Chapter 7
Clinical-, System-, and Population-Level Strategies that Promote Smoking Cessation

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Introduction

Clinical-, system-, and population-level strategies can broadly influence the behavior of smokers as they try to quit or think about quitting smoking. This chapter focuses on these broad strategies that can facilitate the integration of individual components of treatment for smoking cessation, as discussed in Chapter 6, into routine clinical care—making cessation interventions available and accessible to individual smokers and creating conditions whereby smokers become aware of these interventions and are motivated to use them. This chapter does not attempt to provide a review of all tobacco control policy actions that may result in smokers attempting to quit or that may increase quit success outside the context of cessation treatment interventions; these have been covered comprehensively in previous Surgeon General's reports, including the 50th anniversary report, *The Health Consequences of Smoking—50 Years of Progress* (U.S. Department of Health and Human Services [USDHHS] 2014), as well as in other documents (National Cancer Institute [NCI] and World Health Organization [WHO] 2017; WHO 2019). Table 7.1 describes key findings from the 2014 Surgeon General's report that are relevant to smoking cessation.

Strategies that encourage smoking cessation beyond the individual smoker generally involve actions at one of three levels: (1) the clinical setting, (2) the health system, or (3) the population. Actions taken at the clinical and health system levels typically target quitting behavior directly and generally focus on the use or effectiveness of treatments for smoking cessation (Fiore et al. 2008; Centers for Disease Control and Prevention [CDC] 2014b; U.S. Preventive Services Task Force [USPSTF] 2015). These actions include implementing policies that transform systems of care to better address tobacco use and dependence; promoting evidence-based treatments for tobacco cessation; and implementing policies that are clinically focused, address health insurance coverage, and promote cessation. These actions can reach a large proportion of Americans who smoke, considering nearly 70% of U.S. adults who smoke cigarettes visit a primary care clinician each year (CDC 2012c) and millions of U.S. adults see specialty clinicians and are hospitalized annually (National Center for Health Statistics 2018).

In contrast, population-based strategies are aimed at influencing tobacco cessation at a macro level by motivating smokers to quit and by providing an environment that supports or simplifies efforts to quit or lowers barriers that smokers might encounter. These strategies are broader than those at the clinical or health system levels, affecting the larger community or population, not just individuals engaged with the healthcare system. Population-based strategies include increasing the price of and/or the tax on cigarettes and other tobacco products; restricting where tobacco can be used by implementing smokefree and tobacco-free policies; adequately funding tobacco control programs at the state level; carrying out mass media campaigns (e.g., CDC's *Tips From Former Smokers* campaign [*Tips*] [CDC 2018b] and the U.S. Food and Drug Administration's [FDA's] Real Cost Campaign [FDA 2018b]); making changes to the tobacco retail density and point-of-sale environments; and developing product regulations, including regulating nicotine content and requiring pictorial health warnings. Importantly, combining clinical and health system-based and macro-level strategies can have a synergistic effect on improving cessation outcomes. For example, in addition to motivating smokers to make a quit attempt, a mass media campaign (a macro-level strategy), such as the *Tips* campaign, can motivate smokers to use cessation resources, including state quitlines, web-based cessation support, and cessation interventions from healthcare providers.

This classification of strategies to promote smoking cessation is similar to CDC's "three buckets framework," in which prevention approaches include (1) traditional patient-level clinical interventions; (2) innovative clinical prevention provided outside of the clinical or health system setting; and (3) population- or community-wide interventions that reach a broader population, often defined geographically (Auerbach 2016) (Figure 7.1). With this framework in mind, a combination of strategies across the three buckets could potentially provide optimal cessation motivation and support for smokers by helping them quit and creating a broad environment that is conducive to and supportive of quitting.

Literature Review Methods

For the evidence presented in this chapter, PubMed/Medline, Scopus, and Google Scholar were searched for studies that focused on smoking cessation policies as they are impacted by various strategies, technologies, and inducements at both the health system and population levels, with a specific focus on well-designed review articles

Table 7.1 Summary of policies from the 2014 Surgeon General's report that encourage smoking cessation

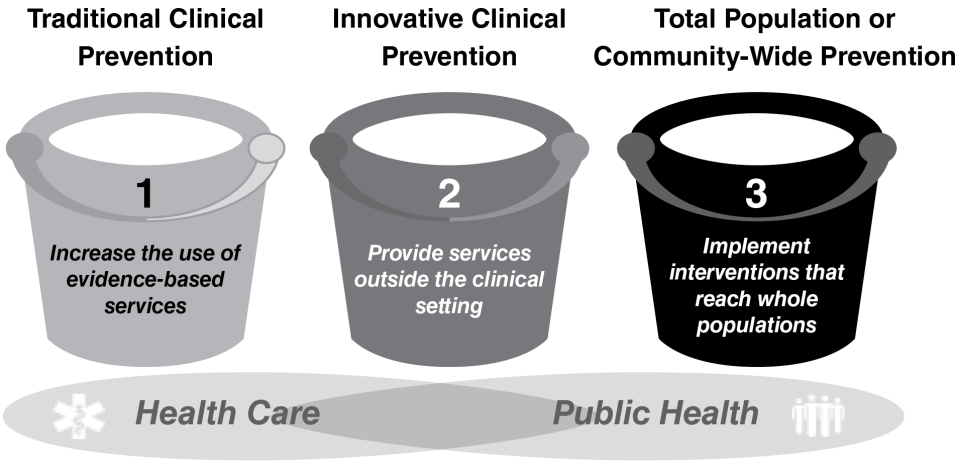
Policy area	Results for smoking cessation
Tax or price	• A 10% increase in cigarette price is associated with a 3–5% decrease in cigarette consumption. • Increasing the price of tobacco products reduces initiation, prevalence, and intensity of smoking in youth and adults.
Smokefree policies	In addition to protecting nonsmokers from exposure to secondhand smoke, strong evidence suggests that smokefree laws and policies: • Reduce the prevalence of tobacco use, • Increase the number of tobacco users who quit, and • Reduce the initiation of smoking among youth and young adults. Specifically, smokefree laws and policies are associated with a: • 3.4% reduction in the prevalence of tobacco use, and • 6.4% increase in tobacco cessation.
Healthcare policies	Federal regulations and legislation have included components to increase the delivery of evidence-based treatments for nicotine dependence in healthcare systems: • The HITECH Act requires the identification and documentation of tobacco use in the EHRs of all patients 13 years of age and older who use tobacco. This has made the identification and documentation of tobacco use in EHRs nearly universal in the U.S. healthcare system. • The ACA contains several tobacco cessation elements: – Mandatory coverage for tobacco cessation medications in state Medicaid programs; – Coverage, without cost sharing, of treatment for nicotine dependence for pregnant smokers in state Medicaid programs; and – The elimination of copayments for preventive services rated A or B by USPSTF, including nicotine dependence treatment for all adults. • In 2010, Medicare expanded coverage of tobacco cessation to all beneficiaries who use tobacco, replacing previous coverage limited to beneficiaries with signs or symptoms of a tobacco-related disease.
Comprehensive statewide tobacco control programs	States that have invested more funds in tobacco control have seen larger and faster declines in the prevalence of smoking. Several elements have been shown to be effective at promoting and facilitating tobacco cessation: • Mass media health communications designed to discourage initiation and encourage cessation among youth. For example, CDC's Tips campaign motivated an estimated 1.6 million additional smokers to make a quit attempt. • Healthcare system- and population-based interventions encouraged by state programs can promote tobacco cessation via increased delivery of evidence-based tobacco use treatments, such as: – Tobacco cessation quitlines and – Evidence-based tobacco cessation programs housed in healthcare delivery systems.

Source: USDHHS (2014).

Notes: **ACA =** Patient Protection and Affordable Care Act; **CDC =** Centers for Disease Control and Prevention; **EHRs =** electronic health records; **HITECH Act =** Health Information Technology Economic and Clinical Health Act; **USPSTF =** U.S. Preventive Services Task Force.

and meta-analysis, when available. Articles were published between January 1, 2002, and December 31, 2016, and included references to other sources (e.g., those in *Clinical Practice Guideline* [Fiore et al. 2008]) that predated 2002. Consistent with the longstanding process adhered to for the development of Surgeon General's reports on tobacco (see Chapter 1), several additional studies published after 2016 were added during the review and clearance process to ensure that the volume includes the most updated scientific literature available. A combination of keywords and phrases were used in conjunction with "cessation" or "quit" to investigate the following topics as they relate to smoking cessation: (1) clinic and health system strategies, including guidelines, insurance coverage, provider payments/incentives, performance measures, and electronic health records (EHRs); and (2) population-based policies, including tobacco taxes/price, quitlines, mass media campaigns, smokefree strategies, tobacco control programs, pictorial health warnings, plain packaging, retail density, low-nicotine-content cigarettes, and menthol or flavors. Chapter conclusions reflect evidence cited in previous Surgeon General's reports and newly available evidence. Search results were limited to studies published in English and to original research.

Figure 7.1 CDC's conceptual population health and prevention framework



Source: Auerbach (2016), with permission.

One hundred sixty-five articles were initially identified for review for this chapter, with additional literature added that was published following completion of the initial literature review. For the first section on clinical and health system-based strategies, 75 articles were initially reviewed. These articles fell into the following categories: clinical guideline training and compliance (15 articles), provider and health system payments/incentives (22 articles), performance measures (4 articles), health information technology (12 articles), insurance coverage and benefits (13 articles), and health system enhancements (9 articles). For the second section on population-based strategies, 90 articles were initially reviewed. These articles fell into the following categories: tobacco taxes/price (19 articles), quitlines (16 articles), EHR enhancement (3 articles), mass media campaigns (16 articles), smokefree policies (17 articles), and pictorial health warnings (5 articles). Subsequent to the initial review, additional reviews were performed that identified articles on the following categories: tobacco control programs, plain packaging, retail density and point-of-sale advertising, and flavor and product restrictions. Each article was screened for level of relevance to the topic, its recency, whether it provided novel or complementary information (relative to other articles), and the quality and soundness of its experimental methods given the goals of the research. Articles that did not meet these criteria were excluded.

Clinical- and Health System-Based Strategies on Smoking Cessation

Although significant progress has been made to integrate tobacco use and dependence treatment into clinical health systems, substantial opportunities remain for improvement. For example, in 2000, 52.4% of cigarette smokers who had seen a health professional during the previous year reported that they had received advice to quit. In 2015, that figure rose to 57.2% (Babb et al. 2017). This suggests that progress on this indicator has been slow, with more than 40% of smokers in healthcare settings not receiving basic tobacco cessation counseling from clinicians. Moreover, the rates at which physicians deliver more intensive interventions, such as cessation assistance and follow-up to help persons plan for and carry out quit attempts, are typically lower than the prevalence of screening for tobacco use and delivering advice to quit (King et al. 2013b; Bartsch et al. 2016); these more intensive steps can play an important role in helping smokers carry out quit attempts (Fiore et al. 2008).

One way to increase smoking cessation interventions from clinicians is through health systems policies and protocols that make smoking cessation a standard of care (Fiore et al. 2008). Systemwide strategies and changes can increase the delivery of clinical cessation interventions by routinizing the approach to smoking cessation, making it easier for clinicians and their teams to consistently provide evidence-based cessation treatments (Fiore et al. 2007; Rigotti 2011; CDC 2014a). In particular, data and experiences from the field suggest that health

systems initiatives are most likely to increase the prevalence of clinical cessation interventions if these initiatives (a) embed policies and protocols for tobacco use screening and intervention into the clinical workflow, including provider reminder systems and support for clinical decisions; (b) embed decision support tools into health records, including EHRs[1]; and (c) delegate specific components of the intervention to the broader healthcare team to reduce the burden on time-constrained physicians (Fiore et al. 2008; Lindholm et al. 2010; Land et al. 2012; Jansen et al. 2014; Moody-Thomas et al. 2015; Smith et al. 2015).

However, evidence is mixed on the impact of health systems change on overall cessation. For example, a 2017 Cochrane Review assessed the effectiveness of systems change interventions in healthcare settings for increasing smoking cessation and/or the provision of cessation care (Thomas et al. 2017). Evidence from the review indicated that systems change interventions improve performance on process outcomes, such as documenting smoking status and providing cessation counseling and treatment, but these interventions do not yet clearly demonstrate that they increase cessation rates. Conversely, a 2012 study of data from more than 100,000 patients in the Harvard Vanguard Medical system during 2005–2010 found that patients in clinics that implemented a systems change approach (defined as using a tobacco use identification system and screening at least half of all patients) had significant reductions in the prevalence of smoking and in the rate of office visits for smoking-related disease (Land et al. 2012).

Chapter 6 details the specific barriers that clinicians may face when delivering smoking cessation interventions to patients, along with approaches to overcoming these barriers. Barriers include time constraints, insufficient training on tobacco dependence and treatment, lack of confidence among clinicians on their ability to effectively deliver cessation interventions, a perception on the part of some clinicians that tobacco dependence treatment is not effective, limited clinician time and reimbursement to provide treatment to patients, and failure to fully engage other clinical staff in providing cessation support to patients (Rojewski et al. 2019). Many of these individual barriers can be overcome by implementing the system-wide policies discussed in this chapter.

In addition to strategies that seek to make the delivery of smoking cessation interventions in health systems more routine, those that remove cost and other barriers (which impede smokers' access to proven cessation treatments) have been shown to increase the delivery and utilization of tobacco dependence treatment, especially when the covered treatments are proactively promoted to health plan beneficiaries. For example, standardized comprehensive, barrier-free cessation coverage by private and public insurers expedites smokers' access to evidence-based cessation treatments and removes confusion about which treatments are covered and related barriers for both smokers and providers, thereby increasing the chances that smokers and providers will make use of these treatments (Fiore et al. 2008; Kofman et al. 2012; CDC 2014b). Clinical guidelines and clinical quality measures also play an important role in ensuring that clinicians and health systems consistently intervene with tobacco users (Ward et al. 2003; Katz et al. 2004, 2014; Lesho et al. 2005; Smith et al. 2005, 2008; Caplan et al. 2011; Moody-Thomas et al. 2011; Shelley et al. 2011; Fiore et al. 2012; Kruger et al. 2015; Siu 2015).

During the past decade, numerous policy and regulatory efforts at the national, state, and local levels have been undertaken in the United States to encourage clinicians and health systems to identify, document, and treat persons who use tobacco (USDHHS 2014; McAfee et al. 2015; Fiore 2016; Thomas et al. 2017) and to encourage health insurers to cover smoking cessation and to promote the covered treatments. Generally, these efforts have focused on achieving several goals, including (1) increasing rates of cessation; (2) improving smokers' awareness of and access to evidence-based treatments; (3) improving patient health and healthcare quality; (4) reducing healthcare costs associated with tobacco use; (5) identifying and promoting evidence-based cessation treatments and programs; (6) establishing clinical standards for tobacco use and dependence treatment and making clinicians and health systems aware of such standards; (7) improving cessation insurance coverage and promoting it to smokers; (8) enhancing compensation for providers or health systems through pay-for-performance quality measures, payment reforms, and improved, simpler reimbursement procedures; and (9) leveraging health information technology to improve and routinize treatment for tobacco use and dependence (CDC 2014b; USDHHS 2014; McAfee et al. 2015; Fiore 2016).

Achieving these goals involves taking action at multiple levels and may involve government (at the local, state, and/or national levels) and nongovernmental entities (e.g., accreditation and nonprofit organizations, health system administrators, and insurers). This section

[1]An EHR is a collection of health-related information for a patient that is generated by one or more visits in any healthcare setting. The EHR typically includes demographic information about the patient, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory data, and radiology reports. EHRs focus on the total health of the patient and thus go beyond the standard clinical data that are collected in a healthcare provider's office, offering a broader view of the patient's care.

describes the major types of strategies at the clinical and health system levels and the evidence regarding their effects on cessation interventions. Because some of the specific strategies were developed relatively recently (McAfee et al. 2015; Fiore 2016), their effects on key endpoints, including increased access to clinical services for cessation and higher rates of cessation, are not yet fully known.

Clinical Practice Guidelines

Clinical practice guidelines from a variety of entities, including governmental, professional, and accrediting agencies, are relevant to clinical and health system policies in two ways. First, they contain best-practice recommendations for clinical treatment that are based on scientific evidence. As such, clinical practice guidelines can increase the likelihood that clinicians will use evidence-based approaches to help their patients quit using tobacco. Second, such guidelines seek to integrate evidence-based cessation interventions into routine clinical practice, serving as standards and laying the groundwork for the effective implementation of other policy levers, including insurance coverage policies and performance quality measures. Two examples of clinical practice guidelines will be described in this report—Clinical Practice Guidelines from the U.S. Public Health Service (Fiore et al. 2008) and the recommendations from the U.S. Preventive Services Task Force (USPSTF 2015). However, there are other guidelines, position statements, and consensus statements from a variety of organizations regarding the clinical treatment of tobacco use disorder (e.g., American Psychiatric Association 2010; Larzelere and Williams 2012; American Academy of Family Physicians 2014; Farber et al. 2015; Barua et al. 2018).

Clinical Practice Guideline from the U.S. Public Health Service

The U.S. Public Health Service first published in 1996 its Clinical Practice Guideline *Treating Tobacco Use and Dependence* (Fiore et al. 1996) and updated it in 2000 (Fiore et al. 2000) and 2008 (Fiore et al. 2008) (also discussed in Chapter 1). The *Clinical Practice Guideline* reviews extensive evidence indicating that health system changes can improve the delivery of treatment for smoking cessation in healthcare settings and can lead to improved downstream quitting behavior and quitting outcomes. Importantly, the findings and recommendations of the *Clinical Practice Guideline* are broadly applicable across most clinical settings, including primary care, specialty, and inpatient settings; dental care settings; and behavioral health settings (Hall et al. 1998; Hayford et al. 1999; Smith et al. 2003; Wagena et al. 2005; Gordon et al. 2006, 2007, 2010). Moreover, the *Clinical Practice Guideline* recommends specific changes in healthcare systems and policies to enhance the delivery of cessation interventions in clinical settings (Fiore et al. 2008). Table 7.2 describes the systems and policy findings of the 2008 *Clinical Practice Guideline* and the evidence base supporting them.

The *Clinical Practice Guideline* (Fiore et al. 2008) identified (a) specific health system strategies and policies that can facilitate or complement clinical treatments for smokers who visit healthcare settings and (b) strategies that can enhance the likelihood that smokers receive evidence-based treatments for tobacco use and dependence and/or subsequently quit tobacco use. For example, the *Clinical Practice Guideline* found meta-analytic evidence that training clinicians increases the likelihood that they will provide cessation treatment (odds ratio [OR] = 3.2; 95% confidence interval [CI], 2.0–5.2) and that such training is associated with subsequent increases in cessation among their patients (OR = 2.0; 95% CI, 1.2–3.4). Similarly, in a Cochrane Review of training health professionals to conduct interventions in smoking cessation, Carson and colleagues (2012) concluded that clinicians who received training were more likely than untrained clinicians (control group) to ask patients to set a quit date, make follow-up appointments, and counsel smokers. However, in general, clinicians' follow-up with patients who are trying to quit remains suboptimal (King et al. 2013b; Bartsch et al. 2016).

Additionally, as outlined in Table 7.2, meta-analytic evidence from the *Clinical Practice Guideline* found that implementing systems to identify the smoking status of patients further increases clinicians' rates of intervention with patients (nine studies: OR = 3.1; 95% CI, 2.2–4.2) (Fiore et al. 2008). Because the prevalence of cigarette smoking remains high in certain subpopulations in the United States, such as persons of lower socioeconomic status (Wang et al. 2018) and those with comorbid mental health and other substance use diagnoses (Substance Abuse and Mental Health Services Administration 2013), specific types of healthcare providers or clinical environments that serve these subpopulations (e.g., psychiatrists, psychologists, social workers, federally qualified health centers) will likely play an increasingly important role in tobacco cessation.

