SPECIFICATION

Service	**Active Intervention Stop Smoking Service**
Council Lead	**Paul Gray**
Provider Lead	**Pharmacist**
Period	**1st April 2018 – 31st March 2019**

1. Population Needs

National/Local Context and Evidence Base
Through Vision 2030 we have set our long term ambition vision for Gateshead
"local people realising their full potential, enjoying the best quality of life in a healthy, equal, safe, prosperous and sustainable Gateshead."

The Council Plan 2015-2020 sets out how we will achieve this vision over the next two years. As identified in the Council Plan, we are committed to achieving our Live Well Gateshead outcome of a healthy, inclusive and nurturing place for all and reducing our smoking prevalence will contribute to this.

The Joint Strategic Needs Assessment (JSNA) for Gateshead assists in identifying the key features facing people in Gateshead. The JSNA identified key strategic priorities to improve the health and wellbeing of our population. The data identifies that around 29 000 adults in Gateshead smoke. Local survey data highlights wide variations across Gateshead, with highest smoking rates in the most deprived areas. Over one in three adults in routine and manual occupations smoke.

Smoking is the single largest cause of preventable mortality in England. This is recognised in the Government's Public Health White Paper 'Healthy lives, healthy people', which states that 'reducing smoking rates represents a huge opportunity for public health.'

Reducing smoking prevalence is identified as a key outcome in the Public Health Outcomes Framework and local prevalence remains above the national average. Key facts for Gateshead include:

- Smoking remains the single greatest contributor to health inequalities and premature death and disease in Gateshead
- The smoking prevalence rate for adults in Gateshead is 17.9% (2016) which is significantly higher than the England average of 15.5% (2016)
- Over 460 Gateshead residents die every year from smoking related illnesses – around one death every 21 hours.

"Towards a Smokefree Generation - A Tobacco Control Plan" (July 2017) sets out a series of national ambitions for a smokefree generation.

NICE guidance clearly identifies a number of effective stop smoking interventions for everyone involved in, or responsible for stop smoking services, including brief intervention, individual behavioural counselling, group behaviour therapy, pharmacotherapy, self-help materials, telephone counselling and quit lines.

The Provider must work with the Council to deliver Services in line with all National Standards including:

- Towards a Smokefree Generation - A Tobacco Control Plan" (July 2017)
- DoH Excellence in Tobacco Control – 10 High Impact Changes to Achieve Tobacco Control
- National Centre for Smoking Cessation and Training Local Stop Smoking Services: Services and delivery guidance (2014)
- Healthy lives, healthy people: Improving outcomes and supporting transparency – Public Health Outcomes Framework (January 2012)
- Stop smoking interventions and services – NICE guideline 92, 2018
- NCSCT Electronic cigarettes: A briefing for stop smoking services http://www.ncsct.co.uk/publication_electronic_cigarette_briefing.php

In recent years e-cigarettes/vaping have entered the market. They have become the most popular, although not the most effective, way of stopping smoking. While they are 95% safer than tobacco, NHS stop-smoking services still provide the best chance of quitting.

2. Key Service Outcomes

Better health for Service Users:

- Longer life
- Better quality of life
- Reduced use of health services
- Fair access to services

Excellent Service User experience

- Safe care
- Efficient treatment
- High quality service
- Timely access to services
- Using your money wisely

3. Scope

3.1 Aims and objectives of the Service

The primary role of the Provider is to enable smokers to live smokefree lives. The Service the Provider is to deliver must also contribute to a reduction in harm from

tobacco and to the achievement of local and national targets as outlined below:

- To contribute to the Council target of individuals stopping smoking at 4 weeks as set out in Schedule 2
- To provide smoking cessation services to a minimum of 5% of local smokers each year
- To help reduce smoking prevalence to 5% in Gateshead by 2025
- To reduce smoking prevalence in the following priority groups:
    - pregnant women
    - people with long term conditions (including cardiovascular disease, type 1 diabetes, asthma and chronic obstructive pulmonary disease)
    - people with mental health problems
    - black, Asian and minority ethnic communities
    - lesbian, gay, bisexual and transgender communities
    - young people
    - smokers who through the NHS Health Checks Programme are identified as being at higher risk of developing cardiovascular disease
    - those living on a low income
    - the homeless
    - people living with disabilities
- To deliver high quality healthcare, value for money, local access to Services and a positive Service User experience

3.2 Service description

The Provider must make the Service available to any smoker living or working in Gateshead who wishes to stop smoking or to reduce the amount they smoke.

Advice

The Provider must give very brief advice, based upon “Ask, Advise, Act”, to all known smokers unless inappropriate to do so.

Active Intervention

The Provider must deliver a stop smoking Service based on the active intervention model, using motivational interviewing and cognitive behavioural techniques. Stop Smoking support must be provided by Staff who are trained active intervention advisors and may be delivered in a variety of evidence based formats including but not exclusive to 1:1 support, group support (open and closed), and telephone or email interventions. The Service must be delivered by the Provider in line with the standards and techniques laid down in the active intervention training manual.

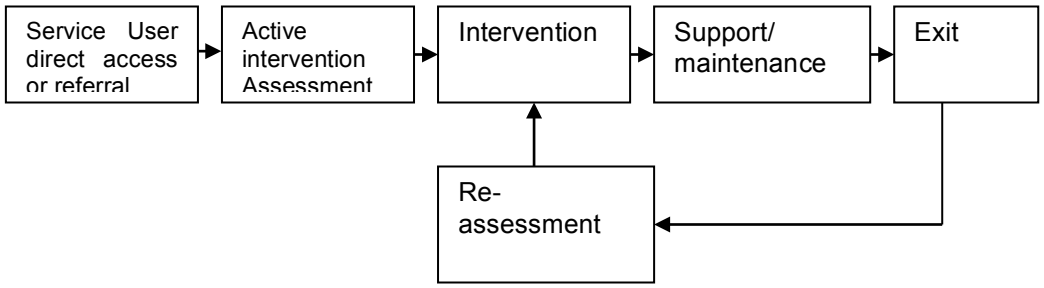
Active interventions are to be provided to Service Users for up to 12 weeks. Additional clinical support may be required for any Service User requiring assessment for prescription only medication.

Definitions

Active Intervention Advisor means the trained advisors appointed by the Provider to provide the Services in accordance with this Contract.

Service means the availability of stop smoking active intervention by the Provider appointed by the Council.

Service Description/Care Pathway



Service User Access

- Service Users may approach the Provider to utilise the Services direct at point of delivery i.e. at a local pharmacy, GP practice, community providers etc.

- The Services are to be provided on a one to one basis or via access to group support, at the discretion of the Provider. The chosen intervention is to be recorded by the Provider for reference at contract monitoring meetings and/or audit. Additional training for stop smoking group work endorsed by the Council can be requested by the Provider.

- The Provider must ensure that dedicated time is available for Active Intervention Advisors to deliver the Service, including the availability of specific appointments times and appropriate private consultation space for Service Users.

