NCI Monograph 23 Treating Smoking in Cancer Patients: An Essential Component of Cancer Care

Chapter 4

Implementing Smoking Cessation Treatment Programs in Cancer Care Settings: Challenges, Strategies, Innovations, and Models of Care

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# **Chapter 4**

# Implementing Smoking Cessation Treatment Programs in Cancer Care Settings: Challenges, Strategies, Innovations, and Models of Care

# The Importance of a Systematic Approach to Treating Tobacco Use in Cancer Care Settings

# Introduction

Patients with cancer who smoke deserve high-quality, evidence-based treatment of their tobacco use as part of comprehensive cancer care. The need for integrating smoking cessation treatment in the cancer care setting is multifactorial. First, the past decade has seen an extensive and growing body of evidence that continued smoking after a cancer diagnosis can markedly worsen oncology treatment side effects, cancer outcomes, cancer mortality, and all-cause mortality<sup>1,2</sup> (see chapters 1 and 2). Second, a cancer diagnosis does not preclude the myriad of other adverse health effects resulting from smoking. Cancer is often diagnosed in patients with other chronic diseases caused by smoking, including cardiovascular and pulmonary diseases.<sup>2</sup> Including smoking cessation treatment as an integral part of cancer care can help address such comorbidities, which is particularly important given the high rates of co-occurrence of cancer and cardiopulmonary diseases.<sup>1,2</sup> Third, the treatment of cancer is frequently associated with compromised immune function and increased risk of upper and lower respiratory tract infections that are exacerbated by smoking; quitting smoking can help protect against such sequelae, given the deleterious impact of smoking on immune function.<sup>2</sup> Fourth, patients with cancer who smoke often feel responsible for their cancer diagnosis. Therefore, assisting them with successful smoking cessation may help ease the guilt, shame, and/or responsibility that they may feel.<sup>3,4</sup> Finally, a cancer diagnosis and/or cancer treatment can serve as a teachable moment for patients who smoke.<sup>5,6</sup> By offering smoking cessation treatment during cancer care, clinicians may seize an opportunity to intervene when motivation to quit could be high.<sup>5,6</sup> Thus, a strong argument can be made for viewing smoking cessation treatment as the "fourth pillar" of cancer treatment, one that could affect cancer treatment outcomes as powerfully as surgery, chemotherapy, or radiation therapy.<sup>7</sup>

Pharmacologic and behavioral smoking cessation treatment strategies and their effectiveness are addressed in chapter 3. In contrast, this chapter focuses on implementing such treatments. Comprehensive cancer care is delivered within acute care, ambulatory, and inpatient hospital settings, and spans the continuum of screening, diagnosis, treatment, and survivorship. Each of these clinical settings serves as an intervention point and provides opportunities to facilitate smoking cessation as part of the delivery of comprehensive cancer care.

The importance of integrating smoking cessation into cancer care is highlighted by the Cancer Center Cessation Initiative (C3I), launched by the National Cancer Institute (NCI) in 2017. As part of the Cancer Moonshot<sup>SM</sup> program, C3I represents a new focus for NCI-Designated Cancer Centers.<sup>8</sup> Specifically, C3I aims to help cancer centers build and implement sustainable tobacco

treatment programs so that they consistently address tobacco cessation among patients with cancer who smoke.<sup>9</sup> The implementation of tobacco treatment at 52 NCI-Designated Cancer Centers, as part of C3I, offers substantial promise to advance the science of tobacco cessation among patients with cancer by evaluating various clinical and health care system approaches to reducing tobacco use.

Clinical, research, and patient organizations have joined NCI in calling on cancer care settings to address tobacco use when treating patients with cancer who smoke (Table 4.1). For example, the National Comprehensive Cancer Network (NCCN) issued guidelines for smoking cessation.<sup>10</sup> The NCCN guidelines emphasize a population health perspective, establishing the clinical expectation that all patients with cancer should be systematically assessed for tobacco use during cancer care visits, and that all patients identified as currently smoking should be advised to quit and prompted to engage in evidence-based smoking cessation treatment. In addition, the American Association for Cancer Research (AACR),<sup>11</sup> the American Society of Clinical Oncology,<sup>12</sup> the International Society of Nurses in Cancer Care,<sup>13</sup> the Oncology Nursing Society,<sup>14</sup> and the International Association for the Study of Lung Cancer<sup>15</sup> all advocate for providing smoking cessation services as a part of cancer care. These guidelines reflect widespread momentum and recognition of the importance of reaching all tobacco users in cancer care settings.

Organization	Guidelines/recommendations
National Comprehensive Cancer Network (NCCN)	<ul> <li>Combining pharmacologic therapy and behavior therapy is the most effective approach and leads to the best results for smoking cessation.</li> <li>Smoking status should be documented in the patient's health record. Patient health records should be updated at regular intervals to indicate changes in smoking status, quit attempts made, and interventions utilized.</li> <li>Smoking relapse and brief slips are common and can be managed. Clinicians, the health care team, and tobacco treatment specialists should discuss this and provide guidance and support to encourage continued smoking cessation attempts. Smoking slips are not necessarily an indication to try an alternative method. It may take more than one quit attempt with the same therapy to achieve long-term cessation.</li> <li>Smoking cessation should be offered as an integral part of cancer treatment and continued throughout the entire cancer care continuum, including surgery, radiation therapy, systemic therapy, and end-of-life care. An emphasis should be put on patient preferences and values when considering the best approach to fostering smoking cessation during end-of-life care.</li> </ul>

# Table 4.1Selected Guidelines and Recommendations from Clinical and Research Organizations<br/>for Addressing Tobacco Use in Cancer Care Settings

Organization Guidelines/recommendations	
American Association for Cancer Research (AACR)	<ul> <li>Patients with cancer from all clinical settings, patients in therapeutic cancer clinical trials, and cancer-screening patients who use tobacco or have recently quit (past 30 days) should be provided with evidence-based tobacco cessation assistance. Ideally, that assistance capacity should be within or associated with the oncology practice. Even if the assistance is provided through an external service, the cancer patient's oncology clinician should assume responsibility for ensuring that the patient receives appropriate care. That capacity can also be supplemented by telephone cessation quitlines in all 50 states that can be reached via a common toll-free telephone number (1-800-QUIT-NOW).</li> <li>Tobacco use should be comprehensively and repeatedly documented for all patients so that the confounding effects of tobacco on cancer treatment, disease progression, comorbid events, and survival can be evaluated in all oncology clinical trials, from registration to survival endpoints, and in all clinical cancer settings.</li> <li>To provide all patients with tobacco cessation assistance and facilitate improved research into the confounding effects of tobacco, the following objectives should be pursued:         <ul> <li>Universal assessment and documentation of tobacco use by patients with cancer in all clinical settings, participants in therapeutic cancer clinical trials, and cancer-screening patients;</li> <li>Development of universal standards for measurement of tobacco use and exposure in clinical and research settings;</li> <li>Incorporation of evidence-based tobacco interventions into review criteria used by research and health care quality and accreditation bodies; and</li> <li>Recognition and support of the value of tobacco cessation interventions by health care systems, payers, and research funders through provision of appropriate incentives for infrastructure development and intervention delivery.</li> </ul> </li> </ul>
American Society of Clinical Oncology (ASCO)	<ul> <li>Treat tobacco dependence as aggressively and compassionately as cancer, discussing the causal relationship between tobacco use and cancer and assisting the patient and family members to end tobacco dependency.</li> <li>Help to ensure tobacco cessation services are widely available.</li> </ul>
International Society of Nurses in Cancer Care (ISNCC)	• Nurses must ensure that tobacco use assessment, documentation, and dependence treatment is an expected part of care in all cancer inpatient and outpatient treatment programs and protocols, including addressing the stigma faced by many patients affected by a tobacco-related cancer and specifically highlighting the benefits of smoking cessation in the context of a cancer diagnosis.
Oncology Nursing Society (ONS)	ONS endorsed the ISNCC Tobacco Position Statement in 2014.
International Association for the Study of Lung Cancer (IASLC)	<ul> <li>All patients with cancer should be screened for tobacco use and advised on the benefits of tobacco cessation.</li> <li>In patients who continue smoking after diagnosis of cancer, evidence-based tobacco cessation assistance should be routinely and integrally incorporated into multidisciplinary cancer care for the patients and their family members.</li> <li>Educational programs regarding cancer management should include tobacco cessation training, empathetic communication around history of tobacco use and cessation, and utilization of existing evidence-based tobacco cessation resources.</li> <li>Smoking cessation counseling and treatment should be a reimbursable service.</li> </ul>

# Table 4.1 (continued)

*Note*: The guidelines/recommendations are taken directly from the sources and the terminology used reflects that of the source. *Sources*: NCCN 2022,<sup>10</sup> Toll et al. 2013,<sup>11</sup> Hanna et al. 2013,<sup>12</sup> Bialous and Sarna 2016,<sup>13</sup> International Society of Nurses in Cancer Care (ISNCC)<sup>14</sup> and Jassem 2019.<sup>15</sup>

This chapter discusses the science regarding the implementation of smoking cessation treatment programs in cancer care settings. Moreover, it provides guidance on implementation strategies by sharing models of care and relevant findings from C3I and elsewhere. This information is designed to foster the efficient and effective implementation of comprehensive smoking cessation treatment programs across multiple types of cancer care settings. This chapter refers to both tobacco use and smoking, recognizing that (a) other forms of tobacco use, beyond cigarette smoking, bear a significant burden on cancer and cancer care, but (b) cigarette smoking is by far the predominant form of tobacco use and dependence in adults, thus giving rise to the importance of smoking cessation. Finally, there are multiple evidence-based options that cancer care settings might implement to deliver smoking cessation treatment more effectively and consistently to patients with cancer who smoke. This chapter describes a broad array of approaches to implementing smoking cessation treatment in cancer care settings that aim to ensure all patients who smoke are provided with effective smoking cessation treatment as part of their cancer care.

# Application of the Reach, Effectiveness, Adoption, Implementation, Maintenance (RE-AIM) Evaluation Framework

The RE-AIM framework<sup>16</sup> is used to inform the evaluation of implementation approaches in this chapter. RE-AIM has been applied broadly to structure the planning, implementation, and evaluation of a variety of health care initiatives,<sup>17</sup> including smoking cessation treatment delivery in cancer care.<sup>18</sup> This well-established evaluation framework consists of five key elements: (1) *Reach* (the absolute number, proportion, and representativeness of targeted individuals who are willing to participate in a given intervention), (2) Effectiveness (how well an intervention affects a specific outcome), (3) Adoption (evidence of organizational support for an intervention and its initiation by relevant clinicians and health care staff), (4) Implementation (the degree to which an intervention is consistently delivered across patients, clinicians, and settings), and (5) Maintenance (how well an implemented intervention or its effects are maintained across time). Of these five elements, Reach and Effectiveness are particularly important in determining overall treatment impact or, in this case, net quit rates within a population. The goal is to broadly reach and engage individuals who smoke in the use of evidence-based smoking cessation treatments, thereby producing the highest possible cessation impact. The RE-AIM evaluation framework fits well within established guidelines for delivery of smoking cessation treatment, most notably the 5A's (Ask, Advise, Assess, Assist, and Arrange).<sup>19</sup> Oncologists and other clinicians can help patients who use tobacco by embracing this fundamental 5A's-based approach in cancer care settings by Asking all patients if they smoke; Advising patients who smoke to quit; Assessing their willingness to quit or reduce their smoking on the way to quitting; Assisting them by offering brief counseling, prescribing smoking cessation medications, and connecting them to additional resources (such as a call-based quitline, a text-based quitting program, or local tobacco treatment specialists); and Arranging follow-up with continued support and additional treatment as needed.<sup>19</sup> Streamlined variations on the 5Å's, including the clinical referral models "Ask, Advise, Refer" (AAR) and "Ask, Advise, Connect" (AAC), discussed below, recognize that clinicians may be unable to provide a comprehensive cessation intervention during oncology office visits. The following sections detail each component of the RE-AIM framework by reviewing literature pertaining to the implementation of smoking cessation treatment and suggesting efficient strategies for integrating such treatment into cancer care.

# Reach

Reach represents the number and proportion of individuals who participate in a given initiative and how representative participants are compared with the target population. In the context of this chapter, Reach refers to the proportion of patients with cancer who participate in health care system–delivered smoking cessation treatment. Among cancer patients and survivors, uptake of evidence-based smoking cessation treatments tends to be low.<sup>20</sup> Low uptake of evidence-based smoking cessation treatments tends to be low.<sup>20</sup> Low uptake of evidence-based smoking cessation treatments is also seen among people who smoke in the general population in which those motivated to quit tend to make quit attempts without using proven quit aids.<sup>21</sup> As reported in the 2020 Surgeon General's report, although most people who smoke cigarettes make a quit attempt each year, less than one-third report use of smoking cessation medications approved by the U.S. Food and Drug Administration (FDA) or engage in behavioral counseling to support quit attempts.<sup>1</sup> Furthermore, less than 5% of people who smoke, in the general and cancer patient populations,<sup>20,21</sup> report using both evidence-based counseling and medication, the standard of care recommended by the Public Health Service (PHS) Clinical Practice Guideline, *Treating Tobacco Use and Dependence: 2008 Update*.<sup>19,21</sup>

Several innovative strategies have been developed over the past decade to improve reach at the health care system level. These include:

- Leveraging the electronic health record (EHR) to track tobacco use status and prompt smoking cessation treatment delivery using chronic disease management approaches.<sup>22</sup>
- Using clinical referral models (e.g., AAR and AAC), which are designed to expand reach by efficiently connecting patients who smoke to existing smoking cessation treatment resources within or outside of the health care system after initial clinician advice to quit.<sup>23</sup>
- **Referring patients to "treatment extenders,"** namely evidence-based tobacco cessation treatment options that can expand upon what the clinician provides directly to the patient who uses tobacco (e.g., state tobacco quitlines, SmokefreeTXT). Such treatment extenders would be provided to the patient via EHR electronic referral (eReferral) or via other referral mechanisms (fax or other referral modalities).<sup>19</sup>
- Utilizing interactive voice response (IVR) or automated call systems to provide followup to patients after a clinic or hospital visit.<sup>24–28</sup>
- **Implementing opt-out** (versus opt-in) approaches where patients who use tobacco receive cessation treatment unless they explicitly indicate that they do not want to receive it.<sup>29</sup>
- **Telehealth**, or virtual treatment services, provides an additional way to expand the reach of tobacco cessation treatment delivery to patients with cancer who smoke.<sup>30</sup>

The following sections review each of these strategies in more detail.

# Enhancing Reach via Leveraging the Electronic Health Record (EHR)

The EHR can serve as an essential resource in the implementation of high-quality, clinically based interventions for nicotine dependence, although it may not be available for every setting that may care for patients with cancer who smoke. Fortunately, more than 95% of U.S. nonfederal acute care hospitals have adopted EHRs.<sup>31</sup> The lack of a universal EHR poses

challenges to implementation due to the use of different EHR platforms across different health care settings and the need for site-based customizations even among sites that share a common EHR. Nevertheless, numerous clinical trials and observational studies have demonstrated the utility of EHR-facilitated screening, referral, and treatment for nicotine dependence.<sup>22,32–35</sup> For instance, enhanced EHRs can now prompt clinicians to identify tobacco users, refer them for behavioral support, and order pharmacotherapy. Importantly, while such functionalities exist, not all clinicians, clinics, and/or health care systems use them or keep them up to date.

Increasingly, the EHR can also enable clinicians to electronically refer individuals who use tobacco to treatment resources, such as state quitlines and text-based quitting programs including NCI's SmokefreeTXT or automated call systems (e.g., IVR). These EHR-based referrals can support both opt-in and opt-out treatment approaches. All of these can extend the impact of the clinical encounter by providing patients with ongoing smoking cessation treatment and support. These treatment extenders<sup>36</sup> also frequently include Health Insurance Portability and Accountability Act of 1996 (HIPAA)-compliant, closed-loop referral components that promote continuity of care by automatically returning information on referral outcomes to clinicians and the EHR.<sup>32,37</sup>

A Cochrane review<sup>22</sup> concluded that EHR enhancements can facilitate smoking cessation treatment by increasing rates of both tobacco use screening and delivery of cessation assistance in clinical settings. The interventions in this Cochrane review included use of the EHR to improve both documentation of smoking status and smoking cessation assistance for patients who use tobacco, including by direct action or by providing feedback on clinical performance.<sup>22</sup>

Clinical decision support systems for smoking cessation treatment that are integrated into the EHR (e.g., alerts, order sets, care summary dashboards) can guide clinicians to deliver guideline-recommended tobacco use interventions and patient-specific assessments during clinical encounters and thereby increase medication orders, counseling, and referrals to additional treatment services, such as state quitlines for telephone counseling.<sup>38,39</sup> The EHR can also provide sample text in multiple languages to help guide clinicians to intervene.<sup>40</sup> Importantly, clinicians and administrators need to work closely with information technology (IT) staff/informatics teams to harmonize and universalize the routine assessment and documentation of tobacco use status as well as its treatment.

EHRs not only help identify people who smoke and systematically deliver smoking cessation treatment to them but can also document the short- and long-term outcomes of treatment. Such outcomes can include treatment side effects; rates of relapse to smoking; and other adverse events such as cancer recurrence, second primary cancers, and other illnesses caused by smoking, such as cardiovascular or pulmonary disease. Assessing short- and long-term outcomes is particularly important given the persistent elevation in risk of illnesses caused by smoking (both cancer and noncancer), underscoring the need for continued monitoring of patients once they successfully quit smoking.<sup>41,42</sup>

# Enhancing Reach via Use of Clinical Referral Models Including "Ask, Advise, Refer" (AAR) and "Ask, Advise, Connect" (AAC)

The EHR can also expand reach by facilitating the use of evidence-based clinical models that trigger core steps in the smoking cessation treatment process, such as the 5A's-based AAR and AAC interventions.<sup>23</sup> These models adapt the 5A's treatment approach<sup>19</sup> for encounters when clinicians are unable to personally deliver all components of the 5A's smoking cessation treatments during clinic visits. These referral models are designed to prompt clinicians and other clinical staff to initiate smoking cessation treatment ("Ask and Advise") and then connect patients who smoke with other treatment resources that are either within or outside of the clinical setting ("Refer" or "Connect"). The AAC model may be even more effective than AAR in increasing the reach of smoking cessation treatment because the treatment team proactively connects the patient who smokes to a treatment program rather than relying on the patient to make the connection.<sup>23</sup> Importantly, these models also guide clinicians to prescribe smoking cessation medications. This guidance is a strength of clinical referral models as clinicians retain the ability to prescribe, monitor medication use, and adjust pharmacotherapy as needed. In practice, treating oncologists may be too busy and/or have little training in nicotine dependence counseling or prescribing pharmacotherapy. This argues for a systems-based approach<sup>19</sup> that utilizes additional members of the treatment team (e.g., health educators, counselors, nurses, rooming staff) to augment those responsible for delivering smoking cessation treatment. In this way, such clinical models may increase the likelihood that patients receive recommended courses of pharmacotherapy rather than the brief courses typically available through quitlines. Prescription of smoking cessation medication also fosters the integration of the patient's smoking cessation treatment into their cancer care.<sup>43</sup> Although there is little published data specific to the cancer care setting as of this writing, clinical referral models hold promise to enhance the implementation of smoking cessation treatment during cancer care visits.

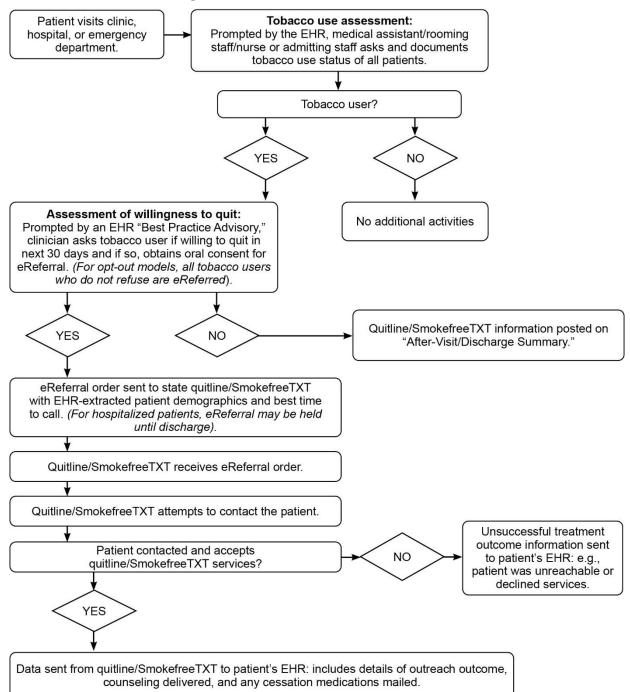
# **Treatment Extender: State Quitlines**

State quitlines offer evidence-based, clinically effective, and cost-effective smoking cessation treatment to a wide range of individuals who smoke, thereby enhancing reach.<sup>44</sup> Quitlines are toll-free telephone services available throughout the United States and Canada and constitute the largest population-based network of smoking cessation treatment in North America.<sup>45–47</sup> They provide services, typically in multiple languages, to approximately 500,000 people who smoke each year, typically reaching about 1% of people who smoke in the United States annually.<sup>48</sup> As of 2019, 15 years after the National Network of Tobacco Cessation Quitlines was launched by the Centers for Disease Control and Prevention (CDC) and NCI, more than 10 million calls had been made to quitlines in the United States.<sup>49,50</sup> Although vastly underutilized, state quitlines have been documented as effective smoking cessation interventions for the general population of people who smoke.<sup>19</sup>

In the United States, each state manages its own quitline services, usually via a contract with a quitline vendor; for example, Optum<sup>TM</sup> and National Jewish Health<sup>TM</sup> provide services to more than 30 states and territories. Some states provide their own quitline services or contract with a university in their state (e.g., California). Typically, people who smoke contact a quitline on their own (via phone or website) but increasingly, they are referred by a clinician or other clinic staff during a health care visit (via EHR-based eReferral) (Figure 4.1). Trained tobacco cessation treatment counselors are often available by phone 7 days a week and typically offer counseling

in multiple languages. Most quitlines offer both free counseling and limited quantities of FDAapproved smoking cessation medications (primarily starter packs [e.g., 2-week supplies] of overthe-counter nicotine replacement products) that are typically delivered via U.S. mail. Some quitlines offer ancillary text messaging programs, and most offer web-based services and print materials.<sup>50</sup> However, due to budget constraints, quitline service intensity varies by state.

