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Title: Evaluating the impact of lowering blood alcohol concentration limits for drivers on road traffic accident rates and alcohol consumption: a natural experiment

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Abstract: Background
Drink-driving is an important risk factor for road traffic accidents (RTAs) which cause high levels of morbidity and mortality globally. Lowering the permitted blood alcohol concentration (BAC) for drivers is a common public health intervention enacted in countries and jurisdictions across the world. In Scotland, on 5th December 2014, the BAC limit for drivers was reduced from 0·08 g/dL to 0·05 g/dL. This study evaluated the impact of this change on RTA and alcohol consumption outcomes.

Methods
We employed an observational, comparative interrupted time series design using data from the whole of the intervention (Scotland) and control (England & Wales) groups for the period January 2013 to December 2016. Weekly counts of RTAs were obtained from police accident records and weekly off-trade and four-weekly on-trade alcohol consumption was estimated from market research data. We used data from automated traffic counters as denominators to calculate RTA rates. We estimated the effect of the intervention on RTA and alcohol consumption outcomes using negative binomial panel regression and seasonal autoregressive integrated moving average models, respectively.

Findings
The change in drink-drive legislation was associated with a 1% increase in total RTA rates in Scotland (rate ratio (RR) 1·01; 95% CI 0·94, 1·08; p=0·77) after adjustment for seasonality and underlying temporal trend. When expressed relative to England & Wales, where the intervention did not happen, the association was estimated as a 7% increase in total RTA rates (RR 1·07; 95% CI 0·98, 1·17; p=0·10). Similar findings were observed for serious/fatal RTAs and single vehicle night-time RTAs. For alcohol consumption, in Scotland, the change in legislation was associated with a 0·3% decrease (relative change) for consumption measured by per capita off-trade sales (-0·3%;-1·7%, 1·1%; p=0·71) and a 0·7% decrease in per capita on-trade sales (-0·7%;-0·8%, -0·5%; p<0.001).

Interpretation
Lowering the BAC limit to 0·05 g/dL from 0·08 g/dL in Scotland was not associated with a reduction in RTAs, but was associated with a small

reduction in per capita on-trade alcohol sales. One plausible explanation is that the legislative change was not suitably enforced, for example with random breath testing measures. Our findings suggest that changing the legal BAC limit in isolation does not improve RTA outcomes. These findings have significant policy implications internationally as several countries and jurisdictions consider a similar reduction in BAC limit.

Funding
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Evaluating the impact of lowering blood alcohol concentration limits for drivers on road traffic accident rates and alcohol consumption: a natural experiment

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Summary

Background Drink-driving is an important risk factor for road traffic accidents (RTAs) which cause high levels of morbidity and mortality globally. Lowering the permitted blood alcohol concentration (BAC) for drivers is a common public health intervention enacted in countries and jurisdictions across the world. In Scotland, on 5th December 2014, the BAC limit for drivers was reduced from 0·08 g/dL to 0·05 g/dL. This study evaluated the impact of this change on RTA and alcohol consumption outcomes.

Methods We employed an observational, comparative interrupted time series design using data from the whole of the intervention (Scotland) and control (England & Wales) groups for the period January 2013 to December 2016. Weekly counts of RTAs were obtained from police accident records and weekly off-trade and four-weekly on-trade alcohol consumption was estimated from market research data. We used data from automated traffic counters as denominators to calculate RTA rates. We estimated the effect of the intervention on RTA and alcohol consumption outcomes using negative binomial panel regression and seasonal autoregressive integrated moving average models, respectively.

Findings The change in drink-drive legislation was associated with a 1% increase in total RTA rates in Scotland (rate ratio (RR) 1·01; 95% CI 0·94, 1·08; p=0·77) after adjustment for seasonality and underlying temporal trend. When expressed relative to England & Wales, where the intervention did not happen, the association was estimated as a 7% increase in total RTA rates (RR 1·07; 95% CI 0·98, 1·17; p=0·10). Similar findings were observed for serious/fatal RTAs and single vehicle night-time RTAs. For alcohol consumption, in Scotland, the change in legislation was associated with a 0·3% decrease (relative change) for consumption measured by per capita off-trade sales (-0·3%;-1·7%, 1·1%; p=0·71) and a 0·7% decrease in per capita on-trade sales (-0·7%;-0·8%, -0·5%; p<0.001).

Interpretation Lowering the BAC limit to 0·05 g/dL from 0·08 g/dL in Scotland was not associated with a reduction in RTAs, but was associated with a small reduction in per capita on-trade alcohol sales. One plausible explanation is that the legislative change was not suitably enforced, for example with random breath testing measures. Our findings suggest that changing the legal BAC limit in isolation does not improve RTA outcomes. These findings have significant policy implications internationally as several countries and jurisdictions consider a similar reduction in BAC limit.

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Research in context

Evidence before this study

Road traffic accidents (RTAs) are a major public health problem with 1·25 million road traffic deaths globally in 2013. There is strong evidence that a person's ability to drive a vehicle is impaired if alcohol is in their bloodstream, and drink driving is an important risk factor of RTAs. There is a dose-response relationship between blood alcohol concentration (BAC) and RTA rates, with evidence showing the odds of fatal injury increase by 1·74 for every 0·02% increase in BAC.

There is international evidence that levels of severe and fatal RTAs reduce when a country or region changes the legal BAC limit from 0·08 to 0·05 g/dL. However, these studies have limitations including confounding of BAC intervention effect with other interventions (random breath testing (RBT)) and poor study design (e.g. before-and-after studies not accounting for temporal trends, not having a control group, and high level of aggregation for units of time in analysis). A European study which analysed data from 15 countries found that the legislation change was associated with a 7·4% reduction in road fatality rates (attenuating to 4·3% after adjustment for RBT). An earlier study which evaluated legislation change in two Australian states in the early 1980s, found a similar effect size in one state and 14-18% reductions in severe and fatal RTAs in the other.

Added value of this study

Our findings indicate that the reduction in Scotland's drink-drive limit in December 2014 did not have the intended effect of reducing RTAs. It reduced on-trade alcohol sales (e.g. in bars, restaurants, etc.) by less than 1% but did not impact off-trade sales (e.g. from supermarkets, convenience stores, etc.) which counts for approximately three-quarters of total sales.

We evaluated a change in drink-drive legislation from BAC 0·08 to 0·05 g/dL in an entire population, reducing the risk of selection biases. RBT was not in place in Great Britain during the study allowing us to isolate the effect of changing the BAC legal limit. A strong counterfactual was provided by neighbouring countries (England & Wales) to the intervention country (Scotland) and the same data sources were used for both groups. This new evidence from a recent intervention is important as it may be that larger effect sizes seen historically may be more difficult to obtain in an era of improved road safety and, regardless of BAC limits, where drink-driving is increasingly socially unacceptable.

Implications of all the available evidence

This drink-drive limit change occurred in the context of a lack of additional police enforcement and without RBT measures in place. Our finding of a null BAC 0·08 to 0·05 g/dL intervention effect supports the hypothesis that enhanced enforcement may be necessary to bring about improvements in RTA outcomes. However, further research is required to test whether an appropriately enforced change in drink-drive legislation from BAC 0·08 to 0·05 g/dL would improve outcomes.

Introduction

Road traffic accidents (RTAs) are a major public health problem with 1·25 million road traffic deaths globally in 2013 (1). In Great Britain (GB), there have been large reductions in RTAs over recent decades, with a 72% reduction in fatal RTAs observed between 1979 and 2017, but they remain a considerable burden on health with 170,993 RTA casualties reported in 2017 (2). Driving under the influence of alcohol is a major risk factor for RTAs with a dose-response relationship observed between blood alcohol concentration (BAC) level and RTAs. It has been estimated that the odds of fatal injury increase by 1·74 for every 0·02% increase in BAC (3). In GB, there were at least 6,070 RTAs involving a drink-driver in 2016 (4).

Since Norway first introduced a legal BAC limit in 1936, other countries across Europe, North America, Japan, Australasia, and US have followed (5), initially with introducing a standard BAC limit (of 0·05, 0·08 or 0·1 g/dL) and with some countries going on to further lower the limit. In Europe, only England & Wales and Malta, have a 0·08 g/dL BAC limit. Such limits, and higher, are the norm in many other jurisdictions including many states in the USA, despite long-standing calls for reductions. According to European Commission recommendations, BAC limits should be set at 0·05 g/dL (6). The British Road Safety Act (BRSA) introduced a legal limit of 0·08 g/dL in 1967, which is still in place today. An exception is Scotland where the BAC limit was reduced to 0·05 g/dL on 5th December 2014. It has been estimated that drink-driver injury accidents cost the Scottish economy £80m per year (7).

There is an evidence base on the effectiveness of reducing BAC levels from countries, and jurisdictions within countries, that have changed legislation to deter drink-driving and in turn to prevent RTAs. Evaluations of the impact of a reduction in drink-drive limits in different parts of the world such as Australia (8), France (9), Austria (10), and Serbia (11), provide evidence that such legislation is effective in reducing RTAs. A recent meta-analysis (12), estimates that a (general) lowering of the BAC limit is associated with a 5% decline in non-fatal alcohol-related crashes, and lowering to 0·05 g/dL is associated with a 11% decline in fatal alcohol-related crashes.

In an interrupted time-series study where the main focus was evaluating random breath testing (RBT), Henstridge *et al.* (8), evaluated a reduction in BAC limit from 0·08 to 0·05 g/dL in New South Wales (NSW) and Queensland (QLD), Australia. These changes in BAC limit occurred in December 1980 (NSW) and December 1982 (QLD) and the evaluation was not confounded by RBT as this was introduced at a later point. In NSW (QLD) the study reported 7% and 8% (14% and 18%) reductions in severe and fatal RTA counts, respectively. Albalate (13) conducted a differences-in-differences analysis of data from 15 European countries for the period 1991-2003 and found that a BAC limit of 0·05 g/dL, or lower, compared to higher limits was associated with a 4·5% and 7·4% reduction in road fatality rates (using population and per distance driven denominators, respectively). Importantly, these effect sizes attenuated to 3·4% and 4·3% and were no longer statistically significant when RBT was adjusted for.

If any BAC intervention effect is homogeneous across the population under study then it could affect absolute levels of socio-economic deprivation inequality for RTAs: level of alcohol consumption is positively associated with the probability of drink-driving (14) and higher levels of socio-economic deprivation are associated with higher levels of alcohol consumption per drinker (15), but also with lower driving rates.

It has been hypothesised that population drinking (i.e. per capita alcohol consumption) is associated with driving under the influence of alcohol (16). If true, an unintended outcome of a change in BAC legislation could be a reduction in per capita alcohol consumption.

We aimed to evaluate whether lowering the permitted blood alcohol concentration (BAC) from 0·08 to 0·05 g/dL in Scotland had an impact on both road traffic accidents (RTAs) rates and population alcohol consumption. Further, we evaluated whether any impacts varied by level of socio-economic deprivation. Our study design allowed us to isolate the effect of changing the BAC legal limit and assessed the sole effect of change in legislation without any enhanced law enforcement measures such as RBT. A strong counterfactual was also provided by neighbouring countries (England & Wales) to the intervention country (Scotland). Furthermore, to our knowledge, no previous study has evaluated whether a legislation change of BAC limit has led to a reduction in that country's population drinking. These matters are of significant policy importance as other countries and jurisdictions across the world consider similar lowering of BAC limits.

Methods

Design

A comparative interrupted time series design using data measured between January 2013 and December 2016 was employed. The intervention group was Scotland and the control group was England & Wales.

Outcome measures

The primary outcome was weekly RTA rates rather than counts as this allows for a 'Differences-in-Differences' (DiD) type measure of effect size (see 'Statistical analysis' below). Weekly counts of RTAs that took place on public roads in GB and were reported to the police (using STATS19 accident reporting form (17)) were obtained. Any given accident could involve more than one driver and casualty but we considered ‘accident’ as the most appropriate unit for analysis. To calculate weekly RTA rates, the number of miles driven by each person at risk of having a RTA would be the ideal denominator but is not available. As a proxy for this, data from automatic traffic counters (ATCs) (18) were used. ATCs count vehicles passing over them 24 hours a day across the road network. The location of the approximately 300 ATCs are placed to be representative of the entire GB road network, including motorways, major roads (providing large-scale transport linkage) and minor roads (feeding traffic between major roads and smaller roads). We accounted for poor quality or missing ATC data by using a multiple imputation approach that is specifically designed for time series data (19).

In STATS19, the severity of an RTA is recorded as the most severely injured casualty, namely fatal, serious or slight. To facilitate comparison with previous literature, and because it can be argued that serious and fatal RTAs are more likely to be influenced by drink-driving, we used weekly serious/fatal RTA rates as a secondary outcome. We tested the sensitivity of combining serious with fatal RTAs by modelling each outcome separately. As an additional outcome likely to be influenced by drink-driving, we used single vehicle night-time (SVN) RTAs and the ratio of SVN to multiple vehicle day-time (MVD) RTAs as secondary outcomes (and MVD RTAs outcomes alone). The final secondary outcome measure, alcohol consumption, was measured by volume of off- and on-trade alcohol retail sales. This is a high quality measure not reliant on individual self-report that is prone to bias. These data were provided by NHS Health Scotland for the period 2013-2016 who obtained them from the market research company, Nielsen (20). Off-trade alcohol sales (from retailers licensed to sell alcohol for consumption on the premises, e.g. bars, restaurants, etc.) were available in weekly units but on-trade alcohol sales (from retailers licensed to sell alcohol for consumption off the premises, e.g. supermarkets, convenience stores, etc.) were only available in 4-weekly units. We used a linear interpolation method to impute weekly on-trade sales. Per capita estimates were obtained by dividing the total volume of pure alcohol sold by adult (16 years and over) population size for Scotland, and England & Wales, combined.

Statistical analysis

To assess the comparability of the intervention and control groups, we compared age, sex and socio-economic deprivation characteristics. As the unit of analysis was an RTA, when the RTA involved more than one vehicle the eldest age group of the drivers, the most frequent sex, and the most 'deprived' socio-economic deprivation level (generated from postcode of driver) was used for analysis. We used an area-based measure of socio-economic deprivation levels separately for Scotland and England & Wales. Socio-economic deprivation was measured by the Index of Multiple Deprivation (IMD) provided by Scottish and UK Governments (21-23). We repeated our analyses using a different rule of 'demographic assignment' (the youngest age group, the least frequent sex, the least deprived socio-economic deprivation level) to check the sensitivity of results.

To test for a change in RTA counts and rates, after the new legislation was in place, negative binomial regression models were fitted to panel data sets, separately for the intervention and control groups. For modelling of rates, traffic flows were used as a denominator. The models were adjusted for underlying temporal trend by fitting a covariate representing week number, and for seasonality by covariates representing 4-weekly periods of the year (13 'months'). The models were then further adjusted for age, sex and socio-economic deprivation. To obtain a 'Differences-in-Differences' (DiD) type measure of effect, the two panel data sets were appended and an interaction term between intervention group indicator and the binary covariate for indicating pre- and post-change in legislation ('pseudo' change for control) was assessed. In this model an interaction term between week number and intervention group indicator allowed for a relaxation of the usual DiD 'parallel trends' assumption. We tested whether socio-economic deprivation moderated any effect of the law change on total RTA rates, by including in our statistical models an interaction term between the intervention group indicator and socio-economic deprivation.

For alcohol consumption, separately for off- and on-trade alcohol sales and for the intervention and control groups, time series seasonal autoregressive integrated moving average (SARIMA) models were fitted. SARIMA was considered the best model choice to account for the very strong seasonality in the alcohol consumption outcome. Logarithms of the outcome measures were used in the modelling to reduce the variability in the time series and to aid interpretation. The form of the autocorrelation for the SARIMA errors was identified from autocorrelation plots and partial autocorrelation plots. SARIMA was designed, for both intervention and control groups, in four different formats. Off-trade sales models controlled for off-trade sales of the alternative group, on-trade sales of the same group, and trend. Similarly, on-trade sales models controlled for on-trade sales of alternative group, off-trade sales of same group, and trend. We conducted tests of residual correlation using correlograms to ensure that final models had a good fit with "white noise" Normally-distributed residuals.

A statistical significance level of 0.05 is used throughout. All analyses were conducted using Stata/SE 14·2 software (Stata Corp., College Station, TX, USA; URL http://www.stata.com).

Results

Weekly RTA counts and rates plotted over time are presented in Figure 1 with a vertical line indicating the change in drink-drive legislation date. It can be seen that, generally, weekly RTA rates are higher in England & Wales than Scotland (broadly, the rates are between 5 to 9 RTAs per 1000 traffic count in Scotland, with the corresponding figures being 6 to 10 for England & Wales (Figure 1b). By contrast, the weekly serious/fatal RTA rates are at similar levels across the four years of the study (Figure 1d). It is worth noting that over the study period fatal RTAs count for 1·9% and 1·1% of all RTAs in Scotland and England & Wales, respectively. Although it was not possible to calculate weekly SVN rates due to time of day not being recorded by the ATCs, the weekly SVN counts are shown in Figure 1e. Figure 2 illustrates weekly off- and on-trade per capita alcohol sales over time. Strong seasonal patterning is shown with large peaks and smaller troughs at the end and start of a calendar year, respectively.

Table 1 shows age, sex and socio-economic deprivation characteristics of the RTAs by intervention and control groups. The distributions are very similar between the groups and this remained true when we changed the demographic assignment rule (see Table S1). The mean (SD) number of drivers (vehicles) per RTA was 1·72 (0·73) and 1·84 (0·71) in Scotland and England & Wales, respectively. The corresponding figures for number of casualties per RTA was 1·29 (0·77) and 1·33 (0·82).