- If a Service User cannot be offered an initial contact within 48 hours and an appointment within 3 days then they must be referred by the Provider to another Active Intervention service provider.

- The Active Intervention Advisor is required to facilitate Service User access to individualised support to stop smoking medicines and aids for a maximum of

12 weeks, as detailed in the 'Guidance for people providing a Stop Smoking Service' (Appendix A)

- Some Service Users may need prescription only medication. This will be accessed via the GP with whom the Service User is registered in order to ascertain whether a person will safely benefit from prescription of stop smoking medication, other than Nicotine Replacement Therapy (NRT).

Assessment

- Delivery of stop smoking interventions must have a clear structure and content, which is to be discussed with the Service User by the Active Intervention Advisor prior to engagement and to which Service Users must commit.

- The Provider must inform Service Users of available treatment options and support (as defined by NICE Guidance) prior to commencing a quit attempt. Service Users must also be made aware that some pharmacological interventions may not be clinically appropriate for all individuals.

- The Provider will submit data on the online database for all Service Users and the Quit status must be recorded for both 4 and 12 weeks as "quit", "not quit", or "lost to follow up". If this information is not supplied by the Provider then a payment (in accordance with Schedule 3) will not be generated by the Council.

- **In all cases, the Provider must obtain consent from the Service User to record and share information in accordance with information governance guidelines (see Clause 17 Service User Health Records of the Terms and Conditions of the Contract).**

Intervention

- The Provider must offer stop smoking interventions within professional practice accountability to Service Users who are motivated to stop or reduce smoking.

- The Provider must ensure treatment options that are delivered comply with NICE and NCSCT guidance and current local 'Guidance for people providing a Stop Smoking Service' (Appendix A)

- The Active Intervention Advisor will deliver stop smoking services using evidence-based interventions as appropriate for the individual Service User. These could include:
    - 1:1 support, group support (open and closed) telephone and online support
    - New, non-evidence-based delivery models, which may be piloted on a small scale if agreed by the Council in advance. These must be carefully evaluated and evidence of such evaluation submitted to the Council before being adopted as a significant contributor to overall

service delivery

- The Provider must facilitate access to, and where appropriate, supply stop smoking drugs and aids based on 'Guidance for people providing a Stop Smoking Service' (Appendix A). The Provider must complete all necessary paperwork to gain extra support and access to stop smoking medication for the Service User.

- The Provider and its Active Intervention Advisor must inform the Service User's GP of any stop smoking drugs supplied and of the outcome of the quit attempt.

- Interventions must be efficiently managed and there must be sufficient administrative support for general organisation, Service User contact processes and data handling to ensure all information is submitted in a timely manner.

Supporting a Quit Attempt

To ensure continued monitoring, Service User compliance and ongoing access to medication:

- In weeks 1 – 4 (i.e. the 4 weeks following the quit date) the Provider must offer weekly support for a quit attempt (to ensure relapse prevention) and appointments for sessions must be scheduled when Service Users are booked into treatment.
- In weeks 4 – 12 the Provider is expected to deliver ongoing support at least once every two weeks via face to face meetings, text, phone (as appropriate)
- For individual support, a minimum of 1hr 50mins should be provided by the Provider in the period from pre-quit to 4 weeks post-quit.

Group-based intervention sessions should be at least an hour in length and offer a minimum total of six hours' contact over a six-week treatment period – i.e. pre-quit to 4 weeks post-quit.

Completion

The Provider must ensure that its Active Intervention Advisors carry out a 4 and 12 week follow-up of all Service Users:

- Service Users who do not complete / drop out of the twelve week support programme must be followed up.

- Follow up must be completed in person or by telephone or text contact, with a minimum of 3 attempts by the Active Intervention Advisor to contact a Service User (where telephone contact is not feasible a letter or email must be sent). Where it has not been possible to contact a Service User after 3 attempts the Service User must be recorded as 'lost to follow-up' on the online database, follow up attempts should be documented on the Service User record.

- Smoking status is to be confirmed for all Service Users reported as having quit at 4 weeks by use of a Carbon Monoxide (CO) monitor (See Appendix B, Carbon Monoxide Monitoring Equipment), with the exception of where follow-up has been carried out by telephone. CO verification must be made in a minimum of 85% of cases.

- Adequate Service User records must be maintained by the Provider to facilitate service audits and comply with clinical governance, and kept for a minimum of 2 years. Data must be collected on all Service Users treated to support the accurate calculation of success rates. Such data must be recorded on the online database as soon as possible after the completion of each session with the Service User **(see Clause 17 Service User Health Records of the Terms and Conditions of the Contract).**

- The expected success rate of Service Users setting a quit date converting to 4 week quitters ranges from 45% to 70%.

Access to Medicines

The Active Intervention Advisor must provide the Service User with access to pharmacological aids in accordance with the 'Stop Smoking Product Guide' (Appendix C). However, behavioural support should still be provided to Service Users who wish to use unlicensed, self-purchased products (ie. vaping devices), whether this use is in combination with or instead of a licensed product.

In some circumstances it may be necessary to refer a Service User to their own GP (if unregistered recommend they register with a GP) e.g. for access to clinical advice.

There are 3 routes to access medication for use in the Stop Smoking Services:

1. Voucher of Recommendation (NRT Only) ***(Active Intervention Advisor). The Provider must make this available to the Service User.***
2. Referral through recommendation for extra support and assessment of an individual's suitability (Bupropion and Varenicline) ***(Clinical Intervention/GP). The Provider must recommend this if appropriate to the Service Users needs***
3. Prescription FP10's (NRT, Bupropion and Varenicline) ***(Prescriber/GP). The Provider must recommend this if appropriate to the Service Users needs***

E-cigarettes/vape mods are not provided by the Service. The Service may suggest that heavily nicotine dependent users consider vaping in addition to using other licensed NRT products, but cannot advise on the use of particular devices. For further advice see - http://www.ncsct.co.uk/usr/pub/Electronic_cigarettes._A_briefing_for_stop_smoking_services.pdf

General Medicines Management

The Provider must ensure that Active Intervention Advisors:

- Only recommend pharmacological treatments that are recommended by NICE technology appraisals.

- Do not offer pharmacological treatments that have not been approved for use in Gateshead.

- Do not offer pharmacotherapy outside its product licence.

- Do not offer pharmacotherapy that is clinically inappropriate for the Service User.

- Are required to maintain a record of all pharmacotherapy e.g. by retaining a copy of the relevant Service User monitoring form or entering a record on the GP clinical system or patient medication record.

- Complete a Yellow Card if an adverse reaction is reported by a Service User. (http://yellowcard.mhra.gov.uk)

Voucher of Recommendation (NRT Only)

- The Provider's Active Intervention Advisors who do not have a prescribing qualification, but who have undertaken the local Active Intervention Advisor training may recommend Nicotine Replacement Therapy (NRT) using the approved local NRT Voucher**.** NRT Vouchers must be issued in line with the local 'Guidance for people providing a Stop Smoking Service' (Appendix A).

