Service	Stop Smoking Service
Commissioner Lead	Wendy Burke, Director of Public Health
Provider Lead	Community Pharmacies in North Tyneside
Period	1 st October 2017 – 31 st March , 2018

1. INTRODUCTION

This Service Specification sets the requirements for the provision of a Public Health Stop Smoking Service within Community Pharmacy in North Tyneside.

The focus of the Service is to offer accessible support and advice to people who want to give up smoking and to supply pharmacological stop smoking aids where appropriate in a choice of venues across the borough.

Participation by Community Pharmacies in this Service is voluntary and guided by identified local need.

2. GENERAL OVERVIEW

Smoking remains the leading cause of preventable death and disease nationally and locally and is one of the most significant factors that affect health inequalities and ill health, particularly cancer, coronary heart disease and respiratory disease. Reducing smoking prevalence therefore remains a key public health priority and a national focus.

Smoking and its associated harms continue to fall hardest on some of the poorest and most vulnerable people in our society. The difference in life expectancy between the poorest and the richest can be as much as nine years and smoking accounts for approximately half of this difference.

The support provided by local stop-smoking services continues to offer some of the best opportunities for people to quit smoking. It is therefore important that evidence-based, high-quality stop smoking support, configured to meet the needs of the local population, and delivered by qualified and well-trained Service Providers, is available to those who require it.

The national tobacco control plan (2017), *Towards a Smokefree Generation: Tobacco Control Plan for England* has set out the following objectives to be achieved by the end of 2022

- reduce the number of 15 year olds who regularly smoke from 8% to 3% or less
- reduce smoking among adults in England from 15.5% to 12% or less
- reduce the inequality gap in smoking prevalence, between those in routine and manual occupations and the general population
- reduce the prevalence of smoking in pregnancy from 10.5% to 6% or less

3. EVIDENCE BASE

Stop Smoking Services that are underpinned by guidance from the National Institute for Health and Care Excellence (NICE) are highly effective in both cost and clinical terms. Smokers are four times more likely to quit using stop smoking behavioural support and medication than quitting unaided or using nicotine replacement therapy over the counter (PHE 2014).

The evidence base is set out below

- National Institute for Health and Care Excellence (NICE) TA123 Smoking cessation – Varenicline (2007)
- National Institute for Health and Care Excellence (NICE) Public Health Guidance 10: smoking Cessation Services (February 2008)
- National Institute for Health and Care Excellence (NICE) Public Health Guidance 26: Smoking: stopping in pregnancy and after childbirth (June 2010)
- National Institute for Health and Care Excellence (NICE) Public Health Guidance 45: Tobacco: Harm Reduction Approaches to Smoking (June 2013)
- National Institute for Health and Care Excellence (NICE) QS43 Smoking cessation: supporting people to stop smoking (2013)
- National Centre for Smoking Cessation and Training (NCSCT) Local Stop Smoking Services: Service and Delivery Guidance (2014)
- National Centre for Smoking Cessation and Training (NCSCT) Electronic Cigarettes: A Briefing for Stop Smoking Services (January 2016)
- Public Health England. 'Use of e-cigarettes in public places and work places' (6 July 2016)
- HM Government Towards a Smokefree Generation: A Tobacco Control Plan for England (2017)

The evidence base for telephone interventions is set out in the following link (www.cochrane.org/reviews/en/ab002850.htm).

4. AIMS, OBJECTIVES AND OUTCOMES OF THE SERVICE

The aim of this Service is to enable Community Pharmacies in North Tyneside to provide accessible Stop Smoking Support which:

- 1. Provides comprehensive individual support for people to successfully quit smoking.
- 2. Offers a choice of the most effective evidence based treatments available.
- 3. Achieves high levels of client satisfaction.

The Stop Smoking Service will contribute to the reduction in:

- a) Smoking prevalence amongst adult smokers
- b) Mortality rates in smoking related conditions such as cardiovascular disease, Chronic Obstructive Pulmonary Disease (COPD) and cancer.
- c) Health inequalities.

5. DESCRIPTION OF THE SERVICE

The Service is available to people who are aged 12 and over and either resident in North Tyneside or registered with a North Tyneside GP Practice and are motivated to stop smoking.

The Service is provided for people who are dependant upon smoking tobacco and still smoking at the time they present.

