journey to change

NHS
Tees, Esk and Wear Valleys
NHS Foundation Trust

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Contents

1. Guidance **3**

1.1. Option 1 - Patients but who do not intend to stop smoking (at discharge) but are suffering acute nicotine withdrawal 3

1.2. Option 2 - Patients who are motivated to stop smoking and are suffering acute nicotine withdrawal 3

1.3. Option 3 - Patients abstaining from smoking but not suffering acute nicotine withdrawal 3

2. Smoking and medication **4**

3. Stop smoking products including NRT **4**

3.1. Nicotine replacement therapy 4

3.2. Bupropion 6

3.3. Varenicline 6

4. Access to NRT during an inpatient admission **6**

5. How this procedure will be implemented **7**

5.1. Training needs analysis 7

6. How the implementation of this procedure will be monitored **7**

7. Related Documents **7**

7.1. References 7

8. Document control (external) **8**

Appendix 1: Smoking and the effect on medicines including clozapine **9**

Appendix 2: The Provision of NRT as a Homely Remedy **13**

Appendix 3: The Administration of NRT as a Homely Remedy **15**

Appendix 4 – Approval Checklist **17**

1. Guidance

To comply with the Trust's Nicotine Management Policy and the NICE guidelines for smoking cessation in secondary care (PH 48, Nov 2013); smokers will need to stop smoking whilst in Trust buildings and grounds during an inpatient admission.

During an in-patient admission a smoker has three options:

1.1. Option 1 - Patients but who do not intend to stop smoking (at discharge) but are suffering acute nicotine withdrawal

- Patients suffering acute nicotine withdrawal can be prescribed NRT to help with withdrawal symptoms (which may include agitation, headaches, moodiness, irritability, nervousness, fidgeting, anger, and cigarette craving)
- All inpatients will be given the opportunity for stop smoking support while in the Trust's care.
- No NRT will be given on discharge to patients who do not intend to stop smoking
- The telephone number of the relevant NHS Stop Smoking Service (SSS) will be given on discharge and if contacted will arrange an appointment as soon as possible
- e-cigarettes can also be used - see Nicotine Management Policy

1.2. Option 2 - Patients who are motivated to stop smoking and are suffering acute nicotine withdrawal

- Patients will be offered NRT
  - On discharge the patient will be given 7 days' supply of NRT and advised on future support
  - The SSS will be informed, and referral arrangements confirmed
  - The GP practice will be informed of NRT provided at discharge and referral arrangements to SSS
- e-cigarettes can also be used - see Nicotine Management Policy

1.3. Option 3 - Patients abstaining from smoking but not suffering acute nicotine withdrawal

- Support should be offered, and withdrawal symptoms monitored
- If withdrawal symptoms occur NRT should be considered

Regardless of which option the patient chooses, every smoker should be offered NRT to manage their tobacco dependence within 30 minutes of arrival to an inpatient unit.

2. Smoking and medication

- Tobaccoo smoke contains polycyclic aromatic hydrocarbons within the tar that increase the activity of certain hepatic enzymes (CYP1 A2 in particular).
- Many commonly used medicines are substrates for CYP1A2: theophylline, fluvoxamine, caffeine, coumarins including warfarin and the antipsychotics clozapine and olanzapine
- Smokers taking a medication that is metabolised by this enzyme may require higher doses than non-smokers
- When people stop or reduce their smoking, there can be a decrease in enzyme activity with a corresponding increase in drug levels: hence they may require a reduction in the dosage of the interacting medication. Conversely if non-smokers restart smoking, a dose increase should be anticipated to maintain therapeutic levels.
- Not all possible drug-smoking interactions are clinically significant
- For patients taking clozapine or olanzapine who are intending to stop smoking, advice should be sought from the clozapine clinic staff or consultant psychiatrist who will formulate a plan, to ensure the patient's ongoing safety.
- For a full list of psychotropic drugs affected by smoking cessation see Appendix 1
- Information should be given to service users and carers regarding the likely need to increase the dose of their medication if they start smoking again

Not all possible drug-smoking interactions are clinically significant. Important factors that determine the clinical significance of an interaction in smokers are:

- The extent to which the medicine is metabolised by the enzyme CYP1A2
- The therapeutic index of the medicine metabolised (where there is little difference between therapeutic and toxic doses).
- See appendix 1 for specific advice relating to medicines including clozapine and olanzapine

