30th April 2020

Review Secretariat
Pharmaceutical Benefits Advisory Committee (PBAC)
Australian Government Department of Health

Dear Sir/Madam,

The Australian Council on Smoking and Health ("ACOSH"), Cancer Council Australia ("CCA"), Lung Foundation Australia ("Lung Foundation"), Quit and the Victorian Health Promotion Foundation ("VicHealth") welcome the opportunity to make a submission to the *Public consultation on the post-market review of medicines for smoking cessation.*

- ACOSH works through advocacy and collaboration to create comprehensive strategies to reduce the health consequences of smoking. ACOSH aims to reduce the overall smoking rate in Western Australia and nationally, including within groups with a high prevalence of smoking, through targeted campaigns.
- CCA is Australia's peak non-government cancer control organisation, involved in all cancer types and all areas of cancer control, and provides advice to Government and other bodies on evidence-based practices and policies to help prevent, detect and treat cancer.
- Lung Foundation is the only charity and leading peak body of its kind in Australia that delivers life-changing research and programs that support and provide hope to people of all ages with a lung disease, and their families, at every stage of the journey. Lung foundation's aim is to ensure lung health is a priority for all, from promoting lung health and early diagnosis, to supporting people with lung disease and championing equitable access to treatment and care.
- Quit is the peak tobacco control body in Victoria and drives the development and implementation of smoking cessation policy and programs in that state. It also has a leadership role in knowledge transfer and policy development related to smoking cessation across the Cancer Council nationally. Quit develops, evaluates and delivers smoking cessation services, principally through the Victorian Quitline, in partnership with academic collaborators.
- Established under the Tobacco Act 1987 (Vic), VicHealth is a world first health promotion agency tasked with promoting the health of Victorians and preventing disease. Since inception, VicHealth has worked to prevent the uptake of tobacco use and support people who smoke to quit through investing significantly in the work of Quit. In 2017, VicHealth funded the Royal Australian College of General Practitioners (RACGP) to update their smoking cessation clinical guidelines *Supporting smoking cessation: A guide for health professionals.*

ACOSH, CCA, Lung Foundation, Quit and VicHealth (together "the Parties to this Submission") are strongly supportive of this post-market review to ensure that more people who smoke become tobacco free. Quit and ACOSH valued the opportunity to make a submission to the draft Terms of Reference and note with thanks that several of our key recommendations were taken into consideration in finalising the Terms of Reference.

As stated in our previous submission, amendments to PBS subsidies for smoking cessation medicines have the potential to reduce tobacco-related health and social inequities through increased access to best practice tobacco dependence treatment. This is of particular relevance for people who have complex health or psychosocial needs and also smoke.

Key recommendations from ACOSH, CCA, Lung Foundation, Quit and VicHealth

Term 1

PBAC should consider smoking cessation clinical guidelines from a range of health settings, and note the following commonalities:

- Combination nicotine replacement therapy (NRT) is considered best practice
- Smoking cessation medicines combined with behavioural intervention is the most effective way to quit
- Some people who smoke will require higher doses and longer durations of NRT (beyond current TGA recommendations).

Term 2

PBAC should review the following in addressing this term:

- Concurrent utilisation of smoking cessation medicines and behavioural intervention
- Proportion of patients using combination NRT (PBS subsidised or otherwise)
- Utilisation of non-PBS listed smoking cessation medicines (in particular, the nicotine mouth spray and nicotine inhalator).

Term 3

In addressing this term, PBAC should also consider reviewing the efficacy and safety of longer durations and higher doses of smoking cessation medicines, particularly NRT.

Term 4

A review of the cost-effectiveness for smoking cessation medicines should include combination NRT and the addition of the nicotine mouth spray and nicotine inhalator to the PBS.

These key recommendations are explained further under each term below.

1. **Collate the current clinical guidelines for medicines for smoking cessation and compare these to the Therapeutic Goods Administration (TGA) and PBS restrictions for these medicines.**

Currently, there are no National Health and Medical Research Council (NHMRC) clinical practice guidelines for smoking cessation. However, several of the Parties to this Submission have been involved in the development of clinical guidelines for smoking cessation medicines currently in use across the Australian health system. These are covered in detail below. While these guidelines may differ in terms of target audience, setting, intended purpose and complexity, their content is similar with respect to:

- Recommending combination nicotine replacement therapy as best practice;
- Emphasising the importance of combining smoking cessation medicines with multi-session behavioural intervention (for example, Quitline); and,
- In many cases, recognising that people who are highly nicotine dependent (or those who continue to have cravings despite use of medicines) will require higher doses and longer durations of NRT (beyond that in the current doses, labelling and indications for these products approved by the TGA).

It is therefore the recommendation of the Parties to this Submission that the following guidelines be considered in addressing Term 1.

