



# Nicotine Replacement Therapy for Inpatients

**Version:** 4.1

**Executive Lead:** Executive Director Quality & Safety  
**Lead Author:** Head of Medicines Management

**Approved Date:** 23<sup>rd</sup> May 2016  
**Approved By:** Drugs and Therapeutic Committee

**Ratified Date:** 24<sup>th</sup> June 2016  
**Ratified By:** Policy Panel

**Issue Date:** 6<sup>th</sup> July 2016  
**Expiry Date:** 6<sup>th</sup> July 2019

**Target Audience:**

This Policy must be understood by all front-line secondary care staff who work with smokers

**P1 - Version Control History:**

Below notes the current and previous Version details- full history is in Part 3

Version	Date of Issue	Author	Status	Comment
V2.1	17 <sup>th</sup> March 2008	Head of Medicines Management	Superseded	Updated
V3	28 <sup>th</sup> April 2014	Head of Medicines Management	Superseded	Full review
V4	6 <sup>th</sup> July 2016	Chief Pharmacist	Superseded	Appendix 2 Protocol inserted and range of NRT products expanded Appendix 3 Smoking Cessation – Effect on Psychotropic Medication including Clozapine
V4.1	17 <sup>th</sup> July 2017	Chief Pharmacist	Current	Minor change - Appendix 2 extended to all nurses who are level 2 trained

**P2 - Relevant Standards:**

- a) **NHSLA Risk Management Standards-Mental Health & Learning Disability.**  
1.2 Policy on Procedural Documents
- b) **Equality and RESPECT:** The Trust operates a policy of fairness and RESPECT in relation to the treatment and care of service users and carers; and support for staff.

**P3 - The 2012 Policy Management System and the Policy Format:**

The PMS requires all Policy documents to follow the relevant Template.

- **Policy Template** is the essential format for most Policies. It contains all that staff need to know to carry out their duties in the area covered by the Policy.
- **Operational Policies Template** provides the format to describe our services, how they work and who can access them.
- **Care Pathways Template** is at the moment in draft and only for the use of the Pathways Team as they are adapting the design on a working basis.
- **Guidance Template** is a sub-section of the Policy to guide Staff and provide specific details of a particular area. An over-arching Policy can contain several Guidance's which will need to go back to the Approval Group annually.

**Symbols used in Policies:**

- RULE** =internally agreed, that this is a rule & must be done the way described
- STANDARD** = a national standard which we must comply with, so must be followed

**Managers** must bring all relevant policies to the attention of their staff, where possible, viewing and discussing the contents so that the team is aware of what they need to do.

**Individual staff/students/learners** are responsible for implementing the requirements appropriate to their role, through reading the Policy and demonstrating to their manager that they understand the key points.

All Trust Policies will change to these formats as Policies are reviewed every 3 years, or when national Policy or legislation or other change prompts a review. All expired & superseded documents are retained & archived and are accessible through the Compliance and Risk Facilitator [Policies@hpft.nhs.uk](mailto:Policies@hpft.nhs.uk)

All current Policies can be found on the Trust Policy Website via the Green Button or <http://trustspace/InformationCentre/TrustPolicies/default.aspx>

## Contents Page

PART:		Page:
<b>Preface</b>	<b>Preface concerning the Trust Policy Management System:</b> P1 - Version Control History P2 - Relevant Standards P3 - The 2012 Policy Management System & Document Formats	<b>2</b>
<b>PART 1</b>	<b>Preliminary Issues:</b>	
	1. Summary	<b>6</b>
	2. Purpose	<b>6</b>
	3. Definitions	<b>6</b>
	4. Duties and Responsibilities Stop Smoking Service Contact details	<b>6</b>
<b>PART 2</b>	<b>What needs to be done and who by:</b>	
	5. NRT is provided in the following circumstances	<b>8</b>
	5.1. For stopping smoking	<b>8</b>
	5.2. For temporary abstinence or harm reduction	<b>8</b>
	5.3. Inpatient referrals	<b>8</b>
	5.4. Under a protocol by level 2 trained smoking cessation advisors in designated areas	<b>9</b>
	6. Management and monitoring mechanisms	<b>9</b>
	7. Discharge after quitting	<b>9</b>
	8. Advice to service users	<b>9</b>
	9. Informed consent	<b>10</b>
	10. Details of record keeping	<b>10</b>
	11. Nicotine Replacement Therapy	<b>10</b>
	11.1. NRT Patches	<b>10</b>
	11.2. NRT Lozenges	<b>11</b>
	11.3. NRT Inhaler	<b>11</b>
	11.4. NRT Oral Film	<b>11</b>
	11.5. NRT Sublingual Tablets	<b>12</b>
	11.6. NRT Nasal Spray	<b>12</b>
	11.7. NRT Oral Spray	<b>12</b>
	12. Dosage and method of administration of NRT	<b>12</b>
	13. Storage of NRT	<b>15</b>
	14. Sources of online information about NRT products	<b>15</b>
	15. Drug Interactions	<b>15</b>
	16. NRT side effects and adverse reactions	<b>16</b>
	17. Choice of NRT and addiction to smoking	<b>16</b>
	18. Training/ Awareness	<b>17</b>
	19. Equality and RESPECT	<b>17</b>
	20. Process for monitoring compliance with this document	<b>19</b>
<b>PART 3</b>	<b>Associated Issues</b>	
	21. Version Control	<b>20</b>
	22. Archiving Arrangements	<b>20</b>
	23. Associated Documents	<b>20</b>
	24. Supporting References	<b>20</b>
	<b>25. Comments and Feedback</b>	<b>20</b>
	Appendices Appendix 1 for the HPFT Smoking Referral Form	<b>21</b>

	Appendix 2 Protocol for the supply of Nicotine Replacement Therapy (NRT) by level 2 trained smoking cessation advisors Appendix 3 Smoking Cessation – Effect on Psychotropic Medication including Clozapine	
--	--	--

### 1. Summary

This guideline has been developed to act as a framework under which appropriately trained staff will operate the Smoke Free Policy. This initiative involves training of appropriate healthcare staff to provide educational support and advice to patients motivated to stop smoking; to manage temporary abstinence or to encourage a harm reduction approach in smokers unable or unwilling to quit.

The objectives of these guidelines are to encourage safe and effective use of NRT by inpatient smokers, including, but not exclusively, those referred to Hertfordshire Stop Smoking Cessation Service.

### 2. Purpose

Inpatients wanting to stop smoking or needing to manage temporary abstinence can be referred to Hertfordshire Stop Smoking Service and receive individually tailored smoking advice. This may involve the recommendation of specific treatment such as NRT and counselling about stopping smoking.

In line with NICE PH 48 Guidance, Smoking Cessation Secondary Care: acute, maternity and mental health services, NRT may be prescribed for patients who are not attempting to stop smoking. It may be prescribed for instances when smokers are unable to quit, but need relief from withdrawal symptoms. Product, dosage and frequency will be determined by the MDT and strict parameters included in the care plan. The level of addiction will need to be assessed and considered, including the number of cigarettes smoked each day, the time to the first cigarette smoked in the morning and the ability of the smoker to not smoke for the duration of their stay, and previous experience of trying to stop smoking as mental health service users are often heavier and more addicted smokers and require larger doses of NRT in order to remain abstinent. This often requires both oral NRT as well as a patch to be used simultaneously.

The information service users are given must be culturally appropriate and meet the individual's communication needs. For example, people with additional needs such as physical, sensory or learning disabilities, and people who do not speak or read English. The Trust Policy on Communicating with Service Users from Diverse Communities provides guidance on communication needs and procedure on the interpreting service.

### 3. Definitions

#### **STANDARD**

NRT – Nicotine Replacement Therapy (NRT)

### 4. Duties and Responsibilities

#### **RULE**

The Executive Director of Quality & Safety is the Executive Lead for this guideline. The author is the Head of Medicines Management and the Drugs & Therapeutics Committee is the approval committee.

The Lead Nurse for Smoking Cessation in HPFT and the Hertfordshire Stop Smoking Service will be responsible for implementing this guideline.

### **Smoking Cessation Advisors**

- Advisors will meet criteria laid out in this guideline and will offer smoking cessation advice to inpatients in the Trust. Advisors should undertake CPD for this role regularly.
- Advisors will be staff members trained by Hertfordshire Stop Smoking Service (HSSS).
- Contact details for the HSSS are:

Email: [stopsmokingservice@hertsc.ccsx.gov.uk](mailto:stopsmokingservice@hertsc.ccsx.gov.uk)

Phone: 01442 453071

#### Address

Hertfordshire Stop Smoking Service  
Public Health Service  
Hertfordshire County Council,  
Apsley One,  
Brindley Way,  
Hemel Hempstead,  
HP3 9BF

## **5. NRT Is Provided In The Following Circumstances**

### **5.1 For stopping smoking**

- Tobacco users identified as sufficiently motivated to quit i.e. willing to set a quit date and to receive appropriate support through the guidance of an appropriately trained Stop Smoking Advisor
- In the unlikely event that NRT is deemed not to be appropriate for the patient, or the patient declines to use NRT after consultation with the stop smoking service and ward doctor, the advisor should continue to provide behavioural support to stop smoking

### **5.2 For temporary abstinence or harm reduction**

Not all patients are able or willing to quit when admitted to secondary care. NRT should be offered and prescribed for patients who are not attempting to stop smoking but who need support to be temporary abstinent. In line with NICE PH48 Guidance, patients should not be permitted to smoke outside and staff should not escort patients outside to smoke.

