



Working in partnership

Local Commissioned Service Specification for Camden and Islington Community **Pharmacy Smoking Cessation (NRT) Services**

April 2015 – March 2016

A Local Commissioned Service (LCS) between Camden & Islington Public Health and Community Pharmacies in Camden & Islington prepared by Camden & Islington Public Health, January 2015

1. **Introduction and Background**

Smoking remains the leading cause of preventable premature death, disease, disability and health inequalities in this country. More people die of smoking every year than obesity, alcohol, suicide, traffic accidents, drug abuse and HIV combined.

Local data

Islington	Camden
 No. of smokers: 36,457 	 No. of smokers: 36,743
 Annuals deaths from smoking: 206 	 Annual deaths from smoking: 229
 Prevalence 24%, (GP dataset) 	Prevalence: 20% (GP dataset)

The Camden and Islington Public Health Department has commissioned Whittington Health to deliver the Community Stop Smoking Service in Islington and Solutions4Health in Camden. Responsibility for the local training of Advisers, supporting and quality assuring cessation services in primary care, data recording and reporting of all cessation activity, and achieving the annual 4week quit target lies with these organisations.

Contact details:

Whittington Health	Solutions4Health
Islington Community	SmokefreeLife Camden
Stop Smoking Service	
0800 093 9030	0800 1070401 / 020 3317 3861
www.smokfeeeislington.nhs.uk	www.smokefreelifecamden.co.uk
stop-smoking-	info@smokefreelifecamden.co.uk
islington.whitthealth@nhs.net	

2. Eligibility and exclusions

General

The service must be supervised by a qualified pharmacist.¹

The lead pharmacist will provide assurance through self-declaration that they and their staff, understand the legal, regulatory and good practice aspects of stop smoking support, clinical standards and expectations. They must also be aware and make use of local guidance and resources, and work closely with the Community-based service which is responsible for ensuring standards for delivery are met and reporting performance from all service providers in the borough.

The pharmacy contractor is responsible for ensuring that any support staff are aware of the key elements of the service.

The setting for the service should be a high street location or popular location with sufficient footfall to maximise access to the service, or be located within the vicinity of a general practice in Camden or Islington, so that registered patients may easily redeem prescriptions for smoking pharmacotherapy. The Provider must also have a private room for consultations available with a network connection for the optimal use of cessation activity and recording software.

Commissioning

Pharmacies delivering this LCS will be expected to achieve a minimum performance of the following over the length of this agreement:

- Quit rate ≥ 35%
- Lost to Follow up² ≤20%
- CO recording ≥85%
- One locally trained Level 2 Adviser confirmed by June 30th in each year of this agreement or
- Evidence that all staff delivering the LCS have completed Level 2 training with the National Centre for Smoking Cessation Training (NCSCT)³ by March 31st in the year preceding the start of this Locally Commissioned Service.
- New advisors complete the NCSCT online training module and receive local training specific to aspects of delivery.

Pharmacies not commissioned or decommissioned for the 2014-15 local commissioned service may be commissioned in 2015/16 on invitation provided they are able to:

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¹A Pharmacist must be responsible for supervising the clinical delivery of this local service. The pharmacist and pharmacy must be registered with the General Pharmaceutical Council (GPhC). The Pharmacist must receive training and updates in the clinical and operational aspects of the service as part of their continuing professional development

²The "Lost to Follow Up" classification is applied to patients treated for whom no treatment outcome is recorded at the 25-42 day outcome measure

³ http://www.ncsct.co.uk/pub_training.php

- Demonstrate the strategies that will be in place to address how they will meet the minimum performance criteria.
- Provide evidence of continuing professional development i.e. Level 2/NCSCT accredited personnel to meet the delivery standards specified.
- Provide confirmation of location and private space for consultations with a network connection
- Demonstrate how they will meet the standards required within this service specification.

Pharmacies new to Camden and Islington or those that have not delivered the local commissioned service in the previous 2 years may be eligible to deliver the NRT local commissioned service and should contact the commissioner to express their interest if they are able to meet the minimum performance criteria. Advisors in these pharmacies will be advised to complete NCSCT Level 2 training with at least one member of staff completing the local update training as a minimum requirement.

Smokers

Any smoker aged 13 and over that lives, works or studies in Camden or Islington and/or is registered with an Islington or Camden GP is eligible to receive the smoking NRT local commissioned service from a community pharmacy. Any smoker registering for treatment may only be treated in their respective (first contact) borough i.e. a smoker registering in Camden cannot complete their treatment in Islington and vice versa.

Smokers using Electronic cigarettes

It is expected that guidance on whether electronic cigarettes containing nicotine become licensed products will be issued in 2016 by the Medical Healthcare products Regulatory Agency. Until then Providers delivering the smoking LCS may not recommend these products. However if a smoker is assessed as motivated to quit, seeking cessation support and it is known that they are using electronic cigarettes as part of a cessation attempt, they are eligible for treatment in line with this service specification.

Exclusions

Not motivated to quit. Any smoker requesting stop smoking support should have their motivation and best route to quit assessed *before* completing the service registration process. Enquirers should be made aware of service setting options (i.e. group, drop in, GP or community-based clinics) and referred as part of offering patient choice as appropriate.

Young smokers <13. These smokers should be referred to the Community Service for behavioural support to stop smoking.

Smokers with previous quit attempts. Smokers that report ≥4 quit attempts in the preceding year may require additional behavioural support and should be referred to the Community Service.

3. Service Specification

General

The service must be supervised by a qualified pharmacist. 4

The lead pharmacist will provide assurance through self-declaration that they and their staff, understand the legal, regulatory and good practice aspects of stop smoking support, clinical standards and expectations. They must also be aware and make use of local guidance and resources, and work closely with the Community-based service which is responsible for ensuring standards for delivery are met and reporting performance from all service providers in the borough.

The pharmacy contractor is responsible for ensuring that any support staff are aware of the key elements of the service.

