



RACGP
Royal Australian College
of General Practitioners

Supporting smoking cessation: A guide for health professionals

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About this guideline

Target population and audience

This guideline applies to all healthcare professionals who support people wishing to quit smoking. It is intended to be relevant to the wider primary care setting, and is not limited to general practice. This is reflected in the multidisciplinary composition of the guideline development Expert Advisory Group.

What is new

A focussed update was undertaken to provide guidance about the rescheduling of nicotine e-liquids. Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Order 2021 (TGO 110) came into effect on 1 October 2021.

Changes to the regulation of nicotine as of 1st October 2021

A revised recommendation and additional practice points were added in response to TGO 110. These are provided in the Summary of recommendations below and further information about prescribing nicotine vaping products is provided in [Pharmacotherapy for smoking cessation – Electronic cigarettes and nicotine vaping products \(https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation/pharmacotherapy-for-smoking-cessation\)](https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation/pharmacotherapy-for-smoking-cessation)

With funding from the Commonwealth Department of Health, the Royal Australian College of General Practitioners was commissioned to develop an evidence-based guidance to support health professionals who may choose to prescribe nicotine vaping products (NVPs) as a quitting aid.

Guideline development for NVPs followed the GRADE (Grading of Recommendations Assessment, Development and Evaluation). The National Centre for Epidemiology and Population Health (NCEPH) at the Australian National University (ANU) was commissioned by the Australian Department of Health to undertake a program of research on electronic cigarettes in the Australian context. This work formed the basis of the [evidence reviews \(https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation/supporting-material/resource-s-for-health-professionals\)](https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation/supporting-material/resource-s-for-health-professionals) and technical support to revise the RACGP GRADE recommendation on e-cigarettes / NVPs.

An [expert advisory group \(https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation/supporting-material/acknowledgements\)](https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation/supporting-material/acknowledgements) (EAG) was assembled to specifically review updated evidence on the efficacy and safety of prescribing NVPs and to examine the practicalities of prescribing them for smoking cessation in the new regulatory environment.

Grading of Recommendations, Assessment, Development and Evaluation (GRADE) process

The RACGP commissioned the Joanna Briggs Institute (JBI) and the JBI Adelaide GRADE Centre to assist with revising this guideline for the second edition.

Using [GRADE \(http://www.gradeworkinggroup.org/\)](http://www.gradeworkinggroup.org/) (<http://www.gradeworkinggroup.org/>) to develop this guideline required JBI and the JBI Adelaide GRADE Centre to conduct an evidence review that resulted in a GRADE 'Summary of findings' table. This table is a summarised representation of the major findings, along with a rating of the certainty in the evidence.

The 'Summary of findings' table was incorporated into the evidence-to-decision framework. The Expert Advisory Group then worked to move from the evidence to making practice recommendations, ensuring all important aspects related to making structured recommendations were considered. This resulted in transparent and practice-based recommendations.

Adapting the previous guideline recommendations to GRADE

The GRADE process allows guidelines to be developed by adopting existing guideline recommendations from others, adapting existing recommendations to suit a new context and creating new recommendations.¹

The GRADE process is a resource-intensive process to create guideline recommendations. Therefore, where appropriate, existing guideline recommendations were retained and converted to the GRADE format.

The guideline recommendations from the first edition were based on the National Health and Medical Research Council (NHMRC) classification system. The NHMRC system classifies the quality of the evidence as follows:²

Level I – Evidence obtained from systematic review of relevant randomised controlled trials

Level II – Evidence obtained from one or more well-designed, randomised controlled trials

Level III – Evidence obtained from well-designed, non-randomised controlled trials, or from well-designed cohort or case control studies

Level IV – Evidence obtained from case series, either post-test or pre-test and post-test

Level V – Opinions of respected authorities based on clinical experience, descriptive studies, reports of expert committees

No evidence – No evidence was found relevant to general practice on the issue being considered

The strength of the recommendations for the first edition were based on the US Preventive Services Task Force (USPSTF) guide:³

A – There is good evidence to support the recommendation **B** – There is fair evidence to support the recommendation **C** – There is poor evidence regarding the inclusion, or exclusion of the recommendation but recommendations may be made on other grounds.

The Expert Advisory Group reviewed the guideline recommendations from the first edition for redundancy, relevance and the strength of evidence. The strength of these recommendations, based on the USPSTF guide, were then converted to the equivalent GRADE strength of evidence format through consensus on a case-by-case basis (Table 1).

Table 1. Comparison of USPSTF and GRADE recommendation descriptors

USPSTF's strength of recommendation	GRADE recommendation descriptor
A – There is good evidence to support the recommendation	Strong recommendation for (or against) the intervention
B – There is fair evidence to support the recommendation	Weak recommendation for (or against) the intervention
C – There is poor evidence regarding the inclusion, or exclusion of the recommendation but recommendations may be made on other grounds	Conditional recommendation for either the intervention or the comparison

Table 1

Comparison of USPSTF and GRADE recommendation descriptors

New smoking cessation questions and recommendations

Since the minor update in 2014, the field of smoking cessation has moved forward. It now includes more sophisticated pharmacology, technology in the form of quitting apps, and controversial nicotine delivery modalities such as electronic cigarettes (ie e-cigarettes).

New topics identified by the Expert Advisory Group included questions on:

- combinations and dosage of pharmacotherapies
- relapse prevention
- use of nicotine replacement therapy (NRT) during pregnancy
- nicotine containing e-cigarettes as a cessation aid.

Clinical questions on these topics were formulated as PICO (patient, intervention, comparator, outcome) questions, which were subjected to the GRADE process.

The prioritised clinical questions were:

- Is combination NRT (ie patch and oral form) more effective than patch alone? If so, is this effective for all people who smoke or only for those who are more nicotine dependent?
- Is the combination of varenicline and NRT more effective than varenicline alone? If so, is this effective for all people who smoke or only for those who are more nicotine dependent?
- Does adding any further course of NRT (any form) reduce relapse in people who have quit smoking at the completion of a standard course of NRT?
- Does adding any further course of varenicline (>12 weeks) reduce relapse in people who have quit smoking at the completion of a standard course of varenicline (ie 12 weeks)?
- Is it safe and effective for pregnant women who smoke to use NRT rather than no NRT?
- Are nicotine-containing e-cigarettes more effective than NRT for smoking cessation?

Explanation for GRADE levels of evidence and strength of recommendations

The GRADE process classifies the **quality of the evidence (certainty)** into one of four scores:

1. **High**: very confident that the true effect lies close to that of the estimated effect.
2. **Moderate**: moderately confident in the estimated effect. The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
3. **Low**: confidence in the estimated effect is limited. The true effect may be substantially different from the estimated effect.
4. **Very low**: very little confidence in the estimated effect. The true effect is likely to be substantially different from the estimated effect.

The GRADE process classifies the **strength of a recommendation** into one of three scores:

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.

Summary of recommendations

The role of health professionals

Recommendation 1 – All people who smoke should be offered brief advice to quit smoking. Strong recommendation, high certainty

Recommendation 2 – A system for identifying all people who smoke and documenting tobacco use should be used in every practice or healthcare service. Strong recommendation, high certainty

Recommendation 3 – Offer brief smoking cessation advice in routine consultations and appointments, whenever possible. Strong recommendation, high certainty

Recommendation 4 – Offer follow-up to all people who are attempting to quit smoking. Strong recommendation, high certainty

Pharmacotherapy for smoking cessation

Recommendation 5 – In the absence of contraindications, pharmacotherapy (nicotine replacement therapy, varenicline or bupropion) is an effective aid when accompanied by behavioural support, and should be recommended to all people who smoke who have evidence of nicotine dependence. Choice of pharmacotherapy is based on efficacy, clinical suitability and patient preference. Strong recommendation, high certainty

Recommendation 6 – Combination nicotine replacement therapy (NRT) (ie patch and oral form) accompanied by behavioural support is more effective than NRT monotherapy accompanied by behavioural support, and should be recommended to people who smoke who have evidence of nicotine dependence. Strong recommendation, moderate certainty

Recommendation 7 – For people who have stopped smoking at the end of a standard course of nicotine replacement therapy (NRT), clinicians may consider recommending an additional course of NRT to reduce relapse. Conditional recommendation for intervention, low certainty

Recommendation 8 –

a) Nicotine replacement therapy (NRT) is safe to use in patients with stable cardiovascular disease. Strong recommendation, high certainty

b) NRT should be used with caution in patients who have had a recent myocardial infarction, unstable angina, severe arrhythmias or recent cerebrovascular events.

Strong recommendation, moderate certainty

Recommendation 9 – For women who are pregnant and unable to quit smoking with behavioural support alone, clinicians might recommend nicotine replacement therapy (NRT), compared with no NRT. Behavioural support and monitoring should also be provided. Conditional recommendation for intervention, low certainty

Recommendation 10 – Varenicline should be recommended to people who smoke and who have been assessed as clinically suitable for this medication; it should be provided in combination with behavioural support. Strong recommendation, high certainty

Recommendation 11 – For people who have abstained from smoking after a standard course of varenicline in combination with behavioural support, clinicians may consider a further course of varenicline to reduce relapse. Conditional recommendation for intervention, low certainty

Recommendation 12 – For people who are attempting to quit smoking using varenicline accompanied by behavioural support, clinicians might recommend the use of varenicline in combination with nicotine replacement therapy, compared with varenicline alone. Conditional recommendation for intervention, moderate certainty

Recommendation 13 – Bupropion sustained release should be recommended to people who smoke and who have been assessed as clinically suitable for this medication; it should be provided in combination with behavioural support. Bupropion is less effective than either varenicline or combination nicotine replacement therapy. Strong recommendation, high certainty

Recommendation 14 – Nortriptyline should be considered as a second-line smoking cessation pharmacotherapy agent because of its adverse effects profile. Strong recommendation, moderate certainty

Recommendation 15 – For people who have tried to achieve smoking cessation with first-line therapy (combination of behavioural support and TGA-approved pharmacotherapy) but failed and are still motivated to quit smoking, NVPs may be a reasonable intervention to recommend along with behavioural support. However, this needs to be preceded by an evidence-informed shared-decision making process, whereby the patient is aware of the following caveats:

- 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 vaping devices and NVPs, which increases the uncertainties associated with their use.

- To maximise possible benefit and minimise risk of harms, dual use should be avoided and long-term use should be minimised.
- It is important for the patient to return for regular review and monitoring.

Conditional recommendation for intervention, low certainty

Practice points – NVPs are unapproved products and it is valid and reasonable for medical practitioners to choose not to prescribe them. Overseas nicotine vaping products are not required to meet all of the TGO 110 requirements for safety. To minimise risk of harms, the EAG recommends the following measures for prescribers:

1. **Recommend NVPs in closed systems and avoid open systems** – to minimise the risk of poisoning, addition of toxic/illegal substances and contamination. High concentration disposable nicotine salt pod devices should also be avoided due to environmental waste and safety concerns, including high risk of diversion.
2. **Use the Authorised Prescriber and Special Access Scheme prescribing pathways** instead of the Personal Importation Scheme – to minimise the risk of the patient accessing NVPs that do not comply with the minimum safety and quality TGO 110 labelling and packaging requirements. In addition, the prescriber can supply the prescription directly to the patient's nominated pharmacy and/or endorse it "**For Local Supply Only**".
3. **Avoid prescribing free-base nicotine at concentrations over 20 mg/mL.** The two trials showing NVP efficacy used a concentration of ≤ 20 mg/mL free-base nicotine. Although they are the most widely available closed system option, there is currently no clinical trial evidence of efficacy for smoking cessation with nicotine salt products. Nicotine e-liquid concentrations of 100 mg/mL are not necessary and should not be prescribed. The risks of poisoning through skin contact and accidental ingestion are far greater where patients choose to dilute their own e-liquids.
4. **Limit the quantity of nicotine vaping products per prescription to a maximum of 3 months' supply.** Consider aligning the duration of supply with the timing of follow-up.
5. **Where possible, avoid flavours or limit to tobacco flavour.**
6. **Provide follow-up and behavioural support**

Behavioural and advice-based support for smoking cessation

Recommendation 16 – Referral to telephone call-back counselling services should be offered to all people who smoke. Strong recommendation, high certainty

References

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2. National Health and Medical Research Council. A guide to the development, evaluation and implementation of clinical practice guidelines. Canberra: NHMRC, 1999.
3. US Preventive Services Task Force, United States Department of Health and Human Services. Guide to clinical preventive services: Report of the US Preventive Services Task Force. 2nd edn. Baltimore, MD: Williams & Wilkins, 1996.

Introduction to smoking cessation

What is new - Guidance updates on smoking and vaping cessation support related to changes to Australia's vaping regulations as of 1 January 2024

[Provisional guidance \(https://www.racgp.org.au/getmedia/2f8ffac1-8751-41aa-906f-f0ec7feca048/RA-CGP-NVP-and-Vaping-Cessation-Consultation-provisional-draft-Dec2023.pdf.aspx\)](https://www.racgp.org.au/getmedia/2f8ffac1-8751-41aa-906f-f0ec7feca048/RA-CGP-NVP-and-Vaping-Cessation-Consultation-provisional-draft-Dec2023.pdf.aspx) has been produced in time for the changes to Australia's vaping regulations the come into force on 1 January 2024.

This document is currently under stakeholder consultation which will close on 19 January 2024 after which time the guidance will be finalised. The document has been prepared by the RACGP Smoking cessation Expert Advisory Group and reviewed by key stakeholders within the Therapeutic Goods Administration and Department of Health.

Eligibility for nicotine replacement therapies - advice for health professionals

Health professionals can use this advice to consider whether their patients are [eligible for subsidised NRTs \(https://www.health.gov.au/resources/publications/eligibility-for-nicotine-replacement-therapies-advice-for-health-professionals\)](https://www.health.gov.au/resources/publications/eligibility-for-nicotine-replacement-therapies-advice-for-health-professionals) under the Pharmaceutical Benefits Scheme

Recommendations

Recommendation 1 - All patients who smoke should be offered brief advice to quit smoking

Strong recommendation, high certainty

Recommendation 2 – A system for identifying all people who smoke and documenting tobacco use should be used in every practice or healthcare service.

Strong recommendation, high certainty

Recommendation 3 – Offer brief cessation advice in routine consultations and appointments, whenever possible.

Strong recommendation, high certainty

Recommendation 4 – Offer follow-up to all people who are attempting to quit smoking.

Strong recommendation, high certainty

Introduction

Australia has made major progress in tobacco control, with population prevalence of smoking falling substantially since the 1960s. Daily smoking nearly halved from 24% in 1991 to 12.8% in 2013. While there has been a slowing in the rate of decline with little change in prevalence from 2013 to 2016 (12.2%),¹ Australia has one of the lowest smoking rates in the Organisation for Economic Cooperation and Development (OECD) countries.² In recent years, smoking rates have also fallen for Aboriginal and Torres Strait Islander peoples, but the prevalence remains unacceptably high.^{1,3,4} Australia has not met the National Tobacco Strategy 2012–18 target, which aimed to reduce the national smoking rate among Australian adults to 10% and halve the 2009 smoking rate for Aboriginal and Torres Strait Islander populations.⁵ Despite the decline in prevalence, smoking remains the behavioural risk factor responsible for the highest levels of preventable disease and premature death.^{6,7} The task of further reducing the number of Australians who are using tobacco requires a collaborative effort between government, health authorities, healthcare professionals and the community at large.

Australia is a signatory to the World Health Organization (WHO) Framework Convention on Tobacco Control, a worldwide effort to control the effects of tobacco smoking on human health.⁸ The framework commits governments to enacting a minimum set of policies proved to curb tobacco use, including:⁹

- a ban on tobacco advertising, promotion and sponsorship
- clear warning labels
- smoke-free policies
- higher prices and taxes on tobacco products
- access to, and availability of, smoking cessation services
- international cooperation in dealing with cigarette smuggling and cross-border advertising.

Australia was the first country to introduce the plain packaging of tobacco products⁹ in 2012; several other countries have since enacted tobacco plain packaging laws.

Tobacco control involves preventing uptake, supporting cessation and implementing harm-reduction strategies. Health professionals play a key role, and have a particular responsibility to assist all people who smoke to stop.^{10,11,12}

Supporting smoking cessation: A guide for health professionals is a practical, succinct and evidence-based resource for use by a wide range of healthcare professionals working in a variety of contexts. The recommendations are based on research evidence and informed by guidelines from other countries with similar populations.

This RACGP guideline seeks to encourage healthcare professionals to offer smoking cessation advice to all people who smoke, and the advice offered herein is consistent with the materials and support services provided through telephone Quitlines nationally.

It supports the momentum for smoking cessation gained through public health measures such as tax increases, restrictions on smoking in public places, changes to tobacco display and the introduction of plain packaging and the social marketing of smoking cessation. The guide also covers the ongoing debate around the role of tobacco harm-reduction strategies.

Since this guideline was first published in 2011, there have been developments in the science and practice of smoking cessation support. These include advances in our understanding of the neurobiology of nicotine addiction, new medicines (eg bupropion, varenicline), substantial changes in the use of nicotine replacement therapy (NRT), the emergence of nicotine-containing e-cigarettes and novel strategies (eg online and text-based cessation support programs). Smoking cessation medicines (ie bupropion, varenicline, NRT) have been listed on the Pharmaceutical Benefits Scheme (PBS) with special provision for Aboriginal and Torres Strait Islander peoples. To keep pace with these changes, the guidelines had minor updates in 2012 and 2014, and have been reviewed and updated in 2019.

Readers of this guide who want to know more about tobacco use and tobacco control measures, including summaries of what is known about the effectiveness of smoking cessation, can access the resource '[Tobacco in Australia \(http://www.tobaccoinaustralia.org.au/home.aspx\)](http://www.tobaccoinaustralia.org.au/home.aspx)'.

Tobacco smoking: Scope of the problem

Prevalence and trends

- Globally, one in 10 deaths is caused by some form of tobacco use.¹³
- Tobacco use is attributable to more than eight million deaths each year worldwide. Of these deaths, approximately 1.2 million are non-smokers exposed to second-hand smoke.^{7,14,15}
- The mortality rate attributable to smoking is expected to rise to 10 million deaths per year by the 2020s or early 2030s, with 70% of those deaths occurring in developing countries.¹⁶
- In Australia, the prevalence of smoking is among the lowest of any OECD nation.²
- Rates of smoking daily among Aboriginal and Torres Strait Islander peoples are still more than three times that of non-Indigenous Australians.³ However, there has been a progressive decrease in daily smoking rates within Aboriginal and Torres Strait Islander populations, from 55% in 1994 to 45% in 2014–15.⁴
- Tobacco smoking accounted for almost a quarter (23%) of the health gap between Aboriginal and Torres Strait Islander peoples and non-Indigenous Australians.¹⁷

Key findings on tobacco from the 2016 National Drug Strategy Household Survey¹

- One in eight Australians smoke tobacco daily, while six in 10 have never smoked.
- Smoking rates have been on a long-term downward trend since 1991, but the daily smoking rate did not decline significantly over the most recent three-year period (ie 12.8% in 2013, 12.2% in 2016).
- Among people who smoke, three in 10 (28.5%) tried to quit but did not succeed, and about one in three (31%) do not intend to quit.
- Smoking rates are higher in remote areas of Australia (ie 13.6% in major cities, 23.8% in remote areas).

As a result of changes in public policy and changing community attitudes to tobacco, the status of tobacco smoking has shifted from a socially acceptable behaviour to an antisocial behaviour.¹⁸

Harms associated with smoking

Smoking causes a higher burden of disease than any other behavioural risk factor, representing 9.3% of the total burden of disease in 2015.^{6,19} The Australian Burden of Disease study estimated that 20,933 deaths were attributable directly to tobacco smoking in 2015,^{6,19} and smoking-related disease contributes as a comorbidity to many more.

In 2015, tobacco use contributed to the burden of disease for:⁶

- 41% of respiratory diseases
- 22.1% of cancers
- 11.5% of cardiovascular diseases
- 3.7% of endocrine disorders.

Tobacco smoking harms almost every organ of the body, causing a wide range of diseases and harming the health of those who smoke (Figure 1.1).^{7,20}

Exposure to second-hand smoke has been shown to damage the health of unborn babies, infants, children and adults, as follows:²⁰

- infants – sudden infant death syndrome (SIDS)
- children – asthma, impaired lung function, respiratory symptoms, middle ear disease
- adults – coronary heart disease, lung cancer, nasal irritation, stroke, reproductive effects in women, low birth-weight babies.

Quitting smoking has immediate and long-term benefits, reducing the risks for diseases caused by smoking and improving physical and mental health (Figure 1.2). If it occurs early enough, successfully quitting smoking can result in a difference of up to 10 years in life expectancy.²¹

Harms associated with smoking in pregnancy

Smoking has adverse effects in pregnancy, both for the mother and the developing fetus. As well as the serious long-term health consequences for the mother, tobacco smoking during pregnancy is the most common preventable risk factor for pregnancy complications. Smoking during pregnancy is associated with poorer perinatal outcomes, including: [22,23,24](#)

- low birthweight
- being small for gestational age
- pre-term birth
- perinatal death
- placental abruption
- SIDS
- cleft palate
- cleft lip
- childhood cancers.

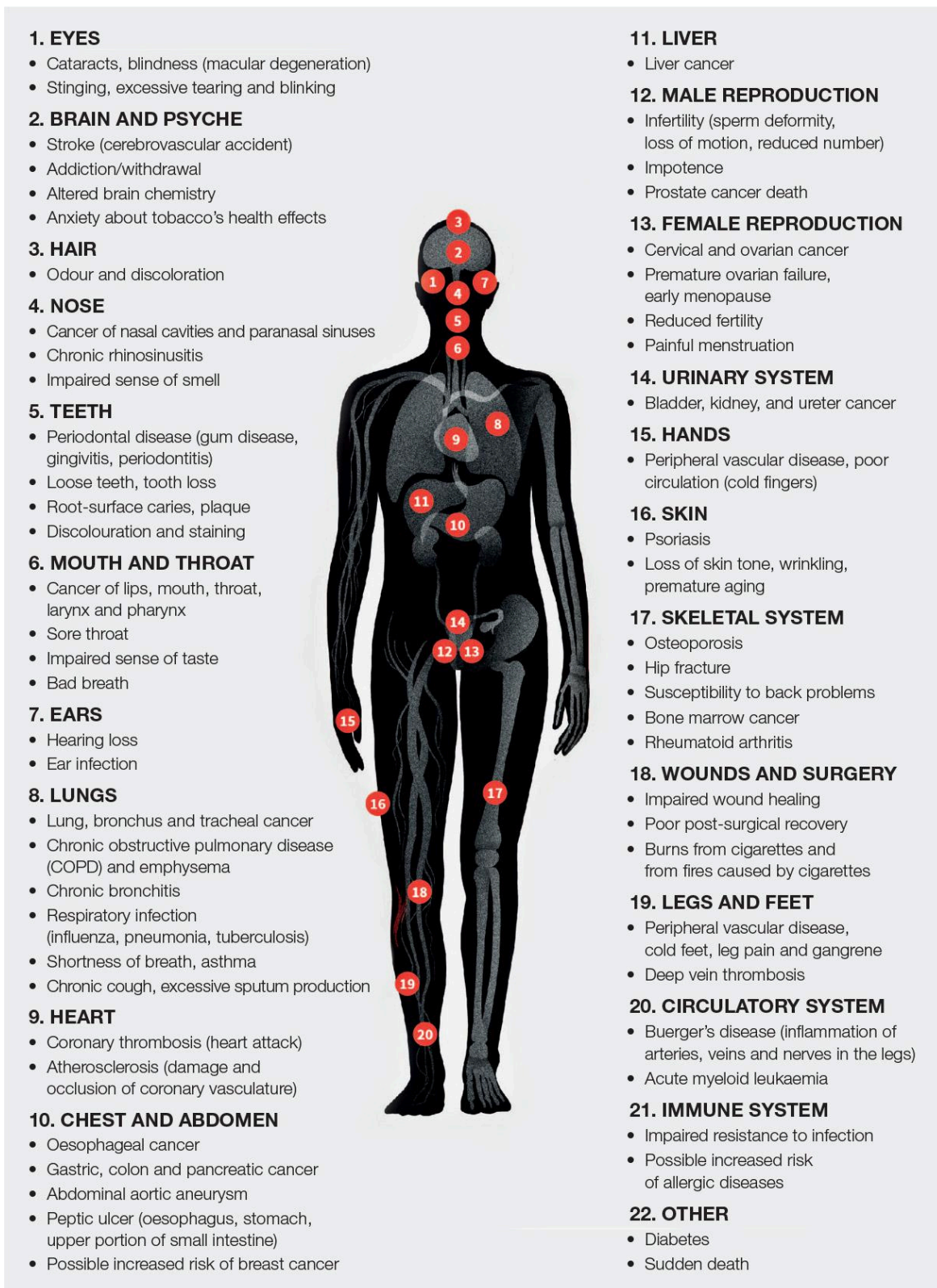


Figure 1.1

Health effects of smoking

Reproduced from Drope J, Schluger NW, editors. The tobacco atlas. 6th edn. Atlanta, GA: American Cancer Society and Vital Strategies, 2018; p. 24. Copyright 2018 [The American Cancer Society \(http://www.cancer.org\)](http://www.cancer.org), Inc. Reprinted with permission.



