


## Guideline Summary NGC-10808

### Guideline Title

**Behavioral and pharmacotherapy interventions for tobacco smoking cessation in adults, including pregnant women: U.S. Preventive Services Task Force recommendation statement.**

### Bibliographic Source(s)

U.S. Preventive Services Task Force. Behavioral and pharmacotherapy interventions for tobacco smoking cessation in adults, including pregnant women: U.S. Preventive Services Task Force Recommendation Statement. *Ann Intern Med.* 2015 Oct 20;163(8):622-34. [47 references] [PubMed](#) 

### Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: 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]

This guideline meets NGC's 2013 (revised) inclusion criteria.

## Scope

### Disease/Condition(s)

- Tobacco dependence
- Tobacco-related diseases

### Guideline Category

Counseling  
Prevention  
Screening  
Treatment

### Clinical Specialty

Family Practice  
Internal Medicine  
Obstetrics and Gynecology  
Preventive Medicine

### Intended Users

Advanced Practice Nurses  
Health Care Providers  
Nurses  
Physician Assistants  
Physicians  
Public Health Departments

### Guideline Objective(s)

To summarize the U.S. Preventive Services Task Force (USPSTF) recommendations on smoking cessation that are relevant to primary care (behavioral interventions, pharmacotherapy, and complementary or alternative therapy) in adults, including pregnant women

**Note:** Although the USPSTF acknowledges that tobacco may be used in other forms and that other substances aside from tobacco may be smoked, they are not the focus of this recommendation.

### Target Population

Adults aged 18 years or older, including pregnant women

**Note:** The U.S. Preventive Services Task Force (USPSTF) previously issued a separate recommendation statement on primary care interventions for tobacco use in children and adolescents.

### Interventions and Practices Considered

1. Asking all adult patients, including pregnant women, about tobacco use
2. Advising patients to stop using tobacco
3. Provision of behavioral interventions and pharmacotherapy (as indicated)
4. Electronic nicotine delivery systems (ENDS) (insufficient evidence to recommend)

## Major Outcomes Considered

- **Key Question 1:** Do tobacco cessation interventions improve mortality, morbidity, and other health outcomes in current adult tobacco users, including pregnant women and individuals with mental health conditions?
- **Key Question 2:** Do tobacco cessation interventions achieve tobacco abstinence in current adult tobacco users, including pregnant women and individuals with mental health conditions?
- **Key Question 3:** What adverse events are associated with tobacco cessation interventions?

## Methodology

### Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

### Description of Methods Used to Collect/Select the Evidence

**Note from the National Guideline Clearinghouse (NGC):** A systematic evidence review and full report were prepared by the Kaiser Permanente Research Affiliates Evidence-based Practice Center (EPC) for the U.S. Preventive Services Task Force (USPSTF) (see the "Availability of Companion Documents" field).

#### Data Sources and Searches

The investigators searched the following databases for relevant reviews from January 2009 to 1 August 2014: PubMed, PsycINFO, Cochrane Database of Systematic Reviews, Health Technology Assessment (HTA) database, and Database of Abstracts of Reviews of Effects of the Centre for Reviews and Dissemination. They also searched the following organizational Web sites: the Agency for Healthcare Research and Quality (AHRQ), the British Medical Journal Clinical Evidence (through 7 August 2013), the Canadian Agency for Drugs and Technologies in Health, Guide to Community Preventive Services, the Institute of Medicine, the National Institute for Health and Care Excellence (NICE), the National Health Service (NHS) Health Technology Assessment Programme, and the Surgeon General. The investigators supplemented their searches with suggestions from experts. They searched PubMed for primary evidence related to electronic nicotine delivery system (ENDS) through 1 March 2015 and for pharmacotherapy interventions among pregnant women through 15 August 2014 (the full report outlines the search strategies for these two searches).

#### Study Selection

Two investigators independently reviewed all identified abstracts and dually reviewed full-text articles against prespecified eligibility criteria. They resolved disagreements through discussion. The investigators included systematic reviews—with or without meta-analysis—that examined the effectiveness of interventions for tobacco cessation for adults, including pregnant women, and were linked to primary care or took place in a general adult population. They excluded nonsystematic meta-analyses and narrative reviews. They also excluded reviews that focused on reduction of tobacco harms, interventions for relapse prevention, or cessation medications that were not approved by the U.S. Food and Drug Administration (FDA) as first-line medications for cessation (such as nortriptyline). The investigators included only the most recent version of updated reviews. They outlined separate selection criteria when considering primary evidence related to ENDS and pharmacotherapy among pregnant women, as described in the full report.

See Appendix B Table 1 in the full report for the inclusion and exclusion criteria

#### Results

The investigators reviewed 638 abstracts and 114 full-text reviews for possible inclusion (see Appendix Figure 2 in the systematic review). They identified 54 systematic reviews that met the eligibility criteria, and 22 of these served as the basis for the primary findings (see Table 1 in the systematic review). In general, results across all included reviews were consistent within each population and intervention grouping. The results are organized by outcomes and subcategories by population and interventions. Eleven of the 54 included reviews synthesized evidence on interventions among specific subpopulations of adults (such as persons with depression and young adults) that are not included here but appear in detail in the full report.

#### Behavioral Interventions Among Adults

Eleven reviews served as primary reviews examining the effects of behavioral interventions for smoking cessation among the general adult population (see Table 1 in the systematic review).

