

Nicotine Replacement Therapy (NRT) Guidelines

Replacing document	New Guidelines
Target audience	All clinical staff
Author	Pharmacist – Karen Bartlett
Group responsible for developing document	Nicotine Management Strategy Group
Status	Approved
Authorised/Ratified By	Drugs & Therapeutics Committee
Authorised/Ratified On	5 May 2015
Date of Implementation	5 May 2015
Review Date	5 May 2018
Review	This document will be reviewed prior to review date if a legislative change or other event otherwise dictates.
Distribution date	June 2015
Number of Pages	26
Contact Point for Queries	policies@kmpt.nhs.uk
Copyright	Kent and Medway NHS and Social Care Partnership Trust 2015

DOCUMENT TRACKING SHEET

NICOTINE REPLACEMENT THERAPY GUIDELINES

Version	Status	Date	Issued to/approved by	Comments
0.1	draft	29 Aug 14	J Stock	
0.2	Draft	25 Sep 14	J Stock, stop smoking strategy group	Updated following advice from professionals from other trusts at the stop smoking conference
0.3	Draft	2 Oct 14	Stop smoking strategy group, St Martin's team	Updated following feedback from St Martin's ward managers
0.4	Draft	28 Jan 15		Updated following feedback from Smoking Strategy Group
0.5	Draft	10 Mar 15	Stop smoking strategy group, St Martin's team, pharmacy team	Updated following feedback from Smoking Strategy Group
0.6	For approval	2 April 15	D&T	Updated following approval of the smoking strategy policy
1.0	Approved	5/ May 15	D&T	
1.1	Approved	Jan 18	Policy Manager	Reference number removed as duplication of another policy reference number.

External references

1. ONS (2002). Living in Britain –Results from the 2001 General Household Survey. London Office for National Statistics
2. Joukamma, M., et al. Mental disorders and cause-specific mortality. British Journal of Psychiatry 2001;179:498-502
3. Department of Health (1998). Smoking kills: a white paper on tobacco. London Stationery Office
4. Smoking Cessation Services: NICE Public Health Guidance PH10, updated November 2013fa
5. McNeill, A. (2004). Smoking and patients with mental health problems. Health Development Agency
6. Nicotine replacement therapy and harm reduction. MHRA Drug Safety Update, Feb 2010, vol 3 issue 7: 6.
7. McRobbie H, McEwen A. PharmacyHealthLink, RPSGB, NICE. Helping smokers to stop: advice for pharmacists in England. 2005
8. Nicotine Replacement Therapy. Guidance for health professionals on changes in the licensing arrangements for nicotine replacement therapy. ASH December 2005. Available at www.ash.org.uk
9. RPS Support alert [info@rpsgb.net]. Guidance on Electronic Cigarettes in response to MHRA's statement on Nicotine-Containing Products (NCPs).18/06/2013.
10. Rostami-Hodjegan A Amin AM, Spencer EP, Lennard, MS, Tucker GT, Flanagan RJ. (2004). Influence of dose, cigarette smoking, age, sex and metabolic activity on plasma clozapine concentrations:A predictive model and nomograms to aid clozapine dose adjustment and to assess compliance in individual patients. J Clin Psychopharmacology, vol24, issue1:1-9.
11. Thomas KH et al. 2013. Smoking cessation treatment and risk of depression, suicide, and self harm in the Clinical Practice Research Datalink: prospective cohort study. BMJ Vol347:f5704)

CONTENT

1	INTRODUCTION	1
2	DEFINITIONS	2
3	PROCEDURE	2
3.1	CRITERIA FOR INCLUSION	2
3.2	CRITERIA FOR EXCLUSION	2
3.3	E-CIGARETTES.....	2
3.4	CAUTIONS FOR USE OF NRT	3
3.5	CAUTIONS FOR PATCHES ONLY:	3
3.6	ADOLESCENTS	3
3.7	PREGNANCY	3
3.8	BREASTFEEDING.....	4
3.9	CARDIOVASCULAR DISEASE.....	4
3.10	DIABETES MELLITUS	4
3.11	RENAL OR HEPATIC IMPAIRMENT.....	4
3.12	PHAEOCHROMOCYTOMA AND UNCONTROLLED HYPERTHYROIDISM	4
3.13	PLACE IN THERAPY FOR VARENICLINE AND BUPROPION.....	4
3.14	VARENICLINE INPATIENTS.....	5
3.15	OUTPATIENTS.....	5
3.16	BUPROPION.....	6
3.17	INITIATION OF NRT	6
3.18	PATIENTS WHO REFUSE NRT	6
3.19	INPATIENT REFERRALS.....	6
3.20	TEMPORARY ABSTINENCE	7
3.21	RECORDING USE OF NRT BY INPATIENTS.....	8
3.22	COMMUNITY REFERRALS	8
3.23	MANAGEMENT AND MONITORING MECHANISMS.....	8
3.24	ADVICE.....	8
3.25	INFORMATION SHARING.....	9
3.26	STAFF REFERRALS	9
3.27	SIDE EFFECTS AND ADVERSE REACTIONS.....	9
4	EQUALITY IMPACT ASSESSMENT	10
5	HUMAN RIGHTS	10

- APPENDIX 1 SMOKING CESSATION AND DRUG INTERACTIONS**
- APPENDIX 2 USING NRT PRODUCTS AT KMPT**
- APPENDIX 3 NRT RECORD CHART**
- APPENDIX 4 NRT FLOWCHART**
- APPENDIX 5 NRT ASSESSMENT FORM – PLEASE UPLOAD ONTO RIO**