Figure 1.2

The effects of quitting over time

Reproduced from Drope J, Schluger NW, editors. The tobacco atlas. 6th edn. Atlanta, GA: American Cancer Society and Vital Strategies, 2018; p. 37. Copyright 2018 The American Cancer Society, Inc. Reprinted with permission from www.cancer.org (<http://www.cancer.org/>)

Smoking during pregnancy is associated with long-term health effects for the child, including:^{25,26}

- neurodevelopmental and behavioural problems
- obesity
- hypertension
- type 2 diabetes
- impaired lung function
- asthma
- wheezing.

While the rate of smoking during pregnancy in Australia is falling, of women who gave birth during 2017, approximately 10% continued to smoke some time during their pregnancy.²⁷

Effectiveness of treating tobacco dependence

Smoking cessation is cost and clinically effective, compared with other medical-preventive and disease-preventive measures such as treatment of hypertension and hypercholesterolaemia.^{28,29,30,31,32} Along with childhood immunisation and aspirin use with high-risk adults, overall efforts to reduce tobacco smoking are among the most beneficial preventive interventions for human health.^{16,31,33,34} The cost per life year saved by smoking cessation interventions makes it one of the most cost-effective healthcare interventions.^{27,31}

Advice from health professionals, including doctors, nurses, pharmacists, psychologists, dentists and dental therapists, social workers, other allied health staff and smoking cessation specialists, helps those who smoke to quit.^{9,35,36,37} While spending more time (>10 minutes) advising those who smoke to quit yields higher abstinence rates than minimal advice,²¹ offering brief advice (as little as three minutes) has been shown to have clear benefits.^{9,38}

On a population level, providing brief advice to most people who smoke is more effective and efficient than spending a long time with a few patients.^{37,39}

Advice-based help and pharmacotherapy can increase the rate of success of quit attempts, and their benefits are cumulative when they are used.²¹

The most effective way to quit is with advice and support from a health professional, combined with smoking cessation pharmacotherapy.⁹ People who smoke should at every opportunity be offered treatment that is customised to their needs and experience.

Quit attempts

Tobacco dependence is a chronic condition that typically requires repeated cessation treatment attempts and ongoing care.^{21,40} A minority of people who smoke achieve long-term abstinence on the first attempt to quit, while the majority cycle through multiple attempts with relapse and remission before achieving long-term or permanent abstinence.^{21,41} Multiple attempts over several years are not unusual; the average person aged 40 years who smokes will have made around 20 unsuccessful quit attempts (ie of 24-hour duration or more), most without any external help. The average person who smokes will make at least one failed attempt at quitting each year; some make a lot more and some people rarely try. Those who smoke can learn something from each quit attempt to help overcome tobacco dependence.^{41,42}

While people can succeed in quitting smoking without any assistance,⁴³ most have better results using some form of help.⁴¹ The decision to try to quit unassisted should be respected and supported;⁴⁴ however, those who smoke should be informed that making use of assistance (eg combination of behavioural support and pharmacotherapy) will increase their chances of quitting successfully. Offering support is especially important for people who smoke who have tried multiple times to quit without long-term success. Those who smoke who are more nicotine-dependent are more likely to need and seek treatment.⁴⁵

The role of health professionals

Health professionals from all disciplines can play an important role in supporting smoking cessation. All health professionals should systematically identify people who smoke and offer them advice and cessation treatment (or referral) at every opportunity.^{9,34,35,36,46}

Health professionals should aim to capitalise on moments in a patient's life when taking action about their tobacco use is particularly relevant:

- presenting with tobacco-related diseases
- during diagnosis or management of any condition where tobacco use affects treatment or outcomes
- during or after hospitalisation
- preparing for surgery, before and during pregnancy, and after the birth of a child.

In addition, there are visits where more detailed assessment and documentation of smoking should occur (eg new patient visits, routine check-ups).

There is a range of evidence-based strategies that can improve the implementation of effective smoking cessation intervention in the healthcare setting.^{47,48,49,50} Providing a systematic approach to smoking cessation is associated with higher levels of success.²¹ Routine enquiry through waiting room surveys^{46,51} or use of additional practice staff to provide counselling are associated with higher quit rates.³⁶

Where health professionals are not able to offer smoking cessation support or treatment within their own practice, they should refer patients who smoke for help elsewhere. In Australia, available options include Quitline, which provides free multi-session behavioural interventions, online programs (eg [QuitCoach \(http://www.quitcoach.org.au\)](http://www.quitcoach.org.au), [iCanQuit \(http://www.icanquit.com.au\)](http://www.icanquit.com.au)) and SMS programs (eg [QuitTxt \(http://www.quitcoach.org.au/QuitTextInformation.aspx\)](http://www.quitcoach.org.au/QuitTextInformation.aspx)), and an emerging group of tobacco treatment specialists coordinated by the [Australasian Professional Society on Alcohol & other Drugs \(http://www.apsad.org.au\)](http://www.apsad.org.au) (APSAD). In some states and territories, there are local programs provided by hospitals or community health facilities.

Barriers to providing smoking cessation advice

Barriers raised by health professionals to them engaging in greater efforts to provide smoking cessation advice include:^{52,53}

- a perception that smoking cessation is ineffective
- lack of time
- lack of smoking cessation skills
- reluctance to raise the issue because of perceived patient sensitivity about smoking
- perceived lack of patient motivation
- lack of confidence in providing smoking cessation advice.

Many of these barriers are based on incorrect assumptions or are barriers that can be overcome. Evidence in relation to these beliefs and barriers is presented in Table 1.1.

Table 1.1 Beliefs and barriers raised by health professionals to offering smoking cessation advice

Beliefs and barriers	Evidence to the contrary
Assistance with smoking cessation is not part of my role	Most patients think smoking cessation assistance is part of your clinical role ^{45,54}
I have counselled all my patients who smoke	Only 45–71% of people who smoke are counselled ^{55,56}
Those who smoke are not interested in quitting	Nearly all who smoke are interested in quitting, although some are temporarily put off by past failures. More than 40% of people who smoke make quit attempts each year and more think about it ⁴⁰
I routinely refer patients for smoking cessation assistance	Referrals to Quitline are low (10–25%) ⁵⁷
I am not effective at encouraging smoking cessation	Clinicians can achieve substantial quit rates over six to 12 months of 12–25%, which contribute to important public health benefits ^{9,58,59}
People who smoke will be offended by enquiry	Visit satisfaction is higher when smoking is addressed appropriately ^{65,60}
I do not have time to counsel those who smoke	Effective counselling or referral can take as little as a minute ²¹
Quitting smoking worsens mental illness	Quitting does not generally cause deterioration of mental illnesses (eg depression, schizophrenia, post-traumatic stress disorder), and is associated with improvements in mood ⁶¹

Table 1.1

Beliefs and barriers raised by health professionals to offering smoking cessation advice

Interventions for smoking cessation

Brief intervention for smoking cessation

The Ask, Advise, Help structure for supporting smoking cessation is a brief intervention that can be provided by a wide range of health professionals working in a variety of settings. The brief intervention can be delivered in a short time, reducing one of the key barriers to health professionals providing smoking cessation advice.^{62,63,64} This three-step model, developed by Quit Victoria, offers patients best practice smoking cessation treatment by linking into multi-session behavioural interventions (eg Quitline) and encouraging the use of pharmacotherapy, as indicated. Three-step approaches for supporting smoking cessation have been used for some time in the UK,⁶⁵ Canada^{66,67} and New Zealand.⁶⁸

The three-step brief intervention model (Figure 1.3) can be summarised as follows:

- **Ask** and record smoking status
- **Advise** all people who smoke to quit and on the most effective methods
- **Help** by offering to arrange referral, encourage use of behavioural intervention and use of evidence-based smoking cessation pharmacotherapy

Options for behavioural support include the Quitline (13 78 48) or a [tobacco treatment specialist \(http://www.apsad.org.au\)](http://www.apsad.org.au).

Recommendation 1 – All patients who smoke should be offered brief advice to quit smoking. Strong recommendation, high certainty

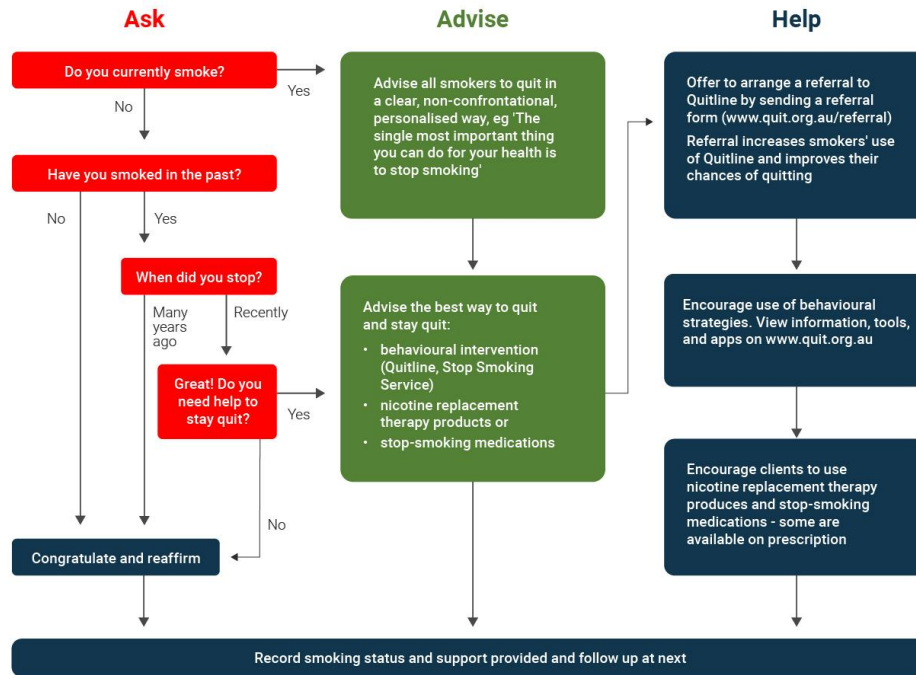


Figure 1.3

Three-step brief intervention – Ask, Advise, Help

Reproduced with permission from Quit Victoria, 2019.

Comprehensive intervention for smoking cessation

Comprehensive support for quitting within the clinical service can be provided using the 5As structure:

- Ask
- Assess
- Advise
- Assist
- Arrange follow-up

The 5As approach (Figure 1.4) is applicable when health professionals are providing assistance personally or with help from other staff within the clinical service. It involves:

- identifying all patients who smoke

- assessing nicotine dependence and barriers to quitting
- advising them to quit
- offering quitting assistance
- arranging follow-up.

The approach is adopted in full or as a modified form in the majority of international smoking cessation guidelines.⁶⁹ Where possible, health professionals should maintain long-term and ongoing relationships with people who smoke in order to foster the person’s motivation and confidence to attempt smoking cessation.

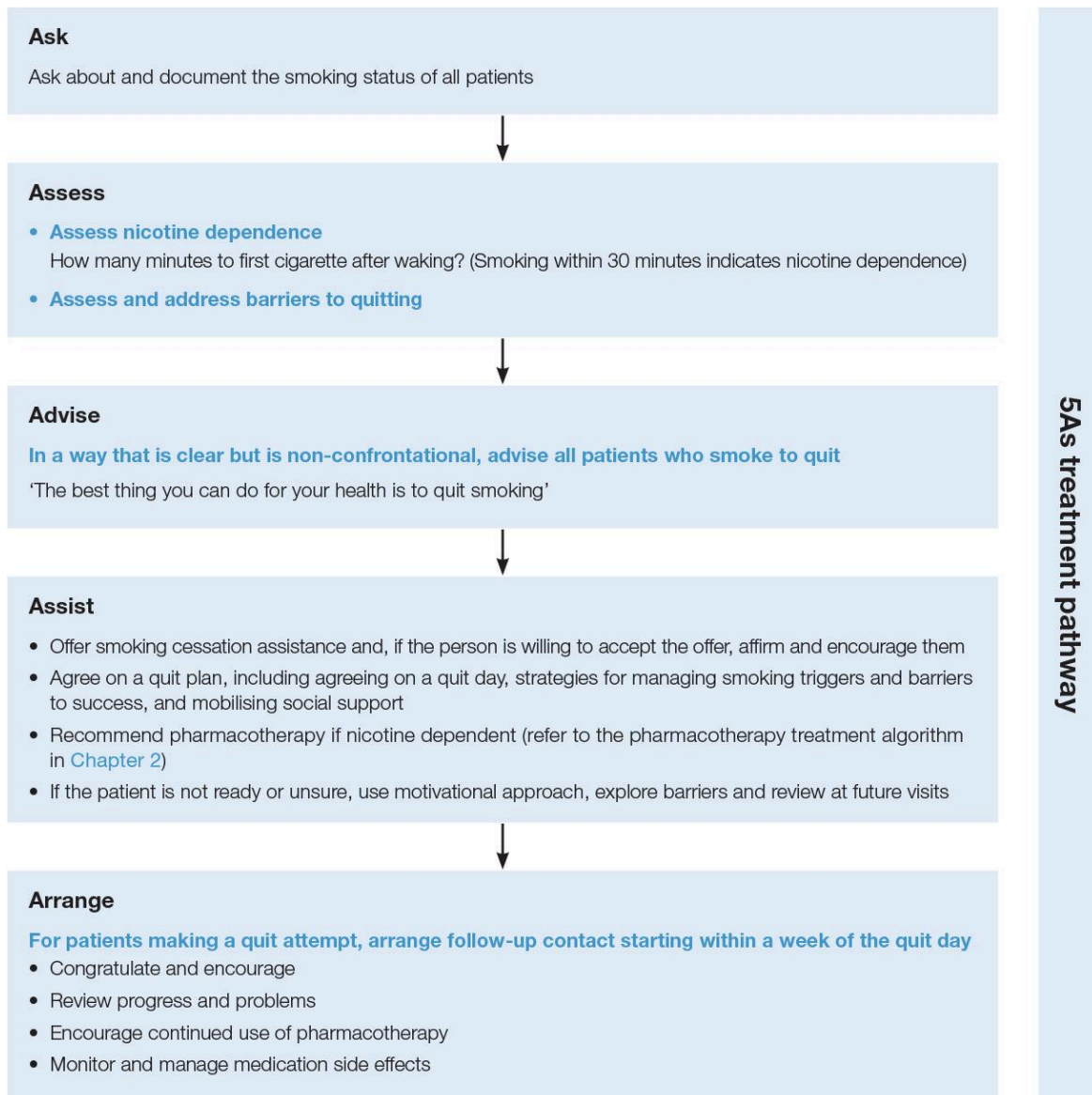


Figure 1.4

5As structure for smoking cessation

Ask all patients about smoking

Ask

Ask about and document the smoking status of all patients

Health professionals should ask all patients whether they smoke tobacco and their smoking status should be recorded. Implementing recording systems that document tobacco use almost doubles the rate at which clinicians intervene with patients who smoke, and results in higher rates of smoking cessation.²¹ For those patients known to smoke, health professionals should try to continue a conversation about their smoking at each visit, even if it is just an offer to discuss options and importance of action at a subsequent visit. It is important for health professionals to be non-judgemental when asking about smoking.

Recommendation 2 – A system for identifying all people who smoke and documenting tobacco use should be used in every practice or healthcare service. Strong recommendation, high certainty

Assess nicotine dependence and barriers to quitting

Assess

Assess nicotine dependence

How many minutes to first cigarette after waking? (Smoking within 30 minutes indicates nicotine dependence) **Assess and address barriers to quitting**

Assess nicotine dependence

The majority of people who smoke are nicotine dependent, and smoking can be conceptualised as a chronic medical illness requiring ongoing care for these people.⁷⁰ As nicotine dependence is under-recognised by clinicians, routine assessment of nicotine dependence can help predict whether a person who smokes is likely to experience nicotine withdrawal on stopping smoking,^{71,72} and the intensity and type of support that may be required to assist quitting.

A quick assessment of nicotine dependence can be made by asking the person who smokes:⁷³

- 'How soon after waking do you have your first cigarette?'
- 'Have you had cravings for a cigarette, or urges to smoke and withdrawal symptoms (refer to 'Nicotine withdrawal symptoms' for examples) when you have tried to quit?'

Smoking within 30 minutes of waking, smoking more than 10 cigarettes per day (although some nicotine-dependent people may not smoke daily) and a history of withdrawal symptoms in previous attempts to quit are all indicators of nicotine dependence.

Time to first cigarette is the most reliable single indicator of nicotine dependence. Since cigarettes per day became a measure of dependence, a combination of public health and clinical interventions have changed smoking habits in developed countries, making it a less robust indicator. As the number of cigarettes per day declines in countries with strong anti-smoking policies, and the fact that those who smoke underestimate their own consumption level, time to first cigarette has been widely accepted as a more reliable marker of dependence in most people who smoke.⁶⁴

Assess and address barriers to quitting

It is important for health professionals to be aware of the potential difficulties patients face when attempting to quit smoking, and identify and address any mistaken beliefs and attitudes about quitting at the time of the quit attempt (Table 1.2).^{74,75} Support could include providing treatment for withdrawal symptoms or mental health issues, or recommending physical activity and a healthy diet to minimise weight gain. It is also important to recognise the broader influence of social determinates on health behaviours and people's capacity to make health choices.

Table 1.2 Attitudes and barriers to quitting

Perceived barrier (mistaken beliefs and attitudes)	Evidence-based strategies to address barriers ⁷⁶⁻⁷⁸
<ul style="list-style-type: none"> I can quit at any time I am not addicted 	<ul style="list-style-type: none"> Ask about previous attempts to quit and success rates
<ul style="list-style-type: none"> Using cessation support is a sign of weakness Help is not necessary 	<ul style="list-style-type: none"> Reframe support Explain that nicotine withdrawal symptoms are reduced by treatment Highlight that unsupported quit rate is 3–5%, but substantially higher with assistance
<ul style="list-style-type: none"> Too addicted Too hard to quit Fear of failure 	<ul style="list-style-type: none"> Ask about previous quit attempts Explore pharmacotherapy used and offer options (eg combination therapy)
<ul style="list-style-type: none"> Too late to quit I might not benefit so why bother 	<ul style="list-style-type: none"> Benefits accrue at all ages, and are greater if cessation is achieved earlier: quitting at 30 years of age achieves similar life expectancy to those who do not smoke Provide evidence and feedback (eg spirometry, lung age, absolute risk score)
<ul style="list-style-type: none"> My health has not been affected by smoking You have to die of something I know someone who smoked heavily who has lived a long time 	<ul style="list-style-type: none"> State evidence that one in two people who continue to smoke after middle age will die prematurely of smoking-related disease Reframe: for example, chronic obstructive pulmonary disease (COPD) = smoker's lung
<ul style="list-style-type: none"> Not enough willpower No point in trying unless you want to To quit successfully, you really have to want to quit, then you will just do it 	<ul style="list-style-type: none"> Explore motivation and confidence Explore and encourage the use of effective strategies (eg Quitline, pharmacotherapy)
<ul style="list-style-type: none"> Cigarettes help me relax 	<ul style="list-style-type: none"> Suggest other relaxation strategies such as breathing techniques and progressive muscle relaxation
<ul style="list-style-type: none"> Fear of weight gain 	<ul style="list-style-type: none"> Average weight gain after smoking cessation is 2–4 kg; only about 10% of people have substantial weight gain (>13 kg) Suggest strategies to minimise weight gain: healthy diet; avoid high-fat and high-sugar foods and drinks; regular physical activity Point out that health benefits of quitting far exceed any adverse health effects of weight gain
<ul style="list-style-type: none"> Peer and social pressure 	<ul style="list-style-type: none"> Suggest avoidance of high-risk social situations early in the quit attempt For some people it can be helpful to rehearse how to say no to a cigarette offer

*Table 1.2**Attitudes and barriers to quitting***Nicotine withdrawal symptoms**

Nicotine withdrawal symptoms commonly include craving for nicotine and onset of other symptoms. The *Diagnostic and statistical manual of mental disorders*, 5th edition (DSM-5) defines nicotine withdrawal as occurring:

'after abrupt cessation of tobacco use, or reduction in the amount of tobacco used, followed within 24 hours by four or more of the following signs or symptoms:

- irritability, frustration, anger
- anxiety
- difficulty in concentration
- increased appetite
- restlessness
- depressed mood
- insomnia.⁷⁹

To meet the DSM-5 definition: 'these symptoms need to cause clinically significant distress or impairment in social, occupational or other important areas of functioning, and not be attributable to another medical condition or better explained by another mental disorder, including intoxication or withdrawal from another substance.'⁷⁹

Other nicotine withdrawal symptoms may include:⁸⁰

- craving for sweet or sugary foods
- constipation
- coughing
- dizziness
- dreaming/nightmares
- nausea
- mouth ulcers
- sore throat.

It is important to inform the person beginning a first or subsequent quit attempt that they may experience nicotine withdrawal symptoms when quitting.

Usually, nicotine withdrawal symptoms begin within 24 hours of the last cigarette and are strongest in the first week (but for some people only in the first 2–3 days). For most people, withdrawal symptoms decline steadily and can disappear after approximately 2–4 weeks.⁸⁰ Symptoms can occur for other reasons, so caution should be exercised in attributing them to nicotine withdrawal.

Nicotine withdrawal symptoms can be reframed as recovery symptoms. Pharmacotherapies will reduce or completely prevent withdrawal symptoms.⁸¹

Urges to smoke and cravings for nicotine are elements of withdrawal, and are strong predictors of relapse.⁸¹ Providing strategies to manage withdrawal is an essential aspect of the healthcare professional's role:

- Quitline services offer a number of patient calls, especially in the first few weeks, to help and encourage those who smoke in a quit attempt to stay on track.
- Smoking cessation pharmacotherapies can prevent or reduce the severity of withdrawal symptoms.^{81,89}
- There is evidence that exercise can help reduce acute cravings and nicotine withdrawal for some people.⁸²

Advise all patients who smoke to quit

Advise

In a way that is clear but non-confrontational, advise all patients who smoke to quit

‘The best thing you can do for your health is to quit smoking’

Health professionals should advise patients who smoke to quit and, where possible, personalise the advice and the benefits of quitting. Establishing rapport and asking permission to discuss smoking minimises any risk of harming the patient–healthcare professional relationship. In fact, asking patients who smoke if they would like help to quit can be appreciated and can strengthen the relationship.⁸³ Patients express greater visit satisfaction when smoking cessation is addressed.^{59,84}

Brief, repeated, positive reminders to quit by a range of health professionals can increase success rates.²¹

Recommendation 3 – Offer brief cessation advice in routine consultations and appointments, whenever possible. Strong recommendation, high certainty

Assist those who smoke to quit

Assist

- Offer smoking cessation assistance and, if the person is willing to accept the offer, affirm and encourage them
- Agree on a quit plan, including agreeing on a quit day, strategies for managing smoking triggers and barriers to success, and mobilising social support
- Recommend pharmacotherapy if nicotine dependent (refer to the pharmacotherapy treatment algorithm in [Chapter 2 \(https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation-1/pharmacotherapy-for-smoking-cessation\)](https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation-1/pharmacotherapy-for-smoking-cessation))
- If the patient is not ready or unsure, use motivational approach, explore barriers and review at future visits

The decision on what assistance to provide those who smoke and those who recently quit depends on:

- willingness to quit
- needs
- preferences
- suitability of available support
- capacity of the health professional and their service.

Assistance could include advice and support, referral, or a combination of these options. When capacity within the clinical service to provide behavioural support is limited, referral to Quitline can be useful in addition to providing support from within the practice, including advice on pharmacotherapy.

For people willing to make a quit attempt:

- help the person develop a quit plan, including
 - agreeing on a quit day
 - providing strategies for managing smoking triggers and barriers to success
 - mobilising social support
- recommend pharmacotherapy if the patient is dependent on nicotine (refer to the pharmacotherapy treatment algorithm in [Chapter 2 \(https://www.racgp.org.au/clinical-resource/s/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation-1/pharmacotherapy-for-smoking-cessation\)](https://www.racgp.org.au/clinical-resource/s/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation-1/pharmacotherapy-for-smoking-cessation)); consider strategies such as pre-cessation nicotine replacement, combination therapy
- discuss the importance of follow-up and behavioural support.

If the person is not ready to quit or unsure about quitting, use motivational approaches, explore barriers and review at future visits. For further details on smoking cessation strategies, refer to [Chapter 2, \(http://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation-1/pharmacotherapy-for-smoking-cessation\)](http://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation-1/pharmacotherapy-for-smoking-cessation) 'Pharmacotherapy for smoking cessation', and [Chapter 3, \(https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation-1/pharmacotherapy-for-smoking-cessation\)](https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation-1/pharmacotherapy-for-smoking-cessation) 'Behavioural and advice-based support for smoking cessation'.

