

FOREWORD

There is now a large body of evidence to show that Nicotine Replacement Therapy is extremely effective in helping smokers to quit. I am therefore pleased to see the launch of these guidelines which will provide practical information to assist those providing support to smokers to choose the most appropriate product for the individual patient. The guidelines were developed by a multidisciplinary team from across primary and secondary care and they incorporate advice from a range of reference sources including NICE guidance on the use of NRT.

This booklet is being distributed to providers of specialist smoking cessation services as well as other members of the Primary Care Team and within the Hospital and Community Trusts.

The NHSSB's Tobacco Control Group provided funding for the development and publication of this booklet and as Chair of the group, I hope you find it an invaluable resource.

Madeline Heaney

Commissioner for Health Promotion NHSSB

Feedback on the Guidelines

The group who developed this booklet is keen to have your feedback and would welcome any comments you may have. Please forward comments to:

Mrs Emer McLean
Community Pharmacy Adviser
NHSSB
County Hall
182 Galgorm Road
Ballymena BT42 1QB
Tel 028 2531 1140
e-mail emer.mclean@nhssb.n-i.nhs.uk

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CONTENTS

Section	Title	Page
1	Introduction	5
	1.1 Background	5
	1.2 Nicotine Replacement Therapy	5
2	Purpose of the Guidance	7
3	Clinical condition or situation to which the guidance applies	8
4	General Information on the Supply of NRT	10
	Cost for NRT product Course	12
5	Which Product for Which Patient?	13
	5.1 Cigarette Equivalents	13
	5.2 Adults over 18 years of age	14
	5.3 Pregnant or breastfeeding smokers	16
	5.4 Adolescent smokers	18
	5.5 Smokers with cardiovascular disease	20
6	Patches	22

7	Gum	26
8	Lozenges	29
9	Inhalator	33
10	Sublingual	35
11	Nasal Spray	37
Appendix 1	Multidisciplinary Group	39
Appendix 2	Risks and benefits in pregnancy	40
Appendix 3	Nicotine Assisted Reduction to Stop	42
	References	44

1. INTRODUCTION

1.1 Background

A key objective of the *Five Year Tobacco Action Plan* published by the Department of Health Social Services and Public Safety is to help smokers to quit. The plan is aimed at the population as a whole but identifies three key target groups that require particular attention: children and young people; disadvantaged adults; and pregnant women. Targets to increase the number of non-smokers in each of these groups have been set for the coming years.

Smoking claims between 2,700 and 3,000 lives in Northern Ireland each year. It is the single greatest preventable cause of premature death and preventable illness. Smoking is a major risk factor for coronary heart disease, stroke and other diseases of the circulatory system, which kill two in every five men and women here. Smoking is responsible for almost one in three of all cancer deaths and 84% of all lung cancer deaths. Lung cancer kills around 800 people here each year.

Second hand smoke is now also widely accepted as being harmful. Tobacco smoke contains around 4,000 chemicals and by breathing in the sidestream and mainstream smoke, the non-smoker is exposed to many of the same health risks as the smoker. Regular exposure to second hand smoke can increase the health risks of lung cancer by 20-30%, heart disease by 25-30%, stroke by 60-80% and asthma by 40-60%.

Smoking in pregnancy is associated with many problems, both for the foetus and newly born baby, including miscarriage, placenta damage, pre-term delivery, low

birthweight, perinatal death and Sudden Infant Death Syndrome.

Seven out of ten smokers say they want to quit but giving up is not easy. It is the nicotine contained in cigarettes that maintains a smoker's addiction. Therefore, when quitting it is the absence of a source of nicotine that produces the widely experienced tobacco withdrawal syndrome. This consists of symptoms such as irritability, restlessness, poor concentration, depressed mood, sleep disturbance, hunger, and perhaps more importantly, urges to smoke. For many smokers it is the occurrence of these symptoms that results in a failed quit attempt.

1.2 Nicotine Replacement Therapy

Nicotine Replacement Therapy (NRT) works by replacing some of the nicotine from cigarettes, reducing the severity of these withdrawal symptoms. Research has shown that using NRT during a quit attempt doubles a smoker's chance of giving up successfully. *The Five Year Tobacco Action Plan* also highlights the importance of NRT in smoking cessation:

The provision of NRT is an integral part of smoking cessation initiatives.in addition to current prescribing arrangements, doctors, dentists, nurses, pharmacists and other health care professionals have major roles in offering advice on these products'

It is also well recognised that behavioural support and counselling improve the quit rate for patients receiving NRT and this holistic approach is recommended in guidance published by the National Institute for Clinical Excellence (NICE). Therefore this guidance recommends that provision of NRT is accompanied by support from an

NHSSB accredited specialist support provider. An up-to-date contact list for Community Pharmacy, GP and Community, Hospital and Voluntary specialist providers is available on the NHSSB Tobacco Control Group website www.nhssbtcg.co.uk, under 'Cessation Services'. Alternatively the Tobacco Control Group Helpline (028 25311169) or the Health Promotion Agency of Northern Ireland telephone helpline (0800 85 85 85) can be called.

The White Paper '*Smoking Kills*' recommended that NRT should be provided free of charge to those smokers least able to afford it, i.e. those who are disadvantaged. Voucher schemes were introduced and then withdrawn when NRT became available on HS21 prescription. Currently only GPs and other extended rights prescribers can write prescriptions for NRT in the primary care setting. This presents supply difficulties for other health professionals who must then develop practical solutions for obtaining NRT with the client's GP practice. Until the situation is addressed it is hoped that GP practices will continue to facilitate the supply of NRT by other specialist services.

2. PURPOSE OF THE GUIDANCE

This guidance is intended to assist prescribers and others e.g. nurses, midwives, pharmacists, who provide a specialist smoking cessation service, in the choice of the most appropriate form of Nicotine Replacement Therapy for an individual patient who has set a quit date.

The intended outcomes are that:

- The most appropriate NRT product is recommended for the individual patient
- The patient is able to make an informed choice about treatment options
- The supply of medicines is appropriate, safe and cost-effective, and
- The patient is managed in a way that does not prolong the condition, mask any underlying disease and referral to a medical practitioner is encouraged where appropriate.

For full details of the NRT products included please refer to the BNF Section 4.10 'Drugs used in substance dependence'.

Each product's Summary of Product Characteristics (SPC) was used in the development of these guidelines and the information provided was more comprehensive than the BNF or MIMS, particularly in relation to contra-indications and cautions.

Information on the new indication for 'Nicotine Assisted Reduction to Stop' is included in Appendix 3.

3. CLINICAL CONDITION OR SITUATION TO WHICH THE GUIDANCE APPLIES

<i>Indications</i>	Aid to treating nicotine dependence in patients receiving specialist support from an accredited NHSSB provider.
<i>Objectives of care</i>	Tobacco abstinence
<i>Patient Groups included</i>	<ul style="list-style-type: none"> Smokers who are assessed as motivated to stop smoking by an accredited service provider.
<i>Medical advice should be sought for these three patient groups before recommending NRT.</i>	<ul style="list-style-type: none"> Smokers who are pregnant or breastfeeding who are unable to stop smoking without NRT.
	<ul style="list-style-type: none"> Young smokers 12-18 years of age who are unable to stop smoking without NRT.
	<ul style="list-style-type: none"> Smokers with cardiovascular disease including uncontrolled hypertension who are unable to stop smoking without NRT.
<i>Criteria for Exclusion</i>	<ul style="list-style-type: none"> Patients not receiving specialist support from a trained accredited NHSSB provider. Patients not sufficiently motivated to quit. Patients who have had an unsuccessful quit attempt in the last 6 months. Patients who have low nicotine dependence. Patient already using NRT. Patients with a previous serious reaction to NRT or ingredient in the product e.g. adhesive on patch. Patches only - patients with chronic generalised skin disease such as psoriasis, chronic dermatitis and urticaria. Nasal spray only - patients with chronic nasal disorders such as polyposis, vasomotor rhinitis and perennial rhinitis or recent nasal surgery.
<i>Patients requiring drug monitoring</i>	Cigarette smoke appears to stimulate liver enzymes resulting in a more rapid breakdown of some drugs and smokers may then require an increase in medicine dose. If the patient then stops smoking a subsequent dose adjustment may be required e.g.

