Investigating the effect of England's smoke-free private vehicle regulation on changes in tobacco smoke exposure and respiratory disease in children: a quasi-experimental study

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Summary

Background Comprehensive tobacco control policies can help to protect children from tobacco smoke exposure and associated adverse respiratory health consequences. We investigated the impact of England's 2015 regulation that prohibits smoking in a private vehicle with children present on changes in environmental tobacco smoke exposure and respiratory health in children.

Methods In this quasi-experimental study, we used repeated cross-sectional, nationally representative data from the Health Survey for England from Jan 1, 2008, to Dec 31, 2017, of children aged up to 15 years. We did interrupted time series logistic or ordinal regression analyses to assess changes in prevalence of self-reported respiratory conditions, prevalence of self-reported childhood tobacco smoke exposure (children aged 8–15 years only), and salivary cotinine levels (children aged 2 years or older) before and after implementation of the smoke-free private vehicle regulation on Oct 1, 2015. Children who were considered active smokers were excluded from the analyses of salivary cotinine levels. Our primary outcome of interest was self-reported current wheezing or asthma, defined as having medicines prescribed for these conditions. Analyses were adjusted for underlying time trends, quarter of year, sex, age, Index of Multiple Deprivation quintile, and urbanisation level.

Findings 21 096 children aged 0–15 years were included in our dataset. Implementation of the smoke-free private vehicle regulation was not associated with a demonstrable change in self-reported current wheezing or asthma (adjusted odds ratio 0·81, 95% CI 0·62–1·05; p=0·108; assessed in 13 369 children), respiratory conditions (1·02, 0·80–1·29; p=0·892; assessed in 17 006 children), or respiratory conditions probably affecting stamina, breathing, or fatigue (0·75, 0·47–1·19; p=0·220; assessed in 12 386 children). Self-reported tobacco smoke exposure and salivary cotinine levels generally decreased over the study period. There was no additional change in self-reported tobacco smoke exposure in cars among children aged 8–15 years following the legislation (0·77, 0·51–1·17; p=0·222; assessed in 5399 children). We observed a relative increase in the odds of children having detectable salivary cotinine levels post legislation (1·36, 1·09–1·71; p=0·0074; assessed in 7858 children) and levels were also higher (1·30, 1·04–1·62; p=0·020; ordinal variable). Despite introduction of the regulation, one in 20 children still reported being regularly exposed to tobacco smoke in cars and one in three still had detectable salivary cotinine levels.

Interpretation We found no demonstrable association between the implementation of England's smoke-free private vehicle regulation and changes in children's self-reported tobacco smoke exposure or respiratory health. There is an urgent need to develop more effective approaches to protect children from tobacco smoke in various places, including in private vehicles.

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Introduction

Environmental tobacco smoke exposure can pose a serious threat to children's health. Among other adverse consequences, it increases the risk of developing asthma, having asthma attacks, and of respiratory tract infections.[1–4] An estimated 40% of all children around the world are regularly exposed to tobacco smoke, and children account for 28% of all deaths and 61% of all disability-adjusted life-years caused by tobacco smoke exposure.[5] Children who

are exposed to tobacco smoke are also more likely to start smoking when they are older.[6–8]

Unlike adults, children usually cannot control their exposure to tobacco smoke. Tobacco control policies can help to protect children from tobacco smoke and its adverse health consequences. The implementation of comprehensive tobacco control policies, as recommended by WHO, has been shown to be associated with lower smoking prevalence, lower tobacco smoke exposure

Research in context

Evidence before this study

Tobacco smoke exposure is the leading cause of preventable morbidity and premature mortality worldwide. Exposure during childhood increases the risk of asthma and respiratory tract infections. Children cannot control their tobacco smoke exposure and therefore need to be protected by tobacco control measures.

Our 2017 systematic review showed that legislation to prohibit smoking in indoor public places and workplaces was associated with substantial child health benefits. These included reductions of 4% in preterm births, 10% in hospital attendance for asthma, and 18% in hospital attendance for lower respiratory tract infections. Evidence indicates that these effects are probably mediated via reduced tobacco smoke exposure in public places, a decline in smoking during pregnancy, and, perhaps most importantly, reduced exposure at home.

Smoking in cars results in particularly high ambient air levels of toxic substances. Expanding national smoke-free legislation to include private vehicles could help to further protect children from tobacco smoke. On Oct 1, 2015, England and Wales were the first UK countries to introduce a national law that prohibits smoking inside private vehicles when children are present. Previous assessments of local smoke-free private vehicle laws in North America have shown significant reductions in self-reported tobacco smoke exposure in cars among children after the law was implemented. However, no previous study has assessed the effect of a national smoke-free private vehicle law, or the effect of such regulations on biochemically validated tobacco smoke exposure and on respiratory health outcomes.

Added value of this study

In this quasi-experimental study, we assessed whether the introduction of the 2015 regulation in England was associated with changes in self-reported and biochemically validated tobacco smoke exposure and in respiratory health outcomes among children up to 15 years of age. To our knowledge, this is the first evaluation of a national legislation that prohibits smoking inside private vehicles with children present, and the first to assess its direct impact on respiratory health and biochemically validated tobacco smoke exposure. Children's tobacco smoke exposure in cars showed an overall decrease over the study period. We did not, however, find a demonstrable effect of implementation of the regulation in England on children's tobacco smoke exposure in cars or in other places and found no impact on respiratory health outcomes. Although salivary cotinine levels also decreased over the study period, indicating an overall reduction in tobacco smoke exposure, there was a relative increase post legislation. Despite introduction of the regulation, one in 20 children still reported being regularly exposed to tobacco smoke in cars and one in three children still had detectable salivary cotinine.