General practice clinical guidelines

In January 2020, The Royal Australian College of General Practitioners (RACGP) released an updated edition of its smoking cessation clinical guidelines *Supporting smoking cessation: A guide for health professionals.*[1] This new edition, the development of which involved a comprehensive evidence review based on Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology, includes clear recommendations on the points listed above.

Primary Health Networks (PHNs), established by the Federal Government, aim to improve primary health care delivery in Australia, by working directly with general practitioners and general practices, and other primary health care providers.[2] HealthPathways, a PHN initiative, is a web-based hub of best practice clinical guidelines and pathways for general practitioners and other health care providers, tailored with local supports and referral pathways. Gippsland PHN, for example, has developed a smoking cessation HealthPathway which includes guidance on smoking cessation medicines and how to maximise quality of their use.

Health service clinical guidelines

Many health services have developed their own smoking cessation clinical guidelines, clinical pathways and NRT prescribing algorithms. An example of these is Queensland Health's smoking cessation clinical pathway.[3] In Victoria, Quit, in collaboration with the Victorian Department of

[1] The Royal Australian College of General Practitioners. Support smoking cessation: A guide for health professionals. 2nd Edn. East Melbourne, Vic: RACGP, 2019.
[2] Australian Government Department of Health. Primary Health Networks (PHNs). Available from: https://www1.health.gov.au/internet/main/publishing.nsf/Content/PHN-Background. [Accessed 6th April 2020].
[3] Queensland Health. Smoking Cessation Clinical Pathway. Available from: https://www.health.qld.gov.au/__data/assets/pdf_file/0031/435469/smoking-pathway.pdf [Accessed 6th April 2020].

Health and Human Services (DHHS), and Alfred Health, has been working with four health services to embed smoking cessation as part of routine care in clinical practice. This has involved the co-development of a tobacco dependence clinical guideline, clinical pathway and NRT prescribing algorithm (intended for the inpatient setting and enables best practice prescribing of NRT). These template documents are included in Appendix A.

Peak body clinical guidelines

The Clinical Oncology Society of Australia (COSA) is finalising a guidance document for the provision of best practice smoking cessation care in cancer settings. This document, co-authored by a multi-disciplinary team of cancer specialists, other health care providers and tobacco experts, advocates combination NRT and the importance of combining this with multi-session behavioural interventions. At the time of writing, this document is expected to be publicly available in November 2020.

Maternity clinical guidelines

There are some priority populations that may require more intensive support to quit, whether that be with respect to more intensive behavioural intervention, or longer durations and/or higher doses of smoking cessation medicines. The latter is particularly true for pregnant women, who have a higher rate of nicotine metabolism than the non-pregnant population.[4] In 2019, Quit commissioned the Royal Women's Hospital Pharmacy Department to conduct an extensive literature review and develop clinical guidelines to facilitate the delivery of best practice smoking cessation care in maternity and general practice settings. These guidelines, informed by the best available evidence to date and good clinical practice, are intended to provide practical NRT prescribing guidelines for maternity health care providers. The guidelines include how to initiate and titrate NRT and recommend combination NRT based on the Heaviness of Smoking Index (HSI). Quit is currently seeking endorsement of these guidelines from the RACGP and the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG). Refer to Appendix B (submitted as a separate document).

International guidelines

New Zealand's Ministry of Health has released *Guidelines for Helping People to Stop Smoking* in addition to a *Guide to Prescribing Nicotine Replacement Therapy (NRT)*.[5] These documents recommend the use of combination NRT, in addition to longer doses and higher durations of NRT.

Of note, the UK's National Institute for Health and Care Excellence is currently updating its guidance *Tobacco: preventing uptake, promoting quitting and treating dependence* (of note, however, the expected publication date is January 2021).[6] The NICE guideline *Stop smoking interventions and*

[4] Dempsey D, Jacob P, Benowitz NL. Accelerated metabolism of nicotine and cotinine in pregnant smokers. Journal of Pharmacology and Experimental Therapeutics. 2002;301:594-598.
[5] New Zealand Ministry of Health. The New Zealand Guidelines for Helping People to Stop Smoking. 2014. Available from: https://www.health.govt.nz/publication/new-zealand-guidelines-helping-people-stop-smoking [Accessed 6th April 2020].
[6] National Institute for Health and Care Excellence (NICE). Tobacco: preventing uptake, promoting quitting and treating dependence (update) (In development). Available from: https://www.nice.org.uk/guidance/indevelopment/gid-ng10086 [Accessed 6th April 2020].

services (last updated in March 2018) highlights the importance of combining smoking cessation medicines with behavioural intervention.[7]

2. **Review the utilisation of PBS-listed medicines for smoking cessation including but not limited to patient demographics, time on treatment, and the proportion using PBS subsidised combination treatment.**

The Parties to this Submission recommend the following be included as part of Term 2.