# Figure 4.1 Typical EHR-Guided Staff Workflow for eReferral of a Patient who Smokes From a Clinical Setting to a State Quitline or NCI SmokefreeTXT



*Note*: Aspects of the eReferral process may vary by clinical care setting and institution. The eReferral employs standardized data elements as determined by the Office of the National Coordinator for Health Information Technology to maximize interoperability, or efficient exchange of information, between health care service providers. For more detailed descriptions of workflow and technical specifications for eReferral to quitlines, please see Adsit and colleagues<sup>32</sup> (outpatient clinical setting) and Tindle and colleagues<sup>60</sup> (inpatient clinical setting). For a detailed description of workflow and technical specifications for eReferral to NCI SmokefreeTXT, see McCarthy and colleagues.<sup>37</sup> EHR = Electronic health record.

Source: Society of Behavioral Medicine 2014, 2020.32,37

A large body of evidence supports the effectiveness of quitlines to promote smoking cessation,<sup>19,51</sup> though none of these studies focused specifically on cancer populations, which may need a more intensive dose of treatment, including counseling interventions combined with pharmacotherapy over multiple session visits.<sup>30</sup> A 2002 study by Zhu and colleagues<sup>52</sup> of 3,282 people who smoke who called the California quitline found that the 12-month, self-reported abstinence rate was 9.1% among those randomized to proactive quitline calls (i.e., calls initiated from the quitline) versus 6.9% for those who did not receive proactive calls (p < .001). Additional studies support the integration of nicotine replacement therapy (NRT) into quitline care.<sup>53–55</sup> Importantly, the 2020 Surgeon General's report concluded that "the evidence is sufficient to infer that tobacco quitlines are an effective population-based approach to motivate quit attempts and increase smoking cessation."<sup>1,p.11</sup>

Individuals have typically connected with the national quitline by calling a toll-free telephone number (1-800-QUIT-NOW) to obtain assistance with tobacco or smoking cessation. Because more than 70% of individuals who smoke visit a clinician each year,<sup>21</sup> such visits provide additional opportunities to link patients with quitline services. Health care systems initially attempted to link patients via paper fax referrals to the quitline call center. However, with the decrease in use of fax machines, this practice does not fit easily into current clinical practices. The advent of near-universal use of EHRs has provided a new means of referring patients during clinic visits. In response, researchers and health care systems have more recently focused on developing EHR-based quitline eReferral capacity (Figure 4.1). A growing body of evidence shows that eReferral to quitlines is an effective means of expanding the reach of smoking cessation treatment into health care settings. Such eReferral has also been facilitated by the North American Quitline Consortium (NAQC), which has produced a technical guide to support its implementation.<sup>56</sup> Multiple studies have explored EHR-embedded automated referral to a state tobacco quitline in primary care<sup>32–34,57</sup> and hospital settings.<sup>38,58–60</sup> Adsit and colleagues,<sup>32</sup> in the first eReferral demonstration study, programmed a closed-loop referral to the quitline into the EHR at two Wisconsin clinics. Closed-loop referral (also referred to as bidirectional referral) is a term used to describe the process whereby clinics use the EHR to refer a patient to the state quitline, which then attempts to reach and treat the patient. The quitline then electronically transmits back to the EHR the outcome of the referral, typically both to the patient's chart and to the referring clinician (Figure 4.1). Compared with a baseline period of fax referral only (0.3% quitline referral), this closed-loop approach significantly increased quitline referral (to 13.9%), while actual guitline usage increased from 0.15% to 4.9%.<sup>32</sup> Later research comparing fax and eReferral in primary care clinics in Wisconsin similarly found increased reach after the implementation of closed-loop eReferral.<sup>33,34</sup> In a randomized trial in 2 health care systems, average rates of referral and quitline connection were at least 13% and 3% higher, respectively, in clinics using eReferral compared with those using fax referral.<sup>34</sup> An observational study assessing the reach of closed-loop eReferral in 30 primary care clinics that previously used fax referral observed increases in both assessment of readiness to quit (24.8% 4 months pre-launch compared with 93.2% 8 months post-launch) and referral rates (1.7% pre-launch compared with 11.3% post-launch) after eReferral implementation.<sup>33</sup>

Tindle and colleagues<sup>60</sup> demonstrated the feasibility of quitline eReferral among hospitalized patients at discharge, through which 36% of hospitalized patients who smoke accepted eReferral, generating 818 eReferrals to the quitline over 8 months. These 818 eReferrals constituted more than one-fifth of all quitline referrals from the entire state of Pennsylvania during that period.

However, only 24% of those referred were reached by the quitline, and only 21% of those reached enrolled in quitline services, thus underscoring the persistent challenge of engaging patients in smoking cessation treatment.

Hood-Medland and colleagues<sup>59</sup> embedded a prompt into the EHR of a large university hospital system to eRefer people who smoke to a state tobacco quitline. The eReferral was initially installed within the EHR of ambulatory sites, and, later, expanded as an order set for use with hospitalized patients who smoke at discharge. From 2013 to 2015, 16,083 encounters with patients who smoked led to 1,137 (7.1%) eReferrals. For all encounters, the reach of the eReferral system with regard to quitline connection was 1.6% (the percentage of identified patients who smoked who were ultimately connected with the quitline). At 6 to 12 months, first-time eReferral patients had a documented cessation rate of 12.2%. This study demonstrated the feasibility of implementing eReferral for both ambulatory and hospitalized patients, although reach rates were quite low.

Bernstein and colleagues<sup>38,58</sup> designed an EHR-embedded package of decision-support resources to identify people who smoke who are admitted to the hospital and link them with treatment, including quitlines. The "Electronic Support Tool and Orders for the Prevention of Smoking" (E-STOPS) package was developed and tested in a cohort of adults who smoke and were admitted to the inpatient medical services of a large U.S. university hospital; 254 physicians were randomized to receive the E-STOPS tool or usual care (control) conditions. The E-STOPS tool consisted of an electronic prompt that appeared when the inpatient physician opened the chart of a person who smokes, offering five components in opt-out fashion, four of which were automated in addition to a medication order that required a physician signature. Physicians in the control condition could choose to carry out all of the above five functions but had to execute them manually.<sup>58</sup>

E-STOPS was found to be effective in improving the delivery of smoking cessation treatment components. Among 10,939 people who smoke and were assigned based on the physician who had initially treated them (5,391 intervention and 5,548 control), intervention physicians were more likely than control physicians to complete 3 of the prompted actions: ordering smoking cessation medication (34% vs. 29%; p < .0001), populating the patient's problem list (42% vs. 2%; p < .0001), and referring to the quitline (29% vs. 0%; p < .0001). Ninety-nine percent of intervention physicians notified the patient's primary care provider (PCP) via email (no data available for control physicians).<sup>38</sup> However, in a subset of 1,044 patients followed for 1 year, quit rates for intervention and control patients were 11.5% and 11.6%, (p = .94), respectively, after controlling for age, sex, race, ethnicity, and insurance status.<sup>58</sup> Hence, while E-STOPS was widely implemented, it did not enhance long-term abstinence. This could reflect inadequate follow-up with and transfer of care from the inpatient team to primary care physicians, and that hospitalization may have led to fairly high abstinence rates among patients in both intervention and control arms.

Overall, quitlines are a promising tool to improve reach, especially in health care settings when referrals can be made electronically via EHRs. Closed-loop, or bidirectional, referral capacity further supports continuity of care through automatic follow-up communication back to the patient's medical record. While limited research has specifically addressed eReferral to quitlines in cancer care settings,<sup>61</sup> 59% of Cohort 1 C3I sites (22 NCI-Designated Cancer Centers) have

adopted the use of quitline eReferral.<sup>9</sup> Additional research is needed to establish the effectiveness of quitline referrals for increasing rates of smoking cessation in cancer patient populations.

# Treatment Extenders: National Cancer Institute's (NCI) SmokefreeTXT

The EHR has also been used to electronically refer patients who smoke to a mobile phone–based resource, SmokefreeTXT, a freely available text messaging program for smoking cessation treatment operated by NCI.<sup>62</sup> Once a patient is eReferred to SmokefreeTXT by their clinician, the patient will receive a text message from SmokefreeTXT inviting them to enroll in the program.<sup>62</sup> McCarthy and colleagues<sup>37</sup> first demonstrated the feasibility of integrating an EHR-enabled, closed-loop eReferral into the outpatient clinic setting. Overall, 12% of eligible patients who smoked were eReferred to SmokefreeTXT. Of those eReferred, 25.7% enrolled, set a quit smoking date, and received text messages, for an overall 3.1% connection rate among all people who smoke cigarettes. Like eReferral to state quitlines, eReferral to SmokefreeTXT may extend reach by facilitating referral, thereby decreasing the burden on clinicians and clinical staff.<sup>37</sup> Also, some patients could prefer technology-delivered, digital interventions that do not entail person-to-person contact. Additional research is needed to optimize the implementation of eReferral to SmokefreeTXT to determine its effects on smoking cessation among patients with cancer.

# Utilizing Interactive Voice Response (IVR) Systems

Among the technological innovations that have been added to the array of tools to connect patients who smoke to cessation resources and interventions is IVR outreach via automated calls.<sup>27</sup> IVR allows individuals to interact with a computer via voice detection mechanisms (or keypad entry) and is an important component of the inpatient Ottawa Model of bedside counseling and follow-up calls.<sup>63</sup> A similar model has also been tested in the United States in two randomized controlled trials (RCTs) conducted in large tertiary care medical centers. In the first of these 2 studies, Rigotti and colleagues<sup>64</sup> reported that among 198 hospitalized patients who wanted to guit smoking, receipt of IVR calls + smoking cessation medication upon discharge resulted in statistically significant higher 6-month post-discharge biochemically confirmed quit rates (26%) than those who received a standard recommendation to use counseling + medication (15%) (p < .009). In the second study, using a similar design (N =1,357), Rigotti and colleagues<sup>65</sup> reported that those who received IVR calls + cessation medications upon discharge did not achieve statistically significant higher 6-month postdischarge biochemically confirmed abstinent rates (17%) versus those who received a standard recommendation upon discharge to use counseling + smoking cessation medication (16%). In a subsequent publication, Rigotti and colleagues<sup>28</sup> described IVR characteristics and use patterns among those randomized to the IVR condition in the two RCTs, finding that participants completed a median of three to five calls, and that higher IVR utilization was associated with higher odds of smoking abstinence at 6-months' follow-up. Evidence has documented that, in addition to positive effects on reach and engagement, the combination of bedside counseling with post-discharge IVR follow-up was cost-saving (i.e., overall adjusted mean health care charges for people who smoke who were exposed to the program were \$7,299 lower than for those who did not receive the tobacco cessation treatment services, p = .047) and resulted in reduced readmissions and fewer total number of hospital days.<sup>66,67</sup> However, there are no specific studies evaluating IVR for smoking cessation in patients with cancer.

# **Opt-Out Versus Opt-In Models of Smoking Cessation Treatment Delivery**

Many health care systems have used an opt-in approach to delivering smoking cessation treatment. Using this approach, patients must request (or accept) a referral for smoking cessation treatment from their oncology clinicians or other clinicians; without this, referral or treatment is not provided. An opt-out model, sometimes referred to as a proactive model, has been recommended in a manner such that all patients who smoke are automatically referred for evidence-based smoking cessation treatment<sup>29</sup> unless they specifically refuse such a referral. Approaches that seek to provide opt-out smoking cessation treatment hold promise to increase treatment reach in ambulatory,<sup>68–70</sup> acute care/emergency,<sup>71</sup> and hospital settings,<sup>27,72,73</sup> and, as with other proactive treatment approaches, could enhance smoking cessation treatment engagement among individuals with lower motivation to quit.<sup>74</sup> Researchers have argued that opt-out approaches may be ethically superior to opt-in services that rely on clinician referral for treatment<sup>29</sup> because of their potential for equitable delivery of such treatment services broadly and to different populations.<sup>73,75,76</sup> Opt-out approaches are based on psychological responses to defaults and have been found in several domains to increase preference-consistent and public health promoting behaviors such as organ donation.<sup>77</sup> Such approaches are not viewed as representing coercion but rather a form of "soft paternalism" in which the freedom of choice is maintained and yet the audience is "nudged" in the direction of a desirable choice.<sup>78</sup>

The NCCN Smoking Cessation Guidelines, a consensus document established in 2016 and reviewed annually by a panel of smoking cessation treatment and oncology experts, recommends the opt-out model for patients with cancer who have used tobacco in the past 30 days.<sup>10</sup> While an opt-out model does not guarantee acceptance of smoking cessation treatment by the patient, it has been shown to increase treatment reach and engagement, including in studies of patients with cancer.<sup>79</sup> An opt-out approach can be used to refer patients to an internal health care system smoking cessation treatment program or to an external community resource, such as a quitline. Another study suggests that an opt-out referral approach can be effective for encouraging referral to smoking cessation support.<sup>80</sup> Patients with cancer who screened positively for smoking via an EHR-based assessment were automatically referred (an opt-out strategy) to smoking cessation treatment. Half of the referred patients were called by the smoking cessation treatment program and half were mailed a letter inviting them to contact that program. The automatic (opt-out) referral with direct phone outreach by the smoking cessation treatment program successfully contacted 81.3% of patients; in contrast, only 1.2% of patients who received a letter contacted the program. The research suggests that an opt-out referral strategy when paired with follow-up phone outreach can be highly effective in linking patients with cancer with smoking cessation treatment.<sup>80</sup> Nolan and colleagues<sup>79</sup> also used an opt-out approach, in this case, to link patients with breast cancer who smoked with smoking cessation treatment. They implemented an opt-out referral process whereby all patients with breast cancer who smoked were referred for smoking cessation treatment. This study showed that the reach of the smoking cessation treatment increased from a baseline rate of 29% to a post-intervention rate of 74%. Among patients referred, treatment engagement (defined as keeping an initial tobacco cessation treatment consultation appointment) increased from 41% to 75% after implementing the opt-out referral method.79

In an additional assessment of the opt-out model for patients with cancer, Taylor and colleagues<sup>81</sup> described the implementation of a smoking cessation treatment program that used

proactive telephone outreach to patients with cancer identified as currently smoking. They reported reaching 69% of eligible people who smoke, and of those reached, 43% engaged in smoking cessation treatment. Gali and colleagues<sup>82</sup> reported that implementing an opt-out referral process in cancer care settings increased referrals from less than 10% to 100%, and increased smoking cessation treatment engagement from 1% to 33%. Himelfarb-Blyth and colleagues<sup>83</sup> similarly reported an increase in reach after implementing an opt-out referral model at a cancer center where accepted referrals to quit support increased from 11.5% under the previous opt-in model to 34.7% under the new opt-out referral process. Jose and colleagues<sup>84</sup> piloted an EHR-based opt-out referral of all tobacco users (regardless of intention to quit) as they were being "roomed" (i.e., the process of taking the patient to the exam room and collecting essential information [e.g., vital signs, medications used] by a medical assistant, nurse, or other staff member prior to the treating clinician seeing the patient) in the cancer clinic. Staff who roomed the patients made the eReferral, which did not require a clinician co-signature. Over 70% of patients who smoked were referred to smoking cessation treatment via this opt-out approach, supporting the potential for broad reach. However, only 17% of patients kept the smoking cessation treatment appointment, underscoring ongoing challenges with engagement.<sup>84</sup>

Lastly, the Michigan Oncology Quality Consortium designed an opt-out approach for identifying people who smoke in Michigan oncology practices and referring them to the state quitline. From 2012 to 2017, they found that annual referrals from oncology practices increased from 364 at baseline (5% of all quitline callers) to 876 (17% of quitline callers).<sup>61</sup> This program achieved a self-reported quit rate of 26% at 6 months. This population-based initiative demonstrates the feasibility of increasing access to evidence-based smoking cessation treatment for patients with cancer using existing statewide resources.

# Using Telehealth

Delivering tobacco cessation treatments to patients with cancer who smoke via telehealth provides an additional opportunity to expand the reach of these treatments, overcoming travel and other challenges. Access to telehealth treatment opportunities expanded during the COVID-19 pandemic, including smoking cessation treatment to patients with cancer who use tobacco.<sup>1,30,34,85</sup>

#### Summary: Reach

To maximize population impact, smoking cessation treatment programs must achieve high rates of reach. Multiple promising strategies to enhance reach have been identified, including: (1) leveraging EHRs to track tobacco use status, offer treatment delivery using a chronic disease management approach, and make eReferrals to external resources, such as state quitlines and NCI's SmokefreeTXT; (2) promoting clinical referral models, including AAR and AAC, to increase patient engagement in smoking cessation treatment and also offload front-line clinician responsibilities for delivering smoking cessation treatments, given that clinicians might not have the time or training to provide a comprehensive smoking cessation intervention; (3) promoting IVR or automated call systems to follow patients after a clinic or hospital visit and provide treatment offers and support; (4) implementing opt-out (versus opt-in) treatment approaches that automatically refer or connect patients who smoke with smoking cessation treatment unless they explicitly decline; and (5) implementing cancer center–based telehealth smoking cessation

treatment delivered to patients directly through smartphones, tablets, and computers in their homes, which offers flexibility and patient convenience. While these strategies hold great promise for patients with cancer who smoke, additional research is needed in clinical cancer care settings.

#### Effectiveness

Effectiveness in this chapter refers to changes in smoking behavior, typically quit rates, across clinic and health care system populations who smoke after implementing a smoking cessation treatment program. Chapter 3 provides an in-depth discussion of smoking cessation treatment effectiveness among the general population and those with cancer. While few well-powered RCTs have been conducted among patients with cancer, the totality of evidence from RCTs across the general population of individuals who smoke, often comprising large samples of diverse types of patients, including patients with cancer, provides strong support for the use of evidence-based smoking cessation treatments. Specifically, evidence has found counseling and medication to be effective across patients differing on a host of important characteristics, including age, gender, socioeconomic status, physical health status, and affective/psychiatric status. This suggests that counseling and medication smoking cessation recommends the provision of both smoking cessation pharmacotherapy and counseling to patients with cancer who smoke.<sup>10</sup> This section summarizes some of the evidence synthesized in chapter 3.

For example, a multisite RCT among patients recently diagnosed with cancer who smoke tested the effectiveness of sustained (four weekly telephone sessions followed by four biweekly sessions followed by three monthly sessions) telephone counseling sessions and choice of FDAapproved cessation medication provided without charge.<sup>86</sup> This treatment arm was compared with standard care, consisting of four weekly telephone counseling sessions and cessation medication advice. The sustained treatment arm produced a statistically significant higher 6month, biochemically verified 7-day point-prevalence abstinence (34.5% of patients, N = 153) than did the standard care arm (21.5% of patients, N = 150). It is worth noting that participants in both study arms used cessation medication (77.0% in the intensive arm and 59.1% in the standard care arm). Thus, the results suggest that sustained smoking cessation counseling and medication can be both feasible and effective for recently diagnosed patients with cancer.<sup>86</sup>

In addition to the experimental study described above, observational cohort studies have shown that providing evidence-based smoking cessation treatment produces high rates of cessation in patients with cancer who smoke (see chapter 3). For example, Cinciripini and colleagues<sup>87</sup> reported 3-, 6-, and 9-month point-prevalence abstinence rates from a large, prospective cohort of people who smoke (N = 3,245) treated at the University of Texas MD Anderson Cancer Center. The authors found that overall self-reported abstinence was 45.1% at 3 months and 45.8% at 6 months. The same high quit rates were seen in patients without cancer who received intensive cognitive behavioral therapy (CBT) treatment. Such high quit rates might reflect, in part, the experience of the MD Anderson Cancer Center smoking cessation program, a long-standing program first established in 2006<sup>88</sup> that offers intensive multisession CBT treatment delivered by tobacco treatment specialists who work with a team of nurses, physician assistants, or nurse practitioners able to prescribe cessation medication. Observational studies limit the ability to assess effectiveness due to the absence of a control group; however, this study suggests

that patients with cancer are highly motivated to quit and can achieve effective treatment outcomes. This evidence, along with the results of the study by Park and colleagues,<sup>86</sup> suggests a role for relatively intense smoking cessation treatments for patients with cancer.

### Summary: Effectiveness

Delivery of intensive CBT counseling along with combination NRT or with varenicline are especially effective smoking cessation treatments in the general population of people who smoke. Relatively few well-powered RCTs have evaluated the effectiveness of implementing smoking cessation treatments in patients with cancer. However, large observational cohort studies have shown that smoking cessation treatment programs can be successfully implemented consistently in cancer care settings and are associated with high long-term rates of abstinence from tobacco. Further research is needed to evaluate the effectiveness of smoking cessation treatments that are targeted and tailored to meet the needs of patients with cancer across the care continuum. Clinically important questions remain about the ideal dose, duration, timing, and delivery of counseling and the acceptability and effectiveness of cessation pharmacotherapy among patients with cancer who smoke.

#### Adoption

In the context of this chapter, Adoption refers to evidence of commitment or support to implement a smoking cessation treatment program by health care systems, clinics, clinicians, or staff. Adoption might be indicated by program leadership providing necessary resources or by clinicians and staff initiating relevant service delivery.<sup>89</sup> Despite the known risks of continued smoking for patients with cancer,<sup>2</sup> the availability of Clinical Practice Guidelines that encourage smoking cessation treatment for such patients,<sup>10,19</sup> and strong endorsement by leading professional organizations, such as the AACR, the NCCN, the American Society of Clinical Oncology, and the International Association for the Study of Lung Cancer,<sup>10–12,15,90,91</sup> tobacco use screening and evidence-based treatment delivery have not been consistently adopted in many cancer care settings. For example, in 2013, a survey of 58 NCI-Designated Cancer Centers found that only about one-half had mechanisms to identify their patients with cancer who smoked and only one-half had a dedicated smoking cessation treatment program embedded within the cancer center.<sup>92</sup> Furthermore, a 2019 review by Price and colleagues<sup>93</sup> found that, although 75% of cancer care clinicians assess tobacco use during an intake visit and more than 60% typically advise patients to quit, a substantially lower percentage recommend or arrange smoking cessation treatment or follow-up after a quit attempt, and less than 30% of oncology care clinicians reported adequate training in cessation interventions.

