

Impacts of EU Tobacco Products Directive regulations on use of e-cigarettes in adolescents in Great Britain: a natural experiment evaluation

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Scientific summary

Exploring the relationship between working from home, mental and physical health and wellbeing: a systematic review

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Scientific summary

Background

Smoking is a leading cause of preventable death and health inequalities in the United Kingdom (UK), and internationally. E-cigarettes are a popular means for smokers to quit. Emerging evidence suggests that E-cigarettes can be highly effective in helping smokers quit and many people argue that e-cigarettes should be endorsed to support smoking cessation, as e-cigarettes are likely significantly less harmful than tobacco.

However, the increasing popularity of e-cigarettes has led to debates surrounding potential positive, and negative public health impacts. Although there is growing consensus that e-cigarettes are less harmful than tobacco, there is also consensus that e-cigarettes are not harmless and, hence, that use of e-cigarettes among non-smokers, particularly young people, should be prevented.

Although there has been concern about direct harms to non-smoking young people, most concerns centre on how e-cigarettes might affect smoking uptake. Since the 1990s, the prevalence of young people's smoking in the UK has steadily declined following two decades of regulation of tobacco markets. At the centre of concerns around e-cigarettes is an argument that these gains may be reversed, by their acting as a gateway to nicotine addiction and tobacco use, or through renormalising smoking by mimicking its action.

Different positions on e-cigarettes are reflected in divergent international approaches to regulation. Some countries ban their sale, whereas other countries have few specific regulations. England and Wales introduced age of sales regulations in 2015, followed by Scotland in 2017. Unsuccessful attempts in Wales were made in 2015 to introduce legislation prohibiting e-cigarette use in public spaces where smoking is banned.

In May 2016, Tobacco Products Directive (TPD) regulations were introduced in European Union (EU) member states. The TPD regulations included a suite of regulations for tobacco, many of which brought EU nations in line with UK regulations. In the UK, the TPD regulations occurred alongside introduction of plain packaging for tobacco cigarettes. The TPD also included specific regulations for e-cigarettes, including bans on cross-border advertising from May 2016, with regulations on the products themselves introduced with a transitional period beginning in May 2016 and full implementation to be achieved by May 2017. Regulations included a warning on the packet that the products contain nicotine, which is a highly addictive substance, restrictions on nicotine strength and mandatory declaration of new products 6 months in advance of their introduction.

The TPD regulations were a cause of concern for some people who argued that regulations might inhibit the usefulness of e-cigarettes as cessation tools. However, the rationale for TPD regulations included that young people's use of e-cigarettes was growing and there were concerns that e-cigarettes mimic smoking and, hence, renormalise it. Regulation of e-cigarettes was motivated, in part, by reducing the appeal to young people. To date, the role of e-cigarettes in renormalising smoking, as well as the impact of e-cigarettes regulation on young people's e-cigarette use, are not well understood. This study investigates the extent to which regulations have affected growth in young people's use of e-cigarettes in England, Scotland and Wales, and explores broader questions about the impact of e-cigarettes on young people's smoking perceptions and behaviour.

Objectives

1. To investigate the role of e-cigarette regulation via the TPD in influencing trajectories in young people's use of e-cigarettes via the following research questions:
 - i. Did increased regulation of e-cigarettes interrupt prior growth in young people's e-cigarette use?
 - ii. How do young people perceive risks and social norms surrounding e-cigarettes:
 - a. as a product in their own right?
 - b. relative to tobacco?
 - iii. How do young people interpret and respond to health warnings on e-cigarette packets?
 - iv. To what extent, and in what ways, do young people continue to interact with e-cigarette marketing after the prohibition of cross-border advertising?
2. To examine trends in young people's smoking behaviour over time, to test theoretical assumptions regarding whether or not e-cigarettes renormalise smoking and to examine whether or not declines in smoking continued following the suite of regulation introduced within and alongside TPD, via the following questions:
 - i. Were declines in young people's ever and current smoking significantly interrupted during the emergence of e-cigarettes?
 - ii. Did the rate of decline in young people's smoking change after additional regulation of tobacco and e-cigarettes in 2016?
3. To explore the implementation and context of TPD regulation via the following questions:
 - i. To what extent was compliance with TPD in product sales achieved, and what are the barriers to, and facilitators and unintended consequences of implementation?
 - ii. To what extent, and in what ways, did variations between UK countries in e-cigarette policy emerge during the study period?
 - iii. What other changes to the regulatory context of tobacco and e-cigarettes occurred during the study period in the UK and across UK countries?

