

Smoking cessation – practice considerations after 1 October

Upcoming legal and regulatory changes to nicotine and considerations for prescribers



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RACGP Smoking cessation guidelines



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Australian Government
Department of Health
Therapeutic Goods Administration

Regulatory changes from 1 October 2021 – nicotine vaping products



Adjunct Prof John Skerritt

Deputy Secretary, Australian Department of Health

Smoking cessation seminar Quit/ Cancer Victoria 8 Sep 2021

TGA Health Safety
Regulation

The current legal situation re nicotine e-cigs

*Nicotine used in e-cigarettes is **already a Prescription Medicine**
when used for smoking cessation*

Nicotine in e-cigarettes for **non-medical use**:

- **Sale is currently illegal** in all Australian States and Territories
- **Possession (even if bought online) is currently illegal** everywhere but SA
 - but confusion exists regarding the legal status of nicotine used in e-cigarettes (nicotine vaping products) when not for therapeutic use
 - current lack of Federal laws means there is no ability to intercept commercial shipments of nicotine / e-cigarettes at the border

From 1 October 2021

Nicotine vaping products may only be imported or supplied in accordance with a doctor's prescription (aligns with existing State/Territory laws)

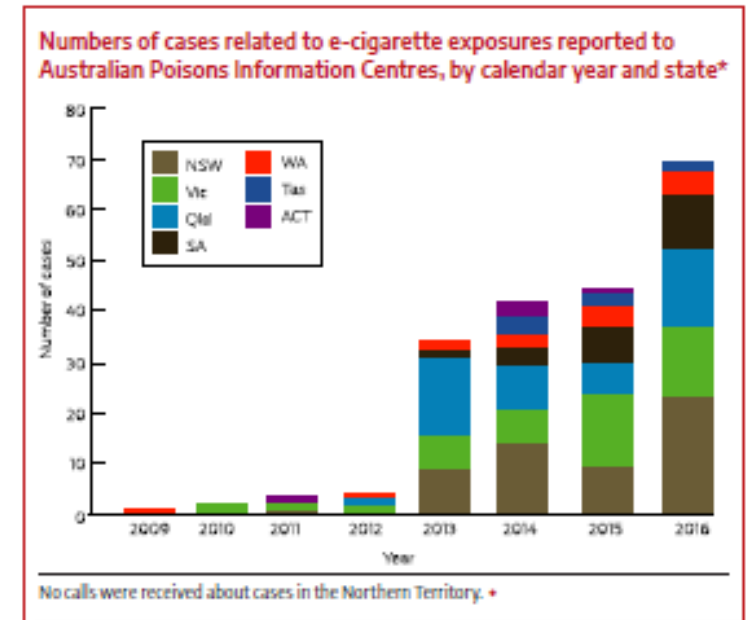
- Ensure consumers receive **advice from their doctor** on use for smoking cessation
 - Recognising that approaches other than nicotine vaping may be trialled with the patient as first-line approaches
- Changes do **not affect access to the current TGA-registered smoking cessation** products such as gums, sprays and patches
- The change is intended **to strike a balance between**
 - protecting young people from risks of using nicotine e-cigarettes and
 - enabling access to e-cigarettes to assist smokers to quit if prescribed by their doctor

How will the change help young people?

- **Significantly increasing use** of nicotine vaping products by youth
 - Australians aged 15-24 - 4.5% are current e-cigarette users in 2019 (up from 2.3 % in 2016)
 - US High Schools - 27.5% are current e-cigarette user in 2019 (up from 11.7% in 2017)
 - Canadians aged 15-19 - 15% are current e-cigarette users in 2019 (up from 6% in 2017)
- Strong evidence of nicotine e-cigarettes as a **gateway to smoking in youth**
- **Adolescent exposure** to nicotine may have long-term impacts on brain development
- **Impact of making nicotine vaping products prescription-only**
 - Highly unlikely that a medical practitioner would prescribe nicotine e-cigarettes to a minor in their clinical judgement
 - Also unlawful in every state and territory for a nicotine vaping product to be dispensed (supplied) to a minor

Accidental poisoning

- Risk of **accidental ingestion** of liquid nicotine
 - just 1-2 mL can kill a toddler
 - fruit/candy flavours can be attractive
- Significant increase in **poison centre calls**
 - 33 cases of liquid nicotine ingestion in Victoria alone in 2019 - up from 22 in 2018
- New product standard (TGO 110) mandates use of **child-resistant packaging**
- Some deliberate but **fewer accidental poisonings in adults**



Toddler killed by mum's liquid nicotine used for vaping

AAP
Mon, 8 July 2019 1:29PM



Evidence for NVP efficacy in smoking cessation is mixedbut success in certain patients

