The impact of compulsory helmet legislation on cyclist head injuries in New South Wales, Australia: A response

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Publication details:
Accident Analysis and Prevention
v. 52
pp. 204-209

Publication Date:
2013

Elsevier Editorial System(tm) for Accident Analysis & Prevention
Manuscript Draft

Manuscript Number: AAP-D-12-00610R1

Title: The impact of compulsory helmet legislation on cyclist head injuries in New South Wales, Australia: A response.

Article Type: Full Length Paper

Keywords: Bicycle helmets; road safety; injury; helmet legislation; Australia

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Abstract: This article responds to criticisms made in a rejoinder (Accident Analysis and Prevention 2012, 45: 107-109) questioning the validity of a study on the impact of mandatory helmet legislation (MHL) for cyclists in New South Wales, Australia. We systematically address the criticisms through clarification of our methods, extension of the original analysis and discussion of new evidence on the population-level effects of MHL. Extensions of our analysis confirm the original conclusions that MHL had a beneficial effect on head injury rates over and above background trends and changes in cycling participation. The ongoing debate around MHL draws attention away from important ways in which both safety and participation can be improved through investment in well-connected cycling infrastructure, fostering consideration between road users, and adequate legal protection for vulnerable road users. These are the essential elements for providing a cycling environment that encourages participation, with all its health, economic and environmental benefits, while maximising safety.

Highlights (for review)

We respond to criticisms of our original study on mandatory cycle helmet laws

We demonstrate that the original analysis is robust to these criticisms

The beneficial effect of helmet laws in New South Wales, Australia is confirmed

Future cycling improvements need to focus on creating a safe cycling environment

The impact of compulsory helmet legislation on cyclist head injuries in New South Wales, Australia: A response.

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Word count:
Abstract 153
Main text 4300

Key words: Bicycle helmets; road safety; injury; helmet legislation; Australia

1. Introduction

A rejoinder (Rissel, 2012a) to our paper examining the impact of mandatory bicycle helmet legislation in New South Wales (NSW), Australia (Walter et al., 2011) raised questions around the data and methodology used in the study. In this paper we respond to each of the points raised, and endeavour to clarify certain aspects of our study.

Our original analysis attempted to assess the impact of mandatory helmet legislation (MHL) in NSW, using an interrupted time-series modelling approach with several sensitivity analyses to check underlying assumptions. As in any observational study that uses routinely-collected data, there were inevitably data limitations, but we attempted to be as transparent as possible about their existence and our methods for dealing with them.

In the introduction and elsewhere in the rejoinder, a paper co-authored by Rissel, which was retracted by the publishing journal due to pervasive data, arithmetic and graphing errors, is cited as evidence against the conclusions of our study (Australasian College of Road Safety (ACRS), 2010; Churches, 2010; Grzebieta, 2011). Citation of and reliance on the results of a scientific paper after it has been formally retracted is an unusual practice in the peer-reviewed scientific literature, and may have negative consequences for the integrity of scientific discourse. For example, Fyhri et al. (2012) have cited the rejoinder as evidence that the decline in head injuries after MHL is similar to declines in other cycling injuries.

2. Window of analytic focus

The rejoinder suggested that we arbitrarily chose an 18 month pre- and post-MHL analysis window. The 18 month window was constrained by data availability prior to the MHL commencement date and was chosen to be symmetrical so as not to overstate the significance of post MHL trends. An imbalance in the time periods pre- and post-intervention may contribute to biased estimates (French and Heagerty, 2008). The rejoinder asserted that using a longer post-law period would "*significantly reduce any impact of helmet legislation in the regression analysis*". However, as a sensitivity analysis we also analysed the data using a longer post-MHL window and the observed benefit was maintained, as described in our paper (p. 2069). The suggestion that our paper found a reduced effect of helmet legislation from 21% to 9% with the inclusion of three and five years of post-law data is a misinterpretation of our reported results. In our paper, we state (p. 2068):