Systems-level recommendations contained in the 2000 and 2008 *Clinical Practice Guidelines* have influenced numerous public and private sector policies and recommendations for treating tobacco use and dependence and have also served as the evidentiary basis for healthcare legislation (Torrijos and Glantz 2006). For example, evidence from the *Clinical Practice Guidelines* helped to inform cessation provisions in the 2010 *Patient Protection*

Table 7.2 Systems-level changes reviewed in the 2008 *Clinical Practice Guideline* to encourage smoking cessation

Strategy	Action	Strategies for implementation	Meta-analytic findings from the 2008 *Clinical Practice Guideline*
1. Implement a tobacco user identification system in every clinic	Implement an officewide system to ensure that tobacco use status is queried and documented for *every* patient at every visit to the clinic	• Office system change: Expand the review of vital signs to include tobacco use or implement an alternative universal identification system • Responsible staff (nurse, medical assistant, receptionist, or other person already responsible for recording the vital signs): Must be instructed on the importance of this activity and serve as nonsmoking role models • Frequency of utilization: Every visit for every patient, regardless of the reason for the visit • System-implementation steps: Routine smoker identification can be achieved by modifying data collection and documentation in EHRs to include tobacco use status as one of the vital signs	• Impact of having a tobacco use status identification system in place on rates of clinician intervention with their patients who smoke (n = 9 studies): OR = 3.1; 95% CI, 2.2–4.2 • Impact of having a tobacco use status identification system in place on abstinence rates among patients who smoke (n = 3 studies): OR = 2.0; 95% CI, 0.8–4.8
2. Provide education, resources, and feedback to promote interventions by healthcare providers	Healthcare systems should ensure that clinicians have sufficient training to treat nicotine dependence; that clinicians and patients have resources; and that clinicians are given feedback about their nicotine dependence treatment practices	• Educate all staff on a regular basis by offering training (e.g., lectures, workshops, in-services) on nicotine dependence treatments and providing continuing education credits and/or other incentives for participation • Provide resources—such as having ready access to tobacco quitlines (800-QUIT-NOW and www.smokefree.gov) and establishing a tobacco quitline referral system—and other community resources, self-help materials, and information about effective tobacco use medications • Report the provision of nicotine dependence interventions on performance measures, report cards, and evaluative standards for healthcare organizations, insurers, accreditation organizations, and physician group practices • Provide feedback to clinicians about their performance, drawing on data from EHRs and quality reporting programs, and evaluate the degree to which clinicians are identifying, documenting, and treating patients who use tobacco	• Effectiveness of clinician training on asking about smoking status (“Ask”) (n = 3 studies): OR = 2.1; 95% CI, 1.9–2.4 • Effectiveness of training on setting a quit date (“Assist”) (n = 2 studies): OR = 5.5; 95% CI, 4.1–7.4 • Effectiveness of training on rates of providing treatment (“Assist”) (n = 2 studies): OR = 3.2; 95% CI, 2.0–5.2 • Effectiveness of training on providing materials (“Assist”) (n = 2 studies): OR = 4.2; 95% CI, 3.4–5.3 • Effectiveness of training on arranging for follow-up (“Arrange”) (n = 2 studies): OR = 2.7; 95% CI, 1.9–3.9 • Effectiveness of training on abstinence rates (vs. no training) (n = 2 studies): OR = 2.0; 95% CI, 1.2–3.4

Table 7.2 Continued

Strategy	Action	Strategies for implementation	Meta-analytic findings from the 2008 *Clinical Practice Guideline*
3. Dedicate staff to provide nicotine dependence treatment and assess the delivery of this treatment in the performance evaluations of staff	Clinical sites should communicate to all staff the importance of intervening with tobacco users and should designate a staff person (e.g., nurse, medical assistant, or other clinician) to coordinate nicotine dependence treatments. Nonphysician personnel may serve as effective providers of nicotine dependence interventions	• Designate a nicotine dependence treatment coordinator for every clinical site • Delineate the responsibilities of the nicotine dependence treatment coordinator (e.g., ensuring the systematic identification of smokers, ready access to evidence-based cessation treatments [e.g., quitlines], and scheduling follow-up visits) • Communicate to each staff member (e.g., nurse, physician, medical assistant, pharmacist, or other clinician) his or her role and responsibility in the workflow and delivery of nicotine dependence services. Discuss these staff responsibilities during training of new staff	No PHS *Guideline* meta-analysis.
4. Promote hospital policies that support and provide inpatient nicotine dependence services	Provide nicotine dependence treatment to all tobacco users who are admitted to a hospital	• Implement a system to identify and document the tobacco use status of all hospital patients • Identify a clinician(s) to deliver nicotine dependence services to inpatients at every hospital and reimburse hospitals for delivering such services • Offer nicotine dependence treatment to all hospital patients who use tobacco • Expand hospital formularies to include FDA-approved nicotine dependence medications • Ensure compliance with The Joint Commission's regulations mandating that all sections of the hospital be entirely smokefree and that patients receive cessation treatments • Educate hospital staff about medications that may be used to reduce nicotine withdrawal symptoms, even if the patient is not intending to quit at that time	• No PHS *Guideline* meta-analysis • Rigotti and colleagues (2012), in a Cochrane review of in-hospital tobacco dependence treatment programs, concluded that intensive counseling interventions that began during the hospital stay and continued with supportive contacts for at least 1 month after discharge increased smoking cessation rates after discharge (n = 25 studies): OR = 1.37; 95% CI, 1.27–1.48 • Rigotti and colleagues (2012) also concluded that adding nicotine replacement therapy to an intensive counseling intervention increased rates of smoking cessation compared with intensive counseling alone (n = 6 studies): OR = 1.54; 95% CI, 1.34–1.79

Table 7.2 Continued

Strategy	Action	Strategies for implementation	Meta-analytic findings from the 2008 *Clinical Practice Guideline*
5. Include nicotine dependence treatments (both counseling and medication), identified as effective in the *Clinical Practice Guideline*, as paid or covered services for all subscribers or members of health insurance packages	Provide all insurance subscribers—including those covered by managed care organizations, workplace health plans, Medicaid, Medicare, and other government insurance programs—with comprehensive coverage for effective nicotine dependence treatments, including counseling and FDA-approved medications	• Cover evidence-based nicotine dependence treatments (counseling and medications) as part of the basic benefits package for all health insurance packages • Remove barriers to tobacco treatment benefits (e.g., copays, prior authorization) • Educate all subscribers and clinicians about the availability of covered nicotine dependence treatments (both counseling and medications) and encourage patients to use these services	• Rates of intervention for persons who received tobacco use interventions as a covered health insurance benefit (vs. persons with no tobacco cessation health insurance benefit) (n = 3 studies): OR = 2.3; 95% CI, 1.8–2.9 • Rates of quit attempts for persons who received tobacco use interventions as a covered health insurance benefit (vs. persons with no tobacco cessation health insurance benefit) (n = 3 studies): OR = 1.3; 95% CI, 1.0–1.5 • Estimated abstinence rates for persons who received tobacco use interventions as a covered health insurance benefit (vs. persons with no tobacco cessation health insurance benefit) (n = 3 studies): OR = 1.6; 95% CI, 1.2–2.2

Source: Fiore and colleagues (2008).
Notes: **CI =** confidence interval; **EHR =** electronic health record; **FDA =** U.S. Food and Drug Administration; **OR =** odds ratio; **PHS =** U.S. Public Health Service.

and Affordable Care Act (ACA) and the approach for documenting tobacco use in EHRs in the *Health Information Technology for Economic and Clinical Health Act* (HITECH) (Table 7.2).

As noted previously in this chapter, the *Clinical Practice Guidelines* were intended to help shape clinical practice, and thereby increase cessation—not just to serve as a repository of evidence on clinical policies. Numerous studies have addressed the impact of the *Clinical Practice Guidelines* on clinical performance and outcomes (Katz et al. 2004, 2014; Lesho et al. 2005; Smith et al. 2005; Caplan et al. 2011; Institute of Medicine, Committee on Standards for Developing Trustworthy Clinical Practice Guidelines 2011; Moody-Thomas et al. 2011; Shelley et al. 2011; Kruger et al. 2015). These studies have generally demonstrated that the implementation of guidelines (e.g., the *Clinical Practice Guidelines* or the "5 A's" [Ask, Advise, Assess, Assist, Arrange] clinical intervention or its abbreviated version, the "AAR" [Ask, Advise, Refer])—via training, systems-level changes, or other actions—is associated with higher rates of delivery of guideline-recommended interventions for smoking cessation (see Chapter 6). Some studies have also demonstrated an association with higher rates of cessation and/or lower smoking prevalence. For example, Caplan and colleagues (2011) noted that training primary care physicians to deliver the 5 A's was associated with significantly greater compliance with the interventions recommended in the *Clinical Practice Guideline*. Data following the release of the guideline also revealed (a) a significant increase in the percentage of patients at U.S. Department of Veterans Affairs (VA) healthcare facilities who were counseled about smoking cigarettes and (b) a significant decrease in the percentage of VA patients who smoked cigarettes (Ward et al. 2003; Katz et al. 2004). Thus, the practices recommended in the *Clinical Practice Guideline* can enhance the provision of treatment for smoking and cessation-related outcomes.

Recommendations from the U.S. Preventive Services Task Force

Created in 1984, USPSTF is an independent, volunteer panel of national, nonfederal experts in prevention and evidence-based medicine who review relevant scientific evidence and make evidence-based recommendations about clinical preventive services, such as screenings, counseling services, and medications (USPSTF 2017).

In 2015, USPSTF conducted an evidence review and updated its recommendations regarding the clinical treatment of tobacco use in primary care practices (USPSTF 2015). The USPSTF recommended that clinicians (a) ask

all nonpregnant adults about their tobacco use, advise them to stop using tobacco, and provide both behavioral interventions and FDA-approved pharmacotherapy for cessation to nonpregnant adults who use tobacco; and (b) ask all pregnant women about their tobacco use, advise them to stop using tobacco, and provide behavioral interventions for cessation to pregnant women who use tobacco. These recommendations are in the process of being updated. A draft research plan was posted on USPSTF's website for public comment in early 2018 (USPSTF 2018).

Although the 2015 USPSTF recommendations focus primarily on clinical cessation interventions, they are included in this chapter because the USPSTF guidelines increasingly serve as the basis for making decisions about insurance coverage and assessing performance and quality measures. The USPSTF "A" rankings have federal regulatory and reimbursement implications (USPSTF 2015). For example, the 2010 ACA used USPSTF's ratings as criteria for coverage requirements, requiring all non-grandfathered, private insurance plans to cover—without cost to the patient—preventive services that received "A" or "B" ratings (*Patient Protection and Affordable Care Act of 2010*), which included provision of tobacco cessation interventions to those who use tobacco (USPSTF 2009). As a result, a growing number of private insurers have included USPSTF "A" recommended preventive services as part of their basic package of covered health benefits; however, the administration and implementation of coverage for smoking cessation still varies widely across the insurance market, including among private insurers, state Medicaid programs, and Medicaid managed care plans (Kofman et al. 2012; American Lung Association 2015).

Overall, the evidence is sufficient to infer that the development and dissemination of evidence-based clinical practice guidelines increases the delivery of clinical interventions for smoking cessation.

Improving and Promoting Coverage of Treatment for Tobacco Use and Dependence

Treatments for tobacco use and dependence can be covered through (1) health insurance, which includes coverage through private insurance (both the individual market and the employer markets), Medicaid, or Medicare, or coverage provided to active-duty military and veterans; and/or (2) employer-based wellness programs that may be offered in conjunction with health insurance. Comprehensive coverage of tobacco cessation treatments includes coverage of evidence-based cessation treatments (individual, group, and telephone counseling) and FDA-approved cessation medications (Fiore et al. 2008). Comprehensive coverage removes or minimizes barriers, such as cost-sharing and prior authorization, that can impede access to cessation treatments (CDC 2014a, 2015; McAfee et al. 2015; Singleterry et al. 2015). As an example, effective 2011, the U.S. Office of Personnel Management (OPM) implemented model comprehensive insurance coverage of evidence-based cessation interventions for federal employees (OPM 2010a,b,n.d.). The insurance covers individual, group, and telephone counseling and all seven FDA-approved cessation medications for at least two quit attempts per year with no copays, coinsurance, or deductibles and no annual or lifetime limits (OPM 2010a,b,n.d.; CDC 2014b). Despite the model coverage approach, one potential limitation of this benefit is that some federal prescription plans require a health risk assessment as a precondition to getting medications covered at 100%; otherwise, there are copays for medications. Additionally, these assessments are primarily completed online, which could diminish utilization, particularly by persons with limited or no access to the Internet (CDC 2014a). Another barrier is that many plans require a prescription for cessation medications, even if they can be purchased over the counter, so persons can be reimbursed.

In spring 2019, OPM included language in its annual call letter and technical guidance for Federal Employees Health Benefits (FEHB) program carriers that reaffirmed and updated the comprehensive tobacco cessation coverage benefit, which was originally introduced in 2011, for federal employees (OPM 2019b). This new language highlights

- The effectiveness of combination nicotine replacement therapy (NRT),
- The fact that the combination of counseling and medication gives smokers the best chance of quitting,
- The importance of making cessation coverage barrier free and of promoting this coverage so that members and providers are aware of it and use it, and
- Opportunities to partner with pharmacists to provide education and decision support on cessation medications.

The call letter (OPM 2019b) and technical guidance (OPM 2019a) also call for FEHB plans to educate parents and healthcare providers on approaches to help prevent youth from using all tobacco products, including e-cigarettes, and on approaches to help youth who already use tobacco products to quit. Beyond its direct impact on 8.2 million federal employees, family members, retirees, and annuitants, this

updated cessation coverage from OPM has the potential to provide a model for private health insurers and employers, and it creates an opportunity to promote the updated cessation coverage to federal employees.

Health insurance coverage for evidence-based treatment of tobacco use and dependence complements the efforts of health systems and healthcare providers by making it easier for them to connect patients with treatment (Fiore et al. 2008; CDC 2014a; McAfee et al. 2015). Regardless of how well designed a coverage benefit may be, coverage alone, without promotion, is insufficient. It is critical that benefits for smoking cessation, whether offered through a health insurer or an employee wellness program, be promoted to increase awareness and use of covered treatments. The next section outlines the scientific evidence base for the coverage and promotion of benefits that address smoking cessation.

Health Insurance Coverage

The availability of comprehensive health insurance coverage for evidence-based treatment of tobacco use and dependence has been associated with higher utilization of cessation treatment and with successful cessation. In an examination of four insurance plans (N = 90,005 enrollees), Curry and colleagues (1998) showed that the highest rates of cessation were achieved for the group of smokers that had no barriers to benefits (i.e., no cost for behavioral counseling and NRT). The study concluded that full insurance coverage, compared with coverage with copays, was associated with a doubling of the overall quit rate in this population. Later, the *Clinical Practice Guideline* (Fiore et al. 2008) reported that providing tobacco cessation treatments as a covered health insurance benefit was associated with a greater likelihood that smokers would make a quit attempt (OR = 1.3; 95% CI, 1.0–1.5); a greater likelihood that persons who smoke would receive treatments for tobacco use and dependence during a healthcare visit (OR = 2.3; 95% CI, 1.8–2.9); and greater odds that they would quit successfully (OR = 1.6; 95% CI, 1.2–2.2) (Table 7.2) (Alesci et al. 2004; Holtrop et al. 2005; Murphy et al. 2005). Using nationally representative data, another study reported that Medicaid enrollees in states with more comprehensive coverage of cessation treatment had higher-than-predicted successful quit rates (8.3%) compared with those living in states with more limited coverage (ranging from 4.0% for pharmacotherapy without copayment to 5.6% for pharmacotherapy with copayment) (Greene et al. 2014). In another study using nationally representative data, Kostova and colleagues (2018) found that state Medicaid coverage of both cessation counseling and cessation medication was associated with an estimated mean increase of 3.0 percentage points ($p < .10$) in past-year quitting among covered Medicaid beneficiaries compared with persons without coverage. In addition, Ku and colleagues (2016) found that among Medicaid enrollees, state Medicaid coverage of at least one form of NRT, bupropion, and varenicline was associated with a 24–34% increase in the use of cessation medications.

Uniform implementation of comprehensive, evidence-based cessation coverage across health insurance products with minimal barriers (e.g., no prior authorizations) may also increase clinicians' delivery of cessation interventions by making it easier for them to understand their patients' coverage and increasing their confidence that their patients will be able to access the treatments they recommend (Kofman et al. 2012; McAfee et al. 2015; van den Brand et al. 2017).

Insurance coverage of tobacco cessation can also be a cost-effective benefit. For example, in 2006, the Massachusetts Medicaid program (MassHealth) began offering and intensely promoting comprehensive coverage for tobacco cessation with minimal barriers to all Medicaid enrollees. During the first 3 years of the program, more than 75,000 MassHealth members who smoked cigarettes (nearly 40% of MassHealth smokers) had used covered cessation treatments, with far more using cessation medications than counseling (Land et al. 2010a,b; CDC n.d.). Use of the benefit substantially influenced cessation, as the rate of cigarette smoking among MassHealth members decreased from 38.3% to 28.3% over 2-1/2 years (Land et al. 2010b). In another Massachusetts-based study, Land and colleagues (2010a) found that coverage for smoking cessation was associated with substantial decreases in hospitalization rates for cardiovascular disease, with annualized declines of 46% and 49% in admissions for acute myocardial infarction and other acute coronary heart disease diagnoses, respectively, among Medicaid smokers who used the benefit. An economic analysis focusing on the costs and savings from the perspective of the Medicaid program indicated that every $1.00 spent on medications, counseling, and promotional outreach was associated with a reduction of $3.12 in cardiovascular-related hospitalization expenditures, resulting in net savings between $2.00 and $2.25 (Richard et al. 2012).

Despite this evidence, numerous insurers have offered several reasons why they believe coverage should not be required, including

- Lack of evidence for effectiveness of interventions;
- Lack of evidence that coverage increases utilization;
- Coverage could decrease participant motivation by removing personal financial commitment to the cessation treatment program, thus potentially decreasing the odds of success;

- Lack of interest from smokers and institutional purchasers;
- The perception that smoking is a societal problem, rather than a healthcare problem;
- Concern that provision of coverage could make insurance unaffordable; and
- Concern that some of the health benefits of smoking cessation take years to be fully realized (e.g., reducing the risk of lung cancer or chronic obstructive pulmonary disease), and therefore this benefit may not accrue to the insurer, since the smoker may no longer be in the health plan when the benefit is realized (Gollust et al. 2008).

Over time, many of these rationales have been systematically refuted, often through large-scale research trials (Curry et al. 1998; Joyce et al. 2008; Hamlett-Berry et al. 2009; Smith et al. 2010; Fu et al. 2014, 2016). Nonetheless, adoption of smoking cessation coverage remains limited and varies widely (Kofman et al. 2012). Coverage mandates at the state and national levels can provide an important lever to encourage the delivery and use of evidence-based treatments and clinical services for smoking cessation and to standardize a minimum level of coverage. Such mandates often have components that are designed to influence the behaviors of both the beneficiary and the clinician or health system.

Examples of current insurance coverage in the United States and considerations for coverage across the major health insurance categories are outlined below, including for private insurance, Medicaid, Medicare, and Military Health System and Veteran's Health Administration. Specific epidemiologic data on the prevalence of quit attempts, use of cessation treatments, and recent cessation success is not covered in this chapter but can be found in Chapter 2.

Private Insurance

In 2017, 67% of insured U.S. adults were covered through the private market, 56% were insured through their employers, and 16% were insured through nongroup plans or health insurance exchanges; these figures do not total 100% because persons may have had more than one type of coverage during the calendar year (Berchick et al. 2018). The 2010 ACA included components designed to increase rates of tobacco cessation among members of private, non-grandfathered health plans via improved coverage for cessation treatments (Kofman et al. 2012; McAfee et al. 2015). Further subregulatory guidance (U.S. Department of Labor 2014; McAfee et al. 2015) clarified that insurers should provide a minimum of two courses of evidence-based treatment for tobacco cessation per year that include both cessation counseling and cessation medication with no cost sharing or prior authorization (Table 7.3).

The limited evidence available suggests that much private insurance coverage continues to fall short of this standard. Bloom and colleagues (2018) reported that some insurance plans may not recognize certain types of clinicians as providers of tobacco counseling for reimbursement purposes. In addition, some plans may explicitly exclude intensive preventive counseling or may charge high copays for longer, more intensive counseling visits. This may be because of a reliance on the 2009 USPSTF tobacco cessation recommendations, which did not clearly define intensive treatment, instead of a reliance on the more detailed 2014 subregulatory guidance from the U.S. Department of Labor (2014). However, the 2015 tobacco cessation recommendations from USPSTF clarified that

Table 7.3 ***Affordable Care Act*** **guidance of coverage of tobacco cessation treatment[a]**

"A group health plan or health insurance issuer will be considered in compliance with the ACA's requirement to cover tobacco-use counseling and interventions if, for example, it covers the following, without cost sharing or prior authorization:

- Screening of all patients for tobacco use; and
- For enrollees who use tobacco products, at least two tobacco cessation attempts per year, with coverage of each quit attempt including:
  - Four tobacco-cessation counseling sessions, each at least 10 minutes long (including telephone, group, and individual counseling); and
  - All FDA-approved tobacco-cessation medications (including prescription and over-the-counter) for a 90-day treatment regimen when prescribed by a health care provider"

Source: McAfee and colleagues (2015, p. 6) and U.S. Department of Labor (2014).
Notes: **ACA =** Patient Protection and Affordable Care Act; **FDA =** U.S. Food and Drug Administration.
[a]FDA has approved seven smoking cessation medications: five nicotine medications (patch, gum, lozenge, nasal spray, and inhaler) and two non-nicotine pills (bupropion and varenicline). Information is adapted from U.S. Department of Labor (2014); additional information is available at American Lung Association (n.d.a).

intensive visits should last at least 20 minutes, multiple sessions should be provided (at least four in-person counseling visits), and cessation rates may plateau after 90 minutes of total counseling contact time (USPSTF 2015).

Public Health England (2017) outlined an example of a model benefit that offers intensive counseling (i.e., individual and group counseling with more frequent and longer visits than outlined in the subregulatory guidance in the United States) and robust medication benefits (e.g., combination short- and long-acting NRT) for every smoker in the country. Table 7.4 includes some examples of cessation benefit models. These models have strengths and weaknesses, with MassHealth and Public Health England having the most comprehensive and intensive models. As noted in Chapter 6, it is important for insurers to adequately and fairly reimburse or "incentivize" healthcare systems and clinicians at a macro level for the costs of providing cessation counseling (Nolan and Warner 2017). Increasing clinician reimbursement for cessation counseling time (including high-intensity counseling) could help to increase reach and quit rates.

