Nicotine Replacement Therapy

Guidelines for Healthcare Professionals on using Nicotine Replacement Therapy for smokers not yet ready to stop smoking

ASH February 2007

1. Introduction

The Therapeutic Goods Administration (TGA) has approved a new indication for two nicotine replacement therapy (NRT) products, Nicorette Gum and Nicorette Inhaler, enabling smokers to cut down on their smoking prior to attempting to stop. This new indication is called "*Cut Down Then Stop*" (CDTS). Nineteen other countries have already approved this indication.

In the past, the conventional wisdom has been to recommend to smokers that it is not worth cutting down, and that it is better to wait until they feel ready to stop, and then make a quit attempt. New research supporting this indication challenges this assumption and provides evidence for nicotine assisted reduction to stop. It suggests that cutting down first with NRT can increase the number of smokers who go on to stop. This finding is extremely important, as it could attract a new group of smokers into stopping. The rationale for nicotine-assisted reduction to quit is that using NRT boosts nicotine levels, making it easier for the smoker to smoke fewer cigarettes, and making compensation less likely, which in turn should mean that the smoker will inhale fewer toxins. By reducing their reliance on cigarettes for their nicotine intake, some smokers can then stop smoking completely.

It is important that smokers do not use the new indication just to reduce smoking as an alternative to stopping. Stopping completely remains the best goal and smokers should be reminded of this. However, it seems likely that for many smokers this new indication will offer a useful introduction to NRT before having to stop completely.

ASH supports this indication because the evidence shows that, if smokers who are not ready to stop, use nicotine gum or inhaler to help them reduce their cigarette consumption by at least 50%, approximately 4% will actually stop smoking as a result. Given that about half of smokers are interested in cutting down rather than stopping, at any one time, this could significantly increase the numbers of smokers that stop. [1 - 4]

When it comes to the safety of nicotine delivered in the form of an NRT, ASH is of the view that using NRT to quit is always safer than continuing to smoke. A summary of the available evidence on the role of nicotine and the safety of NRT has been provided as an attachment to these Guidelines.

2. Key Messages for Healthcare Professionals

1. **Cut Down Then Stop: nicotine gum and inhaler can be used while still smoking, with a view to reducing the amount smoked as a prelude to quitting.** This approach is only appropriate in cases where it is clear that the smoker is not willing to make an immediate quit attempt. Stop smoking advisors may offer brief advice on cutting down and should provide support when smokers want to stop completely.

2. **For abrupt smoking cessation: NRT should be used for at least 3 months before weaning. Regular use beyond 12 months is generally not recommended**

3. **More than one form of NRT can be used concurrently.** Patients with a history of failure of quit attempts using a single form of NRT should be offered a combination of 16 hour patch plus 2mg gum. Any smoker who wishes to use combination therapy should be encouraged to do so. The approved combination in Australia is Nicorette Patch plus Nicorette 2mg Gum.

4. **NRT can be used by pregnant and lactating smokers.** Those prescribing or supplying NRT should ensure that the potential risks and benefits are understood by the patient and that the clinician supervising management of the pregnancy has been consulted. For pregnant women intermittent dosing products may be preferable as these usually provide a lower daily dose of nicotine than patches, however patches may be preferred if the woman is suffering from nausea. Patches should not be used during the night-time sleep. For lactating women NRT patches are not recommended. Women should breastfeed just before using an intermittent NRT product.

5. **All forms of NRT can be used by patients with cardiovascular disease.** NRT should be offered in any case where the alternative is the patient resuming smoking. In patients with cardiovascular disease that is not stable or controlled by treatment, the decision to prescribe should be made in consultation with the supervising physician (GP or consultant).

6. **All forms of NRT can be used by smokers aged 12 to 17 years.** Those prescribing or supplying NRT should check that: a) the young person is nicotine dependent enough to warrant use of NRT; b) is committed to stopping smoking; c) willingness to accept counselling.

