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1 **Nicotine e-cigarettes as a tool for smoking cessation**

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10

11 **There is abundant evidence that e-cigarettes can help some individuals to quit smoking and**  
12 **so they should be more widely recommended as smoking cessation aids.**

13 Electronic- or e-cigarettes are hand-held battery-operated devices that heat a liquid, containing

14 propylene glycol and/or glycerin, flavoring compounds, and typically nicotine, to produce an

15 aerosol that users inhale, or vape. The consequences of nicotine vaping are controversial, with

16 two perspectives dominating discussion: the risks of vaping for young people; and the potential

17 of vaping to increase smoking cessation among adults.<sup>1</sup> This commentary focuses on the latter.

18 First, the paper reviews evidence that vaping increases smoking cessation. Then it examines the

19 health consequences of e-cigarettes. Next, differences across countries in how e-cigarettes are

20 regulated are reviewed. The paper concludes with what the evidence implies for clinical care,

21 taking into account what medical and governmental authorities in various countries consider

22 the appropriate role of e-cigarettes in smoking cessation.

23 **Vaping and smoking cessation**

24 Examining randomized controlled trials (RCTs), a living systematic review in the *Cochrane*

25 *Database of Systematic Reviews*<sup>2</sup> concluded that “There was high certainty that [smoking] quit

26 rates were higher in people randomized to nicotine [electronic cigarettes] than in those  
27 randomized to nicotine replacement therapy.” The authors also found evidence of cessation  
28 benefit comparing nicotine e-cigarettes with non-nicotine e-cigarettes and with behavioural  
29 support or no treatment.

30 Population studies support the RCT findings. Studies in both the UK and the US have associated  
31 increases of 10-15% in smoking cessation with use of e-cigarettes. Studies have consistently  
32 found that smokers who vape frequently are significantly more likely to quit smoking than are  
33 smokers who do not vape.<sup>1</sup> The US Centers for Disease Control and Prevention (CDC) has  
34 reported that smokers are more likely to use e-cigarettes in quit attempts than any other  
35 product, including smoking cessation medications approved by the Food and Drug  
36 Administration (FDA),<sup>3</sup> and with greater success.<sup>4</sup> E-cigarettes are also the most popular quit aid  
37 in England, and are associated with greater success compared to other cessation aids when  
38 used in stop smoking services.<sup>5</sup> That more smokers use e-cigarettes than licensed smoking  
39 cessation medications, presumably because of the availability of the former as consumer  
40 products, further increases the potential of vaping to reduce smoking. Simulation analyses have  
41 generally concluded that by increasing smoking cessation, vaping will avoid large numbers of  
42 premature deaths over time.<sup>1</sup>

43 Market data provide additional evidence, demonstrating an inverse relationship between sales  
44 of cigarettes and e-cigarettes. As the popularity of e-cigarettes grew in the US, cigarette sales  
45 declined at a more rapid rate than in the pre-e-cigarette era. Conversely, when e-cigarette sales  
46 have declined, cigarette sales have approached the more gradual rate of decrease experienced

47 prior to e-cigarettes.<sup>1</sup> Consistent with this pattern, studies by economists provide convincing  
48 evidence that cigarettes and e-cigarettes are substitutes.<sup>6</sup>

49 Support for the conclusion that cigarettes and e-cigarettes are substitutes comes from research  
50 finding that policies intended to restrict e-cigarette use may have unintentionally increased  
51 cigarette smoking. A Minnesota e-cigarette tax was associated with increased cigarette smoking  
52 and reduced cessation among adults.<sup>7</sup> Studies of youths' responses to e-cigarette taxes similarly  
53 have found that, while the taxes decrease use of e-cigarettes, they increase use of combusted  
54 cigarettes, particularly by increasing frequent smoking.<sup>8</sup>

#### 55 **Much less harmful**

56 While e-cigarette use is not harmless, both the US National Academies of Sciences, Engineering,  
57 and Medicine<sup>9</sup> and an independent review commissioned by the UK Department of Health and  
58 Social Care<sup>5</sup> have concluded that e-cigarette use is likely to be much less harmful than smoking.