1 INTRODUCTION

- 1.1 The aim of this guideline is to ensure the safe and effective use of Nicotine Replacement Therapy (NRT) by smokers seen by appropriately trained staff in Kent & Medway Partnership NHS Trust (KMPT).
- 1.2 These guidelines concentrate on the practicalities and the protocol of offering NRT to patients who are admitted to a smoke free unit. They are supplementary to the Trust Tobacco and Smoke Free Policy For Service Users. They also cover the effect of smoking cessation on the metabolism of various medicines and necessary dose adjustments.
- 1.3 Sections 1 – 4 of this guideline are aimed at all clinical staff. The appendices are applicable to medical staff and those staff trained to deliver level 2 smoking interventions. The following areas are covered within the appendices:
 - 1.3.1 Smoking and specific drug interactions
 - 1.3.2 Summary of NRT products available at KMPT
 - 1.3.3 Record of NRT use chart which is for the initiation and recording of NRT use
 - 1.3.4 Documentation for RIO
- 1.4 This guidance document has been generated to reflect the fact that the Trust premises and grounds will be completely Smoke Free from April 2015.
- 1.5 This means that upon admission a patient is unable to smoke and hence may require substitution with a suitable NRT product for the duration of the admission.
- 1.6 This Guideline has been developed to act as a framework under which appropriately trained staff will provide educational support and advice to patients motivated to stop smoking and those who need to stop smoking whilst on Trust premises.
- 1.7 Inpatients wanting to stop smoking can approach or be referred to the service and receive individually tailored smoking advice. This may involve the recommendation of, and counselling about, the most appropriate forms of NRT by the Smoking Cessation Specialist Advisor (SCSA) or by the trained level 2 advisor (qualified nurse or pharmacy employee).
- 1.8 Smoking remains the leading cause of preventable morbidity and premature death in England. It is estimated that between 1998 and 2002, smoking caused an average 86,500 deaths a year¹. Smoking rates are much higher amongst people with mental health problems than in the general population. Smokers with mental health problems are heavier and more dependent smokers than those in the general population. Patients with severe mental illness have a higher risk of premature death and the literature shows an elevated risk of death from cardiovascular disease, coronary heart disease, respiratory disease and suicide. It seems likely that smoking would contribute to the elevated risks of cardiovascular and respiratory diseases¹. For people with schizophrenia, the risk of dying of respiratory disease was found to be almost ten times that for other people².
- 1.9 Despite high cigarette consumption, the majority of smokers with severe mental illness want to stop smoking¹. NHS smoking cessation services across the country are now widely recognised and all smokers who wish to stop smoking should be referred to a

trained advisor for specialist support. Government policy now states that health professionals should refer patients who need support to such a service⁴. This guideline has therefore been produced and concentrates on the practicalities of issuing appropriate NRT to patients during their inpatient stay.

2 DEFINITIONS

2.1 Smoking Cessation Advisors

2.1.1 Advisors will be staff members trained by a Specialist Smoking Cessation Advisor to offer level 2 smoking cessation advice. These advisors will have attended the “Stop Smoking Intervention and NRT Prescribing” (Level 2) training. All the advisors will be registered with their local smoking cessation service provider and on their database. In addition qualified nurses and pharmacy staff who have qualified as level 2 advisors will be able to initiate and continue NRT.

2.2 Complete abstinence

2.2.1 Smokers who are highly motivated to stop smoking and are willing to set a quit date and receive intensive support from a trained smoking cessation advisor for as long as required.

2.3 Temporary abstinence (for the duration of their inpatient stay)

2.3.1 Smokers who need NRT to manage the symptoms of nicotine withdrawal for the duration of the admission but who do not wish to set a quit date.

3 PROCEDURE

3.1 Criteria for Inclusion

3.1.1 As of April 2015 the Trust buildings and grounds will be Smoke Free. This means that no-one is permitted to smoke under any circumstances whilst on Trust property.

3.1.2 NRT can be considered for complete abstinence or temporary abstinence.

3.2 Criteria for exclusion

3.2.1 It has become widely accepted that there are no circumstances in which it is safer to smoke than to use NRT⁶. In the following circumstances it is preferable to quit without the aid of NRT:

- a) People who have had a myocardial infarction or cerebrovascular accident in the last 4 weeks;
- b) Life-threatening cardiac arrhythmias;
- c) Severe or worsening angina pectoris.

3.2.2 If the patient meets the exclusion criteria, the advisor should not recommend the use of an NRT product as it is outside the guidelines. The patient may still be able to use NRT but will need it prescribed by a ward doctor. If NRT is deemed not to be appropriate for the patient after consultation with the ward doctor, an advisor should provide the behavioural support of the level 2 intervention only.

3.3 E-cigarettes

3.3.1 E-cigarettes will be permitted under the circumstances defined in the Tobacco and smoke free policy for service users.

3.4 Cautions for use of NRT

3.4.1 Risks / benefits must be considered before prescribing NRT in the following circumstances (in line with the Committee on Safety of Medicines Recommendations)⁶

- a) Those who are under 18 years old;
- b) Pregnant or breastfeeding women;
- c) Stable Cardiovascular Disease;
- d) Uncontrolled hypertension;
- e) Those with a previous serious reaction to NRT or any ingredients contained in the product, e.g. glue in the patch;
- f) Those taking medicines which interact with cigarette smoke ([appendix 1](#));
- g) Diabetes (additional glucose monitoring is required).

3.5 Cautions for patches only:

3.5.1 Those with a chronic generalised skin disease such as psoriasis, chronic dermatitis or urticaria;

3.5.2 Those who have had a previous reaction to the transdermal patch;

3.5.3 Occasional smokers.

3.6 Adolescents^{6,7}

3.6.1 Many young smokers show signs of nicotine dependence. Although there is little published data demonstrating the efficacy of NRT in young smokers, there is no logical reason why it should not help as long as it is used correctly and the smoker is determined to give up. Ultimately the decision to use NRT should be based on the smoker's determination to quit, and on their level of dependence (as opposed to age). Given that NRT is less harmful than smoking, safety concerns should not be a barrier to use and harm reduction principles should be applied when considering NRT for young people (12-17 years). The recommendations are to use NRT for three months in this age group. If it is needed for longer it should be reviewed by a health professional. Young people have the right to confidential medical advice and treatment if the provider assesses that the young person is able to understand what is being proposed and this will apply to the use of NRT products.

3.7 Pregnancy^{6,7}

3.7.1 Ideally, pregnant women should stop smoking without using NRT but, if this is not possible, NRT may be recommended to assist a quit attempt as it is considered that the risk to the foetus of continued smoking by the mother outweighs any potential adverse effects of NRT.

3.7.2 The decision to use NRT should be made following a risk-benefit assessment as early in pregnancy as possible. The aim should be to discontinue NRT use after 2-3 months. Intermittent forms of NRT are preferable during pregnancy although a patch may be appropriate if nausea and/or vomiting are a problem. If patches

are used, they should be removed before going to bed at night. Liquorice-flavoured products should be avoided.

3.8 Breastfeeding^{6,7}

3.8.1 NRT can be used by women who are breastfeeding. The amount of nicotine the infant is exposed to from breast milk is relatively small and less hazardous than the second-hand smoke they would otherwise be exposed to if the mother continued to smoke. If possible, patches should be avoided.

3.8.2 NRT products taken intermittently are preferred as their use can be adjusted to allow the maximum time between their administration and feeding of the baby, to minimise the amount of nicotine in the milk.

