

Changes in responses to nicotine vaping product warnings and leaflets in England compared with Canada, the US and Australia: findings from the 2016–2018 ITC Four Country Smoking and Vaping Surveys

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ABSTRACT

Background and aims In May 2017, black-and-white text nicotine addiction warning labels ('warnings') and health and safety leaflets ('leaflets') became mandatory for nicotine vaping products (NVPs) in England, in accordance with the European Union's Tobacco Products Directive. We compared changes over time in noticing warnings and leaflets, recall of warnings about nicotine and concerns about using NVP due to noticing warnings in England, compared with Canada, the US and Australia, where no warnings and leaflets were mandated.

Design 19 005 adult (aged 18+) NVP users, smokers and quitters of cigarettes and NVP from the 2016 and 2018 International Tobacco Control Four Country Smoking and Vaping Surveys in England, Canada, the US and Australia, recruited via probability and non-probability sampling.

Findings Noticing warnings increased in England from 4.9% (2016) to 9.4% (2018) (adjusted OR/AOR=1.64, 95% CI=1.15–2.36); this change was larger than changes in Canada (AOR=2.51, 95% CI=1.71–3.69) and the US (AOR=2.22, 95% CI=1.45–3.39). Recall of a nicotine warning increased in England from 86% (2016) to 94.9% (2018) (AOR=5.50, 95% CI=1.57–19.27) but not significantly elsewhere. Noticing leaflets increased in England from 14.6% (2016) to 19.1% (2018) (AOR=1.42, 95% CI=1.15–1.74); this change was larger than in Canada (AOR=1.42, 95% CI=1.12–1.79), the US (AOR=1.55, 95% CI=1.17–2.06) and Australia (AOR=1.51, 95% CI=1.02–2.22). Among those noticing warnings, concern about NVP use did not change significantly between 2016 and 2018 (all countries $p>0.081$).

Conclusions Introduction of mandatory NVP warnings and leaflets in England was associated with small increases in noticing them but not with changes in concerns about NVP use.

INTRODUCTION

The European Union Tobacco Products Directive (EU TPD) requires the inclusion of health and safety leaflets ('leaflets') and health warning labels ('warnings') on packaging for nicotine vaping products (NVPs) and e-liquids containing nicotine.¹ England

implemented the EU TPD in May 2016, mandating warnings by May 2017. The current 30% black-and-white text warning in England reads 'this product contains nicotine which is a highly addictive substance' (online supplemental figure 1).^{2,3} There is no set design for the leaflets, however, they must state that the product is not recommended for young people and non-smokers.¹ In addition to warnings, NVP packaging must include hazard symbols in accordance with the EU classification labelling and packaging of substances regulation.^{2,3} EU legislation was the first to require NVP warnings, with no warnings or leaflets required in Canada, the US or Australia during the current study period (2016–2018), although manufacturers sometimes voluntarily added warnings or toxin symbols^{4,5} (online supplemental figure 2).

Little is known about the effectiveness and salience of NVP warnings and leaflets, or how they might influence concerns about NVP use. It has been suggested that they could increase concerns about use and perceptions of harm among non-smokers.^{6–8} By contrast, qualitative research about heated tobacco products conducted with UK smokers and ex-smokers suggests that text-only warnings might decrease perceptions of harm relative to cigarettes because of the contrast between text-only warnings and the pictorial cigarette warnings.⁹

Comparisons of changes in noticing NVP warnings and leaflets and concerns about NVPs between countries with (England) and without labelling policies (Canada, US, Australia) could provide timely evidence regarding the impact of mandated warnings.

Objective

This study used data from the 2016 and 2018 International Tobacco Control (ITC) Policy Evaluation Project Four Country Smoking and Vaping (4CV) Surveys to investigate, in England compared with countries without labelling policies (Canada, the US and Australia), the impact of NVP warnings and leaflets on noticing warnings/leaflets, recall of a nicotine warning and concerns about using NVPs due to warnings.



