

A Primer on Smoking Cessation in Primary Care

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Smoking in the United States

The decline in cigarette smoking in the United States over the past 50 years has been hailed as one of public health's greatest successes,^[1] marked by a dramatic reduction between 1965, when almost half (42.4%) of all US adults smoked, and 2014, when less than one fifth (16.8%) did so.^[2] Although smoking rates seemed to plateau somewhat after 2004, just-released data from the National Health Interview Survey^[3] contained a surprise. In 2015, an estimated 15% of adults aged 18 and older were smokers, a 2% rate of decline since 2014, which was double the previous year's decline of 1%.^[3]

This is good news, but to achieve the *Healthy People 2020* goal of a smoking rate of 12% or lower (originally set for 2010),^[4] more work will be needed. "Smoking is the leading preventable risk to our patients' health," says Michael Fiore, MD, director of the University of Wisconsin Center for Tobacco Research and Intervention in Madison, Wisconsin. "Seventy percent of smokers tell us that they want to quit, and they need our help."^[1]

Primary care practitioners (PCPs) find it difficult to fit discussions about smoking into the healthcare visit, and training in tobacco cessation interventions is inadequate. Although most patients are asked whether they smoke, and most smokers are advised and helped to make a quit attempt, PCPs are far less assiduous about arranging follow-up tobacco cessation consultations.^[5-7]

Today's Smokers

Although smoking rates have declined, today's smokers have more comorbid conditions, including psychiatric disorders, which have a substantial impact on smoking and quitting.^[8,9] Despite smoking fewer cigarettes than their counterparts in the 1960s, contemporary smokers are at higher risk for lung cancer.^[1] Ventilated filters enable smokers to draw carcinogens more deeply into lung tissue, and levels of some of the 70 known carcinogens in cigarettes have increased with changes in the manufacturing process.^[1]

In the United States, smoking is increasingly concentrated among those with lower levels of income or education. In 2014, more than one fourth (26.2%) of individuals living at or below the poverty level reported smoking compared with 15.2% of those living at or above this level.^[10] Similarly, 43% of those with a high school education smoked, a rate more than five times higher than that seen in those with college degrees (7.9%).^[9] More than twice as many people on Medicaid (29.1% vs 12.9%) smoked compared with those who had private health insurance.^[10]

"Cost is a barrier to treatment," asserts Scott McIntosh, PhD, director of the Greater Rochester Area Tobacco Cessation Center in Rochester, New York. He points out that healthcare reform and Medicaid expansions have brought a huge influx of patients to the healthcare system, a population that is likely to have a high rate (up to 40%) of smoking. "PCPs must be ready to counsel these patients and help them quit smoking," he warns, a task that is made difficult by confusing and inadequate insurance coverage for smoking cessation treatment.^[11]

Healthy People 2020 goals call for Medicaid coverage of US Food and Drug Administration (FDA)-approved smoking cessation medications and counseling in all states.^[4] Although Medicaid is barred from excluding smoking cessation medications under the Patient Protection and Affordable Care Act,^[11] by June 2015, only nine states were covering all evidence-based smoking cessation treatments for Medicaid enrollees.^[12] The table summarizes basic coverage for smoking cessation treatment according to health insurance type.

Table. Health Insurance Coverage of Smoking Cessation Treatment

Insurance Type	Who Is Covered?	What Is Covered?
Medicare	Age ≥65 years; some disabled	<ul style="list-style-type: none"> Cessation medications: nicotine nasal spray, nicotine inhaler, bupropion, and

