

NICOTINE ASSISTED REDUCTION TO STOP (NARS)

**GUIDANCE FOR HEALTH PROFESSIONALS ON THIS
NEW INDICATION FOR NICOTINE REPLACEMENT
THERAPY**

ASH, London, October 2005

Key messages to health professionals

If a smoker approaches you about reducing to stop they should be reminded that stopping completely is the best thing for their health, and that support and medications are available from the NHS.

Smokers who are not ready to make a quit attempt should consider using NRT to help them cut down with a view to stopping later.

PCTs and GPs should give serious consideration to making NRT for reduction available on NHS prescription, especially in the case of low income smokers or smokers with smoking-related diseases such as COPD.

When they do so, they should follow a strict protocol, only providing repeat prescriptions when there is objective evidence of reduced consumption.

All health professionals should be proactively encouraging this new indication to smokers who to date have been unready or unable to stop.

The NHS Stop Smoking Services should encourage smokers to stop completely with their support. The services should also be able to offer brief advice to smokers who ask for help with nicotine assisted reduction to stop, and indicate to smokers that when they are ready to make a quit attempt they can then get intensive specialist support from the services.

Background

In September 2005 the Medicines and Healthcare Products Regulatory Authority (MHRA) approved a new indication for two nicotine replacement therapy (NRT) products, nicorette gum and nicorette inhalator. They can now be used by smokers to cut down on their smoking prior to attempting to stop. Pfizer have called this new indication “Cut Down Then Stop” (CDTS) and advertising for it has already begun. Thirteen other countries, including 10 in Europe, have already approved this indication.

ASH supports this indication because the evidence shows that if smokers who are not ready to stop use nicotine gum or inhalator to help them reduce their cigarette consumption by at least 50%, approximately 4% will actually stop smoking as a result. Given that about half of smokers are interested in cutting down rather than stopping, at any one time, this could significantly increase the numbers of smokers that stop.¹⁻⁴

Currently around a third of smokers attempt to quit in any given year, but something like 70% say they would like to stop.⁵ It is crucial that the third who want to stop continue to be encouraged to stop, but this indication offers a way forward for those unready or unable to stop completely.

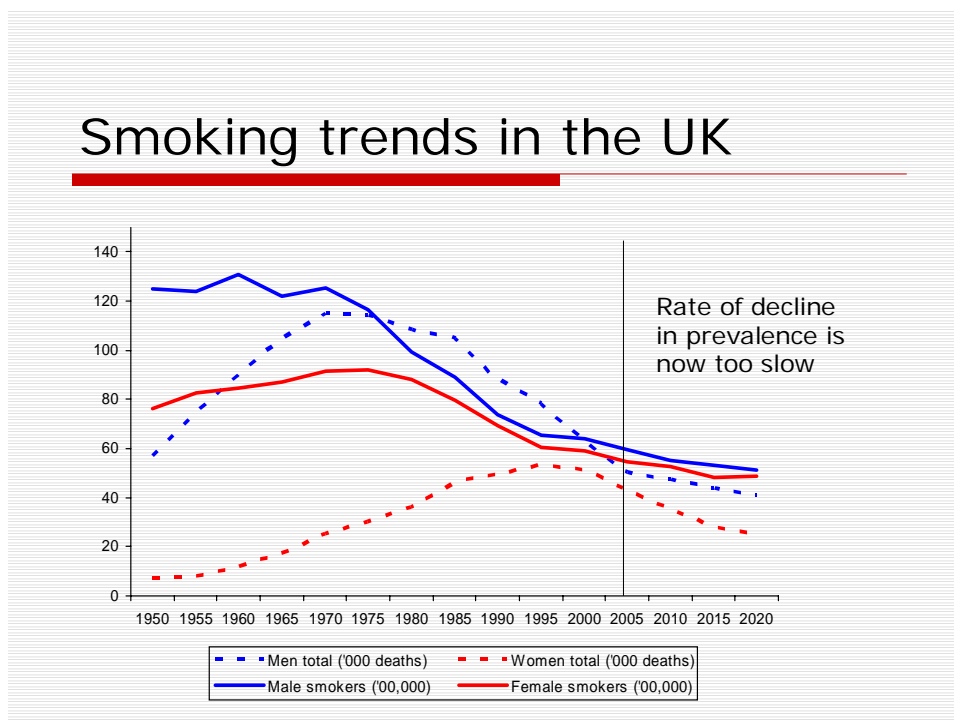
It is very important that this new indication is integrated into existing arrangements for smokers - especially the NHS stop smoking treatment services - in a coherent way.