3.9 Cardiovascular disease^{6,7}

3.9.1 Although nicotine has some acute effects on the cardiovascular system, unlike tobacco smoke it is not a significant risk factor for cardiovascular disease or acute cardiac events. NRT provides less nicotine, less rapidly than cigarette smoking, without substances such as carbon monoxide (which is known to have adverse effects on the cardiovascular system). On this basis, experts agree that smokers with stable cardiovascular disease can safely use all NRT products.

3.9.2 It is recommended that the risks and benefits of using NRT should be assessed for smokers with unstable cardiovascular disease, or who have suffered an acute event in the past four weeks. If the only other option for this group is continued smoking, a risk–benefit assessment invariably leads to recommending NRT. Stopping smoking via non-pharmacological methods should be tried first. When using NRT for smokers with unstable cardiovascular disease, it is advisable to use the shorter-acting oral products, which can be discontinued immediately in the event of any problems. Nicotine patches, even once removed, leave a small reservoir of nicotine under the skin.

3.10 Diabetes mellitus

3.10.1 Nicotine releases catecholamines which can affect carbohydrate metabolism. Diabetic patients should be advised to monitor their blood sugar levels more frequently than usual when starting NRT.

3.11 Renal or hepatic impairment

3.11.1 NRT should be used with caution in patients with moderate to severe hepatic impairment and/or severe renal impairment, as the clearance of nicotine and/or its metabolites may be decreased, with the potential for increased adverse effects.

3.12 Pheochromocytoma and uncontrolled hyperthyroidism

3.12.1 Use NRT with caution.

3.13 Place in therapy for varenicline and bupropion

3.13.1 Although these two products are not NRT therapy they are included here as people may request information about the use of alternatives to NRT. This request may arise especially if NRT and a quit attempt has not been successful previously. The information below is for guidance and is not a recommendation to prescribe for KMPT patients.

3.14 Varenicline Inpatients

3.14.1 Varenicline will not usually be prescribed for inpatients at KMPT, as varenicline is cautioned in patients with a history of psychiatric illness.

3.15 Outpatients

3.15.1 Following assessment by the smoking cessation service and/or GP a patient may be considered suitable for varenicline to aid smoking cessation. When a patient also has a history of mental illness and has not been successful in quitting through non-pharmacological intervention or NRT the risks and benefits of using varenicline should be considered. Information regarding use of varenicline and mental health adverse effects currently published is discussed below.

3.15.2 A paper has been published in the BMJ (Varenicline and suicidal behaviour: a cohort study based on data from the General Practice Research Database D Gunnell et al. October 2009;339:b3805) which concludes that there was no clear evidence that patients prescribed varenicline were at increased risk of self harm, suicidal thoughts or depression when compared to patients prescribed other smoking cessation products. The authors do say that further study is needed regarding the possibility of increased suicide risk with varenicline and that such risk needs to be balanced against the long term health benefits of smoking cessation. Another paper published in Drug Safety in 2013 (Neuropsychiatric events with varenicline: a modified prescriptions study in general practice in England 36:521-531), did not find a statistical association between neuropsychiatric events and varenicline but found that these events were frequently reported as reasons for stopping or as adverse drug reactions by GPs. The study did show that of the neuropsychiatric events anxiety events were the most likely to be associated with varenicline use but this is difficult to analyse as anxiety is also a withdrawal symptom caused by smoking cessation. A further paper published in the Journal of Clinical Psychiatry in 2012 (73(5):654-660) concluded that varenicline was well tolerated with no exacerbation of symptoms for patients with schizophrenia or schizoaffective disorder.

3.15.3 A recent article published in the BMJ (Thomas KH et al. 2013. Smoking cessation treatment and risk of depression, suicide, and self harm in the Clinical Practice Research Datalink: prospective cohort study. Vol347:f5704) found no evidence for increased risk of suicidal behaviour for varenicline (or bupropion) compared to NRT and concluded that this evidence should offer reassurance for users and prescribers of smoking cessation medicines. The study population were selected from primary care databases and did include people with previous history or self harm and mental illness. NRT was more likely to be prescribed for patients with a history of mental illness than bupropion or varenicline.

3.15.4 Any decision to prescribe varenicline for a patient with a history of mental illness needs to be made on a case by case basis and to balance the risks of using varenicline with the benefits of smoking cessation for that individual. Possible exacerbation of mental health symptoms is a concern although emerging evidence and analysis shows that the association between varenicline and neuropsychiatric effects is not confirmed. Should varenicline be initiated in a patient who has a history of mental illness they should be informed of the risks and monitored for re-emerging symptoms. Prior to initiation the patient's mental health should be stable. Varenicline should not be initiated whilst a patient is actively suffering from anxiety as this will be difficult to differentiate from smoking cessation symptoms and possible adverse effects of varenicline.

3.16 Bupropion

3.16.1 Bupropion is contra-indicated in acute alcohol or benzodiazepine withdrawal, severe hepatic cirrhosis, history of seizures, CNS tumours, eating disorders and bipolar affective disorder (may precipitate a manic episode) making it unsuitable for a number of patients of KMPT.

3.16.2 It is also cautioned in the elderly, those with a predisposition to seizures or those taking concomitant drugs which lower seizure threshold (this includes most antidepressants and antipsychotics), alcohol abuse, history of head trauma and diabetes.

3.16.3 Concomitant use of bupropion with monoamine oxidase inhibitors (MAOIs) is contraindicated.

3.16.4 The cautions and contra-indications, including interaction with many psychotropic medicines make bupropion unsuitable for the majority of KMPT patients and will not be in general use.

3.17 Initiation of NRT

3.17.1 Whenever possible NRT should be initiated by a qualified member of nursing or pharmacy staff who has been trained to level 2, a Specialist Smoking Cessation Advisor or a doctor. The process for this is described in section 3.7.

3.17.2 If a patient is suffering withdrawal from nicotine and can not be seen by one of the above then NRT can be initiated by qualified nurses trained in the use of the NRT patient group directive (PGD).

3.17.3 All patients taking clozapine must have a level taken before or within 24 hours of stopping smoking (see appendix 1 for interactions and actions to be taken).

3.17.4 All patients taking clozapine, olanzapine, duloxetine, theophylline or warfarin must be reviewed by a doctor within 48 hours of admission (see appendix 1 for interactions and actions to be taken).

3.18 Patients who refuse NRT

3.18.1 If a patient has capacity to consent to treatment and refuses NRT then their decision must be respected. They should be monitored and if they show signs of withdrawal or nicotine craving then NRT should be offered again.

