INTERIM GUIDANCE ON BUPROPION SR (ZYBAN)

January 2001

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Interim Guidance on the use of bupropion (Zyban)

Summary

- 29% of the adult population in Northern Ireland smoke. This results in some 2,500 - 3,000 deaths per annum. Given these large numbers, even apparently small looking percentage figures for smoking cessation are worth striving for as they actually mean success for quite large numbers of people and significant health improvement. It is recognised that much work has already taken place, both in the health service and in the voluntary sector, to raise awareness of the dangers of smoking and to help people to stop.

- Bupropion (Zyban) is a welcome aid to smoking cessation but, on the basis of the currently available research/evidence, the Group would advise that:-

  a) Buproprion does not currently have clear benefits over nicotine replacement therapy or vice versa; and

  b) Bupropion should only be prescribed:

     - to people highly motivated towards smoking cessation; and
     - in the context of structured intensive behavioural support

     as these are the circumstances in which its effectiveness has been researched. There is no research evidence of any benefit where such circumstances do not apply.

- It is important that intermediate "specialist" smoking cessation services are developed, as soon as possible, in order to ensure that the majority of people in the community have access to them including, those for whom pharmacotherapies are contra-indicated or unsuitable.

- The current evidence shows that the success of specialist smoking cessation practitioners relates to:-

  a) the nature of their training in specialist cessation techniques; and
  b) having dedicated time and funding to provide this service.

- Pharmacotherapies increase the likelihood of a successful quit attempt. When choosing a particular product or approach, practitioners should consider:-

  - the person's wishes;
  - the person's motivation;
  - the proven efficacy of the product/technique;
  - contra-indications, unwanted side effects and drug interactions of particular pharmacotherapies;
  - the availability of local specialist behavioural support and advice; and
  - the cost of the intervention both to the person and to the Health Service.

- Further to a request for bupropion, the person needs to return for a detailed pharmacological and motivation assessment in order to determine the suitability of the product. The person should be required to set a "quit date" and must understand and accept the need for specialist smoking cessation follow-up/behavioural support.

- This follow-up means intensive behavioural support and advice over, at the least, several weeks. This is in keeping with the evidence base upon which successful specialist cessation interventions are based and is in line with the context of the clinical trials in which the use of bupropion was researched.

1.0 INTRODUCTION

1.1 In June 2000, bupropion (Zyban) was licensed as “an aid to smoking cessation in combination with motivation support.” Following its introduction, there was considerable patient demand for buproprion but little guidance was available for practitioners on the place of this medicine in the range of smoking cessation interventions.

1.2 CREST Drugs Advisory Group convened a working group to provide advice on bupropion. The remit of the group was to:

- review the evidence on the effectiveness of bupropion as a smoking cessation aid; and
- provide advice to the service on:

  a) the place of bupropion in the range of smoking cessation interventions; and

  b) the circumstances in which bupropion should be prescribed.

It was agreed that the main focus of the document was to provide guidance for those professionals who work in primary care.

1.3 The guidance contained in this booklet is “interim guidance” as it is known that pharmacotherapies for smoking cessation will be the subject of National Institute for Clinical Excellence (NICE) appraisal process sometime in 2001. Although NICE guidance does not apply to Northern Ireland, it is considered that this CREST document should be reviewed following the publication of the NICE Final Appraisal Determination.

1.4 In addition, although bupropion is a “Prescription Only Medicine” and is available here on an HS21, many of the nicotine replacement products currently available as “Pharmacy” products are not. The Minister for Health, Social Services and Public Safety, Bairbre de Brún, has recently given a commitment to consult upon making all NRT products available on prescription in 2001, in order to help people who wish to stop smoking.

2.0 SMOKING PREVALENCE IN NORTHERN IRELAND

2.1 29% of the adult population in Northern Ireland smoke. Yet it is known that two thirds say they want to give up.

PREVALENCE OF CIGARETTE SMOKING BY AGE BANDS AND GENDER 1998/99

All adults aged and over *Percentages*

Age Bands	Male	Female	All Persons
	%	%	%
16-19	15	24	20
20-24	36	39	38
25-34	37	37	37
35-49	30	35	33
50-59	29	28	28
60+	20	17	18
All ages	28	29	29

Source: Continuous Household Survey

2.2 The harmful effects of smoking are the greatest single cause of premature death and ill health in Northern Ireland. They are also the cause of major inequalities in health. Rates of smoking in the population are higher in NI than in other parts of the UK but even taking an average figure for England and Wales would indicate that the direct costs, per year, of smoking are, at least, £46.20m for our population of 1.6 million people made up of:-

GP Visits	-	£ 8.25m
Related prescriptions	-	4.95m
Inpatient costs	-	10.56m
Day cases	-	6.27m
Outpatient visits	-	16.17m
		£46.20m

Source:- Parrott S, Godfrey C, Raw M et al Thorax 98; 53 (Supl 5): 1-38

The number of people smoking is high; this means that even achieving small looking percentages of smoking cessation translates into significant numbers of people for whom benefits occur.

2.3 Giving up without support is difficult; only about 2% of smokers manage to do so each year. Bupropion and nicotine replacement therapies do have a place in helping smokers quit but it was the view of the Group that prescription of these medicines needs an appropriate supportive environment to maximise the quit attempt.

3.0 BUPROPION

3.1 Dosage and administration

Bupropion is marketed in the UK as a 'prolonged release' 150mg tablet. The Summary of Product Characteristics recommends that smokers aged 18 or over start taking bupropion 1-2 weeks before the intended quit date, taking one tablet daily for the first three days and then two tablets daily for 7-9 weeks. A reduced dose is recommended for the elderly and in those who have liver or renal impairment (see below for details of contra-indications/precautions).

3.2 Evidence on efficacy

The efficacy of bupropion has been established by two randomised, placebo-controlled trials (Hurt et al, 1997; Jorenby et al, 1999). The first of these studies (Hurt et al, 1997) which was double blinded showed that in 615 smokers, who were motivated to stop smoking, 23.1% of patients in the bupropion treatment group were not smoking at 12 months compared to 12.4% in the placebo group. A dose-response curve for bupropion was identified with 150 mg daily and 300 mg daily being statistically more effective than placebo and bupropion 100 mg daily.

The second study (Jorenby et al, 1999) compared the efficacy of bupropion SR with NRT, bupropion and NRT combined and placebo. At one year, 15.6% in the placebo group were not smoking compared with 16.4% in the NRT patch group, 30.3% in the bupropion group and 35.5% in the bupropion/NRT combination group. These figures identify point abstinence, i.e. the person was not smoking at that point in time. Continuous abstinence - those subjects who did not smoke during the 12 months - showed lower cessation rates with 5.6% in the placebo group having not smoked in the 12 months from stopping compared to 9.8% in the NRT patch group, 18.5% in the bupropion group and 22.5% in the group using a combination of bupropion and NRT. Abstinence rates were higher with combination therapy than with bupropion alone, but the difference was not statistically significant (p=0.61).

In both these studies intensive behavioural support was provided to subjects. This does not reflect general medical practice, therefore, it is impossible at this time to predict the efficacy of bupropion in settings where such behavioural support is not provided.

It would appear inappropriate, with the evidence available, to view bupropion as more effective than NRT. In the study where NRT was compared with bupropion, (Jorenby et al, 1999) NRT performed poorly with an odds ratio of 1.1 compared to placebo. A large evidence base consisting of some 80 studies, which demonstrate that NRT is twice as effective as placebo, does not support the level of efficacy of NRT shown in this study.

One finding of both studies was that subjects taking bupropion have less of a weight gain. Since weight gain is often an issue that stops making a cessation attempt, then this might be a motivational factor for consideration.

A relapse-prevention study has been published as an abstract (Hays 2000: Rigotti 2000) which examined whether prolonged treatment with bupropion had any effect on preventing relapse after successful initial cessation with bupropion. A total of 784 smokers were treated with bupropion 300 mg daily for 7 weeks. Of the 432 who successfully achieved abstinence, half were randomised to placebo and half to continue on bupropion for a further 45 weeks. Prolonged treatment with bupropion delayed time to relapse (156 days vs 65 days with placebo). Continuous abstinence rates at 6 months were higher for patients continuing to receive bupropion than those on placebo (55% vs 44%).

3.3 Side effects

The commonest side effects found with bupropion are insomnia (35-40% of users) and dry mouth (10%). Around 6% of patients appear to develop hypertension when treated with a combination of bupropion and NRT. There is a dose dependent risk of seizure with bupropion which is estimated at about 1: 1000 with doses up to 300 mg daily (Dunner, 1998). Rarely bupropion causes a reaction that resembles serum sickness, where patients present with symptoms such as joint and muscle pain, fever, rash and hives. Other common side effects include gastrointestinal pain/upset, tremor, concentration disturbance, headache, dizziness, depression, agitation, anxiety and taste disorders. For details of suspected adverse reactions and safety update see Zyban (bupropion hydrochloride) - safety update. www.open.gov.uk/mca/mcahome/htm.

3.4 Contra-indications

Use of bupropion SR is contraindicated in patients with a history of seizures, a current or prior diagnosis of bulimia or anorexia nervosa or a previous history of allergy to bupropion SR or any other constituent of the formulation. Concurrent use of bupropion SR and a monoamine oxidase inhibitor (MAOI) is contraindicated and at least 14 days should elapse between discontinuation of a MAOI and initiation of treatment with bupropion SR. Other contra-indications include severe hepatic cirrhosis and bipolar disorder.

