# The impact of the introduction of smoke-free legislation on prescribing of stop-smoking medications in England

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# ABSTRACT

Aims To investigate whether there were changes in the rate of prescribing of smoking cessation medications in the months leading up to, and after, the introduction of smoke-free legislation in England. Design Interrupted time-series analysis of prescribing rates using Autoregressive Integrated Moving Average (ARIMA) models. Setting A total of 350 general practices in England who contribute data to The Health Improvement Network (THIN) database. Participants Patients in THIN aged 16+ identified from their medical records as smokers. Measurements Monthly rates of prescribing of nicotine replacement therapy (NRT), bupropion and varenicline were calculated from THIN from 2000 to 2009 for all smokers and for subgroups defined by patient sex, age group, history of chronic disease and quintile of the Townsend Index of Deprivation. ARIMA models were built to assess whether there were changes in prescribing before or after the introduction of smoke-free legislation over and above any long-term and seasonal trends. **Findings** There was a 6.4% (0.7–12.1) increase in prescribing of all smoking cessation medications in the 9 months before the introduction of smoke-free legislation and a 6.4% (1.1–11.7) reduction in the 9-month period afterwards. A 6.2% (1.4–11.0) increase in NRT prescribing and a 13.2% (4.3–22.2) increase in bupropion prescribing occurred in the 6- and 3-month periods, respectively, before smoke-free legislation was introduced, and a 5.5% (2.3–8.7) decline in NRT prescribing and a 13.7% (4.6–22.8) decline in bupropion prescribing in the 9 months post-legislation. The patterns of change in prescribing did not vary with patient demographics. Conclusions Numbers of primary care prescriptions for smoking cessation medications increased prior to the introduction of smoke-free legislation but decreased afterwards, suggesting a temporal displacement in prescribing activity rather than a change in the overall volume of prescribing. Effects observed were consistent across all population subgroups, suggesting that the changes in prescribing will neither widen nor reduce smoking-related health inequalities.

**Keywords** Primary care, smoking cessation, smoke free legislation.

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# INTRODUCTION

Globally, tobacco use kills 5 million people each year, with 600 000 dving as a result of exposure to environmental tobacco smoke [1]. In the past decade, many locations world-wide have implemented smoke-free legislation in an effort to curb the damage caused by smoking. Such smoke-free policies succeeded in their primary aim of reducing non-smokers' exposure to environmental tobacco smoke [2], and there is evidence that the introduction of legislation may also prompt some existing smokers to attempt to quit. Comprehensive smoke-free legislation covering all substantially enclosed public spaces, including work-places, bars and restaurants, was introduced in England on 1 July 2007, 17 months after completing its well-publicized passage through Parliament; there were also some national and local mass media advertising campaigns in the run-up to the implementation of the legislation. A significant increase in the number of smokers reporting making a quit attempt was

seen in England in the 2 months after the introduction of smoke-free legislation on 1 July 2007 compared to the same period in 2008 [3], and several studies have reported transient increases in markers of cessation activity, such as sales [4] and use [5] of nicotine replacement therapy (NRT). Data from New Zealand have highlighted an increase in the number of smokers telephoning cessation helplines in the months before and after the introduction of smoke-free polices [6,7], and studies from several countries have noted reductions in reported daily cigarette consumption [8].

There is a lack of research examining the pathways by which the introduction of smoke-free legislation might exert an impact on quitting activity; one possible route is through the delivery of advice or support to quit through primary care. As cessation advice and pharmacotherapy delivered through primary care is effective [9-12], any increase in the provision of these interventions at the time smoke-free legislation is introduced would demonstrate how legislation exerts some of its effects. Conversely, if such increases were not observed, this could mean that opportunities to maximize the impact of smoking bans (by the provision of interventions through primary care) were being missed. This could have implications for other jurisdictions considering the implementation of smoke-free legislation; improvements in the provision of primary care cessation support to smokers in the lead up to and following smoke-free legislation could help to maximize the number of smokers who attempt to quit and remain permanently abstinent. Therefore, this study uses data from The Health Improvement Network (THIN), a large database of primary care records, to investigate whether there were changes in the rate of prescribing of smoking cessation medications in the months leading up to, or after, the introduction of smoke-free legislation in England on 1 July 2007.