		<p>varenicline</p> <p>Part D plans may cover other medications</p> <ul style="list-style-type: none"> • 4 sessions of individual counseling • Up to 2 quit attempts per year • No cost-sharing for patients not showing symptoms of a tobacco-caused disease • Annual prevention visit
Medicaid (traditional)	Low-income or disabled persons; eligibility varies by state	<p><i>All Medicaid enrollees:</i></p> <ul style="list-style-type: none"> • All FDA-approved smoking cessation medications <p><i>Pregnant women:</i></p> <ul style="list-style-type: none"> • Individual, group, and phone counseling • All FDA-approved smoking cessation medications • No cost-sharing
Medicaid (expansion)	Low-income or disabled persons; up to 138% of federal poverty level in states that expand Medicaid	<ul style="list-style-type: none"> • Tobacco cessation as a preventive service <p>Federal guidance defines this as:</p> <ul style="list-style-type: none"> ◦ 4 sessions of individual, group, and phone counseling ◦ 90 days of all FDA-approved smoking cessation medications ◦ 2 quit attempts per year ◦ No prior authorization for treatments ◦ No cost-sharing
State insurance Marketplace plans	Plans purchased at healthcare.gov or state marketplace; subsidies available if earning 100%-400% of federal poverty level	<ul style="list-style-type: none"> • Tobacco cessation as a preventive service <p>Federal guidance defines this as:</p> <ul style="list-style-type: none"> ◦ 4 sessions of individual, group, and phone counseling ◦ 90 days of all FDA-approved smoking cessation medications

		<ul style="list-style-type: none"> ◦ 2 quit attempts per year ◦ No prior authorization for treatments • No cost-sharing
Employer-sponsored insurance	Insured through employer, union, association, or other organization	<ul style="list-style-type: none"> • Tobacco cessation as a preventive service Federal guidance defines this as: <ul style="list-style-type: none"> ◦ 4 sessions of individual, group, and phone counseling ◦ 90 days of all FDA-approved smoking cessation medications ◦ 2 quit attempts per year ◦ No prior authorization for treatments • No cost-sharing

Data from American Lung Association.^[13]

[Billing, documentation, and coding tips](#)^[14] can help PCPs overcome the perceived barrier of incomplete reimbursement for tobacco cessation interventions.

A Cultural Shift: Tobacco Dependence as a Chronic Disease

Gradually, the medical community has come to recognize tobacco dependence as a chronic disease. "Just as we do for diabetes and other chronic diseases, we need to work with people over time to manage their tobacco dependence and move towards remission," says Dr Fiore. "This may mean intervening with patients multiple times over a number of years. If our first attempt isn't productive, we don't give up. Instead, we work with patients over time to try other treatments. Moreover, long-term management of tobacco dependence needs to take advantage of the whole healthcare team, not just the physician. With other types of chronic disease management, we turn to health educators and nurses to provide ongoing care, and we need to take the same team approach to treating patients who are tobacco-dependent."

Dr McIntosh cautions that it can be more difficult to change cultural attitudes about tobacco dependence. Patients who are willing to accept lifelong treatment for diabetes may resent being told to refrain from smoking, a habit that used to be socially acceptable and is still legal.

Frank T. Leone, MD, director of the Comprehensive Smoking Treatment Programs at the University of Pennsylvania, in Philadelphia, Pennsylvania, believes that as we replace traditional views of smoking, a big shift will occur in how smoking is managed. Smoking has always been considered within a "success or failure" model, with the only outcome being to "cease" smoking. Dr Leone believes that we should view smoking through a chronic disease model and treat smoking (ie, the compulsion to smoke), like other chronic diseases, as the condition to be controlled.^[15] PCPs would move away from an episodic approach and towards repeated evaluation and management of the compulsion to smoke, "analogous to gaining control over diabetes and then monitoring for the desired clinical outcome (control over the compulsion to smoke) over time," explains Dr Leone. He predicts that with this model, primary care practices will become much more effective in dealing with patients who smoke.

Clinical Guidelines

National guidelines for the treatment of tobacco use and dependence were issued in 2008 by the US Department of Health and Human Services (DHHS)^[16] and were updated in 2011 by several of the original guideline authors, including Dr Fiore.^[17] Experts agree that effective treatment of tobacco dependence is a combination of counseling and FDA-approved pharmacotherapy. The DHHS issued an update on prescribing pharmacotherapy in 2012.^[18] In 2015, the US Preventive Services Task Force (USPSTF) recommended combined behavioral and pharmacotherapy interventions for smoking cessation in all nonpregnant adults.^[19] The USPSTF recommendation was recently summarized by the American Academy of Family Physicians (AAFP) for use in primary care clinical settings.^[20]

Golden Minutes

The "5 A's" model, first outlined in 1996,^[21] is still the gold standard evidence-based practice for conducting smoking cessation interventions. Following this model, PCPs:

- Ask all patients about their smoking status;
- Advise every smoker to quit;
- Assess smokers' readiness to quit;
- Assist motivated patients to quit using counseling and pharmacotherapy; and
- Arrange follow-up contacts for those receiving assistance to quit.

