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# Clinician's Guidance Mental Health Clinician Guidance for Managing People's Smoking Cessation

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We acknowledge the Royal Australian College of General Practitioners (RACGP) <u>Supporting smoking</u> <u>cessation: A guide for health professionals (2021)</u>. The RACGP Guide contains evidence-based recommendations that are provided for health professionals in supporting tobacco smoking cessation and from which this guidance is developed.

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## 1. Introduction

- 1.1 Tobacco smoking remains the leading preventable cause of death in Australia and New Zealand.[1] People with mental illness and substance use disorders smoke at rates significantly higher than the general population, have high levels of nicotine dependence and are less likely to be offered treatment to stop smoking. Prevalence rates vary between mental health conditions, ranging from 40%-50% in those with depressive and anxiety disorders (high prevalence disorders), compared with 70%-90% in those with schizophrenia and bipolar affective disorder (low prevalence chronic disorders).[2] Individuals receiving treatment in an inpatient psychiatric unit are more likely to smoke (70%–90%) than those managed in community (32%) or in outpatient services (41%–74%).[3] These high rates are consistent with international trends. Meta-analysis of twenty countries found that people with schizophrenia are five times more likely to smoke than the general population.[2]
- 1.2 The reasons for the high rate of smoking in the mentally ill population are complex, involving biological, environmental and social factors.[4] Common genetic factors, illness symptoms, medications, as well as environmental, cultural and behavioural factors, all play a role.[2] Tobacco smoking in mental health settings is common. A strong smoking culture in both the patient and staff populations of inpatient or residential psychiatric facilities, as well as the use of cigarettes to control certain behaviours and reinforce medication compliance, have been well reported throughout the mental health literature.[4] The enforcement of smoke-free legislation and/or policy is inconsistent in mental health facilities, with some residential facilities still permitting (or turning a blind eye to) smoking indoors. People experiencing severe mental illnesses tend to be part of peer groups where smoking is common, and often do not receive the same prompts and encouragement from health professionals to quit smoking as the general population.
- 1.3 Despite positive results from public health interventions for the general population who smoke tobacco, people with mental illnesses are more likely to die from smoking-related illnesses than their mental health condition, may be more disproportionally impacted by public health measures and are exempt or excluded from specific interventions that reduce the impact and effects of smoking. Yet people with mental illnesses are just as motivated to cease tobacco smoking, and try just as often to quit, as people who smoke who do not experience mental illness.[5-6]
- 1.4 The management of tobacco smoking is one of the most important activities a mental health clinician or service can undertake in terms of reducing mortality, improving quality of life and improving efficacy of mental health treatment.

## 2. Scope of the guidance

- 2.1 **Nicotine dependence and tobacco smoking:** Nicotine is a highly dependence-forming agent with a half-life of one to two hours. People dependent on nicotine thus experience withdrawal symptoms approximately hourly, driving nicotine-seeking behaviour. Nicotine withdrawal symptoms include agitation, anxiety, dysphoria, insomnia and hyperphagia. The experience of smoking tobacco as stress relieving is likely due to the temporary relief from withdrawal symptoms. A meta-analysis by Taylor et al (2014) showed that abstaining from smoking for six weeks, beyond any withdrawal experiences, resulted in reduced depression, anxiety and stress, with improvements noted in mood and quality of life.[8]
- 2.2 An absence of treatment for people with mental illnesses who smoke tobacco: Compared to other chronic health conditions, treatment rates for tobacco dependence are low.[9] Prescription rates are lesser than those for other medical conditions, whilst individuals affected by mental illness are offered treatment for smoking at even lower rates than the general population. GPs and community psychiatrists are unlikely to offer smoking cessation support, with some estimates as low as 1% of patients being offered support. [10] Smoking cessation support for patients on inpatient psychiatric units can be improved, including referral for outpatient smoking cessation support, and encouragement for use of nicotine replacement therapy (NRT) on discharge.[11] It has been argued that smoke-free policies on mental health inpatient units are unsuccessful, as many patients who abstain from smoking during an admission will resume smoking on discharge. This discounts the health and financial benefits of even a brief period of abstinence. The majority of people who smoke require multiple attempts to address their tobacco use. Successfully engaging with an inpatient smoke-free policy can alter individuals' perceptions of their need to smoke, capacity to stop smoking, and increase the likelihood they will successfully guit on future attempts. [12] A lack of treatment availability or access compounds the impact of tobacco smoking and nicotine dependence.
- 2.3 **Harmful effects of tobacco smoking:** The health risks associated with tobacco smoking are numerous and well-documented. Smoking is a major risk factor for cancer, cardiovascular, respiratory and renal diseases, and increases the mortality and morbidity from other chronic health conditions, such as diabetes.[13-14] Tobacco smoking is a major contributor to the significantly poorer physical health outcomes experienced by those with a serious mental illness, with those who smoke far more likely to die as a consequence of smoking, than as a result of their psychiatric illness.[15-16]