## METHODS

#### Data extraction from THIN

THIN contains the primary care medical records of more than 6 million patients from 446 general practices throughout the United Kingdom, all of which use the INPS Vision [13] practice management system. The data set is broadly representative of the UK population in terms of patient demographic characteristics, although is slightly less representative of more deprived social groups [14]. THIN contains information on patients' symptoms, diagnoses and treatment, as well as life-style indicators such as smoking behaviour, recorded by general practitioners (GPs) during the course of routine consultations. Since the introduction of the Quality and Outcomes Framework (QOF) in 2004, GPs have been rewarded financially for documenting their patients' smoking status at least every 27 months, and since 2007 there has been good agreement between the prevalence of smoking recorded in THIN and that reported in nationally representative surveys of smoking behaviour [15]. THIN prescribing data have been validated previously and the recording of prescriptions for smoking cessation medications shown to be complete [16].

For each month, from June 2000 to July 2009, all patients were identified from the THIN data set who were aged 16 or over and registered with one of the 350 practices in England for at least 1 day of the month. All smoking-related Read Codes [17] entered into patients' notes on or after their registration date were extracted from THIN, and smokers identified as those whose lastrecorded Read Code prior to the first day of each month indicated current smoking. The total number of days registered in THIN each month was aggregated across all smokers to give a measure of person-months of follow-up for the calculation of rates of prescribing.

*British National Formulary* [18] drug codes were used to identify smokers with one or more prescriptions for NRT, bupropion or varenicline recorded in their notes each month. Monthly rates of prescribing of each individual drug, or any of these medications, were then calculated, expressed as the number of smokers with one or more prescriptions in that month per 100 000 personmonths of follow-up.

In addition, rates of prescribing were also calculated for subgroups of smokers defined by sex, age group, quintile of the Townsend Index of Deprivation, and whether they have a history of one or more of the following selected chronic diseases recorded in their medical records using relevant Read Codes—asthma, coronary heart disease, chronic obstructive pulmonary disease, diabetes mellitus, hypertension and stroke or transient ischaemic attack.

Given that the recording of smoking status in primary care medical records has been shown to be less complete before 2007 [15], a sensitivity analysis was also carried out, calculating rates of prescribing in all patients (i.e. not just those with recorded Read Codes indicating they were current smokers). This will ensure that the rate of prescribing in the early years of our study period is not underestimated, which could alter the estimates of change at the time smoke-free legislation was introduced.

#### Statistical analysis

Extracted data comprised time–series of monthly prescribing rates and could not be analysed using traditional regression techniques due to autocorrelation between data points; such autocorrelation violates the assumption of independence central to linear regression and biases the standard errors of parameter estimates [19]. Instead, Autoregressive Integrated Moving Average (ARIMA) models were built to assess the impact of the introduction of smoke-free legislation on each prescribing time–series, taking into account the autocorrelation in the data. In addition, ARIMA modelling can account for secular trends or seasonal variation in prescribing to ensure that any changes which may be attributable to the introduction of legislation are outside the normal behaviour of the data. Following procedures outlined in more detail elsewhere [19] each time–series was first log-transformed to stabilize its variance and then differenced and/or seasonally differenced to stabilize the mean

and render the series stationary. The autocorrelation and partial autocorrelation functions of the stationary series were examined to determine the order of the autoregressive (AR) and moving average (MA) parameters needed to model any autocorrelation in the data.

The final ARIMA model for each outcome variable was augmented with binary dummy variables to model the effect of the introduction of smoke-free legislation on the rate of prescribing. Several intervention effects were modelled for each prescribing time-series, based upon hypotheses generated from the existing literature about the potential changes in smoking-related clinical activity that may be seen in primary care and also to allow exploration of the timing and duration of any changes. The existing evidence, summarized above, indicates that any changes in quitting behaviour were likely to be relatively short-lived, with increases in activity prior to legislation and decreases afterwards [3-8]. We therefore hypothesized that the rate of prescribing of cessation medications might increase up to 9 months before the introduction of smoke-free legislation. Similarly, we hypothesized that prescribing might increase for a short period after the introduction of the smoking ban, although ideally it might be hoped that the introduction of legislation would lead to permanent changes in the rate of prescribing. Therefore, pulse effects on prescribing lasting for continuous periods of 1, 2, 3, 6 and 9 months before and after the introduction of legislation were modelled; these assessed whether or not prescribing rates changed for the whole of each of these sustained periods before and/or after the smoking ban. These analyses, potentially, would indicate at what point and how long any changes lasted. Finally, a permanent step change in prescribing at the time smoke-free legislation was introduced was modelled to assess whether or not an abrupt, sustained change in prescribing occurred immediately after the introduction of smoke-free legislation. All results are expressed as percentage changes in prescribing in the intervention period compared to the remainder of the months in the time-series, with 95% confidence intervals and Wald P-values.

