Rotherham NHS
Primary Care Trust

PATIENT GROUP DIRECTION

FOR THE SUPPLY OF NICOTINE REPLACEMENT THERAPY THROUGH NHS STOP SMOKING ADVISORS AND PHARMACIES

March 2005

(Includes under 18's)

- Based on the template issued by the Royal Pharmaceutical Society of Great Britain. Professional Standards Directorate – PGD's
- Supported by RCP, RCGPs, RCN, ASH, Quit

ROTHERHAM NRT PGD FOR NHS STOP SMOKING ADVISORS AND PHARMACIES

MODEL PGD TEMPLATE FOR NRT:

Name of authorising NHS body	Rotherham Primary Care Trust
PGD comes into effect	1st March 2005
PGD to be reviewed	1st March 2006
Supply and legal classification[1] P – Pharmacy GSL – General Sales List	NRT may be supplied in the following forms: **Gum** – 2mg (GSL); 4mg (GSL) **Patch** – 5mg /16 hrs (GSL); 7mg /24 hrs (GSL); 10mg /16 hrs (GSL); 14mg /24hrs (GSL); 15mg /16 hrs (GSL); 21mg /24 hrs (GSL). **Sublingual tablet** – 2mg (P) **Lozenge** – 1mg (GSL); 2mg (P); 4mg (P)[2] **Inhalator** – 10mg / cartridge (P) **Nasal spray** – 500 micrograms / metered spray (P) **All supplies:** Maximum length of treatment is normally 12 weeks (but check individual product specifications – see Appendix 1).[3]

[1] Any updates to SPCs can be checked using the Electronic Medicines Compendium website available at http://www.emc.vhn.net/professional/

[2] Please note that a request has been submitted to the Medicine's Control Agency to reclassify NiQuitin CQ 4mg Lozenge and NiQuitin CQ 4mg Mint lozenge from P to GSL

[3] Please note that Appendix 1 is part of the PGD. Any changes made to the product licences - for example products becoming available on general sale - may require a review of the whole PGD accordingly.

Class of health professional who may supply NRT	All health professionals who have received Rotherham PCT approved training to supply NRT under this PGD
When supply can be made outside the terms of the SPC (Summary of product characteristics)	The use of NRT outside the terms of the SPC is supported by NICE guidance.[4] This may be appropriate for the following groups: • Clients who are under 18 years old • Clients with *severe* cardiovascular disease[5] (including severe arrhythmia or *immediate*[6] post-myocardial infarction period) • Clients with a history of *recent* cerebrovascular disease[5] (including transient ischaemic attacks) OR when: • A combination of NRT products is recommended by the Smoking Cessation Service[8][6] • Continuing supplies are required beyond the specified maximum length of treatment (i.e 3 months) are recommended by the Specialist Smoking Cessation Service

[4] **There is widespread professional recognition that NRT products are much less harmful than tobacco smoking and this was substantiated in the recent NICE report. NICE recommended that smokers under the age of 18 years, who are pregnant or breastfeeding, or who have unstable CVD should discuss the use of NRT with a relevant health-care professional before it is supplied. NHS commissioning bodies might want to authorise the supply of NRT outside the licence specifications to groups where continued smoking might cause considerable harm to themselves or others, or where combinations of NRT products or extended periods of treatment with NRT might be necessary.**

[5] The precise definition of descriptive clinical terms such as 'severe' and 'recent' cardiovascular problems will need to be specified locally by the authorising Senior Clinician or other appropriate expert, and included in the training program for health professionals on the supply of NRT on the NHS. Therefore, The Rotherham Primary Care Trust definition of a severe cardiovascular episode is a Myocardial Infarction (MI), Crescendo Angina, or Cerebral vascular Accident (Stroke). The suggested minimum length of time between any of these episodes and the patient starting a course of NRT is 2 weeks.

[6] NICE recognised that the combination of two different NRTs was in general more effective than a single NRT. Possible combinations of NRT products include the combination of the patch (a slow release form of NRT) with a faster acting NRT such as the gum or nasal nicotine spray (to allow good control over the nicotine dose during cravings). Another combination that might be considered includes the use of two patches (for very dependent smokers).