Providers may offer evidence-based cessation support and advice to any smoker motivated to quit who is aged >13 years and lives, works or studies in Camden or Islington for a period of up to twelve weeks with their smoking status recorded 25 – 42 (and 84) days after their set quit date, as detailed in:

- NCSCT service and monitoring guidance:
 http://www.ncsct.co.uk/publication_service_and_delivery_guidance_2014.php
- NICE Guidance for Smoking Cessation: http://guidance.nice.org.uk/PH1
- NCSCT Clinical Tools: http://www.ncsct.co.uk/pub_clinical-tools.php

Nominate the person(s) responsible for the delivery of the local service⁵ ensuring their completion of Level 2 training to be accredited as a Level 2 Adviser in Islington or Camden, and ensuring attendance at at least one subsequent Level 2 Update training on an annual basis for as long as the local service is available from the pharmacy. The Commissioner and Community Service should be notified if the responsible Adviser changes role or no longer works for the pharmacy during the term of this agreement.

Be responsible for the care and maintenance of a CO monitor loaned from the Community based service for the duration of the local commissioned service. The pharmacy must make the monitor available to the Community service for calibration at least once each year, or more frequently as advised by the Community Service. The monitor must be returned to the Community Service if the service is terminated with no intention of future participation in the local service. If the monitor develops a fault during the loan period or is faulty, it will be replaced with no charge by the Community Stop Smoking Service. If the monitor is damaged or lost while on loan, the Community Service will invoice the pharmacy directly for the cost of the repair or the full cost of a replacement monitor if the monitor is beyond repair.

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⁴A Pharmacist must be responsible for supervising the clinical delivery of this local service. The pharmacist and pharmacy must be registered with the General Pharmaceutical Council (GPhC). The Pharmacist must receive training and updates in the clinical and operational aspects of the service as part of their continuing professional development

This must be the pharmacist responsible for supervising the service delivered under this agreement

Ensure that consent to treatment and non-identifiable data being transferred to the Health and Social Care Information Centre (HSCIC), Public Health and Community based service is discussed with and obtained from patients and indicated on the data recording software provided. Consent to share details of treatment for smokers that are registered with an Islington or Camden GP should also be sought, but does not exclude the smoker from treatment if not obtained. The data collected and its use should be explained using a copy of "Information Sheet for Patients" (a laminated copy of the Patient Information Sheet will be provided to each Pharmacy). It is the responsibility of the Pharmacy to maintain the laminated Information Sheet for use in consultations.

Refer clients to cessation services outside the Pharmacy e.g. Community-based clinics, General Practice, or clinics targeting specific communities or settings to meet the needs of the patient as appropriate.

All patients' treatment to be recorded and reported using the software provided by the commissioner or commissioners designated agent / representative.

Proactive weekly follow up of patients during the treatment period to reduce lost to follow up and increase quit rates.

Record socio-economic status at assessment and CO monitor readings at each appointment to achieve a reading of <9ppm at 4 weeks (25-42 and 84 days) post quit date.

For further treatment (post 42 days) or relapse prevention, patients should be referred to the Community Stop Smoking Service T: 0800 1070401 / 020 3317 3861 (Camden) or T:0800 093 9030 (Islington).

Fully complete (electronic) cessation activity reports using the supplied software, actively closing treatment outcomes to qualify for incentive payments.

During 2015-16 work towards delivering a quality service to achieve:

- An overall quit rate of at least 35%
- Lost to follow up rates ≤20%
- A CO verification rate ≥85%
- 100% Socio-economic status recording

Provide care to meet the requirements of this local service and ensure that the delivery model within the Level 2 Advisers' training is followed.

Participate in Commissioner, Local Pharmacy Committee or Community service-led evaluations or health promotion activities designed to achieve service improvement or motivate smokers to use commissioned services support to stop smoking as invited.

Maintain quality in data recording. Accurate activity recording will help pharmacies, the Community service and Public Health to assess activity, collate and analyse data and provide tailored feedback and support to pharmacies to maximise the quality and outcomes from smoking cessation interventions.

Recording and Reporting

Reimbursement for Activity and Pharmacotherapy dispensed is dependent on the accurate and timely completion of treatment records which capture the pharmacotherapy and behavioural support given to each smoker that registers for treatment at the pharmacy. Treatment records with outcomes i.e. those that have been closed within 25-42 or 84 days of the Quit date set by the client will be included in data submissions to the Health & Social Care Information Centre, performance reporting to Public Health and to assist with performance management and service improvement by the Community Service. To report outcomes for smokers treated at 84days, records must be marked complete and quit at 4 weeks to enable the "Follow Up" function to be enabled to record a further update at 12 weeks (see Appendix 5).

It is recommended that NRT dispensed within the last 7 days of the month is entered onto QuitManager by the last day of each month so that these payments are not rolled over to the following month. This will make it easier to check that payments have been received.

Letters of Recommendation/Vouchers (Islington only)

There is a 7-day cut off for LoR/vouchers to be entered onto QuitManager after they are dispensed to be processed for payment. If NRT is dispensed in the last 7 days of the month and not added to QuitManager for 7 days, it will be processed for payment the following month, rather than the month in which it was dispensed.

All vouchers issued contain the following information:

- 1. Advisor name
- 2. Advisor number
- Contact number
- 4. Voucher number
- 5. Issue date
- 6. Expiry date this is 7 days after the issue date*
- 7. Data entry deadline for pharmacy this is 14 days after the issue date*

No.6: The client must present the voucher to the pharmacy on or before the expiry date; if it presented past this date do not dispense.

No.7: This is the date by which time the voucher must be added onto Quitmanager; vouchers past this date will not qualify for payment

Please call Whittington Health T: 0800 093 9030 with any questions.

4. Payments

^{*} numbers 6 & 7 are new additions to the vouchers.

All activity qualifying for payment must be entered onto the Quitmanager by the end of each calendar month. Deadlines for performance reporting will be communicated separately to pharmacies via the Community Service at the start of each performance year. The software is configured so that all borough providers (other than those in GP settings) can see minimal patient treatment details, sufficient to determine if the patient is already receiving support elsewhere. Any smoker currently in treatment may not be issued with NRT, and pharmacies will not be reimbursed for dispensing medication in these cases. The onus is on the pharmacy provider to confirm smoker eligibility prior to dispensing any medication.