Utilisation of PBS-listed medicines for smoking cessation in conjunction with behavioural intervention

As outlined in our previous submission, this Term should also identify the proportion of patients using PBS-listed smoking cessation medicines who are concurrently using a smoking cessation behavioural intervention service (for example, Quitline). This is in recognition that best practice tobacco dependence treatment is a combination of smoking cessation medicines and multi-session behavioural interventions. The evidence for the effectiveness of this combination approach is well-established. A recently released report from the US Surgeon General concluded that *"Evidence is sufficient to infer that behavioural counseling and cessation medications are independently effective in increasing smoking cessation, and even more effective when used in combination."*[8]

As noted in our previous submission, the PBS clinical criteria restricts prescribing of these medicines i.e. that the *"Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated"*.[9] There is significant discordance between the numbers of PBS prescriptions of these medicines and the numbers of health professional referrals to Quitline.

Of note, for Aboriginal and Torres Strait Islander people, enrolment in a smoking cessation counselling program is *not* part of the clinical criteria for NRT formulations. Instead, the following statement is included as an additional note after the population and clinical criteria:

"Benefit is improved if used in conjunction with a comprehensive support and counselling program."

The failure to require entry into a support and counselling program is contrary to evidence-based treatment and may be contributing to lower quit rates in many Indigenous communities.

Appreciating the difficulty of 'mandating' that a referral to behavioural intervention must accompany every prescription of a PBS-listed smoking cessation medicine (for both Indigenous and non-Indigenous populations), the Parties to this Submission urge PBAC's consideration of stronger wording for the restriction in the PBS subsidy criteria.

[7] National Institute for Health and Care Excellence (NICE). Stop smoking interventions and services 2018. Available from: https://www.nice.org.uk/guidance/ng92/chapter/recommendations#nicotine-replacement-therapy [Accessed 6th April 2020].

[8] U.S. Department of Health and Human Services. Smoking cessation: A report of the Surgeon General-Executive Summary. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2020.

[9] For instance, see https://www.pbs.gov.au/medicine/item/10076H

The current

"Treatment criteria:

- *Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated.*

Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated."

could become

"Treatment criteria:

- *Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated.*

A copy of referral to the Quitline call back counselling service or details of an alternative support and counselling program in which the patient is enrolled must be documented in the patient's medical records at the time treatment is initiated."

Of note, proactive referrals to behavioural intervention (whereby the health professional makes the referral), rather than simply advising the patient to call, has been found to increase enrolment in treatment by 13-fold.[10] A 2019 Cochrane review found that cessation rates were higher for people who received proactive counselling over multiple sessions compared with control (self-help material or brief counselling in one call; RR 1.38 95%CI 1.19-1.61).[11] This review also found that telephone counselling appeared to increase the chances of quitting, regardless of motivation to quit. Similarly, the 2020 Surgeon General Report also concluded that there is sufficient evidence to infer that proactive quitline counselling, provided alone or with pharmacotherapy, increases cessation.[12]

Of note, Quitlines (as a telephone-based service) have a degree of flexibility not afforded by face-to-face behavioural intervention services. They have minimal (or no) patient costs, including no intangible costs (for example, travel time and time off work). And in light of COVID-19, avoiding face-to-face contact where possible is also preferable.

[10] Vidrine JI, Shete S, Cao Y, Greisinger A, Harmonson P, Sharp B, et al. Ask-Advise-Connect: A new approach to smoking treatment in delivery in health care settings. JAMA Internal Medicine. 2013;173(6):458-64.
[11] Matkin W, Ordonez-Mena JM, Hartmann-Boyce, J. Telephone counselling for smoking cessation. Cochrane Database of Systematic Reviews. 2019;5(5):CD002850.
[12] U.S. Department of Health and Human Services. Smoking cessation: A report of the Surgeon General-Executive Summary. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2020.

Proportion of patients using combination nicotine replacement therapy (PBS subsidised or otherwise)

As previously noted, the current PBS subsidy for NRT can only apply to the use of one formulation in a 12- month period:

"*The treatment must be the sole PBS-subsidised therapy for this condition"* and

"*Patient must not receive more than 12 weeks of PBS-subsidised nicotine replacement therapy per 12-month period"*

This provides a significant financial barrier to best practice combination NRT, particularly for those who are disadvantaged and/or those with complex health needs. NRT combinations appear to be more effective than single type use.[13] A 2019 Cochrane review found that combination NRT results in higher quit rates compared to monotherapy (RR 1.25, 95%CI 1.15-1.36).[14]

The review may also like to consider how people may be accessing combination NRT, including, for example, if people are:

- Accessing multiple PBS-subsidised formulations through different prescribers
- Using one PBS-subsidised formulation in conjunction with a formulation obtained over the counter

This may give an indication of the unmet need of people who smoke and require combination NRT.