59 A comparison of cigarette smoke and e-cigarette aerosol helps to explain why. Cigarette smoke  
60 includes more than 7,000 chemicals, including 70 known human carcinogens. The number of  
61 chemicals in e-cigarette aerosol is orders of magnitude lower, and toxicants common to both  
62 products are present in much lower concentration in e-cigarette aerosol. Human biomarker  
63 studies confirm that exposure to tobacco smoke toxicants is much lower with e-cigarette use  
64 compared to smoking. While nicotine is the addictive agent common to both products,  
65 chemicals other than nicotine cause nearly all of cigarette smoking's health risks.<sup>5,9</sup>

66 The two best-described adverse effects of e-cigarette use are nicotine addiction among youth  
67 who have never smoked cigarettes, and a risk of pulmonary symptoms. In 2022, 6.5% of US high

68 school youth reported vaping on 20 or more days monthly,<sup>10</sup> suggestive of nicotine  
69 dependence, but most were current or former cigarette smokers, many presumably already  
70 addicted.

71 Studies exposing cells and animals to e-cigarette liquids or aerosols demonstrate some harmful  
72 pulmonary effects, but it is difficult to extrapolate these effects to human exposures.<sup>11</sup> In young  
73 people, pulmonary harms related to vaping include bronchitis symptoms and aggravation of  
74 asthma. However, among adults with asthma or COPD, switching from cigarettes to e-cigarettes  
75 reduces symptoms and improves lung function, indicating harm reduction.<sup>12</sup> In addition,  
76 exclusive users of e-cigarettes (most of whom are former smokers) report fewer respiratory  
77 symptoms than do cigarette smokers and dual users. Whether vaping causes long-term  
78 pulmonary toxicity is difficult to determine, since most vapers are former smokers and few  
79 have used e-cigarettes long enough to develop COPD.

80 Cardiovascular risk of using e-cigarettes is of concern due to nicotine exposure and evidence of  
81 chronic inflammation and oxidative stress found in some human biomarker studies. Nicotine is  
82 not thought to cause atherosclerotic heart disease or stroke but could promote ischemia and  
83 acute cardiovascular events in people with pre-existing cardiovascular disease.<sup>13</sup> Some human  
84 experimental studies report that acute e-cigarette use impairs endothelial function (a feature of  
85 cardiovascular disease), similar to smoking. However, when smokers quit smoking and switch to  
86 e-cigarettes, endothelial function improves, indicating harm reduction.<sup>14</sup>

87 Reproductive toxicity is a concern with any nicotine delivery device. Nicotine impairs the  
88 maturation of the fetal brain and lung in animals. Cigarette smoking is associated with small-

89 for-gestational-age newborns, and greater risk for preterm delivery. E-cigarette use during  
90 pregnancy has been studied both in those who choose to vape (instead of smoking) and in  
91 pregnant women provided with e-cigarettes to aid smoking cessation. Birthweight outcomes  
92 are conflicting in different studies.<sup>15,16</sup> In any case, given the far greater exposure to toxicants in  
93 cigarette smoke, it seems likely that exclusive vaping during pregnancy should be less harmful  
94 than smoking. Of course, abstinence from all nicotine and tobacco products is preferable.  
95 Given the relative novelty of vaping, its long-term health risks cannot be directly assessed.  
96 However, existing evidence suggests that potential long-term harms are likely to be  
97 substantially less than those associated with smoking.

#### 98 **Contrasting regulations**

99 Country-specific approaches to regulating e-cigarettes range widely. Table 1 illustrates the  
100 diversity of countries' policies, providing examples of countries with each policy and indicating  
101 the minimum number of countries known to have implemented each. Policies range from  
102 restrictions on e-cigarette flavors to outright prohibition of e-cigarette sales, from marketing  
103 regulations to restriction of nicotine content, and from taxes on e-cigarettes to minimum age of  
104 sale laws.

105 At least 42 countries have an [authorisation or notification system](#) before products can be  
106 marketed. The US and the UK provide two examples that demonstrate the differences in these  
107 systems and how those differences impact the number and variety of e-cigarettes accessible to  
108 consumers.

109 The US authorisation process requires companies to submit detailed Premarket Tobacco  
110 Product Applications (PMTAs) to the FDA to seek a Marketing Granted Order that permits a  
111 nicotine-containing e-cigarette to continue to be sold or brought to market. As of November  
112 2022, out of millions of PMTAs filed with FDA, only 23 e-cigarette products from two tobacco  
113 companies and one independent company had received such orders, and these permitted  
114 tobacco flavors only. Numerous applications remain under review, and many e-cigarette  
115 products remain on the market pending review or enforcement of Marketing Denial Orders.

