VIEWPOINT

The Need for a Smoking Cessation "Care Package"

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Tobacco use is the leading cause of preventable disease and death in the US.[1] Cigarette smoking alone kills nearly a half million US residents each year and millions more experience smoking-related illnesses, including cancer and heart disease.[1] The 2009 Family Smoking Prevention and Tobacco Control Act granted the US Food and Drug Administration (FDA) authority to regulate the manufacturing, distribution, and marketing of tobacco products, with the goal of protecting US residents from the devastating effects of tobacco. Substantial progress has been made toward this goal as a result of efforts at the national, state, and local levels: current cigarette smoking among US adults declined from 20.6% in 2009 to 11.5% in 2021.[2] However, tobacco use remains a potent health threat; approximately 47 million US adults currently use tobacco products.[3] Of these individuals, nearly 80% use combustible products such as cigarettes, which are responsible for the overwhelming burden of tobacco-related disease and death.[1]

As society seeks to help people quit smoking, concerns have arisen that biomedical and health enterprises have lost sight of the needs of these individuals. This Viewpoint proposes a comprehensive "care package" framework of resources that maximize cessation, including components focused on strategies at the individual, health system, and population levels. This comprehensive approach should be complemented by continued research and innovation to identify novel strategies.

Individual Level

When individuals stop smoking, their risks of death and serious illness decrease precipitously.[3] But nicotine is a highly addictive substance, and quitting can be difficult. The clinical challenge is magnified by the fact that many people who smoke are also at higher risk for poor health outcomes. Persons who smoke are more likely to have lower income, less education, no health insurance, and higher rates of behavioral health conditions, depression, anxiety, and other serious mental illness.[3]

The 2020 surgeon general's report documented evidence-based interventions for smoking cessation, including counseling and FDA-approved medications.[4] To date, the FDA has approved 7 different types of medications for helping adults quit smoking, including 5 forms of nicotine replacement therapy medication (patch, gum, inhaler, nasal spray, and lozenge) and 2 medications that do not contain nicotine (bupropion hydrochloride and varenicline tartrate).[4] The patch, gum, and lozenge are available without a prescription, whereas the other medications are available by prescription only.[4] Counseling can be delivered in multiple ways, including in person by a health care professional or by telephone, often referred to as "quitlines." Although counseling and medication are independently effective, combining them can more than double the chances of quitting smoking.[5] Digital strategies, such as text messaging and web-based cessation tools, can also facilitate quitting.[4]

No e-cigarette is currently approved by the FDA for smoking cessation. Moreover, the potential benefits of these products among adults who smoke must be weighed against the risks of youth initiation. E-cigarettes have been the most used tobacco product among youth since 2014, and significant work is ongoing to address this concerning public health issue.[3] Although growing evidence indicates that certain e-cigarettes may facilitate smoking cessation among adults,[6] further high-quality research on this issue, including on short- and long-term clinical outcomes, is needed. Such research need not be mutually exclusive of ongoing efforts to rigorously prevent use of e-cigarettes by youth, increase use of effective cessation methods such as counseling and FDA-approved cessation medications, and explore other innovative approaches to assist adults to quit completely.

Health System Level

Common barriers to accessing cessation therapies include co-payments, deductibles, annual or lifetime dollar limits, and requiring prior authorization. Finding ways to maximize barrier-free delivery of proven cessation therapies through available health delivery systems is paramount. Clinical and social service support are important elements of a successful approach, and tobacco use and dependence often require repeated intervention and long-term support to facilitate cessation.

Providing cessation treatment can be reimbursable and can help meet quality measures, but it must be prioritized to give clinicians the needed resources and support. The 2010 Patient Protection and Affordable Care Act (ACA) requires most private health plans to cover, without patient cost sharing, clinical preventive services that have received an A or B rating from the US Preventive Services Task Force.[4] These services include tobacco cessation treatments, and in 2014, the US government issued guidance stating that insurers would be in compliance if they covered a full range of specific cessation treatments. Opportunities exist to ensure that health plans and insurers are aware of and follow this guidance. As of January 2014, the ACA also began prohibiting state Medicaid programs from excluding any of the 7 FDA-approved medications from traditional Medicaid coverage.[4] However, the provision does not require state Medicaid programs to remove barriers to accessing these medications, and few states have completely eliminated barriers to accessing treatment.[4]

