Peterborough Public Health Community Pharmacy
Service Specification: Smoking Cessation 2021 - 22

Contents

Context Update

Cambridgeshire County Council and Peterborough City Council commission stop smoking services from community pharmacies for their local populations. Both Local Authorities are working more closely together which reflects the footprint of the Cambridgeshire and Peterborough Clinical Commissioning Group. Consequently there are a number of Joint Commissioning Units emerging including the Cambridgeshire and Peterborough Public Health Joint Commissioning Unit (JCU). This Public Health JCU launched May 1 2017 commissioning responsibilities will include the services that are provided by primary care. The aim is to standardise the commissioned primary care services across the CCG footprint. Although the JCU will work across the two local authority areas individual Pharmacy Contracts will be contracted by the local authority where they are geographically located. Staff from the JCU will continue to support practices where appropriate as well have a performance management function.

1. Service Description

Smoking remains the main cause of preventable morbidity and premature death in England and it is the primary reason for the gap in healthy life expectancy between the rich and poor. The adult smoking prevalence in Peterborough is 19.5% (APS 2018) which is higher than the average in England (14.4%) and the East of England (14.0%).

Stop Smoking activity will support improvements against relevant outcomes and indicators with in the Public Health Outcomes Framework including:

- Reducing the smoking prevalence in Adults (over 18)
- Reducing the smoking prevalence in 15 year olds
- Reducing the smoking status at the time of delivery

The aim of this service specification is to indicate the requirements for the Community Pharmacy Stop Smoking Service that supports smokers in Peterborough to make a quit attempt in line with NICE Guidance and the Standard Treatment Programme from the National Centre for Smoking Cessation Training (NCSCT). It fully reflects NICE Guidance in terms of the intervention and DH requirements for monitoring.

The Peterborough Community Pharmacy Stop Smoking Contract is for the following:

- The provision of a structured evidence based 4 week quit attempt as part of the 12 week treatment programme that includes setting a quit date alongside behavioural change in conjunction with pharmacotherapy indicated in this specification. This does not include: ‘cut down to quit’ programmes, or the long term use of NRT

- The provision of a structured evidence based 4 week quit attempt as part of the 12 week treatment programme that includes setting a quit date alongside behavioural change in conjunction with a non-licensed/non-evidence based nicotine containing product such as an electronic cigarette.

  Payment will be made for people who are 'four week quitters' when stop smoking services are delivered by Community Pharmacies in accordance with this service specification and related data completed on the PharmOutcomes database.

Please note:
Payments will not be made for clients who have stopped smoking (a four week quitter) but want to use the stop smoking service to cease using an electronic cigarette.

2. Requirements of the Service

This service should be offered to **<u>all</u> identified smokers over the age of 12 years old** who use the pharmacy.

By signing up to this agreement the practice is confirming the intention to work in collaboration with Cambridgeshire and Peterborough Public Health Joint Commissioning Unit.

A structured stop smoking support programme for a quit attempt should be provided and should include the following elements:

2.1 **Assessment:** An assessment of a person's readiness to make a quit attempt and use of appropriate treatments.

2.2 **Setting a quit date** with the patient which marks the commencement of the patient's four week quit attempt.

2.3 **Pharmacological treatments** should be prescribed in line with NICE Guidance and local protocols. An initial two weeks supply will be prescribed and repeated after the first two weeks of the quit attempt and every two – four weeks thereafter for a typical treatment period of up to twelve weeks . Clients are to be informed of the pharmacological treatments (evidence-based and licensed for use for smoking cessation) and options discussed prior to prescribing.

2.4 **Record of the intervention completed on the PharmOutcomes System at every stage**. All datasets must be complete **and all patients must be asked to consent to sharing their treatment data with the local stop smoking service.** All data is to be provided electronically through the PharmOutcomes database.

2.5 **Patient Contact**: The initial assessment should be a minimum of 30 minutes duration, and if the patient/client sets a quit date then a minimum of 15 minutes should be allocated to follow up appointments. In total it is expected that the patient is given at least 1.5 hours of clinical time during the quit attempt to ensure continued monitoring, client compliance and ongoing access to medication. It is acknowledged that some clients do not need weekly consultations; *but there should be a* **minimum of six consultations** including preparation for setting a quit date. This can include telephone contact but it is recommended that the first and final contacts of the 4 week quit attempt should be face to face so that CO reading can be taken.

2.6 **Active management of lost to follow ups** should include the following actions:

- Any clients failing to attend a particular session should be followed up **at least three times** and encouraged to continue the programme in accordance with the agreed protocol.
- People not wishing to initially engage or those who choose not to complete the programme may be offered appropriate health literature or referral to an alternative stop smoking service.
- Clients who are recorded as 'lost to follow up' at the four week stage, should be coded and their data returned.

2.7 **Recording Smoking status at four weeks post quit date** can be assessed by the following:

- Self-reported smoking status at 4 weeks post quit date
- Carbon Monoxide test validation at 4 weeks post quit date
- Not Quit at 4 weeks post quit date
- Lost to follow up at 4 weeks post quit date

2.8 **Completing the twelve week standard treatment programme** by providing regular behavioural support sessions, CO monitoring and NRT prescriptions from 4 week stage to 12 weeks.

2.9 **Data quality**

There should be a strong emphasis on collecting and reporting gold standard data and should be attempted for all quit attempts. Services are expected to meet the minimum quality standards that define best practice locally:

- All smokers set a quit date at the first or second appointment.
- A minimum quit rate (success rate) of 50%.
- At least 85% of quits to be CO validated. Success should be validated by a CO (Carbon Monoxide) monitor reading of less than 6 ppm at the 4-week point.
- Lost to follow up rate to be less than 15% of smokers who set a quit date.
- All occupational codes to be recorded.
- Smokers who have previously failed to quit three times should be offered an automatic referral to the specialist stop smoking service within the Lifestyle Service.
- All Services to offer NRT, varenicline or bupropion (GP prescription only) as first-line treatments (if clinically appropriate).
- All Service Users are to be given an opportunity to evaluate the service that they have received.

3. Core skills and Training

3.1 All staff should be trained to Department of Health, NICE & NCSCT standards and use evidence based approved methodology (training programmes are designed in line with guidance provided by the National Centre for Smoking Cessation and Training).

3.2 Smoking cessation training is compulsory for every staff member involved in the service. Pharmacy Assistants can offer the service by attending the stop smoking training provided by the Lifestyle Services in Cambridgeshire and Peterborough. Where the pharmacy assistant is not working in isolation and has full support and mentoring from their Pharmacist. A minimum of one pharmacist per pharmacy and one pharmacy assistant should attend the training programme to become an accredited pharmacy.

3.3 The pharmacy contractor has the responsibility to ensure that all staff including locums involved in providing the service are appropriately trained i.e. NCSCT online training and attendance at a Cambridgeshire and Peterborough organised smoking cessation training programme.

3.4 The pharmacy contractor has the responsibility to ensure that pharmacists and staff involved in the provision of the service are aware of and act in accordance with the Service Specification, Cambridgeshire and Peterborough protocols (found in Appendix B below), best practice guidance and NICE guidance.

3.5 The pharmacy contractor has the responsibility to ensure that their service has the recommended quality controls in place and that the service can demonstrate compliance.

3.6 Training will be provided free of charge and will be provided by local accredited trainers. Advisors must attend annual update training.

3.7 All advisors are encouraged to access the nationally accredited certification which is available free of charge via the National Centre for Smoking Cessation Training website www.ncsct.co.uk .

3.8 It is recommended that women who are currently pregnant should only be seen by a Pharmacy advisor who have accessed the specialist pregnancy training and it is the Pharmacist's responsibility to supply and monitor smoking cessation medication and for the treatment and care of the pregnant smoker. Alternatively pregnant women can be referred to the specialist stop smoking service with Healthy You.

4. Consultations and Gold Standard service

4.1 The service requirements are summarised in the table below.

One-to-one behavioural support sessions (minimum support for the first six weeks)

Session	Minimum time allocated (minutes)
Session 1: Pre-quit	30
Session 2: Quit date	20
Session 3: 1 week post-quit	15
Session 4: 2 weeks post-quit	15
Session 5: 3 weeks post-quit	15
Session 6: 4 weeks post-quit*	15
Total	1 hour 50 minutes

* Further sessions may be provided as per local protocol. Clients will need to be able to access the full course of their chosen stop smoking medicine(s) (see page 32).