3.18.2 If a patient does not have capacity to consent to treatment then they should be monitored for signs of withdrawal. If NRT is considered to be of benefit to the patient then they can be given a nicotine patch under the relevant mental health act documentation. If necessary and appropriate this can be done using covert documentation and administration.

3.18.3 Patient consent must be obtained before their details are entered onto Quitmanager, the KSSS referral system.

3.19 Inpatient referrals

3.19.1 For those who have agreed a quit date (complete abstinence)

- a) Inpatients who have agreed a quit date (this will be the date of admission) will be seen by a member of KMPT staff who has the relevant level 2 training or by a Specialist Smoking Cessation Advisor. Some patients, particularly those on the rehabilitation units may access smoking cessation advice and products through their GP practice;

- b) The advisor will provide smoking cessation advice and, with the patient's consent, will record the patient's details on Quitmanager, the KSSS referral system;
- c) The patient will be assessed for suitability to receive NRT and from their history and preferences, appropriate NRT will be recommended. This may involve using more than one type of NRT product at the same time e.g. patches and lozenges (see appendix 2 for approved NRT products);
- d) When NRT is recommended by the advisor the consultation will be documented in the patient's progress notes on RIO and the NRT assessment form (appendix 5) uploaded into clinical documents on RIO.
- e) The level 2 smoking cessation advisor or duty doctor will then initiate the recommended product (s) on the nicotine replacement record chart ([appendix 3](#)), checking that there are no contra-indications with current medication. Some medications may require a dose adjustment once smoking has stopped ([appendix 1](#));
- f) The NRT record chart will be attached to the patient's drug chart;
- g) Once the NRT has been initiated on the chart it can be ordered from the pharmacy in the same way other non-stock medication is ordered (if not already kept as stock on the ward);
- h) Once the NRT is available on the ward the advisor will counsel the patient on how to use it;
- i) Patients are entitled to a free supply of NRT for the duration of their inpatient stay. Once discharged, if they are supported by local Stop Smoking Service and normally pay for their
- j) medication then they will pay the usual prescription fee;
- k) When a patient is admitted with NRT already prescribed it is the responsibility of the ward staff to contact the Smoking Cessation Advisor to arrange assessment, counselling and support, as appropriate during their admission. The hospital has a responsibility to continue to provide / pay for NRT until discharge;
- l) As part of the discharge care plan the ward staff should refer those patients continuing to be abstinent to the Community Stop Smoking Service for follow-up;
- m) Upon discharge those patients who intend to continue to be abstinent will receive one week's supply of NRT. After this their ongoing supply will be arranged by the local community smoking cessation advisors.

See appendix 4 for a flow chart for NRT on wards

3.20 Temporary abstinence

- 3.20.1 This applies to those patients who are admitted to an inpatient unit who do not wish to set a quit date, but are not permitted to smoke whilst they are an inpatient;
- 3.20.2 Following an initial assessment the member of staff will refer the patient to a level 2 specialist advisor on the inpatient unit;
- 3.20.3 The advisor will provide smoking cessation advice and, with the patient's consent, will record the patient's details on Quitmanager, the KSSS referral system;
- 3.20.4 The patient will be assessed for suitability to receive NRT and from their history and preferences, appropriate NRT will be recommended;

- 3.20.5 When NRT is recommended by the advisor the consultation will be documented in the patient's progress notes on RIO and the NRT assessment form (appendix 5) uploaded into clinical documents on RIO.
- 3.20.6 The level 2 smoking cessation advisor or duty doctor will then prescribe the recommended product (s) on the nicotine replacement therapy record chart (appendix 3), checking that there are no contra-indications with current medication. Some medications may require a dose adjustment once smoking has stopped ([appendix 1](#));
- 3.20.7 The NRT record chart will be attached to the patient's drug chart;
- 3.20.8 For the purposes of 'temporary abstinence' the wards will have a supply of commonly used NRT products on stock ([appendix 2](#)). Alternative nicotine products to this list can be ordered from pharmacy as a non-stock item in the usual way;
- 3.20.9 The patient should be offered the opportunity to make a quit attempt at regular intervals during their stay and as a minimum prior to discharge;
- 3.20.10 Unless the patient agrees to a 'quit attempt' during their admission, NRT will not be prescribed or supplied on discharge. If a quit attempt is agreed then the level 2 advisor will re-assess and follow Section 3.7.1.

See appendix 4 for a flow chart for NRT on wards

3.21 Recording use of NRT by inpatients

- 3.21.1 Following assessment of capacity to understand the instructions for use of the NRT product (s), risk assessment regarding safe use of the NRT product(s) and ability to manage safe keeping of the product the patient may be given the product to self administer. The record chart ([appendix 3](#)) should be completed whenever the patient is provided with a new stock of NRT;
- 3.21.2 The quantity of NRT product given to a patient is at the discretion of nursing staff, however it is recommended that only one inhalator cartridge be given at one time in order to minimise waste and cost;
- 3.21.3 Where a patient is not able to manage their own NRT product the ward will store the product(s) and a qualified nurse will supervise the patient using the product(s).

Staff should sign the record sheet each time they provide NRT to the patient to use.

3.22 Community referrals

- 3.22.1 People under the care of KMPT Community Mental Health Teams (CMHT) needing smoking cessation advice will be referred to a Specialist Advisor and the Community Stop Smoking Service (see section 3.10 for contact details).

3.23 Management and monitoring mechanisms

- 3.23.1 Advisors will be working under the direction of the specialist smoking cessation service in addition to these guidelines. The specialist smoking cessation service in each locality will follow a set of nationally agreed guidelines for Nicotine Replacement Therapy. The Trust Level 2 advisors will also work to these guidelines.

3.24 Advice

3.24.1 Advice to those who wish to start NRT should include product specific advice (see current edition of BNF).

3.24.2 The following general advice should also be given:

- a) Withdrawal symptoms;
- b) Possible changes in the body on stopping smoking, (e.g. weight gain) and how to manage these;
- c) The effects of smoking tobacco whilst using NRT – particularly in vulnerable groups, e.g. pregnant women, clients with cardiovascular disease;
- d) Follow up and obtaining further supplies of NRT;
- e) Written information on products supplied, self-help leaflets and where to obtain more information, in particular the NHS Helpline numbers for:
 - **NHS Helpline:** 0800 022 4 332
 - **Pregnancy Helpline:** 0800 169 9 169

Further information can also be obtained from the Community Stop Smoking Service:

Kent Stop Smoking Service

Patients: 0300 123 1220

Professionals: 0300 123 1240

Medway Stop Smoking Service

Staff smoking cessation: 01634 334800

Patients (Quit Positive): 01634 331074

3.25 Information sharing

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

3.25.2 Patient consent must be obtained before their details are entered onto Quitmanager, the KSSS referral system.

3.26 Staff referrals

3.26.1 KMPT Staff can seek smoking cessation advice through Occupational Health or through their GP and their local primary care smoking cessation services.