3.5 Precautions

Precautions with the administration of bupropion SR include predisposition to lowered seizure threshold/increased risk of seizures (including previous head injury, brain tumour, other medications, alcohol abuse, diabetes), renal or mild-to-moderate hepatic impairment, elderly, susceptibility to psychotic episodes.

3.6 Drug interactions (information based on the SPC)

These tables have been reproduced with the kind permission of Professor Robert West, St George's Hospital Medical School, London and Mr Nick Beavon Pharmaceutical Advisor, Kingston and Richmond Health Authority, England.

Bupropion - Drug Interactions (Information based on SPC)

Interaction	Examples	Recommended Action
MAOIs	tranylcypromine phenelzine moclobemide	Contra-indicated. At least 14 days should elapse between discontinuation of irreversible MAOIs and initiation of bupropion.
Drugs metabolised by the CYP2D6 enzyme (a subset of the hepatic metabolic enzyme system cytochrome p450)	Antidepressants e.g. desipramine, imipramine, paroxetine, Antipsychotics e.g. thioridazine risperidone Beta-blockers e.g. metoprolol Type 1c antiarrhthmics e.g. flecainaide propafenone	Initiate concomitant therapy at the lower end of the dosage range or decrease dose when bupropion added to the treatment regimen.
Drugs metabolised by CYPA2	theophylline clozapine	Administer with caution.
Drugs that lower seizure threshold	Antipsychotics Antidepressants theophylline Systemic steroids Abrupt discontinuation of benzodiazepines Quinolones (e.g.ciprofloxacin)	Administer with extreme caution.
Drugs which may inhibit the metabolism of bupropion	cimetidine sodium valproate	Administer with caution.
Drugs which may induce the metabolism of bupropion	carbamazepine phenobarbitone phenytoin	Administer with caution. Bupropion is contra-indicated in patients with current or previous seizure disorder.
Drugs which may affect bupropion’s metabolism by the CYP2B6 isoenzyme	orphenadrine cyclophosphamide ifosfamide	Administer with caution.
Other important interactions	levodopa	Administer with caution.

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Bupropion - Special Patient Groups (Information based on SPC)

Patient type	Recommendation
Children and adolescents	Not recommended in patients under 18yrs of age- no data available.
Elderly	Use with caution. Increased sensitivity may be an issue (more likely to have decreased renal function); 150mg once daily is recommended.
Hepatically impaired	Contra-indicated in patients with severe hepatic cirrhosis (reduced clearance leading to high plasma levels). Use with caution in mild-to-moderate hepatic impairment which may lead to higher levels. 150mg daily is recommended. Monitor closely for possible undesirable effects (e.g. insomnia, dry mouth, seizures) indicating high drug metabolite levels.
Renally impaired	Use with caution. 150mg once daily recommended. Monitor closely for possible undesirable effects (e.g. insomnia, dry mouth, seizures) indicating high drug metabolite levels.
Psychiatric	Contra-indicated in patients with a history of bipolar disorder. May precipitate psychotic episodes in susceptible patients; use with caution.
Pregnant/lactating women	Bupropion should not be used in pregnancy/lactation - no data is available on this patient group - risk unknown. * Consider NRT if the patient is unable to stop but see product labelling for cautions and contra-indications.
Predisposed towards seizure	Contra-indicated in patients with current or previous seizure disorder. Use with extreme caution in patients with certain conditions including: • history of brain trauma • brain injury • CNS tumour • concomitant administration of medicines known to lower the seizure threshold e.g. antipsychotics, antidepressants such as SSRIs, theophylline, sytemic steroids. Also use with caution in circumstances of: • alcohol abuse • abrupt withdrawal from alcohol/benzodiazepines • diabetes treated with hypoglycaemics/insulin • use of stimulants/anorectic products.
Eating disorders	Contra-indicated in patients with current or previous diagnosis of bulimia or anorexia nervosa.
Hypersensitivity	Contra-indicated in patients with current hypersensitivity to bupropion or excipients in the tablets (excipients do not include lactose). Discontinue if patient experiences hypersensitivity or anaphylactic reactions e.g. rash, pruritis, urticaria, chest pain, oedema or dyspnoea.

Inserted by CREST

*There is some evidence that nicotine may be implicated in some of the damage to the fetus from smoking in pregnancy, but the harm from NRT would be expected to be less than from smoking. Therefore, a judgement needs to be made in each case about whether the mother would be able to stop without NRT. If NRT is used it would be prudent to advise more strongly than usual that it be stopped if the mother resumes smoking . In addition, it may be preferable for patients to use oral dosing forms rather than transdermal patches because nicotine levels can be reduced more rapidly in the event of problems.
SOURCE: West, Mc Neill and Raw - Thorax; 55, 997

4.0 EVIDENCE ON EFFECTIVENESS OF SMOKING CESSATION INTERVENTIONS

4.1 The main evidence on smoking cessation effectiveness comes from systematic reviews contained in the *Cochrane Database Systematic Reviews 2000* and *Treating Tobacco Use and Dependence 2000* from the Agency for Healthcare Research Quality. *Smoking Cessation Guidelines for Health Professionals and Guidance for Commissioners on the Cost Effectiveness of Smoking Interventions* was published in THORAX in December 1998 and updated guidance is available in the December 2000 edition of the THORAX Journal. A summary of the evidence base can be found in the DHSSPS publication *Smoking Cessation - How health professionals can help (2000)*

4.2 The interventions range from brief opportunistic advice during the course of a routine consultation with a health professional to 'specialist' intensive face to face behavioural support and advice from a health professional either in a group or one to one. This health professional should be specifically trained for this purpose, have dedicated time and be paid for this job. Both of these interventions are more successful if pharmacotherapies, such as bupropion or NRT, are used.

Table 1: *Incremental effects of smoking cessation interventions on abstinence for 6 months or greater (published in THORAX 2000)*

Intervention	Target Population	Effect Size[e]	95% Confidence Interval[f]
Brief opportunistic advice from a physician to stop	Smokers attending GP surgeries or outpatient clinics	2%	1%-3%
Face-to-face intensive behavioural support from a specialist[g]	Moderate to heavy smokers seeking help with stopping	7%	3%-10%
Face-to-face intensive behavioural support from a specialist	Pregnant smokers	7%	5%-9%
Face-to-face intensive behavioural support from a specialist[h]	Smokers admitted to hospital	4%	0%-8%
Pro-active telephone counselling[I]	Smokers wanting help with stopping but not receiving face to face support	2%	1%-4%
Written self-help materials	Smokers seeking help with stopping	1%	0%-2%
Nicotine gum	Moderate to heavy smokers receiving *limited*[J] behavioural support	5%	4%-6%
Nicotine gum	Moderate to heavy smokers receiving *intensive* behavioural support	8%	6%-10%
Nicotine transdermal patch	Moderate to heavy smokers receiving *limited* behavioural support	5%	4%-7%
Nicotine transdermal patch	Moderate to heavy smokers receiving *intensive* behavioural support	6%	5%-8%
Nicotine nasal spray	Moderate to heavy smokers receiving *intensive* behavioural support	12%	7%-17%
Nicotine inhalator	Moderate to heavy smokers receiving *intensive* behavioural support	8%	4%-12%
Nicotine sublingual tablet	Moderate to heavy smokers receiving *intensive* behavioural support	8%	1%-14%
Bupropion (300mg pd SR)	Moderate to heavy smokers receiving *intensive* behavioural support	9%	5%-14%
Intensive behavioural support plus NRT or bupropion[k]	Moderate to heavy smokers seeking help from a smokers' clinic	13-19%	

Source: West R, McNeill A, Raw M. (2000) Smoking Cessation Guidelines for Health Professionals - an update - THORAX . 55, 990

[e] Difference in >6 month abstinence rate between intervention and control/placebo in the studies reported; data from Cochrane meta-analyses unless otherwise stated.

[f] The range within which one can be 95% confident that the true underlying value lies.

[g] Efficacy figures based on subset of studies from general population with biochemical verification.

[h] No Cochrane review available, data from USDHHS meta-analysis.

[I] No Cochrane review available, data from USDHHS

[J] The term 'limited behavioural support' refers to brief sessions required primarily for collecting data. Following the Cochrane definition, 'intensive' behavioural support was defined as an initial session of more than 30 minutes, or an initial session of less than 30 minutes plus more than two subsequent visits.

[k] Expected effect combining effect of medication with effect of behavioural support.

4.3 *Brief Opportunistic Advice* is delivered opportunistically during the course of the consultation regardless of whether or not the patient is seeking help. In general, it is those who smoke less than 10 per day who stop in response to brief advice from the GP, unless some additional assistance or medication is used. Brief advice typically involves;-

ASKING the patient about their current smoking status.

ADVISING them to stop and of the benefits of doing so. A record should be made of the individual's response.

ASSISTING patients by giving them information on (a) professional(s) in their area who has been specifically trained in evidence based smoking cessation techniques.
In addition, information should be given on the benefits and disadvantages of both bupropion and nicotine replacement therapy.

ARRANGING- Follow up.