	SPECIFICATION	WHEN

1a	Initial assessment- Brief advice (5 minutes) ▪ Assessment of person's readiness to make quit attempt and use appropriate treatments	Can be done separately or together. Ideally give patient information in assessment and ask patient to come back for consultation to set quit date
1b	Initial consultation (30 minutes) ▪ Set quit date ▪ Supply 4 weeks NRT however only dispense 2 weeks at a time ▪ Complete monitoring form ▪ Carbon monoxide (CO) test validation ▪ Complete the patient records notes	
1c	Follow up (15 minutes) ▪ Second NRT supply	Weeks 1-3 post quit date
1d	Follow up (15 minutes) • NRT supply	Weeks 1-3 post quit date
1e	Follow up (15 minutes) • NRT supply	Weeks 1-3 post quit date
2	4 week follow up (15 minutes) ▪ Self reported smoking status ▪ CO test validation ▪ Further supply of NRT if appropriate ▪ Complete data return on PharmOutcomes	4 weeks post quit date
3	If client has QUIT 5-8 weeks after ***QUIT*** date (15 minutes) ▪ Further supply of NRT for 4 weeks if appropriate ▪ CO test (optional) ▪ Complete patient notes ▪ Complete data return on PharmOutcomes for reimbursement of NRT	5-8 weeks after Quit date
4	9-12 weeks after ***QUIT*** date (15 minutes) ▪ Further supply of NRT for 4 weeks if appropriate ▪ CO test (optional) ▪ Complete patient notes ▪ Complete data return on PharmOutcomes or reimbursement of NRT	9-12 weeks
N.B.		
If client has **NOT QUIT at the four week stage** start from initial consultation stage again, re-assess their readiness to Quit and negotiate a new quit date (15-30 minutes) ▪ Set a new quit date ▪ Supply 4 weeks NRT however only dispense 2 weeks at a time		

- Complete a new monitoring form
- CO test validation
- Complete the patient notes

4.2 Access routes to this service will be determined locally, however they could include:

- Pharmacy referral as a result of the 'Promotion of healthy lifestyles (Public Health)' or 'Signposting' Essential services
- Direct referral by the individual
- Referral by another health or social care worker.
- Referral from the specialist service

4.3 The ***initial assessment*** should include:

- An assessment of the person's readiness to make a quit attempt
- An assessment of the person's willingness to use appropriate treatments and the community pharmacy scheme programme.

4.4 The ***initial consultation*** should include:

- A carbon monoxide (CO) test and an explanation of its use as a motivational aid
- A description of the effects of smoking and second hand smoke on children and adults
- A description of the main benefits of stopping smoking
- A description of the main features of tobacco withdrawal and the common barriers to quitting
- Identify treatment options that have proved effective
- Describe what a typical treatment programme will look like, its aims, length, how it works and its benefits
- Maximise commitment to quit date
- Apply appropriate support strategies to help the person stop smoking
- Conclude with an agreement on the chosen treatment pathway and process a prescription for NRT for 4 weeks (to be dispensed at fortnightly intervals), ensuring the person understands the on-going support, request consent to follow-up by the Advisor and/or Lifestyle service and monitoring arrangements the development of a personal behaviour strategy for stopping smoking.

4.5 Evidence suggests that week's 1-4 are crucial to the success of a quit attempt, so it is recommended that the community pharmacy smoking cessation service offers as much support to the client during this time to have the greatest success i.e. face to face &/or telephone support weekly from the initial consultation to the four week follow up.

4.6 The ***4-week follow up*** should include self-reported smoking status, followed by a CO test for validation. Smokers would normally be expected to attend regular sessions and at the session 4 weeks after the quit date the client can be classed as a quitter if they have not had a puff of a cigarette at all in the past two weeks.
Although face to face consultations are considered to be the best way to engage with a client, telephone consultations, email and text messaging are also acceptable forms of communication.

4.7 People not wishing to initially engage or those who choose not to complete the programme may be offered appropriate health literature or referral to an alternative stop smoking service.

4.8 The Advisor will have the responsibility to follow up any clients failing to attend a particular session and encourage them to continue the programme. This should be in accordance to an agreed protocol.

4.9 On receipt of clients details who are recorded as 'Not Quit or Lost to follow up' and have given consent to follow up the Lifestyle team will routinely contact them and try and re-engage them with a quit attempt and the appropriate service.

5. Prescribing and Supply of Nicotine Replacement Therapy (NRT) options

5.1 If considered appropriate the pharmacist may supply NRT for the initial four weeks of the treatment programme (to be dispensed every two weeks) and will advise on its use. Supply of treatment must be recorded on the client monitoring form and client notes sheet. After the initial four weeks the client will be reassessed for a further supply of NRT and reassessed again at the eight week stage for a final prescription. Supply of NRT should be in line with the Cambridgeshire & Peterborough prescribing policy which has been agreed with the Cambridgeshire and Peterborough CCG.

Schedule for supply of NRT by pharmacies

Initial assessment	No NRT supplied (No payment will be made for NRT supplied at initial appointment)
Pre-Quit appointment*	1st supply of NRT, 1week, *prescription charge per item if applicable (letter to GP to inform NRT issued)
Weekly follow up (FU) x4 AFTER Quit date FU 1 week post quit FU 2 weeks post quit FU 3 week post quit FU 4 weeks post quit*	 1 week NRT supply 1 week NRT supply 1 week NRT supply 2 weeks NRT supply *prescription charge per item if applicable.
4 week outcome recorded and CO verified.	Letter to GP re outcome of quit attempt.
FU 6 weeks post quit FU 8 weeks post quit*	2 weeks NRT supply 2 to 4 weeks NRT supply as appropriate. *prescription charge per item if applicable
FU 10-12 weeks post quit	As required; complete episode on PharmOutcomes

5.2 If patients are exempt from NHS prescription charges then there is no charge to the client for supply of NRT through this scheme.

5.3 Clients accessing the service who are not exempt from prescription charges will be required to pay one prescription charge for each product type, for every 4 week cycle of NRT supplied e.g. Nicorette patches and Nicorette gum would incur two charges. However, Nicorette 15mg patch followed by 10mg patch would incur one charge provided it is within the same month. Prescription fees collected should be recorded on PharmOutcomes sessions via the ‘fees paid’ button.

If the quit attempt is not successful at the 4 week stage (see criteria for 4 week quit) there should be no further supply of NRT. This should be assessed on an individual basis i.e. one lapse in week 3 or 4 continue with current quit

attempt (but record 4 week outcome as not quit), or if returned to regular smoking the client can restart another quit attempt when appropriate.

Please note: clients on two products a month should be advised that it would be cheaper to pay their prescription charges via the NHS prepayment system.

5.4 Combination therapy: combination of NRT products has been shown to have an advantage over using just one product. Although most combinations are acceptable, this should be discussed and assessed on an individual basis with the client; the most common combination being the NRT patch with an oral product. Where clients are using combination therapy and are not exempt from prescription charges the client should pay one prescription charge per item for each four week supply. **No more than 2 items should be supplied.**

5.5 The pharmacy is not required to staple the NRT product receipt to the monitoring form.

5.6 At the present time there is no mechanism for pharmacists to supply Zyban or Champix without a prescription. If the client is interested in using this product they will be given the necessary product information and provided with the PharmOutcomes 'Treatment' letter for their GP for a medical assessment and prescription after attending the initial session of the stop smoking programme. The pharmacy advisor can provide them with behavioural support and should record the details of the intervention as normal on PharmOutcomes

The decision to supply the client with a prescription for the products will remain with the GP, who must take into account the patient's medical history. It will remain the responsibility of the GP to check the patient's medical record for any possible contra-indications before issuing a prescription.

5.7 Follow up consultations, in line with NICE guidelines, should be agreed with the client and will include smoking status validation using a CO test. A further supply of NRT treatment could be made at these consultations. Consultations can be made via the telephone and a face to face appointment agreed with the client to establish a CO reading.