Kent Stop Smoking Service

Patients: 0300 123 1220

Professionals: 0300 123 1240

Medway Stop Smoking Service

Staff smoking cessation: 01634 334800

Patients (Quit Positive): 01634 331074

3.27 Side effects and adverse reactions

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

3.27.2 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.

3.27.3 Any serious side effects should be discussed with the patient's advisor in the first instance. In addition a "yellow card" should be completed, informing the Medicines and Healthcare Products Regulatory Authority (MHRA). Guidance on the use of the Yellow Card System and Yellow Cards are available in the current edition of the BNF and they can also be completed via: <http://yellowcard.mhra.gov.uk/>

3.27.4 Advisors should seek appropriate advice about any suspected adverse drug reactions from the stop smoking services and offer this advice to the patient. The

advisor should also record details of the adverse drug reaction and an incident form must be completed

4 EQUALITY IMPACT ASSESSMENT

4.1 The Equality Act 2010 places a statutory duty on public bodies to have due regard in the exercise of their functions. The duty also requires public bodies to consider how the decisions they make, and the services they deliver, affect people who share equality protected characteristics and those who do not. In KMPT the culture of Equality Impact Assessment will be pursued in order to provide assurance that the Trust has carefully considered any potential negative outcomes that can occur before implementation. The Trust will monitor the implementation of the various functions/policies and refresh them in a timely manner in order to incorporate any positive changes.

5 HUMAN RIGHTS

5.1 The Human Rights Act 1998 sets out fundamental provisions with respect to the protection of individual human rights. These include maintaining dignity, ensuring confidentiality and protecting individuals from abuse of various kinds. Employees and volunteers of the Trust must ensure that the trust does not breach the human rights of any individual the trust comes into contact with. If you think your policy/strategy could potentially breach the right of an individual contact the legal team.

APPENDIX 1 SMOKING CESSATION AND DRUG INTERACTIONS

Effects on psychotropic drugs

Smoking causes induction of hepatic enzymes

Cigarette smoke contains polycyclic aromatic hydrocarbons (PAHs) and it is these (not nicotine) that induce (increase the amount and/or activity of) the hepatic cytochromes enzymes CYP1A1, 1A2 and 2E1

Induction of these enzymes results in an increase in the metabolism of many drugs that are substrates for these enzymes and causes a subsequent decrease in plasma concentrations of those drugs. Higher doses of these drugs may therefore be required to achieve the same plasma level and therapeutic effect.

It is unclear how quickly the CYP enzymes are induced on commencing smoking; however, it generally takes more than a week before maximal enzyme induction is seen.

The extent or magnitude of induction varies according to the bioavailability of the cigarette smoke components (unfiltered cigarettes produce higher levels of some PAHs than filtered) and the extent of inhalation. Heavier smokers have the greatest increase in drug clearance. In one study (Chetty et al, 1994), the combination of cigarette and cannabis smoking produced a greater increase in drug clearance than cigarette smoking alone.

I. Smoking cessation: reversal of hepatic enzymes induction

In a study investigating the time frame for CYP1A2 changes on smoking cessation it was found that on stopping smoking there was a rapid decrease in activity of CYP1A2 with a new steady state being reached after approximately one week (Faber et al, 2004).

II. Effect of smoking cessation on psychotropic drugs

Smoking cessation can therefore increase levels of drugs that are metabolised via CYP1A2 and so a change in dosing may be necessary. Limited data is available for most drugs. Faber et al recommend that in drugs with a narrow therapeutic index, which are substrates at CYP1A2 (e.g. Clozapine), that a stepwise daily dose reduction of approx 10% until the fourth day after smoking cessation be undertaken. Clear guidelines for clinical practice are not available as there are very few reports on the actual pharmacokinetic changes which occur in psychotropic drugs when patients stop smoking.

III. Other factors to consider in prescribing psychotropic drugs during smoking cessation

Considerations should be given to the following:

- Amount of tobacco smoked – i.e. light, moderate, or heavy smoker. This may correlate with the level of nicotine dependence;
- Smoking status;
- Verification of non-smoking status (has the patient actually stopped smoking?);
- Expected changes to smoking status on leave/discharge (will the patient resume smoking on leave or on discharge?);

- Changes to psychotropic doses for other reasons;
- Time delay for changes to CYP1A2 levels on smoking cessation (or resumption) and subsequently the time delay for changes to steady state levels of the psychotropic drug;
- Age – there is less induction of CYP1A2 enzyme with increasing age;
- Liver dysfunction e.g. acute hepatitis following alcohol binge;

IV. Recommendations for the prescribing of psychotropic drugs during smoking cessation

a. General recommendations:

On admission to non-smoking inpatient unit:

- Ascertain pre-admission smoking status;
- Determine effect on specific medication (see table below);
- Adjust dose taking in to consideration age, hepatic function, time delay for onset of changes to metabolising enzymes;
- Monitor for possible emergence of side effects due to raised serum levels (or for lack of efficacy due to reduced serum levels – usually only the case when a patient is smoking without the knowledge of the treating team) for at least 14 days following smoking cessation;
- Monitor for change in smoking status e.g. when on leave;
- Ascertain likely smoking status on discharge (i.e. is the patient going to resume smoking?)

b. Specific recommendations:

From the NHS evidence website www.evidence.nhs.uk the more significant interactions are considered to be with theophylline, clozapine and olanzapine. More moderate interaction is considered to occur with warfarin, chlorpromazine, methadone and insulin. The table below shows the interactions predicted to occur on smoking cessation with these medicines and what prescribing changes might need to be made. For details of interactions with other medicines please see the full list of interactions at www.evidence.nhs.uk in the document titled 'Which medicines need dose adjustment when a patient stops smoking?' Prepared by UK Medicines Information (UKMi) pharmacists August 2012).

