

E-cigarettes and public health

A summary for policy-makers in Malaysia

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Table of contents

1	Introduction.....	3
1.1	Smoking in Malaysia	3
1.2	What are e-cigarettes?	3
1.3	Tobacco harm reduction – an introduction.....	4
1.4	Regulation of e-cigarettes in Malaysia	4
2	The case for e-cigarettes	5
2.1	The case for legitimising sale of e-cigarettes in Malaysia – a summary.....	5
2.2	E-cigarettes and fundamentals of tobacco control strategy	6
2.3	Tobacco harm reduction is a critical strategy in tobacco control	6
2.4	The experience of users.....	7
2.5	Arguments against prohibition of e-cigarettes	8
2.6	Professional practice with e-cigarettes	9
3	Controversies about e-cigarettes – what the evidence says	10
3.1	Toxicity of e-cigarette vapour.....	10
3.2	Formaldehyde exposure risk	10
3.3	Nitrosamines exposure risk.	11
3.4	Nicotine safety.....	11
3.5	Nicotine and mental health.....	12
3.6	Concerns about accurate labelling of nicotine dose and impact on users.....	12
3.7	Second hand vapour exposure	12
3.8	Particulates	12
3.9	Evidence of effectiveness	13
3.10	Gateway effect and renormalisation: unfounded.....	13
4	How to regulate e-cigarettes.....	14
4.1	Regulation as a poison.....	14
4.2	Regulation as medicines	14
4.3	Regulation as consumer products	14
5	Conclusion – towards a credible endgame for tobacco related disease.....	15
6	About the author	15

1 Introduction

1.1 Smoking in Malaysia

In Malaysia, around 4.2 million adults are regular smokers: 38% of men and 1.4% of women. Smoking accounts for 19% of male and 8.2% of female deaths, amounting to at least 19,000 smoking-related premature deaths annually¹. E-cigarettes are making significant inroads into Malaysia's tobacco market: a sample of smokers and e-cigarette users showed 18% were now regular e-cigarette users, with 69% having tried them in some way². Many Malaysian smokers already have positive attitudes to the opportunities that e-cigarettes offer to reduce harm or to help them quit smoking. A survey carried out by global polling company IPSOS³ showed the following:

The research found that eight-in-ten adult smokers (82%) agree that “e-cigarettes represent a positive alternative to today’s cigarettes.”

Three-quarters (75%) would “consider switching to e-cigarettes if they were legal, met quality and safety standards, and were conveniently available like regular tobacco products.”

...nearly all adult smokers (91%) agree that “through tax and regulatory policies, the Government should encourage adult smokers to switch to less harmful alternatives to cigarettes and ensure they are not used by youth.”

This document explores this popular ‘harm reduction’ agenda in greater depth.

1.2 What are e-cigarettes?

E-cigarettes generally consist of a battery, a heating coil and a liquid containing nicotine held in a tank or cartridge. Drawing on the e-cigarette or pressing a switch activates the battery to heat the coil, which vaporises the liquid without burning it. This is then inhaled and the nicotine absorbed into the blood via mouth, throat and lungs. The liquids usually contain nicotine, water, a ‘diluent’ such as propylene glycol or glycerol, and a flavouring, such as tobacco, mint, vanilla or fruit.



Types of e-cigarette or vaping equipment (not to scale)

There are now hundreds of flavours and these are an intrinsic part of the appeal to smokers and help to break the link to tobacco. The devices and the liquids can be sold as integrated units or with liquids sold separately. Some look like cigarettes (1st generation ‘cig-a-likes’), some look like pens (2nd

¹ World Lung Foundation, American Cancer Society. Tobacco Atlas Fifth Edition, 2015. Fact sheet: Malaysia [\[link\]](#)

² IPSOS for FactAsia: Malaysia Adult Smoker Survey, August 2015 (fieldwork June 2015) [\[link\]](#)

³ IPSOS for FactAsia: Malaysia Adult Smoker Survey, August 2015 (fieldwork June 2015) [\[link\]](#)

generation 'Ego' type), and the larger ones with tanks can look very unusual (3rd generation 'tanks' or 'mods'). There are also many designs for e-shisha, which use electrical heating and e-liquids instead of charcoal or wood and tobacco.

Use of e-cigarettes or any personal vapour product is known as 'vaping' and the users are often referred to as 'vapers'. It is possible to create e-cigarettes without nicotine, but this overlooks their main public health value – as a substitute for nicotine consumption via smoking. Non-nicotine e-cigarettes or liquids typically account for less than 5% of sales, though this is rising in many markets.

1.3 Tobacco harm reduction – an introduction

E-cigarettes work for health because they substitute for many aspects of the smoking experience (nicotine, taste, hand-to-mouth behaviour, ritual etc), but cause far less harm to the body: they are likely to be at least 95% lower harm than smoking. The key to understanding this reduction in harm is that nicotine itself is the reason why people smoke, but it is not what causes the harm arising from smoking – the harm is caused by the toxic particles of burning organic material and hot gases in cigarette smoke. E-cigarettes deliver the nicotine without the smoke and without any products of combustion, and so the risks are greatly reduced.

