











POSITION STATEMENT

Electronic cigarettes: A position statement from the Thoracic Society of Australia and New Zealand*

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ABSTRACT

The TSANZ develops position statements where insufficient data exist to write formal clinical guidelines. In 2018, the TSANZ addressed the question of potential benefits and health impacts of electronic cigarettes (EC).

The working party included groups focused on health impacts, smoking cessation, youth issues and priority populations. The 2018 report on the *Public Health Consequences of E-Cigarettes* from the United States NASEM was accepted as reflective of evidence to mid-2017.

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*This document was endorsed by the Thoracic Society of Australia and New Zealand (TSANZ) Board in February 2020 after external review.

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Handling Editors: Philip Bardin and Paul Reynolds

A search for papers subsequently published in peer-reviewed journals was conducted in August 2018. A small number of robust and important papers published until March 2019 were also identified and included. Groups identified studies that extended, modified or contradicted the NASEM report. A total of 3793 papers were identified and reviewed, with summaries and draft position statements developed and presented to TSANZ membership in April 2019. After feedback from members and external reviewers, a collection of position statements was finalized in December 2019. EC have adverse lung effects and harmful effects of long-term use are unknown. EC are unsuitable consumer products for recreational use, part-substitution for smoking or long-term exclusive use by former smokers. Smokers who require support to quit smoking should be directed towards approved medication in conjunction with behavioural support as having the strongest evidence for efficacy and safety. No specific EC product can be recommended as effective and safe for smoking cessation. Smoking cessation claims in relation to EC should be assessed by established regulators.

Key words: e-cigarettes, public health, smoking cessation, tobacco control, vaping.

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INTRODUCTION

Electronic cigarettes (e-cigarettes) are battery-operated devices which contain a heating element that vaporizes liquid solution. The user inhales or 'vapes' the aerosol produced through heating the liquid. E-cigarettes are also referred to as electronic nicotine delivery systems (ENDS) or electronic non-nicotine delivery systems (ENNDS) when they do not use nicotine-based solutions.

The liquid solution used in e-cigarettes contains propylene glycol and/or glycerine liquid to create the aerosol.¹ The solution often contains flavourants and ENDS solutions contain nicotine.

Early attempts to develop e-cigarettes date to the 1960s, but the first device of the modern era was patented in 2003. E-cigarettes have been widely marketed since about 2006. Use of an e-cigarette is commonly termed 'vaping'.

Tobacco smoking in Australia and New Zealand

The advent of e-cigarettes has occurred after sustained success in reducing tobacco smoking rates in Australia and New Zealand.

Australia has led the world in implementing tobacco control measures including substantial increases in excise on tobacco products; education programmes; bans on smoking in indoor and, increasingly, outdoor public places; plain packaging of tobacco products; bans on retail displays of tobacco products; labelling with updated and larger graphic health warnings; prohibiting tobacco advertising, promotion and sponsorship; and providing support for smokers to quit including subsidized nicotine replacement therapy.²⁻⁵ The rates of regular smoking in Australia (that is either daily or at least weekly) have reduced from 27% in 1995 to 14% in 2016.⁶

Smoking rates in New Zealand Aotearoa are also reducing, with 12.5% of adults currently smoking daily compared to 25% in 1996-1997.⁷ In 2011, the New Zealand Government set a goal of Smokefree Aotearoa 2025, aiming to reduce smoking prevalence and tobacco availability to minimal levels and make New Zealand essentially a smoke-free nation by 2025.⁸ Strategies have included protecting children from exposure to tobacco marketing and promotion; reducing the supply of, and demand for, tobacco; and providing the best possible support for quitting.