5.8 If the quit attempt is successful they should be recorded as 'Quit' at the 4 week stage. The client should be assessed on an individual basis and offered NRT for an additional 8 weeks (at 4 weekly intervals) making the total amount of NRT prescription a 12 week course. Continued use of the NRT product is proven to increase a success rate and supports the client to become smoke free long term.

5.9 If the quit attempt is not successful at the 4 week stage, the client should be recorded as 'Not Quit' and a new assessment and quit date set, where appropriate. The Department of Health have set out in the 'Monitoring Guidance' that there needs to be no set time duration between quit attempts, however the advisor should use their professional judgement when assessing the clients readiness to change before setting a new quit attempt and if the client has had two failed quit attempts the client should be referred to the specialist stop smoking & lifestyle service.

6. NRT Voucher Scheme

6.1 As part of the community pharmacy scheme service the contractor is required to dispense NRT upon receipt of a valid NRT Voucher code. Clients will be receiving behavioural support from an external provider; therefore the contractor is NOT required to provide additional support.

6.2 Pharmacies will supply NRT on receipt of a voucher code from an authorised individual as directed on PharmOutcomes. Pharmacies will confirm that the NRT has been supplied as directed and will confirm that the medication is dispensed on the PharmOutcomes system. The Joint Commissioning team have access to the 'Commissioners only' element of the system which doesn't contain any patients identifiable information.

6.3 All clients accessing this scheme will be provided with stop smoking advice by the smoking cessation advisor completing the voucher. Pharmacies will only be required to supply the required product. Patients should be directed back to their smoking cessation advisor for further stop smoking advice or to obtain another voucher code for NRT. This is also an opportunity for the Pharmacist to offer the pharmacy scheme if this option is easier for the client.

6.4 The EC Labelling and Leaflet Directive applies to all NRT supplied. The pack should be labelled with the following information:

- The address of the clinical area where the supply was made
- 'Keep out of the reach of children'
- Directions for use
- The name of the patient
- Date of supply

6.5 Voucher codes will be valid for two weeks from date stated by Smoking Cessation Advisor. Clients who present an out of date voucher should be signposted back to their original advisor or can be signed up on the community pharmacy scheme if this is a suitable programme for the client.

6.7 NRT supplied should be in accordance with the dispensing essential service.

6.8 If the directions on the voucher code are not clear then the smoking cessation advisor should be contacted for clarification.

6.9 If patients are exempt from NHS prescription charges then there is no charge to the client for supply of NRT through this scheme. Clients accessing the service who are not exempt from prescription charges will be required to pay one prescription charge per product for each 2 week cycle of NRT supplied. The cost of NRT will be reimbursed to the pharmacy through the voucher minus any prescription charges.

6.10 NRT products are licensed for over 12 year's olds. As of Public Health's commitment to reduce the prevalence of smoking in young people, the JCU and local stop smoking services supports the school nurse team to provide NRT products via the voucher scheme after an assessment and Fraser Competency assessment.

6.11 It is the Pharmacists responsibility for the treatment of the smoker and therefore he/she should only dispense the product suggested on the voucher should they deem it appropriate to do so.

7. Record Keeping

7.1 The pharmacy should maintain appropriate records which includes detailed clinical notes through the PharmOutcomes system. A completed record consists of the minimum data set as defined within the ´NHS smoking cessation services: service and monitoring guidance'

7.2 The Commissioner will process the payments on a quarterly basis in line with the claim forms generated by PharmOutcomes.

7.3 Datasets for people setting a quit date between 1st April 2021 - 31st March 2022 must be complete before 5th June 2022. Any data received after this date, for that reporting period will not be used for reporting purposes and reimbursement will not be made.

7.4 2021-22 reporting year begins on 1st April 2021 and finishes on 31st March 2022.

8. Advisor Absences

8.1 Wherever possible continuity of care should be maintained.

8.2 If the advisor is unexpectedly unavailable for a returning client then the pharmacy staff will telephone the client(s) to offer an alternative advisor if available or cancel and rearrange any appointments

9. Stop Smoking Service/Commissioner Responsibilities

9.1 The materials and equipment required to start the service, including CO monitors and disposable mouthpieces ***starter kit***, are supplied free of charge to the pharmacy. Ongoing provision of consumables are the responsibility of the pharmacy.

9.2 Peterborough City Council reimburses the pharmacy for the cost of NRT; excluding VAT.

9.3 The Commissioner provides a framework for the recording of relevant service information for the purposes of audit and the claiming of payment.

9.4 The Stop Smoking Service will work with the Commissioner to promote the service locally, including the development of publicity materials, which pharmacies can use to promote the service to the public.

10. Pharmacy Responsibilities

10.1 The pharmacy will complete the Pharmoutcomes system for each client seen.

10.2 This outcome at four weeks should be either QUIT, NOT QUIT or LOST TO FOLLOW UP (LTF). **Data quality:** There should be a strong emphasis on collecting and reporting gold standard data and should be attempted for all quit attempts. Gold standard data includes a quit rate of above 50%, Carbon monoxide monitoring above 85%, lost to follow up rate of 15% or below, and above 90% of all clients ethnicity, occupations and the medication used.

10.3 It is the Pharmacy's responsibility to inform the client that at the end of the 12 week period they will have to purchase any subsequent NRT products.

10.4 The Pharmacy will ensure that they provide CO monitoring to all clients and it is the Pharmacy responsibility to purchase subsequent CO monitor tubes and D pieces once the starter kit has been used. The Pharmacy is responsible for the disposal of clinical waste & infection control measures in line with their company policy.

10.5 The pharmacy reviews its standard operating procedures and the referral pathways for the service. The pharmacy will maintain links with local lifestyle & smoking cessation services to ensure that referral pathways are maintained.

10.6 The pharmacy can demonstrate that pharmacists and staff involved in the provision of the service have undertaken CPD relevant to this service and Cambridgeshire & Peterborough organised training provided by accredited trainers including an annual Level 2 training update.

10.7 The pharmacy participates in an annual organised audit of service provision and quality which will be completed by the Commissioner.

10.8 The pharmacy co-operates with any locally agreed Commissioner led assessment of service user experience.

10.9 The pharmacy should inform the Commissioner if they are no longer able to participate in the scheme due to movement of trained staff or if they no longer wish to participate in the scheme. A minimum of three months' notice period should be given to Peterborough City Council should the Pharmacy wish to terminate or temporarily put the service on hold.

10.10 When the client has completed their programme of support through the community pharmacy scheme and wishes to continue to receive support, the Pharmacy can offer further behavioural support as set out in or refer the client back to the local Integrated Lifestyle services.

11. Data Returns and Remuneration

11.1 A finite amount of funding is available for community pharmacy provision of a smoking cessation service. The Commissioner will regularly review provision of the service and funding available.

11.2 Smoking cessation data should be updated on the Pharmoutcomes system every month and is based on the month that the client's quit date has been set. For example, if a patient has set a quit date for 30th April 2021 then the data outcome at four weeks should reach the stop smoking services in the month listed on the table below, in this instance by the 5th June 2022.

11.3 The fee structure for community pharmacy participation in the scheme will be:
Payment element one: A fee of £15 will be paid to the pharmacy for return of data on clients entering the scheme and setting a quit date*
Payment element two: An additional fee of £15 will be paid to the pharmacy per successful quitter at 4 week follow up
Payment element three: A dispensing fee of £1 per item will be paid for NRT issued from 6 weeks after quit date up to 12 weeks. Issues should be fortnightly. Maximum dispensing fee claimable £6.
Additional payment elements:
As identified in Section 6 of this specification, Pharmacies will be given the option to participate in the NRT Voucher Scheme. Where this agreement is made, pharmacies will be paid £2.50p for each NRT product dispensed on receipt of an NRT voucher.

Pharmacies will be reimbursed for NRT supplied at the most recent drug tariff cost, as per the BNF values. Please note that Pharmacies are liable for the VAT costs.

11.4 All payment invoices are generated by PharmOutcomes once the client's treatment programme is completed on the system (usually 12 weeks after quit date if successfully quit or sooner if outcome is not quit or lost to follow up). Community Pharmacies can see their claims which are submitted to the C + P Public Health Team on the system.

