

EXPERT CONSENSUS DECISION PATHWAY

# 2018 ACC Expert Consensus Decision Pathway on Tobacco Cessation Treatment



A Report of the American College of Cardiology Task Force on Clinical Expert Consensus Documents

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**PREFACE**

The American College of Cardiology (ACC) develops a wide range of policy documents to provide members with guidance on clinical topics. Although clinical practice guidelines remain the primary mechanism for offering evidence-based recommendations, such guidelines may contain gaps in their guidance regarding clinical decision making, particularly when equipoise is present in a topic. Expert Consensus Documents are intended to provide guidance for clinicians in areas where evidence may be limited, new and evolving, or lack sufficient data to fully inform clinical decision making.

To increase the impact of ACC clinical policy on patient care, an ACC Presidential Task Force was formed in 2014 to examine the processes and format of ACC’s clinical documents. The main recommendation of the Task Force was a new focus on concise decision pathways and/or key points of care, instead of the traditional longer documents. The Task Force also established criteria for identifying high-value clinical topics to be addressed, as well as an innovative approach to collecting stakeholder input through roundtable or think tank meetings. To complement the new focus on brief decision pathways

and key points, Expert Consensus Documents were rebranded Expert Consensus Decision Pathways (ECDPs).

Although Decision Pathways have a new format, they maintain the same goal of Expert Consensus Documents: to develop clinical policy based on expert opinion in areas which important clinical decisions are not adequately addressed by the available existing trials. ECDPs are designed to complement the guidelines and bridge the gaps in clinical guidance that remain. In some cases, topics covered by ECDPs will be addressed subsequently by ACC/American Heart Association guidelines as the evidence base evolves. The writing groups are charged with developing algorithms that are more actionable and can be implemented in the form of tools or apps to accelerate the use of these documents at point of care. ECDPs are intended not to provide a single correct answer, but to encourage clinicians to ask certain questions and consider important factors as they reach a decision on a treatment plan together with patients. There may be multiple pathways that can be taken for treatment decisions, and the goal is to help clinicians and patients make a more informed decision together.

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## 1. ABSTRACT

Tobacco use, especially cigarette smoking, is a major risk factor for cardiovascular morbidity and mortality and is the leading preventable cause of death worldwide. Comprehensive tobacco cessation treatment is a critical component of the clinical care for individuals with or at risk for cardiovascular diseases. The consistent delivery of tobacco cessation treatment remains a significant challenge for healthcare providers. This ECDP provides a structured approach to evaluating and treating tobacco dependence and offers practical guidance for overcoming challenges commonly encountered in the clinical setting. The Decision Pathway recommends that clinicians and practices establish a team-based system of care that recognizes cigarette smoking as a chronic relapsing substance use disorder caused by addiction to nicotine. The care team should ensure that patients are asked about cigarette smoking and other tobacco product use at all clinical encounters. Patients who use any tobacco product should receive clear advice to stop tobacco use and be offered a brief intervention that includes prescriptions for proven pharmacological smoking cessation aids and proactive connection to evidence-based behavioral support based in the healthcare system and/or the community. Former smokers, especially recent quitters (i.e., those who have stopped smoking in the past year), should be monitored closely for possible relapse back to

smoking. Nonsmokers (i.e., both former smokers and never smokers) should routinely be asked about exposure to secondhand smoke and advised to avoid it. This ECDP also addresses steps to follow when implementing evidence-based therapies and treating special patient groups while also acknowledging situations for which few data exist. It provides tables and figures to illustrate the steps and tools needed to successfully provide comprehensive tobacco cessation treatment.

## 2. INTRODUCTION

Tobacco use is the leading preventable cause of morbidity and mortality worldwide, responsible for over 6 million deaths annually (1). Cigarette smoking is the predominant form of tobacco used and is the most dangerous. Despite decades of decline in the prevalence of smoking among both men and women in the United States, 14.1% of U.S. adults—more than 30 million people—smoked in 2017 (2).

Tobacco use can be characterized as a chronic relapsing substance use disorder that is sustained by addiction to nicotine (3). Most smokers attempting to quit pass through repeated cycles of abstinence followed by relapse to smoking before they achieve long-term abstinence. Many smokers do not stop cigarette smoking until they have developed smoking-related complications.

Nearly one-third of U.S. deaths attributed to cigarette smoking are due to cardiovascular disease (CVD) (4). Globally, 10% to 30% of all CVD deaths are attributable to cigarette smoking (5). Tobacco smoking adversely affects all phases of the atherothrombotic disease process, including endothelial dysfunction (6), plaque development and destabilization (7), and imbalances of antithrombotic and prothrombotic factors (8,9), culminating in acute cardiovascular (CV) events (10,11). Clinically, tobacco smoking increases the risk of coronary heart disease (CHD) (including myocardial infarction [MI] and sudden death), cerebrovascular disease (stroke), peripheral artery disease, and abdominal aortic aneurysm (10,12,13). Smoking is also associated with an increased risk of heart failure (14), as well as both atrial and ventricular arrhythmias (15,16). Among those with CHD, continued cigarette smoking after revascularization is associated with adverse clinical outcomes (17,18), particularly stent thrombosis (19).

Experimental, epidemiological, and clinical studies demonstrate a nonlinear dose effect of cigarette smoke exposure on CV function and CVD such that a low level of cigarette use is associated with a disproportionately large excess in CV risk (10,11,20-22). This nonlinear relationship suggests that acute, short-term exposure to cigarette smoke is damaging to the CV system, helping to explain

why nonsmokers exposed to secondhand tobacco smoke have a 25% to 30% increased risk of CVD (20,23), and why it is important to advise all cardiac patients to avoid exposure to secondhand smoke (SHS).

Smoking cessation reduces subsequent CV events and mortality (24,25). Virtually all cigarette smokers, regardless of duration or intensity of smoking, comorbidities, or age, benefit from smoking cessation, even if cessation occurs after the development of clinical CVD. Tobacco cessation programs are cost-effective, and their value compares favorably with the management of other CV risk factors (26,27).

The substantial and potentially reversible relationship between cigarette smoking and CVD provides a strong rationale for healthcare providers—particularly the CV care team—to take action in clinical practice to change this modifiable risk factor. Multiple stakeholders agree that it is important to incorporate smoking cessation efforts into practice. However, there is a paucity of guidance for clinical cardiologists and the CV team regarding effective strategies to treat cigarette smoking. The present document was developed to address the CV community's unmet need for practical smoking cessation guidance. It aims to convey clinical expert consensus recommendations for a feasible comprehensive approach to addressing smoking in clinical practice. Its scope includes assessment of cigarette smoking and nicotine dependence as well as the provision of behavioral, pharmacological, and supportive interventions that can be used in both inpatient and outpatient settings. This document also discusses alternative tobacco products, such as electronic cigarettes, that have appeared more recently in the marketplace. Clinical recommendations about these products are less certain because their net health risks and benefits are still being determined. This document explores the emerging evidence about these alternative tobacco products and CV risk and provides guidance for clinicians discussing such products with patients.

### 3. METHODS

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On January 23, 2017, the Tobacco Cessation Think Tank was convened at ACC's Heart House by the Prevention of Cardiovascular Disease Leadership Council. The purpose of the meeting was to bring together expert clinicians along with a broad group of stakeholders from a variety of professional societies and federal agencies to discuss the ongoing risk of tobacco and nicotine exposure, emergence of new methods of tobacco and nicotine delivery, and challenges to delivering smoking cessation therapy. Think Tank participants identified the need for expert consensus guidance for comprehensive smoking cessation strategies to improve care for patients with CVD. The

purpose of the Decision Pathway was to provide clinical guidance for the CV care team in key areas in which randomized controlled trial (RCT) evidence was inadequate to guide clinical practice. In such instances, experts on the writing committee would provide consensus recommendations for clinical practice while awaiting expansion of the evidence base.

The writing committee was assembled in October 2017. The document and tools provided herein were formulated on the basis of the writing committee's appraisal of current evidence at the time of committee formation, with additional literature review through January 2018. When evidence was lacking or limited, consensus was developed among writing committee members. The writing committee (see [Appendix 1](#)) included representatives from the following areas: clinical cardiology, cardiology fellows-in-training, internists, nursing, pharmacy, clinical pharmacology, psychology, smoking cessation, and vascular medicine. Writing assignments were made according to areas of expertise. Telephone conferences were used to edit contributed content. Writing committee conference calls were confidential and were attended only by committee members and ACC staff. When consensus within the writing committee was deemed necessary by the chair and vice chair, either a roll call vote or an e-mail-generated ballot was implemented. A simple majority prevailed.

The work of the writing committee was supported exclusively by the ACC without commercial support. Writing committee members volunteered their time to this effort. A formal peer review process was completed, consistent with ACC policy, by expert reviewers nominated by the ACC (see [Appendix 2](#)). All writing committee members and peer reviewers were required to disclose relationships with industry and other entities. Writing committee and peer reviewer relationships with industry relevant to this document are included in [Appendixes 1 and 2](#), respectively. A public comment period was also held to obtain additional feedback. Following reconciliation of all comments, this document was approved for publication by the ACC Clinical Policy Approval Committee.

### 4. ASSUMPTIONS AND DEFINITIONS

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#### General Clinical Assumptions

- This document is applicable to anyone who smokes tobacco cigarettes, but it gives special emphasis to individuals with CVD. Many recommendations are generalizable to all patients who use other combustible forms of tobacco products such as little filter cigars and cigarillos, or who are exposed to tobacco smoke. The smoking of nontobacco products such as marijuana is not covered in this document.

- This document primarily addresses the management of cigarette smokers who are seen in the outpatient clinic setting. However, it includes recommendations for smokers in special clinical circumstances, such as those who are hospitalized with acute CVD processes and those in whom surgery is planned. These settings provide important opportunities to promote smoking cessation.
- This document focuses on adults. It does not address tobacco cessation treatment for adolescents or for pregnant women due to special considerations for individuals in these categories.
- This document focuses on cigarette smoking and other forms of combustible tobacco products (as defined below) because the inhalation of smoke generated by tobacco conveys a greater CV risk than do products in which tobacco is not burned.
- Effective treatment of tobacco dependence is best achieved and managed by a team approach. These algorithms assume that the physician will work along with other healthcare providers and key smoking cessation stakeholders, including nurses, pharmacists, psychologists, certified tobacco treatment specialists (where available), and health department quit services (e.g., telephone quitlines 1-800-QUIT NOW), to guide clinical management. These algorithms are based on the best available evidence. However, all clinical decisions should be governed by clinical judgment and influenced by discussions with the patient to incorporate his or her treatment preferences.
- At any point in time, the recommendations and algorithms outlined in the present document may be superseded by new evidence.

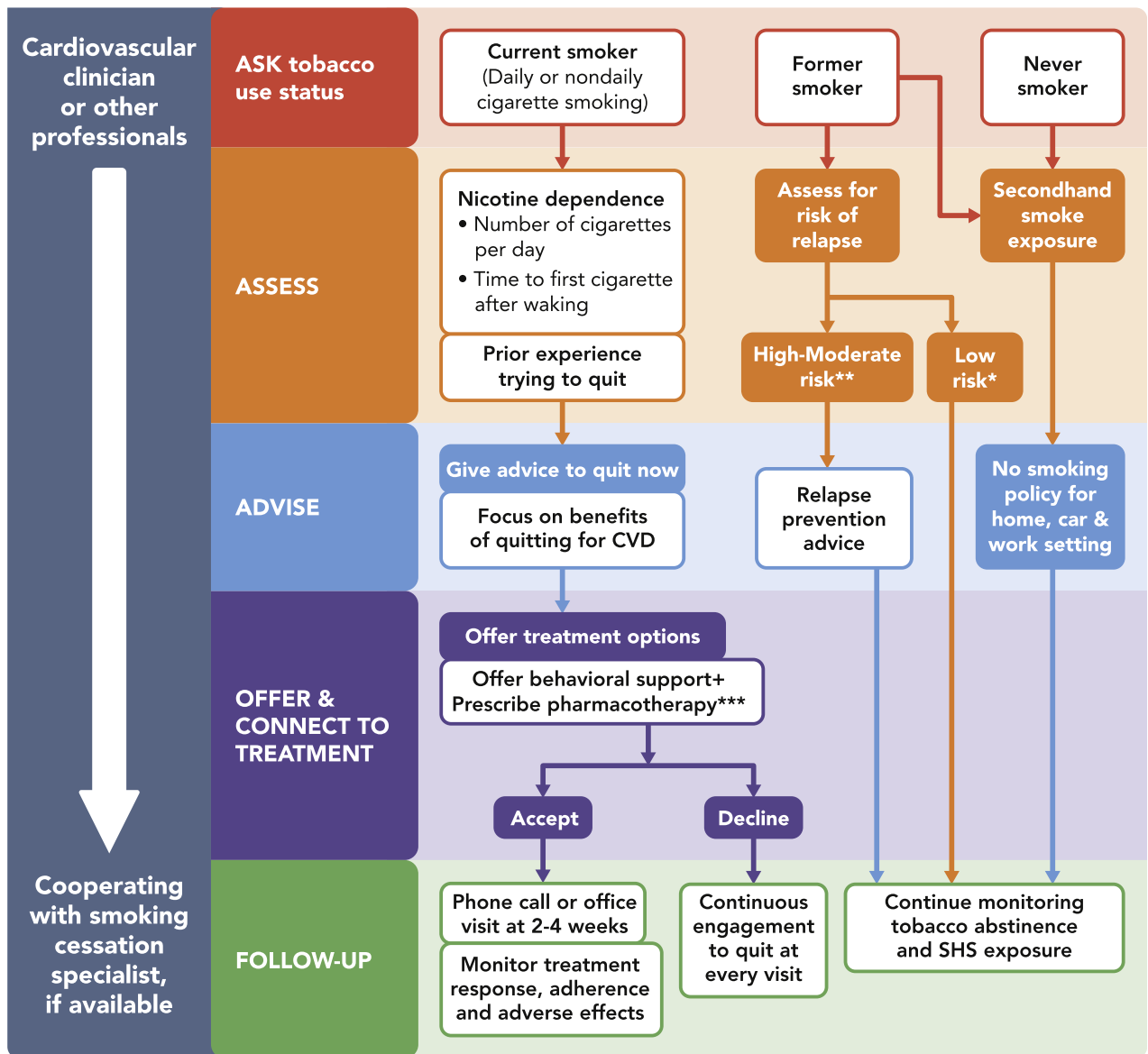
### Definitions

1. **CV patients:** A general reference to patients with primarily atherosclerotic disease involving the coronary arteries and/or peripheral vasculature, but also those with valvular heart disease, congestive heart failure, and heart rhythm disorders in whom tobacco use has been shown to be deleterious.
2. **Tobacco (or nicotine) dependence:** An individual's perception of the need to smoke characterized by difficulty reducing and/or refraining from smoking for extended periods of time, continued use despite knowledge of harm, and, for most daily smokers, nicotine withdrawal symptoms that develop when chronic exposure to nicotine in tobacco products ends.
3. **Current smoker:** As defined in the National Health Interview Survey (NHIS), a person who reports currently smoking tobacco every day (i.e., daily smoker) or on some days (nondaily smoker). NHIS also requires a current smoker to have smoked at least 100 cigarettes (5 packs) in his or her lifetime (2).
4. **Former smoker:** As defined in NHIS, a person who does not currently smoke tobacco but has smoked at least 100 cigarettes in his or her lifetime. Because relapse to smoking occurs frequently after quitting, long-term abstinence is often operationally defined as 6 months of abstinence. Abstinence from smoking for at least 7 days in a row is the criterion often required in clinical studies for an individual to be considered a former smoker in the short-term.
5. **Never smoker:** A person who has not smoked tobacco regularly and does not now smoke every day or some days. NHIS defines never smoker as an individual who has not smoked 100 cigarettes (5 packs) in his or her lifetime (28).
6. **Nonsmoker:** A person who is currently either a former or never tobacco smoker.
7. **Combustible tobacco products:** Products that burn tobacco, producing smoke that users inhale (e.g., cigarettes, cigars, cigarillos, pipe tobacco, hookah). Inhaling smoke exposes the user to a much larger spectrum of harmful chemicals and conveys a much greater risk to CV and overall health than does the use of noncombustible tobacco products (e.g., snuff, chew, dip). However, no tobacco product use is risk-free.
8. **Alternative tobacco products:** Newer nicotine delivery products that differ from conventional combustible and noncombustible tobacco products. This category encompasses electronic nicotine delivery devices, including electronic cigarettes and heat-not-burn (HNB) tobacco products.
9. **Electronic cigarettes (e-cigarettes):** Battery-operated devices that heat a liquid containing nicotine, propylene glycol, and/or vegetable glycerin and flavorant chemicals to generate an aerosol that the user inhales. Because e-cigarettes do not burn tobacco, they do not produce tobacco smoke.
10. **HNB tobacco products (also called heated tobacco products):** A category of tobacco products that heats tobacco to a lower temperature than required for combustion. The result is an aerosol (but not smoke) that the user inhales.