Smoking by young people has fallen markedly. Smoking rates among young Australians aged 16-17 years declined from 30% in 1999 to 10% in 2014, while among those aged 12-15 years, the smoking rate declined from 15% to 3% during the same period.⁹ The prevalence of smoking among Australian teenagers in 2014 was at its lowest since surveys began more than 30 years earlier. Similar improvements have been achieved in New Zealand, where only 3% of young people aged 15-17 years smoked in 2017-2018, down from 16% in 2006-2007 and the daily smoking rate for 14- and 15-year olds fell to 2.1%, the lowest ever recorded.⁷

Harmful effects of smoking

There is no dispute about the harmful effects and significant costs of tobacco smoking. Smoking causes the premature deaths of two-thirds of its long-term users.¹⁰ Respiratory diseases, notably lung cancer and chronic obstructive pulmonary disease (COPD), dominate as causes of smoking-associated disability and premature mortality in both Australia and New Zealand.

In 2015-2016, the costs of smoking in Australia were estimated at \$136.9 billion and smoking was responsible for 20 032 premature deaths and approximately 1.7 million hospitalizations.¹¹ In New Zealand, approximately one person dies from smoking every 2 hours, while in Australia approximately one person dies from smoking every half an hour.^{12,13}

These harmful effects continue to occur despite the significant success in reducing rates of tobacco smoking in Australia and New Zealand, and it is imperative this progress continues. In recent years, the emergence of e-cigarettes has prompted discussion about whether these

devices have a role in supporting smokers to quit or in reducing smoking prevalence rates.

Purpose of this position paper

The Thoracic Society of Australia and New Zealand (TSANZ) position papers reflect the position of the TSANZ where there are insufficient data to support a formal clinical guideline (particularly in areas of public health policy). In contrast to position papers, the TSANZ's guidelines must provide evidence-based recommendations for clinical practice, require a systematic review of the literature and use GRADE levels of evidence.

The TSANZ determined that a position paper was required on e-cigarettes, given the rapidly emerging research in this area, the recognition that the health effects of e-cigarettes are likely to only become fully understood over time and the scant evidence for their use in smoking cessation. This position paper was completed in accordance with the TSANZ requirements for the development of position papers as detailed in the TSANZ publication policy.

The TSANZ is dedicated to ensuring that Australian and New Zealand governments maintain their commitment to reducing smoking prevalence and to the implementation of comprehensive tobacco control measures that include population-wide strategies coupled with individual behavioural support, particularly for groups of people in whom smoking rates have not declined as quickly as they have in others. The TSANZ is committed to preventing and relieving the disability caused by lung disease. Consequently, we are steadfast in our aim to help people stop smoking completely. E-cigarettes are therefore of considerable interest to the TSANZ as we seek to further reduce the morbidity and mortality associated with lung disease. The purpose of this position paper is to outline the TSANZ's position with respect to e-cigarettes. The intended audience is both clinical and non-clinical readers.

This position paper addresses e-cigarettes that use both nicotine-containing and non-nicotine-containing liquids but does not consider 'heat-not-burn' products, a separate product category.

The TSANZ acknowledges the Public Health England Report on e-cigarettes.¹⁴ The TSANZ has considered and accepted the comprehensive report on the *Public Health Consequences of E-Cigarettes* from the United States National Academies of Sciences, Engineering and Medicine (NASEM), January 2018,¹⁵ as well as the June 2018 Literature Review Update from Australia's Commonwealth Scientific and Industrial Research Organisation (CSIRO)¹⁶ as better reflecting the published literature to August 2017 and March 2018, respectively. As such, these reports form the basis for the development of the TSANZ's position.

In developing this position paper, we reviewed the literature to determine if there were new studies that subsequently extended or challenged the findings of the NASEM report. In particular, we reviewed literature predominantly, but not exclusively, post-dating August 2017, that assessed e-cigarettes with respect to:

1. Health impacts,
2. Effects on smoking cessation,

3. Effects on children and young people including the impact of both nicotine- and non-nicotine-containing products on developing lungs and
4. Effects on at-risk groups which included:
 - Aboriginal, Torres Strait Islanders, Maori, Pasifika peoples,
 - Prisoners (or those recently released),
 - People with mental illness,
 - Alcohol and other drug treatment clients and
 - Pregnant women.

