

## **NHS FORTH VALLEY Stop Smoking Guidance**

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## Consultation and Change Record – for ALL documents

|                              |  |   |
|------------------------------|--|---|
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| <b>05.08.13</b>              | Joanne OSuilleabhain   | Removal of 2 Stop Smoking Clinics   |
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| <b>January 2018</b>          | Anita Paterson<br>Scott Robertson  | New authors<br>Version 2<br>Commodity Action Report (CAREB) detailing the award for the framework agreement for Nicotine Replacement Therapy Products, reference NP46216<br>Removal of cautionary black triangle from Varenicline (Champix®)<br>Varenicline and NRT now joint first-line options and prescribing guidance on varenicline expanded.<br>Information on e-cigarettes added |
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## Introduction

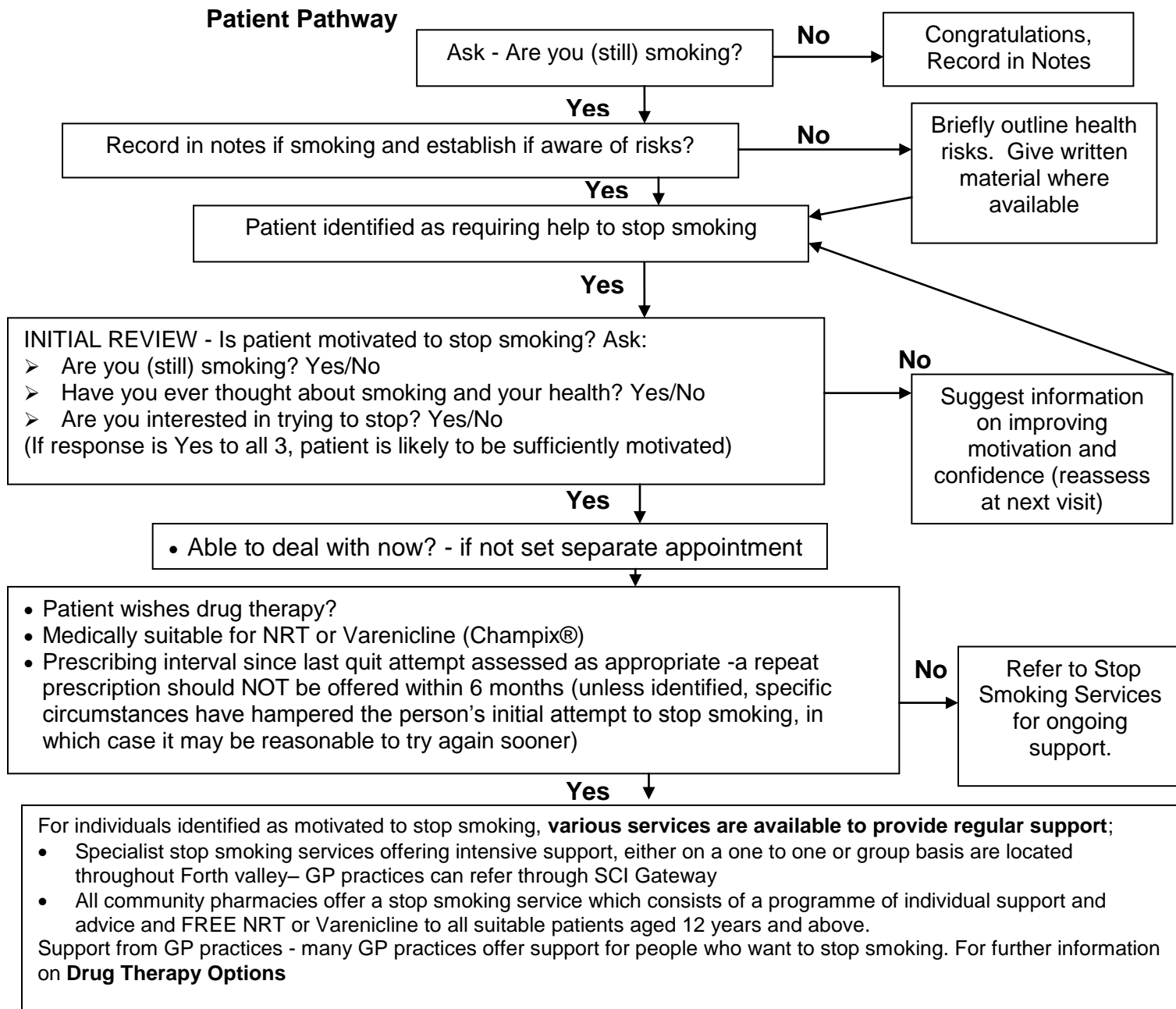
This NHS Forth Valley Stop Smoking Guidance provides information for staff on medicines and services, when undertaking stop smoking interventions. It is aimed at all those practitioners who during their contact with patients discuss patient tobacco smoking.