At registration the Adviser will be prompted to record whether the patient is exempt from prescription charges (£8.25, April 2015). Where a patient is <u>not</u> exempt from prescription charges pharmacists should charge the patient the prescription charge and process in line with any other prescription. The software has been configured to deduct the prescription charge for these patients from the overall payment due to the pharmacy.

To minimise the cost for smokers that pay prescription charges, the maximum supply during treatment should be at fortnightly intervals until week 4, after which 4 weeks supply may be issued (see NRT guidance, Appendix 3). Providers may supply at more frequent intervals post 4 weeks e.g. weekly) to help with increasing the likelihood of recording a verified quit outcome at 84 days (see Payment by Results below).

Pharmacies will be paid for smoking local service activity generated from 2 areas*:

1. The cost of NRT supplied (including VAT where applicable).

2. Payment by Results

Payments for the activities provided under the local commissioned service are as follows:

CO	Payment
Assessment, Registration & Quit date set	£10
Outcome: Lost to Follow Up or Still	£0
Smoking @ 25-42 days	
Outcome: Quit – self reported OR	£20
CO verified quit (in addition to the above	£40 per recorded reading
payment for a quit)	<9ppm
CO verified Quit (12 weeks/84 days post	£20
quit date)*	
Target communities:	
Routine & Manual occupation	£15 for any one of these
BME- i.e. Irish, Black African, Black	groups
Caribbean, Bangladeshi	
Pregnant women.	
Disease groups:	
Respiratory disease, diagnosed Mental	

Health	condition,	Diabetes,	Hyper-					
tension,	Lung Cance	r diagnosis s	≤5 years	£25	for	any	of	these
				disea	ses/co	ondition	าร	
Minimum amount payable per quitter			£30					
Maximum amount payable per quitter		£90 (£110 f	from Ap	oril 20)16)		
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^{*}this payment will be introduced from April 2015

Pharmacies are encouraged to develop their own processes for patient management to ensure that patients receive a full service, and that treatment outcomes are optimised. All treatment episodes must have an outcome recorded as this will generate the information from which payment schedules are generated and performance is assessed.

Islington payment processes

Payments due are processed by Public Health at the start of each calendar month based on the previous months outcomes (payment by results and closed records) and pharmacotherapy dispensed. These are then sent to Islington Clinical Commissioning Group for payment by the end of the same month.

Pharmacies are able to use the software to generate payment schedules of the amounts earned for accounting purposes.

Letters of Recommendation (LoRs) - Islington Only

LoRs will be issued by community-based Advisers trained to deliver the local service by the Islington Community Service or by Islington Community Stop Smoking Service staff. LoRs include a voucher, expiry date (7 working days from issue) within which the smoker must present to their chosen pharmacy, and a further 7 day processing expiry date by which the pharmacy must enter details onto the software provided to qualify for reimbursement.

Pharmacists will be reimbursed the cost of the product and receive a £1.00 handling fee per voucher when supplied via a Letter of Recommendation.

Camden Payment processes

From April 2015 payment schedules will be generated and collated by the Community Stop Smoking Service for Public Health to send on to Camden finance on a monthly basis. Invoices are not generated by each Pharmacy but calculated by the software behalf of each provider. Once invoices have been processed onto the Council's Ebuy System, invoices will then be authorised for payment by Public Health. Payment is then paid to the Pharmacy within 7-9 working days.

Camden Pharmacies will move onto the Quit Manager software during Q4 2014/15. Quit Manager will enable pharmacies to generate their own payments schedules for auditing as in Islington.

Payment queries: Camden and Islington

Pharmacies are advised to check that they have recorded activity and treatment accurately before querying payments that may be overdue or inaccurate. Payment queries should be sent to jasmin.suraya@islington.gov.uk Queries for Activity related to payments should be sent to: Camden: qm7help@smokefreelife.co.uk or Islington: stop-smoking-islington.whitthealth@nhs.net

6. Monitoring

The service delivery model requires the recording of a quit date, pharmacotherapy dispensed, and smoking status 25-42 (or 84 days) after the quit date which using the software supplied will help to manage. During 2015/16 the Quitmanager function to capture (verified) outcomes at 12 weeks will be enabled. Providers will be advised of the go-live date for this function and how to record associated activity once this function is available. Best practice advice is that the patient receives their intervention in the consultation room while the Adviser uses the software to support the intervention and recording process. The person responsible for recording activity must be conversant with using the software and / or attend training to become proficient as this will ensure accurate clinical recording, data collection, reporting and reimbursement (see also, Minimum performance).

Local service activity data including pharmacotherapy dispensed is used to complete reports for the HSCIC. It is also used by Public Health and the Community based service to analyse performance, achievements, areas for improvement, and to inform future strategy and planning for commissioning. Each pharmacy will receive performance feedback from the Community service and / or Commissioner no less than quarterly, and may also receive general feedback via Public Health reports to the Local Authority / CCG. Any Provider achieving a quit rate in excess of 75% may be subject to an audit of activity and/or invited to share their practise with peers contributing to refining clinical practice and overall service improvement. Any Provider not achieving a minimum quit rate of 35% in a year, may be asked to demonstrate how they will improve performance to be eligible to deliver the LCS in subsequent years.

Details of **consenting** smokers treated in community pharmacy that are also registered with a Camden or Islington GP **will** be shared with the GP along with the treatment outcome to ensure records are kept up to date.

7. Review of the Service

Public Health must ensure that the local service is compliant with any guidance issued by DH, NICE or the NCSCT as appropriate, and as such the local service will be revised regularly in line with such guidance as it becomes available.

Public Health will continually review the smoking local commissioned service to ensure that changes to the local service are informed by best practice to meet the health needs of Islington's population. Commissioner-led in year updates and notifications will be communicated electronically and via Community based service Adviser newsletters.

The pharmacy will participate in any Local Authority or Local Pharmaceutical Committee / Clinical Commissioning Group organised audit of service provision where required and will co-operate with the Local Authorities inspection, monitoring and evaluation procedures which may include inspections to evaluate and/or audit the Service Provider's performance.

The pharmacy will co-operate with any locally agreed Local Authority-led assessment of service user experience.

