Brief report

Was the Expansion of the Marketing License for Nicotine Replacement Therapy in the United Kingdom to Include Smoking Reduction Associated With Changes in Use and Incidence of Quit Attempts?

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ABSTRACT

Background: In December 2009 and January 2010, the UK Medicines and Healthcare Products Regulatory Agency expanded the marketing license for a number of nicotine replacement therapies (NRTs) to include smoking reduction without an intention to stop completely. This study examined whether this was associated with a change in incidence of use of NRT for harm reduction (i.e., smoking reduction and/or temporary abstinence) and in smoking cessation activity.

Methods: Data were taken from 10,497 smokers who took part in the Smoking Toolkit Study, which involves monthly representative household surveys of adults aged 16+ in England. Incidence of use of NRT for smoking reduction and/or temporary abstinence and attempts to stop smoking in 2009 was compared with the 2 years following the expansion of the marketing license.

Results: Expansion of the license was not associated with an increase in incidence of NRT use for harm reduction, which was already substantial prior to the change. The odds of a quit attempt were lower in the second year following the license change relative to the year before, but there was no change in the success of quit attempts.

Conclusions: Expansion of the UK marketing license for NRT to include smoking reduction without the intention of quitting was not associated with an increase in use of NRT for this purpose. It was followed by a reduction in the incidence of quit attempts (but not their success) although this may have been a continuation of a pre-existing decline.

INTRODUCTION

Nicotine replacement therapy (NRT) was initially only licensed in the United Kingdom to assist smokers who were attempting to stop smoking abruptly. It was to be used once the quit attempt had started and continue for no more than a few weeks (up to 8–12 weeks). However, in 2005, a few products (i.e., gum and inhalator) were licensed for cutting down smoking as a stepping stone to stop completely (Medicines and Healthcare Products Regulatory Agency [MHRA], 2005). A year later, lozenges could be used for the same indication and lozenges and gum for “temporary abstinence” (MHRA, 2006). By the end of the second quarter of 2007, this indication included microtabs.

In October 2009, the MHRA approved an extension to the indication of NRT to include a “harm-reduction” element for the inhalator, so it could be used by smokers who wished to reduce the number of cigarettes smoked without a specific intention to quit completely and without a limit to the duration of use. Information on this license change was released by the MHRA in their “Drug Safety Update” in early 2010 (MHRA, 2010) and formed part of the wider government tobacco strategy “A SmokeFree Future.” At this point, the Commission on Human Medicines further agreed the principle for many other currently licensed forms of NRT and advised there should be an indication for the approach in pregnancy.

However, other countries have refrained from licensing NRT for harm-reduction purposes. One concern is that such an indication would have unintended consequences, including undermining motivation to stop smoking among smokers attempting harm reduction. However, evidence from both clinical trials and population data demonstrates that such concern is unwarranted. Instead, it appears that the use of NRT for smoking reduction and/or temporary abstinence by those unwilling or unable to quit smoking increases their propensity to quit (Beard, Aveyard, Michie, McNeill, & West, 2013; Moore et al., 2009).

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A second reason may be fear that the promotion of NRT for reduction could have other unintended consequences in populations beyond smokers not trying to quit (Stratton, Shetty, Wallas, & Bondurant, 2001). For example, this promotion could undermine resolve among smokers “about to quit” or send a message to teenagers that small amounts of smoking are safe, that is, tempt more of the general population to start smoking. Two studies have assessed the first possibility by looking at the effects of offering harm-reduction programs to smokers intending to quit. These reported that smokers switching to a reduction program had similar quit rates as those who stuck with a cessation program (Glasgow, Morray, & Lichtenstein, 1989) and that offering smoking reduction as a treatment option doubled the number of smokers willing to participate (Glasgow et al., 2006). In terms of the second possibility, we can look toward another form of harm reduction, oral tobacco use, in particular Swedish Snus. Evidence suggests that the introduction of Snus into the Swedish market did not affect the prevalence of all tobacco use, that is, encourage nonsmokers to use tobacco products; it’s effect purely was to entice current smokers to switch to smokeless tobacco (Rodu, Stegmayr, Nasic, & Asplund, 2002).

Another method for assessing unintended consequences is to observe population-level quit rates before and after the introduction of marketing licenses allowing the use of NRT for smoking reduction. Previous studies have assessed the impact of a number of policy initiatives for NRT using this methodology (Shahab et al., 2009; West, DiMarino, Gitchell, & McNeill, 2005). For example, Shahab and colleagues (2009) found no evidence that licensing the use of NRT for gradual cessation increased the prevalence of NRT use or the concurrent use of NRT and cigarettes.

This article assessed the impact of expanding the indication for the inhalator and other NRT products for smoking reduction on their use for harm reduction and markers of smoking cessation.

