

# The impact of changing nicotine replacement therapy licensing laws in the United Kingdom: findings from the International Tobacco Control Four Country Survey

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## ABSTRACT

**Aim** To evaluate the impact of a new licence for some nicotine replacement therapy products (NRT) for cutting down to stop (CDTS) on changes in the pattern of NRT use. **Design** Quasi-experimental design comparing changes in NRT use across two waves of a population-based, replenished-panel, telephone survey conducted before and after the introduction of new licensing laws in the United Kingdom with changes in NRT use in three comparison countries (Australia, Canada and United States) without a licensing change. **Participants** A total of 7386 and 7013 smokers and recent ex-smokers participating in the 2004 and/or 2006/7 survey. **Measurements** Data were collected on demographic and smoking characteristics as well as NRT use and access. In order to account for interdependence resulting from some participants being present in both waves, generalized estimation equations with an exchangeable correlation matrix were used to assess within-country changes and linear and logistic regressions to assess between-country differences in adjusted analyses. **Findings** NRT use was more prevalent in the United Kingdom and increased across waves in all countries but no wave × country interaction was observed. There was no evidence that the licensing change increased the prevalence of CDTS or the use of NRT (irrespective of how it was accessed) for CDTS in the United Kingdom relative to comparison countries. There was also no evidence for a change in concurrent smoking and NRT use among smokers not attempting to stop in the United Kingdom relative to comparison countries. **Conclusion** The addition of the CDTS licence for some NRT products in the United Kingdom appears to have had very limited, if any, impact on NRT use in the first year after the licence change.

**Keywords** Epidemiology, nicotine replacement therapy, policy implementation, reduce-to-quit, smoking cessation, tobacco use.

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## INTRODUCTION

Nicotine replacement therapy (NRT) is an effective smoking cessation treatment and is currently available in six different forms in the United Kingdom (patch, gum, lozenge, microtab, inhalator or nasal spray), each providing nicotine variously through the skin, the oral or the nasal mucosal membrane [1]. NRT reduces withdrawal symptoms and urges to smoke [2] and has been shown to roughly double a smoker's chances of quitting success-

fully [3]. NRT is effective even with minimal behavioural support and supervision [4].

In the United Kingdom, NRT can be purchased over the counter (OTC) from pharmacies and, with the classification of some NRT products in the general sale category, in supermarkets and at other outlets [5]. NRT also became available subsidized on prescription in the United Kingdom in 2001, which allowed smokers to purchase NRT at a reduced or no cost depending on income level [6]. In September 2005, changes in the licensing for NRT

reduced the number of cautions and contraindications for NRT and thus permit its use by pregnant smokers, adolescent smokers or smokers with heart disease. These changes were implemented as it was felt that the potential risks of NRT use among these smokers were much less than the risks associated with continued smoking [7].

Another change to NRT licensing laws that came into effect in 2005 was to permit smokers to use two NRT products, namely nicotine gum and nicotine inhaler, to cut down the number of cigarettes smoked prior to attempting to stop smoking completely over a 6-month period, and with a view to stopping NRT use within a 12-month period. The change in regulation was informed by an increasing evidence base suggesting that smokers who use NRT to reduce their cigarette consumption gradually are more likely to stop smoking than smokers who try to cut down using a placebo [8–11]. The use of these NRT products for gradual cessation was advertised on TV (although the advertisement showed a smoker using NRT at work, perhaps therefore being more illustrative of use in situations of temporary abstinence) and was also indicated on the packaging. While the licensing change was applied irrespective of how NRT was accessed, it was suggested that the UK smoking cessation services should only become involved once the smoker attempted to stop smoking completely [7]. Hence NRT prescribed by the services (or indeed other prescribers) would have been more likely to have been given for quitting rather than cutting down. Any changes in NRT used for cutting down to stop (CDTS) are likely to have been most pronounced among users of NRT who obtained it OTC.

It has been reported previously that changes in licensing can lead to an increase in the use of NRT [12]. This study evaluates the effect of a new indication for NRT products to allow their use for cutting down prior to attempting to stop completely. Our analysis is based upon data from the International Tobacco Control (ITC) Four Country Survey collected before and after the introduction of the new licensing laws in the United Kingdom. For comparison purposes we also examine data on NRT usage patterns from three countries (Australia, Canada and United States) where no commensurate change in NRT labelling and usage rules had occurred. We hypothesize that the UK licensing will have led to:

- an increase in the use of NRT, in particular NRT obtained OTC, in the United Kingdom relative to comparison countries;
- an increase in the incidence of smokers attempting to stop smoking gradually in the United Kingdom relative to comparison countries; and
- an increase in the incidence of smokers attempting to stop smoking gradually with NRT, especially NRT

obtained OTC, in the United Kingdom relative to comparison countries.