Most studies indicate that, in practice, "advise" occurs most frequently, and "assist" and especially "arrange" happen less often.^[1,22-24] Better training will enable clinicians to provide in-office counseling, but even a 1- to 3-minute intervention limited to one of the "5 A's" increases by 40% the likelihood that the patient will quit.^[1] Dr McIntosh believes that all clinicians need training in smoking cessation counseling and that they shouldn't dwell on the statistic that 60-70 of every 100 patients won't quit smoking. "By doing nothing," he says, "only 7 or 8 patients will quit. We are increasing the public health impact by routinely doing something along the lines of the 5 A's." And spending 30 minutes counseling patients raises the chances of quitting to 90%.^[1]

Dr Leone believes that it is misleading to refer to this intervention as *counseling*. "If you define counseling as talking to patients, it is silly to say that doctors have never been trained to do that. That's what we do all the time," Dr Leone points out. "The type and level of counseling required to help somebody stop smoking has nothing to do with specialized psychological insights. We don't call it counseling anymore; we call it cognitive management. No matter what the problem is, we should be constantly teaching our patients, assessing their understanding, reframing their point of view, and adjusting the type and level of information we are giving them based on their current understanding."

Smoking Cessation Methods

For people who are ready to quit, clinical practice guidelines in the United States encourage abrupt smoking cessation because, compared with gradual smoking reduction, it is more likely to lead to permanent cessation. Dr McIntosh reminds us that "quitting cold turkey has been the number one method of stopping smoking since the 1960s." The superiority of abrupt smoking cessation was supported by a randomized controlled trial in which 22% of abrupt quitters vs. 15.5% of gradual quitters were still not smoking 6 months after quitting.^[25] However, a 2012 Cochrane analysis of 10 clinical trials failed to show any difference in quitting success between gradual and abrupt cessation,^[26] and gradually reducing cigarette consumption is a commonly used approach to quitting smoking.

Pharmacotherapy

All seven FDA-approved pharmacotherapies for smoking cessation are recommended as first-line treatment by both the DHHS^[1] and the USPSTF.^[19] These comprise five nicotine replacement therapy (NRT) products (patch, lozenge, gum, nasal spray, and oral inhaler) as well as two non-nicotine prescription medications: sustained-release bupropion (Zyban®, GlaxoSmithKline) and varenicline (Chantix®, Pfizer). Nicotine nasal spray and oral inhalers require a prescription. (Nicotine oral spray and sublingual tablets, which are available in some countries, are not licensed for sale in the United States.) Nicotine dependence can be transferred from cigarettes to nicotine replacement products, so follow-up with patients to assess continued

use and effectiveness is important. The AAFP has a handy online "[Pharmacologic Product Guide: FDA-Approved Medications for Smoking Cessation](#)."

Combination NRT. Dr Fiore believes that many PCPs are not aware of combination NRT (C-NRT), which he considers one of the two most effective pharmacotherapeutic approaches to smoking cessation. Combining the long-acting nicotine patch with a short-acting medication such as the nicotine mini lozenge (Nicorette®, GlaxoSmithKline) delivers an extra bolus of nicotine to reduce urges to relapse. Dr Fiore adds that NRT has few contraindications and side effects,^[27] can be recommended to almost all tobacco users, and is associated with good compliance.