116 By contrast, the UK Medicines and Healthcare Regulatory products Agency (MHRA) runs a  
117 notification system for nicotine-containing e-cigarettes.<sup>5</sup> This involves manufacturers  
118 submitting a range of details on their products, with those e-cigarettes complying with certain  
119 standards (such as nicotine strength, additives, and packaging) allowed on the market. Since  
120 January 2021, over 15,000 e-cigarette products and e-liquids with a wide variety of flavours  
121 were notified to the MHRA database where retailers and consumers can check whether  
122 products are legally allowed on the market. New Zealand has a similar notification process to  
123 that of the UK.<sup>5</sup>

124 Currently, no country has a medicinally licensed e-cigarette for smoking cessation, although  
125 many countries have mechanisms for enabling licensing. In the UK, the MHRA recently updated  
126 its medicinal licensing process for e-cigarettes to clarify the processes involved and to  
127 encourage manufacturers to pursue a license.<sup>5</sup> In the US, for authorization for smoking  
128 cessation, an e-cigarette would have to go through the FDA's stringent drug approval process,  
129 managed by the Center for Drug Evaluation and Research. Approval requires that drugs are  
130 deemed safe and effective. While all approved drugs have some potential undesirable side

131 effects, this standard could pose a problem for e-cigarettes since they likely involve some  
132 health risks, albeit far less than cigarettes. In Australia, a physician’s prescription is required for  
133 all nicotine e-cigarettes, which are not permitted to be sold as consumer products.

#### 134 **Clinical care**

135 Based on scientific studies and governmental reports and policies, professional medical  
136 organizations synthesize evidence about e-cigarettes and translate it into clinical guidance for  
137 health care professionals involved in smoking cessation. Guidance provided by both  
138 government agencies and medical societies varies, falling into two broad groups.

139 In the US<sup>17</sup> and Canada, government agencies acknowledge a potential benefit of e-cigarette  
140 use but conclude that the evidence to recommend e-cigarettes for smoking cessation is  
141 currently insufficient. Uncertainty about long-term health effects also tempers the agencies’  
142 enthusiasm for e-cigarettes. Reflecting this ambivalence, neither government agencies nor  
143 major medical organizations in the US, Canada, or Australia recommend e-cigarettes as first-line  
144 cessation aids, instead prioritizing governmentally-licensed pharmacotherapies. US and  
145 Canadian medical organizations regard e-cigarettes as appropriate to consider for smokers who  
146 are unsuccessful when trying to quit with licensed pharmacotherapies. Views of health care  
147 professionals and medical organizations vary as to whether they should actively initiate a  
148 discussion of e-cigarettes or only respond if a smoker asks about them.

149 In contrast, government health agencies and professional societies in England and New Zealand  
150 interpret the evidence of e-cigarette effectiveness for cessation and the risk-benefit balance  
151 more favourably, encouraging health care professionals to consider e-cigarettes as a cessation



152 option on par with medically-licensed pharmacotherapies and behavioural support. Both  
153 countries have featured e-cigarettes in government-funded public education campaigns  
154 promoting smoking cessation. Both countries exhort healthcare professionals and stop-smoking  
155 programs to make e-cigarettes readily accessible for adults who smoke along with medically-  
156 licensed products and behavioral interventions. Both countries also provide specific guidance  
157 on how to use these products to achieve optimal outcomes.

158 The cautious tone of professional and government guidance in the US and Canada has limited  
159 health care professionals' enthusiasm to recommend e-cigarettes for cessation. The FDA's  
160 recent market authorization of several e-cigarette devices is an opportunity to reassure US  
161 health care professionals. The authorizations mean that FDA concluded that the approved  
162 brands are "appropriate for the protection of the public health,"<sup>18</sup> the standard they are  
163 required to meet to receive approval for marketing. This action implies indirectly that the FDA  
164 believes that e-cigarettes can help some individuals to quit smoking who would not do so  
165 otherwise. Were some e-cigarettes medically licensed, health care professionals would have  
166 further reassurance and better guidance to help patients choose appropriate devices and  
167 liquids and to use them effectively and safely.

168 Table 2 summarizes the authors' interpretation of desirable clinical practice based on current  
169 evidence and differences in specific countries' positions on e-cigarettes.