Table 2 shows the change in drink-drive legislation was associated with a 2% decrease in total RTA counts in Scotland that did not reach statistical significance (rate ratio (RR) 0·98; 95% CI (0·91, 1·04); p=0·53). However, the pseudo-change in legislation was associated with a 5% decrease in RTA counts in England & Wales (RR 0·95; 95% CI (0·90, 1·00);

p=0·05). Similar results were observed when modelling total RTA rates and the DiD type estimate indicates a 7% increase in total RTA rates for Scotland relative to England & Wales (RR 1·07; 95% CI (0·98, 1·17); p=0·10). The DiD type estimate for serious/fatal RTA rates indicates a 4% increase in serious/fatal RTA rates for Scotland relative to England & Wales (RR 1·04; 95% CI (0·90, 1·19); p=0·59). In a sensitivity analysis, similar results were found when modelling serious and fatal RTA rates separately (see Table S3). For SVN RTA counts, the models show a 1% decrease in Scotland (RR 0·99; 95% CI (0·87, 1·15); p=0·99) and a 7% decrease in England & Wales (RR 0·93; 95% CI (0·88, 0·98); p=0·03). Adjustment for age, sex and socio-economic deprivation changed these results minimally (see Table 2), as did changing the demographic assignment rule (see Table S3). Further, similar null effects for Scotland were observed when SVN/MVD, and MVD, outcomes were modelled (see Table S3).

We found no statistical evidence of effect modification by socio-economic deprivation for total RTA rates (tests of interaction: Scotland – p=0·72 (RTA counts), p=0·71 (RTA rates); England & Wales – p=0·58 (RTA counts), p=0.58 (RTA rates). This is illustrated in Tables S5 and S6 where it can be seen that effect sizes only vary minimally across levels of socio-economic deprivation.

For alcohol consumption, in Scotland, the change in legislation was associated with a non-statistically significant 0.3% relative decrease in per capita off-trade sales (-0·3%; 95% CI (-1·7%, 1·1%); p=0·71) and a statistically significant 0·7% decrease in per capita on-trade sales (-0·7%; 95% CI (-0·8%, -0·5%); p<0·001). The corresponding results for the effect of the pseudo-change in legislation in England & Wales indicate increases in per capita off- and on-trade sales.

Discussion

We found that lowering BAC limit from 0·08 to 0·05 g/dL in Scotland was not associated with a change in the level of RTAs in the first two years post-legislation change. These null findings for total, serious/fatal and SVN RTAs were unexpected given previous evidence generally supports a reduction of RTA outcomes following a lowering of a BAC limit. The 95% CIs of our results (see Table 2) do not include effect sizes of the magnitude that were reported by Henstridge *et al.* (8) and Albalate (13). For off-trade alcohol sales, we found no evidence of an intervention effect and these sales account for a large proportion of alcohol consumption in Scotland (73% of total alcohol sales in 2017 (24)). We did observe a small reduction (less than 1%) in on-trade alcohol sales and further research is underway to explore perceptions of the impact of the BAC limit change from the perspectives of owners/managers in on-trade.

Our study employed a well-designed controlled natural experiment, with England & Wales providing a counterfactual for RTA and alcohol consumption trends in the absence of the BAC intervention. The same data sources were used for both Scotland and England & Wales helping to reduce measurement error. The distribution of demographics was very similar between the intervention and control groups which adds further weight that the choice of control group is appropriate. Using large nationally representative data sets, and with two years pre- and post-legislation change weekly data points, we had a high level of statistical power resulting in good precision around effect size estimates. The long follow-up makes it unlikely that we have missed any lagged effect of the intervention.

Our study has limitations; firstly, we were unable to use alcohol-related RTAs as an outcome measure. BAC levels in drivers/riders involved in RTAs are often not available or are unreliable (8). For example, in GB only half of all drivers/riders involved in RTAs are breath tested by police (25) and for fatal RTAs there are often long delays in getting BAC from coroner's reports and BAC naturally reduces with time. Moreover, in STATS19 the BAC level is not recorded, just whether the reading was "over the limit" which would present a methodological challenge with the limit changing over time in Scotland. Secondly, we have not adjusted for potential time-varying confounding factors such as weather and road quality. This would only be important if they were substantially different in the intervention and control groups and we do not think this is likely. Further, we are not aware of any other concurrent interventions that took part in Scotland and not in England & Wales, or vice versa. Thirdly, we acknowledge that not all RTAs will become known to the police (26), and many casualties of RTAs who attend hospital will not be captured in STATS19. However, this would only bias our results if differential between the intervention groups, and this is unlikely. Lastly, the traffic flow denominators obtained from ATCs are a proxy for distance travelled by each person at risk of having a RTA, and there were data quality issues with the denominator we used for the rates (addressed by multiple imputation), but they are superior to using a population denominator as it more accurately reflects those at risk of event. Moreover, although the location of the (approximately) 300 ATCs across GB are placed to be broadly representative of the entire road network, they provide only a set of point estimates. Nevertheless, they provide good data on how traffic flows vary on a temporal basis and it is noteworthy that the effect sizes we obtained from models using them closely match the results from modelling RTA counts (see Table 2).

The most plausible explanation of no effect of lowered BAC limit on RTA outcome is insufficient enforcement, publicity, or both. The European commission stated that a key to success of lowering drink-drive legislation is the introduction along with enforcement of frequent and systematic random breath testing, supported by public education, publicity and awareness campaigns involving all stakeholders (27). Further, previous research supports an association between increased enforcement level and decreased RTAs (9). In particular, RBT is recognised as the principal drink-driving law enforcement strategy throughout Australia as the best universal example in implementing RBT (28), with evidence illustrating most of the decline in alcohol-related traffic injuries and fatalities has been attributed to the implementation of RBT (29). There is evidence that enforcement levels have reduced in GB with English police force data showing 25% fewer RBTs in 2015 compared to 2011 (30), and in Scotland initial investment in public education and media campaigning at the time of the drink-drive limit reduction in December 2014 was not maintained in the following years. Other explanations are, firstly, it may be that the majority of drink-driving RTAs are caused by people who continue to ignore the law under the new legislation, or that people who previously used to drink-drive between the new and old limits have changed their behaviours but are responsible for only a small fraction of all RTAs. Secondly, it may be that larger effect sizes seen historically for BAC lowering interventions may be more difficult to obtain in an era of improved road safety and where drink-driving is increasingly socially unacceptable. Lastly, it may be that non-alcohol-related RTAs have increased in Scotland over the study period, masking an intervention effect, but given the SVN/MVD and MVD modelling results we think this is unlikely. Further research exploring these and other possible explanations for the findings is needed.

Our findings indicate that the reduction in Scotland’s drink-drive limit in December 2014 did not have the intended effect of reducing RTAs. It was associated with reduced on-trade alcohol sales by less than 1% but there was no association with changes in off-trade sales (which account for approximately three-quarters of total sales). This suggests that a reduction in BAC limit from 0·08 to 0·05 g/dL is not effective in reducing RTAs without being accompanied by other measures such as enhanced enforcement. These findings have significant policy implications internationally as several countries and jurisdictions consider a similar reduction in BAC limit.

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Contributors

HH was the lead researcher on the study, leading the preparation of all analyses and drafting of the manuscript; JL led the design and execution of the study, oversaw all analyses and interpretation, and led the drafting and writing of the manuscript; DFM contributed to the overall design, in particular the design and analysis of the statistical analyses and commented on manuscript drafts; EM contributed to the overall design and commented on manuscript drafts; JP contributed to the overall design and commented on manuscript drafts; AJ contributed to the design, provided advice on aspects of the statistical analyses, and commented on manuscript drafts; NF contributed to the interpretation of results, and commented on manuscript drafts; MR contributed to the overall design, provided interpretation of results, and commented on manuscript drafts.

JL, as corresponding author, confirms that all authors have seen and approved the final text.

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Declaration of interests

HH, JL, DFM, JP and AJ declare no competing interests. EM is a member of the NIHR PHR funding board. NF reports personal fees from World Health Organization-Europe, outside the submitted work. MR reports grants from Scottish Government during the conduct of the study.

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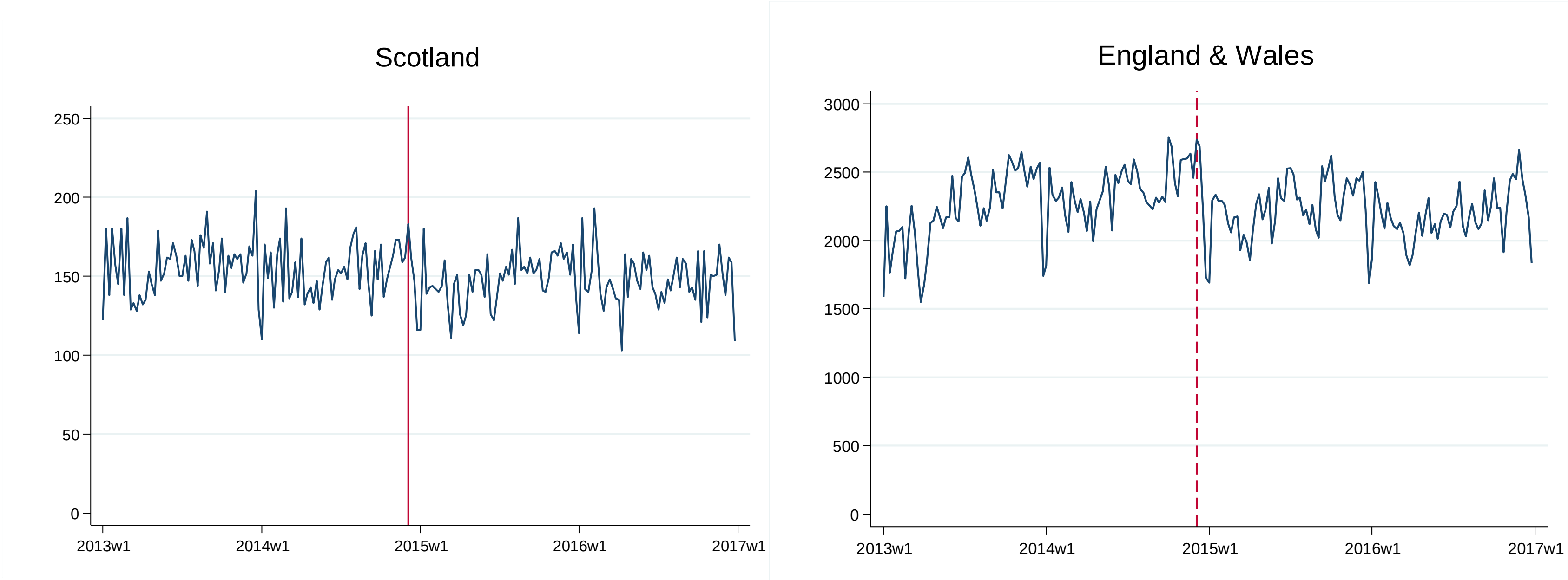
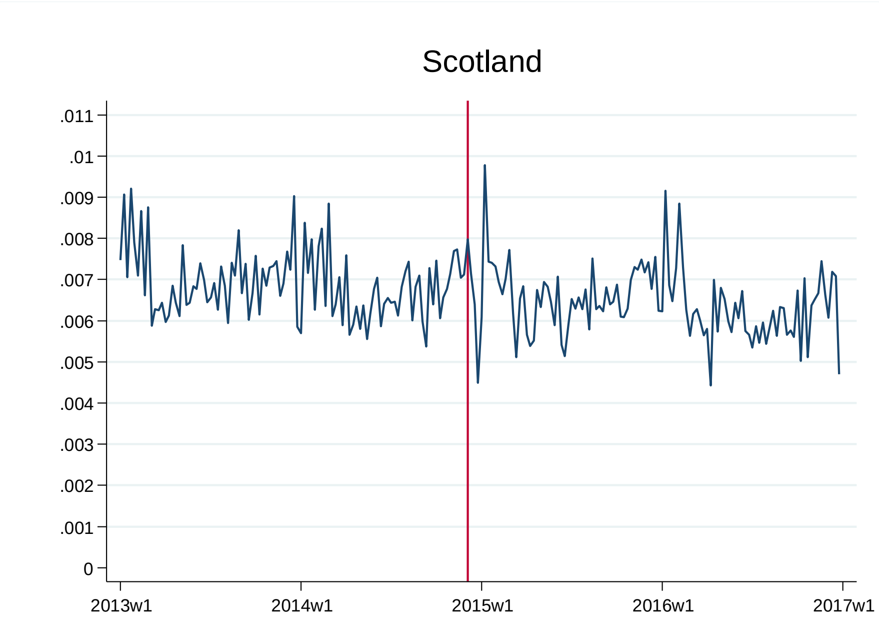
Figure 1: Weekly (a) Total RTA counts, (b) Total RTA rates, (c) Serious/fatal RTA counts, (d) Serious/fatal RTA rates, and (e) SVN counts for Scotland and England & Wales between Jan 2013 and Dec 2016

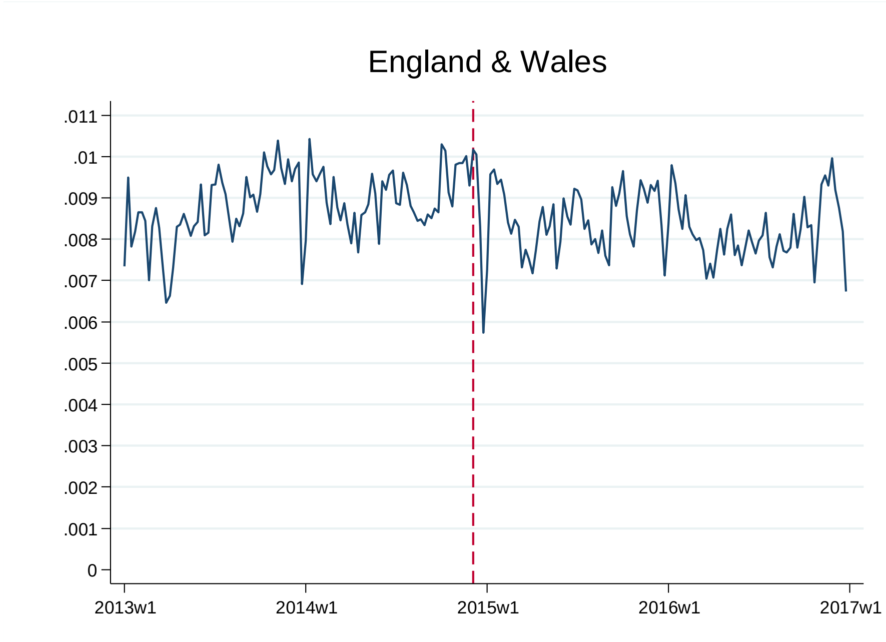
(a) Total RTA counts



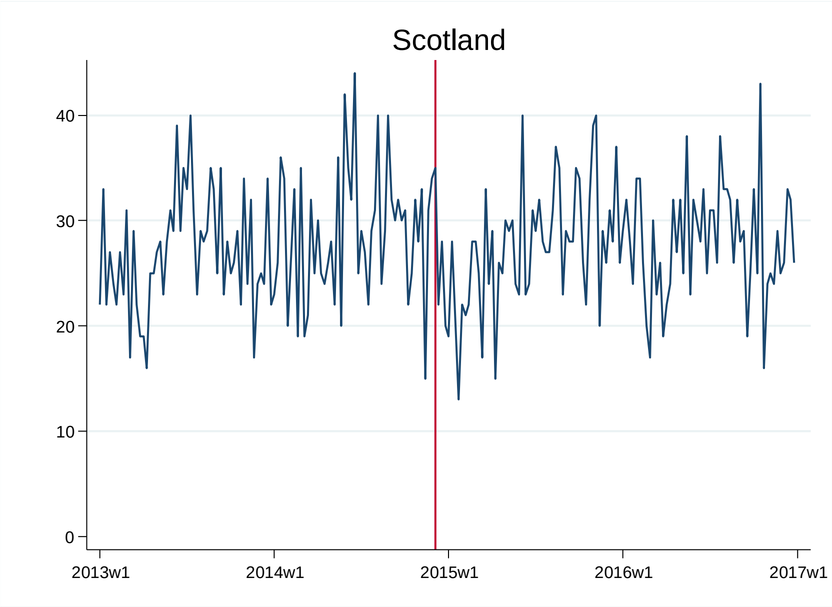
Solid vertical line indicates change in legislation date and dashed line indicates pseudo-change in legislation date; x-axis is weekly time period showing the first week (w1) of each year.