Payments will be made directly to account details provided by the pharmacy.

11.5 It is not permitted for providers to subcontract service provision to other parties and any claims made on this basis will not be paid. To safeguard the service against the possibility of fraudulent claims, by signing this contract, all providers agree to the following declaration.

'I claim payment for the stop smoking services that I have provided which are recorded on Pharmoutcomes. I confirm that the information given is true and complete. I understand that if I provide false or misleading information I may be liable to prosecution or civil proceedings. I understand that the information may be provided to the counter Fraud and Security Management Service, a division of the NHS Business Services Authority for the purpose of verification of this claim and the preventing, detecting and investigation of fraud'.

12. Termination & Agreement period

12.1 Either party (pharmacy or the Commissioner) shall be entitled to terminate this agreement by giving three months' notice in writing to the other party.

12.2 This agreement will continue until March 2022 unless terminated by either party in accordance with the provision of this agreement.

12.3 Pharmacies will be required to sign the agreement each financial year to continue providing the service.

Appendix A-Smoking Cessation Service Data Quality Information Sheet

Definitions

Smoked product
Any product that contains tobacco and produces smoke is a smoked product, including cigarettes (hand-rolled or tailor-made), cigars and pipes. Pipes include shisa, hookah, narghile and hubble-bubble pipes.

Smokeless product
There is evidence to show that the use of smokeless tobacco products (e.g. chewing tobacco, paan, khat) can have negative health effects, including oral cancers. There is some evidence to suggest that behavioural support can be effective.

Quit date
Date a smoker plans to stop smoking altogether with support from a stop smoking adviser as part of an NHS-assisted quit attempt.

Self-reported four-week quitter
A treated smoker whose quit status at four weeks from their quit date (or within 25 to 42 days of the quit date) has been assessed either face-to-face or by telephone, text, or email

Carbon monoxide-verified four-week quitter
A treated smoker whose Co reading is assessed 28 days from their quit date (-3 or + 14 days) and whose Co reading is less than 10ppm. The -3 or +14 day rule allows for cases where it is impossible to carry out a face-to-face follow-up at the normal four-week point (although in most cases it is expected that follow-up will be carried out at four weeks from the quit date). This means that follow-up must occur 25 to 42 days from the quit date (Russell Standard). Co-verification should be conducted face-to-face and carried out for at least 85% of self-reported four-week quitters.

Not Quit at four weeks
A treated smoker who has set a date to stop smoking and when monitored within 25 to 42 days of the quit date has smoked within the past two weeks. This outcome can be assessed by self-report or confirmed with a Carbon monoxide verification test.

Lost to follow-up (LTF)
A treated smoker who cannot be contacted either face to face or via telephone, email, letter or text following three attempts to contact at different times of day, at four weeks from their quit date (or within 25 to 42 days of the quit date). The four-week outcome for this client is unknown and should therefore be recorded as LTFU on the monitoring form. NHS Cambridgeshire LES agreements do not pay for patients who are lost to follow up.

Not completed data
A client who has received an intervention and set a quit date but there is missing data or no clear outcome at four weeks.

Success rate
Is the total number of people who have set a date to stop smoking and have stopped smoking at four weeks: set quit date total – quit. E.g. 30 people set a quit date and 15 were quit at four weeks would be 50% success rate.

CO verified %
This is the total % of people who have had a carbon monoxide test recorded out of the total number of people who have been recorded at Quit when monitored at the four week stage e.g. total number of people who were recorded as quit 20 and of these people 5 had a carbon monoxide test completed= 25% co verified.

Explanations

Why Do We Record Occupation?

Reducing health inequalities is a public health priority. Routine and Manual (R&M) workers have higher smoking prevalence than general population and it is important that we target priority population groups, as well as the general population, to contribute toward a reduction in health inequalities.

Recording occupation also helps service mapping and the development and delivery of the Cambridgeshire service in the future, as well as actually helping you as an advisor to understand and guide your client appropriately.

Please note:

If you are recording 'occupation' on a GP surgery template please first try to type in the generic name of the persons job i.e. chef or cleaner, and this should bring up a shorter picking list to choose from. Please try and avoid leaving it blank or unable to code.

1. Unemployed - A client is classified as long term unemployed if they have currently been unemployed for one year or more. If unemployed for less than a year last known occupation should be used for classification
2. Home Carer - i.e. looking after children, family or home
3. Self Employed - If a client is self-employed please use the flowchart below to determine classification
4. Unable to Code - If you are still unable to establish this, please record as unable to code

Managerial and Professional Occupations:	**Intermediate Occupations:**	**Routine and Manual Occupations:**
Academic	Administrator	Bartender
Accountant	Bank Clerk	Fitter
Artist	Call centre agent	Caretaker
Athlete/sportsperson	Clerical worker	Catering assistant
Civil/mechanical engineer	Electrician	Cleaner
Consultant	Gardener	Farm worker
Doctor/medical practitioner	Inspector	HGV driver
Lawyer	Nursery auxiliary	Labourer
Musician	Office clerk	Machine operative
Nurse	Plumber	Messenger
Police officer	Receptionist	Packer
Physiotherapist	Secretary	Porter
Scientist	Shop manager	Postal worker
Senior manager	Train driver	Printer
Social worker	skilled technical or craft occupations	Sales assistant
Software engineer		Security guard
Solicitor		Sewing machinist
Teacher		Van driver
Welfare officer		Waiter/waitress
those usually responsible for planning, organising and coordinating work or finance		

Why Record Ethnicity?

Recording ethnicity is important as some black and minority ethnic (BME) communities have high smoking prevalence rates compared with the general population. Recording ethnicity also helps service mapping and the development and delivery of the Cambridgeshire service in the future, as well as actually helping you as an advisor to understand and guide your client appropriately.

ETHNIC GROUP*: *(please tick relevant group)*					
a] White		b] Mixed		c] Asian or Asian British	
British	☐	White and Black Caribbean	☐	Indian	☐
Irish	☐	White and Black African	☐	Pakistani	☐
Other white background	☐	White and Asian	☐	Bangladeshi	☐
		Other mixed groups	☐	Other Asian background	☐
d] Black or Black British		e] Other ethnic groups		f] Other	
Caribbean	☐	Chinese	☐	Not stated	☐
African	☐	Other ethnic group	☐		
Other black background	☐				

Why Record Pharmacotherapy?

So that we can know which pharmacotherapies are most commonly used and which are the most effective in helping people stop smoking. It is also an important indicator of data quality and we request that you do record this and that it is not added as free text.

TYPE OF PHARMACOLOGICAL SUPPORT USED: *(please tick all relevant boxes. Use 1 or 2 to indicate consecutive use of more than one medication – e.g. Champix followed by NRT product)*					
NRT – Patch	☐	NRT – Gum	☐	None	☐
NRT – Lozenge	☐	NRT – Inhalator	☐	Zyban	☐
NRT – Microtab	☐	NRT – Spray	☐	Champix	☐

Why Record Carbon Monoxide Levels?

CO verification rates are an important marker of data quality, and should be carried out on all adult smokers to provide a pre-quit and post quit level. Recording carbon monoxide levels is an excellent way to motivate people during a quit attempt. The Government have requested that service achieve at least 85% CO recording for four week quitters. Please contact the service if you need support with your Carbon Monoxide Monitor.

Appendix B- Prescribing Guidance for Smoking Cessation Treatment Programmes

CAMBRIDGESHIRE & PETERBOROUGH STOP SMOKING SERVICE'S

Stop Smoking Pharmacological Products Guidance

This guidance is for use by
Cambridgeshire & Peterborough Stop Smoking Services, GP Practices, Pharmacies participating in the Community Pharmacy Stop Smoking Service and Cessation advisors who have received specialist training through the Cambridgeshire or Peterborough services (such as those based within the School Nursing teams - Cambridgeshire only)**.**

Purpose

The purpose of the Stop Smoking Pharmacological Products Guidance is to ensure consistency and cost effectiveness across Cambridgeshire and Peterborough in the approach taken to advising and supporting people who wish to stop smoking, improving the clinical and cost effectiveness of prescribed medicines and reducing medicines wastage.

