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An oral cancer information leaflet for smokers in primary care: results from two randomised controlled trials

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Abstract – *Objectives:* To investigate whether primary care patients who claim to smoke tobacco gain greater benefit of a patient information leaflet (PIL) on oral cancer than nonsmokers. *Methods:* Two studies were conducted. Study 1 examined the research question initially, and Study 2 acted as a replication and inclusion of additional secondary outcome measures. The leaflet was designed and tested in an earlier study. Knowledge of oral cancer was assessed by a previously validated 36-dichotomous-item scale. A single-item question ascertained self-reported smoking status (kappa = 0.94). Study 1 participants were drawn from 14 practices (6 medical, 8 dental). A randomised control group design was adopted. The experimental group received the leaflet on attendance to the practice and then completed the questionnaire. The control group received the questionnaire only. Complete data were collected from 739 respondents. The design of Study 2 was identical; 786 new respondents from 16 practices (7 medical, 9 dental) were collected. *Results:* Both studies confirmed that smokers knew less about oral cancer than nonsmokers ($P < 0.05$) when access to the leaflet had been denied. On receipt of the leaflet, there was no distinction in oral cancer knowledge between the smoking status categories of respondents. Evidence of reassurance about screening from leaflet exposure was supported by the second study. *Conclusion:* This programmed research has demonstrated an effect of a brief PIL to offset the decrement in oral cancer knowledge observed in primary care patients who use tobacco in comparison to their nonsmoking counterparts. The leaflet reduced anxiety about oral health screening in smokers.

Key words: anxiety; health awareness; oral cancer; patient information leaflets; screening; tobacco smokers

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Control of oral cancer is best achieved through prevention (1). Cessation of tobacco smoking and moderating alcohol consumption is the main approach to reduce risk. Patient awareness of the disease may be an important contributor to persons taking preventive actions (2), including an oral health screen, as late presentation is responsible for reducing survival (3, 4).

A key question within health promotion is the level of knowledge of oral cancer and associated risk factors such as tobacco consumption in groups who suffer a potential disease risk (5). People who smoke tobacco are a clear target group (6); however, one report has shown that a large proportion of patients who smoke, and have been treated with oral cancer, were unaware of the link between smoking and their disease (7). Hence, it is not clear if smokers possess different levels of oral cancer knowledge.

It is possible that smokers may gain more from written information on oral cancer because of the salience of the subject area. Alternatively, smokers may behave defensively and prefer to avoid potentially unappealing information (8). These issues are important in devising campaigns that aim to target high-risk groups and develop materials for

awareness raising, and encouraging health actions (9). The increasing use of information aids and materials in the oral cancer field has been advocated to ensure that the public is aware of risk factors and advised to seek professional assistance if the first signs of the disease are noticed (10).

Moreover, patients with cancer and related symptoms are sometimes reluctant to mention their concerns because of their anxiety when visiting primary care facilities for general check-ups (11). The provision of an information leaflet may not only benefit information levels overall, but also specifically aid individuals who are at greatest risk and who may be reluctant to mention anxiety-provoking symptoms. A patient information leaflet (PIL) for patients has been shown to increase knowledge levels of oral cancer (12), but this work did not specifically focus on high-risk behaviour. Beliefs about visiting the dentist to obtain a check may be altered to a greater degree in smokers who seek reassurance. Health beliefs have been shown to be relevant in the planning of health-education campaigns aimed at high-risk groups for oral cancer (13).

Methods

Therefore, two studies were conducted. Study 1 examined the prediction that smokers attending either medical or dental primary health care facilities would gain greater knowledge from the leaflet than nonsmokers. Study 2 acted as a replication and included additional secondary outcome measures to further assess the influence of the leaflet on health beliefs and anxiety. Both studies were reviewed and given approval from the Local Research Ethical Committee.

Study 1

Aim

To determine the differential influence of a patient information leaflet on oral cancer knowledge with primary care patients who do or do not claim tobacco consumption.

