31 VARENICLINE (CHAMPIX): ITS PLACE IN COMMUNITY PHARMACY

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Since qualifying in Pharmacy in 1982 from Strathclyde University, I have to date, worked in community pharmacy. After moving to Edinburgh in 1985, I have juggled work whilst being a wife and a mother to three daughters. Latterly in 2010 I took up the post of lead pharmacist for smoking cessation within NHS Lothian, supplying training and guidance for 183 pharmacies. More recently, I have taken on the role of pharmacy champion for Midlothian.

KEEPING A RECORD OF YOUR CPD

Patients, the public and the government expect that every pharmacy professional maintains their professional capability throughout their career.

Keeping a record of your CPD enables you to confirm that you are meeting these expectations. It also helps you to retain and build your confidence as a professional and provides evidence that you meet the GPhC's CPD requirement.

You must do the following:

- Keep a legible record of your CPD - either online at uptodate.org.uk, on a desktop computer, or on paper. It needs to be in a format published or approved by the GPhC, carrying the CPD-approved logo (Update: The paper submission facility has been withdrawn from the regular methods for submission of CPD entries, with effect from January 2016. If you are asked to submit your CPD entries in the 2015-16 Call and Review cycle, and you have exceptional circumstances which prevent you from submitting online, you may be eligible to submit by paper. If this is the case and you have been called to submit, please contact us after considering the other submission adjustments available to you. On paper, provided that the format has been approved by the GPhC).
- Make a minimum of nine CPD entries per year for each full year of registration, or the date you joined the register (whichever is later), or the date you last submitted CPD records as part of a Call and Review request, that reflect the context and scope of your practice as a pharmacist or pharmacy technician.
- Keep a CPD record that complies with the good practice criteria for CPD recording published in the GPhC's requirements for undertaking and recording CPD
- Record how your CPD has contributed to the quality or development of your practice using the GPhC CPD framework.
- Submit your CPD record to the GPhC when requested.

BACKGROUND HISTORY TO SMOKING CESSATION

Tobacco is the largest preventable cause of death in our nation, to that end Scotland has a vision of making smoking unfashionable, with the view that fewer than five per cent of the entire population will still be smoking by 2034.

The diagram below shows the timeline of smoking prevalence in Britain as a whole, since the late nineties, highlighting key milestones and initiatives, which have affected the outcome of the smoking population for the better.

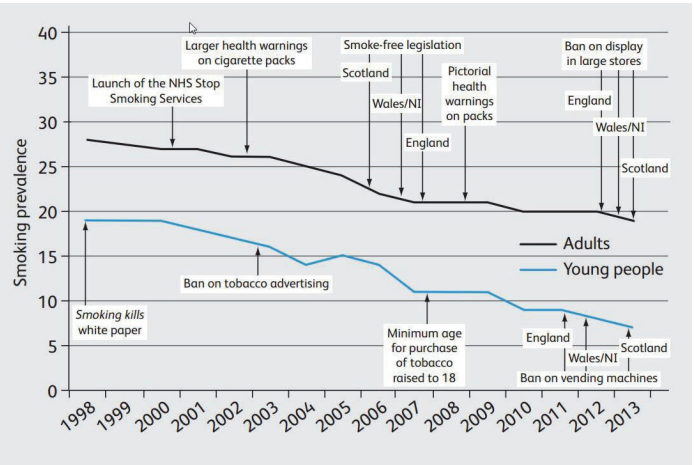
Pharmacy is at the heart of our communities, promoting health and wellness; we are best placed to make a marked improvement in the health of the nation in this field, as we have the knowledge, resources and are conveniently placed in local neighbourhoods making us accessible to our patients.

