NHS
Greater Glasgow and Clyde

CLINICAL GUIDELINE

Smoking Cessation Guidelines for Community Pharmacy

A guideline is intended to assist healthcare professionals in the choice of disease-specific treatments.

Clinical judgement should be exercised on the applicability of any guideline, influenced by individual patient characteristics. Clinicians should be mindful of the potential for harmful polypharmacy and increased susceptibility to adverse drug reactions in patients with multiple morbidities or frailty.

If, after discussion with the patient or carer, there are good reasons for not following a guideline, it is good practice to record these and communicate them to others involved in the care of the patient.

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Lead Author:	Val Reilly & Hilary Millar
Approval Group:	Prescribing Management Group

Important Note:

The Intranet version of this document is the only version that is maintained.
Any printed copies should therefore be viewed as 'Uncontrolled' and as such, may not necessarily contain the latest updates and amendments.

1. Introduction

Tobacco use remains the primary preventable cause of ill health and premature death. It is associated with 127,000 hospital admissions and over 10,000 deaths each year in Scotland - around a fifth of all annual deaths rising to around a third in the most deprived areas. Annual costs to NHS Scotland associated with tobacco-related illness are estimated to exceed £500 million per year[1].

Available evidence continues to suggest that the most effective smoking cessation approach is intensive support and pharmacotherapy. In 2015 the average 12 week quit rate for Scotland was 19% and 18% in the most deprived areas. Where no follow-up information is available the quit attempt is assumed unsuccessful[2].

The national target groups for smoking cessation include:

- Socio-economically deprived groups (SIMD1 & 2)
- Young people (12-18 years)
- Pregnant women

The Quit Your Way Pharmacy Service (QYWP) is based on a brief intervention model. Research has shown that by spending 10 minutes with a client and helping them through their quit attempt, their chances of success increase by more than 230% compared with no intervention[3].

The option of obtaining support from the Quit Your Way Community Service should also be offered to QYWPS clients as this enhances quit rates.

Recent study in NHSGGC has demonstrated that those clients attending community pharmacy for pharmacotherapy and motivational support doubled their chance of a successful quit attempt if they also attended a specialist community group for intensive behavioural support[4]. So collaborative work between community pharmacy and specialist smoking cessation groups can quadruple a client's chance of success!

2. Objectives

These guidelines aim to support community pharmacy staff deliver the NHSGGC Quit Your Way Pharmacy Service (QYWPS).
They will:

- Outline service delivery using both Nicotine Replacement Therapy (NRT) and varenicline.
- Explain how service is delivered in partnership with the wider NHSGGC Quit Your Way Service
- Describe management of special client groups
- Offer technical advice on management of equipment such as CO monitors.
- Outline administration of the service through the Patient Care Record (PCR)
- Describe training required and available to NHSGGC staff

3. Aim of the NHSGGC Quit Your Way Pharmacy Service

The aim of the NHSGGC Quit Your Way Pharmacy Service (QYWPS) is to support smoking cessation clients with a structured weekly supply of Nicotine Replacement Therapy (NRT) or varenicline under Patient Group Direction (PGD) from community pharmacies.

The NHSGGC Pharmacy Public Health Improvement (PPHI) team works with NHSGGC Quit Your Way Services to develop and support a network of Quit Your Way-accredited community pharmacies throughout NHS Greater Glasgow and Clyde to provide an easily accessible, cost-effective smoking cessation service.

4. Setting up service for success

It's important that each community pharmacy has a named Champion or Lead member of staff for smoking cessation and a deputy. These individuals don't have to be pharmacists but it would be their responsibility to ensure the consistent delivery of a good Quit Your Way service e.g. encouraging timely PCR entries and follow-up phone calls, ordering support material and monitoring staff training. This ensures that clients receive a consistent service and pharmacies are appropriately remunerated.

The service should be provided in an approved premises e.g. pharmacy, which must have a suitable area for consultation with clients. Ideally this should be a consultation room but a quiet area where discussion might not be readily overheard may be used if a room is not available.

5. Client recruitment

Clients may be recruited to the pharmacy service:

- Directly as the result of a pharmacy consultation
- After signposting by a healthcare professional or specialist NHSGGC smoking cessation service
- After an opportunistic question about smoking habits in the pharmacy
- Upon request to purchase NRT in the pharmacy
- After direct approach from a client for help with smoking cessation

6. The client journey and pharmacotherapy

6.1 Client journey

1. The QYWPS is offered to a client for a maximum period of 12 weeks (varenicline therapy may be offered for up to 24 weeks at the pharmacist's discretion see Appendix 6 and 7). Although a client may return after a failed quit attempt at any time, pharmacists are asked to consider a client's motivation if they return after only a short period of time. They should discuss the reasons for the previous quit attempt's failure.
2. A client history of a smoking cessation attempt should always be entered on the Client Care Record (Appendix 2 and 3). It is **important** that PCR entries are timely and complete as these trigger payments for the service and allows NHSGGC to plan how to develop future services.
3. The client's smoking dependency should be assessed e.g. number of cigarettes smoked, how soon upon waking. (Appendix 4).
4. Carbon monoxide (CO) monitor readings are mandatory at weeks 4 and 12 but for best practice should be taken weekly* Appendix 5 details use of the CO monitor.

**N.B. tasks 3 and 4 may not be necessary if the client is attending a specialist service. The client should present paperwork with documentation of smoking habit and CO monitor readings from the group. However, if they do not have this, the pharmacy may repeat these steps, carefully explaining the reason why to the client.*

The client journey with NRT or varenicline and varying support structures is described in detail in Appendix 6.

6.2 Follow-up, encouraging further attempts and promotion

At least **three** attempts should be made to follow-up clients who have not presented for their appointment in line with local NHS Board procedures. Dates and times of attempts to contact should be recorded within the smoking cessation support tool.

It is reasonable to attempt to contact the client on the same day at different times or on consecutive days by telephone. It is helpful if pharmacies have a proactive plan to encourage clients who have failed to quit or defaulted from the service to make another quit attempt. This would be a key role for a Champion or Lead for smoking cessation in the pharmacy.

6.3 Pharmacotherapy

The NHSGGC Formulary[5] describes recommended NRT products.

Dual NRT therapy, when two NRT products are used in combination, may be used where clients smoke more than 20 cigarettes a day (except in pregnancy or breastfeeding). N.B. not all NRT products are suitable for dual therapy. Dual NRT can be supplied up to 12 weeks.

Varenicline, delivered under PGD, may be considered as an equal first line therapy choice.

For further information on supplying NRT or prescribing varenicline under PGD, please refer to Appendix 7.

The supply of e-cigarettes is not currently offered under the QYWPS, however evidence suggests some clients may find these useful as part of a quit attempt. The community service, (see Section 8.2) offers support to clients attempting to quit with e-cigarettes.

7. Payment schedule for the Service

The QYWPS is part of the National Community Pharmacy Public Health Service and payments are made to a pharmacy at various stages of the client journey. PCR entries must be submitted at week 1, 4 and 12 but no later than weeks 1, 6 and 14 to qualify (see Appendix 8).

Pharmacies obtain stock for the service from their usual supply chain or wholesaler.

Remuneration for pharmacotherapy used is gained by submitting a weekly prescription for NRT or varenicline as appropriate, using a Universal Claim Form (UCF) (n.b. some pharmacies may be required to use a CPUS(5) until software is updated).

8. Service support

8.1 Teams and agencies

As part of the **Pharmacy Services, t**he **Pharmacy Public Health Improvement (PPHI)** team takes the lead on the QYWPS, offering training and advice to community pharmacies. The team will also undertake to mail out or supply support material, CO monitors etc (appendix 5). However, they work very closely with:

- The **Community Pharmacy Development Team (CPDT),** which has responsibility for delivery of the national community pharmacy contract
- **Local smoking cessation services** based in the Health Improvement teams of Local Health and Social Care Partnerships (LHSCP)

The **PPHI team** will usually be the first point of enquiry for community pharmacies but representatives of any of the above teams may visit pharmacies to offer advice or support training events.

8.2 Training

Before accreditation as an NHSGGC Quit Your Way Pharmacy, a minimum of one pharmacist, (who provides cover for most of the working week) from the community pharmacy premises must attend an approved NHSGGC Quit Your Way Pharmacy Services training session. Smoking cessation training is compulsory for every community pharmacy staff member who wishes to be involved in the service and is usually offered as a full day introductory course.

The training programme, which incorporates the NES Smoking Cessation distance learning pack[6] is offered by the PPHI team at regular points throughout the year.

It is open to all pharmacy staff including pre-registration students and counter assistants. Pharmacies are asked to particularly encourage their locum staff to attend training.

In addition to full day introductory courses PPHI offers shorter (usually half-day) refresher courses. Staff should be encouraged to attend one of these at least once every 3 years.

PPHI may also offer specialist courses in response to service developments e.g. varenicline. It is important that staff attend these whenever they can.

8.3 Audit

The PPHI team has worked with community pharmacy clinical governance facilitators to develop an audit of the QYWPS (Appendix 9.). This document is an effective tool for monitoring service delivery, continuing professional development and providing evidence for GPhC inspections.

9. Specialist services

9.1 Working in partnership

NHSGGC Quit Your Way offers a number of specialist smoking cessation services described in the following paragraphs. Clients will be referred to community pharmacies for supply of NRT or varenicline with appropriate paperwork (see Appendix 10a/b for an example).

As much of the client support work, e.g. CO monitoring, is undertaken by the specialist service, it is sufficient for the pharmacy to open a PCR for the client (except Acute referrals) and supply pharmacotherapy on a UCF as required - the requirement for further input is minimal. However, it is important that the pharmacist assesses each client's suitability for the pharmacotherapy recommended by specialist services advisers, particularly varenicline.

> *"Only individuals who are registered healthcare professionals and are allowed to supply prescription only medicines using a PGD are able to use this process. The clinical decision to supply varenicline using the PGD remains with the registered healthcare professional and must not be directed by other healthcare workers".*

However, when a pharmacist has to change a specialist service pharmacotherapy recommendation, it is helpful if they contact the relevant Quit Your Way adviser to outline the reason why.

9.2 Quit Your Way Community Services

Quit Your Way Community Service offers free, intensive support sessions in local venues across Greater Glasgow and Clyde. These sessions last for one hour each week and are relaxed and friendly. Clients can join at any time and will be supported through their quit journey by experienced stop smoking advisers, who provide behavioural support and advice on NRT and non-NRT products available. Heavier smokers (more than 20 cigarettes a day) find this type of intensive support particularly helpful[7].

Clients who are unable to attend the intensive support sessions can contact their local stop smoking service to find out about other support sessions (e.g. drop- ins or 1:1's) that may be available in their area.

The Quit Your Way Community Service is e-cigarette friendly, and although they can't supply e-cigarettes, will offer support to people using e-cigarettes as part of their quit attempt.

9.3 Quit Your Way Youth Service (12-18yrs)

Under revised guidance8, all forms of NRT can now be used by smokers aged 12 years and over. However, it is not recommended that this group uses NRT unless they have access to a support network to ensure that nicotine dependency and motivation to stop has been assessed. Varenicline is not suitable under 18 years. NHSGGC operates the Quit Your Way Youth Service across the Board area for young people aged 18 and under.

A stop smoking adviser will assess the young person's motivation to quit, and their nicotine dependency. If they are suitable, they will complete an NRT request form for the young person to take to a QYWPS pharmacy.

If it is considered that if a young person would benefit from the Quit Your Way Youth Service they should be provided with the Quit Your Way Scotland number 0800 84 84 84

Despite the limited evidence around the use of NRT in young people aged 12 to 17 and the advice to provide support, if a QYWPS pharmacist considers it appropriate (e.g. the young person is a regular smoker and is motivated to stop), they can be signed up to QYWPS in the usual manner even if they do not wish to access the Youth Service.

N.B. when a young person is not accessing the Quit Your Way Youth Service the pharmacist should, if possible:

- Involve the parent/carer in the quit attempt by asking them to accompany the young person to the pharmacy on a weekly basis, as this will aid success.
- Gain consent of a parent or legal guardian if the client is under 13 years of age.
- Follow the advice of the Caldicott Guardian on establishing and recording consent for clients without capacity[9,10].

9.4 Hospital Service

The NHSGGC In-patient Smoking Cessation Pathway[11] describes the management of smoking cessation for in-patients.

When a client is discharged from hospital, a Quit Your Way adviser will give them a pharmacy booklet (Appendix 10a) to complete any course of NRT or varenicline commenced in hospital and pass their details to a community adviser for continued support for up to 12 weeks.

This support is usually by telephone, although the client might attend local support services if they are well and mobile. If varenicline is being used the pharmacist should complete their own varenicline risk assessment checking it is appropriate under the PGD before prescribing to continue a course already started.

Clients identified as wishing to quit smoking at a hospital pre-op assessment will have an electronic request sent to the Quit Your Way team. Community and hospital advisers will liaise to co-ordinate delivery of the client's quit attempt if the timing between pre-op assessment and admission to hospital is short.

9.5 Pregnancy Service

The Quit Your Way Pregnancy Service provides specialist stop smoking support to pregnant women and their families/partners in maternity hospitals and community settings across NHSGGC.

