About this guideline

The Royal Australian College of General Practitioners (RACGP) first developed *Supporting smoking cessation: A guide for health professionals* in 2011. Since then, there have been two minor updates in 2012 and 2014. This second edition is the most comprehensive update, and brings the guideline in line with new modalities of smoking cessation. It also incorporates GRADE – Grading of Recommendations, Assessment, Development and Evaluation – a new approach to assessing clinical evidence and drafting practice recommendations.

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.

Guideline development process

Expert Advisory Group

The RACGP is grateful for the expert advice from the following content advisors who contributed to the second edition of the guideline.

Professor Nicholas Zwar (Chair) – Executive Dean, Faculty of Health Sciences and Medicine, Bond University, Queensland

Professor Robyn Richmond – School of Public Health and Community Medicine, UNSW Sydney, New South Wales

Professor Ron Borland – School of Psychological Science, University of Melbourne, Victoria

Professor Matthew Peters – Respiratory Medicine, Concord Hospital, New South Wales

Conjoint Associate Professor Colin Mendelsohn – School of Public Health and Community Medicine, UNSW Sydney, New South Wales; Chair, Australian Tobacco Harm Reduction Association

Associate Professor John Litt – College of Medicine and Public Health, Flinders University, South Australia; General Practitioner (retired); Ambassador, Cancer Council SA

Ms Emma Dean – Senior Pharmacist and Project Officer, Alfred Health, Victoria

Associate Professor Mathew Coleman – Rural and Remote Mental Health Practice, Rural Clinical School of Western Australia, University of Western Australia

Ms Kath Sharples – Australian College of Nursing, New South Wales

Mr Scott Walsberger – Heart Health Manager NSW, National Heart Foundation of Australia, New South Wales

Mr George Masri – Assistant Secretary, Tobacco Control Branch (QUIT National), Department of Health, ACT (October–December 2017)

Mr John Power – Acting Director, Tobacco Control Branch, Population Health and Sport Division, Department of Health, ACT (December 2017 – July 2018)

Other contributors

Ms Rhonda Matthews – Senior Project Officer, Centre for Population Health, NSW Health, New South Wales

Ms Mary Sinclair – Medical Writer, New South Wales

Stakeholder consultation process

The RACGP undertook a six-week targeted consultation with a broad range of stakeholders. The Expert Advisory Group gratefully acknowledges the expert reviewers and representatives from the organisations who contributed scholarly feedback.

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

Feedback on supporting smoking cessation for Aboriginal and Torres Strait Islander peoples

Ms Ada Parry, Cultural and Education Advisor, RACGP Aboriginal and Torres Strait Islander Health

Dr Michelle Bovill, NHMRC Early Career Research Fellow, School of Medicine and Public Health, University of Newcastle

Professor David Thomas, Tobacco Control Research, Menzies School of Health Research, Charles Darwin University

Other individual feedback

Dr Johnson George – Senior Lecturer, Centre for Medicine Use and Safety, Monash University; member, Lung Foundation Australia COPD-X Guidelines Committee

Conflicts of interest

This guideline was developed in accordance with the rules and processes outlined in the RACGP's Conflict of Interest Policy.

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.

What is new

A number of recommendations in the first edition were considered redundant because:

- they are now considered standard practice
- the evidence no longer supports practice
- they are superseded by new recommendations.

Six recommendations from the first edition were **removed** from the second edition:

Recommendation 3: Assessment of readiness to quit is a valuable step in planning treatment (Strength: C) – no longer supported by evidence; best practice supports offering brief advice to all people who smoke, regardless of their readiness to quit.

Recommendation 7: Nicotine replacement therapy (NRT) (as monotherapy) should be recommended to all dependent smokers. There is no significant difference in effectiveness of different forms of NRT in achieving cessation (Strength: A) – combination NRT has been found to be more effective and is now preferred over monotherapy.

Recommendation 13: On the evidence available, acupuncture and hypnotherapy are not recommended as aids to smoking cessation (Strength: A) – these approaches are now discussed under 'unproven methods' within the guideline.

Recommendation 14: Use of NRT should be considered when a pregnant woman is otherwise unable to quit. Intermittent NRT is preferred to patches (lower total daily nicotine dose) (Strength: C) – replaced by Recommendation 9.

Recommendation 15: Smoking cessation should be a major focus of the management of people with smoking-related diseases (Strength: A) – considered to be standard practice.

Recommendation 16: People attempting to quit should be advised to ban or restrict smoking by others in their homes (Strength: C) – considered to be standard advice.

As the field of smoking cessation continues to evolve, new clinical questions come into focus. This guideline consists of six new recommendations, resulting in the 16 recommendations summarised below.

In keeping with current international best practice of guideline development, this guideline was updated using the GRADE methodology to build upon the existing evidence base. All recommendations have been formatted using GRADE.

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 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

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 – Nicotine-containing e-cigarettes are not first-line treatments for smoking cessation. The strongest evidence base for efficacy and safety is for currently approved pharmacological therapies combined with behavioural support. The lack of approved nicotine-containing e-cigarettes products creates an uncertain environment for patients and clinicians, as the constituents of the vapour produced have not been tested and standardised. However, for people who have tried to achieve smoking cessation with approved pharmacotherapies but failed, and who are still motivated to quit smoking and have brought up e-cigarette usage with their healthcare practitioner, nicotine-containing e-cigarettes 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:

- no tested and approved e-cigarette products are available
- the long-term health effects of vaping are unknown
- possession of nicotine-containing e-liquid without a prescription is illegal
- in order to maximise possible benefit and minimise risk of harms, only short-term use is recommended
- dual use (ie with continued tobacco smoking) needs to be avoided.

Conditional recommendation for intervention, low certainty

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

1. Schünemann HJ, Wiercioch W, Brozek J, et al. GRADE Evidence to Decision (EtD) frameworks for adoption, adaptation, and de novo development of trustworthy recommendations: GRADE-ADOLOPMENT. J Clin Epidemiol 2017:81:101–10. doi: 10.1016/j.jclinepi.2016.09.009.
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.

We acknowledge the Traditional Custodians of the lands and seas on which we work and live, and pay our respects to Elders, past, present and future.

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