Why not quit completely? While quitting smoking completely may be desirable, many smokers find it difficult because they are dependent on nicotine or they simply do not wish to, because they like smoking and the impact it has on their mood. E-cigarettes therefore provide a solution: smokers can continue using nicotine, but without all the short and long-term health risks. The reason it is an important health strategy, is that many smokers will find it easier to switch to vaping than to give up smoking, nicotine, and all the behavioural rituals in one big effort. The reward for health at both individual and population level is that it offers a new and potentially attractive way to stop smoking that will attract more people to quit smoking.

Instead of the stark choice to “quit or die”, e-cigarettes offer a third way: an alternative to cigarettes that provides much of what people want from smoking, but without the disease, death and anti-social aspects of smoking that no-one wants. The likely alternative is not that more people will quit, but that more people will continue to smoke and die as a result.

1.4 Regulation of e-cigarettes in Malaysia

According to John Hopkins Bloomberg School of Public Health, an existing body of legislation applies to nicotine products – similar to Australia. Nicotine is classified as a class C poison under the Poisons Act and regulated as a drug under Control of Drugs and Cosmetics Regulations. Devices sold without nicotine are classified as electrical appliances. The sale, distribution or importation of nicotine containing e-cigarettes without a license is prohibited⁴. Given no products are licensed, this framework amounts to be seen as a *de facto* prohibition legal prohibition. However, the products are widely available and few Malaysian smokers even realise that nicotine products are technically on sale illegally. Recent media reports⁵ suggest the government already takes a pragmatic approach and that this will continue.

⁴ John Hopkins Bloomberg School of Public Health, Country Laws Regulating E-cigarettes: A Policy Scan, May 2015 (entry for Malaysia) [\[link\]](#)

⁵ The Star, No ban on e-cigs, 9 August 2015 [\[link\]](#)

2 The case for e-cigarettes

2.1 The case for legitimising sale of e-cigarettes in Malaysia – a summary

- Advances in scientific understanding now justify reconsideration of Malaysia's *de facto* prohibition of e-cigarettes in favour of exploiting the opportunities to use e-cigarettes to reduce smoking. This 'tobacco harm reduction' strategy could secure large health gains by enabling smokers switch to much lower risk products without the barrier of quitting nicotine. As part of its tobacco control agenda, Malaysia could develop best practice and leadership in this field.
- The public health priority is to reduce smoking as much as possible. Smokers who switch to e-cigarettes will avoid at least 95% of the major smoking related risks for cancer, heart disease and respiratory illness. They will also experience significant short-term gains in health and wellbeing, and may be financially better off. No government should deliberately try deny smokers this option – now adopted by millions of smokers world-wide.
- A widespread switch to vaping would also reduce exposure to second-hand tobacco smoke, which is thought to be a cause of cancer and cardiovascular disease in non-smokers. By contrast, vapour from e-cigarettes poses no material risk to bystanders.
- Poor media reporting and misrepresentation of scientific findings have exaggerated risks but understated the benefits of e-cigarettes. Policymakers must base decisions with real-world life-or-death consequences on a dispassionate view of the evidence, and the scientific evidence now suggests that these products could be a benefit to millions of Malaysian smokers.
- There is no sign anywhere in the world that e-cigarettes undermine tobacco control, induce young people to smoke, or reduce the rate that adults quit smoking. The evidence shows what we would expect: people use much safer products to reduce their health risks or quit smoking.
- There is no scientific, ethical or legal basis to restrict consumer choice in Malaysia to only those products known to be very dangerous, while preventing access to much lower risk products. There are no precedents for banning safer products while leaving the most dangerous products widely available. A *de facto* ban on e-cigarettes has the perverse effect of protecting the most dangerous products, cigarettes, from competition. The government should not be using regulation to protect the cigarette trade.
- Malaysia should be applauded for developing an advanced tobacco control agenda. However, e-cigarettes will *support* this agenda by giving smokers options to respond to increasing taxes and other controls on smoking. E-cigarettes offer far better options to smokers than switching to shisha or buying cigarettes on the black market. Because smokers use cigarettes primarily to consume nicotine, e-cigarettes will offer an attractive way to stop smoking for many.
- The quality of products available from reputable manufacturers is now very high and they are on widespread sale in the European Union, North America and throughout Asia without any major problems. Many smokers report success at quitting smoking and better health as a result.
- Any of the remaining issues associated with e-cigarettes can be addressed with modest regulation aimed at consumer protection. This could include requiring the use of pharmaceutical grade ingredients, electrical safety standards, child resistant packaging for e-liquids, and technical standards for liquids and devices.