### 5. CENTRAL ILLUSTRATION

**Figure 1** summarizes the 2018 ACC Expert Consensus Decision Pathway for Tobacco Cessation Treatment. Readers should refer to the individual algorithms for the detailed clinical workflow for each patient scenario and clinical setting.

**FIGURE 1** Pathway for Tobacco Cessation Treatment



<b>ABBREVIATIONS:</b>	
CVD = cardiovascular disease	
SHS = secondhand smoke	
*	More than 1 year since last cigarette
**	Refer to Figures 2 and 3
***	If not contraindicated
+	Refer to Tables 1 and 2

**6. DESCRIPTION AND RATIONALE**

**6.1. Overview of the Decision Pathway for Smoking Cessation Treatment**

The ACC Expert Consensus Decision Pathway for Tobacco Cessation Treatment is a systematic stepwise guide for addressing cigarette smoking efficiently and

effectively during a routine office-based clinical encounter. Overall, it builds upon the evidence-based framework outlined in the 2008 U.S. Public Health Service (USPHS) Clinical Practice Guideline for Treatment of Tobacco Use and Dependence (29), with modifications reflecting newer evidence and changing patterns of practice.

The USPHS system for office practice, often referred to as the “5As,” consists of the following 5 steps: 1) ask all patients about tobacco use; 2) advise all smokers to quit tobacco; 3) assess a smoker’s readiness to quit tobacco; 4) assist smokers to quit; and 5) arrange follow-up. Since publication of the USPHS recommendations, tobacco dependence treatment has become increasingly recognized as the management of a chronic relapsing disorder, and an alternative to asking whether a smoker is ready to be treated is simply to offer smoking cessation treatment to every smoker, with patients having the option to refuse treatment (i.e., opt out) (30). This approach is consistent with the management of other chronic diseases such as hypertension and diabetes, for which clinicians offer patients treatment as a standard of care rather than asking if they wish to be helped. The opt-out approach is appropriate for smokers in the inpatient setting as well.

The ACC Expert Consensus Decision Pathway for Tobacco Cessation Treatment reflects a team-based “opt-out” version of the USPHS smoking cessation clinical guidelines, with modifications tailoring the approach for clinicians caring for patients with or at risk for CVD in different treatment settings. The 5 basic steps, which are intended to be the joint responsibility of the CV team, are: 1) *ask* about and document every patient’s tobacco use status and exposure to secondhand smoke at every visit using a standardized assessment method; 2) *assess* current smokers’ degree of nicotine addiction, former smokers’ risk of relapse, and all nonsmokers exposure to SHS; 3) *advise* all tobacco users to quit, emphasizing the personal benefits of cessation rather than the harms of continuing to smoke, and advising all nonsmokers to avoid SHS exposure; 4) *offer and connect* smokers to appropriate treatment options (prescribing pharmacotherapy and actively linking smokers to behavioral support available in their healthcare institution or in the community; and 5) *follow-up with patients* at subsequent visits to monitor smoking status and sustain engagement in smoking cessation treatments as needed. Implementing this system into office and hospital practice requires addressing systems of care delivery, which are considered below in Section 6.1.10., Training and Implementation.

**Tobacco Use Status.** The first step is to ask every patient about smoking and other tobacco use at every visit. An office-wide system should be in place to facilitate the universal identification of tobacco users and the recording of tobacco use status in the electronic health record (EHR) or other healthcare record. To facilitate routine assessment, some health record systems add assessment of smoking and tobacco use to the vital signs module.

Because smokers are increasingly using multiple types of tobacco products, the questions must extend beyond asking about cigarette smoking and encompass the use

of other tobacco products such as cigars, hookah, smokeless tobacco and electronic cigarettes. Because approximately 20% of current smokers, especially young adults, do not smoke daily and may not even consider themselves to be smokers (31), tobacco use should be assessed with a broad question such as “Do you ever use (smoke) any tobacco product?”

Adding the diagnosis of Current Tobacco Use or Former Tobacco Use to the patient’s problem list is recommended to indicate to the patient that it is a chronic health problem requiring sustained attention. Keeping it on the problem list also alerts the patient’s other providers to reiterate smoking cessation advice at their visits and facilitates coordination of tobacco treatment efforts across providers.

**Exposure to Tobacco Smoke.** Because SHS exposure increases nonsmokers’ CVD risk (23), all patients should also be asked about SHS exposure routinely in clinical practice. Smoke-free policies in the United States have made most public places and many workplaces, restaurants, and bars smoke-free. Consequently, the home is now the primary site of SHS exposure. Simple screening questions to assess for SHS exposure include: 1) does any smoker live in your household; and 2) are you exposed to smoke in your home or car? In the context of a cardiology practice, the question, “In the past 7 days, were you exposed to secondhand smoke where you live?” correlated significantly with serum cotinine levels (cotinine is a nicotine metabolite and biomarker of first- and second-hand tobacco exposure) and outperformed other questions asking about SHS exposure (32). Systematic assessment of SHS exposure should be incorporated into EHRs. Although EHRs routinely ask about current smoking, they rarely assess SHS exposure in a systematic way. Beyond screening for SHS exposure, cardiology clinicians are well-positioned to inform patients about the CV risk of SHS exposure and to recommend the adoption of smoke-free policies for home and car and the avoidance of other indoor venues where smoking is permitted (see Section 6.1.8.4., SHS Exposure).

## 6.2. Algorithm for Current Smokers

Actions for current smokers include these 4 tasks: 1) assessment; 2) advice to quit; 3) offer and provide treatment; and 4) follow-up.

**1. Assessment of Tobacco (Nicotine) Dependence.** The strength of an individual’s nicotine dependence is a key predictor of how likely the individual is to relapse after stopping smoking. A simple screen for nicotine dependence is to ask whether an individual smokes every day or only on some days. For treatment purposes, virtually all persistent daily smokers are nicotine dependent and are likely to benefit from

**TABLE 1** Heaviness of Smoking Index: 2 Questions to Assess a Smoker's Degree of Nicotine Dependence

How many cigarettes do you smoke?  
0: 10 or fewer  
1: 11-20  
2: 21-30  
3: ≥31

How soon after waking up do you smoke your first cigarette of the day?  
0: After 60 minutes  
1: 31-60 minutes  
2: 6-30 minutes  
3: within 5 minutes

Level of nicotine dependence is computed by adding the scores together as follows:

- 0-2 = low nicotine dependence
- 3-4 = moderate nicotine dependence
- 5-6 = high nicotine dependence

Adapted from reference (33).

pharmacological and behavioral treatment for smoking cessation. Nondaily smokers, some of whom previously smoked every day, may not have withdrawal symptoms when stopping tobacco use, but they may use cigarettes compulsively in certain situations and have great difficulty quitting. They should also be advised to quit smoking completely and offered assistance to do so, although the need for pharmacotherapy should be evaluated on a case-by-case basis.

Asking the 2 questions that comprise the Heaviness of Smoking Index is a simple, reliable, and validated test to assess the strength of a daily smoker's nicotine dependence (33) (Table 1). The Heaviness of Smoking Index has been shown to have equivalent or stronger validity in predicting relapse back to smoking after a quit attempt than other longer tests of nicotine dependence (e.g., Fagerstrom Test of Nicotine Dependence, the APA Diagnostic and Statistical Manual criteria for assess tobacco use disorder) (33). Understanding the strength of someone's nicotine dependence is important for tailoring the intensity of treatment or dose of pharmacotherapy recommended. Other indicators of nicotine dependence include early initiation of exposure to nicotine, difficulty reducing and/or refraining from smoking for extended periods of time (i.e., several hours or days), evidence of withdrawal symptoms upon abstinence from smoking, and continued use despite knowledge of harm from smoking or established health-related complications.

Other factors that influence the likelihood of relapse back to smoking include: an individual's degree of motivation to stop smoking; perceived confidence in the ability to stop smoking; presence of a comorbid psychiatric disorder (e.g., depression and anxiety); other substance use, especially heavy alcohol use; and living with a smoker. All of these factors should be considered in tailoring treatments for smokers to maximize success.

**2. Advice to Quit:** The second step is to provide strong, clear, personalized advice to the smoker to quit all tobacco use as soon as possible, with helpful phrases like, "As your doctor (or healthcare provider), I want you to know that quitting smoking now is the best way for you to improve your health." Ideally, the advice should be tailored to the individual's specific health situation and should emphasize the benefits of stopping smoking (e.g., financial savings, health benefits, behavioral control, setting an example for others), rather than focusing solely on the harms of continued smoking. For smokers who are post-myocardial infarction, the clinician can emphasize the rapid reduction in the chance of future CV morbidity and mortality by saying, for example, "Quitting smoking now is the best way for you to avoid another heart attack." After percutaneous coronary intervention, coronary artery bypass grafting, or interventions for peripheral artery disease, the clinician can emphasize the importance of quitting to preserve stent or graft patency.

**3. Offer Treatment and Connect to Resources.** The third step is to offer smoking cessation treatment, which translates into providing a pharmacotherapy prescription and actively connecting the patient to behavioral support resources. This can be done with a statement such as, "There are effective treatments to help smokers quit and I can help you identify the best one for you today." Patients are encouraged to set a quit date, usually within the next month, to provide a structure for the quit attempt.

**Pharmacotherapy:** Pharmacotherapy should be offered to every patient who is willing to accept it, with rare exceptions. It can also be started even in patients who are not ready to quit smoking immediately, because it can help motivate patients to reduce their smoking and increase the odds of them eventually making a quit attempt. Discussing and prescribing cessation medications is a critical role for clinicians. Prescriptions should be written even for over-the-counter medications because insurance plans might cover them, thereby reducing cost to the patient, reinforcing the importance of using the medication, and automatically documenting it in the patient's EHR. Choice of pharmacotherapy is discussed in Section 6.1.3., Treatment Options: Pharmacological Interventions.

**Behavioral support:** Either the clinician or office staff should proactively connect a smoker to his/her preferred form of behavioral support. The contents of these programs are described in Section 6.1.5., Treatment Options: Nonpharmacological Behavioral Interventions. Studies have shown that a clinician's active referral to a behavioral support program for smoking cessation is more effective than simply providing advice or information about these



**TABLE 2** Community-Based Behavioral Support Resources to Help Smokers Quit

Resource	Services Provided
Telephone Quitline 1-800-QUIT-NOW (1-800-784-8669)	<ul style="list-style-type: none"> <li>■ Counseling by telephone from a trained tobacco coach who offers support via a series of scheduled telephone calls before and after a smoker's quit date.</li> <li>■ Many quitlines also offer text messaging and web coaching support.</li> <li>■ Many quitlines also offer a free sample of nonprescription nicotine replacement products.</li> <li>■ Providers can directly refer to quitlines using fax or web enrollments. Quitline then contacts smoker directly to offer services.</li> </ul>
<a href="http://Smokefree.gov">Smokefree.gov</a> (National Cancer Institute website)	<ul style="list-style-type: none"> <li>■ SmokefreeTXT (text messaging program)</li> <li>■ QuitGuide (mobile phone app)</li> <li>■ Web-based information about quitting resources</li> </ul>
<a href="http://Becomeanex.org">Becomeanex.org</a> (Truth Initiative)	<ul style="list-style-type: none"> <li>■ Web-based support program that includes support from experts and an online community to help smokers quit</li> </ul>

resources passively to the patient (34). Options include a health center-based tobacco cessation program, if available, or free resources provided by telephone (e.g., 1-800-QUIT NOW) or online (e.g., [www.smokefree.gov](http://www.smokefree.gov), [Becomeanex.org](http://Becomeanex.org)). The patient should leave the visit with a set of freely available resources and a plan and time line for accessing the referred behavioral therapy (Table 2). For current smokers who decline the offer of treatment at the visit, treatments should be offered again at every subsequent visit because the motivation to stop smoking varies over time.

4. **Follow-Up.** Because a smoker's risk of relapse is highest in the first few days and weeks after making a quit attempt, a follow-up contact to monitor a patient's tobacco cessation treatment should occur within 2 to 4 weeks of the initial visit, either in person, by phone from the office, or via a patient portal in the EHR (e.g., MyChart). Close monitoring also demonstrates to patients that the clinician assigns a high priority to tobacco treatment and may encourage patients to sustain their effort to become smoke-free. Actions that should occur in follow-up contacts include assessing smoking status, asking about adherence and response to treatments, providing support and encouragement to remain or become smoke-free, and addressing any issues that have arisen in the interim (such as barriers or side effects from pharmacotherapy).

### 6.3. Treatment Options: Pharmacological Interventions

Pharmacotherapy acts synergistically with behavioral counseling to increase quit rates and should be encouraged for virtually all daily smokers and considered on a case-by-case basis for nondaily smokers (35). The U.S. Food and Drug Administration (FDA) has approved 5 nicotine replacement therapy (NRT) products as well

as bupropion and varenicline for smoking cessation. Meta-analyses and a recent large randomized controlled trial indicate that each of these medications is more effective than placebo in promoting smoking cessation for 6 months or more (36,37) and that each is safe for use in patients with CVD. Table 3 summarizes dosing, precautions, and adverse effects of the FDA-approved smoking cessation medications.

#### Nicotine Replacement Therapy

In the United States, NRT is available over the counter or by prescription as patches, gum, and lozenges, and by prescription only as a nasal spray and oral inhaler. NRT provides nicotine to reduce withdrawal symptoms, including irritability, anxiety, difficulty concentrating, dysphoria, hunger, weight gain, and sleep disturbances, which occur when a smoker stops smoking. However, NRT does not replicate the pleasurable effects of smoking, in part because the nicotine is absorbed more slowly and produces lower peak blood nicotine concentrations than cigarettes, thereby reducing the rewarding effects. NRT may also reduce the satisfaction from smoking a cigarette if there is a lapse.

Nicotine patches deliver nicotine in a sustained manner throughout the day and are the most convenient delivery system for reducing withdrawal symptoms. More rapidly absorbed forms of NRT, such as gum, lozenges, inhalers, and spray, relieve withdrawal symptoms more quickly than the patch and provide some of the satisfaction associated with smoking.

Each NRT product has about the same efficacy in clinical trials, increasing quit rates with risk ratios of ~1.6 compared with placebo in a meta-analysis (35). Consequently, the choice of NRT product can reflect a patient's preference. The patch is generally used as the primary product because compliance is greatest for patch, lower for gum or lozenge, and very low for spray and inhaler. Combining the nicotine patch with a more rapidly absorbed form of NRT is more effective than using a single product, with a risk ratio of 1.34 compared with use of a single product in a meta-analysis (35). Combination NRT is now considered the standard of care for using NRT and should be recommended as initial therapy when NRT is chosen.