Clinical situations for which the medicine is to be used	As an aid to treating tobacco dependence in: • Clients receiving specialist advice and support from the NHS smoking cessation service in Rotherham • Clients receiving specialist smoking cessation advice and support from health professionals in other accredited settings, e.g. pharmacies or practice nurse clinics
Criteria for inclusion	• Tobacco users identified as sufficiently motivated to quit[7] (willing to set a quit date and receive weekly support for 1st four weeks at least) • Tobacco users over the age of 12 and under the age of 18 where assessment is made following the Gillick competencies
Criteria for exclusion	• Tobacco users not sufficiently motivated to quit or use NRT assessed according to PCT protocol (the term sufficiently motivated to quit refers to a clients willingness to set a quit date and receive weekly support for the first four weeks of treatment **If treatment with bupropion is preferred then convenience of supply should not be used to justify a choice of NRT** • Clients who are either pregnant or breastfeeding • Clients with previous serious reaction to NRT or any of the other ingredients contained in the products, e.g. glue in patch. Where a reaction has occurred to an ingredient other than nicotine an alternative supply route may be considered. • *Patches only* – clients with chronic generalised skin disease such as psoriasis, chronic dermatitis and urticaria; clients who have had a previous reaction to transdermal patches; occasional smokers • *Nasal spray only* – clients with chronic nasal disorders such as polyposis, vasomotor rhinitis and perennial rhinitis O*ral products*- active peptic ulcer disease Clients receiving telephone support only

Criteria for referral	When NRT may be appropriate, but supply through Pharmacy is not recommended, then the client should be referred to a GP(appx 2). This *might*[9] include clients with: • Hyperthyroidism • *Severe*[11]cardiovascular[4] disease where sufficient information is not available to allow supply of NRT under PGD • A history of *recent*[12] cerebrovascular[4] disease where sufficient information is not available to allow supply of NRT under PGD • Clients taking theophylline **Nuelin, Sio-Phyllin, Uniphyllin Continus, Aminophylline, Phyllocontin Continus** (see 'Drug Interactions' below) • Where intervention with bupropion might be appropriate (as it is not covered by local PGD arrangements to supply)
Dosage and method of administration	See Appendix 1 for individual product details
Period of administration	Initial supply to be made for 1 week after the target stop date. If client is abstinent then further weekly supplies given with the offer of weekly support. If the client is successful in stopping smoking after week 4 (as per carbon monoxide validation) completion of the recommended course can be given dependent on the product recommendation If the smoker is unsuccessful in staying stopped at 4 weeks then discontinue treatment and suggest they make a fresh start when they are ready again **(normally six months before further NHS funding is given).**

7 Department of Health Smoking Cessation Monitoring Guidance 2002

8 See paragraph 3.2 of the NICE guidance. Please note that NRT is not contraindicated in these patient groups and conveys much less risk than continued smoking. In diabetes smoking cessation may affect the absorption and utilisation of insulin. This is due to smoking cessation *per se* and is not an adverse effect of NRT. It is prudent to ask smokers with diabetes to monitor their blood sugar levels regularly after stopping smoking.

Interactions with NRT Products	Theophylline - as tobacco smoking increases the metabolism of theophylline, smoking cessation can cause theophylline plasma levels to rise. **Clients taking theophylline should be advised to consult with their GP about stopping smoking**. Smoking cessation may also cause alterations in the circulating drug levels of the following (but not normally enough to cause therapeutic problems): • Insulin • Adrenergic agonists and antagonists • Fluvoxamine • Clozapine • Clomipramine • Imipramine • Olanzapine • Flecainide • Pentazocine **Clients who are taking NRT together with any of the above medicines should be advised to liase with their GP whilst they are trying to stop smoking. Letter to inform GP of clients commencement on NRT to be sent (app 4)**
Side effects	These are usually transient but may include the following, some of which are a consequence of stopping smoking: nausea, dizziness, headaches, cold and flu-like symptoms, palpitations, dyspepsia and other gastro-intestinal disturbances, hiccups, insomnia, vivid dreams, myalgia, chest pain, bloodpressure changes, anxiety and irritability, somnolence and impaired concentration, dysmenorrhoea. Product-specific side effects are detailed in Appendix 1.