2.2 E-cigarettes and fundamentals of tobacco control strategy

Tobacco control strategy should be focussed on reducing premature death and serious harms like cancer, cardiovascular and respiratory disease as rapidly as possible. To that end, the most effective tobacco control strategy has four main elements:

1. To provide strong incentives not to start smoking;
2. To motivate and help people to quit smoking;
3. To reduce harm to those who continue to use nicotine;
4. To reduce harm to non-smokers arising from exposure to toxins in second hand smoke.

E-cigarettes fit well into each element of this strategy – they provide options to help people to stop smoking, to use nicotine in a way that is substantially less harmful, and even in the case of young people they are usually an *alternative* to smoking or diversion from uptake of smoking. E-cigarettes make it less likely that people will continue to smoke tobacco, and that non-smokers will be exposed to tobacco smoke rather than relatively benign vapour.

2.3 Tobacco harm reduction is a critical strategy in tobacco control

At the heart of this strategy is the concept of 'tobacco harm reduction' as introduced above. This concept recognises that smoking is primarily driven by consuming nicotine and that there are many people who cannot or will not stop using nicotine. It has been known for 40 years that people "*smoke for the nicotine and die from the tar*"⁶. This creates the prospect that providing nicotine without the tar and toxic gases in tobacco smoke could have significant health benefits. There is strong consensus among scientists that nicotine products that do not involve burning tobacco are far less risky than smoking. The main public health agency in England recently published a comprehensive review of the published evidence on e-cigarette technologies and vaping behaviour⁷ and concluded:

- *the current best estimate is that e-cigarettes are around 95% less harmful than smoking*
- *there is no evidence so far that e-cigarettes are acting as a route into smoking for children or non-smokers*

In fact this 95% estimate is *cautious* advice from a responsible public body designed not to imply that consumers should assume they are perfectly safe. The 95% reduction in risk is likely to be an over-estimate of the residual risk as it includes a large safety margin for unknown future effects. The main underlying assessments of toxic exposure from vapour compared to cigarette smoke suggest much lower levels of exposure and risk. Typically, the harmful constituents of cigarette smoke are not present in vapour at detectable levels, or present at levels 20-1000 times lower. The major reviews of e-cigarette safety^{8 9 10} should give confidence that risks are *at least 95% lower than smoking*.

⁶ Russell MA. Low-tar medium-nicotine cigarettes: a new approach to safer smoking. *BMJ*. 1976. [[link](#)]

⁷ Public Health England. E-cigarettes around 95% less harmful than tobacco estimates landmark review. [[link](#)] E-cigarettes: an evidence update [[link](#)] 19 August 2015.

⁸ Burstyn I. Peering through the mist: systematic review of what the chemistry of contaminants in electronic cigarettes tells us about health risks, *BMC Public Health* 2014;**14**:18. doi:10.1186/1471-2458-14-18 [[Link](#)]

⁹ Farsalinos KE, Polosa R. Safety evaluation and risk assessment of electronic cigarettes as tobacco cigarette substitutes: a systematic review. *Ther Adv Drug Saf* 2014;**5**:67–86. [[Link](#)]

¹⁰ Hajek P, Etter J-F, Benowitz N, Eissenberg T, McRobbie H. Electronic cigarettes: review of use, content, safety, effects

As the Royal College of Physicians of London explained in its landmark report, *Harm reduction in nicotine addiction*¹¹:

This report makes the case for harm reduction strategies to protect smokers. It demonstrates that smokers smoke predominantly for nicotine, that nicotine itself is not especially hazardous, and that if nicotine could be provided in a form that is acceptable and effective as a cigarette substitute, millions of lives could be saved.

The harm reduction strategy works because it does not require a smoker to give up both smoking *and nicotine*, or the behavioural or social rituals that go with it - only the harmful smoke itself. Because it is easier for many smokers to switch to a low risk nicotine product than to quit smoking and nicotine completely, switching therefore increases that likelihood of success in reducing disease.

2.4 The experience of users

Although there is good science to underpin confidence in e-cigarettes, it is also important to consider the human experience. For example, the human stories from Australia¹², United Kingdom¹³ and United States¹⁴ help to explain why and how the products work. Three examples of thousands of user testimonial are included below in their own words:

Example of experience from the UK

“Vaping has probably saved my wife’s and my own life’s, I was a smoker for 50 years, nothing I have ever tried has had the impact of vaping, this alone was the only thing that saved me, how can governments legislate against something that is saving so many peoples life’s.

Example of experience from Australia

“It’s really had to believe it’s been a year. Never in my wildest dreams did I think that I could really quit smoking and make it last this long. I figured my addiction would kill me one day. Now, I am in great health, have managed to slim down to what I weighed in my 20’s, and am fitter than I have been in years. I’ve tried to convert many people, but so far have only succeeded with one friend. I hope to continue to pay forward the time that the Brisbane lady gave me at the airport one year ago and will chat to anyone in the street about vaping.

