain information that might be helpful in determining dose and scheduling.

Sustained-release bupropion, an antidepressant, is recommended as a first-line pharmacotherapy for smoking cessation (Fiore et al., 2000), although little is known about the mechanisms by which it facilitates abstinence (Lerman et al., 2002; Okuyemi et al., 2000; Peters & Morgan, 2002). The suggested mechanism of action is inhibition of neural reuptake of dopamine or noradrenaline. This explanation is likely simplistic given recent research suggesting that bupropion has an impact on negative affect and withdrawal but that only negative affect predicted abstinence at the end of the treatment and met the statistical criteria for a mediating mechanism (Lerman et al.). Additional research is needed on mediating mechanisms of treatment.

The lack of data on bupropion use during pregnancy makes it impossible to assess benefit vs. risk as recommended in the clinical practice guideline. Known risks of immediate-release bupropion include seizures; if seizures do occur during pregnancy, they could have extremely damaging effects on the fetus (Benowitz & Dempsey, 2004). Known risks of sustained-release bupropion in nonpregnant smokers include nausea, insomnia, dry mouth, and sympathetic nervous stimulation with mild hypertension (Benowitz & Dempsey; Peters & Morgan, 2002). Whether these risks are elevated in pregnant women is unclear. All formulations of bupropion have a pregnancy category B status, assigned by the U.S. Food and Drug Administration, indicating that safety in pregnancy has not been determined (see Tables 2 and 3).

The lack of data on efficacy and safety should be addressed in the conduct of clinical trials. Until this information is available, bupropion should be used only in research studies with pregnant smokers.

**Needs for further research:**

- Exploration of effects of nicotine on fetal development and maternal health
- Clinical trials to assess efficacy of NRT for pregnant smokers
- Clinical trials to assess efficacy and safety of bupropion
- Exploration of attitudes of pregnant smokers regarding pharmacotherapy and its risks and benefits
- Examination of pregnant smokers’ compliance and concomitant smoking when using NRT or bupropion

**Financial incentives to help pregnant smokers quit.**

In studies with nonpregnant smokers, financial incentives for abstinence, compared with educational interventions, significantly increased short-term cessation. Incentives also increased participation and, therefore, receipt of treatment. The only studies completed with pregnant women found that financial incentives alone did not increase quit rates as well as financial incentives plus social support or biochemical feedback (Donatelle, Prows, Champeau, & Hudson, 2000).
Although financial incentives have served as an extrinsic motivation that has resulted in increased participation in treatment and short-term abstinence, whether the same results will be found with pregnant smokers is unclear. The concept of reset (starting over with incremental payment if the subject doesn’t maintain abstinence) has not been tested with pregnant women but has been shown to be more effective, with other addictions, than either simply increasing incentives or offering a one-time incentive. Long-term abstinence has not occurred in the absence of financial incentives. How to help all smokers, including pregnant women, develop the intrinsic motivation needed for long-term abstinence when the incentives end is an unanswered question. Initial work needs to be done to determine how financial incentives will maintain both prenatal and postpartum abstinence in pregnant women.

Because the majority of pregnant smokers have low income levels, financial incentives may be especially effective in engaging them in treatment and motivating them to quit. Even with incentives in place, treatment approaches need to emphasize learning self-management skills and to help pregnant smokers internalize their motivation to quit so that they can maintain long-term abstinence. Financial incentives have been effective in (a) motivating attendance or participation, (b) increasing abstinence, and (c) preventing short-term relapse (Donatelle et al., 2004). However, an ethical issue exists regarding “buying” abstinence in a vulnerable population and how to translate financial incentives into routine care. Would low-income pregnant smokers be tempted to lie about smoking status (many already fail to admit smoking), and would incentives work with higher income women? However, given the harm to the fetus of continued smoking during pregnancy, if financial incentives are shown in subsequent trials to increase cessation during pregnancy, policies that permit financial incentives for quitting should be explored. Future research should build on current knowledge of contingency management and combine strategies in multicomponent interventions, including postintervention incentives and investigating the mechanisms by which incentives enhance counseling and pharmacotherapies (Donatelle et al., 2004).