We also hypothesize that a potential side-effect of the policy change may be that:

- smokers not attempting to stop may be more likely to use NRT concurrently in the United Kingdom relative to comparison countries and that therefore fewer smokers attempt to quit.

## METHODS

### Participants and study design

The ITC Four Country Survey is a yearly cohort survey that includes a representative sample of adult smokers and ex-smokers from Australia, Canada, the United Kingdom and the United States. Since 2002, six surveys have been carried out. The ITC survey assesses the impact of national-level tobacco control policies on psychosocial, behavioural and attitudinal correlates of tobacco use. The methodology has been described in detail elsewhere [13]. Briefly, participants were recruited by telephone with a probability sampling method; eligible households, stratified by geographic region and community size, were selected randomly using random-digit dialling methods. Only individuals who were 18 years or older, had smoked more than 100 cigarettes in their life and at least once in the past month were included. Participants were reimbursed the equivalent of US\$10 for their time at each wave. In the five follow-up surveys, the recruited sample has been replenished to ensure a sufficient sample size (2000 per country). Ethical approval was provided by participating research institutes in the four countries. Full details of the sampling design and procedure can be found at <http://www.itcproject.org>.

A quasi-experimental design was chosen for this analysis, comparing changes in NRT use across two waves in the United Kingdom relative to comparison countries where no changes in NRT licensing had occurred. We identified participants who completed either wave 3, which was carried out before the UK licensing change (June–December 2004) and/or wave 5, conducted after the UK licensing change (October 2006–February 2007). For the purpose of this analysis, participants had to be daily smokers at recruitment or recent ex-smokers (stopped < 6 months ago). A total of 7386 and 7013 adults fitting these inclusion criteria participated in waves 3 and 5, respectively, of whom 3307 (44.8% of wave 3 and 47.2% of wave 5) participated in both waves. As waves 3 and 5 of this cohort study were treated as cross-sectional surveys, within-subject interdependence was modelled in the statistical analysis (see Analyses). Table 1 provides sample characteristics for each wave.

Table 1 Demographic and smoking characteristics of sample.<sup>a</sup>

	United Kingdom			Comparison countries <sup>b</sup>			Country × wave interaction	
	Wave 3 (n = 1841)	Wave 5 (n = 1713)	Total (n = 3554) <sup>c</sup>	Wave 3 (n = 5545)	Wave 5 (n = 5300)	Total (n = 10 845) <sup>d</sup>		Significance
<b>Demographic data</b>								
Mean (SD) age	47.4 (14.0)	48.6 (14.4) <sup>***</sup>	48.0 (16.3)	44.5 (14.0)	46.8 (13.6) <sup>***</sup>	45.6 (16.5) <sup>c</sup>		P = 0.005
% (n/N) male	44.7 (823/1841)	43.0 (737/1713)	43.9 (1560/3554)	44.4 (2460/5545)	42.6 (2258/5300) <sup>*</sup>	43.5 (4718/10 845)		P = 0.945
% (n/N) majority culture	96.3 (1770/1838)	96.1 (1643/1710)	96.2 (3413/3548)	87.3 (4825/5530)	87.8 (4650/5294)	87.5 (9475/10 824) <sup>e</sup>		P = 0.404
% (n/N) low income	31.7 (528/1665)	36.7 (575/1565) <sup>***</sup>	34.2 (1103/3230)	33.2 (1725/5192)	32.5 (1611/4955)	32.9 (2186/10 147)		P = 0.001
% (n/N) high level of education	11.7 (213/1824)	13.3 (226/1697) <sup>***</sup>	12.5 (439/3521)	14.4 (796/5329)	16.5 (871/5291) <sup>***</sup>	15.4 (1097/10 820) <sup>e</sup>		P = 0.320
<b>Smoking characteristics</b>								
% (n/N) current smokers	95.1 (1750/1841)	94.8 (1624/1713)	94.9 (3374/3554)	95.5 (5296/5545)	95.0 (5035/5300)	95.3 (10 331/10 845)		P = 0.734
Mean (SD) cigarettes per day <sup>f</sup>	17.2 (8.8)	16.9 (9.3) <sup>**</sup>	17.1 (10.2) <sup>g</sup>	18.0 (10.9)	18.3 (10.4)	18.2 (12.0) <sup>eh</sup>		P = 0.067
Mean (SD) HSI <sup>f</sup>	2.7 (1.4)	2.6 (1.4) <sup>**</sup>	2.7 (1.6) <sup>i</sup>	2.8 (1.5)	2.9 (1.5) <sup>**</sup>	2.8 (1.7) <sup>ej</sup>		P = 0.341
% (n/N) intending to quit <sup>f</sup>	61.8 (1068/1727)	61.1 (972/1591)	61.5 (2040/3318)	72.8 (3797/5216)	72.9 (3604/4944)	72.8 (7401/10 160) <sup>e</sup>		P = 0.447
% (n/N) attempting to quit in last year <sup>k</sup>	32.7 (409/1250)	32.0 (337/1115)	32.4 (766/2365)	38.9 (1410/3621)	36.9 (1227/3328)	37.9 (2637/6949) <sup>e</sup>		P = 0.678
Mean (SD) number of quit attempts in last year <sup>k</sup>	2.3 (3.2)	2.0 (2.4)	2.2 (2.9)	3.1 (12.2)	3.5 (20.0)	3.3 (17.0) <sup>e</sup>		P = 0.413
% (n/N) using NRT in last year	17.7 (325/1841)	22.4 (383/1713) <sup>***</sup>	19.9 (708/3554)	15.0 (833/5545)	19.0 (1006/5300) <sup>***</sup>	17.0 (1839/10 845) <sup>e</sup>		P = 0.752