Medicaid

Medicaid is a joint federal and state program that provides health coverage for some individuals and families with low-incomes, qualified pregnant women and children, senior citizens, and people with disabilities (Medicaid.gov n.d.). Given that Medicaid enrollees comprise a low-income, disadvantaged population with disproportionately high rates of cigarette smoking (CDC 2014a, 2015; Jamal et al. 2016), and that smoking-related disease is a major driver of Medicaid costs (Xu et al. 2015b), comprehensive Medicaid coverage for tobacco use and dependence treatment is especially important. In 2016, almost 20% of insured U.S. adults were covered through Medicaid (Kaiser Family Foundation n.d.b). Smokers who are enrolled in Medicaid are more likely than privately insured and uninsured smokers to have chronic diseases and to experience severe psychological distress (Zhu et al. 2017). In 2017, 24.5% of adult Medicaid enrollees were current cigarette smokers, compared with 10.5% of adults with private health insurance (Wang et al. 2018) amounting to nearly 7.2 million Medicaid recipients, who make up about 21% of all U.S. adult smokers (NHIS, 2017 data). As discussed in Chapter 6, the smoking rate among Medicaid enrollees remained unchanged from 1998 to 2013 (Zhu et al. 2017). During 2006–2010, smoking-related diseases accounted for about 15% (or more than $39 billion) of annual Medicaid spending (Xu et al. 2015b).

National health objectives include a target for all state Medicaid programs to adopt comprehensive coverage of treatments for smoking cessation, including coverage of individual, group, and telephone cessation counseling and all seven FDA-approved cessation medications (DiGiulio et al. 2018). Although Medicaid cessation coverage varies by state, it has been gradually improving in recent years, especially with regard to cessation medications (DiGiulio et al. 2016, 2018). Changes in Medicaid policies have contributed, in part, to improved cessation coverage. For example, the Section 4107 of the 2010 ACA requires traditional (non-expansion) state Medicaid programs to cover cessation counseling and FDA-approved cessation medications for pregnant women with no cost-sharing (effective October 2010), and Section 2502 of the 2010 ACA prohibits these programs from excluding cessation medications from coverage for all traditional adult Medicaid enrollees (effective January 2014) (McAfee et al. 2015). In addition, in 2011, the Centers for Medicare & Medicaid Services (CMS) provided guidance that tobacco quitlines qualified as an allowable Medicaid administrative activity. As a result, state Medicaid programs became eligible to receive a 50% administrative match for quitline services provided to Medicaid beneficiaries (CMS 2011). While this policy does not impact state Medicaid cessation coverage per se, it provides Medicaid enrollees with increased access to evidence-based forms of cessation counseling.

Currently, all states (including the District of Columbia) cover at least some proven cessation treatments for all Medicaid enrollees; about three-fifths of states cover individual cessation counseling, and only about one-fifth of states cover group counseling; and about three-fifths of states cover all seven FDA-approved cessation medications (DiGiulio et al. 2018). Almost all states impose coverage barriers which restrict access to covered cessation treatments, especially cessation medications; common barriers include prior authorization, limits on duration, annual limits on quit attempts, and copayments.

Medicare

Medicare is a health insurance program for people aged 65 or older, people under age 65 with certain disabilities, and people of all ages with permanent kidney failure requiring dialysis or a kidney transplant (CMS 2019). In 2016, about 15% of insured U.S. adults received coverage through Medicare (Kaiser Family Foundation n.d.b). Medicare coverage of tobacco cessation affects a smaller number of beneficiaries compared with Medicaid, but it is still important, particularly because tobacco-related diseases often first become evident or worsen among older smokers, and cessation at any age is beneficial to health (USDHHS 2010). In recent years, Medicare has taken steps to improve coverage for cessation. For example, Medicare now covers—without cost sharing—multisession, individual counseling for two quit attempts per year (eight total visits). However, Medicare does not cover group or telephone counseling (Medicare Interactive n.d.).

Table 7.4 Models of comprehensive tobacco cessation coverage and health insurance benefits

Benefit plan	Counseling visits	Counseling format	Counseling dose/time	Setting	Clinician type	Medications
Mass Medicaid (Massachusetts Department of Public Health 2014)	Up to 16 face-to-face visits per year; more visits with prior authorization[a]	At least two 45-minute intake visits; 14 individual or group visits	Individual >30 minutes; group >60 minutes	Massachusetts	Physicians or nurses, certified tobacco treatment specialists, etc.	Seven FDA-approved medications, 180 days each, combinations
U.S. Office of Personnel Management (n.d.)	At least 8 visits per year	Individual, group, and telephone	>30 minutes for individual visits	Federal employee health benefit	Not specified	Seven FDA-approved medications,[b] 180 days each, combinations
Patient Protection and Affordable Care Act, U.S. Department of Labor (2014)	At least 8 visits per year	Individual, group, and telephone	>10 minutes for each visit	Applicable to group health plans and U.S. private health insurance	Not specified	Seven FDA-approved medications, 180 days each, combinations
Grade A Recommendation (U.S. Preventive Services Task Force 2015)	Multiple sessions, dose response, more or longer sessions improve cessation rates; >4 in-person visits per year; >8 visits largest effect (quit rate)	Individual, group, and telephone	Intensive in-person counseling for >20 minutes per visit[c]; minimal or brief visits also covered	Applicable to U.S. health insurance plans; best and most effective combinations are those that are acceptable and feasible to the patient	Specialized cessation counselors, psychologists, social workers, physicians, nurses, etc.	Seven FDA-approved medications, combinations
Public Health England (2017)	6–12 group[d] visits, 6–12 individual[d] visits, and 6–12 telephone visits	Group, individual, telephone with pharmacotherapy, brief physician or pharmacist with pharmacotherapy	Approximately 60 minutes per group, 30–45 minutes per person, and 15–30 minutes for telephone	England National Health Service primary care, and Stop Smoking Specialist clinics	Tobacco treatment specialists,[d] primary care physicians, and pharmacists	Seven medications and combination medications
Veterans and Military, U.S. Department of Defense (Huang et al. 2018)	Not specified	Individual, group, telephone, and brief primary care	Brief primary care; intensive counseling time not specified	U.S. Department of Defense; Veterans Affairs health system	Not specified	Seven FDA-approved medications, combinations

Notes: **FDA =** U.S. Food and Drug Administration.

[a]In Massachusetts, the telephone quitline is independent of face-to-face treatment, and Mass Medicaid patients can access unlimited phone counseling via the quitline.

[b]For smokers to receive quitting medications covered at 100%, some federal plans require them to complete an online health risk assessment as a precondition. Otherwise, smokers have copayments.

[c]Sixteen of 38 studies reported more than 300 total minutes of counseling. For studies examining combinations of behavioral and pharmacotherapy interventions, the intensity of behavioral counseling was more than 300 minutes in 60% of the studies.

[d]Breath carbon monoxide testing—a validated biomedical outcome measure—occurs at each intensive individual or group visit with a tobacco treatment specialist, which assists with treatment planning and motivation. Clinicians are trained to the standards of the National Centre for Smoking Cessation and Training and receive continued supervision.

Medicare Part D covers prescription cessation medications but not over-the-counter cessation medications (Medicare Interactive n.d.); the covered prescription medications are subject to copays.

Military Health Systems and Veteran's Health Administration

Veterans and active-duty military personnel smoke cigarettes at higher rates than the general U.S. adult population (Bray et al. 2009), making coverage of smoking cessation through health plans from VA and the U.S. Department of Defense (DoD) important. Tobacco use can affect military readiness and is costly to the healthcare systems of the DoD and VA. A DoD (2013) survey estimated that nearly half of all military service members (49.2%) had used a tobacco product (cigarettes, smokeless tobacco, cigars, pipes, or e-cigarettes) during the previous 12 months. Moreover, an estimated 171,000 persons who were active-duty service members in 2014 are projected to die in the coming decades because of tobacco-related disease (Roulo 2014). DoD spends more than $1.6 billion annually on tobacco-related health expenses (Institute of Medicine 2009). Tobacco cessation coverage through DoD's Military Health System or Defense Health Agency is complicated due to varying health policies across the services. Coverage across all services generally includes cessation counseling, a dedicated telephone quitline that serves the military, online support, and access to over-the-counter and prescription cessation medications.

In 2016, VA provided healthcare for approximately 1.3 million enrollees (14.9% of its total enrollment) who currently smoked cigarettes (Huang et al. 2017). Enrollees have access to several evidence-based benefits, including screening for tobacco use, brief counseling in primary care settings and more intensive counseling through clinics that specialize in treating tobacco use, all FDA-approved cessation medications, a dedicated national quitline (1-855-QUIT-VET) that serves veterans who are enrolled in the VA Health Care system, and a mobile texting program (SmokeFreeVET) (Huang et al. 2017). Once found eligible, veterans can receive all their health services from a VA facility or a VA networked facility, which can further help to enhance the provision of and continuity in care to this population.

Removing Barriers to Access

Insurance coverage and benefits can be designed in ways that encourage persons to seek out specific types of care or specific types of clinicians to provide such care. For example, removing barriers to access (e.g., copays, coverage limits, prior authorization) encourages individuals to use covered cessation treatments (Curry et al. 1998; Fiore et al. 2008; Land et al. 2010b; Greene et al. 2014; Friedman et al. 2016; van den Brand et al. 2017). The manner in which care is structured and reimbursed in clinical settings can also improve access to tobacco use and dependence treatment. Several incentive programs and quality measures have been put in place at the federal level to remove barriers and improve access to care. However, because many of these initiatives have been implemented in only the past 5–10 years, limited evidence exists on the effects they can have on cessation, particularly at a national level. Furthermore, evidence is unclear on the extent to which recent policy changes have been successful at removing these barriers. Table 7.5 lists each of these policy initiatives, their enactment date, and the specific provisions designed to encourage cessation through increased access to care or removal of barriers. Although specific studies on these recent policy initiatives have not been conducted, studies generally suggest that removing barriers to access increases the use of evidence-based cessation treatments and rates of quitting (Curry et al. 1998; Fiore et al. 2008; Land et al. 2010b; Greene et al. 2014; van den Brand et al. 2017).

Health insurance premium differentials, which allow insurers to charge higher premiums for tobacco users, could be another barrier to accessing cessation coverage and treatment. Tobacco use is one of only four factors that can be considered in setting health insurance premiums under the ACA (*Patient Protection and Affordable Care Act of 2010*); the other factors are individual (vs. family) coverage, rating area, and age (Curtis and Neuschler 2012; American Lung Association n.d.b). Although charging persons who use tobacco more for health insurance could motivate them to quit, such charges could also cause persons to avoid obtaining health insurance or to conceal their smoking status to avoid the additional charges, which would make it harder to identify smokers and engage them in cessation treatment (Kaplan et al. 2014). Based in part on these potential concerns, as of October 16, 2019, four states and the District of Columbia have barred insurers in both the individual and small group markets from charging smokers more for insurance premiums (Kaiser Family Foundation n.d.a). Because premium differentials based on tobacco use status are a recent phenomenon, only limited data are available on their effect on tobacco use and cessation and on ways to design differentials that can minimize their potential negative impacts and promote tobacco cessation.

Friedman and colleagues (2016) used data from the 2011–2014 Behavioral Risk Factor Surveillance System to examine the effects of surcharges for tobacco use on insurance status and smoking cessation among adults who were the most likely to purchase insurance from health insurance exchanges. The study found that, compared with smokers who faced no surcharges, smokers facing

Table 7.5 Healthcare system approaches designed to encourage smoking cessation

Organization	Date enacted	Provision
Quality Payment Program (n.d.b), part of the Medicare Access and Children's Health Insurance Program Reauthorization Act, provides incentives to providers and health systems to deliver quality, evidence-based clinical care to treat Medicare patients.	2017	Requires the screening of all patients, 18 years of age and older, for tobacco use at least once within 24 months AND the provision of a tobacco cessation intervention if the patient is identified as a tobacco user
Comprehensive Primary Care is a collaboration between CMS and private and public payers that aims to improve the delivery of primary care and achieve better care, smarter spending, and healthier people (CMS 2017c).	2012	Requires the screening of all patients, 18 years of age and older, for tobacco use at least once within 24 months AND the provision of a tobacco cessation intervention if the patient is identified as a tobacco user
Accountable Care Organizations are groups of doctors, hospitals, and other healthcare providers that come together to give coordinated, high-quality care to patients. The goal of coordinated care is to ensure that patients, especially the chronically ill, get the right care at the right time, while avoiding unnecessary duplication of services and preventing medical errors (CMS 2017a).	2010	Identifies and treats all patients who use tobacco
National Quality Forum (n.d.b) is a nonprofit, nonpartisan, public service organization that reviews, endorses, and recommends the use of standardized healthcare performance measures that are frequently used to assess performance in outpatient settings.	2009	Endorses a measure that screens all patients 18 years of age and older for tobacco use at least once within 24 months AND the provision of a tobacco cessation intervention if the patient is identified as a tobacco user. This performance measure is used in numerous programs that measure the quality of performance, including Meaningful Use, Medicare Shared Savings Program, CMS's Accountable Care Organization Program, and Physician Quality Reporting System.
Patient-Centered Medical Home is a care delivery model in which primary care physicians are responsible for coordinating necessary care for their patients (CMS n.d.).	2006	Recommends the use of registries, including a tobacco registry, to drive patient care, including the tracking of patient tobacco use and quit attempts
National Committee for Quality Assurance (n.d.a,b) is a private, not-for-profit organization dedicated to improving healthcare quality and developing quality standards and performance measures for a broad range of healthcare entities.	2000	Measures performance on medical assistance with smoking and tobacco use cessation, including advising smokers and tobacco users to quit, discussing cessation medications, and discussing cessation strategies
Inpatient Prospective Payment System is the Medicare payment program for hospitals tied to performance measurement of: • Acute care hospitals PPS (CMS 2017b) and • Inpatient psychiatric facilities (CMS 2017d).	1983	Uses The Joint Commission's Tobacco Inpatient Measures 1 (in 2015) and 2 and 3 (in 2016) for the prospective payment system for inpatient psychiatric facilities

Notes: **CMS =** Centers for Medicare & Medicaid Services.

medium or high surcharges had significantly reduced insurance coverage (reductions of 4.3 percentage points and 11.6 percentage points, respectively) and no significant change in smoking cessation. However, compared with smokers with no surcharges, smokers facing low (but non-zero) surcharges were significantly less likely to quit smoking, and smokers in groups with high surcharges were more likely to quit smoking. In addition to these data suggesting reduced insurance among smokers who are charged surcharges, premium differentials could also cause financial hardship for tobacco users by substantially increasing the cost of health insurance coverage (see Chapter 6). To decrease the potential negative impact of this barrier on smokers, insurers could offer policyholders access to a comprehensive smoking cessation benefit program, promote the program to increase awareness and use, and waive the differential for those who are making an assisted quit attempt. As of 2017, insurers in the small-group market were required to waive the differential for tobacco users who are participating in a cessation

program, but this requirement does not apply to the individual market (CMS 2013).

Another approach to decreasing barriers is widespread implementation of cessation programs at worksites (Cahill and Lancaster 2014), which can increase employees' access to high-quality treatment, boost employee morale, and give tools to smokers that help them successfully quit (Castellan et al. 2015). Employers and governments are two major purchasers of health insurance, so employers are also a key driver of health insurance coverage. Employers have an even greater economic incentive than insurers to help smokers quit because they stand to benefit from increased worker productivity and reduced healthcare costs; in particular, large self-insured employers have an especially strong incentive to reduce employee smoking rates because they often bear the risk for smoking-related disease costs (Bunn et al. 2006; Gollust et al. 2008; Berman et al. 2014; Xu et al. 2015b). Large employers are also well-positioned to insist that insurers include cessation coverage in standard insurance policies, rather than limiting this coverage to riders.

Promoting Coverage for Utilization of Smoking Cessation Treatments and Benefits

Coverage of proven cessation treatments by insurers and employers is a necessary but not sufficient condition for increasing smokers' use of these treatments and their cessation rates. For such coverage to have an impact, it must be systematically promoted to smokers and healthcare providers to ensure that both groups are aware of the coverage and use the covered treatments (Land et al. 2010b; CDC 2014a, 2015; McAfee et al. 2015). Promotion of coverage benefits is vital to increase use of these interventions, which in turn helps more smokers quit (McMenamin et al. 2004, 2006; Keller et al. 2011). For example, in the MassHealth example discussed previously, widespread promotion of the benefit to members and providers was viewed as central to the program's success (Land et al. 2010b). Similarly, the state Medicaid program in Wisconsin conducted a promotional campaign that targeted both Medicaid-certified providers and Medicaid enrollees. That campaign led to increases in the use of cessation medications and in the number of Medicaid members enrolling in the Wisconsin Tobacco Quit Line (Keller et al. 2011). Finally, following an increase in Minnesota's tobacco tax, ClearWay Minnesota conducted a 6-week media campaign to promote its quitline services (QUITPLAN). This campaign resulted in a 160% increase in calls and web visits combined and an 81% increase in enrollment for QUITPLAN services (Keller et al. 2015). For greatest impact, promotions should target both tobacco users and their healthcare providers, as was done in Massachusetts and Wisconsin. Ideally, states should track utilization of the covered treatments to gauge the effectiveness of the coverage and to encourage improvements in the promotional efforts (Land et al. 2010b; CDC 2014a; McAfee et al. 2015; Singleterry et al. 2015).

Taken together, the evidence is sufficient to infer that with adequate promotion, comprehensive, barrier-free, evidence-based cessation insurance coverage increases the availability and utilization of treatment services for smoking cessation.

Quality and Performance Measures and Payment Reforms

In general, performance measures can motivate quality improvements and create accountability for decisions and behaviors (Smith et al. 2008). Tobacco-related quality measures are tools that can be used to evaluate how well healthcare providers, practices, and systems are doing on the delivery of tobacco use and dependence treatment. Quality measures also exist for health plans. The most widely used tobacco-related quality measures are endorsed by the National Quality Forum (NQF)—a nonprofit, nonpartisan, public service organization that reviews, endorses, and recommends the use of standardized measures of healthcare performance (Kizer 2000). For example, NQF Number 0028 is one of the most widely used measures for tobacco use screening and cessation (NQF n.d.a). It measures the percentage of patients 18 years of age and older who are screened for tobacco use at least once during a 2-year measurement period and, among those who are tobacco users, the percentage who have received an intervention (brief counseling [3 minutes or less]) and/or pharmacotherapy). Currently, this measure is used in several performance and quality measurement programs, including Medicare and Medicaid Electronic Health Record Incentive Programs (commonly referred to as "Meaningful Use"[2]); the Medicare Shared Savings Program; CMS' Accountable Care Organization Program; CMS' Merit-based Incentive Payment System and Medicare Access and Children's Health Insurance Program (or CHIP) Reauthorization Act of 2015; and the Physician Quality Reporting System. Although NQF Number 0028 includes both screening for

[2]*Meaningful Use* is defined as the use of certified EHR technology to improve the quality, safety, and efficiency of healthcare and reduce health disparities; engage patients and families; improve the coordination of care for both population and public health; and maintain the privacy and security of patient health information.

tobacco use and receipt of a counseling intervention, it does not include or require referral to other, more intensive interventions with follow-up (e.g., quitlines, specific behavioral counseling, or coaching).

Linking Quality Measures to Payment

Quality measures can influence the frequency and consistency with which specific interventions are delivered. This effect may be strengthened when quality measurement is linked to payment. Payment-based strategies include (a) performance-based measures that provide financial incentives (or penalties) if a clinician or health system provides (or neglects to provide) the targeted clinical intervention and (b) innovative payment and delivery models that link payment to the outcomes of care rather than the quantity of care provided (i.e., value-based as opposed to volume-based healthcare payment models). The Quality Payment Program (n.d.a) provides a tangible example of this. Substantial scientific evidence shows that "pay-for-performance" programs that target clinicians, clinics, and health systems are associated with higher rates of delivery of clinical interventions for tobacco use and dependence than programs that do not offer an incentive (Kruse et al. 2013). However, the evidence is mixed as to whether such programs are associated with increases in quit rates (Roski et al. 2003; Millett et al. 2007; Twardella and Brenner 2007; An et al. 2008; Hung and Green 2012; Hamilton et al. 2013; Kruse et al. 2013; McLeod et al. 2015). For example, in a systematic review, Hamilton and colleagues (2013) identified 18 studies (including 3 randomized studies and 15 observational studies) that explored the effects of pay-for-performance programs on smoking cessation. The review found that financial incentives appeared to increase the recording of smoking status and the provision of advice to quit and referral to cessation services, but results for quit rates and long-term abstinence were mixed in the five studies that reported these outcomes.

Overall, the evidence is sufficient to infer that strategies that link smoking cessation-related quality measures to payments to clinicians, clinics, or health systems increase the rate of delivery of clinical treatments for smoking cessation.

Health Plan-Based Quality Measures

The National Committee for Quality Assurance (NCQA) works with health plans and others to improve the quality of healthcare. To be accredited by NCQA, health plans must report data for more than 40 performance standards. Health plans in every state, the District of Columbia, and Puerto Rico are NCQA accredited, and recent data indicate that those plans cover 109 million Americans, or 70.5% of all Americans enrolled in health plans (NCQA n.d.a). The Healthcare Effectiveness Data and Information Set (HEDIS) is an NCQA program that measures health plan performance and patient satisfaction; more than 90% of America's health plans use HEDIS. With regard to performance on tobacco use and dependence treatment, HEDIS measures the provision of tobacco cessation advice offered to tobacco users and discussions about cessation medications and other tobacco use and dependence treatment strategies (NCQA n.d.c). Because so many plans collect HEDIS data and the measures are so specifically defined and collected over time, the use of HEDIS makes it possible to compare performance across health plans.

