Lancet commentary – Nicotine without smoke: fighting the tobacco epidemic with harm reduction

written by Clive Bates | 29 August 2019



Abstinence-only or alternatives?

I am proud to be a co-author of a commentary published today in The Lancet: Nicotine without smoke: fighting the tobacco epidemic with harm reduction (PDF) with Robert Beaglehole (lead author), Ruth Bonita and Ben Youdan. In a nutshell, we take issue with the anti-innovation stance of WHO and many groups working in public health:

> *Vaping and other smoke-free products have the potential to reduce the enormous harm of smoked tobacco products. The stakes of getting policy responses to smoke-free products wrong are high, especially if such restrictions stop millions of the world's smokers accessing safer alternatives. It is disappointing that in its latest tobacco report,[3] WHO clings to outdated orthodoxy when it could embrace innovation. Equating smoke-free products with cigarettes only serves to protect the stranglehold of the cigarette trade on*

the world's nicotine users and will nullify the potential of modern tobacco harm reduction strategies.

Before the full text, a word about the authors – Robert Beaglehole and Ruth Bonita are highly experienced in the field of non-communicable diseases. Ben Youdan and I have both campaigned for years to reduce the harms caused by smoking.

- *Emeritus Professor Robert Beaglehole (New Zealand)*.Professor Beaglehole directed the WHO Department of Chronic Disease and Health Promotion between 2004 and 2007. He founded ASH New Zealand in 1982 and now chairs the organisation which actively supports New Zealand's Smokefree Aotearoa 2025 Goal. He also chaired The Lancet's Non-Communicable Disease Action Group. He is Professor Emeritus of the University of Auckland.
- *Emeritus Professor Ruth Bonita*. Professor Bonita served as Director of Surveillance in the Noncommunicable Disease Cluster at the World Health Organization, Geneva, from 1999 to 2005. She is Emeritus Professor at the University of Auckland.
- *Ben Youdan*. Ben Youdan is the former Chief Executive of the UK's national No Smoking Day campaign until 2007 when he moved to New Zealand. He was the Director of ASH New Zealand from 2007 to 2013, and currently works as an independent health advisor.
- *Clive Bates*. Clive Bates is former Director of ASH (UK) 1997-2003, a former senior civil servant in the UK government and now runs a public interest consultancy and advocacy practice, Counterfactual.

Here is the full text of the commentary:

Nicotine without smoke: fighting the tobacco epidemic with harm reduction

The rapid rise of smoke-free nicotine products, especially vaping, is the most disruptive influence on smoking in decades. These products are challenging not only smoked tobacco's stranglehold on the nicotine market but also the public health response to tobacco harm reduction, including by WHO.[1] In October,

2018, 72 experts with no connections to the tobacco industry wrote to the WHO Director-General to argue that WHO should embrace innovation and more actively include tobacco harm reduction in its strategy to tackle the burden of smoking-related disease.[2] However, the WHO Report on the Global Tobacco Epidemic, 2019[3] continues to underappreciate the potential of low-risk alternatives to smoking.

The tobacco harm minimisation strategy complements other tobacco control strategies but has been underappreciated because for many in tobacco control the emphasis has been on achieving abstinence of all tobacco and nicotine use. However, abrupt cessation of nicotine has had low population success rates—for example, 4–5% in the USA.[4] Regrettably, many smokers find it hard to quit and go on to die prematurely—around 8 million a year.

The latest WHO report on the global tobacco epidemic stresses the importance of best-practice tobacco cessation services based on a medical treatment model. Unfortunately, this approach has had limited population-level impacts because of low uptake, and is in contrast to the much more promising consumer-led approach to cessation based on safer alternatives to smoked tobacco. The potential of vaping is that it combines high efficacy with widespread uptake. The latest WHO report is a missed opportunity to embrace innovation and to exploit the potential of low-risk alternatives to smoking. People smoke cigarettes for the nicotine but die from the tar.[5] The modern tobacco epidemic is based on factory-made cigarettes, a commercially successful product that has barely changed in 75 years. There are 1·4 billion tobacco users aged 15 years and older worldwide—1·07 billion smokers and 367 million smokeless tobacco users—a small number of whom use both smoked and smokeless tobacco.[3] Tobacco smoking's dominance of the nicotine market comes at huge cost with over a billion lives expected to be lost to tobacco smoking this century.[6]

Nicotine replacement therapy (NRT) has been available since 1978. These products are designed to partly mitigate nicotine withdrawal and assist an attempt to quit smoking and nicotine use. While this approach suits some people, absolute success rates are low.[7] It is hard to defend the pharmaceutical model as best practice when there is an increasing body of evidence that people who use electronic vaping products to quit are achieving better quit rates than those on phamacotherapies. [8]

Electronic vaping products (e-cigarettes) deliver nicotine through a heated aerosol consisting of a diluent, nicotine, and flavourings; it is inhaled much like smoking but without the damaging by-products of burnt tobacco. Heated tobacco products use a similar approach, with a vapour aerosol drawing the added flavour and nicotine from tobacco that has been heated rather than burnt, but with more toxins in the vapour than in that of e-cigarettes.

