



A critique of the Australian National Health and Medical Research Council CEO statement on electronic cigarettes

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Abstract

This paper critically analyses a statement by Australia's National Health and Medical Research Council (NHMRC) on e-cigarettes in May 2022 that will be used to guide national policy. We reviewed the evidence and the conclusions drawn in the NHMRC Statement. In our view, the Statement is not a balanced reflection of the benefits and risks of vaping because it exaggerates the risks of vaping and fails to compare them to the far greater risks of smoking; it uncritically accepts evidence of harms from e-cigarettes while adopting a highly sceptical attitude towards evidence of their benefits; it incorrectly claims that the association between adolescent vaping and subsequent smoking is causal; and it understates the evidence of the benefits of e-cigarettes in assisting smokers to quit. The Statement dismisses the evidence that vaping is probably already having a positive net public health effect and misapplies the precautionary principle. Several sources of evidence supporting our assessment were published after the NHMRC Statement's publication and are also referenced. The NHMRC Statement on e-cigarettes does not present a balanced assessment of the available scientific literature and fails to meet the standard expected of a leading national scientific body.

KEYWORDS

E-cigarette, nicotine, public health, smoking, tobacco treatment, vaping

INTRODUCTION

The Chief Executive Officer (CEO) of Australia's peak health and medical research organization, the National Health and Medical Research Council

(NHMRC), published a statement on e-cigarettes in June 2022 (the 'Statement') [1]. In our view, the Statement fails to meet the high scientific standard expected of a leading national scientific body because it confuses association with causation; it uncritically accepts evidence of

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harms while adopting a highly sceptical attitude towards evidence of benefits; and inappropriately applies the precautionary principle.

The Statement ignores evidence-based reports by the UK Royal College of Physicians, Public Health England and the UK National Institute for Health and Care Excellence, all of which arrived at very different conclusions on the risks and benefits of e-cigarettes [2–4]. It is also inconsistent with the findings of a systematic review commissioned by the Office of Health Information and Disparities (OHID) in the English government and the 2022 Cochrane Review [5, 6]. Both of these were published after the Statement, but each reviewed evidence available to the NHMRC. The Statement relies heavily upon an analysis by the National Centre for Epidemiology and Public Health at the Australian National University, which commits multiple inferential errors [7, 8].

In this paper, we focus upon the more serious flaws in the Statement. No new or unpublished data were provided for this critique.

RELATIVE SAFETY OF E-CIGARETTES

“All e-cigarette users are exposed to chemicals and toxins that have the potential to cause adverse health effects”; “Recent reports have found over 200 unique chemicals used in e-liquids” (page 3)

In the absence of quantification of the dose of these chemicals, these claims are misleading [9]. In fact, most of the chemicals in the vapour are at low or trace doses and below known thresholds for harm to health [10, 11].

A relative risk assessment is critically important for smokers who use vaping as a substitute for cigarette smoking. The Statement fails to compare the number, amount and toxicity of ingredients in vapour to those in tobacco smoke and hence fails to make clear that smokers are exposed to particulate matter and many more toxicants and carcinogens at far higher doses than e-cigarette users [5, 12].

“Due to limited long-term evidence, it is difficult to assess the relative harms and benefits of using e-cigarettes compared with smoking tobacco cigarettes” (page 4)

A dose–response relationship exists between exposure to toxicants from tobacco smoking and disease risk and is probably the same for vaping [13]. There are substantially fewer harmful and potentially harmful chemicals (HPHCs) in vapour compared to smoke, and at lower concentrations, although there is wide variability between devices [11, 14, 15].

Levels of biomarkers of exposure to HPHCs are significantly lower in former smokers who vape. A review of nine studies of a wide range of biomarkers (published after the NHMRC Statement) concluded that ‘exclusive EC (e-cigarette) use was associated with lower levels of biomarkers of harm than exclusive use of combustible tobacco, or than dual use’ [16].

Exposure to carcinogens is substantially reduced after smokers switch to vaping [5]. Based on the level of carcinogens and their potency, the life-time cancer risk from vaping has been estimated as less than 0.5% of the risk from smoking [17].

Clinical trials and surveys of smokers who completely switched to e-cigarettes have shown short- to medium-term improvements in asthma [18], chronic obstructive pulmonary disease (COPD) [19], blood pressure [20, 21], muco-ciliary clearance [22], respiratory infections [23], lung function [24], respiratory symptoms [25, 26], cardiovascular markers [27, 28] and gum disease [29]. These changes are in the direction of less impairment and are likely to persist over the longer term.