Many NRT products are sold in different strengths. More dependent smokers do better with high doses of nicotine (recommendations in Table 3). Nicotine patches are typically marketed with doses that taper over 12 weeks, but clinical trials have not found that tapering improves cessation rates, so tapering is optional. Although the typical duration of treatment is 12 weeks, smoking cessation experts often treat smokers for longer periods, until the patient is confident that he or she will not return to smoking. No harm from long-term NRT use has been reported (36). Oral NRT products,

**TABLE 3 FDA-Approved Smoking Cessation Medications**

**1st line Medications for Tobacco Cessation Treatment\***

Drug (Available Doses)	How Sold (U.S.)	Dosing Instructions†	Administration	Common Side Effects	Advantages	Disadvantages
<b>Nicotine patch</b> 21 mg 14 mg 7 mg	OTC or Rx	<b>Starting dose:</b> 21 mg for ≥10 cigarettes per day. 14 mg for <10 cigarettes per day. After 6 weeks, option to taper to lower doses for 2-6 weeks. Use ≥3 months. After 6 weeks, continue original dose or taper to lower doses (either option acceptable).	Apply a new patch each morning to dry skin. Rotate application site to avoid skin irritation. May start patch before or on quit date. Keep using even if a slip occurs. If insomnia or disturbing dreams, remove patch at bedtime.	Skin irritation Trouble sleeping Vivid dreams (patch can be removed at bedtime to manage insomnia or vivid dreams)	Easiest nicotine product to use. Provides a steady nicotine level. Combination NRT therapy: Can add prn gum, lozenge, inhaler, or nasal spray to patch to cover situational cravings.	User cannot alter dose if cravings occur during the day.
<b>Nicotine lozenge</b> 4 mg 2 mg	OTC or Rx	If 1st cigarette is ≤30 minutes of waking: 4 mg. If 1st cigarette is >30 minutes of waking: 2 mg. Use ≥3 months.	Place between gum and cheek, let it melt slowly. Use 1 piece every 1-2 hours (Max: 20/day).	Mouth irritation Hiccups Heartburn Nausea	User controls nicotine dose. Oral substitute for cigarettes. May be added to patch to cover situational cravings. Easier to use than gum for those with dental work or dentures.	No food or drink 15 minutes prior to use and during use.
<b>Nicotine gum</b> 4 mg 2 mg	OTC or Rx	If 1st cigarette is ≤30 minutes of waking: 4 mg. If 1st cigarette is >30 minutes of waking: 2 mg. Use ≥3 months.	Chew briefly until mouth tingles, then 'park' gum inside cheek until tingle fades. Repeat chew-and-park each time tingle fades. Discard gum after 30 minutes of use. Use ~ 1 piece per hour (Max: 24/day).	Mouth irritation Jaw soreness Heartburn Hiccups Nausea	User controls nicotine dose. Oral substitute for cigarettes. May be added to patch to cover situational cravings.	Not chewed in same way as regular gum; requires careful instruction. Can damage dental work and be difficult to use with dentures. No food or drink 15 minutes prior to use and during use.
<b>Nicotine inhaler</b> 10-mg cartridge	Rx only	10 mg/cartridge. Each cartridge has ~80 puffs. Use ≥3 months.	Puff into mouth/ throat until cravings subside. Do not inhale into lungs. Change cartridge when nicotine taste disappears. Use 1 cartridge every 1-2 hours (Max: 16/day).	Mouth and throat irritation Coughing if inhaled too deeply	User controls nicotine dose. Mimics hand-to- mouth ritual of smoking cigarettes. May be added to patch to cover situational cravings.	Frequent puffing required.
<b>Nicotine nasal sprayer</b> 10 mg/ml (10 ml bottle)	Rx only	10 mg/ml. 0.5 mg per spray. Each bottle has ~200 sprays. Use ≥3 months.	Use 1 spray to each nostril. Use spray every 1-2 hours. (Max: 80/day).	Nasal and throat irritation Rhinitis Sneezing Coughing Tearing	User controls nicotine dose. Most rapid delivery of nicotine among all NRT products. May be added to patch to cover situational cravings.	Has the most side effects of all NRT products. Some users cannot tolerate local irritation to nasal mucosa.
<b>Varenicline (tablet)</b> 0.5 mg 1.0 mg	Rx only	Days 1-3: 0.5 mg/day. Days 4-7: 0.5 mg twice a day. Day 8+: 1 mg twice a day. Use 3-6 months.	Start 1-4 weeks before quit date. Take with food and a tall glass of water to minimize nausea.	Nausea Insomnia Vivid dreams Headache	Quit date can be flexible, from 1 week to 3 months after starting drug. Dual action: relieves nicotine withdrawal and blocks reward of smoking. Oral agent (pill).	Because of previous FDA boxed warning (now removed), many patients fear psychiatric adverse events, even though they are no more common than with other cessation medications.
<b>Bupropion sustained release (SR) (tablet)</b> 150 mg	Rx only	150 mg/day for 3 days, then 150 mg twice a day. Use 3-6 months.	Start 1-2 weeks before quit date.	Insomnia Agitation Dry mouth Headache	May lessen post-cessation weight gain while drug is being taken. Oral agent (pill).	Increases seizure risk: not for use if seizure disorder or binge drinking.

\*All are FDA-approved as smoking cessation aids and listed as a 1st line medication by U.S. Clinical Practice Guidelines (Fiore, 2008)

†Recommended duration of use for medications is at least 3 months, but extending dose to 6 months is frequently done to prevent relapse to tobacco use. Patch dosing differs slightly from FDA labeling.

FDA = U.S. Food and Drug Administration; NRT = nicotine replacement therapy; OTC = over the counter (no prescription required); Rx = prescription required.

such as gum or lozenges or inhalers (a cigarette-like plastic device), produce relatively low blood nicotine levels and require frequent use (once every 1 to 2 hours) to relieve withdrawal symptoms. Smokers tend not to use the product this frequently unless carefully instructed. Nicotine from oral products is absorbed through the buccal mucosa in the freebase form. Oral products are buffered to be alkaline, keeping nicotine in freebase form. Alkalinity increases the availability of pH-dependent “free base form” or “unprotonated” nicotine, thus enhancing absorption of nicotine through oral mucosa (37). Drinking acidic liquids such as coffee within 10 minutes of using oral NRT acidifies the mouth and impairs nicotine absorption. Smokers should be advised to avoid such beverages before and during product use. Smokers can use an oral NRT product before drinking the morning coffee to avoid impairing nicotine absorption and proactively manage cravings.

#### **Efficacy and Safety of NRT in Smokers With CVD**

The efficacy of NRT for smoking cessation is well-established in the general population and in patients with stable CVD, but it has yet to be demonstrated in clinical trials of smokers with acute coronary syndrome (ACS) (38). No studies of the effects of combination NRT products in smokers with CVD have been reported, but there is no *a priori* reason why NRT would not be effective in these clinical subgroups.

With regard to safety, nicotine could potentially contribute to the worsening of CVD through its sympathomimetic properties (39), by constriction of diseased coronary arteries, or by promoting coronary spasm, pro-atherogenic lipid profiles, insulin resistance, and pro-arrhythmic effects. Nicotine may also contribute to endothelial dysfunction and myocardial fibrosis (39). However, nicotine levels from NRT are generally much lower than those from cigarette smoking, and NRT does not expose users to combustion products in cigarette smoke that are involved in CVD pathogenesis. Controlled trials, longitudinal studies, and case-control studies of NRT in patients with CVD report no increase in adverse CV events compared with those treated with placebo (40-43). A meta-analysis of NRT studies found an increase in CV symptoms such as tachycardia and arrhythmia, which is expected from the sympathomimetic effects of nicotine, but no increase in major CV events (death, myocardial infarction, stroke) (44). One can conclude that although NRT is probably not harmless, it is much less harmful than cigarette smoking.

#### **Bupropion**

Bupropion simulates some of nicotine’s effects on the brain by blocking neuronal uptake of dopamine and, to a lesser extent, norepinephrine (45). It relieves nicotine withdrawal symptoms and reduces the reward from smoking a cigarette. Available as a generic drug,

bupropion is FDA-approved both as an antidepressant and for smoking cessation. Sustained-release bupropion is similar in efficacy to NRT and is effective in smokers with and without depression (46,47). Bupropion reduces seizure threshold and should not be used in patients who are at increased risk for seizures.

Bupropion is approved for 12 weeks’ use, but extended treatment for 1 year reduced the relapse rate after initial cessation in 1 study (48). Combination therapy with bupropion and nicotine patch is more effective than bupropion alone or NRT alone (38). Bupropion has also been studied in combination with varenicline, showing significantly enhanced quit rates at 12 and 26 weeks but not at 52 weeks (49).

#### **Efficacy and Safety of Bupropion in Smokers With CVD**

Bupropion is efficacious in smokers with stable CVD (50) but has not shown efficacy in smokers hospitalized with ACS (51-53), likely because hospitalization is often too brief to allow bupropion to achieve active drug levels before discharge. Clinical trials of bupropion in patients with CVD have found no evidence of increased CV events compared with placebo (50-52). The CATS study (Cardiovascular Safety of Varenicline, Bupropion, and Nicotine Patch in Smokers), involving more than 8,000 smokers, found no evidence of an adverse effect on blood pressure and no increased risk of CV events in smokers treated with bupropion compared with NRT or placebo (54).

#### **Varenicline**

Varenicline is a partial agonist at the  $\alpha 4\beta 2$  nicotinic cholinergic receptor that mediates brain dopamine release and that is believed to be the primary mediator of nicotine addiction (55). As a partial agonist, varenicline activates the nicotine receptor, producing about 50% of the maximal effects as nicotine, and thereby reducing the intensity of nicotine withdrawal symptoms. At the same time, varenicline binds tightly to the nicotine receptor, preventing receptor binding by nicotine from cigarette smoke and reducing the rewarding effects of smoking. Nicotinic receptor antagonism from varenicline results in reduced pleasure from smoking and is believed to explain why some smokers reduce their cigarette consumption even before their designated quit day and why varenicline may reduce the likelihood of transition that an individual who slips and smokes a cigarette will return to regular smoking.

Varenicline is proven to be more effective in promoting smoking cessation than single NRT or bupropion in several clinical trials (56). The largest was the EAGLES randomized controlled trial (Evaluating Adverse Events in a Global Smoking Cessation Study), which included over 8,000 smokers (46). It compared varenicline, bupropion, nicotine patch, and placebo given for 12 weeks along with brief counseling. Continuous quit rates from weeks 9 to 24

were: varenicline (21.8%); bupropion (16.2%); nicotine patch (15.7%); and placebo (9.4%). Quit rates were higher in smokers without psychiatric illness than in those with psychiatric illness, but the relative efficacy across drugs was similar. Extending varenicline for 6 months to prevent relapse is effective and has been approved by the FDA (57). Meta-analyses suggest that varenicline and combination NRT are similarly efficacious as stand-alone therapies, making these 2 approaches first-line recommendations for smoking cessation in smokers with CVD (58).

The efficacy of a combination of varenicline and nicotine patch to promote smoking cessation has been studied with mixed results (59,60). Although the mechanism of benefit for adding nicotine to varenicline is not clear, the combination is generally well-tolerated and is an option for smokers who do not succeed with the individual products alone.

Case reports of possible neuropsychiatric effects of varenicline, including depression, psychosis, and suicide, were received by the FDA soon after varenicline entered the market in 2006 (61). In 2009, the FDA required a black box warning for such events, leading many physicians and patients to be reluctant to use this medication. However, these concerns were not confirmed by the results of the EAGLES trial, and the FDA removed varenicline's black box warning in 2016. Among more than 8,000 smokers in the EAGLES trial, over one-half of whom had stable mild-moderate psychiatric disease, there was no evidence of more frequent neuropsychiatric side effects with varenicline than with NRT or placebo (46). For all medications in the trial, adverse neuropsychiatric effects were more frequent among smokers with a history of psychiatric disease than among those without.

#### **Efficacy and Safety of Varenicline in Smokers with CVD**

Varenicline is more effective than placebo in smokers with stable CVD and ACS (62-64). In the EVITA trial (Evaluation of Varenicline in Smoking Cessation for Patients Post-Acute Coronary Syndrome) 12 weeks of varenicline initiated in hospitalized patients with ACS produced significantly greater smoking cessation rates compared with placebo—a finding that persisted for 52 weeks (point prevalence abstinence 39.9% vs. 29.1%) (62,64). The possibility of adverse CV effects of varenicline has been raised because it has nicotine-like effects (65,66). A large clinical trial of varenicline in smokers with stable CVD found low CV event rates and no significant differences from placebo (63), but a meta-analysis reported a small but significant increased risk of CV adverse events with varenicline (67). Subsequently, several larger meta-analyses, a large retrospective cohort study, and a clinical trial among smokers with ACS all found no

increase in CV risk with varenicline use (62,64,68-71). A recent observational study reported a 34% increase of CV adverse events by subjects while taking varenicline compared with a period preceding the start of varenicline, but the absolute risk was very low, estimated to represent an absolute increase of 3.95 CV adverse events attributable to varenicline per 1,000 varenicline users (72,73). Furthermore, limitations of this report, including the potential for residual confounding in an observational study, have been pointed out (73). The CATS trial examined CV events in 8,058 smokers and found no evidence of increased events compared with bupropion, nicotine patch, or placebo (54). These smokers were not selected for having CVD but did have a moderate prevalence of risk factors that was similar to the general population of middle-aged smokers. Given the overall data, the committee considered varenicline to be safe for use in stable CVD and, with caution, in patients with ACS (see "Pharmacotherapy Recommendations" section and Table 4).

#### **Preloading Pharmacotherapy**

Medication preloading involves starting pharmacotherapy while the smoker is still smoking, with the intent of reducing the satisfaction from smoking, reducing the number of cigarettes smoked per day, and enhancing the likelihood of quitting smoking subsequently. Clinical trials of NRT preloading have had mixed results (74,75). Separate trials of NRT and of varenicline with a flexible quit date have been promising (76). The appeal of the preloading approach is that a smoker who would like to quit but is not ready to set a quit date can be prescribed a medication to reduce tobacco use and make a future quit attempt easier.

#### **Gradual Reduction**

Another approach for smokers not ready to quit abruptly is a gradual reduction of the number of cigarettes smoked per day. A meta-analysis of gradual reduction versus abrupt quitting found similar quit rates (77). A subsequent randomized trial that compared abrupt quitting versus reducing cigarette smoking for 2 weeks prior to quitting found that abruptly quitting cigarette was more effective. It is worth noting that in this trial, a substantial number of those in the gradual reduction group were also successful in quitting. In contrast, varenicline-assisted gradual reduction over 3 months before the quit date was shown to enhance quit rates over placebo in a study that enrolled smokers who were not ready to quit in the next 30 days (78).

#### **Other Smoking Cessation Medications**

In controlled clinical trials, nortriptyline and clonidine have been shown to enhance smoking cessation, but they are not FDA-approved for this indication and are rarely used. Nortriptyline's potential for QT prolongation in patients with CVD should also be considered. Cytisine—a

**TABLE 4** Recommended Pharmacotherapy for Smoking Cessation in Patients with CVD

	Outpatient With Stable CVD	Inpatient With ACS
1st line	Varenicline OR combination NRT*	<i>In-hospital to relieve nicotine withdrawal:</i> Nicotine patch OR combination NRT* <i>At discharge:</i> Combination NRT or varenicline†
2nd line	Bupropion OR single NRT product	<i>At discharge:</i> Single NRT product
3rd line	Nortriptyline‡	Bupropion§
If single agent is insufficient to achieve abstinence	Combine categories of FDA-approved drugs: Varenicline + NRT (single agent) Varenicline + bupropion Bupropion + NRT (single agent)	n/a

\*Combination NRT comprises a nicotine patch plus the patient's choice of nicotine gum or lozenge or inhaler or spray.

†Some committee members planning to use varenicline would start it in-hospital; others would not start until discharge. Regardless, continue nicotine patch or short-acting form for 1 week to manage nicotine withdrawal symptoms during up-titration of varenicline dose.

‡Nortriptyline is not FDA-approved for smoking cessation indication and there are few data on use in patients with CVD.