In those circumstances smokers admitted to an in-patient unit may be provided with an appropriate form of NRT to alleviate craving or withdrawal after suitable assessment and completion of an appropriate care plan. The following actions should be taken:

- Product, dosage and frequency will be determined by the MDT and strict parameters included in the care plan.
- The smokers level of addiction should be assessed which includes: the number of cigarettes smoked each day, the time to the first cigarette in the morning and how difficult the patient would find it not to smoke at all whilst an inpatient. Consideration needs to be given to the likelihood that the patient is a heavier and more addicted smoker than other smokers without a mental health condition and higher doses of NRT are likely to be required.
- In line with Hertfordshire's Smoking Cessation Pharmacological Guidance, heavier and more addicted smokers should be offered two NRT products
- The NRT product may be prescribed in the PRN section of the prescription chart and supplied from stock or on a named patient basis
- A register must be maintained of stock levels with a running total
- A record must be maintained of administration or supply on the prescription chart.

### **5.3 Inpatient referrals:**

- A member of their healthcare team will refer in-patients to an advisor.
- The advisor will provide smoking cessation advice.
- The patient will be assessed for suitability to receive NRT and from the patient's history and preferences, appropriate NRT will be recommended.
- When NRT is recommended, the patient's medical team will be asked to prescribe the relevant NRT product on the patients prescription chart.
- In the unlikely event that the patient may not be suitable for NRT or declines NRT, this should be discussed with the stop smoking service and ward doctor.
- If NRT is supplied the advisor will counsel the patient on how to use it.
- Before giving the NRT pack or supply to the service user, the administering nurse will check that the NRT has been prescribed on the in-patient prescription chart.

- Patients are entitled to free supply of NRT for the duration of their therapy.

#### **5.4 Under a protocol by level 2 trained smoking cessation advisors in designated areas**

The protocol in appendix 2 is intended to support patients admitted to HPFT inpatient settings (currently limited to S136 suite and Swift Ward) when a doctor is unavailable to prescribe NRT products.

- Any NRT supply made under this protocol must be recorded is made in the Nurses' Discretionary Medication section on the front of the inpatient prescription chart as well as in the patient's EPR (Electronic Patient Record).
- NRT needs to be reviewed and prescribed by the team doctor on the inpatient prescription chart at the earliest opportunity

### **6. Management And Monitoring Mechanisms**

This will be determined by the advisor but will normally follow these guidelines:

- Advisors will be working under the protocol of the specialist stop smoking services in addition to these guidelines.
- If service users are successful in stopping smoking after week 4 (preferably with carbon monoxide validation) medication should continue for at least the recommended duration of the product/s whilst they remain abstinent and given at 4 weekly intervals.
- If the smoker is unsuccessful in stopping at 4 weeks then a harm reduction or temporary abstinence approach should be considered and NRT supplied whilst an inpatient to prevent withdrawal symptoms, reduce the number of cigarettes smoked and give the smoker greater confidence in quitting smoking.
- If the smoker is successful in abstaining then treatment should normally be gradually withdrawn after this point unless there is a strong likelihood of relapse without continuing treatment.
- NRT should be gradually withdrawn by 12 weeks unless there is a strong likelihood of relapse without continuing treatment.

Individuals should be assessed for risk of relapse without continuing treatment and it may be appropriate to continue providing NRT beyond the usual 12 week treatment period.

Nicotine replacement products supplied to inpatients because they are not able to smoke in a designated outside area should be prescribed by a doctor in the PRN section of the prescription chart.

### **7. Discharge After Quitting**

If a service user has stopped smoking or is using NRT to reduce smoking and is to be discharged from hospital whilst using NRT then the discharge prescription should be written for NRT for two weeks and the service user referred to Hertfordshire Stop Smoking Service for further support. Refer to Appendix 1 for the HPFT Smoking Referral Form.

### **8. Advice**

Advice to those who wish to start NRT should include product specific advice plus the following general advice on:

- The information, advice and support available from Hertfordshire Stop Smoking Service and the national Smokefree website: [smokefree.nhs.uk](http://smokefree.nhs.uk)
- Withdrawal symptoms, including temporary mood changes and weight gain.
- The benefits to the smoker's physical and mental health.
- Changes required in some medicines' dosage and how to manage these.
- The impact of smoking cannabis and alcohol use on mental health and stopping smoking
- The effects of smoking tobacco whilst using NRT – particularly in vulnerable groups, e.g. pregnant women, clients with cardiovascular disease.
- Guidance on using electronic cigarettes whilst using NRT
- Follow up and obtaining further supplies of NRT.

## 9. Informed Consent

Client information relating to the supply of NRT under these guidelines may be passed to other health service organisations, e.g. a client's GP or specialist clinics for purposes such as referral or audit.

The client's informed consent must be obtained by the prescribing doctor before treatment can commence and this should be recorded in the multi-disciplinary case notes as normal practice.

## 10. Details of Record Keeping

The advisor and other staff involved will record the consultation, treatment plan and behavioural management in the case notes contemporaneously.

Records should be maintained of stock nicotine replacement products.

## 11. Nicotine Replacement Therapy

### **RULE**

#### **NRT MAY BE SUPPLIED IN THE FOLLOWING FORMS:**

**Inpatient wards may maintain a limited stock of NRT products.  
This stock may only be issued to service users who are prescribed NRT:**

- Nicorette Invisi patches
- Niquitin Minis lozenges
- Nicorette Inhalator
- NiQuitin Strip Oral Film
- Nicorette Microtab
- Nicorette Nasal Spray
- Nicorette QuickMist Mouth Spray

### **11.1 Patch**

**Refer to page 10 for method of administration**

The brand of patch available for inpatients is **Nicorette Invisi Patch**:

- 25mg (releasing approx 25mg/16 hours) **Step 1**
- 15mg (releasing approx 15mg/16 hours) **Step 2**
- 10mg (releasing approx 10mg/16 hours) **Step 3**

It is generally recommended that abstinent quitters should use NRT patches for a period of twelve weeks.

### **11.2 Lozenge**

**Refer to page 11 for method of administration**

The brand of lozenge available for inpatients is **Niquitin Minis lozenges**

- 1.5 mg mint flavoured (for those who smoke 20 cigarettes or less daily)
- 4 mg mint flavoured (for those who smoke more than 20 cigarettes daily)

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 10 minutes). The lozenge should not be chewed or swallowed whole. Users should not eat or drink while a lozenge is in the mouth. Sufficient lozenges should be used each day whenever there is an urge to smoke.

**Usually 8-12 lozenges, up to a maximum of 15.**

### **11.3 Inhalator**

**Refer to page 11 for method of administration**

The brand of inhalator available for inpatients is **Nicorette Inhalator**

- 15mg inhalator cartridge  
**Maximum daily dose: 6 cartridges**

Nicorette Inhalator should be used whenever the urge to smoke is felt or to prevent cravings in situations where these are likely to occur. Smokers willing or able to stop smoking immediately should initially replace all their cigarettes with the Inhalator and as soon as they are able, reduce the number of cartridges used until they have stopped completely.

Although the most effective method of quitting smoking is by the abrupt quit method, in line with NICE PH 45, Tobacco Harm Reduction Approaches to Smoking, Hertfordshire Stop Smoking Service recognises that in mental health service users harm reduction, temporary abstinence and cutting down to quit may be more appropriate for service users unable or unwilling to quit abruptly.

### **11.4 Orodispersible film**

**Refer to page 11 for method of administration**

The brand of orodispersible film available for inpatients is **NiQuitin Strips Oral Film**

- 2.5mg mint flavoured oral film  
**Maximum daily dose: 15 films**

The oral film is suitable for smokers who have their first cigarette of the day more than 30 minutes after waking up.

The number of films a day is variable and depends on the patient's needs. Use strips whenever there is a strong urge to smoke in order to reduce the number of cigarettes smoked as far as possible and to refrain from smoking as long as possible. Patients should not take more than 15 films per day.

Oral film may be more effective for heavy smokers since it is more rapidly absorbed, patients still get a nicotine "hit" and this may be preferred by more addicted smokers.

Patients should be encouraged to stop smoking completely as soon as possible.

### **11.5 Sublingual tablet**

**Refer to page 12 for method of administration**

The brand of sublingual tablet available for inpatients is **Nicorette Microtab**

- 2mg sublingual tablet

**Maximum daily dose: 40 tablets**

The sublingual tablet is suitable for the relief of nicotine withdrawal symptoms as an aid to smoking cessation.

In patients currently unable or not ready to stop smoking abruptly, the sublingual tablet may also be used as part of a programme to reduce smoking prior to stopping completely.

If possible, the sublingual tablet should be used in conjunction with a behavioural support programme.

### **11.6 Nasal Spray**

**Refer to page 12 for method of administration**

The brand of nasal spray available for inpatients is **Nicorette Nasal Spray**

- 10mg/ml. Each spray of 50ul delivers 0.5mg nicotine.

**Maximum daily dose: 64 sprays. Subject to a limit of one spray to each nostril twice an hour for 16 hours daily.**

Nicorette Nasal Spray is indicated for the relief of nicotine withdrawal symptoms as an aid to smoking cessation.

If possible, Nicorette Nasal Spray should be used in conjunction with a behavioural support programme.

### **11.7 Oral Spray**

**Refer to page 12 for method of administration**

The brand of oral spray available for inpatients is **Nicorette QuickMist Mouth Spray**

- 1mg/spray. (i.e. 1mg nicotine/spray dose)

**Maximum daily dose: 64 sprays (with up to 4 sprays per hour over 16 hours)**

The oral spray relieves and/or prevents craving and nicotine withdrawal symptoms associated with tobacco dependence. It is indicated to aid smokers wishing to quit or reduce prior to quitting, to assist smokers who are unwilling or unable to smoke, and as a safer alternative to smoking for smokers and those around them.

## **12. Dosage and method of administration of NRT products**

Acidic beverages, such as coffee or fruit juice, may decrease the absorption of nicotine through the buccal mucosa and should be avoided for 15 minutes before the use of oral NRT.

