



Complete Summary

GUIDELINE TITLE

Tobacco use prevention and cessation for adults and mature adolescents.

BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Tobacco use prevention and cessation for adults and mature adolescents. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2004 Jun. 42 p. [46 references]

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

- Passive tobacco exposure
- Tobacco use and addiction

GUIDELINE CATEGORY

Counseling
Prevention
Treatment

CLINICAL SPECIALTY

Cardiology
Family Practice
Internal Medicine
Obstetrics and Gynecology
Pediatrics

Preventive Medicine
Psychology

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Health Plans
Hospitals
Nurses
Physician Assistants
Physicians
Psychologists/Non-physician Behavioral Health Clinicians

GUIDELINE OBJECTIVE(S)

- To define the appropriate interventions in the clinic setting for identification of tobacco-use status in adults and mature adolescents, and provision of counseling and assistance in tobacco-use cessation
- To improve the proportion of patients whose current use of tobacco or exposure to tobacco smoke is obvious in the chart at any primary care clinic encounter
- To improve the proportion of tobacco-users whose interest in quitting is assessed or who receive cessation advice at any clinic encounter
- To increase the number of tobacco-using patients who quit
- To improve the proportion of clinic-visiting tobacco users setting a quit date who received self-help materials along with telephone help-line information

TARGET POPULATION

Adults and mature adolescents

INTERVENTIONS AND PRACTICES CONSIDERED

1. Community intervention, including the establishment of smoke-free public spaces, limiting youth access to tobacco, restrictions on advertising, counter-advertising, and increasing economic disincentives to tobacco use
2. Tobacco use identification and cessation clinic program, including frequent assessment to establish tobacco use, counseling, encouragement, self-help material, nonconfrontational motivational material, advice on smoking cessation, tobacco cessation consultants and classes, social support for cessation, phone line support for smoking cessation counseling, skills training/problem-solving, and follow-up after quit date
3. Pharmacotherapy, including Zyban (bupropion) and nicotine replacement therapy (nicotine gum, nicotine transdermal patches, nicotine lozenges, nicotine inhalers, and nicotine nasal spray)

MAJOR OUTCOMES CONSIDERED

- Success rates of smoking cessation interventions (pharmacotherapy, education, counseling) on smoking cessation
- Safety and adverse effects of pharmacotherapy
- Recidivism rate for tobacco users who quit

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

No additional description of literature search strategies is available.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Key conclusions (as determined by the work group) are supported by a conclusion grading worksheet that summarizes the important studies pertaining to the conclusion. Individual studies are classed according to the system presented below, and are designated as positive, negative, or neutral to reflect the study quality.

Conclusion Grades:

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of any significant doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design for answering the question addressed, but there is some uncertainty attached to the conclusion because of inconsistencies among the results from the studies or because of minor doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusion because of inconsistencies among the results from different studies or because of serious doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from a limited number of studies of weak design for answering the question addressed.

Grade Not Assignable: There is no evidence available that directly supports or refutes the conclusion.

Study Quality Designations:

The quality of the primary research reports and systematic reviews are designated in the following ways on the conclusion grading worksheets:

Positive: indicates that the report or review has clearly addressed issues of inclusion/exclusion, bias, generalizability, and data collection and analysis.

Negative: indicates that these issues (inclusion/exclusion, bias, generalizability, and data collection and analysis) have not been adequately addressed.

Neutral: indicates that the report or review is neither exceptionally strong nor exceptionally weak.

Not Applicable: indicates that the report is not a primary reference or a systematic review and therefore the quality has not been assessed.

Classes of Research Reports:

A. Primary Reports of New Data Collection:

Class A:

- Randomized, controlled trial

Class B:

- Cohort study

Class C:

- Nonrandomized trial with concurrent or historical controls
- Case-control study
- Study of sensitivity and specificity of a diagnostic test
- Population-based descriptive study

Class D:

- Cross-sectional study

- Case series
- Case report

B. Reports that Synthesize or Reflect upon Collections of Primary Reports:

Class M:

- Meta-analysis
- Systematic review
- Decision analysis
- Cost-effectiveness analysis

Class R:

- Consensus statement
- Consensus report
- Narrative review

Class X:

- Medical opinion

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

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

METHOD OF GUIDELINE VALIDATION

Clinical Validation-Pilot Testing
Comparison with Guidelines from Other Groups
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Institute Partners: System-Wide Review

The guideline draft, discussion, and measurement specification documents undergo thorough review. Written comments are solicited from clinical, measurement, and management experts from within the member medical groups during an eight-week period of "Critical Review."

