# Standard Operating Procedure (SOP)

The pharmacy should have a SOP in place for all the services the pharmacy provides, including providing Varenicline according to the PGD. SOPs are necessary to demonstrate to commissioners that the pharmacy is meeting the requirements of the service and to ensure that the service is provided in a safe and consistent way.

A template SOP for the service is available on the following pages.

**Disclaimer:** This template is an example SOP for a Varenicline PGD. Pharmacies may adapt to suit local needs or alternatively develop their own. Each pharmacy is responsible for producing their own SOP which conforms to both the service specification and the usual processes within the pharmacy. Hertfordshire LPC does not accept any responsibility for any errors or omissions within this document.

A SOP should:

* Define staff roles and responsibilities
* Include any relevant signposting information
* Include the process for error and near miss reporting
* Be regularly reviewed and kept up to date
* Be signed and dated by all staff (including locums) operating under the SOP
* State the date of production and review date.

Check with the Superintendent before you write any SOP because they must be involved in writing SOPs for the pharmacy.

# Template Standard Operating Procedure for the Service

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| **Pharmacy Name** |  | **SOP version** |  |
| **Date of SOP preparation:** |  | **Date SOP effective from:** |  |
| **SOP prepared by:** |  | **Review date for SOP:** |  |
| **Objective** To define the service for the supply of varenicline by registered community pharmacists in Hertfordshire as according to the [Patient Group Direction HCC201612](http://www.hertslpc.org.uk/wp-content/uploads/sites/66/2013/10/HCC201612-Varenicline-PGD-FINAL-01.12.16.pdf) (the PGD). This is to ensure that nicotine dependent smokers over the age of 18 who are accessing a community pharmacy stop smoking service commissioned by Hertfordshire County Council for help to stop smoking can be supplied varenicline as part of a treatment programme combined with behavioural support. |
| **Scope** This procedure applies to all staff participating in the provision of the Service. |
| **Responsibilities** The responsible pharmacist in charge of the community pharmacy is responsible for ensuring that the PGD is carried out as within this SOP and in line with the stop smoking locally commissioned service (ie. as commissioned). Each person delivering the PGD is responsible for ensuring that they work under this SOP. All employees are responsible for treating all users of the Service with respect and courtesy. |
| **Person Requirements** The pharmacist delivering the service must: * Be a qualified community pharmacist who is registered with the GPhC AND accredited to use the Patient Group Direction (PGD) by Hertfordshire Stop Smoking Service (HSSS);
* Be aware of the service specification standards for providing a stop smoking service AND training must include attendance at the Varenicline Accreditation Support Event and completion of the CPPE e-learning module in Smoking Cessation ‘Learning about stop smoking support guide’;
* Be working in a community pharmacy that has a current contract with Hertfordshire County Council Public Health Service to deliver stop smoking services;
* Have achieved the competency levels specified in the NICE Competency Framework for Health Professional using Patient Group Directions;
* Keep up to date with any recommendations for the medicine listed
* Ensure that the pharmacy manager and the superintendent pharmacist is apprised of a pharmacies involvement in order to maintain records and names of individuals who are competent and signed up to operate the PGD in the pharmacy.
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| **Facilities**Pharmacies must have a suitable consultation room that meets the specification for provision of NHS advanced services, as described in the Public Health Contract with community pharmacy contractors. All medicines dispensed under this PGD must be procured and stored according to the requirements of the Medicines Act 2012. Details of the product(s) supplied, invoices, and prescription charges collected must be recorded. |
| **The process stages** |
| 1 | **First Contact**Service User presents for help to stop smoking at a local pharmacy. If Service User wants to quit, explain service and expectation of weekly support for best chance of success; give Health Questionnaire, booklet on stopping smoking and make first appointment. Consider referral to specialist service if Service User ispregnant, has a mental health condition or complex needs, or has not quit successfully with your service previously. Explain commitment is for at least 4 weeks following quit date. If Service User not ready to quit, ensure they are welcomed to access service at later date and give harm reduction advice, including advice on e-cigarettes. |
| 2 | **First Appointment** (Usually pre-quit - 30 mins or 45 mins if pregnant)* Establish Service User relationship
* Note relevant medical history/medication from Health Questionnaire
* Assess smoking history and current dependency (Fagerstrom Test)
* Assess motivation and confidence to quit
* CONSENT: complete QuitManager or Service User to sign Monitoring Form
* Explain CO monitoring and record reading (use as motivational tool)
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| 2 (cont) | * Negotiate quit date and discuss planning for it
* Provide literature e.g. Stop Smoking Start Living; Today Tomorrow
* Discuss behaviour change/breaking the habit
* Discuss withdrawal symptoms and coping mechanisms
* Discuss all medication options approved by NICE, in line with local guidelines and patient
* choice, facilitate supply, explain use, and complete clinical record. Complete additional
* Smoking in Pregnancy forms if required
* Make next appointment or follow up any DNAs
* Complete all mandatory fields on QuitManager
* Provide service user evaluation form (and pre-paid envelope).