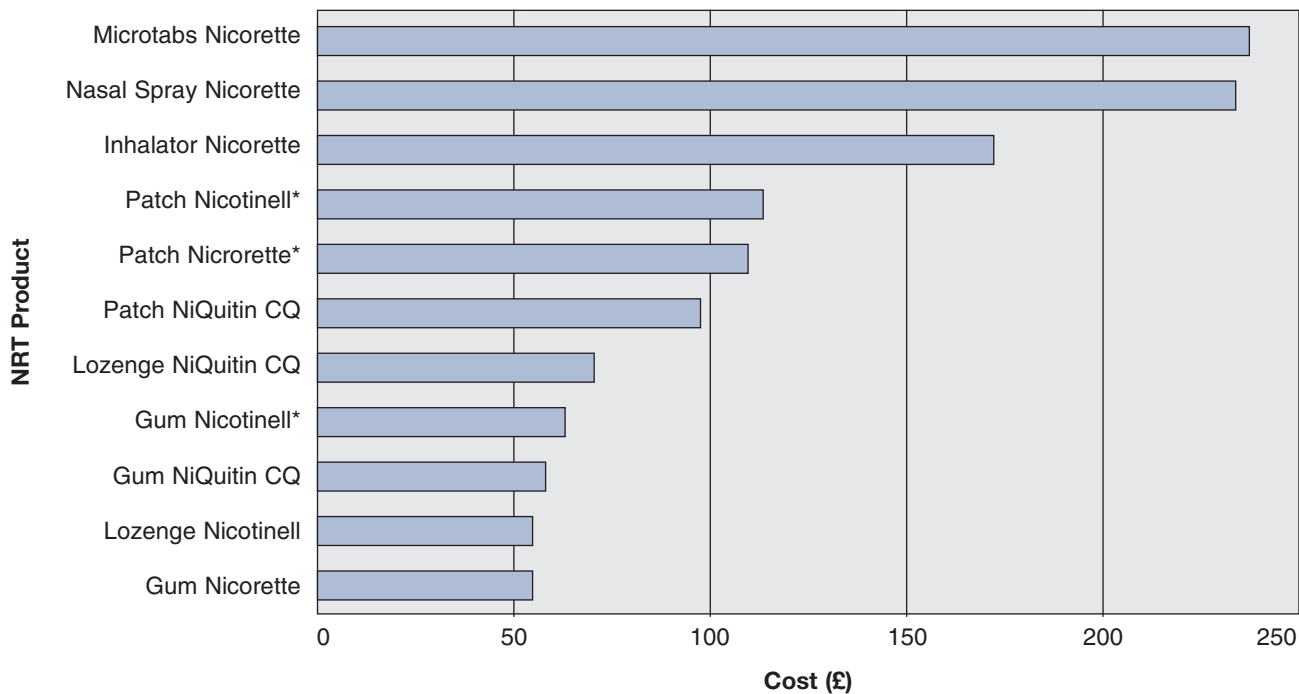
	<ul style="list-style-type: none"> • Patients taking Theophylline should be referred for drug monitoring as stopping smoking increases plasma levels. A reduction in dosage of up to 25-33% may be needed after a week • Stopping smoking has a slight to moderate effect on the response to Warfarin and only the occasional patient will need a small dosage alteration. This should easily be detected in the course of routine INR checks. • Stopping smoking may cause alterations in the circulating levels of some of the following (but not normally enough to cause therapeutic problems): <ul style="list-style-type: none"> • Insulin (increased effect) • Propranolol • Pentazocine • Dextropropoxyphene • Amitriptyline • Imipramine • Nortriptyline
<p><i>Action if patient is excluded</i></p>	<p>Discuss reason for exclusion and refer for medical advice if appropriate.</p> <p>Refer to person providing specialist support, if reason for exclusion is that client is not receiving specialist support.</p>
<p><i>Criteria for referral for medical advice</i></p>	<p>When NRT is thought appropriate but supply through a non-prescriber is not appropriate for one of the reasons listed in the exclusion criteria.</p>

4. GENERAL INFORMATION ON SUPPLY OF NRT

<p><i>Formulation, strength and legal status</i></p> <p><i>GSL = General Sales List medicine</i></p> <p><i>P = Pharmacy medicine</i></p>	<p>NRT is available in the following forms:</p> <ul style="list-style-type: none"> • Patch 5mg/16hrs, 10mg/16hrs, 15mg/16hrs (all GSL) 7mg/24hrs, 14mg/24hrs, 21mg/24hrs (all GSL) • Gum 2mg and 4mg (all GSL) • Lozenge Nicotinell 1mg & 2mg & Niquitin CQ Mint 4mg (all GSL), Niquitin CQ 2mg (GSL) • Sublingual tablet 2mg (P) • Inhalator 10mg/cartridge (P) • Nasal Spray 500micrograms per metered spray (P)
<p><i>Quantity to be supplied</i></p>	<p>Treatment periods vary according to the type of NRT used but should initially be prescribed for 2 weeks.</p> <p>Community Pharmacists providing a specialist service will dispense prescriptions weekly when patients attend for counselling and support, as part of their Service Level Agreement. In this case, prescriptions can be written for 28 days as payment will only be claimed for the NRT supplied each week.</p> <p>GPs should generate prescriptions as 'ACUTES' and not 'REPEATS' as the dose and quantity required changes throughout the course of treatment.</p> <p>Prescribers in secondary care who are asking a GP to continue to prescribe on discharge from hospital are requested to take note of the products available in primary care and their associated costs. (Refer to the graph on page 12).</p>

<i>Length of Treatment</i>	The duration of use should be limited to that indicated in the particular product's license and detailed in this guidance. Most products require a reduction in dose over time.
<i>Undesirable effects</i>	<p>These are usually transient but may include the following, some of which may be a consequence of stopping smoking;</p> <p>Common: Headache, dizziness, nausea, gastro-intestinal discomfort, dyspepsia, hiccups.</p> <p>Uncommon or rare: Confusion, weakness, severe headache, irregular heartbeat, chest pain, stomach pain, vision or hearing changes are more serious side effects of nicotine and may indicate overdosing.</p> <p>Formulation specific effects are detailed in the product section.</p>
<i>Patient advice</i>	<p>Patients should be given specific advice on the NRT product supplied.</p> <p>Additional information should also be provided when necessary e.g. telephone numbers of Help Lines, booklets etc. (Stop Smoking Helpline 0800 85 85 85).</p>
<i>Reporting of adverse reactions</i>	<p>NRT is a well established drug and some adverse events are to be expected. Any adverse event should be reported to the Medicines and Healthcare Products Regulatory Agency in the normal manner through the Yellow Card Scheme if appropriate.</p> <p>If the patient agrees also inform the GP or Consultant of the supply and adverse event.</p>
<i>Records</i>	A record of prescribing or supply should be maintained.

COST OF NRT COURSE FOR PATIENTS SMOKING > 20 CIGARETTES A DAY



Costs based on MIMS August 2005 and reducing doses as indicated in the SPC. * Hospital Contract products

Average cost of smoking 20 cigarettes a day = £438 over 3 months

5. WHICH PRODUCT FOR WHICH PATIENT?

There is currently insufficient evidence to conclude that one form of NRT is more effective than another but there is considerable cost variation across the available products (see the graph on page 12). In deciding which of the available therapies to use and in which order they should be prescribed, practitioners should take into account:

- Intention and motivation to quit, and likelihood of compliance
- The availability of counselling and support
- Previous usage of smoking cessation aids
- Contraindications and potential for adverse effects
- Personal preferences of the smoker.

A full account from the patient regarding their individual smoking habits is required to assess the most appropriate level of nicotine replacement. The initial dose should be matched to the dose of nicotine that would normally be received from smoking.

If the smoker has been using NRT products to cut down, the dose for cessation should be based on the number of cigarettes smoked prior to cutting down.

To help in the choice of product, the following colour coded flowcharts and information will help you decide the most appropriate formulation for the individual patient.

5.1 CIGARETTE EQUIVALENTS

The charts and product information provide guidance based on the number of cigarettes smoked and the following information can be used to calculate 'cigarette equivalents' for smokers who use other types of tobacco.

Pipe Smokers

- One bowl of tobacco is roughly equivalent to 2.5 cigarettes

Cigar Smokers

- One Café Crème (or similar small size cigar) is equivalent to approximately 1.5 cigarettes
- One Hamlet (or similar medium size cigar) is equivalent to approximately 2 cigarettes
- One Havana (or similar large size cigar) is equivalent to approximately 4 cigarettes.

