

Are there any smoking cessation pharmacotherapy guidelines or studies looking at chewing tobacco or electronic cigarettes?

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Multiple American and international governmental or professional organizations address the use of chewing tobacco or electronic cigarettes (e-cigarettes).¹⁻¹⁵ The United States (US) Department of Health and Human Services and the Agency for Healthcare Research and Quality (AHRQ) issued a guideline in 2008 which addresses use of tobacco, including cigarettes and smokeless tobacco (e.g., chewing tobacco).¹¹ This guideline, however, does not address use of e-cigarettes. Similar to cigarette smoking, the AHRQ asserts that smokeless tobacco has notable health concerns including the risk for cancer and nicotine addiction. As such, smokeless tobacco is not considered to be a safer alternative to cigarettes, nor is it an option for smoking cessation. The AHRQ recommends that all patients who use smokeless tobacco be encouraged to quit and be offered the same types of smoking cessation interventions as patients who smoke cigarettes, including pharmacologic and non-pharmacologic treatments. Patients should also be referred to dental healthcare services given the effects of smokeless tobacco on the oral mucosa and teeth.

More recently, the American Academy of Pediatrics (AAP) issued a policy statement regarding use of tobacco products including smokeless tobacco.¹ The statement focuses on exposure of pediatric patients to all types of tobacco products. Notably, the AAP states that use of alternative forms of tobacco such as chewing tobacco, snuff, and flavored cigars has been increasing in adolescent patients.^{1,16} The AAP recommends that pediatric patients be assessed for tobacco use or smoke exposure and be offered education to prevent initiation of tobacco products.¹ Use of tobacco products by parents or caregivers should also be addressed and tobacco cessation treatments should be offered, if needed.

As some of the newest available tobacco-related products, electronic nicotine delivery systems (ENDS) such as e-cigarettes became available internationally in 2007.¹⁷ (See Table 1 for a summary of notable events related to e-cigarettes). Multiple American and international governmental or professional organizations have issued policy/position statements regarding use of ENDS/e-cigarettes.¹⁻¹⁵ (See Tables 2 and 3). Except for the AAP policy (Farber et al), these statements do not include recommendations regarding smokeless tobacco.

Table 1: Timeline of e-cigarettes.¹⁷⁻²⁰

Year	Event
1965	First electric cigarette patented
2003	First aerosolized, high-frequency e-cigarette patented; entered marketplace in China
2007	E-cigarettes first patented internationally
2009	FDA issued warnings regarding health concerns associated with e-cigarettes, including risk of nicotine addiction
2016	FDA given the authority to regulate all tobacco products including e-cigarettes
2018	FDA will require all e-cigarette products containing nicotine to have the following warning statement, "WARNING: This product contains nicotine. Nicotine is an addictive chemical."

FDA=Food and Drug Administration; e-cigarette=electronic cigarette

Table 2: US governmental and professional organizations’ policy/position statements for ENDS/e-cigarettes.*

Organization	Recommendations
AACR/ASCO (2015) ⁸	<ul style="list-style-type: none"> -Supports: (1) regulation of all ENDS by FDA; (2) encourages FDA to require safety warnings on products and restrict youth-oriented marketing; (3) federal regulations requiring internet and mail-order sellers to check age and identification of buyers; (4) prohibition of ENDS in areas where tobacco use is prohibited by existing laws in order to prevent second- or third-hand exposure and potential adverse events -Recommends: (1) prohibition of candy or youth-friendly flavors to prevent use by younger patients; (2) taxes on ENDS at equal or higher levels as combustible tobacco products; (3) use of FDA-approved smoking cessation products instead of ENDS -Further research needed regarding ENDS use in smoking cessation
AAP (2015) ^{1,7}	<ul style="list-style-type: none"> -Asserts that nicotine is highly addictive and neurotoxic to the developing brain; reports of nicotine toxicity have been increasing -ENDS not recommended for smoking cessation -Avoid use of ENDS around children to avoid second- or third-hand exposure; prohibit use of ENDS in all public places -Increase the minimum age to 21 y for all ENDS products; ban all flavors; ban sale of ENDS on the internet and advertising in media/internet/point-of-sale settings; restrict depiction in movies, television, etc.; require adult-rating for media with use of ENDS products -Tax ENDS at same rate as conventional cigarettes
ACP (2015) ⁹	<ul style="list-style-type: none"> -Supports: (1) regulation of all ENDS by FDA; (2) taxes on all tobacco products; (3) legislation to restrict promotion/marketing/advertising for ENDS products; (4) include ENDS in all youth tobacco prevention efforts, highlighting risks; (5) future research on ENDS to examine health effects, toxicity, dual use rates (cigarettes and ENDS) -Ban: (1) flavors from all tobacco products and ENDS due to its appeal to youths; (2) use of ENDS in all public places -Notes long-term effects of ENDS are unknown; further research needed to determine their role in smoking cessation
ACS (2014) ²	<ul style="list-style-type: none"> -Supports regulation of e-cigarettes -Not recommended for smoking cessation as safety and efficacy have not been determined; other FDA-approved methods are recommended
AHA (2014) ⁶	<ul style="list-style-type: none"> -Supports inclusion of e-cigarettes in: (1) the definition of tobacco products and smoking; (2) smoke-free air laws; (3) state and federal laws prohibiting sales to minors; (4) laws which restrict marketing/advertising to minors; (5) tobacco screening questionnaires and prescriber education -Supports: (1) taxing e-cigarettes at a high rate to discourage use by minors and using revenue to fund tobacco cessation/prevention programs; (2) FDA regulations for marketing, access by minors, labeling, and manufacture of quality-controlled products -No evidence for use of e-cigarettes for smoking cessation or as an alternative to combustible tobacco products -Recommends intensive counseling for patients with CVD or stroke or at risk of a CVD event
ALA (2014) ³	<ul style="list-style-type: none"> -Notes concern for: (1) potential health consequences due to nicotine and other harmful chemicals; (2) effects of second-hand exposure; (3) aggressive marketing toward youth such as candy-type flavors; (4) potential for e-cigarettes to act as “gateway” to conventional cigarettes; (5) unproven claims that e-cigarettes will help smokers quit