Implications of all the available evidence

Comprehensive smoke-free legislation covering enclosed public places is a powerful tool to protect children from the adverse health effects of tobacco smoke exposure. Whereas previous evaluations have shown smoke-free private vehicle laws at the local level to be associated with subsequent reductions in children's tobacco smoke exposure, we were unable to confirm this in this first national evaluation. Substantial challenges have been reported in enforcement of the regulation in England, with very few fines or even warnings having been issued. Advocates argue that the primary goal of the regulation is to increase awareness and induce social norm changes. The substantial number of children remaining exposed despite introduction of the law, however, indicates that more effective approaches to protecting children's health via reducing their tobacco smoke exposure in various places, including in cars, are needed.

among children and adults, and improvements in important child health outcomes.[9–11] In particular, substantial evidence indicates that implementation of legislation to prohibit smoking in indoor public places and workplaces is associated with large improvements in important child health outcomes, including a 10% decrease in hospital attendance for asthma and an 18% decrease in hospital attendance for lower respiratory tract infections.[10]

Private vehicles are another important source of childhood tobacco smoke exposure. Smoking inside a car results in extremely high levels of toxins, even when the window is rolled down, and can also expose passengers to the potential health risks of third-hand smoke (ie, environmental contamination of surfaces by tobacco smoke constituents that remain after emission of tobacco smoke into the air).[12–15]

In 2015, England was one of the first nations in the world to implement a law prohibiting smoking in private

vehicles when children are present.[16] Although laws for smoke-free public spaces and workplaces have resulted in important improvements in childhood respiratory health,[10] there is still little evidence on the health effects of smoke-free private vehicle legislation. We identified two North American studies, both describing a significant decline in self-reported childhood car tobacco smoke exposure after a smoke-free law was implemented.[17,18] One of the studies also found an association between the decrease in tobacco smoke exposure and self-reported asthma.[18] Neither of the studies, however, involved biochemical validation of tobacco smoke exposure or evaluated the direct association between the smoke-free private vehicle laws and changes in respiratory health. Also, both studies assessed implementation of regulations at the subnational level, and we are unaware of any evaluations of national smoke-free private vehicle regulations. We therefore aim to evaluate whether this novel policy strategy has been effective in reducing

tobacco smoke exposure and improving child respiratory health in England.

Methods

Study design and setting

We did an interrupted time series analysis to determine whether the introduction of the national smoke-free private vehicle regulation in England on Oct 1, 2015, was associated with changes in salivary cotinine levels, self-reported tobacco smoke exposure, and changes in prevalence of wheezing or asthma and of respiratory conditions overall. We used repeated cross-sectional data from the Health Survey for England (HSE),[19] an annual survey of representative samples of English households aimed at identifying health and lifestyle trends of the English population. We used quarterly data spanning the period Jan 1, 2008, to Dec 31, 2017.

The UK Government enacted the smoke-free private vehicle regulation on Feb 12, 2015, and implemented the regulation on Oct 1, 2015, for England and Wales.[16] From that date onwards, it has been prohibited in these UK jurisdictions to smoke inside private vehicles if a person under the age of 18 years is present in the vehicle. The driver and smokers who break this law risk a £50 (approximately US$60) fine each.[20] Exceptions apply for convertible cars with the roof competely down and for e-cigarettes.

Ethical approval was not required for this study, as the data were already anonymised and publicly available. A detailed description of the HSE has been published elsewhere.[21]

Data sources

Each year since 1991, the HSE has taken an independent representative sample of the population living in private households in England, from here onwards referred to as the core sample, using a multistage stratified probability sampling design.[22] In some years, an additional boost sample is collected to allow the study of a specific population subgroup, such as minority ethnic groups, older people, or children. In the years 2008, 2009, 2010, and 2015, an additional boost sample of children aged 2–15 years was taken. In 2007, England implemented comprehensive national smoke-free legislation in workplaces and other enclosed public places; to avoid interference of this previous policy intervention with the more recent policy intervention, we only used data from 2008 onwards.

All participating households received a home visit during which individual household members were interviewed about their general health, smoking, and alcohol use, and demographic, psychosocial, and socioeconomic indicators. In each household, up to four children were randomly selected to take part in the interview: up to two children aged 2–12 years and up to two children aged 13–15 years. In addition to the interviews, children aged 8–11 years and 12–15 years were also asked to fill in a self-completion questionnaire enquiring about alcohol use, smoking, weight, and other topics not covered in the interviews, including their perceived environmental tobacco smoke exposure in various locations. Children and young adults who filled out the self-completion questionnaire were not interviewed again about the topics covered in this questionnaire. Adults aged 25 years or older did not fill out the questionnaire, but they were interviewed about their perceived tobacco smoke exposure and the other topics covered in the questionnaire.