Roll-your-own Smokers

In the absence of a smoker being able to indicate how many roll-ups they smoke a day, the following can be used:

- 25 gms (1 oz) of tobacco is approximately equivalent to 50 cigarettes

The smoker can be asked how many ounces of tobacco are smoked each week and a daily 'cigarette equivalent' calculated.

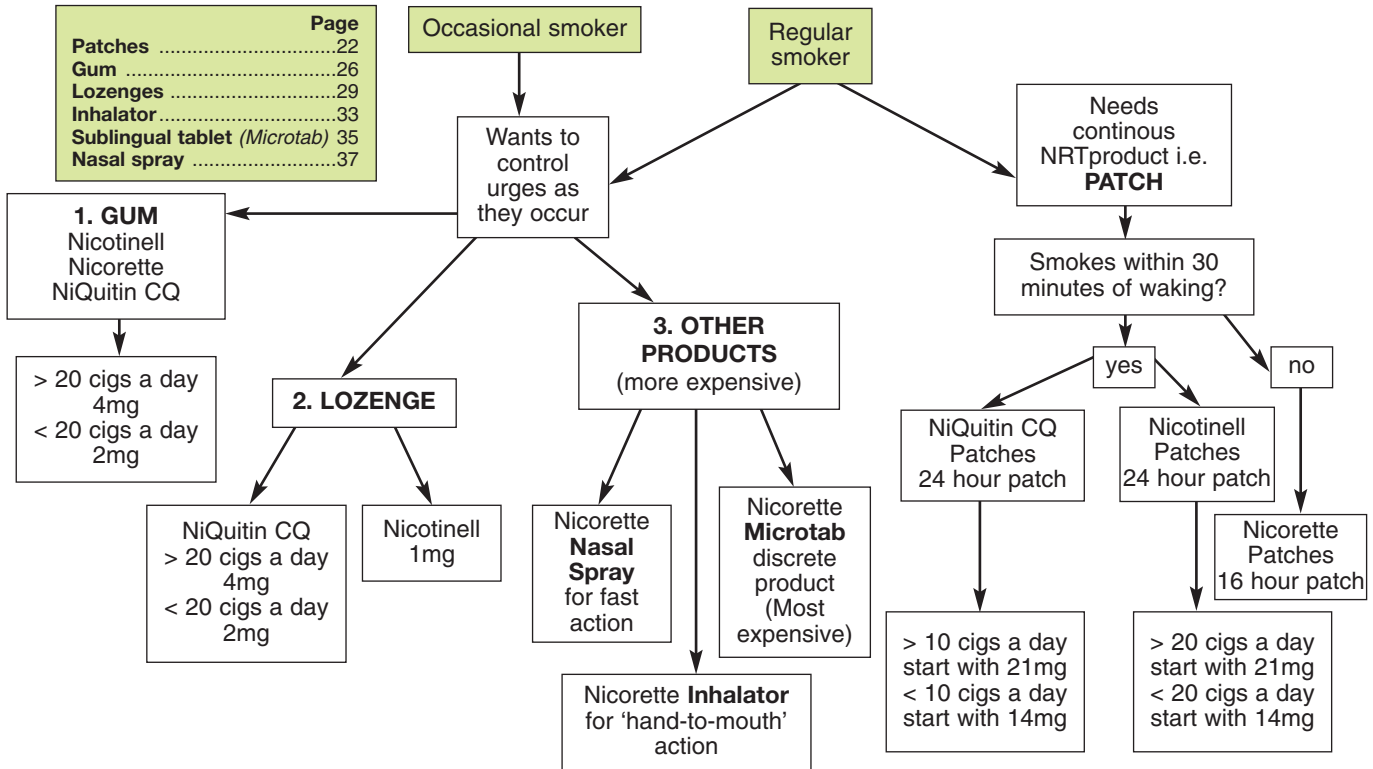
5.2 ADULTS OVER 18 YEARS OF AGE

The following flowchart relates to adults over 18 years of age who are not pregnant or breastfeeding, do not have cardiovascular disease or any other disease for which NRT is contraindicated.

FACT

- Smoking may increase the risk of male sexual impotence by 50% but sexual function can improve rapidly on quitting.
- Smoking can reduce the chance of conception by 10-40% per cycle.

FLOWCHART FOR CHOOSING NRT PRODUCT FOR ADULT > 18 YEARS



5.3 PREGNANT OR BREASTFEEDING SMOKERS

Pregnant smokers are one of the key target groups identified in *A Five Year Tobacco Action Plan* which aims to increase the proportion of pregnant women who do not smoke.

A number of NRT products are contraindicated for use by pregnant or breast feeding smokers and the Summary of Product Characteristics for others caution its use and recommend that NRT is only used after discussion with a physician for a risk-benefit assessment. This is similar to the NICE Guidance which recommends that smokers who are pregnant or breastfeeding should discuss the use of NRT with a relevant healthcare professional before it is prescribed.

This guidance for pregnant or breastfeeding smokers only contains NRT products that are not contraindicated for use in pregnancy or breastfeeding. The goal for treatment is to limit the exposure of the mother and foetus to the minimum effective dose of nicotine and to use intermittent-use formulations as a preferred delivery system. Patches are therefore excluded from this guidance.

When giving advice to pregnant or breastfeeding smokers who have been unable to quit without a cessation aid, healthcare professionals should take into account the significant harm associated with continuing to smoke, and that it can be expected that NRT will deliver less nicotine (and none of the other potentially disease causing agents) that would be obtained from cigarettes.

It is important that the pregnant smoker and her partner are fully informed regarding the risks vs. benefits of smoking or using NRT in pregnancy to enable them to make an informed decision. See Appendix 2 for further information.

Pregnant smokers should not be sent away to try an unaided quit attempt with a requirement to fail first before receiving treatment, but referred to an accredited specialist provider for assessment, advice and behavioural support.

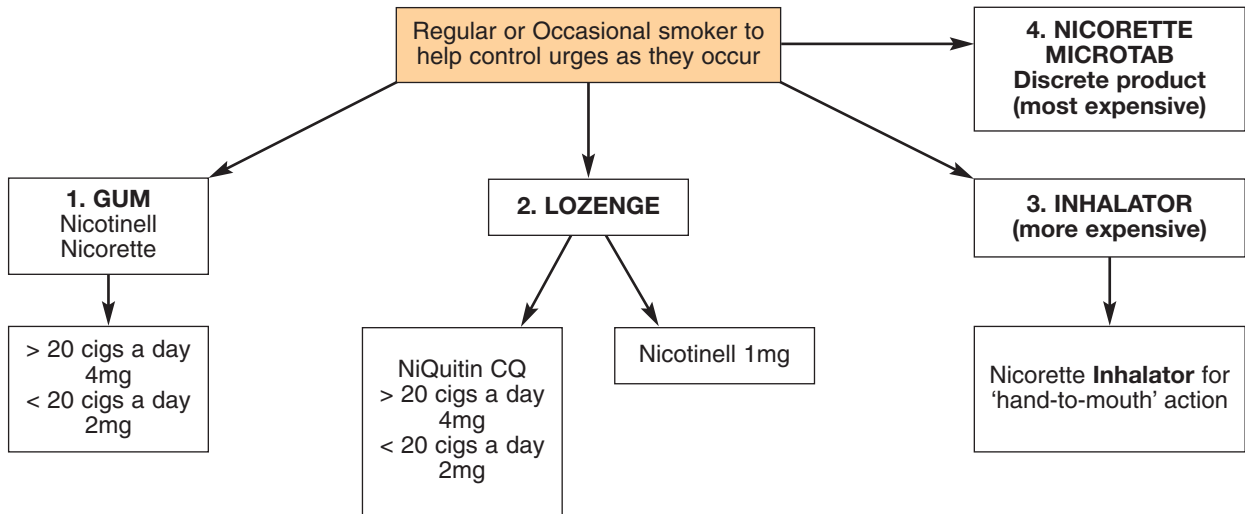
FACT

- Smoking in pregnancy is the largest preventable cause of foetal and infant ill-health and death.
- Stopping smoking at any stage during pregnancy is beneficial.

FLOWCHART FOR CHOOSING NRT PRODUCT FOR A PREGNANT OR BREASTFEEDING SMOKER

Pregnant or breastfeeding smokers should be advised to stop smoking without NRT, but with counselling and support.

If they fail, the following products can be tried but please note that although the products are not contraindicated in pregnancy or breastfeeding, medical advice on risk/benefit should be sought.