The process that has been licensed for gum and inhalator is:

Step	When	Goal
1	0-6 weeks	cut down to 50% of baseline consumption.
2	6 weeks to 6 months	continue to cut down; stop completely by 6 months
3	6 to 9 months	stop smoking completely, continue NRT
4	within 12 months	stop using NRT by 12 months

Why do we need this new indication?

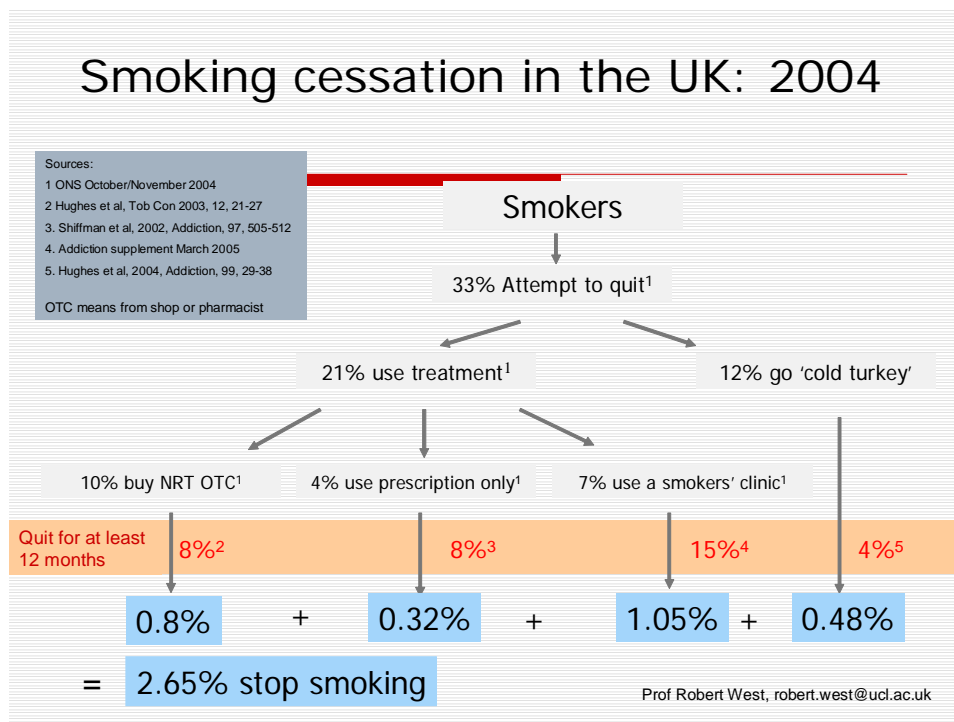
Figure 1



From West R (2005), reference 5.

The first diagram shows how the decline in smoking prevalence in the UK has slowed. It is currently about 0.4% a year.⁶ The second diagram shows that a third of UK smokers try to stop each year, and 2-3% in total manage to stop for at least a year. Approximately 7% of those trying to stop annually use smoking treatment services whilst double that figure, 14%, use some form of medication, separate from the services. The major impact on smoking cessation rates will come from increasing the proportion who attempt to stop and use effective treatments to help them do so.

Figure 2



From West R (2005), reference 5.

There are many possible ways of increasing the rate of quit attempts, including smokefree legislation and raising the cost of smoking. The NARS indication could make a useful contribution.

What is the evidence?

Four double-blind randomised placebo controlled studies provide evidence for the efficacy of cutting down with nicotine replacement.¹⁻⁴ Overall these studies found that in smokers unwilling or unable to stop smoking yet, one third of smokers who successfully cut down their cigarette consumption by half with gum or inhaler, went on to stop smoking within one year, and that NRT was twice as successful as placebo in achieving sustained reduction and later cessation. And although there was some compensatory inhalation when cigarette consumption was reduced, carbon monoxide measurement confirmed that there was a substantial reduction in inhaled tobacco smoke. In addition, motivation to stop smoking was increased in 55% to 80% of smokers (and decreased in very few). The overall number needed to treat was 25, that is to say 1 in every 25 smokers who didn't want to give up but were willing to try cutting down had quit smoking at 1 year. The number needed to treat for NRT, used to stop without behavioural support, is 20, so they are comparable.

Overall there was minimal evidence in these trials of adverse reactions due to nicotine overdosing. Fagerstrom and Hughes⁷ reviewed studies of the concurrent use of cigarettes and nicotine replacement and also found minimal evidence of adverse reactions. With concurrent smoking and gum and inhalator

use, blood nicotine levels remained the same, illustrating how well smokers titrate their nicotine levels. This finding strongly suggests that smoking reduction using NRT is, if sustained, likely to be safer than smoking.