Example of experience from the United States

“I had been a pack-and-a-half a day smoker for 25 years, the majority of my life. I had tried to quit for about a third of that, using methods like the gums, but without success—I could only ever quit for a few days at most. In December of 2014 I first tried vaping, exploring a variety vaporizers and fluids. I cut my smoking down dramatically, and was a dual user for about a month and a half. On my birthday in the following January, I threw my cigarettes away by plan, and have been an EX-smoker for the many months since then.

on smokers and potential for harm and benefit. Addiction [Internet]. 2014 Aug 31 [\[link\]](#)

¹¹ Royal College of Physicians Harm reduction in nicotine addiction: help people who cannot quit, London 2007 [\[link\]](#)

¹² AussieVapers forum, Your story. Accessed 23 August 2015. [\[link\]](#)

¹³ Counterfactual. Vaping testimonies. clivebates.com. Updated May 2015. [\[link\]](#)

¹⁴ Consumer Advocates for Smoke-free Alternatives Association (CASAA), E-cigarette user testimonials. [\[link\]](#)

There is now every reason to encourage similar experiences in Malaysia, and no reason for the government to place obstacles in the way of smokers making the kinds of transformation described here. It would be counterproductive to prevent smokers who want to replicate this experience by denying them access, or forcing them to buy from black market or cross-border internet suppliers. It would be better for Malaysia and the region to have its own legitimate and properly regulated supply chain and to have responsible producers contributing corporate and sales taxes as appropriate.

2.5 Arguments against prohibition of e-cigarettes

The World Health Organisation was careful in its 2014 briefing on ENDS (Electronic Nicotine Delivery Systems)¹⁵ to avoid proposing prohibitions on ENDS. Instead, WHO stressed regulation rather than prohibition, and judged that:

ENDS, therefore, represent an evolving frontier, filled with promise and threat for tobacco control. Whether ENDS fulfil the promise or the threat depends on a complex and dynamic interplay among the industries marketing ENDS (independent makers and tobacco companies), consumers, regulators, policy-makers, practitioners, scientists, and advocates (1)

The citation (1) at the end of this specific statement by WHO refers to a commentary by Dr David Abrams, Executive Director of the Schroeder Institute for Tobacco Research and Policy Studies and Professor in the Department of Health, Behavior and Society at the Johns Hopkins Bloomberg School of Public Health writing in JAMA¹⁶. Abrams concludes:

The more appealing e-cigarette innovations become, the more likely they will be a disruptive technology. Although the science is insufficient to reach firm conclusions on some issues, e-cigarettes, with prudent tobacco control regulations, do have the potential to make the combusting of tobacco obsolete. Strong regulatory science research is needed to inform policy. If e-cigarettes represent the new frontier, tobacco control experts must be open to new strategies. Statements based on ideology and insufficient evidence could prevent the use of this opportunity before it becomes established as part of harm reduction strategy.

It is clear that the leading edge in tobacco control is not in prohibition of these products, but in working out how best to exploit the major opportunities while minimising any residual risks. In other words, tobacco control leadership means skilful design of regulation based on sound science and understanding of smokers' behaviour, not on ideological objections to nicotine use.

In May 2014, fifty-three experts in nicotine and tobacco science and policy wrote to Dr Margaret Chan, Director General of the WHO, to reinforce these points. They urged her organisation and the world community to take a positive approach to 'tobacco harm reduction' and to work towards exploiting the opportunities and to take a sceptical view of misleading scientific analysis^{17 18}.

¹⁵ World Health Organisation. Electronic Nicotine Delivery Systems: report by WHO. Report to the COP-6 of the FCTC. FCTC/COP/6/10 Rev.1 September 2014 [\[link\]](#)

¹⁶ Abrams DB. Promise and peril of e-cigarettes: can disruptive technology make cigarettes obsolete? JAMA. 2014 [\[link\]](#)

¹⁷ Statement from fifty three specialists in nicotine science and public health policy, Reducing the toll of death and disease from tobacco – tobacco harm reduction and the Framework Convention on Tobacco Control (FCTC). 26 May 2014 [\[link\]](#)[\[full context\]](#). A group of non-specialist activists and academics wrote a [response](#) - but this drew criticism

The potential for tobacco harm reduction products to reduce the burden of smoking related disease is very large, and these products could be among the most significant health innovations of the 21st Century – perhaps saving hundreds of millions of lives. The urge to control and suppress them as tobacco products should be resisted and instead regulation that is fit for purpose and designed to realise the potential should be championed by WHO.

2.6 Professional practice with e-cigarettes

E-cigarettes are largely a consumer and market based phenomenon and they work for public health by consumers choosing to use them instead of cigarettes – they do not require public spending or health care system resources. However, there is still a place for involvement of health professionals.