Large national surveys of cancer care clinicians have demonstrated low rates of clinician provision of smoking cessation treatments. An online survey of 1,507 thoracic cancer clinicians conducted by the International Association for the Study of Lung Cancer revealed low levels of smoking cessation treatment adoption with just 39% of respondents indicating that they actively provide smoking cessation assistance.<sup>94</sup> Another online survey of 1,197 clinicians conducted by the American Society of Clinical Oncology revealed that 90% of clinicians asked about tobacco use and 84% of clinicians advised their patients to quit, but only 44% of clinicians discussed medications and 39% of clinicians provided cessation support.<sup>95</sup> Similarly, a national survey of urologists that inquired about the provision of smoking cessation assistance for their patients

with bladder cancer reported that about 56% of urologists never discussed smoking cessation.<sup>96</sup> A survey of the American College of Surgeons' Commission on Cancer programs, published in 2018, examined the adoption of smoking cessation treatment by participating academic and community cancer programs.<sup>97</sup> This survey found that most cancer treatment programs did not have comprehensive, institutional programs to identify patients with cancer who smoke and to provide systematic smoking cessation treatment. Few programs had developed resources that aided clinicians in providing smoking cessation pharmacotherapy. Collectively, these data suggest that both cancer health care systems and cancer care clinicians have often underdeveloped or underutilized smoking cessation treatment resources.<sup>9</sup> However, several types of policy and regulatory actions can encourage the adoption of smoking cessation treatment in health care systems in general and in cancer care programs in particular.

# Payment Models, Quality Metrics, and Regulation

Payment models, quality metrics, and regulatory and legislative actions all have the potential to spur greater adoption of smoking cessation treatment by health care systems and clinicians. Reports on patient safety and quality by the National Academy of Medicine (formerly the Institute of Medicine) catalyzed the quality revolution in health care in the United States.<sup>98,99</sup> These reports identified six domains of health care quality: safety, effectiveness, timeliness, patient-centeredness, equity, and efficiency. Health care policymakers, clinicians, and organizations have recognized that tobacco control could contribute to improving multiple domains of quality. Notably, effective smoking cessation treatment can also improve outcomes obtained across a broad range of health conditions.<sup>2,19</sup>

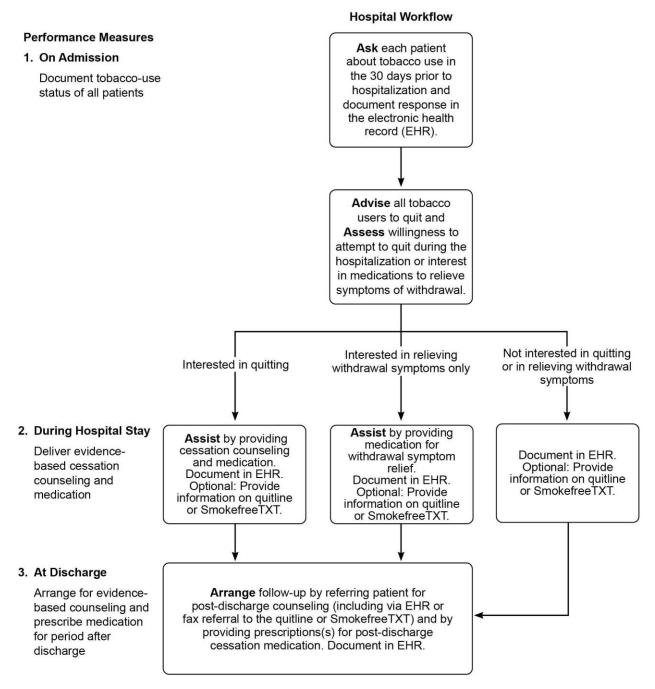
The ongoing transformation of payment models from rewarding volume to rewarding value has further catalyzed the adoption of quality measures that include tobacco control.<sup>1</sup> These policy developments, regulations, and payment models might be highlighted by clinicians and practices who are asking their institutions to enhance the quality and quantity of treatment for nicotine dependence and thereby spur adoption. Four key reporting and payment models that might be used are (1) the Joint Commission performance measure set around smoking cessation treatment, (2) the Oncology Care Model (OCM), (3) other Centers for Medicare and Medicaid Services (CMS) payment models, and (4) outpatient clinical quality measures included in Medicaid and the State Children's Health Insurance Program (CHIP).

For years, numerous regulatory and accreditation agencies, including CMS, the Joint Commission, and the National Quality Forum, have recognized that the delivery of smoking cessation treatments requires assessment of tobacco use during inpatient and outpatient clinical encounters, with reimbursement partially contingent on its documentation.<sup>100,101</sup> In addition to the OCM, several other CMS payment models include tobacco measures. These models include measure sets designed to assess health plans (the Healthcare Effectiveness Data and Information Set, or HEDIS); patient-reported measures of tobacco interventions (the Consumer Assessment of Healthcare Providers and Systems, or CAHPS); and a 2015 update of the basic Medicare value-based program, known as the Medicare Access and CHIP Reauthorization Act (MACRA).<sup>102,103</sup> Collectively, these measures have resulted in a marked increase in the documentation of smoking status in EHRs and referral at discharge to smoking cessation treatment programs and quitlines.<sup>22,32,34,38,58–60</sup>

In 2012, the Joint Commission created an optional performance measure set addressing nicotine dependence in inpatient clinical encounters.<sup>100</sup> This measure set initially had four components: (1) screening all patients age 18 years and older for tobacco use, (2) offering counseling and cessation/withdrawal mitigation medications during hospitalization for all patients who smoke, (3) creating a plan at discharge to continue smoking cessation treatment (i.e., counseling and medications) in the post-hospitalization period, and (4) following up within 1 month of hospital discharge. Psychiatric facilities were required to attest to these quality measures, with resultant increases in documentation of tobacco use assessment and treatment, based on their effectiveness in augmenting smoking cessation treatment in clinical populations.<sup>104,105</sup> The National Quality Forum did not ratify the 1-month post-discharge measure and the Joint Commission subsequently dropped it. Additionally, because of near-universal compliance, the screening measure was retired in 2017 for psychiatric facilities.<sup>1</sup> The current Joint Commission Tobacco Dependence Performance Measures are described in more detail in Figure 4.2.

Hospitals have the option of selecting which 4 Joint Commission Performance Measure Sets to complete from the 10 to 15 sets available each year for Joint Commission accreditation.<sup>1,106,107</sup> Regrettably, the rate of adoption of the tobacco performance measure set has been very low; in 2019, only about 2% of 5,000 hospitals elected to report on these measures.<sup>106</sup> This context illustrates that the low rates of addressing tobacco use in cancer care are reflective of a broader challenge. Encouraging such reporting can serve a key role in maintaining smoking cessation treatment delivery to hospitalized patients, including patients with cancer. In part to encourage such Joint Commission reporting, Sarna and colleagues<sup>106</sup> called on *U.S. News and World Report* to withhold designating a hospital as being among the "Nation's Best" unless they report on the Joint Commission Tobacco Measure set.

# Figure 4.2 Joint Commission Tobacco Cessation Measures



Source: Version 2021A Specifications Manual, The Joint Commission, 304 Fiore et al. 2012.100

The OCM was created in 2015 when CMS launched an episode-based payment model for cancer care.<sup>108</sup> The OCM provides enhanced payment for oncology practices that adhere to certain quality measures and deliver certain services, such as patient navigation and care coordination. As of July 2021, 126 practices and 5 commercial payers, a small proportion of cancer care settings nationwide, participate in the OCM.<sup>109</sup> Although assessing rates of tobacco use and treatment is not an OCM quality measure, incorporating tobacco-related measures into such

payment models would serve to enhance the adoption of cessation efforts. This incorporation might also focus the clinical enterprise on providing services that improve the patient experience or health outcomes, rather than on appointments or procedures for which a clinician typically bills. Moreover, treating tobacco use has the potential to improve other OCM outcomes, including reduced cancer treatment-related side effects and improved cancer outcomes, which should increase the appeal of such treatment.

Regarding outpatient quality measures, the CMS Child and Adult Core Sets support federal and state efforts to collect, report, and use a standardized set of measures to drive improvement in the quality of care provided to Medicaid and State CHIP beneficiaries.<sup>110</sup> Beginning in fiscal year 2024, states will be required to report on the core set of health care quality measures for children enrolled in Medicaid and CHIP and on the core set of behavioral health measures for adults enrolled in Medicaid. The core sets allow states, the public, and CMS to monitor trends in performance on standardized indicators of quality of care provided to Medicaid and CHIP beneficiaries under both fee-for-service and managed care arrangements and examine performance across states. The Child and Adult Core Performance Measure Sets in 2022 include the following tobacco- and smoking-related performance measures:

- **Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention** (National Quality Forum Number 0028/0028e). The percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months and who received tobacco cessation intervention if identified as a tobacco user.<sup>111</sup>
- **Tobacco Use and Help with Quitting Among Adolescents** (National Quality Forum Number 2803). The percentage of adolescents ages 12–20 with a primary care visit during the measurement year for whom tobacco use status was documented and who received help with quitting if identified as a tobacco user.<sup>112</sup>
- Medical Assistance With Smoking and Tobacco Use Cessation (National Quality Forum Number 0027). The three components of this measure assess different facets of providing medical assistance with smoking and tobacco use cessation and include advising smokers and tobacco users to quit, discussing cessation medications, and discussing cessation strategies with patients aged 18 and older who were current smokers or tobacco users.<sup>113</sup>

# Legislative Action

Passed in 2009, the Health Information Technology for Economic and Clinical Health (HITECH) Act accelerated the adoption of the EHR by nearly all U.S. health care systems.<sup>114,115</sup> The HITECH Act required hospitals and health care systems to adopt a set of measures designed to encourage the "meaningful use" of EHRs. Included in the initial meaningful use criteria was a measure requiring the recording of smoking status for all patients aged 13 and older. However, the HITECH Act did not require the systematic clinical assessing, recording, and documenting of tobacco use status.

Passage of the Patient Protection and Affordable Care Act (ACA) in 2010 has also enhanced health care systems' adoption of tobacco interventions.<sup>116</sup> The ACA did this by (1) requiring coverage of A- or B-level U.S. Preventive Services Task Force recommendations (USPSTF),<sup>117</sup> (2) expanding eligibility for Medicaid, (3) mandating coverage by Medicaid and private

insurance of nicotine dependence medications and counseling, and (4) creating new value-based payment models via the Center for Medicare and Medicaid Innovation.<sup>118</sup> The value-based models include the OCM (discussed previously), as well as the Medicare Shared Savings Program (MSSP).<sup>109</sup>

The MSSP encourages clinicians in health care systems to create Accountable Care Organizations (ACOs) in which payment is conditioned on the ACO accepting some financial risk to encourage adoption of coordinated high-value care practices. In the MSSP, adoption of tobacco screening and treatment of identified people who smoke is required to realize full financial benefits. While the effects of the MSSP on the provision of smoking cessation treatment are not yet known, one study suggests that it increases the number of beneficiaries with diabetes mellitus who refrain from smoking.<sup>119</sup>

Of note, the ACA resulted in a substantial increase in the proportion of Medicaid recipients who received pharmacologic treatment for nicotine dependence.<sup>116</sup> A 2017 paper found that expanded Medicaid coverage was associated with a 36% increase in the number of prescriptions for smoking cessation medications.<sup>120</sup> Another study found that states that expanded Medicaid coverage had a 2.1% greater increase in smoking cessation among adults who smoke, ages 18-64, than states that did not expand Medicaid.<sup>121</sup> Similarly, coverage of prescription smoking cessation medication remains incomplete for Medicare patients, even with Part D plans, that do not cover over-the-counter medications and which could still charge co-pays for FDA-approved smoking cessation medication. While the ACA requires expanded Medicaid programs to provide tobacco cessation services with no cost-sharing requirements, it does not require state programs to remove all barriers to accessing these treatments and services. State Medicaid programs have different tobacco cessation coverage requirements resulting in considerable differences in the availability of tobacco cessation treatment across states.<sup>118</sup> Also, according to estimates from the CDC,<sup>122</sup> many states still have high levels of uninsured people (about 11% of the total U.S. population), preventing access to insurance-covered cessation medications. Private insurers could also require prior authorization and co-pays. These restrictions continue to hinder delivery of evidence-based care for people who smoke, including patients with cancer.

#### Summary: Adoption

The adoption of evidence-based smoking cessation treatment delivery in cancer care settings has lagged behind the evidence of its benefit. This lack of adoption appears to be due, at least in part, to health care systems failing to support implementation of smoking cessation treatment programs,<sup>123</sup> as well as many clinicians not providing such treatment. Improved adoption will require focused attention to the factors that influence decisions to adopt smoking cessation treatments, including barriers and facilitators at the patient, clinician, health care system, and health insurance system level (discussed in detail later in this chapter in "<u>Challenges to</u> <u>Implementing Smoking Cessation Treatment in Cancer Care Settings at the Patient, Clinician, and Health Care System Level</u>"). Fortunately, payment models, quality metrics, and regulatory and legislative actions show promise for increasing adoption of smoking cessation treatment in cancer care settings and making it a required standard of clinical care for all patients with cancer who smoke.

#### Implementation

In the RE-AIM framework, Implementation refers to the consistency and fidelity with which elements of an intervention protocol or plan are delivered.<sup>16</sup> Evaluation of implementation can include assessing the consistency of the delivery of discrete intervention elements, whether interventions are delivered as recommended, whether adaptations are made in delivery, and the time and cost of the intervention. There are relatively few assessments of the implementation of smoking cessation treatment in the context of cancer care. However, the existing data suggest that the implementation of screening and treatment for nicotine dependence in patients with cancer is inadequate. A survey of 28 cancer treatment programs located in the northeastern United States accredited by the American College of Surgeons Committee on Cancer reported data on the consistency of implementation of key elements of smoking cessation treatment.<sup>97</sup> This study revealed that while 75% of responding programs linked people who smoke to outside treatment programs (such as quitlines) to "some" extent or a "great" extent, 60% of programs reported that they provided decision aids to support the prescription of smoking cessation medications "very little" or "not at all," and 78% of programs provided prompt follow-up and reevaluation of patients' cessation goals "very little" or "not at all." These results are consistent with those of another study assessing whether the 5A's of smoking cessation treatment were delivered as recommended in cancer care. In that study by Simmons and colleagues, <sup>124</sup> investigators queried patients about whether their oncologist or the oncology staff delivered the full 5A's or a reduced set. Results showed that full implementation of the 5A's was rare. More than 90% of patients reported that their physician or a staff member asked whether they smoked and 76.1% of patients reported being advised to quit. However, less than one-half reported being asked about their interest in quitting and being helped with quitting, and less than 5% of patients reported follow-up support for their quitting. Overall, patients reported that clinicians executed only the first two of the 5A's.<sup>124</sup> These data are consistent with the level of tobacco intervention implementation found in oncology programs in other studies. For instance, Ramsey and colleagues<sup>125</sup> examined rates of tobacco intervention at a large cancer center prior to the implementation of an enhanced point-of-care smoking cessation treatment program. These authors found the following rates of baseline intervention elements (prior to the point-of-care program): health care clinicians assessed 48% of patients for tobacco use, referred less than 1% of patients to smoking cessation counseling, and provided smoking cessation medication to only 3% of patients.

#### Summary: Implementation

Research on the implementation of smoking cessation treatment programs in cancer care settings is limited. Existing data indicate that there is a need to increase referrals to smoking cessation counseling or other cessation support, provision of smoking cessation medication, and follow-up support. Important strides have been made in the implementation of comprehensive treatment of smoking in cancer care settings through NCI's C3I initiative (see "Disseminating and Implementing Tobacco Cessation Treatment in Cancer Care Settings: The National Cancer Institute's Cancer Center Cessation Initiative").

#### Maintenance

Maintenance addresses the extent to which a new program or policy becomes institutionalized and integrated into routine clinical workflows or policies that are sustained over time. This is a

critical issue, insofar as sustained organizational change is difficult, and policies and practices often revert to prior states after the initial energy and enthusiasm that is invested in a new program begins to wane. In fact, there is clear evidence that clinicians and health care systems tend to implement smoking cessation treatment less consistently over time.<sup>33</sup>

Several strategies have been shown to maintain the delivery of tobacco interventions in the general health care context.<sup>1,19</sup> These include (1) securing support from health care system leadership for maintaining a smoking cessation treatment program, as organizational and financial support is crucial to mobilize clinicians and administrative staff, including IT specialists who are likely to be involved; (2) embedding the intervention in a multilevel fashion into the usual workflows, policies, and practices of clinicians, ancillary staff, practices, clinics, hospitals, health care systems, and communities; (3) leveraging health information technologies including the EHR, patient-facing mobile health strategies, and other emerging approaches such as wearables and sensors<sup>126</sup>; and (4) leveraging tobacco-relevant quality metrics, payment models, and regulatory policies by accrediting agencies, governmental agencies, payers, and professional societies.

Below are some examples of how these four maintenance strategies can be implemented and maintained in cancer care clinical settings.

# Secure Support From Health Care System Leadership

Leadership engagement and support is crucial to both initiating and sustaining any substantial organizational change.<sup>92,127–129</sup> Leadership may be persuaded to implement organizational changes because smoking cessation treatment is clinically effective, cost-effective, and helps institutions comply with numerous external regulatory requirements and financial incentives.<sup>1</sup> Value-based payment models, rather than fee-for-service billing, may incentivize smoking cessation treatment for health care leadership.<sup>1</sup> Salloum and colleagues<sup>130</sup> conducted a study to evaluate system-level implementation costs across 15 NCI-Designated Cancer Centers participating in C3I. In 2020, the median cost-per-participant was \$466 (range: \$70–\$2,093) and cost-per-quit was \$2,688 (range: \$330–\$9,628). These real-world data help inform leadership as they contemplate maintaining smoking cessation treatment programs for patients with cancer.<sup>130</sup>

#### Integrate Tobacco Screening and Treatment Strategies Into Clinical Workflows

There is a dearth of evidence on specific health care system changes that enhance maintenance of smoking cessation treatment in cancer care settings. However, strategies that have been effective in other health care contexts, such as primary care,<sup>19,131,132</sup> are likely to be beneficial in cancer care. Thus, routine screening of tobacco use among patients with cancer can be performed at multiple sites and throughout the continuum of cancer care. Such screening and treatment delivery can be incorporated into clinical workflows of practices, clinics, and centers that specialize in the treatment of individuals with cancer and can be performed at intake; at routine follow-up visits; and before procedures, such as chemotherapy infusions and radiation treatments. One strategy that can facilitate the re-engineering of cancer care clinical workforce to deliver evidence-based smoking cessation treatment. This facilitation can be achieved through training and education, and by embedding tobacco treatment specialists into

multidisciplinary oncology teams. The wide-scale implementation of such tobacco treatment specialists has frequently been limited by their inability to bill independently for cessation treatments provided. Finally, tobacco use status and treatment can become an expected part of the care plan discussed at meetings of tumor boards.

# Leverage EHRs

As discussed earlier, several mechanisms exist to leverage the EHR to maintain the delivery of smoking cessation treatments. In addition to their capacity to enhance maintenance, these mechanisms can also be used to enhance the adoption and implementation elements of this framework.

These include:

- Building order sets that guide clinicians in delivering evidence-based counseling and medication;
- Using EHR-based referrals to quitlines and texting programs;
- Scripting clinicians for brief motivational or cessation counseling;
- Automating electronic orders to facilitate prescribing smoking cessation medication; and
- Designing macros to facilitate the identification of and intervention with people who smoke.<sup>32,34</sup>

Macros are EHR text—a phrase, sentence, or series of sentences—that prompt a set of actions. Macros are recorded and saved with the capacity to retrieve and paste for future and repeated ease of use. Such EHR capacities could promote maintenance by reducing the burden for clinical staff (including reducing their counseling responsibilities) and by making smoking cessation treatment an integral part of service delivery. Despite these benefits of the EHR, challenges exist in realizing its full potential, including those related to optimizing the clinical workflow through vendor customizations, clinician engagement, and training. Overcoming these challenges requires an institutional commitment to the effective use of the EHR.

# Leveraging Tobacco-Relevant Quality Metrics, Payment Models, and Regulatory Policies

The use of such metrics, policies, and payment models can incentivize the leadership of oncology practices and cancer centers to prioritize the treatment of nicotine dependence; their use can also prompt clinicians and other oncology staff to adopt and maintain such treatment.<sup>98–100,120</sup>

# Summary: Maintenance

Once a health care system decides to implement a smoking cessation treatment program, key strategies can help ensure its maintenance. These strategies include securing health care system leadership support; engineering tobacco use screening and treatment into clinical workflows, making them an integrated, routine element of health care; and leveraging the power of the EHR to reduce clinician burden and facilitate delivery of cessation interventions. These steps, plus adoption of payment models and regulatory requirements that enhance maintenance, should help sustain tobacco intervention in cancer care settings.

# Assessing and Verifying Tobacco Use Status

Screening for tobacco use status and updated documentation of that status for all patients with cancer is a critical first step in initiating cessation interventions across the cancer care continuum. However, some cancer patients and survivors report a reluctance to acknowledge ongoing tobacco use,<sup>135,136</sup> likely due to the stigma associated with continued tobacco use after a cancer diagnosis.<sup>137–139</sup> Consistent with this, studies have found that misreporting of current tobacco use among cancer patients and survivors ranges from 39% to 48%.<sup>135,136,140–142</sup> The accurate identification of tobacco use by patients with cancer is a necessary first step to providing them with effective treatment. As with all measurement approaches, an optimal solution balances the validity of the assessment with its expense and the staff and patient burden required for implementation.

NCI and AACR convened the NCI-AACR Cancer Patient Tobacco Use Assessment Task Force to develop recommendations for tobacco use measurement and for research priorities regarding tobacco use after a cancer diagnosis.<sup>143,144</sup> The Task Force's consensus measures form the Cancer Patient Tobacco Use Questionnaire (C-TUQ) (Table 4.2; available at https://cancercontrol.cancer.gov/ctuq). The C-TUQ includes four core items that assess current and past cigarette smoking, as well as a more extensive library that includes items designed for cancer patients and survivors (e.g., assessing tobacco use relative to the timeline of cancer diagnosis and treatment). In addition, the Task Force recommended the use of validated procedures to biochemically confirm self-reported tobacco abstinence (e.g., cotinine or breath carbon monoxide tests) when feasible (see "Appendix B: Biochemical Confirmation Reasons and Methods").<sup>145</sup> Biochemical confirmation of self-reported tobacco use status is likely to provide a more accurate index of cessation treatment effects than self-report alone. However, the routine use of biochemical assessment may not be feasible in some clinical practice and research settings. For instance, time constraints and the cost of the tests can affect feasibility. Also, the clinical team must have a clear idea of the actions to be taken if a test result indicates smoking. The Task Force recommended C-TUQ assessment (self-report with or without biochemical confirmation) at diagnosis or at the point of study entry and at the end of treatment, at a minimum. The C-TUQ can also be administered at Day 1 of each chemotherapy cycle, at the onset and conclusion of radiation therapy, at the onset and conclusion of any other systemic cancer therapy, and 6-12 months after the end of cancer treatment.

