ICSI

Institute for Clinical Systems Improvement

# Health Care Guideline

The information contained in this *ICSI Health Care Guideline* is intended primarily for health professionals and the following expert audiences:

- physicians, nurses, and other health care professional and provider organizations;
- health plans, health systems, health care organizations, hospitals and integrated health care delivery systems;
- medical specialty and professional societies;
- researchers;
- federal, state and local government health care policy makers and specialists; and
- employee benefit managers.

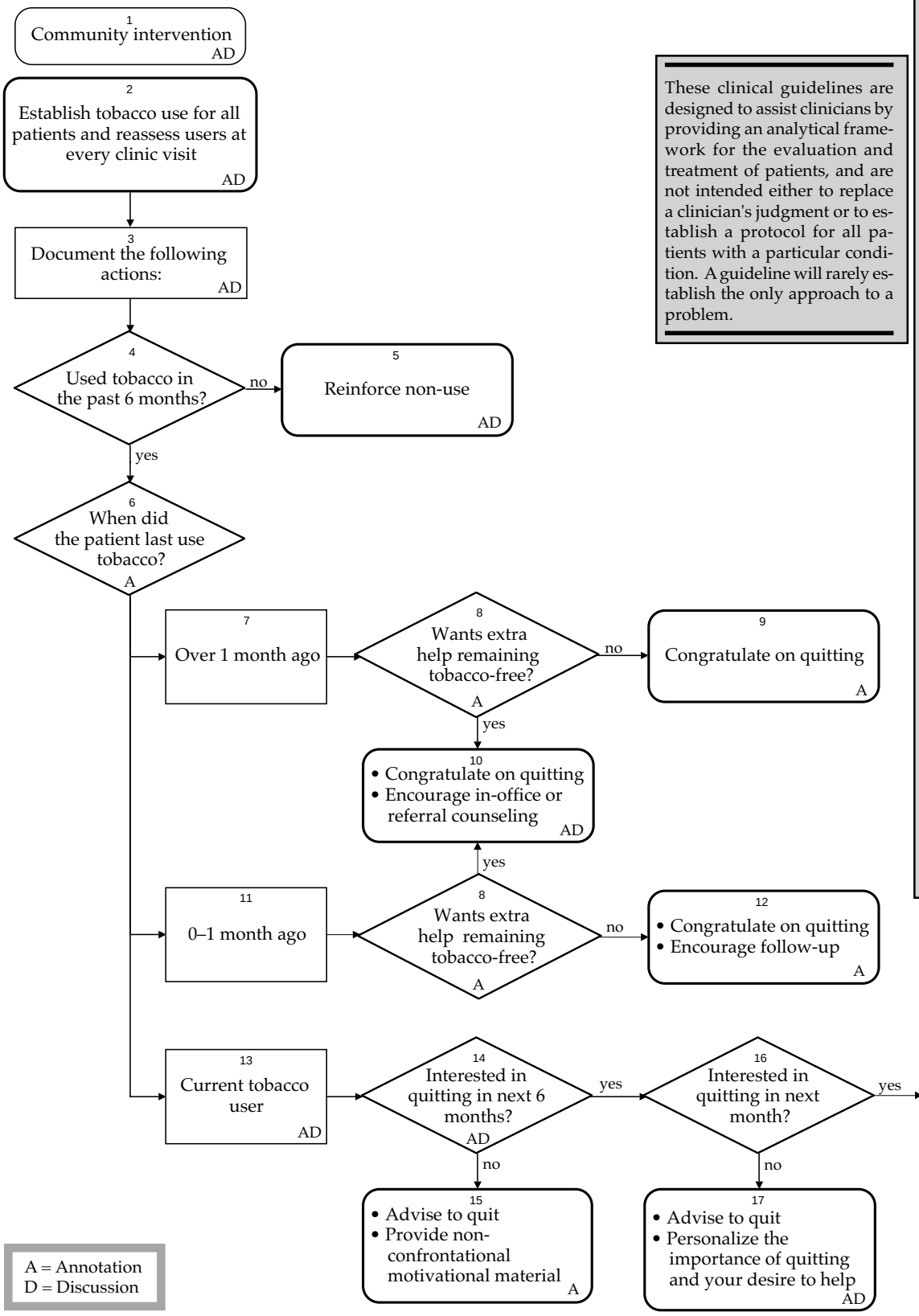
This *ICSI Health Care Guideline* should not be construed as medical advice or medical opinion related to any specific facts or circumstances. If you are not one of the expert audiences listed above you are urged to consult a health care professional regarding your own situation and any specific medical questions you may have. In addition, you should seek assistance from a health care professional in interpreting this *ICSI Health Care Guideline* and applying it in your individual case.

This *ICSI Health Care Guideline* is designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and is not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition. An *ICSI Health Care Guideline* rarely will establish the only approach to a problem.