The Cochrane review of nicotine replacement therapy and smoking cessation concluded: *“Based on pooling 3 trials, there was a significant benefit from the use of NRT on the odds of reducing the number of cigarettes smoked to fewer than 50% of baseline at longest follow up, using point prevalence of reduction (OR 1.80, 95% CI: 1.41 to 1.28); a significant effect on sustained reduction was detected by pooling 2 trials reporting this outcome. There was also a marginally significant increase in odds of cessation (OR 1.62, 95% CI: 1.06 to 2.49).”*⁸

A more recent review identified 19 trials (some unpublished) that tested NRT for smoking reduction in smokers not ready to stop outright. They concluded that NRT consistently helped these smokers make reductions in daily cigarette consumption.⁹

More information on the evidence and copies of relevant research can be seen on the ASH website at: www.ash.org.uk/html/cessationdetail.php#reduction

Summary of the evidence

Taken together the evidence supports the following conclusions:

1. Nicotine replacement helps smokers unwilling or unable to stop achieve sustained reduction in cigarette consumption;
2. This reduction is accompanied by a reduction in smoke intake;
3. There is minimal risk of significant adverse reactions to smoking concurrently with nicotine replacement;
4. Smoking reduction using NRT increases motivation to stop smoking; and
5. Smoking reduction using NRT increases subsequent cessation.

How will this new use of NRT fit alongside the existing treatment services?

As this indication has only just been launched it is too early to see what sort of problems may arise when smokers unable or unwilling to stop smoking yet go to their GP, nurse, pharmacist or smoking treatment service asking for NRT to help them cut down. Any intervention that will persuade or help more smokers to stop is enormously cost effective compared with most of the life preserving interventions the NHS offers (see below). We therefore recommend that as far as possible health professionals incorporate this new indication into their work and into their drugs funding.

If the smoker buys the NRT from a shop or pharmacist there are no cost implications for the NHS and the only issue will be the extent to which health professionals can add advice on cutting down to their existing workload. In the past the conventional wisdom has been to recommend to smokers that it is not worth cutting down, and that it is better to wait until they feel ready to stop, and then make a quit attempt. This new research evidence for nicotine assisted reduction to stop challenges this assumption. It suggests that cutting down first with NRT can increase the number of smokers who go on to stop. This finding is extremely important, as it could attract a new group of smokers into stopping. The rationale for nicotine assisted reduction to quit is that using NRT boosts nicotine levels, making it easier for the smoker to smoke fewer cigarettes, and making compensation less likely, which in turn should

mean that the smoker will inhale fewer toxins. By reducing their reliance on cigarettes for their nicotine intake, some smokers can then stop smoking completely.

It is important that smokers do not use the new indication just to reduce smoking as an alternative to stopping. Stopping totally remains the ideal and smokers should be reminded of this. However it seems likely that for many smokers this new indication will offer a useful introduction to NRT before having to stop completely.

Our current recommendation is that smokers who wish to try cutting down with NRT do so without being referred to the treatment services, many of which are currently working at capacity. We think the right time for smokers to approach the treatment services is when they are ready to make a quit attempt. However this should not preclude the services offering brief advice to smokers seeking it for nicotine assisted reduction to stop.