7. **If a smoker asks about reducing to stop they should be reminded that stopping completely is the best thing for their health, and that support and medications are available.**

8. **Smokers who are not ready to make a quit attempt should consider using nicotine gum or inhaler to help them cut down with a view to stopping later.**

9. **All health professionals should be proactively encouraging this new indication to smokers who to date have been unready or unable to stop.**

3. What is the process for using Nicorette Gum and Inhaler for cutting down then stopping (CDTS)?

Using Nicorette Gum and Inhaler with CDTS approaches to quit smoking

Step	When	Goal
1	0-6 weeks	cut down to 50% of baseline cigarette consumption
2	6 weeks to 6 months	continue to cut down; stop completely by 6 months
3	6 to 9 months	stop smoking completely, continue NRT
4	within 12 months	stop using NRT by 12 months

4. Why do we need this new indication?

The rate of smoking has been declining over the last few decades (see table below). Since 1945, when reliable prevalence data was first made available and published, smoking rates have declined dramatically. In 1945, 72% of the male population smoked compared with 26% in 2004-2005. Women have always had a lower prevalence of smoking than men with 26% of women smoking in 1945 compared with 20% in 2004-2005. Although smoking rates have declined dramatically, a recent survey shows a slowing of the rate of decline in smoking prevalence seen in previous surveys. Data for 2001 and 2004-2005 from ABS National Health Survey: Summary of results 2004-2005 (2006)

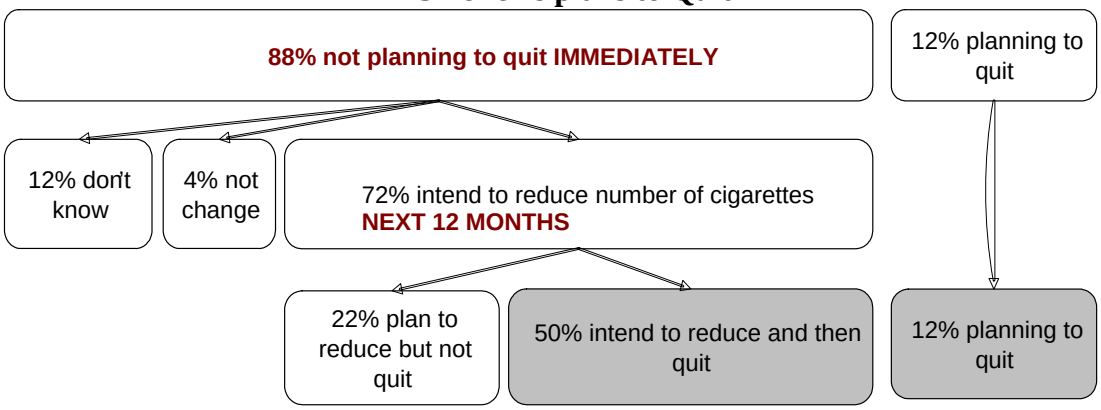
Percentage of smokers * among adult Australians[5]

Year	Male	Female
	% of population	
1945	72	26
1964	58	28
1969	45	28
1974	45	30
1976	43	33
1980	41	31
1983	40	31
1986	33	29
1989	30	27
1992	28	24
1995	27	23
2001	27**	21**
2004-05	26	20

includes cigarette, pipe and cigar smokers
* Data for 2001 and 2004-2005 from ABS National Health Survey: Summary of results 2004-2005 (2006)

While 62%[6] of smokers want to stop smoking in the next 12 months, only 3-5% of those who attempt to quit smoking actually remain quit after 3 months[7]. The diagram below shows that 72% of smokers are planning to reduce the number of cigarettes they smoke in the next 12 months with 50% planning to reduce then quit . Only 12% are planning to quit without first reducing the number of cigarettes they smoke[6] – most smokers want to reduce with the intention of quitting altogether.

Smoker's plans to Quit[6]



The major impact on smoking cessation rates will come from increasing the proportion who attempt to stop and use effective treatments to help them do so.