Households in the core sample were offered an additional home visit from a nurse, who asked questions about prescribed medicines and took anthropometric measurements. With parental consent, the nurses also took saliva samples from participating children aged 2 years or older to quantify cotinine levels. Cotinine is a metabolite of nicotine and is commonly used as a measure of tobacco smoke exposure. Salivary cotinine analyses were done by ABS Laboratories (Welwyn Garden City, Hertfordshire, UK). Cotinine concentrations were quantified using high-performance liquid chromatography coupled to tandem mass spectrometry with multiple reaction monitoring.[23] Participating households of the booster samples were not offered a nurse visit.

Outcomes

Our primary outcome of interest was self-reported current wheezing or asthma, defined as having prescribed medicines for asthma or chronic obstructive pulmonary disease (bronchodilators, inhaled corticosteroids, cromoglicate [ie, mast cell stabiliser] and related therapies, leukotriene receptor antagonists, phosphodiesterase type-4 inhibitors, or supplemental oxygen). This outcome was assessed in respondents who had a nurse visit. Secondary outcomes were self-reported respiratory conditions (appendix p 1; unavailable in 2010 and 2011 due to a technical routing error in the questionnaire[24]) and self-reported respiratory conditions probably affecting stamina, breathing, or fatigue (available from 2012 onwards). Secondary outcomes were assessed in the interview, and thus in all individuals surveyed. We had also intended to evaluate self-reported recent use of prescribed asthma medicines (ie, prescribed asthma medicines used in the week prior to the interview); however, these data were only available up until 2014, precluding investigation of its association with the 2015 legislation.

To explore the possible causal pathway between the introduction of the smoke-free private vehicle law and our outcomes of interest, we also determined the associations between the implementation of the smoke-free private vehicle law and the following intermediate variables: self-reported environmental tobacco smoke exposure (categorised according to the following locations: in a car; at home; in the street; in other people's homes; in outdoor areas of pubs, cafes, and restaurants; in parks or playing facilities; at school; or in any other public places) and

	2008 (n=3473)	2009 (n=1147)	2010 (n=2074)	2011 (n=2007)	2012 (n=2043)	2013 (n=2185)	2014 (n=2003)	2015 (n=2123)	2016 (n=2056)	2017 (n=1985)	Total (n=21 096)
Sex											
Female	1748 (50.3%)	556 (48.5%)	999 (48.2%)	977 (48.7%)	1000 (48.9%)	1085 (49.7%)	967 (48.3%)	1059 (49.9%)	1018 (49.5%)	1014 (51.1%)	10 423 (49.4%)
Male	1725 (49.7%)	591 (51.5%)	1075 (51.8%)	1030 (51.3%)	1043 (51.1%)	1100 (50.3%)	1036 (51.7%)	1064 (50.1%)	1038 (50.5%)	971 (48.9%)	10 673 (50.6%)
Age, years											
0–1	442 (12.7%)	145 (12.6%)	282 (13.6%)	282 (14.1%)	311 (15.2%)	310 (14.2%)	230 (11.5%)	278 (13.1%)	273 (13.3%)	263 (13.2%)	2816 (13.3%)
2–4	663 (19.1%)	229 (20.0%)	459 (22.1%)	445 (22.2%)	428 (20.9%)	456 (20.9%)	435 (21.7%)	453 (21.3%)	451 (21.9%)	415 (20.9%)	4434 (21.0%)
5–7	631 (18.2%)	201 (17.5%)	380 (18.3%)	427 (21.3%)	376 (18.4%)	397 (18.2%)	381 (19.0%)	430 (20.3%)	426 (20.7%)	409 (20.6%)	4058 (19.2%)
8–10	658 (18.9%)	216 (18.8%)	343 (16.5%)	328 (16.3%)	368 (18.0%)	393 (18.0%)	370 (18.5%)	377 (17.8%)	354 (17.2%)	401 (20.2%)	3808 (18.1%)
11–12	441 (12.7%)	155 (13.5%)	237 (11.4%)	202 (10.1%)	260 (12.7%)	255 (11.7%)	251 (12.5%)	252 (11.9%)	245 (11.9%)	196 (9.9%)	2494 (11.8%)
13–15	638 (18.4%)	201 (17.5%)	373 (18.0%)	323 (16.1%)	300 (14.7%)	374 (17.1%)	336 (16.8%)	333 (15.7%)	307 (14.9%)	301 (15.2%)	3486 (16.5%)
Urbanisation level											
Urban	2828 (81.4%)	875 (76.3%)	1687 (81.3%)	1618 (80.6%)	1670 (81.7%)	1842 (84.3%)	1662 (83.0%)	1777 (83.8%)	1720 (83.7%)	1655 (83.4%)	17 334 (82.2%)
Rural	645 (18.6%)	272 (23.7%)	387 (18.7%)	389 (19.4%)	373 (18.3%)	343 (15.7%)	341 (17.0%)	344 (16.2%)	336 (16.3%)	330 (16.6%)	3760 (17.8%)
Missing data	0	0	0	0	0	0	0	2	0	0	2
Index of Multiple Deprivation											
Quintile 1 (least deprived)	734 (21.1%)	250 (21.8%)	476 (23.0%)	446 (22.2%)	419 (20.5%)	421 (19.3%)	458 (22.9%)	428 (20.2%)	354 (17.2%)	376 (18.9%)	4362 (20.7%)
Quintile 2	591 (17.0%)	222 (19.4%)	387 (18.7%)	343 (17.1%)	371 (18.2%)	405 (18.5%)	334 (16.7%)	382 (18.0%)	331 (16.1%)	374 (18.8%)	3740 (17.7%)
Quintile 3	666 (19.2%)	207 (18.0%)	362 (17.5%)	375 (18.7%)	364 (17.8%)	430 (19.7%)	348 (17.4%)	380 (17.9%)	343 (16.7%)	343 (17.3%)	3818 (18.1%)
Quintile 4	656 (18.9%)	234 (20.4%)	384 (18.5%)	381 (19.0%)	439 (21.5%)	430 (19.7%)	400 (20.0%)	367 (17.3%)	414 (20.1%)	417 (21.0%)	4122 (19.5%)
Quintile 5 (most deprived)	826 (23.8%)	234 (20.4%)	465 (22.4%)	462 (23.0%)	450 (22.0%)	499 (22.8%)	463 (23.1%)	566 (26.7%)	614 (29.9%)	475 (23.9%)	5054 (24.0%)