- Eligibility Criteria for access to the NRT voucher scheme are:
    - Service Users must be motivated to stop smoking and be receiving advice by a trained Active Intervention Advisor.
    - Service Users must live or work within the borough of Gateshead.

- The NRT Voucher is to be completed by the Active Intervention Advisor indicating a recommended course of NRT for up to 12 weeks: this comprises two 1-week periods, followed by five 2-week periods. For each period of either one or two weeks, a single voucher of recommendation for NRT can be issued to the Service User.

- The advisor must record details of the recommended NRT in the Service User's records and on the online database as soon as possible after the completion of each session with the Service User (**also see Clause 17 Service User health records of the Terms and Conditions of the Contract**).

- The Providers participating in the local voucher scheme will provide a voucher of recommendation to the Service User.

- The Service User must be advised by the Active Intervention Advisor that the voucher is a recommendation and may be changed or declined at the point of

dispensing by the pharmacist if the product is deemed to be unsuitable for the Service User.

- The Active Intervention Advisor takes full responsibly for any recommendation that they make through the voucher process.

Referral for recommendation for extra support and assessment of Service User suitability (Bupropion and Varenicline)

- The Provider's Active Intervention Advisors who do not have a prescribing qualification may refer to a GP for extra support and assessment of a person's suitability for stop smoking medications other than NRT (Varenicline or Bupropion) using the approved local letter of recommendation (template letter is available to the Provider from the online database)

- Active Intervention Advisors must inform Service Users that treatments recommended may not be considered clinically appropriate by their GP and may be changed or declined based on clinical judgement.

- Active Intervention Advisors recommending and prescribing pharmacotherapy must follow the 'Stop Smoking Product Guide' (Appendix C).

Prescription FP10's (NRT, Bupropion or Varenicline)

- GP prescriber or independent non-medical prescribers providing stop smoking interventions may prescribe approved stop smoking therapy on an FP10 prescription.

- The Provider's Active Intervention Advisors who are also a supplementary non-medical prescriber may supply stop smoking therapy in accordance with a clinical management plan agreed with an independent prescriber.

- The Provider's Active Intervention Advisors prescribing pharmacological therapy must ensure they maintain their professional competence.

- Prescribers must ensure they have a prescriber code and access to a suitable prescribing budget. Prescribing must adhere to local 'Stop Smoking Product Guide' (Appendix C) and other relevant local prescribing guidelines.

Service Promotion

- Every contact with Service Users is also a Health Improvement contact and the Provider's Active Intervention Advisors should emphasise the benefits of stop smoking and smokefree environments, using nationally branded and listed materials.

- The Provider and the Active Intervention Advisor should promote Local and

National events such as No Smoking Day and Stoptober. The promotional materials for these events will be provided through the Gateshead Council Public Health team and/or Public Health England and/or NHSE.

- If the Provider also delivers NHS Health Checks they must ensure that Service Users who are identified as wanting to quit smoking during their check are offered Services under the terms of this Contract.

- Localised promotional materials will be available from Gateshead Council Public Health team and possibly others for display by the Provider. This will include access to other lifestyle services available to people in Gateshead.

- The Provider must work with the Council Public Health Programme Lead to support local marketing campaigns.

Response Time & Detail and Prioritisation

The Provider must make initial contact with the Service User within 48 hours of receiving the referral (including self-referral) with an appointment offered within 3 days.

Appointments for priority groups (see section 3.1) must be made available within 2 days of referral.

Location(s) of Service Delivery

The Service is to be provided within the locality of Gateshead within the opening hours of the Provider.

The Service shall be delivered from facilities and settings which are suitable for the purpose and support the confidentiality and dignity of the Service User.

Where the Service User is housebound and would usually receive care at home the Provider should consider how the Stop Smoking Service could be extended to that individual, possibly by liaising with other local Providers (ie. General Practices).

Information Management

Each Service User must be required by the Provider to sign a consent form to give permission to retain and share their information. The Provider must keep records of these signatures and produce them to the Council when requested for audit purposes.

In accordance with **Clause 17 Service User Health Records of the Terms and Conditions of the Contract,** the Provider's Active Intervention Advisor must create, maintain, store and retain Service User health records for all Service Users. The Provider must retain Service User health records for the periods of time required by Law and securely destroy them thereafter in accordance with any applicable Guidance.

The Provider and the Active Intervention Advisor must enter information onto the online database, Call it Quits, for payment by the Council and for data monitoring purposes as soon as possible after the completion of each session with the Service User.

Confidentiality

The Provider and the Active Intervention Advisors must not disclose any confidential information unless requested by Council's authorised personnel – this includes:

- The identity of any Service User;
- The medical conditions of, or the advice received by, any Service User.
- Any information that may lead to the identification a Service User.

These are examples only and this list should not be considered exhaustive.

See Clause 13 of the Terms and Conditions of the Contract for further information.

Audit & Inspection

The Provider must allow the Council's internal and other nominated auditors access to all or any papers and service records relating to this Contract for the purposes of audit and consent to the disclosure of relevant information for the purpose of fraud prevention, detection and inspection.

The Provider will be required to undertake occasional audits that are sensible, reasonable and agreed in advance between the Council and the Provider.

See Clause 34 of the Terms and Conditions of the Contract for further information.

3.3 Population Covered

The Provider must make the Service available to all smokers over the age of 12 who reside or work in Gateshead in accordance with equality and diversity legislation.

The Service must accept self-referrals and referrals from a range of community and health professionals, these could include midwives; hospital staff, health visitors; occupational health; pharmacists; primary care staff; community workers and others.

3.4 Any Acceptance and Exclusion Criteria

The Service is only available to smokers over the age of 12. Those who have not smoked in the 48 hours prior to attending their first session are considered non-smokers EXCEPT for those whose quit attempt started during a stay in a secondary care facility. Such Service Users should be supported to maintain their quit attempt even though they have abstained from tobacco during their stay in secondary care.

The exclusive use of nicotine vapourisers is not considered as smoking and the service is not available for those who do not smoke tobacco.

3.5 Interdependencies with Other Services

The Provider and the Active Intervention Advisor(s) are required to work closely with Gateshead Council Public Health to ensure that Staff are appropriately trained and to support the referral pathways. Training and support are available through the Gateshead Council Public Health for all Active Intervention Providers.
(See Schedule 1 for further information)

The Provider is responsible for ensuring the Gateshead Council Public Health team is informed of the details of all Active Intervention Advisors delivering the Service on behalf of the Provider. The Provider is responsible for informing the Gateshead Council Public Health team of any change in circumstances which could affect the delivery of the Stop Smoking Service.

The Provider and the Active Intervention Advisors will be required to work with the Mentor based in Gateshead Council's Public Health to support providers to be able to deliver stop smoking support. The role of the Mentor is to provide guidance to the Provider and the Active Intervention Advisor on the operational delivery of the Service including:

- Paper work
- Advertising material
- Accessing resources
- Retaining Service Users
- Use of the online database
- NRT vouchers
- Training

All Providers must comply with Performance Indicator thresholds (see Schedule 2)

3.6 Any Activity Planning Assumptions

Each Active Intervention Advisor of the Provider carrying out the Services under this Contract is expected to achieve a quit rate at 4 weeks the range of 45% to 70%.