> *"With 18 months of post-law data, trends ranged from −7.5% to 21.2% per year, whereas with five years of data the range of trends was −0.6 to 9.2%."*

The values quoted in the rejoinder are the upper limits of a range of post-law trend estimates for models based on three and five years of post–law data, respectively. The correct interpretation is that when longer post-law periods were modelled, the post-law trends in head and arm injuries both approached the horizontal (and thus no trend). This provides evidence that the observed reduction in head injuries was maintained over a longer period. Figure 1 shows trend estimates for the head to arm injury ratio in the 18 month pre-law period and also in the 18 month, 3 year and 5 year post-law periods. With increasing duration of post-law data the confidence intervals narrow while remaining centred around one, which is indicative of no diminution of the helmet effect over time (Bell et al., *in press*).This has been corroborated in a subsequent study of long-term head and limb injury trends in cyclists in NSW following MHL which found that the drop in head injury rates over and above limb injuries has not only been maintained, but has increased over time (Olivier et al., *in press*).

It was also suggested that because we used monthly counts of cyclist hospitalisations it would therefore be appropriate to use more stringent significance tests for the model coefficients than the customary p=0.05 criterion. Stricter tests of significance are appropriate when multiple comparisons are being made, such as in models with large numbers of terms in which stepwise model selection techniques are used. However, our analysis was entirely hypothesis-driven and, as such, all seven predetermined terms remained in the model throughout the analysis, as opposed to a model building approach where non-significant terms are eliminated in an effort to obtain the most parsimonious model possible. As a comparison we also performed a backwards elimination analysis, which resulted in a similar untransformed beta estimate for the LAW×INJURY term (-0.2932) but a much more significant p-value (p<0.0001) for this term. This interaction term estimates the change in head injuries in addition to any changes in arm injuries hence providing an indication of the effect of MHL independent of changes in ridership. The results from the original analysis and the most parsimonious model are given in Table 1. Because our analysis was hypothesis-driven, we did not report this more significant result in the original paper. It is well known that the power to detect significant interaction terms is lower than for main effects (Marshall, 2007). Therefore, it has also been suggested that the significance criterion for interaction terms should be less strict than for first order terms and rely more on the unstandardised effect size when interaction p-values are near the nominal 5% significance level. This further reinforces the observed significance of the head injury reduction in our original model.

3. Data pre-law in NSW

It was suggested in the rejoinder that lack of data prior to 1988 prevents examination of the true effect of MHL. While the availability of pre-MHL data was limited, figures 2A and 2B in our original paper show observed helmet wearing before and after MHL commencement, and indicate that the three-year analytic window included the most dramatic change in helmet wearing rates. The assertion in the rejoinder that general trends in road safety adequately explain observed trends in cyclist injuries ignores the fact that our methodology accounted for such background trends, as mentioned in the preceding section. The rejoinder also included a plot of annual proportions of head injuries for various road users in Western Australia as evidence that long-term trends explain the observed drop in head injuries around the time of MHL. That plot was taken from a study by Hendrie *et al.* (1999) that fitted statistical models to both annual pooled counts of cyclist hospitalisations and individual subject data. After adjusting for possible changes in cyclist numbers, the authors of that study concluded that *"…the helmet wearing legislation was shown to have reduced the number of head-injured bicyclists in the post-law period*".