The main purpose of brief opportunistic advice is to trigger a quit attempt and to give assistance to those who want it. In addition, it can motivate quitters who are unwilling to quit at this time. The Group considered that, during the course of a routine busy consultation, it was not reasonable to do more than give brief advice and ask the patient to return for a more detailed consultation when a decision on whether bupropion should be prescribed would be taken. This may also be seen as a test of the patient's motivation; however, every effort should be made to encourage the patient to return (see below).
If the patient is not interested in returning then, specific advice should be given on the benefits of NRT. (See ***Appendix A*** for current details of NRT products).

4.4 We believe it is important for all professionals involved in encouraging smoking cessation to have an understanding of the process through which people change addictive behaviours. Such understanding of the issues involved in the contemplation of change, the point of motivation, the reasons for relapsing, etc. are likely to enable the professional to help the person better and also to be less frustrated themselves.

4.5 **Specialist behavioural support and advice**

Two examples of specialist cessation services are contained in Appendix B. One is based in primary care, using specially trained practice nurses, the other gives details of how a large specialist clinic serving a population in excess of 250,000 might be run. Both are good examples of evidence based smoking cessation initiatives. For further details on the definitions and monitoring required of DHSSPS smoking cessation services see DHSSPS Monitoring Guidance 2000. In addition, the DHSSPS has asked Boards to collaborate with the voluntary sector when developing local services.

4.6 It is envisaged that a number of models using professionals such as trained nurses and pharmacists in primary care might develop in primary care where people living in local rural communities have access to them. Most of the services delivered in primary care will typically give support over a number of weeks, say 5-8 weeks with the addition of bupropion or NRT, where appropriate. Those wanting to deliver group therapy will require greater training and skills in the facilitation of groups.

4.7 DHSSPS has made available £280,000 for smoking cessation initiatives in 2000-2001. This money, allocated via Health and Social Services Boards, is to promote brief opportunistic interventions and 'specialist' intermediate services in primary care, and services for specific patient groups in the secondary sector. The three main categories targeted are:

- adults who want to stop, particularly those disadvantaged in society;
- pregnant women; and
- preventing children and young people from smoking.

In addition, Health and Social Services Boards have been asked to consider the preparation a joint plan for the future development of a regional specialist smoking cessation clinic, which may also involve outreach clinics. As this will take time to develop, it is not envisaged that this will have commenced before 2001-2002. It is hoped that the money available in 2000-2001 for evidence based services, together with the range of service initiatives currently under development in the primary and secondary sectors, will ensure that those who have been prescribed bupropion or NRT have an appropriate supportive environment. This should enhance the quit attempt. Practitioners will also wish to promote evidence based smoking cessation techniques in routine health promotion and disease management sessions.

4.8 It is recommended that further consideration should be given to the development of a consistent evidence based approach to training in Northern Ireland, building on existing training programmes.

5.0 THE ISSUE OF MOTIVATION

The group was very conscious of the importance of motivation in the context of the clinical trials of the effectiveness of bupropion (Zyban). It was also very aware of the people for whom there are contra-indications to the use of bupropion or of nicotine replacement therapy.

Two different approaches are possible:-

1) To consider first whether there are contra-indications to the use of bupropion or NRT and then, if there are not, to assess the person’s motivation towards smoking cessation.

2) To consider the previous motivation first and then to assess whether there are contra-indications to the use of pharmacotherapies.

The group concluded that motivation should be assessed first as this will still ensure that those who are significantly motivated can still be referred to smoking cessation services with positive reinforcement even though they may not be able to receive additional enhancing pharmacotherapy. This sequence is considered more fair and equitable for all, whether they can or cannot receive pharmacotherapy for reasons of other illness/condition and is less likely to reduce people's motivation. It must be remembered that even the lower levels of success rate are important both to the individual's health and to overall health gain.

6.0 WHAT TO DO WHEN A PATIENT PRESENTS ASKING FOR BUPROPION

6.1 All points outlined below relate to the 4A sequence.

6.1.1 The patient should be congratulated for taking the initiative to come and address their tobacco dependence.

6.1.2 ASK and record current smoking status on file and/or computer.

6.1.3 Check motivation of the patient (see 6.2 for sample protocol).

6.1.4 ADVISE on the benefits of giving up and, if appropriate, highlight dangers of smoking for this particular patient i.e. in the context of previous illness/ chronic disease. Record the individual's response to advice.

6.1.5 ASSIST by briefly going through the options for further support. Advise on NRT or bupropion. Explain that a detailed assessment is needed as to their suitability for bupropion.

6.1.6 ASSIST by giving the patient a leaflet on bupropion and NRT (for example, see ***Appendix C***). Indicate that you will want to discuss it next time.

6.1.7 Advise the patient that setting a quit date will be discussed with them on the next visit and, in the interim, they should consider when commencement of a quit attempt would be suitable.

6.1.8 If the patient indicates that they are willing to return and are likely to proceed with follow up, you may wish to consider taking a baseline CO monitoring. CO monitoring will be required for those wishing to participate in the DHSSPS smoking cessation initiatives but the Group considered that it was not essential to perform CO monitoring to confirm abstinence.

6.1.9 ARRANGE - either make the appointment via the receptionist as part of consultation or ask the patient to make it on the way out. The follow up appointment might be with the GP but it might also be with the practice nurse, practice pharmacist (see below) or other suitably trained professional.

6.2 Sample protocol for bupropion (Zyban) consultation

The following protocol, reproduced with the permission of Professor Robert West, may assist practitioners in determining the course of action that is most suitable to address the needs of a particular patient. We consider that rather than giving the patient literature to digest in the waiting room, the patient should be asked to read it at home and arrangements should be made for them to return another day for further pharmacological assessment, if appropriate. If the patient returns, this is also an endorsement of the patient's motivation.

GP CONSULTATION GUIDANCE FOR PATIENTS COMING TO SURGERY WANTING ZYBAN

The goal of the consultation should go beyond responding to the direct request for bupropion to ensuring that the patient receives the most appropriate form of treatment for their tobacco dependence.

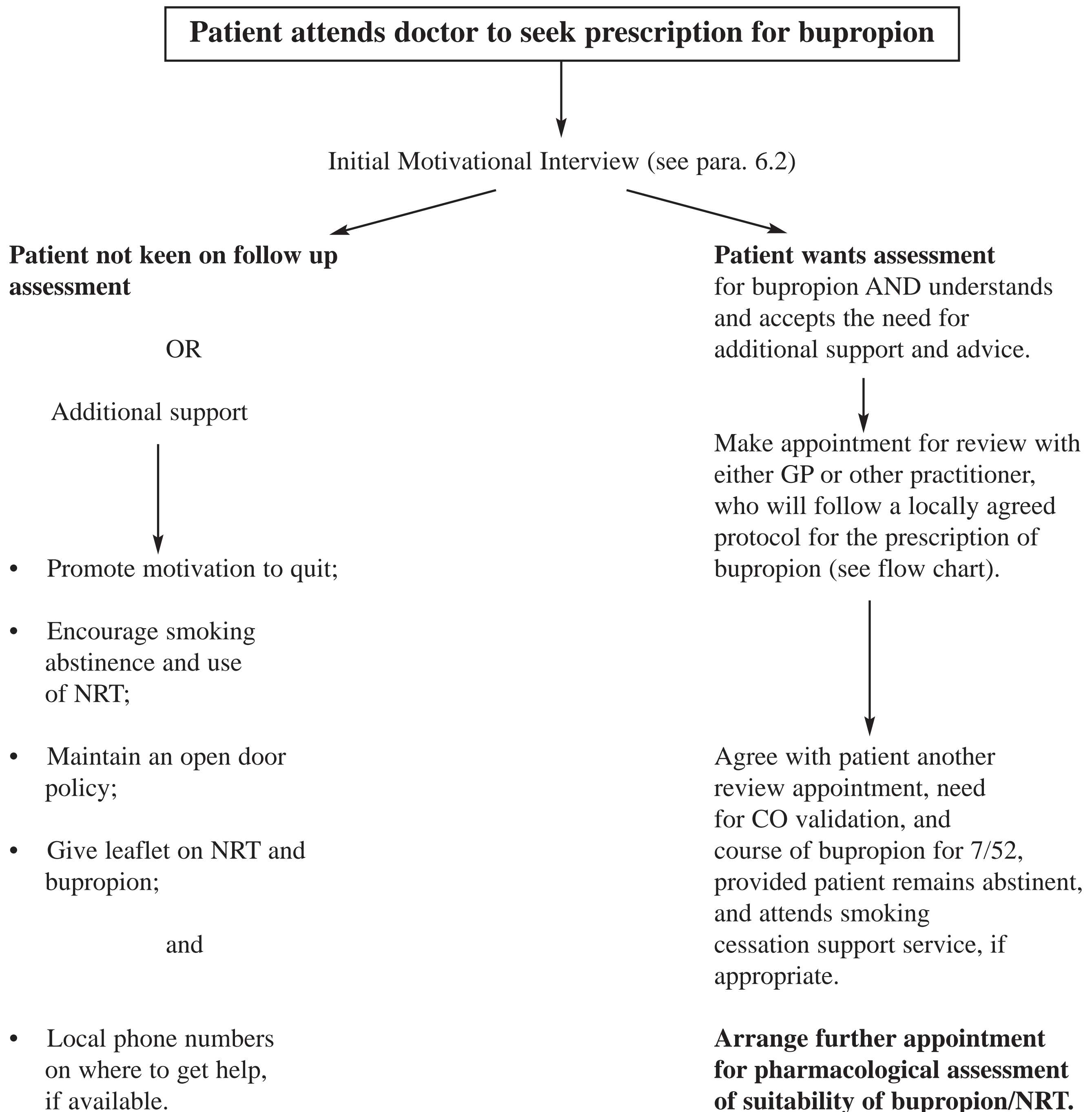
The following protocol may help to achieve this:-

Activity	Possible example
1.Welcome the quit attempt	'I'm delighted that you have decided you want to stop smoking, Mrs Smith.'
2. Inform patient that a range of help is available and check motivation	'I just want to take a moment to go over what we can do to help you stop, including a prescription for Zyban if that is appropriate. 'First of all, can I just check a couple of things?' 'How many cigarettes a day do you smoke?' (If <10 per day Zyban may not be appropriate but referral to specialist service may be.) 'Can you tell me what has prompted you to have a go at stopping now?' 'Are you intending to stop smoking for good? 'Are you ready to stop as soon as possible, say in the next week or so?' (If answers reveal ambivalence about stopping, then consider deferring the quit attempt.)
3. Reinforce the motivation to stop.	'That's fine. Thank you - you've obviously made up your mind that now is a good time to make the break and frankly, I agree with you.'