### 170 **A smoking cessation tool**

171 Vaping of most newer generation e-cigarettes results in delivery of nicotine to the lung in a  
172 manner similar to that of cigarettes.<sup>19</sup> These e-cigarettes pose a risk of nicotine addiction for

173 some young people, but for adults addicted to cigarettes, the single deadliest consumer  
174 product ever invented, they also serve as an important less-hazardous alternative to continued  
175 smoking. Considerable evidence indicates that e-cigarettes help some adults to quit smoking.  
176 Having engaged in substantial research on vaping, each of the authors respects the approach  
177 adopted by the UK and New Zealand governments and medical professional bodies. Further, we  
178 believe that governments, medical professional groups, and individual health care professionals  
179 in countries like the US, Canada, and Australia should give greater consideration to the  
180 potential of e-cigarettes to increase smoking cessation. E-cigarettes are not the magic bullet  
181 that will end the devastation wrought by cigarette smoking, but they can contribute to that  
182 lofty public health goal. However, acceptance of promoting e-cigarettes as a tool for smoking  
183 cessation likely will depend on continuing efforts to reduce youth never smokers' access to and  
184 use of the products. The two objectives can and should co-exist.<sup>20</sup>

### 185 **Competing interests**

186 N.L.B. serves as a consultant to pharmaceutical companies that market or are developing  
187 smoking cessation medications and has provided expert testimony in litigation against tobacco  
188 companies. N.A.R. consults with and has received a research grant from Achieve Life Sciences  
189 for development of a smoking cessation medication and receives royalties from UpToDate (an  
190 online medical textbook) as author of sections on e-cigarettes.

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225

226 **Table 1. Variation in country e-cigarette regulations**

Regulation	Estimated minimum number of jurisdictions implementing regulation	Examples of jurisdictions implementing regulation
Prohibition of sale of all e-cigarettes	39	Brazil, India, Iran, Mexico, Uganda
Pre-marketing authorisation or notification for all or some e-cigarettes	42	EU, New Zealand, Papua New Guinea, Paraguay, UK, US
Ban on non-tobacco flavoured e-cigarettes	6	China, Finland, Hungary, Lithuania, Netherlands, Ukraine
Ban on non-tobacco and non-menthol flavoured e-cigarettes	2	Denmark, Estonia
Ban on nicotine-containing e-cigarettes	2	Jamaica, Japan
Restriction on nicotine content of e-cigarettes	39	Australia, Canada, EU, Iceland, Israel, Jordan, New Zealand, UK
Minimum age of purchase, sale, or use (at one of 18, 19 or 21 years)	56	Australia, Canada, Honduras, New Zealand, Norway, Republic of Korea, Turkey, Tuvalu, UK, US
Regulations prohibiting or regulating e-cigarette marketing	78	Albania, Australia, Canada, Costa Rica, EU, Iran, Nepal, New Zealand, Senegal, UK
Child safety packaging regulations	38	Australia, Canada, EU, Iceland, Lithuania, UK, US
Health warnings on e-cigarette packaging	51	Australia, Canada, Egypt, EU, Greenland, Maldives, New Zealand, Republic of Korea, UK, US
Plain packaging	1	Israel (for all e-liquids)
Bans or restrictions on e-cigarette use in public places	66	Australia, Brunei Darussalam, Canada, Croatia, Ecuador, Jamaica, New Zealand, Togo
Excise tax on e-cigarettes	39	Canada, Costa Rica, Denmark, Ecuador, Germany, Indonesia, Norway

227 There is no data source that provides a comprehensive coverage of all countries' e-cigarette regulations  
 228 and so two sources are used: Johns Hopkins Global E-Cigarette Policy Scan, available at:  
 229 <https://globaltobaccocontrol.org/en/policy-scan/e-cigarettes> (This source indicated that the status of e-  
 230 cigarette regulations in many countries was unknown); and Smoke-free Canada, Restrictions on e-  
 231 cigarette flavours, July 2022, available at: [https://smoke-free.ca/SUAP/2021/e-cigarette-  
 232 flavour%20restrictions.pdf](https://smoke-free.ca/SUAP/2021/e-cigarette-flavour%20restrictions.pdf). Only regulations that apply at a national level are included; countries that  
 233 have adopted these policies in some but not all states or provinces or communities are not included.  
 234 While the third column gives examples of jurisdictions having adopted each relevant regulation,  
 235 Australia, Canada, EU, New Zealand, UK and US are included in all instances in which they have adopted  
 236 the regulation.