## Nicorette invis patches

- Transdermal administration
- 16 hour Patch: it is intended that the patch is worn through the waking hours (approximately 16 hours) being applied on waking and removed at bedtime.
- Specific side effects: Skin irritation/redness
- The patch should be applied once a day, normally in the morning, to a clean, dry, non-hairy area of the skin. Allow several days before replacing the patch on the previously used area.
- Apply to the skin, hold in place for 10-20 seconds.
- Patches should not be applied to broken or inflamed skin.
- Nicorette invis patches should usually begin with 25mg and be reduced according to the following dosing schedule
  - Step 1** Nicorette invis 25mg patch first 8 weeks
  - Step 2** Nicorette invis 15mg patch next 2 weeks
  - Step 3** Nicorette invis 10mg patch last 2 weeks
- Lighter smokers (e.g. those who smoke less than 10 cigarettes per day) are recommended to start at Step 2 (15mg) for 8 weeks and then decrease the dose to 10mg for the final 4 weeks.
- Those who experience excessive side effects with 25mg/16 hour patch (step1), which do not resolve within a few days, should change to a 15mg/16 hour patch (step2). This should be continued for the remainder of the 8 week course, before stepping down to the 10mg/16 hours patch (step 3) for 4 weeks. If symptoms persist the advice of a healthcare professional should be sought.
- Once the patch is spent it should be folded in half and disposed of carefully. Clients should not try to alter the dose by cutting it up.

## NiQuitin Minis Lozenges

- Oral administration.
- Use one lozenge (2/4mg) every hour throughout the day, up to a maximum of 15 lozenges a day.
- Use maximum dosage for 6 weeks, reducing dosage and usage over the next 6 weeks.
- Specific side effects: throat irritation, hiccups
- 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 10 minutes). The lozenge should not be chewed or swallowed whole.
- Users should not eat or drink while a lozenge is in the mouth

## Nicorette Inhalator

- Nicorette Inhalator should be used whenever the urge to smoke is felt, up to a maximum usage of 6 of the 15mg cartridges a day
- Each can be used for 8 x 5 min sessions, and lasts approx 40 mins
- Behavioural therapy, advice and support will normally improve the success rate.

## NiQuitin Strip Oral Film

- Oral administration.
- Place one film on the tongue. Close the mouth and press the tongue gently to the roof of the mouth until the nicotine film dissolves (approximately 3 minutes).
- The number of films a day is variable and depends on the patient's needs. Patients should not take more than 15 films per day.
- The film should not be chewed or swallowed whole.
- Patients should not eat or drink while a nicotine film is in the mouth.
- As an aid for smoking cessation, for weeks 1-6, patients should use 1 film every 1 to 2 hours, then 1 film every 2 to 4 hours for weeks 7 to 9, then 1 film every 4 to 8 hours for weeks 10 to 12.
- During weeks 1 to 6 it is recommended that users take a minimum of 9 films per day.
- To help stay smoke free beyond 12 weeks, users may take 1-2 Strips per day only on occasions when they are strongly tempted to smoke.
- Common side-effects: nausea, pharyngitis, insomnia, headache, dizziness.

### **Nicorette Microtab**

- Oral sublingual administration.
- Each tablet should be placed under the tongue and allowed to dissolve.
- For patients smoking fewer than 20 cigarettes a day, 1 tablet every 1 hour, increased to 2 tablets every 1 hour if required, maximum 40 tablets per day.
- For patients smoking more than 20 cigarettes a day, 2 tablets every 1 hour, maximum 40 tablets per day.
- If attempting smoking cessation, treatment should continue for up to 3 months before reducing the dose.
- Specific side-effects: dry mouth, gastrointestinal discomfort, palpitation.

### **Nicorette Nasal Spray**

- Intranasal administration.
- Use 1 spray as required, patients can spray into each nostril when the urge to smoke occurs, up to twice every hour for 16 hours daily, maximum 64 sprays per day.
- If attempting smoking cessation, treatment should continue for 8 weeks before reducing the dose.
- Specific side-effects: coughing, nasal irritation, epistaxis, sneezing, and watery eyes.

### **Nicorette QuickMist Mouth Spray**

- Oral administration.
- The oral spray should be released into the mouth, holding the spray as close to the mouth as possible and avoiding the lips. The patient should not inhale while spraying and avoid swallowing for a few seconds after use. If using the oral spray for the first time, or if unit not used for 2 or more days, prime the unit before administration.
- Use 1–2 sprays as required, patients can spray in the mouth when the urge to smoke occurs or to prevent cravings, individuals should not exceed 2 sprays per episode (up to 4 sprays every hour); maximum 64 sprays per day.
- No max or min treatment period is specified. Nicorette QuickMist should be used whenever the urge to smoke is felt or to prevent cravings in situations where these are

likely to occur. However, as soon as the patient can, the number of sprays should be reduced until patient has stopped using it completely.

- Specific side-effects: increased salivation, dry mouth, abdominal pain, flatulence, taste disturbance, paraesthesia, palpitations.

### 13. Storage of NRT

#### **RULE**

At each site where a Smoking Advisor is based, the storage of stock NRT products must be in a locked cupboard that is attached to a wall as defined by the Trust Medicines Policy for a medicine. A stock register should be maintained indicating receipts and administration of NRT products. The running total should be checked when a supply is issued.

### 14. NRT Products - Dosage and method of administration

See British National Formulary (BNF) (<http://www.bnf.org/bnf/>) or the Summary of Product Characteristics (SPC) (<http://www.medicines.org.uk/>) for details about the individual products.

### 15. Drug Interactions (also see Appendix 3)

**SMOKING CESSATION/REDUCTION LEADS TO CHANGES IN THE METABOLISM OF MEDICATION. The products of burning tobacco induce liver enzymes (esp: CYP1A2) to metabolise some medicines more quickly.**

- **Clozapine metabolism is increased in smokers. If smokers reduce or stop tobacco consumption it is highly likely their serum levels of clozapine will increase** - toxicity has been observed during tobacco abstinence, and patients being treated with Clozapine therefore need their quit attempt to be monitored closely.
  - Studies indicate that quitting smokers may only need around 2/3 their previous dose of clozapine. Take trough plasma level before conversion to NRT and smoking cessation and after 1 week, or sooner if side-effects develop. Non-smoking levels can be estimated by the equation:  
Level=45.3+(1.474 x smoking level)ng/ml. (350-600ng/ml)
  - Signs and symptoms of clozapine overdose (from SPC for Denzapine ®) :Drowsiness, lethargy, areflexia, coma, confusion, hallucinations, agitation, delirium, extrapyramidal symptoms, hyperreflexia, convulsions; hypersalivation, mydriasis, blurred vision, thermolability; hypotension, collapse, tachycardia, cardiac arrhythmias; aspiration pneumonia, dyspnoea, respiratory depression or failure.
  - Suggested monitoring
    - Pulse (increase in heart rate)
    - Blood pressure (which may be high or low)
    - Temperature (fever)
    - Headaches
    - Tiredness
    - Constipation, upset stomach and vomiting

- Antipsychotics – Olanzapine, chlorpromazine, haloperidol, fluphenazine – service users stopping or reducing smoking may develop side effects and/or need lower doses.
- Antidepressants – fluvoxamine and duloxetine - service users stopping or reducing smoking may develop side effects and/or need lower doses.
- Benzodiazepines - service users stopping or reducing smoking may develop side effects - such as sedation, ataxia or confusion -and/or need lower doses.
- Zolpidem - service users stopping or reducing smoking may develop side effects - such as sedation or confusion - and/or need lower doses
- **Clinicians need to be alert for service users STARTING to smoke again as this will induce liver enzymes and drug metabolism.**
- **NRT ITSELF HAS NO SIGNIFICANT DRUG/DRUG INTERACTIONS.**

Stopping smoking may alter the circulating drug levels of the following

- Insulin
- Adrenergic agonists/antagonists
- Flecainide
- Tacrine
- Pentazocine
- Tamoxifen
- Verapamil
- Zotepine
- Mirtazapine (not significantly)
- Paracetamol
- Propranolol
- Warfarin-R
- Tricyclics (not significantly)
- Theophylline (significantly)

**A useful reference listing which medicines need dose adjustment when a patient stops smoking is available from UKMI Medicines Q&A 136.4 -**

**<http://www.evidence.nhs.uk/search?q=UKMI+Q%26A+136.4>**

## **16.NRT Side Effects and Adverse Reactions**

These are usually transient but may include the following, some of which are consequences of stopping smoking:

- nausea, dizziness, headache, cold and flu like symptoms, palpitations, dyspepsia and other gastro-intestinal disturbances, hiccups, insomnia, vivid dreams, myalgia, chest pain, blood pressure changes, anxiety and irritability, somnolence and impaired concentration, dysmenorrhoea.
- Local skin reactions to the NRT patches.
- Any serious side effects should be discussed with the client's adviser in the first instance. In addition use the 'Yellow Card Reporting Scheme' and inform the Medicines and Healthcare Products Regulatory authority.

- Advisers should seek appropriate advice about any suspected adverse drug reactions from the stop smoking services and offer this advice to the patient. The adviser should also record details of the adverse drug reaction and an incident form is completed.

## 17. Choice of NRT & Addiction to Smoking

Nicotine patches, lozenges or inhalators are generally the treatment of choice for service users in HPFT. These products are intended to be used for inpatients who either wish to quit smoking, or do not wish to stop smoking at this time, but need help to manage withdrawal symptoms and temporary abstinence. The Nicotine Withdrawal Management process aims to encourage NRT use in in-patients not attempting to quit, but to manage not smoking throughout the time their smoking is restricted.

This was introduced in recognition that even those patients who were escorted outside to smoke were likely to suffer withdrawal because they were not escorted out to smoke frequently enough and HPFT staff should not be seen to be condoning or encouraging smoking in service users and should be supporting abstinence whilst on secondary care premises.