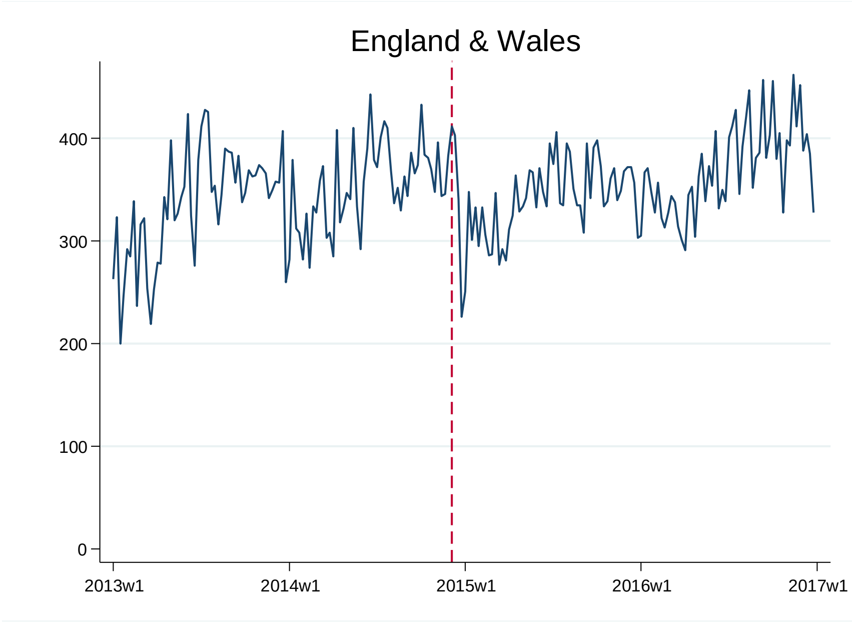
(b) Total RTA rates



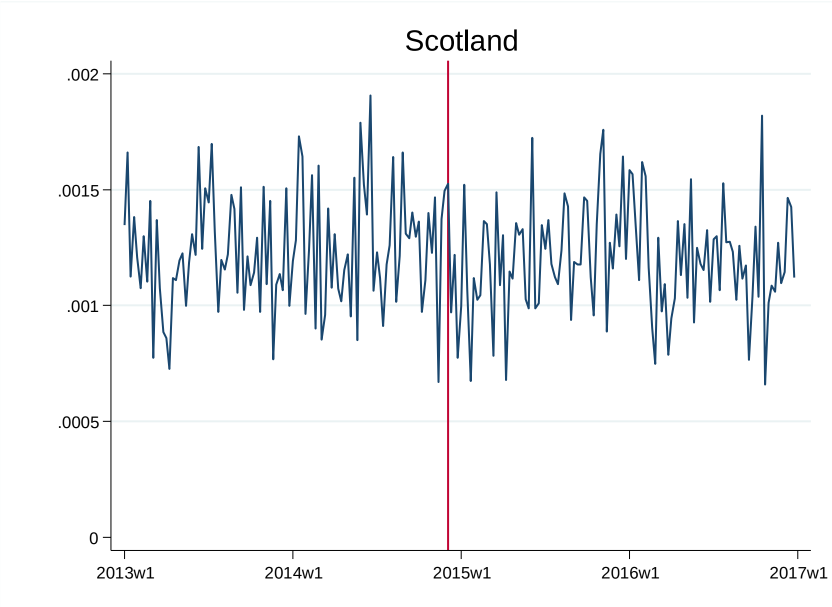


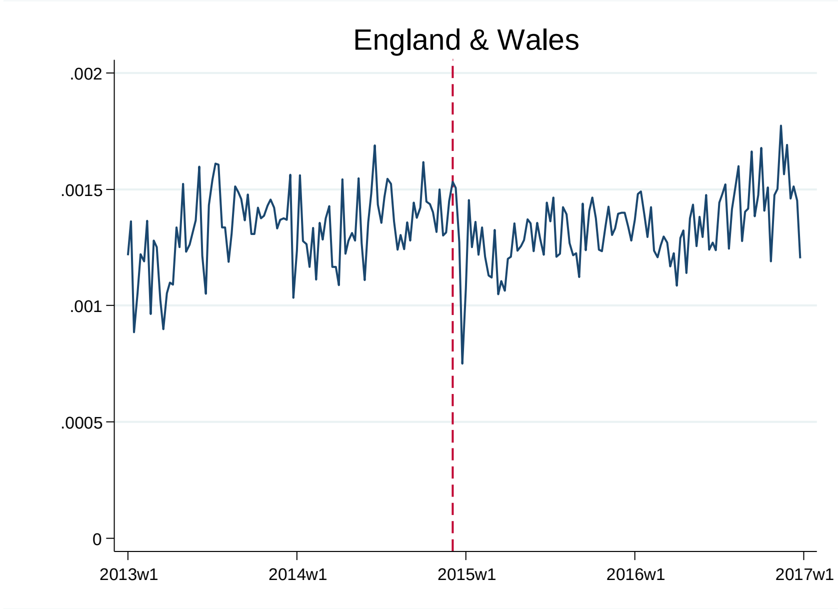
(c) Serious/fatal RTA counts



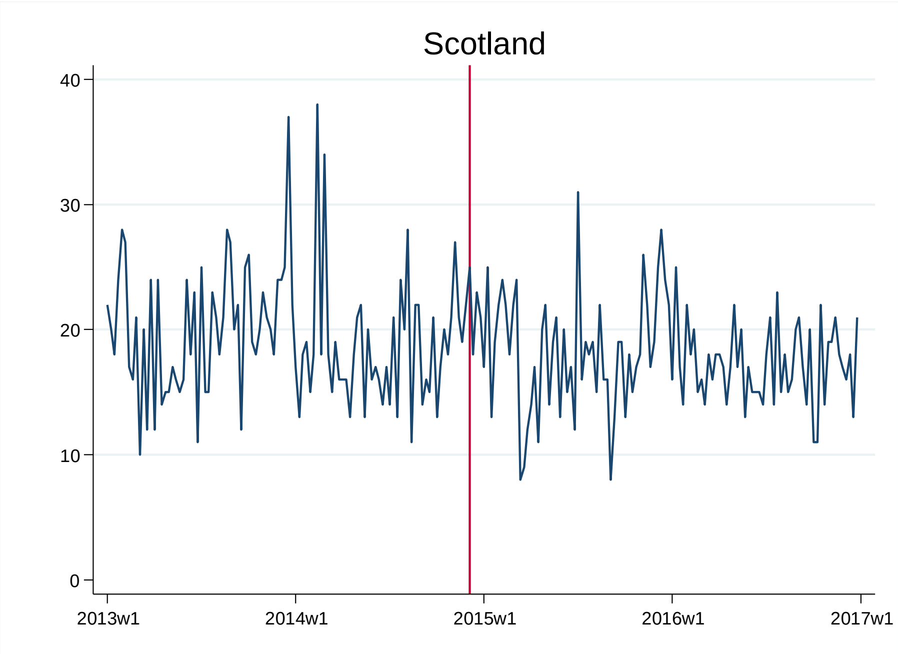


(d) Serious/fatal RTA rates





(e) SVN RTA counts



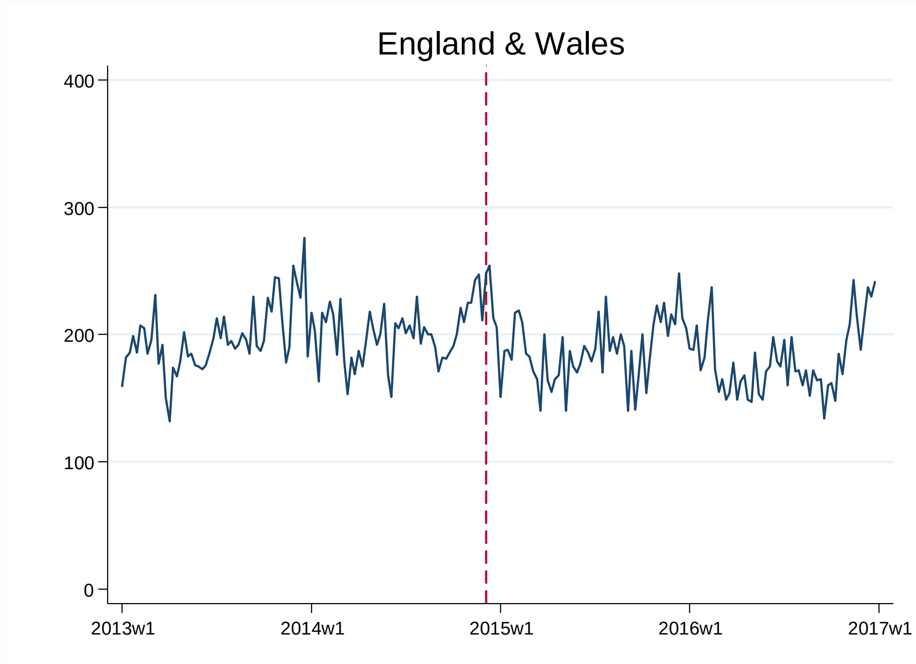
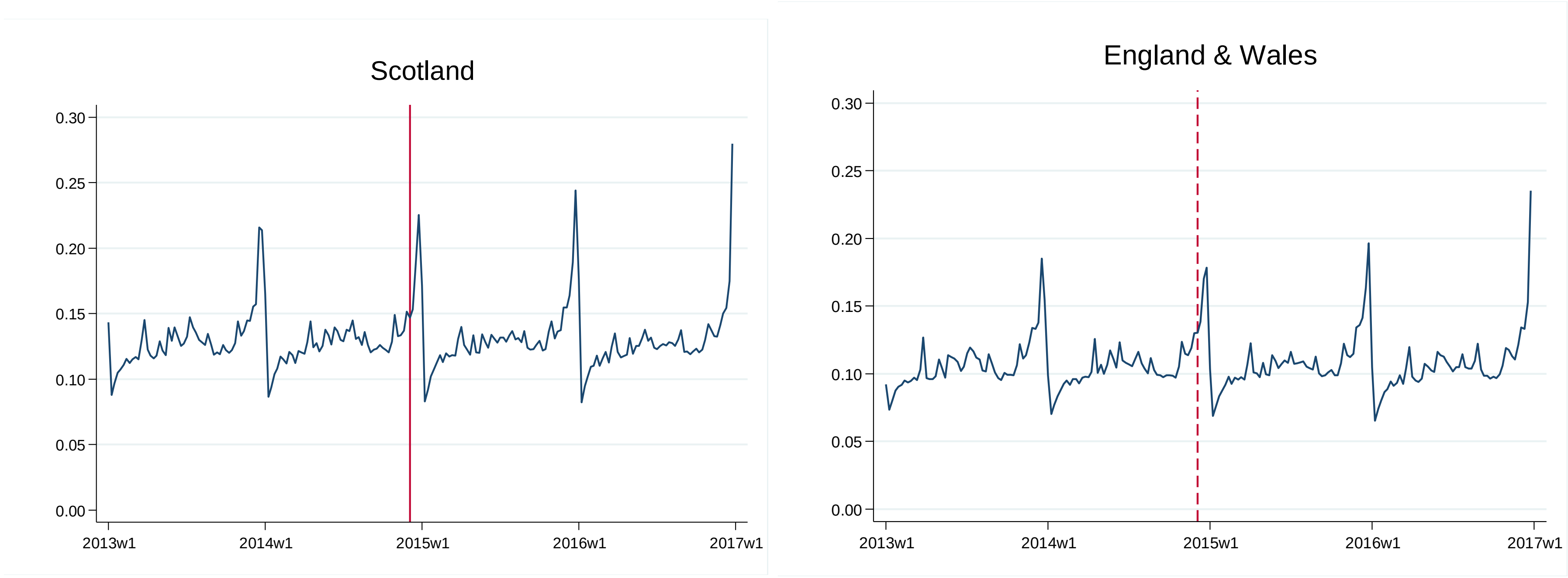


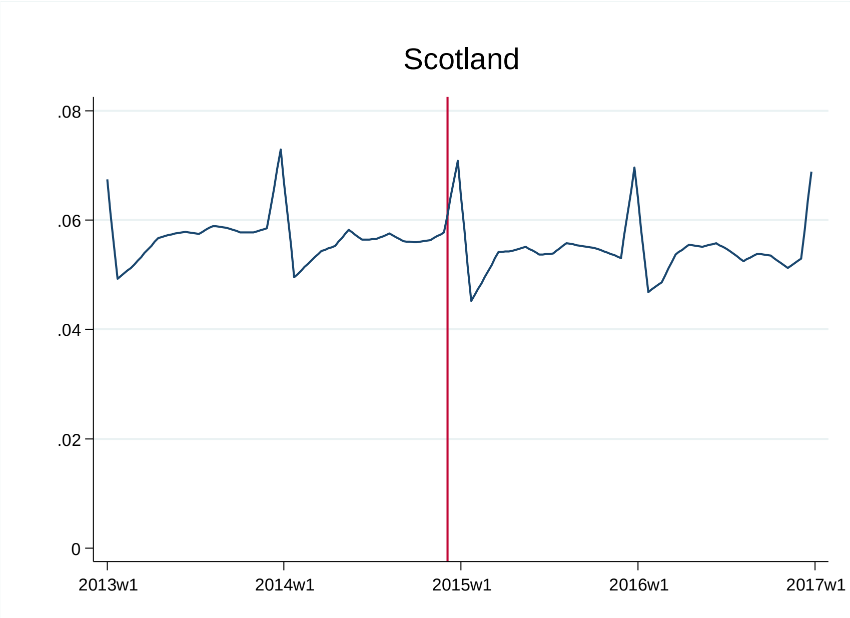
Figure 2: Weekly (a) off-trade and (b) on-trade per capita alcohol sales for Scotland and England & Wales between Jan 2013 and Dec 2016

(a) off-trade



Solid vertical line indicates change in legislation date and dashed line indicates pseudo-change in legislation date; x-axis is weekly time period showing the first week (w1) of each year.

(b) on-trade


Scotland
.08
.06
.04
.02
0
2013w1
2014w1
2015w1
2016w1
2017w1

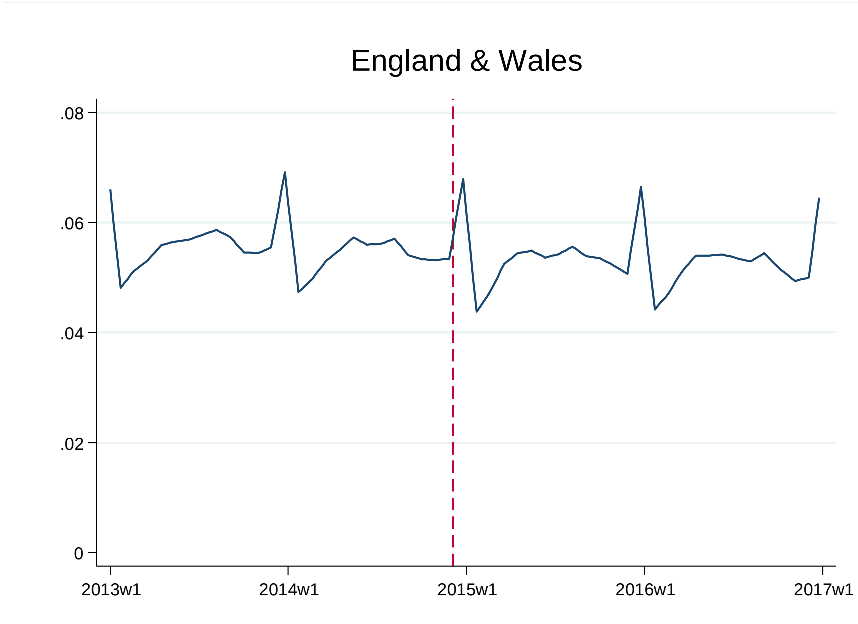

England & Wales
.08
.06
.04
.02
0
2013w1
2014w1
2015w1
2016w1
2017w1

Table 1: Number of road traffic accidents by demographics of driver

		Scotland (n = 34,578)	**England & Wales (n = 527,068)**
Sex	Male	27,075 (78·3)	426,533 (80·9)
	Female	6,938 (20·1)	88,087 (16·7)
	Missing	565 (1·6)	12,448 (2·4)
Age group (years)	< 20	1,716 (4·9)	25,280 (4·8)
	21-25	2,261 (6·5)	38,457 (7·3)
	26-35	5,326 (15·4)	90,880 (17·2)
	36-45	6,343 (18·3)	102,268 (19·4)
	46-55	8,180 (23·7)	111,742 (21·2)
	56-65	5,669 (16·4)	71,698 (13·6)
	66-75	2,798 (8·1)	38,863 (7·4)
	> 75	1,792 (5·2)	25,089 (4·8)
	Missing	493 (1·4)	22,791 (4·3)
Socio-economic deprivation	1 (Most deprived)	4,687 (13·5)	70,881 (13·4)
	2	4,518 (13·1)	69,663 (13·2)
	3	4,118 (12·0)	63,043 (12·0)
	4	3,768 (11·0)	57,301 (10·9)
	5	3,343 (9·7)	50,796 (9·6)
	6	3,082 (9·0)	45,228 (8·6)
	7	2,647 (7·7)	37,540 (7·1)
	8	2,182 (6·3)	31,417 (6·0)
	9	1,735 (5·0)	26,695 (5·0)
	10 (Least deprived)	1,402 (4·0)	19,708 (3·7)
	Missing	3,096 (8·9)	54,796 (10·4)

Data are n (%). An accident can involve more than one driver. Where this occurs, the demographic assignment was based on oldest age group, the most frequent sex, and lowest (most deprived) socio-economic deprivation group (in the supplementary materials, Table S1, shows the corresponding table based on a different demographic assignment – youngest age group, least frequent sex, least deprived socio-economic deprivation group).