### Number of Source Documents

The investigators identified 54 systematic reviews that met the eligibility criteria, and 22 of these served as the basis for the primary findings.

- Systematic reviews included for adults: 42\*: primary reviews: 18
- Systematic reviews included for pregnant women: 8\*: primary reviews: 2
- Systematic reviews included for mental health: 4\*: primary reviews: 2

\*Reviews can be counted in multiple intervention areas.

See the flow diagram (Appendix Figure 2) in the systematic review (see the "Availability of Companion Documents" field) for a summary of evidence search and selection.

### Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

### Rating Scheme for the Strength of the Evidence

The reviewers applied the typical U.S. Preventive Services Task Force (USPSTF) quality scores (i.e., good-quality, fair-quality, or poor-quality) for both reviews and primary evidence. See the "Description of the Methods Used to Analyze the Evidence" field for further information.

### Methods Used to Analyze the Evidence

Meta-Analysis

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

### Description of the Methods Used to Analyze the Evidence

**Note from the National Guideline Clearinghouse (NGC):** A systematic evidence review and full report were prepared by the Kaiser Permanente Research Affiliates Evidence-based Practice Center (EPC) for the U.S. Preventive Services Task Force (USPSTF) (see the "Availability of Companion Documents" field).

#### Data Extraction and Quality Assessment

At least 2 independent reviewers rated the quality of all included systematic reviews using a slightly modified version of the Assessment of Multiple Systematic Reviews tool (see the full report for modifications and methods for determining the overall quality rating of individual reviews). They excluded all poor quality studies. One reviewer completed primary data abstraction, and a secondary reviewer checked all data for accuracy and completeness.

#### Data Synthesis and Analysis

When the reviewers found several fair- and good-quality reviews that met the inclusion criteria in a given population and intervention subgroup, they applied criteria (see Appendix Table 1 in the systematic review) to identify one or more reviews that represented the most current and applicable evidence to serve as the basis for the main findings (called "primary reviews"). They reviewed the remaining reviews for complementary or discordant findings. When the reviewers encountered discordant bodies of evidence, they sought explanations for these differences by examining the eligibility criteria and included studies within each review.

The reviewers used the pooled point estimates presented in the included reviews when appropriate. They did not reanalyze any of the individual study evidence. They evaluated the appropriateness of meta-analytic procedures and used their technical judgment to interpret pooled analyses accounting for limitations or concerns around heterogeneity, statistical approaches, and other factors.

## Methods Used to Formulate the Recommendations

Balance Sheets

Expert Consensus

## Description of Methods Used to Formulate the Recommendations

The U.S. Preventive Services Task Force (USPSTF) systematically reviews the evidence concerning both the benefits and harms of widespread implementation of a preventive service. It then assesses the certainty of the evidence and the magnitude of the benefits and harms. On the basis of this assessment, the USPSTF assigns a letter grade to each preventive service signifying its recommendation about provision of the service (see Table below). An important, but often challenging, step is determining the balance between benefits and harms to estimate "net benefit" (that is, benefits minus harms).

**Table 1. U.S. Preventive Services Task Force Recommendation Grid\***

Certainty of Net Benefit	Magnitude of Net Benefit			
	Substantial	Moderate	Small	Zero/Negative
High	A	B	C	D
Moderate	B	B	C	D
Low	Insufficient			

\*A, B, C, D, and I (*Insufficient*) represent the letter grades of recommendation or statement of insufficient evidence assigned by the USPSTF after assessing certainty and magnitude of net benefit of the service (see the "Rating Scheme for the Strength of the Recommendations" field).

The overarching question that the USPSTF seeks to answer for every preventive service is whether evidence suggests that provision of the service would improve health outcomes if implemented in a general primary care population. For screening topics, this standard could be met by a large randomized, controlled trial (RCT) in a representative asymptomatic population with follow-up of all members of both the group "invited for screening" and the group "not invited for screening."

Direct RCT evidence about screening is often unavailable, so the USPSTF considers indirect evidence. To guide its selection of indirect evidence, the Task Force constructs a "chain of evidence" within an analytic framework. For each key question, the body of pertinent literature is critically appraised, focusing on the following 6 questions:

1. Do the studies have the appropriate research design to answer the key question(s)?
2. To what extent are the existing studies of high quality? (i.e., what is the internal validity?)
3. To what extent are the results of the studies generalizable to the general U.S. primary care population and situation? (i.e., what is the external validity?)
4. How many studies have been conducted that address the key question(s)? How large are the studies? (i.e., what is the precision of the evidence?)
5. How consistent are the results of the studies?
6. Are there additional factors that assist the USPSTF in drawing conclusions (e.g., presence or absence of dose-response effects, fit within a biologic model)?

The next step in the USPSTF process is to use the evidence from the key questions to assess whether there would be net benefit if the service were implemented. In 2001, the USPSTF published an article that documented its systematic processes of evidence evaluation and recommendation development. At that time, the USPSTF's overall assessment of evidence was described as good, fair, or poor. The USPSTF realized that this rating seemed to apply only to how well studies were conducted and did not fully capture all of the issues that go into an overall assessment of the evidence about net benefit. To avoid confusion, the USPSTF has changed its terminology. Whereas individual study quality will continue to be characterized as good, fair, or poor, the term *certainty* will now be used to describe the USPSTF's assessment of the overall body of evidence about net benefit of a preventive service and the likelihood that the assessment is correct. Certainty will be determined by considering all 6 questions listed above; the judgment about certainty will be described as high, moderate, or low.

