The Medical Management of Tobacco Dependency

Updated January 2024 v2.0

Review due in January 2027
Document Control

Revision History:

The latest version will be held on the GMMMG website.

<table>
<thead>
<tr>
<th>Date</th>
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<tr>
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<td>group (Matt Evison¹, Murugesan Raja²,</td>
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<td>Lara Shah³)</td>
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<td>Matt Evison, Andrew Martin</td>
<td>- Introduction of cytisine in the UK</td>
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<td></td>
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<td>- Increased NRT dosing (double patches) in highly dependent patients in line with NCSCT</td>
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<td>- Alignment with British Thoracic Society Clinical Statement</td>
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Approval:

This document must be approved by the following before distribution:

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<td>Medical Management of Tobacco Dependency</td>
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³ Deputy Chief Pharmacist, NHS GM

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## Greater Manchester Tobacco Dependency Treatment Guideline

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Adults (see separate guidance that follows this for Young people 12-17 and Pregnant Women)

Step 1: Offer all people that smoke ‘brief advice’ (in line with NCSCT standards) or ‘advice on the role of nicotine’ (in line with the BTS Clinical Statement for hospitalised people that smoke’

Step 2: Offer referral to a specialist tobacco dependency service PLUS offer pharmacotherapy/advice on evidenced based interventions in line with this protocol.

People that smoke are three times more likely to successfully stop with the help of BOTH medications / stop smoking aids and specialist support. However, if a patient declines a referral to a stop smoking service this should not preclude the provision of pharmacotherapy/stop smoking aids (NICE 2018, 2021)

Patients should be informed about all the available options so they can make an informed choice. However, if they would like to understand which interventions are the most effective this protocol can help guide healthcare professionals in providing this information. Interventions below can be used in combination at the discretion of the healthcare professional on a case-by-case basis (NICE 2021).

Combination treatment is frequently used in the Hospital setting where all patients that smoke are offered nicotine replacement at the point of hospital admission and other medications can be added to this (the ‘building block’ framework – below).

Pharmacotherapies such as varenicline and cytisine commence alongside smoking with the aim of reducing smoking down to zero as the medications take full effect. In the smoke-free setting of a hospital admission, the initial requirement for additional; nicotine can be met by NRT, making combination therapy especially important in the inpatient setting.

BTS ‘Building Blocks’ framework for treating tobacco dependency in hospitalised patients

1. Screen for tobacco dependence
2. Advise on the role of nicotine
3. Initiate combination NRT as soon as possible
4. Complete a referral to an on-site tobacco dependency advisor (TDA)
5. Provide accurate and consistent information about vaping
6. Discuss, Offer and prescribe nicotine analogue medications

- Nicotine analogue medications (varenicline, cytisine) are highly effective treatments and can be discussed & commenced at the point of admission or during the admission
- Combination therapies (e.g. NRT and varenicline) are as effective if not more effective than single therapies and support abstinence in the unique environment of the inpatient setting

Complete a referral to an on-site tobacco dependency advisor (TDA)

- Refer all patients with tobacco dependence to the TDA team unless they opt-out or ensure automated referral processes to the TDA team when the patient is recorded as tobacco dependent, allowing them to opt-out at first approach by the TDA
- Advise on the benefits of working with specialist advisors
- If no on-site team is available, complete an onward referral to local community services to provide ongoing treatment & support after discharge

Advise on the role of nicotine

- Nicotine drives the dependency to tobacco but it is NOT the cause of the harms of smoking
- The harms of smoking come from thousands of toxic chemicals produced when tobacco is burnt to create smoke
- Keeping these poisonous chemicals out of the body during this hospital admission will help acutely unwell patients recover more quickly
- Nicotine withdrawal can be unpleasant and it is important to provide nicotine in safe, alternative ways to help alleviate this
- Being smoke-free does not have to mean being nicotine-free both during a hospital admission and beyond

Provide accurate and consistent information about vaping

- Nicotine vapes deliver high dose short-acting nicotine which can help to alleviate withdrawal and urges to smoke
- Vaping is an effective treatment for tobacco dependency
- Patients should be advised to switch entirely to vaping (and NRT) to maximise the harm reduction, both during the admission and after discharge

Initiate combination NRT as soon as possible

- Use the Rapid Inpatient NRT Prescribing Protocol
- Prescribe a 20mg/1hour nicotine patch plus a short acting nicotine product (inhalator/lozenge/mouth spray)
- The most serious risk of relapsing back to smoking is prescribng an insufficient dose of NRT and not adequately addressing the patients’ withdrawal symptoms and urges to smoke