Needs for further research:
- Exploration of ethical and policy issues related to the use of financial incentives
- Exploration of pregnant smoker response to availability of financial incentives, including reset strategies, as a treatment option
- Determination of level of incentive required to achieve change in smoking status
- Development of multicomponent intervention

- Determination of mechanisms by which financial incentives enhance counseling and pharmacotherapies

**Biomarker feedback as a motivator to quit.** Pregnant smokers acknowledge the harms from smoking to their unborn child and themselves but often underestimate this risk. Pregnant smokers who believe that smoking is very harmful to their baby are more likely to quit smoking. One method to increase women’s perception of their baby’s and their personal risk is to provide them with concrete, biological evidence of the level of tobacco-related toxins in their body. The most common smoking-related biomarkers are carbon monoxide and cotinine. Biomarkers also include genomic evidence, but they are not included in this discussion because they are not modifiable and are therefore not appropriate for motivating behavior change. Biomarker feedback has been a successful cessation aid with nonpregnant smokers. McClure (2004) has discussed the rationale for using biomarkers.

Research with pregnant smokers has provided limited information about the efficacy of biomarker feedback as a cessation aid. Multicomponent studies were not fully implemented or did not untangle biofeedback from other components. Other studies were too small to result in significant findings. When women received the complete intervention, they were more likely to quit or reduce the number of cigarettes smoked. Two Smoke-Free Families projects funded by The Robert Wood Johnson Foundation reported that giving pregnant smokers feedback on cotinine levels created an opportunity to discuss risks and that the pregnant smokers were receptive to this discussion (McClure, 2004).

Biomarker feedback may be successful at increasing motivation to quit among pregnant smokers. However, it must be accompanied by assistance and ongoing support. Incorporating feedback into the *advise* step of the 5 A’s may increase the salience of the advice, but completing the *assess*, *assist*, and *arrange* steps remains critical to helping pregnant smokers quit. The effectiveness or salience of different types of biomarkers has not been tested. The ease and cost of testing as well as the immediacy of the feedback would be important factors for integrating this strategy into routine care. Also, ethical issues need to be explored, such as how does biofeedback information increase guilt (and therefore stress) among pregnant smokers who cannot quit, and would this information, if made a part of the child’s medical record, be used by insurance companies to rate the insured as high risk or refuse coverage.

**Needs for further research:**
- Efficacy of different types of biomarkers and role of timing in providing feedback
Cost of testing and its contribution to the overall cost-effectiveness of cessation interventions
Exploration of ethical and policy issues associated with biomarker feedback
Examination of ways to integrate biomarker feedback into routine prenatal care
Examination of attitudes and acceptance of pregnant women regarding biomarker feedback

Approaches for heavily addicted pregnant smokers. For heavily addicted pregnant smokers (i.e., those smoking more than one pack per day) who are unable to quit either spontaneously or as a result of a brief intervention such as the 5 A’s, the use of more intensive treatment or pharmacotherapies should be considered. Evidence suggests that pregnant women who continue heavy smoking in the second trimester form a selective group with a pharmacokinetic predisposition to a high rate of nicotine metabolism (Selby et al., 2001) or with a history of problem behavior (Wakschlag et al., 2003). Counseling strategies may prove to have minimal impact on the smoking behavior of these women. Preliminary evidence suggests that a small percentage of resistant pregnant smokers may be helped in the short term by an intervention using motivational interviewing strategies (Stotts, DiClemente, & Dolan-Mullen, 2002). If these results can be replicated and refined to achieve greater success, this approach may hold some promise.