Table 2: Modelling results for RTA counts, RTA rates and alcohol consumption

Models	Scotland		England & Wales		Difference-in-difference (Scotland / England & Wales)	
	Effect Size (95% CI)	p-value	Effect Size (95% CI)	p-value	Effect Size (95% CI)	p-value
(a) RTA counts	0·98 (0·91, 1·04)	0·53	0·95 (0·90, 1·00)	0·05	NA	NA
(b) RTA counts	0·98 (0·93, 1·03)	0·40	0·95 (0·93, 0·96)	<0·001	NA	NA
(c) RTA rates	1·01 (0·94, 1·08)	0·77	0·94 (0·89, 0·99)	0·02	1·07 (0·98, 1·17)	0·10
(d) RTA rates	1·00 (0·96, 1·06)	0·73	0·94 (0·92, 0·96)	<0·001	1·07 (1·02, 1·13)	0·007
(e) RTA serious/fatal counts	0·90 (0·80, 1·02)	0·10	0·90 (0·85, 0·96)	0·001	NA	NA
(f) RTA serious/fatal counts	0·90 (0·80, 1·01)	0·08	0·90 (0·87, 0·94)	<0·001	NA	NA
(g) RTA serious/fatal rates	0·93 (0·82, 1·05)	0·24	0·89 (0·84, 0·95)	<0·001	1·04 (0·90, 1·19)	0·59
(h) RTA serious/fatal rates	0·93 (0·83, 1·04)	0·21	0·89 (0·87, 0·92)	<0·001	1·04 (0·92, 1·17)	0·54
(i) SVN RTA counts	0·99 (0·87, 1·15)	0·99	0·93 (0·88, 0·99)	0·03	NA	NA
(j) SVN RTA counts	0·99 (0·87, 1·14)	0·99	0·93 (0·89, 0·97)	0·002	NA	NA
(k) Off-trade per capita alcohol sales	-0·003 (-0·017, 0·011)	0·71	0·012 (-0·005, 0·029)	0·18	NA	NA
(l) On-trade per capita alcohol sales	-0·007 (-0·008, -0·005)	<0·001	0·007 (0·005, 0·008)	<0·001	NA	NA

Negative binomial regression was employed for models a-j. Seasonal autoregressive integrated moving average (SARIMA) was employed for models k & l. Models a, c, e, g & i adjusted for seasonality, underlying temporal trend. Models b, d, f, h & j adjusted for seasonality, underlying temporal trend, age of driver, sex of driver and socio-economic deprivation group of driver. Model k, Scotland - adjusted for on-trade per capita alcohol sales in Scotland and off-trade per capita alcohol sales in England & Wales. Model k, England & Wales - adjusted for on-trade per capita alcohol sales in England & Wales and off-trade per capita alcohol sales in Scotland. Model l, Scotland - adjusted for off-trade per capita alcohol sales in Scotland and on-trade per capita alcohol sales in England & Wales. Model l, England & Wales - adjusted for off-trade per capita alcohol sales in England & Wales and on-trade per capita alcohol sales in Scotland.

Table S1: Number of road traffic accidents by demographics of driver

		Scotland (n = 34,578)	**England & Wales (n = 527,068)**
Sex	Male	9,039 (26·1)	101,420 (19·2)
	Female	24,974 (72·3)	413,200 (78·4)
	Missing	565 (1·6)	12,448 (2·4)
Age group (years)	< 20	4,653 (13·4)	75,155 (14·3)
	21-25	5,560 (16·1)	95,099 (18·0)
	26-35	9,129 (26·4)	142,168 (27·0)
	36-45	6,331 (18·3)	89,037 (16·9)
	46-55	4,847 (14)	59,370 (11·3)
	56-65	2,202 (6·4)	25,673 (4·9)
	66-75	876 (2·5)	11,122 (2·1)
	> 75	487 (1·4)	6,653 (1·3)
	Missing	493 (1·4)	22,791 (4·3)
Socio-economic deprivation	1 (Most deprived)	2,038 (6·0)	30,145 (5·7)
	2	2,476 (7·2)	38,228 (7·3)
	3	2,645 (7·6)	42,216 (8·0)
	4	3,024 (8·7)	45,461 (8·6)
	5	3,183 (9·2)	47,227 (9·0)
	6	3,515 (10·2)	49,942 (9·5)
	7	3,517 (10·2)	51,408 (9·7)
	8	3,663 (10·6)	53,754 (10·2)
	9	3,884 (11·2)	56,955 (10·8)
	10 (Least deprived)	3,628 (10·5)	56,936 (10·8)
	Missing	3,096 (8·9)	54,796 (10·4)

Data are n (%). An accident can involve more than one driver. Where this occurs, the demographic assignment was based on youngest age group, the least frequent sex, and highest (least deprived) socio-economic deprivation group.

Table S2: Modelling results for RTA counts, RTA rates, RTA serious/fatal counts, RTA serious/fatal rates and SVN RTA counts

Models	**Scotland**		**England & Wales**		**Difference-in-difference (Scotland / England & Wales)**	
	Effect Size (95% CI)	p-value	Effect Size (95% CI)	p-value	Effect Size (95% CI)	p-value
(a) RTA counts	0·98 (0·91, 1·04)	0·53	0·95 (0·90, 1·00)	0·05	NA	NA
(b) RTA counts	0·98 (0·93, 1·03)	0·42	0·95 (0·93, 0·98)	<0·001	NA	NA
(c) RTA rates	1·01 (0·94, 1·08)	0·77	0·94 (0·89, 0·99)	0·02	1·07 (0·98, 1·17)	0·10
(d) RTA rates	1·01 (0·96, 1·06)	0·72	0·94 (0·92, 0·97)	<0·001	1·07 (1·01, 1·13)	0·02
(e) RTA serious/fatal counts	0·90 (0·80, 1·02)	0·10	0·90 (0·85, 0·96)	<0·001	NA	NA
(f) RTA serious/fatal counts	0·91 (0·81, 1·02)	0·11	0·91 (0·88, 0·94)	<0·001	NA	NA
(g) RTA serious/fatal rates	0·93 (0·82, 1·05)	0·24	0·89 (0·84, 0·95)	<0·001	1·04 (0·90, 1·19)	0·59
(h) RTA serious/fatal rates	0·94 (0·84, 1·05)	0·28	0·90 (0·87, 0·93)	<0·001	1·04 (0·93, 1·18)	0·48
(i) SVN RTA counts	0·99 (0·87, 1·15)	0·99	0·93 (0·88, 0·99)	0·03	NA	NA
(j) SVN RTA counts	0·99 (0·87, 1·14)	0·99	0·93 (0·89, 0·97)	0·002	NA	NA

Negative binomial regression was employed for models a-j. Models a, c, e, g & i adjusted for seasonality, underlying temporal trend. Models b, d, f, h & j adjusted for seasonality, underlying temporal trend, age of driver, sex of driver and socio-economic deprivation group of driver. Demographic assignment was based on youngest age group, least frequent sex, and least deprived socio-economic deprivation group.

Table S3: Modelling results for SVN/MVD, MVD RTA count, serious RTA rates and fatal RTA rates

Models	**Scotland**		**England & Wales**		**Difference-in-difference (Scotland / England & Wales)**	
	Effect Size (95% CI)	p-value	Effect Size (95% CI)	p-value	Effect Size (95% CI)	p-value
(a) SVN/MVD	1·06 (0·76, 1·47)	0·75	0·98 (0·80, 1·20)	0·84	1·08 (0·73, 1·59)	0·70
(b) SVN/MVD	0·90 (0·72, 1·14)	0·41	0·98 (0·91, 1·05)	0·54	0·92 (0·72, 1·19)	0·55
(c) MVD RTA count	0·95 (0·95, 1·05)	0·31	0·94 (0·88, 1·00)	0·07	NA	NA
(d) MVD RTA count	0·97 (0·89, 1·05)	0·50	0·94 (0·92, 0·97)	<0·001	NA	NA
(e) serious RTA rates	0·94 (0·82, 1·06)	0·32	0·89 (0·84, 0·94)	<0·001	1·05 (0·91, 1·21)	0·46
(f) serious RTA rates	0·94 (0·83, 1·05)	0·29	0·89 (0·86, 0·92)	<0·001	1·05 (0·93, 1·19)	0·40
(g) fatal RTA rates	0·87 (0·62, 1·24)	0·45	0·99 (0·87, 1·20)	0·86	0·88 (0·61, 1·28)	0·51
(h) fatal RTA rates	0·87 (0·62, 1·23)	0·44	0·99 (0·88, 1·11)	0·85	0·88 (0·61, 1·27)	0·50

Gamma regression and negative binomial regression was employed for models a & b and c-h, respectively. Models a, c, e & g adjusted for seasonality, underlying temporal trend. Models b, d, f, & h adjusted for seasonality, underlying temporal trend, age of driver, sex of driver and socio-economic deprivation group of driver. Demographic assignment based on eldest age group, the most frequent sex, and lowest (most deprived) socio-economic deprivation group. In models a & b the covariates of age of driver, sex of driver and socio-economic deprivation group of driver had two levels each due to models with finer categorisation (see Table 1) not converging.

Table S4: Modelling results by level of socio-economic deprivation (interaction model)

Models		**Scotland**		**England & Wales**	
	Socio-economic deprivation (quintile)	Effect Size (95% CI)	p-value	Effect Size (95% CI)	p-value
RTA counts	1st	1·00 (0·92, 1·10)	0·93	0·96 (0·94, 0·99)	0·008
	2nd	1·00 (0·90, 1·10)	0·95	0·96 (0·93, 0·98)	0·004
	3rd	0·93 (0·83, 1·04)	0·19	0·94 (0·91, 0·97)	<0·001
	4th	1·01 (0·87, 1·15)	0·90	0·93 (0·90, 0·97)	0·001
	5th	0·92 (0·79, 1·08)	0·32	0·94 (0·90, 0·98)	0·01
RTA rates	1st	1·03 (0·95, 1·13)	0·44	0·95 (0·93, 0·98)	0·001
	2nd	1·03 (0·93, 1·13)	0·59	0·95 (0·92, 0·97)	<0·001
	3rd	0·96 (0·86, 1·07)	0·44	0·93 (0·90, 0·96)	<0·001
	4th	1·04 (0·91, 1·18)	0·56	0·93 (0·89, 0·96)	<0·001
	5th	0·95 (0·81, 1·11)	0·54	0·93 (0·89, 0·97)	0·003

Demographic assignment based on eldest age group, the most frequent sex, and lowest (most deprived) socio-economic deprivation group.

Table S5: Modelling results by level of socio-economic deprivation (interaction model)

Models		**Scotland**		**England & Wales**	
	Socio-economic deprivation (quintile)	Effect Size (95% CI)	p-value	Effect Size (95% CI)	p-value
RTA counts	1st	1·03 (0·91, 1·18)	0·61	1·00 (0·95, 1·04)	0·92
	2nd	0·98 (0·87, 1·10)	0·77	0·96 (0·92, 1·00)	0·03
	3rd	0·97 (0·87, 1·08)	0·60	0·95 (0·92, 1·00)	0·01
	4th	1·00 (0·90, 1·11)	0·96	0·95 (0·91, 0·98)	0·006
	5th	0·93 (0·87, 1·03)	0·14	0·93 (0·90, 0·96)	<0·001
RTA rates	1st	1·06 (0·93, 1·22)	0·33	0·99 (0·94, 1·03)	0·59
	2nd	1·01 (0·90, 1·14)	0·84	0·95 (0·91, 0·98)	0·008
	3rd	1·00 (0·90, 1·11)	0·98	0·94 (0·91, 0·98)	0·002
	4th	1·03 (0·93, 1·15)	0·53	0·94 (0·90, 0·97)	0·001
	5th	0·95 (0·86, 1·06)	0·37	0·92 (0·89, 0·95)	<0·001

Demographic assignment was based on youngest age group, the least frequent sex, and highest (least deprived) socio-economic deprivation group.

*Manuscript with revisions highlighted

Evaluating the impact of lowering blood alcohol concentration limits for drivers on road traffic accident rates and alcohol consumption: a natural experiment

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Summary

Background Drink-driving is ~~a key~~an important risk factor for road traffic accidents (RTAs) which cause high levels of morbidity and mortality globally. Lowering the permitted blood alcohol concentration (BAC) for drivers is a common public health intervention enacted in countries and jurisdictions across the world. In Scotland, on 5th December 2014, the BAC limit for drivers was reduced from 0·08 g/dL to 0·05 g/dL. This study evaluated the impact of this change on RTA and alcohol consumption outcomes.

Methods We employed an observational, comparative interrupted time series design using data from the whole of the intervention (Scotland) and control (England & Wales) groups for the period January 2013 to December 2016. Weekly counts of RTAs were obtained from police accident records and weekly off-trade and four-weekly on-trade alcohol consumption was estimated from market research data. We used data from automated traffic counters as denominators to calculate RTA rates. We estimated the effect of the intervention on RTA and alcohol consumption outcomes using negative binomial panel regression and seasonal autoregressive integrated moving average models, respectively.

Findings The change in drink-drive legislation was associated with a 1% increase in total RTA rates in Scotland (rate ratio (RR) 1·01; 95% CI 0·94, 1·08; p=0·77) after adjustment for seasonality and underlying temporal trend. When expressed relative to England ~~and~~ & Wales, where the intervention did not happen, the association was estimated as a 7% increase in total RTA rates (RR 1·07; 95% CI 0·98, 1·17; p=0·10). Similar findings were observed for serious/fatal RTAs and single vehicle night-time RTAs. For alcohol consumption, in Scotland, the change in legislation was associated with a 0·3% decrease (relative change) for consumption measured by per capita off-trade sales (-0·3%;-1·7%, 1·1%; p=0·71) and a 0·7% decrease in per capita on-trade sales (-0·7%;-0·8%, -0·5%; p<0.001).

Interpretation Lowering the BAC limit to 0·05 g/dL from 0·08 g/dL in Scotland was not associated with a reduction in RTAs, but was associated with a small reduction in per capita on-trade alcohol sales. One plausible explanation is that the legislative change was not suitably enforced, for example with random breath testing measures. Our findings suggest that changing the legal BAC limit in isolation does not improve RTA outcomes. These findings have significant policy implications internationally as several countries and jurisdictions consider a similar reduction in BAC limit.

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Research in context

Evidence before this study

Road traffic accidents (RTAs) are a major public health problem with 1·~~.~~25 million road traffic deaths globally in 2013. There is strong evidence that a person's ability to drive a vehicle is impaired if alcohol is in their bloodstream, and drink driving is an important risk factor of RTAs. There is a dose-response relationship between blood alcohol concentration (BAC) and RTA rates, with evidence showing the odds of fatal injury increase by 1·~~.~~74 for every 0·~~.~~02% increase in BAC.

There is international evidence that levels of severe and fatal RTAs reduce when a country or region changes the legal BAC limit from 0·08 to 0·05 g/dL. However, these studies have limitations including confounding of BAC intervention effect with other interventions (random breath testing (RBT)) and poor study design (e.g. before-and-after studies not accounting for temporal trends, not having a control group, and high level of aggregation for units of time in analysis). A European study which analysed data from 15 countries found that the legislation change was associated with a 7·4% reduction in road fatality rates (attenuating to 4·3% after adjustment for RBT). An earlier study which evaluated legislation change in two Australian states in the early 1980s, found a similar effect size in one state and 14-18% reductions in severe and fatal RTAs in the other.

Added value of this study

Our findings indicate that the reduction in Scotland's drink-drive limit in December 2014 did not have the intended effect of reducing RTAs. It reduced on-trade alcohol sales (e.g. in bars, restaurants, etc.) by less than 1% but did not impact off-trade sales (e.g. from supermarkets, convenience stores, etc.) which counts for approximately three-quarters of total sales~~)~~.

We evaluated a change in drink-drive legislation from BAC 0·08 to 0·05 g/dL in an entire population, reducing the risk of selection biases. RBT was not in place in Great Britain during the study allowing us to isolate the effect of changing the BAC legal limit. A strong counterfactual was provided by neighbouring countries (England ~~and~~ & Wales) to the intervention country (Scotland) and the same data sources were used for both groups. This new evidence from a recent intervention is important as it may be that larger effect sizes seen historically may be more difficult to obtain in an era of improved road safety and, regardless of BAC limits, where drink-driving is increasingly socially unacceptable.

Implications of all the available evidence

This drink-drive limit change occurred in the context of a lack of additional police enforcement and without RBT measures in place. Our finding of a null BAC 0·08 to 0·05 g/dL intervention effect supports the hypothesis that enhanced enforcement may be necessary to bring about improvements in RTA outcomes. However, further research is required to test whether an appropriately enforced change in drink-drive legislation from BAC 0·08 to 0·05 g/dL would improve outcomes.

Introduction

Road traffic accidents (RTAs) are a major public health problem with 1·~~.~~25 million road traffic deaths globally in 2013 (1). In Great Britain (GB), there have been large reductions in RTAs over recent decades, with a 72% reduction in fatal RTAs observed between 1979 and 2017, but they remain a considerable burden on health with 170,993 RTA casualties reported in 2017 (2). Driving under the influence of alcohol ~~(drink-driving)~~ is a major risk factor for RTAs with a dose-response relationship observed between blood alcohol concentration (BAC) level and RTAs. It has been estimated that the odds of fatal injury increase by 1·~~.~~74 for every 0·~~.~~02% increase in BAC (3). In GB, there were at least 6,070 RTAs involving a drink-driver in 2016 (4).

Since Norway first introduced a legal BAC limit in 1936, other countries across Europe, North America, Japan, Australasia, and US have followed (5), initially with introducing a standard BAC limit (of 0·05, 0·08 or 0·1 g/dL) and with some countries going on to further lower the limit. In Europe, only England ~~and~~ & Wales and Malta, have a 0·08 g/dL BAC limit. Such limits, and higher, are the norm in many other jurisdictions including many states in the USA, despite long-standing calls for reductions. According to European Commission recommendations, BAC limits should be set at 0·~~.~~05 g/dL (6). The British Road Safety Act (BRSA) introduced a legal limit of 0·08 g/dL in 1967, which is still in place today. An exception is Scotland where the BAC limit was reduced to 0·05 g/dL on 5th December 2014. It has been estimated that drink-driver injury accidents cost the Scottish economy £80m per year (7).