# Table 4.2 Consensus Assessment Instrument for Tobacco Use in Oncology (C-TUQ, Selected Items)

Section 1. Basic Tobacco Use Information (C-TUQ Core)

<ol> <li>Have you smoked at least 100 cigarettes (5 packs = 100 cigarettes) in your <u>entire life</u>?</li> <li>Yes</li> </ol>	
Don't know/Not sure	
4) How many total years have you smoked (or did you smoke) cigarettes? Do not count any time you may have stayed off cigarettes.	
Years If you smoked less than one year, write "1."	

# Table 4.2 (continued)

5) On average when you smoked, about how many cigarettes do you (or did you) smoke a day? A pack usually has 20 cigarettes in it.

\_\_\_ Number of cigarettes per day.

- 6) How long has it been since you last smoked a cigarette (even one or two puffs)?
- First check which one of the following choices applies to you. Then, if applicable, write a number on the line for how many days, weeks, months, or years it has been since your last cigarette.
  - $\Box$  I smoked a cigarette today (at least one puff).
  - $\Box$  1-7 days.  $\rightarrow$  Number of days since last cigarette: \_
  - $\Box$  Less than 1 month.  $\rightarrow$  Number of weeks since last cigarette: \_\_\_\_
  - $\Box$  Less than 1 year.  $\rightarrow$  Number of months since last cigarette: \_\_\_\_
  - $\Box$  More than 1 year.  $\rightarrow$  Number of years since last cigarette: \_\_\_\_\_
  - Don't know/Don't remember

#### Section 2. Cigarette Smoking in Relation to Cancer Diagnosis and Treatment

During each of the following time frames, please indicate whether you smoked cigarettes every day, some days, or not at all.

- a. The year before you were first told you had cancer
- b. After diagnosis, and before treatment started
- c. From 2 days before your last cancer surgery to 2 days after
- d. During the course of treatment
- e. After treatment ended
- f. Since your last visit to this clinic

Note: C-TUQ = Cancer Patient Tobacco Use Questionnaire. Sources: Land et al. 2016,<sup>144</sup> National Cancer Institute 2017.<sup>305</sup>

Advances in the design and use of EHRs, particularly given the influence of meaningful use measures included in the HITECH Act of 2009,<sup>146</sup> have greatly increased the frequency of tobacco use assessments in the clinical setting.<sup>147,148</sup> While not addressing the limitations of relying on self-report, EHR-based assessments of smoking by patients with cancer have been shown to increase rates of tobacco use assessment and referral to tobacco cessation treatment,<sup>149</sup> even when such assessment depends upon a single question about current tobacco use.<sup>150</sup> Burris and colleagues<sup>151</sup> recommend the use of a single measure assessing 30-day point-prevalence tobacco use. Further, misreporting of tobacco use because of embarrassment, worry, or shame may be overcome either via the use of empathetic and nonjudgmental approaches to information collection<sup>139</sup> or by using assessment methods that reduce perceived adverse evaluations, such as electronic screening devices.<sup>152</sup> While relatively simple measures of smoking status could be appropriate in the context of routine clinical care, tobacco cessation treatment programs should consider more comprehensive measures of tobacco use status and biochemical validation of selfreported tobacco use status. Across both clinical and research activities, the use of standardized assessments of tobacco use as recommended by the NCI-AACR Cancer Patient Tobacco Use Assessment Task Force, along with procedures to reduce the likelihood of misreporting, can improve the quality of patient care and facilitate research by allowing data pooling and comparisons across different studies and populations.

# Challenges to Implementing Smoking Cessation Treatment in Cancer Care Settings at the Patient, Clinician, and Health Care System Levels

Health care systems, including cancer care settings, are well-positioned to address tobacco use and dependence at a population level because most U.S. adults who smoke self-report that they see a clinician each year, want to quit smoking, and have made a quit attempt in the past.<sup>21,153</sup> Moreover, as discussed in chapter 1, smoking cessation clearly reduces overall tobacco-related morbidity and mortality in cancer care populations. Despite this patient receptivity and the benefits of smoking cessation, oncology practice often falls short of addressing the behaviors that could lead to reduced smoking and its resultant harms.<sup>92</sup> This has led to a call for cancer care settings to implement a systematic approach to delivering smoking cessation treatment and overcoming challenges to such delivery.<sup>154</sup>

Among the factors responsible for the inadequate treatment of smoking in cancer centers are the multiple barriers at the patient, clinician, and health care systems levels.<sup>154</sup> Understanding barriers at each of these levels can aid health care systems in their efforts to reach, engage, and effectively treat patients with cancer who smoke. In particular, it is critical to understand how to engage patients in smoking cessation treatment and how to re-engage them if they relapse. This knowledge can also assist health care systems in allocating resources to best meet the needs of their patient population. Health care systems must similarly address barriers to clinicians' delivery of effective smoking cessation treatment to ensure patients are offered and able to access high-quality smoking cessation treatment. This section summarizes patient, clinician, and health care systems barriers to implementing smoking cessation treatment in cancer centers, as well as potential strategies to address these barriers, summarized in Table 4.3.

Challenges	Potential strategies
Patient	level
Sociodemographic differences in smoking rates by age, sex, race and ethnicity, educational attainment, income level, comorbid psychiatric or substance abuse diagnoses, and medical/physical challenges.	Groups that are disproportionately affected by smoking can be targeted for intervention to equitably reach all populations. Research is needed to improve equitable delivery of smoking cessation treatments, and health care systems should be mindful of these factors when designing and delivering interventions to the patients they serve within their community.
Lack of knowledge or misconceptions about cancer-related risks of smoking and benefits of quitting.	Clinicians can educate patients on how smoking increases the risk of cancer and emphasize the benefits of cessation for cancer patients, including improved response to cancer treatments and quality of life. Health care systems can disseminate educational resources for clinicians and patients.
Low rates of engagement in smoking cessation treatment components (e.g., counseling sessions, medication use) even when they have been offered to and accepted by the patient.	Simplify access and remove barriers to engagement including offering treatments at point of care, providing counseling via multiple modalities (e.g., telehealth, phone), and eliminating copays and other costs.

# Table 4.3 Challenges to Implementing Smoking Cessation Treatment in Cancer Care Settings at the Patient, Clinician, and Health Care System Levels

# Table 4.3 (continued)

Challenges	Potential strategies	
Low motivation and/or confidence to quit smoking.	Clinicians can use brief intervention strategies to build motivation and confidence to quit. Referral to specialized smoking cessation treatment resources, such as an internal smoking cessation treatment program or the state quitline, may be especially helpful.	
Psychological distress related to cancer diagnosis and treatment, including depression, anxiety, stress, shame, guilt, stigma, and other factors that may hinder treatment engagement. Smoking or other tobacco use may also be used as a coping strategy.	Patients can be connected with mental health clinicians as part of their cancer care to manage psychological distress.	
Misperceptions about the quitting process including the following: fears that medications are unsafe, do not work, or are addictive; that severe withdrawal symptoms will not dissipate over time; and/or a fatalism that it is too late to quit and that the benefits of quitting only accrue for those who quit early in life.	Correct misconceptions about medications and highlight their potential to reduce withdrawal symptoms. Emphasize that most individuals feel better when they quit with improvements in health typically experienced within days of quitting (e.g., reducing breathlessness) and that such improvements in health are typically experienced irrespective of the age at which an individual quits.	
Clinicia	n level	
Limited knowledge of or confidence in delivering smoking cessation treatment or lack of awareness of available resources.	Training clinicians can improve knowledge and confidence to provide smoking cessation treatment. <sup>214</sup> Health care systems can promote educational resources to make clinicians aware of available treatment resources.	
Perceptions of patients as unwilling or unmotivated.	Opt-out referral methods may help overcome reluctance or bias on the part of clinicians to address smoking with patients.	
Concerns about alienating patients by addressing the topic of smoking.	Communicate that evidence supports higher patient satisfaction when clinicians address tobacco use during the visit. Training clinicians to use gain-framed messages that are personalized may further reduce alienation concerns (i.e., people who quit smoking feel better due to fewer pulmonary symptoms such as reduced breathlessness, less, pain, quicker recovery from surgery).	
Awareness that patients may be discouraged by their past failures to successfully quit tobacco use and, as a result, may be unwilling to try to quit again.	Frame the treating of tobacco use as a chronic disease, <sup>19</sup> often requiring repeated interventions similar to treating other chronic diseases (e.g., hypertension, diabetes, even cancer). Highlight modest successes by patients (e.g., brief period off cigarettes, reduced number of cigarettes smoked per day).	
Health care system level		
Institutional commitment and accountability (e.g., recognition of smoking cessation treatment as a core component of cancer care).	Health care systems including cancer care settings can formally recognize and promote smoking cessation treatment as a clinical priority, report on the optional Joint Commission tobacco cessation performance measure, and highlight smoking cessation treatment activities as part of reporting for NCI-designation status.	

Challenges	Potential strategies
Time (e.g., clinician time constraints, poor workflow integration).	EHR systems that are well-integrated with easy-to-use cessation treatment functionalities can facilitate documentation and automated referral processes of patients who smoke without disrupting workflows or requiring significant additional time from clinicians.
Referral options (e.g., lack of dedicated, stable smoking cessation treatment programs).	Dedicated smoking cessation staff prioritized by leadership, clinical champions, and opinion leaders can increase smokin cessation treatment.
Funding and reimbursement (e.g., lack of stable funding for smoking cessation treatment resources, inadequate clinician and institutional reimbursement).	A health care system commitment to stable funding can help maintain dedicated smoking cessation treatment programs. Reimbursement for clinicians can increase provision of smoking cessation treatment at point-of-care. At the policy level, reimbursement programs such as the Medicare Shared Savings Program that prioritize population-level health outcomes can promote smoking cessation interventions. Also, including the provision of nicotine dependence treatment as part of certification for health care systems (e.g., Joint Commission <sup>106</sup> ) can encourage implementation of cessation programs.

# Table 4.3 (continued)

Note: NCI = National Cancer Institute. EHR = Electronic health record.

# Patient-Level Barriers to Delivering Smoking Cessation Treatment in Cancer Care Settings Sociodemographic Differences in Smoking Rates

Several studies have used large, nationally representative samples to examine rates of current and former smoking among patients with cancer and cancer survivors compared with those without a cancer diagnosis, revealing sociodemographic factors that are consistently associated with smoking behavior among people with a history of cancer (see chapter 5). Underlying reasons for these patterns are myriad, but may, in part, reflect a failure of health care systems to offer certain populations smoking cessation treatment. For example, among people with a cancer history, current smoking (versus not smoking currently) is associated with younger age,<sup>155–162</sup> female sex,<sup>155,157,159–162</sup> lower levels of educational attainment,<sup>155,157–159,162,163</sup> lower income,<sup>155,161,162</sup> and lack of health insurance.<sup>155,157–159,163,164</sup> Therefore, it is important that health care systems and cancer care settings attempt to ensure that such populations are offered smoking cessation treatment.

Similarly, prospective studies of patients with lung cancer have found younger age and lower income are associated with shorter time to relapse and higher rates of current smoking in the months following surgery.<sup>165,166</sup> Other cancer populations that have especially high levels of current smoking include individuals who report being divorced, separated, widowed, single, or not living with their partner.<sup>158,159,163,167</sup> The causes of these relatively high rates of smoking are unclear, but could involve knowledge gaps, affective or motivational susceptibilities, stress, the presence of comorbid conditions (mental health and/or substance use), or a lack of social support. Regardless, these relationships identify patient groups that are especially likely to smoke and experience harms caused by smoking.

Data on regional variation in smoking rates among people with a cancer history are limited, although one study using nationally representative Behavioral Risk Factor Surveillance System data suggested that rates may be higher among those living in the Midwestern and Southern U.S. states.<sup>155</sup> This finding is consistent with trends in the general population. Smoking rates and tobacco-related disease, including cancer incidence and mortality, vary widely by state and are significantly higher than the national average in a cluster of 13 Southern and Midwestern states.<sup>168–170</sup> These states are less likely to have implemented effective tobacco control policies such as comprehensive smokefree laws than other states,<sup>170</sup> and people living in this region tend to have lower knowledge of the risks of smoking than those in other U.S. regions.<sup>169</sup>

Health care systems can use these data to inform efforts to extend their reach to diverse patient populations. For example, systems serving higher proportions of low-income patients or those living in Southern and Midwestern U.S. states could require that additional resources be allocated to smoking cessation treatment. As discussed in greater detail in chapter 5, it is important that health care systems utilize strategies to increase the representativeness of their reach, to include disproportionately affected patient populations, and to help promote equity in smoking cessation treatment delivery in cancer care. An analysis of reach across NCI-Designated Cancer Centers selected as part of Cohort 1 of NCI's C3I documented improved cessation program reach among racial and ethnic minority groups who smoked over the 2 years of the initiative.<sup>171</sup> Presumably this occurred due to health care system changes that were widely implemented in these programs, such as EHR enhancements that were compatible with clinical workflows, staff training, clear allocation of clinical responsibilities, and facilitation of smoking cessation treatment referral. Moreover, overall cessation program reach among such racial and ethnic minority population rates of reach.<sup>171</sup>

# Knowledge of Risks of Smoking and Benefits of Quitting

Individuals with cancer who smoke often do not understand the cancer-related risks of continued smoking and the benefits of quitting. For example, many bladder and cervical cancer survivors indicated that they were unaware that smoking was a risk factor for their cancer.<sup>172–175</sup> In general, people who currently smoke perceive themselves to be at higher risk of developing lung cancer than never and former smokers, though only about 15% perceive themselves to be at "very high" risk (response options: very low, somewhat low, moderate, somewhat high, very high).<sup>176</sup> This is consistent with the finding that people who smoke tend to underestimate their personal likelihood of developing lung cancer and other diseases caused by smoking.<sup>177</sup> People who smoke who articulate these optimistically biased (i.e., unrealistically low) risk perceptions are in turn more likely to endorse inaccurate beliefs about smoking and are less likely to quit smoking.<sup>178,179</sup> Others could believe that quitting smoking is not important because life is inherently risky.<sup>180</sup>

One prospective study of people receiving care for acute or chronic illness who smoke, including patients with cancer, found that among those with an illness caused by smoking, optimism bias<sup>181</sup> was associated with lower motivation to quit and lower odds of smoking cessation.<sup>178</sup> In an additional analysis, patients with cancer with higher perceived risk of developing another cancer 3 months after surgical resection were more likely to have quit smoking by 12 months,<sup>182</sup> suggesting that perceived cancer risk could motivate smoking cessation among people with cancer. Qualitative and survey research suggests that patients with cancer are receptive to

information about the effects of continued smoking on their health and how quitting smoking would benefit their cancer treatment.<sup>173,183</sup> Evidence suggests that conversations between patients and clinicians can increase patients' awareness of the effects of smoking on their cancer treatment.<sup>139,184,185</sup>

# Motivation and Confidence to Quit

Greater motivation, or readiness to quit smoking, is a consistent predictor of smoking cessation abstinence, including among patients with cancer.<sup>186,187</sup> However, once diagnosed with cancer, demographic and psychological factors likely influence patients' motivation to quit. For example, motivation to quit is lower among older and less educated cancer survivors.<sup>157</sup> In addition, lower motivation is observed among those living with other people who smoke, those with lower self-efficacy, lower perceived benefits of quitting, lower risk perceptions, more emotional distress, and more fatalistic beliefs (i.e., believing that there is no benefit to quitting).<sup>188</sup> A qualitative investigation among patients with gastrointestinal cancer suggested several possible reasons for lower motivation to quit, including fatalistic beliefs and lack of confidence in one's ability to quit based on past failed quit attempts.<sup>189</sup>

It is also likely that the nature and intensity of quitting motivations affect the willingness to engage in and benefit from smoking cessation treatment. For example, people with chronic conditions caused by smoking who reported that health concerns were their primary motivation to quit were twice as likely to quit as those reporting other (unspecified) primary motivations.<sup>190</sup> One qualitative study found that the patients who had remained abstinent after their cancer diagnosis tended to be internally motivated; while those who cited external motivation for their quit attempts, such as lack of opportunity to smoke during a hospital stay or influence from friends and family, tended to have relapsed.<sup>139</sup> Still, nearly half of people with a cancer history who currently smoke report having made a quit attempt in the past year,<sup>157</sup> a rate similar to the general adult population of individuals who smoke,<sup>21</sup> and many patients report a desire for help with quitting smoking and cite the importance of doctors' advice in motivating them to quit.<sup>157,190–192</sup> These data suggest that many patients with cancer are already motivated to quit smoking. However, some patients with cancer who smoke certainly lack motivation to quit. There is a great deal of evidence, however, that clinicians can increase patients' motivation to quit by discussing the patient's personal risk of continued smoking (including the heightened risks of adverse cancer outcomes) and offering to help them in the quitting process.<sup>19,193,194</sup>

# **Psychological Distress**

As discussed in chapters 3 and 5, psychiatric comorbidities, particularly depressive symptoms and active substance use disorders, are associated with a lower likelihood of quitting after a cancer diagnosis and with an increased risk of relapse.<sup>192,195–200</sup> Berg and colleagues<sup>192</sup> found that about 64% of patients who continued to smoke after their cancer diagnosis had significant depressive symptoms, compared with only about 27% of those who had quit smoking. Feelings of depression, stress, and anxiety may be barriers to successful smoking cessation.<sup>19</sup> while stress management skills and more adaptive coping could facilitate smoking cessation.<sup>173</sup> Two model programs describe treating psychological distress symptoms while addressing nicotine dependence.<sup>86,87</sup>

# Coping

Smoking or other tobacco use can be perceived by patients as an important coping strategy during a difficult life experience. Thus, many individuals could be highly likely to be more nicotine dependent and continue using tobacco in response to the anxiety, stress, and pain that often accompanies cancer diagnosis and treatment.<sup>189,201–203</sup> Indeed, the thought of stopping tobacco use can itself be very stressful. These feelings of distress can be compounded by feelings of guilt, shame, or stigma patients experience related to continued tobacco use.<sup>204</sup> One qualitative investigation in the cancer care setting found that about one-half of relapsed patients were uncomfortable discussing smoking with their clinicians, fearing that they would be judged negatively.<sup>139</sup> These concerns about stigma or feelings of guilt and shame may contribute to patients not being completely truthful about their tobacco use.<sup>139</sup> Addressing patients' depressive symptoms and approaching tobacco use cessation with an empathic, nonjudgmental attitude is an important component of successful smoking cessation treatment for people with cancer who smoke.

# Summary: Patient-Level Barriers

Numerous patient-level factors challenge the effective and equitable implementation of smoking cessation treatment in cancer care settings. The observed sociodemographic differences in tobacco use among patients with cancer underscore the importance of consistently offering smoking cessation treatment and monitoring treatment reach for all patients with cancer who smoke, including those in medically underserved and vulnerable populations. Variability in patients' knowledge about the risks of continued smoking after a cancer diagnosis, motivation to quit, and confidence in quitting suggest a need for systems to integrate informational and motivation-building tools into standard care for patients with cancer who smoke. Challenges associated with comorbid distress symptoms, such as depression, anxiety, and worry, and limited capacity to cope with psychological stressors support the potential benefit of integrating smoking and implement smoking cessation treatment programs in cancer care settings, attention to these patient-level barriers is needed to promote treatment engagement and maximize reach.

# Clinician-Level Barriers to Delivering Smoking Cessation Treatment in Cancer Care Settings Lack of Smoking Cessation Knowledge and Training

Although the importance of smoking cessation for patients with cancer is well understood, cancer care clinicians and staff frequently report that they lack the confidence and training to provide smoking cessation treatment (see chapter 3).<sup>92–95,205–211</sup> Surveys of members of the American Society of Clinical Oncology and the International Association for the Study of Lung Cancer revealed that most members agreed that smoking affects cancer outcomes, and that smoking cessation treatment should be a standard part of clinical care.<sup>94,95,210</sup> However, only about one-third of members in each group reported they were adequately trained to provide smoking cessation services to their patients who smoked. A survey of Arkansas clinicians caring for general primary care populations, predominantly Medicaid- and Medicare-covered, found that nearly 75% reported that they had no training in the treatment of tobacco use, as well as very limited knowledge of free treatment programs available in their state.<sup>212</sup> Further, cancer care clinicians could be concerned about smoking cessation medication side effects or their potential interactions with cancer treatments.<sup>207,213</sup> Training efforts should include educating clinicians on

the safety and efficacy of smoking cessation medications for patients with cancer and how to prescribe them.<sup>19</sup>

Perceptions of inadequate knowledge and/or training can stem from uncertainty about the clinician's role in smoking cessation treatment.<sup>203,205</sup> In the United Kingdom, participants in focus groups of radiographers (health professionals delivering radiation therapy for cancer treatment) noted that they did not think smoking cessation was part of their role as it was not part of standard practice, and their departments had no clear policy or process for addressing smoking.<sup>205</sup> One survey of oncologists in Australia found that only 4% of the medical oncologists and none of the radiation oncologists preferred treating patients for tobacco use themselves and instead preferred to refer patients to external services like quitlines, PCPs, or dedicated specialists in their own institutions.<sup>207</sup> These survey results are consistent with qualitative data from interviews with patients with cancer and their clinicians that indicate that cancer care clinicians play a limited role in smoking cessation treatment. Most cancer care clinicians reported that they referred patients to their PCPs for smoking cessation medication prescriptions and other assistance due to feeling unprepared to treat tobacco use themselves or being hesitant to take on the responsibility of long-term follow-up for tobacco use care.<sup>139</sup>

Cancer care settings may vary in their expectations for individual cancer care clinicians, and these expectations should be reflected in health care system policies and processes that clarify clinicians' role in integrating smoking cessation treatment into their patients' care (i.e., whether to provide smoking cessation treatment themselves or to refer patients to other clinicians or treatment-extender programs such as quitlines). The paramount goal is to offer evidence-based smoking cessation treatment that is integrated into patients' cancer care.