Tobacco smoking is also associated with poorer mental health.[17] Although smokers may suggest that smoking offers them mental health benefits, usually as a product of relieving withdrawal symptoms, there is a strong association between smoking and poor mental health, and smokers with mental health disorders tend to be heavier smokers and more dependent.[18] Consequently, numerous systematic reviews strongly indicate smoking cessation is associated with reduced depression, anxiety, and stress and improved positive mood and quality of life compared with continuing to smoke. The effect size seems as large for those with psychiatric disorders as those without.[19]

2.4 Smoking and pregnancy: Smoking has adverse effects in pregnancy, both for the mother and the developing foetus. 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. [20] While breastfeeding is not contraindicated for women who smoke, continued tobacco smoking while breastfeeding exposes infants to smoke through inhalation and tobacco compounds through breast milk.[21] A risk-benefit analysis for pregnant and breastfeeding women who smoke tobacco should be undertaken when considering treatment with NRT.

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 side effects develop). Be alert for increased side effects. Dose reductions may be required if clinically appropriate. Seek specialist advice from treating mental health practitioner.	High
Erlotinib	PK: Increased clearance and decreased plasma concentrations (around two-fold).	Revert to standard dosing if a patient stops smoking. Seek specialist advice. Nb. People who smoke should be advised to stop before therapy is initiated.	High
Irinotecan	$\ensuremath{PK}$ : Increased clearance and decreased plasma concentrations of active metabolite.	Seek specialist advice. Dosing should be closely monitored.	High
Olanzapine	PK: Increased clearance and decreased plasma concentrations.	Be alert for increased side effects (e.g. dizziness, sedation and hypotension). Dose reductions may be required if clinically appropriate. Seek specialist advice from treating mental health practitioner.	High
Pirfenidone	PK: Decreased AUC and decreased Cmax.	Seek specialist advice. People who smoke should be advised to stop before therapy is initiated.	High
Riociguat	PK: Increased clearance and decreased plasma concentrations.	A dose decrease may be required if a patient stops smoking. Nb. People who smoke should be advised to stop before therapy is initiated.	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, nausea). Nb. It may take several weeks for enzyme induction to dissipate.	High
Chlorpromazine	PK: Increased clearance and decreased plasma concentrations.	Be alert for increased side effects (e.g. dizziness, sedation, EPSE). Reduce dose if clinically appropriate.	Moderate
Flecainide	PK: Increased clearance and decreased plasma concentrations.	Monitor for side effects (e.g. dizziness, shortness of breath, arrhythmias). Reduce dose if clinically appropriate.	Moderate
Insulin	<b>Unclear:</b> Possible decrease in insulin absorption secondary to peripheral vasoconstriction. Smoking may also increase insulin resistance.	Advise patient to be alert for signs of hypoglycaemia and to test their BGLs more frequently. Reduce dose if clinically appropriate.	Moderate
Methadone	PK: Metabolism includes 1A2 enzyme. PD: Nicotine affects the endogenous opioid system.	Be alert for signs of opioid toxicity (e.g. sedation, dizziness, respiratory depression). Reduce dose if clinically appropriate. Seek specialist advice. Nb. Methadone attenuates nicotine withdrawal.	Moderate
Ropinirole	PK: Decreased AUC and decreased Cmax.	Be alert for increased side effects. Reduce dose if clinically appropriate.	Moderate
Warfarin	PK: Increased clearance and decreased plasma concentrations.	Monitor for side effects. Monitor INR closely. Reduce dose if clinically appropriate.	Moderate
Antidepressants metabolised by CYP1A2 e.g. fluvoxamine, duloxetine, imipramine	PK: Decreased plasma concentrations.	Be alert for increased side effects. Reduce dose if clinically appropriate.	Low
Benzodiazepines	Likely PD: CNS stimulation by smoking. Nb. Results from pharmacokinetic studies are mixed.	Monitor for side effects (enhanced effect of benzodiazepines). Reduce dose if clinically appropriate.	Low
Beta Blockers	PD: CNS stimulation by smoking opposes the beneficial effects of beta blockers on blood pressure and heart rate.	Monitor for side effects. Reduce dose if clinically appropriate.	Low
Clopidogrel	PK: Data is conflicting. Possible higher antiplatelet effect in people who smoke.	Smoking cessation should still be recommended.	Low
Haloperidol	PK: Increased clearance and decreased plasma concentrations.	Be alert for increased side effects. Reduce dose if clinically appropriate.	Low
Heparin	Unclear: Increased clearance and decreased half-life observed. Smoking has prothrombotic effects.	Monitor for side effects and adjust dose based on APTT as appropriate.	Low
Nintedanib	PK: Decreased exposure in people who smoke.	No dosage adjustment required. People should not smoke during use.	Low