The analysis of THIN data for this study was approved by the Leicestershire and Rutland Research Ethics Committee.

## RESULTS

Figure 1 illustrates changes over time in the rate of prescribing of NRT, bupropion, varenicline and all cessation medications from the month that these were first available on National Health Service (NHS) prescription to July 2009. Throughout the study period NRT was by far the most commonly prescribed smoking cessation medication. Prescribing of bupropion increased rapidly immediately after its introduction then reduced markedly, and has not recovered to previous maximum rates. Prescribing of varenicline also increased rapidly after it was made available on NHS prescription in December 2006, and has remained at a fairly constant level to the end of the study period. The prescribing of NRT and all smoking cessation medications show a strong seasonal pattern, with rates of prescribing highest in the first quarter of each year.

Table 1 shows the estimates of changes in the rate of prescribing of NRT, bupropion and all smoking cessation medications before and after the introduction of smoke-free legislation. Given that varenicline was licensed just 7 months before the introduction of smoke-free legislation, there were not enough data to model trends in prescribing of this medication.

A statistically significant increase in the rate of prescribing of all medications is seen in the 9 months before the smoking ban was enacted, and increases in prescribing of NRT and bupropion individually are seen in the 6and 3-month periods, respectively, before the introduction of smoke-free legislation. Significant decreases in the rate of prescribing of all cessation medications, as well as NRT and bupropion, are seen up to 9 months after the introduction of smoke-free legislation, although these declines are not sustained to the end of the study period. The decline in the rate of prescribing of bupropion appears to be greater than that of NRT, although confidence intervals overlap.

Table 2 shows changes in prescribing by population subgroup in the 3-month period before and 9-month period after the introduction of smoke-free legislation. Similar patterns of findings occurred for the 1- and 2-month periods prior to legislation and for the 1-, 2-, 3and 6-month periods afterwards; selected results shown (3 months before, 9 months after) are, therefore, illustrative of the changes in prescribing seen across all subgroups in the periods before and after the smoking ban was enacted and have been chosen for brevity.

Increases in the rate of prescribing of NRT and all smoking cessation medications were seen in almost all



Figure I Time-series of rates of prescribing of nicotine replacement therapy (NRT), bupropion, varenicline and all smoking cessation medications, with vertical lines indicating the introduction of smoke-free legislation

population subgroups before the introduction of smokefree legislation, with overlapping confidence intervals suggesting a similar magnitude of change. Declines in NRT prescribing after the ban was implemented were seen in all subgroups with the exception of the youngest age groups, again with overlapping confidence intervals. The rate of prescribing of all smoking cessation medications also declined in many subgroups post-legislation, although in other subgroups only marginally failed to reach statistical significance.

Although a significant increase in bupropion prescribing was seen in all patients 3 months before the introduction of smoke-free legislation, significant changes were observed in very few subgroups. Declines in the rate of prescribing of bupropion after the smoking ban was enacted were, however, detected in most subgroups as well in the whole population.

Similar results to those described above were found in our sensitivity analyses analysing changes in the rate of prescribing in all patients, rather than just those recorded in their notes as current smokers.

## DISCUSSION

This study shows that prescribing of all smoking cessation medications in England increased in the months leading up to the introduction of smoke-free legislation, but that this increase was not sustained afterwards. The changes in prescribing patterns did not vary with sex, age, medical history or social class. Confidence in the results presented here is strengthened by the use of ARIMA modelling, which is able to filter out autocorrelation, secular trends and seasonal variation in prescribing to assess whether or not any observed changes at the time smoke-free legislation was introduced were over and above the normal pattern of prescribing.