Each of the Institute's participating medical groups determines its own process for distributing the guideline and obtaining feedback. Clinicians are asked to suggest modifications based on their understanding of the clinical literature coupled with their clinical expertise. Representatives from all departments involved in implementation and measurement review the guideline to determine its operational impact. Measurement specifications for selected measures are developed by the Institute for Clinical Systems Improvement (ICSI) in collaboration with participating medical groups following general implementation of the guideline. The specifications suggest approaches to operationalizing the measure.

Guideline Work Group: Second Draft

Following the completion of the "Critical Review" period, the guideline work group meets 1 to 2 times to review the input received. The original guideline is revised as necessary, and a written response is prepared to address each of the suggestions received from medical groups. Two members of the Preventive Services Steering Committee carefully review the Critical Review input, the work group responses, and the revised draft of the guideline. They report to the entire committee their assessment of two questions: (1) Have the concerns of the medical groups been adequately addressed? (2) Are the medical groups willing and able to implement the guideline? The committee then either approves the guideline for pilot testing as submitted or negotiates changes with the work group representative present at the meeting.

Pilot Test

Medical groups introduce the guideline at pilot sites, providing training to the clinical staff and incorporating it into the organization's scheduling, computer, and other practice systems. Evaluation and assessment occur throughout the pilot test phase, which usually lasts for three months. Comments and suggestions are solicited in the same manner as used during the "Critical Review" phase.

The guideline work group meets to review the pilot sites' experiences and makes the necessary revisions to the guideline, and the Preventive Services Steering Committee reviews the revised guideline and approves it for implementation.

Comparison with Guidelines from Other Groups

Consideration was given to guidelines on smoking cessation from the following groups: U.S. Preventive Services Task Force, the Agency for Healthcare Research and Quality (formerly the Agency for Health Care Policy and Research), the United States Department of Health and Human Services, Public Health Service, and the National Cancer Institute.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The recommendations for tobacco use prevention and cessation for adults and mature adolescents are presented in the form of an algorithm [Tobacco Use Prevention and Cessation for Adults and Mature Adolescents](#), with 16 components, accompanied by detailed annotations. Clinical highlights and selected annotations (numbered to correspond with the algorithm) follow.

Class of evidence (A-D, M, R, X) and conclusion grade (I-III, Not Assignable) definitions are provided at the end of the "Major Recommendations" field

Clinical Highlights

1. Ask about tobacco use and secondhand smoke exposure at every opportunity. (Annotations #2 and 2a)
2. Advise all tobacco users to stop. (Annotations #13 and 15)
3. Assess tobacco user's willingness to make a quit attempt. (Annotations #12 and 14)
4. Assist tobacco user's efforts to quit. (Annotations #8 and 9)
5. Arrange for follow-up. (Annotations #9 and 16)

[Tobacco Use Prevention and Cessation for Adults and Mature Adolescents Algorithm Annotations](#)

1. Community Intervention

Key Points:

- Tobacco use is the single most preventable cause of disease and death in our society.
- The guideline developers urge Institute for Clinical Systems Improvement (ICSI) participating medical groups, clinicians, insurance plans and employers to actively intervene within their community to reduce tobacco use.

Tobacco use is the single most preventable cause of disease and death in our society. The Centers for Disease Control recommend that tobacco control programs be established that are comprehensive, sustainable, and accountable. The goal of a comprehensive tobacco control program is to reduce disease, disability, and death related to tobacco use by:

- preventing the initiation of tobacco use among young people
- promoting cessation among young people and adults
- eliminating nonsmokers exposure to secondhand smoke
- identifying and eliminating the disparities related to tobacco use and its effects among different population groups.

The components of a comprehensive tobacco control program include:

- community programs to reduce tobacco use
- chronic disease programs to reduce the burden of tobacco-related diseases
- school programs
- enforcement
- statewide programs
- counter-marketing
- cessation programs
- surveillance and evaluation
- administration and management

The guideline developers urge ICSI participating medical groups, clinicians, insurance plans and employers to actively intervene within their community to reduce tobacco use. The establishment of smoke-free public spaces, limiting youth access to tobacco, restrictions on advertising, counter-advertising, and increasing economic disincentives to tobacco use are among the most effective community actions to be supported.