There is an evidence base on the effectiveness of reducing BAC levels from countries, and jurisdictions within countries, that have changed legislation to deter drink-driving and in turn to prevent RTAs. Evaluations of the impact of a reduction in drink-drive limits in different parts of the world such as Australia (8), France (9), Austria (10), and Serbia (11), provide evidence that such legislation is effective in reducing RTAs. A recent meta-analysis (12), estimates that a (general) lowering of the BAC limit is associated with a 5% decline in non-fatal alcohol-related crashes, and lowering to 0·05 g/dL is associated with a 11% decline in fatal alcohol-related crashes.

In an interrupted time-series study where the main focus was evaluating random breath testing (RBT), Henstridge *et al.* (8), evaluated a reduction in BAC limit from 0·08 to 0·05 g/dL in New South Wales (NSW) and Queensland (QLD), Australia. These changes in BAC limit occurred in December 1980 (NSW) and December 1982 (QLD) and the evaluation was not confounded by RBT as this was introduced at a later point. In NSW (QLD) the study reported 7% and 8% (14% and 18%) reductions in severe and fatal RTA counts, respectively. Albalate (13) conducted a differences-in-differences analysis of data from 15 European countries for the period 1991-2003 and found that a BAC limit of 0·05 g/dL, or lower, compared to higher limits was associated with a 4·5% and 7·4% reduction in road fatality rates (using population and per distance driven denominators, respectively). Importantly, these effect sizes attenuated to 3·4% and 4·3% and were no longer statistically significant when RBT was adjusted for.

If any BAC intervention effect is homogeneous across the population under study then it could affect absolute levels of socio-economic deprivation inequality for RTAs: level of alcohol consumption is positively associated with the probability of drink-driving (14) and higher levels of socio-economic deprivation are associated with higher levels of alcohol consumption per drinker (15), but also with lower driving rates.

~~Further, i~~It has been hypothesised that population drinking (i.e. per capita alcohol consumption) is associated with driving under the influence of alcohol (16). If true, an unintended outcome of a change in BAC legislation could be a reduction in per capita alcohol consumption.

We aimed to evaluate whether lowering the permitted blood alcohol concentration (BAC) from 0·08 to 0·05 g/dL in Scotland had an impact on both road traffic accidents (RTAs) rates and population alcohol consumption. Further, ~~and~~we evaluated whether any impacts varied by level of socio-economic deprivation. Our study design allowed us to isolate the effect of changing the BAC legal limit and assessed the sole effect of change in legislation without any enhanced law enforcement measures such as RBT. A strong counterfactual was also provided by neighbouring countries (England ~~and~~ & Wales) to the intervention country (Scotland). Furthermore, to our knowledge, no previous study has evaluated whether a legislation change of BAC limit has led to a reduction in that country's population drinking. These matters are of significant policy importance as other countries and jurisdictions across the world consider similar lowering of BAC limits.

Methods

Design

A comparative interrupted time series design using data measured between January 2013 and December 2016 was employed. The intervention group was Scotland and the control group was England & Wales.

Outcome measures

The primary outcome was weekly RTA rates rather than counts as this allows for a 'Differences-in-Differences' (DiD) type measure of effect size (see 'Statistical analysis' below). Weekly counts of RTAs that took place on public roads in GB and were reported to the police (using STATS19 accident reporting form (17)) were obtained. Any given accident could involve more than one driver and casualty but we considered 'accident' as the most appropriate unit for analysis. To calculate weekly RTA rates, the number of miles driven by each person at risk of having a RTA would be the ideal denominator but is not available. As a proxy for this, data from automatic traffic counters (ATCs) (18) were used. ATCs count vehicles passing over them 24 hours a day across the road network. The location of the approximately 300 ATCs are placed to be representative of the entire GB road network, including motorways, major roads (providing large-scale transport linkage) and minor roads (feeding traffic between major roads and smaller roads). We accounted for poor quality or missing ATC data by using a multiple imputation approach that is specifically designed for time series data (19).

In STATS19, the severity of an RTA is recorded as the most severely injured casualty, namely fatal, serious or slight. To facilitate comparison with previous literature, and because it can be argued that serious and fatal RTAs are more likely to be influenced by drink-driving, we used weekly serious/fatal RTA rates as a secondary outcome. We tested the sensitivity of combining serious with fatal RTAs by modelling each outcome separately. As an additional outcome likely to be influenced by drink-driving, we used single vehicle night-time (SVN) RTAs and the ratio of SVN to multiple vehicle day-time (MVD) RTAs as secondary outcomes (and MVD RTAs outcomes alone). The ~~other~~final secondary outcome measure, alcohol consumption, was measured by volume of off- and on-trade alcohol retail sales. This is a high quality measure not reliant on individual self-report that is prone to bias.

These data were provided by NHS Health Scotland for the period 2013-2016 who obtained them from the market research company, Nielsen (20). Off-trade alcohol sales (from retailers licensed to sell alcohol for consumption on the premises, e.g. bars, restaurants, etc.) were available in weekly units but on-trade alcohol sales (from retailers licensed to sell alcohol for consumption off the premises, e.g. supermarkets, convenience stores, etc.) were only available in 4-weekly units. We used a linear interpolation method to impute weekly on-trade sales. Per capita estimates were obtained by dividing the total volume of pure alcohol sold by adult (16 years and over) population size for Scotland, and England ~~and~~ & Wales, combined.

Statistical analysis

To assess the comparability of the intervention and control groups, we compared age, sex and socio-economic deprivation characteristics. As the unit of analysis was an RTA, when the RTA involved more than one vehicle the eldest age group of the drivers, the most frequent sex, and the most 'deprived' socio-economic deprivation level (generated from postcode of driver) was used for analysis. We used an area-based measure of socio-economic deprivation levels separately for Scotland and England & Wales. Socio-economic deprivation was measured by the Index of Multiple Deprivation (IMD) provided by Scottish and UK Governments (21-23). We repeated our analyses using a different rule of 'demographic assignment' (the youngest age group, the least frequent sex, the least deprived socio-economic deprivation level) to check the sensitivity of results.

To test for a change in RTA counts and rates, after the new legislation was in place, negative binomial regression models were fitted to panel data sets, separately for the intervention and control groups. For modelling of rates, traffic flows were used as a denominator. The models were adjusted for underlying temporal trend by fitting a covariate representing week number, and for seasonality by covariates representing 4-weekly periods of the year (13 'months').

The models were then further adjusted for age, sex and socio-economic deprivation.– To obtain a 'Differences-in-Differences' (DiD) type measure of effect, the two panel data sets were appended and an interaction term between intervention group indicator and the binary covariate for indicating pre- and post-change in legislation ('pseudo' change for control) was assessed. In this model an interaction term between week number and intervention group indicator allowed for a relaxation of the usual DiD 'parallel trends' assumption. We tested whether socio-economic deprivation moderated any effect of the law change on total RTA rates, by including in our statistical models an interaction term between the intervention group indicator and socio-economic deprivation.

For alcohol consumption, separately for off- and on-trade alcohol sales and for the intervention and control groups, time series seasonal autoregressive integrated moving average (SARIMA) models were fitted. SARIMA was considered the best model choice to account for the very strong seasonality in the alcohol consumption outcome. Logarithms of the outcome measures were used in the modelling to reduce the variability in the time series and to aid interpretation. The form of the autocorrelation for the SARIMA errors was identified from autocorrelation plots and partial autocorrelation plots. SARIMA was designed, for both intervention and control groups, in four different formats. Off-trade sales models controlled for off-trade sales of the alternative group, on-trade sales of the same group, and trend. Similarly, on-trade sales models controlled for on-trade sales of alternative group, off-trade sales of same group, and trend. We conducted tests of residual correlation using correlograms to ensure that final models had a good fit with "white noise" Normally-distributed residuals.

A statistical significance level of 0.05 is used throughout. All analyses were conducted using Stata/SE 14·2 software (Stata Corp., College Station, TX, USA; URL http://www.stata.com).

Results

Weekly RTA counts and rates plotted over time are presented in Figure 1 with a vertical line indicating the change in drink-drive legislation date. It can be seen that, generally, weekly RTA rates are higher in England & Wales than Scotland (broadly, the rates are between 5 to 9 RTAs per 1000 traffic count in Scotland, with the corresponding figures being 6 to 10 for England ~~and~~ & Wales (Figure 1b). By contrast, the weekly serious/fatal RTA rates are at similar levels across the four years of the study (Figure 1d~~d~~). It is worth noting that over the study period fatal RTAs count for 1·9% and 1·1% of all RTAs in Scotland and England & Wales, respectively. Although it was not possible to calculate weekly SVN rates due to time of day not being recorded by the ATCs, the weekly SVN counts are shown in Figure 1e. Figure 2 illustrates weekly off- and on-trade per capita alcohol sales over time. Strong seasonal patterning is shown with large peaks and smaller troughs at the end and start of a calendar year, respectively.

Table 1 shows age, sex and socio-economic deprivation characteristics of the RTAs by intervention and control groups. The distributions are very similar between the groups and this remained true when we changed the demographic assignment rule (see Table S1). The mean (SD) number of drivers (vehicles) per RTA was 1·72 (0·73) and 1·84 (0·71) in Scotland and England & Wales, respectively. The corresponding figures for number of casualties per RTA was 1·29 (0·77) and 1·33 (0·82).

Table 2 shows the change in drink-drive legislation was associated with a 2% decrease in total RTA counts in Scotland that did not reach statistical significance (rate ratio (RR) 0·98; 95% CI (0·91, 1·04); p=0·53). However, the pseudo-change in legislation was associated with a 5% decrease in RTA counts in England & Wales (RR 0·95; 95% CI (0·90, 1·00); p=0·05). Similar results were observed when modelling total RTA rates and the DiD type estimate indicates a 7% increase in total RTA rates for Scotland relative to England & Wales (RR 1·07; 95% CI (0·98, 1·17); p=0·10). The DiD type estimate for serious/fatal RTA rates indicates a 4% increase in serious/fatal RTA rates for Scotland relative to England & Wales (RR 1·04; 95% CI (0·90, 1·19); p=0·59). In a sensitivity analysis, similar results were found when modelling serious and fatal RTA rates separately (see Table S3). For SVN RTA counts, the models show a 1% decrease in Scotland (RR 0·99; 95% CI (0·87, 1·15); p=0·99) and a 7% decrease in England & Wales (RR 0·93; 95% CI (0·88, 0·98); p=0·03). Adjustment for age, sex and socio-economic deprivation changed these results minimally (see Table 2), as did changing the demographic assignment rule (see Table S3~~2~~). Further, similar null effects for Scotland were observed when SVN/MVD, and MVD, outcomes were modelled (see Table S3).

We found no statistical evidence of effect modification by socio-economic deprivation for total RTA rates (tests of interaction: Scotland – p=0·72 (RTA counts), p=0·71 (RTA rates); England ~~and~~ & Wales – p=0·58 (RTA counts), p=0.58 (RTA rates). This is illustrated in Tables S~~3~~5 and S~~4~~6 where it can be seen that effect sizes only vary minimally across levels of socio-economic deprivation.

For alcohol consumption, in Scotland, the change in legislation was associated with a non-statistically significant 0.3% relative decrease in per capita off-trade sales (-0·3%; 95% CI (-

1·7%, 1·1%); p=0·71) and a statistically significant 0·7% decrease in per capita on-trade sales (-0·7%; 95% CI (-0·8%, -0·5%); p<0·001). The corresponding results for the effect of the pseudo-change in legislation in England & Wales indicate increases in per capita off- and on-trade sales.

Discussion

We found that lowering BAC limit from 0·08 to 0·05 g/dL in Scotland was not associated with a change in the level of RTAs in the first two years post-legislation change. These null findings for total, ~~and~~ serious/fatal and SVN RTAs were unexpected given previous evidence generally supports a reduction of RTA outcomes following a lowering of a BAC limit. The 95% CIs of our results (see Table 2) do not include effect sizes of the magnitude that were reported by Henstridge *et al.* (8) and Albalate (13). For off-trade alcohol sales, we found no evidence of an intervention effect and these sales account for a large proportion of alcohol consumption in Scotland (73% of total alcohol sales in 2017 (24)). We did observe a small reduction (less than 1%) in on-trade alcohol sales and further research is underway to explore perceptions of the impact of the BAC limit change from the perspectives of owners/managers in on-trade.

Our study employed a ~~strong~~ well-designed controlled natural experiment ~~design~~, with England ~~and~~ & Wales providing a counterfactual for RTA and alcohol consumption trends in the absence of the BAC intervention. The same data sources were used for both Scotland and England ~~and~~ & Wales helping to reduce measurement error. The distribution of demographics was very similar between the intervention and control groups which adds further weight that the choice of control group is appropriate. Using large nationally representative data sets, and with two years pre- and post-legislation change weekly data points, we had a high level of statistical power resulting in good precision around effect size estimates. The long follow-up makes it unlikely that we have missed any lagged effect of the intervention.

Our study has limitations; firstly, we were unable to use alcohol-related RTAs as an outcome measure. BAC levels in drivers/riders involved in RTAs are often not available or are unreliable (8). For example, in GB only half of all drivers/riders involved in RTAs are breath tested by police (25) and for fatal RTAs there are often long delays in getting BAC from coroner's reports and BAC naturally reduces with time. Moreover, in STATS19 the BAC level is not recorded, just whether the reading was "over the limit" which would present a methodological challenge with the limit changing over time in Scotland. Secondly, we have not adjusted for potential time-varying confounding factors such as weather and road quality. This would only be important if they were substantially different in the intervention and control groups and we do not think this is likely. Further, we are not aware of any other concurrent interventions that took part in Scotland and not in England ~~and~~ & Wales, ~~and~~or vice versa. Thirdly, we acknowledge that not all RTAs will become known to the police (26), and many casualties of RTAs who attend hospital will not be captured in STATS19. However, this would only bias our results if differential between the intervention groups, and this is unlikely. Lastly, the traffic flow denominators obtained from ATCs are a proxy for distance travelled by each person at risk of having a RTA, and there were data quality issues with the denominator we used for the rates (addressed by multiple imputation), but they are superior to using a population denominator as it more accurately reflects those at risk of event. Moreover, although the location of the (approximately) 300 ATCs across GB are placed to be broadly representative of the entire road network, they provide only a set of point estimates. Nevertheless, they provide good data on how traffic flows vary on a temporal basis and it is noteworthy that the effect sizes we obtained from models using them closely match the results from modelling RTA counts (see Table 2).

The most plausible explanation of no effect of lowered BAC limit on RTA outcome is insufficient enforcement, publicity, or both. The European commission stated that a key to success of lowering drink-~~–~~drive legislation is the introduction along with enforcement of frequent and systematic random breath testing, supported by public education, publicity and awareness campaigns involving all stakeholders (27). Further, previous research supports an association between increased enforcement level and decreased RTAs (9). In particular, RBT is recognised as the principal drink-driving law enforcement strategy throughout Australia as the best universal example in implementing RBT (28), with evidence illustrating most of the decline in alcohol-related traffic injuries and fatalities has been attributed to the implementation of RBT (29). There is evidence that enforcement levels have reduced in GB with English police force data showing 25% fewer RBTs in 2015 compared to 2011 (30), and in Scotland initial investment in public education and media campaigning at the time of the drink-drive limit reduction in December 2014 was not maintained in the following years. Other explanations are, firstly, i~~I~~t may be that the majority of drink-driving RTAs are caused by people who continue to ignore the law under the new legislation, or that people who previously used to drink-drive between the new and old limits have changed their behaviours but are responsible for only a small fraction of all RTAs. Secondly, it may be that larger effect sizes seen historically for BAC lowering interventions may be more difficult to obtain in an era of improved road safety and where drink-driving is increasingly socially unacceptable. Lastly, it may be that non-alcohol-related RTAs have increased in Scotland over the study period, masking an intervention effect, but given the SVN/MVD and MVD

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Formatted: Font: (Default) +Headings CS, 12 pt, No underline modelling results we think this is unlikely. Further research exploring these and other possible explanations for the findings is needed.

Our findings indicate that the reduction in Scotland's drink-drive limit in December 2014 did not have the intended effect of reducing RTAs. It was associated with reduced on-trade alcohol sales by less than 1% but there was no association with changes in off-trade sales (which account for approximately three-quarters of total sales). This suggests that a reduction in BAC limit from 0·08 to 0·05 g/dL is not effective in reducing RTAs without being accompanied by other measures such as enhanced enforcement. These findings have significant policy implications internationally as several countries and jurisdictions consider a similar reduction in BAC limit.

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Contributors

HH was the lead researcher on the study, leading the preparation of all analyses and drafting of the manuscript; JL led the design and execution of the study, oversaw all analyses and interpretation, and led the drafting and writing of the manuscript; DFM contributed to the overall design, in particular the design and analysis of the statistical analyses and commented on manuscript drafts; EM contributed to the overall design and commented on manuscript drafts; JP contributed to the overall design and commented on manuscript drafts; AJ contributed to the design, provided advice on aspects of the statistical analyses, and commented on manuscript drafts; NF contributed to the interpretation of results, and commented on manuscript drafts; MR contributed to the overall design, provided interpretation of results, and commented on manuscript drafts.

JL, as corresponding author, confirms that all authors have seen and approved the final text.