Motivational interviewing

Assistance from health professionals may include motivational interviewing, which is an evidence-based counselling technique based on a therapeutic partnership that acknowledges and explores a person's ambivalence about their smoking behaviour. Motivational interviewing requires more time than brief interventions. It allows the person who is trying to quit to clarify what goals are important to them and to organise their reasons in a way that supports actions. Motivational interviewing values patient autonomy and mutual respect, and uses open-ended questions, affirmations, reflection and summarising.^{85,86,87}

For motivational interviewing strategies, refer to [Chapter 3 \(https://www.racgp.org.au/clinical-resource/s/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation-1/behavioural-and-advice-based-support-for-smoking-c\)](https://www.racgp.org.au/clinical-resource/s/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation-1/behavioural-and-advice-based-support-for-smoking-c), 'Clinical interventions for tobacco use and dependence' and Table B1, page 58 in [Treating tobacco use and dependence: 2008 update \(http://www.tobaccoprogram.org/clientuploads/documents/Consumer%20Materials/Clinicians%20Systems%20Mat/2008-Guidelines.pdf\)](http://www.tobaccoprogram.org/clientuploads/documents/Consumer%20Materials/Clinicians%20Systems%20Mat/2008-Guidelines.pdf).⁸⁸

Arrange follow-up

Arrange

For patients making a quit attempt, arrange follow-up contact starting within a week of the quit day

- Congratulate and encourage
- Review progress and problems
- Encourage continued use of pharmacotherapy
- Monitor and manage medication side effects

Follow-up visits to discuss progress and provide support have been shown to increase the likelihood of successful long-term abstinence.⁸⁹ Additional follow-up leads to further increases in smoking cessation rates when compared with no follow-up.⁸⁹

Encouragement can help maintain motivation, as can affirming the person's decision to quit and reinforcing the benefits (health, social, financial) of quitting and being someone who does not smoke. It is important to review progress and identify and seek to address problems. Examine any slips so that more effective coping strategies can be planned. Explain that slips are valuable learning experiences, not failures, and encourage them to keep trying. Neuropsychiatric symptoms (eg anxiety, agitation, poor sleep, low mood) can be features of nicotine withdrawal; it is important to identify these symptoms and offer support.⁸⁹ Behavioural disturbances and suicidal thoughts can also occasionally occur.⁸⁹

Many people who are trying to quit will discontinue the use of smoking cessation pharmacotherapy prematurely, or may need dosage adjustment. Hence, reviewing the use of medication is important:

- Is the patient taking the medication?
- Are they using it correctly?
- Are they experiencing any side effects?

If NRT is used and there are withdrawal symptoms, a larger dose or combination NRT may be required.⁸⁹

Discuss relapse prevention by offering support and help to identify and manage high-risk situations (eg drinking alcohol, emotional stress, social situations with others who smoke). Encourage the patient to enlist the support of family and friends. Encourage use of support services:

- Quitline – 13 78 48
- Online programs
 - [QuitCoach \(http://www.quitcoach.org.au\)](http://www.quitcoach.org.au)
 - [iCanQuit \(http://www.icanquit.com.au\)](http://www.icanquit.com.au)
- SMS-based support – [QuitTxT \(http://www.quitcoach.org.au/QuitTextInformation.aspx\)](http://www.quitcoach.org.au/QuitTextInformation.aspx)

Relapse in the first weeks after quitting is common and often related to nicotine withdrawal.⁸⁹ There is a later peak in relapse after discontinuation of smoking cessation medication.⁹⁰ Relapse can also be triggered by alcohol, stress and social situations. About 50% of those who quit smoking and who are

still abstinent at 12 months will subsequently relapse.⁹¹ There is as yet no behavioural intervention, including behavioural support or skills training, that has been proven to prevent relapse.^{92,93} Advice, behavioural counselling and pharmacotherapy are recommended to treat symptoms of withdrawal, stress and weight gain.⁹⁴ Health professionals should offer ongoing support to all people who have made a quit attempt and need further help to remain smoke free.

Recommendation 4 – Offer follow-up to all people who are attempting to quit smoking.
Strong recommendation, high certainty

Tobacco dependence

Nicotine, which adversely affects the developing brain, is the main addictive chemical in tobacco smoke.^{20,95,96} Although nicotine is the main chemical making smoking addictive, it is responsible for very few of the harmful health effects of smoking. The harmful health effects of smoking are caused mainly by tar, oxidising chemicals, carbon monoxide and other constituents of tobacco smoke generated by the combustion of tobacco leaf.^{16,20,82}

Dependence on nicotine can develop quickly, especially in adolescents who smoke. Nicotine is one of the most highly addictive substances, perpetuating cigarette and other tobacco-product use, hindering smoking cessation efforts, increasing the risk of other substance use and addiction, and creating a number of adverse health consequences.^{98,99}

Dependence on smoking is a complex process. It requires a close link in time between the context in which smoking occurs, its rituals, the sensory stimuli of touch, taste and smell, and the extremely rapid delivery of nicotine to the brain that occurs when smoking a modern cigarette. Evidence suggests that psychosocial, biological and genetic factors all play a role in nicotine addiction.^{19,82,83}

When cigarette smoke is inhaled, the large surface area of the lungs enables nicotine to be rapidly absorbed into the pulmonary venous circulation and travel quickly to the brain through the bloodstream.¹⁰⁰ Nicotine in tobacco smoke reaches the brain's reward system within seconds of inhalation.¹⁰¹ The nicotine affects multiple types of nicotine receptors in the brain, especially the alpha-4 beta-2 ($\alpha 4\beta 2$) nicotinic acetylcholine receptor. Activation of this and other receptors triggers the release of dopamine and other neurotransmitters.¹⁰² This reward system is the common pathway for the experience of pleasure from many different social, physical and chemical stimulants, including other drugs of addiction (eg cocaine, opiates). As well as the activation of the reward system, the negative effects of nicotine withdrawal are important factors in the continuation of smoking.

Genetic factors play a role in the differing patterns of smoking behaviour and cessation. The degree of susceptibility to developing nicotine addiction and the ease or difficulty of quitting and sustaining abstinence have been reported from twin and adoption studies.¹⁰² This research shows a high degree of heritability of cigarette smoking (50–70%).¹⁰³ The finding points to an understanding of why people who smoke vary widely in their relationship to tobacco and ability to quit. Genetic factors have a substantial role in nicotine withdrawal symptoms, cigarette consumption, difficulty quitting and response to smoking cessation therapies.⁹⁰ However, a useful way to target treatment based on

genetics has not yet been shown. The studies also indicate that there may be some people who smoke who never fully overcome their addiction, or who can never quit all nicotine use.⁸² For these people, a harm reduction strategy may be of help (refer to [Chapter 5, \(https://www.racgp.org.au/clinical-resource/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation-1/to-bacco-harm-reduction\)](https://www.racgp.org.au/clinical-resource/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation-1/to-bacco-harm-reduction) 'Discussion of harm reduction').

Effect of smoking abstinence on medications

Smoking tobacco can alter the metabolism of a number of medicines through pharmacokinetic and pharmacodynamic interactions. Therefore, monitoring the dosage reduction of certain medications will be required. Quit Victoria outlines drug interactions with smoking, detailing the impact of smoking cessation on drug dosages (Table 1.3 and [training and resources for general practitioners \(https://www.quit.org.au/resources/general-practice/resources-general-practitioners/\)](https://www.quit.org.au/resources/general-practice/resources-general-practitioners/)).

Pharmacokinetic interactions are primarily due to substances in tobacco smoke, such as hydrocarbons or tar-like products that cause induction (speeding up) of some liver enzymes (CYP 1A2, in particular). Therefore, medicines metabolised by these enzymes are broken down faster and can result in reduced concentrations in the blood. When a person stops smoking, the enzyme activity returns to normal (slows down), which may result in increased levels of these medicines in the blood. Pharmacodynamic interactions owing to the stimulation effects of nicotine can reduce the effects of some medications, particularly benzodiazepines and methadone.

DRUG	NATURE OF INTERACTION WITH SMOKING Pharmacokinetic (PK) Pharmacodynamic (PD)	ACTION UPON CESSATION OF SMOKING	CLINICAL SIGNIFICANCE
Caffeine	PK: Increased clearance.	Advise to reduce caffeine by half.	High
Clozapine	PK: Increased clearance and decreased plasma concentrations.	Monitor trough plasma concentrations (if possible before stopping smoking and for two weeks after or sooner if adverse effects develop). Be alert for increased adverse effects. Reduce dose if clinically appropriate. Seek specialist advice from treating mental health practitioner.	High
Erlotinib	PK: Increased clearance and decreased plasma concentrations (around two-fold).	Reduce dose to initial starting dose if a patient stops smoking. Seek specialist advice. Nb. People who smoke should be encouraged to stop before therapy is initiated.	High
Irinotecan	PK: Increased clearance. Reduced exposure in people who smoke may lead to decreased haematological toxicity.	Seek specialist advice. Dosing should be closely monitored.	High
Theophylline	PK: Increased clearance and decreased half-life.	Monitor theophylline levels and reduce dose if clinically appropriate. Advise patient to monitor for signs of toxicity (e.g. palpitations, vomiting or nausea). Nb. It may take several weeks for enzyme induction to dissipate.	High
Chlorpromazine	PK: Decreased AUC and decreased plasma concentrations.	Be alert for increased adverse effects (e.g. dizziness, sedation, EPSE). Reduce dose if clinically appropriate.	Moderate
Insulin	Unclear: Possible decrease in insulin absorption secondary to peripheral vasoconstriction. Smoking may also increase insulin resistance.	Reduce dose if clinically appropriate. Advise patient to be alert for signs of hypoglycaemia and to test their BGLs more frequently.	Moderate
Methadone	Likely PK/PD: Nicotine affects the endogenous opioid system.	Be alert for signs of opioid toxicity. Reduce dose if clinically appropriate. Seek specialist advice. Nb. Methadone attenuates nicotine withdrawal.	Moderate
Olanzapine	PK: Increased clearance and decreased plasma concentrations.	Be alert for increased adverse effects (e.g. dizziness, sedation and hypotension). Reduce dose if clinically appropriate.	Moderate
Warfarin	PK: Increased clearance and decreased plasma concentrations.	Monitor INR closely. Reduce dose if clinically appropriate.	Moderate
Antiplatelet drugs (clopidogrel & prasugrel)	PK: Possible higher antiplatelet effect in people who smoke.	Seek specialist advice.	Low
Benzodiazepines	Likely PD: Central nervous system (CNS) stimulation by smoking. Nb. Results from pharmacokinetic studies are mixed.	Monitor for adverse effects (enhanced effect of benzodiazepines). Reduce dose if clinically appropriate.	Low
Beta Blockers	PD: Smoking opposes the beneficial effects of beta blockers on blood pressure and heart rate.	Monitor for adverse effects. Reduce dose if clinically appropriate.	Low
Haloperidol	PK: Decreased plasma concentrations.	Be alert for increased adverse effects (e.g. drowsiness, EPSE and hypotension). Reduce dose if clinically appropriate.	Low
Mirtazapine	PK: Decreased plasma concentrations.	Be alert for increased adverse effects (e.g. sedation). Reduce dose if clinically appropriate.	Low
Selective serotonin reuptake inhibitors (SSRIs)	PK: Decreased plasma concentrations. Nb. Best evidence for fluvoxamine, duloxetine and escitalopram.	Be alert for increased adverse effects (e.g. drowsiness and dizziness). Reduce dose if clinically appropriate.	Low
Tricyclic antidepressants	PK: Decreased plasma concentrations.	Be alert for increased adverse effects (e.g. sedation, dry mouth). Reduce dose if clinically appropriate.	Low

The most clinically significant interactions are provided here. For more information on any of the listed interactions or to search for other drug interactions, please refer to drug interactions references and literature at www.quit.org.au/psa-references

Table 1.3

Drug interactions with smoking

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[urces-general-practitioners](#)). Melbourne, Quit Victoria, 2019 [Accessed 11 September 2019].

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Pharmacotherapy for smoking cessation

Recommendations

Recommendation 5 – In the absence of contraindications, pharmacotherapy (nicotine replacement therapy, varenicline or bupropion) is an effective aid when accompanied by behavioural support, and should be recommended to all people who smoke who have evidence of nicotine dependence. Choice of pharmacotherapy is based on efficacy, clinical suitability and patient preference.

Strong recommendation, high certainty

Recommendation 6 – Combination nicotine replacement therapy (NRT) (ie patch and oral form) accompanied by behavioural support is more effective than NRT monotherapy accompanied by behavioural support, and should be recommended to people who smoke who have evidence of nicotine dependence.

Strong recommendation, moderate certainty

Recommendation 7 – For people who have stopped smoking at the end of a standard course of nicotine replacement therapy (NRT), clinicians may consider recommending an additional course of NRT to reduce relapse.

Conditional recommendation for the intervention, low certainty

Recommendation 8 –

a) Nicotine replacement therapy (NRT) is safe to use in patients with stable cardiovascular disease.

Strong recommendation, high certainty

b) NRT should be used with caution in patients who have had a recent myocardial infarction, unstable angina, severe arrhythmias or recent cerebrovascular events.

Strong recommendation, moderate certainty

Recommendation 9 – For women who are pregnant and unable to quit smoking with behavioural support alone, clinicians might recommend nicotine replacement therapy (NRT), compared with no NRT. Behavioural support and monitoring should also be provided.

Conditional recommendation for the intervention, low certainty

Recommendation 10 – Varenicline should be recommended to people who smoke and who have been assessed as clinically suitable for this medication; it should be provided in combination with behavioural support.

Strong recommendation, high certainty

Recommendation 11 – For people who have abstained from smoking after a standard course of varenicline in combination with behavioural support, clinicians may consider a further course of varenicline to reduce relapse.

Conditional recommendation for the intervention, low certainty

Recommendation 12 – For people who are attempting to quit smoking using varenicline accompanied by behavioural support, clinicians might recommend the use of varenicline in combination with nicotine replacement therapy, compared with varenicline alone.

Conditional recommendation for the intervention, moderate certainty

Recommendation 13 – Bupropion sustained release should be recommended to people who have been assessed as clinically suitable for this medication; it should be provided in combination with behavioural support. Bupropion is less effective than either varenicline or combination nicotine replacement therapy.

Strong recommendation, high certainty

Recommendation 14 – Nortriptyline should be considered as a second-line pharmacotherapy agent because of its adverse effects profile.

Strong recommendation, moderate certainty

Recommendation 15 – For people who have tried to achieve smoking cessation with first-line therapy (combination of behavioural support and TGA-approved pharmacotherapy) but failed and are still motivated to quit smoking, NVPs may be a reasonable intervention to recommend along with behavioural support. However, this needs to be preceded by an evidence-informed shared-decision making process, whereby the patient is aware of the following caveats:

- 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 vaping devices and NVPs, which increases the uncertainties associated with their use.
- To maximise possible benefit and minimise risk of harms, dual use should be avoided and long-term use should be minimised.
- It is important for the patient to return for regular review and monitoring.

Conditional recommendation for intervention, low certainty

Introduction

Key points

- Pharmacotherapy should be recommended to all people who smoke with nicotine dependence.
- The most successful approach to quitting for people who smoke with nicotine dependence is behavioural support combined with first-line pharmacotherapy and follow-up.
- Nicotine replacement therapy (NRT), varenicline and bupropion are licensed and available in Australia to assist smoking cessation.
- Varenicline is the most effective single-form pharmacotherapy for smoking cessation.
- Combination NRT is as effective as varenicline and more effective than single types of NRT.
- NRT may be considered in pregnancy if the patient is unable to quit without medication, but only after the risks and benefits have been carefully explained.
- Considerations guiding choice of pharmacotherapy for people who want to quit smoking are based on evidence of effectiveness, clinical suitability and patient choice.

Three forms of medicine – NRT, varenicline and bupropion – are licensed and available in Australia to assist smoking cessation. These medicines have been shown to assist smoking cessation in meta-analyses of randomised clinical trials.^{1,2,3,4}

Pharmacotherapy should be recommended to all people who smoke with nicotine dependence.⁵ However, an individual's choice to attempt to quit without assistance should be respected and supported.

The most successful quit approach for those who are nicotine dependent is behavioural support combined with first-line pharmacotherapy and follow-up.^{5,6,7,8,9,10} Overall, varenicline or combination NRT almost triples the odds of quitting,¹¹ and bupropion and NRT alone almost doubles the odds of quitting versus placebo (dummy treatments plus brief counselling) at six months.^{11,14}

First-line pharmacotherapy options

First-line pharmacotherapy options are medicines that have been shown to be effective and safe and are licensed for smoking cessation.^{1,11,12,13} In Australia, these medicines include NRT,¹¹ varenicline and sustained-release preparations of bupropion hydrochloride. NRT is also licensed for smoking reduction as a step towards smoking cessation for people who are unable or not willing to stop smoking abruptly.

From current available evidence, varenicline is the most effective form of single pharmacotherapy (monotherapy) for smoking cessation.^{1,11,12,13} A Cochrane collaboration analysis concluded that combination NRT is as effective as varenicline and more effective than single types of NRT.¹¹ Varenicline has been shown to be more effective than bupropion in a number of studies. Head-to-head comparisons between bupropion and NRT monotherapy have shown these medicines are equivalent to each other in efficacy.¹¹

Efficacy of licensed smoking cessation medicine

All randomised controlled trials that examined and analysed smoking cessation pharmacotherapy include at least some behavioural support; for varenicline, this included intensive behavioural support (multiple sessions with at least two hours of total contact time).¹⁵

- Varenicline is effective, and can increase six- to 12-month continuous or sustained abstinence rates by 15% (95% confidence intervals [CI]: 13, 17) compared with placebo and 7% (95% CI: 4, 11) compared with bupropion. It is more effective than nicotine patches.¹¹
- NRT is effective and can increase six- to 12-month continuous abstinence rates by 6% (95% CI: 6, 7) compared with placebo.
- Combining a nicotine patch with a faster-acting NRT (eg gum, lozenge) increases six- to 12-month abstinence rates by 5% (95% CI: 3, 7) compared with single-form NRT.
- Bupropion is effective. Its use can increase six- to 12-month continuous abstinence rates by 7% (95% CI: 6, 9) compared with placebo.
- Bupropion appears to be as effective as NRT monotherapy, but evidence from three randomised controlled trials suggests that it is less effective than varenicline.

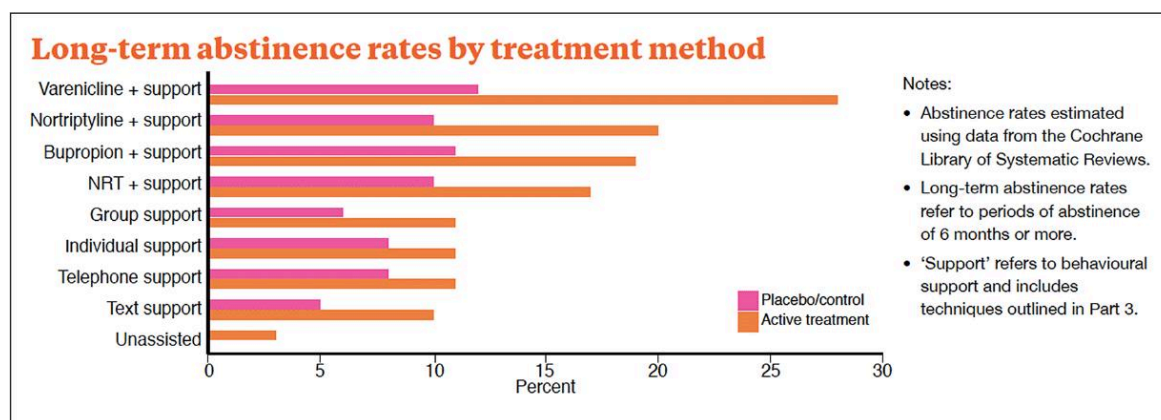


Figure 2.1

Long-term abstinence rates by treatment method¹⁶

Reproduced from New Zealand Government Ministry of Health. [New Zealand guidelines for helping people to stop smoking \(http://www.health.govt.nz/publication/new-zealand-guidelines-helping-people-stop-smoking\)](http://www.health.govt.nz/publication/new-zealand-guidelines-helping-people-stop-smoking). Wellington: Ministry of Health, 2014 [Accessed 8 March 2018].

The choice of pharmacotherapy most likely to assist people who are attempting to quit smoking is based on evidence of effectiveness (Figure 2.1), clinical suitability and patient choice (Figure 2.2). Considerations when helping an individual to select an appropriate form of pharmacotherapy to quit include:

- previous experience with pharmacotherapy

- cost and convenience
- adherence issues (eg individual preferences for a patch or gum, one or more forms of NRT, non-nicotine options)
- prescription medicine versus over-the-counter medicine
- potential for adverse events
- possible drug–drug interactions.

Patients who are quitting smoking using any method are at some risk of increased psychological stress during the process as a result of nicotine withdrawal symptoms, especially patients with a history of mental illness.¹² Clinicians should alert patients to this possibility and encourage them to return promptly if they experience neuropsychiatry symptoms (eg anxiety, depression, behaviour changes, suicidality). Patients can also be encouraged to inform family members about this possibility so they can be alert to any concerning changes. People with mental illness are at higher risk of neuropsychiatric symptoms during smoking cessation and must be carefully monitored during treatment.

It is important on medication cessation to reinforce the quitting process to prevent relapse.¹⁷ Approximately 50% of those who have quit at the end of pharmacotherapy relapse to smoking;⁵ therefore, combining pharmacotherapy and behavioural intervention is important.

Recommendation 5 – In the absence of contraindications, pharmacotherapy (nicotine replacement therapy, varenicline or bupropion) is an effective aid when accompanied by behavioural support, and should be recommended to all people who smoke who have evidence of nicotine dependence. Choice of pharmacotherapy is based on efficacy, clinical suitability and patient preference.

Strong recommendation, high certainty

Key points

- Smoking cessation using NRT is always less harmful than continuing to smoke.
- When used correctly, all forms of NRT (at equivalent doses) are similarly effective in achieving long-term cessation.
- All forms of NRT monotherapy can increase the rate of quitting by 50–60%.
- More than one form of NRT (ie combination NRT) can be used concurrently with increased success rates and no greater safety risks.
- Higher dose forms of nicotine gum (4 mg) are more effective than lower dose forms (2 mg) for more people who smoke with nicotine dependence.
- Nicotine patches can be commenced several weeks before starting smoking cessation to help people who smoke prepare for quitting.
- NRT can be used by people with cardiovascular disease. Caution is advised for people in hospital for acute cardiovascular events, but NRT can be used under medical supervision if the alternative is active smoking.
- NRT may be considered in women who are pregnant if they were unsuccessful in stopping smoking without pharmacotherapy. If NRT is used, the benefits and risks should be explained carefully to the patient by a suitably qualified health professional. The clinician supervising the pregnancy should also be consulted.
- NRT accompanied by behavioural interventions can be used in those aged 12–17 years who smoke.

Nicotine is the main substance in tobacco that causes addiction as it makes people dependent on cigarettes. However, it is the other chemicals in combusted tobacco products that cause cancer, accelerate heart disease and affect other areas of health. While nicotine also has the potential for adverse effects in vulnerable developmental life stages, including pregnancy, childhood and adolescence,^{18,19,20} it is considered to be a safer alternative to tobacco smoking.