Working party membership is listed in Supplementary Appendix S1 and Methodology is outlined in Supplementary Appendix S2.

THE REGULATORY FRAMEWORK

In Australia, the regulation of e-cigarettes is a responsibility shared between Commonwealth and State and Territory Governments across multiple sets of legislation relating to tobacco products, therapeutic goods, poisons and consumer goods. The regulatory frameworks are different in each state and territory. Whereas in New Zealand nicotine-containing e-cigarettes are available as a consumer product, this is not the case in Australia, where e-cigarettes can be purchased as a consumer product, but nicotine cannot. In New Zealand, the *Medicines Act 1981* and the *Smoke-Free Environments Act 1990* regulate the sale, advertising and use of vaping products, including nicotine liquids.

It is illegal in both New Zealand and Australia to sell an e-cigarette while making a claim about therapeutic benefit for smoking cessation unless the product has been approved for that purpose by the Therapeutic Goods Administration (Australia) or Medsafe (New Zealand). In both Australia and New Zealand, e-cigarettes are currently sold as consumer products and not as therapeutic goods.

Smoking cessation products have been subject to stringent regulation through government-managed processes. Regulated therapeutic goods are manufactured under strict codes such as Good Manufacturing Practice to ensure product consistency and quality. E-cigarettes are not regulated as a therapeutic product.

Regulation is the role of government. The Institute for Global Tobacco Control website (https://globaltobaccocontrol.org/e-cigarette_policyscan) provides a detailed overview of how governments internationally have approached the regulation of e-cigarettes.¹⁷ There is no current evidence on the most effective regulatory framework for e-cigarettes.

HEALTH IMPACTS OF E-CIGARETTES

Drawing conclusions about absolute exposure levels and associated risk based on comparisons between e-cigarettes and combustible tobacco use is not possible. There are thousands of e-liquid solution variants and a range of devices with different settings. Exposure to certain toxins in e-cigarettes has been demonstrated to be less than that experienced with conventional cigarette use, whilst for others exposure is greater.¹⁵

Although the NASEM report concluded that there was no available evidence regarding whether e-cigarettes cause respiratory diseases in humans, we identified two subsequently published studies which compared the spectrum of bronchial proteins in non-smokers, smokers and e-cigarette users. They demonstrated alterations in the bronchial proteome and identified changes unique to e-cigarettes, including markers of an aberrant neutrophilic response.^{18,19} In vivo studies have identified specific e-cigarette flavourants that have potential adverse effects on human health,^{20,21} and a study in humans showed addition of a flavourant led to increased plasma nicotine levels.²²

A recent prospective cohort study, based on a large sample of current or former smokers, found that e-cigarettes used alone or in combination with tobacco cigarettes, compared to smoking tobacco cigarettes alone did not substantially improve self-reported health over 4 years of follow-up or decrease the rate of diseases potentially related to tobacco.²³ Nonetheless, the authors acknowledged that the follow-up period may have been too short to detect long-term effects.

The NASEM report concluded that the implications for long-term effects on morbidity and mortality are not yet clear and noted substantial evidence that e-cigarette aerosol induces cellular dysfunction and can promote the formation of reactive oxygen species/oxidative stress. It also noted, however, that the generation of reactive oxygen species and oxidative stress is generally lower from e-cigarettes than from combustible tobacco smoke.¹⁵ The studies identified above further support the NASEM assessment that lung disease is a biologically plausible potential outcome of long-term exposure to e-cigarette vapour.

Continued smoking is seen in the majority of e-cigarette users.²⁴ There is sparse evidence in humans of the health outcomes in these dual users of e-cigarettes and tobacco. The NASEM report noted a lack of clarity regarding the balance of positive and negative effects of e-cigarettes on respiratory health, concluding that there is limited evidence for improvement in lung function and respiratory symptoms among adult smokers with asthma who switch to e-cigarettes completely or in part (dual use) and for reduction of COPD exacerbations among adult smokers with COPD who switch to e-cigarettes completely or in part.