4. Briefly describe the assistance on offer	'Now let me briefly go over what we can offer you. There is a clinic run by a specialist trained in helping people stop smoking and there is plenty of evidence that this gives the best chance of stopping - the clinic offers a range of nicotine products or Zyban, depending on your preference and suitability.' 'Zyban is effective at helping smokers stop but we need to make sure that you are suitable for it and you will need to come back in a few weeks so we can check on your progress.' 'Nicotine patches and other products are also effective and if you have got on well with them in the past you should consider giving them another go.'
5. Give out a brief information leaflet	'Here is a brief guide to what is available. It will also help you see whether you are suitable for medicines such as Zyban.'
6. Ask the patient to read the leaflet and come back in after a few minutes	'I want you take this guide back to the waiting room and look through it for a few minutes then come back in and we can take it from there. When you go out tell the receptionist that I want to see you again in a few minutes and she will book you in.'
7. When the patient comes back - find out how he or she wants to proceed	'You've had a chance to read the guide. Is there anything you would like me to go over with you?' 'How would you like to proceed?'
8. Proceed accordingly	

6.3 Patient attends doctor to seek prescription for Zyban

The following flow chart describes the sequence that should be followed if a patient attends the GP surgery seeking a prescription for bupropion (Zyban).



6.4 Patient returns for pharmacological assessment

The practitioner may wish to consider following the flow chart (below) when assessing the suitability of bupropion or NRT. In addition he should take account of the list of contra-indications and special patient groups. The options that are available are that the patient may:

a) be suitable for bupropion or NRT and may wish to take this medication; or

b) may not be suitable for any pharmacological intervention eg in pregnancy.

Regardless of whether medication is appropriate or not, all patients should receive intensive behavioural support and advice if it is requested and is available.

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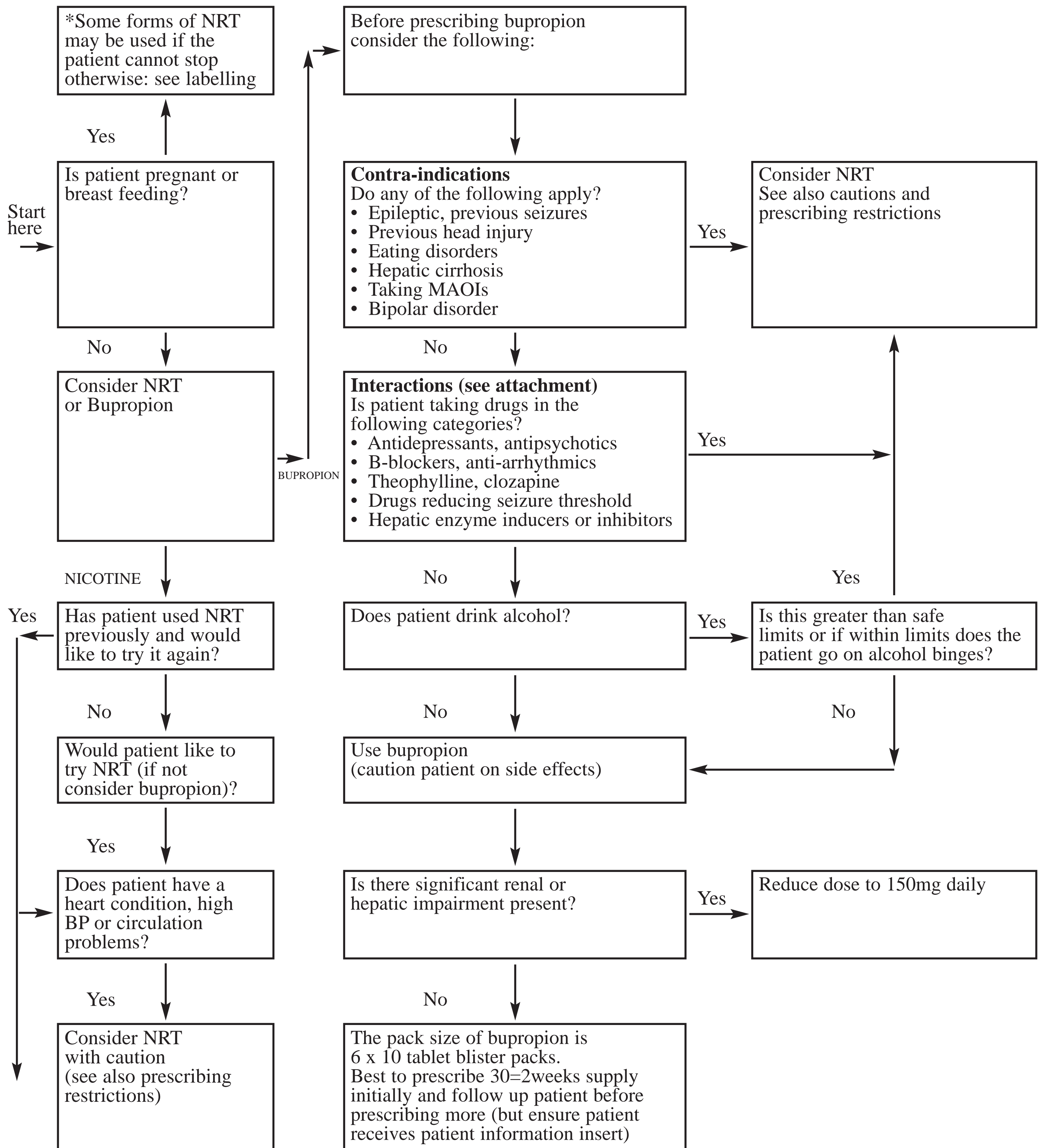
How to choose between NRT and Bupropion (advice to clinicians)

SOURCE: Professor Robert West, St George's Medical School, London.



***Inserted by CREST**

There is some evidence that nicotine may be implicated in some of the damage to the fetus from smoking in pregnancy, but the harm from NRT would be expected to be less than from smoking. Therefore, a judgement needs to be made in each case about whether the mother would be able to stop without NRT. If NRT is used it would be prudent to advise more strongly than usual that it be stopped if the mother resumes smoking . In addition, it may be preferable for patients to use oral dosing forms rather than transdermal patches because nicotine levels can be reduced more rapidly in the event of problems.
SOURCE: West, Mc Neill and Raw - Thorax; 55, 997

6.5 ***Bupropion suitable.*** Discuss and set quit date and *record it*. Give the patient an appointment for follow-up at local specialist cessation service (see paragraph 4.5 above). Give prescription for at least enough bupropion to ensure that patient has a sufficient amount until he/she returns to the review clinic. This should be discussed locally with pharmacists; it could be 2/52 or a month's supply. You need to ensure that a Product Information Leaflet is made available with the amount prescribed.

6.6 Make a specific appointment for follow up with a trained smoking cessation practitioner. You will need to record specific information on a data recording sheet to be eligible to be part of a DHSSPS smoking cessation intervention scheme. You will need to assess whether the patient is suitable for one to one counselling or group support taking account of local availability. If a specialist practitioner is not available either:

(a) rearrange to see the individual yourself on a weekly basis;
or
(b) if review is not possible, refer the individual to the service provided by the pharmaceutical company.

6.7 ***NRT suitable.*** Discuss with patient the most suitable product in the range of products available. *Set quit date and record it.* Consider if patient is eligible for one week's supply of NRT by voucher scheme. If not, advise on how to obtain supplies (see ***Appendix A*** on range of products and availability). You will need to record specific information to be part of a DHSSPS smoking cessation scheme. Make appointment for follow-up with a specially trained smoking cessation practitioner, if available.

6.9 ***Only behavioural support suitable.*** *Set quit date and record it.* You will need to record specific information to be eligible for a DHSSPS smoking cessation scheme. Refer for further behavioural support - as above.

7.0 REFERRAL FOR SPECIALIST CESSATION SUPPORT AND COUNSELLING EITHER IN PRIMARY/ SECONDARY CARE OR IN SPECIALIST CLINIC, WHEN AVAILABLE

7.1 If you are considering setting up your own specialist cessation service in house you will need to consider the evidence base and have a suitably trained professional who can provide intensive specialist advice either on a one to one basis or in a group. See **Appendix B** for examples of good practice in specialist cessation support.