ICSI
Institute for Clinical Systems Improvement

## Health Care Guideline:

# Tobacco Use Prevention and Cessation for Adults and Mature Adolescents




A = Annotation
D = Discussion

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.

**General Implementation January 2000**


**Work Group Members**
**Work Group Leader**
David Klevan, MD
*HealthPartners*
**Cardiology**
Thomas E. Kottke, MD
*Mayo Clinic*
**Family Practice**
Donald A. Pine, MD
*HealthSystem Minnesota*
Michael Schoenleber, MD
*HealthPartners*
David Rossmiller, MD
*FHSM-MinnesotaHealth*
**Internal Medicine**
David Klevan, MD
*HealthPartners*
**Pediatrics**
Susan Asch, MD
*Stillwater Medical Group*
**Ob/Gyn Nurse Practitioner**
Renee Compo, RN, CNP
*HealthPartners*
**Nursing**
Joanne Kellen, RN
*HealthPartners*
**Health Education**
Jane A. Norstrom
*Institute for Research & Education*
**BHCAG Representative**
Sandra Dahl
*Honeywell, Inc.*
**Measurement Advisor**
Diane Jacobsen, MPH
*ICSI*
**Facilitator**
Jenelle Meyer, RN
*ICSI*

The ICSI Tobacco Use Prevention and Cessation work group is a sub group of the ICSI Preventive Services work group.

## *Population of Interest*

Adults and mature adolescents.

## *Related Guidelines*

Other ICSI guidelines whose scope and/or recommendations are closely related to the content of the guideline are:

1. Preventive Counseling and Education
2. Lipid Treatment in Adults
3. Preventive Services for Adults
4. Stable Coronary Artery Disease

## *Priority Aims for Medical Groups When Using This Guideline*

1. 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.

   Possible measure of accomplishing this aim:

   a. The 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.

2. To improve the proportion of tobacco-users whose interest in quitting is assessed or who receive cessation advice at any clinic encounter.

   Possible measure of accomplishing this aim:

   a. The 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.

3. To increase the likelihood that tobacco-using patients who visit the clinic will quit.

   Possible measure of accomplishing this aim:

   a. Although it is difficult to measure the quit rate accurately, this rate can be approximated by the percentage of users now or in the past 6 months who have quit at the time of an office visit.

4. To improve the proportion of clinic-visiting tobacco users interested in quitting who receive self-help materials and offers of support and follow-up after a quit date.

   Possible measure of accomplishing this aim:

   a. The percentage of clinic-visiting tobacco users with documented interest in quitting at the latest visit whose charts also document that they received self-help materials and an offer of support and follow-up after a quit date.

## *EVIDENCE GRADING SYSTEM*

Individual research reports are assigned a letter indicating the class of report based on design type: A, B, C, D, M, R, X. A full explanation of these designators is found in the Discussion and References section of this guideline.

In future versions of this guideline, selected conclusions will include a statement of the grade assigned to the conclusion.

## *ALGORITHM ANNOTATIONS*

### 1. Community Intervention

The work group urges ICSI participating medical groups, clinicians, 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, counteradvertising and increasing economic disincentives to tobacco use are among the most effective community actions to be supported.

### 2. Establish Tobacco Use

Tobacco use includes all forms of tobacco - smoking cigarettes, cigars or pipes, as well as using snuff or chewing tobacco.

Adults who have not used tobacco for at least 6 months and who have an easily visible mark on their chart to that effect should have usage reassessed at nearly every visit.

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 their risk of beginning tobacco use at any time.

Tobacco cessation is particularly important during pregnancy. For more information, see the ICSI Preterm Birth Prevention and Routine Prenatal Care guidelines. We 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 also other ICSI guidelines such as the Stable Coronary Artery Disease, Treatment of Lipid Disorder in Adults, and Hypertension Diagnosis and Treatment guidelines.)

The rest of the algorithm is intended for the provider.

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

### 3. Documentation

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 (see the implementation examples distributed with the initial review copy of the guideline). This documentation should include the user's attitude toward treatment and any quitting plans agreed upon. The documentation can be very brief.

### 5. Reinforce Nonuse

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 6 months.

## 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.

## 8. Patient 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 2-3 minutes available to discuss this topic. Common difficulties include weight gain, stress, withdrawal symptoms, or social/habit/psychological needs.

## 9. Congratulate on Quitting

The first 6 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 3–4 attempts before long-term success is achieved.

## 10. Assistance in Staying Quit

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.

## 11. Patients Who Last Used Tobacco Within the Last Month

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.

## 12. Congratulate on Quitting/ Encourage a Follow-up

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, we believe that there is neither time nor likelihood of return visits happening very frequently, so other arrangements should be made.

## 14. Assessing a User's Interest in Quitting

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 1-3 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.

**Evidence supporting this conclusion is of classes: C, R**

## 15. Patients not Ready to Consider Quitting

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.

## 17. Patients Interested in Quitting in 1-6 Months

The *contemplator* is considering quitting within the next 1-6 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.