3. Stop smoking products including NRT

3.1. Nicotine replacement therapy

Several different forms of NRT can be prescribed; the preparation chosen should be safe for the patient and most likely to succeed

All NRT should be used for 8-12 weeks but may be continued after this time

First line options are NRT patches, lozenges, inhalators, and mouth spray

Treatment Choices	Administration	Dose
Patch	Record administration on a Patch Chart to ensure site rotation. Apply on waking to dry non-hairy skin on the hip, trunk, or upper arm. Avoid applying to broken, red or irritated skin. Skin sites should not be re-used for at least 7 days. Only one patch should be worn at a time. Exercise may increase absorption of nicotine and therefore side effects. Patients/staff should not try to alter the dose of the patch by cutting it up	Individuals who smoke more than 10 cigarettes a day should apply a high strength patch daily for 6-8 weeks, followed by a medium patch for two weeks, then the low strength patch for the final two weeks. Individuals who smoke fewer than 10 cigarettes a day can start with the medium strength patch for 6-8 weeks followed by a low strength patch for 2 weeks.
Lozenges	One lozenge should be placed in the mouth and allowed to dissolve – suck until taste becomes strong, then 'park' at side of the mouth. It should be moved from one side of the mouth to the other until completely dissolved (approximately 20-30 minutes). Do not chew or swallow whole. Use of coffee, acid drinks and soft drinks at the same time may decrease absorption of nicotine and should be avoided for 15 minutes prior to sucking lozenge.	One lozenge should be used every 1-2 hours when the urge to smoke occurs. Individuals smoking less than 20 cigarettes a day should use the lower strength lozenge and those who smoke more than 20 a day should use the higher strength lozenge Patients should not exceed 15 lozenges a day.
Mouth spray	The spray should be released into the mouth holding it as close to the mouth as possible and avoiding the lips. The patient should not inhale whilst spraying and avoid swallowing for a few seconds after use.	One-two sprays in the mouth when the urge to smoke occurs or to prevent cravings. Not more than 2 sprays per episode (up to 4 sprays every hour) Patients should not exceed 64 sprays daily
Inhalator (each cartridge)	Insert cartridge into the device and draw in air through the mouthpiece. Each session can last for approximately five minutes. The amount of nicotine from one puff of the cartridge is less than a cigarette, so it may be necessary to inhale more often.	To be used when the urge to smoke occurs. The maximum of six 15 mg cartridges daily. A single 15 mg cartridge lasts approximately 40 minutes of use. Record when the inhalator is given to the patient.

The detailed guidance on prescribing contained in the current edition of the British National Formulary (BNF) must be followed.

Prescribers must prescribe within their own competencies, comply with current legislation, Trust policies for prescribing and professional guidance.

3.2. Bupropion

Bupropion is contraindicated in bipolar affective disorder, epilepsy, CNS tumours, alcohol withdrawal, benzodiazepine withdrawal and eating disorders. It should not be prescribed with other drugs that can cause seizures. This includes tricyclic antidepressants and some antipsychotic medicines. **In view of the above bupropion is not approved for smoking cessation within TEWV. Treatment may however be continued if initiated prior to admission.**

Bupropion is not approved for use in TEWV Foundation Trust.

3.3. Varenicline

Varenicline: has been linked to depression, suicidal ideation, and exacerbation of underlying psychiatric illness. Other side effects include sleep problems and anxiety. **Varenicline has not been approved for use within TEWV. Treatment may however be continued if initiated prior to admission.**

Varenicline is not approved for use to support smoking cessation in an inpatient setting in TEWV Foundation Trust.

Electronic cigarettes are not classified as a medicinal product and cannot be prescribed as an alternative to nicotine replacement therapy (NRT). They should only be used by staff and patients in line with the Trust smoking policy

4. Access to NRT during an inpatient admission

To treat nicotine withdrawal symptoms effectively and provide the most comfort to the smoker, the patient should be offered NRT within 30 minutes of arrival on a ward. There are two ways of accessing NRT.

1. Prescription by a medical or non-medical prescriber
2. Provision as a" homely remedy" (see Appendix 2)

There are two ways of accessing NRT in the trust. The first one is by a prescription written by a prescriber. The second is as a Homely Remedy – (see Appendix 2)

The detailed guidance on prescribing contained in the current edition of the British National Formulary (BNF) must be followed.

Prescribers must prescribe within their own competencies, comply with current legislation, Trust policies for prescribing and professional guidance.