Hospital-Based Performance Measures

The Joint Commission is an independent, nonprofit organization that accredits more than 21,000 healthcare organizations and programs in the United States (The Joint Commission n.d.). Typically, payment by insurers, including CMS and other federal payers, is contingent upon successful accreditation by a certifying organization, such as The Joint Commission. One criterion in the accreditation process for hospitals is to successfully meet selected performance measures. For certification by The Joint Commission, hospitals must select and report on 6 of 14 performance domains; 1 of these domains is tobacco cessation.

In 2012, The Joint Commission released an updated set of performance measures on tobacco cessation for hospitals (Fiore et al. 2012). To meet these performance measures, hospitals must (1) identify and document tobacco use status for all hospital patients 18 years of age and older, (2) demonstrate that evidence-based cessation counseling and medication are provided or offered to identified tobacco users during hospitalization, and (3) demonstrate that evidence-based cessation counseling and medication are provided or offered to identified tobacco users at discharge. Within certain constraints, hospitals may choose which performance measures they report. As of September 2018, only about 5% of accredited acute care hospitals in the United States (170 of 3,328 reporting hospitals, including 13 VA and 11 DoD hospitals) had selected the tobacco use identification and treatment delivery measures and were reporting relevant data to The Joint Commission (personal correspondence with The Joint Commission, March 18, 2019). This is likely because these performance measures (a) are voluntary and certain other measures are required or tied to payment; (b) are increasingly being reported electronically, and the cessation measures from The Joint Commission have not been fully converted electronically; and (c) may be more difficult to implement and report on than other measure sets (Freund et al. 2008, 2009). If the Joint Commission

cessation measures are not included in a CMS rule, otherwise tied to payment, or required, the number of acute care hospitals reporting on these measures will likely continue to decline. In contrast, two of these measures (offering cessation counseling and medication during hospitalization and again at discharge) are embedded in the Inpatient Psychiatric Facility Quality Reporting Program, and inpatient psychiatric facilities are required to report on these measures (CMS 2006).

Effective October 1, 2016, as part of its fiscal year 2017 payment determination, CMS required inpatient psychiatric facilities to begin reporting on the first two tobacco cessation performance measures from The Joint Commission. CMS extended this requirement to the third Joint Commission cessation measure effective October 1, 2017, as part of its fiscal year 2018 payment determination, and then discontinued the first measure for fiscal year 2019. These requirements, which embedded The Joint Commission's measures in the Inpatient Psychiatric Facility Quality Reporting Program, are associated with an increase in the delivery of tobacco cessation treatments in psychiatric facilities. Specifically, Carrillo and colleagues (2017) documented a 10-fold increase in the number of smokers who received inpatient tobacco cessation treatment after CMS implemented the requirement.

To realize the full potential of The Joint Commission's tobacco measures, reporting on those measures must be tied to payment. Currently, for acute care general hospitals, these measures are available for selection on a voluntary basis. As described previously, hospitals have several other sets of measures to pick from, and there is no incentive for them to select the tobacco cessation measures. Nonetheless, voluntary implementation of The Joint Commission's cessation measures in acute care general hospitals has been associated with increased intervention rates. For example, between 2014 and 2015, among 365 hospitals reporting data on The Joint Commission's tobacco measures in place at that time, the rate of screening for tobacco use increased from 94.1% to 97.8%; the rate at which treatment (brief counseling or NRT) was provided or offered during hospitalization increased from 51.2% to 60.5%; and the rate at which treatment was provided or offered at discharge increased from 36.4% to 40.6% (The Joint Commission 2016). A 2017 study found that EHRs can be leveraged to facilitate integration of The Joint Commission's tobacco measures into routine inpatient care; the study reported a modest increase in orders for cessation medications (OR = 1.35; 95% CI, 1.07–1.70) and a 10-fold increase in rates of cessation counseling (OR = 10.54; 95% CI, 7.87–14.12) (Shelley et al. 2017). Although only limited data are available to assess the impact that The Joint Commission's tobacco measures have had on increasing quit attempts and successful cessation, brief interventions that include screening for tobacco use and provision of brief counseling and/or medication have been shown to double the likelihood of successful quitting (Fiore et al. 2008).

Chapter 6 discusses the benefits of intensive bedside treatment (Rigotti et al. 2014; Mullen et al. 2015; Nahhas et al. 2017; Cartmell et al. 2018). Requiring hospitals to provide bedside counseling to patients who use tobacco and to provide these patients with cessation prescriptions and follow-up appointments for cessation counseling at discharge could facilitate the adoption of tobacco treatment across the continuum of acute care, rehabilitation treatment, and outpatient treatment (Fiore et al. 2012). This approach would make the treatment of tobacco dependence consistent with the treatment of other chronic conditions and could also generate increased patient referrals to face-to-face outpatient programs in hospitals and to state quitlines.

Realigning Payment Incentives

Another approach that has the potential to increase the availability, delivery, and efficacy of treatment for tobacco use and dependence in healthcare settings is the implementation of policies that align clinician and facility payment with the quality of care provided. Although tobacco-specific data are not yet available, broad-based payment reforms, such as value-based purchasing and bundled payments (i.e., payment for what a defined episode of care is predicted to cost), seek to reimburse clinicians or hospitals for the outcomes of care, rather than for separate services provided (as is the case with fee-for-service approaches). Although not designed expressly for tobacco dependence treatment, new payment models could make such treatment more of a focus for clinicians and hospitals because tobacco use causes and exacerbates many common and costly diseases, may lead to hospital readmissions, and delays and complicates healing—all of which increase costs for the healthcare system (USDHHS 2014). Two other approaches of reimbursement for hospitals and physicians also have the potential to increase the delivery of evidence-based cessation interventions: (a) allowing a wider variety of clinicians to bill for brief tobacco interventions and (b) expanding scope of practice to allow pharmacists to write prescriptions for cessation medications.

Alternative quality contracts (AQCs) are another policy mechanism that could enhance and improve the provision of tobacco use and dependence treatment. Such contracts, which are initiated by insurers, combine incentives to reduce healthcare spending with incentives to improve the quality of healthcare. Clinician groups share (a) the benefits of reducing costs (savings) and the financial risks of increased expenditures and (b) the opportunity to earn bonuses for improved quality of care. National data

are not yet available on AQCs, but early regional findings suggest that such strategies may increase rates of delivering tobacco cessation treatments. For example, in 2009, Blue Cross Blue Shield of Massachusetts established an AQC that was designed to pay healthcare service delivery systems a global fixed payment for all the services used by a covered population. Because they face a fixed budget for care delivered, health systems participating in AQCs have an incentive to emphasize preventive interventions, including those for tobacco use and dependence, that have been shown to reduce downstream healthcare costs. Huskamp and colleagues (2016) assessed the impact of the Massachusetts AQC on rates of the use of clinical smoking cessation services. The study found that rates of tobacco cessation treatment use were modestly higher among persons in AQC provider organizations than among those in non-AQC provider organizations: 2.02% vs. 1.87%, overall; 4.97% vs. 4.66 %, among enrollees at risk for tobacco-related complications; and 3.67% vs. 3.25%, among users of behavioral health services.

Enhancing the Technology of Electronic Health Records

EHRs are an important tool to improve the frequency, quality, and consistency of screening for tobacco use and dependence treatment, thereby increasing adherence to the *Clinical Practice Guideline* (Linder et al. 2009; Boyle et al. 2014). EHRs can also be used to connect persons who use tobacco with tobacco quitlines, text message-based support for cessation, and other clinical or community-based treatment resources by electronically referring patients to those services (i.e., through electronic referrals or eReferrals) (Greenwood et al. 2012; Kruse et al. 2012). Federal and state programs to promote the adoption and use of EHRs and health information technology have provided incentives to clinicians and healthcare systems to transition from paper records to EHRs and to use EHRs in ways that are intended to improve the quality, safety, efficiency, and coordination of healthcare while reducing health disparities (The Commonwealth Fund n.d.). For example, the HITECH Act of 2009 was designed, in part, to promote the adoption and use of health information technology, including EHRs. Early on, HITECH provided financial incentives to Medicare- and Medicaid-eligible professionals and hospitals that adopted and demonstrated "Meaningful Use" of EHRs through the Medicare and Medicaid EHR Incentive Programs (Berwick et al. 2008; Institute for Healthcare Improvement 2009), and Medicaid continues to provide those incentives. Meaningful Use criteria have included requirements regarding the documentation of patients' tobacco use and, for outpatient tobacco clinical quality measures, the delivery of cessation treatments for patients who use tobacco.

By 2017, 86% of office-based physicians had adopted EHRs, up from 42% in 2008 (Office of the National Coordinator for Health Information Technology 2019). In addition, 56% of eligible professionals and 97% of eligible hospitals and critical access hospitals (a designation given to eligible rural hospitals designed to improve access to healthcare in these communities) have participated in the Medicare and Medicaid EHR Incentive Programs. Through October 2018, eligible professionals and hospitals had received more than $38 billion from the program as part of incentive payments through Medicare and Medicaid reimbursement for adopting certified EHR technology and for using EHRs to achieve specified performance and technology objectives (i.e., demonstrating meaningful use) (CMS 2018).

As part of the EHR Incentive Programs, eligible professionals and hospitals are evaluated on their rates of asking about and documenting (in their EHRs) cigarette smoking status for patients 13 years of age and older. Meeting this measure has been a requirement for receiving payments through the Medicare and Medicaid EHR Incentive Programs, which is important because the assessment of smoking status is a critical first step for engaging patients in cessation treatment (see Chapter 6). For established users of EHR technology (Stage 2 of Meaningful Use), eligible professionals and hospitals must demonstrate that they use their EHRs to document the smoking status of at least 80% of their patients, 13 years of age and older, to receive performance payments through the program. By 2016, more than 97% of hospitals and eligible professionals that were reporting to the EHR Incentive Programs had met the requirement of documenting smoking status for patients visiting their healthcare facilities (CMS 2016).

In addition to encouraging the identification of patients who use tobacco, the EHR Incentive Programs include an electronic clinical quality measure to assess whether eligible professionals and hospitals provide cessation counseling services to patients identified as smokers and whether that counseling is documented in patients' EHRs. Although not required, this clinical quality measure encourages eligible professionals and hospitals to move beyond documenting tobacco use status to delivering evidence-based cessation counseling. In the United States, clinical quality measures and related financial incentives have been major influences on clinician performance for more than a decade (Papadakis et al. 2010; Thomas et al. 2017). Clinical quality measures help to drive accountability for eligible professionals and hospitals, and the resulting feedback helps to improve medical

care. Accordingly, the EHR Incentive Programs and other incentive-based efforts to increase and improve the use of EHRs have the potential to increase the rates at which tobacco use is identified, documented, and treated when these initiatives are structured to integrate proven clinical tobacco cessation interventions into EHRs (Boyle et al. 2014; Schindler-Ruwisch et al. 2017).

Fiore and colleagues (2019) studied eReferrals to the Wisconsin quitline in which 23 primary care clinics from two healthcare systems were randomized to one of two methods for referring to the quitline adult patients who smoke: a paper-based fax-to-quit referral process or an eReferral process. The eReferral process involved sending referrals from patients' EHRs to the quitline and receiving back into these EHRs outcome reports from the quitline. The fax referral process involved transmitting the same information in both directions via fax. The two systems saw a combined 14,636 smokers. Compared with clinics that were randomized to the fax referral process, clinics that were randomized to the eReferral process generated quitline referral rates 3–4 times higher and also connected patients with quitlines at higher rates (i.e., having patients accept a quitline call and at least begin the process or registering for quitline services). The eReferral method generated especially high rates of referrals among Medicaid recipients. The study, which was the first randomized study on this topic, concluded that eReferrals provide an effective way to refer patients who smoke to quitline services (Fiore et al. 2019).

Overall, the evidence is suggestive, but not sufficient, to infer that EHR technology increases the rate of delivery of smoking cessation treatments.

Population-Based Strategies on Smoking Cessation

In addition to strategies that can be implemented to increase the provision of clinical interventions to help smokers quit, broader population-level tobacco control strategies can also have important effects on tobacco cessation. This section reviews (1) strategies and programs that increase access to and use of evidence-based cessation treatments at the population level (e.g., funding tobacco quitlines) and (2) strategies that affect quit attempt rates, quit success rates, and smoking prevalence at the population level, without necessarily directly influencing cessation support or treatment at the individual level (e.g., price or smokefree laws). Several interventions can fit into both of these categories (e.g., mass media campaigns, state tobacco control programs, pictorial health warnings, very-low-nicotine-content cigarettes). Policy and regulatory details related to very-low-nicotine-content cigarettes and e-cigarettes are also described in this chapter. (Chapter 6 presents details about very-low-nicotine-content cigarettes and e-cigarettes as they relate to cessation outcomes.) The population-based strategies discussed in this chapter are reviewed in the context of their effects on smoking cessation. However, many of these strategies have broader effects. A review of these broader effects is beyond the scope of this report. The 2014 Surgeon General's report includes additional information on the broader effects of many of these strategies (USDHHS 2014).

Quitlines

Although telephone quitlines are a cessation treatment, they are included in this section on macro-level policy actions because they are designed to be accessed on a population-wide basis and are supported through broad policies, including funding at the state and federal levels. This chapter focuses on quitlines as an evidence-based, population-level strategy and on their relationships with cessation insurance coverage requirements and measures of treatment quality. Chapter 6 also addresses quitline services but focuses on their role as cessation treatments and discusses their effectiveness and reach.

Tobacco quitlines have typically been funded at the state level (Beyer et al. 2010), but they can also be used and funded by employers, health plans, and health systems. Quitlines offer a convenient solution to helping health insurers partially meet the ACA requirements for tobacco cessation coverage (Lemaire et al. 2015); they can be used by employers as an employee benefit to promote quitting, help increase employee productivity, and reduce health expenditures related to tobacco use (Hughes et al. 2011). Similarly, health systems can use quitlines as an adjunct to clinical care and to provide ongoing follow-up support to patients who are engaged in a quit attempt (Warner et al. 2012). Finally, health systems can leverage quitlines as a means to reduce hospital readmission rates and to meet tobacco use and dependence treatment quality measures.

A variety of models exist for employers, health plans, and health systems to establish and leverage quitline services, including (1) contracting directly with quitline vendors and other entities for their services; (2) providing funds to the state quitline to cover the costs incurred from directing employees, members, and patients to the state quitline; or (3) having their employees, members, or patients use state-funded quitline services without cost

sharing. The third model is less than ideal for the financial sustainability of state quitlines. Although this has been the default approach in many states, several states have sought to bring health plans and employers to the table to share costs and help sustain quitline services, especially in times of funding reductions for state quitlines. Funding for both service provision and promotion is a primary factor that can limit the reach of quitlines (North American Quitline Consortium 2016).

As briefly described in Chapter 6, quitlines are increasingly serving as "extended treatment" for busy clinicians. The first method that healthcare providers used to refer patients to quitlines is the passive approach of simply giving patients information on how to contact the quitline (e.g., a card or brochure with the quitline's number). In practice, few patients follow through and call the quitline. This method gradually gave way to a second approach: having healthcare personnel fax contact information for patients to the quitline (the "fax-to-quit" method). Quitlines then proactively call patients to deliver treatment. By 2009, all 50 states, the District of Columbia, Puerto Rico, and Guam reported offering fax referral services, although fax referral programs and implementation varied widely across locations. Despite including a proactive step to connect patients with the quitline, fax referrals can be cumbersome and time-consuming (Cantrell and Shelley 2009). For example, staff at quitlines sometimes had trouble reading clinicians' handwriting. In addition, clinic staff often used fax referrals inconsistently (Sheffer et al. 2012), or required an intensive program to promote and routinize the use of fax referrals (Redmond et al. 2010; Schauer et al. 2012; Warner et al. 2012).

Recent efforts have focused on using EHR technology to "eRefer" patients who smoke to the state's quitline (Boyle et al. 2011; Vidrine et al. 2013; Sharifi et al. 2014). This involves having clinicians make a HIPAA (Health Insurance Portability and Accountability Act of 1996)-compliant eReferral to a quitline, which may be operated by a vendor contracting with the state tobacco control program, health plan, employer, wellness vendor, or other entity. The healthcare provider sends an eReferral to the quitline with key information that identifies the patient (e.g., name, telephone number, best time to call). This prompts staff at the quitline to attempt to call the patient to deliver cessation services. Finally, the quitline closes the loop by sending an eReferral back to the patient's EHR with information about the outcome of the referral (e.g., was the patient successfully contacted, did the patient set a quit date, did the patient receive counseling or medication, did the patient make a quit attempt and successfully quit). This type of bidirectional, closed-loop approach is the most effective approach to implementing eReferrals (North American Quitline Consortium 2015), in part because hearing back from the quitline enables the provider to follow up with the patient and support any tobacco cessation attempt.

Data suggest that direct eReferrals to a quitline are more effective in connecting patients with that quitline than either traditional fax referral or passive referral, in which a tobacco user receives a business card or other materials featuring the phone number of the quitline; and both eReferral and fax referral offer benefits over passive referral because they proactively contact the patient to begin services. In a pilot study of eReferrals, Adsit and colleagues (2014) found that 14% of adult smokers who had visited an outpatient clinic were referred to the quitline via eReferral, while only 0.3% were referred using the traditional fax method. Elsewhere, Vidrine and colleagues (2013) conducted a two-arm, group-randomized study of 10 matched family practice clinics that compared eReferral to a quitline that used the passive referral approach of handing patients business cards for the quitline. Of all identified smokers in treatment, 7.8% were referred using eReferral, and 0.6% were referred through a passive referral (OR = 11.6; 95% CI, 5.5–24.3). EReferral serves as a good example of the complementary effects that can occur when healthcare systems respond to policy initiatives. The Meaningful Use program was effective in accelerating healthcare systems' adoption of EHR systems. In turn, eReferrals leverage these EHR systems to link healthcare systems with quitline services in a more seamless, consistent, and effective way.

Overall, the evidence is sufficient to infer that tobacco quitlines are an effective population-based approach to motivate quit attempts and to increase smoking cessation. Quitlines can be connected to health systems with EHRs to further facilitate and routinize the use and utility of quitlines.

Increasing the Price of Tobacco Products

Increasing the price of cigarettes, such as through taxation, is one of the most effective strategies for reducing cigarette consumption (USDHHS 2014). Cigarette price increases reduce cigarette consumption and smoking prevalence by leading some smokers to quit and some smokers to smoke fewer cigarettes per day and also reduce the number of young persons who initiate smoking (DeCicca and McLeod 2008; Reed et al. 2008; Bader et al. 2011; Chaloupka et al. 2011; Ross et al. 2011; Vijayaraghavan et al. 2013; Ross et al. 2014; USDHHS 2014; NCI and WHO 2016; Stevens et al. 2017). A comprehensive review by Chaloupka and colleagues (2011), which was summarized in the 2014 Surgeon General's report (USDHHS 2014), concluded that a 10% increase in cigarette price

would result in a 3–5% reduction in overall cigarette consumption. That review also concluded that increases in cigarette prices would result in decreases in the prevalence of smoking and in the average number of cigarettes smoked. In its report on the global tobacco epidemic, WHO (2017) concluded that raising taxes to increase the price of tobacco products is the most effective and cost-effective means to reduce tobacco use and encourage cessation. Moreover, reports from WHO (2017) and the U.S. Surgeon General (USDHHS 2012b, 2014) have concluded that youth and lower income populations are especially sensitive to price increases.

Research has demonstrated that price increases can also influence tobacco cessation at the national and state levels. Specifically, data indicate that price increases are associated with increases in motivation to quit, quit attempts, and rates of cessation at the population level (Chaloupka et al. 2002; Ross et al. 2011; Bush et al. 2012; Chaloupka et al. 2012; Choi and Boyle 2013; Scollo et al. 2013). For example, Stevens and colleagues (2017) found that each $1.00 increase in the average price of cigarettes was associated with a 6% increase in the quit rate of U.S. smokers 50 years of age and older.

The U.S. Community Preventive Services Task Force recommended increasing the unit price of tobacco products based on strong evidence that such a price increase is effective at reducing tobacco use (The Community Guide 2012a). The Task Force reported that this effect is driven, in part, by an increase in the number of persons who quit. The Task Force reported that for every 10% increase in price, there is a 3.8-percentage-point increase in cessation (The Community Guide 2013). More recently, NCI and WHO (2016) noted that only a few studies have used longitudinal data to examine the specific relationship between taxes or prices and cessation. Those studies generally found that higher prices increase the likelihood of smoking cessation (Tauras and Chaloupka 1999; Tauras 2004; Hyland et al. 2006; DeCicca et al. 2008; Ross et al. 2014). In particular, longitudinal data from the United States and Canada found evidence that (a) smokers living in areas with higher cigarette prices are significantly more motivated to quit, (b) price increases for cigarettes over time appear to increase motivation to quit, and (c) higher cigarette prices increase the likelihood of actual quitting (Ross et al. 2011).