The aim of NRT is to reduce craving and withdrawal symptoms by providing some of the nicotine that would normally be obtained from cigarettes, without providing the harmful components of tobacco smoking. NRT provides lower doses of nicotine at a slower rate than tobacco smoking; none of the available forms of NRT (ie transdermal patch, gum, inhalator, lozenge, mouth spray) offer the same rapid nicotine delivery of a cigarette.²¹

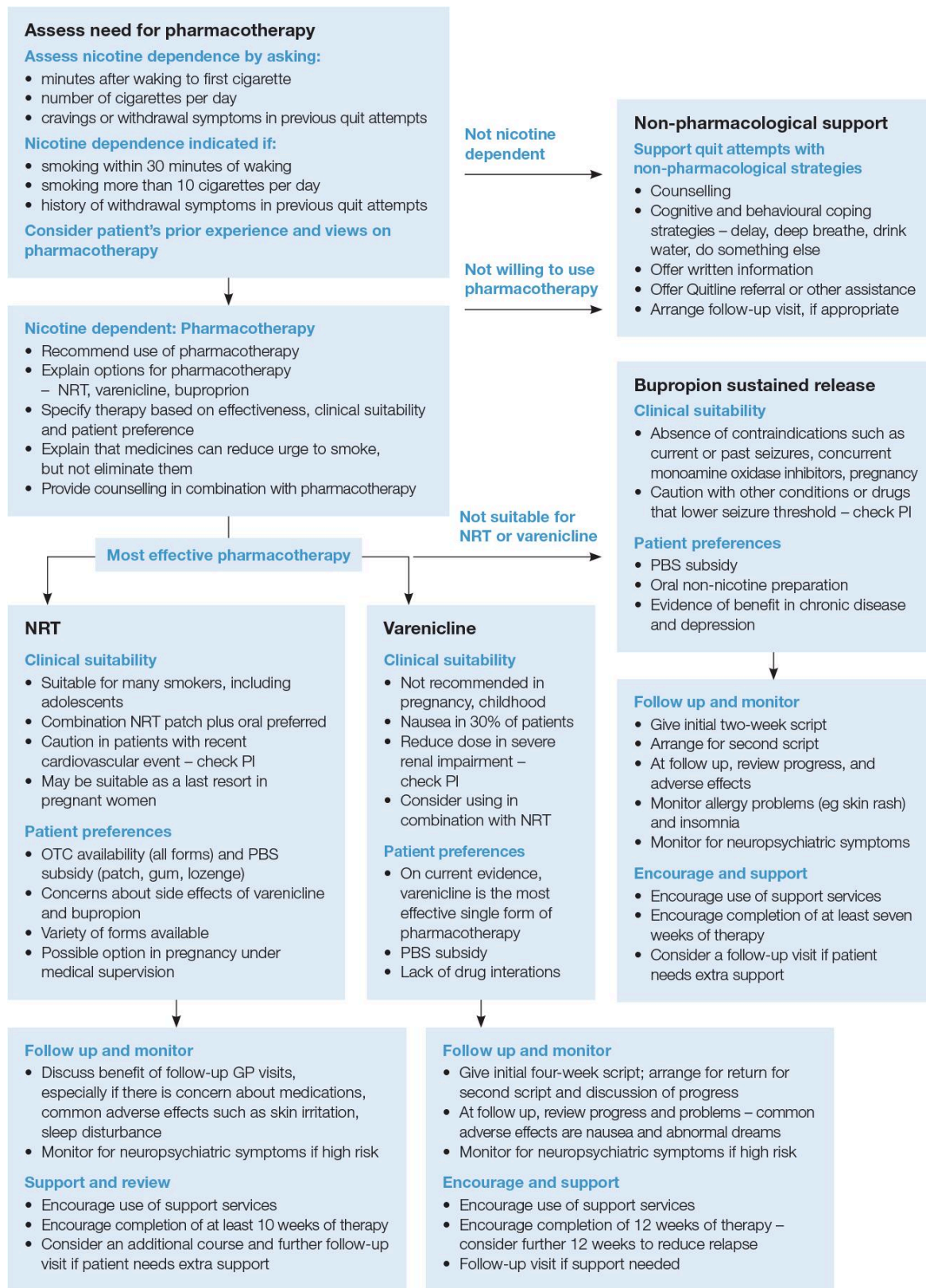


Figure 2.2
 Pharmacotherapy treatment algorithm

GP, general practitioner; NRT, nicotine replacement therapy; OTC, over the counter; PBS, Pharmaceutical Benefits Scheme; PI, product information

Nicotine patches are applied to the skin and deliver nicotine through the skin at a relatively steady rate, while other nicotine products are acute dosing forms of nicotine. Other nicotine products provide relief for general craving and breakthrough craving with faster release of nicotine than the patch. The main advantage of nicotine patches over acute NRT formulations is that patient adherence is simple despite its slow delivery.²² The advantage of acute-dosing NRT is that both the amount and timing of doses can be titrated by the person who smokes.

It is important to advise those who smoke on the correct use of the different forms of NRT and ensure an adequate dose is taken to relieve cravings and withdrawal symptoms (Figure 2.3).^{23,24} Under-dosing is a recognised problem with current NRT, whereby those who want to quit often do not use enough NRT to obtain the best clinical effect.²⁵ Standard dosing references and product information guides for NRT tend to recommend more conservative doses.

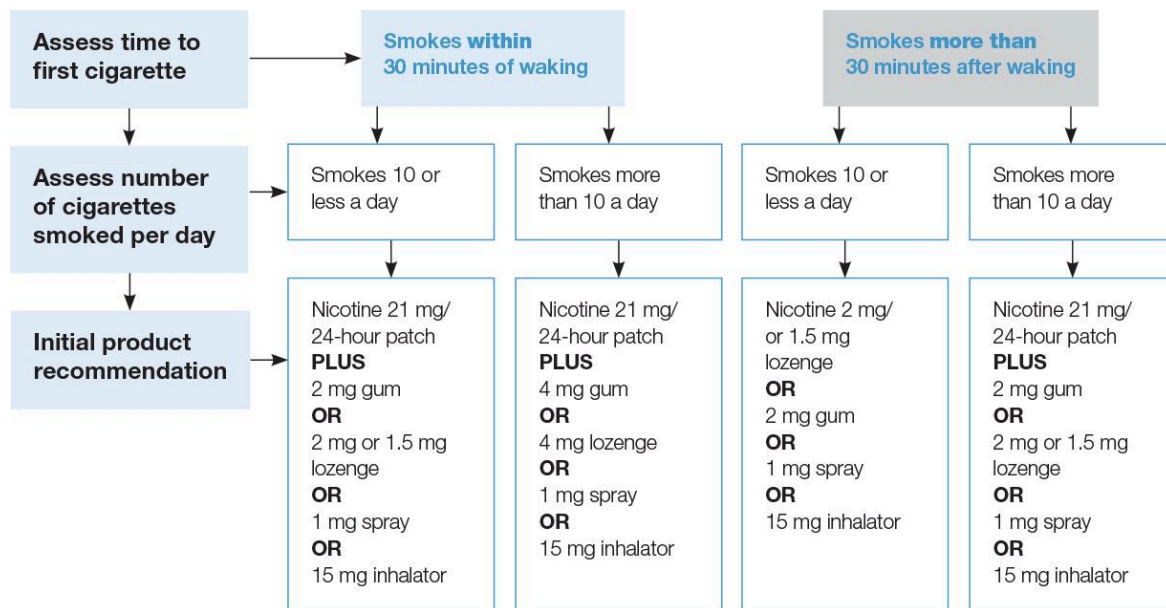


Figure 2.3

NRT initial dosage guideline²⁴

Adapted with permission from Ministry of Health, New Zealand. [Guide to prescribing nicotine replacement therapy \(NRT\)](http://www.health.govt.nz/system/files/documents/publications/guide-to-prescribing-nicotine-replacement-therapy-nrtv2.pdf) (<http://www.health.govt.nz/system/files/documents/publications/guide-to-prescribing-nicotine-replacement-therapy-nrtv2.pdf>). Wellington: Ministry of Health, 2014 [Accessed 9 September 2019].

Patients should be reassured about the safety, efficacy and low addictive potential of NRT, as misinformed concerns are a major cause of poor adherence.^{23,26}

Regular use of NRT beyond 12 months is not generally recommended as there is no evidence of efficacy beyond 24 weeks.²⁷ At the 24-week point, the prospect of stopping NRT can be confronting for some who do not feel ready to stop treatment. An extended but not limitless period of treatment may be reasonable for such patients, although there are no data to support this approach. Current scientific evidence does not support an association between long-term NRT exposure and serious adverse health effects;^{25,28} a longer period of NRT may help some people remain abstinent²⁹ and it is less harmful than tobacco smoking.

While there is evidence that NRT can increase quit rates with or without counselling,^{8,9} research suggests over-the-counter NRT appears to be associated with reduced success rates. More research is needed on the effectiveness of NRT in this context.⁷

Combination NRT

Combining two forms of NRT (eg patch plus an acute form, such as spray, gum, inhalator or lozenge) has been shown to be more efficacious than a single form of nicotine replacement.^{11,30} The patch provides a steady background nicotine level while the oral forms provide additional protection for breakthrough cravings. Oral doses (eg gum, lozenge, inhalator, mouth spray) can be taken on a regular basis (eg hourly) in anticipation of triggers or when cravings occur. Combination NRT, rather than monotherapy, has been recommended for those who smoke and are nicotine dependent, including use of higher dose forms of oral products for those who need them.³

Combination NRT can be recommended:

- as first-line treatment for those who smoke and are nicotine dependent (Figure 2.3)^{4,5}
- for those unable to quit using NRT monotherapy alone
- for those who experience cravings using NRT monotherapy alone.

The evidence review conducted by the Joanna Briggs Institute (JBI) on the use of combination NRT identified 12 randomised controlled trials with a total of 6318 participants. The relative effect was 1.28 (95% CI: 1.15, 1.42). The Expert Advisory Group (EAG) rated the certainty of the evidence as moderate. The EAG concluded that there is a small but not trivial improvement in smoking cessation for combination NRT compared with single NRT. The reviewed studies only included those who smoke with at least low-to-moderate nicotine dependence.

Recommendation 6 – Combination nicotine replacement therapy (NRT) (ie patch and oral form) accompanied by behavioural support is more effective than NRT monotherapy accompanied by behavioural support, and should be recommended to people who smoke who have evidence of nicotine dependence.

Strong recommendation, moderate certainty

Higher dose NRT

Higher dose oral NRT (ie 4 mg gum and lozenge) and higher dose patches (21 mg/24-hour patch and 25 mg/16-hour patch) are recommended for those who smoke with nicotine dependence. Higher dose NRT should also be considered for those who smoke with less nicotine dependence but who continue to report cravings when using the weaker form.³¹ Higher dose therapy with the patch is also possible by adding a second patch. While this approach seems to be safe, a Cochrane review of five randomised controlled trials found no clear evidence of superiority of dual patching over single patch (risk ratio [RR]: 1.09; 95% CI: 0.93, 1.29).³²

Pre-cessation nicotine patch

There is evidence to support the use of nicotine patches before smoking cessation, commonly known as preloading. A meta-analysis found that nicotine patches used before quit day increased success rates when compared with standard therapy.³³

A Cochrane review also found a 34% increase effect from the use of pre-cessation patches.³ The Therapeutic Goods Administration (TGA)-approved approach involves using either a 21 mg/24-hour patch or 25 mg/16-hour patch for two weeks before quitting, then continuing to use the nicotine patch in the usual way for the quit attempt and adding intermittent oral NRT if needed.

Reduce to quit

There is also evidence for the use of NRT to help those who are not willing to quit immediately to reduce their tobacco use and then progress to quitting.³⁴ The TGA-approved approach (cut down then stop or reduce to quit) involves patients using NRT to prevent compensatory smoking (inhaling deeper on fewer cigarettes) when reducing the number of cigarettes they smoke before stopping completely within six months.³⁵ A meta-analysis found that reducing cigarettes smoked before quit day versus quitting abruptly with no prior reduction produced comparable quit rates.^{32,36} Further research is needed to investigate those categories of people who smoke who would benefit the most from each approach.³⁷

Tapering off NRT

Advice to wean off NRT over a period of weeks is included in the product information of NRT products, but it is not something that is supported by the evidence. The main issue is sufficient duration of NRT, not whether tapering occurs before the medicine is ceased.²³

Longer treatment duration

There is limited evidence of benefit from longer term NRT. Two randomised controlled trials compared longer (up to 52 weeks) and standard courses (eight weeks) of NRT, but found no convincing effect from the longer course.^{25,38}

Another use of longer term NRT is for relapse prevention in those who are abstinent at the end of a standard course of treatment or who have abstained unassisted. A systematic review of four trials found that prolonged NRT use was effective for the medium term (12- to 18-month follow-up).³⁹ The evidence review conducted by JBI on the longer term NRT found only one trial that met inclusion criteria, which included abstinence confirmed by exhaled carbon monoxide concentration <8 ppm. The relative effect was 2.17 (95% CI: 0.85, 2.17). The EAG rated the certainty of the evidence as low. There was a lack of evidence on the rate or severity of adverse effects associated with longer term NRT.

Recommendation 7 – For people who have stopped smoking at the end of a standard course of nicotine replacement therapy (NRT), clinicians may consider recommending an additional course of NRT to reduce relapse.

Conditional recommendation for the intervention, low certainty

Contraindications and precautions

There is no safe level of smoking. Using therapeutic nicotine is always less harmful than continuing to smoke.

Contraindications

There are few contraindications associated with NRT use.^{23,33} These include:

- children aged <12 years
- people with known hypersensitivity to nicotine or any other component of the NRT product.

It is important to note that those weighing <45 kg can use NRT, but may require the lower dose (eg 14 mg/24-hour patch).

Precautions

NRT should be used with caution for patients in hospital for acute cardiovascular events, but if the alternative is smoking, NRT can be used under medical supervision.

Side effects

Minor side effects are common with NRT use.^{23,40} Common adverse effects with NRT depend on the delivery system. Patches can cause skin irritation, redness, itch and rash, which are usually mild but can be treated with 1% hydrocortisone cream if troublesome.²³ It is important to rotate the application site each day to reduce irritation. Insomnia and vivid dreams can also occur.³⁸ However, if irritation or sleep disturbance is severe, patients can remove the patch at bedtime or a couple of hours before and re-apply a new patch in the morning.²³

For NRT gum and lozenges, minor side effects include dyspepsia and nausea; for NRT inhalator and mouth spray, mouth and throat irritation may occur.^{23,41}

Use of NRT in cardiovascular disease

All forms of NRT can be used safely in stable cardiovascular disease,^{38,42} however, these should be used with caution in people with recent (six weeks) myocardial infarction, unstable angina, severe arrhythmias and recent cerebrovascular events. NRT can be used in this situation under medical supervision.³⁹

Recommendation 8 –

- a) Nicotine replacement therapy (NRT) is safe to use in patients with stable cardiovascular disease. Strong recommendation, high certainty
- b) NRT should be used with caution in patients who have had a recent myocardial infarction, unstable angina, severe arrhythmias or recent cerebrovascular events. Strong recommendation, moderate certainty

Use of NRT in pregnancy

Given the importance of smoking cessation in pregnancy, every effort should be made to support the expectant mother to quit. Behavioural counselling is recommended as the first-line treatment for quitting smoking in pregnancy. Behavioural intervention can:⁴³

- increase the proportion of women who stop smoking during pregnancy
- decrease the proportion of infants born with low birthweight
- increase smoking cessation after birth.

Refer to [Chapter 4 \(https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation-1/smoking-cessation-for-high-prevalence-groups\)](https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation-1/smoking-cessation-for-high-prevalence-groups), 'Smoking cessation for high-prevalence groups: Pregnant and breastfeeding women' (<https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation-1/smoking-cessation-for-high-prevalence-groups>) for more information.

Pregnant women should be encouraged to use Quitline. In some jurisdictions, there are special programs of support that extend into the postpartum period when risk of relapse to smoking is high.

There is inconclusive evidence of the effectiveness and safety of NRT during pregnancy, and other forms of pharmacotherapy are contraindicated.^{44,45} A Cochrane review and meta-analysis of eight studies and 2199 participants found that NRT as an adjunct to behavioural support was effective for smoking cessation in pregnancy (RR: 1.41; 95% CI: 1.03, 1.93). However, there was no significant difference in cessation rates in a sub-group analysis of placebo-controlled studies. Some observational studies suggest effectiveness in clinical practice.^{46,47} The modest effect of NRT could be due to inadequate dosing, as nicotine clearance is increased by 60% in pregnancy.⁴⁸ Poor adherence is also likely to cause reduced cessation outcomes.⁴⁹

Although nicotine has been linked to harmful effects on the fetus in animal studies, clinical trials have not reported adverse effects from NRT in humans. The Cochrane meta-analysis found no significant difference in health and safety outcomes in four studies.⁴³ Several studies found no adverse effect on birth weight.^{46,50} One study found that infants born to mothers who received NRT had a significantly higher rate of unimpaired development when assessed two years after delivery.⁵¹ However, because of the small number of studies, further evidence is needed before firm conclusions on safety can be made.^{52,53}

The evidence review conducted by JBI examined the outcome of smoking cessation in later pregnancy. This work by JBI focused on the studies within the Cochrane systematic review by Coleman and colleagues.⁴⁵ Eight randomised controlled trials involving 2199 participants met entry criteria. The relative effect was 1.41 (95% CI: 1.03, 1.93), and the EAG rated the certainty of the evidence as low. The review found no evidence of an increase in adverse effects (ie miscarriage, stillbirth, pre-term birth, low birthweight, neonatal care unit admission, neonatal death) in women who used NRT during pregnancy. In fact, all comparisons found lower rates of these effects in the women who used NRT during pregnancy. However, it should be noted that the 95% CI for all RR were analysed to have no effect (ie RR: 1). On current evidence, the EAG concluded that there are important improvements in smoking cessation outcomes associated with use of NRT in pregnancy, while there does not appear to be an increase in harms.

Given this evidence, if quit attempts are unsuccessful without the use of pharmacotherapy, and the patient is motivated to quit:

- pharmacotherapy (usually oral forms of NRT) should be considered
- if NRT is used, the benefits and risks should be considered and explained carefully to the patient by a suitably qualified healthcare professional, and the clinician supervising the pregnancy should be consulted^{49,54,55}
- intense behavioural support and close clinical surveillance of the pattern of any continuing smoking should be provided.

Recommendation 9 – For women who are pregnant and unable to quit smoking with behavioural support alone, clinicians might recommend nicotine replacement therapy (NRT), compared with no NRT. Behavioural support and monitoring should also be provided. Conditional recommendation for the intervention, low certainty

Use of NRT in breastfeeding

Nicotine passes from the mother to child through breastmilk. Depending on the concentration of nicotine in the maternal blood, it is likely to be less harmful than continued smoking.^{56,57} NRT (ie patch, intermittent) is considered an option for breastfeeding mothers.⁵⁸ Infant exposure to nicotine can be reduced further by taking intermittent NRT immediately after breastfeeding.

Women who smoke should be encouraged to continue breastfeeding and provided with strategies to minimise the potential harm to their child through breastmilk and second-hand smoke.⁵²

Varenicline

! Key points

- Varenicline is a nicotinic receptor partial agonist drug for smoking cessation that relieves symptoms of craving and withdrawal.
- The use of varenicline can more than double the chances of long-term quitting.
- In a Cochrane review meta-analysis, varenicline was found to be more effective than bupropion, more effective than NRT monotherapy and similar in effect to combination NRT.
- A second course of varenicline can be considered to reduce relapse.
- Combining varenicline with NRT may improve quit rates.
- Varenicline can be used in those who smoke with mental health problems, but must be monitored during quit attempts. These patients should be advised to report unusual mood changes, depression, behaviour disturbance and suicidal thoughts, and stop using the medicine if these occur.
- Varenicline is not recommended for pregnant and breastfeeding women, nor for adolescents.
- There are two options for quitting with varenicline, both equally effective but chosen by preference:
 - fixed option, which involves the person who smokes setting a date to stop smoking – varenicline should start one to two weeks before this date
 - flexible approach, when the person who smokes begins varenicline dosing, then quits smoking between days 8 and 35 of treatment.

Varenicline was developed specifically for smoking cessation. It acts at the nicotinic acetylcholine receptors (nAChRs) in the reward centre in the brain. Varenicline binds with high affinity at the alpha-4 beta-2 ($\alpha 4\beta 2$) nAChRs, where it acts as a partial agonist to alleviate symptoms of craving and withdrawal. If a cigarette is smoked, the varenicline prevents inhaled nicotine from activating the $\alpha 4\beta 2$ nAChRs agonist activity, and so blocks the pleasure and reward response. This mechanism may explain why quitting can occur later in a course of treatment with varenicline.

Efficacy

At the standard dose, varenicline can more than double the chances of successful long-term smoking cessation when compared with pharmacologically unassisted quit attempts.⁵⁹ A Cochrane meta-analysis of 27 trials of varenicline found it more than doubled sustained abstinence rates at six-month follow-up.¹ Varenicline monotherapy was also more effective than NRT monotherapy at 24 weeks;¹ however, it was of similar efficacy to combination NRT (patch and oral form).¹¹ Varenicline improves smoking cessation rates two-fold over bupropion and is well tolerated.^{60,61}

Recommendation 10 – Varenicline should be recommended to people who smoke and who have been assessed as clinically suitable for this medication; it should be provided in combination with behavioural support. Strong recommendation, high certainty

Two randomised controlled trials have examined varenicline as an aid to relapse prevention in those who smoked and had successfully quit on varenicline.^{62,63} One study continued treatment for an additional 12 weeks,⁶³ the other for an additional 40 weeks.⁶² There was a modest benefit in favour of extended treatment compared to the placebo groups.^{62,63} The benefit appears to be maintained only for the period of use of varenicline.

The evidence review conducted by JBI on this question examined the two trials^{62,63} which, combined, involved 1297 participants that met entry criteria (including that smoking cessation of study participants was biochemically confirmed). The relative effect was 1.23 (95% CI: 1.08, 1.41). The EAG rated the certainty of the evidence as low.

Recommendation 11 – For people who have abstained from smoking after a standard course of varenicline in combination with behavioural support, clinicians may consider a further course of varenicline to reduce relapse. Conditional recommendation for the intervention, low certainty

Combination varenicline and other pharmacotherapy for smoking cessation

Varenicline in combination with NRT patch results in significantly higher abstinence rates than varenicline alone.^{64,65} A systematic review aggregated the reported number of adverse events from these studies, and generated a pooled odds ratio (OR) with a fixed-effect model.⁶⁶ Compared with varenicline monotherapy, participants receiving combination varenicline and NRT reported increased incidence of:

- nausea (28.4% versus 25.7%; OR: 1.15; 95% CI: 0.85, 1.56)
- insomnia (18.7% versus 15.4%; OR: 1.27; 95% CI: 0.89, 1.80)
- abnormal dreams (13.6% versus 10.7%; OR: 1.20; 95% CI: 0.78, 1.84).

Frequency of headaches was similar between groups (7.1% versus 7.8%; OR: 1.01; 95% CI: 0.60, 1.72). Koegelenberg and colleagues reported that skin reactions (of any type) were more prevalent in the combination therapy group (14.4% versus 7.8%; $p = 0.03$).⁵⁹

The evidence review conducted by JBI on this question found two trials involving 787 participants that met entry criteria (including biochemically confirmed cessation). The relative effect was 1.62 (95% CI: 1.18, 2.23). The EAG rated the certainty of the evidence as moderate, and concluded that, on current evidence, there is a small but not trivial improvement in smoking cessation for people taking varenicline in addition to NRT, compared to NRT alone.

Recommendation 12 – For people who are attempting to quit smoking using varenicline accompanied by behavioural support, clinicians might recommend the use of varenicline in combination with nicotine replacement therapy, compared with varenicline alone.
Conditional recommendation for the intervention, moderate certainty

There is no clinical study of varenicline combined with oral NRT. However, in clinical practice, this combination is sometimes used together. Varenicline helps to relieve background cravings and reduce the stimulatory effects of smoking, and oral NRT products alleviate cue-induced triggers.

There is a lack of evidence of the effectiveness of combination varenicline plus bupropion. One study found a benefit at 26 weeks, but not at 52 weeks; a more recent study found no benefit at either of these follow-up points.^{67,68}

There is increasing evidence of the efficacy of varenicline in sub-populations of patients who smoke.

Sub-populations of patients who smoke

People with mental illness

Psychiatric comorbidity is common in those who smoke, and varenicline has been found to be safe and effective in those with stable mental illness or a past history of mental illness.⁶⁹ There is also evidence that varenicline is safe and effective to assist cessation in people with schizophrenia.^{70,71}

Women

Varenicline is more effective than other cessation monotherapies, but the difference is relatively greater for women. Women have lower quit rates with NRT and bupropion compared with men, but the same response to varenicline.⁷²

People who smoke and drink heavily

Varenicline reduces alcohol cravings and overall alcohol consumption in those who drink heavily, and may have a role in the concurrent treatment of alcohol and nicotine dependence, especially in men.^{73,74,75}

Varenicline and mental illness

After initial marketing of varenicline, there were concerns about an association between varenicline and mood changes, depression, behaviour disturbance and suicidal ideation. Subsequent meta-analyses of randomised controlled trials^{76,77} and observational studies^{72,78,79} have not supported a causal link. The large randomised controlled trial, EAGLES (Evaluating Adverse Events in a Global Smoking Cessation Study), has given further reassurance.⁶⁴ In those with or without stable mental illness, the study did not

find a significant increase in the rates of moderate-to-severe neuropsychiatric adverse events in those taking varenicline, compared with those using placebo, bupropion or nicotine patch. As expected, those with mental illness in all treatment groups had higher rates of neuropsychiatric adverse events than those without mental illness.

Patients quitting smoking with any method are at some risk of increased psychological stress, especially those with a history of mental illness. Clinicians should monitor all patients with follow-up for neuropsychiatric changes associated with withdrawals, whether taking varenicline or not, and should promptly report any adverse events.

Cardiovascular safety of varenicline

Safety data from more than a dozen recent randomised controlled trials, including one conducted in the highest-risk patient population studied to date, examined the use of varenicline and cardiovascular events. These randomised controlled trials found that cardiovascular events are rare and not likely to be increased with the use of varenicline.⁸⁰ The findings are consistent with the results of several large cohort studies, which found no increased risk of cardiovascular adverse events between varenicline and bupropion for smoking cessation.^{81,82} There appears to be no substantive evidence to suggest that varenicline increases the risk of cardiovascular adverse events.^{39,75}

It is important to note that smoking is a major risk factor for cardiovascular disease, and the health benefits of quitting smoking are immediate and substantial.⁸³

Pregnancy and varenicline

Due to the limited efficacy and pregnancy safety data, varenicline is not recommended as a smoking cessation aid for pregnant or breastfeeding women.⁸⁴

Side effects

Nausea is the most common adverse effect of varenicline, and was reported in studies of almost 30% of those who are attempting to quit, although less than 3% discontinued treatment due to nausea.^{57,58} There is some evidence that nausea can be minimised by taking tablets with food, titration and self-regulation of varenicline (0.5–2 mg/day).^{85,86} Lower doses of varenicline are also effective if the full dose cannot be tolerated.¹

Sleep disturbance and abnormal dreams were more common in the varenicline group (13.1%) than the bupropion (5.9%) or placebo groups (3.5%).^{57,58}

Other less common side effects include drowsiness, headache, constipation, dizziness and flatulence.