**Evidence supporting this conclusion is of classes: C, R**

## 18. Assist the Patient to Quit

Negotiate the quit date

The NCI 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 Guideline emphasizes that three treatment elements in particular are effective for smoking cessation intervention: nicotine replacement therapy, 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.

Discuss pharmacotherapy

Nicotine Replacement Therapy (NRT) and Zyban (bupropion) *can be very helpful to selected patients*. 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 patients agrees to participate in a follow-up program of some type. NRT includes nicotine gum, nicotine transdermal patches, nicotine inhalers, and nicotine nasal spray.

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 MAO inhibitors.

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.

Other resources

Offer other resources such as self-help brochures and materials from drug companies, community support systems, tobacco cessation consultants, tobacco cessation classes offered in the patient's community, etc. Consideration may be given to making a referral to a clinician interested in tobacco cessation or a center with programs in tobacco cessation.

Encourage follow-up

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

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

Discussion and References:

# Tobacco Use Prevention and Cessation for Adults and Mature Adolescents

- Document Drafted Jul – Sep 1993
- Critical Review Sep – Oct 1993
- Revision/Approval Nov – Dec 1993
- Pilot Implementation Dec 1993 – Mar 1994
- Revision/Approval Apr – May 1994
- First Cycle General Implementation May 1994 – Aug 1995
- Revision/Approval Sep – Nov 1995
- Second Cycle General Implementation Dec 1995 – Aug 1996
- Revision/Approval Sep 1996 – Jan 1997
- Third Cycle General Implementation Feb – Sep 1997
- Revision/Approval Oct 1997 – Mar 1998
- Fourth Cycle General Implementation Apr – Oct 1998
- Revision/Approval Nov 1998 – Jan 1999
- Fifth Cycle General Implementation Feb – Oct 1999
- Revision/Approval Nov 1999 – Jan 2000
- ➤ **Sixth Cycle General Implementation Begins Feb 2000**

Released in January 2000 for General Implementation.
***The next revision will occur within 18 months.***

I. CLASSES OF RESEARCH REPORTS

**A. Primary Reports of New Data Collection:**

| | |
|---|---|
| Class A: | Randomized, controlled trial |
| Class B: | Cohort study |
| Class C: | Non-randomized trial with concurrent or historical controls<br>Case-control study<br>Study of sensitivity and specificity of a diagnostic test<br>Population-based descriptive study |
| Class D: | Cross-sectional study<br>Case series<br>Case report |

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

| | |
|---|---|
| Class M: | Meta-analysis<br>Decision analysis<br>Cost-benefit analysis<br>Cost-effectiveness study |
| Class R: | Review article<br>Consensus statement<br>Consensus report |
| Class X: | Medical opinion |

## *OPPORTUNITY STATEMENT*

Former Surgeon General Koop correctly stated that tobacco use is "the chief single avoidable cause of death in our society and the most important public health issue of our time." Many studies have now confirmed that health professional advice and support are a potentially powerful influence on tobacco cessation. Professional organizations widely agree with the US Preventive Services Task Force in its recommendation that "Tobacco cessation counseling should be offered on a regular basis to all patients who smoke… (or) use smokeless tobacco."

The USPSTF recommendation was based in part on a meta-analysis of "attributes of successful smoking cessation interventions in medical practice." This analysis found that success was strongly associated with reinforcement, and that the best result was produced by "a team of physicians and non physicians using multiple intervention modalities to deliver individualized advice on multiple occasions."

U.S. Preventive Services Task Force. "Counseling to prevent tobacco use." *AFP* 39:99-105, 1989. (Class R)

Kottke TE, Battista RN, DeFriese GH, et al. "Attributes of successful smoking cessation interventions in medical practice: a meta-analysis of 39 controlled trials." *JAMA* 259:2882-89, 1988. (Class M)

Smoking Cessation Clinical Practice Guideline Panel and Staff. "The Agency for Health Care Policy and Research smoking cessation clinical practice guideline." *JAMA* 275:1270-80, 1996. (Class R)

The National Cancer Institute, which is the primary federal agency for tobacco control and which has heavily funded large studies, interventions, and physician/dentist training programs, says that the apparent keys are:

- ASK about tobacco use at every opportunity
- ADVISE all users to stop
- ASSIST users' efforts to quit
- ARRANGE follow-up

Husten CG, Manley MW. "How to help your patients stop smoking." *AFP* 42:1017-26, 1990. (Class R)

This guideline is based upon the above scientific evidence and national recommendations, as well as on growing evidence that these methods can be achieved through an organized effort by an entire clinic. Moreover, there are clinics that have demonstrated the ability to put forth such an effort. The spontaneous quit rate will vary by patient population, but the community average is probably about 3-4% per year. Studies of interested physicians without a system in place to identify users, remind physicians, and to provide assistance, support, and follow-up suggest that these physicians have quit rates equivalent to this 3-4% rate. If a system is in place, one should expect at least a 10% quit rate, and 20% is readily attainable.