Percentages are calculated on all surveyed individuals with non-missing values.

Table 1: Participant demographics in the core samples by survey year

salivary cotinine levels (in the following categories: <0·1 ng/mL [ie, undetectable], 0·1–1·0 ng/mL, or >1·0 ng/mL). A salivary cotinine concentration of 12·0 ng/mL or more was considered indicative of being an active smoker. Although HSE has released data on tobacco smoke exposure in cars since 2009, there was a substantial change in how these data were collected after 2010, resulting in an important trend break in self-reported tobacco smoke exposure in cars. To allow adequate comparisons over time, we therefore restricted our analyses of self-reported tobacco smoke exposure to the period 2011–17. Within each year, the HSE recorded the quarter of the year in which the interview was performed.

Statistical analysis

We did not have a pre-established sample size; there are no established methods for sample size calculations for time series analyses. Furthermore, our sample size was inherently limited to the number of HSE interviews conducted between 2008 and 2017 (the latter date representing the most recent available at the time of this study).

We tabulated key demographic variables, intermediate variables, and respiratory outcomes according to survey year. Using graphs, we also visually compared temporal trends in childhood tobacco smoke exposure in cars to childhood tobacco smoke exposure in other places.

We used interrupted time series logistic or ordinal regression analyses with adjustment for potential confounders to determine the associations between the introduction of the smoke-free private vehicle law and changes in the odds of developing each of the intermediate and respiratory outcome measures. Appropriate selection and non-response weights were used in each model, as recommended and provided for by HSE.[25] The models took into account the underlying temporal trend in odds of developing each outcome, and provided an estimate of either the immediate (step) change or gradual (slope) change, or both, after the introduction of the smoke-free private vehicle law. To account for possible non-linearity, the underlying temporal trend was modelled via linear, quadratic, and cubic B-splines in separate models. The optimal model was then selected using the Akaike information criterion and Schwarz's Bayesian infor-mation criterion. The step change for the odds of developing each outcome was modelled using a dummy variable for the intervention coded 0 before the introduction of the law (ie, up to and including the third quarter of 2015) and 1 after the introduction of the law (from the fourth quarter of 2015). The slope change was modelled using an interaction term of the step change dummy variable and time in quarters (as a continuous variable). A categorical variable for quarter of the year was added to account for seasonality. Due to missing data for respiratory conditions in 2010 and 2011, we modelled time categorically (in quarters) instead of continuously in the analysis of respiratory conditions. For this analysis,

	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	Total
Primary outcome											
Current wheezing or asthma	173/2464 (7·0%)	51/807 (6·3%)	114/1327 (8·6%)	84/1257 (6·7%)	108/1203 (9·0%)	106/1455 (7·3%)	78/1249 (6·2%)	103/1297 (7·9%)	73/1117 (6·5%)	79/1195 (6·6%)	969/13 371 (7·2%)
Secondary outcomes											
Self-reported respiratory condition	256/3473 (7·4%)	82/1147 (7·1%)	..	..	120/2042 (5·9%)	105/2182 (4·8%)	108/2003 (5·4%)	118/2123 (5·6%)	107/2054 (5·2%)	102/1984 (5·1%)	998/17 008 (5·9%)
Missing data	0	0	..	..	1	3	0	0	2	1	7
Self-reported respiratory condition affecting stamina, breathing, or fatigue	..	..	..	..	69/2042 (3·4%)	71/2182 (3·3%)	75/2003 (3·7%)	76/2123 (3·6%)	75/2054 (3·7%)	61/1984 (3·1%)	427/12 388 (3·4%)
Missing data	..	..	..	..	1	3	0	0	2	1	7

The primary outcome is measured on all individuals who had a nurse visit; there were no missing values among these individuals. The secondary outcomes are measured on all surveyed individuals. Percentages are calculated on all individuals surveyed for a given outcome with non-missing values. Empty cells indicate that data were unavailable for that survey year.

Table 2: **Primary and secondary outcomes by survey year**

we were therefore unable to model whether the smoke-free private vehicle law was associated with a slope change and thus included a step change only. Accounting for autocorrelation was not required as we used individual-level data.

