On the use of empirical bayes for comparative interrupted time series with an application to mandatory helmet legislation

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Abstract

Road safety interventions directed at a population such as mandatory helmet legislation (MHL) and seat belt laws are often assessed by interrupted time series (ITS) methods. Such interventions are often controversial since the pre- and post-intervention periods are not randomised making causal inference difficult. It is possible for changes in the time series of interest to be due to unmeasured confounders and not the intervention. For example, it is often argued by those opposing MHL that the decline in bicycle related head injuries following this intervention could be due to declines in cycling ridership and not a safety benefit. The inclusion of a comparative series in ITS designs is a potential way to account for unmeasured confounding; however, statistically rigorous criteria for selecting a comparator are yet to be developed. To that end, this paper examines the use of empirical Bayes methods as a means for detecting unmeasured confounding and for choosing the best comparative time series. ITS using empirical Bayes consists of estimating a post-intervention trajectory, or counterfactual, using the pre-intervention data. The trajectory is then compared to the post-intervention data for deviations from the counterfactual. These methods will be applied to NSW hospitalisation data around the mandatory helmet law as a demonstration.

Introduction

Population-based road safety interventions such as mandatory helmet legislation and seat belt laws are often controversial as they limit personal freedoms and are often difficult to assess. When an intervention is made effective, it is important to assess whether there is a clear benefit to the intended target of the intervention. However, causal inference, whereby changes in a dependent variable are directly attributable to an independent variable, is difficult in these situations due to the lack of randomisation of the pre- and post-intervention periods.

There exist examples in the literature in which a road safety intervention has been successful or unsuccessful depending on the analysis. When assessing seat belt laws in the UK, Harvey and Durbin (1986) demonstrated a significant decline in front vehicle occupants killed or seriously injured compared to rear seat passengers. Adams (2007), on the other hand, found little difference in injury between various European countries with and without seat belt laws in the 1970's. With regards to mandatory helmet legislation (MHL), Walter et al. (2011) demonstrated a 29% reduction in bicycle related head injury immediately following legislation relative to limb injuries. Robinson (2007), in her work critical of helmet legislation, found little difference in the percentage of head injuries between cyclists and pedestrians around the time of the Victorian MHL.

Interrupted time series (ITS) methods are often used to assess population-based interventions. Using sequentially ordered data, an ITS analysis consists of estimating the pre- and post-intervention time series for the outcome of interest which are then compared for differences. If the intervention had an immediate impact, there will be a change in the overall mean (or level) of the pre- and post-intervention series; whereas, a gradual impact will change the overall trend (or slope) of the series. For example, a large increase in helmet wearing coinciding with MHL would be expected to lead to a level change in head injury while increased cycling infrastructure expenditures would be expected to lead to a change in slope in all cycling injuries.

Simple ITS designs are limited due to unmeasured, time-dependent confounding. With regards to helmet legislation, for example, opponents have argued MHL is a major cycling deterrent, increases risky behaviour and makes the cycling environment less safe overall (Robinson, 2007). Note that it is possible for these factors to affect the time series differentially. So, changes in bicycle-related head injury could be due to factors other than increased helmet wearing.

It is highly recommended in the literature to include a non-equivalent, no-treatment control group time series to deal with threats to internal validity such as unmeasured, time-dependent confounding (Cook & Campbell, 1979; Shadish, Cook & Campbell, 2002). Further, the NHMRC considers comparative interrupted time series (CITS) designs to be as strong as case-control and cohort study designs (NHMRC, 2009). However, these are qualitative recommendations and do not appear to be fully justified in the scientific literature. For example, if estimating changes in cycling head injuries relative to MHL, will a comparison with pedestrian head injuries properly account for unmeasured, time dependent confounding? Additionally, given the choice between multiple comparators, e.g., cycling limb injuries or pedestrian head injuries, which one is best?