Advice to clients	Advice to clients should include *specifi cproduct advice* plus the following general advice following PCT protocol • withdrawal symptoms • possible changes in the body on stopping smoking, e.g. weight gain and how to manage this • the effects of smoking tobacco whilst using NRT, particularly in vulnerable groups • written information on products supplied, self-help leaflets and where to obtain more information. Details should be given on how to obtain further NRT supplies and follow up arrangements. Warning should include the advice that smoking should not occur whilist using NRT Clients wanting more information can be referred to: • Rotherham Quit Smoking Service **01709 302444** • The NHS Smoking Helpline: **0800 169 0 169** • The NHS Pregnancy Smoking Helpline: **0800 169 9 169** • The Asian Quit line **0800 169 0 881 (Urdu) 0800 169 0 882 (Punjabi)** **0800 169 0 883 (Hindi) 0800 169 0 884 (Gujarati)** **0800 169 0 885 (Bengali)** • The Hearing Impaired Quit line **0800 169 7 169** • The Quitline: **0800 002200** The client should be informed that information relating to the supply of NRT under PGD may have to be passed to other health service organisations – in particular their GP and the NHS smoking cessation service (if appropriate) for a variety of purposes such as audit. The client's consent will be obtained before information can be passed to the GP (appx 2)

Details of record keeping	Records of the consultation must be kept In line with the PCT's Records Management Policy. With particular focus on: • The letter of 'recommendation to supply' (Appendix 3), or a copy, should be kept with the client's record • The GP notification of supply or referral forms (Appendix 4 and 5) to be completed, signed and sent to the GP, or as per local agreement • Details of the product(s) supplied, invoices and prescription charges collected should be recorded as required for audit purposes (appx 6 and 7) • Audit forms should be completed and returned as required

[19]The Medicines Act (Miscellaneous Provision) 1997 allows client records to be kept electronically.

APPENDIX 1 – Dosage and method of administration of NRT products

Please note the details regarding these products may change frequently so it is prudent to check the latest Summary of Product Characteristics when setting up a local PGD (www.emc.vhn.net/professional).

A) GUM

Dose and method of administration	Oral administration (as resin). *Nicotinell- 4mg gum* For individuals smoking more than 20 cigarettes daily – one 4mg piece to be chewed slowly for 30 minutes on urge to smoke. Maximum 15 pieces daily. ***Nicotinell – 2mg gum*** For individuals smoking 20 cigarettes or less daily – one 2mg piece to be chewed slowly for 30 minutes on urge to smoke. Maximum of 15 pieces daily. Treatment should be continued for at least 3 months followed by a gradual reduction in dosage. *Nicorette – 4mg gum* For individuals smoking more than 20 cigarettes a day – one 4mg piece chewed slowly for 30 minutes on urge to smoke. Maximum number of pieces a day: 15 pieces of 4mg gum. Treatment should be continued for at least 3 months followed by a gradual reduction in dosage. *Nicorette – 2mg 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. *Niquitn CQ 4mg gum* Individuals who smoke within 30 minutes of waking – one 4mg piece chewed slowly for 30 minutes on urge to smoke Maximum 15 pieces daily *Niquitin CQ 2mg gum* Individuals who smoke their first cigarette more than 30 minutes from waking- one 2mg piece chewed slowly for 30 minutes on urge to smoke Maximum 15 pieces daily

Specific side effects	Throat irritation, increased salivation, hiccups.
Specific advice to client	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.

B) PATCHES

Dose and method of administration	Transdermal administration. Apply on waking to dry, non-hairy skin on hip, chest or upper arm. Remove after time specified. 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. *Nicorette – 16 hour patch* 15mg patch for 16 hours daily for 8 weeks THEN 10mg patch for 2 hours THEN 5mg patch for 2 hours THEN review treatment ***Nicotinell – '10' patch*** For individuals smoking 10 cigarettes or less per day – one patch (7mg) daily. ***Nicotinell – '20' patch*** For individuals smoking 20 cigarettes or less per day – one patch (14mg) daily. ***Nicotinell – '30' patch*** For individuals smoking more than 20 cigarettes per day – one patch (21mg) daily. Withdraw treatment gradually reducing the dose every 3-4 weeks. ***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 weeksTHEN review treatment

Specific side effects	Skin reactions. Discontinue use if severe.
Specific advice to client	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, trunk or upper arm. Remove patch after 16 hours or 24 hours depending on product supplied. Allow several days before replacing the patch on a previously 'used' area. Place the patch in the palm of the hand and hold onto the skin for 10-20 seconds. Patches should not be applied to broken or inflamed skin. Clients should not try to alter the dose of the patch by cutting it up.