Solberg LI, Maxwell PL, Kottke TE, et al. "A systematic primary care office-based smoking cessation program." *J Fam Pract* 30:647-54, 1990. (Class D)

Kottke TE, Solberg LI, Brekke ML, et al. "A controlled trial to integrate smoking cessation advice into primary care practice: doctors helping smokers, Round III." *J Fam Pract* 34:701-8, 1992. (Class C)

## 1. Community Intervention

The acceptability of tobacco use is to a great extent socially determined.

Bal DG, Lloyd JC, Manley MW. "The role of the primary care physician in tobacco use prevention and cessation." *CA Cancer J Clin* 45:369-74, 1995. (Class R)

## 2. Establish Tobacco Use

The only way to accomplish the objectives established above is to have tobacco use of all patients established in/on the chart by staff and to remind providers of this status in some way. The average age at which people start to smoke is 17.4 years and 80% of adult smokers began regular smoking by age 21, so age 15 seems a good time to start reviewing this problem at every opportunity. Although it is recognized that tobacco use may preceed the age of 15 in many cases, clinician efforts to establish usage may be compromised by the presence of parents during interview of those under this age.

Cohen SJ, Stookey GK, Katz BP, et al. "Encouraging primary care physicians to help smokers quit: a randomized, controlled trial." *Ann Intern Med* 110:648-52, 1989. (Class A)

U.S. Preventive Services Task Force. "Counseling to prevent tobacco use." *AFP* 39:99-105, 1989. (Class R)

Kottke TE, Battista RN, DeFriese GH, et al. "Attributes of successful smoking cessation interventions in medical practice: a meta-analysis of 39 controlled trials." *JAMA* 259:2882-89, 1988. (Class M)

Husten CG, Manley MW. "How to help your patients stop smoking." *AFP* 42:1017-26, 1990. (Class R)

Solberg LI, Maxwell PL, Kottke TE, et al. "A systematic primary care office-based smoking cessation program." *J Fam Pract* 30:647-54, 1990. (Class D)

Kottke TE, Solberg LI, Brekke ML, et al. "A controlled trial to integrate smoking cessation advice into primary care practice: doctors helping smokers, Round III." *J Fam Pract* 34:701-8, 1992. (Class C)

Centers for Disease Control. "Cigarette smoking among adults–United States, 1988." *JAMA* 266:3113-14, 1991. (Class R)

Pine D, Sullivan S, Sauser M, et al. "Effects of a systematic approach to tobacco cessation in a community-based practice." *Arch Fam Med* 6:363-67, 1997. (Class D)

## 3. Documentation

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 Non-Use

Although a former user can return to tobacco use after years of abstinence, the recidivism rate reaches a low level by 6 months. For this reason Prochaska and DiClemente make 6 months after the quit attempt the transitional point between their *Action* and *Maintenance* stages.

The behavior change stages of use that point for the change from the stage of *Action* to the stage of *Maintenance*.

Prochaska JO, DiClemente CC, Norcross JC. "In search of how people change: applications to addictive behaviors." *Amer Psych* 47:1102-14, 1992. (Class R)

## 10. Assistance in Staying Quit

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 1-3 minutes. The result will be that providers will be understandably reluctant to bring up the topic with every user as is needed for success.

## 11. Patients Who Last Used Tobacco 0-1 Month 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.

Kottke TE, Battista RN, DeFriese GH, et al. "Attributes of successful smoking cessation interventions in medical practice: a meta-analysis of 39 controlled trials." *JAMA* 259:2882-89, 1988. (Class M)

## 14. Assessing a User's Interest in Quitting

We 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. We 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.

Prochaska JO, DiClemente CC, Norcross JC. "In search of how people change: applications to addictive behaviors." *Amer Psych* 47:1102-14, 1992. (Class R)

Fava JL, Velicer WF, Prochaska JO. "Applying the transtheoretical model to a representative sample of smokers." *Addict Behav* 20:189-203, 1995. (Class C)

## 17. Patients Interested in Quitting in 1 Month

Virtually every tobacco-cessation expert and program including the NCI 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 like phone calls are usually substituted.

Husten CG, Manley MW. "How to help your patients stop smoking." *AFP* 42:1017-26, 1990. (Class R)

Fava JL, Velicer WF, Prochaska JO. "Applying the transtheoretical model to a representative sample of smokers." *Addict Behav* 20:189-203, 1995. (Class C)

## 18. Assist the Patient to Quit

Negotiate the quit date

Virtually every tobacco-cessation expert and program, including the NCI 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 Guideline emphasizes that three treatment elements in particular are effective for smoking cessation intervention: nicotine replacement therapy, 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.