§Bupropion is listed as 3rd line because of no evidence of efficacy when started during hospitalization for acute ACS or acute MI. However, there are no special safety concerns for bupropion in this setting.

ACS = acute coronary syndromes; CVD = cardiovascular disease; FDA = U.S. Food and Drug Administration; MI = myocardial infarction; NRT = nicotine replacement therapy.

partial agonist of nicotinic acetylcholine receptors with an affinity for the  $\alpha 4\beta 2$  receptor subtype—has a mechanism similar to varenicline. It has been used as a smoking cessation aid in Eastern Europe for decades but is not approved for use in the United States despite calls for licensing it worldwide after 2 randomized trials found it to be more effective than placebo for short- and long-term abstinence (79,80).

### Pharmacotherapy Recommendations

All FDA-approved smoking cessation medications (NRT, bupropion, and varenicline) promote smoking cessation and are tolerable and effective options for smokers with stable CVD. In the general population of smokers, meta-analyses indicate that varenicline and combination NRT are more effective than bupropion or single NRT products, making these 2 approaches first-line recommendations for smoking cessation, including in smokers with CVD (Table 4). Single NRT and bupropion are considered second-line therapies for individuals with CVD who are not able or willing to use first-line choices. In the general population of smokers, combinations of these classes of medications (NRT plus varenicline or bupropion, or varenicline plus bupropion) are supported by a smaller body of evidence, but these combinations are tolerable to patients and have generated promising efficacy data. The committee recommended using combinations of agents for smokers who have only a

partial response and fail to achieve complete tobacco abstinence with individual agents.

Fewer data about the efficacy and safety of cessation medications for smokers with unstable CVD are available to guide recommendations. Varenicline has demonstrated efficacy in a randomized trial of smokers hospitalized with ACS who started the medication in the hospital; no significant difference in major CV events was found between the varenicline and placebo groups over 52 weeks. In contrast, bupropion was not effective for cessation among hospitalized smokers with acute MI or ACS in 2 trials (51,52). No randomized trial has tested the efficacy or safety of NRT in ACS. However, in light of the evidence on equivalent efficacy of combined NRT and varenicline in the general population of smokers, the committee recommends either treatment for smokers with ACS. The patient's ability to afford the medications can be a consideration. Nonprescription forms of NRT are not uniformly covered by health insurance. Varenicline is often covered, but with copay and sometimes with restrictions.

Committee members differed regarding when to initiate varenicline in patients with ACS. Some recommended starting varenicline in the hospital (accompanied by NRT as needed to manage acute nicotine withdrawal symptoms while varenicline is titrated to full dose), while others recommended starting varenicline at or after discharge. Those favoring initiation in the hospital argued that starting immediately generates effective blood levels more rapidly and having varenicline listed on the discharge medication list maximizes the likelihood of patient adherence after discharge. Other committee members felt that varenicline should start only at or after discharge because CVD has been stabilized before that time. These committee members were concerned about varenicline's tolerability in inpatients who are often receiving loading doses of antiplatelet agents that also cause nausea and other gastrointestinal symptoms. As the discharge medication, these clinicians preferred using NRT, noting that it achieves steady-state dose more rapidly than varenicline.

Traditionally, medications are prescribed to smokers who plan to quit and are willing to set a quit date in the next month/near future. However, given the magnitude of harm from continued tobacco use in the presence of CVD, existing data support the use of pharmacotherapy in alternate ways, including preloading of pharmacotherapies or use as tools to help smokers reduce tobacco use immediately with the goal of achieving complete abstinence subsequently. Finally, most of the clinical trials demonstrating the efficacy of these medications provided behavioral counseling along with pharmacotherapy, highlighting the importance of providing behavioral support either in office or by referral to a

**TABLE 5** Examples of Behavioral Interventions for Nicotine Dependence

Treatment	Examples
Cognitive behavioral skills training	Instructions, modeling, rehearsal, and feedback to teach smokers how to change their smoking behavior. Examples include: <ol style="list-style-type: none"> <li>1. Self-monitoring to identify triggers for smoking. Smokers are asked to keep a real-time record of the times, places, and situations in which smoking occurs.</li> <li>2. Behavioral rehearsals, such as practice quit attempts and practicing how to respond to a lapse back to smoking.</li> <li>3. Practicing self-control over smoking triggers. Avoiding triggers (e.g., putting away ashtrays, abstaining from alcohol), altering trigger situations (e.g., taking work breaks in a place in which you cannot smoke), using substitutes in place of smoking (e.g., gum, candy, a stress ball, exercise), and refocusing thoughts when cravings arise (e.g., statements of self-determination such as "I can do this"; delay statements such as "wait a minute or 2 and the urge will pass").</li> <li>4. Assertiveness training to help smokers better handle social situations likely to trigger cues to smoking.</li> <li>5. Instruction and training (e.g., deep breathing, yoga, mindfulness training) for handling stress and negative emotions that are often linked to smoking urges.</li> <li>6. Instructions on how to use medications properly to increase medication adherence and quit rates.</li> <li>7. Biofeedback to smokers using a simple breath test measuring expired carbon monoxide to educate patients about immediate health risks from smoking and enhance motivation for cutting down and quitting.</li> <li>8. Facilitated discussion with a group of smokers to share effective behavior change experiences and challenges.</li> </ol>
Motivational interviewing	Motivational interviewing is a goal-oriented, client-centered counseling style that aims to elicit behavior change by helping smokers explore and resolve ambivalence about making changes in their behavior. The method relies on counselors eliciting from the clients their own motivations for change, rather than imposing a treatment plan on the smoker.
Incentives	Incentives, usually provided as cash or vouchers, can be used to motivate smokers to try to quit and to reward them for making changes in their smoking behaviors.

Adapted from references 81-85.

community-based resource along with a pharmacotherapy prescription.

**6.4. Treatment Options: Nonpharmacological Behavioral Interventions**

Nonpharmacological treatments for tobacco dependence include behavioral skills training using cognitive behavioral therapy techniques, motivational interviewing, and incentives to motivate and reinforce behavior change (29,81-85). These strategies are often used in combination. Behavioral treatments, based on principles of behavioral and cognitive psychology, attempt to bolster smokers' self-control over their smoking behavior by helping them change unhelpful cognitions (i.e., thoughts, beliefs, and attitudes) and by structuring efforts to change smoking behavior through a range of techniques such as goal setting (e.g., setting a quit day), self-monitoring (e.g., record keeping to identify times and places where at which someone smokes), rewards, and skills training to help smokers learn, practice, and implement techniques to help them resist urges to smoke after quitting (81). Motivational interviewing is a goal-oriented, client-centered counseling style that attempts to help smokers change behavior by exploring and resolving ambivalence about making changes in their behavior.

A recent randomized trial reported that addition of financial incentives to free cessation aids (NRT, bupropion, varenicline) or free e-cigarettes resulted in a significantly higher rate of sustained (6 months) smoking abstinence than did free cessation aids or free e-cigarettes alone. Smokers who received only information and motivational text messages with free cessation aids or e-cigarettes had a significantly lower sustained smoking abstinence rate (86). Financial incentives to promote quit

attempts or achieve tobacco abstinence have not been widely implemented in practice. Examples of how some of the above strategies are applied in smoking cessation interventions are described briefly in Table 5.

A clinician's advice to stop smoking and brief guidance provided in office practice can be made more effective by connecting smokers with other resources available to the treatment team. This may include a tobacco treatment specialist in the healthcare system or a referral to community-based resources (Table 2). Automated systems that link smokers to specialized treatment services can improve outcomes by ensuring all smokers receive assistance to stop smoking (87,88). Behavioral treatments work best when combined with pharmacological smoking cessation treatments and delivered by trained tobacco treatment specialists over multiple face-to-face and/or phone sessions with smokers (29,89-91).

Table 6 describes the delivery formats of different stop-smoking interventions with evidence of effectiveness (89). The most effective delivery formats for providing tobacco cessation treatment are widely underutilized because most clinicians do not have specialized training in delivering such treatment (94). In addition, healthcare systems are inconsistently and inadequately reimbursed for delivering multisession behavioral treatments to smokers. Consequently, brief interventions consisting of advice to stop smoking delivered by a doctor or nurse combined with pharmacotherapy is typically the most common way smokers obtain assistance to stop smoking. Nevertheless, even just advice to quit from a doctor has a positive effect on increasing quit rates (95).

For more complicated cases (i.e., patients not ready to quit, high nicotine dependence, comorbidities), smokers benefit by being connected to providers who have

**TABLE 6 Delivery Format of Stop-Smoking Interventions With Evidence of Effectiveness**

Description of Intervention	Delivery Format	Evidence of Effectiveness
Group support with multiple sessions facilitated by a trained smoking cessation specialist plus pharmacotherapy	Group in-person	When properly implemented, increases quit rates by 300% compared with unassisted quitting.
Individual support with multiple counseling sessions with a trained specialist in smoking cessation, plus pharmacotherapy	Individual in-person	When properly implemented, increases quit rates by 200%-300% compared with unassisted quitting.
Telephone support with multiple counseling sessions with a trained specialist in smoking cessation plus pharmacotherapy	Individual by phone	When properly implemented, increases quit rates by 50%-100% compared with unassisted quitting.
Brief advice delivered by a doctor or other healthcare provider, plus pharmacotherapy	Individual in-person	When properly implemented, increases quit rates by 50% compared with unassisted quitting. Adding follow-up visits/calls can increase quit rates.
Support using mobile phones for smoking cessation. Text messaging, in which smokers receive text messages to support quitting, is the simplest option and does not require a smart phone. Apps that use smart phone technology allow for more complex interaction-based treatments. Some apps are set up to help smokers monitor their smoking behavior and tailor treatment recommendations accordingly; others offer reminders for taking medications; and some can be used to establish reward systems with biofeedback.	Phone	Text messaging increases quit rates by 70% when used alone or as an adjunct to other treatment approaches (92,93). The evidence supporting the effectiveness of smartphone apps is currently limited. On a practical level, not everyone has access and/or the ability to utilize mobile phones, especially apps that require smart phone technology.
Websites that provide information on smoking, tips and tools on how to stop smoking, and links to other treatment resources. <a href="http://www.smokefree.gov">www.smokefree.gov</a> provides an easy-to-navigate website with useful information to help smokers quit.	Online	As an adjunct to other treatment approaches, online systems may be useful. However, as a stand-alone treatment, there is limited evidence that online systems are very effective in increasing quit rates.
Pamphlets and books offering advice to smokers on how to quit.	Written	As an adjunct to other treatment approaches, written materials may be useful. However, there is little evidence that written materials (e.g., self-help guides) are effective in increasing quit rates when used as a stand-alone treatment.

Adapted from reference (89).

received specialized training in the use of behavioral/psychosocial therapies and who can work with patients over multiple sessions by phone or in person (96). The Association for the Treatment of Tobacco Use Dependence (ATTUD) is a nonprofit organization that has developed core competencies for training tobacco treatment specialists (<https://attud.org/>) and has a network of 19 certified programs to train healthcare professionals to deliver specialized tobacco treatment services.

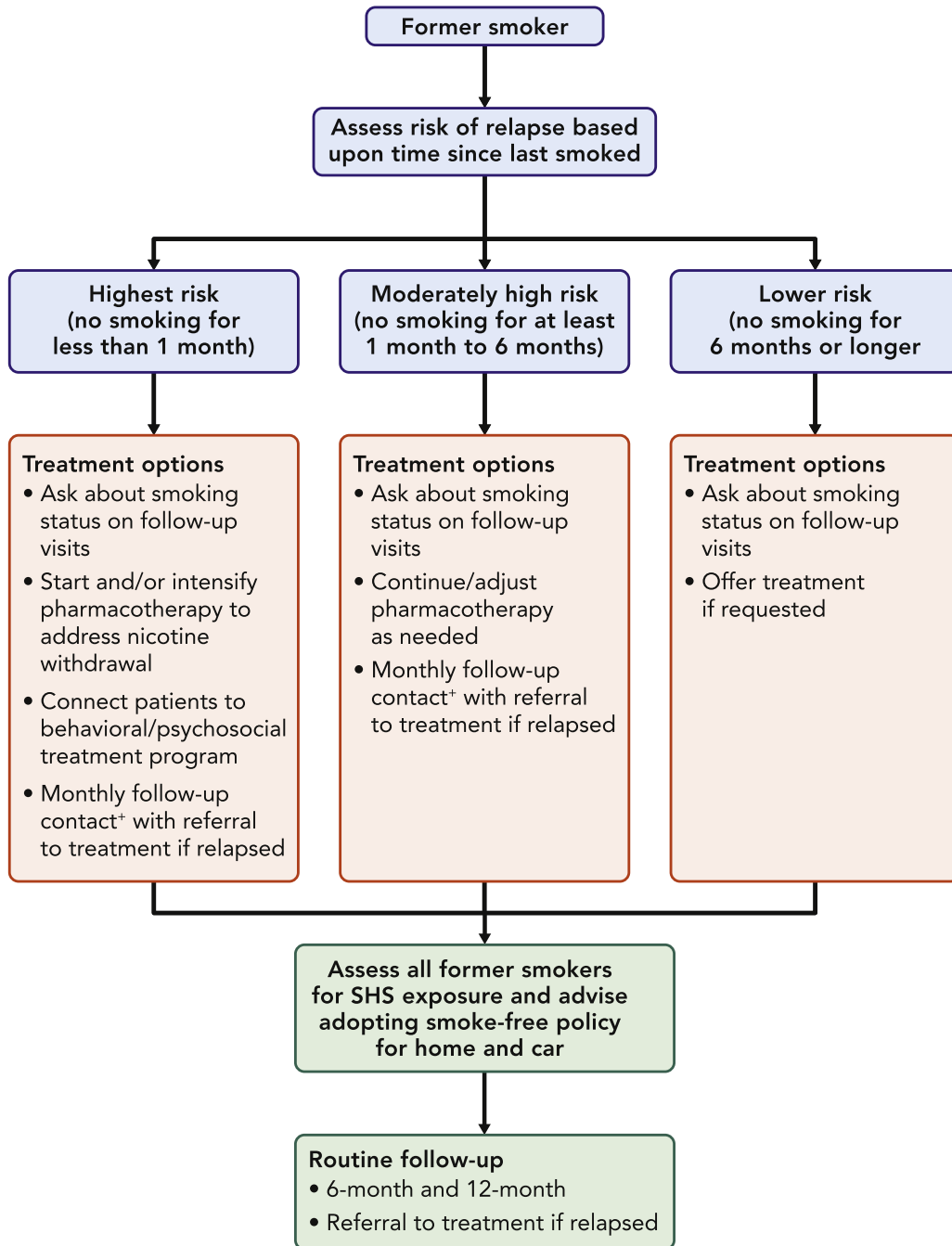
### 6.5. Treatment Algorithm for Former Smokers

Former smokers should receive treatments based on their likelihood of returning to smoking as shown in the Algorithm for a Former Smoker (Figure 2). Determining the risk of relapse to smoking is the key assessment step for former smokers (97-100). Relapse risk is assessed by asking how much time has passed since the individual's last use of tobacco products. Most relapses occur within days to weeks after initiating a quit attempt. The risk of relapse remains high for the first month and declines rapidly over the next 3 months, but relapses still do occur even after 1 year of abstinence from smoking (97-99,101-103). Another useful question for assessing relapse risk is to ask how confident a smoker is that he/she will stay quit for the next year. Practically, this can be done using a 1 to 10 scale, where 1 indicates "not at all confident" and 10, very confident. This measure, called self-efficacy, is a strong independent predictor of long-term cessation success in clinical trials (104).

Individuals using smoking cessation medications should be encouraged to continue use for at least 3 months. Extended use of medications for up to 6 months has been shown to increase long-term abstinence (36,57). Follow-up contacts with the smoker, at least monthly for the first 6 months, are recommended. Such contacts can reinforce the message to remain smoke-free and allow the clinician to both assess whether additional medication is needed to manage nicotine withdrawal and determine whether the patient is struggling and requires linkage to more-specialized tobacco treatment resources (29,81). Contact can be made by sending e-mail or text messages, having office staff call the patient, and addressing smoking routinely at all office visits.