Design

A power analysis was performed to conduct a *t*-test on the primary outcome variable (knowledge) with unequal groups adopting a 0.05 two-sided alpha level (14). It was assumed that the percent smoking level would be approximately 27%. At 80% power to detect a mean difference of one correct question assuming a common SD of 4.5, when the sample sizes in the two groups are 220 and 580, respectively, a total sample size of 800 would be required. Fourteen practices (6 medical, 8 dental) were selected from the North-west of the UK situated in a wide-ranging set of localities. Small area statistics associated with the locality from which the practice resided confirmed a wide variation of material deprivation (15). Each interviewer obtained consent of 50 patients during January and August 1999. Entry criteria included: aged 16 years or above, gave written consent and English language spoken. All refusals were noted. Information and control groups were designated by random assignment of whole sessions, until sample collected. Randomisation achieved by use of computer generated random numbers.

The leaflet was virtually identical to that already described elsewhere (12) and possessed a moderately easy reading level according to the Flesch readability index. Improvements to layout and presentation were made consisting of an A4 glossy paper design printed in full colour, divided into three folded sections. Factual information, aided by bullet points, was provided on the signs and symptoms or oral cancer, risk factors (tobacco and alcohol), prevalence and mortality rates and behaviours to reduce risk and promote early detection. A short description of the oral health screen, referred to as a 'mouth check-up' was given. Zila Europe™ published the leaflet. Inspection copies are available from the authors. The design quality of the leaflet was assessed adopting the new Medical Information Design Assessment Scale (MIDAS) that awards points for recognised positive features (e.g. clarity, legibility, use of headings, etc.) (16). The leaflet attained a total score of 11 points from a possible maximum of 13, which was comparable to the mean (SD) level of expertly prepared leaflets, mean = 11 (0.6) tested by the MIDAS originators (16).

Measures

A 36-dichotomous-item scale described previously assessed knowledge of oral cancer (12). Responses to statements included 'yes' to 'no' or 'true' to 'false' and were coded 1 for correct and 0 for an incorrect answer. The scores were summed to produce a scale that ranged from 0 to 36, which possesses reasonable reliability (KR-20 = 0.76) and good criterion validity (distinguishes between members of the public, nondental and dental health personnel) (12). The

intraclass correlation coefficient of the scale using a test–retest sample ($n = 103$) was 0.68. A single-item question was employed to ascertain self-reported smoking status. Respondents were classified into 'smokers' or 'nonsmokers'. Kappa coefficient of agreement for the question from the test–retest data was 0.94. Questions about gender and age were included, and medical or dental setting was noted.

Participants

Consecutive participants during study sessions were invited to enter the study at the practices on days when nonspecialist, i.e. routine services were provided. Patients were consented to participate in the study and then given the leaflet to read. Second, the leaflet was collected and the patient handed the questionnaire sheet for completion. The control group was given the questionnaire only.

Statistical analysis

Data were analysed by SPSS for Windows v 10^{TM}. Univariate analysis of variance (fixed-effects model) was used to determine the influence of self-reported smoking status on knowledge level across the leaflet access and control groups. Confidence intervals were calculated (17). Two-tailed tests and an alpha level of 0.05 were applied throughout.

Results

Of the 855 patients who were approached, 55 refused. Respondents refused for nonpossession of glasses ($n = 25$), insufficient time ($n = 15$), or other miscellaneous reasons ($n = 15$). The response rate was 94% (see Fig. 1 for trial profile). Drop-out analysis revealed no difference between respondents and refusers, with the exception that the refusers were older ($\chi^2 = 16.17$, df = 2, $P < 0.001$). There was a greater proportion of females in the 'no leaflet' control group ($\chi^2 = 4.89$, df = 1, $P = 0.03$).