Pregnant women can be referred or self-refer directly to the service by contacting the Quit Your Way Pregnancy team on 0141 201 2335 or at Quityourway.pregnancy@ggc.scot.nhs.uk. The service operates
Monday to Friday from 9.00am to 5pm.

9.6 Housebound clients - Pharmacy Direct

From time to time the QYWPS is asked to support clients who wish to stop smoking but are unable to attend the pharmacy every week for their NRT and/or support, due to illness etc. It is desirable that these clients are supported whenever possible.

The client should be contacted by telephone for weekly behavioural support. This is usually done by a community smoking cessation adviser but if this is not possible, QYWPS pharmacies are encouraged to offer this support.

A week zero entry should still be completed on the PCR. The client should be contacted and relevant sections of the smoking cessation support tool on the PCR completed in the normal way.

9.7 Clients with severe and enduring mental health problems

Mental health specialist teams will always highlight the importance of smoking cessation to their clients. However, they would urge clients on clozapine therapy in particular to speak to their consultant first.

The complex hydrocarbons in cigarette smoke induce the metabolism of clozapine, meaning smokers require comparatively greater doses of clozapine than non-smokers. Stopping smoking reverses this and can result in inappropriately high clozapine plasma levels. N.B this is the case whether NRT or varenicline pharmacotherapy is used.

So if an individual being prescribed clozapine wishes to attempt smoking cessation through the Quit Your Way Pharmacy Service, the pharmacist must contact their consultant psychiatrist or community mental health team to agree a coordinated plan to ensure the safe management of their clozapine treatment during the quit attempt.

For more detailed information on how mental health services manage clozapine clients' smoking cessation attempts see Appendix 11 'Clozapine stopping smoking protocol'.

9.8 Client Confidentiality

When working in partnership with other services and in general, it is important to observe client confidentiality.

General Medical Council Statement-:
"Clients are entitled to expect that the information about themselves or others which a doctor learns during the course of a medical consultation, investigation or treatment, will remain confidential."

Any explicit request by a client that information should not be disclosed to particular people, or indeed to any third party, must be respected save in the most exceptional circumstances, for example where the health, safety or welfare of someone other than the client would otherwise be at serious risk"

Pharmacists and their staff must respect this duty of confidentiality and information should not be disclosed to any third party without the client's consent.

10. Adverse effects of smoking cessation

Pharmacotherapy used for smoking cessation has side effects which are discussed in Appendix 7. However, stopping smoking itself can have adverse effects.

Physiological changes resulting from smoking cessation, with or without treatment, may alter the metabolism of some medicinal products, for which dosage adjustment may be necessary.

Polycyclic aromatic hydrocarbons generated by smoking stimulate cytochrome P450 enzymes, particularly CYP1A2. So smoking cessation may result in an increase of plasma levels of CYP1A2 substrates e.g. caffeine, theophylline, clozapine, warfarin. See the factsheet from UK Medicines Information (UKMi) entitled 'Which medicines need dose adjustment when a client stops smoking?

Caution should be used when supporting clients with diabetes mellitus, hyperthyroidism, peripheral vascular disease, hypertension, stable angina, coronary heart disease, renal or hepatic impairment, phaeochromocytoma, active peptic ulcer disease and epilepsy.

It is always important that these clients stop smoking but they may be more likely to suffer adverse effects as a result of cessation itself e.g. deranged blood glucose levels in diabetes or because their condition increases the chance of an adverse effect e.g. skin reactions to patches. Refer to product SPCs for more information.

Where there has been a serious cardiac event, or hospitalisation for a cardiovascular complaint in the previous four weeks including: myocardial infarction, unstable angina, cardiac arrhythmia, coronary artery bypass graft (CABG), angioplasty, stroke, transient ischaemic attack (TIA), it is recommended to wait for the condition to stabilise before treating with pharmacotherapy. The clinician looking after the client should be involved in the decision to attempt smoking cessation.

In the community setting, specialist approval can be assumed if a client has been commenced on pharmacotherapy in hospital. Or the client might be able to reliably report that their specialist has recommended pharmacotherapy. If there is doubt, it is reasonable to check with the GP that the patient's condition is stable enough for them to commence treatment.

11. References and further material:

1. ScotPHO Smoking Ready Reckoner – 2011 Edition, Scottish Public Health Observatory (ScotPHO), January 2012. Access at: https://www.scotpho.org.uk/publications/reports-and-papers/smoking-ready-reckoner/
2. **ASH Scotland website Access at: www.ashscotland.org.uk/**
3. 'Behavioural support with pharmacotherapy for smoking cessation' NICE Eyes on Evidence July 2016. https://www.evidence.nhs.uk/Search?q=smoking+cessation accessed November 2018.
4. **It's difficult but not ImPOSSILble Presentation from November 2016 Scottish Faculty of Public Health accessed November 2018**
5. NHSGGC Formulary http://www.ggcprescribing.org.uk/
6. NES Smoking Cessation Training http://www.smoking2.nes.scot.nhs.uk/index.html accessed December 2019
7. Review of NHS Smoking Cessation Services – Advisory Group Report http://www.healthscotland.com/documents/23527.aspx accessed December 2019
8. NICE Guidelines 45 Smoking-Harm Reduction https://www.nice.org.uk/guidance/
9. The Information Governance Review https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/192572/2900774_InfoGovernance_accv2.pdf accessed November 2018
10. NHSGGC Staffnet page 'Caldicott Guardian' accessed November 2019 http://www.staffnet.ggc.scot.nhs.uk/Corporate%20Services/eHealth/InfoGovIndex/Pages/Caldicott.aspx
11. NHSGGC In-Client Smoking cessation pathway http://www.staffnet.ggc.scot.nhs.uk/Info%20Centre/PoliciesProcedures/GGCClinicalGuidelines/GGC%20Clinical%20Guidelines%20Electronic%20Resource%20Direct/Smoking%20Cessation%20Pathway%20In%20Clients.pdf

Appendix 1: Useful Contacts

Pharmacy Services

Central Pharmacy Health Improvement Team		
Hilary Millar	Lead Pharmacist Health Improvement	Tel: 0141 201 4945 Fax: 0141 201 4949 e-mail: pharmacyhit@ggc.scot.nhs.uk
Annette Robb	Pharmacy Project Administrators	
Stacey Greer		
Joan Walker		

Specialist Services

Service	**Telephone number**
Quit Your Way Scotland (Helpline available 7 days per week)	(Freefone) 0800 84 84 84
Quit Your Way Pregnancy Service (Helpline available Mon-Fri)	0141 201 2335
Youth Service	0800 84 84 84
Acute service	
Gartnavel, Beatson, Stobhill, Western Infirmary and Glasgow Royal Infirmary	0141 232 0729
Queen Elizabeth University Hospital	0141 451 6112
Royal Alexandra, Vale of Leven Hospital and Inverclyde Hospital	0141 314 6692

IT Support for PCR

Catherine Scoular, IT Facilitator	0345 612 5000 (log call with service desk)

Appendix 2: Smoking Cessation Support Tool

INITIAL DATA CAPTURE

Does the client consent to follow-up? ☑ Yes		
CHI:	First Name:	Surname:
Date of Birth: ___/____/____ Gender: ☐ Male ☐ Female		Title:
Address:	Home Telephone:	
	Mobile Telephone:	required for follow-up
	Work Telephone:	
	Email Address	

Is female, pregnant?

White	☐ Scottish	☐ Irish	☐ Other British	☐ Polish	☐ Other	☐ Gypsy Traveller
Asian	☐ Asian Indian	☐ Asian Pakistani	☐ Asian Bangladeshi	☐ Asian Chinese	☐ Asian Other	
Black	☐ Black African	☐ Black Caribbean	☐ Black Other	☐ Other African	☐ Arab	

☐ In paid employment ☐ Unemployed ☐ Retired ☐ Full Time Student ☐ Permanently Sick or Disabled
☐ Homemaker/ Full time parent/ Carer Other (please specify): ☐ Not known/ Missing

On average, how many cigarettes does the client usually smoke per day?
☐ 10 or less ☐ 11-20 ☐ 21-30 ☐ More than 30 ☐ Unknown

How soon after waking up does the client usually smoke their first cigarette?
☐ Within 5 minutes ☐ 6-30 minutes ☐ 31-60 minutes ☐ After one hour ☐ Unknown

How many times has the client tried to quit smoking in the past year?
☐ No quit attempts ☐ Once ☐ 2 or 3 times ☐ 4 or more times ☐ Unknown

Date Referred to Service.. ___/____/____

☐ Self Referral	☐ HealthPoint	☐ Pharmacist	☐ Quit Your Way Scotland
☐ Dentist	☐ Hospital	☐ Practice Nurse	☐ Prison
☐ GP	☐ Midwife	☐ Stop Smoking Roadshow	☐ Incentive Scheme
☐ Health Visitor	☐ Other (please specify)		

Intervention Setting ☑ Pharmacy

Date of initial appointment: ____/____/____

Intervention(s) used in this quit attempt) ☑ One to one sessionsed care between pharmacy and non-pharmacy services? ☐ Yes ☐ No

☐ NRT only (but more than one NRT product)	☐ NRT and Varenicline (change in product)
☐ Varenicline only	☐ Unknown
☐ Buproprion only	☐ None

Total Number of weeks of known product use (likely to be 0 at the beginning of the quit attempt) update weekly

Does assessment indicate that the client's GP should be contacted to confirm appropriateness? ☐ Yes ☐ No

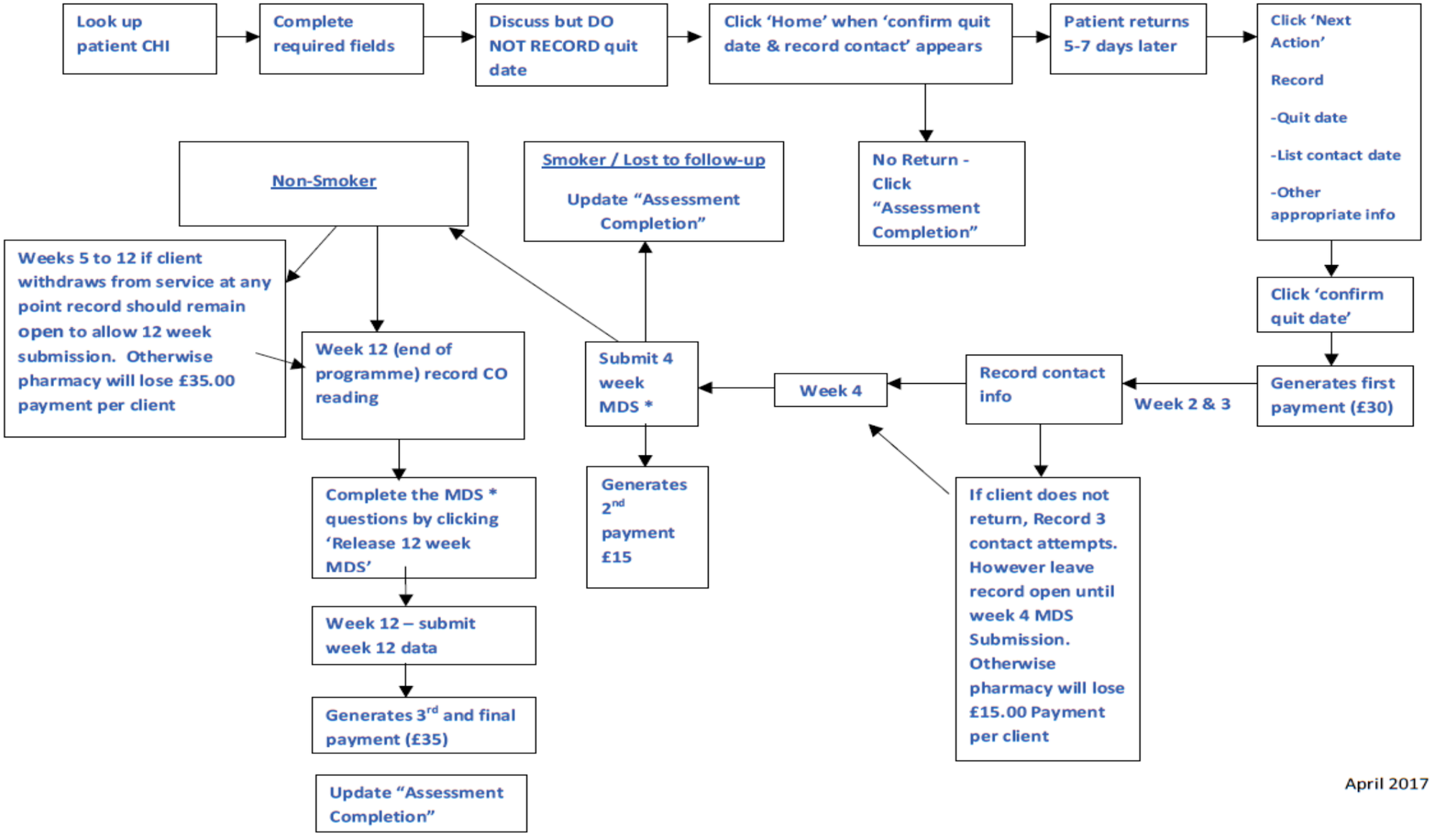
I confirm that I am aware the GP must be informed that the client will begin on Varenicline ☐

Do not set at wk. 0, wait until actual quit starts i.e. wk. 1 – because follow-up/MDS prompts are calculated from the actual quit date. MDS will only be sent once quit date confirmed – triggers remuneration

___/____/____

Quit Your Way Pharmacy Service 0141 201 4945 or pharmacyhit@ggc.scot.nhs.uk

PCR Data Recording Flowchart for Smoking Cessation



April 2017

Appendix 3

Smoking Cessation and Pharmacy Care Record (PCR)

Before starting a new assessment check the following:

- Does the client consent to follow-up? – If No, do not proceed as it is no longer permitted under the new rules.
- Is the client pregnant or breastfeeding? – If Yes, offer referral to the Quit Your Way Pregnancy Service. However, if the client does not wish this, make a note that referral was declined
- Is the client under 18 years? – If Yes, offer referral to the Quit Your Way Youth Service. However, if the client does not wish this make a note that referral was declined
- Is the client taking clozapine? - If yes, advise client that the pharmacist needs to speak to their mental health team before proceeding.