Varenicline. The other "top treatment" in terms of supporting evidence is the partial nicotine receptor agonist varenicline, which has been shown to be effective for smoking cessation^[28] and is more effective than NRT^[29-31] or bupropion.^[29,30,32] Although the FDA issued a black box warning that varenicline may increase the risk for serious neuropsychiatric events, a recent randomized clinical trial showed no increase in neuropsychiatric adverse events (compared with the nicotine patch or placebo) attributable to varenicline.^[32] These findings support previous conclusions of "a lack of clear evidence" associating varenicline with an increased risk for neuropsychiatric events.^[33,34] It has been suggested that the FDA should reconsider the black box warning^[35,36] that led to a sharp decline in prescriptions for varenicline.^[37] Following the recent announcement that the European Medicines Agency had decided to remove its similar black triangle warning for varenicline,^[38] the FDA said that it was reviewing the new evidence and continuing to evaluate the issue.^[39]

Varenicline is generally considered safe, even in patients with cardiovascular disease^[40] or severe mental illness.^[30,37] All patients on varenicline should be monitored carefully. Common adverse effects associated with varenicline, such as insomnia and/or vivid dreams, can be avoided by taking the second of the two daily pills after the evening meal rather than at bedtime, and nausea can be avoided by taking varenicline after breakfast and the evening meal and not on an empty stomach.

Varenicline and NRT. A logical reason for not combining the nicotine patch with varenicline is that, as a partial agonist-antagonist, the varenicline molecule competitively inhibits nicotine, so it would be expected to block the effects of the nicotine patch. However, varenicline may not fully saturate the relevant nicotine receptors in the brain, leaving receptors upon which nicotine can act. Alternatively, NRT may bind to different receptors from those involved in nicotine dependency. The largest clinical trial to date showed that varenicline combined with NRT was more effective than varenicline alone in maintaining smoking cessation at 6 months.^[41]

Bupropion. Combining the nicotine patch with bupropion is another guideline-recommended first-line treatment for smoking cessation. Bupropion is recommended particularly in patients concerned about gaining weight when they quit smoking.^[16,19] Bupropion also has an FDA black box warning about serious psychiatric events, but like varenicline, studies have found no evidence for this effect.^[32,42,43]

Nonregulated Treatments

Patients sometimes express interest in trying such "alternative" treatments for tobacco dependence as acupuncture or hypnotherapy.^[1] According to Dr McIntosh, the strength of evidence for these practices is low but not nonexistent. Although a 2012 meta-analysis suggested that acupuncture and hypnotherapy *can* help smokers quit, and their use should be promoted,^[44] Cochrane analyses found "no consistent, bias-free evidence that acupuncture, acupressure, or laser therapy has a sustained benefit on smoking cessation for six months or more"^[45] and that "the effects of hypnotherapy on smoking cessation claimed by uncontrolled studies were not confirmed by the analyses in randomized controlled trials."^[46]

With respect to alternative treatments, Dr McIntosh says that "results of smoking cessation studies using herbs and supplements and such mind-body practices as yoga, mindfulness, and meditation have not shown any clear effects, but some showed lower craving and less smoking and studies are continuing." Cognitive-behavioral approaches are also being investigated.

E-cigarettes for Smoking Cessation

Electronic cigarettes (e-cigarettes), the battery-operated devices designed to deliver nicotine with flavorings and other chemicals in vapor instead of smoke, have been marketed in the United States since 2007. There were 466 brands of e-cigarettes on the market in 2014.^[47] Surveys showed that 12.6% of adults had tried an e-cigarette, and 3.7% of adults used e-

cigarettes regularly.^[48] Despite a lack of evidence,^[49,50] about 61% of e-cigarettes marketed before 2012 and 48% of newer brands were making indirect claims, mainly through testimonials, that their products were effective for smoking cessation.^[47] Furthermore, 10% of older brands and 11.6% of newer brands were making direct claims about the efficacy of e-cigarettes in helping smokers quit.^[47]

In 2015, the USPSTF concluded that evidence was insufficient to recommend e-cigarettes for tobacco cessation in adults because the evidence was "conflicting and limited."^[19] A more recent review and meta-analysis of clinical trials and observational real-world studies reported that the odds of quitting smoking were 28% lower among those who used or had used e-cigarettes compared with those who had not.^[51] Nonetheless, support for e-cigarettes as smoking cessation aids exists among the medical profession. Recently a group of experts from the United States, Canada, and Australia linked a greater decline in cigarette smoking over the past 2 years with the increase in e-cigarette sales and concluded that e-cigarette use can encourage smoking cessation in people who otherwise would have smoked standard cigarettes.^[52]