7.2 It should be noted that bupropion given successfully in the trials was used in the context of a specialist setting where individuals received regular counselling.

We do not recommend bupropion over nicotine replacement therapy or vice versa. Choice of medication will depend upon the patient's wishes, the unwanted side effects and drug interactions of the products, the cost and availability of the products and whether specialist services can be made available locally to give ongoing support to the patient.

7.3 The follow up should be by a professional who is trained in smoking cessation advice and who has dedicated time set aside and is paid to do it. Note that this individual should have participated in an accredited programme on smoking cessation. One to one counselling or group support may be appropriate. The skills needed to facilitate group support will be different than those of one to one support.

8.0 WHAT TO DO WHEN A PATIENT FAILS IN THE QUIT ATTEMPT BUT RETURNS WITHIN A SHORT PERIOD OF TIME FOR A FURTHER PRESCRIPTION OF BUPROPION.

8.1 It is suggested that part of the agreement of the practitioner with the patient will be, not only to set a quit date but also to agree that the prescription of bupropion will only continue for as long as the patient remains abstinent up to a maximum of 7/52. The patient should understand this when signing up for intensive behavioural support and advice.

8.2 CO monitoring can be used with positive effect as part of the package of interventions. If the patient continues to smoke, he/she should be reassured that many people have unsuccessful quit attempts before managing to quit. Encourage continuation of the quit attempt and suggest that he/she seeks advice from a pharmacist on NRT, if appropriate. You may wish to indicate that a local agreement has been reached that a further appointment at the specialist service will not be made until he/she is ready to try and quit again. There may be a delay in this appointment as it is likely that there will be pressure on local waiting lists for assessment and intensive support. If the patient wants to reconsider bupropion again, indicate that you would be happy to review him in say 4-6/12. There should be local agreement between professionals as to what the time interval should be.

9.0 MONITORING

If participating in forthcoming DHSSPS smoking cessation interventions, monitoring should be in accordance with DHSSPS guidance. This will involve recording patient details and follow up of the specialist intervention being recorded. Where possible, carbon monoxide monitoring will be expected at four weeks and 12 months in DHSSPS funded specialist cessation initiatives. This is to ensure that the service has evidence of effectiveness of the intervention. It will also provide a useful picture for future service development.

10.0 CONCLUSION

Bupropion SR (Zyban) is licensed as an aid for smoking cessation in motivated smokers. It is to be welcomed as an addition to the available range of smoking cessation aids.

However, it is essential to recognise that bupropion has only been shown to be effective at the levels indicated where:-

(a) the individuals attempting to stop smoking are motivated; and
(b) they are supported by an intensive specialist smoking cessation service.

Bupropion or nicotine replacement therapy will increase the chances of a successful quit attempt where the relevant conditions, as outlined above, apply. It should, therefore, always be considered but, at this stage, it is too early to recommend one product over another. It is our view that careful consideration should be given to the person's wishes and motivation, the choice and suitability of pharmacotherapy which might be prescribed and the settings in which bupropion has been shown to achieve optimal success.

The key to successful smoking cessation interventions is:-

- the motivation of the person;
- the promotion of brief opportunistic advice during routine consultations; and
- the development and availability of locally accessible specialist services to support the person during their quit attempt.

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APPENDIX A

NICOTINE REPLACEMENT THERAPY

Medicine/formulation	Strength	Amount	Cost Price	Retail Price
Nicorette Chewing Gum	2mg	15s 30 105	1.71 3.25 8.89	2.99 5.69 15.59
Nicorette Chewing Gum	4mg	15 30 105	2.11 3.99 10.83	3.69 6.99 18.99
Nicorette Inhalator Refill Nicorette Inhalator Starter	10mg 10mg	42s 6	11.37 3.39	19.95 5.95
Nicorette Microtabs	2mg	30s 105s	3.57 9.84	6.25 17.25
Nicorette Nasal Spray	10mg	1	10.99	19.25
Nicorette Patch	5mg 10mg 15mg	7 7 7	7.20 8.36 9.07	12.69 14.79 15.99
Nicotinell Gum	2mg 4mg	12 48 96 12 48 96	1.45 5.13 8.26 1.57 5.70 10.25	2.55 8.99 14.49 2.75 9.99 17.99
Nicotinell Lozenge	1mg	12 36 96	1.70 4.27 9.12	2.99 7.49 15.99
Nicotinell TTS (patch)	"10" "20" "20" "30"	7 7 2(Trial) 21 7 2	9.12 9.40 2.56 24.51 9.98 2.85	15.99 16.49 4.50 42.99 17.49 4.99
NiQuitin CQ Patch	7mg 14mg 21mg 21mg	7 7 7 14	9.97 9.97 9.97 18.78	17.49 17.49 17.49 32.95

- Useful websites with links include:

  www.ash.org.uk (anti-smoking charity with useful information and links)

  www.fda.gov (American Food and Drug Administration)

  www.zyban.com (Prescribing information-American data sheet)

  www.srnt.org (Society for Research on Nicotine and Tobacco)

  www.bmjpg.com/data/tob.htm (Tobacco Journal)

  www.cdc.gov./nccdphp/osh/how2quit.htm (Centre For Disease Control)

  www.who.ch/ (World Health Organisation)

  www.TobaccoWars.com/ (Tobacco Week)

  www.nicnet.org (NicNet Site)

  www.dhsspsni.gov.uk (DHSSPS website where monitoring forms and guidance are available)

  www.n-i.nhs.uk/crest (CREST website where additional copies of this document are available)

  www.open.gov.uk/mca/mcahome.htm (Medicines Control Agency)

  www.surgeongeneral.gov/tobacco/tobaqrg.htm (US Quick Reference Guide for Clinicians - Treating Tobacco Abuse and Dependence)

  www.ahrq.gov (Agency for Healthcare Research Quality)

  www.surgeongeneral.gov/tobacco/smokesum.htm (Summary of Treating Tobacco Use and Dependence)

  www.givingupsmoking.co.uk (Department of Health website providing information and advice to the public on smoking cessation)

APPENDIX B

THE EXISTING SMOKING CESSATION SERVICE IN SHROPSHIRE: HELP 2 QUIT

Shropshire Health Authority has been developing a co-ordinated smoking cessation service since 1995 called Help 2 Quit. Centred on primary care, the service offers smokers local access to intensive quitting support together with one week's supply of free nicotine replacement therapy (NRT). Primary care teams are helped to set up and run the service by a central specialist team based at the Health Authority, consisting of a part-time Director (General Practitioner) and full-time Co-ordinator (Health Promotion Specialist). The service is already underway in all general practices in the County.

The Help 2 Quit model

- Identify smokers who want to quit
- Offer one-to-one patient support through primary care
- Include one week of free nicotine replacement
- Train one or more nurses in each practice team to take the lead
- Offer central support from a smoking cessation specialist team
- Provide dedicated funding for nurse time
- Fund as a core service from a recurring budget

Patients may be recruited by their general practitioner, another health professional, or they may refer themselves. General practitioners are encouraged to intervene with smokers on an opportunistic basis, focussing on establishing how the patient feels about their smoking. This process is expected to be brief (no more than one or two minutes) and to form part of the normal consultation.

The primary objective is to identify smokers who are ready to quit, so that support can be offered to increase their chance of a successful quitting attempt. Those who want to quit are given a supportive 'we can help you' message, before being referred to a Help 2 Quit nurse within the practice. Those who are ambivalent are given brief motivational advice and the offer of support when they need it. If patients are not interested in stopping smoking they are told that their decision is respected but that help is available should their attitude change. The approach is always supportive and aimed at maintaining the trust of the patient.

Help 2 Quit is delivered on a one-to-one basis by one or more nurses from the practice team (practice nurse, health visitor or district nurse). The first appointment normally lasts 30 minutes and includes an assessment of the patient's motivation to quit, their previous experience of quitting, and their suitability for nicotine replacement. A quitting date is set, and a plan of quitting is agreed that is appropriate to the individual's circumstances. In order to encourage NRT use and to demonstrate the commitment of the practice to the quitting smoker, patients suitable for NRT are offered one week's free supply of nicotine patches.