There is now recognition among tobacco control professionals and public sector practitioners that e-cigarettes can be used constructively to reduce harm. For example in Britain the National Centre for Smoking Cessation and Training and Public Health England, the government's public health agency, have developed evidence-based guidance for health professionals. It provides a clear and measured assessment of the state of science and best practice. It could be valuable to any country wishing to exploit the opportunities and minimise the risks¹⁹. This is a summary of the advice given to UK health professionals by the NCSCT and PHE:

Recommendations for practice

1. Be open to electronic cigarette use in people keen to try them; especially in those that have tried, but not succeeded, in stopping smoking with the use of licensed stop smoking medicines

2. Provide advice on electronic cigarettes that includes:

- Electronic cigarettes can provide some of the nicotine that would have otherwise been obtained from smoking regular cigarettes*
- Electronic cigarettes are not a magic cure, but some people find them helpful for quitting, cutting down their nicotine intake and managing temporary abstinence*
- There is a wide range of electronic cigarettes available and clients may need to try various brands, flavours and nicotine dosages before they find a brand that they like*
- Electronic cigarette use is not exactly like smoking and users may need to experiment and learn to use them effectively (e.g. longer 'drags' are required and a number of short puffs may be needed initially to activate the 'vapouriser' and improve nicotine delivery)*
- Although some health risks from electronic cigarette use may yet emerge, these are likely to be, at worst, only a small fraction of the risks of smoking. This is because electronic cigarettes do not contain combustion chemicals which cause lung and heart disease and cancer*

This is a balanced and open-minded approach, and reflects an emerging consensus on how to exploit the opportunities of e-cigarettes, while containing any risks.

from the original authors: *The importance of dispassionate presentation and interpretation of evidence*, for its misleading analysis [\[link\]](#).

¹⁸ McNeill A. et al A critique of a WHO-commissioned report and associated article on electronic cigarettes, *Addiction*, 2014. [\[link\]](#) Release: WHO commissioned report on e-cigarettes misleading say experts [\[link\]](#)

¹⁹ McRobbie H. McEwen A. (ed) E-cigarette briefing. National Centre for Smoking Cessation and Training, Public Health England. London, 2014 [\[link\]](#)

3 Controversies about e-cigarettes – what the evidence says

While the big picture is presented above, there are many controversies that emerge in the press or are promoted by activists. The discussion below picks up some of the most common arguments and misconceptions about e-cigarettes.

3.1 Toxicity of e-cigarette vapour

The presence of a toxin does not necessarily create a risk: for example coffee contains at least 19 carcinogens but does not cause cancer²⁰. What matters is *exposure* or to put it simply: ‘the dose makes the poison’. The concentrations of toxins or carcinogens in e-cigarette vapour are generally tens to thousands of times lower than in cigarette smoke. Many toxins are simply not present at detectable levels or equivalent to the tolerances allowed in medical products²¹. This is the reason why experts believe e-cigarettes to be at least 95% lower risk than smoking^{22 23}

From analysis of the constituents of e-cigarette vapour, e-cigarette use from popular brands can be expected to be at least 20 times safer (and probably considerably more so) than smoking tobacco cigarettes in terms of long-term health risk".

Many news reports have been generated by findings of minute quantities of contaminants that pose negligible risk, and without comparison with the much greater toxic exposure from smoking.

3.2 Formaldehyde exposure risk

A report published in the New England Journal of Medicine in January 2015²⁴ appeared to suggest that formaldehyde exposure from e-cigarettes could be 5-15 times higher than for cigarettes. The problem with this measurement was that it was conducted under conditions that no user would ever experience – so called dry puff conditions. Under these conditions the coil becomes hot and some thermal breakdown of the liquid takes place – creating formaldehyde. However, the taste becomes harsh and acrid, and the human user will stop vaping, change their puffing regime or adjust the settings on the device. The laboratory measurement machines are unable to replicate that human reaction. The measurements have been strongly criticised as unrealistic²⁵ and misleading. The study has even been compared to calculating the dietary risks from consuming a lifetime diet of *blackened toast*²⁶.

Despite world-wide alarming headlines generated by the misleading finding, the results published in the New England Journal actually provided support for e-cigarette safety: under normal operating conditions, there was no formaldehyde detected.

²⁰ Ames BN, Gold LS. The causes and prevention of cancer: the role of environment. *Biotherapy* [Internet]. 1998 Jan [cited 2014 Mar 16];11(2-3):205–20. [\[link\]](#)

²¹ Farsalinos KE, Polosa R. Safety evaluation and risk assessment of electronic cigarettes as tobacco cigarette substitutes: a systematic review (Studies on the safety/risk profile of ECs) *Therapeutic Advances in Drug Safety*, 2014 [\[link\]](#)

²² Hajek P. et al. Electronic cigarettes: review of use, content, safety, effects on smokers and potential for harm and benefit, *Addiction*, 2014 [\[link\]](#)

²³ West R. et al E-cigarettes - what we know so far, Briefing to the All Party Parliamentary Group, June 2014. [\[link\]](#)

²⁴ Jensen RP, Luo W, Pankow JF, et al. Hidden formaldehyde in e-cigarette aerosols. *N Engl J Med* 2015;**372**:392–4. doi:10.1056/NEJMc1413069 [\[link\]](#)