Those Active Intervention Advisors whose rates fall below 45% will be contacted by Gateshead Council Public Health team's Mentor to discuss additional support. Refresher training, observed practice and coaching for Active Intervention Advisors to improve performance will be provided by Gateshead Council Public Health team.

The Gateshead Council Public Health will work with Active Intervention Advisors whose performance falls below 45% for a period of 3 months or more, in which circumstances the Provider will need to agree a specific Performance Improvement Action Plan with the Council. Failure to adhere to the Performance Improvement Action Plan will result in action taken under Clause 25 Termination of the Terms and Conditions of the Contract.

Active Intervention Advisors whose conversion rates are above 70% will also be approached by Gateshead Council Public Health to capture any best practice information about how to achieve these rates so that it can be shared with other providers.

4. Applicable Service Standards

4.1 Applicable national standards e.g. NICE

NICE PH1: Brief interventions and referral for smoking cessation
NICE PH5: Workplace interventions to promote smoking cessation
NICE PH6: Behavioural Change
NICE PH10: Smoking cessation services in primary care, pharmacy, local authorities and workplaces, particularly for manual working groups, pregnant women and hard to reach communities
NICE PH15: Identifying and supporting people most at risk of dying prematurely
NICE PH26: Quitting smoking in pregnancy and following childbirth
NICE PH39: Smokeless tobacco cessation: South Asian Communities
NICE PH45 Tobacco Harm Reduction
NICE PH48 Smoking cessation - acute, maternity and mental health services
NICE quality standard QS43 Smoking: supporting people to stop
NICE quality standard QS82 Smoking: reducing and preventing tobacco use
NICE guideline 92: Stop smoking interventions and services

The Provider and the Active Intervention Advisor are expected to maintain National Centre for Smoking Cessation and Training standards and competencies, including "Local Stop Smoking Services Service and Delivery Guidance (2014)". http://www.ncsct.co.uk/publication_telephone-counselling-for-smoking-cessation-review.php

4.2 Applicable local standards

Not applicable

5. Location of Provider Premises

The Providers address as shown in the Contract Particulars.

APPENDIX A

Guidance for people providing a 'Stop Smoking Service' on the Recommendation and Supply of 'Stop Smoking Medicines' 2014),
http://www.ncsct.co.uk/usr/pub/LSSS_service_delivery_guidance.pdf

Overview

1.1 Intended users
This guidance should be used to support the decision making process of Active Intervention Advisors (Stop Smoking Advisors) when recommending, prescribing or supplying medicines to support stop smoking attempts.
The guidance is intended to cover the Gateshead local authority area.
The guidance is to support the use of medicines, **not alone**, but in conjunction with an evidence based stop smoking support programme delivered by a Stop Smoking Advisor commissioned by Public Health within Gateshead Council.
The guidance therefore relates to the Stop Smoking Service and is not intended to support potential reduction in smoking or periods of abstinence.

1.2 Guidance covers
Medicines only and should be used following appropriate training and in conjunction with Summary of Product Characteristics (SPCs) and Patient Information Leaflet (PILS).
It is the responsibility of the Stop Smoking Advisor to ensure that they have an appropriate knowledge of all products available so that they are able to support the client in making an informed choice about their treatment. This includes, for example, potential side effects, contraindications, cautions and drug interactions.

1.3 Concerns
If the Stop Smoking Advisor has any concerns relating to the provision of medicines, or the health or wellbeing of a client, then they should be referred to an appropriate healthcare practitioner, normally the clients GP.

1.4 Exclusion
The guidance is not intended to remove clinical responsibility for the recommending, prescribing and supply of medicines to support stop smoking attempts.
This guidance does not cover

- The support that is offered in conjunction with medicines
- The process of supply that is employed
- Medicines recommended, prescribed or supplied for reasons other than a stop smoking attempt

1.5 Recommending - for prescription only medicines (varenicline or bupropion)
In making a recommendation to a healthcare practitioner (normally a GP or NMP) to supply a prescription only medicine (POM), it should be remembered that there is a clinical responsibility associated with writing a prescription. It should therefore **not** be assumed that this recommendation will be accepted by the person taking the responsibility for the generation of the prescription. **This should be made explicit to the client at the time of recommendation**.

1.6 Prescribing

The prescriber has clinical responsibility for the generation of the prescription and may choose not to generate a prescription for a client.

1.7 Supply
The supplier, being the pharmacist, has clinical responsibility for the supply of the medicine and retains the right not to dispense a medicine. There would normally be a reason for not dispensing a product and the reason would be made clear to the client. The reason will also be communicated to the Stop Smoking Advisor who made the request to supply. (This would normally be by phone) The potential for the pharmacist to decline to dispense should be made explicit to the client at the time of generation of a voucher or prescription unless the voucher or prescription has been generated with full access to the patient's notes and / or medical history, including concurrent medicines.

1.8 All practitioners should

- **Not** generate a voucher, request a prescription to be generated, prescribe or supply a medicine if they feel that the process is outside their own area of competence.
- **Not** submit to pressure from clients, or other practitioners, to generate a voucher, request a prescription to be generated, write a prescription or make supply of a medicine.
- **Ensure** that they have an appropriate level of indemnity insurance to cover them for their role within the Stop Smoking Service

1.9 Updates and CPD
All practitioners are responsible for ensuring that they are fully aware of the content of the SPCs and the implications of the content on their recommendations

2 NICE Guidance & Gateshead Council Guidance on Choice of Medicine

2.1 NICE (Public health Guidance 10, February 2008)

States that Stop Smoking advisers and healthcare professionals may recommend and prescribe nicotine replacement therapy (NRT), varenicline (Champix®) or bupropion (Zyban®) as an aid to help people to quit smoking, along with giving advice, encouragement and support, or referral to a Stop Smoking Service.

NICE states that one medication should not be favoured over another and that the client should be involved in the choice. However, before recommending, prescribing or supplying a treatment, the following should be taken onto account

- The person's intention and motivation to quit
- How likely it is they will follow the course of treatment
- Which treatments the individual prefers
- Whether they have attempted to stop before (and how)
- Their previous experience of stop smoking aids
- **If there are medical reasons why they should not be prescribed particular pharmacotherapy. (Medicine)**
- **Contraindications highlighted within the product licensing documentation of the pharmacological agents (medicines)**
- **The potential for adverse events associated with the pharmacological agents**
- **Potential drug interactions with other medicines, prescribed or OTC (over the counter,) that the client may be taking**

NRT, varenicline (Champix®) or bupropion (Zyban®) should be recommended, prescribed or supplied as part of an abstinent-contingent treatment, in which the smoker makes a commitment to stop smoking on or before a particular date (target stop date).