Methods

Our study was a mixed-method natural experimental evaluation. Quantitative components drew on repeat cross-sectional survey data from Wales (i.e. the Health Behaviour in School-aged Children Survey and School Health Research Network Survey), Scotland (i.e. the Scottish Schools Adolescent Lifestyle and Substance Use Survey) and England (i.e. the Smoking Drinking and Drug Use Survey). Study populations were nationally representative samples of young people aged 13–15 years (or from the equivalent school years, i.e. years 9 and 11 in Wales and England and S2 and S4 in Scotland). Process evaluation included interviews with young people, retailers, policy stakeholders and trading standards officers (TSOs), and observations of retail premises during and after the transitional phase for TPD implementation.

The survey data from Wales were used for our primary statistical analysis, which assessed change in ever use of e-cigarettes following the introduction of the TPD regulations, using segmented regression analysis. The analysis included 91,687 young people who completed surveys between 2013 and 2019 in Wales, with surveys disaggregated into monthly estimates to provide 16 data points overall. More simple logistic regression analyses were used to examine whether or not trends in Wales were mirrored elsewhere in the UK, using Scottish and English data.

Changes in young people's smoking behaviour before and after emergence of e-cigarettes, but prior to their regulation within the TPD, were examined using a segmented regression analysis of a pooled three-country data set from 1998 to 2015 ($n = 243,111$). The analysis examined whether or not any changes in trend occurred after e-cigarettes began to grow in popularity from around 2011, but prior to their regulation. Analyses of change in trend for smoking following TPD and associated tobacco regulations extended these analyses to 2019 ($n = 359,111$), with 2016 modelled as the intervention point.

For the process evaluation, qualitative interviews were conducted with 76 young people aged 14–15 years during the transitional phase, and 148 young people after full implementation in 2018. Interviews with 12 policy stakeholders, 13 TSOs and 27 e-cigarette retailers were conducted at a single point approximately a year after the date for full compliance. Observations of retail premises were conducted during and after the transitional phase for implementation of TPD regulations.

Data were synthesised using an evaluation and integration framework based on Medical Research Council guidance for process evaluation, with data sources organised and presented chronologically to understand context prior to TPD, how this changed following implementation and finally, changes in young people's e-cigarette use and smoking. Hence, presentation of results with data on the context into which TPD was fully introduced (i.e. pre-implementation trends in smoking and young people's perceptions of vaping), followed by data from policy stakeholders, TSOs and retailers on implementation of legislation, before presenting data on mechanisms of change and post-legislation e-cigarette use and smoking outcomes.

Results

Segmented regression analyses of smoking trends between 1998 and 2015 indicated no significant changes in trend for ever smoking during the period 2011–15 [post-slope odds ratio (OR) 1.01, 95% confidence interval (CI) 0.99 to 1.03]. There was a marginally significant slowing in decline for regular smoking (post-slope OR 1.04, 95% CI 1.00 to 1.08), and this was greatest among subgroups for whom the level of decline pre 2010 was greatest, and was not unique to tobacco, with slowing decline also observed for other substance use behaviours. Negative attitudes towards smoking continued to harden after 2011, and at a faster rate than pre-2011 trends (post-slope OR 0.88, 95% CI 0.86 to 0.90).

In group interviews shortly before the end of the transitional phase for TPD, young people differentiated between e-cigarettes and tobacco, preferring labels such as vaping, which removed association with cigarettes. Although smoking was strongly disapproved of, e-cigarette approval was more nuanced. Regular use was described as something smokers do. Young people described little interest in, or awareness of, whether or not products contained nicotine, with device characteristics, like flavours or the ability to do tricks at parties, described as more significant drivers of experimentation.

Qualitative interviews with policy stakeholders and TSOs following implementation of TPD indicated mixed views about the extent to which e-cigarette regulation was supported. Stakeholders expressed simultaneously positive views of the role of e-cigarettes for smoking cessation, and some anxieties surrounding potential renormalisation and harms from e-cigarette use among young people. Marketing restrictions were largely seen as appropriate, and regulations were described by stakeholders as having been well implemented, despite challenges in communications. However, some aspects of regulation of the products themselves were seen as needing to be further refined.

In interviews with retailers, some retailers argued that although some regulation was needed to prevent use by young people, regulating e-cigarettes as if they are tobacco products may lead to their being perceived as similar in terms of their health risks. In common with a positioning as separate from tobacco, specialist retailers expressed antipathy towards the tobacco industry and emphasised their role as helping people to quit smoking. Observations indicated that, during the transitional phase,

implementation remained mixed, with retailers continuing to sell-off non-compliant old stock, but by the full compliance date all retailers observed were selling compliant products.