Organization	Recommendations
AMA (2014) ⁴	-Recommends stricter regulation of ENDS -Notes public health concern for addiction to nicotine and the potential for increased use of conventional tobacco products
NIOSH (2016) ¹⁰	-Notes potential health concerns due to ENDS and second-hand exposure
US DHHS (2016) ¹³	-Surgeon General report focuses on use of e-cigarettes by youth and young adults -Notes public health concerns including addiction to nicotine, harmful effects on the developing brain, and the potential for harmful additive ingredients -Reports an increase in use of e-cigarettes among youth, which has surpassed use of other tobacco products -Notes that use of e-cigarettes is strongly associated with use of other tobacco products -Recommends adding e-cigarettes to smoking cessation policies, restricting access to youth, implementation of tax/price policies and retail licensure, regulation of marketing towards youth, and educational interventions
USPSTF (2015) ¹²	-Due to a lack of evidence, use of ENDS for smoking cessation is not recommended

*Most statements/recommendations were published prior to FDA being given the authority to regulate e-cigarettes.

AACR=American Association for Cancer Research; AAP=American Academy of Pediatrics; ACP=American College of Physicians; ACS=American Cancer Society; AHA=American Heart Association; ALA=American Lung Association; AMA=American Medical Association; ASCO=American Society of Clinical Oncology; CVD=cardiovascular disease; e-cigarettes=electronic cigarettes; ENDS=electronic nicotine delivery systems; FDA=Food and Drug Administration; NIOSH=National Institute for Occupational Safety and Health; US DHHS=United States Department of Health and Human Services; USPSTF=United States Preventative Services Task Force; y=years

Table 3: International governmental and professional organizations' policy/position statements for ENDS/e-cigarettes.

Organization	Recommendations
FIRS (2014) ⁵	-Notes that the health risks of e-cigarettes have not been adequately studied; use of these products should be restricted until safety is more fully determined
WHO (2016) ¹⁴	-Notes a lack of evidence regarding use of ENDS for smoking cessation -Unknown whether use of ENDS may lead to use of conventional cigarettes -States several regulatory options for consideration: (1) banning sale, distribution, possession to or by minors; (2) banning/restricting advertising and promotion; (3) taxing at a level to which makes ENDS unaffordable to minors; (4) banning/restricting use of flavors; (5) regulation of sales; (6) implementation of measures to prevent illicit use; (7) prohibiting use in indoor areas; (6) requiring use of child-resistant packaging -Recommends requirements for potential health warnings and several measures to minimize potential health risks: (1) testing products for safety; (2) use of ingredients that are not a health risk; (3) following fire safety standards; (4) regulation of product content, devices, etc.
WMA (2012) ¹⁵	-Recommends: (1) regulation of the manufacture and sale of ENDS; (2) marketing for smoking cessation should be based on efficacy and safety data and be approved by regulatory agencies; (3) inclusion of ENDS in smoke-free laws; (4) patient education by prescribers noting potential health risks

e-cigarettes=electronic cigarettes; ENDS=electronic nicotine delivery systems; FIRS=Forum of the International Respiratory Societies; WHO=World Health Organization; WMA=World Medical Association

In summary, 2 organizations make recommendations regarding smokeless tobacco.^{1,11} Due to safety concerns, the AHRQ recommends that patients using smokeless tobacco be encouraged to quit and be offered tobacco cessation treatments.¹¹ (Of note, the AHRQ guideline was not included in Table 2 due to absence of recommendations on e-cigarettes). The AAP guideline focuses on use of tobacco products in pediatric patients and recommends patient assessment and subsequent treatment, if warranted.¹