Needs for further research:
- Efficacy of intensive counseling, including motivational interviewing, and individualized treatment for resistant smokers

Exposure to second-hand smoke

Disclosure of exposure. Self-report of exposure to SHS has been validated for both pregnant women and parents of young children using both biochemical and environmental measures (Hovell, Zakarian, Wahlgren, Matt, & Emmons, 2000; Seifert, Ross, & Norris, 2002). Maternal smoking rates have been a good proxy for in utero and childhood exposure. The Pregnancy Risk Assessment Monitoring System (PRAMS) developed by the Centers for Disease Control and Prevention has used two structured questions to inquire about exposure of the pregnant woman to SHS. Because these questions are asked postpartum as part of a mailed questionnaire, they need to be adapted for use in clinical settings with pregnant women (Figure 2).

For postpartum women, a recent study has presented results validating a five-part screening instrument for assessing a child’s exposure to SHS. An 80% agreement was found between urinary cotinine levels and reported exposure to ETS. Spearman’s ranked correlation coefficient of 0.62 indicated a direct relationship between cotinine and an ETS exposure intensity scale ($p < .0001$; Seifert et al., 2002). The screening questions are presented in Figure 3. Studies suggest that self-reports by parental and nonparental

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**Figure 2.** Question to assess second-hand smoke exposure for pregnant women.
sources have sufficient validity to recommend their use in service and research programs. In addition to these screening questions, including on the problem list an assessment of the number of smokers in the household or the patient’s rules on smoking in her car may encourage discussion of this issue at all health care visits.

Reduction of exposure. Intervention studies have often focused on parents of children with health problems or asthma so that the health of the child is the focus and parents are asked to reduce or eliminate exposure by smoking outside and not allowing others to smoke in the child’s presence. Studies among pregnant women have focused on the postpartum period and the elimination or reduction of the child’s exposure to tobacco smoke. Interventions in clinical settings have produced mixed results, although results in two large trials, one in a pediatric practice and one in a group-model health maintenance organization, were successful in decreasing SHS in the home (Klerman, 2004). More intensive interventions, such as biofeedback on the child’s cotinine level, have resulted in more significant reductions of exposure (Klerman). Home-based programs in which home visitors advocate for not smoking around the child or for smoking outside have had mixed results in decreasing SHS exposure. Smoking in the home or car, but not in the child’s presence, decreases exposure but not eliminate it.

In addition to this approach to harm reduction, support for the routine use of medicinal nicotine is increasing. A recent Institute of Medicine report (Stratton, Shetty, Wallace, & Bondurant, 2001) concluded with recommendations to develop a testing strategy to assess the true harm-reduction potential of products (tobacco or pharmaceutical) and to develop and adopt surveillance and regulatory principles for the protection of public health. In follow-up to this report, others have recommended that the public health community send a strong message now that the best harm-reduction strategy for current smokers, after abstinence, is medicinal nicotine (Kozlowski, Strasser, Giovino, Erickson, & Terza, 2001). The use of medicinal nicotine should be promoted rather than the use of cigarettes altered by the tobacco industry to reduce or eliminate toxic ingredients. Because medicinal nicotine is the least toxic way to get nicotine for both the smoker and those living or working with the smoker, complete substitution of medicinal nicotine for cigarette smoking should be promoted by clinicians as a harm-reduction strategy for smokers who are unable to quit smoking cigarettes (Kozlowski et al., 2001). This approach seems appropriate when attempting to reduce the exposure of nonsmoking pregnant women or infants and children to tobacco smoke.

Barriers to change. Although clinicians in pediatric practices have an excellent opportunity to educate parents about SHS and motivate them to change parental smoking behaviors so that children are not exposed or, at least, are exposed to less tobacco smoke, a number of barriers may inhibit their doing so. Because the parent is not the patient, reimbursement is likely not provided, and clinicians may not have the time and training necessary to intervene with parents. Ways to overcome these barriers and to take advantage of the parent’s strong motivations to protect and care for their children should be explored. Pediatric clinicians also should be aware that some parents may be more receptive to cessation messages, especially if their child has been hospitalized or suffers from otitis media, frequent lower respiratory infections, bronchitis, or asthma (Klerman, 2004).