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Declaration of interests

HH, JL, DFM, JP and AJ declare no competing interests. EM is a member of the NIHR PHR funding board. NF reports personal fees from World Health Organization-Europe, outside the submitted work. MR reports grants from Scottish Government ~~,~~ during the conduct of the study.

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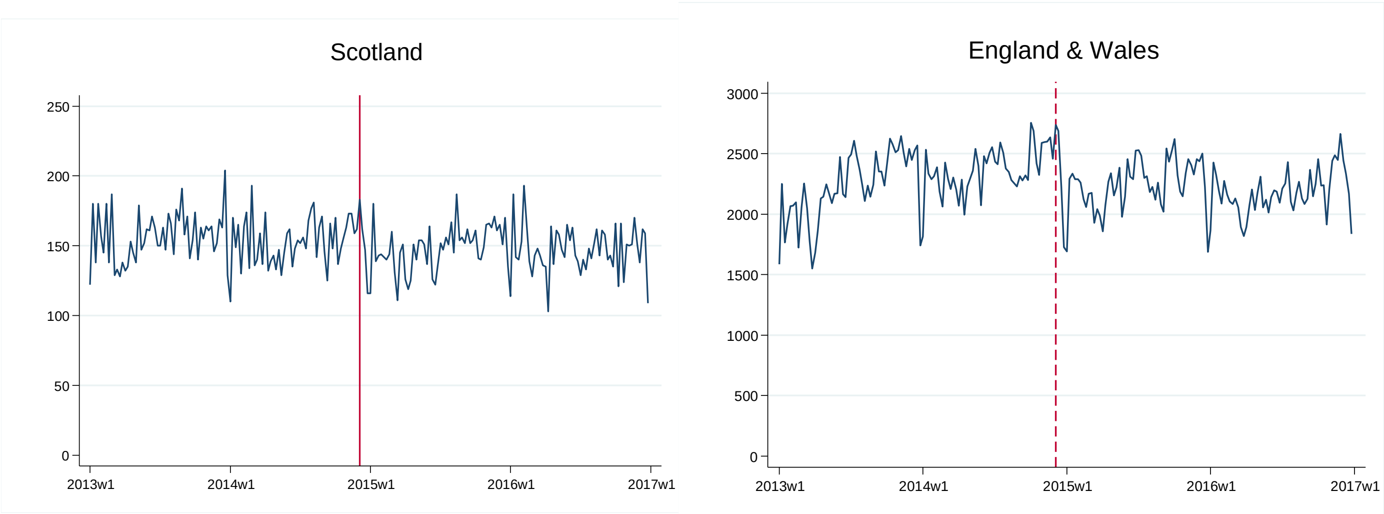
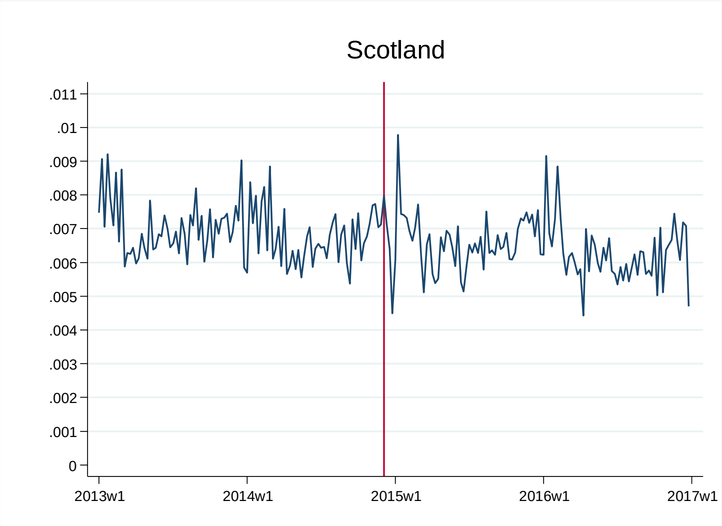
Figure 1: Weekly (a) Total RTA counts, (b) Total RTA rates, (c) Serious/fatal RTA counts, ~~and~~ (d) Serious/fatal RTA rates, and (e) SVN counts for Scotland and England & Wales between Jan 2013 and Dec 2016

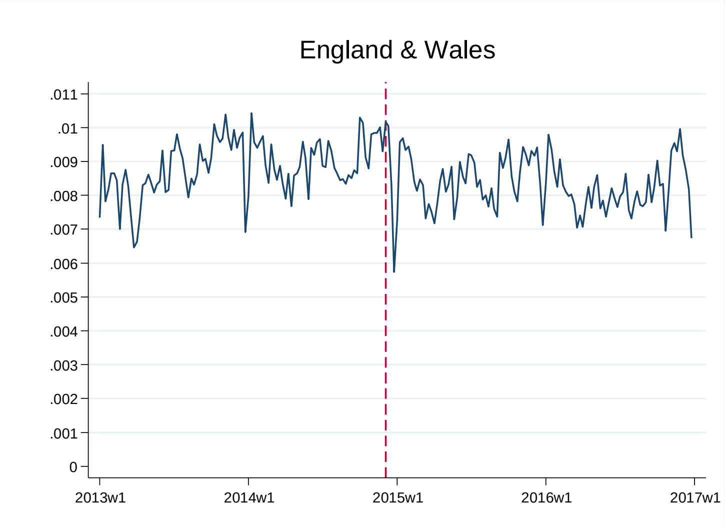
(a) Total RTA counts



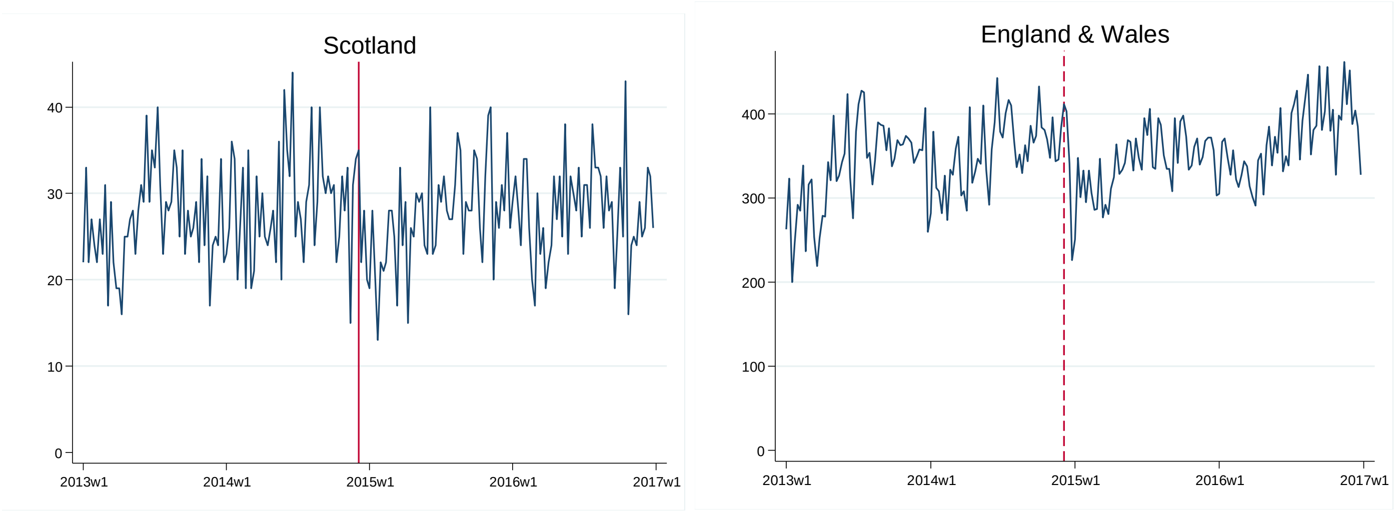
Solid vertical line indicates change in legislation date and dashed line indicates pseudo-change in legislation date; x-axis is weekly time period showing the first week (w1) of each year.

(b) Total RTA rates

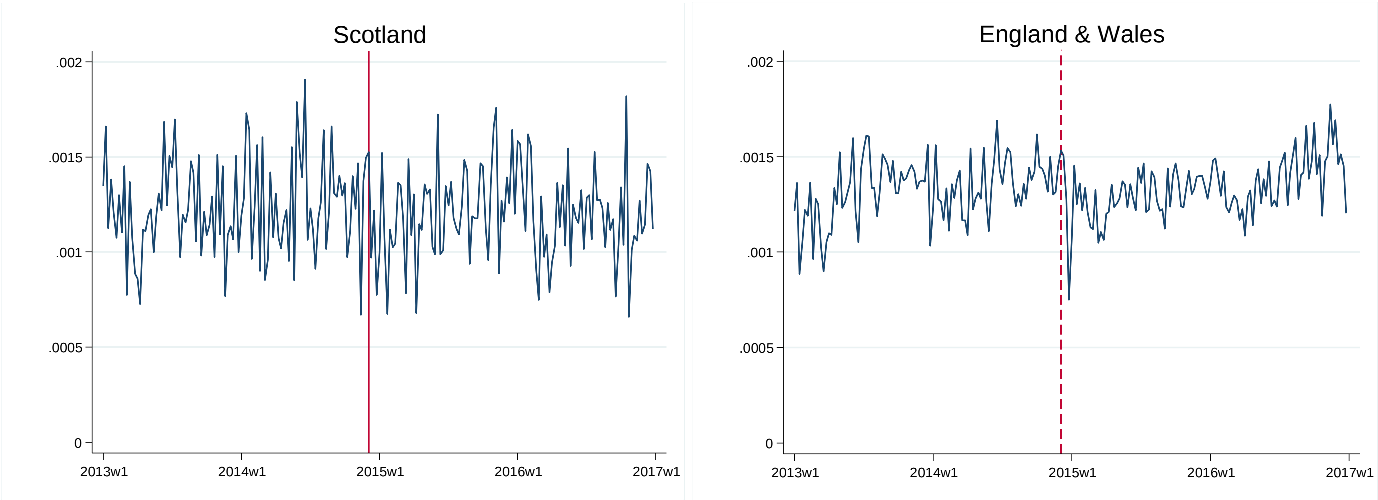




(c) Serious/fatal RTA counts



(d) Serious/fatal RTA rates



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(e) SVN RTA counts

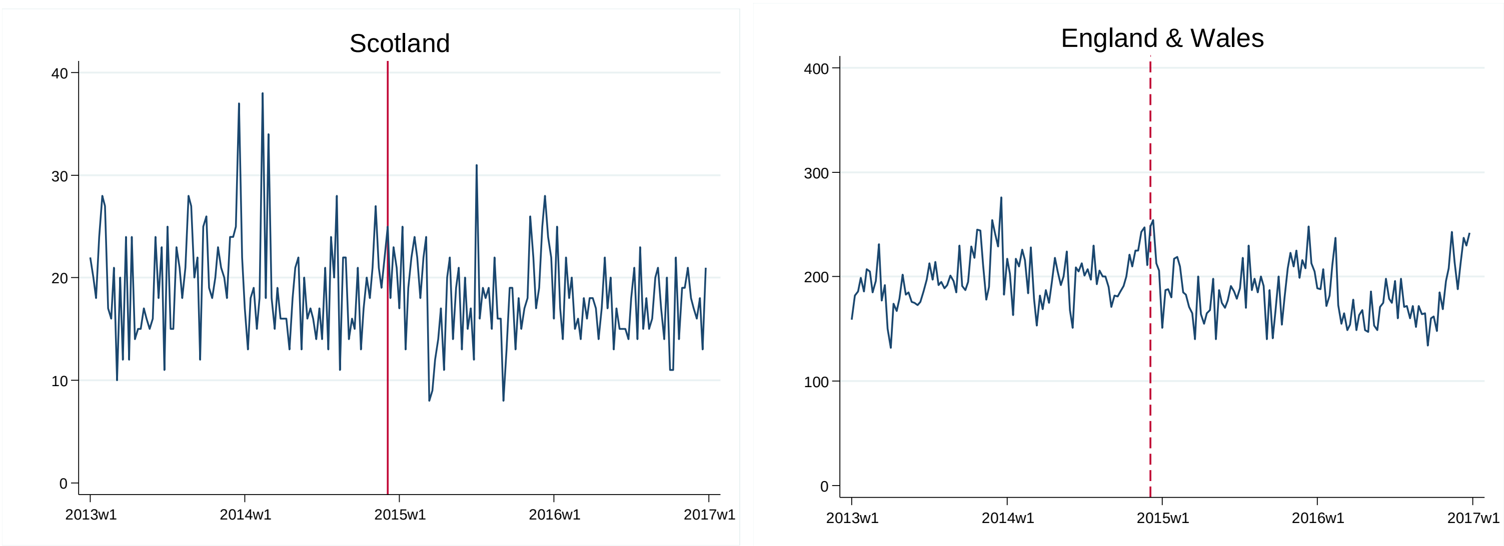

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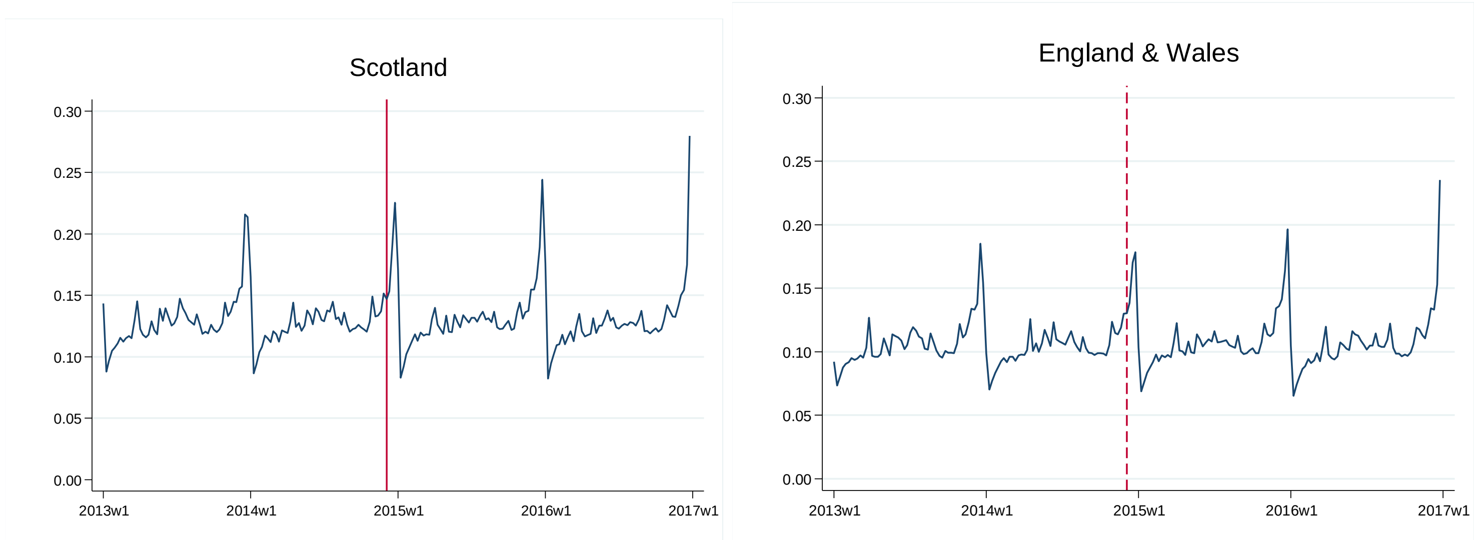
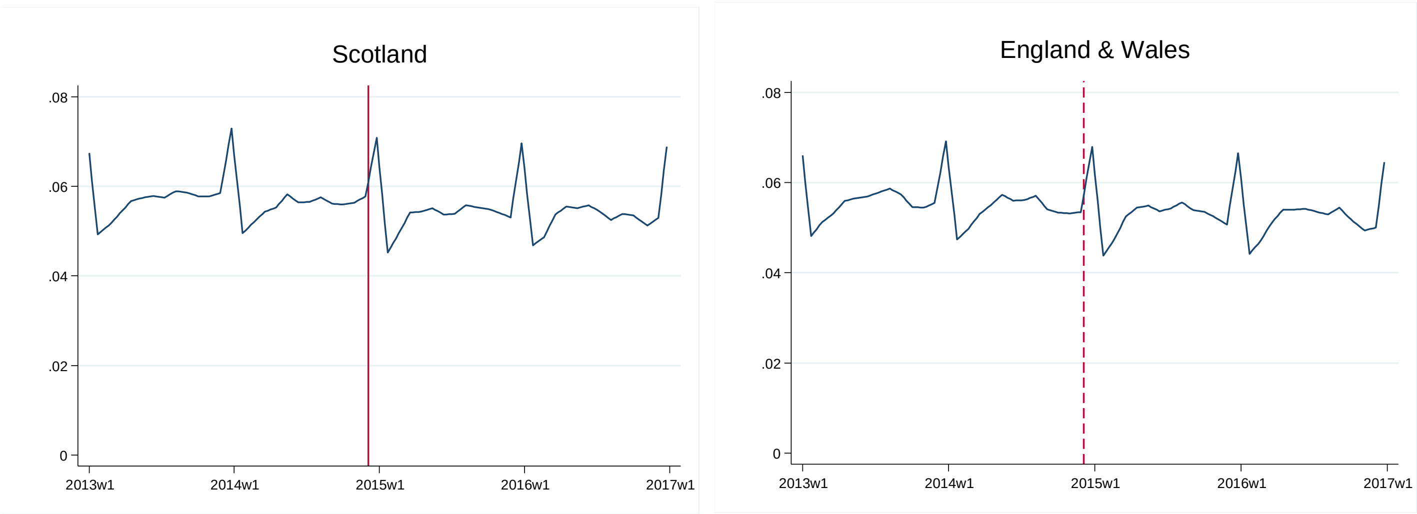
Figure 2: Weekly (a) off-trade and (b) on-trade per capita alcohol sales for Scotland and England & Wales between Jan 2013 and Dec 2016

(a) off-trade



Solid vertical line indicates change in legislation date and dashed line indicates pseudo-change in legislation date; x-axis is weekly time period showing the first week (w1) of each year.