<sup>a</sup>Raw data are presented and comparisons based on generalized estimating equations (GEE); <sup>b</sup>Australia, Canada and United States; <sup>c</sup>824 participants contributed to both waves; <sup>d</sup>2483 participants contributed to both waves; <sup>e</sup>denotes significant differences between United Kingdom and comparison countries (P < 0.025); <sup>f</sup>base is current smokers; <sup>g</sup>six cases missing; <sup>h</sup>eight cases missing; <sup>i</sup>35 cases missing; <sup>j</sup>102 cases missing; <sup>k</sup>excludes participants not in previous survey; NRT: nicotine replacement therapy; SD: standard deviation; HSI: heaviness-of-smoking index. <sup>\*</sup>Significant difference between waves (P < 0.05); <sup>\*\*</sup>significant difference between waves (P < 0.01); <sup>\*\*\*</sup>significant difference between waves (P < 0.001).

## Measures

Survey questions were standardized across countries and waves, but wording was adapted where necessary to account for colloquial differences. Telephone interviews followed a strict protocol using computer-assisted telephone interviewing software to minimize bias and increase reliability.

## Demographics

Age, sex, ethnicity (two categories: 'white/English-speaking at home', 'non-white/non-English-speaking at home'), education level (three categories: 'low/secondary school or less', 'moderate/some post-secondary training', 'high/post-secondary degree or higher') and annual income (three categories: 'low/under equivalent of US\$30 000', 'moderate/US\$30 000–59 999' and 'high/US\$60 000 and over') were all assessed at recruitment and monitored for changes across waves.

## Smoking characteristics

Smoking status was determined by self-report through a series of questions assessing current and past smoking behaviour. Respondents were categorized as current smokers and ex-smokers (quit less than 1 month, 1–6 months or more than 6 months ago). Current smokers were asked about their intention to quit (yes/no). Nicotine dependence was assessed with the heaviness-of-smoking index (HSI), which produces a range of values (0–6) that are based on summative categories of the time to first cigarette and the number of cigarettes per day [14].

Participants were asked about their quitting behaviour, either in the past year if they were newly recruited, or since the last survey (roughly a year ago) if they were followed-up. Those who had attempted to quit at least once in this time-frame (referred to here as 'quit attempters') were asked whether, on their most recent quit attempt, they had stopped smoking gradually or suddenly and whether they had used any cessation aids to do so. Irrespective of NRT use, participants who indicated that they had attempted to stop smoking and had done so by reducing their consumption gradually were defined as using CDTS.