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**Figure 3.** Instrument to assess child’s exposure to ETS/SHS.

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes/No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Does child’s mother currently smoke?</td>
<td>Yes/No</td>
</tr>
<tr>
<td>2. In the home?</td>
<td>Yes/No</td>
</tr>
<tr>
<td>3. Does child’s father currently smoke?</td>
<td>Yes/No</td>
</tr>
<tr>
<td>4. In the home?</td>
<td>Yes/No</td>
</tr>
<tr>
<td>5. Is your child exposed to cigarette smoke on a regular basis (any exposure at least one time a week) from anyone other than the parents, i.e., stepparents, day care providers, grandparents, siblings, friends?</td>
<td>Yes/No</td>
</tr>
</tbody>
</table>

*Source: Seifert, Ross, & Norris, 2002*
Increasing compliance with best practice

Current practice. Publication of the clinical practice guideline (Fiore et al., 2000) and the ACOG (2000) educational bulletin provided, for the first time, specific guidelines about how to treat pregnant smokers, but surveys have shown that the recommended 5 A’s have not been fully implemented as a part of routine prenatal care. Obstetrician-gynecologists care for 85% of pregnant women; 98% reported they always asked about tobacco use at the initial prenatal visit and 95% discussed harm related to smoking and advised smokers to quit (Floyd et al., 2001). However, a more detailed survey of obstetrician-gynecologists in Ohio found that only 66% assessed smokers’ readiness to quit, 43% provided pregnancy-specific materials, and 23% helped arrange social support at home (assist) (Chapin & Root, 2004).

Barriers to adoption and use. Although physicians strongly believe in the importance of treating tobacco use and dependence, competing demands of other medically urgent issues, time constraints, lack of training and resources, little or no reimbursement, and simple inertia are barriers to adoption of the recommended guideline for treating tobacco use and dependence (Cabana et al., 1999; Fiore et al., 2000; Orleans et al., 2004; Whitlock, Orleans, Pender, & Allan, 2002). Most practices lack tools and office systems that aid in the delivery and documentation of behavioral health counseling, both of which are known strategies for positively influencing clinician adoption of new interventions. In addition to these barriers, almost all practicing obstetrician-gynecologists (85%) also reported the smoking cessation counseling methods they used were self-taught and that they (95%) were unsure about what patient education materials were most appropriate for pregnant women (Chapin & Root, 2004). A review of physician noncompliance with clinical guidelines identified these and other practice barriers. Furthermore, successful strategies in one setting may not be successful in another (Cabana et al.).

Effective strategies. A number of strategies for improving clinician compliance have been evaluated. Dissemination-only strategies, such as conferences or mailing unsolicited educational material, though essential to increasing awareness of guidelines and other related issues, have little impact on clinician behavior (Oxman, Thomson, Davis, & Haynes, 1995). Academic detailing (outreach visits); performance audit and feedback, sometimes with financial incentives; reminder systems such as flowsheets, stickers, and checklists; computerized decision support; and participatory continuing medical education are moderately affective in changing practice behavior (Dickey, Gemson, & Carney, 1999; O’Brien et al., 2002; Tu & Davis, 2002). Having a standard form on which to document smoking status as a “vital sign” increases compliance with best practice for tobacco treatment (Fiore et al., 2000). Computerized patient records may prove to be effective tools for changing physician behavior, by enhancing routine assessment, documentation, and monitoring of smoking status (Elson & Connelly 1995) and by triggering reminders for follow-up.