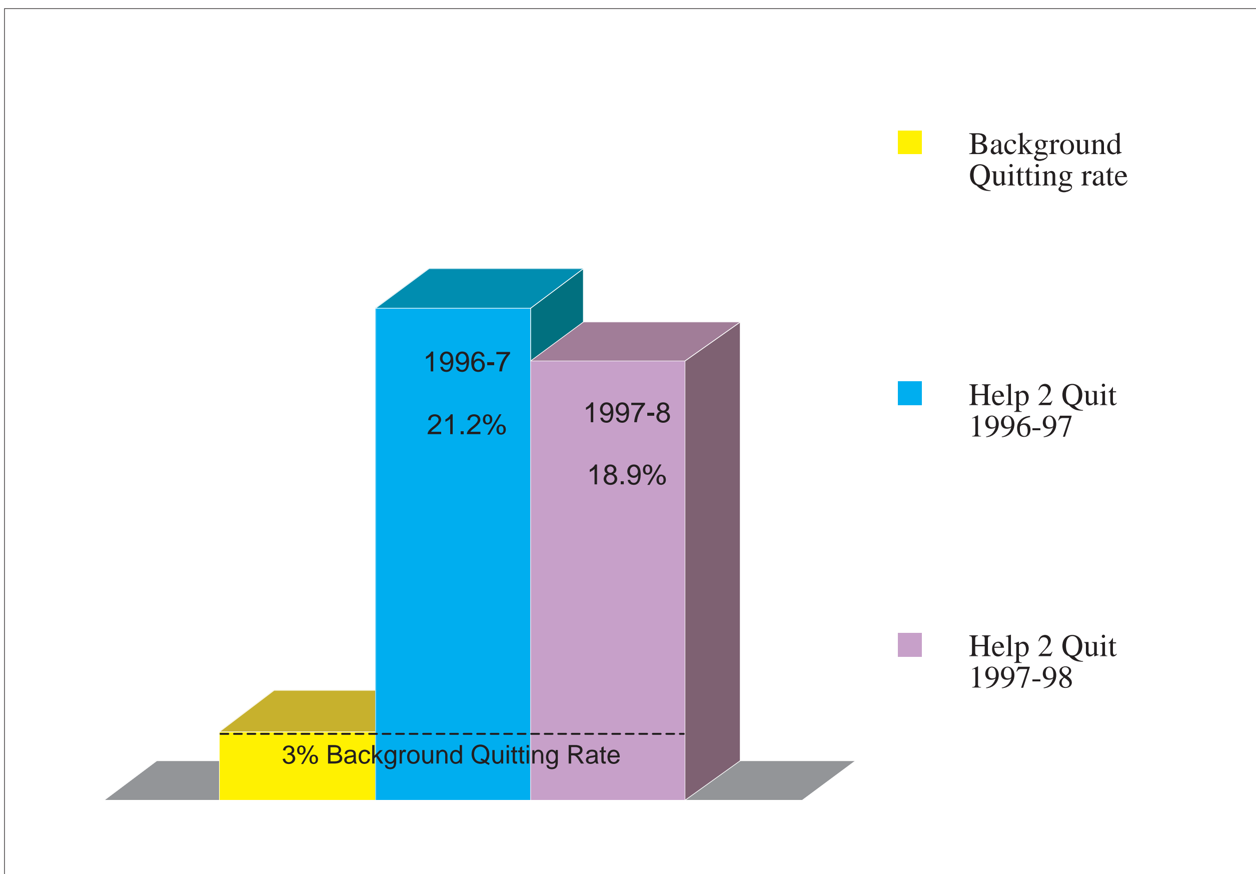
The patient is invited to return for a follow-up appointment within one week of their quitting date and at regular intervals during their first three months as a non-smoker. Follow-up appointments normally last for 10 minutes and are typically held at 1, 2, 3, 4, 6, 8 and 12 weeks post-cessation. Further follow-up at six and twelve months may be by appointment or by telephone. If a patient attends all appointments,

a total of two hours nurse time will have been spent with the patient over the course of a year.
In practice, allowing for patients who relapse, the amount of nurse time spent with each patient entering Help 2 Quit averages one hour.

Each practice team is initially offered a slide presentation about the service from the Director of Help 2 Quit, followed by half a day's nurse training within the practice from the Co-ordinator. Ongoing support is provided by telephone, through informal visits and at regular nurse networking meetings. All the resources that practices need to deliver the service are provided by the Co-ordinator.
This includes monitoring forms, patient information sheets, an NRT assessment protocol, a carbon monoxide monitor and supplies of free NRT.

The quitting rates for patients entered during the first two years of Help 2 Quit are shown below.
An average of 1 in 5 smokers quit successfully for 1 year. This compares well with intensive interventions in other settings. Each practice provides help to an average of 50 smokers a year, with over 5,000 patients having been helped by Help 2 Quit to date.

1-year quitting rates for Help 2 Quit



<u>Dr Kevin Lewis Clinical Director of Smoking Cessation</u>

<u>Eunice Scott-Evans Smoking Cessation Co-ordinator</u>

THE MAUDSLEY HOSPITAL SMOKING CESSATION CLINIC (Provided by Dr Gay Sutherland)

The clinic was set up by Professor Michael Russell nearly 30 years ago to provide assessment, advice and treatment for smokers and until 1998, when it was fully integrated into the Bethlem Maudsley NHS Trust, was part of a programme of research into the treatment of tobacco dependence. The aim was to increase our understanding of the psychological and pharmacological aspects of tobacco dependence and hence to develop more effective approaches to reducing tobacco-related diseases. It was the first full-time clinic in the UK and is the only clinic to have been running continuously since this time.

The clinic has helped many thousands of smokers with state of the art treatment over the years, and its research achievements have given it a world-wide reputation and attracted funding from the MRC and ICRF. During the early years behavioural treatments were to the fore as well as experimental work establishing the addictive nature of nicotine, but in the mid-1970's the major treatment breakthrough started when Professor Russell developed nicotine replacement therapy (NRT) with Leo Pharmaceuticals, Sweden. The clinic produced pioneering studies which demonstrated the effectiveness of nicotine chewing gum. As well as completing a number of distinctive placebo-controlled experimental and phase II studies the clinic conducted the first successful phase III study of the gum, which was later successfully replicated in a large general practice study. These studies, demonstrating a doubling or trebling of success rates combining NRT with a behavioural support programme, have influenced tobacco research and treatment around the world.

Since then the clinic has remained at the forefront of all the major developmental work on new forms of NRT, including the transdermal patch, nasal spray, inhalator and sublingual tablet. NRT is now recognised as a proven effective pharmacological treatment for nicotine addiction and is available as an over-the-counter medication in most countries. Many other non-nicotine pharmacological treatments have also been tested in the clinic, including naltrexone and a major trial of mecamylamine in 1998. Several hundred highly influential publications have resulted from this work and the clinic remains the only European treatment and research centre to rival the large centres which have emerged in the USA over the last 20 years.

The clinic's treatment and research work received mention in the first UK Government White Paper on Smoking, 'Smoking Kills' (1998). The treatment model pioneered by the clinic is considered to comprise 'best clinical practice' in both the White Paper and the more recent 'Smoking Cessation Guidelines for Health Professionals'. For the first time NHS money has been set aside for smoking cessation treatment, with the priority being for clinics based on the Maudsley model to provide a hub for community-wide smoking interventions.

The clinic sees up to 800 new patients per year, and tends to attract the more highly dependent smoker.

Treatment

The clinic aims to provide help that is simple to understand, relatively easy to comply with and of clinically proven efficacy, offering something to every smoker who is sufficiently motivated to attend. Our current standard treatment involves a programme of group support combined with nicotine replacement therapy (NRT), to reduce the severity of nicotine withdrawal symptoms. Depending on the patients' preference and their suitability for a particular product, NRT may be in the form of gum,

transdermal patches, nasal spray, inhalator, or sublingual lozenge. The non-pharmacological element of treatment comprises 5 X 1 hour weekly group sessions for the first month, followed by optional monthly relapse-prevention groups for a year. There is also the option of using a 'walk-in' follow-up clinic for further individual support and NRT as required.

Goal of treatment

The goal of treatment is complete abstinence from tobacco products and we validate patients self-reports of quitting throughout treatment and at one year follow-up using biochemical measures. Both our short and long-term success rates equal the most successful specialist smoking clinics around the world (50-70% and 20-30% respectively).

The three main components that contribute to the success of our approach are:

1. Helping smokers understand their problem as a dependence on nicotine and appreciating the nature and time course of nicotine withdrawal symptoms.

2. A friendly group of about 15-18 smokers that provides support and encouragement. These are structured groups with ample time for people to talk through their problems in coping without cigarettes. They are not health education classes, neither are they psychotherapy sessions.

3. Providing smokers with realistic and positive expectations about the role of NRT and ensuring it is used adequately and effectively.

Treatment process

After referral, smokers are seen individually for an assessment interview. At this session, motivation to quit, severity of nicotine dependence and suitability for inclusion in our group treatment programme are assessed. Objective measures of smoke intake (for example, blood nicotine and cotinine, and expired-air carbon monoxide) are taken together with subjective measures to assess dependence on nicotine.

Those who are suitable and willing to participate in our standard group programme are booked into the next available set of groups. Those who successfully stop smoking while attending the groups are eligible to attend monthly relapse-prevention groups. All initial quitters are followed up by telephone after one year. If they are still not smoking at this time they are invited to an individual appointment to confirm their abstinence biochemically.

Smokers who are unable, unwilling or unsuitable for the group treatment programme are offered individual help and attend weekly sessions. The format of the sessions is tailored to individual needs but includes elements from our group programme and NRT, where clinically indicated.

APPENDIX C

Guidance for patients on use of NRT and Zyban

*Robert West, St George's Hospital Medical School
London, Updated 19/9/00*

There are two forms of medication available to help people stop smoking. **Nicotine products** such as patch and gum and a new product called **Zyban** (bupropion).

Smokers naturally want to receive whatever guidance can be given on which of these they should choose.

This document aims to help take smokers through the decision. It will be updated as new information becomes available.

To the smoker:

1. Are you pregnant or breast feeding?

YES - Using any medication carries risks to the fetus and you must discuss with your doctor the risks and benefits. Many of the nicotine products are not licensed for use in pregnancy. However, if your doctor thinks it's OK then you may try one of the nicotine products such as the microtab or gum.