NICE PH 48 Guidance Smoking Cessation in Secondary Care: acute, maternity and mental health services should be used to support this NRT Policy

## 18. Training/Awareness – STANDARD

Course	For	Renewal Period	Delivery Mode	Contact Information
Brief interventions	All clinical staff working in direct care	One off training	E-learning Face to face	For taught courses, contact the Learning & Development Team: <a href="mailto:Learning@hpft.nhs.uk">Learning@hpft.nhs.uk</a> You can check for future dates  Hertfordshire Stop Smoking Service: Email: <a href="mailto:stopsmokingservice@herts.gcsx.gov.uk">stopsmokingservice@herts.gcsx.gov.uk</a> Or Business Support Officer Hertfordshire Stop Smoking Service Telephone 01442 453071

## 19. Embedding a culture of Equality & RESPECT

The Trust promotes fairness and RESPECT in relation to the treatment, care & support of service users, carers and staff.

RESPECT means ensuring that the particular needs of 'protected groups' are upheld at all times and individually assessed on entry to the service. This includes the needs of people based on their age, disability, ethnicity, gender, gender reassignment status, relationship status, religion or belief, sexual orientation and in some instances, pregnancy and maternity.

Working in this way builds a culture where service users can flourish and be fully involved in their care and where staff and carers receive appropriate support. Where discrimination, inappropriate behaviour or some other barrier occurs, the Trust expects the full cooperation of staff in addressing and recording these issues through appropriate Trust processes.

**RULE:** Access to and provision of services must therefore take full account of needs relating to all protected groups listed above and care and support for service users, carers and staff should be planned that takes into account individual needs. Where staff need further information regarding these groups, they should speak to their manager or a member of the Trust Inclusion & Engagement team. Where service users and carers experience barriers to accessing services, the Trust is required to take appropriate remedial action.

<p><b>Service user, carer and/or staff access needs</b> (including disability)</p>	<p>Effective communication is essential when discussing treatment, especially where there are specific language and sensory communication requirements. The information provided should meet the individual's communication needs e.g. people with physical, sensory or learning disabilities or people who do not read or speak English. Staff may need to access the interpreting service, provide patient information leaflet in different format (eg. Audio, braille, large print), different language and provide support in medicines administration e.g. by supplying medicines in compliance aid etc. Medicines Management Team can direct /signpost staff who may require help in this regard.</p>
<p><b>Involvement</b></p>	<p>Service users / carers' views and belief about the treatment option must be considered and service users / carers must be involved in making decisions about pharmacological treatment. Risk and benefit including common side effects of the proposed treatment option must be discussed with service users / carers before the decision is made.</p>
<p><b>Relationships &amp; Sexual Orientation</b></p>	<p>All service users must be given the same consideration and appropriate advice/treatment by staff in terms of medicines and must be independent of their sexual orientation and relationship circumstances.</p>
<p><b>Culture &amp; Ethnicity</b></p>	<p>All service users must be given the same consideration and appropriate advice/treatment by staff in terms of medicines and must take into account of service users' culture and ethnicity. For example providing information on whether medicines contains gelatin or alcohol, providing information in service user' native language if s/he does not speak/read English etc.</p>
<p><b>Spirituality</b></p>	<p>All service users must be given the same consideration and appropriate advice/treatment by staff with regard to medicines which must take into account their spiritual belief system. For example providing advice about medicines and fasting during Ramadan for Muslim service users.</p>
<p><b>Age</b></p>	<p>Treatment, advice and information should match service users' age group. Unlicensed medicines including off-label use in children. Under 18s and over 65s should be given specific attention when pharmacological treatment decisions are considered owing to their physiological differences in how their body handle medicines and also due to licensing issues.</p>
<p><b>Gender &amp; Gender Reassignment</b></p>	<p>All service users must be given the same consideration and appropriate advice/treatment by staff with regards to medicines which must be independent of their circumstances.</p>

<b>Advancing equality of opportunity</b>	All service users must be given the same consideration and appropriate advice/treatment by staff in terms of medicines, which must be independent of their circumstances.
--	---

Many medicines may not be appropriate during pregnancy and breastfeeding. Some medicines may cause birth defects, congenital malformation if taken prior to or during pregnancy. Specialist advice should be sought when prescribing, dispensing, administering and handling some medicines for child bearing age or during breastfeed. Summary of Product Characteristics (SmPC), BNF, [www.uktis.org](http://www.uktis.org), Drugs in Pregnancy and Lactation (A reference guide to foetal and neonatal risk) by Briggs et al. may provide guidance to healthcare professionals involved in pharmacological management for pregnant, breastfeeding service users or service users of childbearing age.

### **Promoting and considering individual wellbeing**

Under the Care Act 2014, Section 1, the Trust has a duty to promote wellbeing when carrying out any of their care and support functions in respect of a person. Wellbeing is a broad concept and is described as relating to the following areas in particular:

- Personal dignity (including treatment of the individual with respect);
- Physical and mental health and emotional wellbeing;
- Protection from abuse and neglect;
- Control by the individual over day to day life including over the care and support provided and the way in which it is provided;
- Participation in work, training, education, or recreation;
- Social and economic wellbeing;
- Domestic, family and personal;
- Suitability of living accommodation;
- The individual's contribution to society.

There is no hierarchy and all should be considered of equal importance when considering an individual's wellbeing. How an individual's wellbeing is considered will depend on their individual circumstances including their needs, goals, wishes and personal choices and how these impact on their wellbeing.

In addition to the general principle of promoting wellbeing there are a number of other key principles and standards which the Trust must have regard to when carrying out activities or functions:

- The importance of beginning with the assumption that the individual is best placed to judge their wellbeing;
- The individual's views, wishes, feelings and beliefs;
- The importance of preventing or delaying the development of needs for care and support and the importance of reducing needs that already exist;
- The need to ensure that decisions are made having regard to all the individual's circumstances;
- The importance of the individual participating as fully as possible;
- The importance of achieving a balance between the individuals wellbeing and that of any carers or relatives who are involved with the individual;
- The need to protect people from abuse or neglect;

The need to ensure that any restriction on the individuals rights or freedom of action that is involved in the exercise of the function is kept to the minimum necessary

## 20.Process for monitoring compliance with this document

Action:	Lead	Method	Frequency	Report to:
Audit use of NRT products in inpatient wards	Head of Medicines management	Audit	Annual	DTC
Audit of Practice	Head of Nursing and Patient Safety	Audit	Bi-annual	SBU's

**21. Version Control**

**STANDARD**

Version	Date	Author	Status	Comment
V2	June 2008	Head of Medicines Management	Superseded	Archived
V2.1	June 2009	Head of Medicines Management	Superseded	Contact details updated.
V3	28 <sup>th</sup> April 2014	Head of Medicines Management	Superseded	Full review
V4	6 <sup>th</sup> July 2016	Chief Pharmacist	Current	Appendix 2 Protocol inserted and range of NRT products expanded Appendix 3 Smoking Cessation – Effect on Psychotropic Medication including Clozapine

**22. Archiving Arrangements**

**STANDARD:** All policy documents when no longer in use must be retained for a period of 10 years from the date the document is superseded as set out in the Trust Business and Corporate (Non-Health) Records Retention Schedule available on the Trust Intranet

A database of archived policies is kept as an electronic archive administered by the Compliance and Risk Facilitator. This archive is held on a central server and copies of these archived documents can be obtained from the Compliance and Risk Facilitator on request.

**23. Associated Documents**

**STANDARD**

- HPFT Medicines Formulary
- HPFT Medicines Policy
- HPFT Smoke Free Policy

**24. Supporting References**

**STANDARD**

Summary of Product Characteristics for NRT products - [www.medicines.org.uk](http://www.medicines.org.uk)

**25. Comments and Feedback** – List people/ groups involved in developing the Policy.

**STANDARD**

Executive Director Quality & Safety	Lead Nurses
Executive Director of Quality & Medical Leadership	Practice Governance Leads
Quality & Standards Manager	Drugs & Therapeutics Committee
Compliance and Risk Facilitator	Medicines Management Team
Head of Nursing and Patient Safety	



### HPfT Smoking Referral Form

I have discussed smoking with this client. They have agreed to be referred to the Hertfordshire Stop Smoking Service and to be contacted by a member of the Stop Smoking Team to discuss quitting.

Client's name: \_\_\_\_\_

Client's address: \_\_\_\_\_

Town: \_\_\_\_\_ Postcode: \_\_\_\_\_

Client's Date of Birth: \_\_\_\_\_

Client's landline phone number: \_\_\_\_\_

Client's mobile phone number: \_\_\_\_\_

Client's Relevant Medical History: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Please tick this box if the client would like to receive more information about Hertfordshire Stop Smoking Service

Referrer's name: \_\_\_\_\_  
Referrer's phone number: \_\_\_\_\_  
Team/Department: \_\_\_\_\_  
Date: \_\_\_\_\_

Please tick this box if you would like to receive information about the outcome of this client – Please ensure the section above is fully complete.

### Send or Fax or Phone:

Hertfordshire Stop Smoking Service  
Apsley Campus 1, Brindley Way, Hemel Hempstead, HP3 9BF

**Fax: 01442 453070 Phone: 0800 389 3 998**

NB: If the client declines a referral on this occasion, please give them the Hertfordshire Stop Smoking Service number and smoking cessation information.  
Offer support again at a later date.

## Appendix 2

# PROTOCOL FOR THE SUPPLY OF NICOTINE REPLACEMENT THERAPY (NRT) BY LEVEL 2 TRAINED SMOKING CESSATION ADVISORS

Date of authorisation: March 2016

Expiry date: March 2018

This protocol is intended to support patients admitted to HPFT in all inpatient settings when a doctor is unavailable to prescribe NRT products.