4. Phases of helmet legislation and uptake of helmet wearing

It was pointed out in the rejoinder that the MHL for children came into effect in NSW six months after the law for adults, and our analysis was criticised for having only a single pivot point for both adults and children. We clarify this by reference to our original paper (p. 2066):

> *"Eighteen months of pre- and post-law data was therefore included for both age groups resulting in a 36 month analysis period centred on the date that the legislation came into effect and taking into account the different dates for adults and children. Thus for adults the period was from July 1989 to June 1992 and for children from January 1990 to December 1992."*

In Figure 2A in our original paper the helmet legislation commencement dates for adults (1 January 1991) and children (1 July 1991) are plotted as time=0 and the time scale displayed is relative to the legislation coming into effect, not calendar time. By contrast the x-axis of Figure 2B displays calendar time, hence the two age-specific MHL dates being shown separately. Our aim was to assess the impact of MHL, rather than the related but distinct question of the impact of helmet wearing rates, hence the use of a "pivot point." A subsequent sensitivity analysis in which the pivot point was shifted by several months in the pre- and post-law direction showed that our reported model provided the best fit to the data as shown in Figures 2A and 2B in this paper. The Akaike information criterion (AIC) is the smallest and the drop in head injuries relative to arm injuries is significant when the pivot corresponds to the actual MHL commencement dates, i.e. where month on the x-axis is zero.

A rhetorical question was also posed in the rejoinder: "*Helmet usage did ultimately rise to about 80%, but the public health question then becomes, why was there not a corresponding large reduction in head injuries of this magnitude?*" As already mentioned, observed helmet wearing rates in NSW pre- and post-MHL were approximately 25% and 80% respectively. Thus, about 55% of cyclists adopted helmet wearing at the time the laws came into effect. In a recent meta-analysis, Elvik (2011) estimated summary odds ratios for helmet effectiveness in preventing or reducing head injuries of between 0.43 (random effects estimate) and 0.51 (fixed effects estimate) where no adjustment was made for publication bias. Given that the proportion of head injury outcomes in the studies used in this meta-analysis were generally quite low, it is reasonable to treat these summary odds ratios as approximations for incidence density ratios (Rothman and Greenland, 1998). Applying them to the observed change in helmet wearing in NSW cyclists yields an expectation that the commencement of helmet laws would result in a drop in cyclist head injuries of between 27.0% and 31.4% at the population level. Our study estimated 27.5% and 31.0% reductions in observed head injuries at the population level using arm and leg injuries respectively for comparison, and thus corresponds very closely to the expected public health effect. We have not used the pooled odds ratios that were adjusted for possible publication bias from that meta-analysis in our estimate of expected population health effect, because they are known to be incorrect, due to calculation errors (personal communication, Rune Elvik, October 2012).

5. Changes in cyclist numbers over time

The use of limb injuries as a comparison group to head injuries, which we employed as a means to overcome the lack of cyclist exposure data, also takes into account changes in cyclist numbers. A 30-40% reduction in cycling participation in NSW after the commencement of MHL is an often misquoted or selectively quoted figure (Robinson, 1996; Curnow, 2008; Rissel and Wen, 2011) from the surveys by Smith and Milthorpe (1993). In fact, the survey results show a drop in school-aged riders, while adult cycling participation remained largely unchanged in the Sydney metropolitan region where the majority of the population lives, with a modest reduction in rural regions. However, the authors of the survey series explicitly warn that their study was not designed to assess participation, and thus should not be relied on as definitive evidence of changes in participation one way or the other. On the other hand, hospitalisation records as used in our analysis are a census of injured cyclists admitted to hospital and are thus not susceptible to weaknesses common to survey data. In any case, changes in the cycling exposure denominator that occurred during the analysis period obviously applied equally to both head and arm injury rate numerators.

The use of arm injuries as a comparison for head injuries is known as a dependent non-equivalent no-treatment control group (Shadish *et al*., 2002). Unmeasured changes in the cycling environment, safety improvements and the behaviour of cyclists (e.g., cycling rate and distance cycled) would affect head and arm injuries similarly with the exception of interventions directed at one and not the other. Any deviations in the ratio of head and arm injuries over time would indicate the effects of such a differentially targeted intervention. For these reasons, it has been suggested that the use of cyclist arm injuries as a comparison group to account for threats to internal validity is superior to other non-dependent metrics such as pedestrian or motor vehicle related injuries (Shadish et al., 2002).