In making its assessment of certainty about net benefit, the evaluation of the evidence from each key question plays a primary role. It is important to note that the USPSTF makes recommendations for real-world medical practice in the United States and must determine to what extent the evidence for each key question—even evidence from screening RCTs or treatment RCTs—can be applied to the general primary care population. Frequently, studies are conducted in highly selected populations under special conditions. The USPSTF must consider differences between the general primary care population and the populations studied in RCTs and make judgments about the likelihood of observing the same effect in actual practice.

It is also important to note that one of the key questions in the analytic framework refers to the potential harms of the preventive service. The USPSTF considers the evidence about the benefits and harms of preventive services separately and equally. Data about harms are often obtained from observational studies because harms observed in RCTs may not be representative of those found in usual practice and because some harms are not completely measured and reported in RCTs.

Putting the body of evidence for all key questions together as a chain, the USPSTF assesses the certainty of net benefit of a preventive service by asking the 6 major questions listed above. The USPSTF would rate a body of convincing evidence about the benefits of a service that, for example, derives from several RCTs of screening in which the estimate of benefits can be generalized to the general primary care population as "high" certainty (see the "Rating Scheme for the Strength of Recommendations" field). The USPSTF would rate a body of evidence that was not clearly applicable to general practice or has other defects in quality, research design, or consistency of studies as "moderate" certainty. Certainty is "low" when, for example, there are gaps in the evidence linking parts of the analytic framework, when evidence to determine the harms of treatment is unavailable, or when evidence about the benefits of treatment is insufficient. Table 4 in the methodology document listed below (see the "Availability of Companion Documents" field) summarizes the current terminology used by the USPSTF to describe the critical assessment of evidence at all 3 levels: individual studies, key questions, and overall certainty of net benefit of the preventive service.

Sawaya GF, Guirguis-Blake J, LeFevre M, Harris R, Petitti D; U.S. Preventive Services Task Force. Update on the methods of the U.S. Preventive Services Task Force: estimating certainty and magnitude of net benefit. *Ann Intern Med.* 2007;147:871-875.[5 references].

## I Statements

For I statements, the USPSTF has a plan to commission its Evidence-based Practice Centers (EPCs) to collect information in 4 domains pertinent to clinical decisions about prevention and to report this information routinely. This plan is described in the paper: Petitti DB et al. Update on the methods of the U.S. Preventive Services Task Force: insufficient evidence. *Ann Intern Med.* 2009;150:199-205. [www.annals.org](http://www.annals.org).

The first domain is potential preventable burden of suffering from the condition. When evidence is insufficient, provision of an intervention designed to prevent a serious condition (such as dementia) might be viewed more favorably than provision of a service designed to prevent a condition that does not cause as much suffering (such as rash). The USPSTF recognized that "burden of suffering" is subjective and involves judgment. In clinical settings, it should be informed by patient values and concerns.

The second domain is potential harm of the intervention. When evidence is insufficient, an intervention with a large potential for harm (such as major surgery) might be viewed less favorably than an intervention with a small potential for harm (such as advice to watch less television). The USPSTF again acknowledges the subjective nature and the difficulty of assessing potential harms: for example, how bad is a "mild" stroke?

The third domain is cost—not just monetary cost, but opportunity cost, in particular the amount of time a provider spends to provide the service, the amount of time the patient spends to partake of it, and the benefits that might derive from alternative uses of the time or money for patients, clinicians, or systems. Consideration of clinician time is

especially important for preventive services with only insufficient evidence because providing them could "crowd out" provision of preventive services with proven value, services for conditions that require immediate action, or services more desired by the patient. For example, a decision to routinely inspect the skin could take up the time available to discuss smoking cessation, or to address an acute problem or a minor injury that the patient considers important.

The fourth domain is current practice. This domain was chosen because it is important to clinicians for at least 2 reasons. Clinicians justifiably fear that not doing something that is done on a widespread basis in the community may lead to litigation. More important, addressing patient expectations is a crucial part of the clinician–patient relationship in terms of building trust and developing a collaborative therapeutic relationship. The consequences of not providing a service that is neither widely available nor widely used are less serious than not providing a service accepted by the medical profession and thus expected by patients. Furthermore, ingrained care practices are difficult to change, and efforts should preferentially be directed to changing those practices for which the evidence to support change is compelling.

Although the reviewers did not explicitly recognize it when these domains were chosen, the domains all involve consideration of the potential consequences—for patients, clinicians, and systems—of providing or not providing a service. Others writing about medical decision making in the face of uncertainty have suggested that the consequences of action or inaction should play a prominent role in decisions.

### Rating Scheme for the Strength of the Recommendations

#### What the U.S. Preventive Services Task Force (USPSTF) Grades Mean and Suggestions for Practice

Grade	Grade Definitions	Suggestions for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer/provide this service.
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer/provide this service.
C	The USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small.	Offer/provide this service for selected patients depending on individual circumstances.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I Statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality or conflicting, and the balance of benefits and harms cannot be determined.	Read the "Clinical Considerations" section of USPSTF Recommendation Statement (see the "Major Recommendations" field). If offered, patients should understand the uncertainty about the balance of benefits and harms.