	Page
Gum	26
Lozenges	29
Inhalator	33

5.4 ADOLESCENT SMOKERS

It is widely accepted that most smokers start young, become addicted to tobacco or the habit of smoking and continue smoking into their adult life. In the UK smoking rates among girls of 15 years of age are 33% compared to 28% for boys. In NI a recent survey has reported that 30.6% of 5th form girls and 14.3% of boys smoke every day.

As a result children and young people are one of the key target groups identified in *A Five Year Tobacco Action Plan*, with an aim of increasing the proportion of 11-16 year old children who do not smoke from 86.5% in 2000 to 89% by 2006.

A number of NRT products are contraindicated for use by adolescents under 18 years of age because there is no experience in treating this group with NRT. Some Summary of Product Characteristics sheets caution its use and recommend that NRT is only used after discussion with a physician for a risk-benefit assessment. This is similar to the NICE Guidance which recommends that smokers who are under the age of 18 years should discuss the use of NRT with a relevant healthcare professional before it is prescribed.

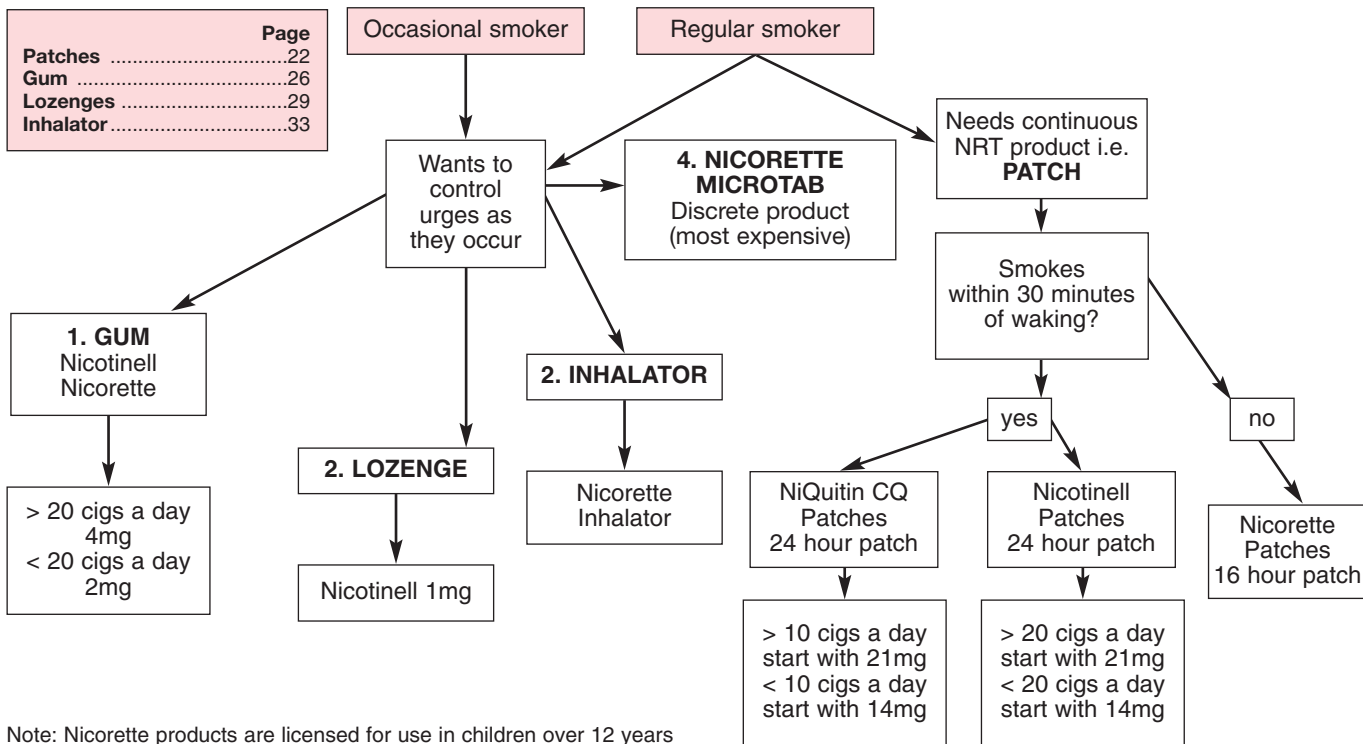
This guidance for adolescents only contains NRT products that are not contraindicated for use in those under 18 years of age.

FACT

- The average cost of smoking 20 cigarettes a day = £438 over 3 months.
- Tobacco smoke contains around 4,000 chemicals.

FLOWCHART FOR CHOOSING NRT PRODUCT FOR AN ADOLESCENT 12-18 YEARS OF AGE

Note: These products are not contraindicated in 12-18 year olds but medical advice on risk/benefit should be sought before recommending



Note: Nicorette products are licensed for use in children over 12 years

5.5 SMOKERS WITH CARDIOVASCULAR DISEASE

As already stated smoking is a major contributory factor to cardiovascular disease. However a number of Nicotine Replacement Therapies are contraindicated in patients who have unstable cardiovascular disorders: during the immediate post-infarction period; unstable angina pectoris (including Prinzmetal's angina); severe cardiac arrhythmias; and recent cerebrovascular accident.

NICE Guidance recommends that this group of smokers should discuss the use of NRT with a relevant healthcare professional before it is prescribed or supplied. Careful risk-benefit assessment should be carried out and NRT should only be used if the patient has found it impossible to quit without NRT.

The Summary of Product Characteristics for most NRT products also recommend that NRT should be used with caution in patients with hypertension, stable angina pectoris, cerebrovascular disease, occlusive peripheral arterial disease and heart failure.

This guidance for patients with cardiovascular disease therefore only includes NRT products which are not contra-indicated for patients with unstable cardiovascular disease which include:

- Patients with severe cardiovascular disease, including arrhythmias
- Patients with a history of a recent cardiovascular or cerebrovascular event. (Recent = one month).

Cardiologists generally aim to prescribe NRT to patients once their condition is stable during an in-patient stay or on discharge, however on occasions this may not occur. A patient's condition would be considered stable if they are discharged, and the provision of NRT can be followed up safely in primary care. It is considered safer for the patient to have NRT than to continue to smoke. If a GP has concerns about initiating NRT in a patient recently discharged following a cardiovascular event, he/she should contact the patient's consultant.

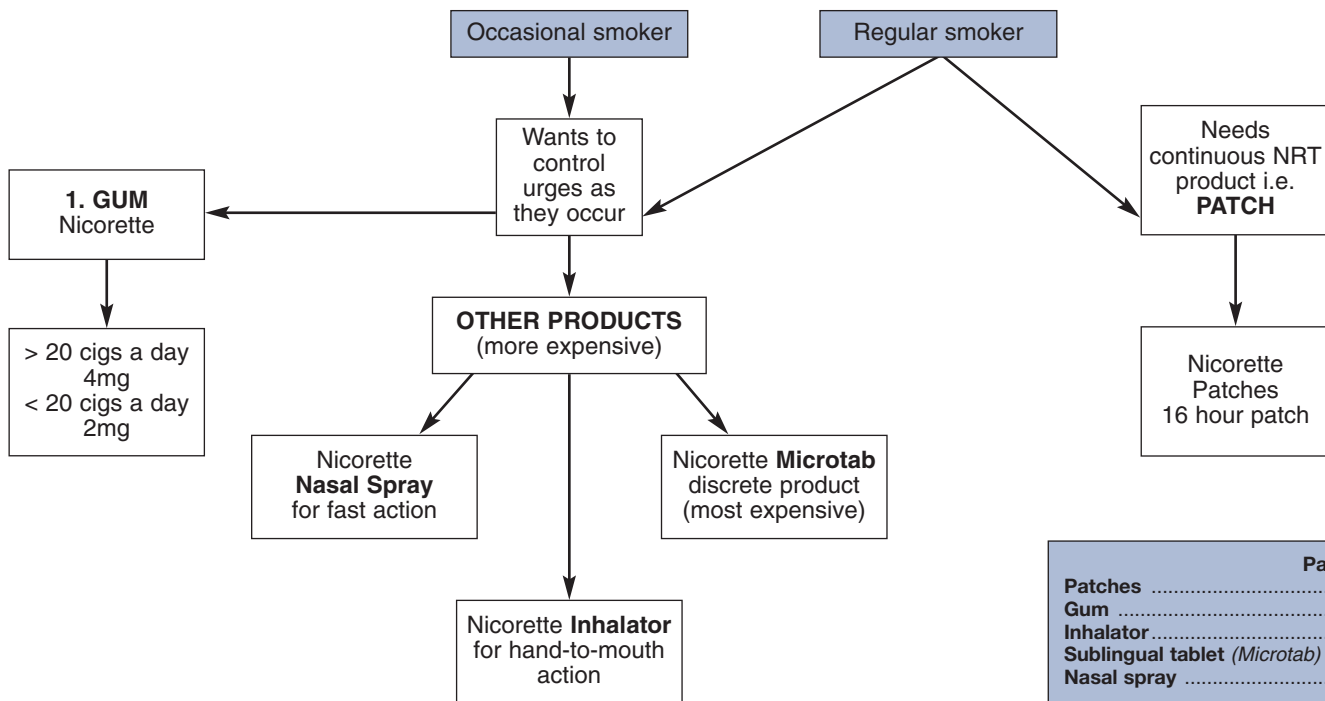
FACT

- Regular exposure to second hand smoke can increase the health risks of heart disease by 25-30%.
- 1 year after quitting, the risk of heart attack falls to half that of a smoker.