### Forth Valley Formulary Options for Prescribers

NRT Single /Combination Therapy OR Varenicline (Champix®) are considered joint 1<sup>st</sup> line treatments.

**NRT or Varenicline should only be prescribed in combination with stop smoking advice and support.**

#### Patient Pathway



**NRT**  
(single or combination therapy)

**1<sup>st</sup> line  
Drug  
therapy  
options**

**Varenicline**

**NRT Prescribing (see pages 5-7)**

- Review product(s) choice, form and strength
- Prescribe by **BRAND name**
- Can be used in patients aged over 12 yrs
- Initially prescribe for only 1 week to ensure patient tolerates product
- Then prescribe monthly instructing "**Dispense weekly**" for the 1<sup>st</sup> 4 weeks to avoid potential waste
- NRT dose is determined by previous level of smoking related nicotine
- See SPC\* for contraindications, cautions, interactions, adverse effects

**Varenicline Prescribing (see page 8)**

- Week 1: Prescribe "Treatment Initiation Pack" (contains 2 weeks supply)
- Week 3: Prescribe "Varenicline 1mg BD" 28 Tabs (2 weeks supply)
- On further supplies consider instructing "**Dispense fortnightly**" to avoid potential waste.
- Normal Dose - 0.5mg daily on days 1-3, 0.5mg BD on days 4-7, 1mg BD for 11 weeks (Review SPC\* for exceptions)
- Patients should be advised to discontinue treatment and seek prompt medical advice if they develop agitation, depressed mood or suicidal thoughts. Monitor closely those with a history of psychiatric illness.
- Varenicline should not be used in patients under 18 years old or in those that are pregnant or breastfeeding.
- See SPC\* for full list of contraindications, cautions, interactions and adverse effects.

**No**

1 month post quit date  
Has patient stopped smoking?

**Yes**

Re-assess motivation to quit.

- NRT
  - Lapse (puff or less than 5 cigarettes) continue with treatment and reinforce need to remain smoke free when using NRT
  - Re-lapse - return to regular smoking - discontinue immediately.
- Varenicline - discontinue therapy

- Not managed to quit - reassess at subsequent visits.
- NB Smoking is a chronic relapsing condition. Many people will take 4-5 attempts at giving up before being successful
- Advise the patient that if they start smoking again, and are thinking about a further quit attempt, make another appointment or self refer to smoking cessation services

At subsequent appointments ask about smoking status annually

**NRT**

- Normal course length is 10-12 weeks
- Some may need longer course

- Review progress and side effects
- Prescribe next supply

**Varenicline**

- Normal course length is 12 weeks

**Action:** Where possible support should continue until the end of the course

**Review:** Managed to stay stopped?

**No**

**Yes**

Record in notes

At subsequent appointments ask about smoking status annually

**General Prescribing Notes**

- Community pharmacies to follow national pharmacy smoking cessation guidelines.
- Physiological changes resulting from stopping smoking may alter the metabolism of some medicines. Dosage adjustment may be necessary, the most important examples are Theophylline, Olanzapine, Clozapine and Warfarin. In such cases prescribers need to be informed that the patient is undergoing a quit attempt.
- Bupropion is an option if a patient fails to quit after attempting NRT (single or dual therapy) or Varenicline or where these are not appropriate.
- Bupropion can also be considered in patients that have previously undergone a successful quit attempt with Bupropion. See SPC\* for full prescribing details for Bupropion.

## Nicotine Replacement Therapy- Choice of Formulations

- All NRT preparations have similar efficacy; giving patients the choice increases success rates. Perseverance is needed.

**Nicotinell<sup>®</sup> 24-hour patches are the 1<sup>st</sup> line choice in Forth Valley.**

If the individual has problems with vivid dreams/sleeping the patch can be removed before going to sleep.