No clinically meaningful drug interactions have been identified.

Varenicline is excreted almost entirely by the kidneys. For people with creatinine clearance below 30 mL/min, the recommended daily dosage is 1 mg/day (0.5 mg/day for three days then increasing to 1 mg/day). Avoid varenicline in those with end-stage renal failure in favour of other approaches to smoking cessation. Dose adjustment is not routinely required in older people or in people with hepatic impairment.⁸⁷

Bupropion

Key points

- Bupropion is a non-nicotine oral therapy, originally developed and approved for use as an antidepressant.
- Bupropion significantly increases cessation rates compared with placebo.
- Bupropion has been shown to be less effective than varenicline for smoking cessation.
- Bupropion is contraindicated in patients with a history of seizures, eating disorders and those taking monoamine oxidase inhibitors.
- Bupropion is not recommended for women who are pregnant or breastfeeding.
- Bupropion should be used with caution in people taking medications that can lower seizure threshold (eg antidepressants, antimalarials, oral hypoglycaemic agents)

Bupropion reduces the urge to smoke and reduces symptoms from nicotine withdrawal.

Efficacy

Bupropion significantly increases the long-term cessation rate by about 60%, compared with placebo over 12 months.²

Bupropion has been shown to be effective in a range of patient populations, including those with depression, cardiac disease and respiratory diseases (eg chronic obstructive pulmonary disease [COPD]).⁸⁸ It has also been shown to improve short-term abstinence rates for people with schizophrenia.^{89,90} In comparison with NRT, varenicline and placebo, bupropion has not been shown to cause an increase in neuropsychiatric adverse events, including in people with a history of mental health disorders.⁶⁴

Clinical trials have shown that bupropion is not as effective as varenicline for smoking cessation.^{1,91} However, bupropion is a useful option in cases where varenicline is not appropriate (eg patient choice, side effects).

Combination bupropion and other pharmacotherapy for smoking cessation

The combination of NRT and sustained-release bupropion has not shown an additive benefit.² As previously stated, there is a lack of evidence of effectiveness of the combination of bupropion plus varenicline.^{62,63}

Safety

Bupropion is contraindicated in patients with a history of seizures, eating disorders and those currently or recently (within the last 14 days) taking monoamine oxidase inhibitors.⁹² The current recommendation is that it should be used with caution in people taking medications that can lower seizure threshold (eg antidepressants, antipsychotics, anti-malarials, oral hypoglycaemic agents).^{2,92} Alcohol consumption should be minimised or avoided completely when taking bupropion, as alcohol can alter the threshold at which bupropion induces seizures. A sudden decrease in alcohol consumption can also alter the seizure threshold, and alternative medication should be considered in these situations.⁹²

Caution is needed if there is concomitant use of bupropion with certain drugs (eg tricyclic antidepressants, selective serotonin reuptake inhibitors [SSRIs]). These drugs should be initiated at the lower end of the dosage range while the individual is taking bupropion. In the more common situation where bupropion is initiated for a person already taking these drugs, these may need to be decreased. Bupropion should not be used in patients taking monoamine oxidase inhibitors, including moclobemide.

A 14-day washout is recommended between completing monoamine oxidase inhibitors and starting bupropion. Consultation with a psychiatrist may be considered for advice on co-prescribing bupropion with other antidepressants.^{93,94}

There is no evidence that the use of bupropion for smoking cessation increases the risk of serious cardiovascular adverse events during or after treatment.³⁹ Due to the limited efficacy and pregnancy safety data, bupropion is not recommended as a smoking cessation aid for women who are pregnant or breastfeeding.⁷⁹

Side effects

Seizures are the most clinically important adverse effect (0.1% risk) with the use of bupropion for smoking cessation, and fatalities have been previously reported.⁹² Therefore, bupropion should not be prescribed to patients with a current seizure disorder or a previous history of seizures. Common adverse effects are insomnia, headache, dry mouth, nausea, dizziness and anxiety. If bupropion is used in combination with NRT, blood pressure should be monitored.⁸³

Recommendation 13 – Bupropion sustained release should be recommended to people who have been assessed as clinically suitable for this medication; it should be provided in combination with behavioural support. Bupropion is less effective than either varenicline or combination nicotine replacement therapy. Strong recommendation, high certainty

Availability of smoking cessation medicines on the Pharmaceutical Benefits Scheme

Health professionals should check for updated [Pharmaceutical Benefits Scheme \(PBS\) listings \(http://www.pbs.gov.au\)](http://www.pbs.gov.au).

Nicotine patches (eg 25 mg/16 hours, 15 mg/16 hours, 5 mg/16 hours, 21 mg/24 hours, 14 mg/24 hours, 7 mg/24 hours) are [listed on the PBS \(http://www.pbs.gov.au/medicine/item/10076H-11612E-11617K-11618L-11619M-3414Q-4571N-4572P-4573Q-5465P-5571F-5572G-5573H\)](http://www.pbs.gov.au/medicine/item/10076H-11612E-11617K-11618L-11619M-3414Q-4571N-4572P-4573Q-5465P-5571F-5572G-5573H) for use as an aid to quitting for people who participate in a support and counselling program. The subsidised patches are not available at the same time as other PBS-subsidised smoking cessation therapies (ie varenicline, bupropion), but those who are unsuccessful at quitting using the nicotine patches are able to access PBS-subsidised medicines during that same 12-month period.

Oral forms of NRT subsidised on the PBS are gum and lozenges for use as the sole PBS-subsidised therapy. This means combination NRT is not currently PBS subsidised.

Under PBS rules, a maximum 12 weeks of PBS-subsidised NRT is available per 12-month period.

All forms of NRT are available over the counter in pharmacies and supermarkets in Australia.

Aboriginal and Torres Strait Islander peoples

Aboriginal and Torres Strait Islander peoples qualify for a PBS-restricted benefit listing, which provides up to two courses of nicotine patches per year, each a maximum of 12 weeks. Under this listing, participation in a support and counselling program is recommended but not mandatory. Nicotine gum (2 mg and 4 mg doses) and lozenge (2 mg and 4 mg doses) are also available on the PBS for Aboriginal and Torres Strait Islander peoples. The PBS listing does not cover two forms of NRT at once (ie no combination therapy). Access to NRT for Aboriginal and Torres Strait Islander peoples can be facilitated through the Closing the Gap PBS co-payment measure (refer to [Chapter 4 \(https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation-1/smoking-cessation-for-high-prevalence-groups\)](https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation-1/smoking-cessation-for-high-prevalence-groups), 'Smoking cessation for high prevalence groups: Closing the Gap PBS co-payment measure').

Availability of varenicline on the PBS

Varenicline is available on the PBS as a short-term adjunctive therapy for nicotine dependence. It can be prescribed as a streamlined authority prescription for up to 24 weeks of continuous therapy for smoking cessation. Eligibility requirements include enrolling in a support and counselling program, and abstinence at 12 weeks. Making use of the Closing the Gap PBS co-payment can further reduce the cost for Aboriginal and Torres Strait Islander peoples.

The first script is a starter pack that lasts for four weeks (including dose titration), followed by a continuation batch for eight weeks of treatment. A third prescription is required for the final 12 weeks of treatment, but only for those who respond to the first 12 weeks. Under PBS rules, a maximum of 24 weeks of PBS-subsidised treatment with this drug is permitted per 12-month period.

Availability of sustained-release bupropion on the PBS

Sustained-release bupropion is available on the PBS as a streamlined authority prescription for a short-term course of treatment (nine weeks) for nicotine dependence, with a comprehensive support and counselling program. Making use of the Closing the Gap PBS co-payment can further reduce the cost for Aboriginal and Torres Strait Islander peoples.

Bupropion is available as a starter pack of 30 tablets and a continuation pack of 90 tablets. The dose of bupropion is 150 mg/day for the first three days, then increased to 150 mg twice per day. The patient should stop smoking in the second week of treatment. Under PBS rules, a maximum of nine weeks of PBS-subsidised treatment with this drug is permitted per 12-month period.

Nortriptyline

Nortriptyline is a tricyclic antidepressant that has been shown in a relatively small number of trials to significantly increase long-term cessation when used as the sole pharmacotherapy.^{2,56} A systematic review found that the use of nortriptyline for smoking cessation resulted in higher prolonged abstinence rates after at least six months, compared with placebo treatment.⁹⁵ The efficacy of nortriptyline does not appear to be affected by a past history of depression, but it is limited in its application by its potential side effects, including dry mouth, constipation, nausea, sedation and headaches, and a risk of arrhythmia in patients with cardiovascular disease. Nortriptyline can be dangerous in overdose.

Nortriptyline is not registered for smoking cessation in Australia.

The dose of nortriptyline used for smoking cessation is approximately 75 mg/day for 12 weeks. Further information about nortriptyline for smoking cessation can be obtained from the *New Zealand smoking cessation guidelines*.¹⁶

Recommendation 14 – Nortriptyline should be considered as a second-line pharmacotherapy agent because of its adverse effects profile. Strong recommendation, moderate certainty

Electronic cigarettes and nicotine vaping products

Terminology	
Nicotine vaping products	Products that contain nicotine (in salt or base form) in a solution designed to be inhaled using a vaping device. Includes vape liquids, e-liquids and e-juices that contain nicotine, and the nicotine solution in nicotine e-cigarettes and pods.

Terminology	
Vaping device	Electronic devices used to heat vaping products to release an aerosol that is inhaled. Includes e-cigarettes, e-cigars, e-hookah pens, e-pens, e-pipes and vape pens.

Note: "Heated tobacco products" are not nicotine vaping products.

Electronic cigarettes, often referred to as e-cigarettes, are a diverse range of battery-powered devices that deliver nicotine aerosol without tobacco or smoke.⁹⁶ E-cigarettes were invented in the 2000s and have since been rapidly changing. The vaping device heats an e-liquid – also known as the nicotine vaping product (NVP) – into an aerosol for inhalation.

Beside nicotine, the e-liquid usually contains propylene glycol and glycerol, with or without flavours. Nicotine in e-liquid can be in free-base (original) or salt form. In both cases the active ingredient is nicotine. The free-base form at concentration >20 mg/mL causes adverse effects including throat irritation and therefore higher concentrations need to be diluted before use. The nicotine salt is associated with less throat irritation allowing for higher concentrations of nicotine to be used. The pharmacokinetics of nicotine delivery, which includes rapidity of onset and peak nicotine levels, is variable and is a function of the form of the nicotine, NVP concentration, the vaping device, and inhalation technique.

There is a broad range of vaping devices, which can be open or closed systems, and refillable or non-refillable.^{96, 97, 98, 99} Open system devices are those that need to be manually filled with e-liquid before use. Closed system devices include prefilled cartridges, pods or other disposables where the e-liquid is enclosed in a sealed container.⁹⁹ Disposable devices cannot be refilled with e-liquid and are non-rechargeable.⁹⁷

Change to regulation of nicotine from 1 October 2021

Under existing state and territory laws, the domestic sale of NVPs to consumers without a prescription is illegal throughout Australia. Additionally, the possession or use of these products without a prescription is illegal in all states and territories. From 1 October 2021, consumers will also require a valid Australian medical prescription to import NVPs (Schedule 4). This means that from 1 October 2021, consumers will require a prescription for all purchases of all NVPs, regardless of where they are sourced from.

Australia's approach to only have NVPs available on prescription is currently unique around the world. The regulatory arrangements for NVPs vary considerably within and across countries, ranging from prohibition to minimal or no regulation. In Australia, NVPs are regulated under various regulatory frameworks that apply to tobacco products, poisons, medicines and consumer products.⁹⁹

Nicotine vaping products are not currently approved therapeutic goods

There are currently no TGA-approved NVPs registered in the Australian Register of Therapeutic Goods (ARTG). Medicines that are not in the ARTG are known as 'unapproved' medicines. There are established pathways for consumers to legally access unapproved NVPs, with a valid prescription. Further details about these pathways are provided below. However, it is important to note that unapproved medicines have not been assessed by the TGA for safety, quality and efficacy.

The TGA has released a product standard for NVPs, which sets out the minimum safety and quality requirements for NVPs supplied in Australia. The [Therapeutic Goods \(Standard for Nicotine Vaping Products\) \(TGO 110\) Order 2021 \(TGO 110\)](https://www.legislation.gov.au/Details/F2021L00595/Download) (<https://www.legislation.gov.au/Details/F2021L00595/Download>) comes into effect on 1 October 2021.

The TGO 110 requirements for NVPs include:

- labelling requirements – ingredient list, nicotine concentration (mg/mL) and warning statements (can be on either the actual product or on an accompanying information sheet). Note that the currently required warning statements do not include the warnings against the risk of ingestion.
- child-resistant packaging¹
- ingredient requirements – including the prohibition of other active ingredients besides nicotine. Note that TGO 110 allows a maximum nicotine concentration of up to 100 mg/mL. This does not mean that products with a nicotine concentration of 100 mg/mL are safe or appropriate (See [Dosing considerations \(#Dosing_considerations\)](#)).
- restriction on certain ingredients that are known to have potential for toxicity
- record-keeping obligations.

Importantly, the TGO 110 labelling and packaging requirements do not apply to NVPs imported by a consumer for their personal use, which is why the Personal Importation Scheme is not a recommended prescribing pathway (See [Prescribing pathways \(https://www.tga.gov.au/nicotine-vaping-products-information-prescribers\)](https://www.tga.gov.au/nicotine-vaping-products-information-prescribers) and [TGA table \(https://www.tga.gov.au/resource/nicotine-vaping-products-and-vaping-devices\)](https://www.tga.gov.au/resource/nicotine-vaping-products-and-vaping-devices) "TGO 110 Requirement").

Minimising risk

The recommended first-line smoking cessation support includes TGA-approved pharmacotherapies and behavioural support. NVPs are NOT first-line treatments for smoking cessation. NVPs may be considered with ongoing behavioural support for people who have tried to achieve smoking cessation with [TGA-approved pharmacotherapies \(https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation/pharmacotherapy-for-smoking-cessation\)](https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation/pharmacotherapy-for-smoking-cessation) combined with [behavioural intervention \(https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation/behavioural-and-advice-based-support-for-smoking-c\)](https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation/behavioural-and-advice-based-support-for-smoking-c) but failed and are still motivated to quit smoking.

Given there is not as yet a TGA-approved NVP, this guidance seeks to provide advice to clinicians on how to minimise risk to the person trying to quit smoking and society in general, and maximise benefit. The risks of NVPs include: [100](#), [101](#)

- unknown long-term health effects
- intentional and accidental poisoning
- acute nicotine toxicity, injuries, burns and lung injury
- dual use with continued smoking [102](#)
- greater long-term exposure to nicotine than the use of other smoking cessation measures [103](#)
- diversion leading to use by non-smokers
- acting as a gateway to tobacco use
- the potential to promote nicotine use and re-normalise smoking among those who do not smoke, especially young people [104](#)
- Nicotine exposure can harm adolescent brain development [104](#)
- potential medicolegal risks for prescribers.

* Child fatalities have occurred following ingestion of liquid nicotine. [96](#)

Nicotine vaping products and smoking cessation: Efficacy and safety

There is a lack of well conducted randomised controlled trials comparing NVPs with TGA-approved pharmacotherapies, such as bupropion and varenicline. [98](#)

An updated evidence review conducted by the Australian National University (ANU) compared nicotine e-cigarettes (nicotine concentration >0.01 mg/mL) versus nicotine replacement therapy. The review identified two randomised controlled trials that met inclusion criteria with a total of 1468 participants. The relative effect was 1.67 (95% CI: 1.21 to 2.28). The RACGP Expert Advisory Group (EAG) concluded there is a small benefit in smoking cessation in the clinical setting for NVPs compared with NRT although the certainty of the evidence is low. The evidence from good quality randomised trials has not improved since the review conducted for the RACGP by the Joanna Briggs Institute in 2019 and there remains limited evidence that NVPs are an effective aid for quitting smoking compared with NRT or usual care. [103](#)

The most commonly reported acute adverse effects in a recent Cochrane review were throat irritation, headache, cough and nausea. [97](#) The ANU also reviewed the available evidence on short- and long-term adverse effects of NVPs. Based on the evidence, the EAG assessed the overall magnitude of acute adverse effects in the clinical setting as small but there may be other short-term effects that have not become evident. The effects of NVPs on other clinically important short- and long-term health outcomes are unknown. (See the [Appendix for the evidence-to-decision framework \(https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation/supporting-material/resources-for-health-professionals\)](https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation/supporting-material/resources-for-health-professionals)).

Recommendation 15 – For people who have tried to achieve smoking cessation with first-line therapy (combination of behavioural support and TGA-approved pharmacotherapy) but failed and are still motivated to quit smoking, NVPs may be a reasonable intervention to recommend along with behavioural support. However, this needs to be preceded by an evidence-informed shared-decision making process, whereby the patient is aware of the following caveats:

- 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 vaping devices and NVPs, which increases the uncertainties associated with their use.
- To maximise possible benefit and minimise risk of harms, dual use should be avoided and long-term use should be minimised.
- It is important for the patient to return for regular review and monitoring.

Conditional recommendation for intervention, low certainty

Navigating prescribing pathways

There are three main [prescribing pathways \(https://www.tga.gov.au/nicotine-vaping-products-information-prescribers\)](https://www.tga.gov.au/nicotine-vaping-products-information-prescribers) for NVPs with the first two being preferred: (see [NPS figure in the Appendix \(https://www.racgp.org.au/FSDEDEV/media/documents/Clinical%20Resources/Appendix-NPS-Medicinewise-accessing-NVPs.pdf\)](https://www.racgp.org.au/FSDEDEV/media/documents/Clinical%20Resources/Appendix-NPS-Medicinewise-accessing-NVPs.pdf))

1. [Authorised Prescriber Scheme \(https://www.tga.gov.au/form/authorised-prescribers\)](https://www.tga.gov.au/form/authorised-prescribers) – The medical practitioner applies to the TGA for authority to prescribe NVPs directly for patients under their immediate care without requiring separate approval for individual patients. The number of patients treated every 6 months must be reported to the TGA. (See the [TGA infographic on becoming an Authorised Prescriber for NVPs \(https://www.tga.gov.au/resource/infographic-become-authorized-prescriber-nicotine-vaping-products\)](https://www.tga.gov.au/resource/infographic-become-authorized-prescriber-nicotine-vaping-products))
2. [Special Access Scheme \(https://www.tga.gov.au/form/special-access-scheme\)](https://www.tga.gov.au/form/special-access-scheme) – The medical practitioner applies to the TGA for approval to prescribe an NVP for a single patient on a case-by-case basis.
3. [Personal Importation Scheme \(https://www.tga.gov.au/personal-importation-scheme\)](https://www.tga.gov.au/personal-importation-scheme) – The medical practitioner supplies a script for the patient to import the product (up to 3 months' supply) for their personal use. The medical practitioner does not need TGA approval or authority.

Supply of NVPs through Australian pharmacies using either the Authorised Prescriber or Special Access Scheme pathways ([apply online \(https://compliance.health.gov.au/sas\)](https://compliance.health.gov.au/sas)) is recommended.

Use of the Personal Importation Scheme is not recommended to **minimise the risk of the patient receiving imported products that do not meet the full TGO 110 requirements**. This is because TGO 110 labelling (ingredient list, nicotine concentration in mg/mL and warning statements), and packaging requirements apply only to [NVPs \(https://www.tga.gov.au/resource/nicotine-vaping-products-and-vaping-devices\)](https://www.tga.gov.au/resource/nicotine-vaping-products-and-vaping-devices) supplied in Australia and not to products imported via the Personal Importation Scheme.

Medical practitioners can choose to take the following steps to minimise the risk of patients using their prescription supplied under the Authorised Prescriber or Special Access Scheme to purchase NVPs through the Personal Importation Scheme:

1. Supply the prescription directly to the patients nominated pharmacy
2. Endorse the prescription “For local supply only” to indicate dispensing within Australia

Note: NVPs are currently under consideration for inclusion in real-time prescription monitoring systems in Australia.

Prescribing

The recommendations depend on whether the patient is new to using NVPs for smoking cessation or is an experienced user of NVPs.

- It is recommended that new users only use devices with closed systems, such as cartridges and pods, to reduce the risk of poisoning and the addition of other potentially toxic substances to the e-liquid. The majority of available closed systems deliver nicotine salt.
- Experienced users may have preferences with regards to type of vaping device and e-liquid, which can be taken into account but are not determinative.

Writing prescriptions

NVP prescriptions should specify the following:

- nicotine concentration (in mg/mL)
- recommended daily dose
- quantity – The EAG recommends limiting the quantity provided per prescription to a maximum 3 months’ supply. Consider aligning the duration of supply with the timing of follow-up.

In addition, since different NVP brands have different nicotine concentrations, prescribers may have to specify product brands to reduce confusion or uncertainty during dispensing. Therefore, prescribers will likely need to be aware of product availability. At the time of writing, the specific products that will be available in Australian pharmacies is not known. Besides consideration of open or closed systems, other issues to consider when choosing a product include certification of adherence to Good Manufacturing Practices and whether the manufacturer provides product liability insurance.

Dosing considerations

The EAG noted it is not possible to provide definitive advice on dosing as there is no clear evidence and no guidelines on dosing exist at this time. In addition, the dose of nicotine received by the person can vary by the type of vaping device (including the electrical power of the device), concentration of nicotine, and inhalation technique.

The evidence shows:

- The amount of nicotine inhaled from NVP can be very variable – between 0.5 and 4 mg with 15 puffs (in comparison, the amount of nicotine per combustible cigarette is 0.5 to 1.5 mg) [105](#)
- Blood concentrations similar to or greater than combustible cigarettes are attainable with liquid nicotine concentrations of ≤ 20 mg/mL. [105, 106](#)

There is currently only limited guidance from the literature on NVP dosing with the free-base nicotine.

The two trials demonstrating significant NVP efficacy, which were included in the ANU review, used a nicotine free-base concentration of ≤ 20 mg/mL. [107, 108](#) One trial involved participants receiving a starter pack of 18 mg/mL liquid nicotine and subsequently choosing their own nicotine concentration up to 20 mg/mL. The other trial, which allowed participants to choose their own nicotine concentration up to 20 mg/mL, reported use of a median of 10 mg/mL initially and 6 mg/mL at 6 months.

It is important to note that there are currently no trials of the efficacy of nicotine in salt form to assist smoking cessation.

The higher-concentration nicotine salt have potential advantages and disadvantages. Potential advantages are that their pharmacokinetics more closely replicate nicotine from smoking, which may facilitate people transitioning away from combustible tobacco. [109](#) Also, the consumption of e-liquid is reduced, which may result in reduced exposure to toxic compounds (including volatile aldehydes) and flavouring molecules with unknown toxicity. [109, 110, 111](#) Along with the lack of evidence of efficacy in smoking cessation, an important disadvantage is the concerning level of uptake of high concentration nicotine salt products in non-smokers including young people. This has been a particular feature in countries with consumer availability such as the United States and Canada. [112, 113](#) Therefore, risk of diversion needs to be considered and minimised.

While acknowledging the lack of evidence, the EAG provided the following suggestions to assist in making prescribing decisions:

- When prescribing for new users to support smoking cessation, choose a starting dose based on the patient's level of nicotine dependence (See Assess Nicotine Dependence in [Chapter 1 Introduction to smoking cessation \(https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation/introduction-to-smoking-cessation\)](#)). If using nicotine free-base a reasonable starting strength for less dependent smokers is 6–12 mg/mL. Higher concentrations (18–20 mg/mL) may be needed for more dependent smokers. If using nicotine salt pods, a reasonable starting strength is 18–30 mg/mL for less dependent smokers. Higher concentrations (>30 mg/mL) may be needed for more dependent smokers.
- Current users of NVPs will likely have their own preferences of concentration, device, and daily

use. If the patient is currently using an open system device and moderate to high nicotine concentration, recommend changing to nicotine free-base concentration $\leq 20\text{mg/mL}$ and/or a closed system device to reduce risk of poisoning.

Device considerations

Premixed 'closed' systems are recommended to avoid the following risks:

- inappropriate or incorrect dilution of liquid nicotine (the dilution process is not straightforward and relies on adequate product labelling)
- intentional or accidental ingestion or exposure through skin or eyes
- addition of potentially toxic or illegal substances, or contamination

Therapeutic guidelines on nicotine toxicity state the potentially lethal oral exposure dose is 5 mg/kg.¹¹⁴ Therefore, about 4 mL of a 100 mg/mL NVP is potentially fatal for an adult and <1 mL is potentially fatal for the average 2-year-old.