Discuss, Offer and prescribe nicotine analogue medications

- Nicotine analogue medications (varenicline, cytisine) are highly effective treatments and can be discussed & commenced at the point of admission or during the admission
- Combination therapies (e.g. NRT and varenicline) are as effective if not more effective than single therapies and support abstinence in the unique environment of the inpatient setting
Very effective: varenicline* (up to 12 weeks, not in pregnancy / breastfeeding)

- 0.5mg once daily Day 1-3
- 0.5mg twice daily Day 4-7
- 1mg twice daily Day 8+
- Reduce smoking aiming to stop date in 1-2 weeks if possible

Evidence Base for this recommendation:

- In a NICE technology appraisal Varenicline was demonstrated to be superior to NRT and bupropion in achieving continuous abstinence. Over a lifetime horizon varenicline dominated bupropion and NRT – it was cheaper and more effective in all sensitivity analysis.
- Varenicline was more effective in achieving short-term and long-term abstinence in a head to head randomized controlled trial in patients both with and without mental health illness in comparison to placebo, NRT and bupropion (EAGLES Study, The Lancet 2016)
- A Cochrane review reported the number needed to treat with varenicline to achieve an additional long-term quitter versus placebo was 11, compared to 22 and 23 for bupropion and NRT respectfully (Cahill. Cochrane Database Syst Rev 2016)

Consider extending varenicline to 24 weeks in the following scenarios:

- Patient was smoking beyond the first six weeks of treatment
- ≥2 quit attempts in the previous 12 months
- Previous successful 12 weeks treatment but subsequent relapse

Take with food and water to help avoid nausea. Warn of sleep disturbance and vivid dreams. Consider reducing to 0.5mg BD if intolerable side effects

* At the time of production of this guideline, varenicline was unavailable. The most effective alternative pharmacotherapy / stop smoking aids are:

- Cytisine
- Nicotine Vapes
- Combination NRT
**Very effective: cytisine** (aged >18 and <65yo, not in pregnancy / breastfeeding)

- 25-day course
- Day 1, day 6 tablets, one every 2hrs
- Then follow the schedule below
  - *Reduce smoking aiming to stop by day 5 of treatment if possible*

<table>
<thead>
<tr>
<th>Days of treatment</th>
<th>1st to 3rd</th>
<th>4th to 12th</th>
<th>13th to 16th</th>
<th>17th to 20th</th>
<th>21st to 25th</th>
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<tbody>
<tr>
<td>Recommended dosing</td>
<td>1 tablet every 2 hours</td>
<td>1 tablet every 2.5 hours</td>
<td>1 tablet every 3 hours</td>
<td>1 tablet every 5 hours</td>
<td>1-2 tablets a day</td>
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<tr>
<td>Maximum daily dose</td>
<td>6 tablets</td>
<td>5 tablets</td>
<td>4 tablets</td>
<td>3 tablets</td>
<td>2 tablets</td>
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</table>

**Evidence Base for this recommendation:**

**RCTs**

1. West et al. NEJM. 2011. Increased 12-month abstinence cytisine vs placebo: RR 3.4 (1.7-7.1)
2. Walker et al. NEJM 2014. Primary outcome: continuous abstinence at 1 month increased with cytisine versus NRT (40% vs 31%, RR 1.3, 1.1-1.5, p=<0.001). Confirmed non-inferiority of cytisine versus NRT.
3. Walker et al. Addiction 2021. Primary outcome: 6-month abstinence increased with cytisine (12.1% vs 7.9%, RR 1.55, 0.97-2.46, p=<0.001). Confirmed non-inferiority of cytisine versus varenicline. Reduced adverse events with cytisine versus varenicline (RR 0.56, 0.49-0.65, p<0.001).
4. Courtney et al. JAMA 2021. Primary outcome: 6-month abstinence equivalent cytisine versus varenicline (11.7% vs 13.3%, the lower bound 97.5% CI was −5.023% for the risk difference, which extended below the lower bound of −5.0% required for noninferiority, did not reach non-inferiority). Reduced adverse events with cytisine (RR 0.88, 0.81-0.95 p=0.002)
5. Rigotti et al. JAMA 2023. Increased abstinence with cytisine versus placebo (OR 8.0, 3.9-16.3, p=<0.001)

**Meta-analysis**

1. Hayek et al. Thorax. 2013. Increased abstinence with cytisine vs placebo: RR 3.29 (1.84-5.90)
2. Leaviss et al. Health technology Assessment 2014. Cytisine more effective than placebo (HR 4.27, 2.05-10.05). Cytisine dominates varenicline: produces more QALYs at lower cost in 90% scenarios
3. Ofori et al. Drug and Alcohol Dependence 2023. Cytisine was superior to placebo (RR 2.25, 1.13–4.47; 5 RCTs, 4325 participants), and superior to NRT but equivalent to varenicline. Cytisine had less adverse events compared to varenicline (RR 0.67; 0.48–0.95; 3 RCTs, 2484 participants).