5. How this procedure will be implemented

- This procedure will be published on the Trust's intranet and external website.
- Line managers will disseminate this procedure to all Trust employees through a line management briefing.

5.1. Training needs analysis

Identified in the Nicotine Management Policy.

6. How the implementation of this procedure will be monitored

Identified in the Nicotine Management Policy.

7. Related Documents

The Medicines Overarching Framework defines compliance requirements for prescribing and initiating treatment safely which you must read, understand, and be trained in before carrying out the procedures described in this document.

CORP-0002 Nicotine Management Policy

7.1. References

Bazire, S. (2018). Psychotropic Drug Directory.

Bleakley, S. & Taylor, D. (2013). The Clozapine Handbook.

Meyer, J.M & Stahl, S.M (2019). Stahl's handbooks: The Clozapine Handbook.

SPS (July 2020 Update) – What are the clinically significant drug interactions with Tobacco smoking?

Taylor, D et al. (2018). The Maudsley Prescribing Guidelines in Psychiatry (13th Edition)

8. Document control (external)

To be recorded on the policy register by Policy Coordinator

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This document replaces:	PHARM-0000-v7.1 – Stop Smoking Products Guidance	
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This document was ratified by:	Name of committee/group	Date
	Drug & Therapeutics Committee	27th May 2021
An equality analysis was completed on this document on:	General Pharmacy EA	
Document type	Public	

Change record

Version	Date	Amendment details	Status
6.1	26/7/18	26/7/18 – page 12 – homely remedy for NRT can be used for up to 7 days in prisons.	Superseded
7.0	22/11/18	Full review – no changes	Superseded
8.0	25/5/21 (delayed publication until 15/12/21)	Full review. New template. Medicines and smoking impact added in appendix 1 and referenced in text.	Approved

Appendix 1: Smoking and the effect on medicines including clozapine

The MHRA advised in October 2009 that the most important medicines to consider in those who smoke, or are trying to quit, include THEOPHYLLINE, OLANZAPINE, CLOZAPINE, CAFFEINE and WARFARIN. In 2020, the MHRA issued a reminder to prescribers of the impact of smoking/changes to smoking status on CLOZAPINE.

Impact of Smoking on Psychotropic Drugs

Drug	Effect of smoking	Action to be taken on stopping smoking	Action to be taken on re-starting smoking
Antipsychotics			
Chlorpromazine	Plasma levels ↓ (Varied estimates of exact effect)	Monitor closely, consider ↓dose	Monitor closely; consider re-starting previous smoking dose
Clozapine	Plasma levels ↓ by up to 50%; plasma level reduction may be greater in those receiving valproate	Take plasma level before stopping; On stopping ↓ dose gradually (over 1 week) until around 75% original dose reached (i.e., 25% reduction). Repeat plasma level 1 week after stopping & anticipate further dose reductions.	Take plasma level before re-starting. Increase dose to previous smoking dose over 1 week. Repeat plasma level.
Fluphenazine	Plasma levels ↓ by up to 50%	On stopping, reduce dose by 25%. Monitor carefully over 4-8 weeks; consider further dose reductions	On re-starting, increase dose to previous smoking dose
Haloperidol	Plasma levels ↓ by around 25-50%	Reduce dose by around 25%. Monitor carefully. Consider further dose reductions	On re-starting, increase dose to previous smoking dose
Loxapine (Inhaled)	Half-life ↓ from 15.7 hours to 13.6 hours	Monitor	Monitor
Olanzapine	Plasma levels ↓ by up to 50%	Take plasma level before stopping. On stopping reduce dose by 25%. After 1 week, repeat plasma level. Consider further dose reductions.	Take plasma level before re-starting. Increase dose to previous smoking dose over 1 week. Repeat plasma level.
Zuclopenthixol	Unclear, but effect probably minimal	Monitor	Monitor
Antidepressants			
Agomelatine	Plasma level ↓	Monitor closely; may need to ↓ dose	Consider re-introducing previous smoking dose
Duloxetine	Plasma levels may be ↓ by up to 50%	Monitor closely; dose may need to be reduced	Consider re-introducing previous smoking dose
Fluvoxamine	Plasma levels ↓by around 1/3	Monitor closely; dose may need to be reduced	Dose may need to be increased to previous level
Mirtazapine	Unclear, but effect probably minimal	Monitor	Monitor
Trazodone	Around 25% reduction	Monitor for increased sedation. Consider dose reduction.	Monitor closely, consider increasing dose.
Tricyclic antidepressants	Plasma levels ↓ by 25-50%	Monitor closely. Consider reducing dose by 10-25% over 1 week. Consider further dose reductions.	Monitor closely, consider re-starting previous smoking dose.