BNF category /	Nature of interaction	Clinical relevanc	Action to take when stopping smoking
2.8.2 Warfarin	Warfarin is partly metabolised via CYP1A2. An interaction with smoking is not clinically relevant in most patients. The dose of warfarin is adjusted according to a patient's INR (International	Moderate	If a patient taking warfarin stops smoking, their INR might increase so monitor the INR more closely. Advise patients to tell the physician managing their anticoagulant control that they are stopping

BNF category /	Nature of interaction	Clinical relevance	Action to take when stopping smoking
3.1.3 Theophylline	Theophylline is metabolised principally via CYP1A2. Smokers need higher doses of theophylline than non-smokers due to theophylline's shortened half-life and increased elimination. Some reports suggest smokers may need twice the dose of non-	High	Monitor plasma theophylline concentrations and adjust the dose of theophylline accordingly. The dose of theophylline may need to be reduced by about one quarter to one third one week after withdrawal. However, it may take several weeks for enzyme induction to dissipate. Monitor theophylline concentration periodically.
4.2.1 Chlorpromazine	Chlorpromazine is metabolised principally via CYP1A2. Smokers have lower serum levels of chlorpromazine	Moderate	Be alert for increased adverse effects of chlorpromazine (e.g. dizziness, sedation, extrapyramidal symptoms). If adverse effects occur, reduce the dose as
4.2.1 Clozapine	Clozapine is metabolised principally via CYP1A2 and clearance is increased in smokers. Serum clozapine levels are reduced in smokers compared with non-smokers; smokers may need higher doses. There have been case reports of adverse effects in patients taking clozapine when they have stopped	High	See guidance below
4.2.1 Olanzapine	Olanzapine is metabolised principally via CYP1A2 and clearance is increased in smokers. Serum olanzapine levels are reduced in smokers compared with non-smokers; smokers may need higher doses. There have been case	High	Be alert for increased adverse effects of olanzapine (e.g. dizziness, sedation, hypotension). If adverse effects occur, reduce the dose as necessary.

BNF category /	Nature of interaction	Clinical relevanc	Action to take when stopping smoking
4.10 Methadone	Methadone is metabolised via isoenzymes including CYP1A2. There has been a case report of respiratory insufficiency and altered mental status when a patient taking methadone for	Moderate	Be alert for signs of opioid toxicity and reduce the methadone dose accordingly.
6.1.1 Insulin	Smoking is associated with poor glycaemic control in patients with diabetes. Smokers may require higher doses of insulin but the mechanism of any	Moderate	If a patient with insulin-dependent diabetes stops smoking, their dose of insulin may need to be reduced. Advise the patient to be alert for signs of hypoglycaemia and to test their

Other psychotropic medications that require monitoring for adverse events and a dose reduction if these occur or worsen are:

Benzodiazepines (especially sedation)

Beta-blockers e.g. propranolol (especially hypotension, reduced heart rate etc)

Duloxetine (especially nausea, dry mouth, sedation etc)

Fluphenazine (especially EPSE side effects)

Fluvoxamine (especially nausea, dry mouth, sedation etc)

Haloperidol (especially EPSE side effects)

Lamotrigine (especially nausea, dizziness, drowsiness, headaches etc)

Lithium (complicated by interaction with caffeine, check levels especially if deterioration evident)

Mirtazapine (especially sedation)

Tricyclic antidepressants (especially nausea, dry mouth, cardiac effects, sedation etc)

Zolpidem (especially sedation and morning hangover)

Clozapin

e

Monitor serum drug levels before stopping smoking or within 24 hours of admission to a smoke free ward. Recheck levels one week after all dose changes.

Be alert for increased adverse effects of clozapine, for example hypotension, seizures, constipation, fever. If adverse effects occur, reduce the dose as necessary.

Reduce clozapine dose according to plasma levels and adverse effects.

One study suggests that in 80% of cases the change in clozapine plasma levels can be predicted by using the formula: Non-smoking clozapine level = 50 + (1.5 x smoking clozapine level) (Meyer, 2001 Desai et al)

If clozapine levels are not available or if clozapine level is high (>700ng/ml) perform a stepwise daily dose reduction of ~ 10% until the 4th day post smoking cessation as well as therapeutic monitoring.

On discharge counsel the patient on the effects of smoking on clozapine levels. Ensure that their GP and community support team are aware that if they start smoking their clozapine levels will need to be monitored one to two weeks later and dose increases may need to be made.

See below for further information.

a. *Metabolism/Induction*

CYP1A2:

Clozapine is metabolised through the CYP1A2 enzyme (cytochrome P450 1A2). In smokers metabolism of clozapine is increased and so serum clozapine levels are reduced. On cessation of smoking, reversal or decay of the induction of CYP1A2 occurs resulting in a 30% reduction in CYP1A2

activity over approximately 4 days (Faber). Serum clozapine levels rise and probably achieve steady state approximately 7-10 days after smoking cessation.

b. *Estimated changes in serum clozapine levels:*

a) At low to moderate serum levels:

The difference in serum clozapine levels can be represented by a linear

equation: $\text{Serum ng/mL Cloz}_{\text{NonSmoker}} = 1.5(\text{Serum ng/mL Cloz}_{\text{Smoker}}) + 50$

(E.g. Clozapine level $_{\text{Smoker}}$ of 400ng/ml, therefore: Clozapine level $_{\text{NonSmoker}} = (1.5 \times 400) + 50 = 650$)

(N.B. For higher initial clozapine level, say above 700ng/ml, serum levels might increase by much more than this formula on smoking cessation e.g. case report 750ng/ml →3000ng/ml).

Set target serum clozapine level and adjust dose

b) High serum levels

At high levels (e.g. levels of clozapine greater 700ng/ml) the CYP1A2 enzyme may become saturated with the substrate clozapine causing greater reductions in the rate of metabolism. Serum levels may then rise by much more than the above formula (e.g. case report - Serum Cloz $_{\text{Smoker}} = 850\text{ng/mL}$; Serum Cloz $_{\text{Nonsmoker}} = 3300\text{ng/mL}$).

In these patients the dose of clozapine should be reduced by 10% a day for the first four days following smoking cessation.

c. *Factors to consider:*

- Smoking status: light / moderate / heavy smoker, preadmission / in community, on admission, on leave from ward, on discharge / return to community;
- Clozapine compliance preadmission;
- Serum clozapine levels: preadmission / outpatient / baseline at admission, at

- what doses, with what degree of compliance, what amount of smoking;
- History of side effects on clozapine and the approximate serum clozapine levels at which these occurred.

d. Specific recommendations regarding clozapine

On admission to a non-smoking inpatient unit:

Assess preadmission smoking status, and clozapine compliance. Review preadmission (outpatient) serum clozapine levels and obtain baseline admission serum clozapine level. Review history of side effects and the serum clozapine levels at which these occurred.