Patients who are abstinent at follow-up contacts deserve praise for their success. For patients who have had a lapse (i.e., smoke a few cigarettes) or relapse (i.e., returned to regular smoking), the clinician should reframe the smokers' self-perception as having failed, pointing out that abstaining for even a short time represents a partial success from which the smoker can learn lessons for future quit attempts. It is helpful to discuss factor(s) that might have precipitated the lapse/relapse, reassess treatment options, and assess willingness to make another quit attempt (105,106). Patients using smoking cessation medications benefit by continuing to use them even after a lapse so long as they are committed to quit (107).

**FIGURE 2** Algorithm for a Former Smoker



+ reassess by connecting with the patient within ~ 1 month via either a face-to-face contact during an office visit, or by sending MyChart query, e-mail or text message, or calling the patient on the phone.



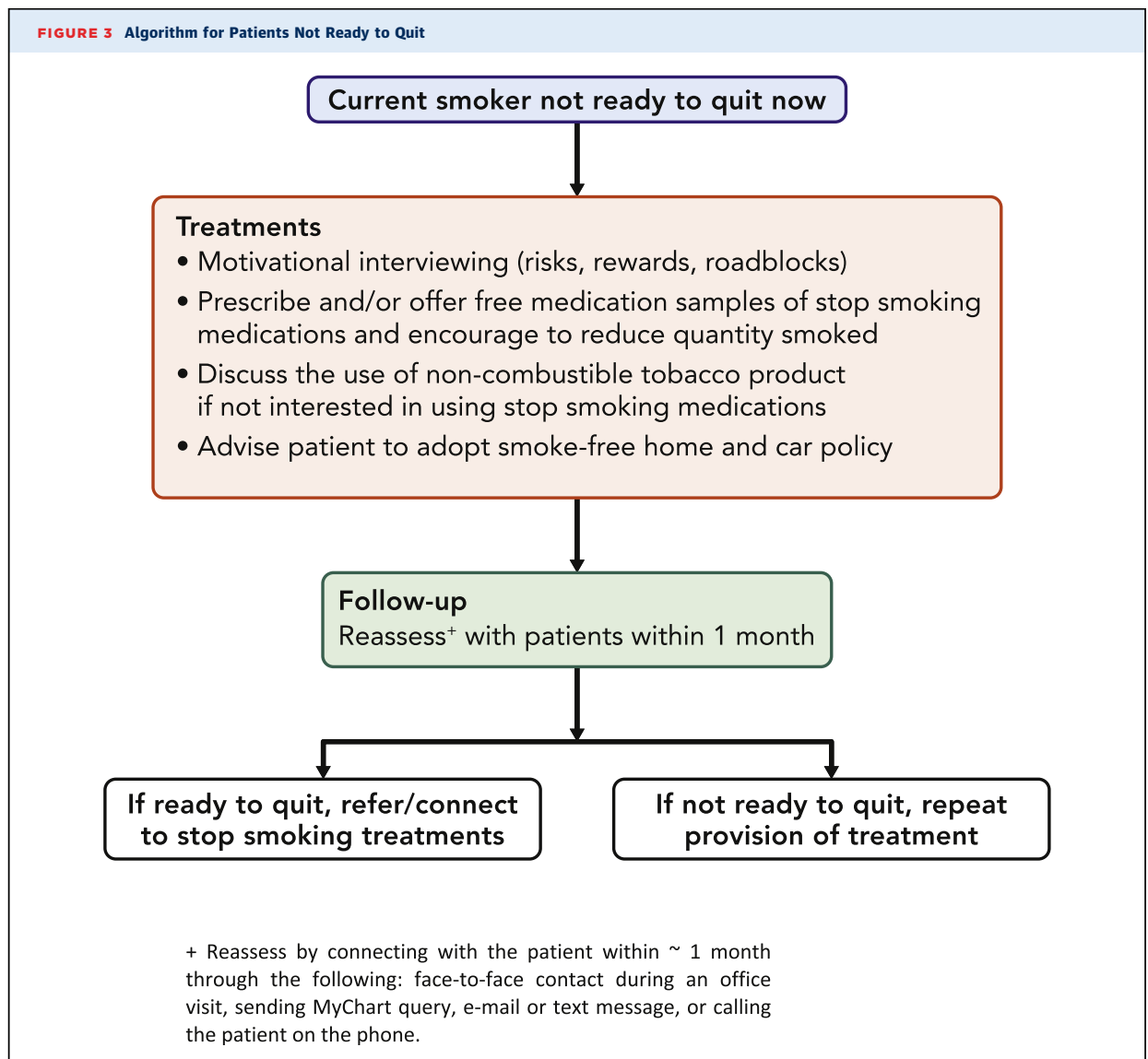
### 6.6. Treatment Algorithm for Patients Not Ready to Make a Quit Attempt

Many smokers, despite their general desire to quit, may be unwilling to set a quit date at a visit (108). Smokers who are not currently ready to accept help to quit should receive at least one of two evidence-based motivational treatments: 1) motivational interviewing; and 2) provision of smoking cessation medications as part of a plan to gradually cut back on smoking (Figure 3).

Emerging evidence suggests that motivational interviewing, a nonconfrontational discussion of the pros and cons of changing behavior, can increase quit attempts among smokers initially unwilling to quit (83,109). A counselor asks open-ended questions to elicit a smoker's understanding of their own risks from smoking, rewards

(benefits) of quitting, and roadblocks (barriers to quitting) (29). Healthcare providers with a variety of clinical backgrounds can be trained to deliver motivational interviewing through programs such as those certified by ATTUD ([www.attud.org/](http://www.attud.org/)).

Reducing cigarettes per day via cessation medication in the setting of continued smoking or suggesting behavioral strategies (e.g., delaying the time interval between cigarettes) can also increase later quit attempts and abstinence (110-113). Reducing cigarette consumption allows a smoker to reduce exposure to cigarette cues, provides an opportunity to practice substitute behaviors and coping skills to avoid smoking, and bolsters self-efficacy for quitting. Cigarette reduction may also decrease the severity of withdrawal during quit attempts. Smoking



reduction predicts later quitting success (114,115). However, reduction does not substantially reduce the excess CV risk associated with tobacco use because of the nonlinear relationship between tobacco smoke exposure and CVD events: a low level of cigarette smoking is associated with a disproportionately large increase in excess CV risk (10,11).

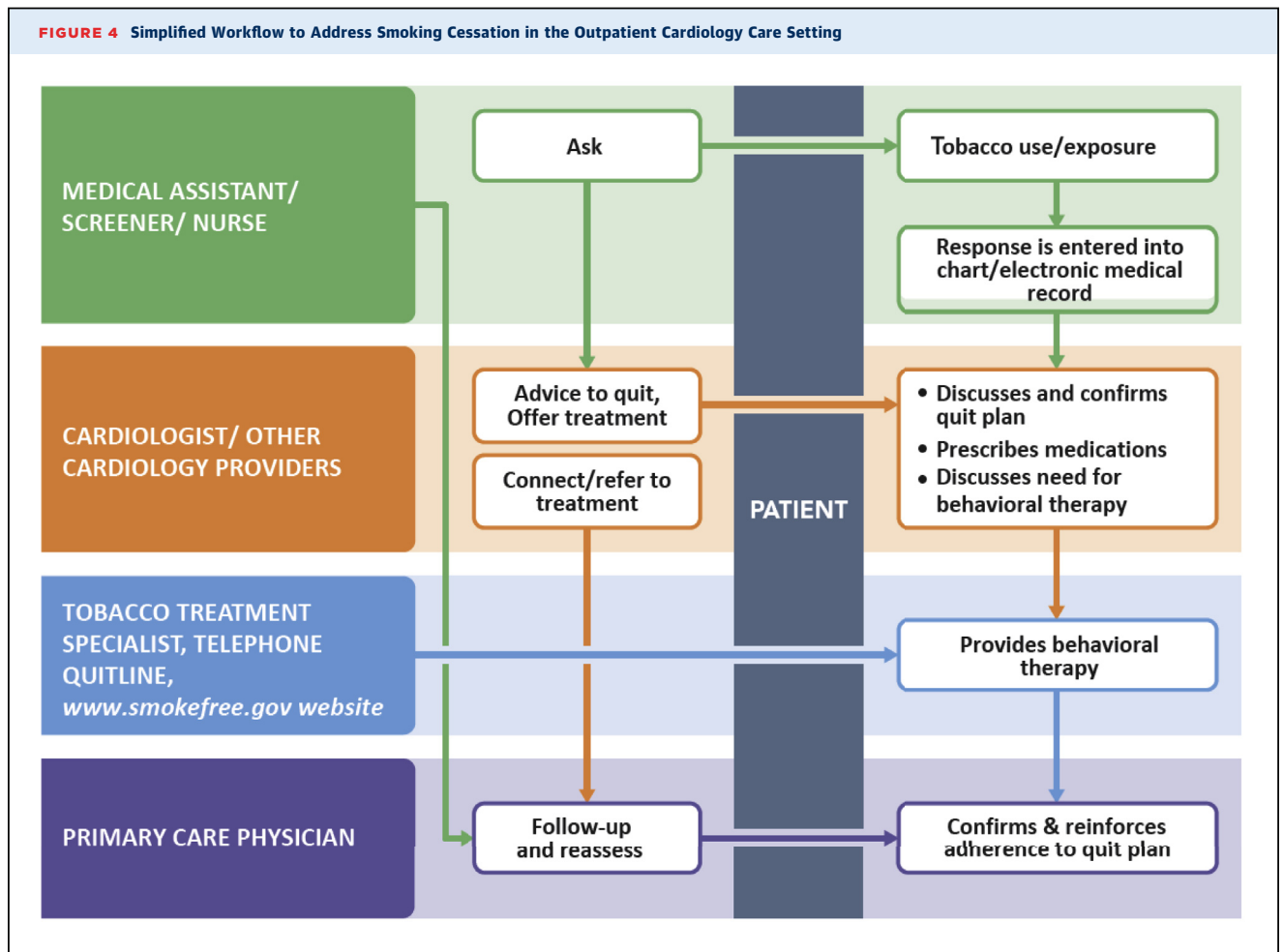
Smokers not ready to quit may ask about alternative nicotine products such as e-cigarettes. Guidance on e-cigarettes is provided in Section 6.9.2. Smokers who are not willing to attempt cessation should be advised to avoid exposing others to secondhand smoke by adopting smoke-free policies for their homes and cars.

### 6.7. Delivery of Tobacco Cessation Therapy in the Outpatient Cardiology Care Setting

Cardiologists may find delivering tobacco cessation therapy to be more challenging than addressing other CVD risk factors for several reasons related to the fact that tobacco use is a chronic relapsing addictive disorder. Cardiologists may be discouraged by a misperception that

patients who express normal ambivalence to making behavior changes lack motivation to quit tobacco. They may be frustrated by relapses to smoking that occur as a normal consequence of the quitting process. Consequently, cardiologists may regard tobacco treatment to be solely the responsibility of the primary care physician or ancillary support staff. However, delivering tobacco cessation therapy is an important element of contemporary cardiology practice as this intervention positively affects progression of disease and improves outcome in patients with CVD.

Figure 4 outlines a simplified workflow to address tobacco cessation in the outpatient cardiology care setting. In brief, a patient is initially asked about tobacco use and secondhand smoke exposure by a medical assistant/screener. The information is documented in the EMR or other health record, and patients who are current or former smokers are flagged for the cardiology provider's (cardiologist, cardiology nurse practitioner, or cardiology physician assistant) attention. The cardiology provider assesses the patient's nicotine dependence (current



**TABLE 7** National Quality Forum Tobacco Treatment Outpatient Quality Measures

Measure Description	Percentage of patients age 18 years and older who were screened for tobacco use 1 or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.
Part A	Percentage of patients age 18 years and older who were screened for tobacco use 1 or more times within 24 months.
Part B	Percentage of patients age 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention.
Part C	Percentage of patients age 18 years and older who were screened for tobacco use 1 or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.

Adapted from reference (116).

smokers) or risk of relapse (former smokers), provides firm advice to stop tobacco use, and offers to help make a plan to quit. The cardiology provider's primary role in treatment delivery is to discuss medication options with the patient and, considering the patient's preferences, select an appropriate product (or a combination) and prescribe the medication as needed. The cardiology provider should also emphasize to the patient the critical role of using behavioral support when quitting smoking. In most cases, the cardiologist will not provide extensive support during the visit but will previously have worked with office staff to ensure a plan exists for staff to make an explicit connection to a behavioral support resource. Depending on local resources, referral might be made to a tobacco treatment specialist or nurse in the office or hospital, to the free state telephone quitline, and/or to text messaging and other resources found at the [www.smokefree.gov](http://www.smokefree.gov) web site. A medical assistant or administrative staff or nurse in the cardiology practice can: 1) arrange an appointment for a tobacco treatment specialist; and/or 2) make a fax or electronic referral to the quitline and help the patient sign up with the [smokefree.gov](http://smokefree.gov) website to receive text messages; and 3) consider making an appointment with the primary care physician for follow-up. The smoker should leave the office with a prescription for a smoking cessation medication(s) and an explicit plan for connection to behavioral support resource. If logistics and resources allow, the medical assistant or nurse from the cardiology practice can make follow-up calls to the patient to assist in monitoring and compliance by following algorithms as outlined previously.

Focusing on measuring quality efforts in a cardiology outpatient practice can be an effective way to drive performance on the assessment and treatment of tobacco use. National Quality Forum 0028—Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention is a three-part quality measure (Table 7). National

Quality Forum 0028 is included in the Cardiology Specialty Measures Group in the Centers for Medicare and Medicaid Services Quality Payment Program Merit-Based Incentive Program (Centers for Medicare and Medicaid Services ID: CMS138v6). It is a mandatory measure for large groups of clinicians who report to the Merit-Based Incentive Program through the web interface.

## 6.8. Special Clinical Settings

### 6.8.1. Hospitalized Smokers

Hospitalization, especially for a tobacco-related disease, provides a unique opportunity to promote smoking cessation (117). The development of a serious illness, especially CHD, makes the risks of tobacco use personally salient. At the same time, admission to the smoke-free environment of a hospital requires temporary tobacco abstinence and provides an opportunity to receive assistance and initiate a quit attempt. Among hospitalized smokers, starting smoking cessation counseling in the hospital and continuing it for at least 1 month after discharge increases long-term quit rates by 37% (117). A cardiologist can be a champion on a team of providers who ensure that each hospitalized smoker's tobacco use is assessed and that current smokers have nicotine withdrawal actively treated during the inpatient stay and are offered advice to quit and assistance to make a plan to remain smoke-free after discharge.

The Joint Commission used this evidence to develop a 3-item tobacco quality measure set for U.S. hospitals (118) that the National Quality Forum endorsed (Table 7). Use of these measures is not mandatory for hospitals, but the committee recommends that all hospitals adopt the measure set, which has been demonstrated to be feasible to implement (119).

The Tobacco Measure Set directs hospitals to document these actions (Table 8):

1. **TOB-1: Assess tobacco use status of all admitted patients.** The guideline defines smoking a cigarette in the 30 days before admission as current smoking. This is a broader definition of current smoking than usual (see Section 4, Assumptions and Definitions). A broader definition was used because individuals may refrain temporarily from smoking during an illness that may precede a hospital admission. The strategy used by most hospitals is to build this question into the templated electronic form routinely completed by clinical staff to admit a patient.
2. **TOB-2: Offer tobacco cessation treatment in the hospital to all current smokers.** Both medication and counseling must be offered. To minimize the discomfort of nicotine withdrawal following abrupt tobacco abstinence, virtually all smokers should be offered NRT

**TABLE 8 Tobacco Treatment National Hospital Inpatient Quality Measures\***

Measure	Definition
<b>TOB-1:</b> Tobacco use screening	Percentage of hospitalized patients who are screened, within the first 3 days of admission, for tobacco product use in the past 30 days. Requires assessment of all tobacco products (cigarettes, cigars, pipes, smokeless tobacco).
<b>TOB-2:</b> Tobacco use treatment provided or offered	Among patients documented as having used tobacco products in the 30 days before admission, percentage who receive or refuse practical counseling† to quit AND receive or refuse FDA-approved cessation medications. This must be completed during the first 3 hospital days.
<b>TOB-3:</b> Tobacco use treatment provided or offered at discharge	Among patients documented as having used tobacco products in the 30 days before admission, percentage who were referred to or refused evidence-based outpatient counseling AND received or refused a prescription for FDA-approved cessation medication upon discharge.