## NRT use

Irrespective of quit attempts, use of stop-smoking medications (including NRT) in the last year was recorded. Respondents were classified as having used NRT if they reported the use of any of the available six NRT products (patch, gum, lozenge, microtab, inhalator or nasal spray). Participants were asked whether, for the most recent use of NRT, they had used it for any of the following: to stop

smoking, to reduce tobacco consumption, to cope with a smoke-free environment or for other reasons. Due to a change in coding at wave 5, only those who had used NRT to stop smoking completely were also asked how they had obtained NRT (prescription, over the counter or off the shelf (OTC), from a friend). All NRT users were also asked whether they had continued to smoke while using NRT.

While the licensing change applied to only two NRT products (gum and inhaler), we have included all NRT in the analysis as (i) licensing for CDTS was restricted to the products of a particular manufacturer, which we were not able to differentiate; (ii) NRT other than gum and inhaler are likely to have been used for CDTS; and (iii) including only gum and inhaler use reduces the sample dramatically and thus power to detect statistical differences where present. However, a sensitivity analysis that was restricted to only gum and inhaler use was carried out to validate our findings, and this showed the same trends as reported in the analysis including all NRT products.

## Analyses

Data were analysed using SPSS version 16.0. Unadjusted preliminary analysis was carried out to identify potential confounders for adjusted analyses (see below). Differences in continuous or dichotomous variables between countries were assessed by  $\chi^2$  or *t*-test and differences between waves by generalized estimating equations (GEE) based on a logit (for dichotomous outcomes) or identity (for continuous outcomes) link function that used an exchangeable correlation matrix to model the interdependence between waves resulting from some participants being present in both waves.

Adjusted analyses used GEE and included age, sex (in comparison countries), income (in United Kingdom), education and, where applicable, nicotine dependence (for ex-smokers HSI values were imputed from the last available data point) as covariates to determine within-country changes and age and income to determine wave–country interactions. Where appropriate, adjusted cross-sectional analyses were carried out to elucidate wave-dependent changes further using logistic or linear regressions and included age, ethnicity, education and, where applicable, nicotine dependence as covariates. In order to control for unidentified, country-specific confounders, a categorical variable specifying each individual country was also included in these adjusted between-country comparisons.

## RESULTS

### Preliminary unadjusted analysis

Age increased from wave 3 to wave 5 in the United Kingdom and comparison countries (Table 1). This

increase in age was more pronounced in comparison countries resulting in a country  $\times$  wave interaction (Table 1). Overall, participants in the United Kingdom were older than in comparison countries. In terms of sex distribution, there was a slight decrease in the proportion of men in comparison countries but not in the United Kingdom across waves, but no overall significant differences (Table 1). There were no changes in the ethnic distribution of participants between waves. Altogether, the United Kingdom was less ethnically diverse than comparison countries. The proportion of participants on a low income increased in the United Kingdom but not in comparison countries, and there was a significant country  $\times$  wave interaction (Table 1). The level of education also increased across waves in all countries but, overall, was lower in the United Kingdom than in comparison countries (Table 1).

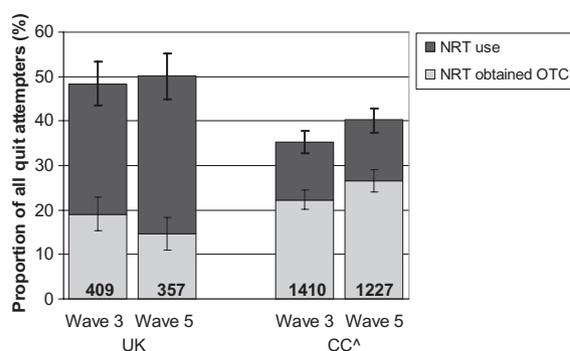
There were no country  $\times$  wave interactions on any of the smoking characteristics considered. Around 95% of the sample consisted of current smokers with no differences within or between countries (Table 1). Nicotine dependence (and in the United Kingdom also cigarette consumption) increased significantly from wave 3 to wave 5 in the United Kingdom and in comparison countries (Table 1), but there were no other within-country changes. Overall, smokers in the United Kingdom were less likely to intend or to have attempted to stop smoking and had carried out fewer quit attempts in the last year than current smokers in comparison countries (Table 1). There was a general trend towards increased NRT use across waves. Overall, more NRT was used in the United Kingdom than in comparison countries (see Table 1).