Evidence supporting this recommendation is of classes: M, R

2. Establish Tobacco Use for All Patients and Reassess Users at Every Clinic Visit

Key Points:

- Adults who have not used tobacco for at least 12 months and who have an easily visible mark on their chart to that effect should be asked about their tobacco use status yearly until abstinent for 5 years.
- Everyone without a tobacco use mark on the chart or those with a mark indicating use within the past 6 months should be asked at nearly every visit.
- Adolescents should have usage reassessed at nearly every visit, regardless of whether there is a chart notation of nonuse.

Everyone without a tobacco use mark on the chart or those with a mark indicating use within the past 6 months should be asked at nearly every visit about current use and the answer documented for the provider. This frequency of use assessment should be established as a clinic policy and should be done by a staff person, preferably the one who rooms the patient.

The two most common ways to indicate tobacco use status are with an appropriate label on the chart or with a vital sign in the progress notes.

Adolescents should have usage reassessed at nearly every visit, regardless of whether there is a chart notation of non-use, due to the risk of beginning tobacco use at any time.

Tobacco cessation is particularly important during pregnancy. For more information, see the related National Guideline Clearinghouse (NGC) summaries of the Institute for Clinical Systems Improvement's (ICSI's)

guidelines: [Preterm Birth Prevention](#) and [Routine Prenatal Care](#). The guideline developers recommend that clinics have a particularly consistent identification and cessation program for pregnant women and preconception visits.

Tobacco cessation is also very important in those individuals with heart disease or other risk factors for heart disease. (See the related NGC summaries of the ICSI guidelines: [Stable Coronary Artery Disease](#), [Lipid Management in Adults](#), and [Hypertension Diagnosis and Treatment](#)).

Evidence supporting this recommendation is of classes: A, C, D, M, R

2a. Establish Secondhand Smoke Exposure for All Patients and Encourage a Smoke-Free Environment

Key Points:

- Inform patients of their increased risk of disease due to second-hand smoke exposure. Encourage a smoke-free living and working environment.

Inform patients of their increased risk of disease due to second-hand smoke exposure. Encourage a smoke-free living and working environment for patients, and assist the exposed patient to communicate with other household members about decreasing smoking in the house. Encourage the patient to support smoking cessation efforts among other household members who use tobacco.

Evidence supporting this recommendation is of classes: M, R

3. Document the Tobacco Use Discussion

Key Point:

- All discussions with tobacco users should be documented.

All discussions with tobacco-users should be documented, either in the progress note or on a special card or flow sheet if a clinic uses that approach. This documentation should include the user's attitude toward treatment and any quitting plans agreed upon. The documentation can be very brief. Documentation is necessary to facilitate coordination between various providers and support staff, to permit follow-up and referral arrangements, and to allow subsequent visits to build on discussions started earlier.

5. Reinforce Nonuse

Key Point:

- Compliment and reinforce nonuse in former tobacco users.

If time permits, it is helpful to compliment former tobacco-users. These former users are considered to be in the Maintenance stage once they have quit for at least 12 months. Although a former user can return to tobacco use

after years of abstinence, the recidivism rate reaches a low level by 12 months. The guideline developers suggest monitoring the patient for 12 months.

Evidence supporting this recommendation is of class: R

6. When Did the Patient Last Use Tobacco?

Although the usual definition of a user is one who uses tobacco daily, it would be ideal to classify any individual using tobacco with any frequency as a user.

7. 0 – 12 Months Ago

Those who have quit using tobacco within the last month (particularly within the past week) are at a very high risk for resuming usage. Reinforcement and follow-up can be crucial for these individuals.

Evidence supporting this recommendation is of class: M

8. Wants Extra Help in Remaining Tobacco-Free?

A former user who is having some trouble remaining tobacco-free may want or need more help than the provider can supply in the 2 to 3 minutes available to discuss this topic. Common difficulties include weight gain, stress, withdrawal symptoms, or social/habit/psychological needs.