The Service is available through the normal working hours of Community Pharmacies who have agreed to offer the Service and comprises of the following elements (each element must be available from the Pharmacy):

- Stop Smoking Behavioural Support.
- The supply of NRT through a voucher scheme.
- The supply of Varenicline under a Patient Group Direction (PGD) using a voucher scheme.

The Service will be provided by trained Advisors and Pharmacists who have an empathic approach to their clients.

Initial appointments should last for at least 30 minutes followed by appointment times of at least 10 minutes thereafter to ensure continued monitoring, client compliance and on-going access to medication.

The Service will be provided for a period of up to 12 weeks and support will be offered at weekly intervals for the first four weeks and at intervals of 2 weeks thereafter. Quitting will be measured at 4 weeks.

Clients should, where possible, remain with the same pharmacy throughout the duration of their behavioural support programme to ensure continuity of care and client safety.

All pharmacotherapy is supplied strictly in accordance with the product license and in the case of Varenicline in accordance with the requirements set out in the Patient Group Direction (PGD). The PGD can be accessed by clicking here

In order to qualify to prescribe Varenicline the Pharmacist must be a qualified pharmacist, premises must be approved and they are authorised to do so by the Authority under the PGD.

The Service is available to people who wish to use e-cigarettes especially in those who have tried and failed to stop smoking using licensed stop smoking medicines and follows guidance set out in accordance with the NCSCT Recommendations for Practice (2016):

http://www.ncsct.co.uk/usr/pub/Electronic_cigarettes. A_briefing_for_stop_smoking_services.pdf

6. SERVICE DELIVERY/OUTLINE OF THE SERVICE

The Pharmacy will accept self-referrals and clients will be sign posted to the Service from a range of community and health professionals.

The Service will be provided by trained advisors but all pharmacy staff will be expected to provide brief advice.

The Service will:

- 1. Assess readiness to make a quit attempt, the appropriateness of pharmacological treatments for the individual and their willingness to use appropriate treatments.
- 2. Provide an outline of treatment options that have proven effectiveness.
- 3. Provide a description of what a typical treatment programme might look like, its aims, length, how it works and its benefits.
- 4. Provide appropriate behavioural support strategies to help the person quit.
- 5. Reach an agreement with the individual on the chosen treatment pathway, ensuring that they understand the on-going support and monitoring arrangements.
- 6. Provide information on the benefits of quitting smoking.
- 7. Provide information on the main features of the tobacco withdrawal syndrome and the common barriers to quitting.
- 8. Set and record a quit date.

Behavioural support

The delivery of behavioural support must include the following:

- Weekly support for a period of 4 weeks from a guit attempt to prevent relapse.
- On-going support between the 4 week and 12 week quit attempt, at least once every two weeks.
- The facilitation, where appropriate, of the supply of NRT or Varenicline by a Pharmacist via completion and issue of the relevant vouchers to clients.
- The use of a Carbon Monoxide (CO) monitor to validate quit attempts. Advisors are expected to achieve a minimum 85% CO validation rate of clients selfreporting at 4 weeks.
- Missed appointments should be followed up (3 attempts) by telephone, letter or email as appropriate.
- A 4 week follow-up after setting a quit date of all clients regardless of quit status should be completed in person, by telephone or text contact or email.
- A minimum of 3 attempts made to contact a client (where telephone contact is not feasible a letter or email should be sent) should be carried out.

- Where it has not been possible to contact a client after 3 attempts they should be recorded as 'lost to follow-up' and this recorded on the client record.
- Smoking status is to be confirmed for all clients self-reporting as having quit at 4
 weeks by use of a CO monitor, with the exception of where follow-up has been
 carried out by telephone. CO verification should be made in a minimum of 85%
 of cases.

The Voucher Scheme for Pharmacological Support

Voucher schemes for stop smoking medications are used in many regions in the UK and are designed to improve access to treatment as they remove the need for a Stop Smoking Advisor to send a letter of recommendation to the GP to obtain a prescription for NRT or Varenicline. This lists the products available under the terms of this Service. The Stop Smoking Advisor will not offer any other pharmacological treatments.

The voucher scheme is only available through this Stop Smoking Service contracted by the Authority and is only available to clients who are motivated to stop smoking and who are receiving behavioural support from a trained Advisor.

Where patients are eligible and assessed as suitable to receive NRT or Varenicline the Advisor will issue a voucher of recommendation indicating a recommended course of medication for a 2 week period (a total of 6 vouchers can be issued to the client). The Advisor takes full responsibility for any recommendation that they make through the vouchers.