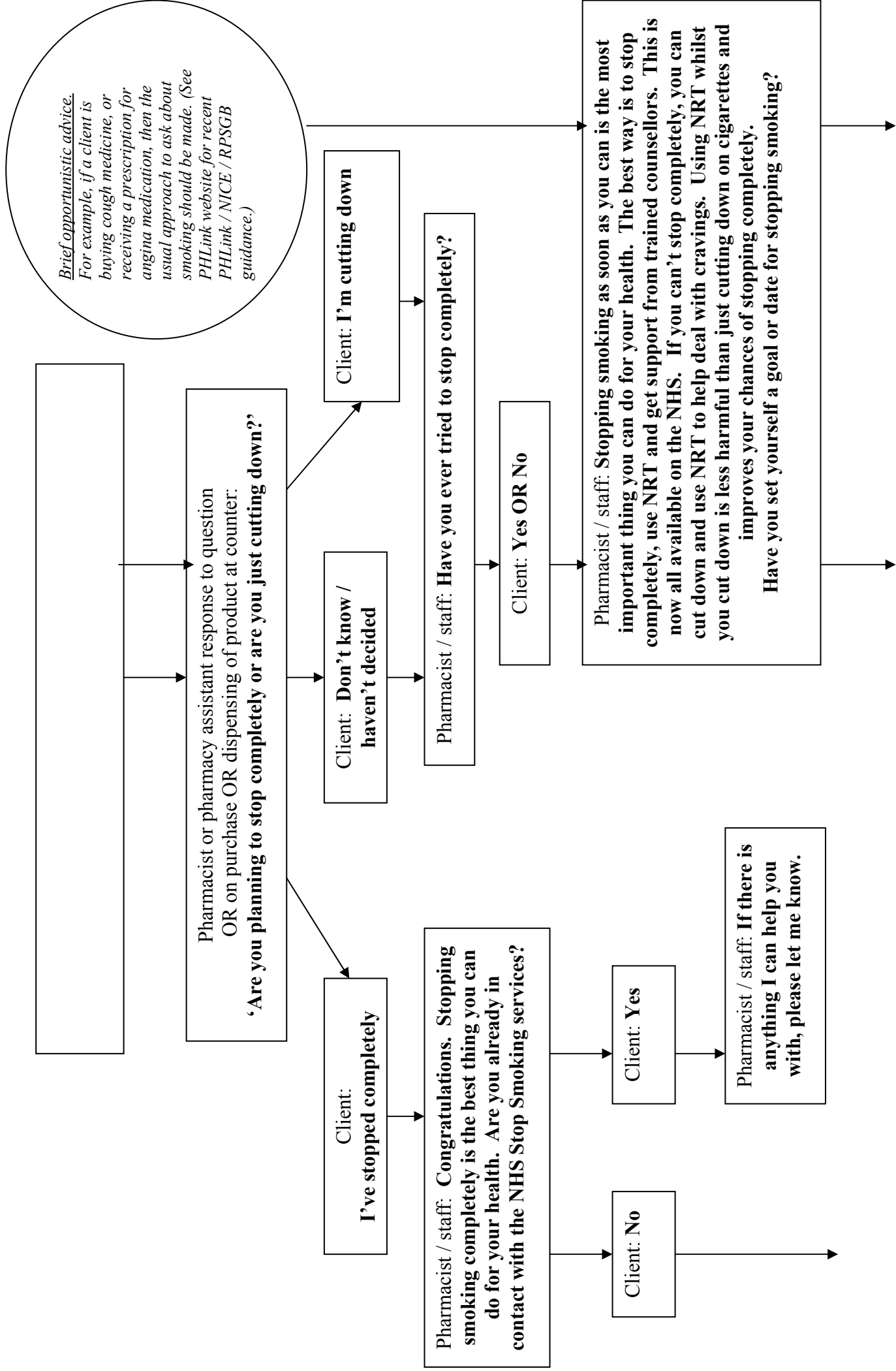
Smokers being given NRT on NHS prescription should not be given repeat prescriptions during the cutting down period unless they report having reduced daily consumption by at least 50% by week 6, and this is confirmed by an expired air carbon monoxide (CO) concentration that is lower than when they started. Note that this means that it will be necessary for prescribers to measure expired air CO using a monitor that gives precise measurement in parts per million (ppm). We recommend that prescribers give two-weekly prescriptions and use CO measurement to confirm that real progress is being made towards the 6 week target of 50% reduction.

When they are ready to stop smoking, smokers may be smoking less than the recommended minimum of 10 a day for them to receive medications for their quit attempt. The consumption level used for this indication – stopping – should be their baseline smoking before they started cutting down. Smokers setting a quit date would then be treated like other clients of local services and receive intensive support.

PharmacyHealthLink has produced a flowchart, reproduced below, to help pharmacists and their staff integrate the new NRT indication into their work. This flowchart has been produced as a guide to pharmacists and their staff. More details on brief opportunistic advice on stopping smoking is available from www.pharmacyhealthlink.org.uk. The general pathway set out in the flowchart may also be useful, in an adapted form, for other health professionals giving opportunistic advice to smokers in the course of their routine work.

Any smoker needing advice can contact the NHS Smoking Helpline **0800 169 0 169** or the Quitline **0800 00 22 00** for advice and support.

FLOW CHART TO OUTLINE PHARMACY POSSIBILITIES FOR NRT FOR REDUCING TO STOP



Brief opportunistic advice. For example, if a client is buying cough medicine, or receiving a prescription for angina medication, then the usual approach to ask about smoking should be made. (See PHLink website for recent PHLink / NICE / RPSGB guidance.)