9. Congratulate on Quitting/Encourage In-Office or Referral Counseling

Key Points:

- The first 12 months after quitting (especially the first 2 weeks) is when one is at the highest risk for relapse.
- Follow-up options include a face-to-face, telephoned or mailed (postal or electronic) expression of support and willingness to help.

Those who have quit using tobacco within the last month (particularly within the past week) are at a very high risk for resuming use. Reinforcement and follow-up can be crucial during this period.

The first 12 months after quitting are the transition between the Action and Maintenance stages. These months (especially the first 2 weeks), when one is at the highest risk for relapse, are the most challenging. Encourage the patient to avoid temptations to use tobacco again. Smoking cessation often takes 3 to 4 attempts before long-term success is achieved.

Counseling can be done by the provider or, preferably, by other staff, and should be designed to help patients problem-solve any of the difficulties referred to in Annotation #8.

Counseling can also be achieved by referring a user to groups, a non-office counselor, or an external tobacco cessation specialist. It should be recognized, though, that most patients are unwilling to attend such groups, especially if they are separate from the clinic. However, any such referrals should not replace clinician advice and assistance.

If a practice does not have a way for providers to easily and efficiently refer to staff or others when a complex quitting problem is brought up, it becomes impossible for the provider to complete the tobacco discussion within 1 to 3 minutes. The result will be that providers will be understandably reluctant to bring up the topic with every user as is needed for success.

Follow-up options include a face-to-face, telephoned, or mailed (postal or electronic) expression of support and willingness to help. The timing of follow-ups should be discussed with the patient; generally, the follow-up should come at the time when it will be most needed or wanted. Follow-ups can be expertly performed by office staff.

Regardless of the desirability of return visits, the guideline developers believe that there is neither time nor likelihood of return visits happening very frequently, so other arrangements should be made.

12. Intending to Quit in Next 6 Months?

Key Points:

- The goal should be to discuss tobacco cessation at nearly every visit.
- Progress from one stage of readiness to quit to the next is valuable.

Assessment of interest in quitting and timing of that interest should be done after the main reasons for the visit have been addressed, and should precede any advice about quitting. This allows a 1 to 3 minute tobacco discussion accommodating both the user's needs and the provider's time limits.

It is recognized that this discussion may not be possible or appropriate at each visit. The goal should be to discuss tobacco cessation at nearly every visit.

Remember that progress from one stage of readiness to quit to the next is valuable.

The guideline developers have incorporated the exciting and scientifically-based concept of readiness stages for behavior change developed by Prochaska and DiClemente, which have been particularly tested in tobacco cessation, into this guideline. The guideline developers believe that these stages (see Annotations #9-12) can focus the physician message and make it more effective and feasible. However, it is necessary for the provider to first assess readiness to quit by asking if a user would consider quitting and then

asking when (> 6, 1-6, or 0-1 months). The strategy taken should then be tailored to the individual user's readiness stage.

Evidence supporting this recommendation is of classes: C, R

13. Patients Not Intending to Quit in Next 6 Months

Key Point:

- A "precontemplator" benefits from nonconfrontational messages about importance of quitting and the awareness that provider help is available when ready.

A user not ready to consider quitting within the next 6 months is called a precontemplator and is helped most when a provider avoids confrontation while conveying both the message that quitting is important and the desire to be helpful when the user is ready to consider quitting. A simple informational pamphlet about the problems attending tobacco use and an expression of the provider's desire to be helpful are far more productive than an attempt to scare or argue unwilling users into quitting.

14. Intending to Quit in Next Month?

See Annotation #12, "Intending to Quit in Next 6 Months?"

15. Patient Not Intending to Quit in Next Month

Key Points:

- A "contemplator" is accepting of supportive urging to quit and encouragement of a plan.
- Ask a tobacco user who is ready to quit to set his/her own date.

The contemplator is considering quitting within the next 1 to 6 months. Contemplators are accepting of supportive and respectful urging to quit and encouragement to start thinking about a serious plan for doing so. Persuasive written, audio, or video information about the pros and cons of quitting may be appropriate for contemplators.

Virtually every tobacco-cessation expert and program, including the National Cancer Institute program, recommends asking a tobacco user who is ready to quit to set his/her own quit date. They also recommend some type of follow-up, often a return visit. Because users are unlikely to keep the appointment, alternatives such as phone calls are usually substituted.