We adjusted for the following potential individual-level confounders: age category (0–4 years, 5–7 years, 8–12 years, or 13–15 years), sex, socioeconomic status based on the Index of Multiple Deprivation in quintiles,[26] and urbanisation level (urban or rural [ie, town, fringe, village, hamlet, and isolated dwellings]). Analyses of self-reported tobacco smoke exposure were not adjusted for the first two age categories (0–4 years and 5–7 years), as these data were collected only among children aged 8–15 years. Children who were considered active smokers (ie, children who reported they smoked regularly or used other nicotine-delivery products including e-cigarettes, or who had a salivary cotinine concentration ≥12·0 ng/mL) were excluded from the analyses of cotinine levels, but not of the other outcomes. Cotinine was analysed in separate analyses as an ordinal (<0·1 ng/mL, 0·1–1·0 ng/mL, or >1·0 ng/mL) or binary (<0·1 ng/mL *vs* ≥0·1 ng/mL) variable. Because household identifiers were no longer collected after 2014, we were unable to account for clustering of children at the household level.

For our main analyses, we used the core samples of the HSE only. The HSE included additional booster samples of children in 2008, 2009, 2010, and 2015. The households in these booster samples were selected from the same sampling units as the core samples. Generally, HSE does not recommend combining the two sample types for the main analyses because the combined sample is not designed to be generalisable to the English population.[25] However, as it increases the sample size and, as such, the power to detect relevant changes, we did sensitivity analyses of our health outcomes combining the core and booster samples.

The HSE questionnaire allows for more than one chronic condition to be registered, and the released datasets do not specify which of these chronic conditions

affect stamina, breathing, or fatigue. Although unlikely, for children with both a respiratory condition and another chronic condition, it is possible that only the non-respiratory condition affected stamina, breathing, or fatigue. In a sensitivity analysis, we therefore repeated the analysis of respiratory conditions affecting stamina, breathing, or fatigue including only those children who registered a respiratory condition but no other chronic condition.

By means of validation, we also explored patterns of adult environmental tobacco smoke exposure to compare changes in adult and child self-reported tobacco smoke exposure in various locations.

All analyses were done using Stata SE 15.1. We used the STROBE and RECORD guidelines to report our findings.[27,28]

Role of the funding source

The funders of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

Between Jan 1, 2008, and Dec 31, 2017, 21 096 children aged 0–15 years were interviewed in the HSE core samples. Of these, 5400 children aged 8–15 years reported on their environmental tobacco smoke exposure. In total, 13 371 children aged 0–15 years had a nurse visit and 7999 children aged 2–15 years had their salivary cotinine concentration determined, 7860 of whom were included in the analysis. The additional booster samples consisted of 4048 children aged 0–15 years in 2008, 2810 children in 2009, 3618 children in 2010, and 3591 children in 2015. The demographic characteristics of the core samples were similar between the annual samples (table 1).

Across the study period, 969 (7·2%) of 13 371 children reported having current wheezing or asthma (table 2). 998 (5·9%) of 17 008 children reported a respiratory
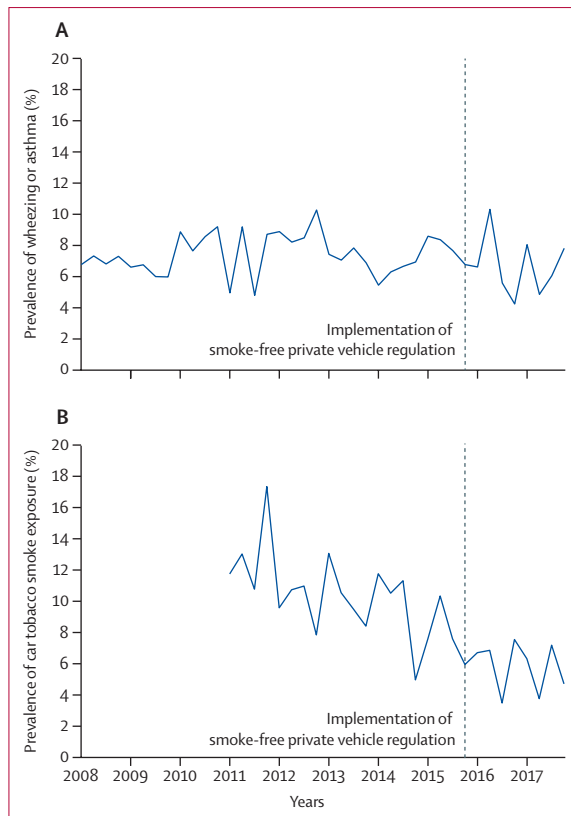
Figure: **Prevalence over time of current wheezing or asthma and of self-reported tobacco smoke exposure in a car**
(A) Prevalence of current wheezing or asthma. (B) Prevalence of self-reported tobacco smoke exposure in a car.

condition, with 427 (3·4%) of 12 388 children noting that their chronic condition affected stamina, breathing, or fatigue (table 2). There was no clear temporal trend in wheezing or asthma (figure), a slight decreasing trend in respiratory conditions overall, and a slight increasing trend in respiratory conditions probably affecting stamina, breathing, or fatigue (table 2; appendix p 2). Self-reported tobacco smoke exposure in a car decreased over the study period (figure), with varying temporal trends for exposure in other places (table 3; appendix pp 3–4).