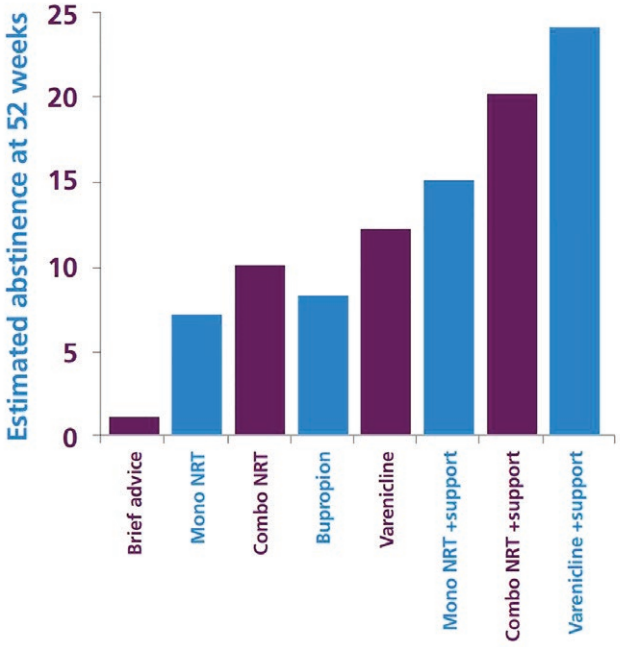
Pharmacists and their supporting staff are at the front line to encourage patients to take a look at the reasons why they smoke and consider giving up. Combining behavioural advice with pharmacotherapy for smokers, who visit the pharmacy with an ailment or long standing condition, could increase their chances of stopping. The suggestion that giving up smoking will improve a smoker's overall health, speed up the healing process and help prevent against disease could enhance their motivation to quit. Having an appropriately trained pharmacy team, pharmacies can offer services such as carbon monoxide testing, one-on-one advice and treatment on an ongoing basis, all year round.

It is important that all smoking cessation therapies be offered to any smoker motivated to quit and the benefits and risks attached to each therapy are explained. Taking into account a patient's medical history and smoking habit, an appropriate therapy can be suggested for each smoker.

The effectiveness of smoking cessation by supporting patients using a variety of methods, can be illustrated in the chart below, this clearly shows that by giving advice and treatment their chance of being abstinent from smoking increases considerably.

(Please note: Bupropion cannot be prescribed via the pharmacy scheme)





For many years we have been successfully guiding patients in our pharmacies through their stop smoking journeys, with support and nicotine replacement therapy (NRT), but latterly we have been able to access another tool in our arsenal to help us in the crusade to support our patients to a successful quit attempt.

Varenicline (Champix) has recently been made available for use in a smoking cessation quit attempt in the pharmacy scheme, prescribed by pharmacists.

The decision came after a review that recommended the service could be improved by increasing the range of products available and by making follow-up arrangements more robust. Varenicline has been successfully used in smoking cessation for a number of years by the medical profession, general practitioners and independent prescribing pharmacists.

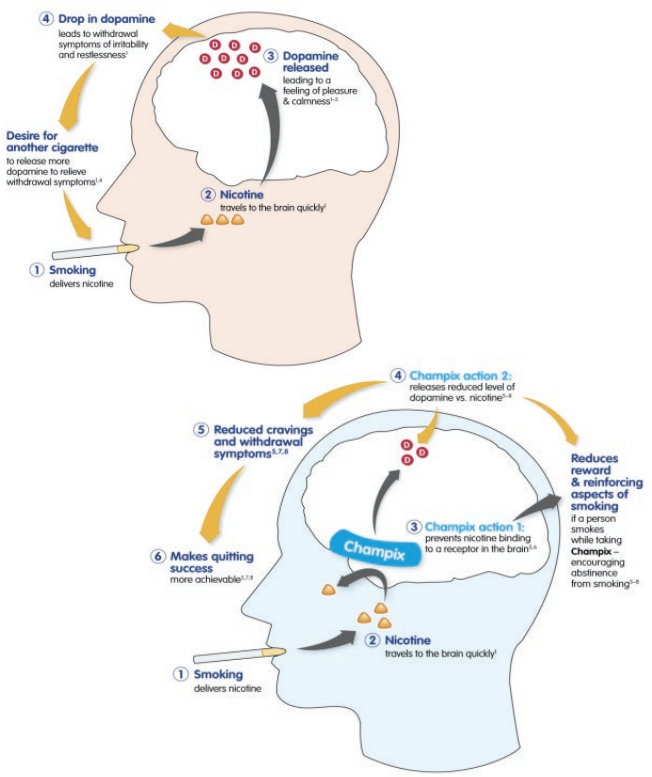
An update to the public health service (PHS) specification in June 2014 for smoking cessation services, now allows varenicline to be supplied to smokers who have already attempted to quit using nicotine replacement therapy (NRT). Patients should be monitored by the pharmacist each week for twelve weeks, and the patient's GP informed of the supply. This weekly follow-up by the pharmacist is crucial to the patient succeeding. Pharmacists should be aware that some patients request varenicline when it is not appropriate for them, and should therefore follow their local patient group direction (PGD) closely.