FLOWCHART FOR CHOOSING NRT PRODUCT FOR ADULT > 18 YEARS WITH CARDIOVASCULAR DISEASE

Adults with cardiovascular disease should be advised to try to stop smoking first without NRT.

If they fail, the following products can be tried but please note that although the products are not contraindicated in cardiovascular disease, medical advice on risk/benefit should be sought.



	Page
Patches	22
Gum	26
Inhalator	33
Sublingual tablet (Microtab)	35
Nasal spray	37

6. PATCHES

Patient Group Information

Patches are most suited to those with a regular pattern of smoking. A 24 hour patch is recommended for patients who smoke first thing in the morning or those who smoke throughout the night.

The 16 hour patch is suitable for patients who do not smoke first thing in the morning or who have experienced sleep disturbances with the 24 hour patch.

Patches as detailed below can be used for:

- adults over 18 years of age
- young people 12-18 years and
- adults with cardiovascular disease.

Patches should **not** be used for occasional smokers or pregnant or breastfeeding women.

Method of Administration

Transdermal administration.

Apply on waking to dry, non-hairy skin on hip, chest or upper arm. Remove after specified time. (16 hour patches should be removed at bedtime).

New patch should be placed on a different area - avoiding “used” sites for several days afterwards.

If successful then gradually reduce dosage with time but review treatment if individual has not stopped smoking at 12 weeks.

Dose

FOR ADULTS OVER 18 YEARS OF AGE

Nicorette (16 hour patch)

15mg patch daily for 8 weeks, then

10mg patch daily for 2 weeks, then

5mg patch daily for 2 weeks then review treatment

Pack size = 7

Nicotinell (24 hour patch)**21mg patch**

For individuals smoking more than 20 cigarettes per day - one patch (21mg) daily.

14mg patch

For individuals smoking 20 cigarettes or less per day - one patch (14mg) daily

7mg patch

Used in gradual withdrawal process.

It is recommended that smokers begin treatment with one of the stronger patches and withdraw treatment gradually reducing the dose every 3-4 weeks.

Pack size = 7

NiQuitin CQ (24 hour patch)

For individuals smoking 10 or more cigarettes daily:

21mg patch daily for 6 weeks THEN

14mg patch daily for 2 weeks THEN

7mg patch daily for 2 weeks THEN review treatment

Individuals who experience persistent side effects with the 21mg patch should switch to the 14mg for the remainder of the 6 weeks followed by the 7mg patch for 2 weeks as above.

For individuals smoking less than 10 cigarettes per day:

14mg patch daily for 6 weeks THEN

7mg patch daily for 2 weeks THEN review treatment

Pack size = 7. Also available as a clear patch

FOR YOUNG PEOPLE 12-18 YEARS**Nicorette (16 hour patch)**

15mg patch daily for 8 weeks THEN

10mg patch daily for 2 weeks THEN

5mg patch daily for 2 weeks THEN review treatment

Pack size = 7

Nicotinell - 21mg patch

For individuals smoking more than 20 cigarettes per day - one patch (21mg) daily.

Nicotinell - 14mg patch

For individuals smoking 20 cigarettes or less per day - one patch (14mg) daily.

Nicotinell - 7mg patch

For individuals smoking 10 cigarettes or less per day - one patch (7mg) daily. It is recommended that smokers begin treatment with one of the stronger patches. Withdraw treatment gradually reducing the dose every 3-4 weeks.

Pack size = 7

NiQuitin CQ

For individuals smoking 10 or more cigarettes daily:

21mg patch daily for 6 weeks THEN

14mg patch daily for 2 weeks THEN

7mg patch daily for 2 weeks THEN review treatment

Individuals who experience persistent side effects with the 21mg patch should switch to the 14mg for the remainder of the 6 weeks followed by the 7mg patch for 2 weeks as above.

NiQuitin CQ

For individuals smoking less than 10 cigarettes per day:

14mg patch daily for 6 weeks THEN

7mg patch daily for 2 weeks THEN review treatment

Pack size = 7. Also available as a clear patch

FOR ADULTS WITH CARDIOVASCULAR DISEASE**Nicorette (16 hour patch)**

15mg patch daily for 8 weeks THEN

10mg patch daily for 2 weeks THEN

5mg patch daily for 2 weeks THEN review treatment

Pack size = 7

Specific Side Effects

Skin reactions. Discontinue use if severe.

Specific Advice to Patient

Exercise may increase absorption of nicotine and therefore side effects.

The patch should be applied once a day, normally in the morning to a clean, dry, non-hairy area of skin on the hip or upper arm.

Allow several days before replacing the patch on previously used area. Place the patch on the palm of the hand and hold onto the skin for 15-20 seconds.

Patches should not be applied to broken or inflamed skin.

Once the patch is spent (used) it should be folded in half and disposed of carefully in normal domestic waste.

Patients should not try to alter the dose of the patch by cutting it up.

Patients should be advised to read the Patient Information Leaflet.

7. GUM

Patient Group Information

Gum is suitable for patients who require a flexible regime of nicotine dosing to control cravings as they occur.

Gum as detailed below can be used for:

- adults over 18 years of age
- pregnant women
- young people 12-18 years and
- adults with cardiovascular disease.

Gum is **not suitable** for patients with dentures.

Method of Administration

Gum should be chewed until the taste becomes strong and then “parked” between the gum and cheek until the taste fades. Recommence chewing once the taste has faded. This “chew-rest-chew” technique should be applied for 30 minutes.

Dose

FOR ADULTS OVER 18 YEARS OF AGE

Nicotinell - 2mg gum and 4mg gum

Pack size = 12, 24 or 96

Flavours = mint, fruit or liquorice and unflavoured classic.

Nicorette - 2mg gum and 4mg gum

Pack size = 30 or 105

Flavours = original, mint or fresh-mint

NiQuitin CQ - 2mg gum and 4mg gum

Pack size = 12, 24 or 96

Flavours = mint

Individuals smoking more than 20 cigarettes daily, 4mg each hour.

Maximum number of pieces a day: 15 pieces of 4mg gum.

For individuals smoking 20 cigarettes or less daily - one 2mg piece chewed slowly for 30 minutes on urge to smoke. Individuals needing more than 15 pieces of 2mg gum a day should consider the 4mg gum instead.

Sufficient gum should be used each day - 8-12 pieces

Treatment should be continued for at least 3 months followed by a gradual reduction in dosage.

FOR PREGNANT AND BREAST FEEDING SMOKERS

Nicotinell - 2mg gum and 4mg gum

Pack size = 12, 24 or 96

Flavours = mint, fruit and unflavoured classic.

NB Liquorice flavour contra-indicated

For individuals smoking more than 20 cigarettes daily, 4mg each hour.

Maximum number of pieces a day: 15 pieces of 4mg gum.

For individuals smoking 20 cigarettes or less daily - one 2mg piece chewed slowly for 30 minutes on urge to smoke.

Individuals needing more than 15 pieces of 2mg gum a day should consider the 4mg gum instead.

Nicorette - 2mg gum and 4mg gum

Pack size = 30 or 105

Flavours = original, mint or fresh-mint

Individual smoking more than 20 cigarettes daily, 4mg each hour.

Maximum number of pieces a day: 15 pieces of 4mg gum.

For individual smoking 20 cigarettes or less daily - one 2mg piece chewed slowly for 30 minutes on urge to smoke.