On May 5, 2016, the FDA announced that it would be extending its authority to all tobacco products, including e-cigarettes, cigars, hookah tobacco, and pipe tobacco marketed after February 15, 2007.^[53] Manufacturers of e-cigarettes will be required to show that their products meet public health standards set out in law and to receive marketing authorization from the FDA. The new regulations were welcomed by professional health organizations, including the American Thoracic Society (ATS),^[54] the American Heart Association,^[55] the American Society of Clinical Oncology,^[56] and the AAFP.^[57] E-cigarettes will be available for up to 2 years while the manufacturers submit a new tobacco product application and for a further year during the FDA review. Some requirements, such as the ban on the use of misleading terms, will not be enforced until 1 year after the final rule takes effect (August 8, 2016).

Dr Leone believes that although the data are not yet conclusive, the idea that e-cigarettes can facilitate smoking cessation is wishful thinking. "Marketers have taken advantage of the hope that something will come along to help people avoid the tragic consequences of smoking without having to give up smoking entirely," he comments. Instead, when patients come in saying that they would like to use e-cigarettes to help them quit tobacco smoking, Dr Leone recommends asking: What is it that you like about the e-cigarette? "The answer may offer clues as to what other reasonable, evidence-based approaches might work for those patients," he suggests. "For example, people who like having a cigarette in their fingers and putting it in their mouths, and like the way it feels in the back of their throats might do well with a nicotine inhaler.

Concerns have also been raised about the safety of inhaling some of the substances contained in e-cigarette vapor. "We don't know what goes into e-cigarettes—manufacturers can put anything they like in them," Dr McIntosh cautions. "The ingredients in e-cigarettes are not labeled, and the amounts of nicotine and other substances delivered by each cartridge are unknown," he adds, citing a study in which he and colleagues found that the vapor of a popular brand of e-cigarette, *Blu* (Imperial Tobacco), contained six times as much copper as that of a tobacco cigarette.^[58] An FDA analysis of 18 samples of cartridges from two leading e-cigarette brands found carcinogens in half of the samples.^[59] With FDA regulation imminent, "and barring any additional congressional actions that may change it," Dr McIntosh predicts that "the measurement of important variables related to harm caused by specific e-cigarette components will become more refined, and we will be guided by increasingly evidence-based conclusions."

Not Ready to Quit?

The "**5 R's**" strategy (relevance, risks, rewards, roadblocks, and repetition)^[16,17] can be effective in motivating people who are not ready to quit smoking. "This can be done very briefly—addressing even a couple of the Rs is known to be helpful," Dr Fiore says. If a smoker is not ready to quit, "we typically urge them to try using NRT (preferably the patch) for 2-6 months, and they will probably cut down on their smoking," an approach supported by the 2011 guidelines. Most people do not have the same desire to smoke when they are getting round-the-clock nicotine through a patch, and there is evidence that many go on to quit as a result of building up their confidence that they can make progress, Dr Fiore explains.

When PCPs ask about smoking and conclude from the patient's response that he or she is conflicted about quitting, the PCP usually moves on to the next problem. But, "the problem to be addressed is the patient's unwillingness to stop smoking," points out Dr Leone, emphasizing an important way of approaching smoking cessation. "Starting patients on medication and at the same time telling them not to worry about quitting will get the compulsion to smoke under control first before we institute the behavior changes. That is a different understanding of the problem that can only happen after a clinician rethinks the nature of this chronic illness."

Treatment Extenders and New Technology

Experts strongly recommend that treatment extenders such as quitlines, web-based interventions, local quit programs, and tailored self-help materials be incorporated in the 5 A's approach. These evidence-based resources are available free of charge across the nation. Any patient can call 1-800-QUIT-NOW, the number operated by the National Cancer Institute (NCI), which will link people to their state's quitline.^[60] The state quitline will advise the caller on quitting, counseling, where to get more information about medications, and in essence provide support for what happened in the clinical office. A related resource under the auspices of the NCI is www.smokefree.gov, which offers cessation support services targeted to different populations of smokers and provides both web- and text-based programs that patients can sign up for free of charge.