MODE OF ACTION OF VARENICLINE

Varenicline(Champix) became available in the UK in 2006. It binds with high affinity and selectivity to the a4ß2 nicotinic acetylcholine receptor, acting as a partial agonist that has lower intrinsic efficacy than nicotine and has antagonist activity in the presence of nicotine. Varenicline helps break the pharmacological basis of addiction in two ways helping patients to be smoke-free and nicotine-free.

When smoking, the nicotine inhaled attaches itself to the a4ß2 receptors in the brain, which then causes the release of dopamine. Varenicline blocks the nicotine's ability to fully activate these receptors and so the reward experience upon smoking is not realised. It is also believed that varenicline causes less dopamine to be released than with nicotine on activation of nicotine receptors. (Figure 1)

Figure 1: VARENICLINE (CHAMPIX) IS A NON-NICOTINE TREATMENT WITH A DUAL MODE OF ACTION



SUPPLY OF VARENICLINE

Varenicline may be supplied as part of the national public health service (PHS) contract to support quit attempts where the pharmacist has completed the patient group direction (PGD) training relevant to this product. The monthly payments associated with supply in this way will be made through the national scheme. Varenicline must be supplied using a CPUS prescription. In order for a patient to be considered, they must have tried nicotine replacement therapy (NRT) on one or more than one occasion, along with support from a recognised stop smoking service. Varenicline must be supplied along with weekly support. The patient must be assessed for suitability before being signed up to the scheme and should be informed of the risks and benefits of using varenicline to support a smoking cessation attempt. Medicine counter staff must be trained to refer each request for varenicline to that pharmacist. The pharmacist must have successfully completed training approved by NES Pharmacy MCQ2 or the local health board. The service can only be provided in an approved pharmacy, which must have a suitable area for consultation with patients. This should be a consultation room (or quiet area within the pharmacy if a room is not available).

INCLUSION CRITERIA

The Patient must be over 18 years of age, a dependent smoker, identified as sufficiently motivated to quit and agrees to receive behavioural support according to the agreed protocol. A full medical history is taken and documented and there are no contraindications or cautions for treatment with varenicline.

EXCLUSION CRITERIA

Smokers who are not sufficiently motivated to quit; are under 18 years of age; pregnant or breastfeeding women (or a women likely to be trying for a baby); have a sensitivity to varenicline or any of its excipients; have a history of severe renal impairment or end stage renal disease; patients with a history of serious psychiatric illness such as schizophrenia, bipolar disorder and major depressive disorder; patients who have epilepsy; and patients on theophylline or warfarin.

Varenicline should not be used in conjunction with other smoking cessation therapies.

DOSING

Following the one week titration, the recommended dose is 1mg twice daily; patients who are unable to tolerate the adverse effects may have the dose lowered to 0.5mg twice daily. The patient should set a quit date to stop smoking, during week two of the course, those unwilling or unable to set a quit date at this time, can chose a flexible quit date up to week four, if no quit is set at this point, the patient should be withdrawn from the service and told to try again at a future date when they are ready for another quit attempt.

The standard course is for twelve weeks. (Figure 4)

Where a patient is struggling at week ten to twelve to stop (taking varenicline), in order to titrate down, you may discuss the option to dose taper at week ten with the aim of stopping varenicline after twelve weeks of treatment.