Other Psychotropics			
Benzodiazepines	Plasma level ↓ (by 0-50%; depends on drug/smoking status	Monitor closely, consider ↓ dose by up to 25% over 1 week	Monitor closely; consider re-starting "normal" smoking dose
Carbamazepine	Unclear; may ↓ levels to a small extent	Monitor for changes in severity of adverse effects	Monitor plasma levels

Note: Only cigarette smoking induces hepatic enzymes; nicotine replacement, vaping devices, and electronic cigarettes (which do not containing polycyclic aromatic compounds) have no effect on enzyme activity.

This guidance highlights the effects of smoking cessation on psychotropic drugs. However, it is essential to consider the potential effects on all medication prescribed, in particular the following physical health drugs:

- **Warfarin** is partly metabolised via CYP1A2. An interaction with smoking is not clinically relevant in most patients. If a patient taking warfarin **stops smoking**, their INR might increase so monitor the INR more closely. It may take up to a week after stopping smoking to see the full effect on the INR.
- Smoking is associated with poor glycaemic control in patients with diabetes. Smokers may require higher doses of **insulin** but the mechanism of any interaction is unclear. 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 blood glucose more frequently.
- **Methadone** is metabolised by numerous enzymes within the liver, if a patient taking methadone stops smoking, they should be monitored for signs of methadone toxicity and the methadone dose should be adjusted accordingly.
- Other physical health drugs which may be affected by changes in smoking status include aminophylline/theophylline, erlotinib, riociguat and flecainide.

Clozapine and smoking

- Tobacco smoke contains polycyclic aromatic hydrocarbons which are potent inducers of CYP1A2; smoking as few as 7-12 cigarettes/day is sufficient to fully induce CYP1A2, with a net increase of 1.66-fold in enzyme activity.
- In a smoker, taking a constant dose of clozapine, on average the plasma levels are 50% lower than non-smokers on the same dose.
- The interaction usually occurs gradually over two to four weeks and can be especially difficult to predict in those sporadically stopping and starting smoking.
- Upon smoking cessation, the CYP1A2 activity declines with a half-life of 38.6 hours (range 27.4-54.4 hours), returning to baseline after around 8 days on average (5 half-lives).
- Stopping smoking can be dangerous for someone taking clozapine, a 50% increase in stable clozapine levels can occur on smoking cessation, which can lead to significant adverse effects such as seizures. In patients whose clozapine level as a smoker was in the high therapeutic range, this can result in severe toxicity as clozapine levels rise and CYP1A2 becomes saturated, resulting in non-linear kinetics.
- Stopping or starting smoking suddenly, can result in significant plasma level changes within 3-5 days.

- Smoking cannabis cut with tobacco is likely to have the same effect on clozapine plasma levels.
- If a patient is also taking valproate with clozapine, the enzyme induction effects may be stronger and so the effect on plasma levels may be more marked when stopping smoking.

Advice should be sought from the clozapine clinic team or consultant psychiatrist to formulate a plan for people taking clozapine who wish to stop smoking, to ensure the patient's on-going safety.

Action to take when a patient prescribed clozapine stops smoking:

- ✓ Check and document current clozapine dose and adherence with treatment
- ✓ Check and document other regular medication
- ✓ Confirm the usual number of cigarettes smoked per day, >10 cigarettes/day is usually indicative of full CYP1A2 enzyme induction
- ✓ Take a trough clozapine plasma level (prior to smoking cessation where possible)
- ✓ Check for adverse effects such as sedation, hypersalivation, hypotension, seizures and other neurological effects, akathisia and prolonged QTc interval.
- ✓ **At the point of smoking cessation** (or as soon as possible afterwards), the **clozapine dose should be reduced** gradually over a week until around 75% of dose remains i.e. reduce by 25% (a reduction of 10% every 48 hours is recommended by some sources).
- ✓ Clozapine plasma levels should be repeated one week after stopping, with further dose adjustments dependent on any emerging side effects or toxicity.
- ✓ Further plasma levels (for 2 - 4 weeks after stopping smoking) and dose adjustments may be necessary.
- ✓ The patient should be advised to be alert for increased adverse effects which may indicate toxicity such as increased sedation, hypersalivation, constipation and dizziness, which they should flag immediately to the healthcare professional managing their clozapine.