If the client has a planned holiday or an absence from home, two vouchers may be issued at the same time, with the reason written on the top of the voucher. More than two vouchers may only be issued in exceptional circumstances following discussion with the Authority's Stop Smoking mentor/trainer.

The voucher can only be presented to a Pharmacist offering this Service contracted by the Authority.

The Pharmacist must check that the voucher is valid (presented within 14 days of issue), and that all relevant details have been completed by the Advisor. If the Pharmacist disagrees with the recommendations made, or if a voucher has been completed incorrectly/incompletely, the client should be redirected to the Advisor that issued the voucher.

The voucher will be recorded on the Pharmoutcomes database.

The Pharmacy will provide advice about NRT/Varenicline to the client in line with the Summary of Product Characteristics. For further information please refer to the summary of product characteristics (SPC) available at http://emc.medicines.org.uk.

The Pharmacy should provide the full course of treatment to ensure continuity of care and should not refer the client to another Pharmacy except in unavoidable circumstances e.g. sickness.

One 12 week course of support and treatment may be provided in a 6 month period. If a client relapses to smoking or is lost to follow up, they must wait 6 months from the date that their last treatment episode started before being supplied again (the interim period). Self–funded over the counter NRT or NRT or varenicline prescribed by a GP may be used during this interim period.

NRT

Only two NRT products can be supplied from the approved product list which can be found on the Voucher of Recommendation.

Supply of NRT products is free to patients who are exempt from prescription charges or have a pre-payment certificate. A fee equal to the prescription charge should be collected from patients who are supplied NRT where the patient is not eligible for free prescriptions. This fee should be deducted from the claim for supply of NRT (please refer to Section 14 of this Specification).

If NRT is used during pregnancy, intermittent therapy is preferable, i.e. the 16 hour patch should be recommended instead of the 24 hour patch. Liquorice flavoured NRT products should be avoided during pregnancy.

If NRT is withdrawn at any stage the Pharmacist must redirect the client to their Advisor so that an alternative treatment may be offered.

The Pharmacist must supply NRT in an appropriately labelled pack.

Varenicline

A voucher for Varenicline can only be presented to a 'Varenicline trained PGD Pharmacist' offering the Service contracted by the Authority.

When a voucher is presented the 'Varenicline trained PGD Pharmacist' will carry out a full assessment and will only supply the medication in accordance with the PGD.

If the 'Varenicline PGD trained Pharmacist' is absent in the pharmacy, the Advisor must contact another pharmacy that provides a Stop Smoking Service to ensure that a Varenicline PGD trained Pharmacist is available to dispense the medication.

Varenicline is free to patients who are exempt from prescription charges or have a pre-payment certificate. A fee equal to the prescription charge should be collected from patients who are prescribed with Varenicline where the patient is not eligible for free prescriptions. This fee should be deducted from the claim for supply of Varenicline (please refer to Section 14 of this Specification).

The Pharmacist must supply Varenicline in an appropriately labelled pack.

E-Cigarettes

The Service does not currently supply e-cigarettes but will provide advice on stopping smoking using e-cigarettes that includes:

- a) E-cigarettes provide nicotine in a form that is much safer than smoking.
- b) Some people find e-cigarettes helpful for quitting, cutting down their nicotine intake and/or managing temporary absence.
- c) There is a wide range of e-cigarettes and people may need to try various types, flavours and nicotine dosages before they find a product that they like.
- d) E-cigarette use is not like smoking and people may need to experiment and learn to use them effectively (e.g. longer 'drags' may be required and a number of short

- puffs may be needed initially to activate the vaporiser and improve nicotine delivery). They may also need to recognise when atomisers need replacing.
- e) People previously using e-cigarettes while smoking (e.g. to reduce the number of cigarettes that they smoke) may need to consider changing devices and/or nicotine concentrations when making a quit attempt.
- f) Although some health risks from e-cigarette use may yet emerge, these are likely, at worst, to be a small fraction of the risks of smoking. This is because e-cigarette vapour does not contain the products of combustion (burning) that cause lung and heart disease, and cancer.

7. COMPETENCIES AND TRAINING

The Pharmacy shall ensure that all Pharmacists involved in the provision of the Service have relevant knowledge and have completed any required training. This may include any required face to face training and / or training through the CPPE Declarations of Competence system.

The Pharmacy must work with the Authority's Stop Smoking Mentor/Trainer to support the Pharmacy to deliver Behavioural Support, by a Stop Smoking Advisor in line with this Service Specification.