Hence, as stated in our paper, the observed reduction in head injuries after MHL was over and above any changes in cyclist numbers or background trends. In fact, our model estimated an absolute decline in head injuries of 35%. Our models adjust this figure to 27.5% and 31.0% when compared to arm and leg injuries respectively. We appreciate that the model design is not particularly intuitive and a more straightforward, but less informative, analysis would be to compare the counts of injuries pre- and post-MHL. In the 18 months before MHL there were 1289 and 1158 head and arm injuries respectively. Post-MHL, head injuries declined substantially by 33% (866) while arm injuries only declined by 8% (1062). The declines for the two injuries were statistically significant by Pearson's chi-square test ($p<0.0001$).

It was also suggested in the rejoinder that our analysis should have been stratified by age group. The original analysis aimed to assess the overall impact of MHL. Incorporating an age variable into a model that already had up to three-way interactions would have increased the complexity of the model and its interpretation considerably, and because differences in seasonal trends for adults and children had been taken into account, age-specific analyses were not conducted as part of the original study. However, it is possible to run separate models on the seasonally adjusted counts for the two broad age groups. Two time series may be correlated with each other at different time lags, known as cross correlation. Because there was strong cross correlation between residuals for head and arm injury counts from within the same month (i.e. a lag of zero), a generalised estimating equations (GEE) approach was used to account for this in the negative binomial models. Bearing in mind that significance for interaction terms may be less stringent than the typical p<0.05, as mentioned previously, the reduction in head injuries over and above any change in arm injuries (given by the INJURY x LAW interaction) was sizable and significant in both age groups. The model coefficients indicate adjusted reductions of 24% (p=0.0008) and 30% (p=0.055) for children and adults, respectively. The significance of these estimates is conservative given that fitting a parsimonious model gives adjusted estimates of a 25% reduction in head injuries in both groups, but with much higher significance: p<0.0001 for children and p=0.001 for adults.

The strong within-month cross-correlation between residuals for head and arm injury counts (=0.60, >>2 standard errors) also provides evidence that arm injuries are an appropriate comparison group. In contrast, there was minimal evidence of such correlation when leg injuries were used as a comparison (=0.27, <2 standard errors). This is consistent with the biomechanics of a cyclist falling from a bicycle or being struck by or running into a car. The head and arms tend to pivot around the legs. The change in velocity (delta V) of the head and arms is typically much higher than for the legs, thus resulting in greater and more frequent injury to these body regions as opposed to the legs. In general a fall from a bicycle often involves outstretched arms and possible impact of the head onto the pavement, but only superficial wounds (scrapes and cuts) to the legs. Impact with a pedestrian is similar, usually involving an outstretched arm, shoulder and possibly the head as the rider falls to the pavement after striking the pedestrian, with little involvement of the legs (Short et al., 2007). When a rider is struck by a car, the thigh region is typically struck by the front grille/hood causing the upper torso, head and arms to rotate around the thigh. This often results in a head and/or upper limb strike into the windshield or the bonnet (hood) area near the windshield (Otte, 2004).

6. Comparison of pedestrian and cyclist injuries

The point was made in the rejoinder that the scope of the International Classification of Disease (ICD) codes for transport accidents in cyclists and transport accidents in pedestrians are not comparable, because the latter does not include falls unrelated to traffic accidents. However, any difference in the scope of these codes for cyclists and pedestrians is irrelevant to our study, because at no stage did we compare the rates of cyclist injuries with the rates of pedestrian injuries. Rather, we compared time-series models of cyclist injuries with time-series models of pedestrian injuries in order to determine whether any observed change in head injury rates at the time of MHL commencement was specific to cyclists. This was done as an additional sensitivity analysis and to check that any apparent shift in injury rates at the time the MHL came into effect was not due to some other prevailing factors, such as general road safety improvements. Differences in ICD coding scope for the two groups does not affect this comparison of models - it only matters that case definitions are valid and consistent within each group.