8. Variation/Termination of Agreement

Please refer to conditions in the general "CONDITIONS OF CONTRACT FOR PROVISION OF LOCALLY COMMISSIONED SERVICES"

9. Protecting Patient Confidentiality

Please refer to conditions in the general "CONDITIONS OF CONTRACT FOR PROVISION OF LOCALLY COMMISSIONED SERVICES."

10. Contract

Acceptance of Terms: Service Specification for (please tick to indicate borough):				
Camden Community Pharmacy, Smoking Cessation Local commissioned Service [] or				
Islington Community Pharmacy, Smoking Cessation Local Commissioned Service []				
Pharmacy Code: F				
Name ofPharmacy:				
By signing this document the pharmacy agrees to provide the LCS in accordance with this specification. This document will become part of the contract documentation between Public Health [commissioner] and				
I hereby confirm my acceptance of the terms of this Local Commissioned Service.				
Please sign and date below to confirm acceptance:				
Signed on behalf of the Pharmacy [provider] by				
Print name Date:				
Signed on behalf of Public Health [Commissioner]				
Print name Date:				

Appendices

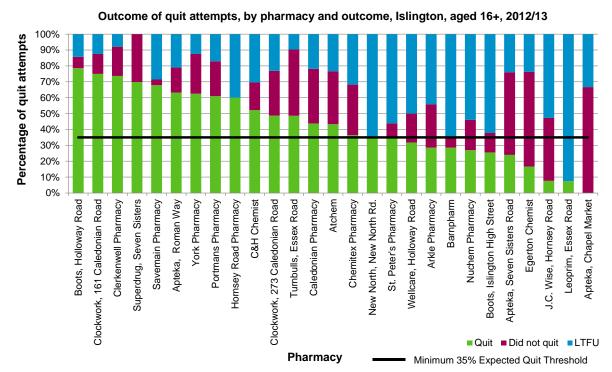
Appendix 1: Equalities and Health Inequalities - Islington

- According to official estimates, around one fifth of Islington residents smoke (24% GP dataset).
- Smoking prevalence is highest among the older and most deprived communities in Islington, which, in turn, fuels the inequalities gap. The peak prevalence found in Islington is in 49 year olds residents (30%).
- Local deprivation quintile analysis indicates that as levels of deprivation increase, so too does smoking prevalence.
- Men are more likely to be current or ex-smokers than women; 29% of men currently smoke compared to 21% of women and in 2010/11 more women than men in Islington successfully quit.
- In Islington, white people are the group most likely to smoke (26% are smokers; 24% are ex-smokers). Black and Asian people are significantly less likely to smoke (18% are current smokers, 13% are ex-smokers).
- 12% of smokers in Caledonian ward attempted at least one quit in the previous year. St. Peter's, St. Mary's and Holloway also had a higher than average number of smokers attempting to quit that year.
- Smokers living in Mildmay ward made the fewest quit attempts with only 4% of smokers making an attempt in the previous year. Fewer than 7% of smokers in Clerkenwell, Tollington and Finsbury Park attempted to quit in the same year.
- In Islington there are 9,539 people, living with at least one long-term condition who are recorded as a current smoker.
- Over one-third of people with a psychotic disorder, chronic depression or COPD are recorded as smokers with 41% of people living with COPD continuing to smoke.
- The proportion of mothers smoking at time of delivery has been decreasing in Islington from almost 10% between 2006/07 and 2008/09 to under 8.5% (215 women) between 2010/11 and 2012/13. This is higher than the London average (6%) but lower than the average for England (13%).
 - Less than half (48%) of quit attempts in Islington were successful in 2012/13, compared to 53% in London as a whole. This percentage is one of the lowest in London, although it is a slight improvement compared to last year.
 - Wider determinants of health such as socioeconomic classification, education and poverty indicate that a cross cutting approach to tobacco control in Islington must be sustained to reduce smoking prevalence.

Equalities and Health Inequalities - Camden

- Around one fifth of Camden residents smoke (GP dataset). That is 36,743 smokers registered in Camden
- Men are significantly more likely to smoke than women (25% vs. 17%).
- Smoking prevalence is highest among the older and most economically deprived communities in Camden, which, in turn, fuels the inequalities gap. Prevalence is highest in the 45-59 age-group although reduces significantly in those aged 60 and over for both men and women.
- People living in the most deprived local quintiles in Camden are significantly more likely to smoke than those living in the least deprived, ranging from 25% in the most deprived group to 15% in the least deprived group.
- There are significant variations in smoking prevalence by wards in Camden, ranging from 13% in Frognal and Fitzjohns to 25% in Kentish Town.
- Smoking prevalence varies significantly between ethnic group, ranging from 8% in the Chinese population to 22% in the White population and 32% in the mixed White and Black Caribbean population.
- Nearly 50% of the population in Gospel Oak are current or former smokers compared to less than 30% in Bloomsbury and Kings Cross.
- Smoking prevalence is significantly higher in those with serious mental illness, chronic obstructive pulmonary disease (COPD), depression, liver disease and myocardial infraction (heart attack). 44% of those diagnosed with COPD in Camden (1,128 people) continue to smoke after diagnosis.
- Quit rates vary significantly between different age groups. For men, the
 chances of success in quitting increase with age; those aged 60 and above are
 more likely to successfully quit smoking that men in younger age groups. For
 women, the chances of success are highest in those aged between 35 and 59
 years: quit rates are significantly higher than men in these age groups.
- Ward-level analysis indicates that quit rates are significantly lower than the average in some wards (Camden Town with Primrose Hill, Highgate and Frognal and Fitzjohns).
- Quit rates for those who had never worked or who were long term unemployed were significantly lower than the average in Camden.
 - Of the 2,633 births in Camden in 2011/12, 139 women were smoking at the time of delivery (5%). This is lower than both the London and England averages (6% and 13%).
- Wider determinants of health such as socioeconomic classification, education and poverty indicate that a cross-cutting approach to tobacco control in Camden must be sustained to reduce smoking prevalence.