(b) on-trade



Scotland
.08
.06
.04
.02
0
2013w1
2014w1
2015w1
2016w1
2017w1
England & Wales
.08
.06
.04
.02
0
2013w1
2014w1
2015w1
2016w1
2017w1

Table 1: Number of road traffic accidents by demographics of driver

		Scotland (n = 34,578)	England & Wales (n = 527,068)
Sex	Male	27,075 (78·3)	426,533 (80·9)
	Female	6,938 (20·1)	88,087 (16·7)
	Missing	565 (1·6)	12,448 (2·4)
Age group (years)	< 20	1,716 (4·9)	25,280 (4·8)
	21-25	2,261 (6·5)	38,457 (7·3)
	26-35	5,326 (15·4)	90,880 (17·2)
	36-45	6,343 (18·3)	102,268 (19·4)
	46-55	8,180 (23·7)	111,742 (21·2)
	56-65	5,669 (16·4)	71,698 (13·6)
	66-75	2,798 (8·1)	38,863 (7·4)
	> 75	1,792 (5·2)	25,089 (4·8)
	Missing	493 (1·4)	22,791 (4·3)
Socio-economic deprivation	1 (Most deprived)	4,687 (13·5)	70,881 (13·4)
	2	4,518 (13·1)	69,663 (13·2)
	3	4,118 (12·0)	63,043 (12·0)
	4	3,768 (11·0)	57,301 (10·9)
	5	3,343 (9·7)	50,796 (9·6)
	6	3,082 (9·0)	45,228 (8·6)
	7	2,647 (7·7)	37,540 (7·1)
	8	2,182 (6·3)	31,417 (6·0)
	9	1,735 (5·0)	26,695 (5·0)
	10 (Least deprived)	1,402 (4·0)	19,708 (3·7)
	Missing	3,096 (8·9)	54,796 (10·4)

Data are n (%). An accident can involve more than one driver. Where this occurs, the demographic assignment was based on oldest age group, the most frequent sex, and lowest (most deprived) socio-economic deprivation group (in the supplementary materials, Table S1, shows the corresponding table based on a different demographic assignment – youngest age group, least frequent sex, least deprived socio-economic deprivation group).

Table 2: Modelling results for RTA counts, RTA rates and alcohol consumption

Models	Scotland		England & Wales		Difference-in-difference (Scotland / England & Wales)	
	Effect Size (95% CI)	p-value	Effect Size (95% CI)	p-value	Effect Size (95% CI)	p-value
(a) RTA counts	0·98 (0·91, 1·04)	0·53	0·95 (0·90, 1·00)	0·05	NA	NA
(b) RTA counts	0·98 (0·93, 1·03)	0·40	0·95 (0·93, 0·96)	<0·001	NA	NA
(c) RTA rates	1·01 (0·94, 1·08)	0·77	0·94 (0·89, 0·99)	0·02	1·07 (0·98, 1·17)	0·10
(d) RTA rates	1·00 (0·96, 1·06)	0·73	0·94 (0·92, 0·96)	<0·001	1·07 (1·02, 1·13)	0·007
(e) RTA serious/fatal counts	0·90 (0·80, 1·02)	0·10	0·90 (0·85, 0·96)	0·001	NA	NA
(f) RTA serious/fatal counts	0·90 (0·80, 1·01)	0·08	0·90 (0·87, 0·94)	<0·001	NA	NA
(g) RTA serious/fatal rates	0·93 (0·82, 1·05)	0·24	0·89 (0·84, 0·95)	<0·001	1·04 (0·90, 1·19)	0·59
(h) RTA serious/fatal rates	0·93 (0·83, 1·04)	0·21	0·89 (0·87, 0·92)	<0·001	1·04 (0·92, 1·17)	0·54
(i) SVN RTA counts	0·99 (0·87, 1·15)	0·99	0·93 (0·88, 0·99)	0·03	NA	NA
(j) SVN RTA counts	0·99 (0·87, 1·14)	0·99	0·93 (0·89, 0·97)	0·002	NA	NA
(k~~i~~) Off-trade per capita alcohol sales	-0·003 (-0·017, 0·011)	0·71	0·012 (-0·005, 0·029)	0·18	NA	NA
(l~~j~~) On-trade per capita alcohol sales	-0·007 (-0·008, -0·005)	<0·001	0·007 (0·005, 0·008)	<0·001	NA	NA

Negative binomial regression was employed for models a-j~~h~~. Seasonal autoregressive integrated moving average (SARIMA) was employed for models k~~i~~ & l~~j~~. Models a, c, e, g & i~~g~~ adjusted for seasonality, underlying temporal trend. Models b, d, f, h & ~~h~~j adjusted for seasonality, underlying temporal trend, age of driver, sex of driver and socio-economic deprivation group of driver. Model k~~i~~, Scotland - adjusted for on-trade per capita alcohol sales in Scotland and off-trade per capita alcohol sales in England & Wales. Model k~~i~~, England & Wales - adjusted for on-trade per capita alcohol sales in England & Wales and off-trade per capita alcohol sales in Scotland. Model l~~j~~, Scotland - adjusted for off-trade per capita alcohol sales in Scotland and on-trade per capita alcohol sales in England & Wales. Model l~~j~~, England & Wales - adjusted for off-trade per capita alcohol sales in England & Wales and on-trade per capita alcohol sales in Scotland.

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Table S1: Number of road traffic accidents by demographics of driver

		Scotland (n = 34,578)	**England & Wales (n = 527,068)**
Sex	Male	9,039 (26·1)	101,420 (19·2)
	Female	24,974 (72·3)	413,200 (78·4)
	Missing	565 (1·6)	12,448 (2·4)
Age group (years)	< 20	4,653 (13·4)	75,155 (14·3)
	21-25	5,560 (16·1)	95,099 (18·0)
	26-35	9,129 (26·4)	142,168 (27·0)
	36-45	6,331 (18·3)	89,037 (16·9)
	46-55	4,847 (14)	59,370 (11·3)
	56-65	2,202 (6·4)	25,673 (4·9)
	66-75	876 (2·5)	11,122 (2·1)
	> 75	487 (1·4)	6,653 (1·3)
	Missing	493 (1·4)	22,791 (4·3)
Socio-economic deprivation	1 (Most deprived)	2,038 (6·0)	30,145 (5·7)
	2	2,476 (7·2)	38,228 (7·3)
	3	2,645 (7·6)	42,216 (8·0)
	4	3,024 (8·7)	45,461 (8·6)
	5	3,183 (9·2)	47,227 (9·0)
	6	3,515 (10·2)	49,942 (9·5)
	7	3,517 (10·2)	51,408 (9·7)
	8	3,663 (10·6)	53,754 (10·2)
	9	3,884 (11·2)	56,955 (10·8)
	10 (Least deprived)	3,628 (10·5)	56,936 (10·8)
	Missing	3,096 (8·9)	54,796 (10·4)

Data are n (%). An accident can involve more than one driver. Where this occurs, the demographic assignment was based on youngest age group, the least frequent sex, and highest (least deprived) socio-economic deprivation group.

Table S2: Modelling results for RTA counts, ~~and~~ RTA rates, RTA serious/fatal counts, RTA serious/fatal rates and SVN RTA counts

Models	Scotland		England & Wales		Difference-in-difference (Scotland / England & Wales)	
	Effect Size (95% CI)	p-value	Effect Size (95% CI)	p-value	Effect Size (95% CI)	p-value
(a) RTA counts	0·98 (0·91, 1·04)	0·53	0·95 (0·90, 1·00)	0·05	NA	NA
(b) RTA counts	0·98 (0·93, 1·03)	0·42	0·95 (0·93, 0·98)	<0·001	NA	NA
(c) RTA rates	1·01 (0·94, 1·08)	0·77	0·94 (0·89, 0·99)	0·02	1·07 (0·98, 1·17)	0·10
(d) RTA rates	1·01 (0·96, 1·06)	0·72	0·94 (0·92, 0·97)	<0·001	1·07 (1·01, 1·13)	0·02
(e) RTA serious/fatal counts	0·90 (0·80, 1·02)	0·10	0·90 (0·85, 0·96)	<0·001	NA	NA
(f) RTA serious/fatal counts	0·91 (0·81, 1·02)	0·11	0·91 (0·88, 0·94)	<0·001	NA	NA
(g) RTA serious/fatal rates	0·93 (0·82, 1·05)	0·24	0·89 (0·84, 0·95)	<0·001	1·04 (0·90, 1·19)	0·59
(h) RTA serious/fatal rates	0·94 (0·84, 1·05)	0·28	0·90 (0·87, 0·93)	<0·001	1·04 (0·93, 1·18)	0·48
(i) SVN RTA counts	0·99 (0·87, 1·15)	0·99	0·93 (0·88, 0·99)	0·03	NA	NA
(j) SVN RTA counts	0·99 (0·87, 1·14)	0·99	0·93 (0·89, 0·97)	0·002	NA	NA

Negative binomial regression was employed for models a-j~~h~~. Models a, c, e, g & ~~g~~i adjusted for seasonality, underlying temporal trend. Models b, d, f, h & ~~h~~j adjusted for seasonality, underlying temporal trend, age of driver, sex of driver and socio-economic deprivation group of driver. Demographic assignment was based on youngest age group, least frequent sex, and least deprived socio-economic deprivation group.

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Table S3: Modelling results for SVN/MVD, MVD RTA count, serious RTA rates and fatal RTA rates

Models	**Scotland**		**England & Wales**		**Difference-in-difference (Scotland / England & Wales)**	
	Effect Size (95% CI)	p-value	Effect Size (95% CI)	p-value	Effect Size (95% CI)	p-value
(a) SVN/MVD	1·06 (0·76, 1·47)	0·75	0·98 (0·80, 1·20)	0·84	1·08 (0·73, 1·59)	0·70
(b) SVN/MVD	0·90 (0·72, 1·14)	0·41	0·98 (0·91, 1·05)	0·54	0·92 (0·72, 1·19)	0·55
(c) MVD RTA count	0·95 (0·95, 1·05)	0·31	0·94 (0·88, 1·00)	0·07	NA	NA
(d) MVD RTA count	0·97 (0·89, 1·05)	0·50	0·94 (0·92, 0·97)	<0·001	NA	NA
(e) serious RTA rates	0·94 (0·82, 1·06)	0·32	0·89 (0·84, 0·94)	<0·001	1·05 (0·91, 1·21)	0·46
(f) serious RTA rates	0·94 (0·83, 1·05)	0·29	0·89 (0·86, 0·92)	<0·001	1·05 (0·93, 1·19)	0·40
(g) fatal RTA rates	0·87 (0·62, 1·24)	0·45	0·99 (0·87, 1·20)	0·86	0·88 (0·61, 1·28)	0·51
(h) fatal RTA rates	0·87 (0·62, 1·23)	0·44	0·99 (0·88, 1·11)	0·85	0·88 (0·61, 1·27)	0·50

Gamma regression and negative binomial regression was employed for models a & b and c-h, respectively. Models a, c, e & g adjusted for seasonality, underlying temporal trend. Models b, d, f, & h adjusted for seasonality, underlying temporal trend, age of driver, sex of driver and socio-economic deprivation group of driver. Demographic assignment based on eldest age group, the most frequent sex, and lowest (most deprived) socio-economic deprivation group. In models a & b the covariates of age of driver, sex of driver and socio-economic deprivation group of driver had two levels each due to models with finer categorisation (see Table 1) not converging.

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Table S~~3~~4: Modelling results by level of socio-economic deprivation (interaction model)

Models	Socio-economic deprivation (quintile)	**Scotland** Effect Size (95% CI)	p-value	**England & Wales** Effect Size (95% CI)	p-value
RTA counts	1st	1·00 (0·92, 1·10)	0·93	0·96 (0·94, 0·99)	0·008
	2nd	1·00 (0·90, 1·10)	0·95	0·96 (0·93, 0·98)	0·004
	3rd	0·93 (0·83, 1·04)	0·19	0·94 (0·91, 0·97)	<0·001
	4th	1·01 (0·87, 1·15)	0·90	0·93 (0·90, 0·97)	0·001
	5th	0·92 (0·79, 1·08)	0·32	0·94 (0·90, 0·98)	0·01
RTA rates	1st	1·03 (0·95, 1·13)	0·44	0·95 (0·93, 0·98)	0·001
	2nd	1·03 (0·93, 1·13)	0·59	0·95 (0·92, 0·97)	<0·001
	3rd	0·96 (0·86, 1·07)	0·44	0·93 (0·90, 0·96)	<0·001
	4th	1·04 (0·91, 1·18)	0·56	0·93 (0·89, 0·96)	<0·001
	5th	0·95 (0·81, 1·11)	0·54	0·93 (0·89, 0·97)	0·003

Demographic assignment based on eldest age group, the most frequent sex, and lowest (most deprived) socio-economic deprivation group.

Table S45: Modelling results by level of socio-economic deprivation (interaction model)

Models		Scotland		England & Wales	
	Socio-economic deprivation (quintile)	Effect Size (95% CI)	p-value	Effect Size (95% CI)	p-value
RTA counts	1st	1·03 (0·91, 1·18)	0·61	1·00 (0·95, 1·04)	0·92
	2nd	0·98 (0·87, 1·10)	0·77	0·96 (0·92, 1·00)	0·03
	3rd	0·97 (0·87, 1·08)	0·60	0·95 (0·92, 1·00)	0·01
	4th	1·00 (0·90, 1·11)	0·96	0·95 (0·91, 0·98)	0·006
	5th	0·93 (0·87, 1·03)	0·14	0·93 (0·90, 0·96)	<0·001
RTA rates	1st	1·06 (0·93, 1·22)	0·33	0·99 (0·94, 1·03)	0·59
	2nd	1·01 (0·90, 1·14)	0·84	0·95 (0·91, 0·98)	0·008
	3rd	1·00 (0·90, 1·11)	0·98	0·94 (0·91, 0·98)	0·002
	4th	1·03 (0·93, 1·15)	0·53	0·94 (0·90, 0·97)	0·001
	5th	0·95 (0·86, 1·06)	0·37	0·92 (0·89, 0·95)	<0·001

Demographic assignment was based on youngest age group, the least frequent sex, and highest (least deprived) socio-economic deprivation group.

General response:

We thank the reviewers for their thoughtful comments. We are pleased that they agree our paper makes an important contribution and that there is general satisfaction with our scientific approach (e.g. reviewer 1 – "…interesting, useful and well-executed analysis"; reviewer 2 – "Very nice study…"; reviewer 3 – "The present article addresses a very important public health issue."; reviewer 4 – "The manuscript is well written").

We have addressed each point raised in detail. In summary, here is how we have addressed the major points:

1) We have defended the use of all RTAs as the primary outcome measure but have added single vehicle night-time RTAs as an extra secondary outcome measure and SVN/MVD RTAs as a supplementary analysis. As for total RTAs and serious/fatal RTAs, the modelling of these outcomes resulted in null findings and did not change the conclusions of the paper.
2) We have defended our use of a traffic flow denominator as a proxy for vehicle miles of travel as the best available weekly measure, disaggregated for Scotland and England & Wales.
3) We have separated serious and fatal RTAs, modelled both those outcomes, and added as supplementary results. When modelled separately, both analyses resulted in a null finding and did not change the conclusions of the paper.

In our specific responses to reviewers' comments, reviewer text is in quotes and our response is in *italics*.

Response to reviewer 1:

"Minor - Use of traffic count as denominator in accident rate

An accident rate is the number of crashes per measure of exposure. Vehicle miles of travel are the preferred exposure measure, and sometimes the number of licensed is used. Use of vehicle counts from automatic traffic counters as exposure is very unconventional. The counters provides a measure of traffic volume, which is the number of traffic units passing a specific point in a unit of time, and if the time unit is an hour, it's called traffic flow. As is, this is not a measure of exposure, because it is a point measurement that is extended to a specific road segment. While the authors explain why they used traffic count as the denominator for crash rates in the limitations portions of the paper, it would be worthwhile to explain the reasoning and justification for choosing this as the exposure measure when they define accident rate. Of interest would be some information about the distributions of these counting stations on the road types that matter, and some evidence that the distributions of counting stations in Scotland and in the control areas are similar enough for a valid comparison."

We agree with the reviewer that our traffic flow denominators are not as good a measure of exposure as, say, vehicle miles of travel. As the reviewer alludes to, we explain in the limitations section that we are using traffic flow as a proxy as information is not available on actual vehicle miles travelled. An alternative approach is to apply methods using fuel duty taxes. Although HMRC do publish estimates at the level of UK constituent country, 'months' are the greatest level of disaggregation reported (and we used weekly RTAs as our unit of analysis). More importantly, a methodology note states that uncertainties at local/regional levels are "expected to be considerably higher" than for the whole of the UK: *https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/719100/Road_Transport_Methodology_and_Changes_for_2016_report_v00.01.pdf*

We therefore argue that using the weekly traffic flow counts from the ATCs remains an attractive approach and is a valid proxy for vehicle miles of travel (and is a superior exposure compared to population estimates – as we state in the discussion). We note that the reviewer regards their comments as minor for this point.