Assess risk of toxicity (e.g. risk of level >1000ng/mL or levels higher than where previous side effects occurred) by predicting likely serum clozapine level using above formula (N.B. for high initial clozapine levels, >700ng/ml, or clozapine doses (>700mg) this formula might not apply).

Set target serum clozapine level taking into consideration the patient's current mental state and the clinical response to the current dose.

Example: Smoker admitted on clozapine dose 600mg with level of 500ng/ml, known to be compliant, clinically unwell on this dose and so requires higher serum level. Estimated serum level if ceases smoking at this dose = 800ng/ml (ie $1.5 \times (600) + 50$).

If clinician determines that target serum level of 800ng/ml is appropriate, then no dose change is necessary. If lower target serum level is desired, say 600ng/ml, then estimate a reduced dose e.g. approximately 500mg

Monitor

- :
 - a. Serum clozapine level
 - at 7 - 10 days, weekly until stable and pre-discharge unless level obtained in previous 48 hours
 - b. clinically for side effects – maybe as late as 2-3 weeks

On discharge / leave:

When a patient is discharged or allowed leave, reassess for potential smoking status and for a potential reduction in serum clozapine if the patient resumes smoking. Clozapine may need to be increased if this is the case.

Post discharge:

Post discharge, repeat serum clozapine weekly until the clinical situation is stable.

APPENDIX 2 USING NRT PRODUCTS AT KMPT

Treatment should be initiated at a dose appropriate to the number of cigarettes used per day. Combination therapy of patches with another form of NRT e.g. lozenges can be tried as a means of increasing efficacy, especially for people who show a high level of dependency or for whom single forms of NRT have been inadequate.

The choice of product should depend on the patient's history, taking into account previous personal experience and preferences. However the preferred option is a patch and or lozenges. People unable to tolerate one type of NRT may benefit from a different NRT preparation.

Details of all NRT products can be found in section 4.10.2 of the British National Formulary (BNF) and are listed briefly below. It is recommended that treatment is prescribed as soon as possible after admission. See section 3.6 for initiating therapy when a trainer advisor or doctor are not available, section 3.7.1 for prescribing for those with a set quit date and section 3.7.2 for those prescribed NRT for temporary abstinence.

NRT for inpatients can be prescribed by a qualified nurse trained in the use of the NRT PGD, any member of staff trained to level 2 smoking cessation or by a doctor.

NRT products will be stocked on all inpatient wards as agreed between the ward manager and the clinical pharmacy team. The recommended minimum is:

- 1 box of 21mg / 24 hour patches (21 in box, Nicotinell)
- 1 box of 14mg / 24 hour patches (7 in box, Nicotinell)
- 1 box mint, sugar free lozenges 4 mg (72 in box, NiQuitin)
- 1 box mint, sugar free lozenges 2 mg (96 in box, Nicorette)
- 1 box 15mg inhalator cartridges (42 in box, Nicorette)
- 3 boxes inhalator mouth pieces (2 in box, Nicorette)

Other products will be ordered for the individual patients as with other medicines.

Nicotine Replacement Products approved for use in KMPT

It is anticipated that other formulations will become available as medicinal products in the future. Applications should be made to the KMPT formulary for new products. Products available at the time of these guidelines being approved include the following formulations.

Evidence supports the use of patches in combination with oral short-acting NRT as the most effective method of using NRT to quit. Therefore all patients who smoke more than 5 cigarettes per day should be offered combination therapy. The preferred KMPT combination is patch and lozenge; however patient preference will be taken into account and it is recognised that many patients find the inhalator the most effective short-acting NRT.

Patches are available as 16 hour or 24 hour patches. 16 hour patches are advised if sleep disturbances/nightmares are experienced or the 24 hour patch should be removed at bedtime.

Lozenges can be used every 1-2 hours when the urge to smoke occurs or to prevent cravings. Those who smoke >20cigarettes a day or fail to stop smoking with the lower strength lozenges should use the higher strength lozenges (4mg). May be used without patches in patients who smoke less than 5 cigarettes per day.

Inhalator simulates cigarette smoking but may cause local irritation of the mouth and throat. More expensive than patches and lozenges as combined use. Repeat issuing of inhalators make this an even more expensive and potentially wasteful product. Should only be used in conjunction with patches (unless these are contra-indicated) because too expensive to be used as the primary product. However it is recognised that this is the most popular product in use on other mental health

wards with a no smoking policy and therefore will be kept as stock on wards.

Sub-lingual tablets can be used hourly and should be allowed to dissolve under the tongue. More expensive than patches and lozenges as combined use.

Oral spray and gum is not authorised for use due to the potential risk they present if given to patients on the ward.

Nasal spray and microtabs are not provided by Kent Smoking Cessation Services; therefore they are not authorised for use by KMPT.

A guide to the relevant cost of each of the NRT products is given below:

Cost of NRT, based on prices in BNF 66

Summary of daily costs for each product based on maximum daily dose

Product	Price range (£)
Patch	1.17 - 1.42
Gum	1.05 – 2.14
Lozenge	1.30 – 2.49
Nasal spray	4.29
Oral spray	4.08 – 5.17
Sublingual tablet	4.83 – 5.25
Inhalator (excluding cost of device)	3.72 – 8.92

Not recommended for inpatient use

Note varenicline and bupropion are not NRT but are medicines to assist in smoking cessation.

Varenicline may be considered for outpatients as per section 3.4. Varenicline is not considered suitable for inpatients as its use is cautioned in those with a history of mental illness, including depression.