Appendix 2: Quit Attempt Outcomes by Pharmacy, Islington*

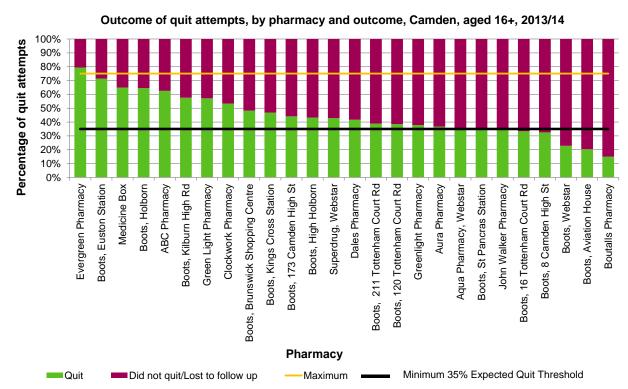


Note: Chart represents attempts, one individual may contribute more than one attempt. 9 pharmacies were not included due to disclosive nature of small number of attempts; **Source:** Islington Stop Smoking Service, 2012/13

*this is the most recent analysis available for Islington

- Fewer pharmacies than GP surgeries achieved the 35% expected quit threshold set by the DH in Islington
- Many pharmacies reported a very small number of quits; seven had less than 20 attempts in the last year.
- 36% of attempts were lost to follow up in pharmacies compared to 12% at GP practices. This may lead to an underestimate of quit rates for pharmacies.
- There was wider variation in both attempts made and successful quits than in GP practices, even within the same group e.g. Boots, Apteka.
- Fewer pharmacies than GP surgeries achieved the 35% expected quit threshold set by DH.

Quit Attempts Outcomes by Pharmacy, Camden



Note: Chart represents attempts, one individual may contribute more than one attempt. 24 pharmacies were not included due to disclosive nature of small number of attempts; Source: Camden Stop Smoking Service, 2013/14

Appendix 3: Local Service Delivery Model

Please refer to the National Centre for Smoking Cessation and Training website section on delivering a Standard Treatment Programme.

http://www.ncsct.co.uk/publication_NCSCT-competences-for-STP.php

Dataset Reporting

The Department of Health Gold Standard requires that Stop Smoking Services collect the following:

- Postcode
- Ethnicity
- Gender
- Age
- Occupation (85% recording threshold)
- Pregnancy status (only if it is positive)
- Disability or long-term condition
- Quit date
- Treatment (NRT, bupropion, varenicline etc.)
- CO validation (85% recording threshold)
- Treated Smokers (number accessing the service)
- Final Outcome (Quit Smoking, Lost to Follow Up, or Still Smoking)

The full guidance can be found at: www.dh.gov.uk/publications

References / Guidelines

National Centre for Smoking Cessation and Training: Local Stop smoking Services, Service and delivery guidance 2014

http://www.ncsct.co.uk/publication_service_and_delivery_guidance_2014.php NICE Smoking clinical guidelines: http://guidance.nice.org.uk/PH1

Camden Smoking prevalence and smoking cessation services, 2013/14 Islington Smoking prevalence and smoking cessation services, 2012/13 Action on Smoking and Health: Smoking and Reproduction, 2011

This Smoking Local Service Specification was prepared by Verena Thompson, Senior Strategist, Behaviour Change Camden & Islington Public Health with support from the Community Stop Smoking Services and Medicines Management teams in Camden and Islington.



Clinical Condition



Working in partnership

Public Health Guidance for the supply of Nicotine Replacement Therapy Local Commissioned Service, 2015-16

for use by community pharmacies authorised to deliver Stop Smoking Services (the public health preferred list for NRT is being updated and will be available from April 1st 2015)

Indication	 Aid to treating tobacco dependence in: Clients receiving specialist advice and support from the Community Stop Smoking Service Clients receiving specialist stop smoking advice and support from pharmacists commissioned to deliver Stop Smoking Services in Islington
Best practice	There is evidence to support combination NRT dispensing as cost effective and most likely to achieve a positive outcome at 4 weeks: http://www.ncsct.co.uk/usr/pub/B7_Cost-effectiveness_pharmacotherapy.pdf
Inclusion criteria	Tobacco users identified as motivated to quit i.e. willing to set a quit date and receive weekly support for a minimum of 4 weeks up to a maximum of 12 weeks NRT may be supplied outside the terms of the SPC based on advice from the MHRA http://www.mhra.gov.uk/home/groups/pl-p/documents/websiteresources/con2022934.pdf to: (all SPCs have been updated to include pregnancy and breastfeeding)

Pregnancy

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

The decision to use NRT should be made following a risk-benefit assessment as early in pregnancy as possible. The aim should be to discontinue NRT use after 2-3 months. Intermittent (oral) forms of NRT are preferable during pregnancy although a patch may be appropriate if nausea and/or vomiting are a problem. If patches are used, they should be removed before going to bed at night.

Breastfeeding

NRT can be used by women who are breast-feeding. The amount of nicotine the infant is exposed to from breast milk is relatively small and less hazardous than the second-hand smoke they would otherwise be exposed to if the mother continued to smoke. If possible, patches should be avoided. NRT products taken intermittently are preferred as their use can be adjusted to allow the maximum time between their administration and feeding of the baby, to minimise the amount of nicotine in the milk.

• Young people <16 years

Clients who are under 16 but over 12 years of age require an assessment to ensure that they comply with Fraser Guidelines by following the proforma in appendix 4. There is limited data on the safety and efficacy of NRT in this age group.

Cardiovascular disease

NRT is a lesser risk than continuing to smoke. Pharmacists must be assured that a client presenting with CVD is stable (physically and medicines prescribed). This should be confirmed by both clinically interviewing the client and reviewing their

medication. If the client's status is unclear then exclude and refer on as appropriate.

Diabetes

Clients with diabetes should be informed to monitor their blood glucose more closely when initiating NRT due to the release of catecholamines.

- Renal or hepatic impairment.
 NRT should be used with caution in patients with moderate to severe hepatic impairment and/or severe renal impairment, as the clearance of nicotine or its metabolites may be decreased, with the potential for increased adverse effects.
- Other
 Clients with thyroid disease, peptic ulcer disease who are not in the exclusion criteria below.
- Amounts to be dispensed
 The available evidence recommends a combination of transdermal patch plus oral product, although in certain circumstances 2 oral products can be combined.