- Any NRT supply made under this protocol must be recorded is made in the Nurses' Discretionary Medication section on the front of the inpatient prescription chart as well as in the patient's EPR (Electronic Patient Record).
- NRT needs to be reviewed and prescribed by the team doctor on the inpatient prescription chart at the earliest opportunity

<b>Indication</b>	<ul style="list-style-type: none"> <li>• To aid smokers wishing to quit or reduce prior to quitting</li> <li>• To assist smokers who are unwilling or unable to smoke, or required to abstain</li> <li>• Safer alternative to smoking for smokers and those around them to reduce potential harm from passive smoking</li> </ul>
<b>Inclusion criteria</b>	<ul style="list-style-type: none"> <li>• Patient wishing to receive NRT for smoking cessation</li> <li>• Patients should be current regular smokers</li> <li>• Patient consent</li> </ul>
<b>Exclusion criteria</b>	<ul style="list-style-type: none"> <li>• Consent refused</li> <li>• Patients under the age of 18 (patients under the age of 18 a doctor will need to assess and prescribe NRT)</li> <li>• Hypersensitivity to any of their excipients/ component of the product.</li> <li>• Patients with chronic generalised dermatological disorders such as psoriasis, chronic dermatitis or urticaria should not use patches<sup>3</sup></li> <li>• Haemodynamically unstable patients hospitalised with severe arrhythmias, myocardial infarction, or cerebrovascular accident (including transient ischaemic attacks), and in patients with phaeochromocytoma or uncontrolled hyperthyroidism</li> <li>• Patients taking bupropion (Zyban®)</li> <li>• Patients taking varenicline (Champix®)</li> </ul>
<b>Special Considerations (including any relevant action to be taken)</b>	<ul style="list-style-type: none"> <li>• Regular monitoring for adverse effects is required and the patient's doctor should be notified for:             <ul style="list-style-type: none"> <li>○ Oral preparations in patients with Oesophagitis, gastritis, or peptic ulcers.</li> <li>○ Patients with moderate to severe hepatic impairment and/ or severe renal impairment</li> <li>○ Patients taking medication with a narrow therapeutic window, e.g. theophylline, <b>clozapine and other antipsychotics</b> and ropinirole. Stopping smoking may result in slower metabolism and a consequent rise in blood levels of medication. When smoking is discontinued, the dose of these drugs, in particular theophylline, cinacalcet, ropinirole, and some antipsychotics (including <b>clozapine, olanzapine, chlorpromazine, and haloperidol</b>), may need to be reduced.</li> <li>○ For patient taking <b>clozapine</b>, ascertain pre-admission smoking status and recent medication compliance, determine effect of smoking cessation and consider adjusting of dose by checking the plasma clozapine level. Continue to monitor emergence of adverse effects. (For</li> </ul> </li> </ul>

	<p>further guidance refer to HPFT NRT for Inpatient Policy).</p> <ul style="list-style-type: none"> <li>○ For patient taking <b>olanzapine</b>, ascertain pre-admission smoking status and recent medication compliance, determine effect of smoking cessation. A reduction in dose of 2.5 – 5mg may be indicated. Continue to monitor emergence of adverse effects. (Refer to HPFT NRT for Inpatient Policy).</li> </ul> <ul style="list-style-type: none"> <li>● NRT in pregnancy should be used only if smoking cessation without nicotine replacement fails. Intermittent therapy is preferable to patches but liquorice-flavoured nicotine products should be avoided. Patches are useful, if the patient is experiencing pregnancy-related nausea and vomiting. If patches are used, they should be removed before bed.<sup>2</sup></li> <li>● NRT can be used by women who are breast-feeding but patches should be avoided. NRT products taken intermittently are preferred as their use can be adjusted to allow maximum time between administration and feeding of the baby, to minimise the amount of nicotine in the milk. Oral forms of NRT are recommended.<sup>1</sup></li> <li>● Care is needed in patients with diabetes mellitus—blood-glucose concentration should be monitored more closely when initiating treatment.<sup>2</sup></li> <li>● NRT products do not pose a significant health risk. This is the case whether it is used as a substitute for, or in combination with, cigarettes<sup>5</sup></li> <li>● When supplying NRT it is important to consider appropriateness and potential for misuse.</li> <li>● The choice of nicotine replacement preparation depends largely on patient preference, and should take into account what preparations, if any, have been tried before.</li> <li>● There is not much evidence about which NRT preparation is best, however the following evidence exists which may aid decision: <ul style="list-style-type: none"> <li>○ Combining preparations (such as patch and inhalator) is more effective than using single agents alone, especially for those who show a high level of dependence on nicotine or have found single forms of NRT inadequate in the past.<sup>6</sup></li> <li>○ Transdermal patches are easiest to use. High-dose nicotine patches appear more effective than standard-dose patches in facilitating long-term smoking cessation particularly those smoking more than 10 cigarettes a day.<sup>7</sup></li> <li>○ Oral film may be more effective for heavy smokers since it is more rapidly absorbed, patients still get a nicotine “hit” and this may be preferred by more addicted smokers.</li> <li>○ Smokers with higher dependency benefit more from higher-dose nicotine products such as 4mg chewing gum.<sup>8</sup></li> <li>○ The inhalator may be preferred by those who wish to continue to hold a cigarette substitute.</li> <li>○ NRT, (nicotine gum in particular), has also been shown to help to control the weight gain commonly experienced after cessation.<sup>9</sup> However, nicotine gum is not approved by HPFT.</li> </ul> </li> </ul> <p>Local or service specific requirements and policies/guidelines that should be adhered:</p> <ul style="list-style-type: none"> <li>● HPFT Nicotine Replacement Therapy for Inpatients Policy</li> <li>● Other references, and further reading, are listed in this protocol.</li> </ul>
<p><b>Arrangements for referral for medical advice</b></p>	<ul style="list-style-type: none"> <li>● When NRT is thought appropriate but supply through this guidance is not recommended (i.e. any patient who fulfils an exclusion criterion) then the patient should be referred to a doctor, who will then be responsible for treatment.</li> <li>● Where intervention with varenicline might be more appropriate.</li> <li>● Any previous adverse reaction to NRT products e.g. palpitations, chest pain</li> </ul>

<b>Action to be taken if patient declines patient excluded</b>	<ul style="list-style-type: none"> <li>• Provide information about the dangers of smoking, the NHS Quit line number and support for all methods of smoking cessation. Refer to Hertfordshire Stop Smoking Service (HSSS) on 0800-3893998 or 01442-453071.</li> <li>• Record that consent was withheld in the medical notes</li> <li>• Refer patient to smoking cessation services or their doctor</li> </ul>
--	--

### Details of the medicine

<b>Name, form and strength of medicine</b>	<p>There are various brands of NRT available, and the brands to be used in the trust are based on the cost and variation in products.</p> <p>Refer to the individual product summary of product characteristics for further information.</p> <p>Not all NRT preparations included in this guidance will be available within the trust. NRT preparations that are stocked on any given site should be agreed with the appropriate unit manager and designated pharmacist.</p> <p>Nicotine transdermal patches are a prolonged-release formulation and are applied for 16 hours (with the patch removed overnight) or for 24 hours.</p> <p>Immediate-release nicotine preparations (gum, lozenges, inhalator, and oral film) are used whenever the urge to smoke occurs or to prevent cravings.</p> <p><b>Nicotine transdermal patches:</b> 16 hour patches (Nicorette<sup>®</sup> invisipatches):</p> <ul style="list-style-type: none"> <li>• 25mg patch (releasing nicotine approx. 25mg/16 hours)</li> <li>• 15mg patch (releasing nicotine approx. 15mg/16 hours)</li> <li>• 10mg patch (releasing nicotine approx. 10mg/16 hours)</li> </ul> <p><b>Nicotine medicated chewing gum:</b> (NOT APPROVED WITHIN HPFT)</p> <p><b>Nicotine inhalation cartridge:</b></p> <ul style="list-style-type: none"> <li>• Nicotine-impregnated plug for use in inhalator mouthpiece</li> <li>• Nicotine 15 mg/ cartridge</li> </ul> <p><b>Nicotine orodispersible film (strips):</b></p> <ul style="list-style-type: none"> <li>• Nicotine 2.5mg oral film</li> </ul> <p><b>Nicotine lozenge: (as Niquitin<sup>®</sup> Minis lozenges)</b></p> <ul style="list-style-type: none"> <li>• Nicotine 1.5mg</li> <li>• Nicotine 4mg</li> </ul> <p><b>Nicotine sublingual tablet:</b></p> <ul style="list-style-type: none"> <li>• Nicotine 2mg</li> </ul> <p><b>Nicotine nasal spray:</b></p> <ul style="list-style-type: none"> <li>• Nicotine 500 microgram per actuation</li> </ul> <p><b>Nicotine mouth spray:</b></p> <ul style="list-style-type: none"> <li>• Nicotine 1mg per actuation</li> </ul>
<b>Legal category</b>	GSL- General Sales List