Leading health and government organizations have concluded that, while the long-term risk of using e-cigarettes will not be fully known for many decades, it is highly likely to be far less harmful than smoking [2, 5, 30–34]. In addition, the dose–response relationship between levels of toxicant exposure and smoking-related disease, biomarker data and clinical studies suggests a benefit of using e-cigarettes compared to smoking.

In the absence of long-term data, modelling studies are a well-accepted way of estimating the population impact of an intervention. Numerous modelling studies suggest that using nicotine e-cigarettes to quit smoking has a net public health benefit under all plausible scenarios [35, 36] and would do so even if it generated 20% of the harm of smoking [37].

The requirement for policy to wait for evidence of long-term safety is not applied to many other medical interventions. A contemporary example is the process used for making COVID vaccines available [38]. Nicotine vaping devices have been used by millions of consumers for far longer than many approved medicines or consumer products. Some ex-smokers have used them for more than a decade and, to date, reports of serious adverse effects are extremely rare [3, 5].

“E-cigarettes have been reported to overheat, catch fire or explode and there is high certainty of evidence that in these cases e-cigarettes cause serious burns and injuries, although this is not common. In some cases, these events have resulted in death, life-threatening injury, permanent disfigurement or disability and major property damage.” (page 4)

Lithium-ion batteries are present in many different consumer products and can cause serious injuries if they ignite or explode. However, this statement exaggerates the risk. Since e-cigarettes were introduced there have only been two deaths reported globally from battery explosions [39, 40].

According to Public Health England, the risk of fire from e-cigarettes ‘appears to be comparable to similar electrical goods’ [41]. Between 2017 and 2021, the London Fire Brigade reported that there were 5076 fires caused by cigarettes and cigarette lighters and 15 fires caused by vaping products, and no fire-related injuries or fatalities in London [5], although by 2021 more than half as many people vaped as smoked in the United Kingdom (7.7 versus 13.3%) [42].

“There is high certainty of evidence from case reports, surveillance reports and case studies that e-cigarette use can lead to seizures” (page 4)

A small number of case studies have reported seizures in people using nicotine e-cigarettes, but these cases do not establish causation and hence do not qualify as ‘high-certainty’ evidence [43]. Many of these cases had a pre-existing seizure disorder, and some had used other drugs [44]. If nicotine e-cigarette use was a cause of seizures, an association between cigarette smoking and seizures would also be expected—but none has been reported.

“There is also high certainty of evidence that intentional or accidental ingestion of nicotine e-liquids can result in poisoning (via nicotine toxicity) which, although not common, can be severe and even fatal” (page 4)

This statement overstates the risks of nicotine poisoning. Overdosing from nicotine e-liquids is rare and usually results in minor symptoms of short duration [31]. E-cigarettes and nicotine accounted for only 0.015% of all calls to Australian Poisons Centres from 2009 to 2016 [45]. Most of these cases had mild, self-limiting symptoms. There were no cases with severe symptoms and no deaths.

The OHID systematic review (published after the NHMRC Statement) identified 22 studies reporting data concerning poisonings related to vaping products [5]. Most involved young children accidentally swallowing e-liquid, including two fatalities. Where exposure was intentional among adults there were reports of 17 deaths. Most accidental poisoning cases were preventable, underscoring the importance of child-proof packaging and safety warnings [5, 46].

“There is high certainty of evidence that e-cigarette use by smokers and never smokers can result in E-cigarette or Vaping Associated Lung Injury (EVALI)” (page 4)

There is no ‘high-certainty’ evidence that nicotine vaping is a cause of EVALI, a serious and sometimes fatal lung condition [47]. The outbreak of EVALI in North America in 2019 was strongly linked to vitamin E acetate (VEA), a contaminant added to illicit tetrahydrocannabinol (THC) vaping oils [48]. VEA is converted at high temperatures to ketene, which is toxic to the lungs. When VEA was removed from the illicit supply chain, EVALI disappeared in early 2020 and no further cases were reported, despite the fact that nicotine vaping continued to be widespread [48]. Some EVALI patients denied vaping THC but vaped nicotine, raising concerns that nicotine vaping was a possible cause. However, no potential causal agent has been identified in nicotine vapes. Furthermore, VEA is not soluble in nicotine e-liquids [49] and has never been detected in them.