We agree with the reviewer that including more information on the counting stations would be informative and therefore have added the following text to the methods (p9, lines 201-204):

"The location of the approximately 300 ATCs are placed to be representative of the entire GB road network, including motorways, major roads (providing large-scale transport linkage) and minor roads (feeding traffic between major roads and smaller roads)."

"Very minor points

1. "On-trade" and "off-trade" retail alcohol sales - (page 4, paragraph 3). These terms are unfamiliar to many non-UK residents. Of course, readers can look this up, but a few words explaining the difference would be very helpful at first mention.

2. Abstract first sentence - "drink driving is a key factor". Drink driving is only one of the important factors in RTAs."

On/off-trade: thank you for making us aware of this. We have added examples of off-trade and on-trade in that section (p4, lines 98-100) and also when first mentioned in the main body of the paper (p9/10, lines 218-221).

Key factor: we do say 'a' key factor rather than 'the' key factor but we have softened this to "…is an important risk factor…" (p2, line 37).

Response to reviewer 2:

"(1) Since the goal of this study was effects on impaired driving crashes, why did you analyze ALL RTAs? Why did you not analyze the ratio of single vehicle nighttime (SVN) (6PM-6AM) crashes to multiple vehicle daytime (MVD) (6AM-6PM) crashes? This has been used as a different perspective on measuring impaired driving crashes. Because police do not test every driver involved in crashes for alcohol (which you acknowledged), the above measure has been used in past research serving as a surrogate measure of impaired driving crashes to account for underreporting of impaired drivers by police. Voas, Romano, and Peck (2009) updated a study by Heeren et al. (1985) confirming the validity of the SVN surrogate for alcohol-related crashes. SVN crashes have a high probability of alcohol involvement while MVD crashes have a low probability of alcohol involvement. The ratio of SVN crashes from 6pm to 6am to MVD crashes from 6am to 6pm also helps to control for other factors. Not using this surrogate measure is a major flaw in your study. By using all RTAs, non-alcohol crashes could have increased while alcohol-related crashes could have decreased, but you could not detect that with your method. Please use SVN/MVD or explain why you did not."

We consider total RTAs to be the most important outcome measure for evaluating the change in BAC law as it best reflects the burden of road traffic accidents on public health. However, we agree that using SVN RTAs is a valid surrogate for alcohol-related crashes, and indeed has been recommended by the WHO. We therefore have added new models using the SVN RTAs outcome alongside the surrogate we already used, namely serious/fatal RTAs. This new modelling produced very similar findings to serious/fatal RTAs and did not change conclusions. This has led to changes in text in the *abstract (p2, lines 57-58), methods (p9, lines 211-213), results (p12, lines 274-276 & 298-300), discussion (p14, line 321), and the addition of Figure 1e (p25).*

We thank the reviewer for bringing to our attention the merits of using the ratio SVN/MVD as an outcome measure. We have carried out modelling of this outcome, and also MVD, and included it in a supplementary table (see Table S3, p32). Again, they show null effects. This has led to changes in the methods (p9, lines 213-214), results (p13, lines 302-303) and discussion (p16, lines 382-385).

> "(2) You used ATCs for exposure. Can you not estimate vehicle miles travelled (VMT) in your countries via the gasoline tax? Explain why you did not estimate VMT."

We could estimate VMT but there are methodological difficulties in doing so. Although HMRC do publish estimates at the level of UK constituent country, months are the greatest level of disaggregation reported (and we used weekly RTAs as our unit of analysis). More importantly, a methodology note states that uncertainties at local/regional levels are "expected to be considerably higher" than for the whole of the UK:
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/719100/Road_Transport_Methodology_and_Changes_for_2016_report_v00.01.pdf

We therefore argue that using the weekly traffic flow counts from the ATCs remains an attractive approach and is a valid proxy for vehicle miles of travel (and is a superior exposure compared to population estimates – as we state in the discussion).

> "(3) What was the impaired driving enforcement in England and Wales during the study period? Exactly the same as Scotland? Explain."

Available data is limited, but suggests that the level of police enforcement of drink-driving in both Scotland and England & Wales fell over the study period, with a sharper decline in enforcement in England & Wales. There was no change in penalties for drink-driving in either jurisdiction over the same period.

> "(4) In your discussion, a probable reason for not finding a decrease in RTAs could be that while alcohol-related crashes decreased, non-alcohol crashes increased."

We think that this is unlikely as the results of the SVN/MVD and MVD modelling results also show null effects. As noted above, we have added these results in Table S3 (p32) and commented on them in the discussion.

Response to reviewer 3:

> "My main concern with the present article is its genuine contribution to the field. To my knowledge, it is the first article assessing the impact on alcohol consumption of such laws, but it is not their objective. Similarly, the expected relationship between BAC laws and economic inequality is not evident. For these reasons, I think that the article needs to be substantially improved before being considered for an eventual publication. My specific comments follow."

We feel that the article makes a strong contribution to the field. As the reviewer acknowledges, it is the first paper to assess the impact of a change in BAC law on alcohol consumption (although it is inaccurate to suggest it was not an objective as it is an original study aim (see p8, lines 175-177)). More importantly, as another reviewer has commented, because this BAC intervention was not accompanied by programmes of heightened enforcement, this provided an opportunity to evaluate just the BAC limit change intervention alone. This real-world evaluation therefore has important implications for other countries/jurisdictions, including within the UK. With regards the comment *that socio-economic deprivation did not influence the intervention effect, the reviewer appears to be criticising us for a null finding rather than poor science.*

> "Literature review
>
> There are several evaluations of laws introducing a lower BAC level on alcohol-related crashes. Instead of reporting country-level experiences, you should focus on results from meta-analyses or systematic reviews. You should also report results based on relevant "moderating" factors such as: (1) administrative vs. criminal laws; (2) legal BAC limit; and (3) other enforcement or media activities supporting the law introduction (you will see that several evaluations were conducted in countries where random breath testing are not allowed, see Blais et al., [2015] for instance). By doing so, it would permit to really highlight the contribution of your study in comparison to previous evaluations of BAC laws."

We defend the approach we took in reporting the existing evidence base in the introduction of the paper. Although we did point out that lowering BAC limits has been evaluated in various countries, we also reference a meta-analysis that estimates the effect of BAC lowering on RTAs. More importantly, there has been no systematic review of interventions that reduced BAC from 0.08 to 0.05 g/dL and that is why we paid close attention to the highest quality papers (in our view) that evaluated the same intervention that we studied, namely Henstridge et al and Albalate (see middle paragraph, p7). For the same reason, we did not expand our literature review to cover other evidence in the manner the reviewer suggests. As this intervention did not include changes in penalties or enforcement methods, and there were no such changes in the comparison area either, we have not included literature on those interventions in our introduction. In summary, we have carried out a non-randomised intervention study and we feel our literature review covers the most pertinent literature in that regard.

> "I do not understand how a homogeneous effect of a BAC intervention across the population could affect absolute levels socio-economic deprivation inequality. There is a positive relationship between levels of alcohol consumption and drinking-and-driving as well as a positive association between socio-economic deprivation and drinking. At last, there is evidence of a negative relationship between economic deprivation and driving rates. It does not mean that BAC laws have an impact on economic deprivation. This is a fallacious reasoning. Furthermore, BAC laws are not designed - like taxes, minimum drinking age and selling hours - to lower alcohol consumption. Such laws seek to dissociate "drinking" and "driving". At best, alcohol consumption could decrease in very specific contexts (e.g., for the designated drivers) but it could remain the same if most people decide to use public transportation, sleep over or change their drinking habit (drink at home instead of at the restaurant). You need to review your argument. It is more than questionable."

Whilst we agree with some of the points made, we feel there has been some confusion here in what this study is aiming to do. The only socio-economic deprivation inequality that we investigate is for the RTA outcome, not alcohol consumption. Reducing inequalities in health (or society) is a priority for governments in the UK and internationally. It is therefore important to consider whether the reduction in BAC limit, as a whole-population intervention, had a differential impact on different socio-economic groups. We agree that we used some imprecise wording in our original "aim" sentence and we apologise if that is the cause of the confusion. As a result of this, we have modified the text (see lines 175-178, p8):

"We aimed to evaluate whether lowering the permitted blood alcohol concentration (BAC) from 0·08 to 0·05 g/dL in Scotland had an impact on both road traffic accidents (RTAs) rates and population alcohol consumption, and whether any impacts varied by level of socio-economic deprivation."

to,

"We aimed to evaluate whether lowering the permitted blood alcohol concentration (BAC) from 0·08 to 0·05 g/dL in Scotland had an impact on both road traffic accidents (RTAs) rates and population alcohol consumption. Further, we evaluated whether any impacts on RTAs varied by level of socio-economic deprivation."

We have also edited the preceding paragraph to make clear we are testing for socio-economic deprivation inequalities in BAC effect on RTAs. Further, we have split the paragraph to make clearer that we are not testing for effect modification on the alcohol consumption outcome. These two paragraphs are shown below and are on lines 164-173 (p7/8) in the paper:

"If any BAC intervention effect is homogeneous across the population under study then it could affect absolute levels of socio-economic deprivation inequality for RTAs: level of alcohol consumption is positively associated with the probability of drink-driving (14) and higher levels of socio-economic deprivation are associated with higher levels of alcohol consumption per drinker (15), but also with lower driving rates.

It has been hypothesised that population drinking (i.e. per capita alcohol consumption) is associated with driving under the influence of alcohol (16). If true, an unintended outcome of a change in BAC legislation could be a reduction in per capita alcohol consumption."

We agree with the reviewer that BAC laws are not designed to lower alcohol consumption. However, we did postulate a priori that it was a plausible unintended outcome and was in our 'theory of change' that we submitted in the grant application to the funding body (NIHR) and will appear in the NIHR PHR final report monograph in due course. Policymakers considering whether or not to reduce the BAC limit are likely to be interested in evidence on any unintended consequences including impact on population level consumption. For example, reducing population-level alcohol consumption is central to Scottish Government strategy on alcohol, and this question is therefore of significant policy interest.

"The previous comment has also implications for the other sections of the paper. You should not only focus on alcohol consumption. It is not the central "moderating" factor or preventing mechanism. You should consider indicators of enforcement activities or traveling methods (e.g., public transportation, bicycle, car). This would be a great contribution. It is lacking in several studies."

Although we agree these suggestions are important for future research they are beyond the scope of our current study.

"Method:

Why did you merge fatal and serious injury accidents? Generally, for each drink-driver involved in a serious accident, two are involved in a fatal accident. Since serious injury accidents are much more frequent than fatal ones, it can affect the ability of your models to detect any significant effects. You need to support your decision. It is questionable."

We merged fatal and serious RTAs because we considered it was reasonable to assume that any intervention effect would be homogeneous for both outcomes, and also to increase statistical power.

It is also worth pointing out that fatal RTAs only account for less than 2% of total RTAs providing further justification for using fatal and serious RTAs combined. However, we have now added modelling of serious RTAs and fatal RTAs into a supplementary table of results (see Table S3, p32). As can be seen, similar results are found as for the combined serious/fatal RTAs outcome variable. This addition led to changes in the methods (p9, lines 210-211) and results (p12, lines 274-276; p13, lines 297-298).

"Similarly, the large volume of accidents recorded in Scotland permits to create proxies of drinking-and-driving incidents such single-vehicle accidents and nighttime accidents. In sum, in addition to your dependent variables, I recommend using accident indicators similar to those found in previous studies to be able to rule out my previous concerns. Your accident variables are not the best ones to capture the potential effect of a BAC law."

This echoes a similar point made by another reviewer. We are pleased that the reviewer implicitly supports our use of total RTAs as a dependent variable, as we consider this outcome to be the most important outcome measure as it best reflects the burden of road traffic accidents on public health. However, we acknowledge the importance of also evaluating other RTA outcomes that relate to alcohol-related crashes. Therefore, we have in addition used single vehicle night-time (SVN) RTAs as a dependent variable (a valid surrogate for alcohol-related crashes that has been recommended by WHO). We have added modelling using the SVN RTAs outcome alongside the surrogate we already used, namely serious/fatal RTAs (see Table 2, p29). This produced very similar findings to serious/fatal RTAs and did not change conclusions.

"At last, you should really think about preventive mechanisms likely to affect the effectiveness of a BAC law. Reduction in alcohol consumption is not the main one. You should focus on enforcement activities (sometimes a law is not immediately enforced), media campaigns supporting the law (the effect can start earlier), and changes in driving habits (are you able to have data from ATCs for specific periods of the day? A decline or not in nighttime driving could be interesting). Adding such variables would address several of limitations presented in the discussion."

We agree that enforcement activities and media campaigns are important factors. As the reviewer acknowledges, we start to explore this in the discussion by providing evidence that enforcement levels have reduced in GB and how initial investment in media campaigning in Scotland was not maintained. We feel that any further exploratory work in this area is beyond the scope of the current study. With regards changes in driving habits, we agree that would be interesting to investigate but unfortunately time of day is not recorded in the UK Department of Transport's ATC data.

"Otherwise, I think that statistical analyses are sound and well described."

Thank you.

"Results and discussion - Results are clearly presented."

Thank you.

"In the discussion, you stress that your study rests on a strong controlled natural experiment design. This is a huge claim. Are both groups really equivalent? Your models for instance do not control for other laws or other environmental variables (characteristics of the road network or the urbanization level, a very important variable when it comes to drink-driving). I would be more cautious, especially since you later address this limitation."

On reflection, we agree that we have been too strong in our language. We have modified to read "Our study employed a well-designed, controlled natural experiment,…" (p14, line 330).

"Regarding limitations, I think that some of them are avoidable. As previously mentioned, you could have used better proxies for alcohol-related accidents. I also wonder why you did not estimate changes in law enforcement activities? If it is just a change in the legal BAC limit, you should notice an increase in arrests if the law is enforced. If it is a new law, creating a new infringement, you could report descriptive statistics. You could also estimate the effect of the law with and without the media campaigns, as you mentioned that it was not maintained in the following years. The removal of the education activity is also an important confounding factor to control for in your models."

As mentioned earlier, we have added other proxies for alcohol-related accidents (and the results are comparable to the original outcomes we used). The other avenues of research that the reviewer mentions are all important but we feel our paper already makes a substantial contribution and we will consider the points made for future research.

"Other comments:

The public health as well as the traffic safety literature use crashes or collisions instead of accidents.

Drink-driving is not the same as driving under the influence of alcohol. Use one or the other."

Thank you for these points. We would prefer to keep using accidents (RTAs) which keeps our reporting consistent with the UK Government Department for Transport and, we would argue, is a well used term in the literature. It also keeps our reporting consistent to that used in reporting to the funding body (NIHR). With regards the second point, we have removed 'drink-driving' from the sentence where we are talking about driving under the influence of alcohol (p6, line 125).

Response to reviewer 4:

"The available data is limited with several assumptions including the assumption that all accidents are reported to the Police. The data used to calculate the denominator is also limited. This may lead to biased results such as lower chance of reporting minor incidents in the control group than in the intervention group which may lead to underestimating accident rates in the control group and subsequently reducing the effect of the intervention. However, the comparison before and after the legislation showed no difference and one wonders whether there was enough time since the legislation for the intervention to be effective."

We consider the data we used to be of the highest available quality although, as with all data, it is not perfect. The bias that the reviewer refers to is fortunately very unlikely as the same data source is used for both the intervention and control groups. With regards the second point, we consider a two-year follow-up period more than adequate to detect a BAC intervention effect, and is a longer follow-up period than other BAC intervention studies.

"At the start of the statistical analysis section, age, sex and socio-economic deprivation characteristics were compared between the intervention and control groups and it is not clear who were the persons here. Later, it becomes clearer that this is related to the drivers involved in accidents. However, I am not sure what is the value of these characteristics when the eldest driver, most frequent sex and most deprived driver were considered. I am not sure what we are supposed to learn from this? It would be more informative if the characteristics of all drivers involved in an accident are included in the descriptive statistics table. This may include average number of drivers involved per accident."

The point we are making is that the demographics of those involved in RTAs in Scotland is very comparable to the demographics of those involved in RTAs in England & Wales. This remains true when we switch demographic 'assignment' to the RTA (least frequent sex, etc.). We thank the reviewer for their useful suggestion, and have added average number of drivers (and casualties) to the text (see p12, lines 284-287). However, we do not feel it would be correct to present the characteristics of all drivers involved in RTAs because it is the RTA itself that is used as the unit of analysis in the inferential statistics.

"The Results section should highlight when associations are not statistically significant."

We do not agree with this but are happy to be directed by The Lancet on whether statistical significance (or not) has to be explicitly reported throughout.

"Have the authors considered examining the research question at city/town level in Scotland to assess whether the results are consistent? This could also help assess the lack of enforcement explanation for the lack of intervention effect as one would expect better enforcement in the cities, although this is an assumption from a non-expert. In all cases, it is worth performing the analysis taking into account the size of city or town and so on."

Geographical variation is worthy of future investigation but we consider it beyond the scope of the current study.

"The Discussion should address the limitations of the study design in more detail. This would include the lack of randomisation and the quality of the available data and it would be good if the ideal non observational study would be briefly described. This would help readers interpret the results while considering the study limitations."

We feel that we have addressed the limitations of our study design and data to a high level of detail. We do not feel it would be appropriate to describe an ideal study, which in pragmatic/real-world evaluations such as this is never achieved, in the reporting of our research. We therefore defend not doing so.

We thank all the reviewers for their insightful comments that helped improve this paper.