7. Re-analysis of the data

The rejoinder stated that we declined to provide a copy of the data, thus impeding re-analysis. Data provision agreements prevented us from providing the data to third parties. However, we have subsequently sought and obtained approval from the data providers to publish the seasonally adjusted hospitalisation count data used in our analysis via an institutional research repository website (http://handle.unsw.edu.au/1959.4/50858).

8. Discussion

A valid criticism of our paper that was not raised in the rejoinder is that we did not account for correlation between monthly head and arm injury counts. A subsequent adjustment of the model to allow for this, via a GEE approach, resulted in the observed MHL benefit becoming even more significant (p<0.001) without any change to model estimates to three decimal places. Also we did not report whether there was evidence of serial correlation in the model residuals in the original analysis. Figure 3 shows that there was no evidence of autocorrelation (cross-correlation of a series with itself) in the head or arm injury residuals. There was evidence of cross-correlation between the head and arm injury residuals in the same month but this is accommodated by the GEE approach discussed above. We also did not previously provide detail of how well the model fitted the data in our original analysis other than to mention that the Pearson chi-square test of model fit was not significant. The deviance residuals from the original model in figure 4 indicate that the model fitted the data well and that the seasonal adjustment appears to have successfully removed any cyclic effects.

At every juncture in our analysis we attempted to take a conservative approach. Despite this, we still observed evidence of a significant benefit due to MHL. We did not and do not claim that our study, on its own, provides sufficient impetus for the introduction of such laws in jurisdictions in which bicycle helmets are currently optional. However, in the Australian context, our study provides robust evidence that MHLs are effective in reducing head injuries, and that such effects can indeed be observed at the population level using routinely collected hospitalisation data. Arguments for the repeal of Australian helmet laws, which have been in force for two decades, must be evaluated very carefully in the light of such evidence.

It was hypothesised in the rejoinder that the magnitude of our observed reduction in head injuries was "optimistic". Given the consistently conservative approach to our analysis, the opposite is more likely to be true, although discussion of bias in either direction is speculative. In support of this hypothesis, results from Hynd *et al*. (2009) and Elvik (2011) were incorrectly quoted, both in the rejoinder and elsewhere (Rissel, 2011; 2012b): *"…two recent reviews of the bicycle helmet literature concluding that helmets protect at best 10% (Hynd et al., 2009) to 15% (Elvik, 2011) of cycling related head injuries*." In fact, the most conservative of the adjusted summary estimates in the Elvik meta-analysis was a greater than 40% reduction in bicycle related head injuries due to helmet wearing (OR=0.58, Table 2). As noted above, it has subsequently been discovered that the publication-bias-adjusted pooled effect estimates in this meta-analysis are incorrect. Hynd *et al*. reported that 10 to 16% of a sample of 116 UK cycling fatalities (due to all types of injury, not just head and brain injury) might have been prevented had the rider been wearing an appropriate helmet, on the basis of detailed biomechanical analyses of police forensic reports.

The suggestion in the rejoinder that helmets can increase angular acceleration during a crash and hence increase risk of diffuse axonal injury (DAI) to the brain is not supported by evidence specific to cyclists and cycle helmets. One of the references provided makes no direct mention of DAI (Curnow, 2006). The other (Curnow, 2007) asserts that Australian experiments found increased angular acceleration caused by a (now obsolete) 1.35kg fibreglass bicycle helmet, although the authors of that report clearly state that the data do not prove such an effect (Corner *et al*., 1987, p24). Two other studies cited in the 2007 Curnow paper link brain injury and angular acceleration, but make no mention of cyclists or cycle helmets (Adams *et al*., 1986; Gennarelli and Thibault, 1982). A recent experimental study, which tested Curnow's hypothesis that bicycle helmets increase angular acceleration during a crash, found that they actually reduced both linear and angular acceleration by a considerable margin (McIntosh et al., *in press*). It has been proposed that not accounting for DAI in studies assessing helmet efficacy created biased results that might overstate any observed benefit (Curnow, 2003; 2007). However, another recent population-based data linkage study (Bambach et al., *re-submitted*) found that of all reported cycling crashes with motor vehicles in NSW between 2001 and 2009 where helmet and hospitalisation information was present, DAI could have occurred in at most 0.2% of cases (12/6745), although due to limitations in the ICD-10-AM coding scheme used, it is not possible to be certain whether DAI occurred in these cases. Seven of these twelve possible cases of DAI were unhelmeted. However, due to rarity of these potential DAI cases amongst injured cyclists, it is unlikely that failure to account for DAI as a separate category of brain injury has introduced any significant bias into bicycle helmet efficacy studies. Neither is there any suggestion that bicycle helmets may contribute to DAI.