Building clinician confidence and competency to address tobacco use is a key component of successfully implementing smoking cessation treatment programs in health care settings, including cancer care. Training programs tested both in primary care<sup>19</sup> and in cancer care settings<sup>214</sup> have significantly improved clinicians' knowledge of smoking cessation treatment and confidence in its provision. Academic detailing-peer-to-peer education, training, technical assistance, and feedback to improve clinical practice in a particular area<sup>215</sup>—has been shown to increase rates of tobacco use assessment and treatment by clinicians and/or clinic staff.<sup>19,216</sup> In one study, 49 primary care outpatient clinics were randomized to a fax-to-quit program only (N =25) or to a fax-to-quit program with academic detailing (N = 24). Over a 13-month period, academic detailing greatly increased the average number of quitline referrals per clinician compared with usual-care fax-to-quit instruction only (8.5 vs. 1.6 referrals).<sup>216</sup> In another study, one peer-to-peer training program was aimed at increasing clinicians' (predominantly radiation therapists and registered nurses) support of patients with cancer in smoking cessation. Clinicians were trained to identify people who currently smoke, provide a basic smoking cessation intervention, and document such interventions for other members of the care team. Of those who completed the post-training survey (30% response rate), most clinicians (88%) agreed that the training had impacted their patients' smoking cessation attempts and many clinicians (67%) reported they had opportunities in their daily practice to use the training to support patients' smoking cessation efforts.<sup>206</sup> Finally, a brief, 1-hour educational program among nurses in several clinical practice settings, including cancer care settings, significantly improved smoking cessation treatment provision, resulting in increased rates of assessment of patients' interest in quitting, assistance with quit attempts, and quitline referrals.<sup>217</sup>

Memorial Sloan Kettering Cancer Center has developed a tobacco treatment training program to increase the competency of cancer care clinicians to intervene with their patients who use tobacco (Tobacco Treatment Training-Oncology [TTT-O]).<sup>214</sup> Since 2017, more than 200 individuals from across the nation have completed the TTT-O training at Memorial Sloan Kettering, which consists of a 2-day workshop followed by 6 monthly, 1-hour collaborative videoconference calls designed to support workshop attendees in implementing NCCN guidelines for smoking cessation in their cancer care settings. The TTT-O workshop training format includes didactic presentations and experiential small group role-play exercises. Enhanced training is likely to play an important role in increasing the reach and effectiveness of smoking cessation treatment services targeting patients with cancer.

In a national survey of Australian oncologists, most of the surveyed oncologists preferred online tobacco cessation skills training, though many also supported face-to-face training in their institutions, training at regional meetings, and via professional society guidelines.<sup>207</sup> Understanding the preferences and logistical constraints facing U.S. oncology clinicians is an important consideration for future tobacco cessation training efforts.

There is growing recognition that increasing access to evidence-based smoking cessation treatment in oncologic practice requires increasing the percentage of the health care workforce that has received sufficient training to effectively intervene with patients who smoke. Certification or accreditation programs can also enhance the quality of training, increase its breadth, and serve as a training quality metric. The Council for Tobacco Treatment Training Programs<sup>218</sup> accredits tobacco treatment training programs. Clinicians who complete one of these programs can receive certification as Certified Tobacco Treatment Specialists (CTTS).<sup>219</sup> Program use has increased markedly, with almost 8,000 clinicians trained from 2016 to 2019.<sup>220</sup> These programs teach clinicians effective counseling skills and core competencies<sup>219</sup> needed to work with tobacco users within health care settings and other settings. Expanding the multidisciplinary cancer care team to include individuals who have obtained tobacco treatment specialist training likely improves the delivery of smoking cessation treatment in cancer care settings. Importantly, a wide array of clinicians can and have obtained CTTS training including health educators, nurses, and other treating clinicians (e.g., physicians, nurse practitioners). Clinicians with advanced tobacco treatment training, compared with those without specialty tobacco treatment training, have been shown to provide treatment of higher fidelity and/or to result in higher quit rates among their patients trying to quit.<sup>86,87,221–225</sup>

### **Clinician Perceptions of Patients With Cancer**

Clinicians' perceptions of their patients with cancer can also influence their provision of smoking cessation treatment. For example, clinicians could perceive their patients with cancer who smoke as unwilling to engage in or unlikely to benefit from smoking cessation treatment.<sup>94,95,208,209,211,226</sup> One survey of oncology clinicians and midlevel clinicians reported the presence of multiple misperceptions of patients that would likely discourage clinicians from intervening with their patients who smoke. The most common responses were that patients were unmotivated, uninterested in quitting, and unwilling to listen to smoking cessation advice. In addition, one-third of clinicians believed that their efforts to help patients quit smoking were never successful, and none believed they were very successful.<sup>211</sup> Similarly, more than 70% of site coordinators at 93 surveyed lung cancer screening (LCS) sites reported patients' lack of

motivation and resistance to smoking cessation advice and treatment as barriers to providing smoking cessation treatment to patients enrolled in screening programs.<sup>208</sup> In contrast, studies of patients with cancer typically report high rates of interest in quitting. For example, Conlon and colleagues<sup>227</sup> reported that more than 85% of patients with head and neck cancer who smoked were interested in quitting and more than 70% were seriously considering quitting smoking within the subsequent 30 days. Meadows-Taylor and colleagues,<sup>228</sup> in a study of patients with thoracic cancer, reported that, among people who currently smoke, 60% were very interested in quitting and 37% would participate in a smoking cessation program.

Clinician perceptions of patients' motivation or readiness to quit can also differ depending on stage of care or treatments. For example, one qualitative study of smoking cessation treatment in the LCS context found that some clinicians believed that referring patients for LCS could increase motivation, whereas others doubted that referral alone would influence smoking behavior. Most agreed that receiving LCS results could be impactful, with many believing that abnormal results could motivate behavior change, while also fearing that normal results could decrease motivation.<sup>185</sup> Some clinicians mentioned that they were especially likely to discuss smoking cessation with people receiving normal LCS results to help them to quit smoking.<sup>185</sup>

Despite believing that key events, such as abnormal LCS results, cancer diagnosis, and cancer treatment initiation can motivate patients, clinicians could still hesitate to encourage smoking cessation at these times because they are concerned about adding to patients' distress.<sup>185,203,229</sup> In the case of LCS, clinicians expressed concern that patients with an abnormal scan might be too overwhelmed by the possibility of a cancer diagnosis to engage in a discussion about smoking cessation.<sup>185</sup> Similarly, radiographers felt the time of diagnosis was a bad time to discuss smoking cessation, citing concerns that patients would be overwhelmed.<sup>205</sup> Clinicians can be especially unwilling to initiate smoking cessation discussions with patients diagnosed with advanced disease, perhaps, due to uncertainty about the usefulness of recommending smoking cessation in this context.<sup>127,203,211</sup>

Clinicians have also expressed concern that smoking cessation treatment discussions could damage their relationships with patients, despite study results reporting that patients who smoke feel that they receive better health care when their clinicians offer to help them quit.<sup>230–233</sup> Some clinicians worry that their patients will feel stigmatized or judged if they are encouraged to quit smoking.<sup>139,203,205,209</sup> In qualitative interviews with clinicians treating patients with cancer, many expressed concerns that addressing smoking around the time of diagnosis could induce feelings of guilt in their patients, adding to their distress in an already overwhelming and difficult time. Rather than risk appearing judgmental to their patients, many avoided the topic unless patients brought it up themselves or clearly indicated they were open to quitting smoking.<sup>203</sup>

In response to staff members' reluctance to approach smoking cessation treatment with patients, Cancer Care Ontario introduced an opt-out approach wherein patients who smoke were automatically referred to an available smoking cessation treatment.<sup>127,128</sup> This approach resulted in improved referral rates, suggesting that integrating an opt-out approach into smoking cessation treatment for cancer care can help clinicians overcome concerns about if, how, or when to initiate it. In addition, multiple C3I sites in the United States have implemented similar opt-out approaches.<sup>18,84,125,128,150</sup> It is worth noting that concerns about adding to patients' feelings of stigma and distress can be well-founded, as patients have described these feelings themselves.

Providing support and treatments that address patients' feelings of cancer-related stress could be warranted to optimize patient outcomes.<sup>86,87,223</sup> These data suggest a need for additional training and research to support appropriate, empathetic, and equitable communication about smoking cessation treatment and stress management in the cancer context rather than avoiding the topic.

#### Summary: Clinician-Level Barriers

Building capacity for expanding smoking cessation treatment delivery within cancer care settings should include addressing cancer care clinicians' concerns about lack of training to accomplish these goals. Academic detailing is one promising strategy to train clinicians; provide performance feedback; and promote the use of treatment extenders, such as eReferral to state quitlines during cancer care visits. Implementing opt-out programs also has the potential to increase rates of smoking cessation treatment delivery and to normalize the delivery of smoking cessation treatment in cancer care settings. Finally, educating clinicians about the safety and efficacy of smoking cessation treatment options, including medications, is essential and can be reinforced by clinician champions.

# Health Care System–Level Barriers to Delivering Smoking Cessation Treatment in Cancer Care Settings

Since health care system institutional changes were first recognized as essential for smoking cessation treatment delivery more than two decades ago,<sup>234</sup> there has been substantial progress in refining and advancing such changes at multiple levels (clinician practice, informatics, hospital policies). However, many barriers remain within health care and health insurance reimbursement systems broadly that can hinder the systematic delivery of smoking cessation treatment in cancer care settings.

#### Institutional Commitment and Accountability

A 2009 NCI conference on treating nicotine dependence at NCI-Designated Cancer Centers identified barriers and challenges at the clinician, health care system, institutional, policy, and research levels.<sup>154</sup> At that time, a key institutional barrier was the failure of cancer care settings to recognize smoking cessation treatment as a core component of cancer care. A subsequent survey conducted in the same year was the first to document tobacco cessation treatment services offered by NCI-Designated Cancer Centers.<sup>92</sup> Among the 58 centers, 12 (21%) reported no tobacco cessation services or were unsure whether there were cessation services, and only 48% reported having designated personnel to deliver or coordinate tobacco cessation treatment delivery (in contrast, 78% reported having a designated nutritionist). Slightly more than one-half (62%) of these centers reported identification of tobacco use in the outpatient and inpatient settings. Finally, only 28% reported that they had selected tobacco use as a quality improvement metric.

The participants in the 2009 conference made four key recommendations for NCI-Designated Cancer Centers<sup>92</sup>:

- 1. All cancer centers who treat patients should have a tobacco use treatment program.
- 2. NCI should facilitate the incorporation of tobacco use treatment services into cancer center clinical care.

- 3. All cancer centers should adopt quality improvement measures and other opportunities to enhance the delivery of tobacco use treatment services.
- 4. Institutional funding should support tobacco use treatment services in these cancer centers.

Achieving these four milestones would position NCI-Designated Cancer Centers to lead by example in delivering evidence-based tobacco cessation treatment that is fully integrated with cancer care.

A 2014 National Academy of Medicine (formerly the Institute of Medicine) workshop entitled "Reducing Tobacco-Related Cancer Incidence and Mortality" suggested that tobacco cessation treatment would be rapidly implemented if this was a requirement for accreditation by the Commission on Cancer or other accrediting bodies, or for receiving designation as a cancer center by the NCI.<sup>235</sup> However, this landscape has changed substantially over the past decade, including efforts by NCI designed to heighten awareness of the importance of tobacco cessation treatment in cancer centers. For example, C3I encourages a population-based approach to increase the reach and effectiveness of tobacco cessation treatment delivery within and beyond cancer centers.<sup>8</sup> While C3I was a competitive supplement limited to NCI-Designated Cancer Centers, the initiative has made its data and resources available to all cancer centers to help accelerate availability and uptake of cessation services for patients with cancer.

### Limitations of Clinician Time and Referral Options

Even when oncology clinicians are trained in smoking cessation and health care systems recognize its value, smoking cessation treatment may not be prioritized amid other vital components of patients' cancer care. A variety of constraints inhibit health care systems' emphasis on providing smoking cessation treatment.<sup>9,91,94,95,185,226</sup> Oncology clinicians are typically overburdened, and express concern about increasing their workload with smoking cessation.<sup>127,128</sup> Nearly one-half of oncology clinicians report having limited time available during patient visits for counseling or making referrals.<sup>94,95,210</sup> As a result, health care systems report that smoking cessation treatment is a lower priority.<sup>211</sup> Indeed, oncology clinical workflows offer health care systems little opportunity to integrate smoking cessation treatment into clinical care. For example, results of LCS are often delivered through written messages or voicemail, leaving health care system staff without a natural opening for a discussion of smoking cessation.<sup>185</sup>

Several systems-level resources can help enable clinicians to provide smoking cessation treatment. Communication regarding such resources is essential given that over a third of surveyed oncology clinicians reported that they did not know where to refer patients for smoking cessation assistance.<sup>211</sup> Moreover, dedicated smoking cessation staff can facilitate treatment and relieve some of the burden on oncology clinicians and advanced practice clinicians.<sup>92,185,236</sup> Having referral systems well-integrated into the EHR can facilitate connections to available smoking cessation treatment resources both internal and external to the health care system.<sup>9,80</sup> Easy-to-use EHR functionalities can facilitate smoking cessation treatment in other ways as well. For example, direct-entry mandatory EHR fields, often completed by rooming staff, can facilitate documentation of smoking status and prompt treatment delivery to either an internal (e.g.,

oncology clinic-based tobacco treatment specialist) or external (e.g., state tobacco quitline) smoking cessation resource.<sup>9,18,57,125,127,150,237</sup>

At the Siteman Cancer Center of the Washington University School of Medicine, the Electronic Health Record-Enabled Evidence-Based Smoking Cessation Treatment Program was designed as part of NCI's C3I to facilitate tobacco cessation treatment at the point of cancer care, rather than relying on referral to specialists or dedicated treatment programs.<sup>125</sup> After its implementation, tobacco use assessment of patients with cancer increased from 48% to 90%, and the percentage of people with cancer who smoke who were prescribed smoking cessation medication increased from 3% to 17%.<sup>125</sup> These results support the potential of highly functional EHR systems to increase reach and help sustain smoking cessation treatment programs in cancer care settings via improved implementation support for cancer care staff and clinicians. Importantly, such systems-based approaches are most effective when they do not disrupt the clinical workflow.<sup>125</sup>

Support from health care system leaders is critical to obtaining and sustaining the resources and infrastructure necessary for smoking cessation treatment programs' success in the cancer context.<sup>92,127–129</sup> The importance of such senior support was highlighted by the previously mentioned 2009 survey of key staff of 58 NCI-Designated Cancer Centers that found that fewer than one-half believed their center's leadership was committed to smoking cessation treatment.<sup>92</sup> The 2009 survey also identified additional factors that respondents perceived as likely to improve smoking cessation treatment in their centers, including stable funding, tobacco treatment specialists on staff, adequate space, additional staff training, a clinician champion, technical assistance for system enhancements, links to available resources, and support from their administrations.<sup>92</sup>

Interviews with smoking cessation staff in cancer centers also suggested that a lack of strong health care system commitment to smoking cessation services hindered their ability to provide effective smoking cessation treatment, and several staff suggested that leadership support would enhance the integration of smoking cessation treatment services into routine cancer care.<sup>203</sup> The importance of tobacco cessation program leadership was highlighted in a C3I program evaluation that found the identification of tobacco cessation program champions who take ownership of initiatives designed to develop, train, and implement tobacco intervention services in clinical settings was associated with enhanced tobacco cessation treatment program delivery.<sup>18</sup> Such champions may be opinion leaders or influencers within institutions who are committed to developing and sustaining tobacco cessation treatment programs. These individuals should be identified and included in implementation plans to facilitate broad staff engagement and to help lead training efforts.<sup>92,128</sup>

#### Funding and Reimbursement for Smoking Cessation Treatment Programs

Financial considerations also affect smoking cessation treatment delivery at the clinician and health care system levels.<sup>1</sup> Specifically, stable funding for smoking cessation treatment programs within cancer centers facilitates their ability to deliver smoking cessation treatment consistently as part of cancer care. More than 80% of key staff at 58 surveyed NCI-Designated Cancer Centers believed that stable tobacco cessation treatment program funding was likely to improve tobacco cessation treatment delivery in their centers.<sup>92</sup> Options for tobacco treatment specialists to bill payers for their efforts could also increase these programs' sustainability.<sup>92</sup>

In addition, billing and reimbursement options for clinicians can further facilitate smoking cessation treatment at the point of care.<sup>208</sup> However, only 10% of outpatient oncology clinicians surveyed reported that reimbursement was a barrier to them giving smoking cessation advice.<sup>211</sup> In contrast, in a survey of members of the International Association for the Study of Lung Cancer (including members in the United States), 32% reported that reimbursement was a barrier to providing smoking cessation care, care that is typically more intensive than brief smoking cessation advice.<sup>94,95,210</sup>

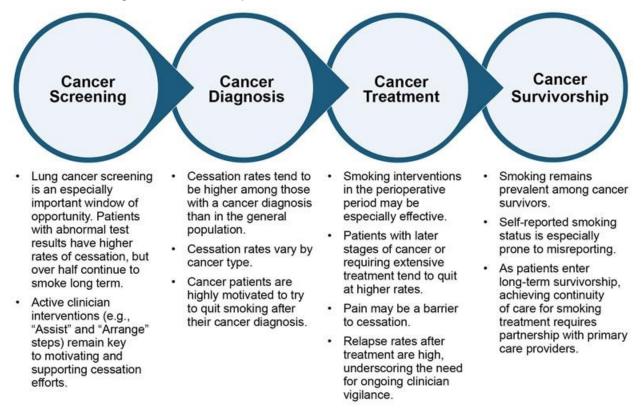
#### Summary: Health Care System–Level Barriers

While health care systems offer unequaled opportunities to systematically address smoking in patients with cancer, this potential requires an institutional approach to maximize success. Multiple health care systems-level barriers constrain effective smoking cessation treatment delivery, including a lack of support and accountability of the smoking cessation treatment program by health care system leaders or champions; competing demands for clinician time; lack of training of clinicians; a perceived lack of referral options; a failure to embed the intervention into clinical workflows; inadequate leveraging of health information technologies including the EHR; inadequate leveraging of tobacco-relevant quality metrics, payment models, and regulatory policies by accrediting agencies, governmental agencies, payers, and professional societies; and inadequate funding for smoking cessation treatment programs and reimbursement for clinicians. Addressing these barriers would likely facilitate the effective integration of smoking cessation treatment into cancer care. A key first institutional step is to expand the health care system's standard of care such that every patient with cancer who smokes can expect to receive evidencebased smoking cessation treatment as part of his or her cancer care. This foundation can help ensure that health care systems provide opportunities to quit tobacco use to all such patients with cancer who smoke and visit cancer care settings.

# A Systems Approach to Providing Smoking Cessation Treatment Across the Cancer Care Continuum

The cancer care continuum is a useful framework to understand the stages at which smoking cessation treatment can be particularly effective. This continuum spans cancer prevention, screening, diagnosis, treatment, survivorship, and end-of-life care, and can be thought of as a circular process rather than a linear one with cancer survivors engaged in cancer prevention. This chapter focuses more narrowly on cancer screening, diagnosis, treatment, and survivorship as phases that represent times when the patient can be especially receptive to smoking cessation treatment (Figure 4.3). Moreover, these moments can be integrated into health care system changes that increase the likelihood that individuals who smoke will receive evidence-based smoking cessation treatments. Some of these cancer continuum stages could be better suited for smoking cessation than others (e.g., smoking cessation rates might be higher at the time of new cancer diagnosis).<sup>6,185,238–241</sup> While intervention to promote smoking cessation is important across the cancer care continuum, specific challenges at each stage may require adaptation of smoking cessation treatment strategies. The following section highlights characteristics of patients, diagnoses, and treatments that can guide health care systems in maximizing the reach and effectiveness of their smoking cessation treatment programs from screening through longterm survivorship.

## Figure 4.3 Smoking Cessation Treatment Across the Cancer Care Continuum, From Screening to Long-Term Survivorship



Note: Intervention to promote smoking cessation is critical across the cancer care continuum. Cancer screening, diagnosis, treatment, and survivorship are all candidate stages for teachable moments that hold the potential for positive behavior change. Specific challenges to smoking cessation treatment implementation may vary by stage.

#### **Smoking Cessation Treatment at Cancer Screening**

Individuals with a history of cigarette smoking are at increased risk for developing a range of malignancies,<sup>2,149</sup> including those of the aerodigestive tract (e.g., lung, throat, and oral cancers). This increased risk creates the potential for early detection strategies that target individuals at increased risk for cancer who are likely to benefit from screening and early detection.<sup>242</sup> This section focuses on LCS via low-dose computed tomography (LDCT), which represents an important opportunity to offer people who smoke assistance to quit with evidence-based strategies. Health care systems can also integrate addressing tobacco use into other cancer screenings, including mammography and colorectal cancer screening.

Findings from the National Lung Screening Trial (NLST) offered the first substantial evidence for the utility of LDCT to reduce lung cancer mortality.<sup>243</sup> In 2001, Ostroff and colleagues used data from the Early Lung Cancer Action Project (ELCAP) trial<sup>244</sup> to examine the association between LDCT screening and smoking status.<sup>245</sup> Based on self-report, nearly a quarter of participants reported smoking cessation following screening, while another quarter reduced their smoking rate. These promising observational data suggested that LDCT LCS is a teachable moment<sup>6,246</sup> to engage individuals who smoke in evidence-based smoking cessation treatment strategies.

#### Eligibility, Guidelines, and Policy for Lung Cancer Screening (LCS)

Following publication of results from the NLST, several organizations provided guidance for LCS implementation. The USPSTF and CMS<sup>247</sup> upgraded LCS using LDCT to a grade B recommendation, making it a covered insurance benefit in the United States under the ACA.<sup>248</sup> LDCT screening guidelines include a strong recommendation for pairing it with evidence-based smoking cessation treatment. During shared decision-making visits to discuss the need for LCS, CMS requires that patients receive counseling on the importance of smoking cessation and abstinence and information about smoking cessation interventions. As of 2015, CMS also requires that radiology imaging facilities make smoking cessation treatment available to people who currently smoke.<sup>248</sup>

#### Impact of LCS on Smoking

Ostroff and colleagues<sup>245</sup> found that nearly one-half of all participants tried to modify their smoking behavior following participation in the ELCAP program, which offered no formal smoking cessation treatment. Data from subsequent studies have shown more modest and varied associations between LCS and changes in smoking.<sup>240,246,249–259</sup>

Ostroff and colleagues<sup>245</sup> also noted the possibility that normal/clear/negative LCS results could incorrectly communicate an invulnerability to the consequences of smoking and might result in individuals continuing to smoke or former smokers to relapse.

Slatore and colleagues<sup>254</sup> conducted a systematic review of LCS trials that reported smoking behavior change outcomes. In contrast with previous studies, this systematic review found little evidence that supported an overall impact of screening program participation on smoking behavior. However, receiving abnormal or suspicious results was associated with increased abstinence. Consistent with results from the NLST, both the number and suspiciousness of abnormal results contributed to an increased likelihood of smoking reduction or cessation.<sup>254</sup> These findings underscore the complexity of risk perceptions and the potential impact of risk perception biases on quit attempts.<sup>179</sup>

#### Enhancing Smoking Cessation Treatment Reach and Effectiveness in the Context of LCS

While LCS can be a "teachable moment,"<sup>260</sup> little is known about how to most efficiently and effectively engage individuals in smoking cessation treatment in the LCS context or process. Extant evidence suggests that the most effective methods could involve clinician interventions that directly facilitate smoking cessation treatment entry. Park and colleagues<sup>261</sup> found that smoking cessation rates among NLST participants were meaningfully higher when PCPs delivered the "Assist" and "Arrange" components of the 5A's after LCS, whereas "Ask, Advise, and Assess" did not significantly influence smoking cessation rates.