²⁵ Farsalinos KE, Voudris V Poulas K. (2015) E-cigarettes generate high levels of aldehydes only in ‘dry puff’ conditions. *Addiction***110**:10.1111/add.v110.8, 1352-1356 [\[link\]](#)

²⁶ Hajek P Commentary on Farsalinos et al . (2015): E-cigarettes do not expose users to dangerous levels of aldehydes. *Addiction* **110**:10.1111/add.v110.8, 1357-1358 [\[link\]](#)

3.3 Nitrosamines exposure risk.

Several studies have looked at nitrosamines in e-cigarette liquids and vapour. These have generally shown levels in e-cigarette *at least 1000 times lower* than in cigarette smoke, and at levels comparable to those found and permitted in medically licensed nicotine replacement therapies. Farsalinos and Polosa summarise the evidence as follows and in Table 3 of their 2014 review²⁷:

The estimated daily exposure to nitrosamines from tobacco cigarettes (average consumption of 15 cigarettes per day) is estimated to be up to 1800 times higher compared with e-cigarette use (Table 3):

Table 3. Farsalinos and Polosa (2014)

Levels of nitrosamines found in electronic and tobacco cigarettes. Prepared based on information from [Laugesen \[2009\]](#), [Cahn and Siegel \[2011\]](#) and [Kim and Shin \[2013\]](#).

Product	Total nitrosamines levels (ng)	Daily exposure (ng)	Ratio ⁴
Electronic cigarette (per ml)	13	52 ¹	1
Nicotine gum (per piece)	2	48 ²	0.92
Winston (per cigarette)	3365	50 475 ³	971
Newport (per cigarette)	3885	50 775 ³	976
Marlboro (per cigarette)	6260	93 900 ³	1806
Camel (per cigarette)	5191	77 865 ³	1497

¹Based on average daily use of 4ml liquid

²Based on maximum recommended consumption of 24 pieces per day

³Based on consumption of 15 cigarettes per day

⁴Difference (number-fold) between electronic cigarette and all other products in daily exposure to nitrosamines

These levels are so low that they do not cause concern in their own right (they are similar to nitrosamine level in medically approved NRT), but importantly, they are *very much lower* than in cigarette smoke – so a smoker who switches would see a very large reduction in exposure.

3.4 Nicotine safety

For *any* nicotine user, an e-cigarette product will be much less risky than continuing to smoke – and that applies to pregnant smokers and adolescents. The safety profile of nicotine has been well established through years of trials of nicotine replacement therapy, and more recently through the assessment of health risks from Swedish snus, which provides nicotine but without smoke. Nicotine is not a carcinogen or a cause of cardiovascular disease. There is also minimal risk of poisoning: recent analysis shows nicotine toxicity is perhaps 20 times lower than widely assumed and huge doses have been ingested without serious consequences²⁸. There is a simple protective measure available: to insist on child resistant packaging, for which there is an ISO standard²⁹.

²⁷ Farsalinos KE, Polosa R. Safety evaluation and risk assessment of electronic cigarettes as tobacco cigarette substitutes: a systematic review. *Ther Adv Drug Saf* 2014;5:67–86. [\[Link\]](#)

²⁸ Mayer B. How much nicotine kills a human? Tracing back the generally accepted lethal dose to dubious self-experiments in the nineteenth century. *Arch Toxicol* 2014; 88: 5–7. [\[link\]](#)

²⁹ ISO 8317 Child resistant packaging [\[link\]](#)[\[guide\]](#)

3.5 Nicotine and mental health

Though nicotine is the addictive agent in cigarettes, there is no evidence of significant harm arising from nicotine use, *per se*³⁰. There is some evidence that nicotine may have a positive effects – a short informal review by the French expert Jacques LeHouezec³¹ notes possible benefits in Parkinson's disease, Alzheimer's, schizophrenia and concludes that:

...the ability of nicotine to regulate mood and improve cognitive functioning, and acting as a strong reinforcer of tobacco dependence, is probably the motivation for its widespread use.

The most important health challenge is not necessarily to prevent people using nicotine, but to reduce the serious harm caused to those who do use it, mostly by smoking tobacco.

3.6 Concerns about accurate labelling of nicotine dose and impact on users

There are cases where the nicotine concentration is mislabelled. This is becoming rare as the industry matures and as manufacturers improve quality control in production facilities to meet consumer quality expectations and to prepare for more demanding regulation. From a health point of view it poses no risks. It does affect the user experience, but not that much: consumers adjust the depth and frequency of their puffs, or change temperature settings to regulate their intake of nicotine to achieve a satisfactory nicotine dose.

3.7 Second hand vapour exposure

Exposure to second hand cigarette smoke is thought to create risks of serious disease in bystanders and is a legitimate cause for restrictions on use in the workplace. E-cigarettes do not emit smoke because there is no combustion. Any toxins and nicotine in exhaled vapour are at extremely low levels compared to the side-stream and mainstream emissions from cigarettes. In his detailed review of the toxicity evidence, Igor Burstyn concluded that risks to active users were well below thresholds used to set workplace exposure standards and concluded that for passive vaping³²:

Exposures of bystanders are likely to be orders of magnitude less, and thus pose no apparent concern.