The key to the public health impact of vaping will be the willingness of more smokers to switch the way they use nicotine rather than to quit completely. Vaping meets the needs of some ex-smokers by substituting physical, psychological, social, cultural, and identity- related aspects of tobacco addiction. Some vapers report that they find vaping pleasurable and enjoyable—being more than a substitute but actually preferred, over time, to tobacco smoking. This suggests that vaping is a viable long-term substitute for smoking, with substantial implications for tobacco harm reduction.[9]

The long-term health implications of vaping cannot be known for certain for decades. However, evidence on the toxicology of aerosols and human exposure to toxins informs judgments about the likely effects of vaping. Estimates suggest that the risks of vaping are unlikely to exceed 5% of those associated with smoked tobacco products.[10,11] The precise figure has been controversial, but other assessments have concurred that e-cigarettes are considerably less harmful than smoking.[12] In April, 2019, the US Food and Drug Administration (FDA) made its first approval of a heated tobacco product, noting "While the authorization of new tobacco products doesn't mean they are safe, the review process makes certain that the marketing of the products is appropriate for the protection of the public health, taking into account the risks and benefits to the population as a whole."[13]

Estimates from 50 countries suggest that at least 40 million adults were vapers in mid-2018.[14] If use of e-cigarettes leads to people stopping smoking completely, this would substantially reduce the population health impacts of tobacco. Evidence on this point comes from trials and real-world experience. For example, a 2019 randomised controlled trial [8] set in stop smoking services, showed e-cigarettes to be approximately twice as effective as NRT, aligning with real-world survey data on quitting.[4,15] Further trials and observational studies, especially on dual use of cigarettes and vaping, will be informative.

A major concern raised about vaping is youth uptake, especially in the USA, where former FDA Commissioner Scott Gottlieb claimed there is an "epidemic" of youth vaping.[16] It has been widely reported that one in five US high school students had used e-cigarettes in the past 30 days when surveyed in 2018.[17] However, a more detailed examination of these data suggests that almost

three-quarters (72%) of the students were not regular vapers, but experimental and occasional users.17 Since most regular US youth vapers have also used other tobacco products, it raises the prospect that vaping might be a gateway out of, not into, tobacco use. In the UK and New Zealand, where youth e-cigarette use is also measured, prevalence of vaping in the age groups surveyed shows e-cigarette use by never smokers is less than 0·4% in both countries.[18,19]

Although increases in youth vaping are likely,[20] the public health impacts of these trends will be small; [21] this issue, however, requires further research from large, long-term longitudinal studies, with assessment of potential confounders. The suggestion that the nicotine from vaping harms the brains of young people is based mainly on rodent studies.[22] We are not aware of any evidence to suggest brain impairment in the generations of smokers who have used nicotine as adolescents.

Smoke-free products are disrupting traditional cigarette markets. In Japan, which has led the world in the use of heated tobacco products, cigarette unit sales declined by a third between 2016 and 2019.[23] In Sweden, oral tobacco (snus) has impacted the smoked tobacco market such that, by 2017, daily smoking among adults had fallen to just 5% compared with the European Union average of 24%.[24]

Some of the responses from the public health and policy community to these disruptive technologies have been negative and focused on minor risks, such as malfunctioning devices, uncertainty about the long-term effects of e-cigarettes, and tobacco industry involvement in the vaping market, rather than appreciating the opportunities. In 2018, WHO reported that e-cigarettes had been banned in 30 of its 194 member countries.[25] Prohibition or regulations, such as banning flavours, and restrictions on marketing, advertising, and sponsorship comparable to smoked tobacco products, will disadvantage smokers wanting to quit and further embed smoking as the most accessible

option for nicotine use (perversely privileging the cigarette). Invoking the precautionary principle to prevent the use of smoke-free products is unjustified in the face of the massive burden of smoked tobacco products, which are ubiquitously available.

The policy response to smoke-free products has to be different from existing tobacco control strategies, which include tax increases, advertising bans for cigarettes, and upstream restrictions on supply. Instead, policy priorities for smoke-free products should be to exempt them from excise taxes to maintain a fiscal incentive to switch; control rather than ban marketing to allow smoke-free products to challenge the dominance of the cigarette; provide public education campaigns on harm minimisation; not force vapers to share smoking areas; and support use of smoke-free products as a quit aid. Risk-proportionate regulation will help adults quit smoked tobacco as well as protecting against being appealing to young people.

Vaping and other smoke-free products have the potential to reduce the enormous harm of smoked tobacco products. The stakes of getting policy responses to smoke-free products wrong are high, especially if such restrictions stop millions of the world's smokers accessing safer alternatives. It is disappointing that in its latest tobacco report,[3] WHO clings to outdated orthodoxy when it could embrace innovation. Equating smoke-free products with cigarettes only serves to protect the stranglehold of the cigarette trade on the world's nicotine users and will nullify the potential of modern tobacco harm reduction strategies.

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We declare no competing interests; we have not received any funds from the tobacco, e-cigarette, or pharmaceutical industries.

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