

Executive Summary

Context

In America today, tobacco stands out as the agent most responsible for avoidable illness and death. Millions of Americans consume this toxin on a daily basis. Its use brings premature death to almost half a million Americans each year, and it contributes to profound disability and pain in many others. Approximately one-third of all tobacco users in this country will die prematurely because of their dependence on tobacco. Unlike so many epidemics in the past, there is a clear, contemporaneous understanding of the cause of this premature death and disability—the use of tobacco. It is a testament to the power of tobacco addiction that millions of tobacco users have been unable to overcome their dependence and save themselves from its consequences: perpetual worry, unceasing expense, and compromised health. Indeed, it is difficult to identify any other condition that presents such a mix of lethality, prevalence, and neglect, despite effective and readily available interventions.

Despite high, sustained tobacco use prevalence, the response of both clinicians and the U.S. health care delivery system is disappointing. Studies show that most smokers present at primary care settings, and they are not offered effective assistance in quitting. The smoker's lack of success in quitting, and the clinician's reluctance to intervene, can be traced to many factors. Until recently, few effective treatments existed, effective treatments had not been identified clearly, and health care systems had not supported their consistent and universal delivery. To single-out the clinician for blame would be inappropriate, when he or she has typically received neither the training nor support necessary to treat tobacco use successfully.

Current treatments for tobacco dependence offer clinicians their greatest single opportunity to staunch the loss of life, health, and happiness caused by this chronic condition. It is imperative, therefore, that clinicians actively assess and treat tobacco use. In addition, it is imperative that health care administrators, insurers, and purchasers adopt and support policies and practices that are aimed at reducing tobacco use prevalence. The chief purpose of this document is to provide clinicians, tobacco dependence specialists, health care administrators, insurers, and purchasers, and even tobacco users, with evidence-based recommendations regarding clinical and systems interventions that will increase the likelihood of successful quitting.

Guideline Origins

This updated guideline, *Treating Tobacco Use and Dependence*, a Public Health Service-sponsored Clinical Practice Guideline, is the product of the Tobacco Use and Dependence Guideline Panel (“the panel”), consortium representatives, consultants, and staff. These 30 individuals were charged with the responsibility of identifying effective, experimentally validated, tobacco

dependence treatments and practices. This guideline is an update of the 1996 *Smoking Cessation Clinical Practice Guideline No. 18* that was sponsored by the Agency for Health Care Policy and Research (now the Agency for Healthcare Research and Quality [AHRQ]), U.S. Department of Health and Human Services. The original guideline reflected the extant scientific research literature published between 1975 and 1994.

The updated guideline was written in response to new, effective clinical treatments for tobacco dependence that have been identified since 1994, and that these treatments promise to enhance the rates of successful tobacco cessation. The accelerating pace of tobacco research that prompted the update is reflected by the fact that 3,000 articles on tobacco published between 1975 and 1994 were collected and screened as part of the original guideline. Another 3,000 were published between 1995 and 1999 and contributed to the updated guideline. These 6,000 articles were reviewed to identify a much smaller group of articles that served as the basis for guideline data analyses and panel opinion.

The updated guideline was sponsored by a consortium of seven Federal Government and nonprofit organizations: the Agency for Healthcare Research and Quality (AHRQ); Centers for Disease Control and Prevention (CDC); National Cancer Institute (NCI); National Heart, Lung, and Blood Institute (NHLBI); National Institute on Drug Abuse (NIDA); Robert Wood Johnson Foundation (RWJF); and University of Wisconsin Medical School's Center for Tobacco Research and Intervention (CTRI). All of these organizations have the mission to reduce the human costs of tobacco use. Given the importance of this issue to the health of all Americans, the updated guideline is published by the U.S. Public Health Service.

Guideline Style and Structure

This guideline was written to be relevant to all tobacco users—those using cigarettes as well as other forms of tobacco. Therefore, the terms “tobacco user” and “tobacco dependence” will be used in preference to “smoker” and “cigarette dependence.” However, in some cases the evidence for a particular recommendation consists entirely of studies using smokers as subjects. In these instances, the recommendation and evidence refers to “smoking” to communicate the parochial nature of the evidence. In most cases though, guideline recommendations are relevant to all types of tobacco users.