Complete data were obtained from 739 respondents. Their mean (SD) age was 43 years (17); 429 (58%) were female, and 200 (27%) claimed to smoke tobacco: 191 (95.5%) cigarettes, 6 (3.0%) cigars and 3 (1.5%) pipes. The mean (SD) number of cigarettes smoked was 16 (7), ranging from 5 to 40 per day. Analysis of variance was performed using the outcome variable: knowledge. Between-subject factors included experimental classification (information vs. control), and smoking status (smokers vs. nonsmokers) and gender, with age in years as a covariate. There was a small overall difference in knowledge across the smoking classification, regardless of leaflet exposure [smokers = 27.18, 95% CI: 26.59, 27.78; nonsmokers = 27.95, 95% CI: 27.58, 28.31; $F(1, 733) = 5.19$, $P = 0.023$]. The interaction of smoking status with experimental condition was significant [$F(1, 733) = 4.65$, $P = 0.031$]. The mean knowledge levels were examined in detail to investigate this interaction (see Fig. 1). Respondents, not shown the leaflet, who claimed to smoke, had lower levels of knowledge than nonsmokers (mean = 24.17, 95% CI: 23.33, 25.01; and mean = 25.65, 95% CI: 25.12, 26.18, respectively), whereas similar knowledge levels were found in smokers and nonsmokers after reading the leaflet (mean = 30.19, 95% CI: 29.35, 31.04; and mean = 30.24, 95% CI: 29.74, 30.75, respectively). Gender, type of practice attended (dental vs. medical) and past smoking history (never smoked vs. smoked previously) did not explain extra variance of oral cancer knowledge when fed into an ANOVA model with leaflet and the associated interaction term ($P > 0.05$) (Fig. 2).

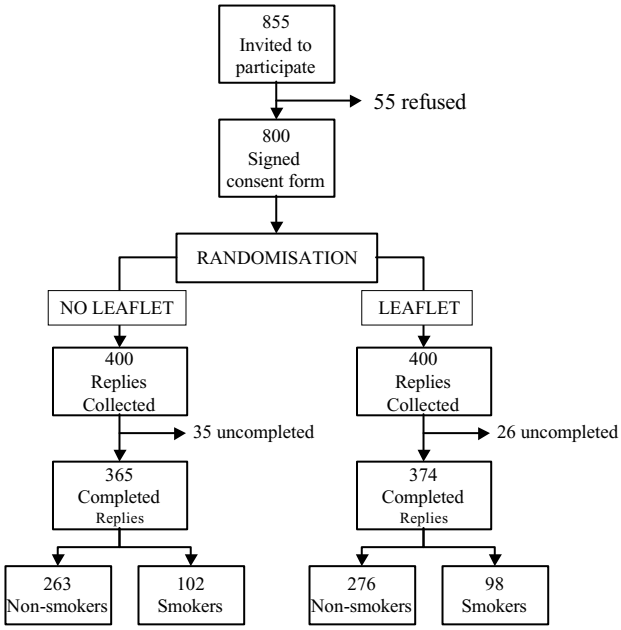

Fig. 1. Study 1 trial profile.

The knowledge improvement in smokers with access to the leaflet was further investigated by inspection of individual questions in the knowledge scale. A comparison between the proportions of respondents who answered each question correctly found that smokers with access to the leaflet gained a marked advantage over their nonsmoking counterparts on five questions. In rank order of effect, smokers were more likely to check as correct (>5% improvement over nonsmokers who also accessed leaflet) that 3000 cases of oral cancer were found each year in the UK, that a painless ulcer was a possible sign of oral cancer, alcohol was a risk

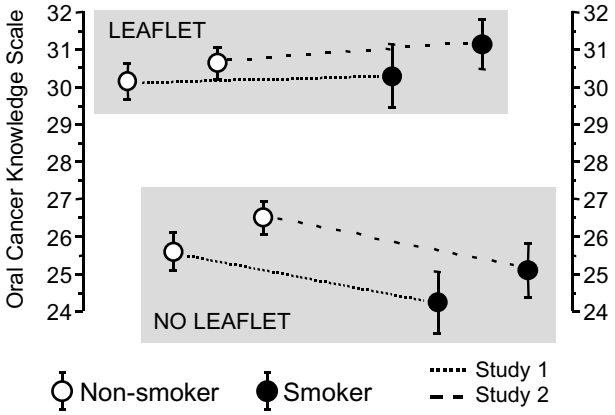

Fig. 2. Mean levels of oral cancer knowledge (circles) and confidence intervals for studies 1 ($n = 739$) and 2 ($n = 786$) broken down into respondents who received or did not receive PIL (identified by labelled shaded areas) and by self-reported smoking status (see key).

factor, women were at lower risk, and a check for oral cancer was painless. Discussion of these results is presented later.

Study 2

Informal contact with patients in Study 1 on collection of completed questionnaires had indicated that some of the concepts of the Theory of Reasoned Action, namely intention and beliefs about the screen, were salient to patients (18). Patients expressed their anxiety about having a check for oral cancer as well as having an opportunity to request or refuse a screen. As the leaflet included specific statements highlighting the benign nature of the check and recommended dental attendance for an oral health screen, we predicted first, that patients may be reassured about the oral health screen and second, their intention to visit the dentist for a screen would be raised.