#### USPSTF Levels of Certainty Regarding Net Benefit

**Definition:** The USPSTF defines certainty as "likelihood that the USPSTF assessment of the net benefit of a preventive service is correct." The net benefit is defined as benefit minus harm of the preventive service as implemented in a general, primary care population. The USPSTF assigns a certainty level based on the nature of the overall evidence available to assess the net benefit of a preventive service.

Level of Certainty	Description
High	The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.
Moderate	The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by factors such as: <ul style="list-style-type: none"> <li>The number, size, or quality of individual studies</li> <li>Inconsistency of findings across individual studies</li> <li>Limited generalizability of findings to routine primary care practice</li> <li>Lack of coherence in the chain of evidence</li> </ul> As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.
Low	The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of: <ul style="list-style-type: none"> <li>The limited number or size of studies</li> <li>Important flaws in study design or methods</li> <li>Inconsistency of findings across individual studies</li> <li>Gaps in the chain of evidence</li> <li>Findings not generalizable to routine primary care practice</li> <li>A lack of information on important health outcomes</li> </ul> More information may allow an estimation of effects on health outcomes.

### Cost Analysis

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

### Method of Guideline Validation

Comparison with Guidelines from Other Groups

External Peer Review

Internal Peer Review

### Description of Method of Guideline Validation

#### Peer Review

Before the U.S. Preventive Services Task Force (USPSTF) makes its final determinations about recommendations on a given preventive service, the Evidence-based Practice Center (EPC) and the Agency for Healthcare Research and Quality (AHRQ) send a draft evidence review to 4 to 6 external experts and to Federal agencies and professional and disease-based health organizations with interests in the topic. The experts are asked to examine the review critically for accuracy and completeness and to respond to a series of specific questions about the document. The draft evidence review is also posted on the USPSTF Web site for public comment. After assembling these external review comments

and documenting the proposed response to key comments, the topic team presents this information to the USPSTF in memo form. In this way, the USPSTF can consider these external comments before it votes on its recommendations about the service. Draft recommendation statements are then circulated for comment among reviewers representing professional societies, voluntary organizations, and Federal agencies, as well as posted on the USPSTF Web site for public comment. These comments are discussed before the final recommendations are confirmed.

### **Response to Public Comment**

A draft version of this recommendation statement was posted for public comment on the USPSTF Web site from 5 May to 1 June 2015. Several comments requested clarification about which types of interventions are being recommended—pharmacotherapy, behavioral interventions, or combinations of both. Several comments also expressed concern that the draft language for the recommendation may cause clinicians to offer only 1 type of intervention. The USPSTF clarified that both intervention types (pharmacotherapy and behavioral interventions) are effective and recommended; combinations of interventions are most effective, and all should be offered. The best and most effective combinations are those that are acceptable to and feasible for an individual patient. Clinicians should consider the patient's specific medical history and preferences and offer and provide the combination that works best for that patient. Comments also sought clarification about which populations are included in the I statement for electronic nicotine delivery system (ENDS); the USPSTF clarified that the I statement for ENDS includes pregnant women. A few comments requested additional implementation resources. The USPSTF revised the recommendation to include a table that highlights effective components of behavioral interventions and provided links to additional resources on pharmacotherapy options and resources for pregnant women. The USPSTF revised its language on ENDS to reflect current terminology.

### **Recommendation of Others**

Recommendations for counseling to prevent tobacco use from the following groups were considered: the American College of Physicians, American College of Preventive Medicine, American Heart Association, American Congress of Obstetricians and Gynecologists, and American Academy of Family Physicians.

## Recommendations

### **Major Recommendations**

The U.S. Preventive Services Task Force (USPSTF) grades its recommendations (**A**, **B**, **C**, **D**, or **I**) and identifies the Levels of Certainty regarding Net Benefit (**High**, **Moderate**, and **Low**). The definitions of these grades can be found at the end of the "Major Recommendations" field.

#### **Summary of Recommendations and Evidence**

The USPSTF recommends that clinicians ask all adults about tobacco use, advise them to stop using tobacco, and provide behavioral interventions and U.S. Food and Drug Administration (FDA)-approved pharmacotherapy for cessation to adults who use tobacco. (**A recommendation**)

The USPSTF recommends that clinicians ask all pregnant women about tobacco use, advise them to stop using tobacco, and provide behavioral interventions for cessation to pregnant women who use tobacco. (**A recommendation**)

The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of pharmacotherapy interventions for tobacco cessation in pregnant women. (**I statement**)

The USPSTF concludes that the current evidence is insufficient to recommend electronic nicotine delivery systems (ENDS) for tobacco cessation in adults, including pregnant women. The USPSTF recommends that clinicians direct patients who smoke tobacco to other cessation interventions with established effectiveness and safety (previously stated). (**I statement**)

#### **Clinical Consideration**

##### **Patient Population Under Consideration**

This recommendation applies to adults aged 18 years or older, including pregnant women. The USPSTF previously issued a separate recommendation statement on primary care interventions for tobacco use in children and adolescents (see the National Guideline Clearinghouse [NGC] summary of the USPSTF guideline [Primary care interventions to prevent tobacco use in children and adolescents: U.S. Preventive Services Task Force recommendation statement](#)). Although the USPSTF acknowledges that tobacco may be used in other forms and that other substances aside from tobacco may be smoked, they are not the focus of this recommendation.