"Drug interactions with smoking" resource (used with permission from Quit). Please note that this table is regularly updated. The latest version can be viewed here.

- 2.5 **Effect of tobacco smoking abstinence on medications:** Polycyclic aromatic hydrocarbons (PAHs), the by-products of tobacco combustion, increase the metabolism of many medications, including psychotropic medication.[22] The resultant reduced response rates to medications may necessitate higher doses.[23] Importantly, this is not an effect of nicotine, the active dependent-forming ingredient that perpetuates tobacco smoking, but rather tobacco smoking itself. The differentiation of the effects of nicotine versus those of tobacco is poorly understood by mental health professionals, which can result in physical and psychiatric harm from changing medication levels with variations in tobacco smoking.
- 2.6 **Effectiveness of treating tobacco smoking and dependence:** Advice, behavioural interventions and pharmacotherapies increase the rate of success of quit attempts, and their benefits are cumulative when they are deployed. Indeed, smoking cessation has been repeatedly shown in systematic reviews to improve mental health outcomes.[24-25]

### 3. The role of health professionals

The RACGP first developed Supporting smoking cessation: a guide for health professionals in 2011. A focused <u>update</u> was undertaken in 2021 to provide guidance about the Australian rescheduling of nicotine e-liquids, and this document refers to the RACGP's update.

- 3.1 **RACGP Recommendation 1** All people who smoke should be offered brief advice to quit smoking. <u>Strong recommendation, high certainty.</u>
- 3.2 **RACGP Recommendation 2** A system for identifying all people who smoke and documenting tobacco use should be used in every practice or healthcare service. <u>Strong recommendation, high certainty.</u>
- 3.3 Barriers and beliefs raised by health professionals to offering smoking cessation advice.
- 3.4 Psychiatrist's assessment of nicotine dependence A quick assessment of nicotine dependence can be made by asking the person who smokes:
  - "How soon after waking do you have your first cigarette?"
  - "Have you had cravings for a cigarette, or urges to smoke and withdrawal symptoms when you have tried to make changes to your smoking?"
  - Time to first cigarette is the most reliable single indicator of nicotine dependence.[5] 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.[7]
- 3.5 Time to first cigarette is the most reliable single indicator of nicotine dependence.[5] 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.[7]
- 3.6 For people with mental illnesses, or primary or co-occurring drug and alcohol problems, careful consideration of these conditions, psychotropic medications, monitoring, and close follow-up is required. People who use cannabis may also be nicotine dependent because of mixing with tobacco, whilst not reporting smoking cigarettes.