**Cochrane review 2023**

- Comprehensive study reveals nicotine e-cigarettes, varenicline and cytisine are the stop-smoking aids most likely to help people quit smoking.
- On average, for every 100 people trying to quit, around 14 are likely to succeed using an e-cigarette, varenicline or cytisine in any given quit attempt. This is compared to 6 in 100 who are likely to quit without using any aids.
- Dual nicotine replacement therapy (NRT) methods, like combining a patch with gum, may be almost as effective, with approximately 12 in 100 people likely to successfully quit. However, this estimate is less certain than those for the other stop-smoking aids.

*There is some evidence to suggest 12 weeks of cytisine is superior to 25 days and could be considered in selected cases though this not in line with the MHRA license*
Contra-indications

- An allergy to cytisine or any of the other ingredients of this medicine.
- Unstable angina
- A recent heart attack or significant heart problems
- A recent stroke
- Taking medications to treat tuberculosis infection (TB)

Warn about sleep disturbance, gastro-intestinal symptoms, change in appetite, mood changes
**Very effective: Nicotine vapes**

Nicotine vapes heat a liquid containing nicotine to create a vapour that the user inhales. This is a popular and effective treatment for tobacco dependency as it mimics the action of smoking and provides higher levels of nicotine in the blood than other forms of NRT.

- Nicotine vapes are twice as effective as NRT (high certainty evidence in 2023 living Cochrane review)
- The risks of nicotine vapes are a fraction of that of smoking tobacco (OHID review 2022)
- There is not enough evidence to know whether there are long-term harms from vaping but this is undoubtedly a fraction of that from smoking tobacco
- Advise patients choosing to vape to switch entirely to using e-cigarettes and stop smoking tobacco completely
- This is dependent upon getting enough nicotine to overcome withdrawal symptoms – advise patients to use the strongest nicotine strength liquid and to vape as much as is required to prevent relapse to smoking
- **Consider combining a nicotine vape with NRT to maximise the alleviation of withdrawal and cravings to smoke (e.g. high dose nicotine patch plus nicotine vape)**

**Evidence Base for this recommendation:**

- ✓ In a 900 patient UK RCT of NRT (patient choice) for up to 3 months vs an e-cigarette starter pack (a second-generation refillable e-cigarette with one bottle of 18 mg/L nicotine) plus at least 4 weeks of behavioural support for all participants the 12-month abstinence rate was 9% vs 18% respectively (Hajek. NEJM 2019).
- ✓ Living Cochrane Review 2023: there is high certainty evidence that vaping is an effective treatment for tobacco dependence using an outcome measure of long-term abstinence (at least 6 months). Nicotine vapes are more effective than NRT (quit rates 50% higher than NRT, RR 1.63, 95% CI 1.30-2.04). Nicotine vapes are more effective than no pharmacotherapy (quit rates 2.5 times higher, RR 2.66, 95% CI 1.52-4.65). No evidence of harm from vaping was detected with a follow-up period of two years.
- ✓ NICE guidelines 2021: Nicotine vapes are more effective at achieving abstinence at 6 months versus non-nicotine vaping (RR 2.02, 95%CI 0.97-4.21, p=0.06, two trials, 489 participants). Nicotine vapes are more effective then usual care (RR 4.92, 95%CI 1.43-16.91, p=0.01, two trials, 1239 participants). A benefit from combining NRT with vaping over NRT alone (RR 1.77, 95%CI 1.07-2.94, two trials, 520 participants).
- ✓ The 2021 Public Health England commissioned report on vaping products found that vaping was the most popular aid used by people trying to quit smoking, and the highest quit rates (74%) were seen when the quit attempt involved using a licensed medicine and a vaping product consecutively.
- ✓ OHID commissioned report ‘Nicotine vaping in England 2022: In the short and medium term, vaping poses a small fraction of the risks of smoking. Vaping is not risk-free, particularly for people who have never smoked. Significantly lower exposure to harmful substances from vaping compared with smoking, as shown by biomarkers associated with the risk of cancer, respiratory and cardiovascular conditions. No significant increase of toxicant biomarkers after short-term second hand exposure to vaping among people who do not smoke or vape. In stop smoking services in 2020 to 2021, quit attempts involving a vaping product were associated with the highest success rates (64.9% compared with 58.6% for attempts not involving a vaping product)

**Advise devices & liquids are purchased from licensed vendors regulated under UK law. Do not use oil-based solvent liquids.**

Be vigilant for any suspected adverse reactions associated with use of e-cigarettes or vaping (including lung injury) and report them to the MHRA via the Yellow Card Scheme.