It is important to note that early LCS trials tended to test the efficacy of screening combined with only minimal smoking cessation treatment (e.g., brochures).<sup>256</sup> It is certainly possible that higher smoking cessation rates might be observed if more intensive treatment was used. Unfortunately, most published studies in this area have significant limitations. Some have evaluated minimal smoking cessation interventions,<sup>249,259</sup> others had small sample sizes,<sup>241,251,252</sup> and others used nonexperimental designs.<sup>261–263</sup>

More recently, additional efforts have been made to identify effective smoking cessation treatments for this population. For example, the Smoking Cessation at Lung Examination (SCALE) Collaboration comprises seven NCI-funded and one VA-funded clinical trials of smoking cessation interventions for LDCT participants designed to test various smoking cessation interventions in the screening context.<sup>264,265</sup> This work could reveal intervention approaches that are especially effective in the provision of LCS.

Importantly, in 2021, the USPSTF issued an updated recommendation on screening for lung cancer that expanded the eligible age range from 55 to 80 years old to 50 to 80 years old and decreased the required smoking history from 30 pack years to 20 pack years. This expands the eligible pool of patients by about 50%<sup>117</sup> relative to the previous USPSTF recommendations and these changes are expected to expand screening access, especially among women and racial and ethnic minority groups.<sup>247,266</sup> In 2022, CMS issued a national coverage determination that provides Medicare coverage for LDCT screening for patients ages 50 to 77 years old with smoking history of at least 20 pack years.<sup>267</sup>

Incorporating cessation into LCS has high potential benefit. Using the Cancer Intervention and Surveillance Modeling Network (CISNET) and the 2021 USPSTF recommended eligibility, Meza and colleagues<sup>268</sup> demonstrated that smoking cessation with LDCT screening would substantially reduce lung cancer deaths and increase life-years. For example, adding a cessation intervention of modest effectiveness (15%) to LDCT screening results in life-year gains that are comparable to increasing screening uptake from 30% to 100%. Based on these results, the authors concluded that "incorporating cessation programs into screening practice should be a priority as it can maximize overall benefits."

There are fundamental differences that distinguish the cancer screening context from traditional smoking cessation treatment contexts.<sup>269</sup> First, the patients are older than the general population of individuals who smoke. Second, many of those screened are not seeking and may not even be expecting smoking cessation treatment interventions. Third, as required by the eligibility criteria for screening, this group has, on average, a longer history of smoking and greater nicotine dependence. These characteristics may require a different treatment approach, perhaps one that emphasizes chronic care and motivational interventions.

While data regarding the effectiveness of smoking cessation treatments offered in the context of LCS remain limited and mixed, the Association for the Treatment of Tobacco Use and Dependence (ATTUD) and the Society for Research on Nicotine and Tobacco (SRNT) have recommended the integration of smoking cessation treatment into LCS.<sup>270</sup> Table 4.4 highlights the six key recommendations. This guidance is informed by evidence from multiple care settings and populations<sup>19</sup> and provides initial recommendations on smoking cessation treatment in the LCS context.<sup>270</sup>

# Table 4.4Guidance from the Association for the Treatment of Tobacco Use and Dependence<br/>(ATTUD)/the Society for Research on Nicotine and Tobacco (SRNT) Regarding Smoking<br/>Cessation Treatment and Smoking Cessation Within Lung Cancer Screening Programs

- Screening program participants who smoke should be encouraged to quit at each visit, regardless of lung cancer screening results.
- Screening program participants who smoke should be assisted with cessation using evidence-based interventions that combine pharmacotherapy and behavioral intervention as outlined in the PHS Clinical Practice Guideline, *Treating Tobacco Use and Dependence: 2008 Update.*<sup>19</sup>
- 3) Screening program participants who smoke should receive follow-up contacts (from the referring clinician or the screening program) to support their smoking cessation efforts.
- 4) For screening program participants who smoke but are not motivated to quit or are not interested in evidence-based interventions, behavioral interventions like the 5R's model<sup>a</sup> are recommended at each visit to motivate patients to change their smoking.
- 5) Screening programs are encouraged to generate data regarding the optimal intensity, delivery platforms, and overall approaches to guide future efforts.
- 6) Screening programs are also encouraged to generate data regarding the potential adverse effects of screening on smoking cessation interventions within lung cancer screening programs as well as the barriers to optimal implementation and outcomes.

Note: PHS = Public Health Service.

<sup>a</sup>5R's model: The clinician should engage the patient in a discussion of the personal *relevance* of smoking cessation, the *risks* of smoking, the potential *rewards* of smoking cessation, and the potential *roadblocks* to quitting (and treatment to address these, if relevant). The fifth step is to *repeat* these steps at subsequent visits.

Source: Fucito et al. 2016.270

#### **Cancer Diagnosis**

The evidence demonstrates that a cancer diagnosis can increase smoking cessation rates, perhaps by motivating quit attempts. A large U.S. prospective cohort study found that 2-year unaided quit rates were higher among people who were diagnosed with cancer compared with those who were not (31.3% vs. 19.5%), with similar differences also observed at the 4-year follow-up point.<sup>271</sup> An observational study of the tobacco cessation treatment program at MD Anderson Cancer Center that included 2.652 people with a cancer history and 593 without a cancer history found that abstinence rates did not differ between groups.<sup>87</sup> In this study, participants without a cancer history included a substantial number of cancer center employees and patients who were being screened for cancer. Thus, they could have been more motivated to quit smoking than members of the general population (see "Smoking Cessation Treatment at Cancer Screening"). Further, participants with a cancer diagnosis had a history of having smoked more cigarettes over a longer time and demonstrated higher nicotine dependence than those without a cancer diagnosis, factors that can hinder smoking cessation success.<sup>188,202</sup> One review suggested that smoking cessation treatment within 3 months of diagnosis yields higher smoking cessation rates than those occurring more than 3 months after diagnosis,<sup>201</sup> underscoring the importance of timely smoking cessation treatment, ideally at or soon after a cancer diagnosis and the initiation of cancer care.188,201

Park and colleagues<sup>86</sup> compared the effects of sustained smoking cessation counseling and provision of medication ("intense treatment") versus shorter-term counseling and medication advice ("standard treatment") on smoking abstinence rates among patients recently diagnosed

with cancer in two NCI-Designated Cancer Centers. These authors observed a statistically significantly higher biochemically confirmed 6-month quit rate among those in the intensive treatment group (34.5%) versus those in the standard treatment group (21.5%). This study demonstrated that integrating evidence-based, sustained tobacco cessation treatment into the care of newly diagnosed patients with cancer can be effective. Overall, these data highlight the potential of a cancer diagnosis to motivate smoking cessation, across a range of cancer types and stages, though more research is needed to understand how to most effectively leverage this teachable moment.

#### **Cancer Treatment**

The initiation of cancer treatment is another opportunity to offer and provide smoking cessation treatment. An analysis of a large, nationally representative longitudinal sample suggested that having major surgery was associated with a doubling of the chances of quitting for a person who smokes, with higher quit rates observed when surgeries were performed to treat diseases caused by tobacco, including cancer, versus diseases not caused by tobacco.<sup>272</sup> While a systematic review and meta-analysis of 10 RCTs and 3 prospective cohort studies found smoking cessation treatment did not significantly increase smoking cessation rates overall in cancer populations, interventions delivered in the perioperative setting were associated with more than a doubling of the odds of smoking cessation compared with those delivered in other settings (e.g., clinic, postoperative).<sup>273</sup> On the other hand, prospective studies following patients in the months following surgery for lung cancer find high rates of relapse, especially among people who quit smoking shortly before their surgeries.<sup>165,274</sup> In 2020, the Society for Perioperative Assessment and Quality Improvement released a Consensus Statement on Perioperative Smoking Cessation based on studies of people who smoke across multiple clinical settings endorsing the delivery of smoking cessation treatment in the perioperative setting.<sup>275</sup> Together, these data suggest that initiation of cancer surgical treatment could be especially conducive to tobacco cessation. However, additional efforts to arrange smoking cessation treatment follow-up post-surgery could be needed to assist people who were able to quit to avoid relapse.

#### **Smoking Cessation Treatment for Patients With Advanced Cancer**

Patients with cancer who are terminally ill or who have been diagnosed with advanced cancer (i.e., cancer that is unlikely to be controlled with treatment) represent a special population regarding smoking cessation treatment. These patients could be receiving cancer treatment to slow the progression of their disease or could be receiving palliative care to relieve symptoms related to their diagnosis. There has been little research on smoking cessation treatment among patients with cancer with terminal illness or advanced disease. However, oncologists' and other clinicians' attitudes toward advising patients with cancer who are receiving curative or palliative care to quit smoking were examined in a study conducted in 16 European countries.<sup>276</sup> An invitation sent to 6,235 members of European medical or clinical oncology societies gleaned 544 eligible responses (response rate = 8.7%). For patients with cancer in palliative settings, 74% of respondents agreed that tobacco use negatively affects treatment outcomes, and 63% of those agreed that smoking cessation should be standard treatment in this setting. Only 14% responded that smoking cessation after diagnosis was a waste of time. However, 43% of oncologists reported "not feeling comfortable taking something away patients enjoy doing" when they are receiving palliative care.<sup>276</sup>

Patients with advanced cancer who quit smoking may experience benefits that include improved oxygenation, lower blood pressure, improved blood circulation and respiration, improved appetite, and less fatigue.<sup>277</sup> However, these benefits can be modest, leading Leventakos and colleagues<sup>277</sup> to conclude that, before advising smoking cessation in patients with advanced cancer, clinicians should consider both the potential negative emotional consequences of this effort, including frustration caused by unsuccessful quit attempts, and patients' personal preferences and goals of care. Although the limited available evidence suggests that smoking cessation could provide short-term physical benefits to patients with a diagnosis of advanced cancer, these benefits could also be outweighed by the potential negative effects of cessation on patients' quality of life. Decisions about smoking cessation treatment for patients with terminal cancer should thus be made on an individual basis, based on discussions between the clinician and the patient, and considering the appropriate goals of care for the patient. For those patients wanting to quit, clinicians should link them to evidence-based treatment. Additional research can focus on how clinicians can best engage in these types of discussions or tailor the approach to smoking cessation treatment for individuals with advanced cancer and limited life expectancy.

#### Post-Treatment and Long-Term Survivorship

A longitudinal study of adult survivors of childhood cancer (mean age = 28 years) found that 19% smoked at baseline, and that smoking rates remained high (14%) over several years of follow-up.<sup>278</sup> While data regarding the persistence of smoking among adult survivors of childhood cancer are limited, these rates reflect a need for more effective smoking cessation treatment in this population. An RCT of a peer-to-peer phone counseling intervention among childhood cancer survivors indicated higher long-term self-reported quit rates among those who had been assigned a peer counselor, compared with those who had received only self-help materials consisting of the "Clearing the Air" manual and a letter from the study physicians about the importance of quitting smoking (quit rates were 20.6% vs. 17.6%, respectively; p < .0003).<sup>279</sup>

However, other evidence suggests that achieving cessation and maintaining quitting success for cancer survivors can be challenging. In 2 prospective trials of quitline interventions for adult survivors of childhood cancer, self-reported smoking cessation rates at 12 months were comparable to rates observed in other smoking cessation trials (i.e., 19%–26%).<sup>280</sup> However, biochemically verified abstinence rates at 12-month follow-up were less than 2% among adult survivors of childhood cancer and less than 5% among adult-onset cancer survivors, indicating that nearly 50% of adult-onset cancer survivors and more than 80% of childhood cancer survivors misreported their smoking status.<sup>280</sup> These results strongly suggest that self-reported smoking status among cancer survivors is prone to misreporting.<sup>281</sup>

Thus, there is mixed evidence regarding the effectiveness of smoking cessation treatment among individuals after they have received cancer treatment. Some have suggested that higher quit rates might be achieved with the use of guideline-recommended treatment, such as the use of both pharmacotherapy and behavioral support.<sup>273,282</sup> In addition, interventions can be made more effective if tailored to the individual's readiness to quit smoking and if intensive treatments are paired with sustained follow-up.<sup>282</sup>

#### Summary: Cessation Across the Cancer Care Continuum

Evidence supports a need for smoking cessation treatment across the cancer care continuum from screening to cancer care to cancer survivorship. Importantly, such interventions can be particularly effective when initiated as early as possible after a cancer diagnosis. Systems that integrate smoking cessation treatment into perioperative workflows hold promise for helping people who smoke quit, although relapse risk remains a concern postoperatively. Finally, as patients with cancer enter the post-treatment phase, continuity of care for smoking cessation treatment can be facilitated through communication between cancer clinicians and those who care for the patient after their cancer care, including primary care clinicians.

# The Economic Rationale for Implementing Smoking Cessation Treatment in Cancer Care

The financial burden of cancer care on the patient is considerable; in 2019, this cost for U.S. patients was estimated to be more than \$21 billion.<sup>283</sup> The annual direct medical care costs for illnesses caused by smoking among adults in the United States, including cancer, were estimated to be more than \$225 billion<sup>284</sup> in 2014. The average annual value of lost productivity due to early mortality from cigarette smoking among adults ages 35–79 years old in the United States was estimated at approximately \$150.7 billion for the period of 2005–2009.<sup>2</sup> The substantial costs of smoking, the economic impact, and the cost-effectiveness of smoking cessation treatment have been investigated for decades.<sup>285</sup> However, only recently has research focused on the economic effects of smoking and on the economics of smoking cessation treatment among individuals with cancer.

#### Incremental Costs Associated With a Smoking History Among Patients With Cancer

Warren and colleagues<sup>286</sup> modeled the incremental cost of additional cancer treatment or retreatment required because of patients' smoking in the United States. The model was developed in 2018 using data from the 2014 Surgeon General's report and considered smoking prevalence in patients with cancer, likelihood of first-line cancer treatment failure attributed to smoking compared with nonsmoking, and cost of cancer treatment after failure of first-line cancer treatment. The model did not incorporate costs associated with noncancer comorbid disease management, end-of-life care, and complications associated with cancer treatment. Assuming a 20% smoking prevalence, a 60% increased risk of treatment failure attributed to smoking, and \$100,000 mean added cost per cancer treatment failure, the analysis estimated an additional \$10,678 in average costs per patient with cancer who smokes. The authors extrapolated this finding to 1.6 million patients with cancer each year to project a potential \$3.4 billion incremental cost of treating cancer failures associated with continued smoking among patients with cancer in the United States each year.<sup>286</sup>

In another study, Isaranuwatchai and colleagues<sup>287</sup> investigated the impact of smoking on health care system costs among patients with cancer using administrative data from a population-based cohort in Ontario, Canada, between 2014 and 2016. The health services incorporated into the analysis were hospitalizations, emergency room visits, drugs, home care services, and physician services. Patients who smoked (defined as patients who smoked at the time of diagnosis or who had smoked in the past 6 months prior to their first ambulatory care visit) were more likely to have advanced cancer stages than nonsmokers. Overall, the unadjusted estimated total monthly

health care costs were almost 20% higher in people who smoked (2016 CAN\$5,649) compared with nonsmokers (2016 CAN\$4,704). From the adjusted regression model estimates controlling for age, sex, income, rurality, stage, cancer site, geographical region, and comorbidity, people who smoked still had significantly higher monthly health care costs (2016 CAN\$5,091) than nonsmokers (2016 CAN\$4,847).

Similarly, Salloum and colleagues<sup>130</sup> evaluated the costs of implementing tobacco cessation treatment programs in 15 cancer centers funded by NCI's C3I between 2018 and 2020. The study calculated the total operating costs for each center within a 6-month period, expressed in local market terms, and taking the perspective of the health care system. The study focused on operating costs to maintain the program after it was developed, as they are most relevant to decision-makers. These costs included program personnel type (e.g., oncologists vs. nurses) and effort (with fringe benefits estimated at 30% of total salary costs), medications covered by the program, educational and training materials, software and technology services, equipment, and office space. Median total monthly operating costs in 2020 were \$11,045 (range: \$5,129–\$20,751), dominated by personnel costs. Median cost-per-participant was \$466 (range: \$70–\$2,093) and cost-per-quit was \$2,688 (range: \$330–\$9,628), with sites offering different combinations of program components.

Kaul and colleagues<sup>288</sup> examined annual health care utilization and expenditures among adult cancer survivors in the 2010–2014 Medical Expenditures Panel Survey. Cancer survivors who were currently smoking, compared with nonsmokers, had significantly fewer office-based/outpatient visits (marginal effect = -3.44, 95% CI = -5.02 to -1.86), significantly more emergency department visits (marginal effect = 0.11, 95% CI = 0.05-0.18), but no significant difference in total health care expenditures.<sup>288</sup>

In addition to studies that estimated health care utilization and costs broadly among all patients with cancer, other economic studies have been limited in scope to the cost of treating patients with a specific cancer site diagnosis. Murphy and colleagues<sup>289</sup> examined pretreatment predictors of total cost and length of stay among patients with locally advanced esophageal adenocarcinoma who underwent esophagectomy between 2002 and 2008. While they did not separate current smoking from former smoking in their cohort, the researchers found that number of pack years smoked was significantly associated with increased inpatient cost of esophagectomy ( $\beta = 0.0022$ , p = .028). Sari and colleagues<sup>290</sup> evaluated the effects of smoking on the cost of hospitalization and length of stay among patients with lung cancer in Iran between 2014 and 2015. Compared with never-smokers, current and former smokers in this study showed a 48% and 35% increase (p = .0001) in hospitalization costs, respectively.

Two studies using 2007–2014 U.S. Department of Defense (TRICARE) administrative claims data examined the association of tobacco use with medical care costs among head and neck cancer survivors.<sup>291,292</sup> Both studies found that patients with a history of tobacco use had significantly increased medical care costs. Tobacco use was associated with an increased number of ambulatory visits, but no significant change in number of hospitalizations.<sup>291,292</sup>

#### **Cost-Effectiveness of Smoking Cessation Treatment for Individuals With Cancer**

To assess the utility of smoking cessation treatment from an economic standpoint among people with cancer who continue to smoke, it is vital to conduct appropriate cost-benefit analyses. Smoking can lead to increases in direct health care costs (e.g., hospitalization costs), direct non-health care costs (e.g., transportation and caregiving costs), and indirect costs (e.g., lost productivity due to illness).<sup>2,293</sup> With the mounting evidence on the health benefits of quitting smoking after a cancer diagnosis, economic evaluations have begun to determine increased cancer medical care utilization rates and treatment costs for patients who continue to smoke compared with those who do not currently smoke. This section examines information from published studies on economic outcomes associated with smoking among individuals diagnosed with cancer and the integration of smoking cessation treatment into cancer care.

Smoking cessation treatment provides substantial economic benefits at both the individual and population levels, and tobacco cessation interventions are cost-effective compared with many other disease prevention interventions.<sup>285</sup> Cost-effectiveness is a form of economic analysis used to compare the change in costs between two scenarios (either two different interventions or between an intervention and "doing nothing") relative to the change in health outcomes between the two scenarios. Cost-effectiveness of smoking cessation has been measured using several different health outcomes, including cost per stop (quit rate), cost per life-year gained, and cost per quality-adjusted-life-year (QALY) saved.<sup>1</sup> Estimates of the incremental cost-effectiveness of smoking cessation treatment have ranged across settings from several hundred to several thousand dollars per life-year or QALY saved and have varied according to the age group quitting smoking, the economic perspective employed, the smoking cessation treatment type, and the baseline (control) intervention used for comparison.<sup>1</sup> The 2020 Surgeon General's report concluded that smoking cessation interventions are cost-effective.<sup>1</sup> However, this report did not examine the economic impacts of smoking cessation treatment among individuals diagnosed with cancer.