Smoking Cessation Clinical Practice Guideline Panel and Staff. "The Agency for Health Care Policy and Research smoking cessation clinical practice guideline." *JAMA* 275:1270-80, 1996. (Class R)

Goldberg DN, Hoffman AM, Farinha MF, et al. "Physician delivery of smoking-cessation advice based on the stages-of-change model." *Am J Prev Med* 10:267-74, 1994. (Class C)

Husten CG, Manley MW. "How to help your patients stop smoking." *AFP* 42:1017-26, 1990. (Class R)

Fava JL, Velicer WF, Prochaska JO. "Applying the transtheoretical model to a representative sample of smokers." *Addict Behav* 20:189-203, 1995. (Class C)

Pine D, Sullivan S, Conn SA, et al. "Promoting tobacco cessation in primary care practice." In Primary care: clinics in office practice - tobacco use and cessation. Spangler JG, ed. Philadelphia: WB Saunders, 1999: 591-610. (Class R)

Kottke TE, Battista RN, DeFriese GH, et al. "Attributes of successful smoking cessation interventions in medical practice: a meta-analysis of 39 controlled trials." *JAMA* 259:2882-89, 1988. (Class M)

Wilson DM, Taylor DW, Gilbert JR, et al. "A randomized trial of a family physician intervention for smoking cessation." *JAMA* 260:1570-74, 1988. (Class A)

Ockene JK, Kristeller J, Goldberg R, et al. "Increasing the efficacy of physician-delivered smoking interventions: a randomized clinical trial." *J Gen Intern Med* 6:1-8, 1991. (Class A)

Cohen SJ, Stookey GK, Katz BP, et al. "Encouraging primary care physicians to help smokers quit: a randomized, controlled trial." *Ann Intern Med* 110:648-52, 1989. (Class A)

Discuss pharmacotherapy

Nicotine Replacement Therapy (NRT) and Zyban (bupropion) *can be very helpful to selected patients*. It is most effective if the patient agrees to completely stop tobacco use with the start of NRT or 1-2 weeks after starting Zyban (bupropion), **and** the patients agrees to participate in a follow-up program of some type. For the purposes of the guideline, NRT includes nicotine gum, nicotine transdermal patches, nicotine inhalers, and nicotine nasal spray.

Nicotine nasal spray had 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 MAO inhibitors.

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.


Imperial Cancer Research Fund General Practice Research Group. "Effectiveness of a nicotine patch in helping people stop smoking: results of a randomised trial in general practice." *BMJ* 306:1304-8, 1993. (Class A)

Tønnesen P, Nørregaard J, Simonsen K, et al. "A double-blind trial of a 16-hour transdermal nicotine patch in smoking cessation." *N Engl J Med* 325:311-15, 1991. (Class A)

Stapleton JA, Russell MA, Feyerabend C, et al. "Dose effects and predictors of outcome in a randomized trial of transdermal nicotine patches in general practice." *Addiction* 90:31-42, 1995. (Class A)

Hurt RD, Dale LC, Fredrickson PA, et al. "Nicotine patch therapy for smoking cessation combined with physician advice and nurse follow-up: one-year outcome and percentage of nicotine replacement." *JAMA* 271:595-600, 1994. (Class A)

Joseph AM, Norman SM, Ferry LH, et al. "The safety of transdermal nicotine as an aid to smoking cessation in patients with cardiac disease." *N Engl J Med* 335:1792-98, 1996. (Class A)

Mahmarian JJ, Moye LA, Nasser GA, et al. "Nicotine patch therapy in smoking cessation reduces the extent of exercise-induced myocardial ischemia." *J Am Coll Cardiol* 30:125-30, 1997. (Class C)

Wright LN, Thorp JM Jr, Kuller JA, et al. "Transdermal nicotine replacement in pregnancy: maternal pharmacokinetics and fetal effects." *Am J Obstet Gynecol* 176:1090-94, 1997. (Class D)

Working group for the study of transdermal nicotine in patients with coronary artery disease. "Nicotine replacement therapy for patients with coronary artery disease." *Arch Intern Med* 154:989-95, 1994. (Class A)

Hajek P, West R, Foulds J, et al. "Randomized comparative trial of nicotine polacrilex, a transdermal patch, nasal spray, and an inhaler." *Arch Intern Med* 159:2033-38, 1999. (Class A)

Hjalmarson A, Nilsson F, Sjöström L, et al. "The nicotine inhaler in smoking cessation." *Arch Intern Med* 157:1721-28, 1997. (Class A)

Hjalmarson A, Franzon M, Westin A, et al. "Effect of nicotine nasal spray on smoking cessation: a randomized, placebo-controlled, double-blind study." *Arch Intern Med* 154:2567-72, 1994. (Class A)

Hughes JR, Goldstein MG, Hurt RD, et al. "Recent advances in the pharmacotherapy of smoking." *JAMA* 281:72-76, 1999. (Class R)

Jorenby DE, Leischow SJ, Nides MA, et al. "A controlled trial of sustained-release bupropion, a nicotine patch, or both for smoking cessation." *New Engl J Med* 340:685-91, 1999. (Class A)

Other resources

Offer other resources such as self-help brochures and materials from drug companies, community support systems, tobacco cessation consultants, tobacco cessation classes offered in the patient's community, etc. Consideration may be given to making a referral to a clinician interested in tobacco cessation or a center with programs in tobacco cessation.