METHODS

Design and Sample

This study used data from the Smoking Toolkit Study (www.smokinginengland.info): a population-based study of adults aged 16+ in England. Full details of the methods are given by Fidler et al. (2011). At baseline (the year prior to the license change: January 2009–December 2009), 4,855 current or recent ex-smokers completed the survey; 5,642 completed the survey in the first year post change (January 2010–December 2010); and 4,800 completed the survey in the second year post the license change (January 2011–December 2011). Table 1 shows the sociodemographic characteristics of these respondents.

Measures

Respondents were asked questions about sociodemographic characteristics (gender, age, and social grade). Social grade was classified as follows: AB = higher and intermediate professional/managerial; C1 = supervisory, clerical, junior managerial/administrative/professional; C2 = skilled manual workers; D = semiskilled and unskilled manual workers; E = on state benefit, unemployed, lowest grade workers. They were also asked whether they had attempted to quit smoking in the previous 12 months and whether they were still smoking. Smokers were also asked, “Are you currently trying to cut down on how much you smoke but not currently trying to stop?”—(yes, no, don’t know). If they answered “yes,” they were asked, “Which, if any, of the following are you currently using to help you cut down the amount you smoke?”—(nicotine patch, nicotine gum, nicotine lozenges/tablets, nicotine inhaler, and nicotine nasal spray). All smokers were asked: “Do you regularly use any of the following situations when you are not allowed to smoke?”—(nicotine patch, nicotine gum, nicotine lozenges/tablets, nicotine inhaler, and nicotine nasal spray).

Analysis

For the reporting of prevalence data, an iterative marginal technique was used for weighting of data to be representative of the English population. Logistic regression analyses were used to assess differences in the odds prior to and following the license change of (a) using inhalator for harm reduction, (b) using any NRT for harm reduction, (c) making a past-year quit attempt, and (d) making a successful quit attempt. Regression analyses were adjusted for gender, age, time to first cigarette of the day (a measure of nicotine dependence), and social grade. In all cases, the year prior to the license change acted as the baseline (January 2009–December 2009) to which Years 1 and 2 following the license change were compared. Although the license change was introduced in October 2009, public information regarding the license change did not come into effect until early 2010, thus it was decided to use January 2009 until December 2009 as the baseline year. We conducted a post-hoc power analysis for the effect of license expansion on each of the variables. In every analysis, the power to detect a medium effect was at least 80% at alpha 0.001.

RESULTS

Prevalence of the Use of the Inhalator for Smoking Reduction and/or Temporary Abstinence

No difference was found in the prevalence of use of the inhalator for smoking reduction and/or temporary abstinence in the year following the license change (4.7% [n = 205]) compared with the year prior to the license change (5.0% [n =229]); OR = 0.96; CI = 0.80–1.15; p = .645). In contrast, fewer smokers used the inhalator in the second year following the license change relative to the year before the license change (3.5% [n = 160]; OR = 0.64; CI = 0.52–0.78; p < .001) (see Figure 1a).

Prevalence of Use of Any NRT Product for Smoking Reduction and/or Temporary Abstinence

There was a significantly lower odds of NRT use in the first year following the license change relative to the year preceding (17.6% [n = 934] vs. 18.5% [n = 888]; OR = 0.89; CI = 0.80–0.99; p = .026). The odds of using NRT were also lower in the second year following the license change relative to the year before the license change (15.5% [n = 702]; OR = 0.76; CI = 0.68–0.85; p < .001) (see Figure 1b).
Prevalence of Quit Attempts in the Past Year

The likelihood of reporting a previous quit attempt was similar in the first year following the license change relative to the year before the license change (35.9% \( n = 2,068 \) vs. 37.0% \( n = 1,832 \); OR = 0.95; CI = 0.88–1.03; \( p = .177 \)). However, the odds of a previous quit attempt in the second year following the license change was significantly lower than in the year preceding (33.5% \( n = 1,637 \); OR = 0.86; CI = 0.80–0.94; \( p < .001 \)) (see Figure 1c).

Prevalence of Successful Quit Attempts

There was no difference in the likelihood of reporting a successful quit attempt in the first year following the license change relative to the year prior to the license change (13.4% \( n = 277 \) vs. 13.6% \( n = 249 \); OR = 0.94; CI = 0.78–1.13; \( p = .525 \)). There was also no difference in the second year following relative to the year preceding the license change (13.7% \( n = 225 \); OR = 0.92; CI = 0.76–1.12; \( p = .412 \)) (see Figure 1d).