Evidence supporting this recommendation is of classes: C, R

16. Assist the Patient to Quit

Key Points:

- Ask a tobacco user who is ready to quit to set his/her own quit date.
- Three treatment elements are effective for smoking cessation intervention: pharmacotherapy, social support for cessation, and skills training/problem-solving.
- On average, nicotine replacement therapy (NRT) and Zyban (bupropion SR) double the probability of success.
- Combining nicotine patches with other self-administered forms of NRT (gum, spray) is more effective than a single form of NRT.
- Minnesotans have high-quality free telephone line counseling for smoking cessation.
- Other resources include local tobacco cessation classes, community support systems, and self-help brochures and materials from drug companies.

Negotiate the Quit Date

The National Cancer Institute program recommends asking a tobacco-user who is ready to quit to set his/her own quit date.

Counsel to Support Cessation and Build Abstinence Skills

The Agency for Health Care Policy and Research Smoking Cessation Clinical Practice Guideline emphasizes that three treatment elements in particular are effective for smoking cessation intervention: pharmacotherapy, social support for cessation, and skills training/problem-solving. The guideline emphasizes the dose-response relationship between the intensity and duration of treatment and its effectiveness. In general, the more intense the treatment, the more effective it is in producing long-term abstinence from tobacco. These principles should be kept in mind when counseling and assisting the patient to stop using tobacco.

Evidence supporting this recommendation is of classes: A, C, M, R

Discuss Pharmacotherapy

On average, nicotine replacement therapy (NRT) and Zyban (bupropion SR) double the probability of success. It is most effective if the patient agrees to completely stop tobacco use with the start of NRT or 1 week after starting Zyban (bupropion), and the patient agrees to participate in a follow-up program of some type. NRT includes nicotine gum, nicotine lozenges, nicotine transdermal patches, nicotine inhalers, and nicotine nasal spray.

The nicotine lozenge has proven to be effective in helping patients quit smoking. [Conclusion Grade I: See Conclusion Grading Worksheet – Appendix A – Annotation #16 (Nicotine Lozenge) in the original guideline document].

Nicotine nasal spray has been shown to be effective. It is, however, the most addictive of the products and is probably best reserved for patients who have

failed other forms of NRT, who still desire to use a product to become completely tobacco-free.

Bupropion (Zyban) has been found to be efficacious in smoking cessation and can be offered to patients who have no history of seizures, no history of eating disorders, or who are not taking any other form of bupropion (i.e., Wellbutrin) or monoamine oxidase (MAO) inhibitors.

Suggestions on the clinical use of nicotine patches can be found in the Annotation Appendix A of the original guideline document; nicotine gum in Annotation Appendix B; nicotine lozenges in Annotation Appendix C; bupropion SR in Annotation Appendix D; nicotine inhalers in Annotation Appendix E; and nicotine nasal spray in Annotation Appendix F.

Evidence supporting this recommendation is of classes: A, R

Combination Therapy

Combining nicotine patches with other self-administered forms of NRT (gum, lozenge or spray) may be more effective than a single form of NRT. [Conclusion Grade I: See Conclusion Grading Worksheet – Appendix B – Annotation #16 (Combination Therapy) in the original guideline document]

If patients use NRT or Zyban, it is important for them to become completely tobacco-free. Ongoing use of tobacco predicts failure long-term. One strategy is to encourage patients to make their tobacco-free program more intense with each use of tobacco after their quit date. They can add an exercise program, call a help line, ask for a friend's help, read a pamphlet, etc.

Although both pregnancy and cardiovascular disease are described as contraindications for the use of NRT, there is evidence of safety in these conditions, and NRT is more safe than smoking.

Clinicians should encourage their patients to check with their insurance plans, as coverage is sometimes available for NRT.

Evidence supporting this recommendation is of classes: A, C, D, M

Offer Phone Line

Minnesotans have high quality free telephone line counseling for smoking cessation. Clinicians are advised to refer patients to their respective health plan quitlines. If a patient does not belong to one of the health plans listed in the original guideline document, s/he should refer to the QUITPLAN Helpline: 1-888-354-PLAN. They are also planning to offer face-to-face counseling soon. It is helpful to provide a handout with tobacco quitline numbers when referring to a quitline. These handouts are available from Blue Cross Blue Shield of Minnesota.