In addition to national examples, robust findings for price-related outcomes at the state level indicate that price increases have both short- and long-term effects. For example, Reed and colleagues (2008) assessed rates of smoking cessation in California after an increase in the state's cigarette excise tax and a subsequent increase in retail prices by a cigarette manufacturer. For the months immediately following cigarette price increases, data from the 1996 and 1999 California Tobacco Surveys showed a significant increase in the proportion of smokers reporting quit attempts (a 45% year-over-year increase from 1995 to 1996 and a 140% increase after the excise tax went into effect in December 1998, $p < 0.05$), and a significant increase in abstinence rates (a 94% year-over-year increase from 1995 to 1996 and a 120% increase after the excise tax went into effect in December 1998, $p < 0.05$). In addition, Tseng and colleagues (2014) used a health informatics system to assess the impact of an increase in the federal cigarette tax on readiness to quit among low-income smokers in Louisiana. In the month following the increase, readiness to quit rose from 22% before the increase to 33%.

Increasing the price of cigarettes would also be expected to lead to smoking fewer cigarettes per day; however, the design of cigarettes has also changed over time in ways that allow smokers to more easily modify their nicotine intake (USDHHS 2010; Land et al. 2014). Jarvis and colleagues (2014) reported that today's smokers may smoke fewer cigarettes, but the nicotine yield per cigarette (based on cotinine levels) has increased 42% from 1988 to 2012. Thus, future research should address (a) how much smokers are compensating for reduced cigarette consumption by smoking more efficiently, (b) the effects of contemporary cigarettes, and (c) how these factors affect overall population health.

Although price increases have a strong impact on cessation at the population level, some recent data suggest that impacts may differ across subpopulations. For example, an analysis of data from the Tobacco Use Supplement to the Current Population Survey in the United States found that price is positively associated with (a) intention to quit among non-Hispanic White smokers ($p < .001$) and non-Hispanic African American smokers ($p < .001$) and (b) quit attempts among non-Hispanic White smokers ($p < .001$) but not among non-Hispanic African American smokers (Keeler et al. 2018). As another example, qualitative studies conducted in New York suggest that some low-income smokers may circumvent price increases by purchasing untaxed cigarettes from Native American reservations, bootlegged cigarettes, and/or single cigarettes or by taking advantage of discounts and coupons from the tobacco industry (Shelley et al. 2007; Curry et al. 2018). However, it is important to note that increasing the price of tobacco products does not automatically result in the creation of substantial black markets (National Research Council 2015). Although taxes and price differentials on tobacco products can create incentives for tax evasion, several environmental and administrative factors play an equal or greater role, including high levels of corruption, lack of commitment to addressing illicit trade, and ineffective administration of customs charges and taxes (NCI and WHO 2016). Substantial evidence from many countries shows that illicit trade can be prevented as the price

of tobacco rises, resulting in increased tax revenues and reduced tobacco use (NCI and WHO 2016).

U.S. tobacco price increases in the form of excise taxes have become an important source of state government revenues (Boonn 2017, 2018), contributing $13–$15 billion annually to state and federal government revenues (Orzechowski and Walker 2017), but little of that tax revenue is invested in tobacco control and cessation efforts (CDC 2012b). Because state tobacco control expenditures are correlated with decreased prevalence of tobacco use and increased use of evidence-based cessation treatments, funding of public education and treatment support related to tobacco cessation through excise taxes, along with funds from the Master Settlement Agreement (MSA) and other funds, could have a large impact on cessation (Ossip-Klein and McIntosh 2003; Farrelly et al. 2008; USDHHS 2014).

In summary, policies increasing the price of tobacco products have two important outcomes for tobacco cessation: (1) they provide incentives that can increase motivation to quit, decrease cigarette consumption, and drive smokers to make quit attempts; and (2) they provide a possible revenue stream to support evidence-based tobacco control strategies, including tobacco cessation activities. As policy makers consider increases in the price of tobacco products, they may consider ensuring that cessation services are funded and available to meet the increased demand. Large increases in price can be particularly effective in reducing smoking among vulnerable populations, including young people and individuals with lower socioeconomic status. Overall, the evidence is sufficient to infer that increasing the price of cigarettes reduces the prevalence of smoking, reduces cigarette consumption, reduces the average number of cigarettes smoked, and increases smoking cessation.

Smokefree Policies

The number of state and local laws that prohibit smoking in indoor public places and workplaces—including restaurants and bars—has increased rapidly in the past two decades (USDHHS 2014). As of June 30, 2018, 27 states and the District of Columbia had implemented comprehensive smokefree laws that prohibit smoking in all indoor areas of private sector worksites, restaurants, and bars (Centers for Disease Control and Prevention 2018a). In many states without comprehensive smokefree laws, local smokefree ordinances have protected substantial proportions of the state population (Tynan et al. 2016). As of October 1, 2019, 61% of the U.S. population is protected by a comprehensive state or local smokefree law (American Nonsmokers' Rights Foundation 2019b). Additionally, several jurisdictions have removed exemptions and included such areas as casinos and other gaming facilities in these laws (American Nonsmokers' Rights Foundation 2019a).

Although smokefree laws are primarily intended to eliminate involuntary exposure to secondhand smoke indoors, thereby protecting nonsmokers from the health risks of exposure to secondhand smoke, a substantial body of evidence has documented an association between the implementation of smokefree laws at the local, state, and national levels and decreased smoking among populations influenced by smokefree policies (USDHHS 2014). For example, USDHHS (2006) concluded that smoking restrictions in the workplace lead to less smoking among workers, and WHO (2009) concluded that smokefree workplaces reduce cigarette consumption among continuing smokers and lead to increased successful cessation. The impact of smokefree policies on cessation can be maximized when these policies are coupled with the promotion of free cessation resources (USDHHS 2006; International Agency for Research on Cancer [IARC] 2009).

The Community Guide (2012b) presented a systematic review on the effects of smokefree policies and concluded that smokefree policies increase the number of tobacco users willing to quit (reported as a mean absolute increase of 3.8 percentage points). Hopkins and colleagues (2010) reviewed 57 studies published between 1976 and 2005 and found that smokefree policies were associated with a median decrease of 3.4 percentage points (interquartile interval: -6.3 to -1.4 percentage points) in the prevalence of cigarette use and an absolute increase of 6.4 percentage points (interquartile interval: 1.3–7.9 percentage points) in cessation. The authors concluded that "the results of this review suggest that smokefree policies reduce consumption by continuing smokers, increase smoking cessation attempts, increase the number of smokers who successfully quit, and reduce the prevalence of tobacco use among workers" (p. S285).

Fichtenberg and Glantz (2002) reviewed 26 studies that evaluated the impact of smokefree ordinances at worksites and found that such ordinances were associated with a 3.8% (95% CI, 2.8–4.7%) reduction in the prevalence of smoking and 3.1% (95% CI, 2.4–3.8%) fewer cigarettes smoked among persons who continued to smoke. Other analyses found higher rates of smoking cessation at worksites that implemented smokefree policies (Longo et al. 2001); greater self-reported interest in quitting (Hammond et al. 2004); and a greater likelihood of smoking cessation the longer the smokefree policy was in effect (comparing rates of quitting at 18 and 36 months after implementation of a smokefree ordinance) (Hahn et al. 2009).

With the increasing adoption of smokefree policies in indoor public places and workplaces, private settings are becoming the major remaining source of exposure to secondhand smoke for many individuals. Residents of multiunit

housing are particularly likely to be exposed to secondhand smoke in their homes. An estimated 80 million people in the United States, or 25% of the U.S. population, reside in multiunit housing (King et al. 2013a). A subset of those individuals resides in government-subsidized housing, including public housing. Recent data indicate increases in the implementation of smokefree policies for subsidized, multiunit housing sites (Pizacani et al. 2012). Notably, the U.S. Department of Housing and Urban Development (2016) finalized a rule requiring public housing authorities to prohibit smoking in their buildings, including inside residents' units. The policy was coupled with promotion of tobacco cessation and cessation resources. This policy could help motivate many smokers to quit and may also encourage more private multiunit housing facilities to adopt similar policies (Levy et al. 2017a).

Promoting cessation resources in conjunction with the implementation of smokefree multiunit housing policies can help to facilitate the successful implementation of such policies and maximizes their impact on cessation. Increasing the adoption of smokefree policies in public and private multiunit housing and the availability of free cessation services to residents of multiunit housing is also important from a health equity standpoint because many residents of multiunit housing are from disadvantaged populations, including low-income persons, persons with behavioral health conditions, persons of minority racial/ethnic groups, persons with disabilities, elderly persons, and children. These populations are more likely to smoke cigarettes and/or to be exposed to secondhand smoke due to a variety of factors, and they often have less access to healthcare, including smoking cessation treatments (USDHHS 2006; CDC 2014a; Jamal et al. 2018).

In addition to federal progress making government subsidized housing smokefree, as of October 1, 2019, more than 56 cities and counties have local laws requiring smokefree policies in all multiunit housing, including both government or subsidized and private-market rate housing (American Nonsmokers' Rights Foundation 2019c). Data have shown that the adoption and maintenance of household smokefree rules in private single-family homes and smokefree policies in subsidized and public multiunit housing are associated with decreased consumption of cigarettes, increased confidence in achieving cessation, increased potentially considerable cost savings, and greater prevalence of successful cessation (Messer et al. 2008; Hyland et al. 2009; Kegler et al. 2012, 2015; King et al. 2014).

Smokefree restrictions can also be established in single-family homes to protect household members and to create an environment that can promote and support cessation (USDHHS 2006; IARC 2009). Household rules are voluntarily made by the occupants of the home (USDHHS 2006). Several studies have found that having rules in place for a smokefree home helps to prevent smoking relapse and increases other cessation behaviors, including quit attempts and successful cessation (Farkas et al. 1999, 2000; Gilpin et al. 1999; Borland et al. 2006; USDHHS 2006; Hyland et al. 2009; IARC 2009). Rules for a smokefree home can also support smoking cessation by making smoking more inconvenient, delaying smoking initiation, disrupting smoking rituals, and causing smokers to reduce their daily cigarette consumption (USDHHS 2006; IARC 2009). Coaching interventions can be (a) an effective way to motivate persons to establish rules for a smokefree home (Kegler et al. 2012; Escoffery et al. 2017; Bundy et al. 2018) and (b) delivered in a brief format through 2-1-1 telephone helplines that are set up with the primary goal of providing low-income populations with support and linkages to essential health and human services (Kegler et al. 2015; Mullen et al. 2016; Williams et al. 2016; Bundy et al. 2018; Thompson et al. 2019). Although beyond the scope of this report, a smaller body of research suggests that rules for a smokefree home can also prevent youth from starting to smoke and perhaps help youth quit smoking, in part by functioning as an expression of antismoking norms (Farkas et al. 2000). IARC (2009) concluded that policies for a smokefree home reduce adult smoking, youth smoking, and children's exposure to secondhand smoke.

Healthcare facilities are another important setting in which to implement smokefree or tobacco-free policies (Sheffer et al. 2009). Behavioral health treatment facilities, including mental health and substance use treatment facilities, are important because of the disproportional impact of tobacco use on populations with behavioral health comorbidities (Marynak et al. 2018). Despite attempts in the 1990s to explore the feasibility and acceptability of implementing smokefree policies in mental health and substance use treatment settings and taking other steps to address the high rates of smoking among persons with behavioral health conditions (Patten et al. 1996), many mental health and substance use providers and treatment facilities have been reluctant to implement tobacco-free facility policies and to integrate tobacco use and dependence treatment into routine clinical care (Schroeder et al. 2017). This may be due, in part, to some misconceptions implying that persons with behavioral health conditions do not want to quit and/or are not able to quit, and that helping smokers quit might undermine recovery from mental health problems and substance use (Schroeder and Morris 2010; American Legacy Foundation 2011; Prochaska 2011; CDC 2013b; USDHHS 2014). In addition, the tobacco industry has opposed smokefree polices in psychiatric hospitals, donated cigarettes to mental health facilities, and funded research suggesting that patients with psychiatric illnesses need tobacco for self-medication

(CDC 2013b; Prochaska et al. 2017; Marynak et al. 2018). However, attitudes toward such polices are changing, and mental health and substance use treatment facilities have increasingly begun to incorporate tobacco cessation into their missions, driven by greater efforts to integrate behavioral healthcare with primary healthcare, an increasing emphasis by behavioral health providers on a holistic approach that addresses patients' overall health and well-being, and the recognition that persons with behavioral health conditions are disproportionately likely to die prematurely of a smoking-related disease (USDHHS 2014; Schroeder et al. 2017). These efforts have coincided with increased adoption of smokefree and tobacco-free policies, including campuswide policies, by state behavioral health facilities (Marynak et al. 2018).

Overall, the evidence is sufficient to infer that smokefree policies reduce the prevalence of smoking, reduce cigarette consumption, and increase smoking cessation. Coupled with the aforementioned evidence, data also indicate that smokefree policies are particularly effective when coupled with the promotion of resources for cessation. Specifically, the Community Guide (2012b) notes that to maximize cessation outcomes, the implementation of smokefree policies should include the provision and promotion, including through quitlines, of proven cessation resources, such as counseling and medication.

Mass Media Campaigns

Scientific evidence shows that mass media educational campaigns can effectively motivate tobacco users to make quit attempts and promote tobacco cessation at the population level (NCI 2008; USDHHS 2014). Some hard-hitting advertisements (ads) seek to motivate smokers to quit by depicting the health consequences of continued smoking in emotionally compelling ways through graphic pictorial images and/or personal testimonials (Durkin et al. 2012). Other ads take a gain-frame approach by emphasizing the benefits of quitting rather than the losses associated with smoking (Toll et al. 2007). The latter type of ads is generally not as effective in motivating quit attempts as the type of ads that focuses on the health consequences of smoking and evokes fear or negative emotions (Durkin et al. 2012, 2018). Very few ads and no ad campaigns have attempted to systematically provide smokers with evidence-based recommendations on how to quit smoking, as recommended in the *Clinical Practice Guideline* (i.e., set a quit date in the near future; abstain from all cigarettes; remove all smoking-related paraphernalia; consider use of counseling and medications; and avoid high-risk social situations, especially use of alcohol, during the first weeks of a quit attempt [Fiore et al. 2008]).

Examples of Campaigns

The Fairness Doctrine campaign of 1967–1970 required stations broadcasting cigarette commercials to donate air time for antismoking messages that would provide the public, for the first time on television, with advertisements that countered messages from the tobacco industry (USDHHS 2014). In 2008, following a number of media campaigns in individual states, the Legacy Foundation (now known as Truth Initiative) launched EX, the first national adult cessation campaign since the Fairness Doctrine (Vallone et al. 2011). EX ran on television and radio from March 31 to September 28, 2008, and was targeted to adult smokers 25–49 years of age (Villanti et al. 2012).

In 2012, CDC launched *Tips From Former Smokers,* the first federally funded, national tobacco education campaign. This campaign provides a particularly strong example of the impact that mass media campaigns can have on adult smoking cessation at the national level. The *Tips* campaign has been on air from 2012 to 2019 for varying durations, ranging from 12 weeks in 2012 to 29 weeks in 2017. The hard-hitting, graphic testimonial campaign profiles real people who are living with serious long-term health effects from smoking and exposure to secondhand smoke (McAfee et al. 2017). Media placements vary from year to year, and the national ad buy has included placements on national broadcast, cable television, and digital properties. The national media campaign has been supplemented with additional ad placements in local media markets that have the highest rates of smoking. The media placements are designed to reach low-income and other groups that have the highest rates of smoking.

In addition to motivating smokers to quit, the *Tips* campaign also directs smokers to services that can provide them help with quitting. All ads in the *Tips* campaign promote a free source of cessation assistance: either the national quitline portal, 1-800-QUIT-NOW, which routes callers, based on their area code, to the quitline in their state, or a website that contains information to help smokers quit.

In January 2018, FDA launched *Every Try Counts,* the agency's first smoking cessation campaign. *Every Try Counts* builds on research that shows it takes many smokers multiple attempts to achieve long-term cessation (USDHHS 2014). The campaign aims to increase motivation to quit among adult smokers, 25–54 years of age, who have tried to quit smoking in the past but were unsuccessful. Complementary to *Tips From Former Smokers, Every Try Counts* uses positive messaging to reframe past quit attempts as important steps toward future success and to underscore that quitting is a process. The campaign is active in media markets with a high prevalence of smoking among adults, and messages are delivered through geotargeted digital, radio, and outdoor print

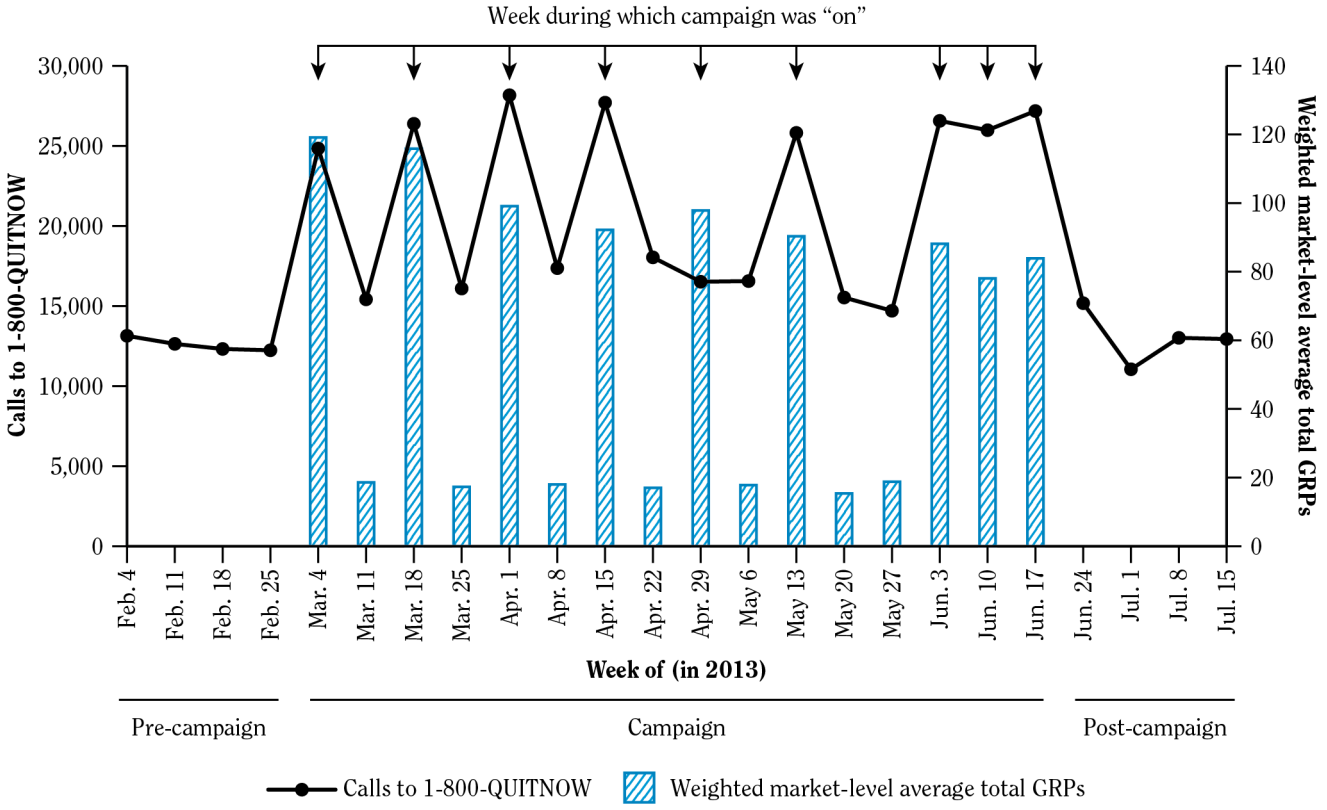
advertisements. Each ad includes a call to action to drive smokers to the campaign's website, which was developed in partnership with NCI, and features quitting tips, text message programs to help smokers "practice the quit," and online cessation counseling.

Features of Antismoking Campaigns that Support the Use of Cessation Resources

Mass media antismoking campaigns are frequently tagged with phone numbers for quitlines, an approach that serves several purposes. From a marketing and psychological perspective, inclusion of the quitline number extends a helping hand to smokers and serves to soften the message of hard-hitting campaigns that feature emotional ads with graphic images or personal testimonials about the consequences of smoking. Studies of antismoking media campaigns have found this approach to advertising to be most effective (Wakefield et al. 2008). Marketing research suggests that when ads offer cessation help, smokers are more likely to consider and accept messages about negative smoking-related health consequences. From the quitline perspective, tagging mass media antismoking ads with quitline numbers is a cost-effective means of increasing calls to quitlines (CDC 2006; Sheffer et al. 2010). The effectiveness of tagging ads with a quitline number is illustrated in Figure 7.2.

In addition to quitline numbers, mass media antismoking ads have been tagged with website addresses that provide cessation support, including information about referral centers that can direct interested persons to a range of cessation resources, including in-person services (ClearWay Minnesota n.d.). Other means of advertising quitline services that have been shown to be effective include systematic encouragement of referrals from healthcare providers (Curry et al. 1998; Redmond et al. 2010), which may also result in an improved capacity of healthcare systems to identify and engage with smokers because the quitline assists in follow-up. In addition, promotion of services emphasizing the availability of cessation

Figure 7.2 Intensity of ad placement for *Tips From Former Smokers (Tips)* campaign and call volume to 1-800-QUIT-NOW, 2013



Source: National Cancer Institute (unpublished data); The Nielsen Company (unpublished data).
Notes: Call volume for 1-800 QUIT-NOW and 2013 *Tips* campaign gross ratings points (GRPs) are measures of the intensity of ad media placement.

medications has been shown to increase quit success and increase calls (An et al. 2006; CDC 2006; Hollis et al. 2007; USPSTF 2015).