Clinicians also may be more inclined to offer cessation services if they know they are not responsible for all the steps in the treatment process: screening, advising, assessing willingness to quit, counseling, and follow-up. Because they are more comfortable with the first three steps and because they experience significant constraints on their time, other treatment resources are often important adjuncts to clinical services. One of the most important of these services is a telephone quitline or helpline that offers proactive, evidence-based cessation counseling for pregnant smokers. At least 28 states now offer these services for pregnant smokers; and a national quitline for pregnant smokers, Great Start, is available round-the-clock, every day. Proactive counseling offered by quitline services has been found to be effective in increasing quit rates (Borland, Segan, Livingston, & Owen, 2001; Fiore et al., 2000). Effective quitlines use best-practice counseling approaches and offer proactive counseling. In some states, quitline users also can receive pharmacotherapy. Clinicians should assess carefully quitline services available to them by state entities or private vendors to determine if the services meet these criteria and refer to them only if satisfied with their findings. Before referring a patient to quitline services, the clinician must obtain consent from the patient. Patient referrals seem to work best when the clinician completes the first three of the 5 A’s steps and then makes the referral, remains informed about the patient’s progress in quitting, and continues to offer intratreatment social support for the patient’s quit attempt.

Medical record review is the most common method of studying implementation of health behavior counseling. In most studies, it is unclear if the proportion of the improvement is due to increased delivery of service or increased documentation. Although increased documentation is positive, this issue warrants further study. Exit interviews with patients provide another method of evaluating counseling service quality and should be used in conjunction with record audits.

Successful approaches to integrating clinical guidelines in routine care involve office staff and nurses as well as clinicians (Dietrich, Woodruff, & Carney, 1994). Delineating tasks and spreading these tasks
among all clinic personnel helps to reduce the burden on each individual and address time constraints. A designated person to monitor these tasks as well as a regular review of the system by all staff helps to maintain provision of smoking cessation services (Dietrich, Carney, Winchell, Sox, & Reed, 1997).

Practices take differing lengths of time to implement changes. Interventions and trainings need to allow practices to proceed at their own pace with their plans for change. Multicomponent interventions for practice change provide the opportunity to tailor strategies based on assessment of the individual practice. Practice characteristics that influence the likelihood of adopting office systems change to support health behavior counseling are not clear. At least two tools for assessing organizational readiness for change are being modified for tobacco treatment and tested in several sites: the Assessing Chronic Illness Care and Organizational Change Manager surveys. Research using these and other tools to identify practice characteristics associated with successful implementation of office systems to support smoking cessation would provide insight into dissemination of the 5 A’s best practice.

In addition, it is not known if strategies that target a single issue such as smoking cessation may improve the delivery rate of that service at the expense of others. Health care providers are often faced with setting priorities among many serious health issues and addressing only one or two with the patient. This situation is particularly true with low-income pregnant women who often have problems such as depression, malnutrition, physical and emotional abuse, and the like. Research on office-based systems and physician training that facilitates assessment and priority setting among multiple health risk behaviors would be helpful to ensure adoption of best-practice guidelines. To implement the 5 A’s into routine care for all pregnant smokers, change strategies need to be tailored to the culture and environment of each practice or clinic on the basis of practice assessment and matched to the unique characteristics of the practice such as size, personnel, and current billing or record-keeping systems (Cabana et al., 1999; Goodwin et al., 2001).

Payment methods also may affect physician behaviors and provision of services. Some evidence suggests that the type of payment made to primary care providers affects their behavior (Gosden et al., 2002). In a pilot study, reimbursement by an insurer for counseling services increased the identification of pregnant smokers but not the delivery of counseling services. Determination of patient eligibility for the service (the insurer covered only a small portion of patients) proved to be major barrier to providing counseling to a specific group of patients. Reimbursement and incentives were not sufficient to prompt offices to systematically alter their practices (Latts, Prochaska, Salas, & Young, 2002). Many managed care organizations use financial incentives linked to performance measures for primary care providers. Incentives that encourage restraint of service are believed to compromise care. Incentives linking quality of care and patient satisfaction are perceived more positively by both providers and the public (Grumbach, Osmond, Vranizan, Jaffe, & Bindman, 1998; Stoddard, Grossmen, & Rudell, 2002). However, current research is inadequate to determine the impact, if any, of different financial incentives or payment schemes (e.g., target, capitation, salary, fee-for-service) on quality of health care (Giuffrida et al., 2002).