There are many possible ways of increasing the rate of quit attempts, including smoke-free legislation and raising the cost of cigarettes. The new NRT indication could make a useful contribution.

5. What is the evidence?

Summary of the evidence

Taken together the evidence supports the following conclusions:

1. NRT helps smokers unwilling or unable to stop smoking achieve sustained reduction in cigarette consumption
2. This reduction is accompanied by a reduction in smoke intake
3. There is minimal risk of significant adverse reactions to smoking concurrently with NRT
4. Smoking reduction using NRT increases motivation to stop smoking
5. Smoking reduction using NRT increases subsequent cessation.

Four double-blind randomised placebo controlled studies provide evidence for the efficacy of cutting down with nicotine replacement. [1-4] Overall these studies found that in smokers unwilling or unable to stop smoking yet:

- One third of smokers, who successfully cut down their cigarette consumption by half with gum or inhaler, were abstinent at one year (7-day point prevalence data), and that NRT was twice as successful as placebo in achieving sustained reduction and later cessation.
- Although there was some compensatory inhalation when cigarette consumption was reduced, carbon monoxide measurement confirmed that there was a substantial reduction in inhaled tobacco smoke.
- Motivation to stop smoking was increased in 55% to 80% of smokers (and decreased in very few).
- One in every 12 smokers who didn't want to give up but were willing to try cutting down had quit smoking at one year. The overall number needed to treat was 24, while the number needed to treat for NRT used to stop smoking abruptly without behavioural support is 20, so they are comparable.

Overall there was minimal evidence in these trials of adverse reactions due to nicotine overdosing. Fagerstrom and Hughes [8] reviewed studies of the concurrent use of cigarettes and nicotine replacement and also found minimal evidence of adverse reactions. With concurrent smoking and gum and inhaler use, blood nicotine levels remained the same, illustrating how well smokers titrate their nicotine levels. This finding strongly suggests that smoking reduction using NRT is, if sustained, likely to be safer than smoking.

The Cochrane review of nicotine replacement therapy and smoking cessation concluded: “Based on pooling 3 trials, there was a significant benefit from the use of NRT on the odds of reducing the number of cigarettes smoked to fewer than 50% of baseline at longest follow up, using point prevalence of reduction (OR 1.80, 95% CI: 1.41 to 1.28); a significant effect on sustained reduction was detected by pooling 2 trials reporting this

outcome. There was also a marginally significant increase in odds of cessation (OR 1.62, 95% CI: 1.06 to 2.49)." [9]

A more recent review identified 19 trials (some unpublished) that tested NRT for smoking reduction in smokers not ready to stop outright. They concluded that NRT consistently helped these smokers make reductions in daily cigarette consumption.[10]

6. Are there any precautions

This new indication also includes precautions for cardiovascular disease, pregnancy and breast feeding, and adolescents. The following information examines the evidence for each of these precautions and also discusses use of more than one NRT product concurrently, long-term use of NRT, smoking whist using NRT to cut down and other precautions such as diabetes.

Use of NRT by smokers with cardiovascular disease

The pharmacology of nicotine suggests that it may have the potential to trigger cardiac events in patients with cardiovascular disease.[11] However, there is now a great deal of experience of NRT use in smokers with cardiovascular disease, and in practice it has not been found to pose a risk.[12,13,14] A recent study of a large cohort of general practice patients has also confirmed that the use of NRT is not associated with an increase in the risk of myocardial infarction, stroke or death.[15] Moreover, there is no doubt at all that it is far safer than continuing the smoke.[15,16]

Although NRT has not been shown consistently to improve smoking cessation rates in this group, the broader evidence of its effectiveness is overwhelming.[17] Stopping smoking is particularly important in cardiovascular patients. However, most smokers who develop CVD are still smoking a year later. The potential benefits of NRT use by smokers with CVD therefore considerably outweigh the potential risks.