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METHODS

Participants and design

This study used data from wave 1 (2016) and wave 2 (2018) of the longitudinal ITC 4CV Survey. Detailed methods can be found elsewhere.^{10–13} Briefly, the sample comprised smokers, vapers and former smokers and vapers from England, Canada, the US and Australia, recruited through probability and non-probability sampling frames (via random-digit dialling or email invitations from web-based or address-based panels). At wave 2, respondents from wave 1 were invited to participate; respondents lost to attrition were replaced by newly recruited respondents using the same recruitment strategy. Data were collected July–November 2016 (wave 1) and February–July 2018 (wave 2).

At wave 1, $n=13\,099$ participants were recruited. At wave 2, $n=5985$ were successfully followed up and $n=7650$ were added for replenishment, providing a sample of $N=20\,749$. The following participants were then excluded: those recruited via the Australian Dedicated Vapers (not representative of Australian NVP users and smokers; $n=896$); had never heard of NVP ($n=214$); long term quitters (those who quit at least 5 years ago; $n=231$); did not respond to questions about education ($n=236$) or ethnicity ($n=143$) or responded don't know to ethnicity ($n=167$). The final sample comprised $N=19\,005$ participants.

Measures

The survey development process is outlined in the ITC technical reports, with measures chosen previously used by McDermott *et al.*^{10 11 13}

Outcomes

Noticing warnings. Participants were asked: 'Now thinking about e-cigarettes, in the last 30 days, have you noticed any health warnings on packaging for e-cigarettes, cartridges or e-liquid containers?' Responses were coded 'Yes' versus 'Other' ('No', 'Refused', 'Don't know').

Noticing leaflets. Participants were asked 'As far as you know, is there health and product safety information contained on leaflets inside the packaging for e-cigarettes or on boxes of components?' Responses were coded 'Yes' versus 'Other' ('No', 'Don't know', 'Refused').

Recall a nicotine warning. Participants were asked 'In the last 30 days, have you read any of the health warnings?' Those who stated that 'Yes' were asked 'What do you recall the health warning(s) saying?' followed by a list of potential warnings (online supplemental table 1), including the current England EU TPD warning. Responses were coded 'Yes' versus 'Other' ('No', 'Don't know', 'Refused').

Effects of warnings on concern about NVP use. Participants who noticed warnings were asked 'What effect have the health warnings had on your thoughts about using e-cigarettes?' Responses were coded 'Concerned' ('Made me concerned about using them') or 'Not concerned' ('Had no effect', 'Reassured me about using them', 'Don't know', 'Refused').

Smoking/vaping behaviour

Smoking and vaping status

Participants were defined as either exclusive 'Daily NVP users', 'Daily smokers', 'Non-daily NVP users', 'Non-daily smokers', or 'Concurrent' users (currently smoking and using NVP) or 'Quitters of NVP and/or smoking' (no longer using either product). Groups were mutually exclusive (online supplemental table 2).¹³

Additionally, a new variable was coded, 'collapsed smoking/vaping status', 'Daily NVP', 'Non-daily NVP' and 'Concurrent'

users were coded 'Vapers'. 'Daily smokers' and 'Non-daily smokers' were coded 'Exclusive smokers'. Groups were mutually exclusive. Quitters of both products were excluded.

Analysis

Logistic regression models employing Generalised Estimating Equations (GEE) (model 1) were conducted to assess changes from wave 1 to 2 in: noticing warnings and leaflets, recall of a nicotine warning (among those who read warnings, $n=1521$) and concern about NVPs due to warnings (among those who noticed warnings, $n=2320$). Interactions between country and wave were used to examine changes in outcomes over time in England compared with Canada, the US and Australia.

A second set of GEE logistic regression models (model 2) were conducted to examine changes over time in the three outcome measures by smoking and vaping status. The same analyses were also conducted in the sample that excluded quitters and used the 'collapsed smoking/vaping' status variable (model 3). In model 3, interactions between exclusive smokers and vapers and wave were used to examine changes in outcomes over time between exclusive smokers and vapers.

Analyses controlled for age, gender, ethnicity, income, education, wave of recruitment, having a friend/relative who uses an NVP, and smoking and vaping status. Having a friend/relative who uses an NVP and smoking and vaping status were treated as time-varying covariates. All other variables were treated as time-invariant. Analyses were weighted and conducted in SPSS V.25.^{10 11}

RESULTS

See online supplemental table 3 for participant demographics.