##### **Assessment of Risk**

According to the 2012–2013 National Adult Tobacco Survey, smoking prevalence is higher in the following groups: men; adults aged 25 to 44 years; persons with a race or ethnicity category of "other, non-Hispanic"; persons with a general educational development (GED) (vs. graduate-level education); persons with an annual household income of less than \$20,000; and persons who are lesbian, gay, bisexual, or transgender. Higher rates of smoking have been found in persons with mental health conditions.

##### **Implementation Considerations of Behavioral and Pharmacotherapy Interventions**

The information on the implementation of interventions for smoking cessation draws from the USPSTF systematic evidence review and the 2008 Public Health Service guidelines. Refer to the original guideline document for information on the assessment of smoking status, considerations for nonpregnant adults and pregnant women, components of effective behavioral interventions for tobacco cessation and other interventions.

##### **Useful Resources**

Primary care clinicians may find the following resources useful in talking with adults and pregnant women about smoking cessation: Centers for Disease Control and Prevention fact sheets on quitting smoking ([www.cdc.gov/tobacco/data\\_statistics/fact\\_sheets/cessation/quitting/index.htm](http://www.cdc.gov/tobacco/data_statistics/fact_sheets/cessation/quitting/index.htm)), the U.S. Department of Health and Human Services' BeTobaccoFree (<http://betobaccofree.hhs.gov/quitnow/index.html#professionals>), the U.S. Department of Health and Human Services' SmokeFreeWomen (<http://women.smokefree.gov/pregnancy-motherhood.aspx>), and the Public Health Service's 2008 clinical practice guidelines.

In addition, the following resources may be useful to primary care clinicians and practices trying to implement interventions for smoking cessation:

- Substance Abuse and Mental Health Services Administration-Health Resources and Services Administration Center for Integrated Health Solutions' resources for smoking cessation ([www.integration.samhsa.gov/health-wellness/wellness-strategies/tobacco-cessation-2](http://www.integration.samhsa.gov/health-wellness/wellness-strategies/tobacco-cessation-2))
- Centers for Disease Control and Prevention state and community resources for tobacco-control programs ([www.cdc.gov/tobacco/stateandcommunity/index.htm](http://www.cdc.gov/tobacco/stateandcommunity/index.htm))
- World Health Organization's toolkit for delivering brief smoking interventions in primary care ([www.who.int/tobacco/publications/smoking\\_cessation/9789241506953/en](http://www.who.int/tobacco/publications/smoking_cessation/9789241506953/en))

##### **Suggestions for Practice Regarding the I Statements**

###### *Pharmacotherapy for Pregnant Women*

Although smoking prevalence is lower in pregnant women than nonpregnant women of the same age, approximately 1 in 6 pregnant women aged 15 to 44 years smoke. Smoking during pregnancy slows fetal growth, doubles the risk for delivering a baby with low birthweight, and increases the risk for fetal death by 25% to 50%. For women in whom behavioral counseling does not work, other options to promote smoking cessation may be beneficial.

A few studies have evaluated the benefit of nicotine replacement therapy (NRT) on perinatal and child health outcomes. Although results generally suggest a potential benefit, the overall evidence is too limited to draw clear conclusions. NRT is a pregnancy category D medication, which means that there is positive evidence of fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans. However, it has been suggested that NRT may be safer than smoking during pregnancy. Potential adverse events reported include increased rates of cesarean delivery, slightly increased diastolic blood pressure, and skin reactions to the patch. Potential adverse events reported in nonpregnant adults include higher rates of low-risk cardiovascular events, such as tachycardia. There is no evidence of perinatal harms from NRT, although few trials reported consistently on these adverse events.

The USPSTF identified no studies on bupropion SR or varenicline pharmacotherapy during pregnancy. These drugs are both pregnancy category C, which means that animal reproduction studies have shown an adverse effect on the fetus but there are no adequate well-controlled studies in humans.

In the absence of clear evidence on the balance of benefits and harms of pharmacotherapy in pregnant women, clinicians are encouraged to consider the severity of smoking behavior in each patient and engage in shared decision making to determine the best individual treatment course.

#### ENDS

Approximately 69% of adults who smoke daily report interest in quitting, and roughly 43% attempted to quit in the previous year. To date, no ENDS manufacturer has applied for or received FDA approval to market its product for smoking cessation purposes. According to a small 2013 study, approximately two thirds of physicians reported that they believed that electronic cigarettes (e-cigarettes) were a helpful aid for smoking cessation, and 35% recommended them to patients. A recent small survey of e-cigarette users found that 56% reported using them to quit or reduce cigarette use, and 26% reported using them to smoke in places where conventional cigarettes were banned. Because of the perception by the public and clinicians that ENDS may be used for quitting conventional smoking, the USPSTF reviewed the evidence in this area. No studies evaluated the use of ENDS for smoking cessation in pregnant women or adolescents. The USPSTF identified only 2 randomized controlled trial (RCTs) that evaluated the effect of e-cigarettes on smoking abstinence in adults and found mixed results. Neither study reported any serious adverse events related to ENDS use; however, potential concerns raised in other literature include the unknown safety and toxicity of their components and aerosols, and poisoning in children who mishandle nicotine cartridges. How the ingredients in ENDS may affect a fetus is also unknown. Overall, the USPSTF found the evidence on the use of ENDS as a smoking cessation tool in adults, including pregnant women, and adolescents to be insufficient.