The updated guideline is divided into eight chapters:

Chapter 1, Overview and Methods, provides the clinical practice and scientific context of the guideline update project and describes the methodology used to generate the guideline findings.

Chapter 2, Assessment of Tobacco Use, describes how each patient presenting at a health care setting should have his or her tobacco use status determined, and how tobacco users should be assessed for willingness to make a quit attempt.

Chapter 3, Brief Clinical Interventions, summarizes effective brief interventions that can easily be delivered in a primary care setting. In this chapter, separate interventions are described for the patient who is *willing* to try to quit at this

time, for the patient who is *not yet willing* to try to quit, and for the patient who has recently quit.

Chapter 4, Intensive Clinical Interventions, outlines a prototype of an intensive tobacco cessation treatment that comprises strategies shown to be effective in this guideline. Because intensive treatments produce the highest success rates, they are an important element in tobacco intervention strategies.

Chapter 5, Systems Interventions: Relevance to Health Care Administrators, Insurers, and Purchasers, offers a blueprint to guideline changes in health care coverage and health care administration such that tobacco assessment and intervention become “default options” in health care delivery.

Chapter 6, Evidence, presents the results of guideline statistical analyses and the recommendations that emanate from them. Guideline analyses address topics such as the efficacy of different pharmacotherapies and counseling strategies, the relation between treatment intensities and treatment success, and whether screening for tobacco use in the clinic setting enhances tobacco user identification. The guideline panel made specific recommendations regarding future research on these topics.

Chapter 7, Special Populations, evaluates evidence on tobacco intervention strategies and efficacy with special populations (e.g., women, pregnant smokers, racial and ethnic minorities, hospitalized smokers, smokers with psychiatric comorbidity and chemical dependency, children and adolescents, and older smokers). The guideline panel made specific recommendations for future research on topics relevant to these populations.

Chapter 8, Special Topics, presents information and recommendations relevant to weight gain after smoking cessation, noncigarette tobacco products, clinician training, economics of tobacco treatment, and harm reduction. The guideline panel formulated specific recommendations regarding future research on these topics.

Findings and Recommendations

The key recommendations of the updated guideline, *Treating Tobacco Use and Dependence*, based on the literature review and expert panel opinion, are as follows:

1. Tobacco dependence is a chronic condition that often requires repeated intervention. However, effective treatments exist that can produce long-term or even permanent abstinence.
2. Because effective tobacco dependence treatments are available, every patient who uses tobacco should be offered at least one of these treatments:
 - Patients *willing* to try to quit tobacco use should be provided treatments identified as effective in this guideline.
 - Patients *unwilling* to try to quit tobacco use should be provided a brief intervention designed to increase their motivation to quit.

3. It is essential that clinicians and health care delivery systems (including administrators, insurers, and purchasers) institutionalize the consistent identification, documentation, and treatment of every tobacco user seen in a health care setting.
4. Brief tobacco dependence treatment is effective, and every patient who uses tobacco should be offered at least brief treatment.
5. There is a strong dose-response relation between the intensity of tobacco dependence counseling and its effectiveness. Treatments involving person-to-person contact (via individual, group, or proactive telephone counseling) are consistently effective, and their effectiveness increases with treatment intensity (e.g., minutes of contact).
6. Three types of counseling and behavioral therapies were found to be especially effective and should be used with all patients attempting tobacco cessation:
 - Provision of practical counseling (problemsolving/skills training);
 - Provision of social support as part of treatment (intra-treatment social support); and
 - Help in securing social support outside of treatment (extra-treatment social support).
7. Numerous effective pharmacotherapies for smoking cessation now exist. Except in the presence of contraindications, these should be used with all patients attempting to quit smoking.
 - Five *first-line* pharmacotherapies were identified that reliably increase long-term smoking abstinence rates:
 - Bupropion SR
 - Nicotine gum
 - Nicotine inhaler
 - Nicotine nasal spray
 - Nicotine patch
 - Two *second-line* pharmacotherapies were identified as efficacious and may be considered by clinicians if first-line pharmacotherapies are not effective:
 - Clonidine
 - Nortriptyline
 - Over-the-counter nicotine patches are effective relative to placebo, and their use should be encouraged.