An important message to convey to smokers is that quitline counselors provide expert advice in a friendly and supportive manner.

- Smokers can consult quitlines for assistance about any issue related to tobacco cessation.
- Quitline counselors can answer brief questions or provide counseling, depending on the needs of the smoker.
- Quitlines can help smokers who are not quite ready to quit as well as those who have set a quit date.
- Smokers who are not quite ready to quit can receive assistance in figuring out the next steps.
- Quitlines can also help smokers who have quit but are having difficulty maintaining cessation.
- Quitlines can send written self-help materials and may provide free NRT.
- The quitlines also can help those who want to know how to support someone who is trying to quit.

Evidence supporting this recommendation is of class: A

Other Resources

Consideration may also be given to making a referral to a tobacco cessation consultant or a center with programs in tobacco cessation. Other resources include local tobacco cessation classes, community support systems, and self help brochures and materials from drug companies.

Evidence supporting this recommendation is of class: A

Encourage Follow-up

Encourage the patient to arrange for a follow-up soon after the quit date.

Evidence supporting this recommendation is of class: R

Definitions:

Classes of Research Reports:

A. Primary Reports of New Data Collection:

Class A:

- Randomized, controlled trial

Class B:

- Cohort study

Class C:

- Nonrandomized trial with concurrent or historical controls
- Case-control study

- Study of sensitivity and specificity of a diagnostic test
- Population-based descriptive study

Class D:

- Cross-sectional study
- Case series
- Case report

B. Reports that Synthesize or Reflect upon Collections of Primary Reports:

Class M:

- Meta-analysis
- Systematic review
- Decision analysis
- Cost-effectiveness analysis

Class R:

- Consensus statement
- Consensus report
- Narrative review

Class X:

- Medical opinion

Conclusion Grades:

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of any significant doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design for answering the question addressed, but there is some uncertainty attached to the conclusion because of inconsistencies among the results from the studies or because of minor doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusion because of inconsistencies among the results from different studies or because of serious doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from a limited number of studies of weak design for answering the question addressed.

Grade Not Assignable: There is no evidence available that directly supports or refutes the conclusion.

CLINICAL ALGORITHM(S)

A detailed and annotated clinical algorithm is provided for [Tobacco Use Prevention and Cessation for Adults and Mature Adolescents](#).

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The guideline contains an annotated bibliography and discussion of the evidence supporting each recommendation. The type of supporting evidence is classified for selected recommendations (see "Major Recommendations").

In addition, key conclusions contained in the Work Group's algorithm are supported by a grading worksheet that summarizes the important studies pertaining to the conclusion. The type and quality of the evidence supporting these key recommendations (i.e., choice among alternative therapeutic approaches) is graded for each study.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Overall Benefits

A comprehensive tobacco control program may reduce disease, disability and death related to tobacco use.

Specific Benefits

Use of appropriate interventions in the clinic setting for identification of tobacco-use status in adults and mature adolescents, and provision of counseling and assistance in tobacco-use cessation

Subgroups Most Likely to Benefit

- Tobacco cessation is particularly important for pregnant individuals and in those individuals with heart disease or other risk factors for heart disease.
- Nicotine replacement therapy (NRT) and Zyban (bupropion) are most effective in patients who agree to completely stop tobacco use with the start of nicotine replacement therapy or 1 week after starting Zyban, and who agree to participate in a follow-up program of some type.

POTENTIAL HARMS

Adverse Effects of Medication

Nicotine

- Patch. Up to 50% of patients using the nicotine patch will have a local skin reaction. Skin reactions are usually mild and self-limiting, but may worsen over the course of therapy. Local treatment with hydrocortisone cream (1%) or triamcinolone cream (0.1%) and rotating patch sites may ameliorate such local reactions. In less than 5% of patients, such reactions require the discontinuation of nicotine patch treatment. Another side effect of the nicotine patch is insomnia.
- Gum. Common side effects of nicotine chewing gum include mouth soreness, hiccups, dyspepsia, and jaw ache. These effects are generally mild and transient, and often can be alleviated by correcting the patient's chewing technique.
- Lozenge. Common side effects include mouth or throat irritation, headaches, nausea, hiccups, upset stomach, or dizziness.
- Inhaler. Local irritation in the mouth and throat was observed in 40% of patients using the nicotine inhaler. Coughing (32%) and rhinitis (23%) also were common. Severity was generally rated as mild, and the frequency of such symptoms declined with continued use.
- Nasal spray. Some 94% of users report moderate to severe nasal irritation in the first 2 days of use; 81% still reported nasal irritation after 3 weeks, although rated severity was mild to moderate. Nasal congestion and transient changes in sense of smell and taste also were reported. Nicotine nasal spray has a dependence potential intermediate between other nicotine-based therapies and cigarettes. About 15 to 20% of patients report using the active spray for longer periods than recommended (6 to 12 months), and 5% used the spray at a higher dose than recommended.