### Adjusted analyses

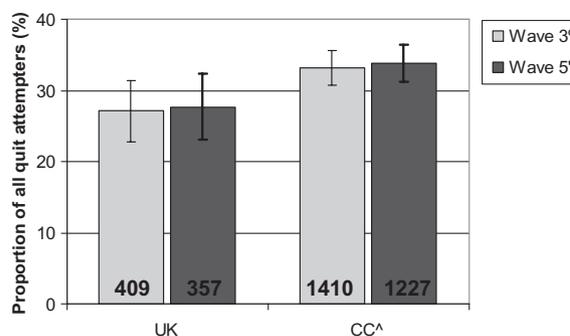
#### *Impact of licence change on NRT use*

Confirming unadjusted analyses, NRT use in the general population increased across waves in both the United Kingdom (Wald  $\chi^2_{(1)} = 12.2$ ,  $P < 0.001$ ) and in comparison countries (Wald  $\chi^2_{(1)} = 28.6$ ,  $P < 0.001$ ), but no country  $\times$  wave interaction was detected. However, among quit attempters, NRT use increased significantly only in comparison countries (Wald  $\chi^2_{(1)} = 5.9$ ,  $P = 0.015$ ) and not in the United Kingdom (Fig. 1). Again, there was no country  $\times$  wave interaction. However, smokers attempting to quit were more likely to use NRT in the United Kingdom than in any of the other countries at both wave 3 [odds ratio (OR) range: 1.44–2.11; 95% confidence interval (CI) range: 1.06–2.96] and wave 5 (OR range: 1.45–1.85; 95% CI range: 1.05–2.60).

There was also an increase in the proportion of smokers attempting to quit who obtained NRT OTC in comparison countries (Wald  $\chi^2_{(1)} = 9.6$ ,  $P = 0.002$ ) but



**Figure 1** Prevalence of recent nicotine replacement therapy (NRT) use among quit attempters by wave and country. Base for each wave (provided in each column): smokers/recent ex-smokers with reported quit attempt since previous survey; \*OTC: over the counter; ^CC: comparison countries; error bars represent 95% confidence interval of proportion

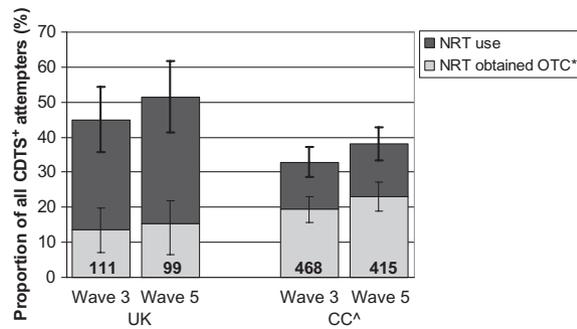


**Figure 2** Prevalence of cut down to stop (CDTS) by wave and country. Base for each wave (provided in each column): smokers/recent ex-smokers with reported quit attempt since previous survey; ^CC: comparison countries; ^98 cases missing; ^19 cases missing; error bars represent 95% confidence interval of proportion

not in the United Kingdom (Fig. 1), which resulted in a significant country  $\times$  wave interaction (Wald  $\chi^2_{(1)} = 5.80$ ,  $P = 0.016$ ). Only at wave 5 (but not wave 3) were quit attempters in the United Kingdom less likely to obtain NRT OTC compared with quit attempters from any other country (OR range: 0.38–0.56; 95% CI range: 0.25–0.87).

#### *Impact of licence change on CDTS*

Among quit attempters, there was virtually no change in the prevalence of people using CDTS in the United Kingdom or in comparison countries, and no country  $\times$  wave interaction was observed (Fig. 2). While more participants in comparison countries attempted to quit by CDTS, there were no persistent significant differences between the United Kingdom and individual countries that were present at both waves.



**Figure 3** Prevalence of recent nicotine replacement therapy (NRT) use among quit attempters using cut down to stop (CDTS) by wave and country. Base for each wave (provided in each column): smokers/recent ex-smokers who used CDTS; \*OTC: over the counter; ^CC: comparison countries; error bars represent 95% confidence interval of proportion

#### Impact of licence change on NRT use for CDTS

A small increase in the use of NRT for CDTS was observed across waves in the United Kingdom and in comparison countries, but this change was non-significant and no country  $\times$  wave interaction was detected. Although more smokers in the United Kingdom used NRT for CDTS (Fig. 3), again there were no persistent differences between the United Kingdom and individual countries present at both waves.