The risk of addition of toxic substances was demonstrated by the occurrence of E-cigarette or Vaping-Associated Lung Injury (EVALI), a severe respiratory illness first identified in the United States in early 2019. Investigations by the US Centers for Disease Control found that in the majority of EVALI cases the e-liquids used contained tetrahydrocannabinol (THC) and that vitamin E acetate, an additive that was much more common in THC-containing vaping products, was strongly linked to the EVALI outbreak. However, 1 in 8 cases are reported in use of nicotine-only products.¹¹⁵

Flavourings

Flavouring chemicals can reduce the harshness of nicotine, increase the appeal and reduce the perceived risk of NVPs.⁹⁸ Fruit and sweet (dessert) flavours are popular with young people and encourage uptake in non-smokers.^{112, 116} Though it is not essential for prescribers to specify the flavour on the prescription, ideally avoiding flavours or limiting to only tobacco flavour may reduce this risk.

The TGA's TGO 110 prohibits certain ingredients being added to NVPs but does not assess the safety of ingredients used in unregistered NVPs. There is limited evidence about the long-term safety of inhaled flavourings. Flavouring chemicals may be safe to consume as food or medication but may not be safe to inhale.^{96, 117}

To minimise risk, the EAG strongly recommends the use of devices with closed systems as users cannot purchase and add their own flavours, and to avoid open systems.

Practice points

NVPs are unregistered products and it is valid and reasonable for medical practitioners to choose not to prescribe them.

Overseas nicotine vaping products are not required to meet all of the TGO 110 requirements for safety.

To minimise risk of harms, the EAG recommends the following measures for prescribers:

1. **Recommend NVPs in closed systems and avoid open systems** – to minimise the risk of poisoning, addition of toxic/illegal substances and contamination. Disposable devices, which contain high concentration nicotine salt and a non-rechargeable battery in a single unit designed to be discarded after use, should also be avoided due to environmental waste and safety concerns, including a high risk of diversion.^{112, 113, 118}
2. **Use the Authorised Prescriber and Special Access Scheme prescribing pathways** instead of the Personal Importation Scheme – to minimise the risk of the patient accessing NVPs that do not comply with the minimum safety and quality TGO 110 labelling and packaging requirements. In addition, the prescriber can supply the prescription directly to the patient's nominated pharmacy and/or endorse it **"For Local Supply Only"**.
3. **Avoid prescribing free-base nicotine at concentrations over 20 mg/mL**. The two trials showing NVP efficacy used a concentration of ≤ 20 mg/mL free-base nicotine.

Although they are the most widely available closed system option, there is currently no clinical trial evidence of efficacy for smoking cessation with nicotine salt products.

Nicotine e-liquid concentrations of 100 mg/mL are not necessary and should not be prescribed. The risks of poisoning through skin contact and accidental ingestion are far greater where patients choose to dilute their own e-liquids.

Disposable devices are not recommended due to the high amount of waste and questionable safety.

4. **Limit the quantity of nicotine vaping products per prescription to a maximum of 3 months' supply**. Consider aligning the duration of supply with the timing of follow-up.
5. **Where possible, avoid flavours or limit to tobacco flavour**.
6. **Provide follow-up and behavioural support**

Use in people with chronic illnesses

There is a lack of high-quality evidence for the use of NVPs in people with chronic illnesses. The risk of using NVPs needs to be weighed against the risk of long-term smoking in people who have not been able to quit with first-line treatments (TGA-approved pharmacotherapies and behavioural support).

Pregnant or breastfeeding women

NVPs are not recommended in pregnant or breastfeeding women. NVPs are not approved for use in pregnancy and their effects on foetal development and obstetric outcomes are not known. For further information about smoking cessation in this group, refer to [Chapter 4: 'Pregnant or breastfeeding women'](https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation/smoking-cessation-for-high-prevalence-groups) (<https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation/smoking-cessation-for-high-prevalence-groups>).

Adolescents

NVPs are not recommended in people under 18 years old. For further information about smoking cessation in this group, refer to [Chapter 4: 'Adolescents and other young people'](https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation/smoking-cessation-for-high-prevalence-groups) (<https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation/smoking-cessation-for-high-prevalence-groups>).

Aboriginal and Torres Strait Islander peoples

Currently there is no evidence on the effectiveness of NVPs to assist quitting in Aboriginal and Torres Strait Islander peoples. For further information about smoking cessation in this population, refer to [Chapter 4: Aboriginal and Torres Strait Islander peoples](https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation/smoking-cessation-for-high-prevalence-groups) (<https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation/smoking-cessation-for-high-prevalence-groups>). The use of specific culturally safe resources, such as Tackling Indigenous Smoking and the Aboriginal Quitline is recommended.

Aboriginal and Torres Strait Islander people are more likely than non-Indigenous people to live in households with children present¹¹⁹ and to experience mental health illness.¹²⁰ Both can increase the risk of accidental and intentional poisoning related to NVPs. Particular care should therefore be taken to avoid prescription of high nicotine concentration liquids and open systems, and to advise on appropriate storage of NVPs, including keeping them out of reach of children.

People with mental illness

Smoking is highly prevalent in people with mental illness, especially those with severe illness. If people with mental illness have not been able to quit with first line treatment, consideration of NVPs in combination with behavioural support may be of value, although evidence specific to this group is currently lacking. People with mental illness are likely to be at greater risk of intentional poisoning from NVPs. Therefore, particular caution should be taken to avoid prescription of high nicotine concentration liquids and open systems. (For further information about smoking cessation in this population, refer to

Chapter 4: People with mental illness (<https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation/smoking-cessation-for-high-prevalence-groups>).

Monitoring NVP use and follow-up

As with any intervention for smoking cessation, follow-up visits to discuss progress and provide support is recommended. Arrange follow-up starting within a week of the quit day (refer to [Chapter 1 “Arrange follow-up”](https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation/smoking-cessation-for-high-prevalence-groups) (<https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation/smoking-cessation-for-high-prevalence-groups>)). Note that dose titration may be needed with regular follow-up and should be discussed with the patient. Follow-up will also support managing and [reporting \(to the TGA\)](https://www.tga.gov.au/reporting-problems) (<https://www.tga.gov.au/reporting-problems>) any adverse effects associated with NVP use. Encourage complete transition to NVPs and cessation of combustible tobacco.

After this initial phase, it is reasonable to review at least every 3 months, which is consistent with prescribing of PBS-subsidised smoking cessation therapy.

There is currently a lack of evidence about the optimal length of use or how to titrate NVPs down to achieve nicotine cessation. A suggested approach would be to attempt weaning or cessation of NVPs after 12 weeks of use. Transfer to NRT is an option for transitioning from NVPs to a form of nicotine less associated with long-term use. Other approved smoking cessation pharmacotherapies may have a role; however, there is a need for further research.

A maximum duration of 12 months' use of NVPs is a reasonable consideration.

NVPs in combination with other smoking cessation pharmacotherapy options

There is currently limited evidence for combination use involving NVPs. The ANU review included one published RCT on the combination of NVPs with NRT, which had a GRADE rating of very low certainty.¹⁰³ According to a 2021 UK briefing paper on NRT combination therapy, there may be benefit from the rapid delivery of nicotine from NVPs alongside steady state nicotine from NRT patches.¹²¹

Tobacco relapse prevention

Cessation of both tobacco smoking and use of other forms of nicotine is always the preferred option. However, there may be instances in selected patients where the doctor and patient agree that a longer term use of NVP is needed to avoid a relapse to tobacco use. Dual use should be avoided. If considering ongoing use of NVPs, counsel the patient on the risks and benefits versus re-trying other approved smoking cessation pharmacotherapies. This discussion includes that the long-term safety of NVPs is unknown, that there is a lack of high quality evidence of the health benefit from a tobacco harm reduction approach using [NVPs](https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation/tobacco-harm-reduction) (<https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation/tobacco-harm-reduction>), and

that people who use NVPs have an approximately double the risk of relapse to combustible tobacco smoking compared with non-NVP users. [122](#) Regular follow-up, monitoring and consideration of re-trialling other first-line interventions over time is recommended.

Clonidine

Based on a small number of trials, clonidine has been found to be more effective than placebo in promoting smoking cessation. [106](#) Prominent side effects for the use of clonidine include postural hypotension, extreme drowsiness, fatigue and dry mouth, which limit the usefulness of clonidine for smoking cessation. [107](#)

Clonidine is not registered for smoking cessation therapy in Australia.

A number of other tobacco cessation therapies are available or in development, as described below. [108,109](#)

Cytisine

Cytisine is a naturally occurring substance, chemically related to varenicline, that has been used for smoking cessation for decades in parts of Eastern Europe. [110](#)

A Cochrane meta-analysis concludes that cytisine increases the chances of quitting, although absolute quit rates in two recent trials were modest. [1](#) A New Zealand study found that cytisine combined with brief behavioural support was superior to NRT in helping people who smoke to quit, but it was associated with a higher frequency of self-reported adverse events. [111](#)

Cytisine is not currently approved by the TGA or available in Australia.

Vaccines

Anti-nicotine vaccines have been in development for a number of years. The rationale for immunisation against nicotine is to induce antibodies that bind nicotine in the blood, thereby preventing it from crossing the blood–brain barrier. [109](#) It is postulated that with less nicotine reaching the brain immediately after smoking, the vicious cycle between smoking and nicotine-related gratification will be broken. The vaccines must be administered regularly to maintain long-term protection. Early pre-clinical trials evaluating different vaccines were encouraging, but to date no study has detected a statistically significant difference in long-term cessation between vaccines and placebo. [112](#) Nicotine vaccines are not yet licensed anywhere in the world for use as an aid to smoking cessation or relapse prevention. [11](#)

Given that the current available first-line medications are all efficacious, and non-drug factors make a substantial contribution to the likelihood of quitting successfully, [8](#) choice should be based on overall evidence of relative efficacy, clinical suitability and patient preference (Figure 2.2).

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Behavioural and advice-based support for smoking cessation

Recommendations

Recommendation 3 – Offer brief cessation advice in routine consultations and appointments, whenever possible.

Strong recommendation, high certainty

Recommendation 16 – Referral to telephone call-back counselling services should be offered to all people who smoke.

Strong recommendation, high certainty

Introduction

The benefits of quitting smoking are well established. Patients should be advised that unassisted quitting has a very low success rate (3–5%),¹ and professional advice can greatly increase their chances of success of prolonged abstinence.^{1,2,3,4} Ideally, they should be offered the most effective method and use it as soon as possible. The most successful quit approach for those who are nicotine dependent is counselling and behavioural support combined with first-line pharmacotherapy and follow-up.^{1,5,6,7,8} Health professionals should offer to assist their patients with a quit attempt, using pharmacotherapy and counselling, either within the health service or by referring them for intensive support to a telephone Quitline (13 78 48), a smoking clinic or a health professional with special expertise in smoking cessation.

The following smoking cessation interventions have been proven to be effective.

Brief advice from health professionals

There is strong evidence that any advice from health professionals (ie doctors, nurses, nurse practitioners, Aboriginal health workers, medical assistants, dentists, hygienists, respiratory therapists, mental health counsellors, pharmacists) is effective in encouraging smoking cessation.^{9,10,11,12,13,14,15} Health professionals can encourage those who smoke to quit with minimal (<3 minutes) intervention;

one in every 33 such conversations will lead to a patient successfully quitting smoking.¹² Examples of how to start the conversation about quitting smoking with a patient is available at [Start the Conversation \(http://starttheconversation.org.au\)](http://starttheconversation.org.au).

More intensive interventions can result in better outcomes, but may not be practical in many clinical contexts.² Brief advice has a reduced impact on those who smoke, if they have tried and failed numerous times to quit.¹⁶ These patients will need help with advice that includes strong recommendations about the use of pharmacotherapy and active referral to Quitline or other cessation programs. Refer to [Chapter 1 \(https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation-1/introduction-to-smoking-cessation\)](https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation-1/introduction-to-smoking-cessation), 'The role of health professionals'.

Those who smoke should be offered at least a brief intervention for smoking cessation¹⁷ that is consistent with the three-step brief intervention model ([Chapter 1 \(https://www.racgp.org.au/\)](https://www.racgp.org.au/), Figure 1.3):

1. Ask and record smoking status
2. Advise all patients who smoke to quit and provide advice on the most effective methods
3. Help by offering to arrange referral, and encouraging use of behavioural support and evidence-based smoking cessation medications.

Options for behavioural support include the Quitline (13 78 48) or a tobacco treatment specialist.

As noted in Chapter 1, **Recommendation 3**, offer brief cessation advice in routine consultations and appointments, whenever possible Strong recommendation, high certainty

Counselling

There is clear evidence that both individual counselling (risk ratio [RR]: 1.57; 95% confidence interval [CI]: 1.40, 1.77)¹⁸ and group counselling (RR: 1.88; 95% CI: 1.52, 2.33)¹⁹ significantly increase quit rates compared with minimal intervention such as brief advice, usual care or provision of self-help materials.

Depending on the time available, counselling strategies could include:

- information about smoking, quitting and withdrawal
- strategies for coping with smoking triggers
- addressing barriers to quitting
- lifestyle changes
- support from family and friends
- rewards
- setting a quit date.

Table 3.1. Practical tips to assist quitting and staying quit

Challenge	Strategy
Psychological cues for smoking (eg stress, anger)	<ul style="list-style-type: none"> • Use muscle relaxation and breathing techniques
Social cues for smoking (eg peer pressure)	<ul style="list-style-type: none"> • Avoid smoking friends and situations early in quit attempt • Rehearse how to say no to a cigarette offer
Smoking triggers (eg alcohol, caffeine)	<ul style="list-style-type: none"> • Avoid or minimise alcohol consumption early in quit attempt • Avoid or reduce coffee and other caffeine-containing drinks
Risk of lapse in quit attempt	<ul style="list-style-type: none"> • Apply 'not a puff' rule
Maintaining motivation	<ul style="list-style-type: none"> • Implement reward system from money saved • Enlist social support from family and friends
Minimising weight gain	<ul style="list-style-type: none"> • Have a healthy diet, avoid high-fat and high-sugar foods, substitute water or low-calorie drinks for snacking, exercise regularly

*Table 3.1**Practical tips to assist quitting and staying quit*

Individual counselling

Individual counselling interventions typically include the following components:

- review a patient's smoking history and motivation to quit
- help identify high-risk situations
- generate problem-solving strategies to deal with high-risk situations.

Counsellors may also provide non-specific support and encouragement, and patients may find additional components such as written materials, video and audiotapes beneficial.¹⁸ More intensive support, usually combined with pharmacotherapy, may involve weekly face-to-face sessions between the patient who smokes and a counsellor trained in smoking cessation for a minimum of four weeks after the quit date. Smoking cessation counselling is in part based on the principles of cognitive behavioural therapy (CBT), an evidence-based treatment that also forms the basis of Quitline counselling.^{20,21} CBT is a psychological intervention that aims to:

- show patients how their thinking affects their mood
- help patients identify and challenge unhelpful thoughts
- learn practical self-help strategies.

Motivational interviewing and mindfulness-based interventions

Motivational interviewing is an approach widely used to help people quit smoking. It supports those attempting to quit by strengthening their own motivation and commitment to change their reactions to the urge to smoke.²²

Motivational interviewing generally requires more time per session than approaches using brief interventions and individual counselling. It is an evidence-based counselling technique based on a therapeutic partnership that acknowledges and explores a patient's ambivalence about their smoking behaviour. Motivational interviewing allows those who smoke to clarify what goals are important to

them and organise their reasons in a way that supports action. Motivational interviewing values patient autonomy and mutual respect, and uses open-ended questions, affirmations, reflection and summarising.²²⁻²⁴

For motivational interviewing strategies, refer to [Chapter 3 \(https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation/behavioural-and-advice-based-support-for-smoking-c\)](https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation/behavioural-and-advice-based-support-for-smoking-c), 'Clinical interventions for tobacco use and dependence' and Table B1, page 58 in [Treating tobacco use and dependence: 2008 update \(http://www.tobaccoprogram.org/clientuploads/documents/Consumer%20Materials/Clinicians%20Systems%20Mat/2008-Guidelines.pdf\)](http://www.tobaccoprogram.org/clientuploads/documents/Consumer%20Materials/Clinicians%20Systems%20Mat/2008-Guidelines.pdf).²

Mindfulness-based interventions may have an important role in helping those who smoke to deal with treatment and abstinence by moderating the relationship between craving and smoking, and promoting the development of coping strategies to deal with triggers to smoke. Mindfulness-based cognitive therapy and relapse prevention appear to reduce negative affect, craving and cigarette use among those who are trying to quit smoking.^{25,26}

Group counselling

Group behaviour therapy involves scheduled meetings (typically four to eight) where patients receive information, advice and encouragement and some form of behavioural intervention to support quitting smoking.¹⁷ Group counselling can provide the opportunity to learn behavioural techniques for smoking cessation and provide mutual social support.²⁷

Group therapy is better for helping people to stop smoking than self-help and other less intensive interventions for quitting; however, there is not enough evidence to evaluate whether it is more effective or cost-effective than intensive individual counselling.¹²

In some states and territories, Quitline will have registers of local support programs led by approved providers.

Telephone counselling and Quitline

Telephone counselling provides individual advice, encouragement and support by specialist counsellors to those who want to quit or have recently quit. Quitline is a clinical service that uses evidence-based guidelines set by the World Health Organization (WHO). Counsellors on Quitline use behaviour change techniques (eg CBT, motivational interviewing) over multiple calls to plan for, assist and sustain quit attempts. Usually, counsellors proactively call the client several times over the period leading up to, and the month following, a quit attempt. Alternatively, the client can call the service. Quitline telephone counselling is provided in each state and territory in Australia. A review of Cochrane systematic reviews of the cost-effectiveness of a variety of interventions found that proactive telephone support is highly cost-effective.²⁸

Some of the advantages of Quitline include:

- accessible throughout Australia
- confidential
- no cost to patient

- one-stop shop for resources
- easy intervention
- evidence-based program
- capacity for frequent follow-up and support.

Despite the demonstrated efficacy of Quitline,^{29,30,31} the rate of uptake in Australia is typically low. For example, an economic evaluation of the Victorian Quitline by Deakin University found that in 2015–16 referrals by health professionals to Quitline were an estimated 0.26% of the Victorian smoking population over age 14.³¹ Further research is needed to understand barriers resulting in the low reach of Quitlines and to examine this in the context of current levels of government investment in anti-smoking public health education mass media campaigns.^{31,32,33,34}

Quitline services in Australia

Quitline (13 78 48) exists in all Australian states and territories. Quitline can provide a free quit pack and confidential, multi-session behavioural intervention over the phone. In some states and territories, Quitline can also assist in linking callers into community programs. Counsellors can help callers find a course and email the link to them.

- All Quitline services in Australia have agreed to national minimum standards of service delivery.
- In most states and territories, those who smoke are offered free proactive telephone counselling. Proactive or call-back counselling protocols usually allow up to two sessions pre-quit and four session post-quit over the first month, with two in the first week. However, this can vary among states and territories.
- Online referral is available (those who smoke can be referred by all health professionals to the Quitline for extended support using the online referral sheet). Services provide feedback to health professionals regarding patients referred to a Quitline.
- Processes for online referral to Quitline through patient management software (Best Practice, Medical Director) are available in some states and territories.
- Callers have direct access to an appropriately trained Quitline counsellor, course leader or coach.
- Adolescent protocols are available for young people.
- Aboriginal and Torres Strait Islander counsellors or liaison people are available.
- Self-help books are available.

Services for people from culturally and linguistically diverse backgrounds

In some states and territories, bilingual educators conduct information sessions in a number of community languages (eg Quit Victoria). Community language-specific Quitline telephone numbers are also available:

- Arabic – 1300 7848 03
- Chinese (Cantonese and Mandarin) – 1300 7848 36
- Greek – 1300 7848 59
- Italian – 1300 7848 61
- Korean – 1300 7848 23
- Spanish – 1300 7848 25
- Vietnamese – 1300 7848 65

Web-based material

[Quitline referral form \(http://www.quit.org.au/referral-form\)](http://www.quit.org.au/referral-form) [iCanQuit \(http://www.icanquit.com.au\)](http://www.icanquit.com.au) [Quit Coach \(http://www.icanquit.com.au\)](http://www.icanquit.com.au) More resources are available on the [Quitnow website \(http://www.quitnow.gov.au\)](http://www.quitnow.gov.au).

Recommendation 16 – Referral to telephone call-back counselling services should be offered to all people who smoke. Strong recommendation, high certainty

Self-help materials

Self-help interventions for smoking cessation in the form of structured programs in written (eg books, brochures, manuals) or electronic (eg CDs, online, mobile phone apps) formats provide support and advice without the help of health professionals, counsellors or group support. There is moderate-certainty evidence that ‘written self-help materials help more people to stop smoking than no intervention’.³⁵

The most recent Cochrane review notes that the tailoring of self-help materials, compared with untailored or generic materials delivered similarly, produced no evidence of additional benefit.³⁵

Current evidence supports a beneficial effect of mobile phone-based smoking cessation interventions on six-month cessation outcomes.³⁶ Studies have found the effectiveness of text message mobile phone support programs in the short and long term.^{34,37} Combined internet and mobile telephone programs can be effective for up to 12 months for assisting people who smoke to quit.^{34,38}

Mobile phone-based apps are listed on the [Australian Government’s quit site \(http://www.quitnow.gov.au\)](http://www.quitnow.gov.au).

Online smoking cessation interventions are low cost and have the potential to reach a large number of people who smoke.^{39,40} A major advantage of the internet over printed material is its interactivity and ability to tailor information to individual needs. However, relatively few sites make use of this possibility – [QuitCoach \(http://www.quitcoach.org.au\)](http://www.quitcoach.org.au) is an example of tailored information. Research shows the structured planning intervention, QuitCoach, can significantly reduce relapse to smoking.⁴¹ Web-based programs are a promising delivery system for assisting and motivating those who smoke to quit; however, further research is needed to identify their most effective use.

Unproven approaches to smoking cessation

There are some approaches that have the potential to assist with maintaining long-term smoking cessation, but have not been adequately investigated for use.

Health professionals should be aware of extravagant claims of success for interventions that have not been subjected to rigorous testing and for which there is no clinical evidence.

Other nicotine-related agents

Nicobrevin is a patented product containing quinine (claimed to reduce cravings), menthyl valerate (supposed sedative properties), and camphor and eucalyptus oil (decongestants).⁴² NicoBloc and Nicobrevin are occasionally recommended by some healthcare professionals. These products are available in some pharmacies,⁴³ despite a lack of any empirical evidence of effectiveness.⁴⁴

Aversive or rapid smoking

Aversive therapy aims to extinguish the urge to smoke through pairing the act of smoking with an unpleasant stimulus. In the context of smoking cessation, this is usually the use of rapid smoking. There is no evidence to suggest that rapid (or aversive) smoking may be effective.⁴⁵

Biomedical feedback

Strategies used as a motivational tool for smoking cessation in primary care include spirometry, expired carbon monoxide levels, vascular ultrasounds and genetic susceptibility. There is little scientific evidence of an effect on quitting smoking for most biomedical tests.⁴⁶

Demonstrating the effects of smoking on estimates of lung age has not been shown to increase quit rates,⁴⁷ although it might increase levels of motivation in patients with chronic obstructive pulmonary disease (COPD) to quit smoking in the early stages of the disease.

Physical activity

There are two major aspects to quitting tobacco use:

1. overcoming nicotine addiction
2. managing the cues for smoking.

It is known that increased physical activity has many benefits for a healthy life. Exercise has been investigated as a way of helping with symptoms of nicotine withdrawal and cravings during attempts to quit. Exercise may also help by increasing self-esteem, improving mental health and managing the weight gain that often follows quitting. However, there is currently no evidence to show higher abstinence rates in the long term with aerobic exercise, resistance exercise, physical activity, and combined aerobic and resistance exercise.⁴⁸ A slight positive effect on smoking cessation at the end of treatment has been shown where yoga plus CBT was used.⁴⁹

Increased physical activity should be encouraged as part of a support program as it brings other health advantages to people who are trying to quit smoking. Exercise should be advised for everyone quitting.

Allen Carr method

Although the Allen Carr method has considerable popular support, there has been a lack of high-quality, empirical evidence that it is effective.⁵⁰ A recent randomised controlled trial involving 300 adults who smoke in Ireland found that Allen Carr's 'easy way to stop smoking' was superior to a standard online national smoking cessation program at 12 months follow-up (22% versus 11%).⁵¹ The intervention consisted of a one-off, five-hour group seminar with a maximum of 20 participants in a routine seminar session. Participants smoke during smoking breaks until there is a ritualistic final cigarette, followed by a 20-minute relaxation exercise. The mechanism of the effect found is not clear and further research is needed.

St John's Wort

St John's Wort (*Hypericum perforatum*) is an antidepressant herb extract that has not been shown to aid in smoking cessation. As yet, there is no convincing evidence that St John's Wort, alone or with individual motivational and behavioural support, is likely to be effective as an aid in smoking cessation.^{40,52,53}

Ineffective approaches to smoking cessation

There are several smoking cessation methods that are in widespread use, but have not been shown in well-designed trials to be effective for quitting other than as a placebo effect, or more than the effect of any counselling and support provided at the same time.