PCR will check for other quit attempts at other community pharmacies recorded in the last 12 weeks. If identified, a new quit attempt cannot be started unless undertaken at the same pharmacy as the previous attempt.

Selecting the client

- It may be necessary to create a record for the client
- A CHI look-up function is available (CHI is mandatory)
- The mandatory client information for smoking cessation clients differs from the normal PCR requirements. It is necessary to record the following additional information:
  - Address 1
  - Postcode – *please ensure this is entered correctly and in full or submission will be rejected.*
  - Home phone number

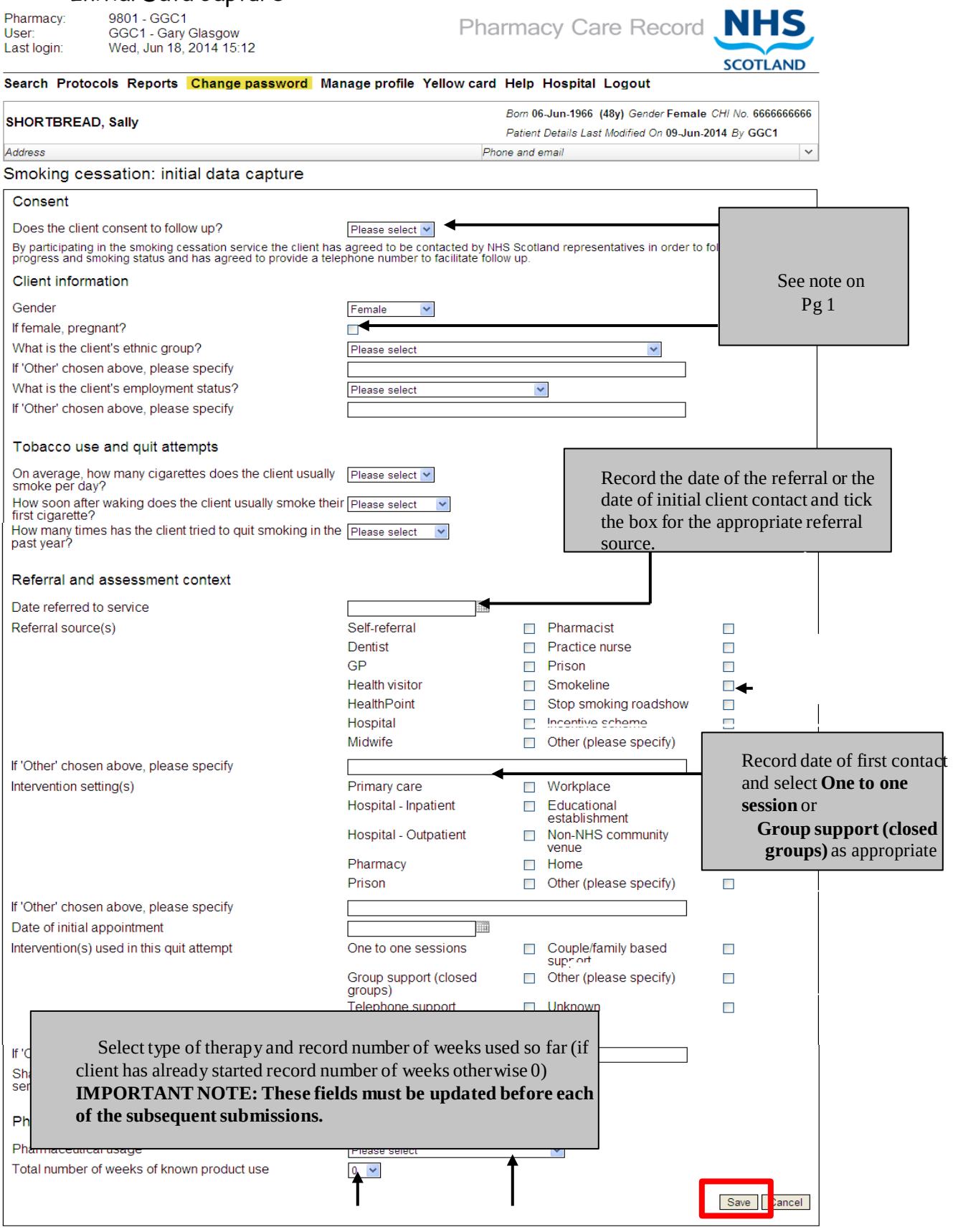
Submission of data sets

After each submission check that the Minimum dataset section **Status** is shown as '**Validated/Failed'** and the **Release Status** as '**Submitted'**.

Reimbursement

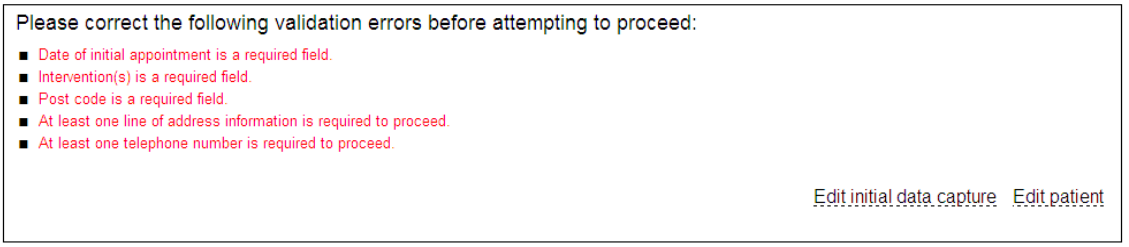
- A UCF form should still be completed for reimbursement purposes
- The client's CHI number should be included

- Initial Data Capture



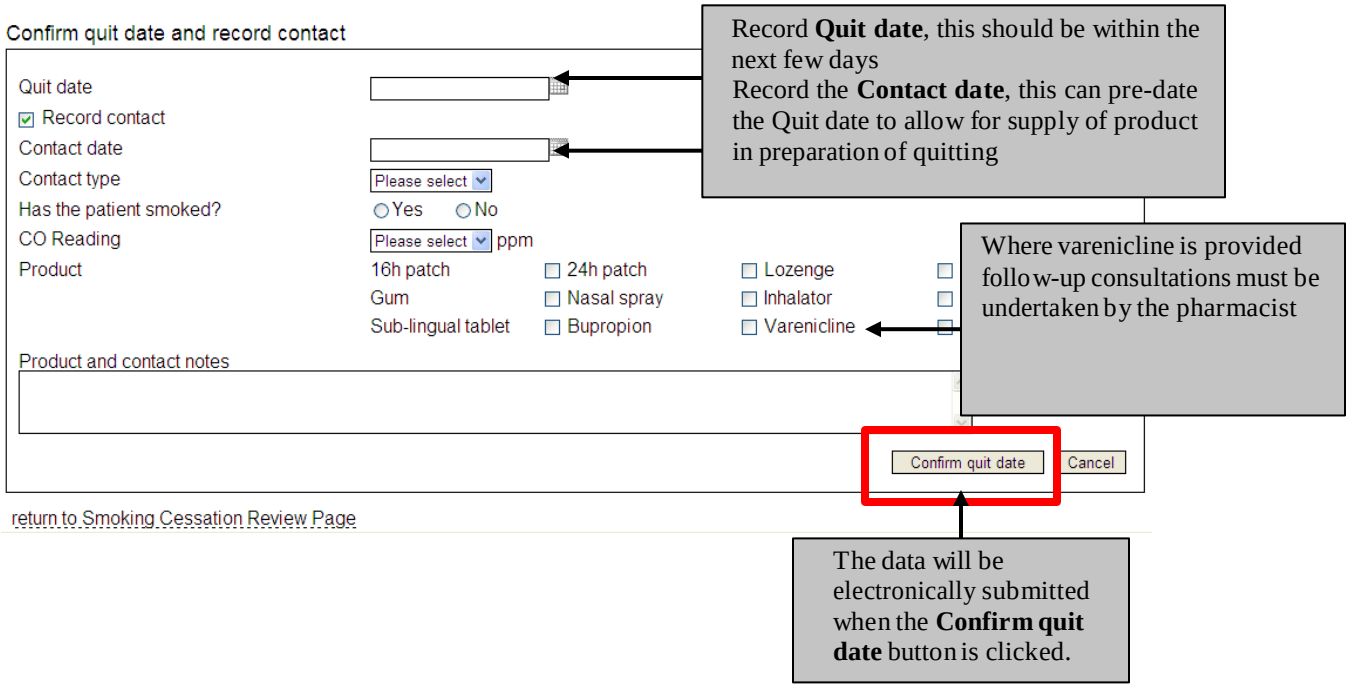
Start Quit Attempt and Confirm Quit Date

Before recording the quit attempt information any missing data will be highlighted. Use the **Edit initial data capture** or **Edit client** links to update.



The quit date is not editable and drives the dates for the 4 week and 12 week submissions. It is recommended that at the point of initial appointment a provisional date is discussed but only recorded at the point of the first return appointment.

When the client returns on the agreed date (around 7 days after initial visit) use the link in the **Next Action** section to record the quit date and first contact.

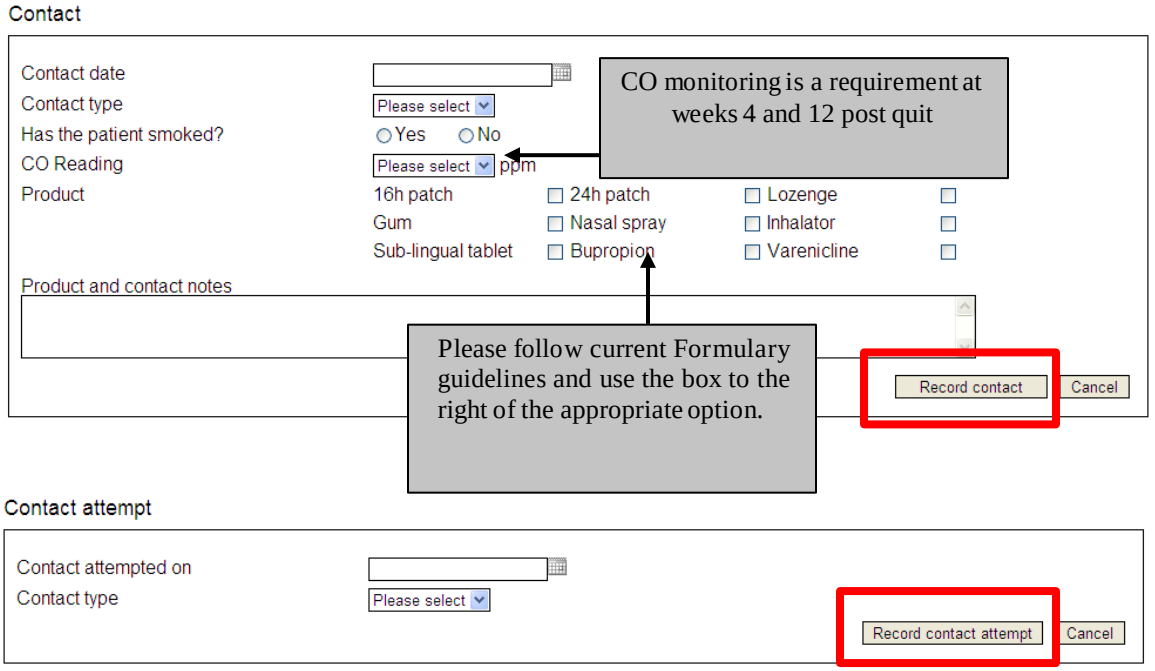


Please continue to follow local formulary guidance when supplying products.