- **Recommended as second line therapy** – trial behavioural approaches, other medicines first
 - Can trial if these have not worked and after patient-doctor discussion
 - Mimicking smoking behaviour and pharmacokinetics of vaping versus nicotine patches may help transition
- **Cochrane meta-analysis (April 2021)**
 - More people probably stop smoking for at least six months using NVP than using nicotine replacement therapy (3 studies, 1498 people), or nicotine-free e-cigarettes (4 studies, 1057 people)
 - NVP may help more stop smoking than no support/ behavioural support only (5 studies, 2561 people)
- **ANU study (not yet published)**
 - There was a small benefit in smoking cessation for NVPs compared to nicotine replacement therapy
 - Significantly greater quit rates for NVP trial participants than those randomised to no intervention or usual care, but evidence was of low certainty



Nicotine and the adolescent brain

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Abstract Adolescence encompasses a sensitive developmental period of enhanced clinical vulnerability to nicotine, tobacco, and e-cigarettes. While there are sociocultural influences, data at preclinical and clinical levels indicate that this adolescent sensitivity has strong neurobiological underpinnings. Although definitions of adolescence vary, the hallmark of this period is a profound reorganization of brain regions necessary for mature cognitive and executive function, a working memory, reward processing, emotional regulation, and motivated behavior. Regulating maturation are nicotinic acetylcholine receptors (nAChRs). However, systems during this time with nicotine, via tobacco or e-cigarettes, have unique perturbations of critical facets of neurochemistry. Nicotine, via its effects on dopamine signaling, argues a low degree of epigenetic regulation. This review highlights the importance of reviewing normative structural and functional development with an emphasis on dopaminergic systems and how drug exposure during this period can have long-term effects on brain development and function.

ADDICTION

RESEARCH REPORT

SSA SOCIETY FOR THE STUDY OF ADDICTION
doi:10.1111/add.14558

Prevalence of awareness, ever-use and current use of nicotine vaping products (NVPs) among adult current smokers and ex-smokers in 14 countries with differing regulations on sales and marketing of NVPs: cross-sectional findings from the ITC Project

Shannon Gravely¹, Pete Driezen¹, Janine Ouimet¹, Anne C. K. Quah¹, K. Michael Cummings², Mary E. Thompson¹, Christian Boudreau¹, David Hammond¹, Ann McNeill^{3,4}, Ron Borland⁵, James F. Thrasher^{6,7}, Richard Edwards⁸, Maizurah Omar⁹, Sara C. Hitchman¹⁰, Hua-Hie Yong^{5,10}, Tonatiuh Barrientos-Gutierrez⁶, Marc C. Willemsen¹¹, Eduardo Bianco¹², Marcelo Boado¹³, Fastone Mathew Goma¹⁴, Hong Gwan Seo¹⁵, Nigar Nargis¹⁶, Yuan Jiang¹⁷, Cristina De Abreu Perez¹⁸ & Geoffrey T. Fong^{1,19}

ABSTRACT

Aims This paper presents updated prevalence estimates of awareness, ever-use, and current use of nicotine vaping products (NVPs) from 14 International Tobacco Control Policy Evaluation Project (ITC Project) countries that have varying regulations governing NVP sales and marketing. **Design, Setting, Participants and Measurements** A cross-sectional analysis of adult (≥ 18 years) current smokers and ex-smokers from 14 countries participating in the ITC Project. Data from the most recent survey questionnaire for each country were included, which spanned the period 2013–17. Countries were categorized into four groups based on regulations governing NVP sales and marketing (allowable or not), and level of enforcement (strict or weak where NVPs are not permitted to be sold): (1) most restrictive policies (MRPs), not legal to be sold or marketed with strict enforcement: Australia, Brazil, Uruguay; (2) restrictive policies (RPs), not approved for sale or marketing with weak enforcement: Canada, Malaysia, Mexico, New Zealand; (3) less restrictive policies (LRPs), legal to be sold and marketed with regulations: England, the Netherlands, Republic of Korea, United States; and (4) no regulatory policies (NRP), Bangladesh, China, Zambia. Countries were also grouped by World Bank Income

Summary report on use of e-cigarettes and relation to tobacco smoking uptake and cessation, relevant to the Australian context

24 September 2020

Prepared by: Emily Banks, Katie Beckwith

Present from reports by: Emily Banks, Miranda Hall, Baenziger, Amelia Yazidjoglou, Sinan Brown, Iqbal, Grace Joshy, Katie Beckwith, Katherine van Maddox, Alexandra Marmor, Christina

Smoking cessation



CPD

Nicholas A Zwar

Background

Although Australia is a world leader in tobacco control, smoking remains the largest behavioural risk factor making the largest contribution to death and disease. Smoking rates remain high in Aboriginal and Torres Strait Islander people and in people with mental health problems. Priority groups for cessation include women who are pregnant and people with cardiovascular disease.

Objective

This article, based on the recently published second edition of *Supporting smoking cessation: A guide for health professionals*, provides an update on support quitting. A brief time-efficient intervention approach (Ask, Advise, Help) is proposed. New approaches to the use of pharmacotherapy are covered, as is the controversial role of nicotine-containing e-cigarettes and advice for groups with high smoking prevalence and those with special needs.

Discussion

A combination of behavioural support along with pharmacotherapy to treat nicotine dependence maximises the chances of successful long-term cessation. Combination nicotine replacement therapy (patch and short-acting oral form) or varenicline are the most effective forms of pharmacotherapy.