Utilisation of non-PBS listed smoking cessation medicines

Specifically, this refers to NRT formulations that are not currently PBS-listed, including the mouth spray and inhalator. These formulations are preferred by some patients and are required in cases where the PBS-listed gum or lozenge may be clinically inappropriate. For example, the nicotine gum is not recommended for patients with dentures or complicated dental work. Quantifying the proportion of patients using these formulations would also be helpful in assessing the potential budgetary impact of listing such formulations should the PBS deem them cost-effective.

[13] Stead LF, Perera R, Bullen C, Mant D, Hartmann-Boyce J, et al. Nicotine replacement therapy for smoking cessation. Cochrane Database of Systematic Reviews. 2012;11:CD000146.

[14] Lindson N, Chepkin SC, Ye W, Fanshawe TR, Bullen C, Hartmann-Boyce J. Different doses, durations and modes of delivery of nicotine replacement therapy for smoking cessation. Cochrane Database of Systematic Reviews. 2019:CD013308.

3. Review the efficacy and safety of nicotine replacement therapy, varenicline and bupropion for smoking cessation including combination therapies not currently PBS subsidised.

The efficacy and safety of smoking cessation medicines is well-established.[15] A 2018 Cochrane review found that each of the faster-acting NRT formulations have comparable efficacy.[16] Combination NRT (faster-acting formulation plus patch) is more effective than single form alone.[17] In 2020, the US Surgeon General's report on cessation found that combination NRT increases smoking cessation compared with monotherapy.[18] It has been suggested that combination therapy is likely to be the most promising means of cessation in the future.[19]

Of note, combination NRT has similar efficacy to varenicline.[20]

As mentioned in our previous submission, this Term should ideally also include a review of the efficacy and safety of longer durations and higher doses of smoking cessation medicines.

Tobacco dependence is a chronic, relapsing clinical condition and people often do not use adequate doses or durations of these medicines. While a recent Cochrane Review did not find a statistically significant increase in quit rates with longer durations of NRT use (both combination NRT and patch alone),[21] some people with complex health and psychosocial needs may require longer durations and higher doses. Research has found that the rate of relapse among people who smoke and have a mental illness can be reduced with longer use of pharmacotherapy.[22]

The National Medicines Policy, currently under review, has four key objectives; (1) timely access to medicines, (2) quality, efficacy and safety of medicines, (3) quality use of medicines and (4) maintaining a responsible and viable medicines industry.[23] Under the Quality Use of Medicines (QUM), the goal is "to make the best possible use of medicines to improve health outcomes for all

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[15] Greenhalgh EM, Stillman S and Ford C. 7.16 Pharmacotherapies. In Scollo MM, and Winstanley MH [editors]. Tobacco in Australia: Facts and Issues. Melbourne: Cancer Council Victoria; 2020. Available from: https://www.tobaccoinaustralia.org.au/chapter-7-cessation/7-16-pharmacotherapy#x7.16.1

[16] Hartmann-Boyce J, Chepkin SC, Ye W, Bullen C, Lancaster T. Nicotine replacement therapy for smoking cessation. Cochrane Database of Systematic Reviews. 2018:CD000146.

[17] Lindson N, Chepkin SC, Ye W, Fanshawe TR, Bullen C, et al. Different doses, durations and modes of delivery of nicotine replacement therapy for smoking cessation. Cochrane Database of Systematic Reviews, 2019; 4(4):CD013308. Available from: https://www.ncbi.nlm.nih.gov/pubmed/30997928

[18] U.S. Department of Health and Human Services. Smoking cessation: A report of the Surgeon General-Executive Summary. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2020.

[19] Carpenter MJ, Jardin BF, Burris JL, Mathew AR, Schnoll RA, et al. Clinical strategies to enhance the efficacy of nicotine replacement therapy for smoking cessation: A review of the literature. Drugs. 2013;73(5):407-26.

[20] Cahill K, Stevens S, Perera R, and Lancaster T. Pharmacological interventions for smoking cessation: An overview and network meta-analysis. Cochrane Database of Systematic Reviews, 2013; 5(5):CD009329. Available from: https://www.ncbi.nlm.nih.gov/pubmed/23728690

[21] Lindson N, Chepkin SC, Ye W, Fanshawe TR, Bullen C, Hartmann-Boyce J. Different doses, durations and modes of delivery of nicotine replacement therapy for smoking cessation. Cochrane Database of Systematic Reviews. 2019;CD013308.

[22] Tidey JW, Miller ME. Smoking cessation and reduction in people with chronic mental illness. BMJ. 2015;351:h4065.

[23] Australian Government Department of Health and Ageing. National Medicines Policy 2000. Canberra: Commonwealth of Australia;1999.

Australians". In cessation, the best possible use of medicines (including combination NRT and concurrent use of behavioural intervention) would meet these objectives.[24]

The current PBS restrictions do not enable this flexibility and do not reflect research that has consistently demonstrated that longer term use of NRT is safe and the rate of serious adverse events is low.[25,26,27] Ideally, the PBS criteria should be updated to reflect the latest evidence for safety and efficacy of longer durations and/or higher doses.