Noticing warnings

Between waves 1 and 2, noticing warnings increased significantly in England (adjusted OR/AOR=1.64, 95% CI=1.15–2.36), increased non-significantly in Australia, decreased significantly in Canada and did not change in the US. The change in England was greater than in Canada (AOR=2.51, 95% CI=1.71–3.69) and the US (AOR=2.22, 95% CI=1.45–3.39), but no different from Australia (model 1, table 1). Noticing increased among daily NVP users, but decreased among daily smokers (model 2, table 1). There was a decrease in noticing warnings between waves 1 and 2 among exclusive smokers, and an increase in noticing warnings among vapers, and the change among vapers was greater than among exclusive smokers (model 3, table 1).

Recall of warnings

Among those who had read warnings (online supplemental table 1), a significant increase was found in recall of a nicotine warning in England between waves 1 and 2 (86.0%–94.9%, AOR=5.50; 95% CI=1.57–19.27, $p=0.008$). Increases were observed in Canada (79.6%–87.0%, AOR=2.00; 95% CI=0.75–5.34, $p=0.168$), the US (71.9%–88.1%, AOR=3.39; 95% CI=0.90–12.75, $p=0.071$) and Australia (71.1%–73.5%, AOR=2.16; 95% CI=0.04–2.46, $p=0.783$) although they were not significant.

Noticing leaflets

Between waves 1 and 2, noticing leaflets increased significantly in England, (AOR=1.42, 95% CI=1.15–1.74), with small and non-significant increases in Australia and small non-significant decreases in Canada and the US. The change between waves in England was greater than in Canada, (AOR=1.42, 95%

Table 1 Change over time in noticing NVP health warning labels, health and safety leaflets, and concern about NVPs between 2016 (wave 1) and 2018 (wave 2) *