Two recent Australian cases of severe acute respiratory distress syndrome (ARDS) have been attributed to nicotine vaping despite neither meeting the EVALI case definition because the authors failed to exclude other plausible diagnoses [50]. In one case, a young woman had a history of urosepsis and polydrug use that could have produced her respiratory symptoms [51, 52]. The other case, an older male, had a long history of heavy tobacco smoking and COPD that preceded his e-cigarette use. His condition was due more probably to an infection related to COPD [53].

“diacetyl and acetylpropionyl are known to cause irreversible lung damage” (page 5)

This alarming statement is seriously misleading. Diacetyl and acetylpropionyl are flavouring agents that are rarely used and are now banned in Australia [46]. Prolonged exposure to high doses of diacetyl in popcorn-microwave factory workers has been associated with a severe lung disease, bronchiolitis obliterans, also known as ‘popcorn lung’ [54]. However, there has never been a case of this condition reported from using nicotine e-cigarettes nor from cigarette smoking, which delivers diacetyl levels hundreds of times higher than those in nicotine vapour [55, 56].

TOBACCO SMOKING CESSATION

“E-cigarettes are not proven ... effective cessation aids” (page 8)

The Statement uses differing standards of evidence in assessing the effectiveness of different methods of smoking cessation. For example, it concludes that nicotine replacement therapy (NRT) and pharmaceuticals are effective, based on evidence from randomized controlled trials (RCTs) of short duration in clinical populations seeking assistance to quit. However, the Statement discounts the same type of evidence for the effectiveness of e-cigarettes.

The Statement describes the evidence as of ‘low certainty’. However, the evidence is accumulating and continues to strengthen. The 2022 Cochrane Review (published after the NHMRC Statement) concluded that ‘there is high-certainty evidence that ECs with nicotine increase quit rates compared to NRT’ [relative risk (RR) = 1.63, 95% confidence interval (CI) = 1.30–2.04] and that ‘in absolute terms, this might translate to an additional four quitters per 100 (95% CI = 2–6)’ [6]. Other meta-analyses report that electronic cigarettes are superior to NRT, although their authors differ in their confidence in the results [57–60].

A recent network meta-analysis of 171 RCTs of all smoking cessation medications published after the Statement concluded that vaping was the most effective monotherapy, followed by varenicline and NRT [61].

Observational evidence suggests that people who smoke are more likely to quit successfully using with modern devices than with the cig-a-like devices used in earlier studies [62, 63]. In other studies,

smokers who did not intend to quit smoking did so after trying vaping [64, 65]. These ‘accidental quitters’ are not included in conventional RCTs.

The Statement also dismisses supportive evidence of the effectiveness of vaping from UK stop smoking services [5], observational studies [66–68], population studies [69, 70] and declines in national smoking rates [42, 71]. While these studies cannot prove causality, their results are consistent with those of RCTs. The ‘triangulation’ of evidence from different study types adds strength to causal inferences since their results point to the same conclusion [72, 73].

“In smokers randomised to nicotine e-cigarettes, dual use was more common than quitting at trial completion” (page 9)

The Statement raises concerns about dual use (concurrent smoking and vaping) in a large RCT by Hajek at study completion [26]. Dual users are a heterogeneous group, consisting of predominant smokers, dual daily users and predominant vapers [74]. Only dual users with sustained daily smoking and vaping are of potential concern, but the frequency of smoking and vaping are not mentioned in the paper or supplementary materials.

Dual use is very likely to be less harmful than exclusive smoking, as most dual users who are trying to quit titrate their nicotine intake and substantially reduce smoking [75]. A significant proportion of dual users in the Hajek study (44 of 345) reduced their smoke intake by at least 50% [26]. Significantly lower levels of biomarkers of exposure in dual users compared to exclusive smokers have been demonstrated when smoking is reduced [16, 75, 76].

Dual use with e-cigarettes is a transitional phase for many smokers, just as it is with NRT. Many vapers initially experiment with different devices and learn how to use them over time, and many dual users go on to quit smoking or vaping or both completely [77]. Many studies show improved clinical outcomes from dual use, such as reduced blood pressure [21] and improved asthma control [78].