There is no direct evidence concerning how soon after an acute event (such as a stroke, myocardial infarction or surgery to relieve angina) it is safe to use NRT but the need to prevent resumed smoking is so great that it should be offered at any stage where it is clear that the alternative is smoking.

Given the theoretical potential of NRT to trigger cardiovascular events in particularly vulnerable patients, it is a sensible precaution to ensure that where a patient is under the active management of a cardiologist or cardiac surgeon, this clinician is involved in the decision to prescribe or dispense NRT.

Use of NRT by pregnant and breast-feeding smokers

The pharmacology of nicotine suggests that it may contribute to some of the damage to the fetus caused by smoking. However, this contribution is likely to be small and there is no doubt at all that NRT use is much safer than smoking. Experience of NRT use in

pregnant women has not so far been associated with significant problems.[18,19,20] Nicotine does pass to the baby through breast milk and so there is a theoretical risk that it could cause harmful effects, however in practice none have been found to date.

There is insufficient evidence to date on the effect of NRT on cessation in pregnant women and new mothers[21,22,23] but the overwhelming evidence for effectiveness generally and the need to stop smoking to protect the baby mean that NRT should be offered to pregnant smokers who have not given up and who feel that they would be unable to give up without it.

It is prudent to offer shorter acting NRT products, such as gum or lozenges rather than patches, to avoid excessive exposure to nicotine over time. However, some pregnant smokers suffering from nausea prefer to use patches, in which case it should be recommended that these not be worn overnight.

Patches are not recommended for breastfeeding women. Advice should be to breast feed just prior to using an intermittent form of NRT to minimize the amount of nicotine transmitted through breast milk.

It would therefore be sensible to adopt the following precautions in this group before prescribing NRT:

- Obtain written confirmation from the mother that the risks and benefits have been explained and understood;
- Have a system in place to ensure that the clinician (who may be the GP) overseeing the management of the pregnancy has been consulted;
- In the case of nicotine patches, recommend that the patient removes the patch at night to avoid nicotine exposure beyond that which is absolutely necessary.

Use of NRT by adolescents

There is no reason to believe that NRT use carries a significant health risk for adolescents. Studies in which NRT has been used by adolescents have found no significant problems[24,25,26]. It is also apparent that some adolescent smokers are addicted to cigarettes[27]. There is insufficient evidence on whether NRT can help this specific group to stop smoking but evidence on its effect in the general population is overwhelming and the risk associated with its use are minimal so there is no reason for it to be contraindicated in adolescents. Hanson and colleagues found that NRT reduced craving in adolescents (compared with placebo) and concluded that although larger trials were needed on efficacy, NRT was a promising treatment for adolescents[25].

Adolescent smokers are different from older smokers in that their motivation to stop smoking tends to be more unstable. It is sensible, therefore, to check that they are fully committed to trying to stop smoking permanently before offering them NRT, and to attempt to establish that they are nicotine dependent, according to earlier guidance: "In the meantime, we suggest that health professionals should assess motivation and

readiness to quit and dependency with adolescent smokers similar to their assessment of adult smokers before offering treatment. Dependence in adolescent smokers may be harder to assess than in adults, as there may be constraints on time to first cigarette of day and daily cigarette consumption, two of the standard dependency measures used with adults; nevertheless, these questions plus additional questions such as difficultly perceived in going without cigarettes, should give some indication of dependence."[28]

We encourage all health professionals to routinely advise adolescent smokers to stop and suggest that those satisfying the criteria outlined here be offered NRT under an abstinent contingency protocol.

Use of more than one NRT product concurrently

There are no grounds for believing that concurrent use of different NRT products poses a significant health risk and there is evidence that it can increase cessation rates above those obtained with one NRT form alone[29]. The combination that appears to make most sense is patch plus an acute delivery form such as gum or inhaler. The combination approved in Australia is 16 hour patch and 2mg gum. The steady nicotine delivery of the patch is enough to reduce the background withdrawal while the acute delivery system enables the user to respond to surges in craving that may arise in particular situations or at particular times.