The health care cost savings in the first year of a child’s life if the mother quits smoking during pregnancy is US$6 to US$1 (Marks et al., 1990). In the United States, smoking-attributable neonatal costs amount to US$366 million annually, averaging approximately US$638 per birth (Adams, Alao, Melvin, & Rivera, 2002). Although the cost benefit of reducing maternal smoking during pregnancy is well documented (Marks et al.), health insurance companies and federal insurance programs have been slow to adopt reimbursement policies for counseling or pharmaceutical treatment of tobacco use and dependence (Barker, Orleans, Kaplin, & Barry, 2004). Methods to increase reimbursement should be researched and reimbursement provided to primary care providers.

Needs for further research:
- Effectiveness of different strategies to provide counseling training to clinicians and to assist practices in making office systems changes
- Impact of financial incentives on clinician and practice provision of the 5 A’s (e.g., Does reimbursement increase compliance with guidelines?)
- Methods to support institutionalization of clinician and practice provision of best practice (e.g., What is needed to sustain changes in clinician and practice behavior over time?)

Recommendations for clinicians

**Recommended treatment for pregnant smokers**

Based on our review, we recommend that all pregnant women be screened for tobacco use using a structured multiple-choice question and that the brief counseling approach, the 5 A’s, be used with all pregnant smokers. We also recommend that the following changes be incorporated into the previously published guidance for treating pregnant smokers. Recommended changes are presented in the context of the 5 A’s.
Ask. In addition to asking every pregnant woman the structured question previously recommended (Melvin et al., 2000) to determine smoking status, every pregnant woman also should be screened at her first prenatal visit to determine exposure to SHS using the questions adapted from PRAMS (see Figure 2). Spontaneous quitters should be congratulated and offered support to maintain abstinence. At this time, the routine use of biochemical markers to verify smoking status is not recommended given the problems with determining accurate cutoff levels, potential damage to the clinician-patient relationship, and cost. Use of these markers should be restricted to research and clinical trials.

Advise. In addition to the current recommendations about advising pregnant smokers to quit, smokers and nonsmokers exposed to SHS should be advised about the harms of exposure and the benefits for their baby and themselves of minimizing or eliminating their exposure to SHS.

Assess. This step remains the same for pregnant smokers, calling for the clinician to assess willingness to quit within the next 30 days. For pregnant women exposed to SHS, whether smokers or not, clinicians should determine if they are willing to discuss ways to minimize or eliminate exposure.

Assist. Recommendations for pregnant women who are light to moderate smokers (i.e., smoking less than one pack per day) remain the same, including recommendations on the use of pharmacotherapy. Research evidence at this time is insufficient to support the routine use of incentives, biomarker feedback, or other adjuncts to cessation counseling.

For heavily addicted pregnant smokers (i.e., those continuing to smoke more than a pack of cigarettes per day), if behavioral counseling has failed and if the pregnant smoker and her clinician have together determined that the likelihood of quitting, with its potential benefits, outweighs the risks of the pharmacotherapy and potential continued smoking, then the following issues should be considered in prescribing or recommending the use of pharmacotherapies:

- Use NRT in combination with behavioral therapy only for those women indicating that they are willing to undertake cessation.
- Use a dose that is effective to achieve cessation.
- Individualize the nicotine delivery system according to the patient’s symptoms.
- Use 16-hour rather than 24-hour patches.
- Start using NRT as early in pregnancy as possible.
- Monitor cotinine levels as recommended in the 2000 guidelines.

- Assess the woman’s comfort with NRT and her preferred method of administration.
- Report experience of NRT use and side effects to a national registry.
- Use bupropion only in clinical trials.
- Clinicians also may choose to discuss the use of medicinal nicotine by household members as a strategy to reduce or eliminate SHS exposure of pregnant women.