TOBACCO SMOKING UPTAKE

“the evidence suggests that e-cigarette use leads to tobacco cigarette uptake” (page 8)

There is no convincing evidence that e-cigarette use is a gateway to smoking. There is an association between vaping and cigarette smoking, but weak evidence that this is a causal relationship. A more plausible explanation is that young people who engage in one form of risky behaviour, such as vaping, are more likely to engage in other risky behaviours such as smoking, hazardous alcohol consumption and illicit drug use [79]. Shared risk factors for vaping and smoking such as genetic factors [80] and environmental, psychological and social causes [81] create a ‘common liability’ for risk-taking [82]. More rigorous prospective studies that adjust for a wide range of common risk

factors for smoking and vaping (confounders) have found that the association largely disappears [83, 84].

The gateway hypothesis also predicts that an increase in the uptake of e-cigarettes among youth will be followed by an increase in cigarette smoking at a population level. Contrary to this prediction, increases in youth vaping have been accompanied by declines in youth and young adult smoking rates in the United Kingdom, the United States and New Zealand [85–87]. The rate of decline also appears to have accelerated from the time that vaping became popular. Population surveys also suggest that vaping is more likely to divert young people from smoking, rather than to encourage them to smoke [88–90].

Most vaping by never-smokers is experimental, and transient and regular vaping is rare [87, 91, 92]. There is also some evidence that vaping first (before trying smoking) reduces the risk of becoming a smoker [93]. Importantly, it does not appear that youth vaping leads to sustained cigarette use, which is the major public health concern [85, 89, 90, 94].

PUBLIC HEALTH IMPACT

“Although tobacco smoking rates have declined ... there is no evidence that this is a result of increased e-cigarette use” (page 8)

Population studies suggest that e-cigarettes increase the rate of quit attempts and quitting success compared to not using an e-cigarette. In the United Kingdom, the United States, New Zealand and other countries where vaping rates are higher than in Australia, the decline in smoking rates has accelerated since vaping became widely available and the rate of decline is faster than in Australia [42, 86, 95–98]. The decline in smoking has many causes, but vaping appears to be making a significant contribution.

A recent Australian population-based study found that vaping during a smoking cessation attempt was associated with greater success compared to not using e-cigarettes [69].

In a large representative sample in the United States, ‘e-cigarette use was associated with an increase in smoking cessation at the population level’ [70]. In two large US population studies, current e-cigarette use was associated with increased past 12-month quit attempts and successful smoking cessation among established smokers [99].

In England, the Smoking Toolkit Study shows a clear association between the prevalence of e-cigarette use and changes in population quitting rates after adjusting for a range of potential confounders [100]. Beard estimated that, in 2017, an additional 50–70 000 smokers in England stopped smoking by using a vaping product who would otherwise have continued to smoke [101].

After vaping nicotine was legalized in New Zealand in August 2020, there was a rapid increase in adult daily vaping from 3.5 to 6.1% from 2021 to 2022, associated with an unprecedented 33% decline in adult daily smoking from 11.9 to 8% [86].

The population impact of an intervention is a function of its effectiveness as well as its reach [102]. Vaping is the most popular aid for

quitting or reducing smoking in Australia [95], the United States [103] and England [100]. Because of its proven effectiveness and wide reach, vaping is likely to have a greater population effect than any cessation therapy.

A modelling study (published after the NHMRC Statement) examined the impact of relaxing nicotine vaping regulations in Australia, so vaping products were as widely and legally accessible as in the United States [104]. Assuming an excess risk of vaping of 5% that of smoking, the study estimated that 104 200 smoking- and vaping-attributable deaths (SVADs) and 2.05 million life-years lost (LYLs) would be averted during 2017–80. Assuming a 40% excess risk, an estimated 70 000 SVADs and 1.2 million LYLs would be averted.

THE PRECAUTIONARY PRINCIPLE

“Given that e-cigarettes are relatively new products, the impact of nicotine e-cigarette use on most clinical outcomes is unknown. ... a precautionary approach to e-cigarettes, particularly among never smokers, remains appropriate” (page 5)

Invoking the precautionary principle to prevent the use of much less harmful smoke-free products is unjustified in the face of the massive burden of smoked tobacco products [105]. In Australia, up to two-thirds of deaths in current smokers can be attributed to smoking [106].

The precautionary principle requires policymakers to compare the risks of introducing a product with the risks of delaying its introduction. In the case of vaping, the relatively small risks of harm will be outweighed by the far more substantial harms from delaying access to current smokers. The precautionary principle is inappropriately applied in these circumstances [107].