Anyone wishing to become an Advisor is required to complete the Stop Smoking Advisor training provided by the Authority.

All Advisors are required to meet update requirements, complete an annual refresher session, and other updates as required.

All staff involved in the delivery of the Service must attend any additional training as directed by the Authority.

It is the role of the Authority's Stop Smoking Trainer and Mentor to provide guidance to Pharmacies on the operational delivery of the Service which includes Advisor competencies, advertising materials, how to access resources, retention of clients and the use of Pharmoutcomes.

Details of how to contact the Authority's Stop Smoking Trainer and Mentor is provided on Pharmoutcomes.

8. PHARMOUTCOMES

Pharmoutcomes will be the means of record keeping and claiming for all service fees.

Pharmacies providing this Service are required to enter data contemporaneously into Pharmoutcomes.

The Advisor must get consent from the client to record and share information in accordance with information governance guidelines.

In the event of an Advisor being inactive on Pharmoutcomes, the following processes will be followed:

- After 3 months they will be contacted by the Authority to review their status.
- If they have been inactive for 6 months then an update session or a visit by the Authority may be required.

If they have been inactive for a period of 12 months they will be required to repeat the Stop Smoking Advisor Training, in order to re-activate their Advisor status.

9. PREMISES AND EQUIPMENT

All equipment must be used in line with manufacturer's guidance. Equipment e.g. CO Monitors supplied by the Authority, remain the property of the Authority and must be returned when no longer in use. In the event of CO monitors developing a fault, the Pharmacy must contact the Authority for replacement.

Where consumables are required i.e. mouthpieces/ D-pieces, wipes, etc. it is the responsibility of the pharmacy to provide.

The Pharmacy will ensure that the part of the pharmacy used for the Service provision provides a sufficient level of privacy for the client.

10. RESPONSIBILITIES OF THE PHARMACY

Continuity of Service

The Pharmacy will ensure adequate contingency planning is in place to ensure continuity of service if disruption occurs such as annual leave, sickness and

unexpected absence. In the event that a suitably trained Pharmacist is not present, the client should be directed to another pharmacy that delivers the Service.

It is the responsibility of the Pharmacy to maintain an acceptable level of staffing at all times, and provide suitably accredited, skilled and trained staff to provide the Service. The Authority may require evidence of this.

The Pharmacy will ensure that interventions are efficiently managed and that there is sufficient administrative support for general organisation, client contact processes and data handling outlined in the specification.

National Guidance

The Pharmacy will deliver the Service in line with national guidance as follows

- 1. NHS (Pharmaceutical Services) Regulations 2005 and any other relevant professional standards.
- 2. NICE guidelines relevant to the Service.
- 3. Best practice in health care and to comply at all times in all respect with the standards and recommendations contained in:
 - National Service Frameworks and National Strategies
 - National Patient Safety Agency alerts and guidance
 - Human Medicines Regulations 2012
 - other quality standards agreed in writing between the Pharmacy and the Authority.

The Pharmacy will comply at all times with the most recent guidance on medicines from the Medicines and Healthcare products Regulatory Agency (MHRA).

Clinical Governance

The Pharmacy must be able to demonstrate to the Authority that clinical governance plans and structure, clinical decision making and accountability processes are in place and in line with guidance. Any clinical governance breaches in relation to this Service will be notified to Wendy Burke, North Tyneside Council's Director of Public Health, wendy.burke@northtyneside.gov.uk

Risk Management / Incident Reporting

The Pharmacy will have robust risk management process in place, including:

Incident reporting and investigation processes

Complaints processes.

The Pharmacy will report all serious incidents to the Authority and provide details of recommendations and remedial actions taken as a result.

If appropriate, Stop Smoking Advisors should complete a Yellow Card if an adverse reaction to medication is reported (http://yellowcard.mhra.gov.uk). All providers should have a process in place to record incidents and a mechanism in place that facilitates learning from incidents. When an incident occurs, associated with the Service, the Provider should submit a copy of their incident form to the Authority

Health Promotion and Health Improvement

Every client contact should be a health improvement contact which emphasises the benefits of stopping smoking and smoke free environments, using nationally branded and listed materials.

All Pharmacies are expected to promote Local and National events in particular Stoptober. Localised promotional materials will be available from the Authority for display by the Provider.