Individual needing more than 15 pieces of 2mg gum a day should consider the 4mg gum instead.

Treatment should be continued for at least 3 months followed by a gradual reduction in dosage.

The gum should be used after breastfeeding and not during the two hours before breastfeeding.

In the third trimester nicotine has haemodynamic effects (e.g. changes in the foetal heart rate) which could affect the foetus close to delivery. The gum should only be used after the sixth month of pregnancy under medical supervision in pregnant smokers who have failed to stop by the third trimester.

FOR YOUNG PEOPLE 12-18 YEARS OF AGE

Nicotinell - 2mg gum and 4mg gum

Pack size = 12, 24 or 96

Flavours = mint, fruit or liquorice and unflavoured classic.

Nicorette - 2mg gum and 4mg gum

Pack size = 30 or 105

Flavours = original, mint or fresh-mint

Individual smoking more than 20 cigarettes daily, 4mg each hour.

Maximum number of pieces a day: 15 pieces of 4mg gum.

For individual smoking 20 cigarettes or less daily - one 2mg piece chewed slowly for 30 minutes on urge to smoke.

Individual needing more than 15 pieces of 2mg gum a day should consider the 4mg gum instead.

Treatment should be continued for at least 3 months followed by a gradual reduction in dosage.*

* If needed for longer than 8 weeks medical advice should be sought

FOR ADULTS WITH CARDIOVASCULAR DISEASE

Nicorette - 2mg gum and 4mg gum

Pack size = 30 or 105

Flavours = original, mint or fresh-mint

Individual smoking more than 20 cigarettes daily, 4mg each hour.

Maximum number of pieces a day: 15 pieces of 4mg gum.

For individual smoking 20 cigarettes or less daily - one 2mg piece chewed slowly for 30 minutes on urge to smoke.

Individual needing more than 15 pieces of 2mg gum a day should consider the 4mg gum instead.

Treatment should be continued for at least 3 months followed by a gradual reduction in dosage.

Specific Side Effects

Throat irritation, increased salivation, hiccups.

Specific Advice to Patient

Acidic beverages such as coffee or soda should be avoided for 15 minutes prior to using the gum.

8. LOZENGES

Patient Group Information

Lozenges are suitable for patients who require a flexible regime of nicotine dosing to control cravings as they occur. The Niquitin CQ 4mg lozenge is recommended for patients who need to smoke within 30 minutes of waking.

Lozenges as detailed below can be used for:

- adults over 18 years of age
- pregnant women and
- young people 12-18 years

Method of Administration

Initially, 1 lozenge to be sucked every 1-2 hours when the smoker feels the urge to smoke.

Nicotinell 1 & 2mg Lozenge

Dose

FOR ADULTS OVER 18 YEARS OF AGE

Nicotinell 1mg & 2mg Lozenge (Sugar free)

The usual dose is 8-12 lozenges per day. The maximum daily dose is 30 x 1mg or 15 x 2mg lozenges. Treatment should be continued for at least 3 months followed by a gradual reduction in the dose (2mg to 1mg if appropriate) and then number of lozenges used. Treatment should be discontinued when the dose has been reduced to 1-2 lozenges per day.

Use beyond 6 months is generally not recommended.

FOR PREGNANT AND BREASTFEEDING WOMEN

Nicotinell 1mg & 2mg Lozenge (Sugar free)

The usual dose is 8 - 12 lozenges per day. The maximum daily dose is 30 x 1mg or 15 x 2mg lozenges. Treatment should be continued for at least 3 months followed by a gradual reduction in the dose (2mg to 1mg if appropriate) and then number of lozenges used. Treatment should be discontinued when the dose has been reduced to 1-2 lozenges per day. **Use beyond 6 months is generally not recommended.**

Immediately after breastfeeding is the optimal time for use.

Use should be avoided in the two hours before breastfeeding.

In the third trimester nicotine has haemodynamic effects (e.g. changes in the foetal heart rate) which could affect the foetus close to delivery. The lozenge should only be used after the sixth month of pregnancy under medical supervision in pregnant smokers who have failed to stop by the third trimester.

FOR YOUNG PEOPLE AGE 12-18 YEARS

Nicotinell 1mg & 2mg Lozenges (Sugar free)

The usual dose is 8-12 lozenges per day. The maximum daily dose is 30 x 1mg or 15 x 2mg lozenges. Treatment should be continued for at least 3 months followed by a gradual reduction in the dose (2mg to 1mg if appropriate) and then number of lozenges used. Treatment should be discontinued when the dose has been reduced to 1-2 lozenges per day. **Use beyond 6 months is generally not recommended.**

Specific Side Effects

Throat irritation, increased salivation, hiccups, slight dyspepsia or heartburn.

Specific Advice to Patient

Direction for use:

1. One lozenge to be sucked until the taste becomes strong.
2. The lozenge should then be lodged between the gum and cheek.
3. When the taste fades, sucking of the lozenge should commence again.

The lozenge will take about 30 minutes to dissolve completely.

Slower sucking usually prevents side effects.

Simultaneous use of coffee, acid drinks and soft drinks may decrease absorption of nicotine and should be avoided for 15 minutes prior to and whilst sucking lozenge.

NiQuitin CQ Lozenges

Dose

ADULTS OVER 18 YEARS OF AGE

NiQuitin CQ 2mg and 4mg Lozenges

Smokers who have their first cigarette of the day more than 30 minutes after waking up should use the 2mg lozenge. Smokers who have their first cigarette within 30 minutes of waking up should use the 4mg lozenge.

Week 1 to 6: 1 lozenge every 1 to 2 hours (recommended that users take a minimum of 1 lozenge per day)

Weeks 7 to 9: 1 lozenge every 2 to 4 hours

Weeks 10 to 12: 1 lozenge every 4 to 8 hours

Weeks 13 to 24: 1 to 2 lozenges per day on occasions when strongly tempted to smoke

During weeks 1-6 a minimum of 9 and maximum of 15 lozenges should be used each day.

Lozenges should not be used for more than 24 weeks.

FOR PREGNANT AND BREASTFEEDING WOMEN

NiQuitin CQ 2mg and 4mg Lozenges

Smokers who have their first cigarette of the day more than 30 minutes after waking up should use the 2mg lozenge. Smokers who have their first cigarette within 30 minutes of waking up should use the 4mg lozenge.

Weeks 1 to 6: 1 lozenge every 1 to 2 hours (recommended that users take a minimum of 1 lozenge per hour)

Weeks 7 to 9: 1 lozenge every 2 to 4 hours

Weeks 10 to 12: 1 lozenge every 4 to 8 hours

Weeks 13 to 24: 1 to 2 lozenges per day on occasions when strongly tempted to smoke. Lozenges should not be used for more than 24 weeks.

Specific Side Effects

Mouth irritation, mouth ulceration, tongue ulceration, pharyngitis.

Specific Advice to Patient

One lozenge should be placed in the mouth and allowed to dissolve.

Periodically, the lozenge should be moved from one side of the mouth to the other and repeated until the lozenge is completely dissolved (approx. 20-30 minutes). The lozenge should not be chewed or swallowed whole. Simultaneous use of coffee, acid drinks and soft drinks may decrease absorption of nicotine and should be avoided for 15 minutes prior to and whilst sucking lozenge.

9. INHALATOR

Patient Group Information

The inhalator is useful for patients who miss the 'hand-to-mouth' action of smoking. It is suitable for patients who require a flexible regime of nicotine dosing to control cravings as they occur. The inhalator can be used for:

- adults over 18 years of age
- young people 12-18 years old
- pregnant or breastfeeding smokers
- adults with cardiovascular disease

Method of Administration

Oral administration (the nicotine is not inhaled but absorbed through the lining of the mouth from the nicotine-impregnated plug in the mouthpiece).

Dose

ADULTS OVER 18 YEARS OF AGE

Nicorette inhalation cartridge 10mg plus mouthpiece

Pack size = 6 or 42 (Refill pack also available)

Inhale when urge to smoke occurs as in previous smoking habit.

Advise using 6-12 Cartridges daily (10mg = 1 cartridge) for up to 8 weeks THEN

Reduce the dose to 3-6 cartridges over the next 2 weeks THEN reduce to 0 over next 2 weeks.

Review treatment if abstinence not achieved in 3 months.

FOR PREGNANT AND BREASTFEEDING SMOKERS

Nicorette inhalation cartridge 10mg plus mouthpiece

Pack size = 6 or 42 (Refill pack also available)

Inhale when urge to smoke occurs as in previous smoking habit.