Isolated case studies and case series have described adverse effects of e-cigarettes on a range of non-respiratory outcomes including accidental poisoning from e-liquids,²⁵ acute nicotine toxicity from excessive vaping²⁶ and increased periodontal inflammation.²⁷

During the process of finalization of this document, a substantial number of cases of severe, acute lung injury in e-cigarette users have been reported in the United States. A summary of this outbreak is provided in Appendix S3 (Supplementary Information).

Non-respiratory adverse effects of e-cigarettes from malfunction of the devices have been identified, including lacerations and burns that have resulted from explosions.^{28–30}

There is little evidence about the effects of e-cigarette use on pregnancy and foetal health.

Research on the effects of second-hand exposure to e-cigarette aerosols has been challenged by difficulty in

creating an effective model of exposure—due to a range of factors including heterogeneity of apparatus and juices, adjustable power settings and varying puff parameters.

The long-term health impact of e-cigarettes remains largely unknown. Given the known short- to mid-term adverse health effects and the risk that chronic lung disease will develop over time, e-cigarettes should not be used by children or non-smokers. Their use by smokers is addressed in the following section on smoking cessation.

EFFECTS ON SMOKING CESSATION

The NASEM¹⁵ and CSIRO¹⁶ reports, together with reports from Australia's National Health and Medical Research Council³¹ and a European Respiratory Society Task Force,³² all conclude that there is limited evidence that e-cigarettes are effective in promoting smoking cessation and a lack of evidence as to whether e-cigarettes are more or less effective than existing approved cessation aids or no treatment.

A literature search identified five additional randomized controlled trials relevant to smoking cessation published since the finalization of the 2018 NASEM report. The trials were heterogeneous in study population and design. In two studies of smokers motivated to quit, one showed an increase in stopping rates with e-cigarettes, with or without nicotine, compared to low-intensity counselling,³³ but the other found no incremental effect when e-cigarettes were added to combined nicotine replacement therapy and counselling.³⁴ Three studies investigated smokers not motivated to quit. They found that the addition of free e-cigarettes to usual care (information and motivational text messages) did not increase sustained smoking abstinence;³⁵ provision of free e-cigarettes for use entirely at the discretion of participants did not significantly influence quit attempts or biologically verified abstinence;³⁶ and randomization to ad libitum nicotine-containing rather than non-nicotine-containing e-cigarettes did not reduce regular cigarette use.³⁷

A recent randomized trial investigated the efficacy of e-cigarettes compared with nicotine replacement therapy, in addition to face-to-face cessation counselling, in smokers attending a smoking cessation service.³⁸ At 1 year, the rate of continuous abstinence from smoking traditional cigarettes among e-cigarette users was 18.0% compared to 9.9% in the nicotine replacement group (relative risk: 1.83; 95% CI: 1.30–2.58; $P < 0.001$). However, after 1 year, 80% of e-cigarette users continued to use e-cigarettes, whereas 9% of nicotine replacement therapy users were still using nicotine replacement.

A time series analysis in the United Kingdom found no significant association between changes in the use of e-cigarettes between 2006 and 2016 and rates of smoking and daily cigarette consumption.³⁹ It concluded that if e-cigarette use had any effect on cigarette smoking, the effect was likely to be very small at a population level.

Most smokers quit smoking unassisted,⁴⁰ but effective healthcare advice and the appropriate use of proven and well-regulated products are essential in providing support for many smokers seeking assistance

in quitting. Guidelines are available for health professionals to assist them in providing expert care.^{41,42} If health practitioners are unable to support smokers, they should refer them to appropriate expert care.