There were also no within-country changes across waves or a country  $\times$  wave interaction in the proportion of quit attempters obtaining NRT OTC for CDTS (Fig. 3).

#### Impact of licence change on quit attempts and concurrent smoking and NRT use among smokers not attempting to quit

Around a third of participants had attempted to stop in the last year, making an average of two to three quit attempts (Table 1). There were no changes in the proportion or number of quit attempts made within the United Kingdom or comparison countries or a country  $\times$  wave interaction. Overall, however, as in unadjusted analysis, UK smokers were less likely to make a quit attempt than smokers from any other country at both wave 3 (OR range: 0.65–0.80; 95% CI range: 0.55–0.97) and wave 5 (OR range: 0.66–0.80; 95% CI range: 0.54–0.98), but there were no differences between the United Kingdom and other countries in the number of quit attempts smokers made per year at either wave.

Concurrent smoking and NRT use among smokers not attempting to stop was not common. In the United Kingdom, there was an increase in NRT use among current smokers from waves 3–5 but no country  $\times$  wave interaction was detected (Table 2). No data were available as to how NRT was obtained among smokers who were not attempting to quit.

In a subanalysis of this sample, there were no changes within the United Kingdom and comparison countries in the use of NRT to simply reduce consumption (as opposed to CDTS) or to cope with temporary abstinence in adjusted analysis and no interactions were observed (Table 2). However, as this sample was small, the power to detect any significant changes was limited in this analysis.

## DISCUSSION

These data suggest that the relaxation in the licensing laws of NRT in the United Kingdom to allow NRT use for CDTS had a very limited, if any, impact on NRT consumption and quitting behaviour in the first year after the change was introduced. NRT use is more prevalent in the United Kingdom than in comparison countries and has generally become more popular across all countries that were evaluated, which may reflect both the increasing denormalization of public smoking and NRT becoming more accessible. However, there was no change in the use of NRT by people attempting to quit in the United Kingdom relative to comparison countries. Moreover, although the relaxation of licensing was thought to impact mainly NRT obtained OTC, there was no change in the use of NRT obtained OTC by smokers attempting to quit in the United Kingdom from 2004 to 2007. Indeed, the use of NRT obtained OTC increased significantly in comparison countries relative to the United Kingdom. It appears that NRT use is more widespread in the United Kingdom but that it is more commonly purchased OTC in countries other than the United Kingdom, possibly because NRT is available relatively cheaply on prescription only in the United Kingdom and not in the comparison countries.

The prevalence of smokers attempting to stop smoking using CDTS also did not change in the United Kingdom compared with other countries and was somewhat lower, which may reflect the great emphasis that has been placed recently on complete cessation in the United Kingdom [15]. In contrast, the use of NRT for cutting down to stop was more common in the United Kingdom but there was no change in the use of NRT (irrespective how it was obtained) for CDTS during the course of this study.

The lack of positive findings may be the result of several factors. First, given that the survey covered the 1-year period just after the introduction of new licensing laws, this time-frame may have been too immediate to detect any changes in consumer behaviour. Secondly, the licensing change applied initially to only two products and not all brands [7]. Thirdly, in contrast to an earlier study reporting an increase in NRT use after it was made available on prescription [12], the policy change considered here may have been too subtle to produce a notable

**Table 2** Prevalence of concurrent nicotine replacement therapy (NRT) use and smoking by wave and country.<sup>a</sup>

	<i>United Kingdom</i>		<i>Comparison countries<sup>b</sup></i>		<i>Country × wave interaction</i>
	<i>Wave 3</i>	<i>Wave 5</i>	<i>Wave 3</i>	<i>Wave 5</i>	
	<i>% (n/N)</i>				<i>Significance</i>
Concurrent NRT use and smoking <sup>c</sup>	5.0 ( <sup>42</sup> / <sub>841</sub> )	8.3 ( <sup>63</sup> / <sub>758</sub> )*	4.8 ( <sup>107</sup> / <sub>2211</sub> )	5.6 ( <sup>118</sup> / <sub>2101</sub> )	<i>P</i> = 0.124
Only to reduce smoking <sup>d</sup>	21.4 ( <sup>9</sup> / <sub>42</sub> )	34.9 ( <sup>22</sup> / <sub>63</sub> )	13.1 ( <sup>14</sup> / <sub>107</sub> )	18.6 ( <sup>22</sup> / <sub>118</sub> )	<i>P</i> = 0.408
Only to cope with temporary abstinence <sup>d</sup>	33.3 ( <sup>14</sup> / <sub>42</sub> )	22.2 ( <sup>14</sup> / <sub>63</sub> )	26.2 ( <sup>28</sup> / <sub>107</sub> )	42.4 ( <sup>50</sup> / <sub>118</sub> )	<i>P</i> = 0.410