Hypnotherapy (without counselling)

Hypnotherapy is widely promoted as an effective way to stop smoking. It is said to assist smoking cessation by weakening the desire to smoke or strengthening the will to stop. Despite being in use for some decades, there are only a few well-designed studies to evaluate its use. A Cochrane meta-analysis was unable to show that hypnotherapy was superior to no treatment, and there are insufficient data to compare hypnotherapy with alternate effective treatments.⁵⁴

Acupuncture

People sometimes have acupuncture to quit smoking, with the aim of reducing withdrawal symptoms. Related therapies include acupressure, laser therapy and electrical stimulation. At present, there is no consistent evidence that acupuncture, or any related therapy, is better than doing nothing. Well-designed trials of acupuncture, acupressure and laser stimulation are needed before these treatments can be recommended as effective in smoking cessation.⁵⁵

Naltrexone

Naltrexone is a long-acting opioid antagonist used in the treatment of alcohol dependence. A meta-analysis of both published and unpublished studies indicates no beneficial effect of naltrexone alone or as an adjunct to nicotine replacement therapy (NRT) on short-term or long-term smoking abstinence.^{56,57} Naltrexone may have a role in reducing post-cessation weight gain.⁵⁸

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Smoking cessation for high-prevalence groups

Introduction

Overall smoking prevalence in Australia has continued to decline since the early 1990s, when smoking rates were at 24%¹. Smoking prevalence has continued to decrease, albeit at a slower rate, reaching 16.6% in 2007 and 12.2% in 2016.² However, the proportion of Australians who smoke is inversely related to the socioeconomic status of where they live and in some populations smoking prevalence far exceeds the national prevalence rate. For instance, in 2016, 17.7% of people in areas with the lowest socioeconomic status smoked daily, compared with 6.5% in areas with the highest socioeconomic status.²

There is extensive evidence that tobacco use contributes to poverty and inequality, and a clear relationship exists between smoking and socioeconomic status.¹ Disadvantaged population groups are more likely to start smoking and remain smoking in the longer term. In particular, the likelihood of smoking daily is:¹

- three times as high in the lowest socioeconomic areas of Australia, compared with the highest
- twice as high in remote areas compared to major cities
- almost three times higher for Aboriginal and Torres Strait Islander peoples, compared with non-Indigenous Australians
- almost six times as high for prison entrants, compared with the general population.

The same guidelines for quitting smoking apply to all patient groups. Every opportunity should be taken to offer all who smoke advice and support to stop smoking.³ Counselling and behavioural interventions may be modified to be appropriate for individuals. Quitline and other service providers have been trained for clients from many high-prevalence groups, including Aboriginal and Torres Strait Islander peoples. All who smoke with nicotine dependence should be offered pharmacotherapy, unless otherwise contraindicated.

Aboriginal and Torres Strait Islander peoples

Prevalence

- Approximately 45% of Aboriginal and Torres Strait Islander people are daily smokers – a prevalence rate almost three times that of non-Indigenous Australians.^{4,5}
- Similar reductions in smoking prevalence have been made across both Aboriginal and Torres Strait Islander populations and non-Indigenous Australian populations, with reductions of around 10% for both groups over the last 20 years.⁴

- However, after controlling for age, sex, remoteness, state/territory and education, the annual relative decrease in smoking was significantly slower for Aboriginal and Torres Strait Islander populations (1% per year) compared with the non-Indigenous Australian population (2.7%) per year.⁴
- Tobacco smoking accounts for 23% of the health gap between Aboriginal and Torres Strait Islander peoples and non-Indigenous Australians.⁶

Aboriginal and Torres Strait Islander peoples are also highly represented in many categories of those with special needs for smoking cessation:

- women who are pregnant⁵
- adolescents⁴
- prisoners^{7,10}
- people with substance use problems¹⁰
- people with smoking-related diseases (eg diabetes).⁶

Barriers to smoking cessation

Specific barriers to accessing smoking cessation treatment for Aboriginal and Torres Strait Islander peoples (eg social contexts that normalise smoking) are being addressed by health workers across Aboriginal and Torres Strait Islander communities.¹⁰ Aboriginal and Torres Strait Islander peoples tend to use medicines at a lower rate than non-Indigenous Australians.⁶ Barriers to the success of smoking cessation strategies for Aboriginal and Torres Strait Islander communities include:^{8,9,10}

- high levels of stress within Aboriginal and Torres Strait Islander communities
- lack of availability and access to culturally appropriate health services
- language barriers and high rates of smoking among Aboriginal health workers.

Data from the Talking About The Smokes project¹¹ indicate that, compared with non-Indigenous Australians who smoke, Aboriginal and Torres Strait Islander people are just as likely to:

- want to quit
- have tried to quit in the past year
- know about the most harmful health effects
- hold negative attitudes to smoking.

However, findings also showed that compared with non-Indigenous Australians, fewer Aboriginal and Torres Strait Islander people:¹¹

- have ever sustained longer quit attempts
- report social norms disapproving of smoking
- report using cessation pharmacotherapies.

Compared with non-Indigenous Australians, more Aboriginal and Torres Strait Islander people who smoke reported having been advised to quit by a health professional in the past year.¹¹

Appropriate interventions

Although various smoking cessation methods are effective across different racial and ethnic groups, there has been less research and evaluation of tobacco interventions within Aboriginal and Torres Strait populations.^{10,12} Smoking cessation methods identified as being effective (eg brief advice, pharmacotherapy) should be provided for all those who smoke, unless otherwise contraindicated, as these are likely to be effective, especially if delivered in culturally sensitive ways.

Culturally appropriate smoking cessation services for Aboriginal and Torres Strait Islander communities can be found at [Tackling Indigenous Smoking \(https://tacklingsmoking.org.au\)](https://tacklingsmoking.org.au). This Australian Government program funds 37 regional Tackling Indigenous Smoking teams. The teams do not provide individualised smoking cessation services; however, they can provide considerable support to general practitioners (GPs) and other health professionals who are working with Aboriginal and Torres Strait Islander communities. [Australian Indigenous HealthInfoNet \(https://healthinfolnet.ecu.edu.au\)](https://healthinfolnet.ecu.edu.au) maintains comprehensive information on programs, resources and publications related to Aboriginal and Torres Strait Islander health, including information on tobacco.

People who identify as Aboriginal or Torres Strait Islander qualify for the Pharmaceutical Benefits Scheme (PBS) authority listing for nicotine replacement therapy (NRT), which provides up to two courses of nicotine patches or oral forms of NRT (ie gum, lozenge) per year for a maximum of 12 weeks. Under this listing, participation in a support and counselling program is recommended but not mandatory.

Closing the Gap PBS co-payment measure

The [Closing the Gap \(http://www.pbs.gov.au/info/publication/factsheets/closing-the-gap-pbs-co-payment-measure\)](http://www.pbs.gov.au/info/publication/factsheets/closing-the-gap-pbs-co-payment-measure) measure is part of the Australian Government's Indigenous Chronic Disease Package. It was established to improve Aboriginal and Torres Strait Islander peoples' access to medicines by reducing the cost of PBS medicines for those who are living with or at risk of chronic disease.

Under this measure, eligible patients must be registered at an Indigenous health service or a general practice that participates in the Indigenous Health Incentive under the Practice Incentives Program to receive a Closing the Gap-annotated PBS prescription.

Depending on the Aboriginal and Torres Strait Islander patient's concessional status, the patient pays a lower, or nil, co-payment for all PBS medicines when a Closing the Gap-annotated prescription is dispensed at a pharmacy. A concession patient's co-payment reduces to nil and a general patient's co-payment reduces to that of a concessional patient. Some pharmacists impose a brand premium on some medicines, which the patient must pay. Brands that carry a manufacturer's surcharge are indicated by a 'B' on the PBS Schedule.

For further information, email [PBS-Indigenous@health.gov.au \(mailto:PBS-Indigenous@health.gov.au\)](mailto:PBS-Indigenous@health.gov.au) or visit [Medicare Australia \(http://www.medicareaustralia.gov.au/provider/pbs/prescriber/closing-the-gap.jsp\)](http://www.medicareaustralia.gov.au/provider/pbs/prescriber/closing-the-gap.jsp).

Culturally and linguistically diverse groups

Prevalence

The patterns of tobacco use and types of products used differ markedly between different ethnic groups, and these are influenced by complex psychosocial and cultural factors.¹³

Appropriate interventions

Tailoring smoking cessation interventions to consider relevant cultural dimensions such as values, beliefs and smoking practices improves cultural acceptability; however, this may not necessarily result in improved quit rates.¹⁴

Health professionals should offer advice, support and pharmacotherapy for all those who smoke, unless otherwise contraindicated. Support for cessation for these groups should use culturally appropriate resource materials.^{14,15}

Quitline provides printed resources in 13 languages other than English, and those who call can ask to have their calls returned with an interpreter, in a range of languages other than English. Bilingual educators from [Quit Victoria \(http://www.quit.org.au\)](http://www.quit.org.au) conduct information sessions in a number of community languages. The [NSW Multicultural Health Communication Service \(http://www.mhcs.health.nsw.gov.au\)](http://www.mhcs.health.nsw.gov.au) provides information and services to help health professionals communicate with non-English speaking communities.

Community language Quitline telephone numbers

- Arabic – 1300 7848 03
- Chinese (Cantonese and Mandarin) – 1300 7848 36
- Greek – 1300 7848 59
- Italian – 1300 7848 61
- Korean – 1300 7848 23
- Spanish – 1300 7848 25
- Vietnamese – 1300 7848 65

Smoking cessation in populations with special needs

There are particular implications regarding nicotine dependence and the effects of smoking, and medicines for smoking cessation for several population groups. Many of these groups have not been extensively studied in clinical trials of pharmacotherapy for smoking cessation:

- women who are pregnant or breastfeeding
- adolescents and other young people
- lesbian, gay, bisexual, transgender and intersex (LGBTI) people
- people with mental illness
- people with substance use disorders

- people in prison
- people with smoking-related diseases
- people who smoke and are in hospital.

The same guidelines for quitting smoking should apply to all groups, and every opportunity should be taken to offer all those who smoke advice and support to stop smoking. Counselling and behavioural interventions may be modified to be appropriate for the individual. In addition, all those who smoke with nicotine dependence should be offered pharmacotherapy unless otherwise contraindicated, and referred to Quitline for intensive treatment, other cessation programs or local face-to-face services, where available.

Pregnant or breastfeeding women

Prevalence and risks

- The rate of smoking during pregnancy in Australia continues to fall; however, approximately 10% of women smoke during pregnancy.⁷
- Teenagers, women living outside major cities, Aboriginal women and those with mental illness are significantly less likely to quit smoking during pregnancy.¹⁶
- A systematic review of smoking cessation interventions during pregnancy concluded that only 13% of women are abstinent at term and, of these women, 43% resume smoking by six months postpartum.¹⁷

There is no safe level of smoking in pregnancy because any level of exposure to tobacco smoke increases the risk of adverse effects to the expectant mother, fetus and pregnancy.^{5,18,19,20} The greatest gain in health benefits comes from quitting rather than cutting down.^{21,22,23}

In addition to the serious long-term health consequences for the mother, tobacco smoking during pregnancy is the most common preventable risk factor for pregnancy complications. It is associated with poorer perinatal outcomes, including low birthweight, being small for gestational age, pre-term birth, perinatal death, placental abruption, sudden infant death, cleft palate, cleft lip and childhood cancers.^{5,24,25} The long-term health effects on child health due to either parent smoking during pregnancy include neurodevelopmental and behavioural problems, obesity, hypertension, type 2 diabetes, impaired lung function, asthma and wheezing.^{24,26}

Barriers to smoking cessation

Women who have tried to quit smoking during pregnancy are an important group to identify and support, as they are more likely to be motivated to try another quit attempt. Health professionals should understand and address the barriers to smoking cessation for pregnant women, including:²⁷

- lack of understanding of risk to themselves and their babies
- influence of close relationships on smoking status
- use of smoking as a way of coping with stress.

Women who are pregnant may feel unsupported or even stigmatised if advice and support provided do not recognise the emotional and psychological stressors associated with pregnancy, and do not seek to address the altered physiological processes that occur during pregnancy.²⁸ Concern about stigma may lead to some pregnant women being reluctant to disclose their smoking status.

Appropriate interventions

All women of childbearing age should be encouraged to stop smoking, ideally before conception. Smoking cessation policy is intended to minimise the effects of smoking for all women; long-term reduction in tobacco exposure during pregnancy can be achieved only by encouraging adolescent girls and young women not to start smoking.²⁷ It is also important to advise partners of pregnant women not to smoke around them, and to encourage them to quit, as this can improve quit rates for women who are pregnant and smoke.²⁷

First-line treatment

Quitting before conception is most ideal; otherwise, quitting should be encouraged as soon as possible during the pregnancy. Quitting during early pregnancy (eg within the first trimester) has been shown to result in similar rates of adverse pregnancy outcomes compared with those who do not smoke.²⁹ These health benefits are not realised if quitting occurs later in pregnancy, as the rates of adverse pregnancy outcomes are more similar to those who continue to smoke during pregnancy.³² Therefore, to optimise the health benefits of quitting smoking during pregnancy, health professionals should offer cessation interventions and ongoing support to pregnant women as early as possible.

Health professionals should inform women who are pregnant and new mothers of the dangers of second-hand (passive) smoke to newborn babies, young children and adolescents.²⁴

Psychosocial smoking cessation interventions (eg counselling, feedback, financial incentives) can:³⁰

- increase the proportion of women who stop smoking in late pregnancy
- reduce the proportion of infants born with low birthweight and complications during pregnancy
- reduce the rate of postpartum smoking resumption.

Assessing smoking status and providing advice about the harms of continued tobacco use are recommended in routine antenatal care. However, there is no current framework for providing financial incentives based on biochemical measures of abstinence. There is convincing evidence of the effectiveness of financial incentives as a motivational and engagement strategy for tobacco cessation during pregnancy. Providing financial incentives will likely play an important role in future public health strategies to support pregnant women to quit smoking.³¹

Women who are pregnant should be encouraged to use Quitline, which has special programs of support in some states and territories, and extend into the postpartum period when risk of relapse is high.

Quitline during pregnancy

Quitline provides an extended call-back service specifically for women who are pregnant. A Quitline adviser calls at agreed times and provides information, offers help to deal with problems, and gives encouragement and practical support with quitting. The adviser schedules calls during pregnancy and after the birth. Quitline callers may receive between four and 10 calls as part of the extended call-back service.

In some states and territories, Quitline also provides online training to midwives to help those who are pregnant to quit smoking.

Health professionals should encourage women who are pregnant and smoke to attempt cessation using counselling, advice and behavioural support interventions before using pharmacological approaches. The current evidence is insufficient to assess the safety of pharmacological approaches during pregnancy.³²

Second-line treatment

If quit attempts are unsuccessful without the use of pharmacological approaches, and the woman is motivated to quit, pharmacotherapy (usually oral forms of NRT) should be considered.^{27,33}

Oral forms of NRT and nicotine patches are approved by the Therapeutic Goods Administration (TGA) for use in pregnancy. The findings of a Cochrane systematic review (2015), which included eight randomised controlled trials and 2199 participants, found no increase in adverse effects (ie miscarriage, stillbirth, pre-term birth, low birthweight, neonatal care unit admission, neonatal death).³³ However, given the small number of available studies, no firm conclusions on safety can be made. Improvements to smoking outcomes using NRT were modest,³³ and given that there may be potential for fetal harm from intrauterine nicotine exposure, NRT should only be considered if and when:

- the woman has not been able to stop with non-pharmacological assistance
- the uncertainty about the benefits and risks have been explained to the woman.

For further information, refer to [Chapter 2 \(https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation-1/pharmacotherapy-for-smoking-cessation\)](https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation-1/pharmacotherapy-for-smoking-cessation), 'Use of NRT in pregnancy'.

Varenicline and bupropion have not been shown to be effective or safe for smoking cessation treatment in women who are pregnant and breastfeeding. If a woman becomes pregnant while taking either agent, treatment should be ceased. With her express consent, reporting her pregnancy outcome to health authorities and the manufacturer may over time help better understand any risk.

While nicotine passes from mother to child in breastmilk, it is unlikely to be harmful.^{34,35} Women who continue to smoke after the birth should be encouraged to breastfeed their babies and be provided with strategies to minimise the potential harm to their child through breastmilk and from second-hand smoke.³⁶

Key points

- Any level of tobacco smoke exposure increases the risk of adverse outcomes for the mother, fetus and pregnancy.
- Women who are pregnant should be encouraged to stop smoking completely.
- Women who are pregnant should be offered intensive behavioural support and proactive face-to-face or telephone counselling.
- If these interventions are not successful, NRT may be considered in pregnancy, after clear explanation to the woman of the risks involved.
- Women who quit should be supported to stay smoke-free in the long term.

Adolescents and other young people

Prevalence and risks

Most adults who smoke become addicted to nicotine as teenagers.^{37,38,39}

Accumulating evidence that suggests nicotine adversely affects adolescent development provides a strong incentive to protect children and adolescents from nicotine exposure.¹⁹ Nicotine exposure during adolescence is associated with:¹⁹

- deficient working memory
- deficient attention
- deficient auditory processing
- increased impulsivity
- increased anxiety.

It is also suggested that nicotine has a priming effect that increases addiction liability for other drugs.¹⁹ The popularity of alternative tobacco products and e-cigarettes are creating new health challenges in this age group.

The reasons young people commence smoking are varied and relate to genetic factors, peer influence, parental smoking, desire for weight control and stress.³⁷ Recruitment and retention of adolescents in formal smoking cessation programs are difficult and major determinants of interventions targeting young people. Computer and internet cessation programs are potential vehicles for programs aimed at young people, but there is no clear evidence of efficacy as yet.⁴⁰

Appropriate interventions

There is increasing evidence that starting to smoke at a younger age is associated with lower success rates of quitting, regardless of treatment.⁴¹ Many adolescent anti-tobacco programs focus on preventing teenagers from starting to smoke, rather than quitting.⁴² There is insufficient evidence to show that smoking cessation programs to help teenagers who already smoke are effective.⁴³ There are

also few studies that provide evidence of effectiveness of pharmacological interventions for adolescents who smoke. Reducing parental smoking rates is the intervention with the clearest effect on youth smoking uptake.⁴⁴

Some smoking cessation medications can be used by younger people who smoke. NRT is approved for use from 12 years of age, and can be offered if the adolescent who smokes is nicotine dependent and ready to quit.³ Although NRT has been shown to be safe in adolescents, there is little evidence that these medications, and bupropion or varenicline, are effective in promoting long-term quitting in this population group.³ The majority of studies included an intensive counselling component (>6 sessions). Adherence is likely to be a major factor in this age group.³

Good listening skills are important in creating a trusting relationship to deal successfully with adolescents (refer to [Chapter 3 \(https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation-1/behavioural-and-advice-based-support-for-smoking-c\)](https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation-1/behavioural-and-advice-based-support-for-smoking-c), 'Motivational interviewing and mindfulness-based interventions'):

- ask open-ended questions
- be non-judgemental and affirm their experiences
- summarise what you have heard to help them understand what they want.

Strategies for health professionals helping young people quit smoking

- Provide information about nicotine addiction and difficulties with quitting once symptoms of nicotine addiction appear.
- Provide information about the harms of smoking.
- Reinforce messages that smoking is not 'cool'.
- Discuss the immediate effects of smoking. The long-term health effects of smoking (eg cancer, heart disease) are less relevant to young people. Focus instead on immediate issues, including:
 - bad breath, smelly hair, yellow teeth, discoloured skin
 - increased wrinkles
 - reduced fitness
 - shortness of breath, wheezing
 - higher stress levels
 - reduced sense of taste and smell
 - more coughs and colds
 - being unattractive to non-smoking peers
 - the cost of smoking.
- Discuss weight control, particularly for young women. Smoking does help control weight, but it also causes many unhealthy effects that outweigh any perceived benefits, as opposed to weight management with exercise and healthy eating.
- Identify triggers and discuss coping skills.
- Refer the young person who smokes to Quitline.

Key points

- Reducing parental smoking rates is the intervention with the clearest effect on youth smoking uptake.
- Counselling is considered to be vital in this age group.
- Health professionals should ask adolescents about smoking and provide a strong anti-smoking message.
- NRT can be offered if the adolescent who smokes, in conjunction with behavioural support, is nicotine dependent and willing to make a quit attempt.
- Bupropion and varenicline are not approved for use by those under 18 years of age.

Lesbian, gay, bisexual, transgender and intersex people

Prevalence and risks

- Homosexual or bisexual people are more likely to smoke cigarettes (18.7%) compared with the general population of Australia (12.8%).²
- LGBTI youth are more likely to smoke (23%) compared with the general youth population (5%).²

It should be noted that LGBTI people have substantially higher smoking rates than the general population.¹ LGBTI people may begin to smoke or continue to smoke for a variety of reasons, including higher levels of psychological stress than heterosexual adults.¹

Identifying and reporting on the health of the LGBTI population is extremely challenging, due to a lack of data sources that include information on sex, gender and sexual orientation. While LGBTI people are recognised as a specific minority population group, they come from all walks of life and are part of all other population groups.¹

People with mental illness

Prevalence and risks

- Population surveys indicate much higher smoking prevalence rates among those with mental disorders (meeting ICD-10 criteria), of approximately 33% for those with anxiety disorder, 43% for those with affective disorders and 54% for those with substance use disorders.⁴⁵
- In 2016, Australian adults who reported having been diagnosed or treated for mental illness in the past year were more than twice as likely to smoke regularly as the rest of the population (24% versus 10%).¹
- For people with psychotic illness, the prevalence of current tobacco smoking rate is up to 66%.⁴⁶

Mental illness is associated with both higher rates of smoking and heavier smoking.⁴⁸ People with mental illness (eg schizophrenia, depression, bipolar disorder, anxiety) often experience physical, financial and social disadvantages because of their illness.^{47,48} There are links between smoking and mental health; smoking and mental health and physical illness; and smoking, mental health, debt and poverty.⁴⁹

Appropriate interventions

Actively encouraging and assisting smoking reduction and cessation are important to improve the quality of life of all who smoke.⁵⁰ Treating tobacco dependence is an important intervention for people with severe mental health illness; however, cessation rates are generally lower in this group for any given level of assistance.⁴⁴ A mix of face-to-face help augmented by Quitline calls is as effective as intensive face-to-face help.⁵¹ Smoking cessation should not worsen the mental health illness of people with stable psychiatric conditions.^{52,53} In fact, smoking cessation is associated with reduced depression, anxiety and stress together with improved mood, compared with continuing to smoke. This finding is true in those with and without a diagnosed psychiatric disorder.⁵¹

Health professionals should offer people with a mental illness smoking cessation interventions that have been shown to be effective in the general population. Mental illness is not a contraindication to stopping smoking; however, the illness and its treatment needs to be monitored carefully during smoking cessation.^{51,54,55} This is particularly important as neuropsychiatric symptoms are more common during quit attempts in this population compared to those who smoke but do not have a history of mental health illness.⁵⁶ Higher levels of dependence in people with mental illness may need more intensive treatment (eg higher doses of NRT, closer follow-up and monitoring). Varenicline has been found to be safe and effective for smoking cessation in people with stable mental illness or a past history of mental illness.⁵⁷

Smoking and drug interactions in people with a mental illness

Nicotine does not interact with psychiatric medications. However, the tar in tobacco smoke induces certain liver enzyme activity (cytochrome P450 1A2 [CYP1A2]), which increases the metabolism of certain medications, including some psychotropic drugs. Those who smoke may therefore require larger doses of these medications.^{58,59}

In the event of smoking reduction or cessation, the dose of drugs metabolised by the CYP1A2 system may require dose reduction and increased monitoring.⁶⁰

Key points

- Intensive smoking cessation counselling and close follow-up are important in this patient population group.
- Consultation with a psychiatrist or addiction specialist may be considered for advice on use of medicines for smoking cessation in people with significant mental health illness, including:
 - advice on use of smoking cessation medicines
 - need for adjustment of psychotropic medications
 - monitoring of neuropsychiatric symptoms.
- NRT is safe and effective for people with a mental health illness. Combination NRT is generally needed as people with mental illness have higher levels of nicotine dependence.
- Both varenicline and bupropion can be used in people with significant mental illness. A large randomised trial showed no increase in neuropsychiatric adverse events attributable to varenicline or bupropion relative to a nicotine patch or placebo.⁵⁹

People with substance use disorders

Prevalence and risks

- Smoking rates in people with alcohol and other drug dependencies are two to four times those of the general population.
- Cannabis and tobacco are often used together as a way of smoking cannabis. As rates of cigarette smoking decline, it is now more common for cannabis dependence to lead to tobacco dependence than was previously the case.⁶¹

Appropriate interventions

Smoking cessation has not been a major part of clinical interventions for people with alcohol and other drug dependencies, as the attention is usually focused on the alcohol or illicit drug use. There is good evidence that smoking cessation can enhance short-term abstinence, rather than compromise the outcome of drug and alcohol treatments,^{62,63} and that smoking cessation efforts may actually support long-term drug and alcohol abstinence.⁵³

People with alcohol dependence typically have lower success rates in smoking cessation, compared with the general population.^{16,64} Continued smoking has been found to adversely affect treatment for cannabis dependence. Success in smoking cessation for people with opiate dependence is lower than the general population. However, the conclusion from a Cochrane review suggests that providing tobacco cessation interventions targeted to smokers in treatment and recovery for alcohol and other drug dependencies increases tobacco abstinence.⁶⁵

Monitoring and support are needed for smoking cessation in people with substance use problems who may benefit from the involvement of other health professionals. This may include drug and alcohol counsellors, addiction specialists or psychiatrists with an interest in substance use disorders and intensive counselling from Quitline.