Dr Fiore says that clinicians "should not use the quitline as a substitute but as an *extension* of what we do." Dr Leone agrees, saying, "I have not relinquished my role in managing the patient's dependence just because I am using tools that exist outside of the office." He sees this as qualitatively different from the more traditional approach in which a clinician would leave all of the counseling to a quitline adviser. "Our currency as a PCP is the counseling we provide to our patients. How is this any different from when we counsel diabetics or patients with congestive heart failure and provide them with very practical advice?" he asks. "PCPs are being asked to do more with less time, but there are ways to address that. You can counsel briefly, and then your nurse can extend your message. New technologies can link the patient in the clinic directly to the quitline."

The electronic health record (EHR) is increasingly becoming "the busy physician's friend" in facilitating smoking cessation interventions, Dr Fiore believes. Most EHRs now include documentation of tobacco use status, and many include algorithms that guide the clinician in delivering an evidence-based intervention. Prompts to document tobacco use during healthcare visits can increase documentation of tobacco status and referral to cessation counseling.^[60,61] A New York City Department of Health and Mental Hygiene initiative on EHRs in community health centers found that the proportion of patients with documented smoking status who received an intervention increased from 20% to 62%.^[62]

"We want to make it easy for those who have limited time to address smoking cessation, to make a 'meaningful use type of referral,' and not just advise a patient to quit," Dr McIntosh says. He cites a New York State program designed to support office practices, clinics, and hospitals in which a patient can opt to be electronically referred, via the EHR, to the *Opt-to-Quit* system.^[63] This system links patients to the evidence-based services of the New York State Smokers' Quitline, which contacts the patient within 72 hours of referral. The quitline services include one-on-one behavioral cessation coaching, a free 2-week supply of nicotine patches, web-based support and information, and links to health plan cessation services.^[64] "The quitline sends information automatically back to that patient's chart, and it is out of the physician's hands until he or she follows up with the patient at the next visit," Dr McIntosh explains.

Dr McIntosh expresses disappointment that recent guidelines have not addressed web-assisted tobacco intervention, "although it is difficult to get strong evidence about any particular strategy because the technology changes so fast." He is currently studying whether interactivity of information on a web site influences cessation. A lot of research still needs to be done on digital interventions, he notes, because "one person's cues and triggers are entirely different from another's, so quitting is entirely different from person to person. One person might want to go online and read the latest information on how to quit, get off the computer, and never return to that website. That's all some people need to successfully quit. Someone else might need daily momentary affective mood reminders on a cell phone, social support, blogging, and journaling. It that is what they need, we need to provide that too."

Lost in Translation

"Nothing is more important to our patients' current and future health than quitting smoking," asserts Dr Fiore. "If they don't quit, fully half of all smokers will die prematurely from disease directly caused by their smoking, on average robbing them of 10-15 years of life. It is a healthcare imperative to reach out and do all we can to help the smokers among our patient populations. Dr Fiore stresses that, "Although we are thinking about the *how*, the more important thing is to *do*."

In the past, translation of tobacco dependence research findings to clinical practice tended to be lost. "The field is now evolving," says Dr Leone. Professional societies, such as the American Academy of Pediatrics, the ATS, American College of Chest Physicians, and the American College of Thoracic Surgeons, are starting to adopt positions on this issue, whereas in the past they considered it to be the responsibility of other fields. In 2015, the ATS put out a statement on current and future research needs around tobacco.^[65] "It is not a guideline to smoking cessation, but it can be useful in fundamentally helping the

practitioners see the problem differently," Dr Leone says. "Traditionally this problem has been seen in terms of the illness that it causes—the COPD, the heart disease, and the cancer—but smoking is about the smoking. Smoking is about what happens to the brain after it has been exposed to nicotine. The ATS position statement is very useful in moving people in that direction."

One development that Dr Leone predicts may be useful for general practitioners in the future is connected with the ongoing research showing that people interact with smoke in a way that is specific to their biology. "We may be able to identify clinically important phenotypes that will help us personalize treatment strategies," Dr Leone says. "People who are in practice today will see a time when we send a cheek swab for DNA analysis, and the results will indicate the greater probability of a patient's quitting with one technique as opposed to another. That is going to be useful in a couple of different ways, from biological phenotypes and clinical phenotypes, and I think will provide a much higher resolution level of guidance to practicing physicians."

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