One of the first published studies to evaluate the cost-effectiveness of smoking cessation treatment in cancer treatment was a model by Slatore and colleagues<sup>294</sup> examining the implementation of a smoking cessation treatment program at the time of surgery for lung cancer. Initiating a smoking cessation treatment program before surgical lung resection was found to be cost-effective (compared with usual care that omitted offer of a smoking cessation treatment program) at both 1 year and 5 years post-surgery. The incremental cost per QALY and cost per life-year were \$16,415 and \$45,629 at 1 year post-surgery and \$2,609 and \$2,703 at 5 years postsurgery, respectively. Djalalov and colleagues<sup>295</sup> conducted an economic evaluation of smoking cessation programs in the regional cancer programs of the Canadian province of Ontario. The study modeled the potential cost-effectiveness of two smoking cessation treatment approaches: the current-practice smoking cessation treatment program established in 2012 consisting of screening for tobacco use, advice, and referral,<sup>128</sup> and a best-practice smoking cessation treatment program that included the current basic program with the addition of pharmacological therapy, counseling, and follow-up. For the modeled population (people with cancer who smoke), the best-practice smoking cessation treatment program was both more effective and more costly than the basic smoking cessation treatment program. The incremental costeffectiveness ratio of the best-practice smoking cessation treatment program compared with the basic smoking cessation treatment program (in 2015 dollars) was CAN\$3,367 per QALY gained

and CAN\$5,050 per life-year gained for men, and CAN\$2,050 per QALY gained and CAN\$4,100 per life-year gained for women—suggesting that a best-practice smoking cessation treatment program could be a highly cost-effective option.<sup>295</sup>

In addition to studies examining the cost-effectiveness of smoking cessation treatment within the context of active cancer treatment, there has been at least one economic evaluation of smoking cessation treatment in cancer survivorship. Emmons and colleagues<sup>296</sup> tested a smoking cessation treatment intervention consisting of peer-delivered counseling for people who smoke in the Childhood Cancer Survivors Study. Participants (mean age = 31 years) were randomly assigned to either a self-help or a peer-counseling program that included up to 6 telephone calls from a trained adult survivor of childhood cancer, tailored and targeted materials, and free NRT. The smoking cessation rate at 12 months was significantly higher in the counseling program (15%) compared with self-help (9%), and the cost of delivering the peer-counseling intervention was approximately \$300 per participant. The incremental cost-effectiveness of the peer-counseling intervention compared with the self-help program was \$5,371 per additional quit.<sup>296</sup>

#### **Cost-Effectiveness of Smoking Cessation Treatment in the Context of LCS**

Patients who are eligible for LCS represent a population that is at high risk for cancer due to their smoking history. The prospect of preventing cancers and other illnesses caused by smoking in this high-risk population has led to the development of smoking cessation treatment interventions for such individuals. Villanti and colleagues<sup>297</sup> modeled the cost-utility (i.e., incremental cost per QALY gained) of annual LCS with no smoking cessation treatment versus LCS with a light or an intensive smoking cessation treatment intervention. In a hypothetical cohort of current and former smokers between the ages of 50 and 64 years with a smoking history of at least 30 pack years, adding a smoking cessation treatment intervention to annual LCS improved the costutility. Cost-utility ratios versus no screening (using 2012 dollars) ranged from \$28,240 per QALY gained for annual screening without any smoking cessation treatment intervention to \$23,185 per QALY gained for annual screening with a light intervention to \$16,198 per QALY gained for screening with an intensive intervention. The authors concluded that repeat annual LCS in a high-risk cohort of adults ages 50–64 is highly cost-effective and offering smoking cessation interventions with the annual screenings improves the cost-effectiveness by 20%-45%.<sup>297</sup> Another study by Goffin and colleagues<sup>298</sup> compared the outcomes and costs between annual and biennial LDCT screening in Canada using a simulation modeling approach. Relative to no screening, either annual or biennial screening that included smoking cessation treatment was more cost-effective; however, the cost-effectiveness of annual compared with biennial screening did not differ. Additional studies have found that offering smoking cessation treatment in the context of LCS could provide several benefits (e.g., more people quitting smoking, thus preventing some lung cancers as well as other diseases and resulting in life-years saved) at reasonable costs.<sup>299–301</sup>

#### Summary: Economic Outcomes Related to Smoking in Patients With Cancer

The small number of published studies suggests that individuals who continue smoking after a cancer diagnosis have increased health care costs. In addition, smoking cessation treatment interventions among patients with cancer are highly likely to be cost-effective. As with smoking cessation treatment interventions among individuals without a cancer diagnosis, the cost-

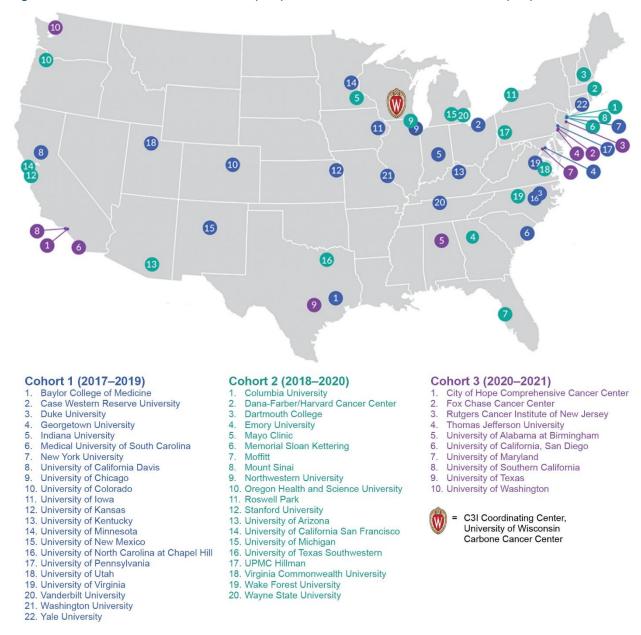
effectiveness of smoking cessation treatment interventions among individuals diagnosed with cancer will likely vary by type of intervention and economic perspective, as well as the clinical characteristics of the patient (e.g., type and stage of cancer diagnosed).

### Disseminating and Implementing Tobacco Cessation Treatment in Cancer Care Settings: The NCI Cancer Center Cessation Initiative (C3I)

Despite clear recommendations from national and international cancer organizations, tobacco use screening and delivery of/referral to smoking cessation services have been inconsistently implemented in NCI-Designated Cancer Centers and other cancer care settings.<sup>92</sup> While there are clear guidelines for what types of smoking cessation services are most effective for helping people who smoke to quit, how to implement these services within the context of cancer care delivery is less well understood. Although hundreds of research studies have been conducted to identify the most effective smoking cessation treatments,<sup>19</sup> less research has addressed RE-AIM strategies to foster Reach, Adoption, Implementation, and Maintenance of these treatments in health care generally. Even fewer have addressed these challenges in the context of cancer care.

In 2017, NCI established the C3I as part of the Cancer Moonshot Initiative to help NCI-Designated Cancer Centers build and implement sustainable tobacco cessation treatment. The overall goal was to improve the delivery of evidence-based tobacco cessation treatment services to every patient with cancer who smokes. This initiative was developed in response to a critical unmet need identified for cancer care—the routine assessment of tobacco use and provision of assistance in quitting.<sup>7</sup> The implementation and progress of C3I since 2017 provides real-world examples and lessons learned for how to address the multilevel challenges in integrating tobacco cessation treatment into clinical cancer care. In addition to C3I in the United States, Cancer Care Ontario designed its own program to improve the quality of cancer care by implementing evidence-based tobacco cessation treatment delivery for patients newly diagnosed with cancer who use tobacco.<sup>127</sup>

In 2017, the first cohort of 22 NCI-Designated Cancer Centers received 2 years of funding<sup>8</sup>; in 2018, a second cohort of 20 additional cancer centers was funded. Finally, in 2020, a third cohort of 10 additional centers was funded and 11 previously funded centers received 1 additional year of support (52 total NCI-Designated Cancer Centers funded, as of October 2020 – Figure 4.4). To increase the likelihood of ensuring that programs had an impact across the cancer center patient population that was sustained after NCI support ended, the initiative encouraged systems-level changes to prompt tobacco cessation treatment delivery. Importantly, while not prescriptive in terms of the type of tobacco cessation programs provided, C3I sites were mandated to evaluate outcomes every 6 months including rates of (a) screening of all patients with cancer for smoking, (b) referral for treatment of patients who smoked, (c) the proportion of patients referred who received tobacco cessation treatment, and (d) abstinence rates of those treated.



#### Figure 4.4 National Cancer Institute (NCI) Cancer Center Cessation Initiative (C3I) Sites

In addition to funding the 52 cancer centers, NCI established the C3I Coordinating Center at the University of Wisconsin Carbone Cancer Center to provide scientific and technical assistance and to serve as a knowledge hub for implementing tobacco cessation treatment programs in cancer care settings. The Coordinating Center's responsibilities include facilitating program implementation and assisting the 52 funded sites in the modification of their EHRs, with a goal of systematizing the universal identification and delivery/referral of patients with cancer who smoke to tobacco cessation treatment. C3I grantees provide data to the Coordinating Center twice annually including tobacco cessation treatment program characteristics, such as services offered, staff hired, implementation strategies and progress, tobacco use screening rates, and the reach and effectiveness of their tobacco cessation treatment programs.

As noted, cancer centers participating in C3I designed their programs by taking a populationbased approach to delivering evidence-based tobacco cessation treatment to every patient with cancer who smokes. Publications from cancer centers participating in C3I are included in <u>Appendix A</u>. As a result, the interventions implemented at various C3I sites comprise a variety of clinical practices designed to provide evidence-based smoking cessation treatments to patients with cancer who smoke. Three general categories of programs were implemented by C3I sites with many sites using a combination of these program types (Figure 4.5):

- 1. Point-of-Care Delivery of Tobacco Cessation Treatment Programs, which includes internal programs, such as counseling and pharmacotherapy provided at the point of cancer care;
- 2. Refer Patients to Internal Tobacco Cessation Treatment Programs, which includes counseling and medication delivered via health care system personnel; and
- 3. Refer Patients to External Tobacco Cessation Treatment Programs, which includes referring patients who smoke to external cessation treatment options such as state quitlines and text/mobile programs like NCI's SmokefreeTXT.

Centers were strongly encouraged to use the EHR to facilitate the identification of patients with cancer who smoke, to support treatment delivery, to refer tobacco users for cessation services, and to report on program reach and effectiveness. As of mid-2019, 40 of the 42 C3I centers funded at that time offered in-person counseling services, with 24 of those delivering advice to quit at the point of care; 28 centers offered connections to the state quitline via a fax or EHR referral. Some centers engineered their EHRs to streamline both the identification of tobacco users and their referral to tobacco cessation treatment via automatic EHR-based referral systems (i.e., eReferral). eReferral has been shown to be a promising method for increasing the reach of tobacco cessation treatment programs implemented in cancer care.<sup>302</sup> Prior to receiving C3I funding, only 7 of the 22 centers in the first cohort used eReferral to facilitate tobacco cessation treatment delivery<sup>9</sup>; by mid-2019, all 22 had implemented eReferral EHR functionalities. One innovative component of eReferral is that it sometimes provides closed-loop referral capacity (based on whether such closed-loop functionality is programmed into the EHR). This capacity both facilitates EHR-based referral of patients to cessation services, often to outside service providers such as a state quitline or NCI's SmokefreeTXT, and also feedback on the outcome of the referral (e.g., successfully contacted, patient quit) to the patient's EHR and/or the referring clinician in a HIPAA-compliant way.<sup>32,37</sup>

Prior to receiving C3I funding, only 10 of the 22 cancer centers in the first C3I cohort had the ability to report on the proportion of patients screened for tobacco use, the proportion of people who smoke who engaged in or were connected with smoking cessation treatment (i.e., reach), or the proportion of people who smoke who received specific evidence-based tobacco cessation treatment components (e.g., counseling, pharmacotherapy, quitline/text to quit referrals). C3I Coordinating Center biannual data showed that among those 10 centers, 81% of patients were screened for tobacco use in 2017; this increased to 93% in 2019, 2 years after receiving funding. These 10 cancer centers also reported that their tobacco cessation treatment programs reached an average of 19% of people who identified as currently smoking prior to C3I funding. After 2 years of funding, all 22 centers in Cohort 1 had developed capacities to report on reach. Across those 22 centers, mean reach was 36% (range: 0.5%–100%), demonstrating that C3I funding

increased funded centers' capacity to track treatment engagement accurately and with an increased likelihood that individuals would engage in tobacco cessation treatment.

#### Models of Tobacco Cessation Treatment Employed by C3I Sites

Depending on the resources available and site preferences, three broad models of tobacco cessation treatment were implemented across the C3I sites (Figure 4.5). Sites frequently combined components and treatment elements from the three models. Regardless of which model or which combination of models was used, all patients with cancer who smoke were offered at least the minimum standard of care for treatment, which included a combination of brief smoking cessation counseling and FDA-approved smoking cessation medication.<sup>19</sup> Typically, this goal was accomplished through a combination of point-of-care treatment, such as advice to quit and a medication prescription from the oncologist at the time of the clinic visit followed by referral to an internal or external program. Such a scenario exemplifies precisely how clinical referral models such as the 5A's, AAR, and AAC can be applied in cancer care settings. The following section describes in more detail the three models of care shown in Figure 4.5.

# Figure 4.5 Elements of Exemplar Tobacco Cessation Treatment Programs: Three Models Used Successfully in Cancer Care Settings

#### **Common Elements for All Tobacco Treatment Programs (TTPs)**

- · Screen all patients for tobacco use and document status in EHR.
- Offer all tobacco users both counseling and medication for smoking cessation via one or more of the three treatment models below.
- Leverage the EHR to facilitate delivery of program elements and to monitor program utilization and outcomes.

Oncology clinics and their health systems can adapt one of the three treatment models below or combine elements of these models.

#### Model 1 Point-of-Care Delivery of Tobacco Cessation Treatment Programs

- · Oncology clinicians:
  - · Advise tobacco cessation.
  - Prescribe cessation medication.
  - · May provide counseling.
  - Emphasize the impact of continued tobacco use on both cancer and non-cancer outcomes.
- Nurse or health educator in oncology clinic:
  - Typically delivers bulk of counseling care.
  - Sometimes including referral to internal/external TTPs (see models 2 and 3).
- Point-of-care treatment occurs as part of cancer care visits.

#### Model 2 Refer Patients to an Internal TTP

- Oncology clinicians and/or clinic staff:
  - · Advise tobacco cessation.
- Refer patients to dedicated TTP within the cancer center health care system.
- Internal TTPs are staffed by trained tobacco treatment specialists or other trained clinicians. Such staff typically:
  - Provide feedback, usually via the EHR, to the oncology care clinicians.
  - Oversee cessation follow-up care (e.g., continuing counseling, troubleshooting medication problems, renewals, changes).
- Internal TTPs also typically include (either via opt-in or optout system):
  - EHR-based outreach to all patients within the cancer care setting identified as patients who smoke (e.g., via the EHR Tobacco User Registry function).
- Internal TTPs cessation services are typically delivered apart from oncology care visits.

#### Model 3 Refer Patients to an External TTP

- Oncology clinicians and/or clinic staff:
  - Refer patients to TTPs outside of the cancer center/ health care system, such as state quitline or SmokefreeTXT.
- Outcomes of external TTP referral and care are shared with oncology care team:
  - Ideally, via closed-loop e-Referral capacities that now exist for state quitline and SmokefreeTXT to inform treating clinicians of referral outcomes.
- Prescribing of cessation medications may be delivered by the oncology care clinical team or by the external TTP referral.
- Referral to external TTPs can be offered via EHR-based outreach to all patients who smoke within the cancer care setting, typically via the EHR Tobacco User Registry function.
- External TTP cessation services are typically delivered apart from oncology care.

Note: EHR = Electronic Health Record.

#### **Point-of-Care Treatment Models**

Point-of-care treatment models typically utilize the EHR to prompt a variety of clinic staff members (e.g., medical assistants, nurses, health educators, treating clinicians) to deliver evidence-based treatment components themselves, including smoking cessation counseling. The use of multiple team members helps reduce the time burdens on busy cancer care clinicians (physicians, physician assistants, nurse practitioners) whose charge is focused on highlighting the importance of tobacco cessation and prescribing or endorsing the use of tobacco cessation medications. Such multi-clinician-delivered care was a frequent choice for C3I health care systems and may be particularly helpful for cancer care settings that (1) have an in-house tobacco cessation "specialist program" that is underutilized, (2) have tobacco cessation programs without dedicated tobacco treatment specialists, or (3) want to increase patient engagement using existing internal program resources. For example, the C3I-supported Siteman Cancer Center at the Washington University School of Medicine implemented a full point-of-care treatment model where the health care delivery team together delivered the 5A's.<sup>125</sup> The clinical workflow was modified so that the nurse or medical assistant taking patient vital signs was prompted by the EHR to ask about tobacco use, provide brief advice to quit, assess interest in cessation counseling and medication, and connect the patient to external cessation counseling resources via eReferrals. During the cancer care encounter, based on clinical data collected by the nurse or medical assistant, the prescribing clinician was prompted with a best practice alert to address tobacco use with the patient who smokes. Additional EHR tools (e.g., "smart sets") then provided guidance options for the clinician to prescribe appropriate tobacco cessation medications.

#### Internal Referral Treatment Models

Internal referral treatment models typically identify patients who smoke during the rooming process and then refer those patients to an internal tobacco cessation counseling program, either in person, telephone based, or both. This model was also commonly implemented at C3I Cancer Centers. It requires additional staff, often in the form of trained tobacco treatment specialists or other health care professionals trained in tobacco cessation counseling. Many centers opted to train nurse practitioners or physician assistants to serve as tobacco treatment specialists, to see patients specifically for tobacco cessation (because of their capacity to provide counseling, write prescriptions, and bill for treatment services provided). However, many programs also use tobacco treatment specialists, professionals typically with bachelor's- or master's-level education who receive extensive training on tobacco cessation treatment options including a variety of evidence-based counseling approaches to become certified in this role.<sup>219</sup> Referrals to these specialists could be initiated by rooming staff or treating clinicians via an EHR referral during cancer care encounters.<sup>150</sup> Alternatively, tobacco cessation treatment program staff could use the EHR to target patients who smoke using the EHR registry function and by providing outreach to all people who smoke who visit the cancer care setting regardless of their interest in quitting (i.e., opt-out treatment delivery).<sup>82</sup>

#### **External Referral Treatment Models**

External referral treatment models typically refer patients who smoke to external programs such as state tobacco quitlines, an IVR telephone program, and/or a text/mobile program, such as NCI's SmokefreeTXT, designed to aid in smoking cessation or to increase motivation to quit.

Such programs often utilize the EHR and an opt-out approach, designed to increase the proportion of patients who are offered treatment. While such programs have the potential to enhance reach, some of these interventions (IVR, text programs) may have lower quit rates.<sup>303</sup> As noted, many of the C3I sites implemented components of more than one model.

#### Lessons Learned From Implementation of C3I

The 52 funded C3I sites identified important lessons regarding integration of evidence-based tobacco cessation treatment into cancer care settings that should be relevant to implementing tobacco cessation programs in cancer care settings broadly, although they were not necessarily tested via randomized trials. These lessons were compiled via C3I Coordinating Center site visits when funding ended for funded centers and are described in detail below.

Secure Organizational Buy-In Through Clinical, Administrative, and IT Champions. C3I

sites highlighted the key role that champions play in facilitating implementation. Effective champions were typically knowledgeable about the health benefits of smoking cessation for patients with cancer, enthusiastic about the initiative, viewed as trusted clinicians, and influential within the cancer care setting. C3I centers with clinical champions reported that these individuals facilitated interactions between the clinical staff and the tobacco cessation treatment program staff, including helping both to implement changes to the clinical workflow and to facilitate training of clinical staff in the new workflow. Effective champions were also identified in other areas.<sup>18</sup> While clinical champions helped to obtain clinical staff agreement to alter their responsibilities and workflows, administrative and IT champions were critical for obtaining the necessary organizational and EHR modification approvals and implementation. For most cancer care settings, modifying the clinical workflow, including adapting EHR changes to support that workflow, typically requires several levels of approval. Thus, champions can help pave the way for the implementation of an effective tobacco cessation treatment program—both within cancer centers and within community cancer care clinical settings.

**Systematically Implement Workflow and EHR Changes.** After determining which workflow changes are both necessary and possible, it is essential to work with health care system and clinician leadership, as well as front-line clinicians, to communicate these changes prior to implementation. It is vital to provide information, such as why the changes are necessary, the expected benefits resulting from the changes, and efforts made to minimize extra burden. Adoption can be further enhanced by systematizing the changes via simple EHR adaptations.

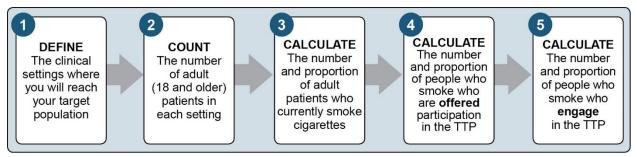
Once the new clinical workflow has been determined and the necessary EHR changes identified, the timeline for IT staff to make those changes needs to be included in the project implementation timeline. All clinicians, including medical assistants, nurses, oncologists, and others with a role in the identification, treatment, and referral of patients who smoke must be trained on the new workflow. C3I sites have used a variety of instructional methods for training, including in-person and video-based demonstrations and simulated patient encounters using test records in the EHR.<sup>18</sup> Progress in implementing a tobacco cessation treatment program can be enhanced if training and EHR adaptations occur in tandem (i.e., training occurs contemporaneously with the implementation of planned EHR changes by IT staff).

**Reduce Barriers for Patients to Participate.** For models of care that provide tobacco cessation treatment counseling at separate appointments, coordinating these visits with other patient oncology appointments can increase attendance and, thereby, reach. Alternatively, telehealth/telephone visits can be offered to patients for whom travel is a barrier. Cost can also present a barrier for patients, whether it is an insurance co-pay for counseling, surcharges based on smoking status, or the cost of smoking cessation pharmacotherapy. Working with patients to find low- or no-cost options for tobacco cessation treatment and pharmacotherapy can reduce barriers to participation. Cancer centers often have integrated patient support resources, such as social workers, who may be able to assist tobacco cessation treatment programs and patients with finding resources.

**Monitor Program and Patient Outcomes Using the EHR.** The EHR can be utilized to track whether patients are screened for smoking, advised to quit, and have received treatment from either a cancer center–based cessation program or via referral to external cessation treatment services. Developing functionalities that can provide reports on these measures is critical for evaluating implementation outcomes of the program, including program reach. As discussed earlier in this chapter, reach refers to the proportion of people who currently smoke who engage in or are connected with evidence-based tobacco cessation treatment. Each C3I site first defined the target population of its current tobacco cessation treatment, such as the cancer center as a whole or specific clinical settings such as hospitalized patients with cancer.

As part of its reporting requirements, C3I sites counted the number of adult patients in each setting, reported the number and proportion who were identified as people who currently smoke, and evaluated the number and proportion of people who currently smoke who were offered treatment and who engaged in it (Figure 4.6). The EHR can be used for this purpose, or programs could develop databases where follow-up visits and smoking cessation outcomes are documented for program participants. A challenge to measuring smoking cessation outcomes is that it relies on both program-level resources to contact patients, and on the patient completing follow-up assessments. Conducting follow-up assessments via telephone can possibly increase rates of follow-up. Moreover, utilizing the EHR during subsequent clinic visits to track patient smoking status can provide additional data to assess outcomes when resources are not available for dedicated patient follow-up.<sup>18</sup> Additionally, program reach and effectiveness should be examined as a function of patient sociodemographics in order to ensure effective implementation for the entire patient population and to monitor whether there are sociodemographic disparities in smoking cessation rates.

# Figure 4.6 Methods Used by Cancer Center Cessation Initiative (C3I) Sites to Track Program Reach and Effectiveness



Note: As part of the C3I program, "Reach" is defined as the proportion of people who currently smoke who engage in or are connected with evidence-based tobacco treatment. TTP = Tobacco Treatment Program.

### Summary

The C3I program and other research has demonstrated that health care systems can successfully and effectively integrate smoking cessation treatment into cancer care settings. Applying findings from implementation science can enhance that integration. Each clinical setting, whether an acute care, ambulatory, or inpatient site, can provide smoking cessation treatment as part of comprehensive cancer care. Guidelines put forth by clinical, research, and patient organizations, such as the NCCN, reflect the growing momentum and recognition of the importance of providing evidence-based smoking cessation treatment to all patients with cancer who smoke.

The RE-AIM framework has been applied broadly to structure the planning, implementation, and evaluation of smoking cessation treatment delivery in cancer care. Specific strategies that have been shown to facilitate such treatment delivery at the health care system level include leveraging EHRs to enhance current smoking identification and treatment delivery, implementing opt-out approaches to expand population reach, utilizing IVR systems to automate follow-up, and using telehealth to connect clinicians with patients who smoke. Payment models, quality metrics, and regulatory and legislative actions all have the potential to spur greater adoption of smoking cessation treatment by health care systems and clinicians. Strategies to promote maintenance of smoking cessation treatment programs in clinical care settings include securing support from health care system leadership, integrating tobacco-relevant quality metrics, payment models, and regulatory policies. These components can provide a foundation for the use of evidence-based smoking cessation treatment models such as the 5A's in the PHS Clinical Practice Guideline, *Treating Tobacco Use and Dependence: 2008 Update*.