We agree that cycling participation in Australia is considerably lower than in many other wealthy countries, and that there are many environmental, economic and health benefits to be gained from increased participation. However, in the handful of available historical survey reports there is scant evidence that the introduction of MHLs in Australia in the 1990s played a significant role in reducing adult cycling participation at the time, or in the two decades since. There is a body of more recent evidence that suggests other factors are a greater impediment to participation than MHL. The rejoinder mentions a population-based survey by the Cycling Promotion Fund (2011) that reported 16.5% of adults who cycle at least once per month nominated helmet wearing as a barrier to more cycling. This survey also reported that MHL was the thirteenth most common reason given for not riding for transport by non-cyclists, and the tenth most common reason for not riding more frequently for transport by cyclists. The barriers most frequently nominated by respondents were unsafe road conditions, traffic speed and volume, and a lack of separated bicycle lanes. Another report (Bauman *et al*., 2008) also listed lack of cycling infrastructure and perceived danger as major impediments to adult cycling, but made no mention of helmets or helmet laws.

A recent survey asked respondents about government control including MHL. The results estimate that 94% of Australians approved of MHL and 65% strongly approved while only 1% strongly disapproved of MHL (Essential Vision, 2012). Other factors identified as having a significant effect on cycling participation and uptake are weather, seasonal effects and petrol prices (Smith, 2011), changes in the built environment (Beenackers *et al*., 2012) and the extent of bike paths and lanes (Buehler and Pucher, 2012). A follow up analysis to our original study examining long-term trends in cyclist injuries post-MHL found a significant relationship between spending on cycling infrastructure and decreasing injuries, particularly head injuries (Olivier et al, *in press*). This evidence strongly indicates that infrastructure improvement is an effective way to increase both participation and safety.

Finally, the following association was made in the rejoinder: "…*when mandatory bicycle helmet legislation was introduced in 1991 obesity and diabetes epidemics were only just beginning, and Australia now has among the highest rates in the world*…". There are several other wealthy countries that do not have mandatory helmet laws but have similar or worse obesity and metabolic disease rates than Australia, and similarly low cycling participation rates. To our knowledge there is no evidence in support of a link between MHL and obesity rates, but the influence of MHL on behavioural changes, either positive, negative or otherwise, at a population level may be an area worthy of further inquiry.

9. Conclusion

Safety concerns tend to dominate media coverage of cycling in Australia (Rissel *et al*., 2010). This public discourse is often framed, or re-framed, around removal or relaxation of mandatory helmet laws (Piper *et al*., 2011), despite the wearing of helmets by cyclists forming only one part of the safety picture. In contrast, the high levels of cycling participation and the excellent cycling safety environment in northern European countries such as the Netherlands, Denmark and Germany appear to have been predicated on substantial and sustained investment in well-connected networks of thoughtfully designed bike lanes, bike paths and other cycling infrastructure. Other important factors are low speed limits on urban streets, the fostering of consideration and understanding between road users, and adequate legal protection for vulnerable road users, both cyclists and pedestrians alike. These are the essential elements for providing a cycling environment that encourages participation, with all its health, economic and environmental benefits, while maximising safety.