Varenicline option: Accredited pharmacist prescribes, recommends or supplies varenicline within NICE guidance and Hertfordshire guidance: Stop smoking medication and the [Summary of Product](http://www.medicines.org.uk/emc/medicine/19045)[Characteristics](http://www.medicines.org.uk/emc/medicine/19045) as according to the [PGD](http://www.hertslpc.org.uk/wp-content/uploads/sites/66/2013/10/HCC201612-Varenicline-PGD-FINAL-01.12.16.pdf). An agreed quit date should be recorded, preferably 7-14 days after initiation of treatment. The patient’s GP must be informed of the supply of varenicline to any of their patients using the [template letter](http://www.hertslpc.org.uk/wp-content/uploads/sites/66/2013/10/Varencline-PGD-Pharmacist-letter-to-patients-GP.doc). This is to manage any risk to receiving the medicine if there are clinical concerns which do not come to light during the patient assessment. This can be sent by secure email or fax and must occur at the time of initial supply.  Please note that the information for the first appointment can be given by a stop smoking advisor and does not have to be undertaken by the accredited pharmacist prescribing Varenicline. |
| 3 | **Appointments 2, 3 and 4** (10-15 minutes on or shortly after quit date and each and every following week)* Assess progress so far - congratulate any constructive behaviour change/efforts
* Confirm quit date/set quit date
* Take CO reading to use as a motivator
* Monitor use of medication – ensure adequate use and monitor side effects (adjust dose or change medication if severe adverse
* effects)
* Ensure adequate medication until next appointment
* Complete clinic notes in QuitManager
* Discuss any lapses or barriers to quitting/difficulties to be overcome
* Discuss withdrawal symptoms and coping mechanisms
* Build on repertoire of coping strategies and identify and help patient overcome any perceived obstacles
* Follow up service users who have failed to attend appointments.
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| 4 | **Final Appointment** (between 25 and 42 days after quit date (NHS reporting deadlines)* Assess progress so far - quit or not quit at this four-week follow-up appointment
* Congratulate success if appropriate and encourage staying stopped
* For those who haven’t quit, suggest returning for another course when ready
* Complete CO reading (must be less than 10ppm to validate non-smoking status)
* Service User must be smoke free for the last 14 days of the 28 days since setting a quit date
* Complete Quit Status on QuitManager for monitoring and payment purposes
* Complete clinical record
* Identify risks to staying stopped and ensure patient empowered to access service in future without fear of failure if relapse occurs. Agree additional support for complex Service Users or refer to HSSS.

Ensure sufficient supply of varenicline to complete full course of medication. At the end of the treatment |
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| 4 (cont) | course dose tapering (reducing to 1mg per day during last week) can be recommended if client is concerned about suddenly stopping medication. Clients should be assessed for any signs of changes in mental health status especially in relation to depressed mood, agitation and extreme thoughts at every visit to the pharmacy. Varenicline cannot be supplied beyond 12 weeks. |
| 5 | **Supply** Please note that for varenicline quantity to be administered and/or supplied should follow the process according to the PGD:* 1st supply – 2 weeks (initiation pack containing 11 x 0.5mg tablets & 14 x 1mg tablets)
* 2nd supply – 2 weeks (1mg tablets x 28)
* 3rd supply – 2 weeks (1mg tablets x 28)
* 4th supply – 2 weeks (1mg tablets x 28)
* 5th supply – 2 weeks (1mg tablets x 28)
* 6th supply – 2 weeks (1mg tablets x 28)

Where the dose is reduced to 0.5mg twice a day a pack of 28 tablets to be supplied as above. Each supply must be labelled and include a patient information leaflet (PIL). |
| 6 | **Records*** Date of supply
* Client assessment form (Appendix 2 of PGD) must be completed in full and signed by pharmacist and client or completed electronically and verbally agreed by the client
* Dose
* Manufacturer / Brand
* Batch number
* Expiry date
* Any adverse reactions experienced
* Advice given

Records must be kept securely in compliance with the Data Protection Act and Caldicott guidelines. Records may be paper-based or kept electronically on a secure database app. |
| **Clinical Governance**Confidentiality is a matter of both law and ethics. All staff must respect the confidentiality of information relating to the patient and their family acquired in the course of the Service. Such information should not be disclosed to anyone without the consent of the patient. All forms and paperwork containing personal information of a patient should not be left unattended and must be kept securely when not in use, to prevent any unauthorised access to the data. A written or electronic record of consent must be obtained in accordance with Hertfordshire County Council’s Public Health Contract with community pharmacy contractors. Clients must be informed that information relating to the supply of varenicline under a PGD will be shared with HSSS, and may be shared with their GP. |
| **Incident and Near Miss**Any near miss or incident occurring while undertaking this PGD should be reported to the ResponsiblePharmacist immediately. The Responsible Pharmacist must carry out any necessary action and report the incident / near miss as per the pharmacies own Incident Reporting policy and procedure.All adverse drug reactions to varenicline must be reported immediately to the client’s GP. Clients should be advised to discontinue treatment and seek prompt medical advice if they develop agitation, depressed moodor suicidal thoughts beyond what is expected during a normal smoking cessation attempt. Serious adverse reactions (e.g. anaphylaxis) to varenicline should be reported. Should such a reaction occur the pharmacist must inform their line manager and the client’s GP and immediately complete an Incident Form. The incident should be reported to the Medicines and Healthcare Products Regulation Agency (MHRA) using theYellow Card System. Yellow Cards are available in the BNF as well as online (www.yellowcard.mhra.gov.uk). |
| **Audit (Review procedure)** Competency checks and audits will be carried out at random intervals to ensure that every member of pharmacy staff delivering the Service is familiar and up to date with the procedure at all times. This SOP will be reviewed at least every 2 years or following any critical incident. |

**Staff signature** (To be signed by all those working within the SOP (including locums)

I have read and understood the implications of the SOP:

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| --- | --- | --- | --- |
| **Name** | **Job Role** | **Signature** | **Date** |
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