Long-term use of NRT

NRT has no known adverse health effects from long-term use. A significant minority of smokers stopping with the aid of NRT feel it necessary to continue beyond the previously recommended (see table) 8 to 12 week treatment period[30,31]. There is some evidence of increased relapse when NRT treatment is discontinued[32]. While research with nicotine patches has not shown a clear benefit with extended use[33], there have not been adequately powered studies specifically in smokers who still feel a need for medication.
Given the safety of NRT and the clinical experience of need for continued NRT beyond the acute treatment period, it is sensible to permit smokers who feel they need it to use NRT for longer than 8 to 12 weeks.

Other changes

Several other changes have been made to the indications, including that:

- Smokers with diabetes mellitus should be advised to monitor their blood sugar levels more closely than usual when NRT is initiated because catecholamines released by nicotine can affect carbohydrate metabolism and vasoconstriction may delay/reduce insulin absorption,
- NRT should be used with caution in patients with moderate to severe hepatic impairment and/or severe renal impairment as they may be at risk of increased adverse effects.

Because of theoretical risk associated with these conditions[34,35,36] as with patients undergoing treatment for cardiovascular disease, the clinician responsible for the management of the patient should be consulted.

7. What is the process when smokers are ready to quit?

When they are ready to stop smoking, smokers may be smoking less than the recommended minimum of 10 a day for them to receive medications for their quit attempt. The consumption level used for this indication – stopping – should be their baseline smoking before they started cutting down.

8. Flow chart regarding pharmacy opportunities to provide advice to customers

The chart below details a step-wise approach for use by both pharmacists and pharmacy assistants to provide advice to customers wishing to stop smoking.

FLOW CHART RE PHARMACY OPPORTUNITES WITH CUSTOMERS FOR QUIT SMOKING

Pharmacist or pharmacy assistant response to question OR on purchase OR dispensing of product at counter: *Are you planning to stop smoking completely or are you planning on cutting down?*

Brief opportunistic advice. For example, if a client is buying cough medicine, or receiving a prescription for angina medication, then the usual approach to ask about smoking should be made.

Client: *I've stopped completely*

Client: *Don't know/ haven't decided*

Client: *I'm cutting down*

Pharmacist/staff: *Congratulations. Stopping smoking completely is the best thing you can do for your health. Are you already in contact with the Quitline?*

Pharmacist/staff: *Have you ever tried to stop completely?*

Client: *Yes OR No*

Client: *No*

Client: *Yes*

Pharmacist staff: *If there is anything I can help you with, please let me know.*

Pharmacist/staff: *Stopping smoking as soon as you can is the most important thing you can do for your health. The best way is to stop completely, use NRT and get support from trained advisors. If you can't stop completely, you can cut down and use NRT to help deal with cravings. Using NRT while you cut down is less harmful than just cutting down on cigarettes and improves your chances of stopping completely.*
Have you set yourself a goal or date for stopping smoking?

Client: *No*

Client: *Yes*

Pharmacist/staff: *Quitline can give you extra help with staying off cigarettes. They can be contacted on 13 7848. Let me know if there is anything else I can help with.*

Pharmacist/staff: *Setting yourself a goal is the best way to keep track of your smoking. Do you want to stop completely or just cut down?*

Pharmacist/staff: *Good – setting yourself a goal is the best way to keep track of your smoking. Are you going to stop completely or just cut down?*

If STOPPING COMPLETELY: give general stop smoking advice: you may also want to get help from Quitline. They can be contacted on 13 7848.

If CUTTING DOWN: we recommend you try to cut your cigarettes down by at least half (over 6 weeks) and use NRT – as this helps you deal with nicotine cravings. When you want to stop completely you can come back and see me or call the Quitline on 137848

Any smoker needing advice can contact Quitline on 13 7848 for advice and support.