Regarding ENDS/e-cigarettes, multiple American or international governmental and professional organizations have issued policy or position statements.^{1-10,12-15,21} These organizations recommend regulation of e-cigarettes and/or note public health concerns including addiction and use by minors (individuals less than 18 years of age). In the US, some of these concerns have been assuaged by federal action enabling FDA regulation of ENDS as tobacco products.²² The FDA may prohibit sales of ENDS to minors and requires the submission of documentation supporting any efficacy or safety claims by manufacturers. Importantly, several organizations advise against the use of these products or assert that further research is needed regarding the role of ENDS in smoking cessation.^{1,3,5-9,12,14}

References:

1. Farber HJ, Walley SC, Groner JA, Nelson KE. American Academy of Pediatrics. Clinical practice policy to protect children from tobacco, nicotine, and tobacco smoke. *Pediatrics*. 2015;136(5):1008-1017.
2. American Cancer Society. Questions about smoking, tobacco, and health. 2014; <https://web.archive.org/web/20140923045623/http://www.cancer.org/cancer/cancercauses/tobaccocancer/questionsaboutsmokingtobaccoandhealth/questions-about-smoking-tobacco-and-health-e-cigarettes>. Accessed March 30, 2017.
3. American Lung Association statement on e-cigarettes. 2015; <http://www.lung.org/our-initiatives/tobacco/oversight-and-regulation/statement-on-e-cigarettes.html>. Accessed April 4, 2017.
4. McCarthy M. American Medical Association calls for stricter regulation of electronic cigarettes. *BMJ*. 2014;348:g4034.
5. Schraufnagel DE, Blasi F, Drummond MB, et al. Electronic cigarettes. A position statement of the Forum of International Respiratory Societies. *Am J Respir Crit Care Med*. 2014;190(6):611-618.
6. Bhatnagar A, Whitsel LP, Ribisl KM, et al. Electronic cigarettes: a policy statement from the American Heart Association. *Circulation*. 2014;130(16):1418-1436.
7. Walley SC, Jenssen BP. Electronic Nicotine Delivery Systems. *Pediatrics*. 2015;136(5):1018-1026.
8. Brandon TH, Goniewicz ML, Hanna NH, et al. Electronic nicotine delivery systems: a policy statement from the American Association for Cancer Research and the American Society of Clinical Oncology. *Clin Cancer Res*. 2015;21(3):514-525.
9. Crowley RA. Electronic nicotine delivery systems: executive summary of a policy position paper from the American College of Physicians. *Ann Intern Med*. 2015;162(8):583-584.
10. National Institute for Occupational Safety and Health. Current intelligence bulletin 67: promoting health and preventing disease and injury through workplace tobacco policies. 2015; <https://www.cdc.gov/niosh/docs/2015-113/>. Accessed April 4, 2017.
11. U.S. Department of Health and Human Services. Agency for Healthcare Research and Quality. Clinical practice guideline: treating tobacco use and dependence: 2008 update. <https://www.ahrq.gov/professionals/clinicians-providers/guidelines-recommendations/tobacco/index.html>. Accessed March 28, 2017.

12. Siu AL. U.S. Preventive Services Task Force recommendation statement. Behavioral and pharmacotherapy interventions for tobacco smoking cessation in adults, including pregnant women. *Ann Intern Med.* 2015;163(8):622-634.
13. United States Department of Health and Human Services. Centers for Disease Control and Prevention. E-cigarette use among youth and young adults. A report of the Surgeon General. 2016; https://e-cigarettes.surgeongeneral.gov/documents/2016_SGR_Full_Report_non-508.pdf. Accessed April 5, 2017.
14. World Health Organization (WHO). Conference of the Parties to the WHO Framework Convention on Tobacco Control. 2016; http://www.who.int/fctc/cop/cop7/FCTC_COP_7_11_EN.pdf. Accessed April 4, 2017.
15. World Medical Association (WMA). WMA statement on electronic cigarettes and other electronic delivery systems. 2012; <https://www.wma.net/policies-post/wma-statement-on-electronic-cigarettes-and-other-electronic-nicotine-delivery-systems/>. Accessed April 4, 2017.
16. Nasim A, Khader Y, Blank MD, Cobb CO, Eissenberg T. Trends in alternative tobacco use among light, moderate, and heavy smokers in adolescence, 1999-2009. *Addict Behav.* 2012;37(7):866-870.
17. Bell K, Keane H. Nicotine control: E-cigarettes, smoking and addiction. *Int J Drug Policy.* 2012;23(3):242-247.
18. Gilbert H. Smokeless non-tobacco cigarette. US patent 3200819A. August 17, 1965.
19. Ruyan asserts patent rights to e-cigarette in key China court ruling. Minneapolis, MN: Ruyan America: February 23, 2009.
20. Foulds J, Veldheer S, Berg A. Electronic cigarettes (e-cigs): views of aficionados and clinical/public health perspectives. *Int J Clin Pract.* 2011;65(10):1037-1042.
21. World Lung Foundation. WHO right to call for e-cigarette regulation. 2014; <http://worldlungfoundation.org/ht/d/ReleaseDetails/i/32757>. Accessed April 7, 2017.
22. U.S. Food and Drug Administration (FDA). FDA's new regulations for e-cigarettes, cigars, and all other tobacco products. 2016; <https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm394909.htm>. Accessed March 30, 2017.