<sup>a</sup>Raw data are presented and comparisons based on generalized estimating equations (GEE). <sup>b</sup>Australia, Canada and United States; <sup>c</sup>base: smokers not attempting to quit; <sup>d</sup>base: NRT users not attempting to stop. \*significant difference between waves (*P* < 0.025).

effect. Fourthly, a large number of smokers in these four countries reported using NRT to reduce cigarette consumption prior to 2005 [16]. For this reason, the already established use of NRT for reducing cigarette consumption in the United Kingdom before the licensing change may have contributed to a ceiling effect, thus reducing the potential to detect any substantial changes following the implementation of new licensing. Finally, advertisement of the licensing change may have been insufficient to penetrate the market; approximately £1.5 million were spent on the advertising campaign for using NRT for CDTS (Johnson & Johnson, personal communication). The licensing change did not incorporate any specific promotion to educate the public or providers about how to conduct CDTS or about its benefits. Rather, the packaging was modified and the licensing change advertised on TV, which may have been too minimal to change awareness, smoker behaviour or NRT utilization. Indeed, it has been suggested that intensive outreach would be required before any benefit can be seen, as most of the evidence supporting the use of NRT for CDTS has come from trials with considerable patient–investigator interaction [17].

One potential negative side effect of more relaxed NRT licensing laws is that fewer people may attempt to stop smoking altogether, and instead simply use NRT while continuing to smoke. When comparing the proportion of quit attempts in the United Kingdom and comparison countries, the change in licensing does not appear to have depressed the frequency or number of quit attempts across waves. There was some evidence that people continuing to smoke were more likely to use NRT in the United Kingdom after the licensing change, but this increase was not significant relative to changes observed in comparison countries.

This study had a number of limitations. Owing to its quasi-experimental design it may be that other, potentially relevant, changes occurred in the United Kingdom or in the comparison countries that were not considered here and which could have affected results. Subtle trends such as growing ‘cessation fatigue’ following intensive

campaigning may have confounded outcomes. Moreover, variations in the pricing of NRT across countries and the impending smoking ban in the United Kingdom may have contributed to results. Although this possibility cannot be excluded, we are not aware of any drastic changes in pricing over the period considered, and the eventual introduction of a smoking ban in the United Kingdom was not announced until some time after data collection for the last wave had started. Indeed, the relaxation in NRT licensing laws in the United Kingdom was the only directly relevant legislative change implemented between waves. Furthermore, the inclusion of fairly comparable countries that—with the exception of NRT licensing—would have been exposed to similar, potentially relevant, changes across waves provides some measure of control. It can thus be assumed reasonably that differences in outcome measures in the United Kingdom relative to other countries can be attributed to the relaxation in NRT licensing in the United Kingdom that took place between waves.

Another limitation of this study is its reliance on self-report to assess smoking status, quitting behaviour and NRT use, which may have resulted in some recall bias or misreporting. However, even if this is the case, there is no reason to believe that this should have differentially biased data from the United Kingdom and comparison countries. Lastly, owing to low numbers we were not able to look at changes statistically in the use of particular forms of NRT. This would have been useful, given that the licensing change targeted only two products initially. However, it is unclear that consumers would have differentiated between products in this respect. Indeed, the sensitivity analysis, restricted to these two forms, revealed similar trends suggesting that potential changes in NRT use appear to have applied to the whole range of products.

In conclusion, our data imply that over the time-period covered by the two surveys, there was an overall increase in NRT use irrespective of whether or not people were from the United Kingdom. While there was no relative increase in the use of NRT for CDTS, the results also suggest that

making NRT available for gradual cessation has not had a detrimental effect on the proportion of quit attempts in the United Kingdom or led to an increase in the number of people attempting to stop gradually. Further research is required to substantiate these findings and evaluate their relevance for future public health policy.

#### Declarations of interest

Lion Shahab has received an honorarium for a talk and travel expenses from a pharmaceutical company making smoking cessation products. Robert West undertakes research and consultancy for developers and manufacturers of smoking cessation treatments such as nicotine replacement products. All other authors here no declarations of interest to make.

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