Greater Manchester supports the provision of vaping kits as part of tobacco dependency treatment offers and the commissioning of services to include this offer.

* Selling or supply of E-Cigarettes/Vaping devices is illegal in persons under 18 years of age.
Effective: Combination Nicotine Replacement Therapy (NRT):
Patients will naturally wean dose as able but to be supplied for as long as is needed to prevent relapse (NICE 2021)

Prescribe or provide a high dose nicotine patch
- **21mg / 24hrs** (preferred if craving to smoke is significant from moment of waking – e.g. within 30 minutes)
- **25mg / 16hrs** (preferred if 24hr patch causes sleep disturbance or concerns over sleep disturbance)

Prescribe or provide high dose short acting nicotine
- Nicotine gum/lozenge: 4mg prn
- Nicotine microtab: 4mg prn
- Nicotine nasal spray: up to 4 sprays both nostrils prn (0.5mg/spray)
- Nicotine mouth spray: 4mg prn (1mg/spray)
- Nicotine inhalator: use as much as needed

Agree a quit date and ensure the person has NRT ready to start the day before the quit date

Evidence Base for this recommendation:
- ✓ Cochrane review (63 trials, 41,509 participants) Combination NRT (fast-acting form + patch) results in higher long-term quit rates than single form (RR 1.25, 95% CI 1.15 to 1.36, 14 studies, 11,356 participants)
- ✓ 21 mg patches more effective than 14 mg (24-hour) patches (RR 1.48, 95% CI 1.06 to 2.08, one study, 537 participants).
- ✓ 25 mg patches more effective than 15 mg (16-hour) patches (RR 1.19, 95% CI 1.00 to 1.41, three studies, 3,446 participants)
- ✓ 4 mg gum more effective than 2 mg gum (RR 1.43, 95% CI 1.12 to 1.83, five studies, 856 participants)

Encourage patients to use the short acting nicotine regularly e.g. on the hour every hour.
Cravings for nicotine are extremely powerful and NRT is weaker than cigarettes. Patients cannot overdose on nicotine except for causing mild symptoms such as light-headiness or nausea. However, under-dosing will affect how well NRT can alleviate cravings!

Please note that NRT prescribing in pregnancy differs to this pathway – see separate guidance on page 9.

For patients with a severe dependency to tobacco, e.g. >40 cigarettes per day (cpd), the use of two high strength nicotine patches (2x21mg or 2x25mg patch) is recommended by the NCSCT and the evidence supports this approach
Less Effective: Bupropion and single agent NRT

Pharmacotherapy interventions that have demonstrated efficacy for smoking cessation versus placebo but are considered less effective than the interventions described above are:

- Bupropion
- Single NRT – short acting
- Single NRT – long acting

Bupropion *(Ensure medication review & assessment of seizure risk completed)*

- The initial dose is 150mg to be taken daily for six days, increasing on day seven to 150mg twice daily.
- Bupropion treatment course is 7-9 weeks.
- There should be an 8 hour gap between doses of bupropion (insomnia is a common side effect which can be reduced by avoiding doses at bedtime provided there is at least 8 hours between doses.
- **Agree a quit date set within the first 2 weeks of treatment, reassess the person shortly before the prescription ends**

*Reduce dose to 150mg OD in the elderly, renal impairment, hepatic impairment or any of the following medications: anti-psychotics, anti-depressants, anti-malarials, tramadol, theophylline, corticosteroids, quinolones, anti-histamines.*

Due to seizure risk avoid in patients with the potential for lowered seizure threshold e.g. alcohol abuse, diabetes with hypoglycaemic episodes, head trauma. Due to mania risk avoid in bipolar disease. Avoid prescription with tamoxifen (reduces serum levels)

Stopping smoking and mental health illness

Smoking prevalence is significantly higher in those with mental health illness (40-50%) and stopping smoking is one of the best treatments for mental health disease with an effect larger than anti-depressants (BMJ 2014). Stop smoking medications are highly effective in patients with mental health disease (RCPsych) and significant benefit could be made by increasing access to these medications (ASH).