Smokers seeking to quit require access to qualified, personal behavioural support regardless of whether they use existing therapies. Smokers who enquire about using e-cigarettes as a cessation aid should be provided with appropriate information about approved medication in conjunction with behavioural support (as these have the strongest evidence of efficacy to date). E-cigarettes are not the first-line treatment for smoking cessation.⁴¹ However, for smokers who express a desire to use e-cigarettes for cessation, health professionals should ensure they have access to, and are utilizing, behavioural support with the aim of achieving complete smoking cessation and subsequent cessation of e-cigarette use as promptly as possible.

IMPLICATIONS FOR CHILDREN AND YOUNG PEOPLE

The NASEM report found substantial evidence that e-cigarette use results in young people taking up smoking of conventional cigarettes (the gateway effect).¹⁵ The reports from the CSIRO,¹⁶ NHMRC³¹ and European Respiratory Society Task Force³² agreed. The Forum of International Respiratory Societies recommends that, to protect youth, e-cigarettes should be considered as tobacco products and regulated as such.⁴³ The addictive power of nicotine, particularly in the developing adolescent brain, and its adverse effects should not be underestimated. The Forum stated that flavourings further encourage use by young people.

The United States Surgeon General concluded that e-cigarette use among youth and young adults is a public health concern.⁴⁴ In 2014, use of e-cigarettes by young adults aged 18–24 years in the United States exceeded that of adults aged 25 years or over. The Surgeon General concluded that e-cigarette use is strongly associated with the use of other tobacco products among youth and young adults, including combustible tobacco products.

One hundred and ninety-four papers concerning the implications of e-cigarettes for children and young people published since the NASEM report were consistent with the NASEM findings. Many provided additional supportive data. Seven reports challenged the cautionary approach recommended by the NASEM analysis.^{45–51}

IMPLICATIONS FOR AT-RISK GROUPS

Smoking rates are higher than average in some population groups including Aboriginal and Torres Strait Islander and Māori and Pasifika peoples. Smoking rates are also elevated in people with mental illness or substance-use disorder and people in correctional facilities. Women who are pregnant, or are planning to become pregnant, have special health needs relating to smoking.

We considered any studies published after the NASEM report reporting on the groups identified above in which e-cigarettes were considered as a cessation

aid, attitudes towards e-cigarettes were examined or the level of use was assessed. We conclude that, due to the low quality of evidence, it is uncertain whether e-cigarettes are effective for smoking cessation in populations with high smoking rates.⁵² Individual studies, reported both before and since the NASEM review, varying in sample size from 12 to 84 participants showed some sustained reduction in the number of cigarettes smoked at 1 year (similar to the efficacy to a nicotine replacement patch),^{53,54} reduced tobacco use at 9 weeks,⁵⁵ acceptability as a form of nicotine replacement therapy in alcohol-dependent patients during a hospital admission,⁵⁶ acceptability and some efficacy in military veterans receiving psychiatric services⁵⁷ and reduced smoking rates at 6 weeks in people with severe mental illness.⁵⁸

A 2015 review on behalf of the United States Preventive Services Task Force examined e-cigarette use in all adults.⁵⁹ It identified no specific studies on the impact on smoking cessation in pregnant women and stated that the effects of e-cigarette ingredients on the foetus are unknown. Five studies published since this review examined attitudes to e-cigarette use in groups that included pregnant women, people with mental illness and Māori and Pasifika people in New Zealand.^{60–64} They identified positive views about e-cigarettes. Participants considered them safer than tobacco products.

The prevalence of e-cigarette use in at-risk populations has been assessed in a number of studies. It was estimated that 11–13% of pregnant women in the United States had prior or current use and 0.6% currently used them daily.⁶⁵ In American patients hospitalized for mental illness, the prevalence of e-cigarette use increased from zero in 2009 to 25% in 2013.⁶⁶ A survey of 6051 Americans found people with mental illness were 1.5 times more likely to have ever used e-cigarettes and almost twice as likely to be current users compared to people without mental illness.⁶⁷ Among Americans with drug- and alcohol-use disorders, two studies showed 30–34% had used e-cigarettes in the last 30 days,^{68,69} while another found that 17.7% used them at least weekly.⁷⁰

A study of 390 Indigenous Australians, of whom 184 were current smokers and 75 former smokers, found that only 7 (2%) were currently using e-cigarettes.⁷¹ In a 2013–2014 survey, 21% of Indigenous smokers had tried an e-cigarette, virtually identical to the rate of 20% in all Australian smokers.⁵

The literature and evidence base for cessation, acceptability and prevalence for each population were sparse and the quality of the studies was not sufficiently robust to enable conclusions to be drawn. Given the burden of smoking in these populations, further high-quality research utilizing e-cigarettes and existing cessation aids is urgently required.