The aims of the second study were:

- to confirm that smokers gain greater knowledge from the leaflet than nonsmokers, thereby replicating Study 1, and
- to determine if the leaflet confers positive effects in favour of smokers in providing reassurance and increasing their intention to accept a screen.

Design

Sixteen practices (9 dental, 7 medical) were selected from areas of the North-west of the UK that were situated in a wide-ranging set of localities. The deprivation levels of the wards associated with the practices were comparable to the regional average (19). The design was identical to that of the first study, with an experimental and control group, and randomisation by session. Data were collected during October 1999 and September 2000. Patients completed questionnaires immediately after leaflet access in the experimental group only.

Measures and participants

The participants received the same procedure and questions (knowledge and self-reported smoking) as those in the previous study. Ten additional questions were added under four headings. The scale – intention to accept a mouth cancer check – was assessed with the question: 'how likely would you agree to have an oral health screen to check your mouth for cancer'. A 7-point rating scale was employed and coded 1 'extremely unlikely' to 7 'extremely likely'. Beliefs about having an oral cancer screen were assessed by four questions: 'the dentist checking my mouth for oral cancer will ... (i) ... be a waste of time; (ii) ... give me discomfort; (iii) ... give early diagnosis of mouth cancer; and (iv) ... reassure me'. A 5-point (coded 1–5) Likert 'strongly agree' to 'strongly disagree' response format was used. The sense of control that the patient may think s/he possesses in accepting the screen was tapped by two questions: 'I feel that I am able to decide whether to allow the dentist to examine my mouth for cancer' and 'If I wanted I could easily ask for my mouth to be checked for cancer at the dentist', using the same answering format. Three questions about distress associated with a screen using the common stem: 'How do you feel about having a check for mouth cancer?' Patients responded to each question by a 5-point rating scale (coded 1–5) with verbal anchors for anxiety ('not anxious' to 'extremely anxious'), worry ('not worried' to 'extremely worried') and concern ('not concerned' to 'extremely concerned'). Agreement of these 10 questions on test–retest with a student sample ($n = 103$) ranged from fair to very good (mean kappa = 0.54; range = 0.39–0.75). The questionnaire is available from the corresponding author with further psychometric details.

Results

Of the 949 patients who were approached, 88 refused (see Fig. 3 for trial profile). Reasons for refusal included: no spectacles for reading ($n = 33$); not interested or too busy ($n = 22$); did not have time ($n = 21$); medical condition ($n = 7$); and does not take part in surveys ($n = 5$). The response rate was 91%. The refusers were of similar gender composition

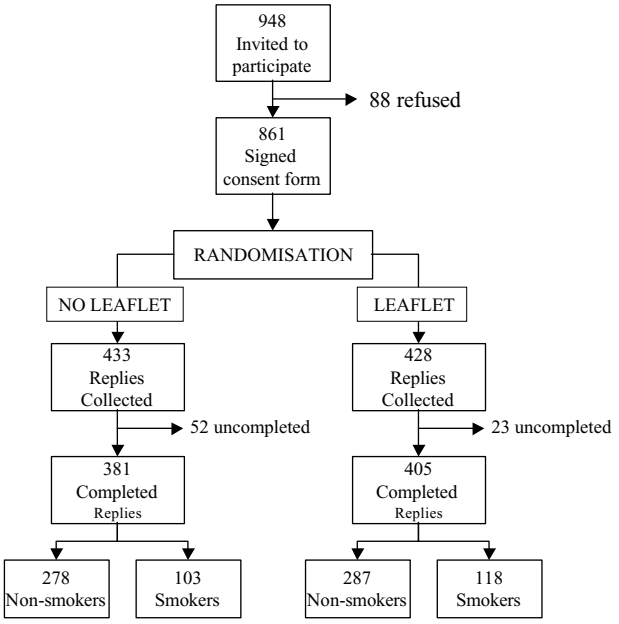

Fig. 3. Study 2 trial profile.

($\chi^2 = 1.65$; df = 1; $P = 0.2$) but older ($\chi^2 = 39.97$; df = 5; $P < 0.001$) than the respondents.