Australia has been a global leader in tobacco control and has one of the lowest rates of daily smoking in the world (currently 12.2%). However, national targets to reduce daily smoking to <10% and to halve the Aboriginal and Torres Strait Islander adult daily smoking rate by 2018 were not achieved. Smoking rates remain high in key population groups including people with mental illness. Smoking still causes a higher burden of disease than any other behavioural risk factor; in 2015, nearly 21,000 deaths in Australia were attributable directly to tobacco smoking. Smoking in pregnancy has serious adverse effects both for the mother and the developing fetus. As shown in Figure 1, quitting smoking has remarkable and rapid health benefits.

Primary care practitioners including general practitioners (GPs) and practice nurses are familiar with the challenges in promoting and supporting smoking cessation. This article addresses the perspective from a patient and provider up-to-date evidence-based solutions to support busy practitioners. Brief advice and is highly cost effective. The most effective approach is a combination of cessation pharmacotherapy and smoking support.

For the publication *Supporting smoking cessation: A guide for health professionals*, on which this article

is based, the Expert Advisory Group (EAG) reviewed the recommendations from the first edition and also posed new questions in the PICO (patient, intervention, comparator, outcome) format. The Royal Australian College of General Practitioners commissioned the Joanna Briggs Institute (JBI) and the JBI Adelaide GRADE Centre to conduct evidence reviews on these questions, which resulted in Grading of Recommendations, Assessment, Development and Evaluation (GRADE) 'Summary of findings' tables. These tables were incorporated into an 'evidence to decision' framework, which the EAG used to move from the evidence to making practice recommendations. All recommendations received a GRADE rating on the quality of the evidence (certainty) and the strength of recommendation. Recommendations arising from the new PICO questions are shown in Table 1.

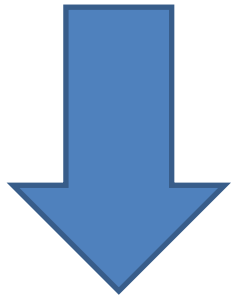
Brief intervention: Ask, Advise, Help

One of the barriers mostly frequently cited by health professionals to offering smoking cessation advice is the time required. When time is short, an option is the three-step Ask, Advise, Help structure developed by Quit Victoria. This brief intervention model (Figure 2) can be summarised as:

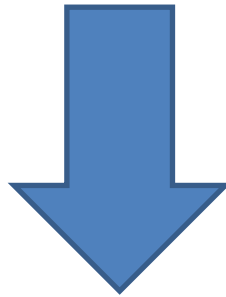
- Ask and record smoking status

Lawful access from 1 October - pathways:

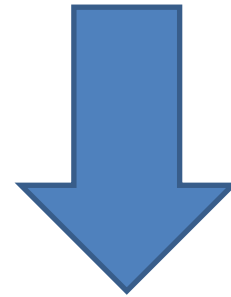
- Presently **no nicotine vaping products** approved by the TGA
- **But detailed discussions with several companies underway**