Arrange. In addition to current recommendations, it may be helpful to begin relapse-prevention counseling focused on the benefits of quitting for the woman and on the reduction or elimination of infant exposure to SHS toward the end of pregnancy, rather than waiting until the pregnancy is ended (Mullen, 2004). At the postpartum visit, current smoking status should be assessed and continued abstinence congratulated and reinforced. If the postpartum patient has resumed smoking, pharmacotherapy should be considered as appropriate.

Recommended treatment for parents who smoke

Pediatric providers should screen all parents for tobacco use and exposure to SHS using the question in Figure 3. Parents identified as smokers should be

- Advised to quit and given information about the benefits of quitting for themselves and their children.
- Advised to consult their primary care clinician about obtaining help, including pharmacotherapy, if they are willing to try to quit.
- Provided with information about NRT for smokers who are breast feeding and are unwilling to try to quit but want to minimize exposure of their infants and other household members (Dempsey & Benowitz, 2001).

Recommended treatment for parents whose infants and children are exposed to SHS

Parents and caregivers of children exposed to SHS, whether from their own or someone else’s smoking, smoking should be

- Advised of the harms associated with SHS exposure and the benefits of eliminating or minimizing this exposure.
- Assisted in problem solving about ways to deal with others smoking around infants and children.
- Provided with information on the health impacts of SHS exposure, on possible cessation services available to smokers to prompt quitting, or on the use of medicinal nicotine among household members.
Recommendations for increasing compliance with best-practice guidelines

To reach the goal of identifying and treating all pregnant and parenting smokers, office systems must be modified to support this change in provision of care. At this point, changing organizational and clinician behavior remains more of an art than a science, but we recommend that clinicians

- Seek continuing education on counseling techniques for smoking cessation
- Work with staff to modify office systems to incorporate documentation of tobacco use for all patients
- Support provision and documentation of the 5 A’s for patients who smoke
- Incorporate monitoring of the provision of 5 A’s into a quality-control program and provide feedback
- Become aware of local and national resources to help them help their patients who smoke

Conclusion

For women who are light to moderate smokers, the treatment recommended in 2000 is still the best choice for clinicians. The 5 A’s approach offers an efficacious and safe counseling approach that improves quit rates by 30%–70%. This approach can be improved by considering new findings to inform the use of pharmacotherapies for women who are heavy smokers and by including ways to assess and treat exposure to SHS by pregnant women.

Clinicians offering care to postpartum women and parents should assess smoking status and SHS exposure at each visit. For parents willing to quit, including women who are breast feeding, cessation strategies (including the use of pharmacotherapies) outlined in the 2000 guideline should be used to help them quit. Clinicians should offer (a) education about the benefits to infants and other household members of reducing this exposure and (b) advice to eliminate or minimize this exposure.

To further enhance this treatment approach, additional research is recommended on (a) ways to improve accurate disclosure of smoking status, (b) maintenance of cessation during pregnancy and postpartum, (c) safety and efficacy of pharmacotherapies to aid cessation, (d) use of biomarker feedback or incentives as motivators to quit, (e) partner involvement, and (f) interventions to eliminate or reduce SHS exposure of pregnant women, infants, and children.

To improve compliance with best-practice guidelines, research should include (a) evaluations of the effectiveness of different strategies to provide counseling training to clinicians and to assist practices in making office systems changes, (b) assessment of the impact of financial incentives on clinician and practice provision of the 5 A’s, and (c) identification of methods to support institutionalization of clinician and practice provision of best practice.

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References

- Cnattingius, S. (2004). The epidemiology of smoking during preg-
nancy: Smoking prevalence, maternal characteristics, and preg-
nancy outcomes. Nicotine & Tobacco Use, 6(Suppl 2), S125-S140.
Randomized controlled trial using social support and financial incentives for high risk pregnant smokers: Significant other supporter (SOS) program. Tobacco Control, 9(Suppl. 3), III67–III69.