Prochaska JO, DiClemente CC, Velicer WF, et al. "Standardized, individualized, interactive, and personalized self-help programs for smoking cessation." *Health Psychol* 12:399-405, 1993. (Class A)

Encourage follow-up

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

U.S. Preventive Services Task Force. "Counseling to prevent tobacco use." *AFP* 39:99-105, 1989. (Class R)

# Tobacco Use Prevention and Cessation for All Ages

When measuring for improvement, it is critical that the measurements used are responsive to individual medical groups, and support medical groups' own clinical improvements. The following section of Specifications for Selected Measures is included in the guideline document to serve as an aid to the medical groups' own implementation efforts. It is likely that medical groups may need to adapt these measures to specific clinical practice or administrative systems.

## *Overview of Ideas for Measurement*

The following aims were identified by the guideline work group as key areas in which medical groups may receive benefits in implementing this guideline.

The measures associated with these aims are presented as suggested measures. Measures of aim help medical groups determine progress in achieving a particular aim. However, additional approaches may be customized by individual medical groups to ferret out improvement information important to the medical group's individual practice.

## *Priority Aims for Medical Groups When Using This Guideline*

1. 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.

   Possible measure of accomplishing this aim:

   a. The 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.

2. To improve the proportion of tobacco-users whose interest in quitting is assessed or who receive cessation advice at any clinic encounter.

   Possible measure of accomplishing this aim:

   a. The 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 o quit.

3. To increase the likelihood that tobacco-using patients who visit the clinic will quit.

   Possible measure of accomplishing this aim:

   a. Although it is difficult to measure the quit rate accurately, this rate can be approximated by the percentage of users now or in the past 6 months who have quit at the time of an office visit.

4. To improve the proportion of clinic-visiting tobacco users interested in quitting who receive self-help materials and offers of support and follow-up after a quit date.

   Possible measure of accomplishing this aim:

   a. The percentage of clinic-visiting tobacco users with documented interest in quitting at the latest visit whose charts also document that they received self-help materials and an offer of support and follow-up after a quit date.

## Possible Success Measure #1a

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.

## Population

All patients visiting the practice, regardless of age.

## Data of Interest

$$\frac{\text{\# of patients audited whose current tobacco status is documented in the medical record}}{\text{total \# of patients audited}}$$

## Numerator/Denominator Definitions

Numerator: "Current tobacco status documented" means that the medical record shows that the patient either does not use tobacco or, if a user, that the use status was documented at the most recent visit to a clinician. For children and adolescents, being a user includes having a parent or guardian who smokes.

Denominator: Random sample of at least 50 charts with patients of all ages who visited a clinician within the past month.

## Method/Source of Data Collection

**Sample Selection:**

Records should be selected in a random way designed to represent a cross section of patients of all age and gender groups seen by a clinician at a clinic in the last month for any reason. There are various ways to accomplish this:

1. Use the appointment list or lists (if various specialties and departments are present) from a recent day or days and take every name (if a small list) or every 5th or 10th name (if a large list) until at least 50 charts have been found. Note that it is important to include documentation of the recent visit, so if this information is dictated, choose a date that will assure that the dictated record is back in the chart.
2. Select charts randomly from those that are being refiled from a recent visit (if they contain documentation of the visit) until at least 50 charts have been found. These should be selected in a way that allows inclusion of all types of patients being seen.
3. If charts are refiled before visit documentation is included, you may randomly select from the dictated notes as they are being prepared to be filed in the charts.

**Data Collection:**

Use the Tobacco Use Status Audit Form and enter the patient's name or ID # and age in the appropriate column for every chart audited until at least 50 have been entered. In order to know exactly how to record each chart audited, use the following definitions:

Current Non-User = a label or mark anywhere on the chart (or on general forms like a problem list) or on the most recent visit progress note that shows that the patient has been asked at least once and reported not using tobacco. If the patient is a child or adolescent, a similar identification should be used to show that the child is not exposed to smoke from a parent or guardian (i.e., if the child is breathing the smoke of others regularly, s/he is a smoker)

Current User = information at the most recent visit progress note that shows that a user was asked about use at that visit. This task will be simplified if the clinic uses some type of label or general mark on the chart that shows that the patient was a user once. However, for this category it is necessary to document at the most recent visit just what the tobacco use is. If there is a general label but no notation at the most recent visit, the chart should be included in the unknown category

Unknown = either no label or mark on the chart, or a label as a user with no documentation at the recent visit as to the current use status.