## 4. Assessment of barriers to quitting

Perceived barrier (mistaken beliefs and attitudes)	Evidence-based strategies to address barriers
<ul><li>I can quit at any time</li><li>I am not addicted</li></ul>	Ask about previous attempts to quit and success rates
<ul> <li>Using cessation support is a sign of weakness</li> <li>Help is not necessary</li> </ul>	<ul> <li>Reframe support</li> <li>Explain that nicotine withdrawal symptoms are reduced by treatment</li> <li>Highlight that unsupported quit rate is 3–5%, but substantially higher with assistance</li> </ul>
<ul><li>Too addicted</li><li>Too hard to quit</li><li>Fear of failure</li></ul>	<ul> <li>Ask about previous quit attempts</li> <li>Explore pharmacotherapy used and offer options (eg combination therapy)</li> </ul>
<ul><li>Too late to quit</li><li>I might not benefit so why bother</li></ul>	<ul> <li>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</li> <li>Provide evidence and feedback (eg spirometry, lung age, absolute risk score</li> </ul>
<ul> <li>My health has not been affected by smoking</li> <li>You have to die of something</li> <li>I know someone who smoked heavily who has lived a long time</li> </ul>	<ul> <li>State evidence that one in two people who continue to smoke after middle age will die prematurely of smoking-related disease</li> <li>Reframe: for example, chronic obstructive pulmonary disease (COPD) = smoker's lung</li> </ul>
<ul> <li>Not enough willpower</li> <li>No point in trying unless you want to</li> <li>To quit successfully, you really have to want to quit, then you will just do it</li> </ul>	<ul> <li>Explore motivation and confidence</li> <li>Explore and encourage the use of effective strategies (eg Quitline, pharmacotherapy)</li> </ul>
Cigarettes help me relax	• Suggest other relaxation strategies such as breathing techniques and progressive muscle relaxation
• Fear of weight gain	<ul> <li>Average weight gain after smoking cessation is 2–4 kg; only about 10% of people have substantial weight gain (&gt;13 kg)</li> <li>Suggest strategies to minimise weight gain: healthy diet; avoid high-fat and high-sugar foods and drinks; regular physical activity</li> <li>Point out that health benefits of quitting far exceed any adverse health effects of weight gain</li> </ul>
Peer and social pressure	<ul> <li>Suggest avoidance of high-risk social situations early in the quit attempt</li> <li>For some people it can be helpful to rehearse how to say no to a cigarette offer</li> </ul>

#### 5. Nicotine withdrawal symptoms

- 5.1 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[26]:
  - irritability, frustration, anger
  - anxiety
  - difficulty in concentration
  - increased appetite
  - restlessness
  - depressed mood.
- 5.2 Other nicotine withdrawal symptoms may include:
  - craving for sweet or sugary foods
  - constipation
  - coughing
  - dizziness
  - dreaming/nightmares
  - nausea
  - mouth ulcers
  - sore throat.

## 6. Advise all patients who smoke to quit, and offer follow up

6.1 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'

This statement may, however, need to be supplemented by positive statements around nicotine replacement therapy, other evidence-based interventions, support, assistance, and regular follow-up. Brief, repeated, positive reminders to quit by a range of health professionals can increase quit rates.[7]

People with mental illness and other substance use disorders benefit from addressing tobacco dependence, with respect to both their mental health symptoms and support in long-term drug and alcohol abstinence.[7]

- 6.2 **RACGP Recommendation 3** Offer brief smoking cessation advice in routine consultations and appointments, whenever possible. *Strong recommendation, high certainty.*
- 6.3 Arrange follow-up contact, preferably weekly, either in person, by phone or telepsychiatry. Follow-up contact has been shown to increase the likelihood of long-term abstinence.[7] More intensive and closer follow-up is required for people with a mental illness who want to stop smoking. Congratulate and encourage a person's decision to quit through a process of regular review of progress and address any problems that arise. Encourage continued use of pharmacotherapy at clinically appropriate doses and monitor and manage medication side effects.
- 6.4 **RACGP Recommendation 4** Offer follow-up to all people who are attempting to quit smoking. *Strong recommendation, high certainty.*

- 6.5 **Pharmacotherapy for smoking cessation:** Three first line pharmacotherapies NRT, varenicline and bupropion are licensed and available in Australia and New Zealand to assist smoking cessation. Current supply issues have resulted in varenicline being unavailable at the time of publishing this guidance. These medicines have been repeatedly shown to assist smoking cessation in meta-analyses of randomised clinical trials.[7] Considerations when helping an individual to select an appropriate form of pharmacotherapy to quit include"
  - previous experience with pharmacotherapy
  - cost and convenience (e.g., whether it is subsidised under the Pharmaceutical Benefits Scheme)
  - adherence issues (e.g., individual preferences for a patch or gum, one or more forms of NRT, nonnicotine options)
  - prescription medicine versus over-the-counter medicine
  - potential for adverse events
  - possible interactions with other drugs.[7]
- 6.6 Approximately 50% of those who have quit at the end of pharmacotherapy relapse to smoking; therefore, combining pharmacotherapy and behavioural intervention is important.[27]