Some recommended criteria for choosing a comparative time series has been proposed in the literature. Linden and Adams (2011) have recommended the pre-intervention primary and comparative time series should be similar. Walter et al. (2013) chose arm injuries over leg injuries as comparators to head injuries since the estimated head/arm within-month correlation was greater than that for head/leg.

In addition to the recommendations in the literature, this paper will explore the use of empirical Bayes interrupted time series analysis (French & Heagerty, 2008) as an analytic method for (1) checking if a comparative time series has accounted for unmeasured confounding and (2) choosing between competing comparative time series.

Mandatory Helmet Legislation in NSW

Mandatory helmet legislation (MHL) for bicyclists in NSW came into effect on 1 January 1991 for adults (>15 years) and on 1 July 1991 for children. Since helmets protect the head, MHL will be associated with a decline in bicycle-related head injuries, if successful. However, it has been argued that MHL is associated with declines in cycling, increased risk to cyclists and riskier behaviour among helmeted cyclists. These potential confounders are time dependent factors and, therefore, a comparative time series subjected to the same factors would strengthen an assessment of MHL.

Previous research has utilised arm and leg injuries (Povey, Frith & Graham, 1999; Walter et al., 2011), and pedestrian head injuries (Hendrie et al., 1999) as comparators to bicycle related head injuries.

The NSW Admitted Patients Data Collection (APDC) is a census of hospitalisations in NSW since 1988/89. In the eighteen month periods before and after MHL (36 months total), adult cycling injuries to the head, arm and leg, and head injuries for pedestrians were identified using International Classification of Diseases, 9th Revision, Clinical Modification (ICD 9-CM) as described in Walter et al. (2011). Non-hospitalisable cycling injuries to the limbs that are concurrent with head injuries could change with MHL due to less head injuries. That is, less severe limb injuries that do not require hospitalisation could decline with MHL due to fewer hospitalisable head injuries. To account for this potential bias, cyclists with arm or leg injuries with concurrent head injury were only counted as a head injury.

As a sensitivity analysis, monthly beer production in Australia over the same period was used as a potential comparator (ABS, 1995). This comparative time series was chosen as it is readily available over the same time period and is unrelated to cycling. However, it is not known whether this is genuinely the case as, for example, both could be independently related to economic changes.

Statistical methods for interrupted time series

An interrupted time series model must account for various features of sequentially collected data including overall trend, seasonal/cyclical effects, time-dependent covariates and the intervention effect. For a single time series y_t, these effects can be decomposed as

$$\log(y_t) = \mu_t + \gamma_t + \sum_{j=1}^{k} \delta_j x_{jt} + \lambda w_t + \varepsilon_t, \quad t = 1, \ldots, T$$

where μ_t is the trend, γ_t is the seasonal component, x_{jt} is the j^{th} explanatory variable at time t and δ_j is its coefficient, w_t is an indicator variable for the pre- and post-intervention periods, λ is the intervention effect and ε_t is the irregular component (Harvey and Durbin, 1986). Let $t = \tau$ be the intervention point, so that $w_t = 0$ during the pre-intervention period (i.e., $t < \tau$) and $w_t = 1$ during the post-intervention period (i.e., $t > \tau$). These components can be stochastic to account for temporal dependence or deterministic with one random error term ε_t. In the absence of temporal dependence, this model simplifies to a linear model or generalised linear model depending on the distributional assumption of y_t. The focus here is on injury, i.e., count data, which often follows a Poisson distribution, thus the log-linear representation.

When assessing population-based interventions, potential explanatory variables are not always available. For example, although all bicycle-related hospitalisations are recorded in NSW since mid-year 1988, estimates of cycling ridership do not exist until yearly exercise surveys began in 2001 (ABS, 2001). So, with regards to assessing MHL and many other population-based interventions, the time-dependent process $\eta_t = \sum_{j=1}^{k} \delta_j x_{jt}$ is often not estimated.