This study focused on one route of quitting only: smokers receiving a prescription in primary care. Currently, nearly one-half of all smokers in England attempting to quit do so unaided, with 29% using NRT they have bought over-the-counter (OTC), 17% using a pharmacotherapy obtained on prescription and 6% using a stop smoking service [20]; it is possible that smoke-free legislation impacts on these other routes too, perhaps in different ways. The prescribing of any medication does not necessarily mean that patients will redeem their prescription and use this as directed, although the good agreement between THIN prescribing rates and rates of dispensed prescriptions for smoking cessation treatments suggests this is not a major problem [16]. Some smokers may use NRT to support temporary abstinence from smoking, as it has been licensed for this since 2006 [21]; however, as this is a relatively new use for NRT, it seems likely that most primary care NRT prescribing is aimed at

Table 1 Changes in prescribing	of smoking cessati	ion medications in all	patients aged	16+ in England	J.ª					
NRT				Bupropion			All medications			
Cha	1ge (%) 959	% CI	P-value	Change (%)	95% CI	P-value	Change (%)	95% CI		P-value
9 months before 4.0		1.3 to 9.3	0.135	5.2	-1.8 to 12.3	0.147	6.4	0.7 to	12.1	0.027
6 months before 6.2		1.4 to 11.0	0.012	7.1	-0.4 to $14.5$	0.062	11.1	5.5 to	16.7	<0.001
3 months before 10.4		5.0 to 15.7	<0.001	13.2	4.3 to 22.2	0.004	9.9	5.2 to	14.6	<0.001
2 months before 13.6		8.1 to 19.1	<0.001	18.9	9.2 to 28.6	<0.001	14.7	10.4 to	19.1	<0.001
1 month before 17.5	1	1.1 to 24.0	<0.001	44.7	20.4 to 69.0	<0.001	22.3	17.9 to	26.8	<0.001
1 month after –1.1	-32	2.2 to 30.0	0.945	-6.8	-40.1 to 26.6	0.691	7.7	-13.0 to	28.4	0.468
2 months after –6.5	T	0.3 to -13.4	0.040	-25.3	-4.9 to -45.7	0.015	-5.3	-17.2 to	6.7	0.387
3 months after –9.0	T	3.9 to -14.2	0.001	-21.1	-2.1 to -40.1	0.029	-10.0	-0.2 to	-19.9	0.046
6 months after –6.7		2.1 to -11.2	0.004	-19.7	-5.5  to  -34.0	0.007	-7.4	-16.3 to	1.5	0.101
9 months after -5.5		2.3 to -8.7	0.001	-13.7	-4.6 to -22.8	0.003	-6.4	-1.1 to $-1$	-11.7	0.019
Permanent change -1.7	Ţ	4.4 to 1.0	0.229	-3.5	-8.8 to 1.9	0.206	-2.2	-5.6 to	1.2	0.209
		3 months before le	egislation			9 months after legisla	tion			
		NRT	Bupropion		All medications	NRT	Bupropion		All medicati	suc
All natients	England	10.4 (5.0–15.7)	13.2 (4.3	to 22.2)	9.9 (5.2 to 14.6)	-5.5 (-2.3 to -8.7)	-13.7 (-4.6	to -22.8)	-6.4 (-1.1	to -11.7)
Gender	Men	10.8 (4.5–17.2)	16.8 (6.2	to 27.5)	13.8 (8.5 to 19.2)	-5.2 (-0.7  to  -9.7)	-11.6 (-5.5	(10 - 17.8)	-4.1 (-8.5	to 0.3)
	Women	10.6(5.2 - 15.9)	5.6 (-2.	1  to  13.4	9.7(5.1  to  14.3)	-7.3 (-2.1 to -12.4	) -7.3 (-2.4	(10 - 12.1)	-6.5(-1.0)	(0.12.0)
Age group (years)	16 - 19	16.5(0.3 - 32.8)	5.9 (-21	1.6 to 33.4)	14.7 (-0.9 to 30.2)	0.8 (-1.3 to 3.0)	4.3 (-31.	.5 to 40.0)	-1.7 (-4.5	to 1.2)
	20-24	15.7 (5.4–25.9)	3.8 (-17	7.4 to 25.0)	15.4 (7.3 to 23.5)	-4.6 (-10.4  to  1.3)	-10.4(-5.1)	to -15.6)	1.0(-2.4)	to 4.3)
	25-34	13.3 (6.3–20.3)	11.7 (-1.	1 to 24.4)	12.2 (6.3 to 18.1)	-6.4 (-0.5  to  -12.2  to  -12.2		(10 - 14.4)	-6.4 (-13.3	$\frac{12}{12}$ (1)
	50-59	11.9 (3.0-10.0) 8 8 (3 1_146)	10.0 (3.2	(0.1.5 0)	7 9 (3 0 to 12 8)		) -12.0 (-0.0	to -1 3.3)	-/. <del>1</del> (-1.) -3 9 (-8 3	(0.61-0)
	60+	8.9 (2.0-15.8)	11.2 (-13	3.9  to  36.3	11.9 (6.0  to  17.8)	-4.3 (-9.3  to  0.7)		(10 - 16.6)	-5.2 (-11.4	to 0.9)
Number of chronic conditions	0	10.7(5.0-16.3)	5.4 (-2.1	0 to 12.9)	9.3 (4.3 to 14.3)	-5.8 (-1.3 to -10.3	) -14.5 (-3.8	(10-25.1)	-7.0 (-1.1	to -12.8)
	$^{1+}$	10.2 (4.0–16.5)	6.1 (-6.	8 to 19.0)	16.2 (10.3 to 22.2)	-4.9 (-1.5 to -8.3)	-9.4 (-2.3	to -16.4)	-5.0 (-10.2	to 0.3)
Townsend Index of Deprivation	Least deprived	14.0 (5.6–22.3)	10.5 (-9.	1 to 30.0)	15.4 (9.0 to 21.8)	-4.1 (-8.3 to 0.0)	-10.3 (-4.4	to -16.1)	-3.8 (-9.4	to 1.8)
	Quintile 2	12.2 (7.2–17.2)	13.2 (-1.	3 to 27.8)	20.7 (14.5 to 26.9)	-6.3 (-1.9  to  -10.6  to  -10.6	(-9.0)	to -19.7	-8.2 (-1.3	(0 - 15.1)
	Quintile 5 Ouintile 4	10.0 (5.4-10.2)	0.7 (-2.	9 to 10.3) 4 to 21 6)	10.2 (5.0 to 15.4) 14.0 (9.1 to 18.8)	-5.2 (-0.5 10 -9.9) -6 1 (-2 6 to -9 7)	-/.0 (-1.2	(0 - 12.0)	-0.1 (-0.4	(0 - 11.0)
	Most deprived	6.7 (1.1-12.3)	2.6 (-16	$\frac{1}{5}$ .1 to 21.2)	10.4 (5.6 to 15.1)	-5.1 (-0.5  to  -9.6)	-12.3 (-9.0	1  to  -15.7	-6.4 (-12.9	(100.1)