If continuing supplies are required beyond the recommended 8 weeks, the pharmacist should contact the Specialist Clinics Smoking Cessation Advisor and refer the smoker for continued support. Supply will not be authorised beyond 8 weeks.

Exclusion criteria

- Tobacco users not motivated to quit or use NRT
- Tobacco users who continue to smoke.
- Clients who are under 13 years of age.
- Clients with a myocardial infarction (MI), severe dysrhythmia or recent cerebrovascular accident (CVA) in the last 4 weeks.
- Clients who have uncontrolled hypertension.

- Clients already taking bupropion (Zyban) or varenicline (Champix).
- Clients with previous serious reaction to NRT or any of the other ingredients contained in the products, e.g. glue in patch.
- Patches only clients with chronic generalised skin disease such as psoriasis, chronic dermatitis and urticaria; clients who have had a previous reaction to transdermal patches.
- Nasal spray only clients with chronic nasal disorders such as polyposis, vasomotor rhinitis and perennial rhinitis.
- Liquorice flavoured products are excluded during pregnancy.

Clients using NRT products that have relapsed and returned to smoking – an assessment of motivation to quit should be conducted before a new quit date is set.

Action if patient is excluded Refer to GP or Specialist Stop Smoking Service Where clients would benefit from more intensive behavioural support refer to the Community Stop Smoking Service: Islington T: 0800 093 9030

Camden T: 0800 107 0401

Refer to doctor

When NRT is thought appropriate but supply through pharmacy is not recommended then the client should be referred to a GP.

This might include any of the conditions referred to as exclusion criteria above but also:

Clients with serious cardiovascular event/hospitalisation in previous four weeks or uncontrolled hypertension.

Clients taking theophylline (see Drug interactions below).

Where intervention with bupropion or

varenicline might be more appropriate.		
This guidance allows the supply of NRT to pregnant smokers who are unable to quit with non-pharmacological interventions. However, before a supply is made the risks and benefits must be discussed with the pregnant smoker. Nicotine is not 100% safe in pregnancy, however, foetal risk is probably lower than that expected with tobacco smoking due to lower plasma nicotine concentration than with inhaled nicotine, no additional exposure to polycyclic hydrocarbons and carbon monoxide, improved chances of		
quitting smoking by the third trimester.		

Drug details	See below
Name, form & strength of medicine	NRT may be supplied in the following forms (all products are GSL)
	Gum:
	2mg and 4mg
	Patch:
	5mg /16 hrs 10mg /16 hrs
	15mg /16 hrs
	25mg / 16 hrs ('Invisipatch')
	7mg /24 hrs 14mg /24 hrs
	21mg /24 hrs
	Lozenge:
	1mg , 2mg and 4mg
	Mini Lozenge
	1.5mg and 4mg
	Sublingual Tablet:
	2mg
	Inhalator:
	10mg / cartridge
	Nasal spray:
	500 micrograms / metered spray
Dosage, Route, Method	• <u>Gum</u>
	Oral administration (as resin).
	Treatment should be continued for at least 3
	months followed by a gradual reduction in dosage if necessary.
	Dogo 21 of 24

Specific advice to client

Gum should be chewed until the taste becomes strong and then 'parked' between the gum and cheek until the taste fades.

Recommence chewing once the taste has faded. This 'chew-rest-chew' technique should be applied for 30 minutes.

Gums 2mg and 4mg

For individuals smoking 20 cigarettes or less daily – one 2mg piece chewed slowly for 30 minutes on urge to smoke. For individuals smoking more than 20 cigarettes a day – one 4mg piece chewed slowly for 30 minutes on urge to smoke.

Nicorette – Maximum of 15 x 2mg or 15 x 4mg Nicotinell – Maximum of 25 x 2mg or 15 x 4mg "Own brands" – follow SPC dosages

Specific side effects

Throat irritation, increased salivation, hiccups.

Inhalator

Oral administration (nicotine-impregnated plug in mouthpiece)

Each cartridge can be used for approximately 3 sessions, with each one lasting approximately 20 minutes.

Inhale when urge to smoke occurs. Advise using 6-12 cartridges (10mg/cartridge) daily for up to eight weeks.

Post intervention guidance on dosage: Refer to Stop Smoking Service Admin T: 020 7530 4205 or Freephone 0800 093 9030

Specific side-effects

Throat irritation, cough, rhinitis, pharyngitis, stomatitis, dry mouth

Specific advice to client

Air should be drawn into the mouth through the mouthpiece. Clients should be warned that the inhalator requires more effort to inhale than a cigarette and that less nicotine is delivered per inhalation. Therefore the client may need to

Specific advice to Client

inhale for longer than with a cigarette.

The inhalator is best used at room temperatures as nicotine delivery is affected by temperature. Used cartridges will contain residual nicotine and should be disposed of safely. Advise the client to keep them in the case and dispose of them in household rubbish.

Lozenge

Oral administration (nicotine as bitartrate).

Nicotinell

Maximum of 30 x 1mg or 15 x 2mg lozenges in 24 hours

Niquitin CQ 2mg and 4mg

Weeks 1-6 1 lozenge every

1-2 hours

Weeks 7-9 1 lozenge every

2-4 hours

Weeks 10-12 1 lozenge every

4-8 hours

The 2 mg lozenge is suitable if the client has their first cigarette after 30 minutes of waking, the 4 mg lozenge is suitable if the client has their first cigarette within 30 minutes of waking.

Niquitin Minis Lozenge

If smoking more than 20 cigarettes per day suck one 4mg lozenge when urge to smoke. If smoking less than 20 cigarettes per day suck one 1.5mg lozenge when urge to smoke.

Maximum 15 x 1.5mg or 15x4mg lozenges per day.

Specific side-effects

Throat irritation, increased salivation, hiccups

Specific advice to Client

Specific advice to client

Lozenge should be sucked until the taste is strong and then 'parked' between the gum and the cheek until the taste fades. Once faded then the sucking should recommence. Simultaneous use of coffee, acid drinks and soft drinks may decrease absorption of nicotine and should be avoided for 15 minutes prior to sucking lozenge.