Effectiveness of Campaigns

The Fairness Doctrine campaign was associated with significant declines in cigarette smoking rates among both adults and youth (Hamilton 1972). An evaluation of the EX campaign that focused on adult smokers who were aware of the campaign in eight media market areas at baseline and approximately 6 months later found that EX had significantly increased quit attempts (OR = 1.24; p = .048) (Vallone et al. 2011).

In several studies, the *Tips* campaign was found to be associated with rapid and substantial increases in calls to states' quitlines, which persisted for the duration of each *Tips* campaign cycle (CDC 2012a, 2013a; Davis et al. 2015). The *Tips* campaign has also been associated with increases in visitors to the websites featured in *Tips* ads (CDC 2012a, 2013a; Shafer et al. 2016). Although call volumes to quitlines provide a tangible early indicator of the *Tips* campaign's impact, the campaign has a much broader impact on cessation, with many smokers indicating that they intend to quit smoking, that they tried to quit, or finally succeeded in quitting without ever calling a quitline. An analysis of nationally representative cohorts of 3,051 smokers who completed baseline and follow-up assessments during the first 3 months of the 2012 *Tips* campaign, found that quit attempts among smokers increased significantly from 31.1% (95% CI, 30.3–31.9) to 34.8% (95% CI, 34.0–35.7). Moreover, 13.4% of smokers who reported making a quit attempt reported abstinence at follow-up. Although the 3.2% absolute increase in quit attempts observed may seem small, this translates into an estimated 1.6 million additional smokers making a quit attempt, and an estimated 220,000 of these smokers remained abstinent at 3-month follow-up (McAfee et al. 2013; USDHHS 2014). Analyses from the first year of the *Tips* campaign suggest that the campaign saved an estimated 179,099 quality-adjusted life-years (QALYs) and prevented 17,109 premature deaths. The campaign was also cost-effective, costing an estimated $480 per quitter, $2,819 per premature death averted, $393 per life-year saved, and $268 per QALY gained (Grosse 2008; Xu et al. 2015a). In the United States, a commonly used threshold to consider an intervention cost-effective from a societal perspective is $50,000 per QALY gained (Xu et al. 2015a). In their evaluation of *Tips,* Neff and colleagues (2016) found that (a) exposure to the campaign was associated with increased odds of making a quit attempt in the previous 3 months (OR = 1.17; 95% CI, 1.02–1.36, p <0.05) compared with baseline and (b) *Tips* was associated with an estimated 1.8 million additional quit attempts, suggesting that the effectiveness of the campaign was not diminishing over time. Murphy-Hoefer and colleagues (2018) found that during 2012–2015, the *Tips* campaign was associated with approximately 9.15 million total additional persons who made a quit attempt and approximately 522,000 persons who quit smoking.

In 1997, Australia began a national tobacco cessation campaign with an intense and long-running mass media component that targeted adults (Hill and Carroll 2003). An analysis of quit attempts in a cohort of 3,047 Australian smokers exposed to the national tobacco cessation television ad campaign between 2002 and 2008 found that exposure to tobacco control advertising in the previous 3 months was associated with a greater likelihood of making a quit attempt, with each 1,000 increase in gross ratings points per quarter corresponding to an 11% increase in making a quit attempt (Wakefield et al. 2011).

In a detailed review of 70 studies (from January 2000 to July 2012) about mass-reach health communications campaigns for tobacco cessation, The Community Preventive Services Task Force identified 64 studies that assessed intervention campaigns in which television was the primary medium. Overall, the mass-reach campaigns were associated with decreased prevalence of tobacco use, increased cessation, and increased use of available cessation services and decreased tobacco use initiation among young persons. The campaigns were associated with an average 3.5-percentage-point absolute increase in cessation rates (2.0–5.0 in 12 studies); this translates to an approximate 14% relative increase (The Community Guide 2013).

Studies also showed that a dose-response relationship between quitting rates and greater exposure to mass media campaigns was associated with increased calls to a quitline and increased quit rates (The Community Guide 2013). Since that review, Davis and colleagues (2012) reported a 13% relative reduction in the prevalence of smoking and a 35% increase in quit attempts after a smoking cessation campaign in New York. Minnesota has also conducted extensive media campaigns to promote cessation, noting "a positive relation between weekly broadcast targeted rating points and the number of weekly calls to a cessation quitline and the number of weekly registrations to a web-based cessation program" (Schillo et al. 2011, p. 1).

Overall, the evidence is sufficient to infer that mass media campaigns increase the number of calls to quitlines and increase smoking cessation.

State Tobacco Control Programs

CDC's Office on Smoking and Health created the National Tobacco Control Program (NTCP) in 1999 to provide funding and technical support to U.S. state and territorial health departments, with the goal of encouraging

coordinated, national efforts to reduce tobacco use and tobacco-related disease and death. In particular, NTCP-funded state programs seek to achieve the four core goals of a comprehensive tobacco control program outlined in *Best Practices for Comprehensive Tobacco Control Programs* (or *Best Practices*):

- Prevent initiation among youth and young adults,
- Promote quitting among adults and youth,
- Eliminate exposure to secondhand smoke, and
- Identify and eliminate tobacco-related disparities among population groups (CDC 2014a).

To achieve the goal of promoting quitting among adults and youth, as well as the other three goals, comprehensive state tobacco control programs should include the following components: state and community interventions; mass-reach health communication interventions; cessation interventions; surveillance and evaluation; and infrastructure, administration, and management (CDC 2014a). As recommended in CDC's *Best Practices,* support for both direct provision of treatment and support for health systems and population-based tobacco control policies is what contributes to a comprehensive program (CDC 2014a), which has the greatest impact on increasing quit success.

The Community Preventive Services Task Force concluded that, based on the evidence, comprehensive tobacco control programs are effective in reducing tobacco use and exposure to secondhand smoke (The Community Guide 2014). Evidence indicates that such programs reduce the prevalence of tobacco use among adults and young people, increase the rate of quitting, and contribute to reductions in tobacco-related diseases and deaths. The Task Force concluded that comprehensive tobacco control programs are cost-effective, with savings from averted healthcare costs exceeding the costs of cessation interventions (The Community Guide 2014).

The Task Force reviewed 61 studies (through August 2014) on the impact of comprehensive tobacco control programs (The Community Guide 2014). Fifty-six of the studies evaluated the effects of such programs on cigarette use. Comprehensive tobacco control programs implemented over a median of 9 years were associated with an overall median decrease of 3.9 percentage points (-5.6 to -2.6 percentage points in 16 studies) in the prevalence of smoking among adults. More specifically, national studies showed a median decrease of 2.8 percentage points (-3.5 to -2.4 percentage points in 12 studies) in the prevalence of smoking among adults.

One of the studies reviewed by the Task Force compared California, a state with a comprehensive tobacco control program, with two states (New Jersey and New York) with similar policy climates but without comprehensive tobacco control programs from 1992 to 2002. The study found that long-term smoking cessation rates among adults were significantly higher in California compared with the other two states (Messer et al. 2007). In another study, Farrelly and colleagues (2008) examined the association between cumulative expenditures for state-specific antitobacco programs and changes in the prevalence of smoking among adults from 1985 to 2003. The authors concluded that expenditures on state tobacco control programs were associated with overall reductions in adult smoking. Rhoads (2012) used data from 1991 to 2006 in the Behavioral Risk Factor Surveillance System to examine the effects of comprehensive state tobacco control programs on cigarette smoking among adults. This study found that state programs had a significant impact on reducing the prevalence of cigarette smoking among adults, and that if all states had funded comprehensive tobacco control programs at the CDC-recommended level every year from 1991 to 2006, the prevalence of adult smoking in 2006 would have been between 18.5% and 19.8% instead of the observed prevalence of 20.07% (i.e., a 1.4–8.8% change), which translates into 635,000–3.7 million fewer cigarette smokers.

Despite the strong evidence base for many components of comprehensive tobacco control programs, the specific effects of state-funded clinical treatment programs for smoking cessation are less clear, and these effects appear to depend, in part, on sustained funding, availability, and promotion of cessation services. For example, two states have demonstrated that clinical cessation programs can yield high quit rates. New Jersey, with minimal funding, demonstrated high quit rates among moderate-to-heavy tobacco users who were treated at 15 clinics, worksites, or state-funded community cessation centers (Foulds et al. 2006; University of Medicine & Dentistry of New Jersey and School of Public Health 2007). Similarly, Minnesota developed QUITPLAN cessation treatment centers that operated for approximately 6 years (An et al. 2010). In an observational study of cohorts of participants of the service in 2004, 616 adults enrolled in the treatment centers, and 2,351 adults contacted the telephone-based helpline. Smokers at the treatment centers had a higher level of nicotine dependence than those who used a worksite, phone, or web-based treatment program. The 30-day quit rate was higher among smokers who contacted the telephone-based helpline (29.3%) than among smokers who attended the treatment centers (25.8%) (An et al. 2010). In another example, England's Stop Smoking Services have demonstrated high long-term quit rates with sustained funding for clinical treatment (>16 years) (Public Health England

2017). Existing evidence suggests that states that sustain adequate funding for comprehensive tobacco control programs can achieve higher rates of cessation.

Overall, the evidence is sufficient to infer that comprehensive state tobacco control programs can reduce the prevalence of smoking among adults, increase quit attempts, and increase smoking cessation. Because state tobacco control programs typically involve multiple strategies and components, it is difficult to attribute their effects to specific cessation strategies (such as support for clinical or onsite cessation services). The final section of this chapter describes how simulation studies can be used to evaluate the individual and synergistic effects of multiple tobacco control strategies.

Pictorial Health Warnings

Since 1965, Congress has enacted legislation requiring cigarette packages in the United States to carry small, text-based health warnings. Health warnings on cigarette packages can be an important means of conveying information to smokers about the health effects of smoking and available cessation resources. Nearly 50 countries now require large pictorial health warnings (also called graphic warning labels), often covering 50% or more of the cigarette package, that feature graphic depictions of smoking-related disease and a phone number for a tobacco cessation quitline (Hammond 2011; USDHHS 2014). However, health warnings on cigarette packages in the United States are weaker and less prominent than health warnings used on packages in many other countries (USDHHS 2000, 2014).

Evidence suggests that large, pictorial health warnings are a more effective means of reaching smokers than small, text-based messages (Hammond 2011). Furthermore, substantial evidence suggests that large pictorial health warnings that highlight the health risks of smoking are associated with increased knowledge of the harms of smoking, increased perceptions of risk associated with smoking, increased interest in quitting and motivation to quit, increased number of quit attempts, increased likelihood of remaining abstinent after a quit attempt, and reduced prevalence of smoking (Borland et al. 2009; Hammond 2011; USDHHS 2012; NCI and WHO 2016; Noar et al. 2016a,b; Reid et al. 2017). Given this evidence, the NCI-WHO Monograph 21 concluded that "Large pictorial health warning labels on tobacco packages are effective in increasing smokers' knowledge, stimulating their interest in quitting, and reducing smoking prevalence" (NCI and WHO 2016, p. 13).

Noar and colleagues (2016b) conducted a meta-analysis of 37 experimental studies about the effects of pictorial health warnings on tobacco packages in 16 countries. The study reported that "relative to text-only warnings, pictorial warnings (1) attracted and held attention better, (2) garnered stronger cognitive and emotional reactions, (3) elicited more negative pack attitudes and negative smoking attitudes, and (4) more effectively increased intentions to not start smoking and to quit smoking" (p. 341).

In a separate meta-analysis of longitudinal studies, Noar and colleagues (2016a) found that pictorial health warnings were associated with a 13% relative reduction in the prevalence of smoking among adults and with increased quit attempts. In another study with a nationally representative sample of Canadians, Azagba and colleagues (2013) assessed the impact of pictorial health warnings on smoking and quitting and found that the implementation of such warnings nationwide in Canada was associated with decreased prevalence of smoking (OR = 0.875; 95% CI: 0.82–0.93) and increased odds of making a quit attempt (OR = 1.33; 95% CI: 1.19–1.49). In a study of 14 countries that implemented graphic pictorial warnings, CDC (2011) found that the percentage of smokers thinking about quitting increased by at least 25% in 13 of the 14 countries.

Studies have also found that pictorial health warnings can lead to increased engagement in cessation treatment (Willemsen et al. 2002; International Tobacco Control Policy Evaluation Project 2009; Wilson et al. 2010; Noar et al. 2016a; Guydish et al. 2018). For example, in an experimental study, Guydish and colleagues (2018) found that smokers exposed to pictorial health warnings on their cigarette packages were significantly more likely to engage in a cessation group program compared with controls who did not receive pictorial warnings on their cigarette packages. Additionally, Australia, Brazil, the Netherlands, New Zealand, and the United Kingdom reported significant increases in calls to their national quitlines after the telephone numbers for the quitlines were included on pictorial health warnings (Willemsen et al. 2002; Miller et al. 2009; Hammond 2011, 2012; Noar et al. 2016a).

In summary, the evidence is sufficient to infer that pictorial health warnings increase smokers' knowledge of health harms from smoking, motivation and intention to quit, and quit attempts, and decrease the prevalence of smoking, particularly when the labels cover at least 50% of the cigarette package and identify specific resources and contact information for cessation support, such as a phone number for a tobacco quitline.

Although pictorial health warnings have been implemented in numerous countries worldwide as part of recommendations from the WHO Framework Convention on Tobacco Control (FCTC), the United States is not a party to the FCTC. In the United States, the *Family Smoking*

Prevention and Tobacco Control Act of 2009 (or Tobacco Control Act) (2009) requires FDA to implement pictorial health warnings on cigarette packages and advertisements. On June 22, 2011, FDA published a final rule requiring color graphics depicting the negative health consequences of smoking to accompany the nine textual warning statements set out in the *Tobacco Control Act*. However, several tobacco companies challenged the final rule in court, and on August 24, 2012, the U.S. Court of Appeals for the District of Columbia Circuit vacated the rule on First Amendment grounds and remanded the matter to the agency (*R.J. Reynolds Tobacco Co., et al. v. FDA et al.* 2012).

FDA conducted further research on pictorial health warnings. A subsequent lawsuit by public health groups filed in 2016 resulted in a September 2018 decision by the U.S. District Court of Massachusetts that ordered FDA to expedite the issuance of a final rule for cigarette health warnings, after finding that FDA had unlawfully withheld and unreasonably delayed execution of the provision in the *Tobacco Control Act* that requires the implementation of such warnings (*American Academy of Pediatrics v. FDA 2018; FDA* 2018a). In March 2019, the U.S. District Court of Massachusetts ordered FDA to submit the proposed rule for publication in the *Federal Register* by August 15, 2019, and to submit the final rule for publication in the *Federal Register* by March 25, 2020 (*American Academy of Pediatrics v. FDA* 2019a).

FDA issued new cigarette health warnings through a proposed rule on August 16, 2019 (*Federal Register* 2019). When finalized, the new health warnings on cigarette packages and in advertisements would promote greater public understanding of the negative health consequences of smoking. The 13 proposed warnings, which feature text statements and photo-realistic color images of the lesser-known health risks of cigarette smoking, stand to represent the most significant change to cigarette labels in the United States in 35 years.

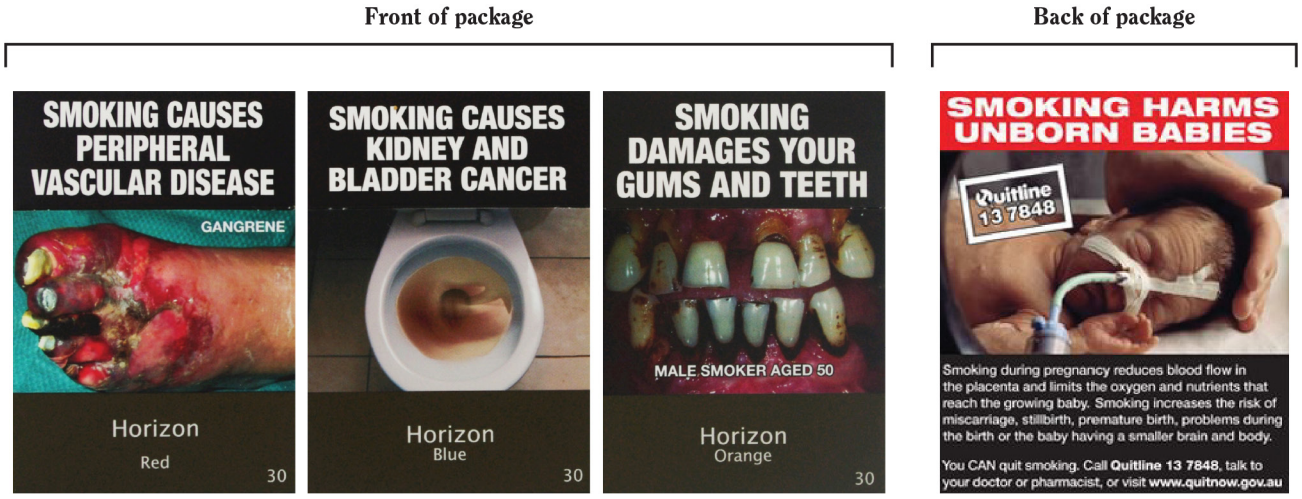
Plain Packaging

Plain packaging requirements standardize the appearance of cigarette packages by removing all brand imagery; using a standard background color and specific text size, font, and position; and including government-mandated information, such as health warnings (Figure 7.3) (USDHHS 2012b). In 2011, Australia became the first country to enact plain packaging requirements. Since then, some countries have passed similar laws standardizing the packaging of tobacco and/or cigarette products—including France, Ireland, New Zealand, Norway, Saudi Arabia, and the United Kingdom—and other countries are in the process of implementing such laws (Campaign for Tobacco-Free Kids 2019a). These laws are often combined with laws about pictorial health warnings.

Plain packaging can have several possible effects, particularly with regard to reducing the appeal of tobacco products (USDHHS 2012b; WHO 2016b). Plain packaging can:

- Make smoking less appealing because plain packages are less attractive and engaging than packages with normal branding (USDHHS 2012b; Hughes et al. 2016; WHO 2016b);

Figure 7.3 Pictorial warning on cigarette packages in Australia



Source: Tobacco Labelling Resource Centre (n.d.a,b), with permission.

- Enhance the effectiveness of health warnings by increasing their noticeability (Hammond 2010; WHO 2016b); and

- Reduce false beliefs about the absolute risks of different tobacco products (Hammond 2010; WHO 2016b).

Taken together, the scientific literature indicates that removing the color and brand imagery from cigarette packages reduces the appeal of cigarettes, enhances the effectiveness of health warnings, and may reduce the consumption of cigarettes (USDHHS 2012b; NCI and WHO 2016; WHO 2016b). Evaluation studies indicate that these reductions may, in turn, result in increased quit attempts and decreased prevalence of smoking (Durkin et al. 2015; McNeill et al. 2017).

Plain packaging can further support and enhance cessation efforts by removing misleading packaging and labeling and reducing false beliefs about the relative risks of different brands of cigarettes. The 2012 Surgeon General's report found that plain packaging has the potential to reduce false beliefs on the part of youth and adults that one cigarette brand is less harmful or easier to quit than another (USDHHS 2012b). In addition, plain packaging could counteract efforts by tobacco companies to color-code packages as a way to communicate a hierarchy of supposed relative harm within brand families (Dewhirst 2018). This activity occurs in countries, including the United States, that prohibit the use of unauthorized modified risk descriptors, such as "light," "mild," or "low tar" (*United States v. Philip Morris USA, Inc.* 2015; Dewhirst 2018). Reducing false beliefs about differences in risks between brands and within brand families could increase the number of current smokers who quit entirely instead of switching to other perceived "less risky" brands of cigarettes.

The tobacco industry has filed lawsuits alleging violations of domestic laws and international laws and treaties in response to regulatory proposals to remove brand imagery in the United States and in other countries (USDHHS 2012b; WHO 2016b). This speaks to the importance of brand imagery in sustaining purchases and, thus, tobacco use (Wakefield et al. 2002). Studies have concluded that plain packaging requirements can reduce cigarette consumption (WHO 2016b); and Australia's plain packaging requirements, which were implemented in conjunction with requirements around pictorial health warnings, have helped to reduce the national prevalence of smoking (Chipty 2016; Australian Department of Health n.d.).

The evidence is suggestive, but not sufficient, to infer that plain packaging increases smoking cessation (Moodie et al. 2011; Mannocci et al. 2013; USDHHS 2014; WHO 2014; McNeill et al. 2017). Although the body of evidence on the efficacy of plain packaging continues to grow, further evaluation of these policies is required to better understand the specific impacts of plain packaging requirements on smoking cessation behavior.

Reduced Retail Point-of-Sale Advertising and Retail Density

Population-based policies linked to the sale and retailing of tobacco products have the potential to increase rates of smoking cessation, but the level of evidence is not yet sufficient to draw broad conclusions about their impacts on cessation behavior. These policies include decreasing point-of-sale tobacco marketing or exposure to advertising and decreasing the retail availability of tobacco products.

The 1998 MSA between 46 U.S. states and the four largest tobacco companies in the United States requires those companies to make payments to the settling states in perpetuity to offset medical costs associated with smoking. The MSA also restricts the advertising, marketing, and promotional activities of the four companies, including the use of cartoons, billboards, or merchandise branding to advertise cigarettes (National Association of Attorneys General n.d.). Although smoking rates in the United States have continued to decline since 1998 (USDHHS 2014), evidence suggests that the tobacco industry has shifted its marketing strategy to focus on the retail environment in direct response to the MSA (Ruel et al. 2004). Retail stores are now the primary means by which the tobacco industry advertises and promotes its products. In 2017, the tobacco industry spent more than $1 million per hour marketing cigarettes and smokeless tobacco, a large majority of which was spent on discounts to help retailers reduce the price of tobacco products for consumers (Federal Trade Commission 2019a,b). In addition to offering price discounts, the tobacco industry advertises its products in the interior and on the exterior of retail stores (USDHHS 2012b; Center for Public Health Systems Science 2016).