**Analysis:**

Add up all of the charts that are in either the User or the Non-User columns for the numerator. Then add to this number all of the Unknown charts to obtain the denominator. Divide and multiply by 100 in order to obtain the % measure.

## Time Frame Pertaining to Data Collection

The suggested schedule is to audit monthly until 75% identification has been achieved. Then it is acceptable to measure only every 3 months until 85% has been achieved, at which time yearly measures will be satisfactory. However, whenever a measure falls below the 85% or 75% level, the reporting frequency should revert to quarterly or monthly as appropriate until the rate has been raised above the cutoff point described.

## Notes

This measure is important as a baseline or threshold indication of clinic tobacco activity because until the use status is known, it is not possible to perform any of the actions recommended by the guideline. However, once an organized system is in place that produces consistent documentation of use, then it is possible and desirable to move on to a more direct reflection of those actions.

## Possible Success Measure #2a

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.

## Population

All patients visiting the practice, regardless of age, who have any indication on their charts that they are or may be users of tobacco, or in the case of children that they are regularly exposed to tobacco smoke

## Data of Interest

$$\frac{\text{\# of tobacco users advised to quit or whose readiness to quit was assessed at the latest visit}}{\text{total \# of tobacco users audited}}$$

## Numerator/Denominator Definitions

Numerator: Tobacco user = Any indication on a chart or in the note from the latest visit that the patient uses tobacco (or, for a child, is regularly exposed to tobacco smoke). Documentation in the progress note from the latest visit with a clinician of either advice to quit or information about the user's current interest or readiness to quit will satisfy the rest of the definition

Denominator: See definition of tobacco user above

## Method/Source of Data Collection

**Sample Selection:**

The charts for this measure are to be obtained in the same way as those for Measure #1 above. In fact, they will be readily identified in the course of that measurement by including in the denominator all those charts in the Tobacco Use Status Audit Form in either:

1. The Current User column; or
2. The Unknown column if they have a chart label/marker showing tobacco use but no indication of current use in the latest progress note.

**Data Collection:**

Using the Tobacco Use Status Audit Form, write a "+" in the Advice/Assessment column next to every user (as defined above) if there is any evidence in the latest progress note that there was a discussion about tobacco that included either advice to quit **or** an expression of the user's interest in quitting. If neither is present in the note, write a "-".

**Analysis:**

Add up all the + marks to obtain the numerator and all the + and - marks to obtain the denominator. Divide and multiply the answer by 100 in order to obtain the % measure.

## Time Frame Pertaining to Data Collection

The suggested schedule is to audit monthly until 75% identification has been achieved. Then it is acceptable to report only every 3 months until 85% has been achieved, at which time yearly measures will be satisfactory. However, whenever a measure falls below the 85% or 75% level, the reporting frequency should revert to quarterly or monthly as appropriate until the rate has been raised above the cutoff point described.

## Notes

Although documentation of advice and/or assessment of quit status is only a measure of the process of raising the issue with tobacco users, there is considerable research to suggest that if this is done regularly in a non-confrontational way, tobacco users will quit. If your group/clinic is interested in a more direct measure of this outcome, see the optional additional implementation success measure.

We recognize that if your group only audits 50 charts for the Identification measure, you may only end up with about 10 users for this measure. That is a small enough number that it will cause considerable fluctuation from measure to measure. In order to obtain a more stable measure that is a more valid reflection of the frequency of advice/assessment, you may want to extend the Identification audit process beyond 50 charts specifically to identify more users until you reach at least 20-25 users.

## *PROBING MEASURES*

1. Use of the Identification and the Advice/Assessment measures for individual clinics

We strongly recommend doing this for each clinic. As a medical group, doing this audit on a clinic basis will allow you to learn which clinics need the most attention. In addition, unless an individual clinic knows how it is doing, it will not be able to make use of the data for improvement. An overall average value is of neither interest nor value to each clinic site. The technique is the same and having staff at each site collect their own data on this may help to provide them more ownership of the process and its improvement.

## *ADDITIONAL SUGGESTED MEASURES*

1. Descriptive statistics of the process of assisting users to quit

Once your group/clinic has achieved a satisfactorily high frequency of user identification and advice, you may want to gather more information about the process being used to help users to quit. This can be done by simply collecting more information during the same audit used to assess Measure #2. The attached Cessation System Rapid Audit Form is designed to facilitate this. The points identified are those directly related to the guideline and have been associated with better quit success in studies of smoking cessation. However, you may wish to modify them or to add other questions.

2. Estimation of a quit rate

Although it is fairly difficult to actually perform a direct measure of the cessation rate for your patients, two indirect measures are fairly simple to gather and will provide you with a reasonable approximation of the quit rate:

A. Identification of recent quitters

This requires that as your staff identifies user status on patients, two types of labels or other notations are used - one for those who have quit in the last 6 months, and one for those who have quit more than 6 months ago or who have never smoked. A simpler way to accomplish this is to simply put a date (mo/yr) notation by the label or other mark used to show that a patient is not a user. Then, when you perform a chart audit for Measure #1, add another column to show whether the nonuser has quit within the last 6 months or longer ago. Use the number of recent quitters as the numerator and the total number of current users + the recent quitters as the denominator to calculate a percentage estimate of the quit rate.