\*Developed by the Joint Commission, endorsed by the National Quality Forum.  
 †Practical counseling has 3 components: recognizing risks and danger situations (i.e., triggers to use), developing coping skills, and providing basic information about quitting tobacco use.  
 FDA = U.S. Food and Drug Administration.

at admission, regardless of whether the patient plans to quit after discharge. NRT is used because of its rapid onset of action and overall safety. The nicotine patch is the most often used product because of its ability to sustain nicotine levels over a 24-hour period. It can be supplemented by short-acting nicotine products (lozenges, gum, or an inhaler) on an as-needed basis to manage acute cravings in the hospital. Using nicotine replacement in the hospital also increases the odds that a smoker will use the medication after discharge (120). Adding nicotine replacement to counseling increased hospitalized smokers' odds of long-term abstinence (117). Hospitals can provide the required brief tobacco cessation counseling in different ways. Physicians and nurses should provide brief advice to quit to admitted smokers. Additional "practical counseling" (defined in Table 6) can be accomplished by training nurses to deliver a brief intervention or by having on staff a dedicated hospital smoking counselor who works hospital-wide.

- 3. TOB-3: Offer tobacco cessation treatment at hospital discharge.** Hospitals document the offer (and acceptance or refusal) of both pharmacotherapy and counseling that will continue after discharge. A prescription for a smoking cessation medication put into the list of discharge medication satisfies the pharmacotherapy criterion. All cessation medications (NRT, bupropion, and varenicline) are safe to prescribe at hospital discharge, even in patients admitted with ACS. Combination NRT and varenicline are considered first-line

options (Section 6.1.3., Treatment Options: Pharmacological Interventions).

Sustaining counseling support after discharge is a more challenging task. Smoking cessation should be discussed at routine post-hospitalization office visits or cardiac rehabilitation sessions, but this alone is considered insufficient to meet the needs of patients struggling to maintain abstinence because clinicians are often managing multiple CV comorbidities in these settings. The committee recommends that the discharge plan arrange for a dedicated encounter (in person or by phone) for smoking cessation. The visit could be conducted by anyone trained as a tobacco treatment specialist. Hospitals lacking an outpatient smoking cessation program should make a proactive referral to any local community resources and/or to the free telephone quitline system (1-800-QUIT-NOW). Calling this single number results in automatic triage to individual state quitlines, which provide access to evidence-based tobacco cessation services nationwide (Table 2). Referral can be facilitated by creating a proactive electronic referral link (eReferral) between EHRs and state quitlines.

**6.8.2. Special Clinical Circumstance: the Perioperative Patient**

CV specialists and internists refer patients for surgery and provide consultations for perioperative CV risk assessment. Both actions offer opportunities to initiate treatment for smoking cessation. The preoperative context provides unique motivation, a favorable environment, and a tangible incentive to quit smoking (121). Intervening at this key moment may increase the quit rates not only around the time of surgery, but also over the long-term (122). Therefore, smoking cessation before surgery should be routinely recommended to every smoker seen for a preoperative evaluation, regardless of how soon surgery is planned. The benefit to the smoker increases in proportion with the duration of preoperative abstinence, but even brief cessation has benefit (123,124).

The perioperative risks of smoking are well-established. Preoperative smoking has been linked to infection, MI, neurological complications, increased requirement for pain medications, prolonged length of stay, intensive care unit admission, and death (125,126). Smokers undergoing elective surgery have increased odds of thromboembolism, respiratory and wound complications, unplanned hospital readmissions, and mortality, with excess risk lasting at least 1 year after surgery (127). Patients continuing to smoke following percutaneous coronary intervention or coronary artery bypass grafting face poorer long-term outcomes, losing 2 to 3 years of life expectancy compared with those who stop smoking (128,129). Smoking after lower-extremity bypass surgery

increases the risk of graft failure at least three-fold, whereas smoking cessation can restore patency rates to the level of nonsmokers (130). Former or current smoking is also an independent predictor of restenosis after carotid artery revascularization, with both endarterectomy and carotid stents (131).

The optimal timing of smoking cessation before surgery has been debated. Four weeks of tobacco abstinence before surgery clearly reduces the risk of major pulmonary and wound-healing complications (132). If 4 weeks is not feasible, data indicate that the sooner the patient quits, the better, especially for reducing pulmonary complications (124,132). Most important, no convincing data demonstrate that quitting immediately before surgery is harmful (133). Even short durations of preoperative abstinence may reduce perioperative complications and may also lead to continued cessation postoperatively (133). Considering the relatively brief half-lives of both nicotine (~2 h) and carbon monoxide (~4 h), even abstinence on the morning of surgery may have benefit. Morning abstinence is associated with a reduced risk of surgical site infections (134). Thus, patients should be advised that just as they should not eat the morning of surgery, they also should not smoke. Finally, if the patient does not quit preoperatively, quitting postoperatively is still beneficial (135).

The approach to smoking cessation in the perioperative period should mirror the algorithm outlined in **Figure 1**. Clinicians should clearly convey the urgency to quit as soon as possible when surgery is planned or being discussed. Patients should be informed explicitly of the risks described in the previous text. Both pharmacological and behavioral treatment should be initiated at the initial preoperative consultation, regardless of how long before surgery it occurs, and continued postoperatively. Among patients scheduled for elective noncardiac surgery, varenicline (combined with 1 counseling session and referral to a quitline) increased long-term abstinence by 62% compared with brief counseling and self-referral to a quitline (136). NRT has also been used preoperatively. If cessation does not occur preoperatively, NRT can be used in the immediate postoperative period to mitigate the nicotine withdrawal symptoms triggered by the tobacco abstinence required during hospitalization (135).

In some cases, the patient and the care team (including the surgeon, cardiologist, anesthesiologist, and/or primary care provider) may consider a delay in surgery until the patient has successfully quit for at least 4 weeks. Some surgeons may mandate complete smoking cessation prior to elective surgery. In these circumstances, patients may be uniquely motivated to quit, and CV consultants and internists have an important opportunity to assist the patient contemplating surgery to achieve smoking cessation.

### 6.8.3. Postcessation Weight Gain

Weight gain after smoking cessation is a common concern for many smokers and may limit both initial willingness to try to stop smoking and long-term abstinence from smoking. Although about 80% of smokers gain weight (an average of 3 to 6 kg) in the first 3 months postcessation (137), prospective studies demonstrate that postcessation weight gain does not attenuate the CV benefits of tobacco abstinence (138-140). Mechanisms for post-smoking-cessation weight gain include a reversal of the appetite-suppressive effect of nicotine, decreased metabolic rate due to less nicotine exposure, and increased caloric intake (141). NRT can help patients control or at least mitigate weight gain following smoking cessation. A Cochrane review found that bupropion, NRT, and varenicline reduced postcessation weight change while the medication was being used (142), but these medications appear to delay rather than prevent postcessation weight gain. On the basis of available data, it is reasonable to advise patients not to replace cigarettes with food and to instead decrease high fat consumption and increase physical activity (142).

In general, patients with an elevated body mass index who smoke should be advised to focus first on smoking cessation rather than on weight loss. Attempting to quit smoking and lose weight at the same time is often an insurmountable challenge. The concept of “Maintain, Don’t gain” can be recommended. Daily exercise should be strongly encouraged, following current national physical activity guidelines that recommend that adults achieve 30 minutes per day of brisk exercise on most days of the week (143).

### 6.8.4. SHS Exposure

There is a clear scientific consensus that SHS exposure increases the risk of acute CV events and hospitalizations (23,144,145), causing an estimated 33,000 deaths from heart disease annually in the United States. SHS exposure in nonsmokers is also associated with increased risks of atrial fibrillation, peripheral artery disease, and poorer quality of life in heart failure patients. The rapid reduction of CV risk when SHS exposure is eliminated by smoke-free laws emphasizes the potential value of clinician advice to patients with CVD to avoid SHS exposure (23,146,147). Clinicians should screen all patients for SHS exposure. Screening is most important for nonsmokers, because smokers are already exposed to higher levels of toxins when they inhale cigarette smoke directly (**Section 6.1.2., Starting Point: Documentation of Tobacco Use and Exposure**). However, discussing SHS with current smokers can make them aware of the harm that their smoke causes to others and may prompt them to take actions to protect family and friends. Physician advice to adopt a smoke-free policy for home and car may prompt an action that smokers not yet ready to quit smoking are

**TABLE 9 Recommended Actions Regarding SHS Exposure**

- Routinely ask all patients (especially nonsmokers) about their exposure to SHS.
- Inform patients that SHS exposure increases the risk of cardiovascular events in nonsmokers.
- Advise all patients (especially nonsmokers) to adopt a smoke-free policy for their home and car and avoid other sites of SHS exposure.
- Actively support smoke-free policies for worksites, including healthcare centers, and promote smoke-free legislation in their communities.

SHS = secondhand smoke.

willing to take. In longitudinal studies, smokers who implement smoke-free home policies are more likely to try and succeed at quitting (148).

Table 9 outlines actions that the committee recommends that CV healthcare providers take regarding SHS exposure.

## 6.9. Other Tobacco Products

### 6.9.1. Smokeless Tobacco

Approximately 3.4% of U.S. adults use smokeless tobacco products (145). Products used in the United States are primarily oral snuff (moist ground tobacco placed between the lips and gums) or chewing tobacco (shredded flavored tobacco). Smokeless tobacco products that are sucked and dissolve in the mouth are also sold in a variety of forms.

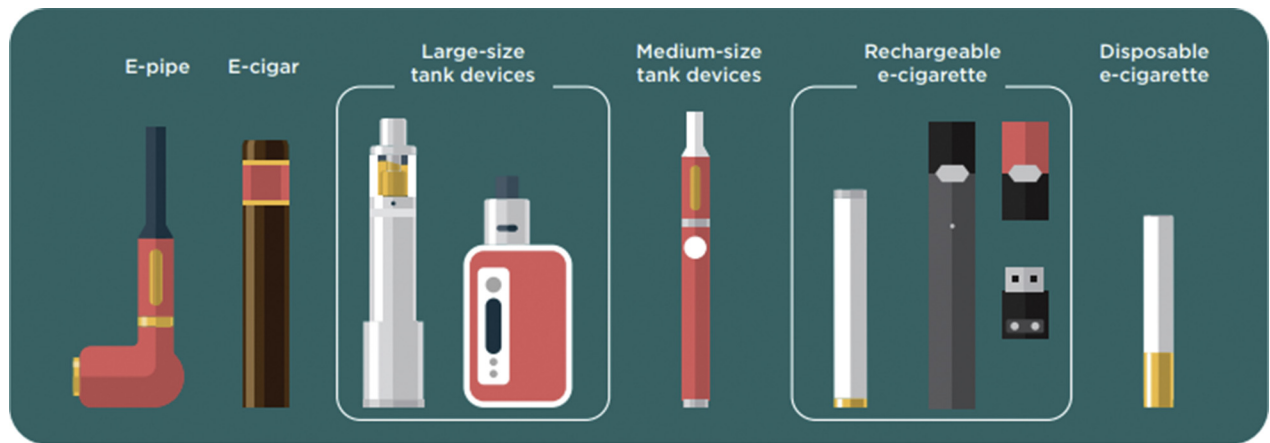
Smokeless products contain nicotine and sodium bicarbonate, which increases pH to increase nicotine absorption across the oral mucosa. They also contain carcinogenic nitrosamines, low levels of other combustion products generated during curing, and other potential toxins (149). The major health risks of smokeless tobacco use are diseases of the oral cavity, including periodontal disease and tooth decay, and a slightly higher risk of oral cancer (150). Smokeless tobacco use has also been associated with an increased risk of pancreatic and esophageal cancer in some studies (151). Whether long-term smokeless tobacco use can cause or aggravate CVD is less certain because evidence is conflicting (152-154). A meta-analysis of 11 studies found an increased risk of fatal MI (relative risk: 1.13; 95% confidence interval: 1.06 to 1.21) and fatal stroke (relative risk: 1.40; 95% confidence interval: 1.28 to 1.54) among smokeless tobacco users compared with nonusers (155). The studies included in that meta-analysis from the United States and Sweden showed an increased risk of death from myocardial infarction and stroke (155). A review by the American Heart Association concluded that although smokeless tobacco use may convey a much lower risk of CVD than does cigarette smoking, it does pose some risk, particularly in patients with CVD (156). Given the overall evidence, the committee recommends against the use of smokeless tobacco, particularly in patients with CVD. Providers should screen for smokeless tobacco use, advise smokeless users

to stop, and offer treatment. Evidence for treatment of smokeless tobacco dependence is less well-established than treatment for cigarette smoking because fewer studies have been conducted. The strongest evidence to date favors varenicline and behavioral support to promote quitting (157). Nicotine lozenges also appeared to enhance quitting. Studies testing use of a nicotine patch and/or bupropion for cessation of smokeless tobacco use have not found these treatments to be effective (157).

### 6.9.2. Alternative Tobacco Products: E-Cigarettes

E-cigarettes, also known as electronic nicotine delivery systems, differ from cigarettes and other combustible tobacco products in that they do not produce smoke by burning tobacco. Instead, they heat a solution (e-liquid) that usually contains nicotine, propylene glycol or vegetable glycerin, and flavorings to generate an aerosol that the user inhales (12). E-cigarette devices vary considerably in design (Figure 4). First-generation products are disposable devices that mimic the appearance and experience of smoking a combustible cigarette. Second-generation devices are larger and have rechargeable batteries and/or replaceable cartridges of e-liquid. Third-generation e-cigarette designs allow the user to customize the devices by manipulating features such as batteries, temperature, and dose of nicotine (158). The design features of an e-cigarette can have a large impact on cost, safety, and nicotine delivery. Users' exposure to nicotine and other chemicals in the aerosol depends on the type of device, the components of the e-liquid, and on how the devices are used. Experienced users can achieve levels of nicotine intake similar to that obtained from smoking combustible tobacco cigarettes (158).

Recently, a novel vaping device emerged that differs from previous e-cigarettes in its technology, product design, and marketing. Exemplified by JUUL, the device is designed to resemble a computer flash drive and encapsulates nicotine, flavorings, and other contents in small replaceable cartridges called "pod-mods" (Figure 5) (159,160). The device's battery, rechargeable via a USB port, heats the liquid to produce vapor. The product differs from prior e-cigarettes in the chemical formulation of nicotine used in the product. Pod-mod devices use nicotine salts, which produces more protonated nicotine at a lower pH than the free-base form of nicotine used in other e-cigarettes, which has a higher pH and activates nicotine sensory receptors. Therefore, the nicotine in the newer devices is less irritating when inhaled. Additionally, these devices can deliver a higher concentration of nicotine to the user (160). A higher dose of nicotine might benefit adult smokers who are seeking to quit cigarettes but might also promote nicotine dependence among nonsmoking adolescents and young adults (161). The product's sleek design, sweet flavors, marketing strategy

**FIGURE 5** Electronic Nicotine Delivery Systems, Including Electronic Cigarettes

e-cigarette = electronic cigarette. Source: U.S. Department of Health and Human Services, 2016 (28).

and social-media presence appear to have made it more attractive to youths than earlier e-cigarette products. During 2017, JUUL's sales accelerated and it captured the largest share of the e-cigarette retail market (159). Although national data on youth use of the products are not yet available, multiple anecdotal reports of youth uptake of JUUL devices appeared in the media during 2018 (160).