Several policies that regulate the advertising of tobacco products in retail spaces have the potential to reduce the affordability, availability, and attractiveness of tobacco products (Center for Public Health Systems Science 2016) and to help support persons who are trying to quit using tobacco (Clattenburg et al. 2013; Mantey et al. 2017). For example, in addition to increasing smoking initiation among youth (USDHHS 2012b, 2014), the advertising of tobacco products in retail stores may undermine cessation attempts among adult smokers by increasing their cravings or prompting them to make unplanned purchases (McCarville and Bee 1999). The number and

location of tobacco retail stores (retail density) also can influence cessation. Proximity to tobacco retail outlets and higher retailer density are associated with reduced quit attempts for adults and can foster disparities in tobacco use and cessation behaviors (Chuang et al. 2005; Henriksen et al. 2008; Center for Public Health Systems Science 2014, 2016; Lipperman-Kreda et al. 2014; Young-Wolff et al. 2014).

Regarding exposure to point-of-sale tobacco marketing, in a study of 999 adult smokers in Nebraska, Siahpush and colleagues (2016) found that exposure to greater amounts of point-of-sale advertising in one's neighborhoods was associated with a lower probability of quit success among smokers who reported making a quit attempt in the previous 6 months. In a study of adult smokers in Australia, Germain and colleagues (2010) found a negative association between sensitivity to point-of-sale tobacco marketing and making a quit attempt. Some jurisdictions have also restricted the use of coupons and discounts, because evidence clearly shows that increasing price is the single most effective policy strategy to reduce tobacco use (USDHHS 2000, 2012b).

Reducing the number of retailers is another policy strategy that may reduce tobacco use, given the relationship between tobacco retailer density and tobacco use (Institute of Medicine 2007; Luke et al. 2017). Several studies have associated decreased long-term tobacco cessation with the increased availability of tobacco in retail markets, after considering retail density (i.e., the number of retailers per area or population) and retail proximity (i.e., the distance to the nearest retailer from one's home or school). For example, in a study of more than 400 adult smokers in Houston, Texas, Reitzel and colleagues (2011) found that even after adjusting for several sociodemographic variables, residential proximity to tobacco outlets provided unique information for predicting long-term continuous abstinence from smoking during a specific quit attempt. Those living less than 250 meters or less than 500 meters from a tobacco outlet were less likely to sustain a quit attempt than those living farther than 250 or 500 meters ($p = 0.01$ and $p = 0.04$, respectively). In the United Kingdom, Han and colleagues (2014) could not replicate Reitzel and colleagues' (2011) findings; however, the location and coding of retail outlets differed between the two studies. In a study of 8,751 adult smokers in Finland, Halonen and colleagues (2014) found that, among men who were moderate to heavy smokers at baseline, those living less than 0.5 kilometers (km) from the nearest tobacco store had a 27% lower likelihood of cessation at follow-up compared with those living 0.5 km or more from such a store, and that having a store within 0.5 km of one's home decreased cessation in men who were moderate or heavy smokers.

In summary, the evidence is suggestive, but not sufficient, to infer that decreasing the retail availability of tobacco products and exposure to point-of-sale tobacco marketing and advertising increases smoking cessation. Although causal conclusions cannot be drawn at this time, these findings should not prevent tobacco control practitioners from taking action to reduce the retail density of tobacco outlets and the impact of point-of-sale tobacco marketing and product offerings and to evaluate and report the results of such actions. A strong theoretical basis exists for limiting tobacco retail density, in part, because of the causal relationship between tobacco marketing and increased tobacco consumption (NCI 2008). Furthermore, evidence from alcohol control research indicates that limiting alcohol retail density can reduce excessive alcohol consumption (Campbell et al. 2009); this relationship may translate to tobacco.

Restricting the Sale of Certain Types of Tobacco Products

The 2014 Surgeon General's report concluded that imposing greater restrictions on the sale of certain types of tobacco products may also help to accelerate the decline of tobacco use (USDHHS 2014), particularly when coupled with other cessation strategies. This may include restricting the sale of certain tobacco products (e.g., menthol-flavored tobacco products, products with other flavors) or restricting the sale of all tobacco products in a setting (e.g., a pharmacy). The appeal of flavored tobacco products to youth and young adults is well-documented (USDHHS 2012b, 2016). Congress, concerned about tobacco use among youth, enacted the *Tobacco Control Act* of 2009, which banned cigarettes with characterizing flavors (e.g., cherry, chocolate, etc.) other than menthol (USDHHS 2012a). Menthol is a widely used flavor-characterizing additive in cigarettes among all age groups (Rose et al. 2019), with approximately 39% of all smokers reporting use of menthol cigarettes in 2012–2014 (Villanti et al. 2016). Use of menthol cigarettes is more prevalent among African Americans, Hispanics, smokers of lower socioeconomic status, and women (Delnevo et al. 2011; Giovino et al. 2015; Rath et al. 2016).

Menthol has been found to impede tobacco cessation (FDA n.d.; Villanti et al. 2017). In a rigorous review of the scientific evidence, FDA's Tobacco Products Scientific Advisory Committee concluded that menthol in cigarettes is associated with increased dependence and reduced success in smoking cessation, especially among African American smokers (Stahre et al. 2010; Hoffman and Miceli 2011; Levy et al. 2011a; FDA n.d.). Several reviews (Foulds et al. 2010; Villanti et al. 2017; FDA n.d.) and randomized

controlled trials (Faseru et al. 2013; Rojewski et al. 2014; Smith et al. 2014) have reached the same conclusions. Specifically, smokers of menthol cigarettes make more quit attempts than smokers of nonmenthol cigarettes but have a more difficult time quitting successfully (Trinidad et al. 2010; Delnevo et al. 2011; Levy et al. 2011a; Villanti et al. 2017). Potential explanations for the negative impact of menthol on cessation is that menthol leads to greater nicotine exposure and dependence (Benowitz et al. 2004; Giovino et al. 2004) or enhances the rewarding effects of nicotine (Wickham et al. 2015; Henderson et al. 2017).

However, not all studies have found an association between menthol use and cessation (Hyland et al. 2002; Fu et al. 2008; Steinberg et al. 2011). Differences in sampled populations, settings, study designs, and control variables may account for inconsistencies (Smith et al. 2019). Although, a meta-analysis of 19 studies of nearly 150,000 cigarette smokers did not find a significant association between menthol use and cessation (adjusted OR = 0.95; 95% CI, 0.89–1.03), it found that Black or African American menthol users were significantly less likely to quit than their nonmenthol-using counterparts (adjusted OR: 0.88, $p < .05$) (Smith et al. 2019). Many studies that have not found an association between menthol cigarette use and cessation in the general population have found an association by race/ethnicity, with African American menthol smokers having a lower likelihood of smoking cessation (Lewis et al. 2014; Smith et al. 2019; FDA n.d.). Use of menthol cigarettes has been shown to contribute to tobacco cessation-related disparities in the United States (Gardiner and Clark 2010; Garrett et al. 2016; FDA n.d.). Smith and colleagues (2019) concluded that menthol bans will have a favorable impact on smoking cessation rates among Black or African American smokers.

In 2016, WHO conducted a review of menthol in tobacco products and based on the evidence, recommended a ban on menthol in cigarettes, including menthol analogues, precursors, and derivatives (WHO 2016a). WHO also recommended prohibiting menthol in products other than cigarettes. Several countries have since adopted these WHO recommendations (WHO 2016a; 2018). In the United States in 2013, the city of Chicago was the first U.S. jurisdiction to restrict the sale of menthol tobacco products. After local retailers sued the city to block the policy, the court found that local governments have the authority to restrict the sale of menthol tobacco products (*Independents Gas & Service Stations Associations, Inc. v. City of Chicago* 2015; Tobacco Control Legal Consortium 2018). As of October 2019, more than 50 U.S. municipalities have restricted the sale of menthol tobacco products (Campaign for Tobacco-Free Kids 2019b).

In several studies, menthol smokers reported that they would quit smoking if the sale of menthol cigarettes was prohibited (Tobacco Products Scientific Advisory Committee 2011; Pearson et al. 2012; Wackowski et al. 2014, 2018; Zatonski et al. 2018; Rose et al. 2019; FDA n.d.), but cessation and health impacts could be diminished if other types of menthol-flavored tobacco products were still available (Wackowski et al. 2015; Pacek et al. 2019; Rose et al. 2019). For example, initial evaluations of quit behaviors and restrictions on the sales of menthol tobacco products in Ontario, Canada, suggested that such restrictions may impact cessation (Chaiton et al. 2018a,b; 2019a). Another study that evaluated the long-term, population-level impact of the menthol restriction in Ontario showed that during the first year of implementation, a significantly higher percentage of persons who smoked menthol cigarettes quit smoking than those who smoked nonmenthol cigarettes and quit that same year (Chaiton et al. 2019b).

Less is known about the potential impacts that broader flavor bans could have on cessation. However, the role of flavors in promoting initiation of tobacco product use among youth is well established. Youth are more likely than adults to initiate tobacco product use with flavored tobacco products (Villanti et al. 2017, 2019), and appealing flavor is cited by youth as one of the main reasons for using e-cigarettes (USDHHS 2016; Villanti et al. 2017). Moreover, longitudinal analyses of data from the PATH Study show that first use of a flavored tobacco product is associated with an increased likelihood of subsequently using tobacco products (flavored or unflavored) compared with those who initiate tobacco use with an unflavored tobacco product (Villanti et al. 2019). Given the role of flavors in promoting tobacco product initiation among youth, more than 220 U.S. municipalities have restricted the sale of flavored tobacco products, including e-cigarettes, and several states have adopted partial restrictions on the sale of flavored tobacco products, including those that passed emergency rules in 2019 to restrict the sale of flavored e-cigarettes (Campaign for Tobacco Free Kids 2019b; Public Health Law Center 2019). Most studies to date about restrictions on the sale of flavored tobacco products have focused on the impact of restrictions on sales, product availability, and use by youth (Courtemanche et al. 2017 ; Farley and Johns 2017; Rogers et al. 2017, 2019; Brock et al. 2019; Czaplicki et al. 2019; Kingsley et al. 2019). More research is needed to understand the impacts that these types of policies have on cessation behaviors, and the implementation of such policies should be accompanied by a comprehensive cessation approach that seeks to make available and promote evidence-based cessation treatment.

Policies restricting the sale of certain tobacco products may extend beyond flavors and encompass restrictions on the sale of all tobacco products in certain retail settings. A limited amount of evidence exists on the impacts that these policies may have on cessation, and their impact

likely depends on the level of evidence-based cessation support made available to smokers in conjunction with enacting such policies. For example, in September 2014, CVS Health stopped selling tobacco products in its pharmacies and launched a comprehensive program to support smokers in their efforts to quit, including smoking cessation counseling offered through healthcare providers and retail pharmacists, promotion of NRT products, a dedicated quitline, and other resources (Brennan et al. 2014). Nearly 1 year after the policy change, an evaluation found that in states in which the intervention was implemented, the average smoker purchased five fewer packs of cigarettes each month compared with three control states with no CVS stores (Polinski et al. 2015). Moreover, smokers who had purchased cigarettes exclusively at CVS were 38% more likely to stop buying them (Polinski et al. 2017). Cessation and quitting outcomes were not directly assessed.

Overall, the evidence is suggestive, but not sufficient, to infer that restricting the sale of certain types of tobacco products, such as menthol and flavored products, increases smoking cessation. Rigorous evaluation of policies addressing this topic in the United States and abroad would be useful to better understand the effects that such policies have on tobacco cessation.

Very-Low-Nicotine-Content Cigarettes

Benowitz and Henningfield (1994) first proposed the idea of systematically reducing the levels of nicotine content in cigarettes as a way to prevent the development of nicotine addiction in youth. However, the authors noted that this strategy might also increase the likelihood that addicted (adult) smokers would stop smoking, because as the nicotine in cigarettes was lowered to nonaddictive levels, they would become less reinforcing and less satisfying. The authors estimated that, to avert addiction, daily intake of nicotine should be limited to 5 milligrams or less. Assuming a 30-cigarette-per-day smoker, this translates to less than 0.5 milligrams of nicotine per cigarette. Thus, very-low-nicotine-content cigarettes could achieve the dual goals of promoting cessation and preventing smoking initiation.

Since that time, several studies have tested the effects of experimental very-low-nicotine-content cigarettes on key relevant outcomes, and have suggested that such products may reduce smoking and dependence, increase abstinence, and reduce exposure to toxicants (Benowitz et al. 2007, 2012; Donny et al. 2007, 2014, 2015; Donny and Jones 2009; Hatsukami et al. 2013; Dermody et al. 2018). This approach was noted as one of several potential "end game" strategies in the 2014 Surgeon General's report (USDHHS 2014). Furthermore, the growing body of evidence (see Chapter 6 for a full review) has led to recent regulatory actions.

Although the *Tobacco Control Act* (2009) bars FDA from requiring nicotine yields of a tobacco product to be reduced to zero, it allows FDA to promulgate regulations regarding the construction; components; ingredients; additives; constituents, including smoke constituents; and properties of tobacco products if such regulations are appropriate for the protection of the public health. In July 2017, Dr. Scott Gottlieb, then Commissioner of FDA, announced "a new comprehensive plan for tobacco and nicotine regulation that will serve as a multi-year roadmap to better protect kids and significantly reduce tobacco-related disease and death. The approach places nicotine, and the issue of addiction, at the center of the agency's tobacco regulation efforts" (FDA 2017). With that policy proposal, FDA had planned to "begin a public dialogue about lowering nicotine levels in combustible cigarettes to nonaddictive levels through achievable product standards" (FDA 2017). In 2018, the agency issued an Advance Notice of Proposed Rulemaking to seek input on the potential public health benefits and any possible adverse effects of lowering the level of nicotine in cigarettes (FDA 2018c). As outlined in the evidence review in Chapter 6 of this report, such regulatory action could reduce nicotine dependence and increase tobacco abstinence. No country, to date, has implemented such a policy around cigarettes.

E-Cigarettes

The scientific evidence surrounding e-cigarettes and cessation occurs within a broader environmental context with important policy and regulatory considerations. E-cigarette use has increased considerably among U.S. youth since 2011, with the U.S. Surgeon General declaring it an epidemic in 2018 (Office of the U.S. Surgeon General n.d.). By contrast, based on currently available evidence, e-cigarettes could benefit adult smokers if the products are used as a complete substitute for conventional cigarettes (see Chapter 6). However, the health effects of e-cigarettes to date remain uncertain. Furthermore, CDC, FDA, state and local health departments, and public health and clinical partners have been investigating a multistate outbreak of lung injury associated with the use of e-cigarette, or vaping, products since August 2019. The latest national and state findings suggest e-cigarette, or vaping, products containing tetrahydrocannabinol (or THC), particularly those obtained off the street or from other informal sources (e.g., friends, family members, illicit dealers), are linked to most of the cases and play a major role in the outbreak (Siegel et al. 2019). Federal, state, and local

governments have implemented, or are considering, regulations and other policy activities related to e-cigarettes in an effort to respond to this outbreak.

In the United States, e-cigarettes can be regulated as either tobacco products or, when marketed for therapeutic purposes, as medical products (*Federal Register* 2016). The *Tobacco Control Act* defines the term "tobacco product," in part, as any product, "made or derived from tobacco," including component, parts or accessories of a tobacco product that is not a "drug," "device," or "combination product" as defined by the *Food, Drug, and Cosmetic Act* (21 U.S.C. 321 (rr)) (*Family Smoking Prevention and Tobacco Control Act* 2009, §101(a)). In 2010, the U.S. Court of Appeals for the D.C. Circuit held that FDA has the authority to regulate customarily marketed tobacco products under the *Tobacco Control Act* and products made or derived from tobacco that are marketed for a therapeutic purpose under the medical product provisions of the *Food, Drug, and Cosmetic Act* (*Sottera, Inc. v. Food & Drug Administration* 2010).

The Center for Tobacco Products (CTP) issued a final rule (the "deeming rule") in May 2016 extending the FDA's authority to regulate tobacco products to all products meeting the definition of a "tobacco product" under the *Food, Drug, and Cosmetic Act,* except accessories of tobacco products. Therefore, all newly deemed tobacco products, including e-cigarettes must undergo premarket review and authorization by FDA (FDA 2016). In July 2017, FDA extended the compliance period for premarket applications to August 2022 for electronic nicotine delivery systems (or ENDS) and removed the "sunset policy," whereby FDA deferred enforcement for products on the market while their application is reviewed. A lawsuit filed by American Academy of Pediatrics (AAP) and other public health groups challenged this compliance period. On July 12, 2019, the court issued the final order in the AAP case as follows: Premarket applications must be submitted within 10 months of the order (May 12, 2020) for deemed products on the market as of the Deeming Rule (August 8, 2016). Deemed products that submit an application by the deadline might remain on the market for up to 1 year while FDA reviews the application and then would be required to come off the market (sunset provision) if the products have not yet received a marketing authorization (*American Academy of Pediatrics v. FDA* 2019b).

The statutory standards for tobacco products differ from those applied to FDA-approved NRTs, which are approved by the Center for Drug Evaluation and Research (CDER). For example, CDER requires evidence for the safety and efficacy of drugs, including cessation medications, generally coming from randomized controlled trials. By contrast, CTP employs a public health standard, which considers risks and benefits to users and nonusers of tobacco products and the population effects, for evaluating the evidence base to support commercial marketing of tobacco products. Regarding the potential for regulation of an e-cigarette product as a tobacco product, on October 11, 2019, one tobacco company announced the submission of a Premarket Tobacco Product Application (PMTA) to the FDA seeking orders authorizing the marketing of an ENDS product (Reynolds American 2019). E-cigarettes currently on the market that meet the definition of tobacco product under the federal *Food, Drug, and Cosmetic Act* are classified as tobacco products.

Under the *Tobacco Control Act,* states, localities, territories, and tribes maintain broad authority to adopt additional or more stringent requirements regarding tobacco product use, sales, marketing, and other topics. Accordingly, several states have enacted laws related to e-cigarettes in recent years, primarily to reduce youth initiation and use (Marynak et al. 2017). State, local, and territorial strategies to reduce initiation of e-cigarettes among youth and population-level exposure to e-cigarette aerosol, including educational initiatives, coupled with federal regulations around tobacco product manufacturing, labeling, and marketing, could help to reduce the risks of e-cigarettes on population health, especially among young persons (USDHHS 2016; Office of the U.S. Surgeon General n.d.). However, the extent to which population-based policies focused on e-cigarettes impact adult use of e-cigarettes or conventional cigarettes, including cessation behaviors, is unknown.

Modeling to Assess the Impact of Policy and Regulatory Changes on Cessation

As part of empirical policy evaluations, statistical analyses can generally identify the effects of a single strategy or group of strategies over a time period soon after the strategies are implemented. Simulation modeling, an alternative approach, generally synthesizes information from empirical strategy evaluations and other sources to predict the long-term effects of a policy or a combination of strategies. In the context of tobacco use and cessation, simulation modeling estimates the individual and combined effects of strategies on such outcomes as

quit attempts, smoking prevalence, smoking-attributable deaths, and other health variables.

Most policy-oriented simulation models used for the United States have focused on the effects of implementing stronger tobacco control strategies, either individually or in combination, on the prevalence of future smoking and cessation (NCI 2007; USDHHS 2014). This section focuses on simulation models that examine the effects of strategies that are relevant to tobacco cessation in the United States. The Appendix to Chapter 15 of the 2014 Surgeon General's report (USDHHS 2014) offers an in-depth summary of tobacco control simulation models.

The most widely modeled policies are tax- and price-related strategies (USDHHS 2014). The SimSmoke model is a commonly used model. It utilizes a discrete Markov model that projects smoking prevalence and smoking-attributable deaths in the absence of policy change, and then estimates the effect of tobacco control policies on those outcomes; the policy effects are based on published reviews of the literature and the advice of an expert panel. The model has been described extensively in the scientific literature, as well as in previous U.S. Surgeon General's reports, and has been shown to predict well at the national and state levels (Levy et al. 2000; USDHHS 2014). The SimSmoke model (Levy et al. 2000) predicts that a $1.00 tax increase applied to an initial price of $2.00 would yield a 13% reduction in the prevalence of cigarette smoking among adults after 5 years (short-term) and a 30% reduction after 40 years. Other models have projected similar reductions in smoking prevalence associated with comparable tax increases (Emery et al. 2001; Kaplan et al. 2001; Ahmad 2005; Ahmad and Franz 2008), and one study of Latino smokers in California predicted a larger effect (Emery et al. 2001). A review of tax simulations found a linear relationship between the dollar amount of the tax and the relative reduction in the prevalence of smoking through both a reduction in initiation and an increase in cessation (Feirman et al. 2017). The decrease in smoking prevalence attributable to a tax on cigarettes ranged from 8% (from a $0.71 tax) to 46% (from a $4.63 tax).