**The exception to 24-hour use would be pregnant women, who should not use patches for more than 16 hours in any 24-hour period. All pregnant women should be routinely advised to remove the patch at bedtime (NICE 2010)..**

**See protocol under the pregnancy section (page 12).**

- Patch formulation is suitable for individuals who prefer a continuous dose of nicotine throughout the day. Other formulations may be suitable for individuals who prefer to self dose when urge to smoke occurs.
- Patients who are **heavy smokers** or have felt insufficiently supported with a patch previously may, in addition to a patch, be offered the use of a second intermittent NRT product to use as required to prevent relapse (eg lozenges or gum). If a second product is required the maximum recommended daily dose of the intermittent NRT product should be reduced.

**Nicotinell<sup>®</sup> gum or Lozenges are the Forth Valley ‘when required’ products of choice.**

- Some **lighter smokers** may benefit from having a ‘when required’ product as a ‘safety net’, to allow flexibility
- Other ‘when required’ formulations are available such as; inhalator, oral spray and nasal spray but these are not so cost-effective and should be reserved **ONLY** for those patients for whom Nicotinell<sup>®</sup> gum or lozenges are not suitable.

**If combination NRT treatment is required, Nicotinell<sup>®</sup> patches in combination with Nicotinell<sup>®</sup> gum or lozenges should be considered as first-line choice as this is the most cost-effective combination.**

- Normal course length is 10-12 weeks.
- For details on doses, adverse effects, cautions and contra-indications of individual products refer to the Summary of Product Characteristics. ([www.emc.medicines.org.uk](http://www.emc.medicines.org.uk)).

## Nicotine Replacement Therapy Prescribing Recommendations from 1<sup>st</sup> March 2017

### Preferred NRT product - Nicotinell<sup>®</sup> (ALWAYS PRESCRIBE BY BRAND NAME)

The Nicotinell<sup>®</sup> range of products are the Forth Valley formulary choice and the most cost effective. These products should be suitable for the majority of patients.

- Nicotinell<sup>®</sup> 24hr Patch 7mg, 14mg and 21mg
- Nicotinell<sup>®</sup> Gum 2mg and 4mg
- Nicotinell<sup>®</sup> Lozenge 1mg and 2mg (*18yrs and over only*)

### Second choice product – Niquitin<sup>®</sup> Patch (ALWAYS PRESCRIBE BY BRAND NAME)

This should only be used when the Nicotinell<sup>®</sup> range does not offer a suitable formulation (e.g. problem with patch adhesive) or the Nicotinell<sup>®</sup> range does not include a second product that is felt appropriate for dual therapy.

- Niquitin<sup>®</sup> patches – 24 hour patch 7mg, 14mg and 21mg

### In conclusion:

- 1<sup>st</sup> line NRT choice in Forth Valley is Nicotinell<sup>®</sup> Patch.
- In those who require combination therapy a Nicotinell<sup>®</sup> Patch with Nicotinell<sup>®</sup> Gum or Nicotinell<sup>®</sup> Lozenge is preferable.
- If the individual has an issue with the adhesive of Nicotinell<sup>®</sup> Patch then a Niquitin<sup>®</sup> Patch could be used. If combination therapy is required with a Niquitin<sup>®</sup> patch then Nicotinell<sup>®</sup> Gum or Nicotinell<sup>®</sup> Lozenge is preferable.
- **All other NRT preparations are less cost-effective and are not the formulary choice. These should only be used where a formulary choice is unsuitable.**
- **Always prescribe by brand name.**