A model with a step change only was the optimal model for each of the outcomes. In our primary analyses, introduction of the smoke-free private vehicle law was not associated with significant changes in the prevalence of current wheezing or asthma (adjusted odds ratio [aOR] 0·81, 95% CI 0·62–1·05), self-reported respiratory conditions (1·02, 0·80–1·29), or self-reported respiratory conditions probably affecting stamina, breathing, or fatigue (0·75, 0·47–1·19; table 4). Similarly, we did not observe significant changes after introduction of the law in the prevalence of self-reported tobacco smoke exposure (table 5). Although salivary cotinine levels generally decreased over the study period (appendix p 4), there was a relative increase in the odds of having detectable

salivary cotinine post-legislation, and these levels were also higher after the smoke-free private vehicle regulation (table 5).

When including data from the booster samples in sensitivity analyses, we also did not observe significant changes in the prevalence of self-reported respiratory conditions (aOR 1·02, 95% CI 0·83–1·26), self-reported respiratory conditions probably affecting stamina, breathing, or fatigue (0·76, 0·54–1·09), and self-reported tobacco smoke exposure in a car (0·88, 0·62–1·24; appendix pp 5–6). When limiting the analysis to the 12 386 children who only reported a respiratory condition and no other chronic illnesses, we also did not observe a significant change in the prevalence of self-reported respiratory conditions affecting stamina, breathing, or fatigue (0·59, 0·34–1·03; appendix p 7).

By means of validation, we related the observed patterns in paediatric tobacco smoke exposure to reported exposure and smoking patterns among adults. Implementation of the smoke-free private vehicle regulation was not associated with significant changes in active smoking or tobacco smoke exposure in cars among adults (appendix pp 8–15). However, implementation of the smoke-free private vehicle regulation was associated with an increase in smoking at home for smokers older than 24 years of age but a decrease in smoking in other people's homes for smokers aged 16–24 years (appendix pp 11, 15).

Discussion

In this national study using data representative of the English population, implementation of a regulation prohibiting smoking in cars with children present was not associated with demonstrable improvements in asthma outcomes, in self-reported chronic respiratory diseases, or self-reported tobacco smoke exposure in cars among children.

There is compelling evidence from various countries including England that implementation of comprehensive legislation prohibiting smoking in enclosed public places is associated with improved respiratory health among children, particularly improvements in asthma exacerbations and lower respiratory tract infections necessitating hospital attendance.[10,29–31] When considering the negative findings of the current study, it is important to note that the smoke-free private vehicle regulation was introduced in a setting of existing comprehensive smoke-free legislation in England. Evidence from England and elsewhere indicates that smoke-free legislation, in addition to protecting children from tobacco smoke exposure in public places, also induces social norm changes resulting in many families making their own homes and cars smoke free.[32–35] It is possible that such norm changes also contributed to the observed gradual decrease in smoking in cars with children present in the period before the smoke-free private vehicle law came into force.[36]

Although there was a clear reduction in children's tobacco smoke exposure in cars over the study period, we

	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	Total
Perceived tobacco smoke exposure*											
Number surveyed	..	..	..	734	798	859	804	812	746	747	5500
In a car	..	..	..	93 (12.8%)	74 (9.4%)	85 (10.1%)	74 (9.4%)	59 (7.4%)	42 (5.8%)	37 (5.0%)	464 (8.6%)
At home	..	..	..	147 (20.2%)	133 (17.0%)	155 (18.4%)	125 (15.9%)	109 (13.7%)	127 (17.4%)	97 (13.2%)	893 (16.5%)
In other people's homes	..	..	..	178 (24.5%)	168 (21.4%)	181 (21.5%)	188 (23.9%)	143 (17.9%)	128 (17.5%)	132 (18.0%)	1118 (20.7%)
In the street	..	..	..	360 (49.6%)	382 (48.7%)	408 (48.5%)	419 (53.3%)	451 (56.5%)	405 (55.5%)	435 (59.2%)	2860 (53.0%)
Outdoor areas of pubs, cafes, or restaurants	..	..	..	229 (31.5%)	228 (29.1%)	241 (28.7%)	266 (33.8%)	274 (34.3%)	241 (33.0%)	265 (36.1%)	1744 (32.3%)
In the park or playing field	..	..	..	132 (18.2%)	136 (17.3%)	141 (16.8%)	131 (16.7%)	135 (16.9%)	161 (22.1%)	144 (19.6%)	980 (18.1%)
Other public places	..	..	..	166 (22.9%)	194 (24.7%)	202 (24.0%)	240 (30.5%)	261 (32.7%)	226 (31.0%)	225 (30.6%)	1514 (28.0%)
In school	..	..	..	82 (11.3%)	71 (9.1%)	90 (10.7%)	73 (9.3%)	62 (7.8%)	62 (8.5%)	56 (7.6%)	496 (9.2%)
Missing data	..	..	..	8	14	18	18	14	16	12	100
Salivary cotinine†											
Number surveyed	1518	496	759	710	721	868	770	783	656	718	7999
Median cotinine concentration, ng/mL (IQR)	0.1 (0.0–0.6)	0.0 (0.0–0.3)	0.0 (0.0–0.3)	0.0 (0.0–0.3)	0.0 (0.0–0.2)	0.0 (0.0–0.3)	0.0 (0.0–0.2)	0.0 (0.0–0.2)	0.0 (0.0–0.2)	0.0 (0.0–0.2)	0.0 (0.0–0.3)
Cotinine level, ng/mL											
<0.1 (undetectable)	636 (43.0%)	266 (54.6%)	445 (60.0%)	422 (60.5%)	483 (68.5%)	498 (58.1%)	508 (66.9%)	508 (66.1%)	435 (67.0%)	463 (64.8%)	4664 (59.3%)
0.1–0.9	556 (37.6%)	156 (32.0%)	193 (26.0%)	177 (25.4%)	150 (21.3%)	252 (29.4%)	181 (23.9%)	191 (24.8%)	153 (23.6%)	195 (27.3%)	2204 (28.0%)
≥1.0	288 (19.5%)	65 (13.3%)	104 (14.0%)	98 (14.1%)	72 (10.2%)	107 (12.5%)	70 (9.2%)	70 (9.1%)	61 (9.4%)	57 (8.0%)	992 (12.6%)
Geometric mean cotinine concentration, ng/mL (95% CI)	0.57 (0.52–0.61)	0.50 (0.42–0.59)	0.56 (0.48–0.64)	0.55 (0.48–0.64)	0.58 (0.49–0.68)	0.49 (0.43–0.55)	0.45 (0.39–0.52)	0.46 (0.40–0.53)	0.49 (0.41–0.58)	0.41 (0.36–0.48)	0.51 (0.49–0.54)
Excluded from analysis	38	9	17	13	16	11	11	14	7	3	139