Key points

- Health professionals should offer encouragement, motivation, advice and counselling to people with substance use disorders who smoke.
- NRT is effective for quit attempts.
- Bupropion should be monitored carefully when used concurrently with alcohol use.
- Varenicline can be used; however, prescribers should ask patients to report any mood or behaviour changes.³

People in prison

Prevalence and risks

The prevalence of smoking in the prison population is 5.7 times higher than in the general population (74%).⁶⁶

Although smoking rates have fallen dramatically in recent decades in the general Australian population, rates remain high among those in prison.^{3,66} There is a clear association between smoking tobacco and social disadvantage; people from low socioeconomic groups, including Aboriginal and Torres Strait Islander peoples, people who use drugs, those with low levels of education and those experiencing mental health illness are overrepresented in the prison system. Each of these factors predicts higher smoking rates.⁶⁶

Appropriate interventions

A number of corrective services systems have implemented free or subsidised smoking cessation pharmacotherapy.⁶⁷ In New Zealand, smoke-free prisons have been successfully implemented since 2011, including freely available NRT for those in prison and staff who smoke.⁶⁸ Since 2016, a complete smoking ban has been introduced in most Australian prisons (except in Western Australia, the ACT and South Australia).⁶⁵ NRT may be provided on entry in some smoke-free prisons. Cessation support in the form of free or subsidised NRT, smoking cessation groups and telephone support from Quitline is available for people in some Australian prisons.⁶⁸

Motivation to quit smoking is high among the prison population. Half (50%) of all prison entrants who were current smokers reported that they would like to quit smoking.⁶⁶ Of those who have been discharged from prisons with smoking bans, 59% intended to smoke after release.¹ Trends among Australians in prison are comparable with the growing body of literature that suggests that smoking

bans have no gross impact on post-release cessation. A Queensland study found 72% of those who have been discharged relapsed within the first day of release, and 94% had returned to smoking within two months.⁶⁹

Smoking cessation programs conducted in prisons should address prison-specific difficulties by including items (eg stressor pack) to assist those in prison during transfer to other prisons and court appearances.⁷⁰ Support programs should also discuss how to prevent relapse on release from prison.

Key points

- Health professionals should take every opportunity to offer brief advice to quit.
- Health professionals should advise proactive telephone counselling (eg Quitline).
- Health professionals should closely follow up those attempting to quit or maintain cessation post-release.

People with smoking-related diseases

Prevalence and risks

- Tobacco smoking significantly increases the risk of cardiovascular disease, respiratory diseases and other health problems.⁷¹
- In Australia, 80% of lung cancer burden and 75% of chronic obstructive pulmonary disease (COPD) burden are attributable to tobacco smoking.⁷²

There is clear evidence that people with a smoking-related disease or with other risk factors for cardiovascular disease (eg diabetes, lipid disorders, hypertension) who continue to smoke greatly increase their risk of further illness. It is important to target these people for quit interventions, given the role that smoking plays in exacerbating their conditions.^{5,73} For example, second heart attacks are more common among cardiac patients who continue to smoke. Additionally, people with successfully treated cancers who continue to smoke are at increased risk of a second cancer.⁷⁴ Ceasing smoking also improves cancer treatment efficacy and reduces treatment side effects.

Quitting smoking after a heart attack or cardiac surgery can decrease a person's risk of death by at least one-third.⁷⁵

Appropriate interventions

Offering smoking cessation support should be central to the clinical encounter with those who smoke and have cardiovascular, respiratory and other health comorbidities. Those who smoke need to quit completely rather than cut down in order to avoid most of the risk associated with heart disease and stroke.²⁵

It is important that smoking cessation is integrated into the routine chronic disease management programs for these patients. High-intensity behavioural interventions, coupled with appropriate pharmacotherapy, are effective in this group.^{76,77,78}

Smoking cessation is the most important treatment for those who smoke with COPD. Smoking in those with COPD is associated with a faster decline in lung function, increase in symptoms, and increased risk for respiratory tract infection and hospitalisation.^{74,79} There is strong evidence that a combination of behavioural treatment and pharmacotherapy is effective in helping those who smoke with COPD to quit smoking.⁸⁰

In people with asthma, smoking further impairs lung function, increases symptoms and impairs the effectiveness of treatment.^{61,81,82} First-line management of all who smoke with asthma should always be strong encouragement to quit. Providing personalised quitting strategies, and inpatient NRT and counselling, have been shown to be effective for smokers who are hospitalised for asthma.⁸³

Cigarette smoking is linked to the development of diabetes, impaired glycaemic control and diabetic complications.²² Smoking cessation is a crucial aspect of diabetes care.²² People with diabetes who smoke increase their risk of cardiovascular disease, peripheral vascular disease, progression of neuropathy and nephropathy.²²

Key points

- Health professionals should advise those who smoke that there is no safe level of smoking for smoking-related diseases (eg cardiovascular disease, COPD, asthma).
- Use the medical condition as an opportunity to integrate quitting into a management program for other diseases.
- Encourage the use of a combination of behavioural support and pharmacotherapy after assessment of nicotine dependence and clinical suitability.

People who smoke and are in hospital

Risks

People who smoke are at an increased risk for conditions requiring hospitalisation. Smoking also complicates outcomes for patients undergoing procedures in hospital.

Appropriate interventions

The period of hospitalisation can provide opportunities to encourage those who smoke to quit. All patients who smoke should have nicotine withdrawal symptoms managed while in hospital, and should be supported with brief advice and interventions that may lead to smoking cessation after leaving hospital.^{75,76,84}

Those who smoke who are admitted to hospital should be advised that complete cessation is the best approach for optimum outcomes. The smoking status of all patients being admitted to hospital should be noted in their medical record. Smoking cessation support and management of withdrawal symptoms should be offered during the hospital stay. Regular medications that interact with smoking should be reviewed, and doses adjusted for patients admitted to hospital.

There is convincing evidence that those who smoke who undergo surgery have higher risks of cardiac and respiratory complications, and increased wound infection rates.^{85,86} In order to reduce surgical complications and improve postoperative outcomes, those who smoke who are planning surgical procedures should be supported to quit smoking at least four to six weeks before their admission date.^{85,87}

Support to manage nicotine dependence for those who smoke and are in hospital includes the use of NRT (oral forms and patch) in adequate strength to control nicotine withdrawal symptoms throughout the day. An oral form of NRT is often required in addition to the patch to manage cravings and other withdrawal symptoms. Patients should be assessed for contraindications and precautions and monitored while in hospital for side effects and drug interactions.⁸⁷ Longer term smoking cessation rates are achieved when counselling and NRT that begin during hospitalisation are continued after hospital discharge for at least one month.⁷⁵

Key points

- Ask patients about their tobacco status and note it in their medical record.
- Offer assistance to every patient who smokes while admitted to hospital to begin treatment to quit or manage cravings and other nicotine withdrawal symptoms.
- For best outcomes, manage a patient's nicotine dependence while in hospital and encourage the patient to remain smoke-free after leaving hospital.
- For those who smoke with planned surgery, advise quitting four to six weeks before the surgery date.
- Monitor patients on NRT to assess response, provide support and modify treatment as needed.
- Recommend a referral to Quitline.

People exposed to second- and third-hand smoke

Second-hand smoke

Risks

Second-hand smoke, or environmental tobacco smoke or passive smoke, can affect the health of people who do not smoke. There is clear evidence of the harms of exposure to environmental tobacco smoke:^{24,27}

- in pregnancy
- to children – including higher rates of respiratory and middle ear infections, meningococcal infections and asthma
- to adults – including increased risk of lung cancer, coronary heart disease and stroke.

The evidence for the health effects of second-hand smoking has been summarised by a number of health authorities, including the National Health and Medical Research Council.^{88,89,90,91}

Any exposure to tobacco smoke – even an occasional cigarette or exposure to second-hand smoke – is harmful,²⁷ especially to children.⁹²

Appropriate interventions

There is a lack of evidence on the effectiveness of advising non-smokers to limit exposure to tobacco smoke. There is evidence that providing information to parents on the harms of exposing children to environmental tobacco smoke can reduce their exposure.⁵ Due to the evidence of harms from exposure, non-smokers, especially parents of babies and young children and pregnant women, should be strongly advised to limit exposure to tobacco smoke. Parents who smoke should be encouraged not to smoke in the house or confined space (eg motor vehicle) at any time.

Third-hand smoke

Third-hand smoke refers to residual tobacco smoke constituents that remain on surfaces and dust after tobacco has been smoked. These substances are then re-emitted as gases or react with other compounds in the environment to create new toxicants and carcinogens.⁹³ The main constituents of third-hand smoke are nicotine, 3-ethenylpyridine, phenol, cresols, naphthalene, formaldehyde and tobacco-specific nitrosamines.⁹⁴

Third-hand smoke exposure can take place over a longer time than second-hand smoke exposure. Third-hand smoke components are difficult to remove from carpets, furniture and surfaces, compared with second-hand smoke that is removed by ventilation. Further research is needed to understand and respond to the potential harms posed by third-hand smoke.

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Supplementary material

Disclaimer

Guideline disclaimer

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Dr Shane Jackson is a community pharmacy owner.

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Dr Hester Wilson declared no conflicting interests.

Mr William Parry declared no conflicting interests.

Ms Belinda Nowland declared no conflicting interests.

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Australian Commonwealth Government Departments of Health

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Pharmacological & Special Access Branch

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NSW Health

Queensland Health

WA Health

SA Health

Tasmanian Government, Department of Health

NT Health

Non-Governmentt & Not- for-Profit Organisations

Lung Foundation

Heart Foundation

Thoracic Society

Stroke Foundation

Cancer Victoria

Diabetes Australia

Consumer Health Forum of Australia

National Aboriginal Community Controlled Health Organisation

Medical Defence

MDA National – mutual Medical Defence Organisation

Avant Medical Indemnity Insurance

MIPS – Medical Indemnity Protection Society

MIGA – Medical Insurance Group Australia

Medical Colleges & Societies

Australian College of Rural and Remote Medicine

Pharmaceutical Society Australia

Pharmacy Guild

Royal Australian College of Physicians

Australian College of Nursing

Australian Medical Association

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Alcohol and Drug Services, Department of Health and Human Services, Tasmania Australasian Professional Society on Alcohol and other Drugs Australian College of Nursing Australian Government Department of Health Cancer Council Australia Cancer Council Victoria Consumers Health Forum of Australia National Heart Foundation of Australia NSW Ministry of Health Public Health Services, Department of Health and Human Services, Tasmania RACGP Specific Interests – Addiction Medicine network RACGP Specific Interests – Respiratory network Royal Australian and New Zealand College of Psychiatrists Royal Australasian College of Physicians SA Health Stroke Foundation

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Conflicts of interest

This guideline was developed in accordance with the rules and processes outlined in the RACGP's [Conflict of Interest Policy \(https://www.racgp.org.au/support/policies/organisational\)](https://www.racgp.org.au/support/policies/organisational).

All Expert Advisory Group members completed a Declaration of Interests register before the commencement of guideline development. Any potential conflicting interests further arising were declared at the start of all meetings and recorded appropriately. If a member declared an interest that was identified as a conflict to a specific intervention, they did not participate in the decision making and were excluded from the voting process for that particular recommendation. Disclosures of interests can be found below.

The second edition of the RACGP's *Supporting smoking cessation: A guide for health professionals* was funded in part by the Australian Government Department of Health and VicHealth.

Disclosure of interests

Professor Nicholas Zwar has provided expert advice on smoking cessation education programs to Pfizer Pty Ltd and GlaxoSmithKline Australia Pty Ltd, and has received support to attend smoking cessation conferences. He has no interests to declare in the last five years.

Professor Ron Borland has developed QuitCoach, onQ and QuitTxt smoking cessation programs, but he has no commercial interest in them.

Associate Professor John Litt has provided smoking cessation advice and training at meetings supported by Pfizer Pty Ltd. He is a member of the Pfizer Champix Advisory Board, a member of the Pfizer Smoking Exchange Summit planning committee, and he spoke at the Exchange Smoking Cessation conference in Melbourne, October 2018. Associate Professor Matthew Peters has received honoraria from Pfizer Pty Ltd for his contribution to the varenicline advisory board and for continuing medical education (CME) lectures at meetings supported by Pfizer Pty Ltd and GlaxoSmithKline Australia Pty Ltd in relation to asthma/chronic obstructive pulmonary disease treatments.

Associate Professor Colin Mendelsohn has received honoraria for teaching, consulting and conference expenses from Pfizer Pty Ltd, GlaxoSmithKline Australia Pty Ltd, Johnson & Johnson Pacific Pty Ltd and Perrigo Australia. He is chair of the Australian Tobacco Harm Reduction Association (ATHRA), a health promotion charity established to raise awareness of safer alternatives to smoking. While he contributed to discussion, he was not able to cast any votes on developing recommendations relating to e-cigarettes.

Ms Emma Dean is employed by Alfred Health. The Victorian Department of Health and Human Services, VicHealth and Victorian Aboriginal Community Controlled Health Organisation (VACCHO) fund Alfred Health to deliver prevention initiatives, including Smokefree.

Mr George Masri worked for the Department of Health, which contributed funding to update this smoking cessation guideline.

Mr John Power worked for the Department of Health, which contributed funding to update this smoking cessation guideline.

Associate Professor Mathew Coleman disclosed no conflicting interests.

Professor Robyn Richmond disclosed no conflicting interests.

Ms Kathryn Sharples disclosed no conflicting interests.

Mr Scott Walsberger disclosed no conflicting interests.

Resources for health professionals

Australia

[RACGP clinical guidelines \(https://www.racgp.org.au/your-practice/guidelines\)](https://www.racgp.org.au/your-practice/guidelines)

[Quit Victoria \(http://www.quit.org.au\)](http://www.quit.org.au)

[Australian Government: How to quit smoking \(http://www.health.gov.au/health-topics/smoking-and-tobacco/how-to-quit-smoking?utm_source=quitnow.gov.au&utm_medium=redirect&utm_campaign=digital_transformation\)](http://www.health.gov.au/health-topics/smoking-and-tobacco/how-to-quit-smoking?utm_source=quitnow.gov.au&utm_medium=redirect&utm_campaign=digital_transformation)

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[Australasian Professional Society on Alcohol and other Drugs \(APSAD\) \(http://www.apsad.org.au/about\)](http://www.apsad.org.au/about)

[SANE: Resources on mental illness and smoking such as the Smokefree Zone resource pack and the Smokefree Kit for health professionals \(http://www.sane.org/mental-health-and-illness/facts-and-guides/smoking-and-mental-illness\)](http://www.sane.org/mental-health-and-illness/facts-and-guides/smoking-and-mental-illness)

[Pharmaceutical company support programs: Including Breakroom \(http://www.breakroom.com.au\)](http://www.breakroom.com.au)

United Kingdom

[Treattobacco.net: Evidence-based information about the treatment of tobacco dependence \(http://www.treattobacco.net/en/index.php\)](http://www.treattobacco.net/en/index.php)

[UK National Centre for Smoking Cessation and Training: Very Brief Advice \(VBA\) training module \(http://www.ncsct.co.uk/publication_very-brief-advice.php\)](http://www.ncsct.co.uk/publication_very-brief-advice.php)

United States

US Department of Health and Human Services: *Treating tobacco use and dependence: 2008 update* (<http://www.ncbi.nlm.nih.gov/books/NBK63952>), clinical practice guideline

[Agency for Healthcare Research and Quality: Help for smokers and other tobacco users \(http://www.aqr.gov/professionals/clinicians-providers/guidelines-recommendations/tobacco/clinicians/tearsheets/helpsmokers.html\)](http://www.aqr.gov/professionals/clinicians-providers/guidelines-recommendations/tobacco/clinicians/tearsheets/helpsmokers.html)

New Zealand

Ministry of Health: *The New Zealand guidelines for helping people to stop smoking* (<http://www.health.govt.nz/system/files/documents/publications/nz-guidelines-helping-people-stop-smoking-jun14.pdf>)

Ministry of Health: Background and recommendations of the *New Zealand guidelines for helping people to stop smoking* (<http://www.health.govt.nz/system/files/documents/publications/background-recommendations-new-zealand-guidelines-for-helping-stop-smoking-mar15-v2.pdf>)

Other

[World Health Organization: Tobacco Free Initiative \(TFI\) \(http://www.who.int/tobacco/en\)](http://www.who.int/tobacco/en)

Evidence reviews

[Smoking cessation technical report \(https://www.racgp.org.au/getmedia/6ffb3de5-ab86-43b8-ab81-650885093b1b/Smoking-Cessation-Technical-Report.pdf.aspx\)](https://www.racgp.org.au/getmedia/6ffb3de5-ab86-43b8-ab81-650885093b1b/Smoking-Cessation-Technical-Report.pdf.aspx) (PDF 3.5 MB)

[E-cigarettes for smoking cessation technical report \(https://www.racgp.org.au/getmedia/ed222cc7-f399-490c-8e37-999a35c927f6/ECigarettes-for-Smoking-Cessation-Technical-Report.pdf.aspx\)](https://www.racgp.org.au/getmedia/ed222cc7-f399-490c-8e37-999a35c927f6/ECigarettes-for-Smoking-Cessation-Technical-Report.pdf.aspx) (PDF 1.4 MB)

[Appendix Evidence to decision report \(https://www.racgp.org.au/FSDEDEV/media/documents/Clinical%20Resources/Appendix-Evidence-to-Decision-Report.pdf\)](https://www.racgp.org.au/FSDEDEV/media/documents/Clinical%20Resources/Appendix-Evidence-to-Decision-Report.pdf) (PDF 539 KB)

Accessing Nicotine Vaping Products (NVPs)

[Appendix NPS Medicinewise accessing NVPs \(https://www.racgp.org.au/FSDEDEV/media/documents/Clinical%20Resources/Appendix-NPS-Medicinewise-accessing-NVPs.pdf\)](https://www.racgp.org.au/FSDEDEV/media/documents/Clinical%20Resources/Appendix-NPS-Medicinewise-accessing-NVPs.pdf) (PDF 775 KB)

[Infographic-Become an Authorised Prescriber of nicotine vaping products \(https://www.racgp.org.au/FSDEDEV/media/documents/Clinical%20Resources/Infographic-Become-an-Authorised-Prescriber-of-nicotine-vaping-products.pdf\)](https://www.racgp.org.au/FSDEDEV/media/documents/Clinical%20Resources/Infographic-Become-an-Authorised-Prescriber-of-nicotine-vaping-products.pdf) (PDF 6 MB)

Tobacco harm reduction

Introduction

The goal for those who smoke should always be to stop smoking altogether in order to reduce or eliminate the harms from smoking. However, some people are unable or unwilling to give up tobacco or nicotine use completely. For this group of people, a tobacco harm reduction approach has been suggested. Possible approaches to reduce the exposure to toxins from smoking include:

- reducing the amount of tobacco used
- using less toxic products (eg pharmaceutical nicotine, potential reduced-exposure tobacco products [PREPs]) as an alternative to cigarettes.

There is limited available evidence of the health effects that reduced smoking may have on the incidence of tobacco-related diseases.^{1,2} A reduction in smoking by 50% may slightly reduce the risk of lung cancer in people who were smoking 15 or more cigarettes each day,³ however, there is no risk-free level of exposure to tobacco smoke.² A decrease in the number of cigarettes smoked per day (eg to less than 10 per day) does not reduce the risk of:^{1,4,5,6}

- fatal or non-fatal myocardial infarction
- hospitalisation for chronic obstructive pulmonary disease (COPD)
- all-cause mortality.

While long-term health benefits of smoking reduction is limited, those who embark on this path may have an increased likelihood of quitting, even if they did not initially intend to do so. For example, those who use nicotine replacement therapy (NRT) for smoking reduction are approximately twice as likely to progress to quitting as those who do not.⁷

Reducing to quit with nicotine

Those who are not willing to quit can be advised to partially substitute their cigarette intake with NRT. Gradually, cigarette intake can be reduced and NRT increased. The use of NRT in this way can double the odds of progressing to complete smoking cessation.^{7,8} Long-term partial replacement with nicotine is not recommended as no clear health benefit has been demonstrated.

Reducing to quit without nicotine

Reducing cigarette intake without a nicotine supplement is not recommended and has little proven health benefit.^{4,5,6} Research has found that when reducing cigarette intake, those who smoke adjust their smoking topography (ie number of puffs, depth of inhalation) to maintain the desired level of nicotine.⁹

Electronic cigarettes and nicotine vaping products for harm reduction

Terminology	
Nicotine vaping products	Products that contain nicotine (in salt or base form) in a solution designed to be inhaled using a vaping device. Includes vape liquids, e-liquids and e-juices that contain nicotine, and the nicotine solution in nicotine e-cigarettes and pods.
Vaping device	Electronic devices used to heat vaping products to release an aerosol that is inhaled. Includes e-cigarettes, e-cigars, e-hookah pens, e-pens, e-pipes and vape pens.

Note: "Heated tobacco products" are not nicotine vaping products

Electronic cigarettes, often referred to as e-cigarettes, are a diverse range of battery-powered devices that deliver nicotine aerosol without tobacco or smoke. E-cigarettes were invented in the 2000s and have since been rapidly changing. The vaping device heats an e-liquid – also known as the nicotine vaping product (NVP) – into an aerosol for inhalation. The nicotine content of e-cigarettes can vary from zero to up to over 50 mg/mL. E-cigarette users are referred to as 'vapers' and e-cigarette use as 'vaping'.¹⁰

The use of e-cigarettes is controversial as its long-term safety profile is still largely unknown.^{11,12,13} Nicotine e-cigarettes have a potential role as a tobacco harm reduction strategy for people who do not wish to give up tobacco or nicotine use completely. Proponents of e-cigarettes point to the situation in Sweden where the prevalence of combustible tobacco use is low (5%), perhaps in part related to the use of oral tobacco products.¹⁴ In the United Kingdom, increasing use of e-cigarettes has been associated with a decrease in use of combustible tobacco.¹⁵ Population studies in the United Kingdom and United States suggest a higher uptake of nicotine e-cigarettes by those who smoke and are motivated to quit.^{14,16} However, many contextual factors, including the strength and maturity of tobacco control policies, influence the prevalence of tobacco use;¹⁷ therefore, comparisons between countries need to be made with caution.

Concerns about e-cigarettes include:¹⁷

- lack of evidence for long-term safety
- intentional and accidental poisoning, burns and lung injury
- continued concurrent use with smoking (ie dual use)
- potential to promote nicotine use and renormalise smoking among non-smokers, especially young people.

Data on uptake of vaping products among youth is rapidly changing and varies between countries. The US National Youth Tobacco Survey data found a dramatic increase in current e-cigarette use among high school students: 1.5% in 2011 to 20.8% in 2018.¹⁸ The Australian National Drug Household Survey conducted in 2019 found that 22.3% of people aged 15-24 years reported ever using e-cigarettes while 4.5% reported current or recent use (up from 2.3% in 2016).¹⁹ An association has been observed in

young people between e-cigarette use and future experimentation with smoking.²⁰ There has been particular concern about the role of flavourings in attracting young people to e-cigarettes, leading to an immediate ban on these additives in the US.²¹ It remains to be seen whether such increases will also occur in other countries that allow access to nicotine-containing e-cigarettes as a consumer product.

The potential role of e-cigarettes as a harm reduction strategy is particularly relevant to people with mental illnesses. In recognition of the disproportionately high smoking prevalence and low quit rates among people living with mental health illnesses, the Royal Australian and New Zealand College of Psychiatrists supports the legalisation and regulation of nicotine e-cigarettes and other vaporised nicotine products to facilitate their use as harm reduction tools.²² However, other organisations oppose use of e-cigarettes for this purpose. Adding to the uncertainty is the fact that NVPs are not approved therapeutic products and the constituents of the vapour produced by e-cigarettes has not been rigorously tested and standardised.

In Australia, a precautionary approach²³ to the use of e-cigarettes has been taken.

From 1 October 2021 nicotine has been re-scheduled to a Schedule 4 medicine, available by prescription only. Consumers require a prescription for all purchases of NVPs regardless of where they are sourced from. There are currently no Therapeutic Goods Administration (TGA) approved NVPs in the Australian Register of Therapeutic Goods (ARTG). Nicotine vaping products are unapproved medicines. For information about the evidence and safety on NVPs for the purpose of smoking cessation and considerations in prescribing these products for that purpose see [Chapter 2 Electronic cigarettes and nicotine vaping products \(https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation/pharmacotherapy-for-smoking-cessation\)](https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation/pharmacotherapy-for-smoking-cessation).

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