2.2 Combinations
Consider offering a combination of nicotine patches and another form of NRT (such as gum, inhalator, lozenge or nasal spray) to people who

- show a high level of dependence on nicotine or
- who have found single forms of NRT inadequate in the past

However, varenicline (Champix®) or bupropion (Zyban®) should not be offered in any combination. Further information relating to combinations can be found in Appendix 1

2.3 Supply
The initial supply of medicines should only last until 1 week after the target stop date. Further recommendations, prescribing or supply should be for a maximum of 2 weeks provided that the client has demonstrated, on re-assessment, that their quit attempt is continuing.

The Stop Smoking Service supports clients for 12 weeks; this includes the facilitation of supply of medicines.

Towards the end of the 12 week period of support it may be that, in exceptional circumstances, there are clients who have maintained abstinence for almost 12 weeks but who are not yet able to cope without the support of medicines.
In these circumstances an extended period of medicines support may be requested, provided that this extension falls within the product licence of the agent being utilised by the patient.

It is considered that an extension of medicines support, for clients who have been abstinent for three months, is appropriate when weighed up against the potential for the client to recommence smoking and when the risks of smoking are weighed up against the risks, and potential benefits, of continuation of treatment.

It is usual for clients requiring support for more than 12 weeks to be referred to a healthcare professional.

In addition to this, provision of treatment beyond 12 weeks is outside the terms and conditions outlined within the Service Level Agreement. Therefore, if it is envisaged that if a client may require treatment beyond 12 weeks via the voucher scheme the commissioner of the service should be contacted in advance of the provision for authorisation to supply. (**0191 4332929**).

If a smoker's attempt to quit is unsuccessful further attempts may be supported.

2.4 Reporting Side Effects and 'Yellow Card Scheme'
Any side effects that the client experiences should be reported using the 'Yellow Card Scheme'. This can be done directly to the CSM (Committee on the Safety of Medicines) using the yellow cards found at the back of the BNF (British National Formulary) or on line at http://yellowcard.mhra.gov.uk/

Advisors who are not in a position to report directly should seek advice from their line manager or the person responsible for the delivery of the stop smoking service within their organisation (this would normally be the contractor who has signed the contract for the service or their deputy).

Clients may also report any side effects or on line at http://yellowcard.mhra.gov.uk/
Further information relating to the Yellow card Scheme can be found at http://yellowcard.mhra.gov.uk/.

Any risks that may be associated with NRT are substantially outweighed by the well established dangers of continued smoking.
Users should stop smoking completely during therapy with NRT. They should be informed that if they continue to smoke while using NRT, they may experience increased adverse effects, including cardiovascular effects. (i.e. effects on the heart and circulation)

NICE has published further guidance on 'quitting smoking in pregnancy and following childbirth' (June 2010).

3. Useful Phone Numbers

Paul Gray
Commissioner of Stop Smoking Service 0191 4332929

Appendix B

Carbon Monoxide monitoring Equipment

All Active Intervention Advisors are allocated an individual Carbon Monoxide monitor (CO monitor) by the Council by the Gateshead Council Public Health team when they complete their basic Active Intervention training.

The Provider is responsible for the management and maintenance of all allocated equipment e.g. CO monitors. The monitors remain the property the Council.

All equipment shall be regularly cleaned, maintained and serviced as required by the Active Intervention Advisors / Provider.

CO monitors are to be calibrated by the Provider according to manufacturer's guidance to ensure accurate recording of results (usually on an annual basis).

Calibration will be carried out at Active Intervention Advisor update training sessions. Support to calibrate equipment can be obtained via Gateshead Council Public Health if required in between routine calibration dates.

Consumables

Disposable mouth pieces and other consumables to support the use of CO monitors are provided free to the Provider by the Council through Gateshead Council Public Health. For information about consumables please contact:

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https://sotw.callitquits.co.uk

APPENDIX C

Stop Smoking Product Guide

Treatment Options

Varenicline (Champix)
Prescription only

0.5mg/1mg (If patient experiences sickness remain at 0.5mg)

Treatment period
12 weeks

Dependency
(fagerstrom score)
Titration is required to optimal dose
Days 1-3 0.5mg once daily
Days 4-7 0.5mg twice daily
Weeks 2-12 1mg twice daily
Set quit day between day 8 - 14

The dose can be reduced to 500 micrograms (0.5mg) twice daily in those who do not tolerate the 1mg dose. Another twelve weeks of treatment can be given to abstinent individuals to reduce the risk of relapse, at the discretion of the GP.

Advantages
Blocks nicotine receptors, reducing cravings and pleasure from smoking.

Disadvantages
Should be used with care in patients with history of a depression. Can cause sickness and drowsiness and dizziness. No licence for under 18 yrs. Not for use in pregnancy, breastfeeding or renal failure. Cautioned with epilepsy. Close monitoring of patients is recommended (particularly those on anti psychotic medication).

Available Products
0.5, 1mg

Zyban (Buproprion)
Prescription only

150mg tablet

Treatment period
7-9 weeks

Dependency
(fagerstrom score)
One 150mg tablet to be taken for the first 6 days, followed by 2 tablets per day for the following 6 to 8 weeks (with at least 8 hours between each tablet). A quit date should be set for between day 11 and 14.

Note: Patient can drop to one tablet per day if they are experiencing side effects.

Advantages
Proven to be effective medication with long-term abstinence rates doubled compared to placebo.

Disadvantages
Many possible contraindications and side effects including drowsiness, dry mouth, insomnia and headaches. Not to be prescribed for use in pregnancy or breast feeding, under 18's, history of liver disease, kidney disease, eating disorders, head injury, seizure risk

Available Products
0.5, 1mg

Assessing dependence

Fagerström test for smoking dependency		**Score**
How soon after waking up do you smoke your first cigarette?	a) Within 5 minutes b) 6-30 minutes c) 31-60 minutes d) After 60 minutes	3 2 1 0
Do you find it difficult not to smoke in places where smoking is not allowed (e.g., hospital, cinema, train)?	a) Yes b) No	1 0
Which cigarette would you find hardest to give up?	a) The first one in the morning b) Any other	1 0
How many cigarettes do you smoke in a typical day?	a) 31 or more b) 21-30 c) 11-20 d) 10 or less	3 2 1 0
Do you smoke more frequently during the few hours after waking than the rest of the day?	a) Yes b) No	1 0
Do you smoke if you are so ill that you are in bed most of the day?	a) Yes b) No	1 0

Scoring

0-2 Very low dependence
3-4 Low dependence
5 Medium dependence
6-7 High dependence
8-10 Very high dependence

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Produced by Gateshead Council | 1465-SS-Sept17