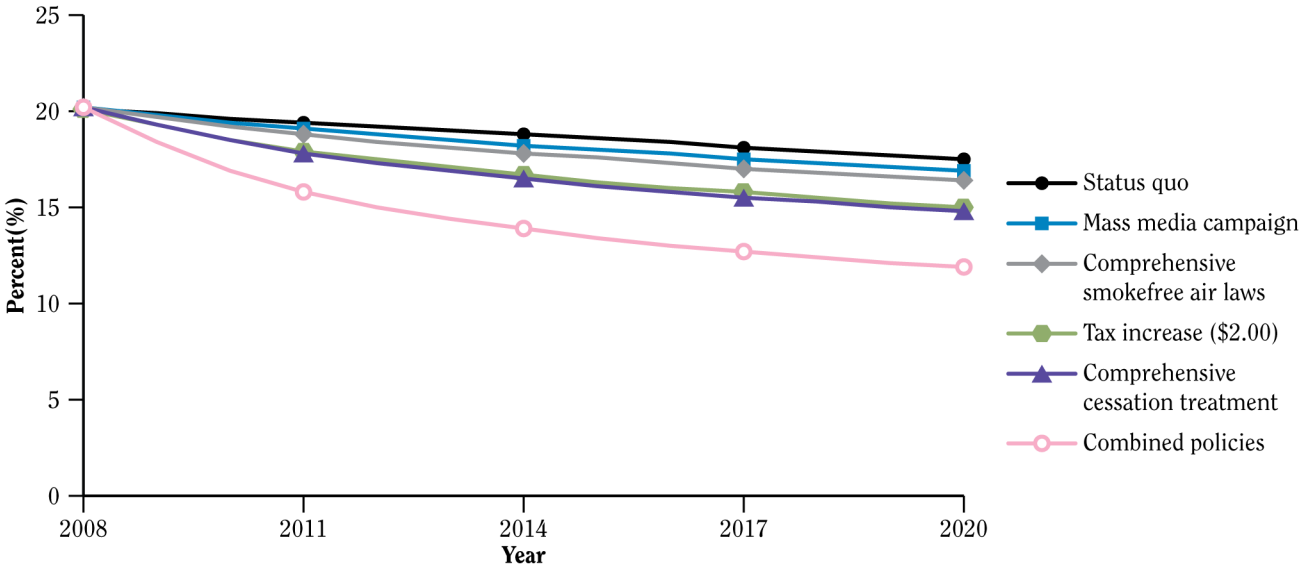
In analyses that focused on the use of cessation treatments rather than on taxes or price, Apelberg and colleagues (2010) estimated that there would be 40,000 fewer smoking-attributable deaths in the United States with a gradual increase in the proportion of NRT-aided quit attempts to 100% by 2025, and the BENESCO (Benefits of Smoking Cessation on Outcomes) model projected that the provision of bupropion and varenicline to a hypothetical cohort of U.S. adult smokers, who made a one-time quit attempt, would increase the cessation rate from 5% (unaided) to about 15% and 22%, respectively, and the provision would be cost-effective (Howard et al. 2008; Knight et al. 2010). Importantly, some of the assumptions in both of these models, especially assumptions related to the utilization of medications, were based on data from clinical trials and are unlikely to correspond to findings on the effectiveness of medications outside of a clinical trial setting.

In contrast to these studies, which focused on policies involving specific cessation treatments, the SimSmoke model considers a set of more comprehensive government cessation policies, including expansion of cessation treatment coverage and provider reimbursement; adequate funding for the use and promotion of evidence-based state quitlines; and support for health system changes to prompt, guide, and incentivize tobacco treatment (Abrams et al. 2010; Levy et al. 2010) (Figure 7.4). The SimSmoke model projected that, if these evidence-based policies for cessation were undertaken in 2008, the prevalence of cigarette smoking would be reduced from 20.1% in 2008 to 9.7% in 2020 (a 10.4-percentage-point change) (Levy et al. 2010). Finally, Ong and Glantz (2005) estimated that a free NRT program could reduce the prevalence of smoking by 20% among smokers in Minnesota.

Simulation models have also been used to consider the impact of smokefree air laws and mass media campaigns on smoking and smoking cessation behaviors. The SimSmoke model projected that implementing comprehensive smokefree laws would reduce the prevalence of cigarette smoking by 10% in the short term and 13% in the long term (Levy and Friend 2001), and Ong and Glantz (2005) estimated that 14.7% of current smokers would quit smoking if all U.S. indoor workplaces went smokefree. The SimSmoke model has predicted that large-scale mass media campaigns can reduce the prevalence of smoking by 6% in the short term and 10% in the long term (Levy and Friend 2001). Elsewhere, Rivara and colleagues (2004) estimated that a hypothetical multimedia campaign implemented for a cohort of 18-year-olds in the year 2000 would produce a 9% decrease in the prevalence of smoking in this cohort by 2067.

In an assessment of the historical impacts of combined strategies, a SimSmoke model for the United States attributed a 53% reduction in the prevalence of cigarette smoking by adults to strategies that were implemented between 1964 and 2012 (Levy et al. 2016). In terms of relative reductions in the prevalence of smoking for states with relatively comprehensive cessation strategies, SimSmoke models predicted a 25% reduction from strategies implemented in California between 1988 and 2003 (Levy et al. 2007a), a 20% reduction from strategies implemented in Arizona between 1993 and 2002 (Levy et al. 2007b), and a 29% reduction from strategies implemented in Minnesota between 1993 and 2011 (Levy et al. 2012). All of these models were validated against actual rates of smoking by age and sex during the time periods considered and were found to have high predictability.

Figure 7.4 Effects of individual and combined policies on the prevalence of smoking among men and women 18 years of age and older, using the SimSmoke Model



Notes: Model is described in Levy and colleagues (2010). The authors examined three evidence-based treatment policies related to cessation: (1) expand cessation treatment coverage and provider reimbursement; (2) mandate adequate funding for the use and promotion of evidence-based, state-sponsored tobacco quitlines; and (3) support healthcare system changes to prompt, guide, and incentivize tobacco treatment.

The aforementioned simulation models focused on strategies that directly affect cigarette use by individual smokers, but other simulation models have examined the effects of strategies at the population level. For example, in a recent modeling study, Apelberg and colleagues (2018) assessed the impact that reducing the nicotine content in cigarettes to minimally addictive levels would have on smoking cessation. The study predicted that approximately 5 million additional smokers would quit smoking within 1 year after implementing such a strategy and that this number would increase to 13 million within 5 years. The model accounted for dual use and switching behaviors by assuming that certain other combustible and noncombustible tobacco products (e.g., premium cigars, hookah, e-cigarettes), which might serve as substitutes for conventional cigarettes, would be excluded from the hypothetical nicotine reduction strategy. An older model of the potential impact of reducing the nicotine content in cigarettes projected a 75% reduction in the prevalence of smoking among adults over the long term (Tengs et al. 2005). Another model, which estimated the impact over time of a ban on menthol cigarettes, predicted a 4–8% reduction in the prevalence of smoking among adults in the short term and a 5–10% reduction in the long term; percentage reductions were larger among African Americans (Levy et al. 2011b).

The *Tobacco Control Act* (2009) provides a regulatory framework in which companies may introduce and market tobacco products with lower exposure or risk claims, but only after such products have been reviewed and their marketing authorized by FDA. These products are classified as modified risk tobacco products (MRTPs) (i.e., products "sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products" [*Family Smoking Prevention and Tobacco Control Act of 2009,* p. 1812]). Products such as heated tobacco products, snus, and e-cigarettes may have the potential to reduce the individual- and population-level harms associated with tobacco use, and several companies have submitted applications to FDA seeking authorization to market specific products as MRTPs (Murphy et al. 2017). On October 22, 2019, FDA (2019) granted the first-ever modified risk orders to Swedish Match USA, Inc., for eight snus smokeless tobacco products sold under the "General" brand name.

Several models have assessed the projected population-level impact of potential reduced-harm products relative to cigarettes (Bachand and Sulsky 2013; Vugrin et al. 2015; Weitkunat et al. 2015), including e-cigarettes (Cobb et al. 2015; Kalkhoran and Glantz 2015; Cherng et al. 2016; Levy et al. 2017b) and smokeless

tobacco (Near et al. 2014). These models vary in structure, population focus, and modeling methods.

Three simulation models estimated the population health impact after introduction of a potentially reduced-harm product that is associated with lower health risks than cigarettes. Bachand and Sulsky (2013) estimated changes in all-cause mortality when potential or actual cigarette smokers substitute some or all of their cigarettes with a potentially reduced-harm product. The study concluded that partial or complete substitution of cigarettes with a lower risk product should provide some overall health benefit at the individual level. Vugrin and colleagues (2015) provided a range of scenarios using a multiple product model that included product switching and dual use. The authors found a potential population-level benefit if cigarette smokers switched to a lower risk product, but the benefit could be offset over time through increased initiation of the new product. Another model, developed by researchers at Philip Morris International, estimated a hypothetical reduction in smoking-attributable deaths in a 20-year period following the introduction of a reduced-harm product (Weitkunat et al. 2015). This model suggests a reduction of approximately 935,000 smoking-attributable deaths if cigarette smoking were to completely disappear. If a reduced-harm product completely replaced cigarette smoking, there would be an expected decrease of 516,944–780,433 deaths, provided a new, similarly harmful alternative was not introduced. Near and colleagues (2014) examined the effects of tobacco control strategies on the prevalence of cigarette smoking, use of smokeless tobacco (snus), and premature mortality in Sweden. The authors adapted the SimSmoke model with data from Sweden and found that significant reductions in the prevalence of smoking, use of snus, and premature mortality could be achieved through tax increases, especially when combined with other strategies. The prevalence of smoking could decrease by as much as 26% in the first few years, reaching a 37% reduction within 30 years.

Several models have estimated the impact of e-cigarettes on population health. However, results can vary greatly depending on parameter inputs, underlying assumptions, and other factors. Cobb and colleagues (2015) demonstrated a limited impact on patterns of current and former cigarette use. The model also projected that prevalence of e-cigarette use and dual use would be low (1% at Years 1 and 5 and 2% at Year 10). According to the authors, this limited transition between e-cigarette, dual, and former use suggests that this model may have been based on insufficient data or that it may have been too early to draw inferences regarding the public health impact of e-cigarettes. Kalkhoran and Glantz (2015) estimated a wide range of population health effects from the increased promotion and use of e-cigarettes. Population health benefits are found in scenarios where (1) the use of e-cigarettes increases only among smokers who are interested in quitting, (2) there is no increased initiation of e-cigarette use among nonsmokers, and (3) e-cigarettes are used only by youth who would otherwise have smoked conventional cigarettes. However, net population harms were predicted in scenarios where (1) e-cigarette promotion leads to the renormalization of cigarette smoking and (2) e-cigarettes are used primarily by youth who never would have smoked. Cherng and colleagues (2016) concluded that e-cigarettes could have a greater effect on smoking cessation than on smoking initiation. However, the rapid increase in e-cigarette use among youth in recent years and the substantial proportion of youth and young adults who use e-cigarettes but never smoked conventional cigarettes (Mirbolouk et al. 2018) suggest that this conclusion may need to be re-evaluated. The study also suggested that if the use of e-cigarettes led to smoking initiation in never smokers, even small increases in smoking cessation due to the use of e-cigarettes could counteract any potential impact on the prevalence of smoking. The study also found that if e-cigarettes decreased smoking cessation by allowing current dual users to continue to smoke cigarettes, then the prevalence of smoking at the population level could increase considerably.

More recently, using a Mendez-Warner modeling approach, the National Academies of Sciences, Engineering, and Medicine (2018) found that the use of e-cigarettes will generate a net public health benefit, at least in the short term. The model found that the harms from increased initiation by youth will take time to manifest, occurring decades after the benefits of increased cessation are observed. However, for long-term projections, the net public health benefit was projected to be substantially less and was negative under some scenarios in the model. Importantly, irrespective of the range of assumptions used, the model projected a net public health harm in the short and long terms if the products do not increase net combustible tobacco cessation in adults. Warner and Mendez (2019) used a similar approach, concluding that potential life-years gained as a result of e-cigarette-induced smoking cessation would exceed potential life-years lost due to e-cigarette-induced smoking initiation, and that these results would hold over a wide range of assessed parameters. In contrast, Soneji and colleagues (2018), using a Monte Carlo simulation model, found that 2,070 additional current cigarette smoking adults (25–69 years of age) (95% CI, -42,900–46,200) would, because of e-cigarette use in 2014, quit smoking in 2015 and remain continually abstinent from smoking for 7 or more years. The model also estimated 168,000 additional never-cigarette smoking adolescents (12–17 years of age) and young adults (18–29 years of age) (95% CI,

114,000–229,000) would, because of e-cigarette use in 2014, initiate cigarette smoking in 2015 and become daily cigarette smokers at 35–39 years of age. Based on the existing scientific evidence related to e-cigarettes and optimistic assumptions about the relative harm of e-cigarette use compared with cigarette smoking, the authors concluded that e-cigarette use currently represents more population-level harm than benefit.

Overall, simulation models generally indicate greater effects of individual strategies as the effects fully unfold over time. The models also indicate that comprehensive, multicomponent, evidence-based tobacco control strategies have the potential to yield substantial reductions in the prevalence of smoking. Such reductions are driven more by increases in smoking cessation than by reduced smoking initiation, but models are subject to some limitations (Levy et al. 2001). Simulation models are useful and can often be the most reliable sources for estimating long-term effects of interventions, but the projections are only as valid as their underlying assumptions and their input and transitional probability parameters, which are generally based on available data and sensitivity analysis (see Appendix 15.1 in USDHHS 2014). More research is warranted to assess the effects of strategies on specific cessation behaviors and to distinguish between their effects on quit attempts, successful quitting, and relapse.

Limitations and Methodologic Gaps

Despite considerable evidence about the effects of certain strategies (e.g., media campaigns, price increases, and smokefree policies) on the population-wide prevalence of cigarette smoking and cessation, the available evidence for some strategies is not adequate to reach conclusions about the extent to which they influence quit attempts and successful quitting. Some analyses can generate estimates of the effects of certain policies on these and other specific outcomes, but for many policies, this evidence is limited. For example, some healthcare strategies (e.g., modifying EHRs and adopting EHR-based referral systems) have been shown to improve the identification of smokers and the delivery of tobacco use and dependence treatment, but there is less evidence on the degree to which they directly influence quit attempts and successful quitting.

In theory, both healthcare- or clinically oriented tobacco use and dependence treatment strategies and population-based tobacco control strategies should influence successful cessation, and thus ultimately improve health and reduce healthcare costs. Although it is well documented that any strategy that reduces the prevalence of smoking by a meaningful amount will improve health and thus reduce cost, specific information on strategies' effects on those outcomes would be beneficial. For example, strategies may differ in their relative effects on increasing successful quitting versus reducing smoking initiation, and such differences would affect how soon effects on health outcomes and health-related costs would be expected to occur.

The effects of population-based strategies on rates of cessation reflect many factors, such as the types of effects the strategy produces (e.g., effects on initiation vs. cessation), the time lag between the strategy's implementation and its effects, and the maintenance or duration of its effects (e.g., the elasticity between the price of cigarettes and cigarette consumption appears to change over time [NCI and WHO 2016]). Thus, although some evidence is available on the effects of certain policies on certain health outcomes (e.g., the effects of smokefree policies on the occurrence of coronary events [Meyers et al. 2009; Hahn 2010; Institute of Medicine 2010; Mackay et al. 2010; USDHHS 2014]), the scarcity of data on some potential outcomes of specific policies has made comprehensive evaluation strategies challenging.

A further limitation to better understanding the effects of policies—particularly population-level strategies—on tobacco cessation is the challenge of isolating the effects of a particular strategy from those of other past or current strategies. The attempt to identify the contribution of a specific strategy to an outcome is complicated by the fact that these strategies are rarely implemented in isolation. Specifically, the joint effects of new strategies may involve additive or interactive effects among similar or apparently dissimilar strategies at the federal, state, and local levels. A similar complexity is often encountered in analyzing strategies surrounding healthcare policies because healthcare systems often adopt a suite of tobacco-related strategies at the same time (Papadakis et al. 2010).

Progress is being made in addressing these analytic challenges, in part by taking advantage of the greater availability of relevant data and methodologic advances. For example, in the area of econometrics, the availability of improved longitudinal data for such key variables as income, cigarette consumption, cessation, tax avoidance, and tobacco price makes some analytic approaches more feasible (e.g., advanced time series analyses). Progress is aided by the greater availability of higher quality data, longitudinal data, and more comprehensive data (e.g., data that include measures of key covariates). In addition,

uniform approaches to data collection are increasingly being used across different sampling units, such as states and nations (International Tobacco Control Policy Evaluation Project 2017; WHO n.d.). The greater availability of uniform data across states and countries permits more powerful pooled analyses, which have the potential to permit statistical control of unmeasured factors that might otherwise bias results.

The greater availability of data and methodological advances could enhance the ability to accurately estimate the effects of different policies on tobacco use and cessation. Still, heightened focus on the effects of certain policies is needed because of their potential impacts on public health. These include policies applying to the use of cigarettes and noncigarette tobacco products and strategies addressing populations that have limited access to cessation interventions (e.g., the rural poor, psychiatric populations, low-income and unemployed persons, homeless populations, and individuals who are incarcerated). More research is also needed on the effects of the mechanisms through which policies ultimately influence outcomes for smoking cessation; on the interactive effects of strategies used to implement various policies; and on how strategies that are carried out to implement certain policies affect the use of nontraditional resources for promoting cessation (e.g., cessation apps, social media).

Summary of the Evidence

Strategies at the clinical, system, and population levels can influence the behavior of smokers in ways that increase their likelihood of attempting to quit smoking and/or of successful smoking cessation.

At the clinical level, important milestones in the evolution of a health systems approach to increasing tobacco cessation include the relevant recommendations and clinical guidelines issued by The Community Preventive Services Task Force, notably its recommendations on provider reminder systems (Hopkins et al. 2001), the recommendations in the *Clinical Practice Guideline* (Fiore et al. 2008), and the guidelines issued by USPSTF (2015).

At the systems level, a growing body of research has documented the effectiveness of a health systems approach in increasing tobacco screening and cessation interventions and in increasing cessation and reducing smoking rates at the health system and/or population level. Several studies have taken this a step further, reporting reductions in primary care office visits for and healthcare-related costs from smoking-related diseases (Land et al. 2012; Moody-Thomas et al. 2015).

At the population level, several evidence-based tobacco control strategies—including tobacco quitlines; policies that raise the price of tobacco; smokefree policies; government-funded mass media and public education campaigns; pictorial health warnings; and adequately funded, sustained, comprehensive state tobacco control programs—have been shown to reduce the prevalence of smoking among adults by increasing quit attempts and successful quitting. Although additional strategies—including those focused on retail density, point-of-sale tobacco advertising, and very-low-nicotine-content cigarettes—have been associated with reductions in the prevalence of smoking, more research could further clarify the impact of these policies on cessation behavior.

Overall, a landscape that combines both clinical and treatment-oriented strategies, as well as systems- and population-level strategy changes, is likely to create the most supportive environment for quit attempts and successful cessation. The clinical strategies and interventions described here and in Chapter 6 focus primarily on behaviors at the individual level, and such behaviors become more routine and consistent when strategies and systems are put in place that reinforce the delivery of clinical cessation interventions. The systems- and population-level strategies described in this chapter have a broad impact, can change the context and environment to make it easier for individuals to quit, and are more likely to be effective in helping people quit and stay quit when coupled with individual-level clinical interventions. Accordingly, clinicians and public health practitioners should seek to better bridge clinical work with population-based policy approaches to maximize tobacco cessation and reduce the overall prevalence of tobacco use.

Conclusions

1. The evidence is sufficient to infer that the development and dissemination of evidence-based clinical practice guidelines increase the delivery of clinical interventions for smoking cessation.

2. The evidence is sufficient to infer that with adequate promotion, comprehensive, barrier-free, evidence-based cessation insurance coverage increases the availability and utilization of treatment services for smoking cessation.

3. The evidence is sufficient to infer that strategies that link smoking cessation-related quality measures with payments to clinicians, clinics, or health systems increase the rate of delivery of clinical treatments for smoking cessation.

4. The evidence is sufficient to infer that tobacco quitlines are an effective population-based approach to motivate quit attempts and increase smoking cessation.

5. The evidence is suggestive but not sufficient to infer that electronic health record technology increases the rate of delivery of smoking cessation treatments.

6. The evidence is sufficient to infer that increasing the price of cigarettes reduces smoking prevalence, reduces cigarette consumption, and increases smoking cessation.

7. The evidence is sufficient to infer that smokefree policies reduce smoking prevalence, reduce cigarette consumption, and increase smoking cessation.

8. The evidence is sufficient to infer that mass media campaigns increase the number of calls to quitlines and increase smoking cessation.

9. The evidence is sufficient to infer that comprehensive state tobacco control programs reduce smoking prevalence, increase quit attempts, and increase smoking cessation.

10. The evidence is sufficient to infer that large, pictorial health warnings increase smokers' knowledge about the health harms of smoking, interest in quitting, and quit attempts and decrease smoking prevalence.

11. The evidence is suggestive but not sufficient to infer that plain packaging increases smoking cessation.

12. The evidence is suggestive but not sufficient to infer that decreasing the retail availability of tobacco products and exposure to point-of-sale tobacco marketing and advertising increases smoking cessation.

13. The evidence is suggestive but not sufficient to infer that restricting the sale of certain types of tobacco products, such as menthol and other flavored products, increases smoking cessation, especially among certain populations.

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