

# Relapse prevention in UK Stop Smoking Services: current practice, systematic reviews of effectiveness and cost-effectiveness analysis

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## *Executive summary*

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## Executive summary

### Background

Smoking remains a major, international cause of death and disease, and killed approximately 80,000 people in England in 2007. Reducing smoking is a major priority for governments and health systems like the UK National Health Service (NHS). The UK has implemented a comprehensive tobacco control strategy over recent years, involving a combination of population tobacco control interventions (such as price rises, advertising ban, smoke-free legislation) combined with treatment for dependent smokers through a national network of NHS Stop Smoking Services (NHS SSS). The NHS SSS provide evidence-based smoking cessation treatment, which is highly cost-effective. In England, over 4 million people have set a quit date through the services since their inception in 2000, with over 4 million of these having stopped smoking 4 weeks after their quit date. However, it is estimated that approximately 75% of these '4-week quitters' will have subsequently relapsed back to smoking ('relapsers') 6 months after their quit date. This project aimed to investigate whether and how the NHS SSS could reduce this proportion of relapsers, by providing relapse prevention interventions (RPIs) or treatments in order to improve the effectiveness of services in helping smokers to stop.

### Objectives

1. To survey NHS SSS managers across the UK in order to:
  - i. Describe and categorise RPIs that are currently used in the NHS SSS.
  - ii. Describe the current treatment provided by NHS SSS for smokers who are trying to stop.
  - iii. Ascertain barriers to the trialling or introduction of RPIs within current clinical practice.
2. To update estimates of effectiveness in the Cochrane review on interventions for preventing relapse to smoking, altering analysis methods, as appropriate, to enhance interpretation of findings.

3. To assess which studies, included in (2) above, provide findings that are generalisable to NHS SSS and which test interventions that might be acceptable to introduce within the UK.
4. To determine the cost-effectiveness of those RPIs, identified in (3) above, which could potentially be delivered by the NHS SSS.
5. To derive 'relapse to smoking' curves for smoking cessation attempts made with the support of evidence-based cessation treatments, such as those delivered by NHS SSS, using (1) prolonged and (2) point abstinence from smoking as outcome measures.
6. To identify deficiencies in the evidence base concerning the use of RPIs for smoking cessation and to identify priorities for future research.

### Methods

The project was divided into four distinct phases with very different methodologies:

1. Qualitative research in a convenience sample of health professionals working in the NHS SSS, followed by an online survey of managers of the NHS SSS across the UK to assess current delivery of RPIs by cessation services and the feasibility of introducing such interventions if found to be effective. For the survey, the definition used for RPIs, based on our qualitative work and previous literature, was: 'behavioural or drug therapies delivered after acute smoking cessation treatment has ended and resulted in abstinence from smoking. RPIs, therefore, seek to reduce relapse to smoking among abstinent smokers'.
2. A systematic review to update and refine the previous Cochrane review of RPIs, using an identical search strategy to identify randomised trials of behavioural and pharmacological studies of smoking RPIs, published up to July 2008 in databases such as the Cochrane Tobacco Addiction Group register of trials, MEDLINE, EMBASE, etc. In contrast to the Cochrane review and to

obtain estimates for treatment effects which might reflect those obtained by use of RPIs in NHS SSS, our primary analyses examined the effectiveness of RPIs among recently-abstinent smokers (abstainers), pooling outcome data from similar follow-up time points (defined as short term (permitted range 1–3 months), medium term (range 6–9 months) and long term (range 12–18 months), with the long-term follow-up point considered as the primary end point time, and separating the studies by type of intervention and population group. We also analysed, using a similar methodology, the effectiveness of RPIs used alongside traditional smoking cessation treatments by assessing trials which randomised non-abstinent smokers and which delivered RPIs and cessation therapies simultaneously.

3. A health economic analysis to provide estimates for interventions' cost-effectiveness compared to 'no intervention' using a cohort simulation approach to model the costs of smoking and the quality-adjusted life-years (QALYs) gained by using RPIs. Model estimates for effectiveness of interventions were taken from the systematic review (in 2 above) and sensitivity analyses investigated the impacts of substantially varying background population quit rates, costs and effectiveness of interventions and the longevity of intervention effects.
4. A systematic review to describe rates of relapse to smoking amongst smokers stopping with the support of evidence-based treatment and from which relapse curves relevant to NHS SSS users could be drawn. We examined routinely-available NHS SSS data to assess their comprehensiveness for describing relapse patterns of smokers attending the NHS SSS. We searched for randomised controlled trials (RCTs) in which intervention group smokers received evidence-based interventions similar to those provided by the NHS SSS including trials of nicotine replacement therapy (NRT), bupropion and varenicline delivered with behavioural support. We then selected trials of adult smokers in which a clearly identified quit date was used and smoking status was recorded at least three times in the next month and at least 12 months after this. The smoking status data from the intervention groups were synthesised enabling relapse curves to be drawn.