If appropriate e.g. client is sufficiently prepared, the quit date and contact can be recorded at the initial appointment

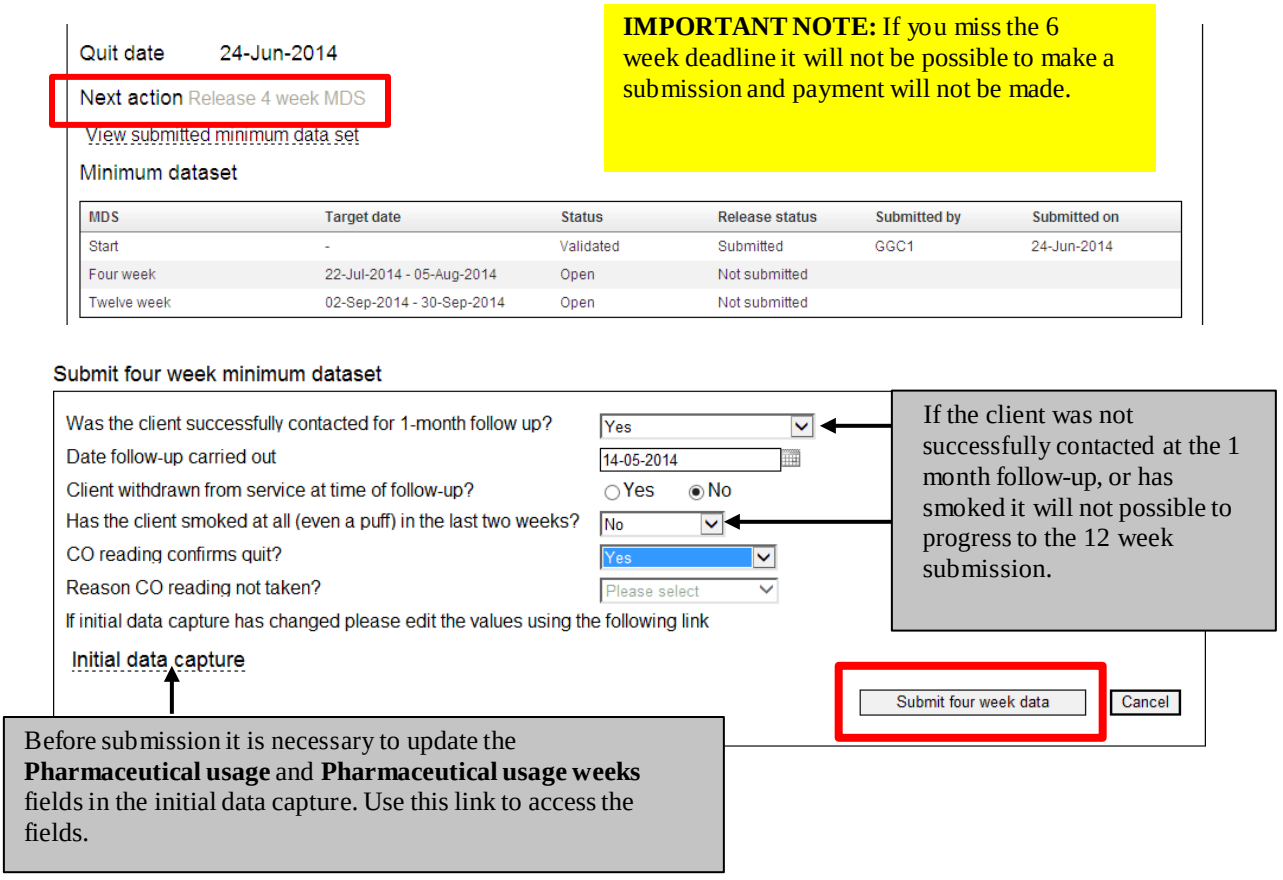
Recording a Contact

Record a contact each week as current practice. If this is not possible record the date and type under the Contact attempt section.



Submit 4 Week Data

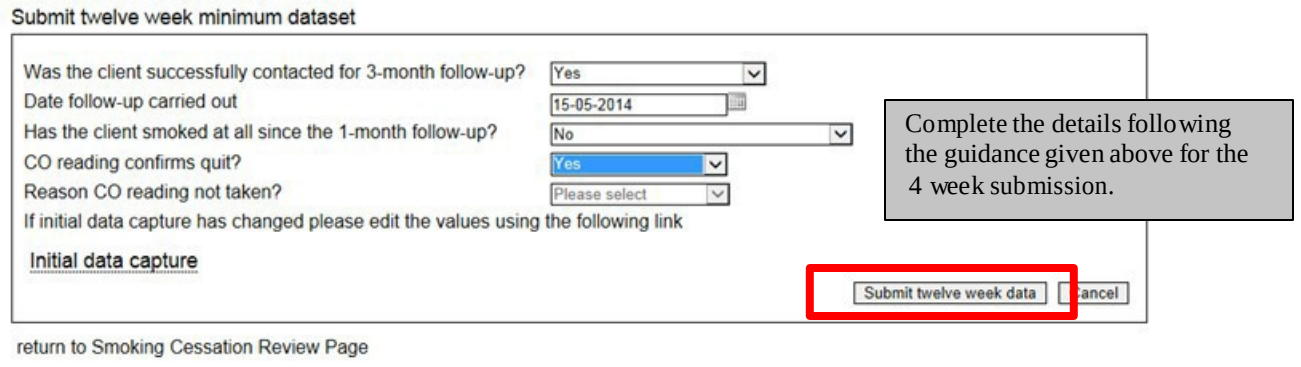
The link to release the data will be made available in the **Next Action** section between 4 and 6 weeks.



Submit 12 Week Data

The link to release the data will be made available in the **Next Action** section between 12 and 14 weeks.

It is not possible to submit the date if this submission window is missed and payment will not be made.

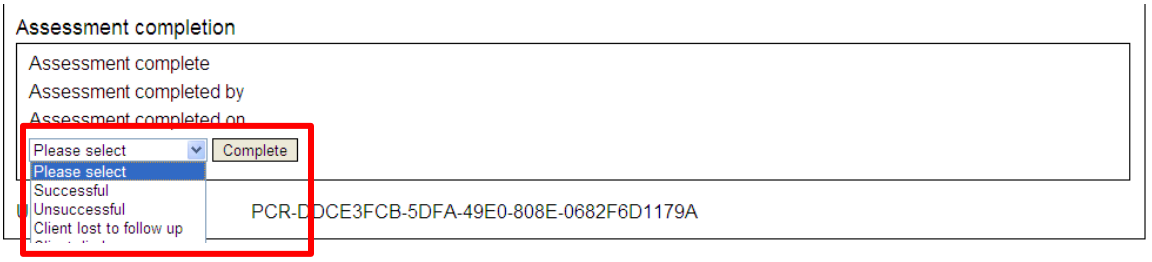


Recording the Assessment Outcome

If at any point the client is no longer attending the pharmacy and is not contactable, it should be recorded in the **Assessment completion** section as **client lost to follow-up**.

If the client is found to have smoked in the 2 weeks prior to the 4 week submission or smoked more than five cigarettes since the last submission at week 12 an **Unsuccessful** result should be recorded.

If the client has quit at week 12 then the assessment should be recorded as **Successful**.



At least 3 separate attempts must be made to contact the client at week 4 and 12 before recording that they have been lost to follow-up.

If recording as lost to follow-up the Health Board should be informed using the local protocol.

Smoking Cessation Reports

Additional reports have been created to support the smoking cessation service.

It is recommended that you familiarise yourself with these and in particular:

- **Expiring within next 7 days** – IF A SUBMISSION IS MISSED IT IS NOT POSSIBLE TO PROCEED AND PAYMENT WILL NOT BE MADE.
- **No interactions in last 7 days**

Appendix 4: Cigarette equivalents for tobacco users

Cigarette equivalents for tobacco users
Pipe smokers
One bowl of tobacco is roughly equivalent to 2.5 cigarettes Take the total number of bowls of tobacco smoked per day and multiply by 2.5

Cigar smokers	**Approximate number of cigarettes**
One small size cigar e.g. Café Crème	**1.5 cigarettes**
One medium size cigar e.g. Hamlet	**2 cigarettes**
One large size cigar e.g. Havana	**4 cigarettes**

Roll-your-own smokers
The smoker may not know how many 'roll ups' they smoke in a day or assert that they vary the quantity of tobacco they use. However, they should be able to estimate how many grams or ounces of tobacco they use weekly. 25gms (1oz) of tobacco is approximately equivalent to 50 cigarettes. N.B. Most common weights of rolling tobacco purchased are 25g and 50g. However, packs available for sale in UK might range in weight from 9g to 100g. To calculate cigarette equivalents, multiply the number of 25g (1oz) units of tobacco used weekly by 50 divided by 7 to approximate the daily smoking habit. e.g. 75g tobacco smoked weekly is calculated 75/25 = 3 X 50/7 = 21.4 So approximately 21 cigarettes per day are consumed.

Grams (ounces) of tobacco smoked per week	**Approximate number of cigarettes per day**
25gms tobacco (1oz)	*7*
50gms tobacco (2oz)	14
75gms tobacco (3oz)	21
100gms tobacco (4oz)	28
125gms tobacco (5oz)	35
150gms tobacco (6oz)	42

Appendix 5: Carbon monoxide (CO) monitoring

What is CO?

Carbon monoxide is a toxic, odourless, colourless, tasteless gas. When a smoker inhales smoke from a cigarette, CO is absorbed into their blood through their lungs. It is dangerous because it binds to the haemoglobin in the red blood cells about 200 times as readily as oxygen, depriving the body of oxygen.

What does a CO breath test show?

A CO breath test shows the amount of carbon monoxide in parts per million (ppm CO) in the breath, which is an indirect, non-invasive measure of the percentage of blood carboxyhaemoglobin (%COHb).

Please consult the user manual for more detailed information on the CO monitor.

General infection control processes

The general infection control processes described below must be adhered to when using the CO monitor.

A new **single-use** disposable mouthpiece should be used for each breath test taken.

Bedfont – piCO$^+$ Smokerlyzer CO Monitor Protocol for use

In order to minimise the chance of infection when using CO monitors, we would recommend the following procedure.

1. Wash hands with hot water and soap before starting session or if no hot water and soap available, use non-alcohol hand gel
2. Attach D-piece
3. Attach new disposable mouthpiece
4. Use a new mouthpiece for each client
5. After each test ask the client to remove the mouthpiece and place in a leak-proof bag for disposal
6. Remove D-piece to allow air to circulate through sensor
7. Clean D-piece with a non-alcohol wipe after each use and replace the D-piece every month.
8. After CO reading is completed, wash hands with hot water and soap or if no hot water and soap available, use non-alcohol hand gel
9. Replace D-piece every month or more frequently if visibly soiled

If the monitor screen shows the image of a screwdriver or you have any concerns, switch off, remove the batteries and leave for ten minutes approximately. At the end of that time, after replacing the batteries, the machine should work. If not, please call 0141 201 4945.

Avoid using perfume, hairspray, air freshener or alcohol hand gels near the sensor as they may affect the reading. N.B. Alcohol on the client's breath should have no effect as the monitor's filters can process this.

If using gloves, avoid risks of latex allergy by using latex-free gloves.

Extra mouthpieces and D-pieces are available from the Quit Your Way Pharmacy Service office.

Appendix 6: Client journey through the Pharmacy Service

Pre-quit attempt: week 0 – Discussing the options

The first client consultation may require 10 to 15 minutes Clients can be seen by either a trained assistant or pharmacist, except if the client is:

- under 18 years of age
- pregnant/breastfeeding
- has a medical condition or
- is asking about varenicline

Where the pharmacist must be consulted.

N.B. Specialist service clients won't be seen in pharmacy at Week 0, as their pre quit status will have been assessed at their session.

Check that the client isn't presenting from a specialist service.
If they are, ask them for the relevant paperwork to enable data upload to the PCR.

Assess the client's current smoking status and previous quit attempts.

Confirm the client is motivated to stop smoking.

Ascertain if specialist smoking cessation support is preferable and highlight specialist services such as Pregnancy and Youth Services.
Refer as appropriate. **Discuss**:

- Pharmacotherapy options and suitability for these: NRT- patches, lozenges, gum, dual therapy, varenicline - refer to pharmacist if required*.
- The advantages and disadvantages of stopping smoking.
- The 'How to stop smoking and stay stopped' booklet available at . Showing relevant sections to the client and encouraging them to complete these.
- The return appointment in about a week's time if client is ready to quit.

Obtain consent to follow-up the client. This would include phone calls after occasions when the client fails to attend the pre-arranged appointment. N.B. If client does not consent, they are ineligible to join the Service.

Record the client's details and motivation to quit in the smoking cessation support tool within PCR. This must include contact details for follow-up. Include area dialling code if a landline number is given e.g. 0141…

Do not set the quit date in the smoking cessation support tool at this stage and do not provide pharmacotherapy.

***** *Only a pharmacist who has signed the Varenicline PGD may carry out the varenicline risk assessment. They may contact the GP for additional clinical information as required to complete the clinical checklist*

Appendix 6: Client journey through the Pharmacy Service

If a suitably trained pharmacist is not available, arrange for the client to return at a suitable time for assessment.

The varenicline risk assessment form should be retained in the pharmacy for three years.

Return appointment - week 1- Setting the quit date

This may be more or less than a week from the initial contact with the client depending on the time it takes for them to consider their quit attempt.

The client may be seen by a trained assistant who can take them through most stages of this consultation.

However, if varenicline is required, a suitably qualified pharmacist must assess and counsel the client for pharmacotherapy.