Nasal Spray

Nasal administration (500 micrograms / metered spray).

Apply one spray into each nostril as required up to a maximum of twice per hour, over a 16 hour period (= maximum of 64 sprays daily) for a period of eight weeks **THEN** prepare smoker for referral to the Community Stop Smoking Service for continued treatment to reduce dosage.

Recommended period of treatment: 3 months

Specific side Effects

Nose and throat irritation, nosebleeds, watering eyes, ear sensations.

Specific advice to Client

Specific advice to Client

Advise on correct use of spray.
Warn of possible local effects but also that these tend to lessen within a few days.

CAUTION – the nasal spray should not be used whilst driving or operating machinery as local effects can predispose to an accident.

Patches

Nicorette 15, 10, 5

Daily treatment commences with one 15mg patch applied on waking (usually in the morning) and removed 16 hours later. Treatment should continue for 8 weeks during which the smokers should be prepared for referral to the Community Stop Smoking Service for the weaning off period (an additional 4 weeks).

Nicorette Invisipatch 25

NB Invisi Patch only available as '25' strength. Supply plain patches for all other strengths.

For individuals smoking 10 or more cigarettes daily; initially 25mg patch for 16 hours daily for 8 weeks, then if abstinence achieved 15mg patch for 16 hours daily for 2 weeks, then 10mg patch for 16 hours daily for 2 weeks.

For individuals smoking less than 10 cigarettes per day; initially 15mg patch applied for 16 hours daily for 8 weeks then 10mg patch for 16 hours daily for 4 weeks.

NB Patients who experience excessive side effects with the 25mg patch that do not resolve within a few days should be switched to the 15mg patch for the remainder of the 8 weeks before switching to the 10mg patch for the final 4 weeks.

Nicotinell TTS 10, 20, 30

For individuals smoking 20 cigarettes or more a day, it is recommended that treatment be started with Nicotinell TTS 30 (Step 1) once daily. Those smoking less than this are recommended starting with Nicotinell TTS 20 (Step 2). Apply a new patch every 24 hours. Use treatment period of 3 – 4 weeks for each size patch. The treatment is designed to be used continuously for 3 months but not beyond.

Niguitin CQ 7, 14, 21

NiQuitin CQ therapy should usually begin with NiQuitin CQ 21 mg and be reduced according to the following dosing schedule:

Dose		Duration
Step 1	NiQuitin CQ 21 mg	First 4 weeks
Step 2	NiQuitin CQ 14 mg	Next 2 weeks
Step 3	NiQuitin CQ 7 mg	Last 2 weeks

Cutting down: No clinical evidence that this is more effective- than staying on same dose for full eight weeks if necessary. Forced or premature reductions can often lead to a relapse.

Light smokers (e.g. those who smoke less than

10 cigarettes per day) are recommended to start at Step 2 (14 mg) for 6 weeks and decrease the dose to NiQuitin CQ 7 mg for the final 2 weeks.

For optimum results, the 10 week treatment course (8 weeks for light smokers or patients who have reduced strength as above), should be completed in full. It should not extend beyond 10 consecutive weeks.

"Own brands"

Follow SPC dosages

Specific advice to Client

Specific side Effects

Skin reactions. Discontinue use if severe.

Exercise may increase absorption of nicotine and therefore the side effects.

The patch should be applied once a day, normally in the morning, to a clean, dry, non-hairy area of skin on the hip, chest or upper arm.

Allow several days before replacing the patch on a previously 'used' area.

Place the patch in the palm of the hand and hold onto the skin for 10-20 seconds.

Patches should not be applied to broken or inflamed skin.

Once the patch is spent it should be folded in half and disposed of carefully. Clients should not try to alter the dose of the patch by cutting it up.

• Sublingual Tablet

Oral administration (sublingual) – 2mg.

For individuals smoking 20 or less cigarettes daily – 2mg per hour.

For patients who fail to stop smoking or have significant withdrawal symptoms consider increasing to 4mg per hour sublingually.

For individuals smoking more than 20 cigarettes a day – 4mg per hour.

Maximum dose: 80mg per day

Treatment should be continued for at least three months up to a maximum of six months. Dosage should be gradually reduced after three months.

Specific side-effects

Throat irritation, unpleasant taste.

Specific advice to clients

Tablets should be placed under the tongue and allowed to dissolve slowly

Nicorette Combi Patch and Gum

Pack contains 7x15mg Nicorette Invisipatch and 70 x 2mg gum

Initially one patch applied for 16 hours daily for 12 weeks with gum as required; maximum 15 pieces of gum per day. Then discontinue the patch and use gum as required up to a maximum of 15 pieces per day, gradually weaning use after 12 weeks.

For side effects and advice see individual sections above.

As above

Maximum length of treatment under this guidance is 8 weeks (most individual Summary of Product Characteristics (SPC) state 12 weeks)

www.emc.medicines.org

All smokers in treatment that may require on-going support or medication after 8 weeks supply, must be prepared as part of this treatment for referral to the Community Stop Smoking Service T: 0800 093 9030

Fortnightly supplies to be given for four weeks with the offer of weekly support. Maximum

Specific advice to Client

Frequency

Duration of treatment

Quantity to supply/ administer

supply 12 weeks.

If the client is successful in stopping smoking after week 4 (preferably with carbon monoxide validation) treatment is to be given for another four weeks to maintain abstinence.

If the smoker is unsuccessful in stopping at four weeks then discontinue treatment and suggest they make a fresh start when they are ready to set another Quit Date. Discuss other routes to quit that are available in Islington

If the smoker is successfully stopped at *eight* weeks and requires additional supply of NRT, refer the client to their GP or contact the Stop Smoking Service to discuss a referral as appropriate.

These are usually transient but may include the following, some of which are a consequence of stopping smoking: nausea, dizziness, headaches, cold and flu-like symptoms, palpitations, dyspepsia and other gastro-intestinal disturbances, hiccups, insomnia, vivid dreams, myalgia, chest pain, blood pressure changes, anxiety and irritability, somnolence and impaired concentration, dysmenorrhoea.

Product-specific side effects are detailed in the SPC.