Further studies of daily vaping for 2 years or more are needed to more precisely define the long-term risk. However, in the absence of conclusive long-term evidence of harms, the future population impact of vaping can be estimated with modelling studies. The majority of such studies, especially the more rigorously designed and conducted studies, have concluded that the public health benefits of vaping are considerably greater than the risks, even when modelling the impact of significant increases in youth vaping [35–37].

CONFLICTS OF INTEREST

“It is also important to consider whether the authors of the research had any conflicts of interest that could bias their findings or whether the research was funded by an organisation with a financial interest in the outcomes” (page 10)

Funding by the vaping and tobacco industries is not the only way in which statements on e-cigarettes can be biased.

Public health advocates who have opposed the introduction of e-cigarettes can be biased in their interpretation of the evidence in support of their predetermined policy position. It is important to note that three members of the NHMRC Electronic Cigarette Working Committee have published papers opposing vaping and have established views that can influence the interpretation of the data [108]. Other members of the committee represent organizations that have made strong public anti-vaping statements.

CONCLUSION

The Statement on e-cigarettes by the CEO of the NHMRC has selectively cited evidence in support of its 2017 Statement rather than objectively evaluating this position in the light of research published since that date [109]. The Statement exaggerates the risks of vaping and fails to compare them to smoking; incorrectly claims that the association between adolescent vaping and subsequent smoking is causal and discounts evidence of the benefits of e-cigarettes in assisting smokers to quit. The Statement dismisses the evidence that vaping is probably already having a positive net public health effect, and misapplies the precautionary principle.

Many of the leading scientists in the field internationally hold more supportive views on the potential of e-cigarettes as a strategy for tobacco control [110]. An independent and impartial Australian review of the evidence is required.

DECLARATION OF INTERESTS

C.P.M. was an unpaid board member of the Australian Tobacco Harm Reduction Association (ATHRA), a registered health promotion charity, from October 2017 to January 2021. ATHRA accepted unconditional seed funding from the vape retail industry to become established. Funding ceased in March 2019. C.P.M. was a Director of ATHRA in March 2018 when it received a donation from KAC Communications. The donation was sourced from a surplus arising from the Global Forum on Nicotine conference in May 2017. C.P.M. is the author of *Stop Smoking Start Vaping*, published by Aurora Press. C.P.M. has never received payments from electronic cigarette or tobacco companies. A.W. has been an unpaid board member of the Australian Tobacco Harm Reduction Association (ATHRA), a health promotion charity, since October 2017. ATHRA received unconditional funding for establishment costs from small Australian vape businesses. Vape industry funding has not been accepted since March 2019. A.W. was a Director of ATHRA in March 2018 when it received a donation from KAC Communications. The donation was sourced from a surplus arising from the Global Forum on Nicotine conference in May 2017. A.W. has never received payments from electronic cigarette or tobacco companies. N.L.B. is consultant to pharmaceutical companies that market or are developing smoking cessation medications and is an expert witness in litigation against tobacco companies. C.B. is the lead investigator and recipient of research contracts from the NZ Ministry of Health on tobacco cessation and tobacco control in New Zealand; a co-investigator on grants funded by the NZ Health Research

Council; and is a Board member and President-Elect of the Society for Research on Nicotine and Tobacco. C.B. received payment for a consultancy to J&J Japan on nicotine replacement therapy, in 2019. N.A. R. has received no funding (current or past) from e-cigarette or tobacco companies. N.A.R. is a consultant for, and her institution has received research funding from, Achieve Life Sciences for an investigational smoking cessation pharmacotherapy. All other authors have no conflicts of interest to declare.

AUTHOR CONTRIBUTIONS

Colin P. Mendelsohn: Conceptualization-lead; formal analysis-lead; project administration-lead; supervision-lead; writing – original draft-lead. **Wayne Hall:** Writing—review and editing. **Ron Borland:** Writing—review and editing. **Alex Wodak:** Conceptualization; writing—review and editing. **Robert Beaglehole:** Writing—review and editing. **Neal L. Benowitz:** Writing—review and editing. **John Britton:** Writing—review and editing. **Chris Bullen:** Writing—review and editing. **Jean-François Etter:** Writing—review and editing. **Ann McNeill:** Writing—review and editing. **Nancy A. Rigotti:** Writing—review and editing.

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