In the absence of material harm to bystanders there is no real case to use the law to ban vaping indoors, rather than to allow owners and managers to decide whether or not to allow it.

3.8 Particulates

Though particulates from diesel engines, power stations and cigarette smoke are harmful, it cannot be assumed that particles from e-cigarette vapour are harmful simply because they may be the same size. The aerosol particles in e-cigarette vapour do not have the same aggressive surface

³⁰ Farsalinos KE, Polosa R. Safety evaluation and risk assessment of electronic cigarettes as tobacco cigarette substitutes: a systematic review (Risk differences compared with conventional cigarettes and the issue of nicotine) *Therapeutic Advances in Drug Safety*, 2014 [\[link\]](#)

³¹ Le Houzec J. The positive effects of nicotine. *Nicotine Science and Policy*. 2014 [\[link\]](#)

³² Burstyn I. Peering through the mist: systematic review of what the chemistry of contaminants in electronic cigarettes tells us about health risks. *BMC Public Health*, 2014 [\[link\]](#)

chemistry and physics as smoke particles, which contains thousands of products of combustion. The size of the particles is of little importance if they are not actually toxic³³.

3.9 Evidence of effectiveness

There are now millions of ex-smokers who use e-cigarettes or smokeless tobacco. For example in Britain, there are 2.6 million e-cigarette users of which 1 million are ex-smokers³⁴. They are not using e-cigarettes as a smoking cessation treatment, but as a relatively low risk alternative to harmful smoking as way of consuming nicotine. The authoritative Cochrane Review has published its first report e-cigarette trials. This suggests that, on the limited data available, vapour products are likely to be effective for smoking cessation³⁵.

There is evidence from two trials that e-cigarettes help smokers to stop smoking long-term compared with placebo e-cigarettes.

Note that e-cigarettes work by replacing the consumer smoking habit, rather than as a traditional medical intervention, and involve experimentation, learning and changing habits. For this reason, randomised controlled trials can only provide limited insights. Most studies have therefore been *observational*, rather than trials, and have generally shown success with e-cigarettes. For example, one of the best-designed observational studies found³⁶:

People attempting to quit smoking without professional help are approximately 60% more likely to report succeeding if they use e-cigarettes than if they use willpower alone or over-the-counter nicotine replacement therapies.

3.10 Gateway effect and renormalisation: unfounded

There is no evidence anywhere in the world supporting a 'gateway effect' in which low risk products such as e-cigarettes cause people who would not have smoked to become cigarette smokers. Generally we have seen declines in teenage smoking accompany any rise in e-cigarette use and e-cigarette use highly concentrated among smokers. It is likely that e-cigarette use is an *alternative* to smoking in young people who would otherwise have started to smoke - and thus have a protective effect. Longer-term data are needed but there is no basis to draw any conclusion that use of e-cigarettes leads to an increase in smoking.³⁷ Professor Linda Bauld of the leading expert in cancer prevention at the major research charity Cancer Research UK summarised the evidence in August 2015³⁸:

³³ Bates C. Scientific sleight of hand: constructing concern about 'particulates' from e-cigarettes. *Counterfactual blog*. 2014 [\[link\]](#)

³⁴ Action on Smoking and Health (ASH), Use of electronic cigarettes (vapourisers) among adults in Great Britain, London, May 2015 [\[link\]](#)

³⁵ McRobbie H. et al. Electronic cigarettes for smoking cessation and reduction. *Cochrane Database of Systemic Reviews*, 2014 [\[link\]](#)

³⁶ Brown J et al. Real-world effectiveness of e-cigarettes when used to aid smoking cessation: a cross-sectional population study, *Addiction*, May 2014 [\[link\]](#) Press Release: E-cigarettes can help smokers quit, new research shows [\[link\]](#)

³⁷ Abrams DB, Niaura R. The importance of science-informed policy and what the data really tell us about e-cigarettes. *Israel Journal of Health Policy Research*, 2015 [\[link\]](#)

³⁸ Cited in: Public Health England. E-cigarettes around 95% less harmful than tobacco estimates landmark review. [\[link\]](#) 19 August 2015.

Fears that e-cigarettes have made smoking seem normal again or even led to people taking up tobacco smoking are not so far being realised based on the evidence assessed by this important independent review. In fact, the overall evidence points to e-cigarettes actually helping people to give up smoking tobacco.

If there are people or organisations that are claiming a much safer product will somehow cause harm to health, it is their responsibility to show this is really happening, not for others to prove that it is not. There is no evidence anywhere that e-cigarettes are causing harm or increasing smoking.

4 How to regulate e-cigarettes

4.1 Regulation as a poison

There is no case to apply poisons legislation to e-cigarettes or e-liquids. At the nicotine concentrations used in retail devices and liquids (0-3.6%) these do not present a significant hazard that cannot be addressed with the same approach as any other chemical present in the home. As an example, UK legislation sets a 7.2% (72mg/ml) threshold for definition of nicotine liquids as poisons – primarily for use as pesticides.