*There is no increased risk of moderate to severe neuropsychiatric adverse events with varenicline, NRT or bupropion (EAGLES study 2016, The Lancet).* The act of stopping smoking carries a small risk of moderate to severe neuropsychiatric events and this is regardless of the treatment used. The risk is higher in those with a history of psychiatric illness (5%) versus those without (2%). **Advise patients to seek help in the event of a neuropsychiatric event. Mental health illness is not a contraindication to prescribing stop smoking pharmacotherapy.**
Young people 12-17 years of age

**Step 1:** Offer all smokers brief advice *(in line with NCSCT standards)*

**Step 2:** Offer all smokers a referral to a specialist stop smoking service and use professional judgement when deciding whether to offer NRT to young people who are dependent on nicotine. Do not prescribe varenicline, cytisine or bupropion to people aged under 18 years old.

**Nicotine Replacement Therapy**

*Selling or supply of E-Cigarettes/Vaping devices are illegal in children and in this age group.*

There is limited evidence which suggests that there is no specific intervention (including pharmacotherapy) that is more successful than stopping unaided in the adolescent population.

A combination of long-acting and short-acting NRT may be beneficial for young people >12 years if they have a high level of nicotine dependence or in those who have failed on previous NRT treatment. *All preparations are licensed for children over 12 years with the exception of Nicotinell® lozenges which are licensed for children less than 18 years only when recommended by a doctor.*

Prescribing NRT in children and young people should be in line with the licensing of the medicine and as per cBNF.

A quit date should be agreed when NRT is prescribed, and treatment should be available before the child stops smoking. Young people should be prescribed enough treatment to last 2 weeks after their agreed quit date and be re-assessed shortly before the prescription ends.
Pregnancy

Step 1: Identify pregnant smokers, offer brief advice (in line with Greater Manchester Smokefree Pregnancy programme standards) and, if they wish, refer immediately to their specialist stop smoking midwifery team to receive evidence-based stop smoking support.

Step 2: Prescribe Nicotine Replacement Therapy (NRT) as a safe alternative to smoking until the first appointment with the midwife. Do not prescribe varenicline or bupropion to pregnant or breastfeeding women. Consider nicotine vapes as an alternative or additional to NRT.

There is strong evidence that smoking or being exposed to second-hand smoke during pregnancy increases the risk of miscarriage, certain birth defects, premature birth, poor growth of the baby and increased risk of stillbirth, exposure has also been directly linked to health problems later on in life.

Nicotine Replacement Therapy

NRT is an effective stop smoking aid and is licensed for use in pregnancy. Although studies have not been able to demonstrate its effectiveness in isolation, primarily due to problems with compliance, NICE supports use of NRT in pregnancy in conjunction with behavioural support to help women quit and stay smoke free.

Consider the following:
• Pregnant smokers metabolise nicotine faster than other smokers so NRT may be required to manage nicotine withdrawal. Intermittent therapy is preferable to patches - avoid liquorice-flavoured nicotine products as manufacturers advise caution due to potential for adverse effects associated with excessive amounts of liquorice root. As other flavours are available, pregnant women are advised to choose an alternative, such as fruit or mint.
• Patches are useful in the presence of pregnancy-related nausea and vomiting – however 24-hour patches should be avoided or removed before bed.
• Prescribe NRT to manage nicotine withdrawal until the first appointment with the midwife and prior to commencing the Smokefree Pregnancy pathway.
• Do not offer varenicline or bupropion.

Nicotine Vapes

A randomized controlled trial in 1,140 participants compared nicotine vapes versus with nicotine patches, published in 2022. Nicotine vapes were more effective than patches (6.8% versus 3.6%; RR = 1.93, 95%CI: 1.14–3.26, P = 0.02). The safety profile was found to be similar for both study products, however, low birthweight (<2,500 g) was less frequent in the e-cigarette arm (14.8% versus 9.6%; RR = 0.65, 95%CI: 0.47–0.90, P = 0.01).

The Royal College of Midwives recommends that pregnant smokers choosing to use vaping as an aid to smoking cessation should be supported to do so and offered referral to the midwifery team where they will be supported by the specialist stop smoking midwife.

• Consider combining a nicotine vape with NRT to maximise the alleviation of withdrawal and cravings to smoke (e.g. nicotine patch plus nicotine vape)

Advise devices & liquids are purchased from licensed vendors regulated under UK law. Do not use oil-based solvent liquids.

Additional information

The Smokefree Pregnancy programme is an evidence-based programme across Greater Manchester, providing a standardised Smokefree Pregnancy pathway and enabling those who are pregnant and their partners to protect their babies through pregnancy and beyond. The programme aims to deliver quit rates above the national average and ultimately for no person to smoke during their pregnancy.