Where local NHS Board guidelines allow we can supply beyond the twelve weeks, this is another option for the pharmacist to consider and discuss with the patient, However, you will only be remunerated for the cost of the medication supplied.

Note: A fourteen-day starter pack (11 x 500microgram tabs with 14 x 1mg tabs) can be supplied for the last two weeks of treatment either at week ten or twelve [as above]. Ensure the patient has clear instructions to take the tablets in the starter pack in reverse order to facilitate tapered discontinuation [unless on 24 weeks of therapy]. Alternatively, where no local NHS Boards scheme is in place, and the patient requires advice beyond the twelve-week period, then they should be advised that they can also seek support from the local specialist smoking cessation services and the national telephone support line Smokeline 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 www.canstopsmoking.com

Figure 2

2 WEEK STARTER PACK	Days 1–3	0.5 mg once-daily
	Days 4–7	0.5 mg twice-daily
	Days 8–14	1 mg twice-daily
2 OR 4 WEEK MAINTENANCE PACKS	Days 15+	1 mg twice-daily

COMMON ADVERSE EFFECTS

The most common side effects of varenicline, which patients should be made aware of are nausea, gastrointestinal disturbances, appetite changes, headache, sleep disturbances and dizziness. These effects are usually self limiting, but in severe cases treatment may have to be stopped, although in most cases the dose can be reduced to 0.5 mg twice daily, given after food or taken with a large glass of water. This should help reduce the nausea and gastrointestinal disturbances (GI). The second dose, if taken a few hours before bed, or after an evening meal, should reduce the sleep disturbances that can manifest as vivid abnormal dreams. In general, these adverse reactions occur in the first week of therapy.

Smoking cessation is often associated with nicotine withdrawal symptoms:

PHYSICAL

- GI – nausea, abdominal cramps, constipation diarrhoea
- Headache
- Cough or nasal drip
- Mouth ulcers
- Chest discomfort
- Hunger + weight gain
- Sleepiness

PSYCHOLOGICAL

- Irritability
- Fatigue, drowsiness, insomnia
- Dizziness
- Poor concentration
- Anxiety
- Depression
- Suicidal thoughts

- some of which can be mistaken as side effects of varenicline. It is therefore important to take this into consideration when a patient presents with them. Patients should exercise caution before driving or using machinery until they are reasonably certain that varenicline does not adversely affect their performance.

REFERRAL CRITERIA

Pharmacists should refer patients to their GP when a patient is considered eligible for varenicline but supply through pharmacy is not recommended due to the exclusion criteria. Patients on theophylline, clozapine and warfarin should be referred as close monitoring of these patients is required.

Caution should be applied to diabetic patients they may be supplied with varenicline, however patients should be advised to monitor their blood glucose level closely.

GUIDANCE

The suitability for this treatment in patients is governed by your local patient group direction (PGD),

CONSULTATIONS

A Risk Assessment form must be completed for each patient.

If the patient answers 'YES' to any of the questions, the patient is either declined varenicline or may need to be referred to their GP. (Figure 6)

The new public health service (PHS) specification also includes changes to the follow-up reporting process. Patients should be followed up at four weeks and twelve weeks post-quit date, with a carbon monoxide breath test, taken at each week and the results electronically recorded in the smoking cessation support tool in the patient care record (PCR). Payment will be linked to the submission of electronic data. (Figures 6 and 7)

NEW STUDIES AND CLINICAL DATA

The EAGLES Study Design

The study was the largest comparative randomised controlled trial of pharmacotherapy for smoking cessation conducted to date.

Main Objectives:

Safety: Characterise the neuropsychiatric safety (NPS) profiles of varenicline and bupropion vs. placebo in subjects with and without a diagnosis of psychiatric disorder.

Efficacy: Compare smoking abstinence rates of varenicline and bupropion relative to placebo in subjects with and without a diagnosis of psychiatric disorder.

Design: Randomised, double-blind, 24-week, and NRT Patch active comparator and placebo-controlled.