Determine the client's smoking status using the CO monitor and provide feedback to the client as appropriate.

Record the results of the CO reading in PCR and on the client's *CO Monitoring Card*.

Discuss pages from the relevant sections of the *'How to stop smoking and stay stopped'* booklet to ensure the client wants to stop smoking.

Encourage the client to provide a quit date and record this in the PCR. N.B. This will depend upon the pharmacotherapy chosen, see below.

Provide pharmacotherapy in line with GGC formulary*.

Complete a UCF form for all product(s) supplied. N.B. The UCF form should be written weekly and the client's CHI number must be on the form for payment to be processed.

Explain to the client that their data will be recorded on the national database, i.e. that by signing the UCF form they are consenting tor data-sharing with relevant NHS personnel, they may be contacted for follow-up later and if they do not attend arranged appointments they will be contacted to reschedule.

Arrange follow-up appointments at weekly intervals for up to a 12 week period.

Give encouragement to continue the quit attempt.

Submit the MDS data detailing the 'quit date' from PCR electronically immediately after the appointment. This will trigger the **first payment of £30.** N.B The PCR will set week 4 and 12 dates by the 'quit date' set at this time.

***NRT clients**:*

***Ensure** that the client has been fully assessed for the use of NRT in relation to medical conditions, medicines, and pregnancy/breastfeeding.*

***Confirm** quit date for within the next few days.*

Check dose of NRT is adequate for needs of client e.g. clients using the Nicotinell 21mg patch who are smoking on average 20 cigarettes or more per day are eligible for a small quantity of a second NRT product throughout their 12 week journey for breakthrough cravings.

Varenicline clients (Pharmacist only):

***Provide** the 2 week titration starter pack and explain how to take.*

***Confirm** the quit date between 7 and 14 days after starting.*

Appendix 6: Client journey through the Pharmacy Service

Request the client returns in 1 week for support only.

Inform the client's GP that they will be prescribed varenicline from the pharmacy, (See Appendix 7).

Follow-up – weeks 2 and 3

This is a crucial period: the client is just starting their quit attempt and will require encouragement. They may require reassurance about side effects in particular

As week 1 but in addition or particular:

Discuss any difficulties with cravings.
Offer suggestions on how to cope with cravings if required.
Assess compliance with and suitability of pharmacotherapy.
Reinforce the correct use of product and discuss any concerns about side effects**.
Provide further supply of pharmacotherapy in line with GGC formulary
Complete a UCF form for all pharmacotherapy supplied. N.B. supply is weekly and the client's CHI number must be on the form for payment to be processed.
Remind the client that they have given permission to record their data on the national database, and that by signing the UCF form they are consenting for data-sharing with relevant NHS personnel and may be contacted for follow-up later. If they do not attend arranged appointments they will be contacted to re-schedule.

Give encouragement to continue in the quit attempt!

Follow up clients who do not present as anticipated e.g. through a pro-active telephone call. At least **three** attempts should be made to follow up clients who have not presented in line with local NHS Board procedures. Dates and times of attempts to contact should be recorded within the smoking cessation support tool.

If the client is deemed to have ended their quit attempt, keep the quit attempt open on PCR and once the 4 week MDS data is released record the attempt as unsuccessful, and submitted. This will ensure the follow up payment. It can then be closed down.

***If client is experiencing side-effects with varenicline, consider reducing the dose to 0.5mg twice daily or alternatively stopping varenicline and commencing on a course of NRT.*

Appendix 6: Client journey through the Pharmacy Service

Follow-up - week 4:
The client should now be established in their quit attempt. They must be encouraged to continue with their pharmacotherapy for the best chance of success. They should have stopped smoking by this stage.

If the client reports they are still smoking i.e. reports having smoked 5 or more cigarettes at the 4-week post-quit date, the quit attempt is deemed unsuccessful.

A new quit attempt can be started at any point thereafter only if the new quit attempt is undertaken at the same community pharmacy. If a client wishes to attend a different community pharmacy, they would have to wait until 12 weeks after their last quit attempt because a different community pharmacy PCR would not accept their details until that period had elapsed.

In general it is best to allow time to elapse for clients to renew motivation, re-prepare, and have a better chance at a subsequent quit attempt.

As week 1 but in addition or particular:

Record the results of the CO reading on the CO monitoring card and in the smoking cessation support tool within PCR. A record of the CO reading at **4** and **12** weeks is mandatory.
Issue the ***Four Week Certificate***, if the client is a non-smoker***.
Submit the MDS data detailing the quit date from PCR electronically preferably **immediately** after the 4-week post-quit date appointment but no later than 6-week post-quit date. This will trigger the **second payment of £15** N.B if the PCR data is not submitted by week 6 no subsequent payments may be claimed even if the client is a non smoker at 12 weeks.
Complete a UCF form for all product(s) supplied. N.B. supply is weekly and the client's CHI number must be on the form for payment to be processed.
Follow up clients as detailed in weeks 2 and 3. This should be completed for all clients *even* if they have defaulted at an earlier week of treatment. This is important as recording follow-up attempts for defaulting clients will trigger the **£15** payment.

- ensure that an entry into the PCR is made for week 4 no later than week 6. If this is not done then subsequent information entered onto the system will not generate a payment.

****A reading below 10ppm on the CO monitor suggests a non-smoker. The client's own history is most important. Investigate higher than expected CO levels in clients with unexpected high CO readings as this may be due to environmental exposure e.g. faulty gas boiler or heater.*
Reported smoking of 5 cigarettes or more means that the client is a smoker and a new quit attempt should be started.

Appendix 6: Client journey through the Pharmacy Service

Follow-up - Subsequent weeks up to the 12 week
As week 1 but in addition or particular: **Issue** the ***8 Week Certificate*** at 8-weeks-post-quit date. **Continue** to give encouragement and advice as required by the client and in line with national and local guidance to support the quit attempt. **Follow up** clients as detailed in weeks 2 and 3
12 week date follow-up appointment:
Determine the client's smoking status using the CO monitor to provide feedback****. **Record** the results of the CO reading in the smoking cessation support tool within PCR. **Congratulate** the client and encourage them to stay quit. **Issue** the ***12 Week Certificate.*** **Submit** the MDS data from PCR electronically **immediately** after the appointment but no later than 14 weeks after the quit date. This will trigger the **final payment of £35.** **Follow up** clients as detailed in weeks 2 and 3. If they have defaulted between weeks 7 and 12, contact the client, record smoker or successful quit and submit MDS data. **If the client is lost to follow up record this on the PCR and submit the MDS data. Lost to follow up clients can be followed up by the PHHI team. Once the 12 week payment is verified the quit attempt can**
Beyond week 12
If at the week 12 appointment, the client reports having more than five cigarettes since the 4 week follow-up, they are deemed a smoker. Any further cessation support to such a client should be defined as a **new quit attempt**. This may be started at any point thereafter based on the professional judgment of the pharmacist. Occasionally a client who has stopped smoking may benefit from varenicline therapy beyond 12 weeks. Usually this may just be for a few weeks while the client is reassured cravings will not return. Treatment up to 24 weeks is described in the product SPC and at the pharmacist's discretion may be offered, although no further payment is offered under QYW. Where a client has quit smoking but requires advice beyond the 12 week period then they should be advised that they can also seek support from local specialist smoking cessation services and the national telephone support line, Quit Your Way Scotland on 0800 848 484. The service is open every day from 8am – 10pm and is supported by a website which offers interactive web chat with trained support staff http://www.nhsinform.scot/smokeline

Appendix 6: Client journey through the Pharmacy Service

Promotional materials

Pharmacies may use promotional material provided by manufacturers. Promotional materials which may be used throughout the client journey are also available from Pharmacy Health Improvement.
Subject to availability. Call 0141 201 4945 or email:
pharmacyhit@ggc.scot.nhs.uk.

See Appendix 12. For order form

Appendix 7: Pharmacotherapy

Nicotine Replacement Therapy (NRT)

Detailed information on the types of NRT available may be found at http://emc.medicines.org.uk/ in the manufacturer's Summary of Product Characteristics (SPC)

Nicotine patches have been used for a long time and are very cost effective, however inhalators, nasal or mouth sprays are very expensive and do not represent good value to the NHS and should not be used without prior consent from the QYW Pharmacy team (0141 201 4945)

National Procurement (Scotland) has negotiated advantageous prices for supply of certain therapies.

So the choice of NRT should be guided by the NHSGGC Formulary whenever possible.

1st Line formulary products		
	Dose	**Usual number of packs to be supplied**
Nicotinell patches	**Nicotinell Patch** (21mg,14mg or 7mg) 24 hour patch Max. one daily	1 pack of 7 patches
2nd line/ Suitable for dual NRT For the products below which may be used 'as required' check the quantity the client requires on a weekly basis and adjust their prescription to suit		
Gum	**Nicotinell** (2mg and 4mg) Gum, mint, fruit, liquorice. Max. 15 pieces daily	1 pack of 96 pieces
Lozenge	**Nicotinell** (1mg and 2mg) Lozenges, mint Max. 15 lozenges daily	1 pack 96 lozenges
Minis lozenge	**NiQuitin®** (1.5mg & 4mg) Mint or Orange Max. 15 minis lozenges daily	2 x 60 pack size.

N.B. All NRT pharmacotherapy supplied under a UCF should be issued with a prescription label as a dispensed item.

Dosage regimens

Nicotinell® 24 hour patch

	Step 1 Weeks 1 to 4	**Step 2 Weeks 5 to 9**	**Step 3 Weeks 9 to 12**
	Initial treatment period	Step down treatment period	Step down treatment period
< 20 cigarettes a day	14mg	7mg	May not be needed but further supply may be made if necessary
20cigarettes a day or more	21mg	14mg	7mg

These are 24 hour patches but clients may remove the patch at bedtime if preferred, especially if they are experiencing problematic vivid dreams.

Pregnant and breastfeeding women are also advised to remove the patch at bedtime to reduce exposure to nicotine.
It should be noted that NICE guidance does not differentiate between the efficacy of 16 and 24 hour patches.

Nicotinell® Mint, Fruit or Liquorice Gum 2mg and 4mg Less than **30** cigarettes daily 2mg gum (max **15** pieces/day) Over **30** cigarettes daily 4mg gum (max **15** pieces/day)
N.B liquorice gum is not suitable for pregnant clients

Nicotinell® Mint Lozenge 1mg and 2mg
A smoker of **20-30** cigarettes daily should be prescribed 1mg or 2mg lozenge based on level of dependency (max **15** Lozenges daily).

NiQuitin® Minis Lozenge (Mint 1.5mg and 4mg, Orange 1.5mg)
Less than **20** cigarettes daily 1.5mg (max **15** lozenges/day). Over **20** cigarettes daily 4mg (max **15** lozenges/day).

Guidance on quantities and strengths of second NRT therapy to supply
A second NRT product serves only as a top-up dose, therefore, small realistic pack size quantities should be prescribed initially.

The quantity of the second NRT product to be given should be assessed on a weekly basis and if a larger pack size is required then this should be dispensed. Assess the necessity for extra NRT to be supplied each week. Dual NRT can be given throughout the 12 week quit attempt.

When prescribing second NRT products, guidance would be to initially prescribe the lower strength and then increase to higher strength if required. However, decisions should be made on an individual client basis and pharmacist should prescribe the most appropriate strength product for the client.

N.B. No second NRT product should be prescribed to pregnant clients, breastfeeding women or those planning a pregnancy.

Contraindications and side-effects

Any risks that may be associated with NRT are substantially outweighed by the well-established dangers of continued smoking. However there are some contra-indications to certain types of this therapy.

NRT should not be administered to clients with:

- Hypersensitivity to the active ingredient or any component of the NRT product.
- Temperomandibular joint disease - should not use NRT gum.
- Active gastric or duodenal ulcers - should not use NRT nasal spray
- Some oral preparations may not be suitable for individuals with phenylketonuria or fructose intolerance.

Cautions

Cardiovascular disease

Where there has been a serious cardiac event, or hospitalisation for a cardiovascular complaint in the previous four weeks including: myocardial infarction, unstable angina, cardiac arrhythmia, coronary artery bypass graft (CABG), angioplasty, stroke, transient ischaemic attack (TIA), it is recommended to wait for the condition to stabilise before treating with NRT. The clinician looking after the client should be involved in the decision to recommend NRT.

Pregnancy and breastfeeding

There are limited clinical data for the use of NRT in pregnancy and breastfeeding - even so it is not necessarily contra-indicated.

This is because there are clear clinical data on the harm caused by smoking during pregnancy to the developing foetus and its impact on maternal and child mortality. In breastfeeding, the risks towards the mother of continuing to smoke and to the baby of exposure to second-hand smoke far outweigh the potential adverse effects of the comparatively small amount of nicotine in breast milk from NRT

Current advice is that NRT can be prescribed for pregnant and breastfeeding women but only if they cannot quit without it.

Ideally, pregnant and breastfeeding women who smoke should be referred to the Quit Your Way Pregnancy Service to see a specialist adviser who will ensure the client fully understands the risks of NRT use against the benefits of smoking cessation and complete a risk benefit analysis document. A copy of the document will be retained in the client's medical records.