For demonstrative purposes, the remainder of this manuscript will consider only deterministic time series and the interested reader is directed to Harvey (1996) and Commandeur et al. (2013) for a more in-depth treatment of intervention time series using this decomposition. That is, models will be estimated herein using Poisson methods for segmented regression.

Using a segmented linear model approach, a single interrupted time series can be written as

$$\log(y_T) = \beta_0 + \beta_1 T + \beta_2 I + \beta_3 TI + \sum_{j=1}^{k} \alpha_j + \varepsilon$$

where T is a continuous time measure with $T = 0$ corresponding to the intervention point, I is a pre- and post-intervention indicator, α_j is the cyclical effect for $j = 1, \ldots, k+1$ cyclical components and ε is a random error term. When modelling seasonal effects, for example, $k = 3$ and the α_j are measures of seasonal departures from a referent category.

Using the model parameterisation above, the coefficients β_2 and β_3 are readily interpreted, respectively, as the intervention effects change in level and slope. A graphical representation of these effects is given in Figure 1. The term *counterfactual* represents the trajectory of the time series in the post-intervention period when there is no intervention effect. So, the coefficients β_2 and β_3 are measures of deviation in the time series following an intervention.

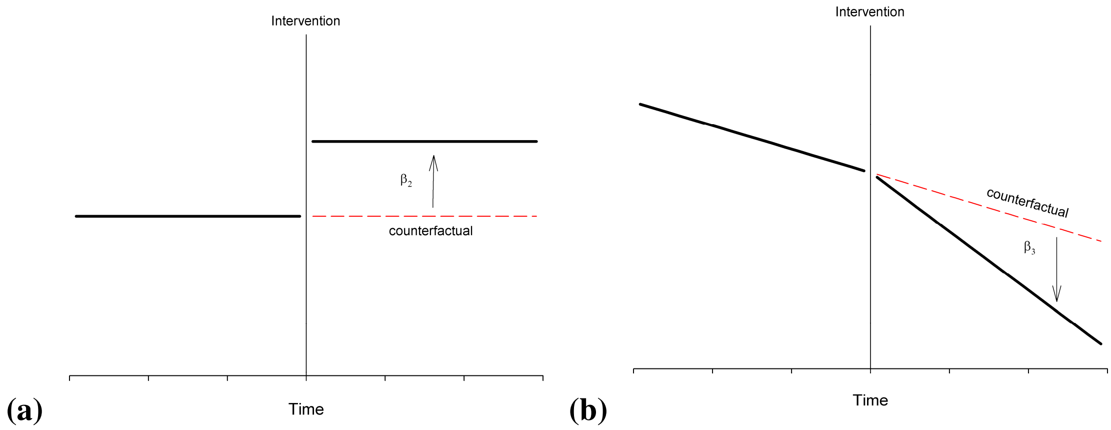

***Figure 1*. Graphical illustration of intervention effects for a single interrupted time series design for (a) change in level and (b) change in slope**

As noted above, changes in a time series could be due to other factors, so that β_2 and β_3 are biased intervention effects if the time series is subjected to unmeasured confounding. In these instances, the use of a comparative interrupted time series (CITS) approach is recommended. In a CITS design, another time series subjected to the same unmeasured confounding factors as the primary series yet not subjected to the intervention is chosen. That is, the unmeasured confounding component for the primary time series $\eta_t^p = \sum_{j=1}^{k} \delta_j^p x_{jt}^p$ is identical or similar to that of the comparator $\eta_t^c = \sum_{j=1}^{l} \delta_j^c x_{jt}^c$, so that $\eta_t^p \approx \eta_t^c$.