#### 6.7 Key points in pharmacotherapies for smoking cessation:

- Pharmacotherapy should be recommended to all people who smoke and are nicotine dependent (i.e., time to first cigarette after waking is usually less than 30 minutes).
- One of the most successful approaches to quitting for people with nicotine dependence is behavioural support, combined with first-line pharmacotherapy and follow-up.
- NRT, varenicline and bupropion are approved by the Therapeutic Goods Administration to assist smoking cessation.
- Varenicline is the most effective single-form pharmacotherapy for smoking cessation.
- Combining NRT options 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. The risks and benefits of NRT should be discussed with the woman prior to initiation. Risk-benefit discussions should be delivered in the context of continued nicotine use compared to continued smoking, rather than nicotine use alone. Further detailed guidance can be found <u>here</u>.
- Considerations guiding choice of pharmacotherapy for people who want to quit smoking are based on evidence of effectiveness, clinical suitability, and patient choice.
- 6.8 **RACGP Recommendation 5** In the absence of contraindications, pharmacotherapy (NRT, 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. <u>Strong</u> recommendation, high certainty.

## 7. Nicotine Replacement Therapy (NRT)

7.1 NRT aims to reduce the need and craving for tobacco smoking by delivering nicotine without the harmful effects of combusting tobacco, which produces the smoke. While nicotine also has the potential for adverse effects in vulnerable developmental life stages, including pregnancy, childhood, and adolescence, it is considered a safer alternative to tobacco smoking.[7] NRT comes in a variety of forms based on its system of delivery and onset of action. Combing two forms of NRT (e.g., patch plus a faster-acting form, such as mouth spray, gum, inhalator, or lozenge) has been shown to be more efficacious than a single form of nicotine replacement.[28]



Figure 1: (Used with permission from Quit); NRT products are depicted

- 7.2 Common causes for previous attempts of NRT failing include:
  - Underdosing of NRT
  - Incorrect administration of NRT.[7]

Evidence indicates more than four weeks of use is more likely to result in successful cessation.[29] Eight weeks of use is considered to be equally effective as longer durations of use, although patients experiencing withdrawal symptoms eight weeks after quitting may benefit from longer durations.[29] Current evidence does not support an association between long-term NRT exposure and serious adverse health effects.[7] A longer period of NRT may help some people remain abstinent and it is far less harmful than tobacco smoking.[30] This may especially be the case for people with serious mental illness.[31] Higher dose and combination NRT are often required in people with severe mental illnesses who are often highly nicotine-dependent. Continuing to smoke tobacco while using NRT may indicate the dose provided is too low, or NRT products are used incorrectly. Preloading with the use of NRT patches prior to reducing smoking, and not recommending tapering and longer-term use is recommended in heavy smokers. Further information can be accessed in the RACGP Smoking cessation guidelines.[7]

- 7.3 **RACGP Recommendation 6** Combination NRT (i.e., patch and faster-acting forms) accompanied by behavioural support, is more effective than NRT monotherapy accompanied by behavioural support and should be recommended to people who have evidence of nicotine dependence. <u>Strong</u> recommendation, moderate certainty
- 7.4 **RACGP Recommendation 7** For people who have stopped smoking at the end of a standard course of NRT, clinicians may consider recommending an additional course of NRT to reduce the chance of relapse. <u>Conditional recommendation for intervention, low certainty</u>