Summary

Helping an individual to stop smoking requires understanding their lifestyle and personal preferences. It is therefore important to provide a choice of interventions, accompanied by supporting information regarding relative chances of success, possible side effects and ease of access.

Clients will be seen initially at their GP surgery (if there is a level 2 stop smoking advisor), Cambridgeshire or Peterborough Stop Smoking Services, the Community Pharmacy, through the school nursing team or community based level 2 smoking cessation advisor where they will be given behavioural support and advice regarding stopping smoking.

Clients should be assessed carefully with regard to their motivation to quit smoking using a nicotine dependence assessment tool and assessment of readiness to quit tool. If their level of motivation to quit is not sufficiently high then the client should be given appropriate information and advised to make a further appointment when they feel they may be ready to make a serious attempt to quit or should be followed up by a stop smoking advisor.

If the individual is ready to make a serious attempt to quit smoking then the following approach should be taken:

A full discussion should take place and should include information on the standard treatment 12 week programme, setting a quit date and medication options and ongoing support. This may include the use of pharmacotherapies that are available to the client to help them quit smoking using the protocols below.

Pharmacotherapy options

CAUTION:
Clinicians should be aware of the possible emergence of significant depressive symptoms in patients undergoing a stop smoking attempt with or without pharmacotherapy, and should advise patients accordingly.
The MHRA has recommended that varenicline should be discontinued immediately if agitation, depressed mood, suicidal thoughts/behaviour or other changes in behaviour are observed.

If the decision is taken that pharmacotherapy is necessary, then the initial treatment option should be chosen by the patient based on information provided by the stop smoking advisor through their assessments and consultations. This should consist of a product that meets the needs and lifestyle of the client in order to increase adherence to the programme and to increase long term success. This should be used in conjunction with formal counselling, advice and support from the stop smoking advisor.

All smokers should be given the optimum chance of success in any given quit attempt. Licenced pharmacotherapy, currently nicotine replacement therapy (NRT), Champix (varenicline) and Zyban (bupropion) should all be made widely available in combination with intensive behavioural support as equal first-line treatment (where clinically appropriate)[1]

First Line Therapy choices:

a) NRT product + Behavioural counselling

b) A combination of two NRT products + Behavioural counselling (e.g. a baseline patch the strength of which is suitable to the level of cigarette usage and an additional product such as lozenges, gum, inhalator, spray, thins or microtabs for occasional use).

c) Varenicline (Champix) + Behavioural counselling

d) Bupropion (Zyban) + Behavioural counselling

The following should be noted carefully:

[1] http://www.ncsct.co.uk/usr/pub/LSSS_service_delivery_guidance.pdf

A combination of NRT products (combination therapy) has been shown to have an advantage over using just one product. It is also considered cost-effective. Stop smoking service providers should therefore routinely offer clients combination therapy whenever appropriate.

Combinations of NRT with Varenicline (Champix®) or Bupropion (Zyban®) should **NOT** be offered. There is no evidence available for the use of NRT in combination with Varenicline or Bupropion Hydrochloride.

Varenicline and Bupropion are only available on prescription and it is at the discretion of the individual prescriber whether a request to prescribe is agreed to.

Combining behavioural support with pharmacotherapy increases a smoker's chances of successfully quitting by up to 35%[2]

Stop Smoking medications approved by NICE[3] are NRT, Varenicline (Champix®) and Bupropion (Zyban®).

The effectiveness of pharmacotherapy, using individual behavioural support gives four-week quit rates of[4]:

- No medication – 22%
- Mono NRT – 37%
- Combination NRT – 50%
- Bupropion (Zyban®)– 39%
- Varenicline (Champix®) – 52%

Supporting information regarding the relative effectiveness of each intervention type should be given. The Department of Health have smoking cessation booklets free of charge, patient information leaflets through the website electronic medicines compendium www.medicines.org.uk.

The Cambridgeshire and Peterborough Stop Smoking Service Healthy You (formerly CAMQUIT) also have patient information leaflets available via their website: www.healthyyou.org.uk or via **0333 005 0093**.

All pharmacotherapies should remain available for the period recommended in the product SPC and access to supplies should be made simple and easy.

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[2] Stead LF, Perera R, Bullen C, Mant D and Lancaster T (2008) 'Nicotine replacement therapy for smoking cessation.'
Cochrane Database of Systematic Reviews

[3] https://www.nice.org.uk/guidance/PH10/chapter/4-Recommendations#pharmocotherapies-and-other-treatment

[4] http://www.ncsct.co.uk/usr/pub/LSSS_service_delivery_guidance.pdf

Prescribing duration

Prescriptions for supplies of NRT, Varenicline (Champix®) or Bupropion (Zyban®) should not exceed a maximum of 4 weeks. It is recommended that prescription requests are processed every one-two weeks for the course of treatment (up to twelve weeks from the quit date). This duration allows for re-assessment of product suitability & correct use and quit attempt progress up to the 4 week monitoring and reporting stage. It is recommended that all prescriptions for smoking cessation medications are recorded as 'acute' and are ***not*** added to the clients repeat prescription list.

Pharmacotherapies should be available for more than one treatment episode. **There is no definitive period between quit attempts**, and provided the client remains motivated they should be given a new course of treatment in line with a new treatment episode. This includes intervention with Prescription Only Medications such as Varenicline (Champix®) or Bupropion (Zyban®).

If a client relapses and does not wish to begin a new treatment episode, no further prescriptions should be given until such time they are motivated to quit again.

Smoking cessation specification extract

<table>
<tr><th></th><th colspan="3">SPECIFICATION</th></tr>
<tr><td>1a</td><td colspan="3">Initial assessment- Brief advice (5 minutes)
Ask and record smoking status
Assessment of person's readiness to make quit attempt and provide referral to cessation service</td></tr>
<tr><td>2a</td><td colspan="3">Initial consultation (15-30 minutes)
Set quit date
Supply 1-2 weeks NRT/Zyban/Champix
Complete monitoring form
Carbon monoxide (CO) test validation
Complete the patient records notes</td></tr>
<tr><td>3a</td><td>Follow up (10 minutes)
Re-assess cessation progress and smoking status
Supply 1-2 weeks NRT/Zyban/Champix
Complete monitoring form
Carbon monoxide (CO) test validation
Complete the patient records notes</td><td>3b</td><td>Follow up (10 minutes)
Re-assess cessation progress and smoking status
Supply 2 weeks NRT/Zyban/Champix
Complete monitoring form
Carbon monoxide (CO) test validation
Complete the patient records notes</td></tr>
<tr><td>4a</td><td>4 week follow up (10 minutes)
If client has QUIT</td><td>4b</td><td>If client has NOT QUIT</td></tr>
</table>

	5-8 weeks after ***QUIT*** date (5-10 minutes) ▪ Re-assess cessation progress and smoking status ▪ **Supply 4 weeks NRT/Zyban/Champix** ▪ Complete monitoring form ▪ Carbon monoxide (CO) test validation ▪ Complete the patient records notes		5-8 weeks after QUIT date (5-10 minutes) ▪ Re-assessment motivation to make a quit attempt ▪ Consider re- setting the quit date and beginning the programme again at stage 1
5	9-12 weeks after ***QUIT*** date (5-10 minutes) ▪ Further **supply of NRT for 4 weeks** if appropriate CO test (optional) ▪ Complete patient notes		

Dispensing procedure

FP10 fees should be collected for supply of medication if patient exemption does not apply.

GP practice based smoking cessation service

1. GP Practice based stop smoking services should ensure they have an established practice procedure for issuing stop smoking pharmacotherapy's in line with Cambridgeshire's & Peterborough's guidance.

Stop Smoking Service Advisors who are not based within a GP surgery - NRT

1. Should complete a prescription request form for NRT and send to the clients GP surgery. No patient appointment is required unless the practice procedure states otherwise or the client presents contraindications to NRT.
2. Alternatively a nicotine replacement therapy voucher can also be given to the client to be processed by the local Pharmacist as part of the Pharmacy voucher scheme contract

Stop Smoking Service Advisors who are not based within a GP surgery - Zyban or Champix

1. Clients who are a medically suitable candidate for Varenicline or Bupropion should be referred for an appointment with their GP with their completed Healthy You / CAMQUIT Champix or Zyban prescription request form.