Actions can also be taken at the health system level to promote cessation, including implementing a system to screen for and ensure treatment of tobacco use; providing education, resources, and feedback to promote interventions by health care providers, including clinical practice guidelines; dedicating health care staff to provide cessation

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treatment; promoting policies that support and provide inpatient cessation services; and including the full range of proven cessation treatments as paid or covered services for all members of health insurance packages.[3]

Additionally, health care professionals can promote cessation by advising patients to quit at each encounter, offering brief counseling, prescribing cessation medications, directing patients to additional resources, and following up with continued support. Every member of the clinical care team can play a role, and it can take patients several tries before they successfully quit; delegating these tasks to various members of the health care team can improve efficiency and support a coordinated-care approach.[3]

Population Level

Evidence-based population-level interventions such as tobacco product price increases, comprehensive smoke-free policies, and health communications campaigns promote cessation by creating an environment in which tobacco products are less accessible, acceptable, and desirable.[1] Responding to the challenge of realizing a society free from tobacco-related disease and death, novel population-level endgame strategies have also been proposed that focus on eliminating combustible tobacco product use.[3]

One endgame strategy involves strict standards for ingredients in tobacco products to make them less toxic and appealing. In April 2022, the FDA proposed 2 rules that would prohibit sales of menthol-flavored cigarettes and all flavored cigars.[7,8] The public comment period for these rules ended in August 2022, and the FDA received nearly 250 000 comments on both rules combined. The FDA is currently reviewing these comments and is committed to completing the rulemaking process as quickly as possible. The proposed rules are based on strong science and build on the 2009 Tobacco Control Act, which prohibited characterizing flavors, except tobacco and menthol flavors, in cigarettes. Because approximately 30% of all US cancer deaths are attributable to smoking, the proposed standards will contribute substantially to the administration's reenergized Cancer Moonshot goal of reducing deaths from cancer by at least 50% during the next 25 years.[7,8] These product standards also represent a crucial step in advancing health equity by reducing tobacco-related health disparities, including among Black individuals due to the disproportionate use of menthol cigarettes and flavored cigars in this population.

Another end-game strategy involves reducing nicotine yield in cigarettes to minimally addictive or nonaddictive levels. The FDA has published plans to develop a proposed rule that would establish a maximum nicotine level for cigarettes and certain other combustible tobacco products; preparation of a proposed rule is presently under way.[9] FDA modeling research indicates that more than 33 million people could avoid becoming regular consumers of cigarettes by 2100 if such a rule were implemented, reducing adult smoking rates from the current 12.5%[3] to 1.4% and translating to more than 8 million fewer people dying from tobacco-related illnesses.[10]

FDA's Comprehensive Approach

The FDA is committed to examining all avenues at its disposal to optimize a cessation care package. The Center for Tobacco Products will continue to diligently regulate tobacco products, including advancing product standards that promote cessation. The Center for Drug Evaluation and Research encourages development of novel therapeutic approaches to smoking cessation and has published guidance to assist industry in developing new products. The Center for Devices and Radiological Health encourages development of safe and effective devices that leverage digital technologies in support of smoking cessation. Additionally, the FDA commissioner's Nicotine Steering Committee is aggregating knowledge across FDA centers and disciplines to identify potential synergies. The FDA is also working with agencies across the US Department of Health and Human Services to maximize resources and expertise as it identifies new partnerships and innovation to promote cessation.

Conclusions

The progress made in reducing cigarette smoking in the US is one of the most notable public health achievements of the past century. However, the work to reduce tobacco-related disease and death is far from over. More can be done, and with greater expediency and innovation. As we accelerate efforts to reduce tobacco-related disease and death, it is essential that the public health, clinical practice, and medical products communities rise to the occasion and that payers identify people who use tobacco and provide barrier-free access to support clinical and other services to address this critically important public health issue.

ARTICLE INFORMATION

Published Online: December 29, 2022. doi:10.1001/jama.2022.24398

Conflict of Interest Disclosures: Dr Califf is an employee of the US Food and Drug Administration (FDA); reported being an employee of and holding equity in Verily Life Sciences and Google Health (Alphabet) before his appointment to the FDA as Commissioner of Food and Drugs; and reported serving on boards of directors for Cytokinetics, Centessa, Clinetic, Keystone Symposia, the Center for Policy Analysis on Trade and Health (CPATH), the Clinical Research Forum, and OneFifteen. No other disclosures were reported.

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