Data are n (%) unless indicated otherwise, with percentages calculated on all individuals surveyed for a given outcome with non-missing values (or who were not excluded from the analyses). Empty cells indicate that data were unavailable for that survey year. *Measured in children aged 8 years or older. †Non-smoking children or children with salivary cotinine concentration <12 ng/mL only. Children who reported active smoking or children with salivary cotinine concentration ≥12 ng/mL were excluded from the analysis.

Table 3: **Intermediate outcomes by survey year**

	Total sample	Direct change in outcome after smoke-free car regulation	
		Adjusted odds ratio (95% CI)	p value
Primary outcome			
Current wheezing or asthma	13 369	0·81 (0·62–1·05)	0·108
Secondary outcomes			
Self-reported respiratory condition*	17 006	1·02 (0·80–1·29)	0·892
Self-reported respiratory condition probably affecting stamina, breathing, or fatigue	12 386	0·75 (0·47–1·19)	0·220

Reported changes are step changes. All analyses were adjusted for underlying time trends, quarter of year, sex, age, Index of Multiple Deprivation quintile, and level of urbanisation. Only cases with no missing variables were included. *The analysis of self-reported respiratory conditions included time in years as a categorical variable because outcome data were unavailable for years 2010 and 2011.

Table 4: Associations between the smoke-free car regulation and primary and secondary outcomes

	Total sample	Direct change in outcome after smoke-free car regulation	
		Adjusted odds ratio (95% CI)	p value
Tobacco smoke exposure*			
In a car	5399	0·77 (0·51–1·17)	0·222
At home	5399	1·17 (0·83–1·64)	0·369
In other people's homes	5399	0·93 (0·70–1·24)	0·630
Salivary cotinine†			
Cotinine level (ordinal: <0·1, 0·1–0·9, ≥1·0 ng/mL)	7858	1·30 (1·04–1·62)	0·020
Detectable cotinine (≥0·1 ng/mL)	7858	1·36 (1·09–1·71)	0·0074

Reported changes are step changes. All analyses were adjusted for linear time trends, quarter of year, sex, age, Index of Multiple Deprivation quintile, and level of urbanisation. Only cases with no missing variables were included. *Tobacco smoke exposure is measured in children aged 8–15 years. †Non-smoking children or children with salivary cotinine concentration <12 ng/mL only.

Table 5: Associations between the smoke-free private vehicle regulation and intermediate outcomes

could not definitely attribute this to implementation of the smoke-free private vehicle law. While the 95% CI was wide, thus preventing definite conclusions, the point estimate indicates that a relative reduction of 23% in self-reported exposure in cars might have occurred. This figure corresponds well with earlier studies that did show significant findings. In a difference-in-difference analysis comparing Canadian regions according to whether they had implemented smoke-free private vehicle regulations, such laws were associated with a 26% relative reduction in tobacco smoke exposure among 10–17-year olds.[17] In California, self-reported tobacco smoke exposure in cars among school-age children diminished by 13% per year after implementation of a state-wide smoke-free private vehicle law.[18] Of concern, however, our study shows that 6% of all children surveyed in the year following implementation of the English smoke-free private vehicle law were still regularly exposed to tobacco smoke in cars, compared with 9% in the previous year. These figures clearly indicate that compliance with the smoke-free law was weak and they are in stark contrast with the excellent compliance with England's 2007 smoke-free law in enclosed public places and workplaces; in the year following this law's introduction, more than 98% of public places were found to be compliant.[37]

For obvious reasons, enforcement of a regulation that prohibits smoking in a private vehicle when children are present is challenging. Prior to implementation of the smoke-free private vehicle law in England, police spokesmen announced that the police force was not planning to actively enforce the law or issue fines to violators.[38,39] This argument appears to have been embedded within a broader message relating to the planned financial cuts regarding police forces at the time. Freedom of Information responses from 42 English and Welsh police forces indeed indicated that only one fine and almost no warnings were issued in the first 7 months after the law's introduction.[40] At the time of introduction, supporters of the law argued that its predominant anticipated impact would be to induce social norm changes regarding smoking in the presence of children. While previous studies have indicated that such norm changes occurred after legislation prohibiting smoking in enclosed public places,[33,36,41–47] our study fails to provide evidence that the smoke-free private vehicle regulation resulted in children being less exposed to tobacco smoke; in fact, cotinine levels indicated that overall exposure increased over and above the underlying decreasing temporal trend. At the same time, adult smokers more often reported having smoked in or around their homes, although this was not accompanied by a significant increase in children's self-reported tobacco smoke exposure at home in our primary analyses. Whether displacement of smoking from cars to homes might in fact be an issue therefore warrants further study.