4. **Subject to the findings of Terms of Reference 1, 2 and 3, review the cost-effectiveness of medicines for smoking cessation.**

The Parties to this Submission commend the inclusion of this Term in the finalised terms of reference. Several international studies have demonstrated the cost-effectiveness of smoking cessation medicines[28,29] and this Term should include review of combination NRT and the addition of the nicotine mouth spray and nicotine inhalator to the PBS.

Given tobacco smoking remains the leading cause of preventable death and disease in Australia,[30] with the annual costs of tobacco use estimated at well over $130 billion,[31] it is unfeasible that optimisation of PBS-subsidised smoking cessation medicines (specifically, to include combination NRT and the other faster-acting formulations not currently listed) will not be cost-effective. At worst, it is possible that failure to optimise this undermines the public health messaging in which millions of dollars are invested in tobacco mass media campaigns each year.

Finally, as noted in our previous submission, investments in this optimisation must not be undone by the lack of an accompanying proactive referral to behavioural intervention services. The review must

[24] Australian Government Department of Health. Quality Use of Medicines (QUM). [Updated March 2020, accessed 22/04/2020]. Available from: https://www1.health.gov.au/internet/main/publishing.nsf/Content/nmp-quality.htm-copy2

[25] Schnoll RA, Goelz PM, Veluz-Wilkins A, Blazekovic S, Powers L, Leone FT, Gariti P, Wileyto EP, Hitsman B. Long-term nicotine replacement therapy: a randomised clinical trial. JAMA Internal Medicine. 2015;175(4):504-511.

[26] Moore D, Aveyard P, Connock M, Wang D, Fry-Smith A, Barton P. Effectiveness and safety of nicotine replacement therapy assisted reduction to stop smoking: systematic review and meta-analysis. BMJ. 2009;338:b1024.

[27] Hartmann-Boyce J, Chepkin SC, Ye W, Bullen C, Lancaster T. Nicotine replacement therapy versus control for smoking cessation. Cochrane Database of Systematic Reviews. 2018:CD000146. Available from: https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD000146.pub5/full

[28] Greenhalgh EM, Hurley S, Lal A. 17.4 Economic evaluations of tobacco control interventions. In Greenhalgh EM, Scollo MM and Winstanley MH [editors]. Tobacco in Australia: Facts and Issues. Melbourne: Cancer Council Victoria; 2020. Available from: https://www.tobaccoinaustralia.org.au/chapter-17-economics/17-4-economic-evaluations-of-tobacco-control-interventions#ENREF_122

[29] Filby A, Taylor M. National Institute for Health and Care Excellence (NICE) Smoking cessation interventions and services. York Health Economics Consortium. 2018. Available from: https://www.nice.org.uk/guidance/ng92/evidence/economic-modelling-report-pdf-4790596573

[30] Australian Institute of Health and Welfare 2019. Burden of tobacco use in Australia: Australian Burden of Disease Study 2015. Australian Burden of Disease series no.21. Cat. No. BOD 20. Canberra: AIHW.

[31] Whetton S, Tait RJ, Scollo M, Banks E, Chapman J, Dey T et al. Identifying the social costs of tobacco use to Australia in 2015/2016. National Drug Research Institute, Curtin University. 2019. Western Australia:NDRI.

consider the mechanisms by which prescribers can be more strongly compelled (if not mandated) to make these proactive referrals.

If you require further information, please contact [redacted]

Thank you for your consideration of this submission.

Maurice Swanson
Chief Executive
ACOSH

Libby Jardine
Chair, Tobacco Issues Committee
Cancer Council Australia

Mark Brooke
Chief Executive Officer
Lung Foundation Australia

Dr Sarah L. White
Director
Quit

Dr Sandro Demaio
Chief Executive Officer
VicHealth

Appendix A. Tobacco dependence clinical guideline, clinical pathway, and NRT prescribing algorithm

Tobacco Dependence Clinical Guideline and Clinical Pathway (template)

Target audience

All <Insert name of health service> employees involved in providing care for patients who smoke.

Purpose

<Insert name of health service> is committed to maintaining a safe and healthy smokefree environment in the best interests of patients, residents, visitors, contractors, volunteers, students and employees. Tobacco smoking remains the leading cause of preventable death and disease in Victoria. The primary purpose of this guideline is to provide patients who smoke with effective, evidence-based treatments to manage temporary abstinence or support long term smoking cessation.

Process

Tobacco dependence is a chronic relapsing disease that warrants medical management like any other drug dependency or chronic disease. Brief advice from a health professional is a major external trigger in prompting someone who smokes to attempt to quit.

This guideline is based on the AAH model. It is a systematic approach designed to be delivered to all people who smoke regardless of their intention to quit.