4.2 Regulation as medicines

There is no case to regulate these products as medicines, because they are not medicines and the application of medicines regulatory is a highly expensive and burdensome regime that would have the effect of providing a regulatory protection to the cigarette trade and favouring large tobacco companies in the e-cigarette market³⁹. For these reasons, the approach of using medicines regulation was rejected in 2013 by the European Union legislature⁴⁰ and rejected by the courts in the United States and several EU member states.

4.3 Regulation as consumer products

E-cigarettes are consumer products that compete with and displaced cigarettes in the market for recreational nicotine use. This market is worth \$800 billion worldwide and dominated by the cigarette trade. The e-cigarette trade is worth \$6.5 billion but growing at more than 50% per annum. A careful regulator will ensure regulation is proportionate to risk, and does not favour the more risky product. To that end, a sound regulatory regime for e-cigarettes would include the following:

- Standards for liquids such as use of pharma grade ingredients and food grade flavours
- Standards for devices – including electrical and thermal safety and material leaching
- True and fair information about the product ingredients and sell by date
- Proportionate warnings and consumer messages
- Controls on marketing and retailing to ensure products are targeted at adult smokers
- Child-resistant containers for liquids
- Stewardship requirements – like responsible person and means to recall

³⁹ Bates C, Stimson G. Costs and burdens of medicines regulation for e-cigarettes, September 2013 [\[link\]](#)[\[context\]](#)

⁴⁰ Bates C, 10 reasons not to regulate e-cigarettes as medicines. Counterfactual June 2013. [\[link\]](#)

5 Conclusion – towards a credible endgame for tobacco related disease

The only thing really threatened by e-cigarettes is smoking and the manufacture, import and sale of *cigarettes*. To prohibit e-cigarettes when they compete with cigarettes but have far lower risk to the user would be an unscientific, unethical and a lethal error based on current evidence. Derek Yach, the former WHO Director for tobacco policy who led development of the global Framework Convention on Tobacco Control, summarises this perspective⁴¹

At the moment, it's estimated that there will be a billion tobacco-related deaths before 2100. That is a dreadful prospect. E-cigs and other nicotine-delivery devices such as vaping pipes offer us the chance to reduce that total. All of us involved in tobacco control need to keep that prize in mind as we redouble efforts to make up for 50 years of ignoring the simple reality that smoking kills and nicotine does not.

The science shows that Dr Yach is correct in this assessment, and that the opportunities from e-cigarettes far outweigh any conceivable risks. The main risks in relation to e-cigarettes arise from excessively restrictive policy positions or prohibition: these will have the affect of causing more smoking, ill-health and unhappiness than there would otherwise be.

6 About the author

Clive Bates runs Counterfactual, a public interest consulting and advocacy organisation focussed on a broad approach to sustainability, policy-making for the long term and good governance. He was formerly a senior civil servant and Director of Action on Smoking and Health (London) as well as a founder of the NGO Framework Convention Alliance, set up to support the development of the WHO Framework Convention on Tobacco Control. He has been a long-term advocate of tobacco harm reduction^{42 43 44}, a critic of the public health establishment approach to harm reduction⁴⁵ and wrote about the policy challenge of products like e-cigarettes well before they were invented⁴⁶.

Disclaimer. Views expressed in this brief do not necessarily reflect the views of former employers or affiliates. Clive Bates has no competing interests with respect to tobacco, pharmaceutical or e-cigarette industries.

⁴¹ Yach D. E-cigarettes save lives. Commentary in The Spectator. February 2015 [\[link\]](#)

⁴² Bates C, Fagerström K, Jarvis MJ, *et al.* European Union policy on smokeless tobacco: a statement in favour of evidence based regulation for public health. *Tob Control* 2003;**12**:360–7. [doi:10.1136/tc.12.4.360](https://doi.org/10.1136/tc.12.4.360)

⁴³ McNeill A, Foulds J, Bates C. Regulation of nicotine replacement therapies (NRT): a critique of current practice. *Addiction* 2001;**96**:1757–68. [doi:10.1080/09652140120089508](https://doi.org/10.1080/09652140120089508)

⁴⁴ Bates C. Taking the nicotine out of cigarettes--why it is a bad idea. *Bull World Health Organ* 2000;**78**:944. [\[link\]](#)

⁴⁵ Bates C. Flaw in WHO Framework Convention on Tobacco Control: letter identified wrong problem with the framework convention. *BMJ* 2004;**328**:1320. [doi:10.1136/bmj.328.7451.1320](https://doi.org/10.1136/bmj.328.7451.1320)

⁴⁶ Bates C. What is the future for the tobacco industry? *Tob Control* 2000;**9**:237–8. [doi:10.1136/tc.9.2.237](https://doi.org/10.1136/tc.9.2.237)