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- 7.5 There are few contraindications associated with NRT use.[7] These include:
  - Children aged <12 years
  - People with a known sensitivity to nicotine or any other component of the NRT product
  - People weighing less than 45kg, who can use NRT but may require the lower dose (e.g., 14 mg/24-hour patch)
  - NRT should be used with caution for patients in hospital with acute cardiovascular events, but if the alternative is smoking, NRT can be still used under medical supervision.[7]
- 7.6 **RACGP Recommendation 8** NRT is safe to use for patients with stable cardiovascular disease. <u>Strong</u> recommendation, high certainty.
  - 7.6.1 NRT should be used with caution in patients who have had a recent myocardial infarction, unstable angina, severe arrhythmias, or recent cerebrovascular events. <u>Strong</u> recommendation, moderate certainty.
  - 7.6.2 Minor side effects are common with NRT use and are often associated with the formulation. Patches can cause skin irritation, redness, itch, and rash, which are usually mild but can be treated with 1% hydrocortisone cream if troublesome. Rotating the site of application each day can reduce irritation. People may experience insomnia or vivid dreams, but these may also be associated with other pharmacotherapies and psychopathology. Decreasing caffeine intake by half and avoiding caffeine after 4pm can reduce sleep disturbance. However, if sleep disturbance is severe and thereby disrupting daily activities, patients can remove the patch at bedtime or a couple of hours before and re-apply a new patch in the morning. Consider use of a faster-acting form of NRT in the morning, as it can take up to 3 hours for optimal nicotine levels to be reached after removal of a patch overnight.[25] For nicotine gum and lozenges, minor side effects include dyspepsia and nausea; and mouth and throat irritation can occur when using a nicotine inhalator or mouth spray.[7] Consult the product information for further details.

#### 8. Smoking cessation pharmacotherapy in pregnancy

- 8.1 Given the importance of smoking cessation in pregnancy, every effort should be made to support the expectant mother to quit. Behavioural intervention is recommended as the first-line treatment for quitting smoking in pregnancy.[7] Refer to Smoking Cessation for high-prevalence groups: Pregnant and breastfeeding women (RACGP Guidelines) for further information.
- 8.2 **RACGP Recommendation 9** For women who are pregnant and unable to quit smoking with behavioural intervention alone, clinicians may recommend NRT. Behavioural intervention and monitoring should also be provided. *Conditional recommendation for intervention, low certainty.*

## 9. Varenicline

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 meta-analysis review, varenicline was found to be more effective than bupropion, more effective than NRT monotherapy, and similar in effect to combination NRT.[32] A second course of varenicline could be considered to reduce the chance of relapse for people who have previously relapsed when ceasing a course of treatment.[7] Combining varenicline with NRT may improve quit rates.

- Varenicline can be safely used for people who smoke with mental health problems but must be monitored during quit attempts.[34-36] These patients should be advised to report unusual mood changes, depression, behaviour disturbance and suicidal thoughts, and stop using the medicine if these occur. Early adverse reactions, including precipitated nicotine withdrawal symptoms from varenicline use, suggest a trial of varenicline may need to be ceased. The tolerability of varenicline may be pharmacodynamically determined and related to the genetic variability of the α4β2 subunit of the nACh Receptors, and therefore continued use or re-trialling may not be appropriate in those who have already experienced adverse reactions to this preparation.
- 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 and observational studies have not supported a causal link.[37-39] The large randomised controlled trial, EAGLES (Evaluating Adverse Events in a Global Smoking Cessation Study), has given further reassurance.[40] 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 a nicotine patch. As expected, those with mental illness in all treatment groups had higher rates of neuropsychiatric adverse events than those without mental illness.
- Varenicline is not recommended for pregnant and breastfeeding women, nor for adolescents.
- A common side effect of varenicline includes nausea which can be minimised if it is taken with food. Other side effects include sleep disturbance, drowsiness, headache, constipation, dizziness, and flatulence. No clinically meaningful drug interactions are reported.[7]
- 9.1 **RACGP 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.*
- 9.2 **RACGP 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.*
- 9.3 **RACGP 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. <u>Conditional recommendation for intervention, moderate certainty.</u>

## 10. Bupropion

- 10.1 Bupropion is a non-nicotine oral therapy, originally developed and approved for use as an antidepressant. Bupropion significantly increases cessation rates compared with placebo but has been shown to be less effective than varenicline and NRT for smoking cessation. Bupropion is contraindicated in patients with a history of seizures, eating disorders, and those taking monoamine oxidase inhibitors or pregnant/breastfeeding women.[7]
  - Bupropion should be used with caution in people taking medications that can lower seizure threshold (e.g., other antidepressants, antipsychotics, antimalarials, oral hypoglycaemic agents).
- 10.2 **RACGP 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.*