Best practice care for people who smoke involves a combination of pharmacotherapy (such as nicotine replacement therapy [NRT]) and multi-session behavioural intervention (such as that offered through Quitline).

AAH involves the following steps:

- Ask
- Advise
- Help

Ideally, care aims to assist long term cessation, however, for some patients, this care may be more focused on the temporary management of nicotine withdrawal.

[Health services to advise - Insert statement about responsibilities of who is responsible to implement this guideline, should include who and any requirements e.g. education/training to be completed.]

ASK:

- XX are responsible for asking all patients (where clinically possible) about their smoking status (and e-cigarette use, as relevant) upon admission.

- Patients who use e-cigarettes should also be assessed for nicotine dependence and offered care to be smokefree in the same way as patients who smoke tobacco-based products.[32]
- Response to be recorded in patient medical record on <insert name of relevant document(s)>.
- If a patient responds yes or has recently quit (within 30 days), XX should complete the Tobacco Dependence Clinical Pathway.

ADVISE:

- Advise patients who smoke to quit in a clear, non-confrontational and personalised way.
- Advise patients who smoke about the benefits of quitting smoking (tailored to the patient's clinical situation, as relevant. e.g. "Stopping smoking will help with your recovery from surgery.").
- Let them know that the best way to quit smoking is with a combination of pharmacotherapy (e.g. NRT) and multi-session behavioural intervention, through services such as Quitline.
- Inform patients that <insert name of health service> is completely smokefree.

HELP:

- Use the Heaviness of Smoking Index (HSI) to assess the nicotine dependency of all patients who smoke or have recently quit. If a patient has recently quit, use their previous cigarettes per day (see Appendix 1- Tobacco Dependence Clinical Pathway).
- Offer NRT as clinically appropriate (see Appendix 2- NRT Prescribing Algorithm).
- Inform patients that even if they are not ready to make a quit attempt, using NRT while in hospital will make their stay more comfortable. Inform patients that NRT is provided free of charge during their inpatient stay.
- Offer all patients who smoke or have recently quit a referral to multi-session behavioural intervention (e.g. Quitline or another smoking cessation service). Complete referral to Quitline or another smoking cessation service for those patients who accept the offer.
- Offer written information.

Nicotine replacement therapy (NRT)

NRT works to reduce cravings and other withdrawal symptoms associated with stopping smoking. NRT increases the success of quitting smoking by 50-60%.[1] Combination therapy involves the use of a faster-acting formulation combined with the patch. Combination NRT further increases quit rates over one formulation alone.[2]

Formulations of NRT available at <insert name of heath service> are:

- Nicotine patches [Health services to advise - <Insert strengths available>]
- [Health services to advise - <Insert faster-acting forms of NRT available and strengths>].

NRT formulations are available [Health services to advise - <Insert location(s)>].

[32] *It is not currently possible to provide specific clinical recommendations for patients who use e-cigarettes due to the significant uncertainty in the type and composition of e-liquids accessible in Australia. At this time there is no validated tool, like the HSI, to assess nicotine dependence specifically in patients using e-cigarettes.*

Most patients who are nicotine dependent will require combination NRT. Patients who are nicotine dependent require timely and effective management with NRT to prevent the onset of withdrawal symptoms.

All evidence indicates that nicotine administered as medication is less harmful than that obtained by smoking.

[Health services to advise - <Insert statement regarding process for prescribing e.g. Nurse initiated NRT>].

[Health services to advise as relevant for their patient cohort - <Insert statements about precautions for prescribing and/or exclusions for nurse initiated NRT>].

Nicotine withdrawal

Several signs and symptoms characterise withdrawal from nicotine. These are listed in the Diagnostic and Statistical Manual of Mental Disorders (DSM-V) and include urges to smoke alongside irritability, frustration or anger, anxiety, difficultly concentrating, increased appetite, restlessness, depressed mood and insomnia.

There can be significant variation in the severity of these symptoms amongst individuals. If the patient is experiencing nicotine withdrawal symptoms, it is important to consider strategies such as:

- Increasing the dose of NRT as appropriate
- Advising the patient to reduce or halve their caffeine intake
- Reinforcing the use of behavioural strategies.

Regular monitoring of the effectiveness of NRT in managing nicotine withdrawal symptoms should be undertaken by the [Health services to advice - <insert relevant health professionals>].

Nicotine toxicity

Symptoms of nicotine toxicity can include nausea, vomiting, headache and light-headedness. If the patient is experiencing signs of toxicity, consider the following strategies:

- Reducing the dose of NRT as appropriate
- Advising the patient to reduce or halve their caffeine intake
- Removing the patch prior to bedtime, if disrupting daily activities

Sleep disturbance is common upon smoking cessation and may not be the result of nicotine toxicity.

Drug interactions

It is important to check the patient's current medication regimen for any potential drug interactions. Dose adjustment may be required for a patient when they stop smoking.
See Appendix 3- Drug Interactions with Smoking for further information. If required, contact the Pharmacy Department for further advice.