The single ITS model using segmented regression can be extended as

$$E(\log(y_T)) = \beta_0 + \beta_1 T + \beta_2 I + \beta_3 C + \beta_4 TI + \beta_5 TC + \beta_6 IC + \beta_7 TIC$$

where C is an indicator function for the primary and comparative time series. This model can be decomposed into two models for the primary (i.e, $C = 1$) and comparative (i.e, $C = 0$) time series respectively as

$$E(\log(y_T^p)) = (\beta_0 + \beta_3 + (\beta_2 + \beta_6)I) + (\beta_1 + \beta_5 + (\beta_4 + \beta_7)I)T$$

and

$$E(\log(y_T^c)) = (\beta_0 + \beta_2 I) + (\beta_1 + \beta_4 I)T .$$

Using this modelling framework, $E(\log(y_T^p / y_T^c)) = (\beta_3 + \beta_6 I) + (\beta_5 + \beta_7 I)T$. It is clear then that the coefficients β_6 and β_7 are measures of change in level and slope, respectively, in the primary time series relative to the comparator.

This model can be used to assess the usefulness of the comparative time series using the recommendations by Linden and Adams (2011) and Walter et al. (2013). First, the primary and comparative time series are identical in the pre-intervention period precisely when $\beta_3 = 0$ and $\beta_5 = 0$, so a statistically significant result would indicate the two series are dissimilar before the intervention. However, in practice, it is unlikely two time series would be identical and the purpose of the comparator is to account for time-dependent confounding; the comparison of time-varying components $\beta_5 = 0$ is the only one of importance.

The within-time period correlation

$$\phi = \frac{\operatorname{cov}(\varepsilon_t^p, \varepsilon_t^c)}{\sqrt{\operatorname{var}(\varepsilon_t^p)\operatorname{var}(\varepsilon_t^c)}}$$

where ε_t^p and ε_t^c are the errors for the decomposed primary and comparative time series respectively. Larger values of $|\phi|$ indicate greater correlation between two time series and can easily be estimated using generalised estimating equations within the above modelling framework. As noted above, Walter et al (2011, 2013) used estimates of ϕ to choose between arm and leg injuries as potential comparators to head injuries.

Empirical Bayes ITS

Empirical Bayes for interrupted time series (EB-ITS) uses the conceptual framework of a Bayesian analysis with frequentist estimation methods. The primary components of an EB-ITS analysis is (1) the pre-intervention data is used to estimate a "prior" model, (2) this model is extrapolated over the post-intervention time period to construct a trajectory or counterfactual and (3) the post-intervention observations are analysed relative to the counterfactual (French & Heagerty, 2008).

The pre-intervention model can be represented by

$$E(\log(y_T^{EB})) = \alpha_0 + \alpha_1 T + \alpha_2 C + \alpha_3 TC$$

where $T < 0$. Using the estimated coefficients from this model, the counterfactual for the post-intervention period, i.e., $T > 0$, is $\hat{y}_T^{EB} = \exp(\hat{\alpha}_0 + \hat{\alpha}_1 T + \hat{\alpha}_2 C + \hat{\alpha}_3 TC)$. A sample of counterfactual residuals are then computed for each post-intervention observation y_t as

$$\Delta_t = \log(y_t) - \log(\hat{y}_t^{EB}).$$

The intervention is associated with a change in the primary time series relative to the comparative series when the average counterfactual residual $\overline{\Delta}_t$ significantly differs from 0, i.e., $\overline{\Delta}_t = 0$ signifies no effect since the post-intervention data does not significantly differ from the counterfactual.

EB-ITS to assess unmeasured confounding

As with CITS designs, an EB-ITS analysis assumes the primary and comparative time series have similar unmeasured, time-dependent components, although EB-ITS makes this assumption on the pre-intervention analysis only. In cases when $\eta_t^p \neq \eta_t^c$ in the post-intervention time period, the counterfactual residuals will have a biased time dependent component, so the model residuals will not behave in a random fashion. In other words, a temporal trend in the observed Δ_t suggests a poor choice in the comparative time series.

Results

It is known that cycling exposure varies over the course of a year; however, the cyclical pattern of cycling in NSW is unknown. With that in mind, three single ITS models for cycling head injuries were fit with monthly, seasonal and winter indicators. The model with an indicator for winter (June, July and August in Australia) resulted in the best Akaike information criterion and was thus retained for the remaining analyses.