Four Treatment Arms: varenicline, bupropion, NRT Patch*, placebo.

Primary comparisons: varenicline vs. placebo and bupropion vs. placebo.

NRT Patch was used as an active control.

Figure 3: TREATMENT PLAN

Consultations	Treatment plan
1st week- Assessment week	Patient should set a quit date between the next 8-14 days. Supply 14 day starter pack (11 x 500 mcg tabs with 14 X 1mg tablets) *Make arrangement to see patient again before tablets run out i.e. between days 10- 14
3rd week	Patient should have set a quit date. Monitor carbon monoxide level. If patient is still smoking, he/she should be informed that treatment with varenicline would have to be stopped if he continued to smoke. Supply 14 x 1mg varenicline tablets Make arrangement to see patient the following week
4th- 12th week	Monitor carbon monoxide level and check if patient has stopped smoking. **If patient is still smoking, treatment with varenicline should be stopped.** If patient has quit smoking supply varenicline tablets. If side effects are tolerable then continue supplying one **week's supply at a time (14 x 1mg tablets)**. If patient is troubled by side effects assess whether they are tolerable or whether supply should be stopped.

Triple dummy design: all three active study drugs were blinded.

Twelve weeks of active treatment followed by twelve weeks of non-treatment follow-up.

All participants received counselling of up to ten minutes at each clinic visit.

Targeted Sample Size: 8000 total randomised subjects.

2000 per treatment arm, including 1000 with and 1000 without psychiatric disorder.

UPDATES TO THE VARENICLINE SUMMARY OF PRODUCT CHARACTERISTICS

As a result of the EAGLES study, the varenicline SPC has been updated effective as of May 23rd 2016. The black triangle and associated warning have been removed.

- Changes in behaviour or thinking, anxiety, psychosis, mood swings, aggressive behaviour, depression, suicidal ideation and behaviour and suicide attempts have been reported in patients attempting to quit smoking with varenicline in the post-marketing experience.
- A large randomised, double-blind, active and placebo-controlled study was conducted to compare the risk of serious neuropsychiatric events in patients with and without a history of psychiatric disorder treated for smoking cessation with varenicline, bupropion, nicotine replacement therapy patch (NRT) or placebo. The primary safety endpoint was a composite of neuropsychiatric adverse events that have been reported in post-marketing experience.
- The use of varenicline in patients with or without a history of psychiatric disorder was not associated with an increased risk >

Figure 4: VARENICLINE CLINICAL RISK ASSESSMENT FORM

Is patient under 18 years of age
Is patient pregnant or breastfeeding?
Does patient suffer from renal impairment or has end stage renal disease?
Does patient have a history of psychiatric illness ?
Does patient suffer from epilepsy?
Is patient currently on another smoking cessation therapy?
Is patient on any other medication?
Is patient hypersensitive to varenicline or any of its excipients?
Only make a supply if you are certain that to the best of your knowledge, it is appropriate to do so

of serious neuropsychiatric adverse events in the composite primary endpoint compared with placebo. Depressed mood, rarely including suicidal ideation and suicide attempt, may be a symptom of nicotine withdrawal.

- Clinicians should be aware of the possible emergence of serious neuropsychiatric symptoms in patients attempting to quit smoking with or without treatment. If serious neuropsychiatric symptoms occur whilst on varenicline treatment, patients should discontinue varenicline immediately and contact a healthcare professional for re-evaluation of treatment.

A GP sample letter (Figure 5) is also part of standard documentation and should be given to the GP to confirm the patient has been supplied with this medication by you, allowing the GP to update their records and to make them aware of the supply.

Figure 5: GP SAMPLE LETTER

Dear Dr

Patient's name: Address: DOB:

I saw the above patient at the pharmacy today and I have recommended and supplied him/her with varenicline tablets to help him/her give up smoking. The patient would be taking varenicline for a maximum of 12 weeks. Could you please add this medicine to the patient's medication records? No further action would be required from you, as the patient would 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)

CONCLUSIONS OF STUDY

There is no significant increase in neuropsychiatric adverse effects (AEs) in varenicline compared with NRT patch or placebo.