Children have the right to grow up smoke free, and protecting children from the harms associated with tobacco smoke exposure is essential.[48] Air concentrations of toxic substances upon smoking in a car easily exceed levels typically observed in smoky bars.[49] Public support for smoke-free private vehicle regulations is widespread. In England, 87% of all adults, including 76% of all smokers, supported such regulations in 2016, and these numbers were higher than in a comparable survey done before the law was implemented.[50] We believe that lack of enforcement is the most likely explanation for the weak compliance with the smoke-free private vehicle regulation as shown in our study. This indicates that additional measures are necessary to address challenges in enforcement of such regulations and accordingly enhance compliance.[40] Before implementing similar laws in other countries, policy makers should align with the various stakeholders, including the parties responsible for enforcement, to ensure that unambiguous and consistent messages are communicated towards the public and that realistic and sustainable plans for enforcement are in place. Media campaigns should precede and accompany implementation, clearly referring to the substantial health benefits of protecting children from tobacco smoke.

Regulatory aspects of a law aimed at protecting children from tobacco smoke exposure in cars should also be considered. For example, a law prohibiting smoking in private vehicles might be easier to regulate if smoking is prohibited irrespective of whether children are present. In a 2016 survey among adults in England, 62% supported such an extension of the law.[50] Here, we showed that in the years following the English smoke-free private vehicle law, one in five adult smokers had still smoked in a car during the previous week. The fact that smoking in a car has in itself been associated with being involved in a traffic accident could provide another argument for regulating smoking in private vehicles more generally.[51] Such a comprehensive smoke-free private vehicle law might also help to reduce exposure of children (and other passengers) to the potential dangers of third-hand smoke lingering in the car after the cigarette is extinguished.[52] Last, given that vaping in a car can still expose children to nicotine and perhaps other harmful substances, the current exception of vaping from the smoke-free private vehicle regulation might require revisiting.[53]

It is essential that policy makers continue to explore opportunities for introducing effective measures to protect children from tobacco smoke exposure and that the effectiveness of such regulations is assessed via robust policy evaluations. Such evaluations have clearly shown that legislation prohibiting smoking in public places effectively reduces child tobacco smoke exposure and, through doing so, substantially benefits child health.[10] Whereas earlier studies have indicated that smoke-free private vehicle regulations might also be effective in reducing children's exposure to tobacco smoke,[17,18] we were unable to replicate this finding in England, observing no demonstrable health benefits in the children surveyed; this lack of effect was probably owing to little compliance and enforcement of the regulation. Additional studies in, and perhaps across, other countries are needed to further evaluate the effectiveness of smoke-free private vehicle regulations and to explore the regulatory aspects determining effectiveness.

To our knowledge, this is the first study to have evaluated the direct association between the introduction of a smoke-free private vehicle law and changes in childhood respiratory diseases. It is also unique in its evaluation of a smoke-free private vehicle law implemented nationally. Unlike earlier studies assessing subnational regulations, we included both subjective and objective measures of tobacco smoke exposure among children in our evaluation. We made use of weighted survey data from HSE, which contained timely data for a substantial number of children, including both self-reported and biochemically validated data, and was designed to be representative of the entire population of England. The use of individual-level data allowed us to account for several potential confounders, thus addressing a key drawback of population-level (ie, aggregated) interrupted time series analyses. The nature of HSE data also provided us with much more granular data over time (ie, quarterly *vs* biennially or annually), allowing us to more reliably estimate and account for temporal trends.

Our study has some potential limitations. National policy interventions are typically not implemented in a randomised fashion, and although we used a robust quasi-experimental design considered optimal for evaluating such interventions, the observational nature of our study and the lack of a control group inherently limit causal inference.[54] We sought to at least partly address this by accounting for important known and available confounding factors. Relying on data that were collected by the HSE, our sample size was inherently limited to the number of children surveyed, individual children could not be followed up, and the post-intervention observation period was relatively short. Additionally, we were limited by missing datapoints and temporal changes in definitions for a number of variables. Finally, from HSE data, it is not possible to discern whether self-reported tobacco smoke exposure might partly include exposure to vaping, although any effect on our findings is likely to be small.[55]

In conclusion, although children's environmental exposure to tobacco smoke in cars has been decreasing in England over the past 10 years, we found no additional reductions in children's tobacco smoke exposure in cars or prevalence of asthma or respiratory health problems following implementation of England's 2015 national legislation prohibiting smoking in private vehicles when children are present. Stricter enforcement might be required to improve compliance, which seems much weaker than with the 2007 legislation prohibiting smoking in enclosed public places. There is an urgent need to investigate more effective approaches to protecting children from tobacco smoke in cars and elsewhere.

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