NO - go to next question

2. Do you have a heart or circulation problem?

YES - Although the nicotine products have been found to be safe in people with these problems you should discuss with your doctor whether it would be OK for you to use them and if the doctor agrees, you should consider using one of the nicotine products such as the microtab or gum. Zyban can be used in patients with these problems and in any case requires a prescription from a doctor who should know your medical history.

NO - read on

If you answered no to the two questions above you should read this:

There are two types of product available.

Both have been shown to help smokers to stop and at the moment we do not know if either of them is better than the other.

Nicotine products give you some of the nicotine you were getting from smoking while Zyban uses a different kind of drug to help control your cravings and withdrawal symptoms. Both are safe and effective when used correctly.

If you have tried nicotine products and would like to try something different, you are willing to see your doctor for a prescription and are prepared to allow your doctor to keep an eye on you to make sure everything is OK, you may wish to consider the new drug, Zyban. You should note that you should not use Zyban if you have ever had a major blow to the head or had any fits, no matter how minor, or if you are using drugs to control depression.

If you have tried a nicotine product before and got on well with it, then you should consider using it again, or trying another nicotine product. There are now many different types to choose from. If you have difficulty chewing gum then you should try the patch, microtab, inhaler, or lozenge. If you have a sensitive skin you should try one of the non-patch forms. There is little to choose between the 16 hour and 24 hour patches but if you smoke more than 10 cigarettes per day you should use the standard dose in each case and not one of the low dose forms. If you are a heavy smoker and want to use gum you should use the 4mg rather than the 2mg gum.

If you have not tried either nicotine products or Zyban before, then as long as you are eligible, we strongly advise you to use one or other of them. They are not a magic cure by any means and you will still need a lot of determination but they will double your chances of success and could well save your life. We cannot say which one would be best for you.

Whichever medication you use, remember:

1. It will help ease the cravings and withdrawal symptoms but you will still have to deal with your desire to smoke.

2. You MUST read the label for the product carefully:

- If you do not follow the instructions they cannot help you. In particular do not use less than the recommended dose.

- These medicines are safe for most people but you should make sure you do not have a medical condition which might make using the product unsafe.

- All medications have side effects and you should ensure that you know what to expect. For example, the gum, microtab and lozenge all have a strong taste but remember that they are not designed as sweets - they are medicines.

CREST
CLINICAL RESOURCE EFFICIENCY SUPPORT TEAM

Bupropion - Drug Interactions (Information based on SPC)

(Reproduced with the permission of Professor Robert West and Mr Nick Beavon.)

Interaction	Examples	Recommended Action
MAOIs	tranylcypromine phenelzine moclobemide	Contra-indicated. At least 14 days should elapse between discontinuation of irreversible MAOIs and initiation of bupropion.
Drugs metabolised by the CYP2D6 enzyme (a subset of the hepatic metabolic enzyme system cytochrome p450)	Antidepressants e.g. desipramine, imipramine, paroxetine, Antipsychotics e.g. thioridazine risperidone Beta-blockers e.g. metoprolol Type 1c antiarrhthmics e.g. flecainaide propafenone	Initiate concomitant therapy at the lower end of the dosage range or decrease dose when bupropion added to the treatment regimen.
Drugs metabolised by CYPA2	theophylline clozapine	Administer with caution.
Drugs that lower seizure threshold	Antipsychotics Antidepressants theophylline Systemic steroids Abrupt discontinuation of benzodiazepines Quinolones (e.g.ciprofloxacin)	Administer with extreme caution.
Drugs which may inhibit the metabolism of bupropion	cimetidine sodium valproate	Administer with caution.
Drugs which may induce the metabolism of bupropion	carbamazepine phenobarbitone phenytoin	Administer with caution. Bupropion is contra-indicated in patients with current or previous seizure disorder.
Drugs which may affect bupropion's metabolism by the CYP2B6 isoenzyme	orphenadrine cyclophosphamide ifosfamide	Administer with caution.
Other important interactions	levodopa	Administer with caution.

January 2001

Bupropion - Special Patient Groups (Information based on SPC)

Patient type	Recommendation
Children and adolescents	Not recommended in patients under 18yrs of age- no data available.
Elderly	Use with caution. Increased sensitivity may be an issue (more likely to have decreased renal function); 150mg once daily is recommended.
Hepatically impaired	Contra-indicated in patients with severe hepatic cirrhosis (reduced clearance leading to high plasma levels). Use with caution in mild-to-moderate hepatic impairment which may lead to higher levels. 150mg daily is recommended. Monitor closely for possible undesirable effects (e.g. insomnia, dry mouth, seizures) indicating high drug metabolite levels.
Renally impaired	Use with caution. 150mg once daily recommended. Monitor closely for possible undesirable effects (e.g. insomnia, dry mouth, seizures) indicating high drug metabolite levels.
Psychiatric	Contra-indicated in patients with a history of bipolar disorder. May precipitate psychotic episodes in susceptible patients; use with caution.
Pregnant/lactating women	Bupropion should not be used in pregnancy/lactation - no data is available on this patient group - risk unknown. * Consider NRT if the patient is unable to stop but see product labelling for cautions and contra-indications.
Predisposed towards seizure	Contra-indicated in patients with current or previous seizure disorder. Use with extreme caution in patients with certain conditions including: • history of brain trauma • brain injury • CNS tumour • concomitant administration of medicines known to lower the seizure threshold e.g. antipsychotics, antidepressants such as SSRIs, theophylline, sytemic steroids. Also use with caution in circumstances of: • alcohol abuse • abrupt withdrawal from alcohol/benzodiazepines • diabetes treated with hypoglycaemics/insulin • use of stimulants/anorectic products.
Eating disorders	Contra-indicated in patients with current or previous diagnosis of bulimia or anorexia nervosa.
Hypersensitivity	Contra-indicated in patients with current hypersensitivity to bupropion or excipients in the tablets (excipients do not include lactose). Discontinue if patient experiences hypersensitivity or anaphylactic reactions e.g. rash, pruritis, urticaria, chest pain, oedema or dyspnoea.

Inserted by CREST

*There is some evidence that nicotine may be implicated in some of the damage to the fetus from smoking in pregnancy, but the harm from NRT would be expected to be less than from smoking. Therefore, a judgement needs to be made in each case about whether the mother would be able to stop without NRT. If NRT is used it would be prudent to advise more strongly than usual that it be stopped if the mother resumes smoking . In addition, it may be preferable for patients to use oral dosing forms rather than transdermal patches because nicotine levels can be reduced more rapidly in the event of problems.
SOURCE: West, Mc Neill and Raw - Thorax; 55, 997

January 2001

GP CONSULTATION GUIDANCE FOR PATIENTS COMING TO SURGERY WANTING BUPROPION (reproduced with the permission of Professor Robert West, St George's Medical School, London)

The goal of the consultation should go beyond responding to the direct request for bupropion to ensuring that the patient receives the most appropriate form of treatment for their tobacco dependence.

We consider that rather than giving the patient literature to digest in the waiting room, as indicated in this protocol, the patient should be asked to read it at home and arrangements should be made for them to return another day for further pharmacological assessment, if appropriate. If the patient returns, this is also an endorsement of the patient's motivation.

The following protocol should help to achieve this.

Activity	Possible example
1. Welcome the quit attempt	'I'm delighted that you have decided you want to stop smoking, Mrs Smith.'
2. Inform patient that a range of help is available and check motivation	'I just want to take a moment to go over what we can do to help you stop, including a prescription for bupropion if that is appropriate.' 'First of all, can I just check a couple of things?' 'How many cigarettes a day do you smoke?' (If <10 per day bupropion may not be appropriate but referral to specialist service may be.) 'Can you tell me what has prompted you to have a go at stopping now?' 'Are you intending to stop smoking for good?' 'Are you ready to stop as soon as possible, say in the next week or so?' (If answers reveal ambivalence about stopping, then consider deferring the quit attempt.)
3. Reinforce the motivation to stop.	'That's fine. Thank you - you've obviously made up your mind that now is a good time to make the break and frankly, I agree with you.'
4. Briefly describe the assistance on offer	'Now let me briefly go over what we can offer you. There is a clinic run by a specialist trained in helping people stop smoking and there is plenty of evidence that this gives the best chance of stopping - the clinic offers a range of nicotine products or bupropion, depending on your preference and suitability.' 'Bupropion is effective at helping smokers stop but I need to make sure that you are suitable for it and you will need to come back in a few weeks so we can check on your progress.' 'Nicotine patches and other products are also effective and if you have got on well with them in the past you should consider giving them another go.'
5. Give out a brief information leaflet	'Here is a brief guide to what is available. It will also help you see whether you are suitable for medicines such as bupropion.'
6. Ask the patient to read the leaflet and come back in after a few minutes	'I want you to take this guide back to the waiting room and look through it for a few minutes, then come back in and we can take it from there. When you go out tell the receptionist that I want to see you again in a few minutes and she will book you in'
7. When the patient comes back - find out how he or she wants to proceed	'You've had a chance to read the guide. Is there anything you would like me to go over with you?' 'How would you like to proceed?'
8. Proceed accordingly	