The neuropsychiatric safety warning has been amended, to read a patient with or without psychiatric disorder is not associated with an increased risk of serious neuropsychiatric adverse events compared with placebo.

Care should be taken with patients with a history of psychiatric illness.

Varenicline shows superior abstinence rates compared to other methods and placebo.

A superior efficacy statement has been added, where patients treated with varenicline demonstrated an increased abstinence during weeks nine through twelve compared to NRT or placebo. •

Figure 6: PCR ADDITIONAL INITIAL DATA SET QUESTIONS FOR VARENICLINE

Smoking cessation

Initial data capture

Client information		**Referral and intervention context**	
Gender	Male	Referral date	19-Aug-2014
Pregnant	No	Referral source	Self-referral
Ethnic group	White Scottish	Referral source (other)	
Ethnic group (other)		Intervention setting(s)	Primary Care
Employment status	In paid employment	Intervention setting (other)	
Employment status (other)		Date of initial appointment	19-Aug-2014
Tobacco use and quit attempts		Intervention(s) used in this quit attempt	One to one sessions
Cigarettes smoked	10 or less	Intervention (other)	
Time after waking	31 to 60 minutes	Is shared care	No
Number of quit attempts	2 or 3 times	**Consent**	
Pharmaceutical usage		Consent to follow up	Yes
Pharmaceutical usage	Varenicline only		
Pharmaceutical usage weeks	3		

Varenicline - *a Varenicline risk assessment must be completed prior to supply*

Does the Varenicline risk assessment indicate that the patient's GP should be contacted to confirm Varenicline appropriateness?	No - GP contact not required
I confirm that I am aware the GP must be informed that the patient will begin on Varenicline	Yes

Figure 7

If 'Other' chosen above, please specify	
Date of initial appointment	19-08-2014
Intervention(s) used in this quit attempt	One to one sessions ☑ Couple/family based support ☐ Group support (closed groups) ☐ Other (please specify) ☐ Telephone support ☐ Unknown ☐ Group support (open/rolling groups) ☐
If 'Other' chosen above, please specify	
Shared care between pharmacy and non-pharmacy services?	○ Yes ◉ No
Pharmaceutical usage	
Pharmaceutical usage	Varenicline only
Total number of weeks of known product use	3
A Varenicline risk assessment must be completed prior to supply	
Does the Varenicline risk assessment indicate that the patient's GP should be contacted to confirm Varenicline appropriateness?	No - GP contact not required (Please select / Yes - GP has been contacted / No - GP contact not required)
I confirm that I am aware the GP must be informed that the patient will begin on Varenicline	

TRAINING AND EDUCATION

When involved with the smoking cessation service, the pharmacist and support staff offering the service must complete the online NHS Education for Scotland (NES) Multiple Choice Questions (MCQ1) accessed at:

www.nes.scot.nhs.uk/education-and-training/by-discipline/pharmacy/about-nes-pharmacy/educational-resources/resources-by-topic/public-health-and-emergency-planning/public-health/smoking/smoking-cessation/smoking-cessation-training.aspx

Studied the Public Health Service (PHS) circular June 2014 service specification accessed at:

www.communitypharmacyscotland.org.uk/media/75131/PCA2014-P-12.pdf#Page=3

The Pharmacist must also, as well as completing the PGD, have satisfactorily completed the approved online training by NHS Education for Scotland (NES) Multiple Choice Questions (MCQ 2) which can be accessed at:

www.nes.scot.nhs.uk/education-and-training/by-discipline/pharmacy/about-nes-pharmacy/educational-resources/resources-by-topic/public-health-and-emergency-planning/public-health/smoking/smoking-cessation/smoking-cessation-training.aspx

Varenicline Patient Group Direction (PGD) associated with your local NHS board accessed at :

www.communitypharmacy.scot.nhs.uk/nhs_boards.html

FOOT NOTE

In my personal experience, I feel it is one of the most rewarding parts of our profession where we can make substantial health and financial improvements to a person's life and make a real difference.

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