## Results

1. Qualitative research with 16 health professionals working in NHS SSS indicated that there was no shared understanding of what relapse prevention meant or the kinds of interventions that should be used for this, but a willingness to provide such treatments was apparent. In the online survey, 96 NHS SSS managers from across the UK returned completed survey questionnaires (52% response rate). Of these, 58.3% ( $n = 56$ ) reported running services that provided RPIs for clients (RPI definition provided within survey). The most commonly provided RPIs were behavioural support: telephone (77%), group (73%) and individual (54%). Pharmacotherapy was less frequently used for relapse prevention, just under half (48%,  $n = 27$ ) offered NRT and 21.4% ( $n = 12$ ) bupropion. Over 80% of those reporting providing RPIs do so for over 6 months after smokers become abstinent. Nearly two-thirds of all respondents thought it was likely that they would either continue to provide or commence provision of RPIs in their services. Of the remaining respondents, it was believed that the government's focus on 4-week quit rates (66.7%,  $n = 22$ ), and the inadequate funding for the provision of RPIs [42.9% (14 services)] were major barriers to introducing such interventions into routine care.
2. The systematic review included 36 studies which randomised and delivered interventions to abstainers. 'Self-help' behavioural interventions delivered to abstainers who had achieved abstinence unaided were effective for preventing relapse to smoking at long-term follow-up [odds ratio (OR) 1.52, 95% confidence interval (CI) 1.15 to 2.01]. The following pharmacotherapies were also effective as RPIs after their successful use as cessation treatments: bupropion at long-term follow-up (pooled OR 1.49, 95% CI 1.10 to 2.01); NRT at medium- (pooled OR 1.56, 95% CI 1.16 to 2.11) and long-term follow-ups (pooled OR 1.33, 95% CI 1.08 to 1.63) and one trial of varenicline also indicated effectiveness. Eighteen studies randomised smokers prior to quit attempts; although a few trials reported significant findings at some follow-ups, where pooled analyses were possible, there was no evidence for the effectiveness of any interventions.

3. The health economic analysis found that, as with other interventions which reduce smoking, RPIs are highly cost-effective. Compared with 'no intervention'; using bupropion resulted in an incremental QALY increase of 0.07, with a concurrent NHS cost saving of £68; for NRT, spending £12 resulted in a 0.04 incremental QALY increase; varenicline resulted in a similar QALY increase as NRT but at almost seven times the cost; however, findings were derived from a single trial and require cautious interpretation. Extensive sensitivity analyses demonstrated that cost-effectiveness ratios were more sensitive to variations in effectiveness than cost and that for bupropion and NRT, cost-effectiveness generally remained, even when input parameters are varied greatly, suggesting that this will be apparent in routine clinical practice. Varenicline also generally demonstrated cost-effectiveness at a 'willingness-to-pay' threshold of £20,000 per QALY, but exceeded this when inputted values for potential effectiveness were at the lower end of the range explored. With available data, only indirect comparisons between RPIs are possible and, therefore, assessments of their relative cost-effectiveness should only be made with caution.
4. There were no data available from smokers attending NHS SSS which could be used to draw relapse curves to reflect their experiences of relapse to smoking; curves derived were, therefore, based entirely on data from cessation trials in which smokers received interventions similar to those delivered by NHS SSS. Systematic searching and consideration of retrieved articles identified 16 RCTs meeting all review inclusion criteria, investigating NRT, bupropion and varenicline combined with intensive behavioural support. For all drugs, there was substantial relapse to smoking after treatment courses had finished (i.e. between 3 and 12 months into quit attempts). Eliminating such relapse would improve cessation rates at 12 months by 13%, 14% and 19% for NRT, bupropion and varenicline, respectively (though these figures are derived using some pooled abstinence estimates which have substantial heterogeneity). Quit attempts involving NRT appeared to have the highest early relapse rates, when trial participants would be expected to still be on treatment, but for those involving bupropion and varenicline little relapse was apparent during this time. However, this observation could have arisen

because bupropion and varenicline trials assessed smoking cessation by repeatedly assessing short periods of abstinence from smoking, rather than asking about continuous cessation between participants' quit dates and all follow-up points.