E-cigarettes have the potential for large public health benefit if they help smokers to quit smoking combustible cigarettes, especially smokers who have not been willing or able to quit using current treatments. This potential benefit must be balanced against e-cigarettes' own long-term health risks, which are largely unknown at this time, and against the potential for e-cigarettes to attract youth and young adults who might not otherwise smoke to take up their use and perhaps increase the uptake of cigarettes.

In August 2016, the FDA gained regulatory authority over e-cigarettes, allowing it to enforce laws preventing the sale of e-cigarettes to persons under the age of 18 years, ban provision of free product samples, and regulate the labeling and content of e-cigarettes. A 2018 systematic evidence review by the National Academies of Sciences, Engineering, and Medicine (NASEM) concluded that while scientific evidence is insufficient to allow reliable conclusions to be made about the long-term health effects of e-cigarettes (including CV outcomes or measures of sub-clinical atherosclerosis), such risks could be less than those associated with smoking, because toxicants and carcinogens present in cigarette smoke are absent or present at much lower concentrations in e-cigarette aerosols (158).

The NASEM report also reviewed existing evidence about the effects of e-cigarette exposure on intermediate disease outcomes. It found "substantial" evidence that short-term exposure to e-cigarette aerosols can cause acute endothelial cell dysfunction, DNA damage, and signs of oxidative stress, as well as temporarily increase heart rate. However, the report noted that the long-term consequence of these changes or the effects of chronic e-cigarette exposure on CV or other biomarkers of chronic disease remain unknown (148). A subsequent cross-sectional study using nationally-representative self-report data found a positive association between daily e-cigarette use and a history of MI (162). However, the study's cross-sectional design precluded a conclusion about any causal relationship between these two events. The study had no assessments of temporality in exposure, and it is unclear if e-cigarettes were used prior to or after the MI events. More robust studies will be needed to confirm the association between MI and e-cigarette use.

The NASEM noted other safety concerns with e-cigarette devices, such as defective batteries causing explosion and injuries as well as risks of accidental or intentional exposure due to ingestion of or contact with the e-liquids (158). The NASEM report also noted that certain flavorings sometimes found in e-liquids (i.e., diacetyl, cinnamaldehyde) may pose a health hazard and should be avoided (158).

The NASEM report concluded that completely switching from combustible tobacco products to e-cigarettes should reduce short-term adverse health effects of continued smoking, indicating e-cigarettes' potential for harm reduction (158). However, the report found far less evidence that dual use of both cigarettes and e-cigarettes

**TABLE 10** Guidance for Clinicians' Discussions of E-Cigarettes With Patients

**Recommendations:**

- Emphasize to smokers the importance of the goal of *complete* cessation of all combustible tobacco products. Even a single cigarette per day increases cardiovascular risk.
- Recommend that smokers use evidence-based, FDA-approved smoking cessation aids, which are known to be safe and effective.
- Clinicians should be prepared to discuss the evidence about e-cigarettes' risks and benefits with patients who ask about them.

**Points to cover in a discussion with a patient who asks about e-cigarettes:**

- E-cigarettes are devices that heat a nicotine-containing liquid, producing an aerosol that differs from the smoke produced by burning tobacco.
- E-cigarettes contain chemicals in addition to nicotine, including propylene glycol, glycerin, and flavoring chemicals that may pose a risk.
- Because they do not burn tobacco, e-cigarettes expose the user to fewer and lower levels of toxic compounds than smoking a cigarette does.
- Therefore, if used as a complete substitute for combustible tobacco products, e-cigarettes are expected to be less harmful than smoking combustible tobacco products in the short-term, but their long-term safety is uncertain.
- Because e-cigarettes are new products, scientific information about their health effects and effectiveness to help smokers quit is limited and rapidly evolving. They are not currently approved by the FDA as safe and effective cessation aids.
- E-cigarettes vary considerably in their design, in the contents of the e-liquids, and in nicotine and toxicant delivery to the user.

**If smoker chooses to use e-cigarettes, provide evidence-based advice:**

- Switch completely to e-cigarettes. Avoid dual use of both combustible tobacco products and e-cigarettes.
- The eventual goal is cessation of e-cigarettes as well as combustible cigarettes, because of uncertainty about e-cigarettes' long-term health risks. After stopping combustible tobacco, plan to taper off e-cigarettes.
- Heed safety instructions. Choose products with child-proof packaging to minimize the risk of nicotine poisoning of children. Follow instructions for device maintenance, battery recharging, and storage to minimize the risk of explosion.
- Avoid using e-cigarettes around children.

FDA = U.S. Food and Drug Administration.

reduces exposures to toxicants or health risks. Currently 60% of adult e-cigarette users also continue to smoke cigarettes (163). The concern is especially relevant to CVD risk, because smoking even one cigarette daily increases CVD risk in epidemiological studies. The NASEM report found only limited evidence that e-cigarettes are effective as cessation aids when compared with no treatment or current FDA-approved cessation therapies, but it found moderate evidence that e-cigarettes may be more likely to lead to smoking cessation when used more frequently as compared to infrequent or intermittent use (158). However, the report found substantial evidence that e-cigarette use by adolescent never smokers increases their likelihood of subsequently trying a cigarette and moderate evidence that this increases the frequency and intensity of subsequent smoking (158). There is widespread agreement that regulatory oversight of e-cigarettes is needed to reduce the risk of youth use of e-cigarettes and transition to combustible cigarettes.

Despite gaps in the evidence base about the effectiveness of e-cigarettes for smoking cessation, many smokers are asking physicians in clinical practice for guidance about e-cigarettes (164). Writing committee members were unanimous on 3 points (Table 9). First, the clinician's role is to encourage and support a smoker's efforts to stop using cigarettes and other combustible tobacco products. Second, given the uncertainties of the long-term effects of e-cigarettes on health, a clinician should advise cigarette smokers seeking to quit to use evidence-based, FDA-approved, safe, and effective smoking cessation pharmacotherapies as first-line treatments in preference to e-cigarettes. Third, clinicians should be prepared to discuss the risks and benefits with patients who ask about or are already using an e-cigarette. If a

smoker decides to use e-cigarettes, the committee felt that the clinician should play a supportive role, helping the patient to use the product in a way that minimizes risk to themselves and others and indicating that the eventual goal is complete abstinence from all products, including e-cigarettes. Table 10 provides some guidance for clinicians' discussions with patients about e-cigarette use.

Committee members had a range of opinions about the use of e-cigarettes as a cessation aid, reflecting differing interpretations of the limited evidence about e-cigarettes' effectiveness for smoking cessation and possible health effects. Approximately one-half of the committee felt e-cigarettes are associated with less short-term harm than combustible cigarettes and may be of benefit for smokers who have been unable to quit smoking after multiple attempts using FDA-approved medications and behavioral support or for smokers who are unwilling to quit but seek to reduce tobacco-related health harms. In these situations, e-cigarette use is likely to minimize risk if smokers switched completely to e-cigarettes, avoided dual use, and used e-cigarettes temporarily as an aid to cessation of both cigarettes and e-cigarettes. Other committee members felt that the limited evidence of benefit of e-cigarettes for cessation of combustible tobacco products and the insufficient evidence regarding long-term health effects outweighed any potential benefits of e-cigarettes at this time.

Like smokers using conventional cessation therapies, those using e-cigarettes should be followed regularly by the clinician or smoking cessation professional. Although there are no data yet to show that behavioral support enhances the potential effectiveness of e-cigarettes for cessation, it is reasonable to encourage e-cigarette users to use the standard resources for behavioral support (Table 2).



**TABLE 11** Strategies for Addressing Barriers to Implementing and Sustaining Smoking Cessation Treatment in the Clinical Setting

Barrier	Strategy	Additional Information
Providers Lack of education	Include smoking cessation treatment content and practice opportunities in healthcare providers' curriculum.	Advocate for inclusion of questions about smoking cessation information for both licensure and specialty certification in cardiology.
	Provide continuing education for current practitioners.	Require that all providers in cardiology settings receive education about smoking cessation.
	Provide annual updates about new treatments for smoking cessation.	Include updates in communications to healthcare providers.
Providers Lack of time	Utilize existing resources, including state quitlines, for additional support.	
	Hire a dedicated smoking cessation counselor to develop a smoking cessation clinic for referral, especially for patients having difficulty quitting.	
	Involve and educate ancillary personnel (e.g., assistants, front desk staff) so that all are aware of resources.	
Smoking among healthcare providers	Provide access to smoking cessation treatment to all.	Celebrate and enforce a smoke-free workplace. Inform new hires about smoke-free policies.
Healthcare delivery system Smoking cessation is not an expected part of care.	Modify the electronic health record to create alerts and clinician reminders to ensure that all patients who smoke receive treatment.	Downloadable print resources to give to patients at discharge or end of visit.
	Create a dashboard to monitor the number of smokers identified and those who have received treatment.	Contact the state quitline to create proactive referral and provide feedback about contact, receipt of treatment, and quit status to providers.
	Provide feedback to clinicians about the frequency of their delivery of smoking cessation treatment for identified patients.	
	Expand smoke-free policies for the entire healthcare system to denormalize smoking.	Ensure that signage is adequate to inform patients and visitors about the institution's smoke-free policy. Include communications about smoke-free environments to all patients.

### 6.9.3. Alternative Tobacco Products: HNB Tobacco

“Heat-not-burn” devices are also alternative tobacco products that, like e-cigarettes, do not burn tobacco (165). Unlike e-cigarettes, which heat a nicotine-containing liquid, HNB products heat tobacco itself. A pen-like device heats a tobacco stick to a temperature lower than that required for combustion but high enough to release an aerosol that users inhale. Several tobacco companies are developing these products. They claim that the products mimic the experience of conventional combustible cigarettes, providing the taste of tobacco without smoke, ash, or odor, and thereby reducing the health risks of smoking cigarettes (165). Studies funded by the manufacturers have reported that HNB products produce lower levels of harmful chemicals compared with conventional cigarettes (166). Studies from independent researchers replicating this work are just beginning to be published and raise some question about whether HNB products may actually burn tobacco and whether some harmful chemicals are generated (167-169). Consequently, little is known about the health effects of HNB products. Novel HNB products are not currently approved for sale in the United States, but one tobacco company has applied to the FDA for approval to market its product as a modified-risk tobacco product (158).

### 6.10. Training and Implementation

#### **Implementation of Tobacco Cessation Treatment Recommendations**

Making tobacco cessation treatment a routine component of clinical care provided in cardiology practice requires thoughtful preparation and careful implementation to support alterations in workflows and systems of care. Making healthcare delivery system-level changes does increase the delivery of tobacco treatment interventions, although evidence that these system changes improve cessation rates is more limited (170). **Table 11** displays strategies for addressing provider, healthcare delivery system, and educational barriers to implementing tobacco treatment programs in cardiology clinical settings.

An effective strategy requires examination of the workflow and responsibilities for the delivery of tobacco cessation treatment. This includes how patients who smoke are identified, offered treatment, referred for treatment, and followed, to ensure the delivery of treatments for those who want them. Understanding what tobacco treatment resources are available outside of the office and how office staff can effectively connect patients to them is essential. Hiring a trained smoking cessation specialist to deliver treatment in person or by phone can

provide needed smoking cessation support but may not be practical outside of large healthcare systems. A team approach with the involvement of multiple providers may be the most realistic strategy to ensure that the perceived burden is not on any individual healthcare provider.

The EHR provides opportunities to facilitate the implementation of tobacco treatment. If tobacco use information is collected routinely at patient intake, the EHR can push alerts to clinicians to prompt delivery of quit advice and cessation treatment to smokers (171,172). The EHR may be tailored to include prepopulated “Smart Sets” that can facilitate medication prescriptions, referrals for behavioral treatment, and printing of downloadable materials for patients and families. Data analytics in some systems can create, for physicians or practices, a registry of their smokers and the interventions delivered.

Support from key stakeholders in the healthcare system is a critical component to help build consensus and facilitate new or enhanced tobacco treatment services. Strong support from healthcare system leaders is essential for system changes to occur. Clinical champions (e.g., physicians, nurses, physician assistants, respiratory therapists, pharmacists, care coordinators) can provide support during the implementation period. The adoption of smoke-free policies throughout healthcare systems, including outdoor areas, can support implementation of tobacco treatment interventions in clinical practice. Feedback systems that provide information about performance to the provider and the system will help to ensure adoption and maintenance of the change in clinical practice.

#### **Education of Healthcare Providers**

Education of healthcare providers is important so that they know the process by which patients should be screened, offered tobacco treatment, referred to tobacco treatment, and followed up. Although education is necessary, it is not sufficient to ensure routine delivery of cessation treatment in medical settings. Healthcare providers also need to know their specific role in the tobacco cessation treatment team. Although healthcare providers are generally aware of the CV health risks of tobacco use, few have received the necessary training to deliver behavioral and pharmacological treatments for tobacco dependence treatment (173). Evidence indicates that providers who are trained are more likely to screen and intervene with smokers (174,175). Education can also increase referrals to dedicated tobacco treatment resources in the healthcare system or externally such as state quitlines (176,177). Many online courses in delivering smoking cessation therapy are available. These vary in length and

quality. **Table 12** lists resources for educational information to support implementation of tobacco dependence treatment.

#### **Implementation of Hospital-Based Smoking Interventions**

Hospital practice patterns often provide a challenge to the effective delivery of smoking cessation interventions to patients hospitalized for CHD. The low proportion of smokers admitted with acute MI or CHD who receive a cessation medication during or soon after hospitalization (178,179) highlights the need for an evidence-based strategy. Successful program implementation requires buy-in from key hospital officials and tailoring to local strengths, limitations, and priorities. The adoption of completely smoke-free campuses (including outdoor areas) will support a hospital cessation program. Examples of successful implementation of inpatient smoking cessation programs and protocols exist (87,180,181). **Table 13** outlines recommended components of a program.

#### **Insurance Coverage of Tobacco Cessation Treatment**

Smoking cessation counseling is typically covered by insurance. Medicare Part B covers 2 cessation attempts per year. The current procedural terminology (CPT) codes for smoking and tobacco use cessation counseling visits include 99406 (intermediate session; >3 minutes up to 10 minutes) and 99407 (intensive; >10 min). Minimal counseling (<3 min) is not billable as a separate service, as it is included in the Evaluation & Management (E&M) visit. Each quit attempt includes up to 4 sessions (intermediate or intensive), with a total of 8 sessions per year. The modifier “-25” should be added to the primary E&M service code when adding a tobacco cessation counseling service code on the same date. To bill as a separate service, clear documentation should include the amount of time spent and the pertinent points of the discussion, including current tobacco use, advice to quit, adverse effects of smoking on the patient’s health conditions (medical necessity), willingness to quit, a treatment plan including pharmacotherapy, resources provided, and follow-up arrangements.

Alternatively, reimbursement for the time spent may also be via the primary E&M visit code, assuming that the CV specialist is seeing the patient for other CV issues. The primary diagnosis code for the visit should then reflect the biological impact of tobacco use. Some payers may view the diagnosis code of “tobacco dependence” as a behavioral health service, which may not be covered (182). The American Lung Association has produced a guide to help clinicians bill for tobacco cessation treatment (183).