Waves	Noticed a health warning label (n=19 005)			Noticed a health and safety leaflet (n=19 005)			Concern about NVP among those who noticed a health warning label (n=2320)†		
	N (%)	AOR (95%CI)	P value	N (%)	AOR (95%CI)	P value	N (%)	AOR (95%CI)	P value
Model 1: changes within each country between wave 1 and wave 2									
England	1	201 (4.9)	ref	599 (14.6)	ref		52 (25.8)	ref	
	2	430 (9.4)	1.64 (1.15–2.36)	877 (19.1)	1.42 (1.15–1.74)	0.001	63 (14.7)	0.52 (0.25–1.08)	0.081
Canada	1	254 (7.0)	ref	680 (18.7)	ref		95 (37.3)	ref	
	2	188 (5.1)	0.65 (0.50–0.86)	643 (17.4)	1.03 (0.85–1.19)	0.977	62 (33.1)	0.68 (0.40–1.16)	0.157
US	1	188 (7.0)	ref	398 (14.9)	ref		55 (29.2)	ref	
	2	180 (6.5)	0.74 (0.54–1.02)	385 (13.8)	0.91 (0.73–1.15)	0.450	51 (28.5)	0.93 (0.46–1.90)	0.843
Australia	1	39 (2.7)	ref	156 (10.6)	ref		5 (13.9)	ref	
	2	71 (4.8)	0.94 (0.56–1.60)	186 (12.5)	0.94 (0.67–1.33)	0.734	8 (11.2)	1.58 (0.38–6.56)	0.526
Changes between wave 1 and 2 by country interactions									
Change between waves									
England	4.50%			4.50%			Change between waves		
Canada	–1.90%			–1.30%			–11.10%		
US	–0.50%			–1.10%			–4.20%		
Australia	2.10%			1.90%			–0.70%		
Model 2: changes within smoking and vaping status between wave 1 and wave 2									
Concurrent	1	299 (9.7)	ref	729 (23.8)	ref		111 (37.3)	ref	
	2	328 (11.5)	1.02 (0.82–1.28)	712 (24.9)	1.10 (0.94–1.28)	0.237	93 (28.3)	0.60 (0.27–0.98)	0.042
Daily NVP	1	107 (17.4)	ref	191 (30.9)	ref		4 (3.8)	ref	
	2	315 (37)	2.40 (1.51–3.81)	416 (49)	2.11 (1.46–3.05)	<0.001	21 (6.6)	1.67 (0.38–7.28)	0.493
Non-daily NVP	1	49 (8.8)	ref	128 (23.1)	ref		15 (30.9)	ref	
	2	55 (10.5)	0.91 (0.43–1.90)	140 (26.7)	1.35 (0.73–2.13)	0.416	15 (27.3)	0.70 (1.18–2.75)	0.604
Daily smokers	1	110 (2.7)	ref	424 (10.3)	ref		31 (28)	ref	
	2	106 (2.1)	0.69 (0.48–0.98)	472 (9.3)	0.89 (0.74–1.07)	0.209	36 (34.1)	1.09 (0.47–2.52)	0.846
Non-daily smokers	1	55 (5.4)	ref	106 (11.3)	ref		13 (24.5)	ref	
	2	36 (4.8)	0.73 (0.41–1.30)	83 (10.8)	1.11 (0.75–1.63)	0.609	9 (24.2)	0.88 (0.24–3.30)	0.855
Quitters	1	63 (2.5)	ref	253 (10.1)	ref		32 (50.8)	ref	
	2	31 (1.2)	0.43 (0.17–1.06)	268 (10.7)	1.06 (0.74–1.53)	0.747	11 (37.4)	0.43 (0.09–1.96)	0.267
Model 3: changes within exclusive smokers or vapers between wave 1 and wave 2 (n=17 923)‡									
Exclusive smoker	1	165 (3.2)	ref	530 (10.3)	ref		44 (26.9)	ref	
	2	142 (2.4)	0.68 (0.50–0.93)	556 (9.6)	0.93 (0.78–1.10)	0.367	45 (31.6)	1.13 (0.53–2.39)	0.754
Vapers	1	455 (10.7)	ref	1049 (24.8)	ref		130 (28.7)	ref	
	2	698 (16.5)	1.26 (1.01–1.59)	1289 (30)	1.28 (1.10–1.50)	0.002	129 (18.40%)	0.58 (0.36–0.92)	0.022
Changes between wave 1 and 2 by exclusive smokers or vapers interaction									
Change between waves									
Exclusive smokers	–0.80%			–0.70%			Change between waves		
Vapers	5.80%			5.20%			4.70%		
	1.85 (1.33–2.58)			1.38 (1.13–1.69)			–10.30%		
	<0.001			0.002			0.089		

Continued

Table 1 Continued

Waves	Noticed a health warning label (n=19 005)		Noticed a health and safety leaflet (n=19 005)		Concern about NVP among those who noticed a health warning label (n=23 20)‡	
	N (%)	AOR (95%CI)	P value	N (%)	AOR (95%CI)	P value

Bold represents p<.05

*Models used weighted data. Country, age, gender, education, income, wave of recruitment, smoking and vaping status and having a friend who uses NVP were all included as covariates within modelling procedures. AOR represent the odds at wave 2 compared with wave 1.

†The interaction explored the difference in difference between current smoking or vaping status over time, comparing the change in vapers to the change observed among exclusive smokers. Quitters were excluded from this analysis. Vapers included daily NVP users, non-daily NVP users and concurrent users. Exclusive smokers include daily smokers and non-daily smokers.

#Sample only included those who reported noticing a health warning label.

§The interaction explored the difference in difference between countries over time, comparing changes in key outcome measures over time within England relative to the changes seen in Canada, the US and Australia.

¶Quitters were excluded from this analysis. Vapers included daily NVP users, non-dailyNVP users and concurrent users. Exclusive smokers include daily smokers andnon-daily smokers.

AOR, adjusted OR; NVP, nicotine vaping product.

CI=1.12–1.79), the US (AOR=1.55, 95% CI=1.17–2.06) and Australia (AOR=1.51, 95% CI=1.02–2.22) (model 1, [table 1](#)). Noticing leaflets increased among daily NVP users (model 2, [table 1](#)). There was an increase in noticing leaflets between waves 1 and 2 among vapers, and this change was greater than that among exclusive smokers (model 3, [table 1](#)).