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| <p><b>Nicotine patch (Nicotinell® 1<sup>st</sup> line choice<br/>Niquitin® 2<sup>nd</sup> line choice)</b></p> <ul style="list-style-type: none"> <li>• Discreet and easy to use.</li> <li>• Available in different strengths, lasting 24 hours.</li> <li>• Supplies nicotine continuously throughout the day (helps relieve withdrawal symptoms and physical cravings).</li> <li>• Rotate the patch site to avoid itching, redness or skin dryness under the patch.</li> </ul> <p><b>Nicotine lozenge (Nicotinell® 1<sup>st</sup> line choice)</b></p> <ul style="list-style-type: none"> <li>• Discreet, flexible and offers good dose control.</li> <li>• An effective alternative to gum and available in several strengths and flavours; mint flavour may be more palatable.</li> <li>• One lozenge is used every 1-2 hours for the first few weeks reducing the number gradually each day and over the next few weeks until they are not needed anymore.</li> <li>• Do not chew or swallow.</li> </ul> <p><b>Nicotine gum (Nicotinell® 1<sup>st</sup> line choice)</b></p> <ul style="list-style-type: none"> <li>• Available in two strengths and several flavours.</li> <li>• Nicotine is absorbed through the lining of the mouth therefore discourage constant chewing by “chew/park/chew” technique for around 30 minutes.</li> <li>• Can taste slightly peppery at first.</li> <li>• Can irritate the mouth and throat, increase salivation and aggravate stomach ulcers.</li> <li>• Gum is not recommended in denture wearers.</li> </ul> | <p><b>Nicotine inhalator (NOT a formulary choice)</b></p> <p>The inhalator is helpful if the smoker misses the ritual of smoking.</p> <p>The inhalator looks like a cigarette holder, inside which a cartridge containing nicotine is placed. Nicotine is taken into the mouth and the back of the throat by a short suck on the inhalator when craving a cigarette.</p> <p>Use 6-12 cartridges daily for up to 8 weeks then reduce and stop over next 4 weeks.</p> <p><b>Nicotine sublingual tablet (NOT a formulary choice)</b></p> <p>Discreet, flexible and offers good dose control. The small tablet dissolves under the tongue. The tablet must not be sucked, chewed or swallowed, as this will reduce the amount of nicotine absorbed.</p> <p><b>Nicotine oral spray (NOT a formulary choice)</b></p> <p>Useful for people with severe withdrawal symptoms or heavy smokers.</p> <p>Starts to act in 60 seconds to give quick relief from cravings. The nicotine is absorbed quickly through the mouth lining, helping to rapidly relieve the urge to smoke.</p> <p>1 or 2 sprays when required (max 4 sprays hourly, max 64 in 24hours) for up to 12 weeks</p> <p><b>Nicotine nasal spray (NOT a formulary choice)</b></p> <p>Useful for people with severe withdrawal symptoms or heavy smokers.</p> <p>Presented as a bottle with a nozzle that delivers a dose of nicotine via a fine spray into each nostril. The nicotine is quickly absorbed through the lining of the nose and mimics cigarettes more closely by giving a relatively fast effect. The spray may initially irritate the nose and throat.</p> <ul style="list-style-type: none"> <li>• Apply 1 spray per nostril when required (max twice hourly) for up to 8 weeks, then reduce and stop over next 4 weeks.</li> </ul> |
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## Varenicline (Champix®)

- Varenicline may be a more suitable alternative to NRT in the following situations:
  - a patient expresses a desire to use Varenicline and there are no contraindications to its use,
  - Previous quit failure on a wide range of NRT formulations, either individually or in combination..
- The recommended starting dose is 500micrograms once daily for three days then 500micrograms twice daily for four days then 1mg twice daily thereafter. It should usually be started 1-2 weeks before planned smoking stop date and treatment continued for 12 weeks. See Summary of Product Characteristics (SPC) for details of dose reduction in patients with renal impairment and other relevant prescribing information.
- Prescribing should be avoided in pregnancy and breastfeeding and cautioned in those with conditions that may lower seizure threshold or predisposition to seizures; history of cardiovascular disease; history of psychiatric illness (may exacerbate underlying illness including depression).
- Common side-effects include taste disturbances; abnormal dreams; appetite changes; dizziness; dry mouth; gastro-intestinal disturbances; headache and sleep disorders. See SPC for full list of undesirable effects. Any suspected adverse reaction should be reported via the Yellow Card Scheme ([www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)).
- Patients should be advised that this medicine may make them sleepy and if this occurs then to not drive or use tools or machines.
- Patients who cannot tolerate adverse reactions may have the dose lowered temporarily or permanently to 500micrograms twice daily.
- Patients should be advised to discontinue treatment and seek prompt medical advice if they:
  - Develop agitation, depressed mood, or suicidal thoughts. Patients with a history of psychiatric illness should be monitored closely while taking varenicline, or
  - develop new or worsening cardiovascular symptoms such as signs and symptoms of myocardial infarction or stroke, or
  - Develop signs of hypersensitivity such as facial swelling or skin reactions.
- Based on clinical experience to date, no clinically meaningful drug interactions have been identified; however, the safety and efficacy in combination with other smoking cessation therapies (e.g. NRT) has not been studied.
- Patients should usually be treated for 12 weeks duration and then discontinued; however, in exceptional circumstances a further 12 weeks may be considered as maintenance of abstinence in those successfully stopped smoking. The maximum duration of treatment is 24 weeks.