Community based advisors who are not commissioned by Peterborough City Council, Cambridgeshire Community Services or Cambridgeshire County Council

1. Should contact their link advisor within the specialist services once their client is ready to access treatment medications. The link advisor will be responsible for supporting the advisor and client with following the necessary prescribing procedures.

Pharmacy based stop smoking service

1. Should ensure that there is an established procedure for issuing stop smoking NRT pharmacotherapy choices and that it is the Pharmacists responsibility to issue the medication in line with the Cambridgeshire and Peterborough's Stop Smoking Service guidance.
2. Clients who wish to use Varenicline or Bupropion should be referred for an appointment with their GP but can continue to use the pharmacy service for behavioural support alone.

CCS School Nurse smoking cessation advisors

1. Should complete a prescription request form for NRT and send to the clients GP surgery. No patient appointment is required unless the practice procedure states otherwise or the client presents contraindications to NRT.
2. Alternatively a nicotine replacement therapy voucher can also be given to the client to be processed by the local Pharmacist as part of the Pharmacy voucher scheme contract.

Stopping treatment

All products (NRT, Champix and Zyban) should be used as indicated in the SPC and if the client has successfully quit at the four week stage they should continue to use the product for the full treatment course as indicated in the SPC (usually up to12 weeks). At the end of the treatment course the medication use should cease and the patient should be informed about self-care, if they require NRT in the future this can be purchased from local pharmacies and supermarkets.
All products should be used as part of a smoking cessation standard treatment programme along with behavioural support from an approved smoking cessation advisor.
Treatment should be stopped immediately and the clients quit attempt reassessed if:

- The client reports a suspected adverse reaction after authorisation of the medicinal product. The risk/benefit balance of the product should be monitored. Healthcare professionals are asked to report any suspected adverse reaction via the Yellow Card Scheme, www.mhra/gov.uk/yellowcard.
- The client is recorded as 'not quit' or 'lost to follow up' at the four week stage. Continued treatment should cease until a full re-assessment and new quit date has been established.
- The client under 18 years old is not deemed 'Fraser competent' to use the treatment appropriately.
- The client develops a new medical condition/illness which is not associated with nicotine withdrawal. The GP/Health professional should then make assess the risk/benefit of continued use of the medication.
- The treatment choice is not suitable for the client and a new product is issued.
- The client chooses to use an electronic cigarette to stop smoking.

Smoking Cessation in Pregnancy & Breastfeeding

Special considerations
Smoking during pregnancy causes serious complications both during the pregnancy and afterwards and is a major cause of infant mortality and Sudden Infant Death Syndrome.
The use of nicotine replacement therapy in pregnancy is preferable to the continuation of smoking, but should be used only if smoking cessation without nicotine replacement fails. Advice regarding the risks and benefits of using NRT in pregnancy should be given by a trained adviser who has attended the specialist smoking and pregnancy training.

Access to NRT during pregnancy should be available on the recommendation of an adviser who has completed the Smoking in Pregnancy training. Pregnant smokers with an obstetric/medical condition and/or taking regular medication should be seen by a health professional or referred to the specialist service.

Medication choices

- Intermittent products are preferable to patches but avoid liquorice-flavoured nicotine products. Patches should be made available to women who cannot tolerate oral NRT products, if the patient is experiencing pregnancy-related nausea and vomiting. If patches are used, they should be removed before bed.

- Combination Therapy can be made available for heavily dependent smokers when considered to be clinically appropriate.

- Breast feeding is not a contraindication to the use of NRT. The use of intermittent NRT products is preferred in order to allow maximum time between NRT use and breastfeeding.

- Varenicline and Bupropion Hydrochloride are contraindicated for pregnant and breast feeding women.

Prescribing procedure

GP practice based smoking cessation service

1. GP Practice based stop smoking services should ensure they have an established practice procedure for issuing stop smoking pharmacotherapy's in line with Cambridgeshire's & Peterborough's guidance.

Stop Smoking Service Advisors who are not based within a GP surgery who want to use NRT

1. Should complete a prescription request form for NRT and send to the clients GP surgery. No patient appointment is required unless the practice procedure states otherwise or the client presents contraindications to NRT.

2. Alternatively, a nicotine replacement therapy voucher can also be given to the client to be processed by the local Pharmacist as part of the Pharmacy voucher scheme contract, but it is the responsibility of the Pharmacist to provide the intervention and issue the NRT. Under the terms of the Public Health Contract all pharmacists in Peterborough who have registered to deliver smoking cessation interventions ideally must have had specialist smoking and pregnancy training prior to providing smoking cessation interventions for pregnant women.
   The Pharmacy should ensure that there is an established procedure for issuing stop smoking NRT pharmacotherapy choices and that it is the Pharmacists responsibility to issue the medication in line with the Cambridgeshire and Peterborough's Stop Smoking Service guidance.

   The GP or clinician overseeing the pregnancy should be informed.

Pharmacy based stop smoking service

1. Pregnant women can be provided with NRT directly through a community pharmacy without consultation with their GP but it is the responsibility of the Pharmacist to provide the intervention and issue the NRT. Under the terms of the Public Health Contract all pharmacists in Cambridgeshire and Peterborough who have registered to deliver smoking cessation interventions ideally must have had Healthy You (formerly CAMQUIT) specialist smoking and pregnancy training prior to providing smoking cessation interventions for pregnant women.
   The Pharmacy should ensure that there is an established procedure for issuing stop smoking NRT pharmacotherapy choices and that it is the Pharmacists responsibility to issue the medication in line with the Cambridgeshire and Peterborough's Stop Smoking Service guidance.

   The GP or clinician overseeing the pregnancy should be informed.

Smoking Cessation for clients with Mental Health illness

Due to higher levels of nicotine dependence, the amount of NRT required by smokers with mental illness is likely to be higher than the rest of the population. Licensed nicotine products contain lower levels of nicotine than tobacco and the way these products deliver nicotine makes them less addictive than smoking. NRT does not interact with any mental health medicines or affect the blood levels of medication, ***though smoking and stopping smoking can affect such levels.***
It is safe to give NRT to smokers with a mental illness, even those who receive high doses of psychotropic medication and those who continue to smoke.
In a minority of cases, smoking cessation, with or without pharmacotherapy, is associated with an
exacerbation of depression. Stop smoking practitioners should be aware of the possible emergence

of depression in clients undertaking a quit attempt.

Effect of smoking cessation on medication blood levels

Tobacco smoke speeds up the metabolism of some antipsychotic medications, as well as some antidepressants and benzodiazepines, by inducing certain liver enzymes (CYP4501A2 isoenzyme). This effect is not caused by nicotine but is secondary to the polycyclic aromatic hydrocarbons from the tar in tobacco smoke. A consequence of speeding up the metabolism of some medicines is that smokers need higher doses of some psychotropic medicines compared to non-smokers. Blood levels of medication will be affected by many things such as age, gender and how well they adhere to their prescribed treatment. Stopping smoking can result in an increase in blood levels of some medicines (see chart below) these are likely to increase within seven days of quitting. Because this could potentially led to toxicity, doses of affected psychotropic medicines **may need to be reduced by 25–50% once someone stops smoking.**

Blood levels, clinical symptoms and any changes in the frequency and severity of side effects all need to be closely monitored when cigarette consumption is reduced or stopped, but also for a few weeks after patients are discharged, as they may start smoking again. Blood levels of clozapine may still be altered for up to six months after stopping smoking.

Therefore, dose reduction needs to be considered if a patient stops smoking.
This NHS Specialist Pharmacy Service Medicines Q&A (Appendix 2) summarises those drug interactions with cigarette smoking that are considered to be most clinically important**.**

Young People

Special considerations

- NRT is licensed for use in young people aged 12 and above but medical advice should be obtained if it is necessary to use beyond 12 weeks or if the client has medical conditions which are listed as contraindications for NRT.
- For people aged 13-16 year olds please assess and complete a Fraser competency form so that young people under the age of 16 can consent to medical treatment if they have sufficient maturity and judgement to enable them fully to understand what is proposed.
- For anyone under the age of 12 years please seek the child's parental consent or refer the smoker back to their GP or Pharmacist.
- Dispensing procedure is the same as Dispensing procedures on page 4.
- Zyban and Champix are contraindicated for under 18 year olds.