Treatment Options Table illustrating NRT VS dependency

Treatment option	NRT PATCH for single use or as first product when used as a dual therapy	NRT Lozenge & NRT Mini lozenge for single use (max dose of 15 pieces per day)	NRT Lozenge & NRT Mini lozenge when used as a second product (max dose of 15 pieces per day)	NRT Inhalator for single use (max dose 6 cartridges per day)
NRT Available	25/15/10mg 16hr patch 21/14/7mg 24 hr patch	4mg/2mg/1mg (Lozenge) 4mg/1.5mg (Mini lozenge)	4mg/2mg/1mg (Lozenge) 4mg/1.5mg (Mini lozenge)	15mg
Dependency (Fagerström score) Please note: **All doses shown are per day** **Treatment period: 12 weeks**	Weeks 1-4 **Very high / high** 25mg/21mg 1 per day **Medium** 25mg/21mg 1 per day **Low/very low** 15mg/14mg 1 per day Weeks 5-8 **Very high / high** 15mg/14mg 1 per day **Medium** 15mg/14mg 1 per day **Low/very low** 10mg/7mg 1 per day Weeks 8-12 **Very high / high** 10mg/7mg 1 per day **Medium** 10mg/7mg 1 per day **Low/very low** 10mg/7mg 1 per day	Weeks 1-4 **Very high / high** 4mg/ 12-15 pieces **Medium** 4mg/ 8-15 pieces **Low/very low** 2mg /1.5mg 8-12 pieces Weeks 5-8 **Very high / high** 4mg/8-12 pieces **Medium** 4mg/8-10 pieces **Low/very low** 2mg/1.5mg 6-10 pieces Weeks 8-12 **Very high / high** 4mg/ 1-6 pieces **Medium** 4 mg / 1-5 pieces **Low/very low** 2mg/1.5mg 1- 5 pieces	Weeks 1-4 **Very high / high** 4mg/ 8-12 pieces **Medium** 2mg/1.5mg 8-12 pieces **Low/very low** 2mg/1.5mg 3-6 Weeks 5-8 **Very high / high** 4mg/ 4-8 pieces **Medium** 2mg/1.5 mg 4-8 pieces **Low/very low** 2mg/ 1.5mg 1-4 pieces Weeks 8-12 **Very high / high** 4mg/ 1-6 pieces **Medium** 2mg/1.5mg 1-6 pieces **Low/very low** None	Weeks 1-4 **Very high / high** Not suitable **Medium** 6 cartridges per day **Low/very low** 3-6 cartridges per day Weeks 5-8 **Very high / high** Not suitable **Medium** 3-5 cartridges per day **Low/very low** 2-4 cartridges per day Weeks 8-12 **Very high / high** Not suitable **Medium** 1-4 cartridges per day **Low/very low** 1-2 cartridges per day
Advantages	Easy to use with excellent safety and tolerability profile.	Minis more discreet than the standard lozenge. Fast acting.	Easy to regulate dose,could prevent over eating; helpful with cravings; sugar free.	Helps to keep hands/ mouth busy.
Disadvantages	Localised itching/ discomfort may occur at first but should fade. 24 hour patches may cause sleep disturbance.	Stomach upset; stinging in mouth; hiccups; localised irritation. Large lozenge-high sodium content, bulky.	Stomach upset; stinging in mouth; hiccups; localised irritation. Large lozenge-high sodium content, bulky.	Most effective if used with shallow puffing action. Not to be inhaled into the lungs.
Available Products	NRT 16 hour patch: 7 pack NRT 24 hour patch: 7 pack	Lozenge 4mg, 2mg, 1mg pack of 96 or 72 Mini lozenge 4mg, 1.5mg pack of 60	Lozenge 4mg, 2mg, 1mg pack of 96 or 72 Mini lozenge 4mg, 1.5mg pack of 60	Pack of 20, 36

NRT Inhalator when used as a second product (max dose 6 cartridges per day)	NRT Microtab for single use (max dose 40 pieces per day)	NRT Microtab when used as a second product (max dose 40 pieces per day)	NRT Nasal Spray for single use (max dose 32 doses/ 64 sprays per day)	NRT Nasal Spray when used as a second product (max dose 32 doses/64 sprays per day)
15mg	2mg	2mg	Nicotine 10mg mitred spray	Nicotine 10mg mitred spray
Weeks 1-4 **Very high / high** 4-6 cartridges per day **Medium** 2-4 cartridges per day **Low/very low** 1-3 cartridges per day	Weeks 1-4 **Very high / high** 30-40 pieces per day **Medium** 20-25 pieces per day **Low/very low** 12-15 pieces per day	Weeks 1-4 **Very high / high** 20-30 pieces per day **Medium** 15-25 pieces per day **Low/very low** 5-10 pieces per day	Weeks 1-4 **Very high / high** 20-32 doses/40-64 sprays **Medium** 10-20 doses/20-40 sprays **Low/very low** Not suitable	Weeks 1-4 **Very high / high** 5-20 doses/10-40 sprays **Medium** Not suitable **Low/very low** Not suitable
Weeks 5-8 **Very high / high** 3-5 cartridges per day **Medium** 2-3 cartridges per day **Low/very low** 1-2 cartridges per day	Weeks 5-8 **Very high / high** 20-30 pieces per day **Medium** 10-20 pieces per day **Low/very low** 7-12 pieces per	Weeks 5-8 **Very high / high** 15-25 pieces per day **Medium** 5-15 pieces per day **Low/very low** 3-7 pieces per day	Weeks 5-8 **Very high / high** 10-20 doses/20-40 sprays **Medium** 5-10 doses/10-20 sprays **Low/very low** Not suitable	Weeks 5-8 **Very high / high** 3-15 doses/6-30 sprays **Medium** Not suitable **Low/very low** Not suitable
Weeks 8-12 **Very high / high** 1-4 cartridges per day **Medium** 1-2 cartridges per day **Low/very low** None	Weeks 8-12 **Very high / high** 1-15 pieces per day **Medium** 1-8 pieces per day **Low/very low** 1-5 pieces per day	Weeks 8-12 **Very high / high** 1-15 pieces per day **Medium** 1-10 pieces per day **Low/very low** 0-3 pieces per day	Weeks 8-12 **Very high / high** 3-10 doses/6-20 sprays **Medium** 1-5 doses/2-10 sprays **Low/very low** Not suitable	Weeks 8-12 **Very high / high** 1-15doses/2-10 sprays **Medium** Not suitable **Low/very low** Not suitable
Helps to keep hands/ mouth busy.	Can be used discretely; easy to adjust dose; very few side effects.	Can be used discretely; easy to adjust dose; very few side effects.	Works quickly and easy dose adjustment.	Works quickly and easy dose adjustment.
Most effective if used with shallow puffing action. Not to be inhaled into the lungs.	Stomach upset, stinging in mouth; hiccups, localised irritation.	Stomach upset, stinging in mouth; hiccups, localised irritation.	May cause sneezing and irritation at first, runny nose, watering eyes.	May cause sneezing and irritation at first, runny nose, watering eyes.
Pack of 20, 36	2mg Microtab pack of 100	2mg Microtab pack of 100	10mg Nasal Spray (200 sprays per bottle)	10mg Nasal Spray (200 sprays per bottle)