At the end of treatment, discontinuation has been associated with an increase in irritability, urge to smoke, depression and/or insomnia and therefore prescribers should inform patients and consider the need for dose tapering (as required)



## Selected NRT and Champix® Product Range

| NRT Products           |                     |   |
|------------------------|---------------------|---|
| Patches                | Strengths           | Additional information  |
| Nicotinell®            | 7mg                 | 1 <sup>st</sup> line product 24 hr patch**  |
| Nicotinell®            | 14mg                | 1 <sup>st</sup> line product 24 hr patch**  |
| Nicotinell®            | 21mg                | 1 <sup>st</sup> line product 24 hr patch**  |
| Niquitin®              | 7, 14 and 21mg      | 2 <sup>nd</sup> line product 24 hr patch where a different patch is required due to problem with patch adhesive |
| Nicorette®             | 5, 10 and 15mg      | 16 hr patch NOT formulary choice  |
| Nicorette Invisipatch® | 10, 15 and 25 mg    | 16 hr patch NOT formulary choice  |
| Gum                    | Strengths           |   |
| Nicotinell Gum®        | 2mg                 | 1 <sup>st</sup> line product  |
| Nicotinell Gum®        | 4mg                 | 1 <sup>st</sup> line product  |
| Nicorette Gum®         | 2mg                 | NOT formulary choice  |
| Nicorette Gum®         | 4mg                 | NOT formulary choice  |
| Niquitin CQ gum®       | 2mg                 | NOT formulary choice  |
| Niquitin CQ gum®       | 4mg                 | NOT formulary choice  |
| Lozenges/Tabs          | Strengths           |   |
| Nicotinell®            | 1mg                 | 1 <sup>st</sup> line product  |
| Nicotinell®            | 2mg                 | 1 <sup>st</sup> line product  |
| Niquitin CQ®           | 2mg                 | NOT formulary choice  |
| Niquitin CQ®           | 4mg                 | NOT formulary choice  |
| Niquitin CQ Minis®     | 1.5mg               | NOT formulary choice  |
| Niquitin CQ Minis®     | 4mg                 | NOT formulary choice  |
| Nicorette Microtab®    | 2mg                 | NOT formulary choice  |
| Nicorette Cools        | 2mg                 | NOT formulary choice  |
| Inhalator              | Strengths           |   |
| Nicorette Inhalator®   | 15mg                | NOT formulary choice  |
| Nasal Spray            | Strengths           |   |
| Nicorette Nasal Spray® | 500mcg/dose         | NOT formulary choice  |
| Quickmist              | Strengths           |   |
| Nicorette Quick Mist®  | 1mg                 | NOT formulary choice  |
| Champix                | Strengths           |   |
| Varenicline (Champix®) | 500mcg, 1mg tablets | 1 <sup>st</sup> line product  |

\*\* A 24 hour patch can be removed before sleeping if the individual experiences problems with vivid dreams/sleeping.

## E-cigarettes

E-cigarettes have been available for purchase for just over a decade in Scotland. They have and continue to be popular and many smokers report using them.

In 2017 Health Scotland developed a consensus statement on e-cigarettes aimed at both health professionals and members of the public.

<http://www.healthscotland.scot/publications/e-cigarettes-consensus-statement>

The clear message for health professionals is to be proactive in ways to quit which are most effective. Patients should be advised that expert support and medicinal products have the strongest evidence base to help people to stop smoking. However, patients choosing to use an e-cigarette in their quit attempt should not be discouraged and should be referred to the Stop Smoking Service.

Health Scotland has developed a resource highlighting the facts about e-cigarettes and how they might help patients to stop. These are available to order through the Health Improvement Resources Library.

<https://nhsforthvalley.com/health-services/health-promotion/resources-and-design/>

**Please note that patients using e-cigarettes are not eligible for the smoking cessation service offered by community pharmacies at present.**

It should be kept in mind that use of e-cigarettes, their role in cessation and long-term effects is an emerging area, with its evidence base still developing.

## Specialist Stop Smoking Services

### Community

NHS Forth Valley provides local clinics to help people give up smoking. Details of these can be found at the following link:

<http://nhsforthvalley.com/health-services/az-of-services/stop-smoking-service-clinics/>

Patients can also self refer by telephone and email.