Advise using 6-12 Cartridges daily (10mg = 1 cartridge) for up to 8 weeks THEN

Reduce the dose to 3-6 cartridges over the next 2 weeks THEN Reduce to 0 over next 2 weeks.

Review treatment if abstinence not achieved in 3 months.

FOR YOUNG PEOPLE AGE 12-18 YEARS

Nicorette inhalation cartridge 10mg plus mouthpiece

Pack size = 6 or 42 (Refill pack also available)

Inhale when urge to smoke occurs as in previous smoking habit.

Advise using 6-12 Cartridges daily (10mg = 1 cartridge) for up to 8 weeks THEN

Reduce the dose to 3-6 cartridges over the next 2 weeks THEN reduce to 0 over next 2 weeks.

Review treatment if abstinence not achieved in 3 months.

ADULTS WITH CARDIOVASCULAR DISEASE

Nicorette inhalation cartridge 10mg plus mouthpiece

Pack size = 6 or 42 (Refill pack also available)

Inhale when urge to smoke occurs as in previous smoking habit.

Advise using 6-12 Cartridges daily (10mg = 1 cartridge) for up to 8 weeks THEN

Reduce the dose to 3-6 cartridges over the next 2 weeks THEN reduce to 0 over next 2 weeks.

Review treatment if abstinence not achieved in 3 months.

Specific Side Effects

Throat irritation, cough, rhinitis, pharyngitis, stomatitis and dry mouth.

Specific Advice to Patient

Air should be drawn into the mouth through the mouthpiece. Patients should be warned that the inhalator requires more effort to inhale than a cigarette. Deep drawing or short sucks on the mouthpiece can be used as techniques and after about 20 minutes of intense use the maximal dose will be achieved.

The inhalator is best used at room temperature as nicotine delivery is affected by temperature.

Used cartridges will contain residual nicotine and should be disposed of safely. Advise the patient to keep them in the case and dispose of them in household rubbish.

10. SUBLINGUAL TABLET

Patient Group Information

The sublingual tablets are useful for patients who prefer a discreet product. They are suitable for patients who require a flexible regime of nicotine dosing to control cravings as they occur. Sublingual tablets can be used for:

- adults over 18 years of age
- pregnant and breastfeeding smokers
- adults with cardiovascular disease
- adolescents 12-18 years of age.

Method of Administration

Sublingual tablet to be placed under the tongue, and allowed to dissolve slowly.

Dose

ADULTS OVER 18 YEARS OF AGE

Nicorette 2mg Microtab

One tablet per hour or, for heavy smokers smoking more than 20 cigarettes per day, two tablets per hour.

Maximum daily dose: 40 tablets

Treatment should be continued for at least 3 months followed by a gradual reduction in the number of tablets used. Treatment should be discontinued when the dose has been reduced to 1-2 tablets per day. **Use beyond 6 months is generally not recommended**

ADULTS WITH CARDIOVASCULAR DISEASE

Nicorette 2mg Microtab

One tablet per hour or, for heavy smokers smoking more than 20 cigarettes per day, two tablets per hour.

Maximum daily dose: 40 tablets

Treatment should be continued for at least 3 months followed by a gradual reduction in the number of tablets used. Treatment should be discontinued when the dose has been reduced to 1-2 tablets per day. **Use beyond 6 months is generally not recommended**

Specific Side Effects

Heartburn, mouth irritation, hiccups, nausea, dizziness, unpleasant taste, headache, sensation of a lump in the throat, palpitation and atrial fibrillation.

Specific Advice to Patient

Explain method of administration as above.

PREGNANT AND BREASTFEEDING SMOKERS

Nicorette 2mg Microtab

One tablet per hour or, for heavy smokers smoking more than 20 cigarettes per day, two tablets per hour.

Maximum daily dose: 40 tablets

Treatment should be continued for at least 3 months followed by a gradual reduction in the number of tablets used.

Treatment should be discontinued when the dose has been reduced to 1-2 tablets per day. **Use beyond 6 months is generally not recommended**

ADOLESCENT 12-18 YEARS OF AGE

Nicorette 2mg Microtab

One tablet per hour or, for heavy smokers smoking more than 20 cigarettes per day, two tablets per hour.

Maximum daily dose: 40 tablets

Treatment should be continued for at least 3 months followed by a gradual reduction in the number of tablets used.

Treatment should be discontinued when the dose has been reduced to 1-2 tablets per day. **Medical advice should be sought if use beyond 12 weeks is required.**

11. NASAL SPRAY

Patient Group Information

The nasal spray is the fastest acting product currently available and may be beneficial to highly dependent smokers.

The nasal spray can be used for:

- adults over 18 years of age and
- adults with cardiovascular disease.

Method of Administration

One spray into each nostril.

Dose

ADULTS OVER 18 YEARS OF AGE

Nicorette Nasal Spray (500 micrograms per metered spray (dose) and 200 doses per nasal spray pack)

The frequency of use depends on the previous smoking habits of the individual and levels of nicotine dependence.

Apply one spray into each nostril as required (maximum, twice an hour for 16 hours daily or 64 sprays daily) for 8 weeks.

Reduce gradually over next 4 weeks (reduce by half at end of first 2 weeks, stop altogether at end of next two weeks).

Maximum treatment length: 3 months

ADULTS WITH CARDIOVASCULAR DISEASE

Nicorette Nasal Spray (500 micrograms per metered spray (dose) and 200 doses per nasal spray pack)

The frequency of use depends on the previous smoking habits of the individual and levels of nicotine dependence.

Apply one spray into each nostril as required (maximum, twice an hour for 16 hours daily or 64 sprays daily) for 8 weeks.

Reduce gradually over next 4 weeks (reduce by half at end of first 2 weeks, stop altogether at end of next two weeks).

Maximum treatment length: 3 months

Specific Side Effects

These occur commonly at the start of therapy but usually decline within the first few days of treatment.

Local: Nasal irritation (sneezing, running nose), watering eyes and throat irritation.

Systemic: Nausea, headache and dizziness (some symptoms such as dizziness and headache may be related to withdrawal symptoms associated with smoking cessation).

Other: Additionally an incidence greater than 1% compared with placebo was noted in clinical studies for the following:- sore nose, ear sensations, increased urination, tingling or burning sensation in the head, nose bleed, dyspepsia.

Specific Advice to Patient

Use of the Spray

- 1) Remove the protective cap.
- 2) Prime the Nasal Spray by placing the nozzle between first and second finger with the thumb on the bottom of the bottle. Press several times firmly and quickly until a fine spray appears (up to 7-8 strokes).

Important

Point the spray safely away when priming it. Do not prime it near children or pets.

- 3) Insert the spray tip into one nostril, pointing the top towards the back of the nose. Press firmly and quickly. Give a spray into the other nostril.
- 4) Put on the protective cap.

MULTIDISCIPLINARY GROUP

Name	Role	Organisation
Annette Barclay	Midwife	Causeway Hospital
Helen Bell	Clinical Pharmacist	United Hospitals Trust
Siobhan Bradley	Respiratory Nurse Specialist	United Hospitals Trust
Dr Carol Dalzell	GP	Coagh Medical Practice
Hazel Kelso	Health Promotion Officer	United Hospitals Trust
Geraldine MacManus	Health Visitor	Inver Surgery Larne
Fiona McConnell	Prescribing Adviser	NHSSB
Emer McLean	Community Pharmacy Adviser	NHSSB
Lorraine McPeake	Health Promotion Officer	Homefirst Community Trust
Pat Purvis	Smoking Cessation Co-ordinator	NHSSB
Hilary Robinson	Primary Care Facilitator	NHSSB
Naomi Thompson	Education and Training Officer	Ulster Cancer Foundation

The following people were also consulted on the development of the Guidelines:

Name	Role	Organisation
Dr Robin Ashe	Consultant Obstetrician	United Hospitals Trust
Dr Geoff Todd	Consultant in Respiratory Medicine	United Hospitals Trust
Dr O Finnegan	Consultant Physician	Causeway HSST
Dr T Matthew	Consultant Cardiologist	United Hospitals Trust
Dr T Trouton	Consultant Cardiologist	United Hospitals Trust
Caroline Keown	Midwife	United Hospitals Trust
Julie Conn	Community Pharmacist	Boots the Chemists, Ballymena
Vincent Campbell	Community Pharmacist	Campbells Pharmacy, Portrush
Iain McKay	Community Pharmacist	Pharmacy Facilitator, Mid-Ulster
Roisin McKenna	Community Pharmacist	Carrickfergus Chemists
Sheila Kelly	Practice Nurse	Coagh Medical Practice
Sharon McMurtry	Practice Nurse	Scotch Quarter Practice