However, if the client does not wish referral to the Quit Your Way Pregnancy Service but still wishes to be treated with NRT through the Quit Your Way Pharmacy Service, they should be referred to the pharmacist who can use their professional judgment to make a risk assesment and counsel appropriately.

Intermittent pharmacotherapy is the preferred option for pregnant or breastfeeding women e.g. Nicotinell gum* or lozenge or Niquitin mini lozenge. The overall goal is to minimise exposure to nicotine while providing enough pharmacotherapy to support the client's quit attempt.

If gums or lozenges can't be tolerated and a patch must be used, the 24 hour Nicotinell patch should be prescribed with the advice to remove it before going to bed.

N.B. Dual therapy should **not** be used in pregnancy or breastfeeding and for those trying to conceive.

* Pregnant women should not use Nicotinell® Liquorice gums

Adverse effects

A range of adverse effects associated with smoking cessation itself are discussed in Section 10 of the NHSGGC Smoking Cessation Guidelines.

Common side- effects are localised reactions (for example, skin irritation (with patches), irritation of the nose, throat and eyes (with nasal spray) and minor sleep disturbances).
These side-effects are unlikely to lead to discontinuation of therapy.

The Medicines and Health Products Regulatory Agency (MHRA) asks that all suspected reactions (including those not considered to be serious) are reported through the Yellow Card Scheme. An adverse drug reaction (ADR) should be reported even if it is not certain that the drug has caused it, or if the reaction is well recognised, or if other drugs have been given at the same time. Report ADRs online at https://yellowcard.mhra.gov.uk/

NRT beyond the 12 week treatment phase

Under revised guidance, NRT can now be used beyond the 12 week treatment period. However, because there is limited evidence of the benefit of continued use of NRT beyond 12 weeks, it has been agreed that all NHSGGC Quit Your Way services supply only up to 12 weeks of treatment. Smokers who require additional NRT beyond this period should be advised to purchase this.

E-cigarettes

Use of E-cigarettes (Electronic nicotine devices), (vaping) is not classed as smoking because liquid in the device is heated and not burned and they contain no tobacco.

E-cigarettes are currently unlicensed but the National Institute for Health and Clinical Excellence (NICE) and Medicines Healthcare Regulation Association (MHRA) acknowledge that their use is safer than continued smoking.

E-cigarettes are not supplied by the community pharmacy stop smoking service. Users who wish to quit using their e-cigarette can be directed to the Community Service who can support them to quit.

Clients using e-cigarettes are classified as non-smokers and so cannot receive NRT or varenicline from the pharmacy service.

Varenicline

General Notes

Varenicline is classified as a prescription only medicine (POM). It may normally only be prescribed by medical e.g. doctors or independent non-medical prescribers. However, arrangements have been put in place for supply of varenicline to be made by an appropriately qualified healthcare professional e.g. pharmacist under a Client Group Direction (PGD) from community pharmacy[1].

It must be supplied using an Unscheduled Care Form (UCF), details of the quit attempt should be recorded on the Pharmacy Care Record (PCR) and Minimum Data Set (MDS) data submitted within required timescales (see Appendix 6).

It is important that when varenicline is prescribed the client is given appropriate motivational support to ensure that their quit attempt is successful[2,3]. Varenicline should be supplied along with weekly support and the client should be advised that treatment should be maintained for 12 weeks to ensure success[4].

Clients must be assessed for varenicline suitability by an accredited pharmacist before being signed up to the scheme. However, after clinical assessment by the pharmacist, behavioural support may be provided as usual by staff normally involved in smoking cessation support e.g. CO monitor readings[5].

Additionally the client should be:

- Made aware of the need for them to provide medical information to allow the healthcare professional to make an informed assessment of their suitability for varenicline.
- Informed of the risks and benefits of using varenicline to support a smoking cessation attempt in order that the client can make an informed decision.
- Warned that if the GP has to be contacted e.g. to enquire after a medical history or confirm their suitability for varenicline, there may be a delay to starting therapy.

Accredited Pharmacists

Varenicline may **only** be prescribed by an accredited pharmacist who is either an independent prescriber or who has signed the latest copy of the NHSGGC Varenicline PGD. To gain accreditation a pharmacist must have successfully completed recognised training and the MCQs approved by NES Pharmacy.

Medicine counter staff must be trained to refer each request for varenicline to the accredited pharmacist.

Using the Varenicline PGD

Only individuals who are registered healthcare professionals and are allowed to supply prescription only medicines using a PGD are able to use this process. The clinical decision to supply varenicline using the PGD remains with the registered healthcare professional and should not be directed by other healthcare workers.

Indemnity

The healthcare professional working under the PGD must ensure that the organisation providing their professional indemnity has confirmed that this activity will be included in their policy.

Clinical Support

An accredited pharmacist should not be working in isolation and must feel confident to refer to other sources of information and support services including NHS GGC Quit Your Way Community Services and the client's GP.

Adverse drug reactions (ADRs)

The Medicines and Health Products Regulatory Agency (MHRA) asks that all suspected reactions (including those not considered to be serious) are reported through the Yellow Card Scheme. An adverse reaction should be reported even if it is not certain that the drug has caused it, or if the reaction is well recognised, or if other drugs have been given at the same time. Report ADRs online at: https://yellowcard.mhra.gov.uk/

If the client experiences any extreme side-effects they should seek medical advice especially if the following symptoms are experienced:

- Varenicline should be discontinued immediately if agitation, depressed mood or changes in behaviour that are of concern to the pharmacist, client's family or caregiver are observed. Or if the client develops suicidal thoughts or suicidal behaviour.
- New or worsening cardiovascular symptoms e.g. angina pain.
- New or worsening symptoms of asthma or COPD.

Treatment course and dosage

First consultation (Assessment)

Complete varenicline clinical risk assessment form. If appropriate, discuss setting a formal quit date and the need to start varenicline 7 days before the quit date. Arrange an appointment for the client to return to receive the varenicline starter pack at least 7 days before the quit date.

Second consultation (before quit date)

Confirm quit date and enter onto the Pharmacy Care Record (PCR). Supply 14 day starter pack
(11 x 500mcg tabs with 14 X 1mg tablets) and take a carbon monoxide (CO) reading.

Third consultation (first follow-up).

Monitor carbon monoxide reading and confirm abstinence.

Supply 7 days' supply of varenicline tablets as required 14x 1mg tablets or reduced dose if required - **Record on PCR**.

Subsequent consultations

Supply 7 days' supply of varenicline tablets if client has stopped smoking and carbon monoxide reading confirms abstinence - **Record on PCR**

Final consultation (week 12)

Discuss coping strategies when the support service is finished

Supply 7 days' varenicline tablets (if required) if client has stopped smoking and carbon monoxide reading confirms abstinence - **Record on PCR.**

Dosing information summary

Adult, over 18 years - Start 1-2 weeks before the target stop date.	
Weeks 1 and 2	Supply 14 days therapy for first two weeks ideally as a starter pack:- 0.5mg daily on days 1-3 0.5mg twice daily on days 4-7 1mg twice daily days 8-14
Weeks 3 to 12	Supply weekly* 1mg twice daily (reduce to 0.5mg if intolerable side effects)
Beyond week 12	Occasionally a client who has stopped smoking may benefit from varenicline therapy beyond 12 weeks. Usually this may just be for a few weeks while the client is reassured cravings will not return. Treatment up to 24 weeks is described in the product SPC and at the pharmacist's discretion may be offered, although no further payment is offered under QYW.

*In exceptional circumstances, discretion may be used in the number of days' treatment supplied if for example a client is planning to go on holiday or away on business. It would be good practice to annotate the PCR stating the reason when (other than the starter pack) more than 7 days' supply is given.

Dose adjustment for side-effects

Clients (particularly the elderly) may find that the side-effects of varenicline are intolerable after they have increased their varenicline dose to 1mg twice daily. It is possible that therapeutic plasma levels of varenicline are achieved with a lower dose. So reduce the dose to 0.5mg tablets twice daily. Be aware that some clients, having found varenicline therapy beneficial but unable to face the side-

effects, might make their own decision to reduce their dose to 1mg once a day. However, a twice daily regimen is better.

Clients with renal conditions

Varenicline is cleared through the kidneys. It follows that clients with end-stage renal disease may not adequately clear the drug. Moreover there are no supporting data for use of varenicline in this group, so it should not be prescribed.

However, clients with less severe renal disease may be prescribed varenicline. If a client describes kidney problems, refer to the GP for details of their condition.

The client may build up higher plasma levels of the drug and suffer more side-effects. As with all clients they may be prescribed a lower dose if they do not tolerate the recommended dose.

Refer to section 4.2 of the varenicline SPC for further details https://www.medicines.org.uk/emc/medicine/19045

Clients with severe mental health conditions

Diagnosis of severe mental health conditions can be difficult by the nature of the illness and might often only be made after a period of watchful waiting.

A major depressive disorder can encompass a spectrum of symptoms and should not be confused with mild or moderate depression. For the purposes of the PGD it might be simplified as a client whose depression has required psychiatric intervention. Typically the client will be managed by a psychiatrist and might have a CPN assigned to them.

Pharmacists should be mindful that many such clients may have been stable for a long time, and their diagnosis doesn't mean they aren't suitable for varenicline. If this is a consideration, community pharmacists are asked to contact the GP or psychiatry team for discussion and advice before making a supply.

The EAGLES[6] study has provided evidence that there is no association with the use of varenicline and an increased risk of serious neuropsychiatric adverse events compared with placebo.

Clients with epilepsy

The Varenicline SPC states that 'In clinical trials and post-marketing experience there have been reports of seizures in clients with or without a history of seizures, treated with Champix®. It should be used cautiously in clients with a history of seizures or other conditions that potentially lower the seizure threshold'. Refer these clients to their GP. While they are excluded from the PGD, their GP may be able to conduct a more thorough clinical risk assessment of the client and subsequently prescribe.

General advice to clients

The major reasons for varenicline failure are:

- Unrealistic expectations
- Lack of preparation for the fact that tablets may cause nausea

Pharmacists should discuss with the client about the need for motivation to quit.
It is also good practice to ensure that the client is aware of the following:

- Successful varenicline therapy requires client motivation to stop smoking.
- Varenicline works by acting on receptors in the brain which are affected by the nicotine in cigarettes
- Varenicline does not remove all the temptation to smoke, but it does make abstinence easier
- Around a third of clients may experience mild nausea usually about 30 minutes after taking it. This reaction often diminishes gradually over the first few weeks, and most clients tolerate it without problem.

QUIT YOUR WAY with our support

Varenicline Pathways

Before prescribing varenicline, pharmacists must complete the NES varenicline training and MCQs, read the NHSGGC PGD and NHSGGC Smoking Cessation Guidelines for Community Pharmacy. Fax relevant forms back to the Community Pharmacy Development Team (0141 201 9387)
N.B. pharmacists must sign and return paperwork for each health board area they work in. PGDs may differ between health board areas

General Notes

- Regardless of which service a patient has been referred from, the pharmacist should complete a **Varenicline clinical risk assesment form** before prescribing**.** Completed forms should be retained for 3 years. N.b. it's good practice to use the form even if a patient presents a GP10 (see below)
- The patient's GP must be notified when varenicline is being prescribed under PGD to allow them to annotate patient notes
- Apart from the initial supply where a two week **starter pack** should be provided, varenicline should be prescribed **weekly**
- Use Universal Claim Form (UCF)
- Complete Patient Care Record (PCR) weekly (see below)
- Submit the 4 week Minimum Data Set (MDS) information to ensure payment
- If patient is a non-smoker at 4 weeks continue to supply weekly complete the database and submit at 12 weeks to ensure **final payment** is made
- If patient is still smoking at 4 weeks mark attempt as unsuccessful and close it down on PCR. Encourage them to consider whether they are committed to cessation attempt or whether they should start again after a short break

Community Services

Client should submit a Pharmacy request form from the service. If the varenicline box is ticked, assess the client as above.
The client **will not** have had a clinical assessment and the pharmacist may not be directed to prescribe, if the client is unsuitable for varenicline discuss alternative therapy.
Select 'Health Point' and 'Shared Care' options on PCR
Discuss quit date and record on PCR with CO reading

Pharmacy Service

(Client has presented directly to pharmacy)

Proceed as above

Hospital Service

Clients may present a Hospital /Pharmacy booklet to continue therapy commenced in hospital.
Conduct Varenicline clinical risk assessment.
Prescribe weekly as above
Do **not** enter data on PCR.
At 12 weeks therapy submit the booklet to the Pharmacy Public Health team for payment.

GP Prescription

A GP10 for varenicline may come directly from a GP or be requested by a community service for the client.
If given **directly from a GP**, It may be dispensed with no details added to the PCR. However, encourage the client to sign up to weekly support as they will have more success.
Enter the client on the PCR under 'GP' in 'Shared Care' options. If the GP10 was **requested by a community service** the client should have a 'Quit your Way' referral form. They will have weekly support from the service but enter the client on the PCR selecting 'Health Point' and 'Shared Care' options. Dispense weekly.
In both cases remind the client when a new prescription is required.