Log-linear models over the entire pre- and post-intervention periods were fit for cycling head injuries using cycling arm injuries, cycling leg injuries, pedestrian head injuries and beer production as potential comparators. The scale parameter was estimated by the deviance to account for any overdispersion. Estimates for differences in time varying components and within-month correlation for each model are given in Table 1. The beer production time series performs best versus the other comparators as it has the least significant time-dependent comparison in the pre-intervention period and the greatest within-month correlation with the head injury time series.

Table 1. Model estimates for pre-intervention differences in time varying components (standard error) and within-month correlation.

	Arm	**Leg**	**Head (Peds)**	**Beer**
$\hat{\beta}_5$	-0.008 (0.015)	0.023 (0.021)	-0.008 (0.020)	0.003 (0.015)
$\hat{\phi}$	0.026	0.096	-0.063	0.185

Next, using pre-intervention data, log-linear models were estimated using bicycle-related head injuries as the primary outcome along with bicycle-related arm injuries, bicycle-related leg injuries, pedestrian-related head injuries and beer production. The results are given in Table 2. With the exception of arm injuries, head injuries significantly differed with the other time series in terms of overall magnitude measured by $\hat{\alpha}_2$. Additionally, the winter indicator was statistically significant for each model with the exception of head injuries to pedestrians.

Table 2. Untransformed log-linear model estimates (standard error) for bicycle-related head hospitalisations for eighteen months prior to mandatory helmet legislation

	Arm	**Leg**	**Head (Peds)**	**Beer**
$\hat{\alpha}_0$	-13.656 (0.172)	-13.725 (0.181)	-12.532 (0.114)	-11.203 (0.063)
$\hat{\alpha}_1$	0.001 (0.014)	-0.020 (0.017)	-0.002 (0.011)	0.002 (0.006)
$\hat{\alpha}_2$	0.167 (0.181)	0.792 (0.221)	-0.459 (0.182)	-1.766 (0.163)
$\hat{\alpha}_3$	-0.008 (0.018)	0.023 (0.021)	0.008 (0.018)	0.004 (0.016)
$\hat{\alpha}_4$ (winter)	-0.564 (0.120)	-0.491 (0.132)	-0.078 (0.102)	-0.213 (0.069)

For each model, trajectories were then extrapolated over the post-law period and the counterfactual residuals Δ_t were computed using the post-intervention data for the primary and comparative time series. The difference in the primary and comparative counterfactual residuals,

$$\Delta_t^p - \Delta_t^c = \log(y_t^p / y_t^c) - \log(\hat{y}_t^{EB-p} / \hat{y}_t^{EB-c}),$$

can be interpreted as a comparison of the logarithm of the observed and expected ratio of the primary and comparative time series. There is a clear analytic benefit to comparing the ratio of injuries since two outcomes are collapsed into one. The results from linear models were fit to the observed differences in the counterfactual residuals are given in Table 3. Residual plots from these models are given in Figure 2.

In each case, the slope terms are not statistically significant indicating similar post-law time-varying components between head injury and each comparator. The intercepts were statistically significant, with the exception of leg injuries which were marginally insignificant, indicating an abrupt change in head injury with the helmet law relative to each comparator. Curiously, beer production as a comparator resulted in the largest intervention effect.