NRT QuickMist for single use (max dose 32 doses/ 64 sprays per day)	NRT QuickMist when used as a second product (max dose 32 doses/ 64 sprays per day)	NRT Gum for single use (max dose of 15 pieces per day)	NRT Gum when used as a second product (max dose of 15 pieces per day)
13.2ml spray	13.2ml spray	4mg/2mg/1mg	4mg/2mg/1mg
Weeks 1-4 **Very high / high** 20-32 doses/40-64 sprays **Medium** 10-20 doses/20-40 sprays **Low/very low** Not suitable Weeks 5-8 **Very high / high** 10-20 doses/20-40 sprays **Medium** 5-10 doses/10-20 sprays **Low/very low** Not suitable Weeks 8-12 **Very high / high** 3-10 doses/6-20 sprays **Medium** 1-5 doses/2-10 sprays **Low/very low** Not suitable	Weeks 1-4 **Very high / high** 5-20 doses/10-40 sprays **Medium** 4-15 doses/8-30 sprays **Low/very low** Not suitable Weeks 5-8 **Very high / high** 3-15 doses/6-30 sprays **Medium** 2-10 doses/4- 20 sprays **Low/very low** Not suitable Weeks 8-12 **Very high / high** 1-15doses/2-10 sprays **Medium** 0-5 doses/0-10 sprays **Low/very low** Not suitable	Weeks 1-4 **Very high / high** 4mg/ 12-15 pieces **Medium** 4mg/ 8-15 pieces **Low/very low** 2mg/ 8-12 pieces Weeks 5-8 **Very high / high** 4mg/8-12 pieces **Medium** 4mg/8-10 pieces **Low/very low** 2 mg/6-10 pieces Weeks 8-12 **Very high / high** 4 mg/1-6 pieces **Medium** 4mg/1-5 pieces **Low/very low** 2 mg/1-5 pieces	Weeks 1-4 **Very high / high** 4mg/ 12-15 pieces **Medium** 2mg/ 8-12 pieces **Low/very low** 2mg/ 4-8 pieces Weeks 5-8 **Very high / high** 4mg/8-12 pieces **Medium** 2mg/4-8 pieces **Low/very low** 2 mg/1-6 pieces Weeks 8-12 **Very high / high** 4 mg/1-6 pieces **Medium** 2mg/1-6 pieces **Low/very low** None
Works quickly and easy dose adjustment.	Works quickly and easy dose adjustment.	Helps to keep hands/ mouth busy.	Helps to keep hands/ mouth busy.
Hiccups, stinging mouth, localised irritation.	Hiccups, stinging mouth, localised irritation.	Difficult with dentures, jaw ache, stomach upset, hiccups, localised irritation.	Difficult with dentures, jaw ache, stomach upset, hiccups, localised irritation.
13.2ml spray, 2 x 13.2ml Spray (150 sprays per bottle)	13.2ml spray, 2 x 13.2ml Spray (150 sprays per bottle)	Nicorette: x 105, x 30 Niquitin CQ: x 96, x 24 Nicotinell: x 96, x 24	Nicorette: x 105, x 30 Niquitin CQ: x 96, x 24 Nicotinell: x 96, x 24

SCHEDULE 1

CONDITIONS PRECEDENT

1. **GPhC**
   Provide the Council the General Pharmaceutical Council Registration Number for the pharmacy premises along with details of a Pharmacy Superintendent and their GPhC Number.

2. **Insurance**
   Provide the Council with a copy of the insurance policies to illustrate that the Required Insurances (as detailed in the Terms and Conditions and Invitation to Tender) are in place;

3. **Training & Qualifications**

- Anyone wishing to provide an Active Intervention NHS Stop Smoking Service must complete the training endorsed by the Council and approved by Gateshead Council Public Health and meet the national competencies for Stop Smoking Advisors (as set out by the National Centre for Smoking Cessation and Training ('NCSCT') http://www.ncsct.co.uk/).

- All Active Intervention Advisors should have completed the NCSCT Stage One online training programme in order to access the 2 days training course. http://www.ncsct.co.uk/

- In addition the Provider/ Active Intervention Advisors are required to meet update requirements, currently attendance at annual update training, or undertake other updates by the Council and be responsible for ensuring that their CO Monitor is maintained and calibrated in line with manufacturer's guidance.

- In the circumstance that an Active Intervention Advisor has been inactive for a period of 6 months then a refresher training session be required to be undertaken before Service delivery can commence.

- In the circumstance that an Active Intervention Advisor has been inactive for a period of one year or more they will be required to complete the full Active Intervention Advisor Training (2 days) to continue practising as an advisor.

- Staff involved in delivery of 'rolling groups' or 'drop in clinics' must be trained to national standards and such groups must be delivered by advisors with sufficient expertise to support quitters at different stages of the quitting process simultaneously. Training to provide this support is in addition to the Active Intervention Advisor training.

4. **Patient Group Directive**

   Not applicable

SCHEDULE 2

PERFORMANCE INDICATORS

The Provider must supply the Council with such information as it may reasonably request for the purposes of monitoring the Provider's performance in relation to this Service.

Data Collection

Service User monitoring forms must be completed by the Provider for each quit attempt using the online database provided by the Council (**https://sotw.callitquits.co.uk**) for each Service User who sets a quit date.

All fields must be completed to ensure data is not lost.

Data returns should include details of Service Users receiving NRT, Bupropion (Zyban) or Varenicline (Champix), as appropriate.

Individual Service User records should be updated on the online database as soon as possible after the session with the Service User.

Data Submission Dates

Data entered onto the database (online database) will automatically be used by the Council to generate payments at the end of each month.

It is the responsibility of the Provider to ensure information is up to date for payment.

Any delay in submitting data will result in a delay in payment.

NHS Stop Smoking Services are monitored nationally and regionally on a quarterly basis. The information for this submission will be taken from the database.

The following table sets out the Performance Indicator Threshold levels to be met by the Provider:

Performance Indicators	Threshold	Method of Measurement	Consequence of breach
Quit rate at 4 weeks	45-70%	Data taken from Online database	Quit rate below 45% support from mentor. Below 45% for 6 months referred to Council's commissioners to review the Contract.
Minimum number of individuals setting quit dates per annum	6	Data taken from Online database	Action under Clause 24 of the Terms and Conditions (Default and Suspension)

CO verified 4 week quit	85%	Data taken from Online database	Action under Clause 24 of the Terms and Conditions (Default and Suspension)
Quit rate at 12 weeks	To be monitored	Data taken from Online database	Action under Clause 24 of the Terms and Conditions (Default and Suspension)

Data will be taken from the online database in the following areas to assess where support is required to the Provider from Gateshead Council Public Health. The Provider must ensure that data is recorded on the online database:-

- Number of individuals setting a quit date
- Number of 4 week quits
- Number of CO verified 4 week quits
- Number of 12 week quits
- Number of CO verified 12week quits
- Number of lost to follow ups

SCHEDULE 3

PRICING

In consideration of the Provider delivering the Service the Council will pay the Provider the following Price

Element to be Delivered	Amount
Quit Date Set	£15.50
4 week quit	£41.00
12 week quit	£41.00

The Provider shall submit to the Council on a monthly basis all information relating to number of quit dates set, 4 week quits and 12 week quits achieved using the online database which will automatically generate a claim for each payment.