The randomisation procedure successfully achieved equivalence between experimental and control groups, as age, gender and setting of the waiting room (dental or medical) were found not to be statistically different between groups (all *P*-values > 0.05).

Complete data were received by 786 respondents; mean age was 43 years (SD 16); 464 (59%) were female, and 221 (28%) reported smoking tobacco: 204 (91.8%) cigarettes, 10 (4.5%) cigars and 7 (3.2%) pipes. The mean (SD) number of cigarettes smoked was 16 (9) ranging from 2 to 60 per day. Analysis of variance was performed specifying the same model as Study 1. There was a small overall difference in knowledge across the smoking classification regardless of whether respondents had read the leaflet [smokers = 28.01, 95% CI: 27.52, 28.49; nonsmokers = 28.61, 95% CI: 28.30, 28.92; $F(1, 778); = 4.17$, $P < 0.048$]. As Study 1, the interaction of smoking status with experimental condition was significant ($F[1, 778] = 10.32$, $P < 0.001$). Further inspection of the means enabled a clear interpretation of this significant result (see Fig. 1). Similar to the first study, in those respondents without access to the leaflet (control group) it was found that the smokers had lower levels of knowledge than nonsmokers (mean = 25.06, 95%CI: 24.35, 25.77; and mean = 26.54, 95% CI: 26.08, 27.01, respectively). Respondents who had read the leaflet (information group) had similar levels of knowledge regardless of smoking status (smokers: mean = 31.07, 95% CI: 30.40, 31.73; nonsmokers: Mean = 30.72, 95% CI: 30.29, 31.15).

Similar to Study 1, seven items of knowledge out of 36 were rated correctly by more than 10% of the smokers compared with nonsmokers on sight of the leaflet. For example, smokers with access to the leaflet showed a 26% (95% CI: 13.5, 37.4) improvement in knowledge that 3000 cases of oral cancer were found each year in the UK over their nonleaflet counterparts in comparison to only 5% (95% CI: −2.7, 11.6) of nonsmokers who had access or not to the leaflet. After reading the leaflet with the following items: the oral screen would take only a few minutes to complete, oral cancer is indicated by a non-healing ulcer, oral cancer is not indicated by dizziness or stomach ache.

To determine if the knowledge increase because of leaflet exposure was consistent across self-reported regularity of dental attendance (often vs. only in trouble) and alcohol consumption (abstinent vs. consumes), controlling for age as a covariate, separate ANOVAs were run and the leaflet by additional factor interaction was inspected. No significant ($P < 0.05$) effects from these two further runs were found.

Additional significant effects were found on inspection of the 10 questions assessing intentions, beliefs and effect. *t*-tests were performed on the nonsmokers and smokers separately, with leaflet access the grouping factor (leaflet vs. no leaflet). Effect sizes (and 95% CIs) were calculated (see Table 1). As predicted, the smokers with access to the leaflet were more reassured and less anxious about having an oral health screen (effect sizes: 0.30 and 0.32, respectively, *P*-values < 0.05). The effect of behavioural intentions was in a positive direction consistent with prediction (effect size: 0.21, $P = 0.126$) but statistically nonsignificant. Nonsmokers, in comparison, showed enhanced intentions (effect size: 0.21, $P = 0.017$) but no other advantage with leaflet exposure.

Discussion

This replication study reflected the near identical finding to Study 1, that patients without reading the leaflet showed significant variation across the self-reported smoking status classification, i.e. leaflet by smoking status interaction. One description of these two similar findings was that smokers were reporting identical knowledge levels to their non-smoking

Table 1. Effect sizes for attitudinal variables of the impact of the leaflet on smokers and nonsmokers in Study 2