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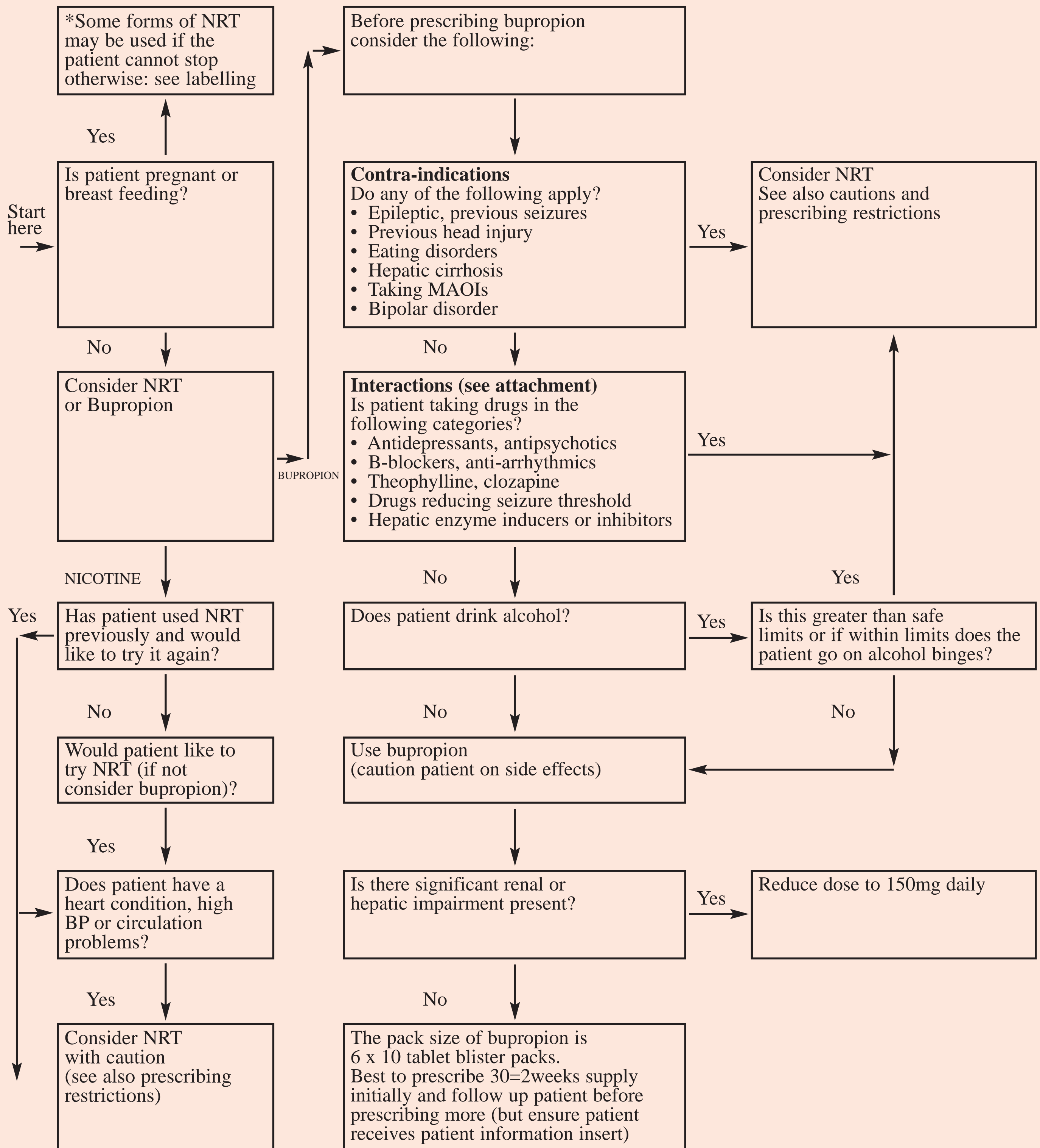
How to choose between NRT and Bupropion (advice to clinicians)

SOURCE: Professor Robert West, St George's Medical School, London.



***Inserted by CREST**

There is some evidence that nicotine may be implicated in some of the damage to the fetus from smoking in pregnancy, but the harm from NRT would be expected to be less than from smoking. Therefore, a judgement needs to be made in each case about whether the mother would be able to stop without NRT. If NRT is used it would be prudent to advise more strongly than usual that it be stopped if the mother resumes smoking . In addition, it may be preferable for patients to use oral dosing forms rather than transdermal patches because nicotine levels can be reduced more rapidly in the event of problems.
SOURCE: West, Mc Neill and Raw - Thorax; 55, 997

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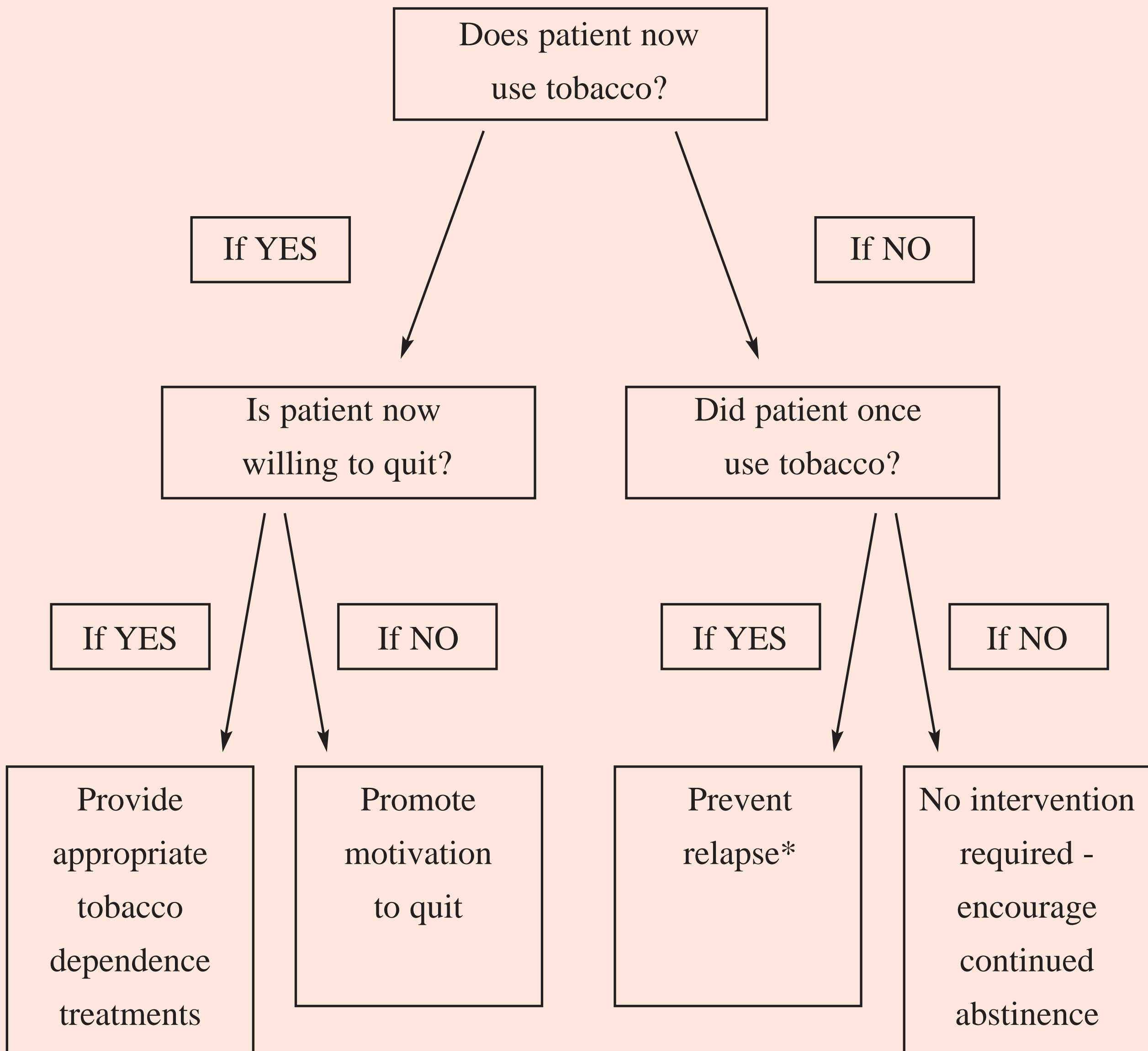
Screen for Tobacco Use Status



***Note:** Relapse prevention interventions are not necessary in the case of the adult who has not used tobacco for many years.

Source: Treating Tobacco Use and Dependence: Quick Reference Guide for Clinicians. www.surgeongeneral.gov/tobacco/qrgfig1.htm

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Patient attends doctor to seek prescription for bupropion

Initial Motivational Interview (see para. 6.2)

Patient not keen on follow up assessment

OR

Additional support

- Promote motivation to quit;
- Encourage smoking abstinence and use of NRT;
- Maintain an open door policy;
- Give leaflet on NRT and bupropion;

and

- Local phone numbers on where to get help, if available.

Patient wants assessment for bupropion AND understands and accepts the need for additional support and advice.

Make appointment for review with either GP or other practitioner, who will follow a locally agreed protocol for the prescription of bupropion (see flow chart).

Agree with patient another review appointment, need for CO validation, and course of bupropion for 7/52, provided patient remains abstinent, and attends smoking cessation support service, if appropriate.

Arrange further appointment for pharmacological assessment of suitability of bupropion/NRT.

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