Electronic Cigarettes

Electronic cigarettes are not currently licensed for smoking cessation and as with other unlicensed nicotine
containing products, the stop smoking service cannot provide or prescribe them. However clients who register with the stop smoking service should be given information on licensed products such as Nicotine replacement therapy, Zyban and Champix and also the non licensed products such as electronic cigarette so that they can make an informed decision about their stop smoking plan.
In 2015 Public Health England said *'E-cigarettes are significantly less harmful to health than tobacco and have the potential to help smokers quit smoking'.*

For further information about electronic cigarettes

1) http://www.ncsct.co.uk/usr/pub/e-cigarette_briefing.pdf
2) https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/680964/Evidence_review_of_e-cigarettes_and_heated_tobacco_products_2018.pdf
3) https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/457102/Ecigarettes_an_evidence_update_A_report_commissioned_by_Public_Health_England_FINAL.pdf

Background information on the local smoking cessation services

In Peterborough the Public Health Delivery team transferred from NHS Peterborough to Peterborough City Council in October 2012 under the People and Communities Directorate where the smoking services was delivered in conjunction with other public health priorities including, lifestyle programmes, health checks and health improvement accredited training. On April 1 2017, the Public Health stop smoking team was outsourced to Solutions4Health who were commissioned to deliver an integrated lifestyle service within Peterborough. On 1st October 2020 Public Health commissioned Everyone Health to deliver the integrated lifestyle services across Cambridgeshire and Peterborough, including the stop smoking services. These services are now being delivered under the Healthy You branding.

The Public Health Directorate transferred from NHS Cambridgeshire to Cambridgeshire County Council in April 2013 as a result of the Health and Social Act 2012.

The Public Health Directorate manages contracts with health and social care providers to deliver smoking cessation services and this policy aims to provide good practice guidance when prescribing smoking cessation treatment medications.

Local stop smoking services follow The National Centre for Smoking Cessation and Training (NCSCT) Standard Treatment Programme which sets out a standard method for supporting an individual to stop smoking involving an initial assessment and continued motivational interviewing sessions whereby the advisor forms an understanding about the clients' health, lifestyle, circumstances and preferences. It is therefore important to provide a choice of interventions, accompanied by supporting

information regarding relative chances of success, possible side effects and ease of access so that the client can make an informed choice about their quit attempt.

APPENDIX B.1

PHARMACOTHERAPIES AVAILABLE

Please refer to BNF or each product SPC for full prescribing information including contraindications cautions and drug interactions:
https://bnf.nice.org.uk/
http://emc.medicines.org.uk

Nicotine Replacement Therapy (NRT)
NRT can be prescribed as single or combination therapy

Patches
Nicorette Invisi (16 hour) 25mg, 15mg, 10mg
Nicotinell TTS(24 hour) 21mg, 14mg, 7mg
Niquitin & Niquitin Clear (24 hour) 21mg, 14mg, 7mg

Lozenges
Nicorette Cools 2mg, 4mg,
Nicotinell 1mg, 2mg
Niquitin CQ 2mg, 4mg
Niquitin Minis 4mg, 1.5mg

Nicorette Microtabs
Nicorette 2mg

Chewing Gum
Nicorette Gum 2mg, 4mg, 6mg
Nicotinell Gum 2mg, 4mg
Niquitin CQ Gum 2mg, 4mg

Inhalator
Nicorette 15mg

Nasal Spray
Nicorette 10ml (0.5mg per dose)

Mouth Spray
Nicorette Quickmist 1mg per spray

Any new NRT product which is licensed as GSL

Champix (Varenicline®)

Starter Pack: 0.5mg & 1mg oral tablets
Maintenance: 1mg tablets, 0.5mg oral tablets

Dose: start 1–2 weeks before target stop date.
Initially 500 micrograms once daily for 3 days,
Increased to 500 micrograms twice daily for 4 days,
Then 1 mg twice daily for 11 weeks (reduce to 500 micrograms twice daily if not tolerated);

Contraindications:
Pregnancy or breastfeeding – not licensed
Patients under 18 years of age – not licensed
End stage renal disease – not licensed

Cautions:

- Patients with a history of psychiatric illness should be monitored closely when taking Champix
- Patients should be advised to discontinue treatment and seek medical advice if they develop depressed mood or changes in behaviour, agitation or suicidal thoughts
- Patients with renal disease can take a reduced dose

The Medicines and Healthcare products Regulatory Authority (MHRA) issues the following advice

Patients and their family or caregivers should be made aware of the possibility that trying to stop smoking might cause symptoms of depression

- Patients who are taking varenicline who develop suicidal thoughts or behaviour should stop their treatment and contact their doctor immediately
- Varenicline should be discontinued immediately if agitation, depressed mood, or changes in behaviour are observed that are of concern for the doctor, patient, family, or caregiver
- Patients with serious psychiatric illness did not participate in the premarketing studies of varenicline, and the safety and efficacy of varenicline in such patients has not been established. Care should be taken when prescribing varenicline to patients who have a history of psychiatric illness.

Varenicline and Cardiovascular events

- Smoking is a major risk factor for cardiovascular disease;
- A recent review indicated that it may be worth investigating the link between cardiovascular events and Varenicline further, but currently there is little reason to avoid this medication on these grounds. This view is in line with European

Medicines Agency that confirmed a positive benefit-risk balance Varenicline and concluded that its benefits as a smoking cessation medicine outweigh any slight increase in cardiovascular events. People with Cardiovascular disease who taken Varenicline should report to their doctor any new or worsening symptoms of cardiovascular disease. For example: shortness of breath or trouble breathing; new or worsening chest pain; new or worse pain in the legs when walking.

Interactions:

- Champix has no clinically significant drug interactions.

GP Prescribing protocol - Varenicline for Smoking Cessation

Do not use Varenicline with those who are:
- Under 18 years old
- Pregnant and/or breastfeeding
- End stage renal disease

Clients using the local smoking cessation services and wishing to use Varenicline will be referred to their own GP with an accompanying letter/prescription request form. The GP will make a clinical assessment of the client to establish their suitability for Varenicline. It remains the clinical decision of each individual GP as to whether a prescription for Varenicline is issued. **Decision to prescribe?**

Caution: do any of the following apply?
- Client has epilepsy
- Client has a psychiatric illness
- Client has heart disease
- Client has diabetes
- Client has COPD
- Client has renal disease

Yes

Is the condition stable and regularly monitored?

No

Refer client back to the smoking cessation service/advisor for further advice and assessment for NRT to be considered as part of the treatment programme.

Yes

No

A quit date is set for two weeks time and a follow up appointment should be arranged with the stop smoking advisor.

Prescribe Varenicline for a maximum 12 week course at 2 weekly intervals in conjunction with behavioural support and regular monitoring sessions with a smoking cessation advisor.

≥ 30 ml/min estimated creatinine clearance (no renal impairment, mild and moderate renal impairment)

Day 1 – 3	0.5mg	Once daily
Day 4 – 7	0.5mg	Twice daily (8 hours between each dose)
Day 8 to end of treatment (12 wks)	1.0mg	Twice daily (8 hours between each dose)

Monitor progress and reassess for any adverse events every 2 -4 weeks for the 12 week treatment duration

Please note: If full dose cannot be tolerated Lower dose to 0.5mg b.d. either temporarily or permanently depending on response.