8. Tobacco dependence treatments are both clinically effective and cost-effective relative to other medical and disease prevention interventions. As such, insurers and purchasers should ensure that:
 - All insurance plans include as a reimbursed benefit the counseling and pharmacotherapeutic treatments identified as effective in this guideline; and
 - Clinicians are reimbursed for providing tobacco dependence treatment just as they are reimbursed for treating other chronic conditions.

Guideline Update: Advances

A comparison of the findings of the year 2000 guideline with the previous 1996 guideline reveals the considerable progress made in tobacco research over the brief period separating these two works. Among many important differences between the two documents, the following deserve special note:

- The updated guideline has produced even stronger evidence of the association between counseling intensity and successful treatment outcomes, and also has revealed evidence of additional efficacious counseling strategies. These include telephone counseling and counseling that helps smokers enlist support outside the treatment context.
- The updated guideline offers the clinician many more efficacious pharmacologic treatment strategies than were identified in the previous guideline. There are now seven different efficacious smoking cessation medications, allowing the clinician and patient many more treatment options. Further information also is available on the efficacy of combinations of nicotine replacement therapies and pharmacotherapies that are obtained over-the-counter.
- The updated guideline contains strong evidence that smoking cessation treatments shown to be efficacious in this guideline (both pharmacotherapy and counseling) are *cost-effective* relative to other routinely reimbursed medical interventions (e.g., treatment of hyperlipidemia and mammography screening). The guideline panel concluded, therefore, that smoking cessation treatments should not be withheld from patients given the fact that they are both cost-effective and clinically effective.

Coordination of Care: Institutionalizing the Treatment of Tobacco Dependence

There is increasing evidence that the success of any tobacco dependence treatment strategy cannot be divorced from the health care system in which it is embedded. Data strongly indicate that the consistent and effective delivery of tobacco interventions requires *coordinated interventions*. Just as a clinician must intervene with his or her patient, so must the health care administrator,

insurer, and purchaser foster and support tobacco dependence treatment as an integral element of health care delivery. Health care purchasers should demand that tobacco intervention be a contractually covered obligation of insurers and providers. Health care administrators and insurers should ensure that clinicians have the training and support, and receive the reimbursement necessary to achieve consistent, effective intervention with tobacco users.

Future Promise

About 20 years ago, data indicated that clinicians too frequently failed to intervene with their patients who smoke. Recent data confirm that this picture has not changed markedly over the past two decades. One recent study reported that only 15 percent of smokers who saw a physician in the past year were offered assistance with quitting, and only 3 percent were given a followup appointment to address this topic. These data are disheartening. The updated guideline reports a family of findings that creates tremendous tension for change. This guideline reveals that multiple efficacious treatments exist, these treatments can double or triple the likelihood of long-term cessation, many cessation treatments are appropriate for the primary care setting, cessation treatments are more cost-effective than many other reimbursed clinical interventions, and the utilization and impact of cessation treatments can be increased by supportive health system policies (e.g., coverage through insurance plans). In sum, the updated guideline identifies and describes scientifically validated treatments and offers clear guidance on how such treatments can be consistently and effectively integrated into health care delivery.

The guideline panel is optimistic that this updated guideline is a harbinger of a new and very promising era in the treatment of tobacco use and dependence. The guideline codifies an evolving culture of health care—one in which every tobacco user has access to effective treatments for tobacco dependence. This new standard of care provides clinicians and health care delivery systems with their greatest opportunity to improve the current and future health of their patients by assisting those addicted to tobacco. Tobacco users and their families deserve no less.