<b>Off-label use</b>	All NRT preparations by Nicorette <sup>®</sup> , Nicotinell <sup>®</sup> (Except Nicotinell lozenges <sup>®</sup> ), and NiQuitin <sup>®</sup> are licensed to aid smokers wishing to quit or reduce prior to quitting, to assist smokers who are unwilling or unable to smoke, and as a safer alternative to smoking for smokers and those around them.
<b>Route/ method of administration</b>	<p><b><u>Prolonged-release formulation</u></b></p> <ul style="list-style-type: none"> <li>• <b>Nicotine transdermal patches:</b> Topical, to clean, dry, non-hairy skin site. Apply patch to a dry non-hairy area of the skin on the trunk or upper arm and hold in place for 10-20 seconds. Allow several days before replacing the patch on the previously used area.<sup>2,3</sup></li> </ul> <p><b><u>Immediate-release nicotine preparations</u></b></p> <ul style="list-style-type: none"> <li>• <b>Nicotine inhalation cartridge:</b> Insert the cartridge into the device and draw in air through the mouthpiece; each session can last for approximately 5 minutes. The amount of nicotine from 1 puff of the cartridge is less than that from a cigarette; therefore it is necessary to inhale more often than when smoking a cigarette. A single 15 mg cartridge lasts for approximately 40 minutes of intense use.<sup>2,3</sup></li> <li>• <b>Nicotine orodispersible film (strips):</b> oral. Place one film on the tongue. Close the mouth and press the tongue gently to the roof of the mouth until the nicotine film dissolves (approximately 3 minutes).<sup>1</sup></li> <li>• <b>Nicotine lozenge:</b> Each lozenge should be slowly dissolved in the mouth and periodically moved from one side of the mouth to the other. Lozenges last for 10–30 minutes, depending on their size.</li> <li>• <b>Nicotine sublingual tablet:</b> Each tablet should be placed under the tongue and allowed to dissolve.</li> <li>• <b>Nicotine nasal spray:</b> Initially 1 spray should be used in both nostrils but when withdrawing from therapy, the dose can be gradually reduced to 1 spray in 1 nostril.</li> <li>• <b>Nicotine oral spray:</b> The oral spray should be released into the mouth, holding the spray as close to the mouth as possible and avoiding the lips. The patient should not inhale while spraying and avoid swallowing for a few seconds after use. If using the oral spray for the first time, or if unit not used for 2 or more days, prime the unit before administration.</li> </ul>
<b>Dose and frequency</b>	<p><b><u>Prolonged-release formulation</u></b></p> <p><b>Nicotine transdermal patches:</b></p> <ul style="list-style-type: none"> <li>• For patients smoking 10 cigarettes or more a day, it is recommended that treatment be commenced with the highest strength patch (25mg/16hrs).<sup>2</sup></li> <li>• For patients smoking fewer than 10 cigarettes daily can usually start with the medium strength patch (15mg/16hrs).<sup>2</sup></li> </ul> <p>Apply 1 patch once daily, remove 16 hours later or before bed, apply fresh patch next morning.</p> <p><b><u>Immediate-release nicotine preparations</u></b></p> <p><b>Nicotine inhalation cartridge:</b></p> <ul style="list-style-type: none"> <li>• Inhale when urge to smoke occurs for 40 minutes per cartridge throughout the day as required, up to a maximum usage of 6 cartridges per day.</li> <li>• Each cartridge can be used for approximately eight 5-minute sessions, with</li> </ul>

	<p>each one lasting approximately 40 minutes of intense use.</p> <ul style="list-style-type: none"> <li>• Smokers willing or able to stop smoking immediately should initially replace all their cigarettes with the inhalator and as soon as they are able, reduce the number of cartridges used until they have stopped completely</li> <li>• Smokers aiming to reduce cigarettes should use the inhalator as needed, between smoking episodes to prolong smoke-free intervals and with the intention to reduce smoking as much as possible.</li> </ul> <p><b>Nicotine orodispersible film:</b></p> <ul style="list-style-type: none"> <li>• Suitable for smokers who have their first cigarette of the day more than 30 minutes after waking up.</li> <li>• The number of films a day is variable and depends on the patient's needs. Use strips whenever there is a strong urge to smoke in order to reduce the number of cigarettes smoked as far as possible and to refrain from smoking as long as possible. Patients should not take more than 15 films per day</li> <li>• Users should be encouraged to stop smoking completely as soon as possible.</li> </ul> <p><b>Nicotine lozenge:</b></p> <ul style="list-style-type: none"> <li>• One lozenge every 1–2 hours when the urge to smoke occurs. Patients should not exceed 15 lozenges daily.</li> <li>• For patients who smoke less than 20 cigarettes each day should usually use the lower-strength lozenges</li> <li>• For patients who smoke more than 20 cigarettes each day and those who fail to stop smoking with the low-strength lozenges should use the higher-strength lozenges.</li> </ul> <p><b>Nicotine sublingual tablet:</b></p> <ul style="list-style-type: none"> <li>• For patients smoking fewer than 20 cigarettes a day, 1 tablet every 1 hour, increased to 2 tablets every 1 hour if required, maximum 40 tablets per day.</li> <li>• For patients smoking more than 20 cigarettes a day, 2 tablets every 1 hour, maximum 40 tablets per day.</li> </ul> <p><b>Nicotine nasal spray:</b></p> <ul style="list-style-type: none"> <li>• Use 1 spray as required, patients can spray into each nostril when the urge to smoke occurs, up to twice every hour for 16 hours daily, maximum 64 sprays per day.</li> </ul> <p><b>Nicotine oral spray:</b></p> <ul style="list-style-type: none"> <li>• Use 1–2 sprays as required, patients can spray in the mouth when the urge to smoke occurs or to prevent cravings, individuals should not exceed 2 sprays per episode (up to 4 sprays every hour); maximum 64 sprays per day.</li> </ul>
<p><b>Quantity to be administered and/or supplied</b></p>	<ul style="list-style-type: none"> <li>• <b>For patients in the community and in secure environments</b> : up to two original packs can be supplied</li> <li>• <b>For inpatients maximum quantity (for 72 hours):</b> <ul style="list-style-type: none"> <li>○ <b>Nicotine transdermal patches:</b> Maximum supply: Three patches.</li> <li>○ <b>Nicotine inhalation cartridge:</b> One inhalator unit and maximum 18 cartridges.</li> <li>○ <b>Nicotine strips oral film:</b> Maximum supply: 45 strips</li> <li>○ <b>Nicotine lozenge:</b> Maximum supply: 45 lozenges</li> <li>○ <b>Nicotine sublingual tablet:</b> Maximum supply: 120 tablets</li> <li>○ <b>Nicotine nasal spray:</b> Maximum supply: One 200-spray unit</li> </ul> </li> </ul>

	<ul style="list-style-type: none"> <li>○ <b>Nicotine oral spray:</b> Maximum supply: One 150-dose pack</li> </ul>
<b>Maximum or minimum treatment period</b>	<p><b>Nicotine transdermal patches:</b></p> <ul style="list-style-type: none"> <li>• Patients who smoke more than 10 cigarettes daily should apply a high-strength patch daily for 6–8 weeks, followed by the medium-strength patch for 2 weeks, and then the low-strength patch for the final 2 weeks.</li> <li>• Patients who smoke fewer than 10 cigarettes daily can usually start with the medium-strength patch for 6–8 weeks, followed by the low-strength patch for 2–4 weeks.<sup>2,3</sup></li> <li>• A slower titration schedule can be used in patients who are not ready to quit but want to reduce cigarette consumption before a quit attempt.<sup>2</sup></li> <li>• If abstinence is not achieved, or if withdrawal symptoms are experienced, the strength of the patch used should be maintained or increased until the patient is stabilised.<sup>2</sup></li> <li>• Patients using the high-strength patch who experience excessive side-effects, that do not resolve within a few days, should change to a medium-strength patch for the remainder of the initial period and then use the low-strength patch for 2–4 weeks.<sup>2</sup></li> </ul> <p><b>Nicotine inhalation cartridge:</b></p> <ul style="list-style-type: none"> <li>• As an aid for smoking cessation, the inhalator should initially be used to replace all cigarettes. As soon the person is able, reduce the number of cartridges used until they have stopped completely. Those who have quit smoking but are having difficulty discontinuing their inhalator should be referred to a doctor.</li> </ul> <p><b>Nicotine oral film:</b></p> <ul style="list-style-type: none"> <li>• As an aid for smoking cessation, for weeks 1-6, patients should use 1 film every 1 to 2 hours, then 1 film every 2 to 4 hours for weeks 7 to 9, then 1 film every 4 to 8 hours for weeks 10 to 12.</li> <li>• During weeks 1 to 6 it is recommended that users take a minimum of 9 films per day.</li> <li>• To help stay smoke free beyond 12 weeks, users may take 1-2 Strips per day only on occasions when they are strongly tempted to smoke.</li> </ul> <p><b>Nicotine lozenge:</b></p> <ul style="list-style-type: none"> <li>• If attempting smoking cessation, treatment should continue for 6–12 weeks before attempting a reduction in dose.</li> </ul> <p><b>Nicotine sublingual tablet:</b></p> <ul style="list-style-type: none"> <li>• If attempting smoking cessation, treatment should continue for 3 months before reducing the dose.</li> </ul> <p><b>Nicotine nasal spray:</b></p> <ul style="list-style-type: none"> <li>• If attempting smoking cessation, treatment should continue for 8 weeks before reducing the dose.</li> </ul> <p><b>Nicotine oral spray:</b> No max or min treatment period is specified. Nicorette QuickMist should be used whenever the urge to smoke is felt or to prevent cravings in situations where these are likely to occur. However, as soon as the patient can, the number of sprays should be reduced until patient has stopped using it completely.</p>
<b>Adverse effects</b>	For a comprehensive list refer to the manufacturer's Summary of Product Characteristics

**General side effects of NRT:**

These are usually transient but may include the following, some of which are a consequence of stopping smoking:

- Nausea, dizziness, headache and cold and influenza-like symptoms, palpitations, dyspepsia and other gastro-intestinal disturbances, hiccups, insomnia, vivid dreams, myalgia; other side-effects reported include chest pain, reversible atrial fibrillation, blood pressure changes, anxiety and irritability, somnolence and impaired concentration, abnormal hunger, dysmenorrhoea, rash.