**Authorised
prescriber**

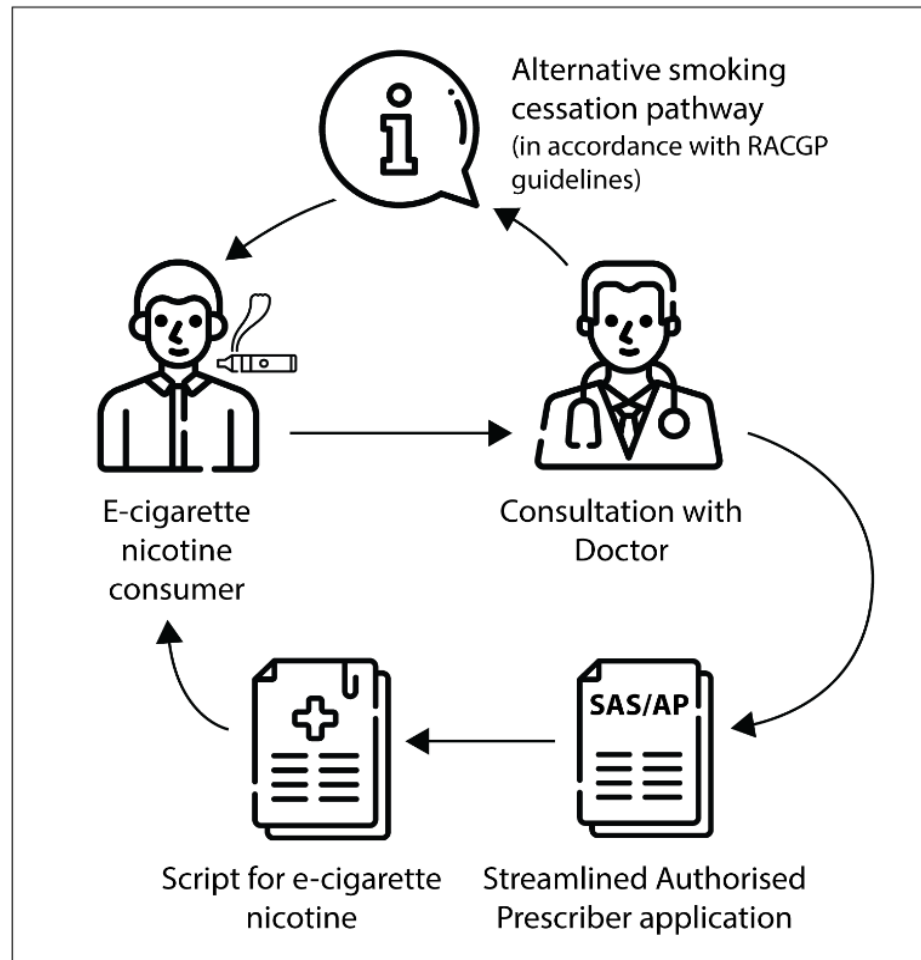


**Special Access
Scheme B**



**Personal importation
scheme**

DOCTORS: What the changes mean



Streamlined Authorised Prescriber

- Can prescribe for unlimited number of patients
- Online application only requires name, address and AHPRA number
- Free of charge, valid for five years

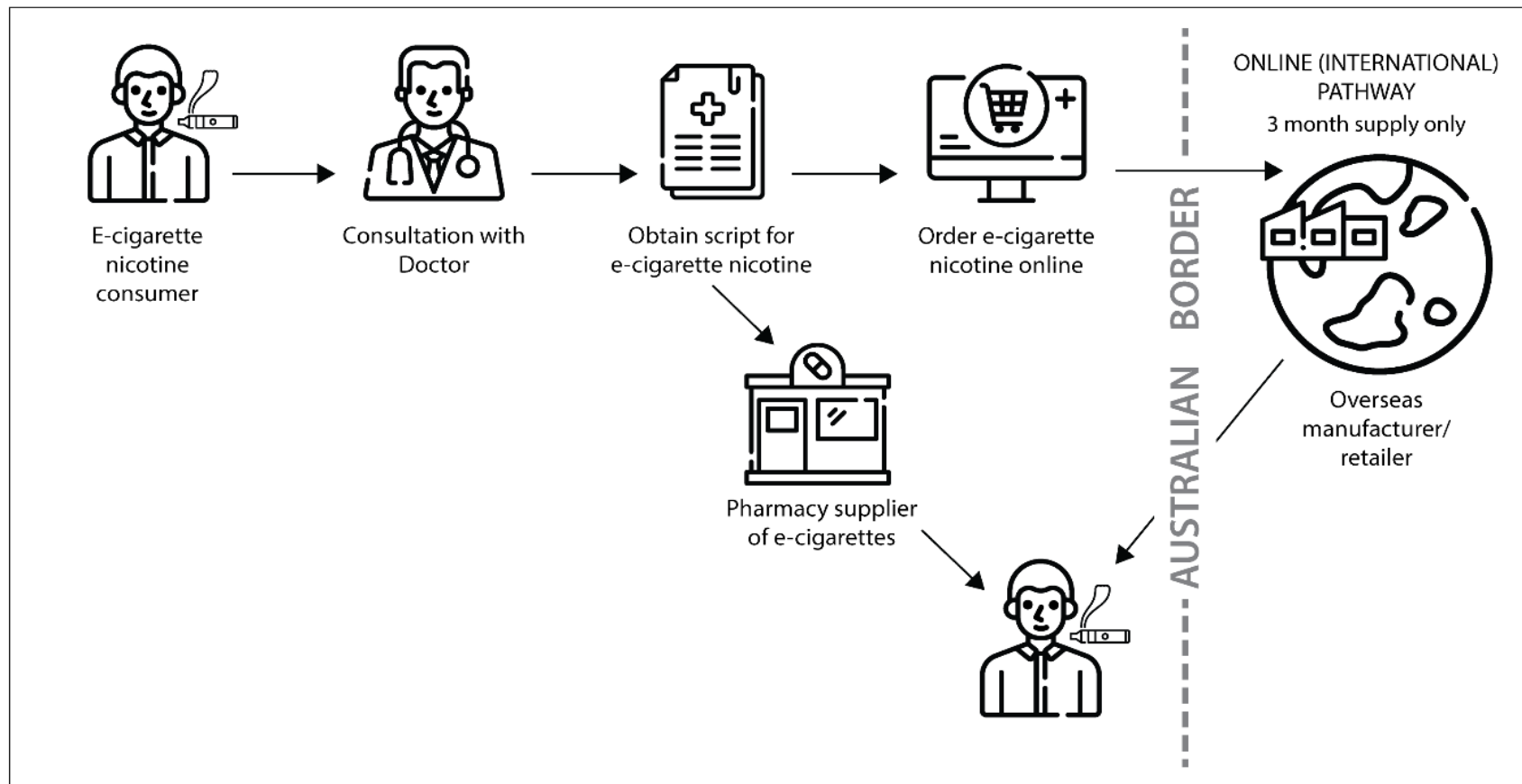
Special Access Scheme B

- Applications for individual patients
- Free of charge

Personal Importation Scheme

- Patient imports up to 3 months supply from overseas
- Using a script from any registered Australian doctor