### 11. Nortriptyline

- 11.1 Nortriptyline has been shown in a relatively small number of trials to significantly increase long-term cessation when used as the sole pharmacotherapy.[41-42] However, its utility is limited by its potential side effects, including dry mouth, constipation, nausea, sedation and headaches, risk of arrhythmia in patients with cardiovascular disease, and lethality in overdose.
- 11.2 **RACGP Recommendation 14** Nortriptyline should be considered as a second-line smoking cessation pharmacotherapy agent because of its adverse effects profile. <u>Strong recommendation, moderate certainty.</u>

### 12. Behavioural interventions

- 12.1 Advice from health professionals is effective in encouraging smoking cessation attempts.[7]
- 12.2 More intensive interventions provide better outcomes but may not be practicable in some clinical settings. There is clear evidence that simple counselling techniques, including motivational interviewing techniques, improve quit rates compared with minimal intervention.[43-44] Individual, group and telephone-based (e.g., Quitline) formats have also been shown to be effective when barriers to accessing these services are addressed.[7] In Australia, Quitline has tailored protocols for people living with a mental illness who access the <u>service</u>.
- 12.3 **RACGP Recommendation 16** Referral to telephone call-back counselling services should be offered to all people who smoke. *Strong recommendation, high certainty.*
- 12.4 There are high rates of smoking for Aboriginal and Torres Strait Islander peoples and Māori in Australia and New Zealand.[46-47] Cultural interventions are needed alongside biological and psychological interventions. For more information, please see the <u>RANZCP Position Statement 105: Cultural safety</u>, <u>Position Statement 104: Whānau Ora</u>, and <u>Position Statement 76: Partnering with carers in mental healthcare</u>.

## 13. Unproven and ineffective approaches to smoking cessation

13.1 There are 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.[7]

#### 13.2 Unproven approaches include:

- Other nicotine-related products e.g., Nicobloc, Nicobrevin
- Aversive or rapid smoking
- Biomedical feedback
- Physical activity
- Allen Carr method
- St John's Wort.

#### 13.3 Ineffective approaches include:

- Hypnotherapy (without counselling)
- Acupuncture
- Naltrexone.

## 14. Nicotine Vaping Products (NVPs)

- 14.1 In Australia, as of the 1st October 2021, liquid nicotine for use in an electronic cigarette (e-cigarette), a "nicotine vaping product" (NVP), requires a prescription from a medical practitioner. NVPs can only be prescribed for people over the age of 18. NVPs are not first-line treatments for smoking cessation. The strongest evidence base for efficacy and safety is for currently TGA approved pharmacological therapies combined with behavioural support. The certainty of evidence for NVPs is low. This creates many uncertainties for patients and clinicians, as the constituents of the aerosol produced have not been well tested and standardised. However, for people who have had unsuccessful smoking cessation attempts with approved pharmacotherapies, and who are still motivated to quit smoking and have brought up e-cigarette usage with their healthcare practitioner, NVPs may be a reasonable intervention to recommend. This needs to be preceded by an evidence-informed shared decision-making process, whereby the patient is aware of the following:
  - Possession of nicotine-containing e-liquid without a prescription is illegal.
  - To maximise possible benefit and minimise risk of harm, only short-term use is recommended.
  - To maximise possible benefit, NVP use should be combined with behavioural support.
  - Dual use (i.e., with continued tobacco smoking) needs to be avoided.
  - The long-term health effects of vaping are unknown.
  - Other potential safety issues include accidental poisoning, burns, lung injury, acute nicotine toxicity, and child safety.

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- 14.2 **RACGP Recommendation 15** For people who have tried to achieve smoking cessation with firstline 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. Conditional recommendation, low certainty
- 14.3 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 harm, dual use of cigarettes and NVPs should be avoided, and long-term use of NVPs should be minimised.
  - It is important for the patient to return for regular review and monitoring.
- 14.4 As with any intervention for smoking cessation, follow-up visits to discuss progress and provide support is recommended. 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. A maximum duration of 12 months' use of NVPs is a reasonable consideration. Transfer to NRT is an option for transitioning from NVPs to a form of nicotine less associated with long-term use. Approved smoking cessation pharmacotherapies may have a role; however, there is a need for further research.

The RACGP has developed specific guidance to clinicians regarding NVPs, see: <u>Supporting smoking cessation</u>: <u>A guide for health professionals (2021)</u>

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