**Specific side effects:****Nicotine transdermal patches:**

- Insomnia (remove patch at night if affected)
- Skin reactions:
  - Very common >1/10: itching
  - Common  $\geq 1/100 < 1/10$ : erythema
  - Uncommon  $\geq 1/1,000 < 1/100$ : urticaria
  - Discontinue use if severe or persistent. Another form of NRT can be used

**Nicotine medicated chewing gum:**

- Wind
- Very common >1/10: hiccups, sore mouth or throat irritation, jaw- muscle ache, nausea
- Common  $\geq 1/100 < 1/10$ : vomiting
- Uncommon  $\geq 1/1,000 < 1/100$ : urticarial, erythema
- Rare  $\geq 1/10,000 < 1/1,000$ : allergic reaction including angioedema

**Nicotine inhalation cartridge:**

- Rhinitis
- Very common >1/10: coughing, irritation in throat and mouth
- Common  $\geq 1/100 < 1/10$ : nausea, vomiting, nasal congestion

**Nicotine oral film:**

- Very common  $\geq 1/10$ : nausea
- Common  $\geq 1/100$  to  $< 1/10$ : insomnia headache, dizziness, pharyngitis, cough, pharyngolaryngeal pain, vomiting, dyspepsia, abdominal pain upper, diarrhoea, dry mouth, constipation, hiccups, stomatitis, flatulence, oral discomfort

**Nicotine lozenge:**

- Very common >1/10: Sore mouth or throat, nausea, gastrointestinal discomfort, hiccups
- Common  $\geq 1/100 < 1/10$ : Vomiting, coughing
- Uncommon  $\geq 1/1,000 < 1/100$ : Erythema, urticaria
- Rare  $\geq 1/10,000 < 1/1,000$ : Allergic reactions including angioedema

**Nicotine sublingual tablet:**

- Common  $\geq 1/100 < 1/10$ : Dizziness, headache, palpitation, coughing, gastrointestinal discomfort, hiccups, nausea, sore mouth or throat, dry mouth, burning sensation in the mouth, rhinitis.

**Nicotine nasal spray:**

- Very common >1/10: Epistaxis, running nose, sneezing, watering eyes.
- Common  $\geq 1/100 < 1/10$ : Dizziness, headache, coughing, gastrointestinal

	<p>discomfort, nausea, vomiting.</p> <ul style="list-style-type: none"> <li>• Uncommon <math>\geq 1/1,000 &lt; 1/100</math>: Palpitations.</li> </ul> <p><b>Nicotine oral spray:</b></p> <ul style="list-style-type: none"> <li>• Very common <math>&gt;1/10</math>: Dysgeusia, headache, hiccups, nausea, dyspepsia, oral soft tissue pain and paraesthesia, stomatitis, salivary hypersecretion, burning lips, dry mouth and/or throat</li> <li>• Common <math>\geq 1/100 &lt; 1/10</math>: Dizziness, vomiting, flatulence, abdominal pain, diarrhoea, throat tightness, fatigue, chest pain and discomfort and toothache.</li> <li>• Uncommon <math>\geq 1/1,000 &lt; 1/100</math>: Paraesthesia, lacrimation increase, palpitations, flushing, rhinorrhoea, dyspnoea, bronchospasm, sneezing, nasal congestion, gingivitis, glossitis, dry skin, hyperhidrosis, rash, urticaria, pruritus, hypersensitivity, musculoskeletal pain.</li> </ul> <p>Report all suspected serious reactions for established drugs and <b>all</b> suspected reactions for black triangle drugs, to the MHRA, using the BNF or go to <a href="http://www.yellowcard.gov.uk">www.yellowcard.gov.uk</a></p> <p>All adverse reactions / incidents should be reported to the service lead. Record details in clinical record. All significant incidents should be reported on DATIX.</p>
<b>Interacting Medicines</b>	<ul style="list-style-type: none"> <li>• No clinically relevant interactions between nicotine replacement therapy and other medicinal products have definitely been established; however nicotine may possibly enhance the haemodynamic effects of adenosine.</li> <li>• Smoking cessation itself may require the adjustment of some drug therapy (see special considerations section)</li> </ul>
<b>Records to be kept</b>	<p>Record:</p> <ul style="list-style-type: none"> <li>• Patient's name, address, date of birth and consent given in clinical notes</li> <li>• Dose and form administered, batch details, expiry date and brand or manufacture in clinical notes</li> <li>• Advice given to patient (including side effects)</li> <li>• Date of administration</li> <li>• Name of staff that supplied or administered the medication, plus signature for paper-based records (signature not needed for computer based records with password protection). Also if relevant, signature/name of staff who removed/discontinued the treatment. (signature not needed for computer based records with password protection)</li> <li>• Details of any adverse drug reaction and actions taken including documentation in the patient's medical record, and reporting to the doctor and/or Commission on Human Medicines if serious. See <a href="http://www.yellowcard.gov.uk">www.yellowcard.gov.uk</a> or BNF.</li> <li>• All suspected adverse reactions to "black triangle" medicines should be reported to the CHM via a yellow card.</li> <li>• Referral arrangements (including self-care)</li> </ul>

### Patient information

<b>Written information to be given to patient or carer</b>	<ul style="list-style-type: none"> <li>• Advice about adverse reactions and follow-up. Patients experiencing unexpected, unusual or worrying side effects should be advised to contact the nurse/ or physiotherapist for further advice. HSSS can be contacted on 0800-3893998 or 01442-453071 if staff have queries or speak to L2 trained stop smoking adviser.</li> <li>• Patients should be advised of minor side effects, offered symptomatic advice, and encouraged to persevere with treatment/cessation.</li> <li>• Stopping smoking may result in slower metabolism and a consequent rise in blood levels of theophylline, clozapine and ropinirole.</li> </ul>
--	--

- Manufacturer's Patient Information Leaflet (PIL) to be offered to patient and discussed as required.

**Nicotine transdermal patches:**

- Patches should not be placed on broken or inflamed skin
- Minor skin reactions are seen at the patch application site in a proportion of patients when commencing treatment. If skin reactions become more severe or more generalized, patients should be advised to discontinue use of patches and seek advice
- Exercise may increase absorption of nicotine and therefore side effects.
- Once the patch is spent it should be folded in half and disposed of carefully.
- Patients should not try to alter the dose of the patch by cutting it up.
- Used patches will contain residual nicotine and should be disposed of safely.

**Nicotine inhalation cartridge:**

- 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 and that less nicotine is delivered per inhalation. Therefore the patient 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. In cold conditions (below 15°C) the nicotine evaporates less readily and it will be necessary to inhale more frequently, whilst in warm conditions (above 30°C) nicotine will evaporate more readily and inhalation should be less frequent to avoid overdose.<sup>3</sup>
- 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 waste.<sup>3</sup>

**Nicotine orodispersible film:**

- The film should not be chewed or swallowed whole.
- Users should not eat or drink while a nicotine film is in the mouth.
- Oral films are individually foil packaged.<sup>1</sup>

**Nicotine lozenge:**

- When there is an urge to smoke, suck 1 lozenge until taste becomes strong. Rest lozenge between gums and cheek. When taste fades, resume and continue until lozenge dissolves completely.
- Patients should be advised not eat or drink while a lozenge is in the mouth.

**Nicotine sublingual table:**

- Place the tablet under your tongue and allow it to slowly dissolve. This will release nicotine, which you will absorb through the lining of your mouth.
- The tablet should NOT be chewed or swallowed.

**Nicotine nasal spray:**

- If patient is using the nasal spray for the first time or if patient has not used the spray for 2-3 days, patient must first prime the spray pump. (refer the product leaflet for instructions).
- Insert the spray tip into one nostril, pointing the top towards the back of the nose. Press firmly and quickly. Then, insert the spray tip into the other nostril and repeat.
- The spray should be stored protected from light.
- Patient may find that in the first few days of use the spray may irritate their nose and make them sneeze and their eyes water. If this occurs, advise

	<p>them not to drive or operate machinery until these unwanted effects have stopped.</p> <p><b>Nicotine oral spray:</b></p> <ul style="list-style-type: none"> <li>• If patient is using the oral spray for the first time or if patient has not used the spray for 2 days, patient must first prime the spray pump.(refer to product leaflet for instructions)</li> <li>• After priming, point the spray nozzle as close to the open mouth as possible. Press the top of the dispenser and release one spray into the mouth, avoiding the lips. Do not inhale while spraying to avoid getting spray down your throat. For best results, do not swallow for a few seconds after spraying.</li> <li>• The patient should not eat or drink when administering the oral spray.</li> <li>• Care should be taken not to spray the eyes whilst administering the oral spray.</li> </ul>
<b>Follow-up advice to be given to patient or carer</b>	<ul style="list-style-type: none"> <li>• Advise patient if they need further follow up as appropriate</li> <li>• Patients who receive NRT under this protocol or wish to stop smoking should be offered specialist behavioural support (e.g. in the form of advice) to encourage patients to maximise the benefits that they can gain from NRT. This support might be from the nurse and/or physiotherapist</li> <li>• NICE recommends offering, and if they agree, using measurements of exhaled carbon monoxide 4 weeks (Nice quality standard) after the quit date and during each contact, to motivate and provide feedback on progress.<sup>4</sup></li> <li>• Patients taking NRT should have contact with their nurse and/ or physiotherapist at least every 2 weeks for the first month. Once successfully using NRT, support may be reduced to every four weeks.</li> </ul>

### Training and competency

	<b>Requirements of working under the WI</b>
<b>Qualifications</b>	<ul style="list-style-type: none"> <li>• Healthcare staff member who have completed Level 2 training from a Trust approved Specialist Smoking Cessation course</li> <li>• The healthcare staff member must be signed off as having completed the training by their line manager</li> </ul>
<b>Initial training</b>	<ul style="list-style-type: none"> <li>• Successful completion of minimum Level 2 training from a Trust approved Specialist Smoking Cessation course</li> <li>• Contraindications, specific considerations and possible side effects of NRT</li> <li>• Competency and knowledge of pharmacotherapy therapies for smoking cessation: <ul style="list-style-type: none"> <li>➢ Level 2 smoking cessation course</li> <li>➢ Knowledge of Trust Guidelines on NRT</li> <li>➢ Has undertaken appropriate basic life support CPR/ anaphylaxis training</li> </ul> </li> </ul>
<b>Ongoing training and competency</b>	<p>The Healthcare staff member should:</p> <ul style="list-style-type: none"> <li>• Be aware of any change to the Summary of Product Characteristics for the medicine</li> <li>• Keep up-to-date with continued professional development, in line with their professional registering body.</li> <li>• Attend training in basic life support</li> <li>• Reflection/ evaluation at annual appraisal including smoking cessation</li> <li>• The practitioner should be aware of any change to the recommendations for the medicine listed. It is the responsibility of the individual to keep up-to-date with continued professional development.</li> </ul>