CONSUMERS: What the changes mean



Pharmacist dispensing through either/both:

- Local community pharmacies
- Online Australian pharmacies

Personal importation scheme

- Overseas manufacturer or retailer
- 3 months maximum supply

A new product quality and labelling standard

A Therapeutic Goods Order (product standard) **CAN** specify minimum safety and quality requirements for:

- ✓ Labelling
- ✓ Packaging
- ✓ Ingredients



A TGO **CANNOT** specify requirements for:

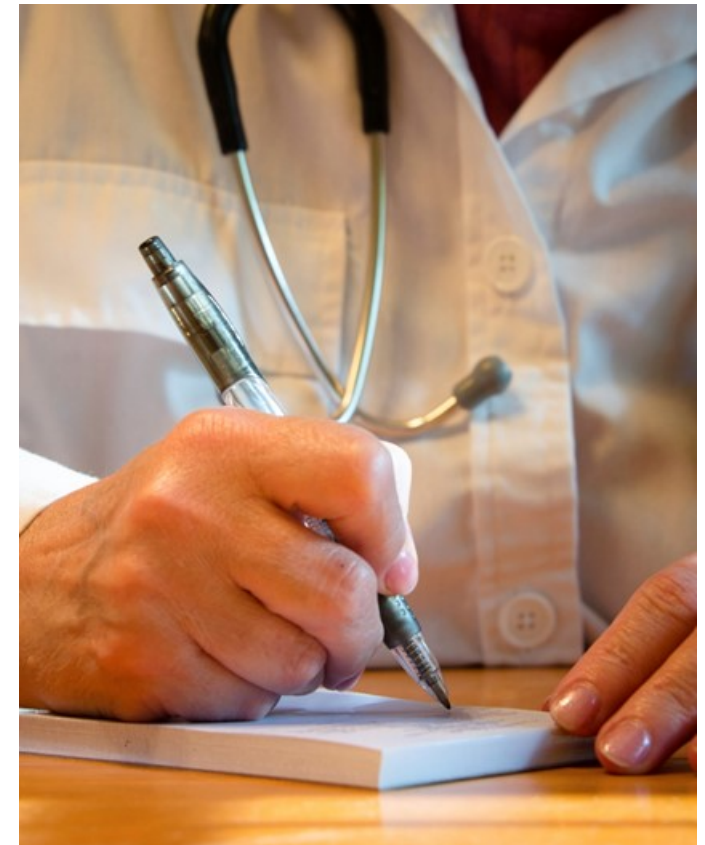
- ✗ Dosage regimes
- ✗ Nicotine vaping products that do not contain nicotine and are not for therapeutic use
- ✗ Vaping devices themselves (regulated separately if used therapeutically)

Ingredients and nicotine limits

- **Ingredients with known health risks** including ethylene glycol, diethylene glycol, diacetyl, 2,3- pentanedione, vitamin E acetate; benzaldehyde, acetoin, cinnamaldehyde are **prohibited**
 - Most suppliers do not use the first 5 ingredients
- **No limits on flavours**
- Nicotine concentration limited to **100 mg/ml or below**
- **No limit on container volume**

Concentration, volume supplied and any flavours are determined and limited by the doctor's prescription

*So doctors can prescribe **the right product for their patient***



Labelling and packaging

- The **label or information sheet** is required to list active ingredients (nicotine) + all excipients (vegetable glycerine, propylene glycol) except components of flavours
- The **label** must state **nicotine concentration**
- **Nicotine concentration must be within 90-110% of labelled content**
- The **label** is required by **state and territory law** to include **warning statements** – e.g. 'KEEP OUT OF REACH OF CHILDREN' , 'Avoid contact with eyes', 'Avoid contact with skin'
- **Packaging must be child resistant**