It is the responsibility of the Provider to ensure that all data entered onto the online database is accurate and up to date by the end of each month. Any delay in submitting data will result in a delay in payment.

The Council shall pay the Provider the price following verification of the online claims, within 30 days of the end of the month.

The Price shall remain as set out in this Schedule during the financial years 2018 and 2019.

In the event that the Contract is extended in accordance with Clause 2.4 of the Terms and Conditions the Price shall continue at the same rate, unless a variation is agreed with Council. Where appropriate, the Council shall pay the Price on a pro-rata basis in respect of any extension period.

SCHEDULE 4

DATA SHARING FOR SMOKING ACTIVE INTERVENTION SERVICE

DEFINITIONS

Agreed Purposes: The performance by each party of its obligations under this Contract and in order to deliver the Service under the provisions of the National Health Service Act 2006 with the Localism Act 2011 providing the incidental powers to share data in order to allow for payment to be made for the provision of the Service.

Controller, data controller, processor, data processor, data subject, personal data, processing and appropriate technical and organisational measures: as set out in the Data Protection Legislation in force at the time.

Data Protection Legislation: (i) the Data Protection Act 1998, until the effective date of its repeal (ii) the General Data Protection Regulation (*(EU) 2016/679*) **(GDPR)** and any national implementing laws, regulations and secondary legislation, for so long as the GDPR is effective in the UK, and (iii) any successor legislation to the Data Protection Act 1998 and the GDPR, in particular the Data Protection Bill 2017-2019, once it becomes law.

Permitted Recipients: The parties to this agreement, the employees of each party and the Call It Quits Service.

Shared Personal Data: the personal data to be shared between the parties under clause 1.1 of this agreement. Shared Personal Data shall be confined to the following categories of information relevant to the following categories of data subject:

a) NHS number of Service User;

b) Name of Service User;

c) Gender of Service User;

d) Date of birth of Service User;

e) Address and postcode of Service User;

f) Telephone numbers and email address of Service User;

g) Ethnicity of Service User;

h) GP practice and name of GP of Service User;

i) Whether Service User is exempt from prescription charges, pregnant, breastfeeding, their occupational code, health problems of Service User, whether Service User is a user of mental health services, dates relating to the Service User's quit attempts, type of Service intervention received, pharmacological support used, treatment outcomes and notes relating to intervention received by Service User.

j) Name of stop smoking advisor.

1. DATA PROTECTION

1.1 **Shared Personal Data.** This clause sets out the framework for the sharing of personal data between the parties as data controllers. Each party acknowledges that one party (the Data Discloser) will regularly disclose to the other party (the Data Recipient) Shared Personal Data collected by the Data Discloser for the Agreed Purposes and shared via the Call It Quits system.

1.2 **Effect of non-compliance with Data Protection Legislation.** Each party shall comply with all the obligations imposed on a controller under the Data Protection Legislation, and any material breach of the Data Protection Legislation by one party shall, if not remedied within 30 days of written notice from the other party, give grounds to the other party to terminate this agreement with immediate effect.

1.3 **Particular obligations relating to data sharing.** Each party shall:

(a) ensure that it has all necessary notices and consents in place to enable lawful transfer of the Shared Personal Data to the Permitted Recipients for the Agreed Purposes;

(b) give full information to any data subject whose personal data may be processed under this agreement of the nature such processing. This includes giving notice that, on the termination of this agreement, personal data relating to them may be retained by or, as the case may be, transferred to one or more of the Permitted Recipients, their successors and assignees;

(c) process the Shared Personal Data only for the Agreed Purposes;

(d) not disclose or allow access to the Shared Personal Data to anyone other than the Permitted Recipients;

(e) ensure that all Permitted Recipients are subject to written contractual obligations concerning the Shared Personal Data (including obligations of confidentiality) which are no less onerous than those imposed by this agreement;

(f) ensure that it has in place appropriate technical and organisational measures, reviewed and approved by the other party, to protect against unauthorised or unlawful processing of personal data and against accidental loss or destruction of, or damage to, personal data.

(g) not transfer any personal data received from the Data Discloser outside the EEA unless the transferor:

(i) complies with the provisions of Articles 26 of the GDPR (in the event the third party is a joint controller); and

(ii) ensures that (i) the transfer is to a country approved by the European Commission as providing adequate protection pursuant to Article 45 GDPR; (ii) there are appropriate safeguards in place pursuant to Article 46 GDPR; or (iii) one of the derogations for specific situations in Article 49 GDPR applies to the transfer.

1.4 **Mutual assistance.** Each party shall assist the other in complying with all applicable requirements of the Data Protection Legislation. In particular, each party shall:

(a) consult with the other party about any notices given to data subjects in relation to the Shared Personal Data;

(b) promptly inform the other party about the receipt of any data subject access request;

(c) provide the other party with reasonable assistance in complying with any data subject access request;

(d) not disclose or release any Shared Personal Data in response to a data subject access request without first consulting the other party wherever possible;

(e) assist the other party, at the cost of the other party, in responding to any request from a data subject and in ensuring compliance with its obligations under the Data Protection Legislation with respect to security, breach notifications, impact assessments and consultations with supervisory authorities or regulators;

(f) notify the other party without undue delay on becoming aware of any breach of the Data Protection Legislation;

(g) at the written direction of the Data Discloser, delete or return and delete Shared Personal Data and copies thereof to the Data Discloser on termination of this agreement unless required by law to store the personal data;

(h) use compatible technology for the processing of Shared Personal Data to ensure that there is no lack of accuracy resulting from personal data transfers;

(i) maintain complete and accurate records and information to demonstrate its compliance with this Schedule 4 and allow for audits by the other party or the other party's designated auditor; and

(j) provide the other party with contact details of at least one employee as point of contact and responsible manager for all issues arising out of the Data Protection Legislation, including the joint training of relevant staff, the procedures to be followed in the event of a data security breach, and the regular review of the parties' compliance with the Data Protection Legislation.

1.5 **Indemnity.** Each party shall indemnify the other against all liabilities, costs, expenses, damages and losses (including but not limited to any direct, indirect or consequential losses, loss of profit, loss of reputation and all interest, penalties and legal costs (calculated on a full indemnity basis) and all other reasonable professional costs and expenses) suffered or incurred by the indemnified party arising out of or in connection with the breach of the Data Protection Legislation by the indemnifying party, its employees or agents, provided that the indemnified party gives to the indemnifier prompt notice of such claim, full information about the circumstances giving rise to it, reasonable assistance in dealing with the claim and sole authority to manage, defend and/or settle it. The liability of the indemnifying party under this clause shall be subject to the limits set out in 22 of the Terms and Conditions of this Contract.