#### Additional Approaches to Prevention

Given the public health significance of the consequences of tobacco use, numerous public health interventions aim to prevent tobacco use and promote smoking cessation. The Community Preventive Services Task Force offers several recommendations on interventions that can be used in community settings (available at [www.thecommunityguide.org/tobacco/index.html](http://www.thecommunityguide.org/tobacco/index.html)). The Surgeon General's report, "The Health Consequences of Smoking—50 Years of Progress," discusses initiatives to end the tobacco use epidemic in the United States. In addition, the USPSTF recommends that primary care clinicians provide interventions, including education or brief counseling, to prevent the initiation of tobacco use among schoolaged children and adolescents (see the NGC summary of the USPSTF guideline [Primary care interventions to prevent tobacco use in children and adolescents: U.S. Preventive Services Task Force recommendation statement](#)).

#### Definitions

##### What the U.S. Preventive Services Task Force (USPSTF) Grades Mean and Suggestions for Practice

Grade	Grade Definitions	Suggestions for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer/provide this service.
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer/provide this service.
C	The USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small.	Offer/provide this service for selected patients depending on individual circumstances.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I Statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality or conflicting, and the balance of benefits and harms cannot be determined.	Read the "Clinical Considerations" section of USPSTF Recommendation Statement (see the "Major Recommendations" field). If offered, patients should understand the uncertainty about the balance of benefits and harms.

#### USPSTF Levels of Certainty Regarding Net Benefit

**Definition:** The USPSTF defines certainty as "likelihood that the USPSTF assessment of the net benefit of a preventive service is correct." The net benefit is defined as benefit minus harm of the preventive service as implemented in a general, primary care population. The USPSTF assigns a certainty level based on the nature of the overall evidence available to assess the net benefit of a preventive service.

Level of Certainty	Description
High	The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.
Moderate	The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by factors such as: <ul style="list-style-type: none"> <li>The number, size, or quality of individual studies</li> <li>Inconsistency of findings across individual studies</li> <li>Limited generalizability of findings to routine primary care practice</li> <li>Lack of coherence in the chain of evidence</li> </ul> As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.
Low	The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of: <ul style="list-style-type: none"> <li>The limited number or size of studies</li> <li>Important flaws in study design or methods</li> <li>Inconsistency of findings across individual studies</li> <li>Gaps in the chain of evidence</li> <li>Findings not generalizable to routine primary care practice</li> <li>A lack of information on important health outcomes</li> </ul> More information may allow an estimation of effects on health outcomes.

#### Clinical Algorithm(s)

None provided

## Evidence Supporting the Recommendations

#### Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

## Benefits/Harms of Implementing the Guideline Recommendations

### Potential Benefits

#### Benefits of Interventions

##### Nonpregnant Adults

The U.S. Preventive Services Task Force (USPSTF) found convincing evidence that behavioral interventions (including in-person behavioral support and counseling, telephone counseling, and self-help materials) alone or combined with pharmacotherapy substantially improve achievement of tobacco cessation in nonpregnant adults who smoke. The USPSTF found convincing evidence that pharmacotherapy interventions, including nicotine replacement therapy (NRT), bupropion hydrochloride sustained-release (bupropion SR), and varenicline—with or without behavioral counseling interventions—substantially improve achievement of tobacco cessation in nonpregnant adults who smoke. The USPSTF also found convincing evidence that using 2 types of NRT moderately improves achievement of tobacco smoking cessation over using 1 type and that addition of NRT to treatment with bupropion SR provides additional benefit over use of bupropion SR alone. The USPSTF found inadequate evidence to determine the effect of electronic nicotine delivery system (ENDS) on achievement of tobacco smoking cessation.

##### Pregnant Women

The USPSTF found convincing evidence that behavioral interventions substantially improve achievement of tobacco smoking abstinence in pregnant women, increase infant birthweight, and reduce risk for preterm birth. The USPSTF found inadequate evidence on the benefits of NRT and no evidence on the benefits of bupropion SR, varenicline, or ENDS to achieve tobacco cessation in pregnant women who smoke or to improve perinatal outcomes in infants.

### Potential Harms

#### Harms of Interventions

##### Nonpregnant Adults

The U.S. Preventive Services Task Force (USPSTF) determined that there is adequate evidence to bound the magnitude of harms of behavioral interventions for tobacco cessation in nonpregnant adults who smoke as small to none. The USPSTF found adequate evidence that the harms of nicotine replacement therapy (NRT), bupropion sustained release (bupropion SR), or varenicline for tobacco cessation in adults who smoke are small. The USPSTF found inadequate evidence to determine the harms of electronic nicotine delivery system (ENDS).

##### Pregnant Women

The USPSTF determined that there is adequate evidence to bound the magnitude of harms of behavioral interventions for tobacco cessation in pregnant women who smoke as small to none. The USPSTF found inadequate evidence on the harms of NRT and no evidence on the harms of bupropion SR, varenicline, or ENDS for tobacco cessation in pregnant women who smoke.