Telephone 01786 433 293

Email [FV-UHB.FVStopSmokingService@nhs.net](mailto:FV-UHB.FVStopSmokingService@nhs.net)

Stop Smoking Advisers deliver cessation support within 12 local GP practices. Please call the number below or email for further information.

GPs and Dentists can refer patients to the Stop Smoking Service through SCI Gateway.

Community pharmacies can refer complex patients or those requiring additional support to the Stop Smoking Service by telephone or email as below:

Telephone 01786 433 293

Email [FV-UHB.FVStopSmokingService@nhs.net](mailto:FV-UHB.FVStopSmokingService@nhs.net)

**All Community Pharmacies provide a FREE smoking cessation support service** as part of the Public Health Service element of the community pharmacy contract.

This includes the provision of patient centred behavioural support and evidence based pharmacotherapies (NRT and Varenicline (Champix<sup>®</sup>)).

The service is available to any patient aged 12 years or over.

### Acute settings

The national smoking cessation guidance (2010) makes several recommendations relevant to acute settings, including;

- Health professionals are well placed to provide brief interventions by raising the topic of smoking that arise around other contact with patients to advise them to stop smoking and to recommend support to do so.
- All patients should have their smoking status discussed and recorded at all stages in their treatment phase from pre admission to discharge and should be encouraged to stop smoking before surgery or admission e.g. pre-admission and be offered timely access to an intensive support service (normally an NHS smoking cessation service).
- Hospital patients who use tobacco in any form should be asked if they are interested in stopping and referred to specialist services and those not ready to quit should be considered for NRT to alleviate nicotine withdrawal symptoms.

<http://www.healthscotland.scot/media/1096/a-guide-to-smoking-cessation-in-scotland-2010-aug10.pdf>

Following referral to stop smoking services patients should be assessed on site where possible and offered specialist support whilst they are an inpatient. Upon discharge, and with patient consent, they should continue to be supported by the Specialist Stop Smoking Service.

Benefits of an Integrated Care Pathway for the management of Nicotine Addiction in Acute settings:

- Provides accountability and protection to staff by following the pathway and documenting the actions taken around patients smoking.
- Increases access to cessation support.
- Supports the implementation of No Smoking/Smoke-free Policies
- Offers patients an alternative to smoking potentially reducing the need for patients to leave the building to smoke.
- Reduces the fire risk associated with smoking in an acute setting.
- May initiate a quit attempt from patients who otherwise may not access cessation services.
- Supports Mental Health staff to work towards providing a smoke free environment for their patients.
- Improved patient comfort (due to alleviation of nicotine withdrawal symptoms)
- Appropriate referrals from all clinical areas to the Stop Smoking Service
- Patient choice
- Equity and consistency of care
- Increase staff knowledge of nicotine addiction and treatment
- Increased availability of NRT

Please refer to the acute stop smoking inpatient and out of hours pathway available from:

<http://guidelines.staffnet.fv.scot.nhs.uk/wp-content/uploads/sites/2/2017/11/Stop-Smoking-Service-IP-Pathway-and-OOH-NRT-1.pdf>

## **Pregnancy**

Encouraging women to stop smoking as soon as a pregnancy is confirmed is important. In the third trimester nicotine has a haemodynamic effect (e.g. changes in foetal heart rate) which could affect the foetus close to delivery, therefore early intervention is extremely valuable.

**National protocol:- It is requested that Maternity services follow the national protocol of universal CO monitoring with “opt-out” onward referral to specialist services.**

As per the national protocol all pregnant women in Forth Valley receive carbon monoxide monitoring. All women with a reading of  $\geq 4$ ppm are automatically referred to the Stop Smoking Service.

**After a woman has engaged with a specialist service the following protocol should be followed with all pregnant women: -**

- Discuss Risks/Benefits
- 1<sup>st</sup> recommendation –Behavioural support only (No NRT)
- 2<sup>nd</sup> recommendation - NRT oral products (No Liquorice gum)
- 3<sup>rd</sup> recommendation- continuous use NRT product – only 16-hour patch

***Neither Varenicline nor Bupropion should be used in pregnancy or whilst breastfeeding***

NRT may be recommended for breastfeeding women. If a breastfeeding woman expresses a wish to receive NRT clinical judgement should be used. Any risk is likely to be small in comparison with the amount of nicotine from cigarettes and the smokefree environment will also outweigh any risk.

Using intermittent NRT may minimise the amount of nicotine in breast milk as the time between administration of NRT and feeding can be timed to ensure levels of NRT are at their lowest level.