Pharmacist or pharmacy assistant response to question OR on purchase OR dispensing of product at counter: **'Are you planning to stop completely or are you just cutting down?'**

Client: **I've stopped completely**

Pharmacist / staff: **Congratulations. Stopping smoking completely is the best thing you can do for your health. Are you already in contact with the NHS Stop Smoking services?**

Client: **Yes**

Pharmacist / staff: **If there is anything I can help you with, please let me know.**

Client: **No**

Client: **Don't know / haven't decided**

Pharmacist / staff: **Have you ever tried to stop completely?**

Client: **Yes OR No**

Pharmacist / staff: **Stopping smoking as soon as you can is the most important thing you can do for your health. The best way is to stop completely, use NRT and get support from trained counsellors. This is now all available on the NHS. If you can't stop completely, you can cut down and use NRT to help deal with cravings. Using NRT whilst you cut down is less harmful than just cutting down on cigarettes and improves your chances of stopping completely. Have you set yourself a goal or date for stopping smoking?**

Client: **I'm cutting down**

Client: **No**

Client: **Yes**

Pharmacist / staff: **Setting yourself a goal is the best way to keep track of your smoking. Do you want to stop completely or just cut down?**

Pharmacist / staff: **Good - setting yourself a goal is the best way to keep track of your smoking. Are you going to stop completely or just cut down?**

Pharmacist / staff: **The NHS Stop Smoking Services can give you extra help with staying off cigarettes. I can help you get in touch with them (*put local NHS Stop Smoking Services information in pharmacy bag with NRT*) or let me know if there is anything else I can help with.**

If STOPPING COMPLETELY give general stop smoking advice: You may also want to get help from the NHS Stop Smoking Services. I can help you get in touch with them. Put local NHS Stop Smoking Services information in pharmacy bag with NRT.

If CUTTING DOWN: We recommend you try to cut your cigarettes down by at least half (over 6 weeks) and use NRT - as this helps you deal with nicotine cravings. It is also less harmful than just cutting down on cigarettes and improves your chances of stopping completely. When you want to stop completely you can come back and see me or get more help, including NRT, from the NHS Stop Smoking Services. I can help you get in touch with them. Put local NHS Stop Smoking Services information in pharmacy bag with NRT.

How much might this new indication cost?

Because this new indication is for smokers not yet ready to stop, we believe they should use nicotine replacement to reduce smoking by themselves, and ideally, only be given help by the treatment services when they are ready to try to stop. The main cost burden to the NHS will therefore be the cost of prescribing NRT for cutting down.

We have attempted to estimate what might be the additional cost for England. These estimates are based on current cessation data (see figure 2 above), good clinical practice (for example repeat prescriptions should not be issued for smoking reduction unless reduction is confirmed using a carbon monoxide monitor), and estimates based on clinical experience. We want to emphasize that our bottom line figure below is a worst case estimate. The real figure may well be less.

1	Number of smokers in England	10 million
2	Number trying to cut down 50%	5 million
3	Number expected to be interested in NRT	2.5 million
4	Estimated 40% asking for prescription	1 million
5	80% would only use 1 script	£30 million
6	20% would use 2-3 scripts	£20 million
7	Additional NRT cost of those who go on to quit	£5 million
8	Total	£55 million

Explanation of table:

- 1) there are about 10 million smokers in England;
- 2) about 50% of smokers try to cut down in a given year;
- 3) fewer than half would be expected to be interested in using NRT to do it as a prelude to stopping;
- 4) of these we would expect a maximum of 40% to want a prescription for NRT rather than buying it themselves;
- 5) about 80% of these would probably get one script only because they would not be able to cut down by 50% and show a decrease in CO at the 6-week point so this would cost about £30 million, bearing in mind that they would not be using as much as smokers who are stopping;
- 6) the rest might require an average of 2-3 scripts before they either stop smoking or go back to normal smoking, which would cost an estimated £20 million;
- 7) we would also have to add the cost of the additional NRT used in those who go on to try to quit, which could be perhaps an extra £5 million, although against that, some of the money would be recovered by prescription charges;
- 8) so a rough estimate would be a **maximum** of £55 million for the country as a whole, or about £5,000 per GP practice.

These figures are educated guesswork, but altogether the maximum cost realistically would be a doubling of the NRT bill. A rough estimate of the cost per life year gained from the additional smokers who would stop is about £5,000. This is based on a conservative estimate of £1,000 for the current NRT indication, a conservative estimate that the effect size is about half in this new group and that on average about 2-3 times as much NRT would be used.

Even if the correct cost effectiveness figure is as high £5,000 per life year gained, this still represents good value for money compared with most other life preserving NHS treatments, and compared with the benchmark of £30,000 accepted by NICE for new treatments.⁹

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