Concern about using NVPs after noticing NVP warnings

Concern about NVP after noticing warnings decreased in England between waves 1 and 2, although this was non-significant when adjusted for covariates. Concern also decreased non-significantly in Canada and Australia and did not change in the US (model 1, [table 1](#)). Concern decreased significantly among NVP users and increased, but not significantly, among exclusive smokers (model 2, [table 1](#)). The change in concern among NVP users was not significantly different to changes in concern among exclusive smokers (model 3, [table 1](#)).

DISCUSSION

This study reports on changes in noticing NVP warnings and leaflets among adult smokers and NVP users before and after mandating of NVP packaging policies in England compared with other countries without such policy. Noticing warnings and leaflets increased between 2016 and 2018 in England, compared with the other countries. Moreover, noticing warnings or leaflets increased among vapers with the changes being significantly different to those among exclusive smokers. Overall, findings suggest that the enforcement of mandatory warnings and leaflets led to increases in noticing them.

Noticing warnings and leaflets was low across all countries (4.8%–9.4%); this was expected in Canada, the US and Australia where warnings and leaflets were not mandatory. However, noticing was relatively low in England in 2018 even after enforcement of mandatory warnings and leaflets. There may be several reasons. First, the warning is only present on NVP and e-liquid packaging, so consumers may only notice them at initial purchase and when refilling e-liquids, which may limit exposure. Also, the warning message on NVPs may not be especially salient since most consumers already know nicotine is addictive and is in the NVP that they are using.¹⁴ Moreover, compared with the warnings found on cigarette packs, the warnings on NVP packaging and e-liquids are smaller and text-only. It is well established that, for cigarettes, larger pictorial warnings are more likely to be noticed,^{15 16} although such warnings might not be warranted on NVP given their likely lower health risks compared with cigarettes.^{17–19}

While noticing leaflets was low across all countries, it was higher than expected in Canada and the US given they were not mandatory in these countries at the time of this study. However, this may be due to voluntary safety information placed on product information leaflets by manufacturers.²⁰ Concern over the use of NVP due to warnings decreased between 2016 and 2018 in England, however when adjusted for covariates this change was not significant. There was also a decrease in concern between 2016 and 2018 among vapers, suggesting that the nicotine warnings may not influence concern about NVP among current users. Increases in concern about NVP were seen among smokers, this increase was not significant when adjusting for covariates, possibly due to small cell counts. Future research should further investigate warning perceptions among smokers, who might use NVP to help them quit smoking, and among non-smokers, who the warnings are aiming to deter from using NVP.

Study limitations included that our analysis was not a clear pre-post comparison since NVP companies in England may have applied warnings and included leaflets during the 2016 implementation year. Even with this limitation we observed a small, but significant,

increase in noticing warnings and leaflets in England. We acknowledge that small sample sizes, especially for Australia, and analysis of concerns about NVP, limit the robustness of our conclusions. Finally, measures were derived from well-established measures used to examine the impact of cigarette health warnings but have limited use in the context of NVI.¹³

What this paper adds

- ▶ Following the 2014 European Union Tobacco Products Directive (EU TPD), nicotine addiction warning labels and health and safety leaflets on nicotine vaping products (NVPs) became mandatory in England in 2017.
- ▶ This is the first study to investigate and compare changes in noticing and recall of warnings and leaflets on NVPs in England, to countries where no warning or leaflets were mandatory (Canada, the US and Australia).
- ▶ The findings show that noticing warnings and leaflets on NVPs was higher in England after EU TPD implementation than before. Moreover, concerns about using NVPs did not change after warnings on labels and leaflets were introduced.

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Competing interests MC has received payment as a consultant to Pfizer for service on an external advisory panel to assess ways to improve smoking cessation delivery in healthcare settings. MC also has served as paid expert witness in litigation filed against the tobacco industry. GTF, DH and JT have served as expert witnesses on behalf of governments in litigation involving the tobacco industry. AM is a UK National Institute for Health Research (NIHR) Senior Investigator.

Patient consent for publication Not required.

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