237

238 **Table 2. Recommendations for health care professionals**

Status	Guidance	Source	Message		
For a person who smokes tobacco	Advice to patients about e-cigarette benefits and risks	Authors	E-cigarettes can help some people to quit smoking combustible cigarettes.		
			Using e-cigarettes is substantially less harmful than continuing to smoke cigarettes, but e-cigarettes are not completely harmless. Questions remain about their health effects, especially if used long-term for years.		
	Recommendations about use of e-cigarettes for smoking cessation	Authors	If using e-cigarettes to quit smoking, a person should switch completely to e-cigarettes, use them regularly, and stop smoking all cigarettes as soon as possible.		
			When switching from cigarettes to e-cigarettes, a person may experience a period of using both products, known as dual use, during a transition period prior to complete smoking cessation. With dual use, the greater the reduction in cigarettes smoked, the greater the likelihood of reduced risk. However, long-term dual use means that the dangers associated with cigarette smoking will not be completely avoided.		
			E-cigarettes are likely to be most effective when accompanied by a behavioral support program, as is true when smoking cessation medication is used.		
			Because of the uncertainty about the risk of using e-cigarettes long-term, former smokers should plan to quit e-cigarettes eventually but only when they are confident that they will not go back to smoking combustible cigarettes.		
			People should not tamper with commercial e-cigarette products.		
			Side effects or safety concerns should be reported to a health care professional and to governmental health authorities. For example, in the UK, they should be reported through the Yellow Card system. In the US, they should be reported to the FDA.		
			Guidance from medical organizations and government agencies <sup>2</sup>	US and Canada	Persons seeking an aid to quit smoking should first use products that have been medically licensed as safe and effective smoking cessation aids. These include nicotine replacement products, varenicline, and bupropion.
					Government agencies and many professional organizations recommend that individuals who are unable to quit smoking with government-approved medications should discuss with their health care professional the risks and benefits of using e-cigarettes to reduce their smoking-related health risks. Health care practitioners and professional organizations vary in their comfort about, or willingness to recommend e-cigarettes to smokers.
			U.S. health care professionals should be aware that the US Food and Drug Administration (FDA) has authorized the		

			marketing of several e-cigarette brands as consumer products on the grounds that their public health benefits outweigh harms. However, the FDA has not licensed any e-cigarette as a smoking cessation medication.
		Authors	Many health care professionals will initiate a conversation and recommend e-cigarettes to selected smokers – this is supported by the evidence. FDA authorization of the marketing of some e-cigarette brands implies that the FDA believes that some e-cigarettes will help a subset of people to quit smoking who would not do so otherwise.
		England and New Zealand	Patients seeking to quit smoking should have access to a choice of products that includes e-cigarettes, several licensed medications, and behavioral support programs.
			Health care professionals should give clear, consistent, and up-to-date information about nicotine-containing e-cigarettes to adults who are interested in using them to stop smoking and advise patients about how to use e-cigarettes.
		Australia	E-cigarettes are not considered first-line treatments for smoking cessation. Individuals who have tried unsuccessfully to quit smoking using approved medicines should speak to their doctors about whether or not e-cigarettes containing nicotine are a suitable option. Doctors can prescribe nicotine-containing e-cigarettes for their patients who smoke.
For a person who does not smoke tobacco	Advice to patients about e-cigarettes	Authors	People of all ages who do not use any combustible tobacco products should be discouraged from using e-cigarettes. E-cigarette use is not completely harmless to health and can lead to nicotine addiction for people not using any other nicotine products.

239 **Note:** The authors’ advice is consistent with public health agencies’ guidance in the US, UK, Canada, and  
240 New Zealand, but not Australia. Australia’s National Health and Medical Research Council states: “E-  
241 cigarettes can be harmful.”; Australia’s government website states: “Even though scientists are still  
242 learning about e-cigarettes, they do not consider them safe”, “Currently, there is insufficient evidence to  
243 promote the use of e-cigarettes for smoking cessation,” and “They are sometimes marketed as a way to  
244 quit smoking, but there's not enough evidence to show that they help – or are safe.”  
245