**TABLE 12 Resources for Educational Information to Support Implementation of Tobacco Dependence Treatment in Clinical Cardiology Settings**

Organization	Title	Information
Agency for Healthcare Research and Quality	Treating Tobacco Use and Dependence: 2008 Update <a href="https://www.ahrq.gov/professionals/clinicians-providers/guidelines-recommendations/tobacco/index.html">https://www.ahrq.gov/professionals/clinicians-providers/guidelines-recommendations/tobacco/index.html</a>	Section for clinicians and system decision makers, including systems change information for integration of tobacco dependence in clinical practice.
American Heart Association	Why Quit Smoking? <a href="https://www.heart.org/en/healthy-living/healthy-lifestyle/quit-smoking-tobacco">https://www.heart.org/en/healthy-living/healthy-lifestyle/quit-smoking-tobacco</a>	Reviews reasons for quitting focused on heart disease, includes a "Cost of Smoking" calculator.
Centers for Disease Control and Prevention	Health Care Providers: How You Can Help Patients Quit <a href="https://www.cdc.gov/tobacco/campaign/tips/partners/health/index.html">https://www.cdc.gov/tobacco/campaign/tips/partners/health/index.html</a>	Provides general information for healthcare providers based on the Tips for Former Smokers <sup>R</sup> Campaign.
Centers for Disease Control and Prevention	Smoking and Heart Disease and Stroke <a href="https://www.cdc.gov/tobacco/campaign/tips/diseases/heart-disease-stroke.html">https://www.cdc.gov/tobacco/campaign/tips/diseases/heart-disease-stroke.html</a>	Specific examples of the impact of smoking and exposure to secondhand smoke on heart disease and stroke, videos from the TIPs campaign featuring real people with heart disease and stroke to promote motivation to quit.
University of Wisconsin- Center for Tobacco Research and Intervention	Providers Overview <a href="https://ctri.wisc.edu/providers/providers-overview/">https://ctri.wisc.edu/providers/providers-overview/</a>	Offers tobacco treatment training through webinars, onsite videos, or online programs; updates on the evidence for electronic cigarettes, including vaping regulations by state.
Million Hearts	Tobacco Cessation Protocols <a href="https://millionhearts.hhs.gov/tools-protocols/protocols.html#TCP">https://millionhearts.hhs.gov/tools-protocols/protocols.html#TCP</a>	Models for clinical decision making, including <i>Implementation of the Tobacco Cessation Protocol</i> , with performance feedback and implementation evaluation suggestions, and <i>Protocol Example for Identifying and Treating Patients Who Use Tobacco</i> , including ICD-10 Codes for Tobacco and Nicotine Dependence, and Secondhand Smoke Exposure.
North American Quitline Consortium	State telephone support lines for smoking cessation <a href="http://www.naquitline.org/">http://www.naquitline.org/</a>	Provides information about availability and details of telephone quitlines for smoking cessation across the United States, as well as electronic referral, other resources, and availability of nicotine replacement.
Rx for Change	Clinician-assisted tobacco cessation education <a href="http://rxforchange.ucsf.edu/">http://rxforchange.ucsf.edu/</a>	An online training program with a specific 1-hour module on cardiology and smoking cessation based on the <i>Clinical Practice Guideline for Treating Tobacco Use and Dependence</i> .
Smokefree partner toolkit	Smokefree.gov <a href="https://smokefree.gov/help-others-quit/health-professionals">https://smokefree.gov/help-others-quit/health-professionals</a>	Provides comprehensive list of evidence-based resources, guides, and government reports aimed for clinicians, including smokefree mobile interventions.
Society for Research on Nicotine and Tobacco	Resources for Clinicians <a href="https://www.srnt.org/?page=Resources_Clinicians">https://www.srnt.org/?page=Resources_Clinicians</a>	Provides many science-based resources and a searchable index for abstracts related to cardiovascular disease.
American College of Cardiology	Stop Smoking <a href="https://www.cardiosmart.org/Healthy-Living/Stop-Smoking">https://www.cardiosmart.org/Healthy-Living/Stop-Smoking</a>	Provides information about smoking and heart disease, how to quit smoking, infographics and resources related to smoking cessation.

**TABLE 13 Potential Participants in an Inpatient or Outpatient Smoking Cessation Program**

Participant*	Primary Roles
Medical director	Advocacy within the organization, addressing medical concerns regarding pharmacotherapy, engaging treating clinicians, limited training obligations. In some models, the medical director will prescribe smoking-related therapies. In other models, he or she will ensure that the treating physicians or advanced practice providers are equipped to do so.
Administrative leader: nurse, advanced practice provider, pharmacist, physician, hospital/clinic administrator	Program management, budget, daily/weekly process improvement leadership, engagement with informatics for reporting, reporting program successes and challenges to hospital leadership.
Pharmacist	Reviewing medication safety concerns for order sets, care pathways, and individual cases; acting as a resource for clinician questions regarding dosage, effectiveness, or safety of medications; ensuring formulary alignment.
Counselor(s)—certified tobacco treatment specialists, nurses, social workers, advanced practice providers or physicians	Delivering motivational counseling, providing recommendations to treating clinicians on engagement in appropriate care pathways.
Tobacco treatment coordinators—medical assistants or health educators	Coordinating with medical director, counselors, clinicians, and pharmacists to provide education, conduct follow-up, and determine adherence.

\*Small-scale programs can be initiated with part-time efforts by a physician and administrator only.

## 7. DISCUSSION AND IMPLICATION OF PATHWAY

The primary objective of this document is to provide a framework for the many decisions required in delivering smoking cessation therapy in clinical practice setting. No guideline, pathway, or algorithm should ever supersede clinical judgments. The effective provision of smoking cessation support to patients requires a team approach. Additionally, clinical practice guidelines evolve over time as new information appears. In this context, we have highlighted important literature citations explaining the rationale for treatment approaches and possible candidate best practices. With more evidence generated from ongoing research, refinement of this decision pathway will be needed. For now, the writing committee hopes that this decision pathway will help clinicians to improve the quality and effectiveness of the tobacco cessation strategies that they provide to their patients.

### 7.1. Key Points

- Tobacco use, especially cigarette smoking, is a major risk factor for CVD-associated morbidity and mortality. The reversible relationship between cigarette smoking and CVD provides a strong rationale for healthcare providers—especially the CV care team—to make the routine delivery of tobacco cessation treatment a standard component of CV care.
- Cigarette smoking is a chronic relapsing substance use disorder caused by addiction to nicotine. Most smokers pass through repeated cycles of short-term abstinence followed by relapse to smoking before achieving long-term tobacco abstinence. Treating tobacco dependence, therefore, requires clinicians to adopt a chronic

disease management strategy, monitoring tobacco use over time and making repeated efforts to encourage and assist smokers to quit using tobacco.

- Current evidence strongly supports combining pharmacotherapy with behavioral/psychosocial interventions as the most effective way to help smokers sustain abstinence. Pharmacological therapies help smokers adjust to the absence of nicotine following cessation of smoking by lessening the symptoms of nicotine withdrawal. Behavioral and psychosocial treatments are based upon principles of behavioral and cognitive psychology that attempt to bolster smokers' self-control over their smoking.
- Provider and system barriers in implementing and sustaining smoking cessation treatment need to be recognized and addressed to improve the smoking cessation care in the clinical setting.

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**APPENDIX 1. AUTHOR RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES (RELEVANT) — 2018 ACC EXPERT CONSENSUS DECISION PATHWAY ON TOBACCO CESSATION TREATMENT**

**Relationships with Industry and Other Entities**

To avoid actual, potential, or perceived conflicts of interest that may arise as a result of industry relationships or personal interests among the writing committee, all members of the writing committee, as well as peer reviewers of the document, are asked to disclose all current healthcare-related relationships, including those existing 12 months before initiation of the writing effort. The ACC Task Force on Clinical Expert Consensus Documents reviews these disclosures to determine what companies make products (on market or in development) that pertain to the document under development. Based on this information, a writing committee is formed to

include a majority of members with no *relevant* relationships with industry (RWI), led by a chair with no *relevant* RWI. RWI is reviewed on all conference calls and updated as changes occur. Author RWI pertinent to this document is disclosed in the table below and peer reviewer RWI is disclosed in [Appendix 2](#). Additionally, to ensure complete transparency, authors' *comprehensive disclosure information*—including RWI not pertinent to this document—is available online (see [Online Appendix](#)). Disclosure information for the ACC Task Force on Expert Consensus Decision Pathways is also available [online](#), as is the [ACC disclosure policy for document development](#).

Committee Member	Employment	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Rajat S. Barua (Chair)	Kansas City VA Medical Center—Director, Cardiovascular Research & Interventional Cardiology; University of Kansas School of Medicine—Associate Professor of Medicine	None	None	None	None	None	None
Nancy A. Rigotti (Vice-Chair)	Massachusetts General Hospital—Professor of Medicine	■ Pfizer*	None	None	■ NIH/ NHLBI† ■ Pfizer	None	None
Neal L. Benowitz	UCSF Center Tobacco Control Research/Education—Professor of Medicine	■ Pfizer	None	None	None	■ Pfizer*	■ 2016, Plaintiff, tobacco litigation†
K. Michael Cummings	Medical University of South Carolina—Professor, Department of Psychiatry & Behavioral Sciences; Co-leader Hollings Cancer Center Tobacco Research Program	■ Pfizer	None	None	None	■ Pfizer†	■ 2016, Plaintiff, tobacco litigation†

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## APPENDIX 1. CONTINUED

Committee Member	Employment	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Mohammad-Ali Jazayeri	University of Kansas Medical Center—Fellow, Division of Cardiovascular Diseases	None	None	None	None	None	None
Pamela B. Morris	Medical University of South Carolina—Associate Professor of Medicine, Division of Cardiology	None	None	None	None	None	None
Elizabeth V. Ratchford	Johns Hopkins University School of Medicine— Director, Johns Hopkins Center for Vascular Medicine; Associate Professor of Medicine	None	None	None	None	None	None
Linda Sarna	UCLA School of Nursing— Dean & Professor, Lulu Wolf Hassenplug Endowed Chair	None	None	None	None	None	None
Eric C. Stecker	Oregon Health & Science University— Associate Professor of Medicine	None	None	None	None	None	None
Barbara S. Wiggins	Medical University of South Carolina— Clinical Pharmacy Specialist in Cardiology	None	None	None	None	None	None

This table represents the relationships of committee members with industry and other entities that were determined to be relevant to this document. These relationships were reviewed and updated in conjunction with all meetings and/or conference calls of the writing committee during the document development process. The table does not necessarily reflect relationships with industry at the time of publication. A person is deemed to have a significant interest in a business if the interest represents ownership of  $\geq 5\%$  of the voting stock or share of the business entity, or ownership of  $\geq \$5,000$  of the fair market value of the business entity; or if funds received by the person from the business entity exceed 5% of the person's gross income for the previous year. Relationships that exist with no financial benefit are also included for the purpose of transparency. Relationships in this table are modest unless otherwise noted.

According to the ACC, a person has a *relevant* relationship IF: a) the *relationship or interest* relates to the same or similar subject matter, intellectual property or asset, topic, or issue addressed in the *document*; or b) the *company/entity* (with whom the relationship exists) makes a drug, drug class, or device addressed in the *document* or makes a competing drug or device addressed in the *document*; or c) the *person or a member of the person's household*, has a reasonable potential for financial, professional or other personal gain or loss as a result of the issues/content addressed in the *document*.

\*No financial benefit.

†Significant relationship.

NHLBI = National Heart, Lung, and Blood Institute; NIH = National Institutes of Health.

## APPENDIX 2. PEER REVIEWER INFORMATION—2018 ACC EXPERT CONSENSUS DECISION PATHWAY ON TOBACCO CESSATION TREATMENT

This table represents the individuals, organizations, and groups that peer reviewed this document. A list of

corresponding comprehensive healthcare-related disclosures for each reviewer is available [online](#).

Reviewer	Representation	Employment
David Macleod Donaldson	Official Reviewer—ACC BOG	Brown University/Warren Alpert Medical School, Cardiovascular Institute of New England—Clinical Assistant Professor of Medicine, Cardiac Electrophysiology
Karol E. Watson	Official Lead Reviewer—Task Force on Expert Consensus Decision Pathways	David Geffen School of Medicine at UCLA—Professor of Medicine/Cardiology; Co-director, UCLA Program in Preventive Cardiology; Director, UCLA Barbra Streisand Women's Heart Health Program
Elise Albro	Organizational Reviewer—The Ohio State University Wexner Medical Center	The Ohio State University Wexner Medical Center, Richard M. Ross Heart Hospital—Specialty Practice Pharmacist, Ambulatory Care
Kathy Berra	Organizational Reviewer—PCNA	The LifeCare Company—Co-Director
Brian King	Organizational Reviewer—CDC	Centers for Disease Control and Prevention—Deputy Director for Research Translation, Office on Smoking and Health, National Center for Chronic Disease Prevention and Health Promotion
Suchitra Krishnan-Sarin	Organizational Reviewer—AHA	Yale University School of Medicine—Professor of Psychiatry, Chair Human Investigations Committee II & IV, Human Research Protections Program
Rachel Grana Mayne	Organizational Reviewer—National Cancer Institute	National Cancer Institute—Behavioral Scientist, Program Director, Tobacco Control Research Branch

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**APPENDIX 2. CONTINUED**

<b>Reviewer</b>	<b>Representation</b>	<b>Employment</b>
Jennifer Irvin Vidrine	Organizational Reviewer—Oklahoma Tobacco Research Center	Stephenson Cancer Center—Peggy and Charles Stephenson Endowed Chair in Cancer; Associate Director for Prevention and Control; Director, Oklahoma Tobacco Research Center; University of Oklahoma Health Sciences Center—Professor, Department of Family & Preventive Medicine
David O. Warner	Organizational Reviewer—Mayo Clinic of Medicine and Science	Mayo Clinic—Professor of Anesthesiology
Roger S. Blumenthal	Content Reviewer—Co-Chair, 2019 Prevention Guideline Writing Committee	Johns Hopkins Hospital Ciccarone Preventive Cardiology Center—Pollin Professor of Cardiology
Gerald W. Bourne	Content Reviewer—Roundtable Participant	The Encore Physicians—Consultant
Andrew M. Freeman	Content Reviewer—Prevention Section Leadership Council	National Jewish Health—Director, Clinical Cardiology; Director, CV Prevention and Wellness; Associate Professor of Medicine
William J. Hucker	Content Reviewer—Task Force on Expert Consensus Decision Pathways	Massachusetts General Hospital—Fellow in Cardiac Electrophysiology
Elizabeth A. Jackson	Content Reviewer—Roundtable Participant	UAB Division of Cardiovascular Disease—Robert C. Bourge and Cutessa D. Bourge Endowed Professorship in Cardiovascular Disease; Director, Cardiovascular Outcomes and Effectiveness Research (CVOER) Program; Professor of Medicine
Richard A. Josephson	Content Reviewer—Prevention Section Leadership Council	Case Western Reserve University School of Medicine—Professor of Medicine; Harrington Heart & Vascular Institute University, Hospitals Health System—Director, Cardiovascular and Pulmonary Rehabilitation, Division of Cardiovascular Medicine
Richard J. Kovacs	Content Reviewer—Roundtable Participant	Krannert Institute of Cardiology—Professor of Clinical Medicine
Dharam J. Kumbhani	Content Reviewer—Task Force on Expert Consensus Decision Pathways	UT Southwestern Medical Center—Assistant Professor, Interventional Cardiology, Department of Internal Medicine
Gilead I. Lancaster	Content Reviewer—Health Affairs Committee	Yale New Haven Health Bridgeport Hospital—Director, Non-Invasive Cardiology; Yale University School of Medicine—Associate Clinical Professor of Medicine
L. Samuel Wann	Content Reviewer—Individual Expert	Ascension Healthcare Wisconsin—Cardiologist

ACC = American College of Cardiology; AHA = American Heart Association; BOG = Board of Governors; CV = cardiovascular; PCNA = Preventive Cardiovascular Nurses Association; UAB = University of Alabama at Birmingham; UCLA = University of California, Los Angeles; UT = University of Texas.

**APPENDIX 3. ABBREVIATIONS**

ACC = American College of Cardiology

ACS = acute coronary syndrome

CHD = coronary heart disease

CVD = cardiovascular disease

ECDP = Expert Consensus Decision Pathways

EHR = electronic health record

FDA = Food and Drug Administration

NRT = nicotine replacement therapy

SHS = secondhand smoke