POSITION OF THE TSANZ

The TSANZ embarked upon the development of this position paper having accepted the NASEM report as the most comprehensive review on e-cigarettes to date. After reviewing recent literature on e-cigarettes, it is the position of the TSANZ that there is, at present, insufficient evidence to refute the findings of the

NASEM report. We believe that this position statement is also fully consistent with relevant sections of the 2020 report of the US Surgeon General on Smoking Cessation.²⁴

The TSANZ, with its particular concern with respiratory health, has taken the position that:

1. All smokers should be able to easily access effective, existing cessation treatments complemented by behavioural support services.
2. Access to effective, adequately funded smoking cessation support services is particularly important for those smokers in population groups where the prevalence rates have remained high.
3. Smokers who enquire about using e-cigarettes as a cessation aid should be provided with appropriate information about approved medication in conjunction with behavioural support (as these have the strongest evidence for efficacy and safety).
4. For smokers who express a desire to use e-cigarettes for cessation, health professionals should ensure the smokers have access to, and are utilizing, behavioural support with the aim of achieving complete smoking cessation and subsequent cessation of e-cigarette use as promptly as possible. It should be clearly communicated that no product can be recommended, and nor can an assurance be provided as to either effectiveness or safety.
5. As e-cigarettes have been demonstrated to cause adverse lung effects and their safety for long-term use is unknown, they should not be used by non-smokers or for extended periods by ex-smokers. E-cigarettes, whether containing nicotine or not, are not suitable consumer products.
6. Australia and New Zealand must take every action to prevent burgeoning use of e-cigarettes in young people as has occurred in other countries. The sale or supply of e-cigarettes, e-liquids and devices to people under the age of 18 years should not be permitted and active surveillance is required by bodies responsible for enforcing this.
7. Flavours in e-liquids are attractive to young people and never smokers. Bans on flavourings should be actively considered by governments.
8. As Australia and New Zealand both have well-established processes to manage products making a therapeutic claim, we recommend that any product about which a therapeutic claim regarding smoking cessation is made be managed through these processes.
9. Noting existing regulations in Australia and New Zealand, there is a clear need for the development of a more comprehensive regulatory framework for both e-cigarette devices and e-liquids.
10. Further high-quality research is urgently required, including regarding the potential risks and benefits of e-cigarette use in groups with higher rates of smoking and those with special health needs.

CONCLUDING REMARKS

Australia and New Zealand must remain focused on *proven* effective population tobacco control strategies to reduce prevalence rates. We must also ensure

smokers have access to behavioural support and, where required, therapeutic products which have been through stringent regulatory approval processes.

TSANZ reconfirms its commitment to Article 5.3 of the World Health Organization (WHO) Framework Convention on Tobacco Control: *'In setting and implementing their public health policies with respect to tobacco control, parties shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law'*.

Abbreviations: CSIRO, Commonwealth Scientific and Industrial Research Organisation; EC, e-cigarette; ENDS, electronic nicotine delivery system; NASEM, National Academies of Sciences, Engineering and Medicine; TSANZ, Thoracic Society of Australia and New Zealand

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Supplementary Information

Additional supplementary information can be accessed via the *html* version of this article at the publisher's website.

Appendix S1. Working Party Membership and Conflict of Interest Declarations.

Appendix S2. Methodology.

Appendix S3. Outbreak of acute lung injury associated with e-cigarette use.