11. RECORDS TO BE KEPT

The Pharmacy shall maintain appropriate and accurate records to ensure effective on going service delivery and audit. This includes records covered under the Varenicline PGD and the voucher scheme.

Records of all consultations shall be entered in full on Pharmoutcomes.

Records of patient participation in the Service, and supply of NRT or Varenicline shall be kept on the pharmacy Patient Medication Record and Pharmoutcomes. The voucher of recommendation must be retained by the Pharmacy for audit purposes.

Client records should be maintained and stored in line with national policy and guidance.

12. KEY PERFORMANCE INDICATORS AND QUALITY STANDARDS

Stop Smoking Services are monitored on a quarterly basis by PHE and Fresh and it is the Authority's responsibility to report required data, supplied by the Pharmacies, to NHS Digital on a quarterly basis. Stop Smoking Services can provide behavioural support to clients who are using e-cigarettes and can include this in their national data returns.

The Service provided is monitored by the return of stop smoking data and the following 4 week quitter definition should be followed - 'continuous absence from smoking from day 14 to the 4 week follow-up point'. This means that occasional smoking is permitted in the first 2 weeks of the quit attempt but should NOT be interpreted clinically that this is a strategy that is encouraged.

Performance Indicators

Community Pharmacies are expected to achieve a level of success which is consistently within national limits. The expected success rate of people setting a quit date converting to 4 week quitters ranges from 35% to 70%. Results which fall below the minimum threshold will be investigated in accordance with the exception reporting procedure specified by PHE.

Smoking Status at four weeks from quit date should be CO verified in a minimum of 85% of cases.

The Authority may periodically request information in addition to regularly monitoring the monthly claims for payment submitted to the Authority.

Quality Standards

The Pharmacy will:

- have in place a standard operating procedure for the delivery of the Service.
- participate in any audits of the Service as directed by the Authority.
- demonstrate that Pharmacists and staff involved in the provision of the Service have undertaken CPD relevant to this Service.
- fully comply with North Tyneside's Local Safeguarding Children's Board and Northumberland and North Tyneside Safeguarding Adults Board.
- co-operate with any national or local assessment of service user experience.
- stock and maintain appropriate health promotion material available for the client group and promote its uptake and is able to discuss the contents of the material with the client group, where appropriate.
- ensure Advisors complete annual refresher training sessions.

13. SERVICE SPECIFICATION REVIEW

It is recognised within this Specification that the Service may be subject to change due to a range of national and local policy initiatives, for example, government guidance and legislation, industry professional standards, NICE Guidance, Public Health England or North Tyneside Council policy.

The Service specification will be reviewed annually as a minimum and updated to reflect changes in legislation. Adequate notice will be given to Community Pharmacies of any significant changes which may impact on the service provided and will ensure sufficient transition arrangements are secured to ensure service continuity.

14. FINANCIAL INFORMATION

Payment and reimbursement structure

- A payment of £15.50 will be made for each new client accessing the Service and setting a quit date. This is payable regardless of whether the person has quit smoking or not.
- A payment of £41.00 will be made for every person who has quit smoking at 4 weeks.
- A payment of £2.00 will be made for each supply of NRT through the voucher scheme up to a maximum of 6 vouchers per person (total 12 weeks supply).
- A payment of £13.00 will be made for each initial consultation for Varenicline.
 An additional £4.00 for a first review and £2.00 for each subsequent supply (max 4) (total 12 weeks supply) will be payable.

The relevant drug cost is also payable. The prescription fee will be deducted from payment if collected.

Claims for Payment

Details of registration, consultations and 4 week monitoring must be entered on to Pharmoutcomes in a timely manner to meet claims deadlines to generate claims for payment. This is by the 5th of every month.

All mandatory fields on Pharmoutcomes must be completed in full in order to trigger payment.

For all clients the quit status must be recorded at 4 weeks after the quit date. This must be recorded as a **week 5** entry on Pharmoutcomes. The week 5 outcome must specify whether the client has quit, not quit or is lost to follow up. If this information is not supplied then a payment will not be generated.

Pharmacies will receive a quarterly payment in arrears, which will be generated automatically from data input to Pharmoutcomes. To ensure prompt and accurate payment Pharmacies are required to record information contemporaneously.

The Authority will only make payments for quit dates set and four week quits if they are claimed by the Pharmacy in the same financial year that they occurred.

PAYMENTS WILL ONLY BE MADE UPON RECEIPT OF A SIGNED CONTRACT WITH THE AUTHORITY