## Conclusions

Study findings suggest that extending pharmacotherapy treatment (such as NRT, bupropion or varenicline) after smokers have stopped smoking using these drugs, is both effective and cost-effective for preventing relapse to smoking. UK managers of the NHS SSS indicated that they were favourably inclined towards providing RPIs, but currently used ones for which there is no evidence of effectiveness. We identified apparently different trajectories of relapse across the three main treatments used in the NHS SSS (NRT, bupropion and varenicline), but similar declines in abstinence after 3 months when most treatment would have ended, illustrating the potential impact of extending the treatment period for preventing relapse.

## Recommendations for research (in priority order)

1. Further research investigating the use of NRT, bupropion and varenicline (the three pharmacotherapies used in the NHS SSS) for relapse prevention is required, including the following:
  - i. Placebo RCTs to investigate the (cost) effectiveness of these RPIs as an extension to current NHS SSS cessation support – most review trials were conducted in countries without organised cessation services and, hence relapse prevention interventions may have different outcomes in the UK.
  - ii. Studies of the acceptability of extended use of pharmacotherapies for relapse prevention in NHS SSS users, and particularly of bupropion, which is the least frequently used cessation therapy in England, the acceptability of these pharmacotherapies for relapse prevention will influence their uptake.
  - iii. Whether or not the addition of behavioural RPIs, delivered in the early stages of quit attempts using NRT can have an adjunctive, positive impact on cessation rates.

- iv. Confirmation of whether the different trajectories of relapse that we observed for NRT, bupropion and varenicline are valid (i.e. a more rapid relapse rate for users of NRT in the first month compared with the other two drug treatments) and occur when these treatments are used in routine NHS SSS clinical practice.
2. The following research into behavioural relapse prevention interventions is required:
  - i. RCTs to confirm or refute the finding that self-help interventions, delivered to smokers who have achieved abstinence unsupported, have long-term effectiveness for preventing relapse to smoking.
  - ii. RCTs to investigate whether or not self-help interventions delivered to smokers who have achieved abstinence with NHS SSS support are effective.
  - iii. Further research on interventions that showed potential effectiveness, such as individual counselling for pregnant women and the use of telephone support after cessation treatment, and test whether or not these might have long-term effectiveness.
3. Methodological standardisation: among relapse prevention trials identified for this report, there was huge variation in the definition of RPIs, the characteristics of smokers these were delivered to, follow-up periodicity and outcome measurement after randomisation. Also among cessation trials used to derive relapse curves, reporting of outcomes seriously restricted the data available. In order to permit coherent synthesis of future research findings in this important field, we recommend that practitioners and researchers investigating this field agree common standards for:
  - i. The definition of RPIs: in particular, consensus is needed as to whether behavioural RPIs, delivered alongside smoking cessation interventions to smokers either prior to or soon after quit attempts have started *can* or *should* be categorised

as different to smoking cessation interventions. If there is consensus about such interventions being different, clear definitions for both are required.

- ii. Methodological standards for the conduct and reporting of behavioural and pharmacological relapse prevention trials.
- iii. Cessation trials should report the percentage of participants who make no attempt to stop smoking on target quit dates and should report continuous and point prevalence smoking cessation measures simultaneously at all follow-ups.

## Implications for health care

Some NHS SSS are providing RPIs, but where this occurs, those with the weakest evidence base are generally used, illustrating a requirement for the emerging evidence base and guidance to be made available as soon as possible. Should the NHS decide to encourage and fund the use of RPIs for smokers who have become abstinent with NHS SSS support, new incentives are likely to be required before NHS SSS will substantially adopt their use. Currently, NHS SSS are performance-managed on their ability to achieve targets set for short-term (i.e. 4-week) periods of cessation; managers perceived these targets were a clear disincentive to spending on interventions such as RPIs, which might enhance longer term abstinence but not their clients' initial, monitored cessation rates. Any integration of RPIs into the NHS SSS should include sufficient monitoring such that an assessment of their cost-effectiveness in routine use can be made.

## Publication

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# NIHR Health Technology Assessment programme

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