Table 3. Linear regression results for difference (standard error) in counterfactual residuals over the post-intervention period

	Arm	Leg	Head (Peds)	Beer
Intercept	-0.263 (0.138)	-0.263 (0.157)	-0.383 (0.190)	-0.494 (0.165)
Slope	0.010 (0.013)	-0.025 (0.015)	0.001 (0.018)	0.010 (0.016)

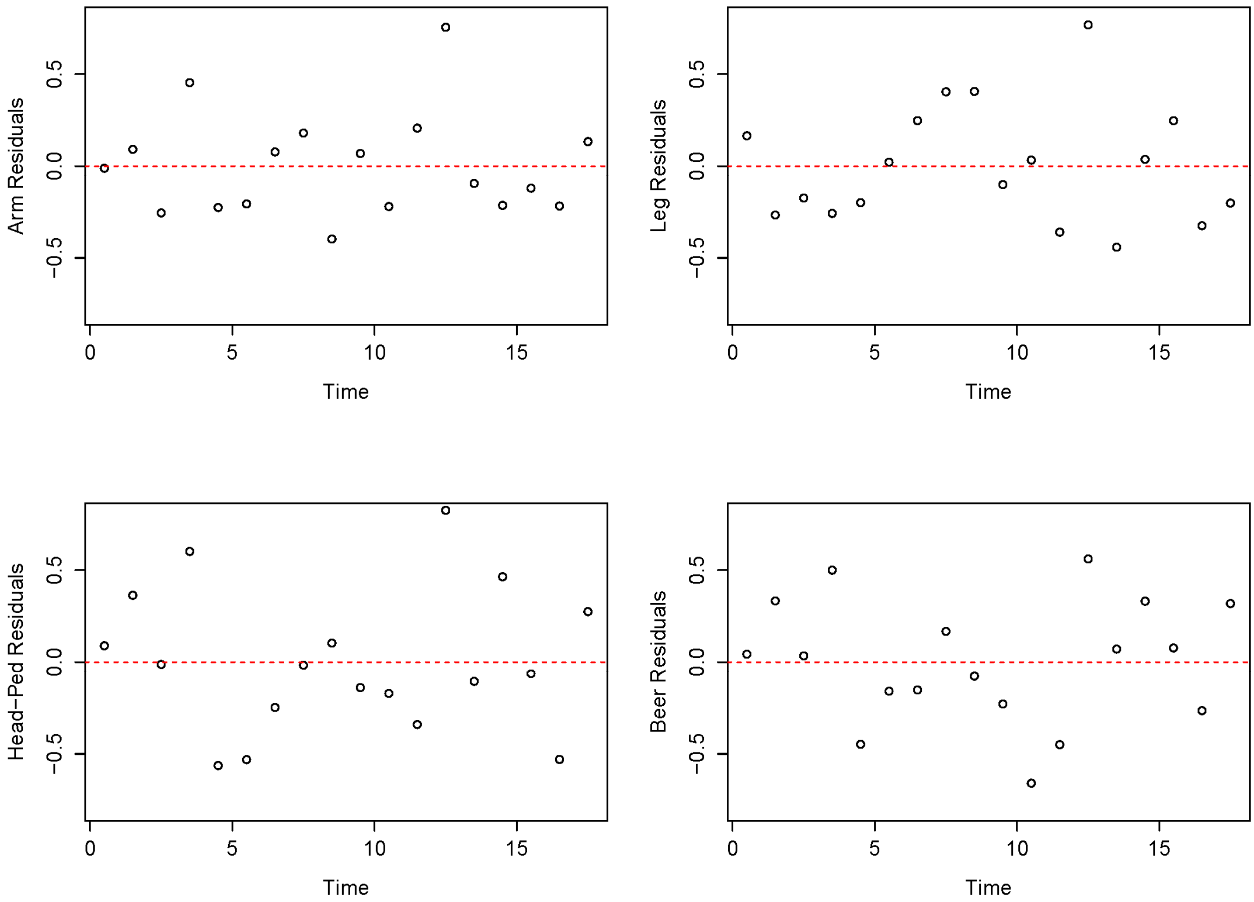

Figure 2. Linear model residual plots from difference in counterfactual residual

There is systematic variability in the residual plots using cycling leg injuries, pedestrian head and beer production as comparators, suggesting the model assumptions, and therefore statistical inferences, are invalid. Further, the systematic pattern is similar for head injuries for pedestrians and beer production as comparators. On the other hand, arm injuries as a comparator results in a random residual pattern suggesting valid statistical results.