Supporting forms

Pharmacy and Prescribing Support Unit

Varenicline Clinical Risk Assessment Form

Client name: Address:	Telephone number: Date of birth: GP's name & address:

Pharmacy Stamp

Factor	Yes	No	Notes
Is the client under 18 years of age?			If 'yes' – offer nicotine replacement therapy (NRT)
Is the client pregnant?			If 'yes' – offer NRT, referral to specialist services
Is the client breastfeeding?			If 'yes' offer NRT
Does the client suffer end-stage renal disease?			If 'yes'- offer NRT or refer to GP
Is the client aware that they have renal failure or stage of CKD			If 'yes'- refer to GP to enquire about degree of functional impairment. See SPC for dosage recommendations
Does the client have a history of serious psychiatric illness or are they on clozapine?			If 'yes' - consider referring to GP, CPN or psychiatrist for opinion
Does the client suffer from epilepsy?			If 'yes' – offer NRT or refer to GP
Is the client on insulin?			If 'yes' – advise re additional blood glucose monitoring
Is the client currently on another smoking cessation aid			If 'yes' – varenicline not applicable
Is the client on warfarin or theophylline?			If 'yes' – advise re importance of monitoring INR or respiratory symptoms
Is client on any other medication? Please note:			If 'yes' There are very few if any interactions between varenicline and other medicines. Check the BNF and/or SPC if unsure
Is client hypersensitive to varenicline or any of its excipients?			If 'yes' – Recommend NRT

Special circumstances and any other relevant notes:
Only make a supply if you are certain that to the best of your knowledge, it is appropriate to do so.

Action taken:

Supply: ☐ Referral to: GP: ☐ Quit Your Way: ☐ Advice given: ☐

The above information is correct to the best of my knowledge. I have been counselled on the use of varenicline and understand the advice given to me by the pharmacist.

Client's signature:

Date:

The action specified was based on the information given to me by the client, which, to the best of my knowledge, is correct

Pharmacist's signature:

Date:

GP referral letter

Pharmacy address

Date:

Dear Dr

Client's name:
Address:
DOB:

I saw the above client at the pharmacy today and I have completed the varenicline clinical risk assessment form (attached) with a view to supplying **varenicline** tablets to help him/her give up smoking.

As you will see the client answered 'yes' to one or more questions and is therefore excluded from the pharmacy service.

Can you please review this client, and if appropriate provide a prescription for Varenicline. The treatment period is for a maximum of 12 weeks.

Yours sincerely

……..(Signature)

…….(PRINTNAME)

GP information letter

Pharmacy Address

Date

Dear Dr

Client's name:
Address:
DOB:

I saw the above client at the pharmacy today and I have recommended and supplied him/her with **varenicline** tablets to help him/her give up smoking. The client will be taking varenicline for a maximum of 12 weeks. Please add this medicine to the client's medication records. No further action will be required from you as the client will be receiving all supplies of varenicline from my pharmacy. Please do not hesitate to contact me should you require further information.

Yours sincerely

……..(Signature)

……..*(PRINT NAME)*

References

1. NHSGGC Varenicline PGD https://www.communitypharmacyscotland.org.uk/ accessed 10/8/20

2. CPO letter Community Pharmacy Public Health Service Smoking Cessation Specification

3. Champix® eSPC https://www.medicines.org.uk/emc/medicine/19045 accessed 10/8/20

4. NHS Scotland National Template Client Group Direction for the supply of Varenicline (Champix®) by Authorised Community Pharmacists working in Scotland

5. Neuropsychiatric safety and efficacy of varenicline, bupropion, and nicotine patch in smokers with and without psychiatric disorders (EAGLES): a double-blind, randomised, placebo-controlled clinical trial. http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(16)30272-0/abstract (accessed 10/8/20)

Appendix 8: Schedule of payments

There are three payments for the pharmacy smoking cessation service. Payments of £30, £15 and £35 are made at weeks 1, 4 and 12.

N.B. Reimbursement for pharmacotherapy is made by submission of a **weekly** UCF prescription

Week Number	Action and Payment
Week 0	Record the client's details and motivation to quit in the smoking cessation support tool within PCR. Discuss setting a formal quit date around 7 days after initial visit if the client is deemed ready to quit. Record Carbon monoxide (CO) reading on PCR. N.B. A week 0 entry is not required for Shared Care clients whose motivation to quit has already been assessed. **Do not set the quit date in the smoking cessation support tool at this stage.**
Week 1 (immediately)	**If client is ready to quit:-** Record any additional client data not collected at week 0 and the results of the CO reading on PCR. Electronically submit the MDS data detailing the quit date from PCR immediately after the appointment. **This triggers the first payment, £30.**
Weeks 2 and 3	Record client progress and CO readings in PCR
Week 4 (no later than Week 6)	**If client still engaged with service and attends appointment:-** Electronically submit the MDS data from PCR immediately after the 4-week post-quit date appointment but no later than 6-week post-quit date. **This triggers the second payment of £15.** **If client is not smoking but has left the pharmacy service:-** mark as non-smoker, send submission but do not update client's 'Assessment completion' at this point. This will keep the client 'open', allow follow-up at 12 weeks and a further claim to be processed if appropriate.
Weeks 5 to 11	Record client progress and CO readings in PCR
Week 12 (no later than week 14)	**If client still engaged with service and attends appointment or is not smoking but has left the pharmacy service:-** Electronically submit the MDS data from PCR immediately after the appointment but no later than 14 weeks after the quit date. **This triggers the third payment of £35.**

Carbon monoxide readings

Carbon monoxide (CO) readings should ideally be taken at each client appointment. They **must** be recorded on the PCR at weeks 4 and 12.

The pharmacy does not need to repeat a CO reading for Shared Care clients. Instead the CO reading from the Shared Care paperwork should be entered onto the PCR.

Many clients have found weekly CO readings to be an effective motivator to return to receive weekly pharmacy support and ultimately quit.

N.B. If a client has left the service but asserts that they have stopped smoking on follow-up, no CO reading is required.

Follow-up and repeat quit attempts

Three attempts should be made to follow-up with clients who have not presented according to local NHS Board procedures.

Dates and times of attempts to contact the client should be recorded within the smoking cessation support tool.

If there is no response after two missed visits and three attempts of contact then record the client as lost to follow-up in the MDS within PCR and submit it electronically.

Any further cessation support to the client should be defined as a new quit attempt.

No payment or therapy for a non-smoking client's quit attempt is available after 12 weeks.

Where a client requires support beyond the 12 week period then they should be advised that they can also seek this from local specialist smoking cessation services and the national telephone support line, Quit Your Way Scotland on 0800 84 84 84. The service is open Monday to Friday from 9am to 5pm and is supported by a website which offers interactive web chat with trained support staff https://www.nhsinform.scot/care-support-and-rights/nhs-services/helplines/quit-your-way-scotland

Appendix 9

NHSGGC Community Pharmacy 'Quit Your Way' Self-audit 2018

This self-audit is designed to highlight areas for improvement in the smoking cessation service provided in community pharmacies in NHSGGC. We would appreciate it if every pharmacy would complete and return it.

Undertaking this audit will help you to systematically review your procedures, contribute to your continuous professional development and is an important quality improvement activity. It should take less than 15 minutes to complete. Please return to the Pharmacy Health Improvement team, West House, Gartnavel Hospital, 1055 Great Western Road, Glasgow G12 OXH or email to pharmacyhit@ggc.scot.nhs.uk by the end of November 2018.

Once the results are collated we will provide you with an individualised report highlighting areas for improvement along with the smoking cessation figures for your pharmacy.

Your help and co-operation are appreciated.

General information

Date of self-audit completed	
Pharmacy 'Quit Your Way' contact name	
Pharmacy name	
Contractor number	

Section 1: Personnel and Training		Yes	No	N/A	comment
1.1	Do you have a named champion or lead member of staff for smoking cessation?				
1.2	Is there always a trained staff member available to deliver smoking cessation advice?				
1.3	Are all appropriate healthcare staff trained to provide the smoking cessation service to clients?				
1.4	Have all the trained pharmacists/staff attended the smoking cessation training day or a refresher course in the last 3 years?				
1.5	If NRT is appropriate Nicotinell is used first line?				

Section 2: Resources		Yes	No	N/A	comment
2.1	Do you have an a copy of the current 'Clinical Guideline – Smoking cessation guidelines for community pharmacy'?				
2.2	Does the pharmacy have a working CO monitor and an adequate stock level of D pieces and mouth pieces?				
2.3	Do you have the current Quit your Way resources?				
	• Window sticker				
	• Poster				
	• Leaflet				
	• Business cards				
2.4	Do you know how to order Quit your Way resources?				
2.5	Do you use other resources to encourage Quit your Way clients e.g. certificates, money banks etc?				
	Which resources do you use? Please list:				
2.6	Are consultations held in the consultation room?				

Section 3: Varenicline		Yes	No	N/A	comment
3.1	Have you a pharmacist who has completed the Varenicline training?				
3.2	Have they signed and returned the current (March 2018) varenicline PGD?				
3.3	Is there always a pharmacist on duty who is able to prescribe varenicline under PGD?				
3.4	Are you aware that varenicline is a 1st line option for smoking cessation now?				
3.5	Does the pharmacist have any reservations about prescribing varenicline to clients? If "yes", please provide details				

Section 4: Recording on Patient Care Record (PCR)		Yes	No	N/A	comment
4.1	Do you add client's details to PCR on the day they sign up?				
4.2	Each week, are the current details and CO reading recorded in a timely manner?				
4.3	Do you submit the 4 and 12 week MDS data at the correct time, maximising payment?				
4.4	Do you make up to 3 phone calls to clients who do not come back for their pharmacotherapy?				
4.5	Do you have a plan in place to encourage failed clients to get back the smoking cessation programme?				

Section 5: Referral and Promotional activities		Yes	No	N/A	comment
5.1	Are you aware of the specialist 'Quit Your Way' services?				
	• Community				
	• Pregnancy				
	• Acute				
5.2	Do you make referral to the specialist 'Quit Your Way' services?				
5.3	Do you have the contact details of the specialist Quit your way services?				
5.4	Do you actively promote smoking cessation to?				
	• Pregnant patients				
	• Diabetic patients				
	• Patients with respiratory disease				
	• Patients with cardiac disease				

Any other comments:

Thank you for taking the time to complete this Smoking Cessation Programme Audit. **Please send a copy to the Pharmacy H.I team (details on page 1).** Should you require any information regarding this service, please contact us on

Tel 0141 201 4945 or e-mail to pharmacyhit@ggc.scot.nhs.uk

Appendix 10a

The patient named within this record card was assessed by a Quit Your Way Hospital Stop Smoking Advisor and a quit plan agreed following consultation. He/she wishes to use Nicotine Replacement Therapy (NRT) (or Varenicline) and receive ongoing support. Please assess this patient's suitability for NRT / Varenicline use and if appropriate, prescribe the product on a CPUS with a maximum of 12 weeks supply (dispensed weekly) in accordance with the SPC recommendations.

Please post booklets back on completion Quit Your Way Pharmacy Service
West House
Gartnaval Royal Hospital
1055 Great Western Road
Glasgow, G12 0XH

Or scan and email to: PharmacyHIT@ggc.scot.nhs.uk

Hospital/Pharmacy Booklet

Instruction for patient	-	take this booklet to your local pharmacy once discharged from hospital
Instruction for local pharmacy	-	Please retain in Pharmacy
	-	**DO NOT enter data on PCR**

Pharmacy Name & Contractor code:

Quit Your Way Hospital Service - Pharmacy Record

Appendix 10b

QUIT YOUR WAY with our support

INTENSIVE SMOKING CESSATION SUPPORT
PHARMACY REQUEST FORM

NHS Greater Glasgow and Clyde

MUST BE SELECTED ON PCR

Source of Referral:

☐ Select HEALTH POINT as this is a Community shared care

☐ Select MIDWIFE as this is a Pregnancy shared care

Also...

Shared Care between pharmacy and non pharmacy services – TICK YES on PCR

Patient Name:	Address:
QUIT DATE:	DOB: CHI:

The above patient consulted a smoking cessation advisor recently and intends giving up smoking. Please assess this patient's suitability for the indicated product (s) and if appropriate, provide the patient with a maximum of 12 weeks supply (dispensed weekly) and submit a CPUS.