Action to take if a patient prescribed clozapine re-starts smoking:

- ✓ Take trough clozapine level prior to restarting smoking (where possible)
- ✓ Increase clozapine dose to previous smoking dose over one week
- ✓ Repeat clozapine plasma level and adjust dose as appropriate

Olanzapine and smoking

- Olanzapine clearance may be higher and half-life 21% shorter in smokers compared with non-smokers, probably due to induction of CYP1A2.
- Smoking cessation can lead to olanzapine toxicity through removal of CYP1A2 induction.

- Olanzapine dose reduction of between 30% and 50% may be necessary if a patient stops smoking.
- If the patient advises of a plan to stop smoking: Prior to smoking cessation, a plasma level should be taken, **at the point of stopping smoking**, **the olanzapine dose should be reduced by 25%**, a plasma level should be taken after 1 week, with further dose adjustments where appropriate.
- The patient should be advised to be alert for increased adverse effects which may indicate toxicity such as increased sedation, muscle stiffness, tremor, and dizziness which they should flag immediately to the healthcare professional managing their olanzapine.
- If a former smoker prescribed olanzapine re-starts smoking, where possible, a plasma level should be taken before re-starting smoking, the olanzapine dose should be increased to the previous smoking dose over one week, a further plasma level should be taken after one week, with dose adjustments where appropriate.

Appendix 2: The Provision of NRT as a Homely Remedy

What is a Homely Remedy?
A homely remedy is a product that can be obtained, without a prescription, for the immediate relief of a minor, self-limiting ailment for a short period of time.

Which NRT products are available as Homely Remedies?
Only 25 mg and 15 mg 16-hour NRT patches and 15 mg inhalators are available as Homely Remedies. Other NRT Preparations can be prescribed by registered prescribers.

How long can NRT be given as a Homely Remedy?
NRT can be given for 72 hours or until a register prescriber can write a prescription. In the prison environment, this can be given for up to 7 days.

Which products should be chosen?
Nicotine patches are a pro-longed release formulation and are applied for 16 hours and the patch removed overnight. Inhalators can be used whenever the urge to smoke occurs or to prevent cravings. The choice of NRT preparation depends largely on patient preference. Patients with a high level of nicotine dependence may benefit from using a combination of patches and inhalators.

Patches and inhalators are licensed for adults and children over 12 years old.

When should NRT be administered as a Homely Remedy?
If a patient is admitted who smokes cigarettes and a registered prescriber is unavailable to write a prescription for NRT then qualified nursing staff can administer either a patch and/or an inhalator to prevent nicotine cravings and treat nicotine withdrawal.

When should NRT not be used?

It is safer to use licensed nicotine-containing products than to smoke. Any risks associated with NRT are substantially outweighed by the well-established dangers of continued smoking. The effects of cigarette smoking in conjunction with NRT are similar to those of cigarette smoking alone. Excessive use of NRT by those who have not been in the habit of inhaling tobacco smoke could possibly lead to nausea, faintness, or headaches

Pregnancy: NRT can be used by pregnant smokers. Ideally, smoking cessation in pregnancy should be achieved without NRT. NRT is recommended as the risk to the unborn baby is far lower compared to continuing to smoke. Those prescribing or supplying NRT should ensure that the potential risks and benefits are understood by the mother.

Homely remedies in-patient pathway

Step 1 – Identification of smokers
Ask every patient if they currently smoke tobacco
Record smoking status in PARIS

Step 2 – Advise and offer support

To comply with the Trust's Smoke Free Policy and NICE guidelines for smoking cessation in secondary care smokers will need to abstain from smoking whilst in Trust buildings and in the grounds during an in-patient admission.

Establish whether the smoker would like NRT to manage their nicotine cravings and their withdrawal symptoms.

Step 3 – Act on smoker's response
Ask smoker how many cigarettes a day do they smoke? Past use of NRT. Patient's choice of NRT product. Known allergies to NRT products. Current medical conditions.

Light smoker – Smokes 1-10 cigarettes a day
Choose 15 mg 16-hour patch **or** an inhalator

Moderate smoker – Smokes 11-20 cigarettes and Heavy Smokers who smokes more than 20 cigarettes a day
Choose 25 mg patch **and/or** an inhalator

Choose one product for light smokers or a combination of two products for moderate to heavy smokers.