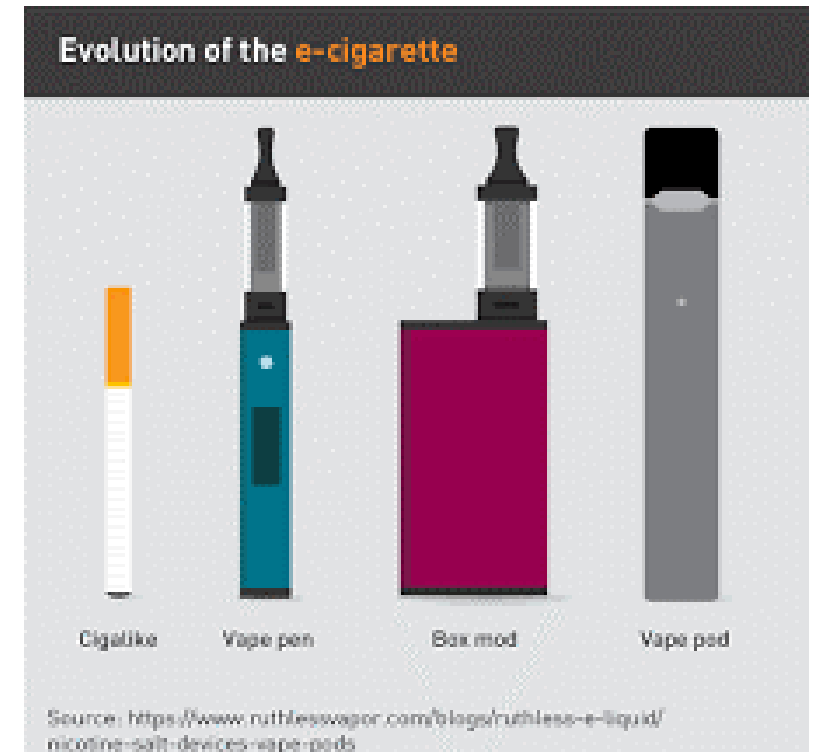
Personal imports and TGO 110

- Products purchased from overseas via the Personal Importation Scheme are **subject to TGO 110 controls on ingredients**
 - nicotine concentration, other active ingredients forbidden, prohibited ingredients
- Products from major import sources (e.g. NZ, EU, UK, USA and Canada) have **similar or stricter requirements**. For example:
 - EU product labels must show nicotine content per dose, all ingredients and warnings
 - NZ product labels must show ingredients/quantities, nicotine concentration, excipient details, warnings
- **Some other countries** may not have similar labelling requirements
 - should personal importation be discouraged from those countries ?



Vaping devices

- TGA only has remit over vaping devices that are intended to be used **exclusively** to vaporise and administer a medicine (such as vaporiser nicotine)
- These **devices must be**:
 - Included in the ARTG; or
 - Accessed via one of the access pathways for unapproved goods
 - Subject to manufacturing and quality requirements
- Devices that can be used to vaporise products that are **not medicines** (e.g. non-nicotine vapes) are not regulated by the TGA



Compliance at the border

After 1 October 2021 nicotine is prescription only, so

- Individuals using the personal importation scheme will require evidence of holding a valid prescription
- Importers for Australian pharmacy dispensing will require a pharmaceutical wholesale licence

TGA and Border Force already work closely to detain over 4000 importations of products annually

- Intelligence and education programs already underway

Products suspected of containing undeclared nicotine can be intercepted and tested by TGA's laboratories

Significant civil and criminal penalties apply for illegal imports



More information is available

www.tga.gov.au/nicotine-vaping-products

TGA nicotine web hub – healthcare professionals, industry and consumers

- information on the product standard and prescribing and patient access pathways
 - Blog on Facebook, Twitter and LinkedIn
 - Educational videos with a call to action to speak to your health care practitioner about smoking cessation

Information for Aboriginal and Torres Strait Islander communities

Information and communications for disabled/ carers, mental health and NESB groups

For GPs and other healthcare practitioners

- Very soon - new RACGP, psychiatrist and pharmacist smoking cessation guidelines dealing with vaping nicotine products prepared by peak bodies
- NPS Medicine Wise, Quit (Cancer Council Victoria), GPET presentations and booth
- Information for healthcare professions serving Aboriginal and Torres Strait Islander communities

Supporting smoking cessation: A guide for health professionals



Update to 2nd Edition
Nicotine Vaping Module

**Leading the fight
against the most
preventable cause
of death in Australia.**

*Supporting smoking cessation:
A guide for health professionals*

Now available at

www.racgp.org.au/

[supporting-smoking-cessation](http://www.racgp.org.au/supporting-smoking-cessation)



Updating the Guide

Two stage process

- Development of a Nicotine Vaping Products (NVP) Module (March 2021 to October 2021)
- Broader review and update of the entire guide (January 2022 to June 2024)

Updating the Guide: NVPs

Multidisciplinary EAG:

- General practice
- Public Health/ epidemiology
- Respiratory Medicine
- Clinical Pharmacology
- Addiction Psychiatry
- Indigenous Health
- Pharmacy
- Therapeutic Goods Administration
- Health Policy – tobacco control

Evidence reviews & guideline development:

- Meta analyses were conducted by the Australian National University (ANU)
- ANU facilitated a transparent evidence review process using the GRADE format
- Based on the evidence, ANU facilitated the development of new recommendations

Rigorous declaration of interest management was maintained throughout the process

The Grading of Recommendations, Assessment, Development & Evaluation (GRADE) process

GRADE quality (certainty) of evidence:

1. **High**: very confident that the true effect lies close to that of the estimated effect
2. **Moderate**: moderately confident in the estimated effect
3. **Low**: confidence in the estimated effect is limited
4. **Very low**: very little confidence in the estimated effect.