Bupropion SR

The most common side effects reported by bupropion SR users were insomnia (35 to 40%) and dry mouth (10%).

Subgroups Most Likely to be Harmed

Precautions

Nicotine Patch, Gum, Lozenge, Inhaler, and Nasal Spray

- Pregnancy. Pregnant smokers should be encouraged to quit first without pharmacologic treatment. The nicotine patch, gum, lozenge, inhaler or nasal spray should be used during pregnancy only if the increased likelihood of smoking abstinence, with its potential benefits, outweighs the risk of nicotine replacement and potential concomitant smoking. Similar factors should be considered in lactating women.
- Cardiovascular diseases. Nicotine replacement therapy (NRT) should be used with caution among particular cardiovascular patient groups: those in the immediate (within 2 weeks) post myocardial infarction period, those with serious arrhythmias, and those with serious or worsening angina pectoris.

Bupropion SR

- Pregnancy. Bupropion SR should be used during pregnancy only if the increased likelihood of smoking abstinence, with its potential benefits, outweighs the risk of bupropion SR treatment and potential concomitant smoking. Similar factors should be considered in lactating women.
- Cardiovascular diseases. Generally well tolerated; infrequent reports of hypertension.

CONTRAINDICATIONS

CONTRAINDICATIONS

- Although both pregnancy and cardiovascular disease are described as contraindications for the use of nicotine replacement therapy (NRT), there is evidence of safety in these conditions, and NRT is more safe than smoking.
- Nicotine nasal spray should not be used in persons with severe reactive airway disease.
- Bupropion SR is contraindicated in individuals with a history of seizure disorder, a history of an eating disorder, who are using another form of bupropion (Wellbutrin or Wellbutrin SR), or who are using or have used a monoamine oxidase (MAO) inhibitor in the past 14 days.

QUALIFYING STATEMENTS

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- These clinical guidelines are designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and are not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition. A guideline will rarely establish the only approach to a problem.
- This clinical guideline should not be construed as medical advice or medical opinion related to any specific facts or circumstances. Patients are urged to consult a health care professional regarding their own situation and any specific medical questions they may have.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Once a guideline is approved for general implementation, a medical group can choose to concentrate on the implementation of that guideline. When four or more groups choose the same guideline to implement and they wish to collaborate with others, they may form an action group.

In the action group, each medical group sets specific goals they plan to achieve in improving patient care based on the particular guideline(s). Each medical group shares its experiences and supporting measurement results within the action group. This sharing facilitates a collaborative learning environment. Action group learnings are also documented and shared with interested medical groups within the collaborative.

Currently, action groups may focus on one guideline or a set of guidelines such as hypertension, lipid treatment, and tobacco cessation.

Detailed measurement strategies are presented in the original guideline document to help close the gap between clinical practice and the guideline recommendations. Summaries of the measures are provided in the National Quality Measures Clearinghouse (NQMC).

Key Implementation Recommendations

1. Establish a system whereby the tobacco use of each patient is identified.
2. Establish a system to remind providers to assess attitudes of each tobacco user toward quitting and to provide cessation advice.
3. Establish a system to make it easy for a provider to give a tobacco user self-help quit books, to arrange for quit counseling and to arrange for follow-up after the planned quit date.
4. Establish a system to collect data at least every three months on the success of these interventions and to provide the data to providers and clinic staff to assess implementation success.