B. Tobacco user flow sheets ("Smoke Card")

In order to use this approach to identifying a quit rate, you must have decided to keep a current flow sheet or card in each tobacco user's chart that shows at each visit what that user's status is. It has been demonstrated that such a flow sheet can be very helpful for providing continuity of follow-up, especially for making follow-up phone calls after a quit date. If this system is being used for the purpose of providing more effective advice and support, then it becomes easy to look at this form in the chart of any user and to calculate the percentage of quits, both overall and for specific time periods, among users.

# Measurement Tool –
# Tobacco Use Status Audit Form



## Directions

Randomly sample 50 charts of patients seen during the past month (See sample selection in the Measurement Section). Write the number of the medical record or patient name in the appropriate column per the definitions in the Measurement Section. For those charts without any label indicating tobacco use status or with a user label on the chart, go into the chart looking only at the most recent visit to determine whether it documents tobacco use status as of that visit. If the patient is a current user, indicate with a "+" or "-" in the space provided whether documentation exists that the patient was advised to quit and/or the patient's readiness to quit was assessed.

| | Current Non-users | Current Users | *Advised to Quit and/or Readiness to Quit Assessed?* | Unknowns |
|---|---|---|---|---|
| 1 | | | | |
| 2 | | | | |
| 3 | | | | |
| 4 | | | | |
| 5 | | | | |
| 6 | | | | |
| 7 | | | | |
| 8 | | | | |
| 9 | | | | |
| 10 | | | | |
| 11 | | | | |
| 12 | | | | |
| 13 | | | | |
| 14 | | | | |
| 15 | | | | |
| 16 | | | | |
| 17 | | | | |
| 18 | | | | |
| 19 | | | | |
| 20 | | | | |
| 21 | | | | |
| 22 | | | | |
| 23 | | | | |
| 24 | | | | |
| 25 | | | | |
| 26 | | | | |
| 27 | | | | |
| 28 | | | | |
| 29 | | | | |
| 30 | | | | |
| 31 | | | | |
| 32 | | | | |
| 33 | | | | |
| 34 | | | | |
| 35 | | | | |
| 36 | | | | |
| 37 | | | | |
| 38 | | | | |
| 39 | | | | |
| 40 | | | | |
| 41 | | | | |
| 42 | | | | |
| 43 | | | | |
| 44 | | | | |
| 45 | | | | |
| 46 | | | | |
| 47 | | | | |
| 48 | | | | |
| 49 | | | | |
| 50 | | | | |

## Directions for Auditing

For each patient, place a "y" or an "n" in each box if applicable. The 9 questions audited should be done sequentially (question 1 should be assessed before assessing question 2). "N/a" should be used in the table if an item is not appropriate to answer given earlier answers. For example, if no discussion took place, all the other rows will be n/a for that patient. Similarly, if a patient is not interested in quitting, the following rows should show n/a.

## Directions for Scoring

For each question, determine the percentage of yes entries by using the formula:

$$\frac{\#\text{ "yes"}}{\#\text{ "yes"} + \#\text{ "no"}} \times 100$$

For example, of the 20 patients there were 10 yes responses, 5 no responses, and 5 n/a for question 2. The formula would show that 10 out of 15 or 67% of eligible patients were advised to quit.

ICSI recommends auditing 10 to 20 charts per month and plotting the results on run charts.

| QUESTION | Pt 1 | Pt 2 | Pt 3 | Pt 4 | Pt 5 | Pt 6 | Pt 7 | Pt 8 | Pt 9 | Pt 10 | Pt 11 | Pt 12 | Pt 13 | Pt 14 | Pt 15 | Pt 16 | Pt 17 | Pt 18 | Pt 19 | Pt 20 | Totals |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1. Tobacco use discussed? | | | | | | | | | | | | | | | | | | | | | |
| 2. Advised to quit? | | | | | | | | | | | | | | | | | | | | | |
| 3. Asked about interest in quitting? | | | | | | | | | | | | | | | | | | | | | |
| 4. Wants to quit? (if so, when?) | | | | | | | | | | | | | | | | | | | | | |
| 5. Quit date set? | | | | | | | | | | | | | | | | | | | | | |
| 6. Help offered? | | | | | | | | | | | | | | | | | | | | | |
| 7. Follow-up plan? | | | | | | | | | | | | | | | | | | | | | |
| 8. NRT prescribed?* | | | | | | | | | | | | | | | | | | | | | |
| 9. Bupropion (Zyban®) prescribed?* | | | | | | | | | | | | | | | | | | | | | |

* Assess this for adults over age 15 only.