Patch

Dose	Correct Use	Side effects (>1/10)
Nicorette: 15mg, 25mg Invisi Patches (16- hour patches)	1] Take the adhesive stickers off patch, 2] Hold patch in palm of hand; apply one patch to non-hairy, dry skin on upper arm, hip, or chest. 3] Hold down for 20 seconds. 4] Alternate sites and try not to use the same site for a few days. 5] Remove old patch before applying new patch. 6] Do not apply to broken or inflamed skin	Site reactions are common in the first 2-3 weeks, including rash, itching, burning, tingling, numbness, swelling, pain, and urticaria. They resolve quickly following removal of the patch. Sleep disturbance (e.g., insomnia and abnormal dreams) may occur with 24 hr patch
On the first day of using the patch, it takes approximately 9 hours to reach the highest level in the blood.		

Inhalator

Dose	Correct Use	Side effects (>1/10)
Nicorette 15mg Inhalator Maximum: 6 a day	Each cartridge can be used for approximately eight 5-minute sessions, with each cartridge lasting approximately 40 minutes of intense use. The amount of nicotine from a puff is less than that from a cigarette. To compensate for less nicotine delivery from a puff it is necessary to inhale more often than when smoking a cigarette	Headache, coughing, mouth and throat, tongue irritation
When used like a cigarette the inhalator on average delivers 1mg in 80 puffs (e.g., 8 puffs per minute for 10 minutes). When used in this way this results in, a degree of nicotine substitution of about 50% compared to hourly smoking		

How is the administration of Homely Remedies recorded?

They are recorded using a Homely Remedy Administration form, see Appendix 3

Appendix 3: The Administration of NRT as a Homely Remedy

Patient name and date of birth:	**Ward:**

Nicotine Patch issued

	16 Hour 15mg Smokes less than 10 cigarettes per day			**16 Hour 25mg** Smokes more than 10 cigarettes per day		
Date						
Time						
Given by						

Nicotine Inhalator issued, maximum 6 cartridges x 15 mg in 24 hours

Date									
Time									
Given by									
Date									
Time									
Given by									

Date referred to prescriber:	Date Individualised assessment completed:	Signature of prescriber:

IN PATIENT PERMISION AS HOMELY REMEDIES IF PRESCRIBER IS UNAVAILABLE

Does the patient smoke?

YES

1

Record smoking status on PARIS

NO
(No further action required)

How many cigarettes do they smoke a day?

Smokes 1-10 cigarettes

Choose

15mg / 16hr NRT Patch

OR

15mg Inhalator

Smokes more than 10 cigarettes

Choose

AND/OR

25mg/16hr NRT Patch

15mg Inhalator

Appendix 4 – Approval Checklist

To be completed by lead and attached to any document which guides practice when submitted to the appropriate committee/group for consideration and approval.

	Title of document being reviewed:	Yes/No/ Not applicable	Comments
1.	**Title**		
	Is the title clear and unambiguous?	Yes	
	Is it clear whether the document is a guideline, policy, protocol or standard?	Yes	
2.	**Rationale**		
	Are reasons for development of the document stated?	Yes	
3.	**Development Process**		
	Are people involved in the development identified?	Yes	
	Has relevant expertise has been sought/used?	Yes	
	Is there evidence of consultation with stakeholders and users?	Yes	
	Have any related documents or documents that are impacted by this change been identified and updated?	Yes	
4.	**Content**		
	Is the objective of the document clear?	Yes	
	Is the target population clear and unambiguous?	Yes	
	Are the intended outcomes described?	Yes	
	Are the statements clear and unambiguous?	Yes	
5.	**Evidence Base**		
	Is the type of evidence to support the document identified explicitly?	Yes	

	Title of document being reviewed:	Yes/No/ Not applicable	Comments
	Are key references cited?	Yes	
	Are supporting documents referenced?	Yes	
6.	**Training**		
	Have training needs been considered?	Yes	
	Are training needs included in the document?	yes	In Nicotine Management Policy
7.	**Implementation and monitoring**		
	Does the document identify how it will be implemented and monitored?	Yes	
8.	**Equality analysis**		
	Has an equality analysis been completed for the document?	Yes	
	Have Equality and Diversity reviewed and approved the equality analysis?	Yes	
9.	**Approval**		
	Does the document identify which committee/group will approve it?	Yes	
10.	**Publication**		
	Has the document been reviewed for harm?	Yes	
	Does the document identify whether it is private or public?	Yes	
	If private, does the document identify which clause of the Freedom of Information Act 2000 applies?	N/A	