## Qualifying Statements

### Qualifying Statements

- The U.S. Preventive Services Task Force (USPSTF) makes recommendations about the effectiveness of specific preventive care services for patients without related signs or symptoms.
- It bases its recommendations on the evidence of both the benefits and harms of the service and an assessment of the balance. The USPSTF does not consider the costs of providing a service in this assessment.
- The USPSTF recognizes that clinical decisions involve more considerations than evidence alone. Clinicians should understand the evidence but individualize decision making to the specific patient or situation. Similarly, the USPSTF notes that policy and coverage decisions involve considerations in addition to the evidence of clinical benefits and harms.
- Recommendations made by the USPSTF are independent of the U.S. government. They should not be construed as an official position of the Agency for Healthcare Research and Quality (AHRQ) or the U.S. Department of Health and Human Services.

## Implementation of the Guideline

### Description of Implementation Strategy

The experiences of the first and second U.S. Preventive Services Task Force (USPSTF), as well as that of other evidence-based guideline efforts, have highlighted the importance of identifying effective ways to implement clinical recommendations. Practice guidelines are relatively weak tools for changing clinical practice when used in isolation. To effect change, guidelines must be coupled with strategies to improve their acceptance and feasibility. Such strategies include enlisting the support of local opinion leaders, using reminder systems for clinicians and patients, adopting standing orders, and audit and feedback of information to clinicians about their compliance with recommended practice.

In the case of preventive services guidelines, implementation needs to go beyond traditional dissemination and promotion efforts to recognize the added patient and clinician barriers that affect preventive care. These include clinicians' ambivalence about whether preventive medicine is part of their job, the psychological and practical challenges that patients face in changing behaviors, lack of access to health care or of insurance coverage for preventive services for some patients, competing pressures within the context of shorter office visits, and the lack of organized systems in most practices to ensure the delivery of recommended preventive care.

Dissemination strategies have changed dramatically in this age of electronic information. While recognizing the continuing value of journals and other print formats for dissemination, the USPSTF will make all its products available through its [Web site](#). The combination of electronic access and extensive material in the public domain should make it easier for a broad audience of users to access USPSTF materials and adapt them for their local needs. Online access to USPSTF products also opens up new possibilities for the appearance of the annual, pocket-size *Guide to Clinical Preventive Services*.

To be successful, approaches for implementing prevention have to be tailored to the local level and deal with the specific barriers at a given site, typically requiring the redesign of systems of care. Such a systems approach to prevention has had notable success in established staff-model health maintenance organizations, by addressing organization of care, emphasizing a philosophy of prevention, and altering the training and incentives for clinicians. Staff-model plans also benefit from integrated information systems that can track the use of needed services and generate automatic reminders aimed at patients and clinicians, some of the most consistently successful interventions. Information systems remain a major challenge for individual clinicians' offices, however, as well as for looser affiliations of practices in network-model managed care and independent practice associations, where data on patient visits, referrals, and test results are not always centralized.

### Implementation Tools

Foreign Language Translations

Mobile Device Resources

Patient Resources

Pocket Guide/Reference Cards

## Institute of Medicine (IOM) National Healthcare Quality Report Categories

### IOM Care Need

Staying Healthy

### IOM Domain

Effectiveness

Patient-centeredness

## Identifying Information and Availability

### Bibliographic Source(s)

U.S. Preventive Services Task Force. Behavioral and pharmacotherapy interventions for tobacco smoking cessation in adults, including pregnant women: U.S. Preventive Services Task Force Recommendation Statement. *Ann Intern Med.* 2015 Oct 20;163(8):622-34. [47 references] [PubMed](#)

### Adaptation

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

### Date Released

2015 Oct 20

### Guideline Developer(s)

U.S. Preventive Services Task Force - Independent Expert Panel

### Guideline Developer Comment

The U.S. Preventive Services Task Force (USPSTF) is a federally-appointed panel of independent experts. Conclusions of USPSTF do not necessarily reflect policy of the U.S. Department of Health and Human Services (DHHS) or its agencies.

### Source(s) of Funding

The U.S. Preventive Services Task Force (USPSTF) is an independent, voluntary body. The U.S. Congress mandates that the Agency for Healthcare Research and Quality (AHRQ) support the operations of the USPSTF.

### Guideline Committee

U.S. Preventive Services Task Force (USPSTF)

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Former USPSTF member Susan Curry, PhD, also contributed to the development of this recommendation.

\*Members of the USPSTF at the time this recommendation was finalized. For a list of current Task Force members, go to <http://www.uspreventiveservicestaskforce.org/Page/Name/our-members> .

### Financial Disclosures/Conflicts of Interest

The U.S. Preventive Services Task Force (USPSTF) has an explicit policy concerning conflict of interest. All members disclose at each meeting if they have a significant financial, professional/business, or intellectual conflict for each topic being discussed. USPSTF members with conflicts may be recused from discussing or voting on recommendations about the topic in question.

#### Disclosures

Authors followed the policy regarding conflicts of interest described at [www.uspreventiveservicestaskforce.org/Page/Name/methods-and-processes](http://www.uspreventiveservicestaskforce.org/Page/Name/methods-and-processes) . Disclosures can be viewed at [www.acponline.org/authors/icmje/ConflictOfInterestForms.do?msNum=M15-2023](http://www.acponline.org/authors/icmje/ConflictOfInterestForms.do?msNum=M15-2023) .

### Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: 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]

This guideline meets NGC's 2013 (revised) inclusion criteria.

### Guideline Availability

Available from the [Annals of Internal Medicine Web site](#) .

### Availability of Companion Documents

The following are available:

Evidence Reviews:

- Patnode CP, Henderson JT, Thompson JH, Senger CA, Fortmann SP, Whitlock EP. Behavioral counseling and pharmacotherapy interventions for tobacco cessation in adults, including pregnant women: a review of reviews for the U.S. Preventive Services Task Force. Full report. Evidence Synthesis No. 134. AHRQ Publication No. 14-



05200-EF-1. Rockville (MD): Agency for Healthcare Research and Quality; 2015 Sep. 209 p.

- Patnode CP, Henderson JT, Thompson JH, Senger CA, Fortmann SP, Whitlock EP. Behavioral counseling and pharmacotherapy interventions for tobacco cessation in adults, including pregnant women: a review of reviews for the U.S. Preventive Services Task Force. *Ann Intern Med.* 2015 Oct 20;163(8):608-621.

Available from [U.S. Preventive Services Task Force \(USPSTF\) Web site](#).

Background Articles:

- Barton MB et al. How to read the new recommendation statement: methods update from the U.S. Preventive Services Task Force. *Ann Intern Med* 2007;147:123-127.
- Guirguis-Blake J et al. Current processes of the U.S. Preventive Services Task Force: refining evidence-based recommendation development. *Ann Intern Med* 2007;147:117-122.
- Sawaya GF et al. Update on the methods of the U.S. Preventive Services Task Force: estimating certainty and magnitude of net benefit. *Ann Intern Med* 2007;147:871-875.
- Petitti DB et al. Update on the methods of the U.S. Preventive Services Task Force: insufficient evidence. *Ann Intern Med.* 2009;150:199-205.

Available from the [USPSTF Web site](#).

The following are also available:

- Behavioral and pharmacotherapy interventions for tobacco smoking cessation in adults, including pregnant women: clinical summary. Rockville (MD): U.S. Preventive Services Task Force. 2015 Sep. Available from the [USPSTF Web site](#).
- A continuing medical education (CME) activity is available from the [Annals of Internal Medicine Web site](#).
- The guide to clinical preventive services, 2014. Recommendations of the U.S. Preventive Services Task Force. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2014. 144 p. Available from the [AHRQ Web site](#).

The [Electronic Preventive Services Selector \(ePSS\)](#) is an application designed to provide primary care clinicians and health care teams timely decision support regarding appropriate screening, counseling, and preventive services for their patients. It is based on the current, evidence-based recommendations of the USPSTF and can be searched by specific patient characteristics, such as age, sex, and selected behavioral risk factors.

### Patient Resources

The following are available:

- Behavioral and pharmacologic treatments to help adults quit smoking: U.S. Preventive Services Task Force recommendation statement. Summaries for patients. *Ann Intern Med.* 2015;163(8):I-40. Available from the [Annals of Internal Medicine Web site](#).
- Behavioral and pharmacotherapy interventions for tobacco smoking cessation in adults, including pregnant women. Understanding task force recommendations. Rockville (MD): U.S. Preventive Services Task Force; 2015 Sep. 4 p. Available from the [U.S. Preventive Services Task Force \(USPSTF\) Web site](#).
- Women: stay healthy at any age. 2014 update. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ). AHRQ Pub. No. 14-IP007-A. 2014 Mar. 5 p. Available in [English](#) and [Spanish](#) from the AHRQ Web site.
- Men: stay healthy at any age. 2014 update. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ). AHRQ Pub. No. 14-IP006-A. 2014 Mar. 5 p. Available in [English](#) and [Spanish](#) from the AHRQ Web site.
- Women: stay healthy at 50+. 2014 update. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ). AHRQ Pub. No. 14-IP002-A. 2014 Mar. 5 p. Available in [English](#) and [Spanish](#) from the AHRQ Web site.
- Men: stay healthy at 50+. 2014 update. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ). AHRQ Pub. No. 14-IP009-A. 2014 Mar. 5 p. Available in [English](#) and [Spanish](#) from the AHRQ Web site.

Myhealthfinder is a tool that provides personalized recommendations for clinical preventive services specific to the user's age, gender, and pregnancy status. It features evidence-based recommendations from the USPSTF and is available at [www.healthfinder.gov](http://www.healthfinder.gov).

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

### NGC Status

This NGC summary was completed by ECRI on June 30, 1998. The information was verified by the guideline developer on December 1, 1998. This summary was updated by ECRI on November 12, 2003. The information was verified by the guideline developer on November 13, 2003. This summary was updated by ECRI Institute on November 6, 2007, following the U.S. Food and Drug Administration advisory on Antidepressant drugs. This summary was updated by ECRI Institute on April 23, 2009. The updated information was verified by the guideline developer on June 16, 2009. This summary was updated by ECRI Institute on July 20, 2009 following the U.S. Food and Drug Administration advisory on Varenicline and Bupropion. This summary was updated by ECRI Institute on July 15, 2011 following the U.S. Food and Drug Administration advisory on Chantix (varenicline). This summary was updated by ECRI Institute on January 14, 2013 following the revised U.S. Food and Drug Administration advisory on Chantix (varenicline). This summary was updated again by ECRI Institute on December 16, 2015. The updated information was not verified by the guideline developer.

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