Bupropion

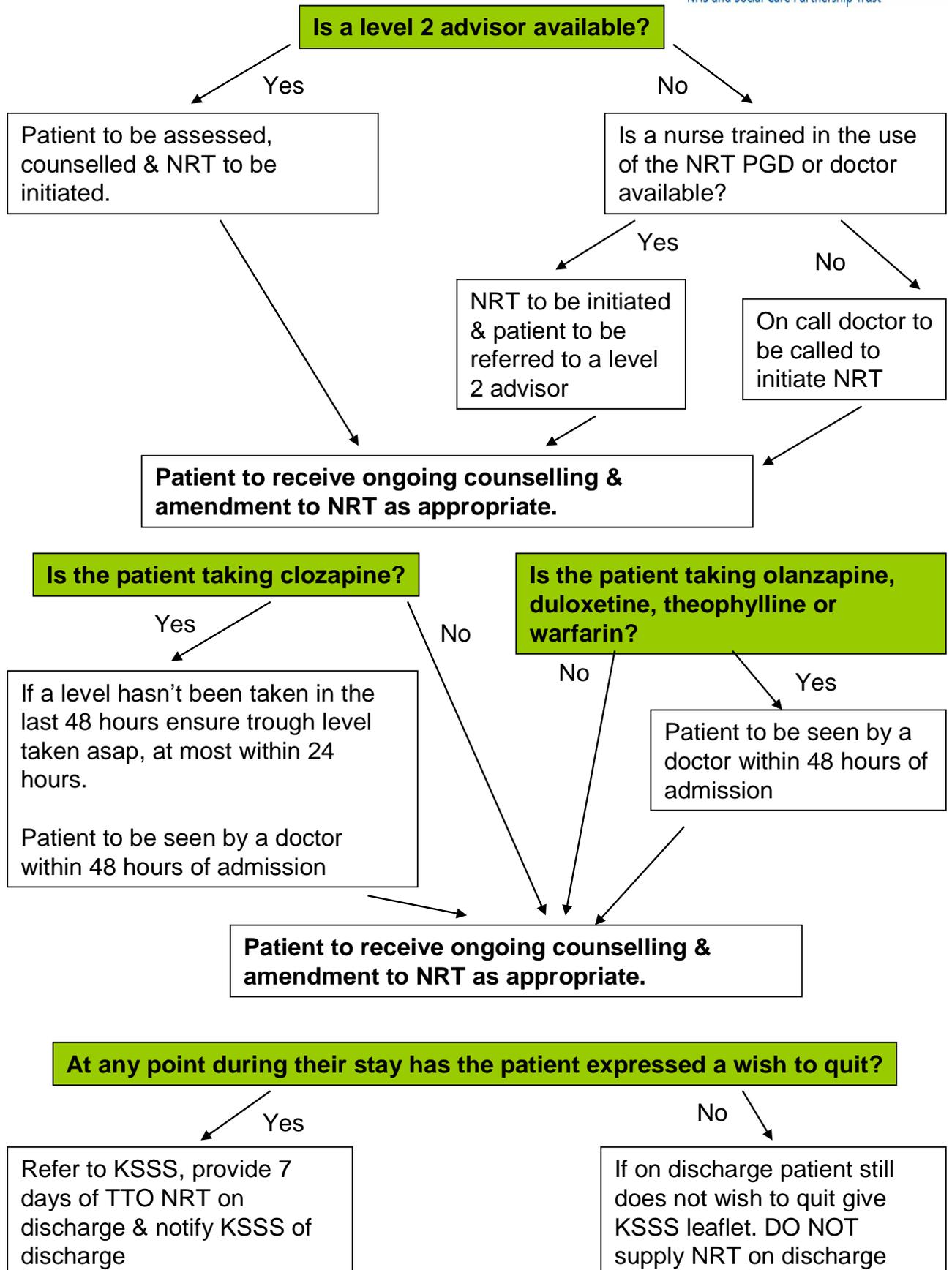
See section 3.4 for details as cautions and contra-indications which make this medication unsuitable for most patients of KMPT

Combinations of NRT and Varenicline or Bupropion KMPT do not utilise NRT, varenicline or bupropion in any combination as per NICE PH10 Smoking Cessation Guidance.

Electronic cigarettes (e-cigarettes)⁹ will not be supplied by KMPT as they are not currently available as licensed medical products. This means that the manufacturers do not have a licence from the Medicines and Healthcare Products Regulatory Agency (MHRA) for e-cigarettes and so assurance cannot be given regarding quality, safety or efficacy. We do not know if production follows Good Manufacturing Practice and the e-cigarettes are not subject to the same Quality Control (QC) processes as a licensed medicine. The MHRA has conducted research into the e-cigarettes currently available on the market and cannot be satisfied that they reach the required standards.

APPENDIX 4 NRT FLOWCHART

NRT flowchart



APPENDIX 5 NRT ASSESSMENT FORM – PLEASE UPLOAD ONTO RIO

To be completed by a doctor or level 2 trained advisor

Name of patient.....**D.O.B**.....

NHS Number

Patient's current medication

Allergies.....

Questions	Eligibility for inclusion	Liable for Exclusion
Was the patient taking nicotine every day prior to admission?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Does the severity of the patient's withdrawal from nicotine and / or cravings require pharmacological intervention?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Age of patient	<input type="checkbox"/> 18 years or over	<input type="checkbox"/> Below 18 years
Has the patient given consent for NRT?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Questions	Answer yes or no	If yes, Have the risks & benefits of NRT been considered?
Is the patient pregnant?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
Is the patient breast-feeding?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
Does the patient have stable cardiovascular disease?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
Does the patient have uncontrolled hypertension?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
Has the patient had a serious reaction to any NRT in the past?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
Does the patient have diabetes? (Additional blood glucose monitoring will be required)	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
Does the patient have chronic generalised skin disease such as psoriasis, chronic dermatitis or urticaria?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
Has the patient had a myocardial infarction in the last 4 weeks?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
Has the patient had a stroke in the last 4 weeks?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
Does the patient have life-threatening cardiac arrhythmias?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
Does the patient have severe or worsening angina pectoris?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No

EXCLUSION

If the patient is not to have NRT the following checklist for further action is to be completed.

- Reason for not giving NRT has been recorded on RIO
- Patient is taking clozapine and has had a level taken prior to stopping smoking or within 24 hours of admission
- Patient is taking clozapine, olanzapine, duloxetine, theophylline or warfarin and has been referred to / seen by a doctor for review within 48 hours

ACTION

INCLUSION

Using your professional judgement you may decide to supply NRT. Please complete the following checklist for the supply of NRT.

- The patient has been advised on the use of NRT and its side effects.
- The patient consents to treatment

Patient's

signature.....

Details of NRT to be given:

Strength of patch

supplied/administered.....

Strength of lozenge / inhalator

supplied/administered.....

- Patient has been referred to a level 2 smoking cessation advisor or a doctor if necessary
- Patient is taking clozapine and has had a level taken prior to stopping smoking or within 24 hours of admission
- Patient is taking clozapine, olanzapine, duloxetine, theophylline or warfarin and has been referred to a doctor for review within 48 hours

Does the patient wish to make a quit attempt Yes / No (delete as appropriate)

Has the patient given consent for their details to be entered onto Quitmanager
Yes / No (delete as appropriate)

Signature of doctor / level 2 advisor

.....

Date

.....