<sup>ap</sup>igures in bold type are statistically significant at the 5% significance level. NRT: nicotine replacement therapy.

promoting smoking cessation. The monthly rates of prescribing analysed here include all recorded prescriptions, including any repeat prescriptions to the same patient. It is difficult in THIN to identify courses of prescriptions associated with individual quit attempts, but most prescriptions are likely to be for short-term use, as it is very unusual for smoking cessation medications to be prescribed repeatedly in primary care in the United Kingdom. Although our results cannot be interpreted as changes in the proportion of smokers initiating a quit attempt, they are likely to approximate to this.

As the ARIMA technique is unable to distinguish between the effects of multiple policy changes occurring simultaneously, it is possible that other tobacco control interventions or unknown events are responsible for the changes in prescribing reported here. For example, the rate of value-added tax (VAT) on NRT sold OTC was reduced to 5% in July 2007, and it may be that smokers who would previously have sought a prescription for NRT from primary care bought it instead OTC, contributing to the decline in prescribing seen after July 2007. However, despite the VAT reduction, NRT is still more expensive when bought OTC compared to the cost of a prescription. Therefore, the tax change is unlikely to be responsible for the post-legislation decline in NRT prescribing seen in our data. In addition, bupropion is not available OTC in the United Kingdom and a similar decline in bupropion prescribing was observed in our data. The picture is complicated by the licensing of varenicline in December 2006, which was followed by the publication of National Institute of Health and Clinical Excellence (NICE) guidance in July 2007, which recommended that GPs prescribe the new medication to smokers motivated to quit [22]. However, as our principal analyses investigated the impact on prescribing for all cessation medications (including varenicline), this does not affect the relevance of our overall findings. The rate of all prescribing increased prior to legislation, but afterwards the predominant pattern was of non-statistically significant reductions in overall prescribing with larger and statistically significant reductions in prescriptions for NRT and bupropion. Presumably, this pattern was observed as the newly introduced medication, varenicline, began to be prescribed instead of NRT and bupropion [23]. Declines in prescribing of NRT, bupropion and all medications were not sustained to the end of the study period-inspection of the time plots suggests that rates of prescribing seem to increase again the first few months of 2009. More data are needed to assess whether this apparent increase in prescribing at the start of 2009 is sustained.