GRADE strength of recommendation:

1. **Strong** recommendation for (or against) the intervention
2. **Weak** recommendation for (or against) the intervention
3. **Conditional** recommendation for either the intervention or comparison

Questions considered for NVP Module

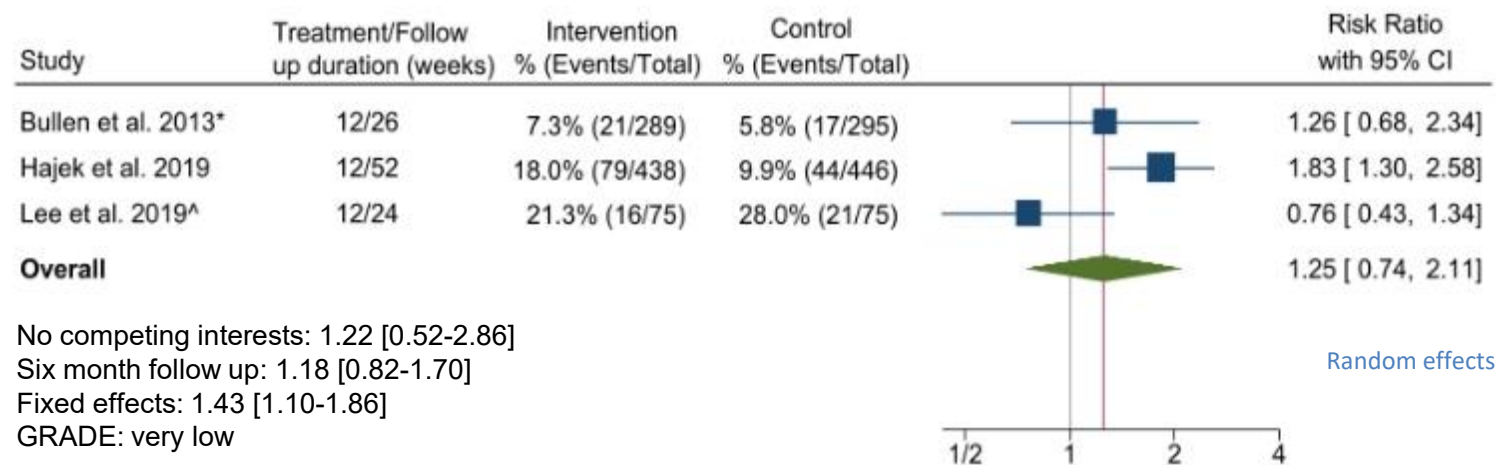
Should nicotine e-cigarettes be recommended for smoking cessation?

PICO (patient, intervention, comparator, outcome) question:

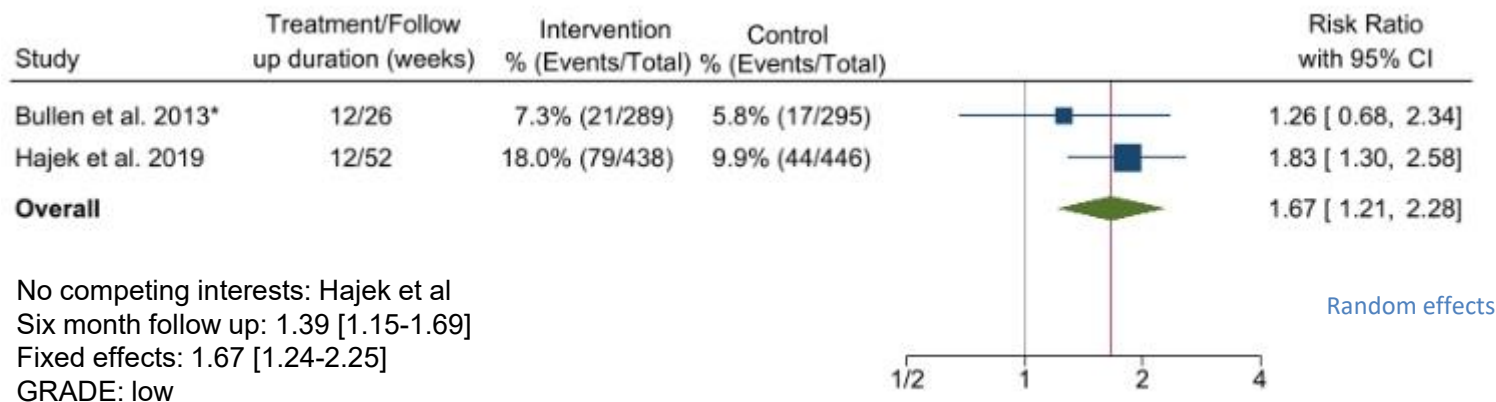
- Nicotine e-cigarettes versus nicotine replacement therapy for smoking cessation

Smoking cessation in smokers randomised to nicotine e-cigarettes vs:

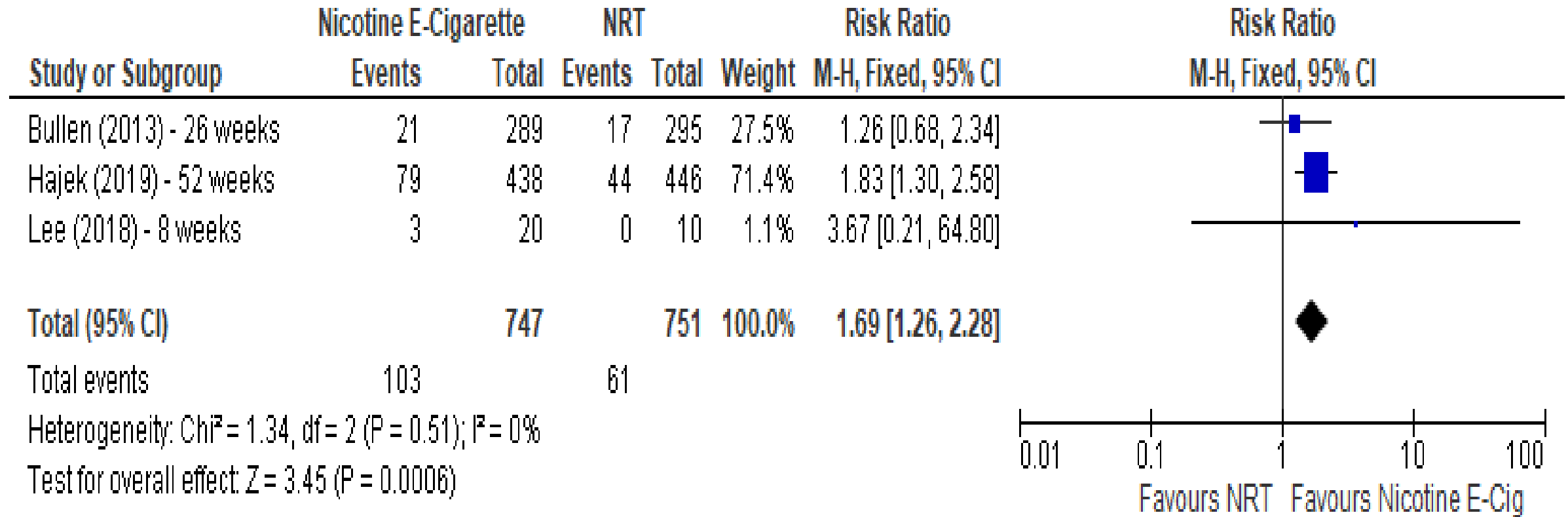
NRT (all nicotine concentrations)



NRT (nicotine concentrations >0.01mg/mL)



Findings 2019 review - Nicotine containing e-cigarette versus NRT



Findings - Nicotine containing e-cigarette versus therapeutic NRT

Outcomes	No of participants (studies) Follow up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects* (95% CI)	
				Risk with Nicotine Replacement Therapy	Risk difference with Nicotine Containing E-Cigarettes
Smoking Cessation assessed with: Biochemically Validated (Expired Carbon Monoxide Concentration <= 10ppm) follow up: range 8 weeks to 52 weeks	1498 (3 RCTs)	⊕⊕○○ LOW ^{a,b,c}	RR 1.69 (1.26 to 2.28)	Study population	
				81 per 1,000	56 more per 1,000 (21 more to 104 more)

- a. Significant issues of contamination bias and other types of bias (performance and detection) present.
b. Participants of Lee et al. (2018) were patients presenting to the anaesthesia pre-operative clinic for elective surgery.

Confidence Intervals are somewhat imprecise, ranging from a potentially small effect to a large effect (1.26 -2.28). However there are a low number of events, with 164 events not meeting the Optimal Information Size threshold of 476.

Nicotine vaping products recommendation

For people who have tried to achieve smoking cessation with first line therapy (combination of behavioural support and approved pharmacotherapy) but failed and are still motivated to quit smoking, NVPs may be a reasonable intervention to recommend. However, this needs to be preceded by an evidence-informed shared-decision making process, whereby the patient is aware of the following:

- Due to the lack of available evidence, the long-term health effects of NVPs are unknown.
- NVPs are not registered therapeutic goods in Australia and therefore their safety, efficacy and quality have not been established.
- There is a lack of uniformity in delivery devices and e-liquids, which increases the uncertainties associated with their use including their efficacy as a quitting aid.
- To maximise possible benefit and minimise risk of harms, dual use needs to be avoided and long-term use minimised.

Conditional recommendation for the intervention, low certainty

Considerations for prescribers

- Minimising risk in the context of no ARTG registered nicotine vaping product
 - Prescribing pathways
 - Prescribing practicalities
 - Dosing considerations
 - Device considerations
 - Flavourings

Considerations for prescribers

- Use in people with chronic illnesses
- Use in specific populations
- Monitoring nicotine vaping product use and follow-up
- Tobacco relapse prevention

Current edition available at
<https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation>



Royal Australian College *of* General Practitioners

Healthy Profession.
Healthy Australia.

QUESTIONS?



Adj. Prof. John Skerritt



Prof. Nick Zwar

Website and link references

Nicotine vaping products (TGA):

<https://www.tga.gov.au/nicotine-vaping-products>

Prescribing changes for nicotine vaping products for health professionals:

<https://www.nps.org.au/professionals/prescribing-nicotine>

Training for practitioners will become available on this page:

<https://www.quit.org.au/resources/general-practice/resources-general-practitioners/>

From 1 October 2021

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