Please note: Ensure prescription is 'Acute' only and consider dose tapering on completion of 12-week course

Reviewed Feb 2018

Zyban (Bupropion®)

150mg tablets

Dose:
Start 1–2 weeks before target stop date, initially 150 mg daily for 6 days
then 150 mg twice daily (max. single dose 150 mg, max. daily dose 300 mg;
minimum 8 hours between doses);

Period of treatment 7–9 weeks; discontinue if abstinence not achieved at 7 weeks;
Consider max. 150 mg daily in patients with risk factors for seizures;

ELDERLY max. 150 mg daily

Contraindications:

- History of seizures or eating disorders, bipolar disorder, CNS tumour, patients experiencing abrupt withdrawal of alcohol or benzodiazepines, factors which lower the threshold for seizure such as antimalarials and antidepressants etc., sedating antihistamines, diabetes, severe hepatic cirrhosis
- Pregnancy or breastfeeding
- Patients under 18 years of age

Cautions:

- Mild to moderate renal impairment
- Diabetes
- Monitor BP before and during treatment, especially in patients with pre existing hypertension, monitor BP weekly
- History of psychiatric illness or head trauma
- Elderly maximum dose 150mg

Interactions:
In patients receiving medicinal products known to lower the seizure threshold, Zyban must only be used if there is a compelling clinical justification for which the potential medical benefit of smoking cessation outweighs the increased risk of seizure.
For full list of interactions check latest SPC[5]

[5] https://www.medicines.org.uk/emc/product/3827#INTERACTIONS

GP Prescribing Protocol- Bupropion Hydrochloride for Smoking Cessation

Clients using the local smoking cessation services and wishing to use Bupropion Hydrochloride will be referred to their own GP with an accompanying letter/prescription request form. The GP will make a clinical assessment of the client to establish their suitability for Bupropion Hydrochloride. It remains the clinical decision of each individual GP as to whether a prescription for Bupropion Hydrochloride is issued.

Decision to prescribe?

Do not use Bupropion Hydrochloride with those who are/ have:

- Under 18 years old
- Pregnant and/or breastfeeding
- A history of seizures, bipolar disorder or eating disorder
- A acute alcohol or benzodiazepine withdrawal
- Severe hepatic cirrhosis
- CNS tumour
- Heart disease
- Using Antidepressants and/or Antimalarials
- Sedating antihistamines

Refer client back to the smoking cessation service/advisor for further advice and assessment for NRT to be considered as part of the treatment programme.

Caution: do any of the following apply?

- Client has a history of psychiatric illness
- Client has heart disease
- Client has COPD
- Has mild to moderate renal impairment
- Diabetes
- Client has hepatic impairment and Diabetes

Yes

No

Is the condition stable and regularly monitored?

Yes

A quit date is set for two weeks time and a follow up appointment should be arranged with the stop smoking advisor.

Prescribe Bupropion Hydrochloride for a maximum 8 week course at 2-3 weekly intervals in conjunction with behavioural support and regular monitoring sessions (including mood and blood pressure weekly) with a smoking cessation advisor.

Day 1 – 6	150mg	Once daily
Day 7 to end of treatment (8 wks)	150mg	Twice daily (8 hours between each dose)

Monitor progress and reassess for any adverse events every 2 -4 weeks for the 8 week treatment duration

Please note: Ensure prescription is 'Acute' only and consider dose tapering on completion of 8 week course

Please note: If full dose cannot be tolerated lower dose to 150mg once daily. For the elderly the dose is 150mg once daily.

APPENDIX B.2

CLINICALLY SIGNIFICANT DRUG INTERACTIONS

The following criteria have been considered in grading clinical relevance of drug interactions:
High: Documented pharmacokinetic interaction with clinically important effects in a number of patients.
Moderate: Documented pharmacokinetic interaction with minor clinical effects, or isolated reports of clinically important effects.
Table. Clinically significant drug interactions with cigarette smoking.

Drug name	Nature of interaction	Clinical relevance	Action
Aminophylline Theophylline	Aminophylline is a stable mixture of theophylline and ethylenediamine. Theophylline and aminophylline are metabolised principally via CYP1A2, therefore clearance is increased in smokers. Heavy smokers (20-40 cigarettes per day) may need much higher doses than non-smokers, due to the shortened theophylline half-life and increased elimination rate	HIGH	When stopping smoking, a reduction in theophylline dose of up to 25-33% might be needed after one week. However, it may take several weeks for enzyme induction to dissipate. Monitor plasma theophylline concentrations and adjust theophylline dose accordingly. Advise the patient to seek help if they develop signs of theophylline toxicity such as vomiting, diarrhoea, palpitations, nausea or vomiting
Clozapine	Clozapine is metabolised principally via CYP1A2 therefore clearance is increased in smoker. Smoking reduces plasma levels of clozapine by up to 50% so smokers may need higher doses. Likewise, patients who stop smoking may experience a 50% increase in plasma level so will need dose reduction	HIGH	Blood levels of clozapine should be measured before stopping or restarting smoking. On stopping smoking, reduce dose gradually over a week until around 75% of original dose reached (i.e. reduce by 25%). Repeat plasma level one week after stopping smoking. Anticipate further dose reductions If re-starting smoking take a plasma level before re-starting. Increase dose to previous smoking dose over one week. Repeat plasma level
Olanzapine	Olanzapine is metabolised principally via CYP1A2 and clearance is increased in smokers. Serum olanzapine levels are reduced in smokers compared with nonsmokers; smokers may need higher doses.	HIGH	On stopping smoking, reduce dose by 25%. Consider further dose reductions. Be alert for increased adverse effects of olanzapine such as dizziness, sedation, and hypotension. If adverse effects occur, reduce the dose as necessary
Erlotinib	Erlotinib is metabolised primarily by CYP3A4 and to a lesser extent CYP1A2. Smokers have an increased rate of erlotinib clearance leading to decreased drug exposure.	HIGH	Current smokers should be advised to stop smoking prior to starting treatment. When given to patients who smoke, increase the daily dose in 50mg increments at 2-week intervals, up to a maximum dose of 300mg. If the patient stops smoking the dose should be immediately reduced to the initial starting dose
Riociguat	Riociguat is metabolised by CYP1A1, CYP3A4, CYP3A5 and CYP2J2 . In cigarette smoking, riociguat exposure is reduced by 50-60%	HIGH	Current smokers should be advised to stop smoking prior to starting treatment. A dose increase to the maximum of 2.5mg three times a day may be needed in patients who are smoking or start smoking during treatment. If the patient stops smoking during treatment the dose may need to be reduced

Warfarin	Warfarin is partly metabolised via CYP1A2.	MODERATE	Monitor smoking status during warfarin therapy. If a patient taking warfarin changes their smoking status this may increase their INR. In such cases, monitor INR more closely and adjust dose as needed . Advise patients to tell the healthcare professional managing their anticoagulant control that they are changing their smoking status
Chlorpromazine	Chlorpromazine is extensively metabolised in the liver. Smokers have lower serum levels of chlorpromazine compared with nonsmokers.	MODERATE	Monitor patient closely if they plan to abruptly stop smoking and consider a dose reduction. Advise patients who smoke or who start to smoke to be alert for increased adverse effects of chlorpromazine (e.g. dizziness, sedation, nausea). If adverse effects occur, reduce the dose as necessary
Methadone	Methadone is extensively metabolised in the liver by CYP isoenzymes including CYP1A2	MODERATE	Monitor patient closely if they plan to abruptly stop smoking. Advise patients who plan to abruptly stop smoking to be alert for signs of opioid toxicity. Reduce methadone dose accordingly

Summary: Most interactions between drugs and smoking are not clinically significant. • Healthcare professionals giving smoking cessation advice should be aware of a small number of medicines, in particular aminophylline, theophylline, clozapine, olanzapine, erlotinib and riociguat, which may require dose adjustment or increased monitoring when smoking status is altered. • Patients taking narrow-therapeutic-index drugs should be monitored closely when any lifestyle modification is made.

Limitations: This Q&A does not include drugs which have a low risk, theoretical interaction without documented cases and/or drugs metabolised partly by CYP1A2 and with a wide therapeutic range. • It does not consider interactions with pharmacological agents used for smoking cessation (e.g. bupropion, varenicline), or pharmacodynamics interactions (e.g. effects of smoking on blood pressure). It does not include potential interactions of e-cigarettes.

Reference: https://www.sps.nhs.uk/wp-content/uploads/2017/11/UKMI_QA_Drug-interactions-with-smoking-cigarettes_update_Nov-2017.pdf

GLOSSARY

LEVELS OF SERVICE (NICE)
Level 1: Brief Interventions
Level 2: Intensive 1:1 support and advice
Level 3: Group interventions
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