C) SUBLINGUAL TABLET

Dose and method of administration	Oral administration (sublingual) – 2mg. For individuals smoking 20 cigarettes or less daily – 2mg per hour. For patients who fail to stop smoking or have significant withdrawal symptoms consider increasing to 4mg per hour sublingually. For individuals smoking more than 20 cigarettes a day – 4mg per hour. Maximum dose: 80mg per day Treatment should be continued for at least 3 months up to a maximum of 6 months. Dosage should be gradually reduced after 3 months.
Specific side effects	Throat irritation, unpleasant taste.
Specific advice to client	Tablets should be placed under the tongue and allowed to dissolve slowly. Users should not eat or drink at the same time as using the product

D) LOZENGE

Dose and method of administration	Oral administration (nicotine as bitartrate). ***Nicotinell – 2mg lozenge*** Maximum dose 15 lozenges per day Withdraw treatment gradually after 3 months ***Nicotinell – 1mg lozenge*** Initially one lozenge (1mg) every 1-2 hours on urge to smoke. Maximum dosage: 25 lozenges per day. Withdraw treatment gradually after 3 months. Maximum period of treatment: 6 months ***NiQuitin CQ – 2mg and 4mg lozenges*** Use **4mg lozenges** for smokers who have their first cigarette of the day within 30 minutes of waking up. Use **2mg lozenges** for smokers who have their first cigarette of the day more than 30 minutes after waking. **Weeks 1- 6**: 1 lozenge every 1-2 hours. *Users should take AT LEAST 9 lozenges per day, but should not exceed 15 lozenges a day* **Weeks 7 – 9**: 1 lozenge every 2-4 hours **Weeks 10 – 12**: 1 lozenge every 4-8 hours
Specific side effects	Throat irritation, mouth ulcers, increased salivation, hiccups.
Specific advice to client	***Nicotinell Lozenge:*** Lozenge should be sucked until the taste is strong and then 'parked' between the gum and the cheek until the taste fades. Once faded then sucking should recommence. Simultaneous use of coffee, acid drinks and soft drinks may decrease absorption of nicotine and should be avoided for 15 minutes prior to sucking lozenge. ***NiQuitin CQ Lozenge:*** 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 (approximately 20 –30 minutes). The lozenge should not be chewed or swallowed whole. Users should not eat or drink while a lozenge is in the mouth.

E) INHALATOR

Dose and method of administration	Oral administration (nicotine-impregnated plug in mouthpiece). Inhale when urge to smoke occurs or regularly to prevent overpowering urges to smoke. Advise using 6-12 cartridges (10mg / cartridge) daily for up to 8 weeks THEN Reducing 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, dry mouth, mouth ulcers.
Specific advice to client	Air should be drawn into the mouth through the mouthpiece. Clients should be warned that the inhalator requires more effort to inhale than a cigarette and that less nicotine is delivered per inhalation. Therefore the client may need to inhale for longer than with a cigarette. The inhalator is best used at room temperatures as nicotine delivery is affected by temperature. Used cartridges will contain residual nicotine and should be disposed of safely. Advise the client to keep them in the case and dispose of them in household rubbish.

F) NASAL SPRAY

Dose and method of administration	Nasal administration (500 micrograms / metered spray). Apply one spray into each nostril as required up to a maximum of twice per hour, over a 16 hour period (=maximum of 64 sprays daily) for a period of 8 weeks THEN Reduce dosage gradually over next 4 weeks achieving half the dose reduction required in the first 2 weeks THEN Continue to reduce dosage to 0 over next 2 weeks. Maximum period of treatment: 3 months
Specific side effects	Nose and throat irritation, nosebleeds, watering eyes, ear sensations.
Specific advice to client	Advise on correct use of spray. Tip the head slightly back to avoid spraying too high into the nose and thus reduce the occurrence of post-nasal drip. The nicotine is absorbed through thee nasal mucosa without the need to inhale Warn of possible local effects of sneezing and eye watering but also that these tend to lessen within a few days. CAUTION – the nasal spray should not be used whilst driving or operating machinery as side effects could cause an accident.

DECLARATION by authorising body:

This PGD has been authorised by: Signature:
Name: Chris Macklin
Director of Finance
On behalf of Teaching Primary Care Trust
Countersigned by: Signature:
Name: Dr G Stephenson
Senior / Lead Clinician
Countersigned by: Signature:
Name: Greg Moorhouse
Senior / Lead Pharmacist
Enquiries relating to this PGD should be addressed to:
Ms Christine Jordan
Tobacco Control/Cancer Co-ordinator
Sunderland Teaching Primary Care Trust
Health Development Unit
Monkwearmouth Hospital
Newcastle Road
Sunderland
SR5 1NB
DECLARATION by pharmacists authorised to supply:
I have been appropriately trained to understand the criteria listed above and the administration required to supply NRT in accordance with this PGD.
Pharmacist 1 Pharmacist 2 Pharmacist 3
Name
Professional registration
number:
Signature:
Date:
Pharmacy Address:
Review Date: 1st October 2004