Advice to clients should include specific product advice plus the following general advice regarding:

- Client information relating to the supply of NRT under the treatment given will shared with the client's GP (if registered in Islington), the Community Stop smoking Service and LB Islington (Public Health) for purposes such as referral, audit, payment or research.
- The client's informed consent must be obtained before information can be shared (Use Patient Information Sheet Appendix X, Service Specification and LCS 2014-15).

Adverse reaction / side effects

Advice to patient/carer

- If there is no informed consent then the client is excluded from the scheme and should be referred back to their GP or advised to contact the National NHS Helpline T: 0800 169 0169
- Withdrawal symptoms.
- Possible changes in the body on stopping smoking, e.g. weight gain, and how to access local services for weight management support
- The effects of smoking tobacco whilst using NRT – particularly in vulnerable groups, e.g. pregnant women, clients with cardiovascular disease.
- Follow-up and obtaining further supplies of NRT.
- Written information on products supplied, self-help leaflets and where to obtain more information, in particular NHS Helpline numbers for:

NHS Helpline: 0800 169 0 169 Pregnancy Helpline: 0800 169 9 169

Special considerations / additional information.

Drug Interactions

Tobacco smoking increases the metabolism of *theophylline*. Thus stopping smoking may cause theophylline plasma levels to rise. Clients taking theophylline should be supplied with NRT as appropriate but the pharmacist should inform their GP of their attempt to stop smoking. Permission to pass this information to the GP will need to be obtained from the client. If the patient refuses consent then refer without supplying NRT.

Stopping smoking may alter the circulating drug levels of the following (but not normally enough to cause therapeutic problems):

	 Insulin Adrenergic agonists and antagonists Fluvoxamine Clozapine Clomipramine Imipramine Olanzapine Flecainide Tacrine Pentazocine
Records/audit trail	All patient details and treatment sessions conducted including exclusion from prescription charges, the dose, form and quantity of NRT supplied must be recorded using the software provided for the Smoking Cessation Service. The software allows for the recording of any
	adverse drug reaction and actions taken including reporting to the doctor and/or Committee on Safety of Medicines if appropriate.
	Referral arrangements (including self-care).
	The "Letter of Recommendation" to supply or a copy, should be kept securely for no less than 2 years for audit purposes.

Staff Requirements	
Professional Qualifications	Pharmacists and others trained by the Community Stop Smoking Service (commissioned by LB Islington Public Health) to supply NRT under this guidance and have been accredited in line with National Smoking Cessation Training Centre (April 2010) standards, NICE guidance and Fraser guidelines.
Specialist competencies or qualifications	Has undertaken appropriate Level 2 training with the NCSCT to carry out clinical assessment of patient leading to diagnosis that requires treatment according to the indications listed in this guidance, and attends annual Level 2 Local Update training to maintain their skills.
Continuing education & training	The supervising pharmacist should be aware of any change to the recommendations for the medicines listed, and report these to Public

Health and the CCG Medicines Management, for updating the guidance. It is the responsibility of the individual to keep up-to-date with continued professional development.

The supervising pharmacist is required to attend Community Stop Smoking Service training at least annually and at interim intervals where significant changes are made to the licensed products or the service specification as advised.

Level 2 Advisors should attend annual updates with the Community Service.

The practitioner is also required to attend any training that may become mandatory (either at national or local level) from changes to the guidance and/or the associated Service Specification and Locally Commissioned Service.

References / Resources and feedback

Please direct feedback specifically relating to information within this NRT guidance to:

Islington

Medicines Management
Islington Clinical Commissioning Group
338-346 Goswell Road
London EC1V 7LQ
T: 020 3688 2900
mmt.islington@nhs.net

<u>Camden</u>

Medicines Management
Camden Clinical Commissioning Group
Stephenson House
75 Hampstead Road
London NW1 2PL
020 3688 1700
enquiries@camdenccg.nhs.uk

References:

- 1. Summary of Product Characteristics www.emc.medicines.org.uk
- 2. British National Formulary www.bnf.org
- 3. MIMS Online www.mims.co.uk
- 4. NICE guidance www.nice.nhs.uk

New advice on use of nicotine replacement therapy (NRT): wider access in at-risk

populations. 29/12/05 www.mhra.gov.uk

Appendix 4: Fraser Guidelines

The legal age of consent for medical treatment is 16 years or over, as determined by Section 8 of the Family Law Reform Act, 1969 (However, it should be noted that a 'child' is defined by the Children Act 1989 as anyone who has yet to reach their 18th birthday). In such cases, there is no legal requirement to obtain consent from a parent or guardian. The question of the rights of children under 16 years of age to consent to treatment on their own behalf was reviewed by the House of Lords, in connection with contraception (Gillick v West Norfolk and Wisbech Area Health Authority [1985]). The House of Lords ruled that young people under the age of 16 could give valid consent to medical treatment, as long as they had sufficient understanding and intelligence to appreciate fully what is proposed, and are capable of expressing their own wishes (often referred to as the Fraser ruling). In light of this ruling stated that health professionals should consider the following issues before giving NRT advice/treatment when seeing young people under 16 years of age:

- Whether the young person understands the potential risks and benefits of the treatment and any advice given.
- The value of parental support should be discussed, and health professionals must encourage the young person to discuss their consultation with their parents. Although the health professional is legally obliged to discuss the value of parental support, he/she must respect confidentiality.
- The health professional should take into account whether the young person is likely to continue smoking without treatment.
- The health professional should assess whether the young person's physical and/or mental health will suffer if they do not receive advice or treatment,

The health professional should consider whether it is in the young person's best interest to receive NRTadvice and/or treatment without parental consent.

Fraser guidelines for prescribing to under 16s

Yes No

Does the young person understand the advice given?

Parental consent discussed

Young person is very likely to continue smoking without treatment

Young person's physical or mental health or both are likely to suffer unless she receives treatment

NRT treatment is in the best interest of the young person

Appendix 5: Follow Up at 12 weeks or 82 days

Advisors will be able to record the 12 week follow up via the 'Follow Up' link in the left navigation. This will only appear once the 4 week outcome has been recorded and the episode marked as complete.