Discharge

Discharge presents an opportunity to encourage the patient to sustain the quit attempt that was made during their stay or to consider quitting, and to provide appropriate referrals. It also provides an opportunity to communicate with the patient's GP about the support they have received during their admission and to facilitate ongoing care.

On discharge:

- Include the patient's smoking status, action taken and the plan for follow up in discharge communication as relevant
- Ensure prescription of NRT or other related pharmacotherapy on discharge as appropriate and in accordance with current PBS guidelines (see NRT availability on the PBS below) [Health services to advise – Note: PBS will only subsidise NRT monotherapy and limited faster-acting products]
- Ensure referral made to behavioural intervention (e.g. Quitline).

It is recommended that if NRT is being used to achieve long term cessation, the treatment regimen should be continued for a minimum of 8 weeks, longer for some people.

NRT availability on the PBS

Some formulations of NRT are available on the PBS. There are criteria for eligibility. Refer to the PBS website as current listings change from time to time. For details http://www.pbs.gov.au

Appendices

Appendix 1 Tobacco Dependence Clinical Pathway
Appendix 2 NRT Prescribing Algorithm
Appendix 3 Drug Interactions with Smoking

Key related documents

- Key aligned policies
  - Smokefree policy
- Key legislation, acts and standards
  - Charter of Human Rights and Responsibilities Act 2006
- Other relevant documents
  Individual health service to advise
  - Smokefree guideline
  - Other relevant guidelines
  - Non-compliance/Disciplinary policy
  - Others?

References

1. Hartmann-Boyce J, Chepkin SC, Ye W, Bullen C, Lancaster T. Nicotine replacement therapy versus control for smoking cessation. Cochrane Database of Systematic Reviews 2018, Issue 5. Art. No.: CD000146. DOI: 10.1002/14651858.CD000146.pub5.
2. Lindson N, Chepkin SC, Ye W, Fanshawe TR, Bullen C, Hartmann-Boyce J. Different doses, durations and modes of delivery of nicotine replacement therapy for smoking cessation. Cochrane Database of Systematic Reviews 2019, Issue 4. Art. No.: CD013308.

Authors/Contributors

Individual health service to advise

- To include key contact and a broad range of contributors

Appendix 1 - Tobacco Dependence Clinical Pathway

Use for all patients, to ascertain smoking status and to assist in the management of nicotine dependence and, where relevant, smoking cessation.

<table>
<tr><td colspan="2">XX Health Service

Tobacco Dependence Clinical Pathway
A-Ask, A-Advise, H-Help</td><td colspan="2">Surname: UR Number:
Given names:
D.O.B: Sex:
Admission Date:
Consultant: Ward/Clinic:
USE LABEL IF AVAILABLE</td><td rowspan="5">MR

Tobacco Dependence Clinical Pathway</td></tr>
<tr><td>ASK</td><td>Do you currently smoke?</td><td colspan="2">☐ Yes (Continue pathway)
☐ Previously smoked (Congratulate, consider continuing pathway for those recently quit (<30 days), otherwise sign and file)
☐ Never (Congratulate, sign and file)</td></tr>
<tr><td>ADVISE</td><td colspan="3">Advise all people who smoke to quit in a clear non-confrontational and personalised way
‘The single most important thing you can do for your health is to stop smoking’
‘Stopping smoking will help with your recovery from surgery and will reduce the risk of any complications’
‘The best way to quit is to use combination NRT for a minimum of 12 weeks along with tailored support and follow-up like Quitline or other stop smoking service’</td></tr>
<tr><td rowspan="7">HELP</td><td colspan="2">Nicotine dependency assessment- Heaviness of Smoking Index (HSI)</td><td>SCORE</td></tr>
<tr><td colspan="2">When you wake up each day, when do you smoke your first cigarette?
☐ Within 5 mins ☐ 5-30mins ☐ 31-60mins ☐ >60mins
Score=3 Score=2 Score=1 Score=0</td><td></td></tr>
<tr><td colspan="2">How many cigarettes a day do you smoke on a typical day?
☐ 31 or more ☐ 21 to 30 ☐ 11-20 ☐ 10 or less
Score=3 Score=2 Score=1 Score=0</td><td></td></tr>
<tr><td colspan="2">Add two scores above to gain the total Heaviness of Smoking Index (HSI)</td><td>HSI =</td></tr>
<tr><td colspan="3">☐ Low nicotine dependence 0-2 ☐ Moderate nicotine dependence 3-4 ☐ High nicotine dependence 5-6</td></tr>
<tr><td colspan="3">Offer NRT as per NRT Prescribing Algorithm (Appendix 2)- Check precautions and drug interactions</td></tr>
<tr><td colspan="3">Management Plan
NRT charted on medication chart ☐ Yes ☐ No (If No, document reason:_____)
NRT offered & accepted ☐ Yes ☐ No (If No, document reason: _____)
☐ Nurse initiated ☐ Medical Officer initiated ☐ Pharmacist initiated
Note: <insert reference to hospital policy/guidelines around nurse/pharmacist initiated NRT if relevant></td></tr>
</table>