Much can be learned from the models of care identified as part of NCI's C3I program. The realworld experiences of C3I can help guide the successful implementation of comprehensive smoking cessation treatment programs across multiple types of cancer care settings. Applying the findings of C3I, along with the research reviewed in this chapter, provide effective and practical evidence-based examples for health care systems and cancer care settings that aim to implement smoking cessation treatment programs to assist patients with cancer who smoke to quit.

### Conclusions

- 1. Challenges to implementing smoking cessation treatment in cancer care settings persist at the patient, clinician, and health care system levels. It is important that these multilevel barriers be understood and addressed so that health care systems can provide cessation treatment equitably and effectively to all patients with cancer who smoke.
- 2. Successful implementation of smoking cessation treatment in cancer care settings requires health care system changes designed to increase the reach, effectiveness, adoption, implementation, and maintenance (i.e., the RE-AIM framework) of smoking cessation treatment interventions.
- 3. Effective strategies to improve smoking cessation treatment reach and engagement in oncology care start with the consistent and accurate assessment of tobacco use status for all patients across the cancer care continuum. Assessment of tobacco use for all patients with cancer needs to be empathic and nonjudgmental to reduce patient anxiety, embarrassment, or guilt, and to encourage accurate disclosure of tobacco use status.
- 4. Clinic-wide opt-out (as opposed to opt-in) smoking cessation treatment engagement strategies show promise as a means of enhancing the reach and delivery of smoking cessation treatments to patients with cancer who smoke.
- 5. Clinical decision supports, prompts, and order sets embedded in electronic health records (EHRs) can improve the rate of both screening for tobacco use and delivering smoking cessation treatments. Such EHR tools can aid in the delivery of smoking cessation treatment, either as part of the cancer care or via a referral to an internal health care system tobacco treatment specialist or to an external option, such as a state tobacco quitline, state quitline-provided texting program, or the National Cancer Institute's (NCI) SmokefreeTXT.
- 6. Health care system accreditation guidelines, publicly reported quality metrics, and payfor-performance programs can encourage health care systems to improve the frequency of tobacco use screening and treatment for all patients who smoke, including those with cancer.
- 7. Research has identified multiple smoking cessation treatment program models (e.g., smoking cessation treatment delivered during cancer care or via referral to internal or external smoking cessation treatment services) that can be effectively implemented in a variety of cancer clinical settings.
- 8. Continued smoking after a cancer diagnosis is associated with increased health care costs relative to not smoking. Smoking cessation interventions provided to patients with cancer are highly likely to be cost-effective.
- 9. The NCI Cancer Center Cessation Initiative (C3I) has developed a variety of implementation strategies to enhance the reach and effectiveness of smoking cessation treatment delivery in NCI-Designated Cancer Centers. These approaches exemplify how smoking cessation treatment strategies can be implemented broadly in cancer care settings.
- 10. Strategies to reduce system-level barriers to cessation among patients with cancer who smoke include ensuring that evidence-based cessation treatments are provided as a covered benefit by health insurers and other payers, without barriers to access and/or use.

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## **Appendix A. C3I Grantee Publications**

Below is a selected list of C3I Grantee Publications that may be useful for cancer centers to refer to. Further information and an extended list of publications, presentations, and posters may be found on the National Cancer Institute's C3I website (<u>https://cancercontrol.cancer.gov/c3i</u>) and the University of Wisconsin-Madison C3I website (<u>https://c3i.wiscweb.wisc.edu/publications/</u>).

Year Published	Title	Authors	Site	Publication Information
2022	Increased reach and effectiveness with a low-burden point-of-care tobacco treatment program in cancer clinics	Ramsey, A.T., Baker, T.B., Stoneking, F., Smock, N., Chen, J., Pham, G., James, A.S., Colditz, G. A., Govindan, R., Bierut, L.J., & Chen, L.S.	Alvin J. Siteman Cancer Center— Washington University	Journal of the National Comprehensive Cancer Network, 20(5), 488-495.e4. doi:10.6004/jnccn.2021.7333
2022	Reach and effectiveness of the NCI Cancer Moonshot-funded Cancer Center Cessation Initiative	D'Angelo, H., Hohl, S.D., Rolland, B., Adsit, R.T., Pauk, D., Fiore, M.C., & Baker, T.B.	C3I Coordinating Center	Translational Behavioral Medicine, ibac009. doi:10.1093/tbm/ibac009
2022	The tragic triad of tobacco dependence, cancer, and COVID-19 pandemic: An urgent call for attention by health care systems and professionals	Presant, C.A., Macalintal, J., Ashing, K.T., Yeung, S., Tiep, B., West, H., Merla, A., & Phillips, T.	City of Hope Comprehensive Cancer Center	Journal of Clinical Oncology Practice, 18, 99-105. doi:10.1200/OP.21.00625
2022	Changes in cigarette smoking behavior in cancer survivors during diagnosis and treatment	Jose, T., Schroeder, D.R., & Warner, D.O.	Mayo Clinic Cancer Center—Mayo Clinic	Nicotine & Tobacco Research, ntac072, Advance online publication. doi:10.1093/ntr/ntac072
2022	Assessment and counseling gaps among former smokers eligible for lung cancer screening in U.S. adults: A cross-sectional analysis of National Health and Nutrition Examination Surveys (NHANES), 2013- 2018	Hood-Medland, E.A., Dove, M.S., & Tong, E.K.	UC Davis Comprehensive Cancer Center—University of California Davis	Journal of General Internal Medicine, Advance online publication. doi:10.1007/s11606-022-07542-0
2022	Proposing a model of proactive outreach to advance clinical research and care delivery for patients who use tobacco	Burris, J.L., Borger, T N., Baker, T. B., Bernstein, S L., Ostroff, J.S., Rigotti, N.A., & Joseph, A.M.	N/A	Journal of General Internal Medicine, Advance online publication. doi:10.1007/s11606-022-07553-x

Year Published	Title	Authors	Site	Publication Information
2021	Introduction to the Cancer Center Cessation Initiative Working Groups: Improving oncology care and outcomes by including tobacco treatment	The Cancer Center Cessation Initiative Coordinating Center and Expert Advisory Panel	C3I Coordinating Center	Journal of the National Comprehensive Cancer Network, 19(Suppl_1), S1-S3. doi:10.6004/jnccn.2021.7095
2021	Achieving equity in the reach of smoking cessation services within the NCI Cancer Moonshot-funded Cancer Center Cessation Initiative	D'Angelo, H., Webb Hooper, M., Burris, J.L., Rolland, B., Adsit, R., Pauk, D., Rosenblum, M., Fiore, M.C., & Baker, T.B.	C3I Coordinating Center	Health Equity, 5(1):424-430. doi:10.1089/heq.2020.0157
2021	Time to put it out—nurse-facilitated tobacco treatment in a comprehensive cancer center	Katz, D.A., Mott, S.L., Utech, J.A., Bahlmann, A.C., Dukes, K.A., Seaman, A.T., Laux, D.E., Furqan, M., Pollack, Z.J., & Vander Weg, M.W.	Holden Comprehensive Cancer Center—University of Iowa	Translational Behavioral Medicine, 11(9):1726-1738. doi:10.1093/tbm/ibab073
2021	Presumed consent with opt-out: an ethical consent approach to automatically refer patients with cancer to tobacco treatment services	Ohde, J., Master, Z., Tilbert, J., & Warner, D.	Mayo Clinic Cancer Center—Mayo Clinic	Journal of Clinical Oncology, 39(8):876- 880. doi:10.1200.
2021	Nicotine addiction and its treatment	Prochaska, J.J., & Benowitz, N.L.	Stanford Cancer Institute	In S. Hecht & D. Hatsukami (Eds.), Tobacco and cancer: The science and the story. Singapore: World Scientific Publishing
2021	Integrating diversity, equity, and inclusion approaches into treatment of commercial tobacco use for optimal cancer care delivery	The Cancer Center Cessation Initiative Diversity, Equity, and Inclusion Working Group	N/A	Journal of the National Comprehensive Cancer Network, 19(Suppl_1), S4-S7. doi:10.6004/jnccn.2021.7091
2021	Involving family and social support systems in tobacco cessation treatment for patients with cancer	The Cancer Center Cessation Initiative Family and Social Support Systems Working Group	N/A	Journal of the National Comprehensive Cancer Network, 19(Suppl_1), S8-S11. doi:10.6004/jnccn.2021.7090
2021	Implementation science to improve tobacco cessation services in oncology care	The Cancer Center Cessation Initiative Implementation Science Working Group	N/A	Journal of the National Comprehensive Cancer Network, 19(Suppl_1), S12-S15. doi:10.6004/jnccn.2021.7094
2021	Sustainability of tobacco treatment programs in the Cancer Center Cessation Initiative	The Cancer Center Cessation Initiative Sustainability Working Group	N/A	Journal of the National Comprehensive Cancer Network, 19(Suppl_1), S16-S20. doi:10.6004/jnccn.2021.7093

Year Published	Title	Authors	Site	Publication Information
2021	Telehealth delivery of tobacco cessation treatment in cancer care: An ongoing innovation accelerated by the COVID-19 pandemic	The Cancer Center Cessation Initiative Telehealth Working Group	N/A	Journal of the National Comprehensive Cancer Network, 19(Suppl_1), S21-S24. doi:10.6004/jnccn.2021.7092
2021	Mixed-methods economic evaluation of the implementation of tobacco treatment programs in National Cancer Institute- designated cancer centers	Salloum, R.G., D'Angelo, H., Theis, R.P., et al.	N/A	Implementation Science Communications, 2(41). doi:10.1186/s43058-021-00144-7
2020	Low burden strategies are needed to reduce smoking in rural healthcare settings: a lesson from cancer clinics	Ramsey, A.T., Baker, T.B., Pham, G., Stoneking, F., Smock, N., Colditz, G.A., James, A.S., Liu, J., Bierut, L.J., & Chen, L.S.	Alvin J. Siteman Cancer Center— Washington University	International Journal of Environmental Research and Public Health, 17(5), 1728. doi:10.3390/ijerph17051728
2020	Implementation of tobacco cessation services at a comprehensive cancer center: A qualitative study of oncology providers' perceptions and practices	Rodgers-Melnick, S.N., & Webb Hooper, M.	Case Comprehensive Cancer Center—Case Western Reserve University	Supportive Care in Cancer. doi:10.1007/s00520-020-05749-7
2020	Health benefits and economic advantages associated with increased utilization of a smoking cessation program	Datta, S.K., Dennis, P.A., & Davis, J.M.	Duke Cancer Center—Duke University	Journal of Comparative Effectiveness Research, 9(11), 817-828. doi:10.2217/cer-2020-0005
2020	Comparison of referral methods into a smoking cessation program	Davis, J.M., Thomas, L.C., Dirkes, J.E., Datta, S.K., & Dennis, P.A.	Duke Cancer Center—Duke University	Journal of Comparative Effectiveness Research, 9(11), 807-815. doi:10.2217/cer-2020-0004
2020	Strategies for referring cancer patients in a smoking cessation program	Davis, J.M., Thomas, L.C., Dirkes, J.E., & Swartzwelder, H.S.	Duke Cancer Center—Duke University	International Journal of Environmental Research and Public Health, 17(17), 6089. doi:10.3390/ijerph17176089
2020	Implementation of the Smoking Treatment and Recovery (STAR) program: Healthy cancer survivorship through integrated tobacco control	Taylor, K.L., Fallon, S., Subramaniam, D., Davis K.M., To, C., Lobo, T., Tercyak, K.P., Friberg, J., Tynan, M., Russell, E., Ahmed, W., Ponder, M.C., Cusaac, L., Thompson, J., Gardner, K., Kim, C., & Weiner, L.M.	Georgetown Lombardi Comprehensive Cancer Center— Georgetown Lombardi	Journal of Cancer Survivorship, 14(1), 53–58. doi:10.1007/s11764-019-00826-1

Year Published	Title	Authors	Site	Publication Information
2020	Design and pilot implementation of an electronic health record-based system to automatically refer cancer patients to tobacco use treatment	Jose, T., Ohde, J.W., Hays, J.T., Burke, M.V., & Warner, D.O.	Mayo Clinic Cancer Center—Mayo Clinic	International Journal of Environmental Research and Public Health. 17(11). doi:10.3390/ijerph17114054
2020	Improved documentation of electronic cigarette use in an electronic health record	Jose, T., Hays, J.T., & Warner, D.O.	Mayo Clinic Cancer Center—Mayo Clinic	International Journal of Environmental Research and Public Health, 17(16), 5908. doi:10.3390/ijerph17165908
2020	Integration of tobacco treatment services into cancer care at Stanford	Gali, K., Pike, B., Kendra, M.S., Tran, C., Fielding-Singh, P., Jimenez, K., Mirkin, R., & Prochaska, J.J.	Stanford Cancer Institute	International Journal of Environmental Research and Public Health, 17(6), 2101. doi:10.3390/ijerph17062101
2020	Special issue: tobacco use and treatment among cancer survivors	Goldstein, A. & Warren, G.	N/A	Special Issue of the International Journal of Environmental Research and Public Health, guest edited by Dr. Goldstein and Dr. Warren
2020	Effect of sustained smoking cessation counseling and provision of medication vs shorter-term counseling and medication advice on smoking abstinence in patients recently diagnosed with cancer: A randomized clinical trial	Park, E.R., Perez, G.K., Regan, S., Muzikansky, A., Levy, D.E., Temel, J.S., Rigotti, N.A., Pirl, W.F., Irwin, K.E., Partridge, A.H., Cooley, M.E., Friedman, E.R., Rabin, J., Ponzani, C., Hyland, K.A., Holland, S., Borderud, S., Sprunck, K., Kwon, D., Peterson, L., Miller-Sobel, J., Gonzalez, I., Whitlock, C.W., Malloy, L., de León-Sanchez, S., O'Brien, M., & Ostroff, J.S.	N/A	JAMA, 324(14):1406-1418. doi:10.1001/jama.2020.14581
2020	Leveraging patient reported outcomes measurement via the electronic health record to connect patients with cancer to smoking cessation treatment	May, J.R., Klass, E., Davis, K., Pearman, T., Rittmeyer, S., Kircher, S., & Hitsman, B.	Robert H. Lurie Comprehensive Cancer Center—Northwestern University	International Journal of Environmental Research and Public Health, 17(14), 5034. doi:10.3390/ijerph17145034

Year Published	Title	Authors	Site	Publication Information
2020	Tobacco dependence treatment in oncology: initial patient clinical characteristics and outcomes from Roswell Park Comprehensive Cancer Center	Sheffer, C.E., Stein, J.S., Petrucci, C., Mahoney, M.C., Johnson, S., Giesie, P., Carl, E., Krupski, L., Tegge, A.N., Reid, M.E., Bickel, W.K., & Hyland, A.	Roswell Park Comprehensive Cancer Center	International Journal of Environmental Research and Public Health, 17(11):E3907. doi:10.3390/ijerph17113907.
2020	Engagement and effectiveness of a smoking cessation quitline intervention in a thoracic surgery clinic	Mustoe, M.M., Clark, J.M., Huynh, T.T., Tong, E.K., Wolf, T.P., Brown, L.M., & Cooke, D.T.	UC Davis Comprehensive Cancer Center—University of California Davis	JAMA Surgery, 155(9), 816-822. doi:10.1001/jamasurg.2020.1915
2020	The emergence of a sustainable tobacco treatment program across the cancer care continuum: A systems approach for implementation at the University of California Davis Comprehensive Cancer Center	Tong, E.K., Wolf, T., Cooke, D., Fairman, N., & Chen Jr., M.S.	UC Davis Comprehensive Cancer Center—University of California Davis	International Journal of Environmental Research and Public Health Special Issue Tobacco Use and Treatment among Cancer Survivors, 17(9), 3241. doi:10.3390/ijerph17093241
2020	Using a family systems approach to treat to bacco use among cancer patients	Ruebush, E., Mitra, S., Meyer, C., Sisler, L., & Goldstein, A.O.	UNC Lineberger Comprehensive Cancer Center—University of North Carolina at Chapel Hill	International Journal of Environmental Research and Public Health, 17(6), 2050 doi:10.3390/ijerph17062050
2020	Intensive smoking cessation counseling for patients with cancer	Goldstein, A.O., Shoenbill, K.A., & Jolly, T.A.	UNC Lineberger Comprehensive Cancer Center—University of North Carolina at Chapel Hill	JAMA, 324(14):1401-1403. doi:10.1001/jama.2020.13102
2019	Building systems to address tobacco use in oncology: Early benefits and opportunities from the Cancer Center Cessation Initiative	Jenssen, B.P., Leone, F., Evers- Casey, S., Beidas, R., & Schnoll, R.	Abramson Cancer Center— University of Pennsylvania	Journal of the National Comprehensive Cancer Network, 17(6), 638-643. doi:10.6004/jnccn.2019.7312
2019	Care-paradigm shift promoting smoking cessation treatment among cancer center patients via a low-burden strategy, electronic health record-enabled evidence- based smoking cessation treatment	Ramsey, A.T., Chiu, A., Baker, T., Smock, N., Chen, J., Lester, T., Jorenby, D.E., Colditz, G.A., Bierut, L.J., & Chen, L.S.	Alvin J. Siteman Cancer Center— Washington University	Translational Behavioral Medicine, 10(6):1504-1514. doi:10.1093/tbm/ibz107
2019	Addressing a core gap in cancer care—The NCI Moonshot program to help oncology patients stop smoking	Croyle, R., Morgan, G., & Fiore, M.	C3I Coordinating Center	New England Journal of Medicine, 380: 512-515. doi:10.1056/NEJMp1813913

Year Published	Title	Authors	Site	Publication Information
2019	Tobacco treatment program implementation at NCI Cancer Centers: Progress of the NCI Cancer Moonshot-funded Cancer Center Cessation Initiative	D'Angelo, H., Rolland, B., Adsit, R., Baker, T., Rosenblum, M., Pauk, D., Morgan, G., & Fiore, M.	C3I Coordinating Center	Cancer Prevention Research, 12(11):735- 740. doi:10.1158/1940-6207.CAPR-19- 0182
2019	Effective cessation treatment for patients with cancer who smoke—The fourth pillar of cancer	Fiore, M., D'Angelo, H., & Baker, T.	C3I Coordinating Center	JAMA Network Open Oncology, 2(9):e1912264. doi:10.1001/jamanetworkopen.2019.1226 4
2019	Mitigating the adverse health effects and costs associated with smoking after a cancer diagnosis	Warren, G.W.	Hollings Cancer Center—Medical University of South Carolina	Translational Lung Cancer Research, 8(Suppl 1), S59-S66. doi:10.21037/tlcr.2019.04.07
2019	Association of a comprehensive smoking cessation program with smoking abstinence among patients with cancer	Cinciripini, P.M., Karam-Hage, M., Kypriotakis, G., Robinson, J.D., Rabius, V., Beneventi, D., Minnix, J.A., & Blalock, J.A.	MD Anderson Cancer Center—The University of Texas	JAMA Network Open Oncology. doi:10.1001/jamanetworkopen.2019.1225 1

## Appendix B. Biochemical Confirmation Reasons and Methods: Evidence Based on the Society for Research on Nicotine and Tobacco (SRNT) Working Group on Biochemical Verification

In 2020, the Society for Research on Nicotine and Tobacco (SRNT) provided updated recommendations on whether and how to use biochemical markers in determining tobacco use and abstinence. The following information is relevant to both the research and clinical treatment contexts.

- 1. Rationale for use of biochemical confirmation. There is evidence of significant levels of misreporting of smoking status.
  - a) Misreporting appears to be increasing over time.
  - b) Misreporting appears to be especially common in patients who have smoking-related diseases.
  - c) Some evidence suggests that as many as one-third to one-half of patients with cancer who smoke deny it.<sup>135,142</sup>
- 2. Purposes
  - a) Use of biochemical assessment will likely detect more smokers in the patient population so that smoking cessation treatment can be offered and encouraged and to aid treatment planning (e.g., the scheduling of surgery).
  - b) Use of regular biochemical assessments will help determine whether a patient has successfully quit smoking after a quit attempt.
- 3. Types of biochemical verification and relevant information
  - a) Carbon monoxide (CO) via a breath sample
    - i) CO can be measured quickly and accurately with a relatively inexpensive device that requires little training for clinic staff to use routinely.
    - ii) Provides immediate information about smoking status.
    - iii) Smoking levels are typically over 4–5 ppm CO but nonsmokers may sometimes exceed these levels due to environmental exposure or marijuana smoking.<sup>306</sup>
    - iv) In the case of high levels of CO in a person who denies the use of combustible tobacco, the clinician should inquire about other forms of exposure in a nonleading manner.
    - v) CO assessment detects elevated CO due to combustion products and therefore will not show high values due to use of NRT.
    - vi) CO assessment has a relatively short half-life of about 4 hours, it is influenced by pulmonary ventilation and exercise, and may reach a "non-smoking" value in a regular smoker after 6–24 hours of non-smoking.
  - b) Cotinine from laboratory assay
    - i) Is a relatively stable, major proximate metabolite of nicotine.
    - ii) Can be determined from a blood sample serum, plasma, or whole blood routinely collected as part of clinical care or can be determined from saliva or urine.
    - iii) Serum levels of free cotinine in individuals who smoke typically range from 100–250 ng/ml; those not using nicotine should have values <15 ng/ml.<sup>307,308</sup>
    - iv) Detection in urine is less sensitive than in blood; a cut-point for regular nicotine use is  $\geq$  30 ng/ml.<sup>309</sup>

- v) Individual variation in cotinine level is influenced by environmental exposure, pregnancy status, and metabolic rate.
- vi) Cotinine half-life can vary from 8–30 hours; typically, it would take about 2 days or more for cotinine levels to fall to nonsmoking levels after nicotine intake is discontinued (from a blood level of 200 ng/ml).
- vii)Cotinine reflects the use of NRT; therefore, individuals with high values who deny smoking should be queried in a nonleading manner about use of noncombustible nicotine products (NRT, ENDS).
- c) Cotinine (from commercially available dip sticks)
  - i) These are relatively inexpensive, widely available, and provide immediate feedback as to smoking status.
  - ii) They provide easily interpreted evidence of cotinine level from urine or saliva.
  - iii) They are less sensitive than laboratory assays using blood or urine and provide only nonquantitative (categorical) evidence.
  - iv) Lateral flow immunoassay cotinine strips for urine are inexpensive, provide a binary outcome (smoking vs. nonsmoking), and are meaningfully associated with total cotinine in urine.<sup>310</sup>
  - v) As with any cotinine assay, dip-stick cotinine tests will reflect the use of nicotine from any source (NRT, ENDS).

*Note*: NRT = nicotine replacement therapy. ENDS = electronic nicotine delivery systems. *Source*: Benowitz et al. 2020.<sup>145</sup>