Discussion

This paper set out to explore various criteria for selecting a comparator within an interrupted time series analysis. With regards to assessing mandatory helmet legislation, we are primarily concerned with head injuries and potential comparators should be a related process not subjected to the intervention. With that in mind, we chose other, common cycling injuries (arm and leg), head injuries for another vulnerable road user group (head injuries for pedestrians) and a seemingly unrelated time series (beer production) as a sensitivity analysis.

The criteria used were (1) similar pre-intervention trend, (2) within-month correlation, and (3) lack of systematic variability from EB analysis. Based on those criteria, the results were decidedly mixed. All potential comparators did not significantly differ from head injuries in the eighteen month pre-intervention period. The within-month correlation with head injures was inconsequential with the exception of beer production, while EB using arm injuries as a comparator resulted in a non-systematic residual pattern. Using these criteria, cycling arm injuries and beer production performed better than the others; however, the within-month correlation between head injuries and beer production was unexpected.

The lack of correlation between head injuries with either arm or leg injuries runs counter to previous analyses (Walter et al., 2013). However, although sourced from the same database, case definitions were not identical. First, due to the staggered nature of helmet laws for adults and children, we only considered adults in the present study. Secondly, hospitalisations with concurrent injuries to the head, arm and/or leg were considered separate injuries in the previous study, while the present analysis only considered arm or leg injuries that were without a concurrent head injury. Lastly, cyclical adjustments in the original study were made using the X11 method which was done prior to analysis, whereas this adjustment was made within the modelling framework.

Further analyses were performed to investigate the influence of concurrent injuries on the estimates of within-month correlation. The data was subsetted to include each head/arm/leg injury (*All injuries*) and arm/leg injuries with concurrent head injuries were coded as head injuries (*Arm/leg only*) or as arm/leg injuries (*Head only*). Further, separate models were fit with and without an indicator for winter months. The results are given in Table 4.

Table 4. Estimates of within-month correlation for different subsets of concurrent injuries and the inclusion/exclusion of a winter indicator.

	Arm		**Leg**	
	Winter Term	No Winter Term	Winter Term	No Winter Term
All injuries	0.027	0.222	0.137	0.257
Arm/leg only	0.026	0.217	0.096	0.228
Head only	0.034	0.234	0.136	0.260

The inclusion/exclusion of concurrent injuries has little effect on the within-month correlation; however, the inclusion/exclusion of an indicator for winter months has a large effect on the correlation. The results indicate that much of the correlation between head injuries and other cycling injuries is due to cyclical patterns which can be modelled explicitly.

Although it is unclear which comparator better fits the data, each model estimates a benefit to the helmet law of varying degrees. Cycling arm injuries as a comparator results in the smallest estimated benefit, $e^{-0.263}-1=-0.23$, while beer production estimated the greatest benefit, $e^{-0.494}-1=-0.39$.

It is possible these criteria only help to identify a potential (as shown by all series in this study leading to consistent conclusions), but are not sufficient to select a comparator that gives an accurate assessment of the intervention. Hence, further criteria may need to be developed for this purpose. In the absence of such criteria, a conservative approach is to opt for smallest estimated effect among the comparators satisfying the three established criteria.

This study has a few limitations. Although the data used was taken from a census of all NSW hospitalisations, other serious cycling injuries may have only presented to emergency departments and are thus not represented here. Additionally, little is known about cycling exposure around the helmet law in NSW. The Roads and Traffic Authority did commission a series of surveys around this time; however, surveys were only taken over three out of 36 possible months (Walker, 1992). The counts of cyclists from these surveys increased from October 1990 to April 1991 followed by a decline in April 1992 to approximately the pre-law total in 1990. Lastly, the motivating example uses 36 total time points (pre- and post-law) and the results may be more clear with a longer time series. This is a limitation that cannot be overcome for this example due to the lack pre-law hospitalisation data in NSW.

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