Product Request

☐ Single NRT ☐ Dual NRT ☐ Varenicline

PRODUCT	First line product STRENGTH / DOSAGE	First line product WEEKLY QUANTITY	Dual NRT Product (pharmacist to discuss quantity with client)
NICOTINELL PATCH	24 Hour ☐ 21mg ☐ 14mg ☐ 7mg	1 Box x 7 Patches	
NICOTINELL GUM	☐ 4mg ☐ 2mg	1 Box x 96 Pieces	☐
NICOTINELL LOZENGE	☐ 2mg ☐ 1mg	1 Box x 36 Lozenges plus 1 Box x 72 Lozenges	☐
NIQUITIN MINIS LOZENGES	☐ 4mg ☐ 1.5mg	2 x pack of 60	☐
Other –Please specify:			☐

Advisor Name (Print): _____ **Designation:** _____

Co-ordinator Tel: _____ **Date:** _____

Created: 26.07.18
• 306931

QUIT YOUR WAY with our support

Smoking Cessation Support
Questionnaire

NHS Greater Glasgow and Clyde

1. Details			
Does client consent to follow up?	☐ Yes (shared care - must say yes to access product) ☐ No		
Mr/Mrs/Miss/Ms/Other	Forename:	Surname:	
Date of Birth:		CHI:	
Address:		Postcode:	
Tel No:		Mobile:	
Gender	☐ Male (Go to Q2 Ethnic Origin)	☐ Female	
Pregnant ☐ Yes ☐ No	Breastfeeding ☐ Yes ☐ No		

2. Ethnic Origin					
White	☐ Scottish	☐ Irish	☐ Other British	☐ Polish	☐ Gypsy/traveller ☐ Other
Asian	☐ Indian	☐ Pakistani	☐ Bangladeshi	☐ Chinese	☐ Other
Caribbean/Black	☐ African	☐ Caribbean	☐ Black Other	☐ Other African	☐ Arab
Mixed/Multiple (Please specify)	Other (Please specify)				☐ Not Disclosed/Refused ☐ Unknown

3. Information about you	
☐ In paid employment	☐ Retired
☐ Full time student	☐ Permanently Sick or Disabled
☐ Homemaker/Fulltime parent or carer	☐ Unemployed
☐ Other (Please specify)	☐ Not known/missing

4. Smoking History				
How many cigarettes/roll-ups do you usually smoke per day?	☐ <=10	☐ 11-20	☐ 21-30	☐ 30 + ☐ Unknown
How soon after wakening do you smoke?	☐ Within 5 mins	☐ 6-30 mins	☐ 31-60 mins	☐ After 1 hour ☐ Unknown
How many times have you tried to stop smoking in the past year?	☐ No quit attempts	☐ Once	☐ 2-3 times	☐ 4 or more ☐ Unknown

5. Referral and Assessment			
Date of Referral:		Initial Appointment Date:	
Shared Care between pharmacy and non-pharmacy services? ☐ Yes ☐ No			
Source of Referral			
☐ **Health Point** (Shared Care - Community)		☐ **Midwife** (Shared Care - Pregnancy)	
Quit Date:		Intervention Setting (select pharmacy if shared care)	
		Intervention used in quit attempt (select one to one sessions if shared care)	

NHS • 306930

Protocol for the management of clozapine patients who stop smoking

Background

Tobacco smoke contains polycyclic aromatic hydrocarbons that increase the activity of certain hepatic enzymes especially CYP1A2. For patients who smoke, this means that some drugs including clozapine undergo increased metabolism and consequently reduced plasma levels. This means a higher dose may be necessary to achieve a therapeutic effect. The effect of smoking is dose related i.e. the more cigarettes smoked, the greater the enzyme induction. This also means that any reduction in the number of cigarettes smoked per day may result in increased clozapine plasma levels. This is worth bearing in mind should a patient begin to reduce their smoking in preparation for a quit attempt.

When a patient stops smoking, the increased enzyme activity reduces over a week or so. Once the enzyme activity returns to normal, the dose of clozapine the patient is taking may be too high resulting in unwanted dose related side effects e.g. sedation, dizziness, hypersalivation, tachycardia, postural hypotension, constipation and seizures. The Maudsley Guidelines suggest the mean increase in plasma levels is 50% but as this is an average figure, the actual increase could be lower or higher than this.

For patients on clozapine who smoke and are also prescribed valproate, the increase in clozapine plasma levels seen after stopping smoking may be greater than that seen in patients not taking valproate.

With the introduction of a smoke free environment in mental health, patients will be compelled to stop smoking and therefore those on clozapine need to be carefully managed. This protocol describes the steps to be taken when a patient who is being treated with clozapine stops smoking. The guidance is in two sections. Part 1 describes the management of patients undergoing a planned quit attempt and part 2 describes the management of patients who have to quit temporarily due to being admitted to hospital.

Part 1: Guidance for the management of patients on a stable clozapine dose who wish to stop smoking.

In addition to offering general smoking cessation advice, or signposting towards smoking cessation services The following steps should be undertaken when patients are making a planned attempt to stop smoking.

1. Take a clozapine plasma level before the patient stops smoking if possible. Note this must be a trough level (take in the morning **before** the next clozapine dose or 12 hours post dose if prescribed clozapine once daily) and the results of clozapine plasma assays take about a week to come back from Magna Labs.

2. One week after stopping, repeat the clozapine plasma level. During that initial week observe the patient for dose related side effects. If any emerge, consider reducing the clozapine dose gradually to around 75% of the pre-quit dose. If the dose is reduced, take the post-quit plasma level one week after the dose is stable.

3. Depending on the result of the post-quit plasma level, consider further dose reductions on a weekly basis. Subsequent plasma levels should be taken one week after any dose change.

4. Seek advice from pharmacy over interpretation of clozapine plasma assay results.

5. Please note that clozapine plasma levels may continue to rise for several months after the patient has stopped smoking.

6. Patient's smoking status should be reviewed at each MDT meeting.

Part 2: Guidance for the management of patients who abruptly stop smoking due to a hospital admission

The introduction of the smoking ban on all mental health sites means that patients will be unable to smoke on admission to our wards. This presents a challenge due to the unpredictable length of an admission and the likelihood that many patients will resume smoking on discharge. This guidance provides pragmatic advice on how to manage patients who are treated with clozapine in this situation.

1. Identify the smoking status of all patients on clozapine admitted to hospital.
2. Advise them of the Smokefree Policy, of services available to help them quit and determine, if possible, if they are likely to resume smoking on discharge.
3. If no recent clozapine level is available (within last month – contact pharmacy to confirm) take a baseline level. Trough level as per NHS GG&C Clozapine TDM guidance.
4. W hilst awaiting the result of any baseline levels assay monitor the patient for any dose related side effects e.g. sedation, dizziness, hypersalivation, tachycardia, postural hypotension, constipation and seizures. If such symptoms emerge consider dose reduction if clinically appropriate.
5. If the plasma levels are out with the accepted range (0.35 – 0.6mg/L) contact pharmacy for advice.
6. If the levels are within the acceptable range monitor the patient for the emergence of any dose related side effects e.g. sedation, dizziness, hypersalivation, tachycardia, postural hypotension, constipation and seizures. If such symptoms emerge repeat the plasma level and consider dose reduction if clinically appropriate.
7. Patient's smoking status should be reviewed at each MDT meeting

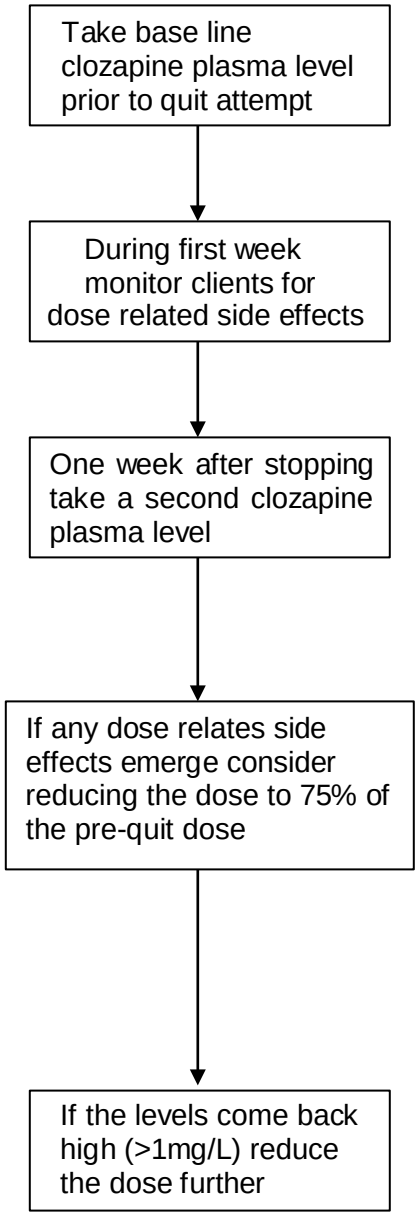
Notes:

1. The complex individual patient circumstances e.g. patient variability, variability of smoking e.g. whilst on time out of ward or on pass, access to NRT mean a formulaic approach to this situation cannot be adopted. Therefore it was decided to adopt the pragmatic approach above.

2. W henever possible the impact of smoking on clozapine treatment should be explained to the patient. It should be stressed that whenever patients make a change to their smoking status it must be discussed with someone responsible for their care.

References:
Maudsley Prescribing Guidelines in Psychiatry 12th Edition
NHS GG&C Mental Health Services Clozapine Plasma Level Monitoring Guidelines

Flowchart 1- Guidance for the management of patients on a stable clozapine dose who wish to stop smoking

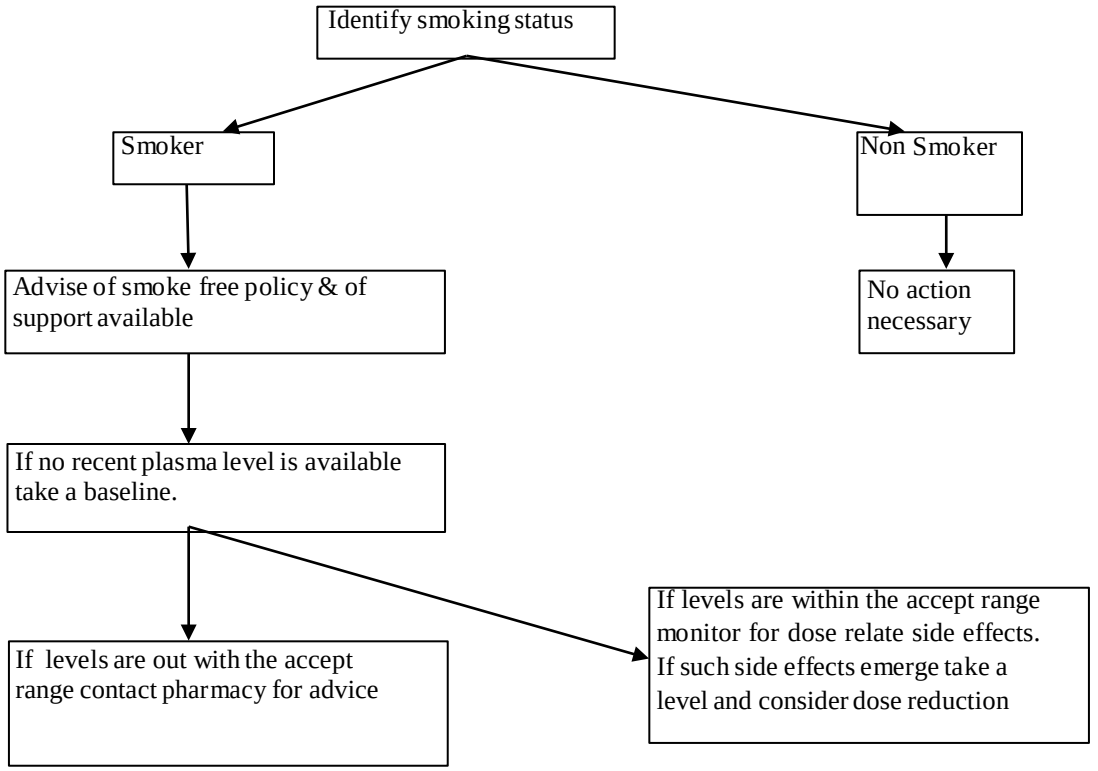


- **Must be trough level. Send to Magna Labs**

- **Dose related side effects include sedation, dizziness, hypersalivation, tachycardia, postural hypotension, constipation & seizures**

- **If the dose is reduced take a plasma level 7 days after the reduction**
- **Subsequent levels should be taken 7 days after any dose change.**

Flowchart 2 Guidance for the management of clients who abruptly stop smoking due to a hospital admission



PUBLIC HEALTH PHARMACY
Telephone: 0141 201 4945
Fax: 0141 201 4949
E-mail: pharmacyhit@ggc.scot.nhs.uk

Appendix 12

Resource Name	Quantity ordered
QUIT YOUR WAY PHARMACY GUIDANCE NOTES	
INFORMATION LEAFLET Use for all enquiries about stopping smoking Includes details of Pharmacy and other Quit Your Way services	
HOW TO STOP SMOKING AND STAY STOPPED booklet Supply to client at week 0	
QUIT YOUR WAY BUSINESS CARDS	
POSTER A4	
WINDOW STICKER	
MOUTHPIECES **For CO monitor**	
HYGIENIC CLEANSING WIPES For CO monitor (alcohol-free)	
D-PIECES For CO monitor	
CO MONITORING CARDS	
4/8/12 WEEK QUIT YOUR WAY CERTIFICATES	
QUIT YOUR WAY TEXTING SERVICE LEAFLET	

If you require resources for a smoking cessation event within your pharmacy,
please phone for details

Pharmacy Quit Your Way Service
Greater Glasgow & Clyde NHS Board
Gartnavel Hospital
West House, Ground Floor
Great Western Road **Tel:0141 201 4945**
GLASGOW
G12 0XH **Fax:0141 201 4949**

Contractor Code - ……..

Pharmacy Name or Stamp- …… March 2019