	Nonsmokers 95% CI ($n = 565$)				Smokers 95% CI ($n = 221$)			
Variable	Effect	Lower	Upper	*P*	Effect	Lower	Upper	*P*
Behavioural								
Intention to have MCaC	0.21	0.04	0.38	0.017	0.21	−0.06	0.49	0.126
Control beliefs								
Easy to ask for MCaC if I wanted to have	0.12	−0.05	0.29	0.155	0.14	−0.14	0.42	0.325
Able to decide to allow dentist to give MCaC	0.05	−0.12	0.22	0.544	0.19	−0.08	0.47	0.168
Beliefs about MCaC								
Gives early diagnosis of mouth cancer	0.10	−0.07	0.27	0.266	0.04	−0.24	0.32	0.778
Will reassure me	0.04	−0.13	0.21	0.619	0.30	0.02	0.58	0.032
Will give discomfort (R)	0.11	−0.06	0.28	0.204	0.11	−0.17	0.39	0.439
A waste of time (R)	0.01	−0.16	0.18	0.939	0.03	−0.25	0.31	0.816
Affective response to MCaC								
MCaC concern	0.06	−0.11	0.23	0.480	0.11	−0.17	0.39	0.428
MCaC worry	0.05	−0.12	0.22	0.552	0.24	−0.04	0.52	0.087
MCaC anxiety	0.02	−0.15	0.19	0.812	0.32	0.04	0.60	0.024

MCaC = Mouth Cancer Check; R = reverse scored.

counterparts, but only when having read the leaflet. Without access to the leaflet, patients who smoked were not as knowledgeable about oral cancer.

Smokers appeared to selectively attend to the mortality figures presented in the leaflet when compared to nonsmokers. Consistent findings in both studies showed that smokers rather than nonsmokers, after reading the leaflet, were more likely to show awareness of the correct mortality figure for oral cancer in the UK. Risk perceptions of smokers are known to be biased and difficult to change (20). Smokers have a tendency to believe that they are less vulnerable to the negative effects of smoking compared with others who smoke (21). In addition, a community survey confirmed that optimistic biases are most prevalent with hazards that had yet to occur, strengthening the belief that they were extremely unlikely in the future (22). Some support for this view can be found from Ostroff's report of levels of perceived oral cancer risk in smokers (23). This research group showed that smokers significantly underestimate their risk of oral cancer when asked to make comparisons with other hypothetical smokers. Attempts to attenuate this bias have been difficult to achieve (20). Success is partially dependent on engaging the smoker into learning more about risk factors and chances of contracting fatal disease (24). An important finding of the present study has been the demonstration that simple written information can offset some of the knowledge disadvantage, especially concerning mortality, in high-risk individuals.

The reduction in distress about having a check and an ability to give reassurance may remove an important barrier to agreeing to have an oral health screen. The role of reassurance in decision making for cancer screening in high-risk groups requires further investigation (25). The intention to have a screen was marginally, and positively, influenced in smokers after reading the leaflet. The psychological impact of reducing anxiety may require further consolidation over time, to change relevant health beliefs and consequent intentions. A prospective study would enable a test of this hypothesis.

The limitations of these studies bear inspection. First, we adopted self-report to categorise the patients' smoking status rather than cotinine testing. This later approach would have raised the costs of the study considerably. Further, as the correlation between self-report and cotinine testing is very high particularly when demand characteristics of the question are low (anonymous questionnaire), as in this case (26), a second limitation was that a post-test only design was employed. A more informative approach would have been to adopt a pretest to assess change with the leaflet introduction. Previous work, however, by our group suggests that the advantage of this more complex design, especially in a primary care setting, might be marginal (12). Third, the external validity of the findings, that is generalisability, should be treated with some caution. Randomisation was conducted by session rather than by individual. In addition, both studies were conducted in the North-west of the UK. Study 1 however confirmed that the variation of deprivation level (as assessed by the Townsend score) was independent of mean knowledge level for the participating patients at the range of practices sampled.

Further, knowledge improvements were not associated with the practice attended. Attention should be paid to the wider effects of using written information. We have included some broader issues apart from knowledge including patient beliefs and intentions to accept a screen. Developments of the intervention in the form of a more extensive information booklet, or specific targeting of patients and their subsequent evaluation, will benefit from a closer reference to theoretical frameworks, as shown in other health screening fields (27). Finally, these studies were designed to show immediate effects of reading the leaflet and longer term effects require demonstration (28).

An issue that warrants further investigation is the extent that introducing written materials, similar to the PIL used in this study, may influence clinician behaviour; for example, a recent US survey found that 40% of dentists did not routinely ask their patients about tobacco consumption (29). The inclusion of the PIL for distribution in practices may help to trigger the clinician to identify tobacco users, thereby conferring a further benefit to the introduction of the leaflet.

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