Acknowledgements

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This document is available on the following websites:
- www.ashaust.org.au
- www.nicorette.com.au

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NICOTINE FACT SHEET

Myth: Nicotine causes the disease related to smoking

Fact: Cigarettes are a well-known cause of cancer, chronic lung disease, heart disease, and other disorders[1A]. It is the myriad of toxins in cigarette smoke, rather than the nicotine content, that is responsible for the majority of the harmful effects[1B]. In other words, it is the delivery system, not the addictive drug, which is responsible for the vast majority of tobacco-related diseases[1C].

Myth: Nicotine is carcinogenic

Fact: Nicotine is not proven to cause cancer[2A]. There are more than 4,000 other chemicals in cigarette smoke, many of which are known to cause cancer[1D]. The risks associated with NRT when used to help stop smoking significantly outweighed by the risks of smoking[3A].

Myth: NRT is just as bad as smoking if you have cardiovascular disease

Fact: Patients with cardiovascular disease reduce the risk of further events by stopping smoking and, therefore, should be encouraged to use the most effective therapies available to reach this goal.[4A] Trials confirm that NRT, even with concurrent smoking, demonstrates a good safety profile in patients with cardiac disease.[5A-8A]

Myth: Nicotine is responsible for adverse health effects related to smoking

Fact: The main adverse effect of nicotine in tobacco products is addiction, which sustains tobacco use[3B]. Because most smokers are nicotine-dependent, they continue to expose themselves to toxins from cigarettes. It is the harmful chemicals in cigarettes, not nicotine, which are responsible for most of the adverse health effects related to smoking.[3C]

Myth: Nicotine causes yellow stains on fingers and teeth

Fact: It is not the nicotine in cigarettes, but the tar that causes the unsightly yellow-brown stains on fingers and teeth.[9A]

Myth: NRT is more harmful than smoking because of nicotine's addictive nature

Fact: Nicotine is an addictive drug. When smoked, it is delivered into the lungs and is rapidly absorbed by the blood, reaching the brain within approximately 10 seconds[10A]. At this point, smokers experience a nicotine 'hit' – causing the brain to produce dopamines[10B], a neurotransmitter that regulates emotion and feelings of pleasure[11A]. The brain soon comes to expect regular doses of nicotine and suffers withdrawal symptoms when the supply is interrupted. The addictive nature of nicotine is largely due to its dose and rapid delivery to the brain when smoking cigarettes. Compared to cigarette smoking, NRT provides a lower dose of nicotine (without the harmful chemicals that are in

cigarettes) which is delivered more slowly, in a controlled way, and over a shorter period of time with the dose being stepped down.

Myth: NRT is no safer than smoking

Fact: The benefit of NRT used to help give up cigarettes far outweighs the risks of smoking[3D]. NRT delivers nicotine without any of the other carcinogenic elements in a cigarette. In addition the nicotine that is in NRT is manufactured through regulated pharmaceutical methods, as opposed to that in cigarettes, which is unregulated. Cigarettes contain more than 4,000 other chemicals like nitrosamines which are responsible for the harmful effects of smoking, rather than the nicotine content.

Myth: NRT substitutes one addiction for another

Fact: The addiction risk of nicotine in medications has proved to be very low compared to the risk posed by tobacco products[1E]. NRT has low abuse liability compared to tobacco products[3E]. The likelihood of abuse (ie use for reasons other than smoking cessation) and of dependence with currently available nicotine medications is very low. [3F]

Myth: NRT results in weight gain

Fact: Cigarettes contain nicotine, which acts as a stimulant, and can therefore increase metabolic rate. When individuals stop smoking their metabolic rate can decrease, which can result in weight-gain[12A]. NRT works by releasing nicotine (at a lower level than cigarettes), reducing the rate at which the metabolism decreases, which in turn may help control weight gain while stopping smoking[13A].

Myth: Nicotine is a man-made substance

Fact: Nicotine is a naturally occurring substance derived from the tobacco (*Nicotiana*) plant. Most nicotine comes from *Nicotiana tobacum*, but there are 66 other species of plants that also contain the substance[14A]. It belongs to a group of chemical compounds called alkaloids. [15A]

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