RISKS OF SMOKING IN PREGNANCY, SECOND HAND SMOKE FOR INFANTS AND THE USE OF NRT IN PREGNANCY

**Smoking in pregnancy is the largest preventable cause of foetal and infant ill-health and death.
Stopping smoking at any stage during pregnancy is beneficial**

Smoking in pregnancy increases the risk of:

- Miscarriage by 25%. Each year in the UK smoking accounts for at least 5000 miscarriages of which at least 130 are in Northern Ireland
- Stillbirth by 40%. Each year in the UK smoking accounts for up to 400 stillbirths each year in the UK
- Death of the newborn by 40%. Each year in the UK smoking accounts for up to 260 deaths in the first four weeks of life
- Low birth weight by 300%. The decrease in birth weight is independent of other factors, and can be greatly reduced by cessation of smoking in early pregnancy. Each year in the UK smoking accounts for at least 14,000 low birth weight babies - up to 420 in Northern Ireland
- Premature birth by 200%
- Premature rupture of the membranes by 300%
- Foetal malformation (cleft lip, cleft palate) by 30%
- Placental complications by 240%
- Ectopic pregnancy by 250%
- Second hand smoke exposure during pregnancy increases the risk of miscarriage, premature birth and low birth weight.

Smoking and Infant Health

- It is estimated that annually 17,219 hospital admissions in the UK for children under 5 can be directly attributed to second hand smoking
- Children are at increased risk of cot death, respiratory illnesses and impaired lung function
- Exposure to second hand smoke before or after birth also makes babies twice as likely to suffer from colic.

Smoking and Breastfeeding

- Smoking affects prolactin and therefore reduces milk supply and milk quality
- Exposure to second hand smoke also compromises breastfeeding.

Smoking vs NRT

- It is unclear which components of the cigarette smoke actually do the damage and most studies have concentrated on the effects of nicotine
- Carbon monoxide is known to impair oxygen availability by binding with foetal haemoglobin, thereby reducing the availability of oxygen to the foetus
- Many of the other chemicals may lead to adverse outcomes associated with smoking in pregnancy. This table shows potentially fetotoxic chemicals in cigarettes
- Pure nicotine as found in NRT does have potential adverse effects on human health, but it does not appear to cause cancer or significant cardiovascular disease. Its short term use is likely to be less hazardous than smoking during pregnancy
- Studies have reported no adverse maternal or foetal effects from the use of NRT relative to smokers
- Studies have shown that plasma and salivary cotinine levels were significantly lower from using NRT than from smoking
- By using NRT, exposure to the other chemicals in cigarettes including carbon monoxide is eliminated
- Even with this evidence the safety goal is to limit the exposure of the mother and foetus to the minimum effective dose of nicotine, and to use intermittent use formulations as the preferred delivery system in those smokers from whom behavioural support therapies have failed.

Selected potentially fetotoxic chemicals in cigarettes	
Chemicals	Dose per cigarette
Carbon monoxide	10-23mg
Nicotine	1-3mg
Hydrogen cyanide	400-500 mcg
Aniline	360-655 mcg
Catechol	200-400mcg
Nitrogen oxide	100-600mcg
Methanol	10-600mcg
Phenol	70-160mcg
Acrolein	60-140mcg
Pyridine	16-40mcg
Ammonia	10-130mcg
Hydrogen sulphide	10-90mcg
Arsenic	40-129mcg
Hexavalent chromium	4-70ng
Cadmium	4-70ng
Nickel	0-600ng
Lead	34-85ng
Carcinogens	
Polynuclear aromatic hydrocarbons	60-190ng
Heterocyclic compounds	3-14ng
N-Nitrosamines	200-4900ng
Aromatic amines	30-670ng
N-Heterocyclic amines	40-300ng
Aldehydes	570-1500ng
Volatile Hydrocarbons	500-1150ng

NICOTINE ASSISTED REDUCTION TO STOP

Background

In September 2005, the Medicines and Healthcare Products Regulatory Authority (MHRA) approved a new indication for two NRT products, Nicorette® Gum and Nicorette® Inhalator. These two specific products are now licensed for use by smokers to cut down on their smoking prior to attempting to stop. This section is intended to provide guidance on this new indication for healthcare professionals in the NHSSB area.

Key Points

If a smoker approaches you 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 through specialist smoking cessation services.

The Cochrane Review of NRT 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 and a significant effect on sustained reduction” (based on 2 trials).

However there is currently limited evidence to suggest that smokers go on to stop when they use the ‘reduction to stop’ indication. The Cochrane Review also concluded: “There was a marginally significant increase in the odds of cessation”. ASH has indicated that this figure is 4% (compared to 17% quit rate when NRT is used and the smoker stops smoking completely).

Until further evidence is available the NHSSB recommends that NRT is not prescribed for the ‘reduction to stop’ indication. However, if a smoker asks about this indication the following brief advice can be provided:

- Stopping completely is the best thing for their health and support and medications are available through specialist smoking cessation services
- Using these NRT products can help to reduce their cigarette consumption by at least 50%, however the odds of stopping completely are only 4%. To put this in perspective, if 100 people use this method to cut down only 4 will stop smoking successfully. However, if the same group of 100 people instead chose to stop completely and use NRT, 17 (i.e. more than four times as many individuals) would stop successfully
- If the patient wants to use the ‘reduction to stop’ method, they should be advised to purchase the products over the counter. Please note, currently only Nicorette® Gum and Nicorette® Inhalator are licensed for this method
- Over the first 6 weeks consumption should be reduced to 50% of the baseline consumption

- Between 6 weeks and 6 months they should continue to cut down
- Between 6 and 9 months they should aim to stop completely
- At this stage when they are ready to make a quit attempt, they can get intensive specialist support and NRT from cessation services (NRT dose should be determined by the baseline cigarette consumption before any reduction occurred).

Further points to note about the 'reduction to stop' indication include:

- There is currently no mechanism to verify that the smoker has reduced their daily consumption to 50% by week 6 because CO monitors have been withdrawn from use
- Specialist smoking cessation services are working at capacity to help smokers who are motivated to stop and the increase in workload associated with this indication would overstretch the service
- Prescribing costs for NRT within NHSSB rose by almost 15% from 2003/04 to 2004/05 and current resources would be overstretched if NRT was prescribed for this indication.

REFERENCES

The following documents were used in the development of this guidance:

Guidance on the use of nicotine replacement therapy (NRT) and bupropion for smoking cessation.

National Institute for Clinical Excellence

Guidance No 39 March 2002

Nicotine Replacement Therapy Supply to Clients of Stop Smoking Services.

Reading Primary Care Trust

April 2004

Protocol for the use of Nicotine Replacement Therapy in Pregnancy

Sunderland Teaching Primary Care Trust

December 2002

BNF 48

September 2004 and March 2005

MIMS

February 2005 and August 2005

Nicotine replacement therapy (NRT) in smoking cessation

Prescriber Supplement

2003

A Five Year Tobacco Action Plan 2003-2008

DHSSPS June 2003

Smoking Kills - A White Paper on Tobacco

The Stationery Office, December 1998

Patient Group Direction for NRT - 24 Hour Patches (Nicotinell TTS)

Scarborough and North East Yorkshire Healthcare NHS Trust April 2005

Stockley's Drug Interactions (Sixth Edition)

Stockley Ivan H. Pharmaceutical Press November 2002

The A to Z of Smoking Cessation

Northern Ireland Centre for Postgraduate Pharmaceutical Education and Training 2005

Smoking and reproductive life: the impact of smoking on sexual, reproductive and child health.

British Medical Association 2004

Manufacturer's Summary of Product Characteristics for the following products:

Nicorette [®]	Patch 5,10, 15mg Gum 2, 4mg Inhalator Microtab Nasal Spray	Pharmacia/ Pfizer
Nicotinell [®]	Chewing gums Lozenges Patches	Novartis
NiQuitin CQ [®]	Patch 7,14,21mg Lozenges 2,4mg Gum 2,4mg	GlaxoSmithKline

Nicotine assisted reduction to stop: Guidance for health professionals on this new indication for Nicotine Replacement Therapy

ASH, October 2005