DISCUSSION

There is no evidence that expanding the indication for the inhalator or other NRT products to use for smoking reduction was associated with a reduction in the success of attempts to quit smoking. This lack of association is unsurprising given that the change in license appears not to have been associated with an increase in the use of NRT products for harm reduction. In contrast, there has been a slight reduction in the rate of quit attempts. However, previous analysis of data from the Smoking Toolkit Study suggests that this effect may be an artefact of a decline that began before the license change and has been consistent over the study period (West & Brown, 2012).

The lack of impact from changing the license is consistent with the finding that licensing of NRT for “cut to quit” did not affect uptake of NRT or the number of smokers reporting the concurrent use of NRT and cigarettes (Shahab et al., 2009). It may be that licensing changes in NRT are too subtle to produce detectable effects. However, a large number of smokers reported using NRT to reduce cigarette consumption prior to 2010, which may have contributed to a “ceiling effect.” The licensing change also did not incorporate any specific promotion to educate smokers about how to use NRT for harm-reduction purposes; rather, only the packaging was modified and the licensing change advertised on TV. Although many NRT users reportedly read package inserts (Bansal et al., 2004; Beard, Vangeli, Michie, & West, 2012). It would be worth examining this further in population surveys. A great deal of time and resources go into these inserts and regulators subject them to close scrutiny (MHRA, 2010). If they are not being read fully, it raises a question concerning whether key items of information should be extracted and presented in a different way.

It remains to be seen whether an increase in use of NRT for harm reduction results in a concomitant reduction in motivation to stop smoking completely. However, this seems unlikely given the previously reported positive association between quit attempts and use of NRT products for harm reduction (Beard et al., 2013; Moore et al., 2009). Yet, many countries considering licensing the use of NRT for harm-reduction purposes remain hesitant. The United States Food and Drug Administration, for example, has not licensed the use of NRT for noncessation purposes, despite the Institute of Medicine’s report (Stratton et al., 2001) concluding a decade ago that: “The FDA should therefore be prepared to consider the chronic administration of nicotine products as a reasonable exposure reduction strategy” (p. 227).

This study has a number of limitations. First, a key finding is that the license change was not associated with an increase in use of NRT. However, it is possible that there were subtle effects on use that could not be detected in logistic regressions comparing annual figures. Time-series analysis, which uses statistical modelling of collected data at regular intervals over time to estimate the on-going monthly impact of population-level interventions over and above seasonal variation and underlying trends, would have provided a more sensitive test. However, this analysis currently does not lend itself well to the data reported here. The monthly sample size of the Smoking Toolkit Study is relatively small (around \( n = 500 \) past-year

### Table 1. Sociodemographic Characteristics of Respondents

<table>
<thead>
<tr>
<th>Age M (SD)*</th>
<th>Smokers and recent ex-smokers in the year prior to the license change (( n = 4,855 ))</th>
<th>Smokers and recent ex-smokers in the first year following the license change (( n = 5,642 ))</th>
<th>Smokers and recent ex-smokers in the second year following the license change (( n = 4,800 ))</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male % (n)**</td>
<td>50.9 (2,472)</td>
<td>53.4 (3,012)</td>
<td>53.2 (2,553)</td>
</tr>
<tr>
<td>Social grade % (n)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AB</td>
<td>15.2 (738)</td>
<td>17.0 (957)</td>
<td>15.7 (755)</td>
</tr>
<tr>
<td>C1</td>
<td>26.4 (1,284)</td>
<td>25.6 (1,443)</td>
<td>25.7 (1,232)</td>
</tr>
<tr>
<td>C2</td>
<td>24.2 (1,175)</td>
<td>25.1 (1,417)</td>
<td>25.0 (1,198)</td>
</tr>
<tr>
<td>D</td>
<td>20.9 (1,016)</td>
<td>19.3 (1,087)</td>
<td>20.6 (990)</td>
</tr>
<tr>
<td>E</td>
<td>13.2 (642)</td>
<td>13.1 (738)</td>
<td>13.0 (625)</td>
</tr>
</tbody>
</table>

Notes. AB = higher and intermediate professional/managerial; C1 = supervisory, clerical, junior managerial/administrative/ professional; C2 = skilled manual workers; D = semiskilled and unskilled manual workers; E = on state benefit, unemployed, lowest grade workers. Data were weighted to match the 2001 census.

*Significant difference \( p < .05 \), detected using chi-square for percentages and analysis of variance (ANOVA) for means.

**Significant difference between \( p < .01 \), detected using chi-square for percentages and ANOVA for means.
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DECLARATION OF INTERESTS

EB has received conference funding from Pfizer. RW undertakes research and consultancy, and receives fees for speaking from companies that develop and manufacture smoking cessation medications. He also has a share of a patent for a novel nicotine delivery device. There are no other relationships or activities that could appear to have influenced this work.

REFERENCES