Follow-up qualitative interviews with young people indicated continued tendency to distinguish between cigarettes and e-cigarettes. However, e-cigarette use was increasingly described as a fad that had begun to run its course. Although in qualitative interviews young people described little exposure to advertising, in surveys after implementation most young people reported seeing at least one form of advertising in the past month. Young people described limited interaction with components of TPD, such as device labelling, having often not seen devices inside their packets. Survey data from Wales indicated a growing tendency for young people to view e-cigarettes as being as risky as tobacco.

Our primary statistical analysis of change in ever e-cigarette use following the implementation of TPD indicated that in Wales, the growth prior to TPD had plateaued or declined following implementation. Prior monthly growth in the odds of ever e-cigarette use had stalled around the time of TPD implementation, with evidence of a negative change in trend thereafter (OR 0.96, 95% CI 0.95 to 0.97). Change in trend was significant in only long-term analysis, although OR were of similar magnitude in short- (to 2017) and long-term (to 2019) analyses. Data from England and Scotland exhibited a similar pattern of rapid growth in experimentation prior to TPD regulations, with little or no increase thereafter. In all countries, the secondary outcome of regular e-cigarette use exhibited this similar pattern of growth prior to TPD regulations, with flattening or a slight decline thereafter. Regular use of e-cigarettes remained at $\leq 1\%$ among never smokers throughout.

Post TPD regulations, however, declines in young people's smoking uptake followed the opposite change in trend to e-cigarettes. A significant positive change in trend for both ever (OR 1.09, 95% CI 1.06 to 1.11) and regular smoking (OR 1.13, 95% CI 1.09 to 1.18) indicated that as growth in e-cigarette use stalled so too did the decline in tobacco use. This was driven, in particular, by data from Wales and Scotland where estimates remained unchanged between the most recent surveys, with surveys in England still providing some indication of continued decline in young people's smoking. Change in trend was also observed for other substances, indicating a broader social trend in slowing of decline in adolescent risk behaviours beyond smoking specifically, with stalling decline in ever tobacco use lagging behind the stalling decline for ever use of other substances.

Conclusions

Our primary aim was to understand the effects of TPD regulations on young people's use of e-cigarettes. To achieve this, we first explored the context of young people's smoking and e-cigarette use prior to the TPD regulations, during the implementation of TPD, and the mechanisms and outcomes that followed from implementation. The study provides limited evidence that e-cigarettes were renormalising smoking prior to the TPD regulations, although some forms of e-cigarette use itself appeared to be becoming normalised. Although stakeholders reported a range of perceptions of the TPD regulations, they were well implemented. Young people's use of e-cigarettes peaked around the time of TPD implementation, with evidence that this became flat or declined across the nations of Great Britain. The disruption of the secular growth in e-cigarette use following TPD is consistent with an effect of the regulations, although caution is needed in causal attributions because of the observational nature of the study. Further support for a conclusion that this may be a causal effect is, however, provided by comparison to external data sources, which indicate that in other less-regulated environments, such as the USA, young people's use of e-cigarettes continued to grow during the period where it appeared to peak in the UK. Although smoking continued to decline during the growth of e-cigarette use, there is evidence within more recent data sets that this decline has begun to stall. Recommendations for future research include the following:

- Continued collection of survey data to monitor population trends in young people's tobacco and e-cigarette use remain important.
- Harmonised international data sets may be particularly valuable in enabling changes following new policies to be compared with an external comparator.
- Although young people's use of e-cigarettes was no longer growing, experimentation was still high at our latest measurements points, and understanding whether or not this diminishes, or further intervention is warranted, is important.
- As regulation has diverged, international comparative research on variation in use trajectories according to differences in regulatory environment offers an opportunity to provide nuanced insights into optimal regulatory measures for limiting young people's use of e-cigarettes, while maximising benefits for smoking cessation.
- There are high levels of confusion among young people on harms of e-cigarettes relative to smoking. Research could seek to better understand how to reinforce the role of e-cigarettes as cessation devices, while discouraging use among non-smokers and acknowledging remaining ambiguity about long-term harms.
- Further understanding how young people interact with e-cigarettes via the internet, including via social media platforms, is an important area for further research.
- Although much has been achieved in reducing young people's use of tobacco, there is some evidence that this progress may be beginning to stall. Further research is needed to reach the minority of young people who continue to take up smoking in contemporary society.

Study registration

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