RELATED NQMC MEASURES

- [Tobacco use prevention and cessation for adults and mature adolescents: percentage of patients' charts that either show that there is no tobacco use/exposure or \(if a user\) that the current use was documented at the most recent clinician visit.](#)
- [Tobacco use prevention and cessation for adults and mature adolescents: percentage of patients with documented tobacco use or exposure at the latest visit who also have documentation that their cessation interest was assessed or that they received advice to quit.](#)

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)

Institute for Clinical Systems Improvement (ICSI). Tobacco use prevention and cessation for adults and mature adolescents. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2004 Jun. 42 p. [46 references]

ADAPTATION

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

DATE RELEASED

1994 May (revised 2004 Jun)

GUIDELINE DEVELOPER(S)

Institute for Clinical Systems Improvement - Private Nonprofit Organization

GUIDELINE DEVELOPER COMMENT

Organizations participating in the Institute for Clinical Systems Improvement (ICSI): Affiliated Community Medical Centers, Allina Medical Clinic, Altru Health System, Aspen Medical Group, Avera Health, CentraCare, Columbia Park Medical Group, Community-University Health Care Center, Dakota Clinic, ENT SpecialtyCare, Fairview Health Services, Family HealthServices Minnesota, Family Practice Medical Center, Gateway Family Health Clinic, Gillette Children's Specialty Healthcare, Grand Itasca Clinic and Hospital, Hamm Clinic, HealthEast Care System, HealthPartners Central Minnesota Clinics, HealthPartners Medical Group and Clinics, Hennepin Faculty Associates, Hutchinson Area Health Care, Hutchinson Medical Center, Lakeview Clinic, Mayo Clinic, Mercy Hospital and Health Care Center, MeritCare, Minnesota Gastroenterology, Montevideo Clinic, North Clinic, North Memorial Health Care, North Suburban Family Physicians, NorthPoint Health & Wellness Center, Northwest Family Physicians, Olmsted Medical Center, Park Nicollet Health Services, Quello Clinic, Ridgeview Medical Center, River Falls Medical Clinic, St. Mary's/Duluth Clinic Health System, St. Paul Heart Clinic, Sioux Valley Hospitals and Health System, Southside Community Health Services, Stillwater Medical Group, SuperiorHealth Medical Group, University of Minnesota Physicians, Winona Clinic, Winona Health

ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; e-mail: icsi.info@icsi.org; Web site: www.icsi.org.

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GUIDELINE COMMITTEE

Preventive Services Steering Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Work Group Members: David Klevan, MD (Work Group Leader) (HealthPartners Medical Group) (Internal Medicine); Thomas E. Kottke, MD (Mayo Clinic) (Cardiology); Donald A. Pine, MD (Park Nicollet Health Services) (Family Practice); Michael Schoenleber, MD (HealthPartners Medical Group) (Family Practice); David Rossmiller, MD (Family HealthServices Minnesota) (Family Practice); Renee Compo, RN, CNP (HealthPartners Medical Group) (Obstetrics/Gynecology Nurse Practitioner); Janice Taramelli (Methodist Hospital/Park Nicollet Institute) (Health Educator); Penny Carson (Institute for Clinical Systems Improvement) (Measurement/Implementation Advisor); Peter Lynch, MPH (Evidence Analyst) (Institute for Clinical Systems Improvement); Pam Pietruszewski, MA (Institute for Clinical Systems Improvement) (Facilitator)

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

In the interest of full disclosure, Institute for Clinical Systems Improvement (ICSI) has adopted the policy of revealing relationships work group members have with companies that sell products or services that are relevant to this guideline topic. The reader should not assume that these financial interests will have an adverse impact on the content of the guideline, but they are noted here to fully inform users. Readers of the guideline may assume that only work group members listed below have potential conflicts of interest to disclose.

Thomas E. Kottke, M.D. receives grant support from Merck, and is a consultant for Bayer and AstraZeneca.

No other work group members have potential conflicts of interest to disclose.

ICSI's conflict of interest policy and procedures are available for review on ICSI's website at www.icsi.org.

GUIDELINE STATUS

This is the current release of guideline.

It updates a previous version: Institute for Clinical Systems Improvement (ICSI). Tobacco use prevention and cessation for adults and mature adolescents. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2003 Jul. 36 p.

GUIDELINE AVAILABILITY

Electronic copies: Available from the [Institute for Clinical Systems Improvement \(ICSI\) Web site](http://www.icsi.org).

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: www.icsi.org; e-mail: icsi.info@icsi.org.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

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