## Key references

1. Manufacturer's Summary Product Characteristics:  
<http://www.medicines.org.uk/emc/>
2. New advice on use of nicotine replacement therapy (NRT): wider access in at-risk populations. December 2005. The Medicines and Healthcare products Regulatory Agency (MHRA)  
[www.mhra.gov.uk](http://www.mhra.gov.uk)
3. British National Formulary Number 70 Joint Formulary Committee (online). London: BMJ Group and Pharmaceutical Press Year 2015 <http://www.medicinescomplete.com/bnf/current>
4. NICE guidance: Smoking cessation in secondary care: acute, maternity and mental health services, Issued: November 2013, NICE public health guidance 48
5. NICE Guidance: Tobacco: harm-reduction approaches to smoking Issued: June 2013 last modified: July 2013 NICE public health guidance 45
6. NICE Guidance on Smoking cessation services in primary care, pharmacies, local authorities and workplaces, particularly for manual working groups, pregnant women and hard to reach communities. <http://www.nice.org.uk/> Public health guidance no. 10 February 2008. National Institute for Clinical Excellence. [www.nice.org.uk](http://www.nice.org.uk)
7. West, R., McNeill, A. and Raw, M. (2000a) Smoking cessation guidelines for health professionals: an update. *Thorax* 55(12): 987-99.
8. West, R. and Shiffman, S. (2004) Smoking cessation. Fast facts: indispensable guides to clinical practice. Oxford: Health Press, pp. 63-5.
9. Andrew Molyneux ABC of smoking cessation: Nicotine Replacement Therapy (NRT) *BMJ Clinical Review* 2004; 328:454-45
10. National Institute for Health and Care Excellence (2013). Patient Group Directions. Good practice guidance 2  
<http://www.nice.org.uk/mpc/goodpracticeguidance/GPG2.jsp>
11. Nursing and Midwifery Council (NMC) (2008) Standards for medicine management  
<http://www.nmc.org.uk/globalassets/siteDocuments/NMC-Publications/NMC-Standards-for-medicines-management.pdf>
12. Nursing and Midwifery Council (NMC) (2015) The code: Standards of conduct, performance and ethics for nurses and midwives (Record keeping guidance is incorporated in the code)  
<http://www.nmc-uk.org/The-Code/The-Code-in-full/>
13. HPFT Medical treatment for mental disorder under the MHA Policy
14. HPFT Policy in Anaphylactic Reaction Emergency Treatment
15. HPFT Policy in Nicotine Replacement Therapy for Inpatients

**Authorization Record**

- This protocol must be agreed to and signed by all health care professionals involved in its use.
- The Service Lead should hold the original signed copy. The protocol must be easily accessible in the clinical setting. A copy should be available on the Trust Intranet.
- Authorised staff should be provided with an individual copy of the protocol and a photocopy of the document showing their authorisation.

I have read and understood the protocol and agree to supply/ administer this medicine only in accordance with this protocol

Name of Professional	Signature	Ward/Unit Manager	Date

## Appendix 3

### Smoking Cessation – Effect on Psychotropic Medication including Clozapine

#### Background

Cigarette smoking can affect the plasma levels of certain medications including those used in psychiatry. The products of burning tobacco induce the liver enzymes (esp CYP1A2) to metabolise some medicines more extensively. This enzyme inducing effect is removed on cessation of smoking, potentially giving rise to higher plasma levels of affected medicines.

**Nicotine (NRT) does not have the same enzyme inducing effect** as it is the polycyclic aromatic hydrocarbons in tobacco smoke NOT nicotine that affects hepatic enzymes.

Patients who stop smoking on admission to an in-patient unit may develop or experience a worsening of side-effects as a result of increased drug levels in the body and may need to have doses of certain medications reduced. Similarly, on discharge from an in-patient unit, if the patient is likely to resume smoking the dose may need to be increased.

The most significant effects on plasma levels are seen with **clozapine** and **olanzapine** where increases of up to 70% and 20% respectively have been reported. See overleaf for specific advice on **clozapine**. For **olanzapine** a reduction in dose of 2.5 – 5mg may be indicated (see factors to consider for dose adjustment below).

There are other medications that may also be affected by cessation of smoking - see table below. Service users must be monitored for adverse effects and each case must be considered individually.

#### Action recommended on admission / assessment:

- Ascertain pre-admission smoking status and recent medication compliance
- Determine effect of smoking cessation on psychotropic drugs from the table below
- Consider adjustment of dose, based upon the number of cigarettes the patient regularly smokes, the patient's mental state, and how well the patient tolerates the prescribed dose, and the time delay for drug plasma level changes to occur – usually not within the first 7 days. Continue to monitor for emergence of adverse effects
- Ascertain and monitor smoking status on leave / discharge. Readjust dose if indicated.

Psychotropic drugs	Plasma level of these drugs:-
chlorpromazine, fluphenazine, haloperidol, <b>olanzapine</b> , duloxetine, fluvoxamine, <b>clozapine</b> – see overleaf.	<i>Is likely to rise, therefore...</i> a dose reduction may be required. The patient must be monitored for adverse effects and plasma drug levels of clozapine must be monitored.
flupentixol, zuclopenthixol, trifluoperazine, mirtazapine, tricyclic antidepressants, lamotrigine, valproate, most benzodiazepines, zolpidem, propranolol	<i>May possibly rise, but...</i> this is not generally found to be clinically significant. If adverse effects occur, consider decreasing dose.
amisulpride, aripiprazole, quetiapine, risperidone, citalopram, escitalopram, fluoxetine, paroxetine, sertraline, moclobemide, reboxetine, venlafaxine, carbamazepine, chlordiazepoxide. (Note – lithium levels may reduce).	<i>Is unlikely to rise, therefore...</i> no interaction is expected. However, data are often limited so patients should be monitored for adverse effects.

NB: This guidance relates only to the effects of smoking cessation on psychotropic drugs. However it is essential to consider the potential effects on all medication prescribed. Other important medicines to consider in

those who smoke, or are trying to quit, include **theophylline, methadone** and **warfarin**. Smoking cessation can also affect glycaemic control in patients on **insulin**.  
Contact the Medicines Management or Kingsley Green Pharmacy for further information.

## CLOZAPINE AND SMOKING CESSATION

### Guidance on smokers who are taking clozapine and are admitted to in-patient units

1. **Review** latest (outpatient) serum clozapine levels (if available) and order a new baseline serum clozapine level as soon as practicable. (**Note – no ‘call-out’ is required, as dose reduction need not be immediate. Arrange bloods in normal ‘office hours’**).
2. **Review** side-effects history and, if possible, check against the serum clozapine levels at which they occurred.
3. **Assess** the risk of toxicity (i.e. if level exceeds 1000ng/ml) by estimating the non-smoking serum clozapine level using the formula below:

$$\text{Serum clozapine}^{(\text{Non-smoker})} = [1.5 \times \text{Serum clozapine}^{(\text{Smoker})}] + 50$$

**e.g. smoking level of 500ng/ml gives a non-smoking level of 800ng/ml**

**Note** The formula is considered to give a suitably accurate result in approximately 80% of cases. However, in patients with higher smoking clozapine levels or doses, (e.g. above 700ng/ml or above 700mg daily), the CYP1A2 enzyme may have been saturated resulting in much higher rates of metabolism. Greatly increased levels may then occur in these patients when they stop smoking and the formula may be wildly inaccurate.

4. **Set a target** (non-smoking) serum clozapine level, taking into consideration the patient’s current condition and clinical response to current dose / level. If indicated, adjust the clozapine dose accordingly. (**Note – if compliance has been poor prior to admission, the baseline level may be artificially low. This should be taken into consideration**).

For example

*Smoker admitted on clozapine 600mg daily and serum level found to be 480ng/ml. Compliant with medication but clinically unwell on this dose and considered to need a higher level. Estimated serum level on cessation of smoking is  $(1.5 \times 480) + 50 = 770\text{ng/ml}$ . If clinician considers that a target serum level of 770ng/ml is appropriate then no adjustment of dose may be necessary. However, if it is felt that the target level should be in the region of 600ng/ml, then the patient’s dose may need reducing to 450mg or 475mg daily. For levels above 500ng/mL consider seizure prophylaxis.*

5. Necessary reductions in daily dose should normally be made at a rate of approximately 10% per day.
6. **Monitor** serum clozapine level 5 to 7 days after smoking stopped and then weekly (until stabilised to target level). Also, pre-discharge level (unless done in previous 48 hours).
7. **Monitor** for adverse effects – bearing in mind that some may take as long as 2 to 3 weeks after adjustment of dose to become apparent.
8. **On discharge or leave**, reassess patient’s likelihood to recommence smoking and the potential reduction in serum clozapine level in response. If this occurs it is likely that the clozapine dose will have to be increased.

On discharge communicate to the receiving clinician eg any medication dose changes that have been made as a result of smoking cessation during an in-patient stay and the need to reassess smoking status and possible need to increase dose of medication if smoking is restarted.

9. **Post-discharge**, where possible, monitor serum clozapine level once each week, (or fortnightly if total dose change was less than 20%), until stable.

Medicines Management Team Sep 2015 (Adapted from Sussex Foundation NHS Trust)

	<i>we are...</i>	<i>you feel...</i>
<b>Our Values</b>	<b>Welcoming</b>	✔ Valued as an individual
	<b>Kind</b>	✔ Cared for
	<b>Positive</b>	✔ Supported and included
	<b>Respectful</b>	✔ Listened to and heard
	<b>Professional</b>	✔ Safe and confident

Our  values  
 Welcoming Kind Positive Respectful Professional