	Referral to Quitline or smoking cessation service offered ☐ Yes; Quitline ☐ Yes; Smoking cessation service (specify:_____) ☐ No (If No, document reason: _____) Referral accepted & completed ☐ Yes ☐ No (If No, document reason: _____) Written information on quitting provided ☐ Yes ☐ No (If No, document reason: _____)	
	Discharge Plan- tick all that apply	
	☐ Smoking status, action taken and required follow up documented on discharge communication ☐ NRT written on discharge prescription (if appropriate) ☐ Referral to Quitline or smoking cessation service completed (if accepted) ☐ Patient declined any further support on discharge	

Name:	Signature:	Designation:	Date:

Appendix 2 - NRT Prescribing Algorithm

The following algorithm is a guide to the initial prescribing of NRT.

Low dependence HSI score 0-2 or mild cravings with previous quit attempts	Moderate dependence HSI score 3-4 or significant cravings with previous quit attempts	High dependence HSI score 5+ or severe cravings with previous quit attempts
NRT may not be required. Offer **if needed:** Nicotine 2mg chewing gum 1 piece of gum to be chewed as directed PRN up to every 1-2 hours (Maximum 12 pieces in 24 hours) (Avoid using >1 piece/hour) **OR** Nicotine 2mg lozenges 1 lozenge to be used as directed PRN up to every 1-2 hours (Maximum 15 lozenges in 24 hours) **OR** Nicotine 15mg inhalator The contents of one cartridge to be inhaled PRN (Maximum of 6 cartridges in 24 hours) **OR** Nicotine 1mg mouth spray Use 1 spray PRN up to every 30-60 minutes (Maximum of 64 sprays in 24 hours)	Combination NRT is needed Nicotine patch21mg/24 hour **PLUS** Nicotine 2mg chewing gum 1 piece of gum to be chewed as directed PRN up to every 1-2 hours (Maximum 12 pieces in 24 hours) (Avoid using >1 piece/hour) **OR** Nicotine 2mg lozenges 1 lozenge to be used as directed PRN up to every 1-2 hours (Maximum 15 lozenges in 24 hours) **OR** Nicotine 15mg inhalator The contents of one cartridge to be inhaled PRN (Maximum of 6 cartridges in 24 hours) **OR** Nicotine 1mg mouth spray Use 1 spray PRN up to every 30-60 minutes	Combination NRT is needed Nicotine patch 21mg/24 hour **PLUS** Nicotine 4mg chewing gum 1 piece of gum to be chewed as directed PRN up to every 1-2 hours (Maximum 10 pieces in 24 hours) (Avoid using >1 piece/hour) **OR** Nicotine 4mg lozenges 1 lozenge to be used as directed PRN up to every 1-2 hours (Maximum 15 lozenges in 24 hours) **OR** Nicotine 15mg inhalator The contents of one cartridge to be inhaled PRN (Maximum of 6 cartridges in 24 hours) **OR** Nicotine 1mg mouth spray Use 1-2 sprays PRN up to every 30-60 minutes

	(Maximum of 64 sprays in 24 hours)	(Maximum of 64 sprays in 24 hours)

NOTES:

- These recommended doses differ from those listed on the medication packaging/information leaflets. This guide to initial NRT recommendation aims to simplify and ensure patients receive adequate nicotine to prevent and manage withdrawal and promote cessation.
- HSI is used as a measure of nicotine dependence. The higher a person's HSI, the higher their dependence is likely to be and therefore will benefit from higher doses of NRT.
- After clinical review, if the patient's urge to smoke or other withdrawal symptoms are not sufficiently managed, the dose of NRT can be increased.
- Consider commencing at higher dosages if the patient has experienced severe cravings with previous quit attempts.
- Some patients may require two 21mg/24 hour patches to be worn concurrently. Generally, the second patch will be worn during daytime hours only (removed overnight).
- Lower strength patches are generally only used for weaning, however their use is not strictly necessary.
- Consider reducing patch strength initially to 14mg/24hrs if the patient weighs less than 45kg.

Escalation of NRT

- Continue to monitor for withdrawal symptoms
- If withdrawal symptoms not well controlled

1. Ensure correct use of NRT
2. Consider more frequent use of faster-acting formulation
3. Consider additional patch (if appropriate)

Appendix 3 - Drug Interactions with Smoking

Drug_interactions_
with_smoking.pdf

For the most up to date version of this table, visit:
https://d1pz9rwztkrv8y.cloudfront.net/media/documents/drug-interactions-with-smoking.pdf