Our results suggest that, during 2007, a temporal displacement of prescribing occurred rather than an increase in the overall volume; prescriptions which otherwise might have been offered to smokers later in the

year appear to have been offered earlier. Similar patterns are seen in throughput figures from the NHS Stop Smoking Services in England [24] and Scotland [25], and analysis of self-reported quit attempts from national survey data [3], where there appears to have been a redistribution of quit attempts over the course of the year in which smoke-free legislation was introduced. Additionally, OTC sales of NRT were increased in the 6-month period spanning the introduction of smoke-free legislation in Scotland, but not in the longer term [4], and selfreported NRT use was higher in Scotland than in the rest of the United Kingdom 6 months before the introduction of the Scottish legislation, and declined more post-ban [5]. Qualitative research has suggested that, while the introduction of smoke-free legislation may indeed prompt some smokers to attempt to quit, other contextual factors and social norms continue to influence smoking behaviour [26]. Factors such as the provision of outdoor facilities for smoking, or spending time with smoking friends, may mean that smoke-free legislation does not act as a continuing stimulus to quit [26].

There is no way to test directly for effect modification by subgroup in interrupted time-series analysis. Therefore, in order to judge whether the effects of smoke-free legislation differ by subgroup we have compared the magnitude and confidence intervals of the changes in prescribing estimated to have occurred in each subgroup. Although prescribing in population subgroups followed a very similar pattern to that in all smokers, analyses failed to detect significant changes in some subgroups. This is probably explained by low statistical power to detect small changes in prescribing in these groups, particularly where the number of patients is relatively small, as is the case in patients with a history of chronic disease, and/or the rate of prescribing is low, such as is seen with prescribing of cessation medications to smokers aged 16-19 years. In addition, it should be remembered that one in 20 ARIMA models can be expected to produce a statistically significant estimate of a change in the outcome variable at the 5% significance level, and thus the results of multiple hypothesis testing should be interpreted with caution-some of the statistically significant results presented here may in fact be non-significant, and vice-versa.

The introduction of smoke-free legislation appeared to have only transient effects on the prescribing of cessation medications in primary care. Impending legislation may motivate smokers who wish to quit but, even in England, where well-developed NHS Stop Smoking Services are ideally placed to support smokers to quit, it is not clear how the motivational effect of a new smoking ban can be capitalized upon most effectively. In England, in addition to national advertising, local councils were given £29.5 million to help raise awareness about the impending introduction of smoke-free legislation, and in some areas campaigns were launched to encourage people to quit before the legislation was enacted [27]. However, these campaigns were not continued in the period following the implementation of the ban. Ensuring that smokers are reminded of the support available to them through primary care to help them quit in the months after a ban is enacted may increase the number of smokers who attempt to quit and succeed in their efforts. This may be equally relevant in other countries that have already, or are planning in the future to introduce. smoke-free legislation. Any benefits resulting from increased prescribing of smoking cessation medications in the run-up to the introduction of smoke-free legislation are not concentrated in particular population subgroups and are therefore not likely to either widen or reduce smoking-related health inequalities. Further work would be of benefit to understand whether any other public health interventions, such as novel ways of making cessation support available in disadvantaged communities, have the potential when delivered alongside the introduction of smokefree legislation to increase quitting activity and reduce smoking prevalence and the devastating effects of tobacco use in the least advantaged sections of society.

#### Declarations of interest

In the last 5 years, Tim Coleman has been paid for consultancy work by Johnson & Johnson and Pierre Fabre Laboratories (manufacturers of nicotine replacement therapy). However, this paper has not been discussed with any third parties.

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