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Figure Captions

Figure 1. Trend estimates in head to arm injury ratio for 18 months pre-law data, and 18 months, 3 years and 5 years post-law data

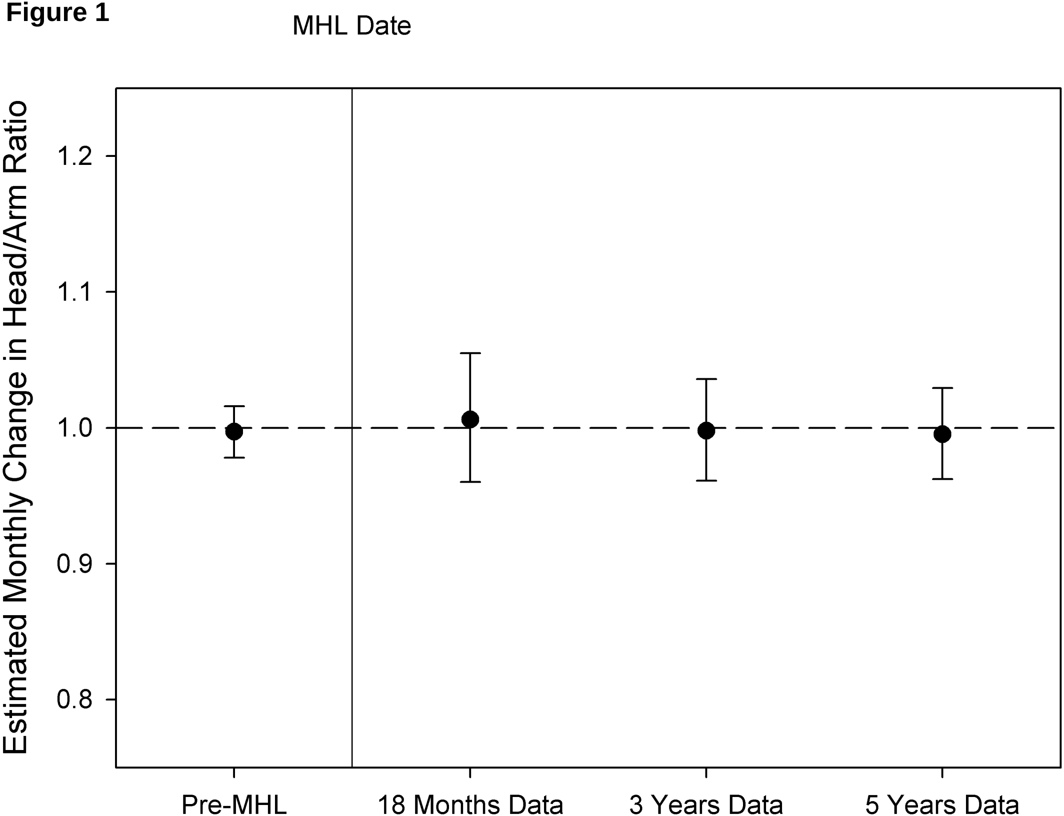
Figure 2A. Significance of the INJURY x LAW interaction term in the negative binomial model of head and arm injures for assumed mandatory helmet law dates ranging from -18 to +18 months from actual date.

Figure 2B. Aikake Information Criterion (AIC) for negative binomial model of head and arm injures for assumed mandatory helmet law dates ranging from -18 to +18 months from actual date.

Figure 3. Autocorrelation and cross correlation for monthly head and arm injury counts for zero to twelve lags

Figure 4. Deviance residuals by month relative to law commencement date for negative binomial model of cyclist head and arm injuries

Figure 1



MHL Date
Estimated Monthly Change in Head/Arm Ratio
1.2
1.1
1.0
0.9
0.8
Pre-MHL
18 Months Data
3 Years Data
5 Years Data

Figure 2A

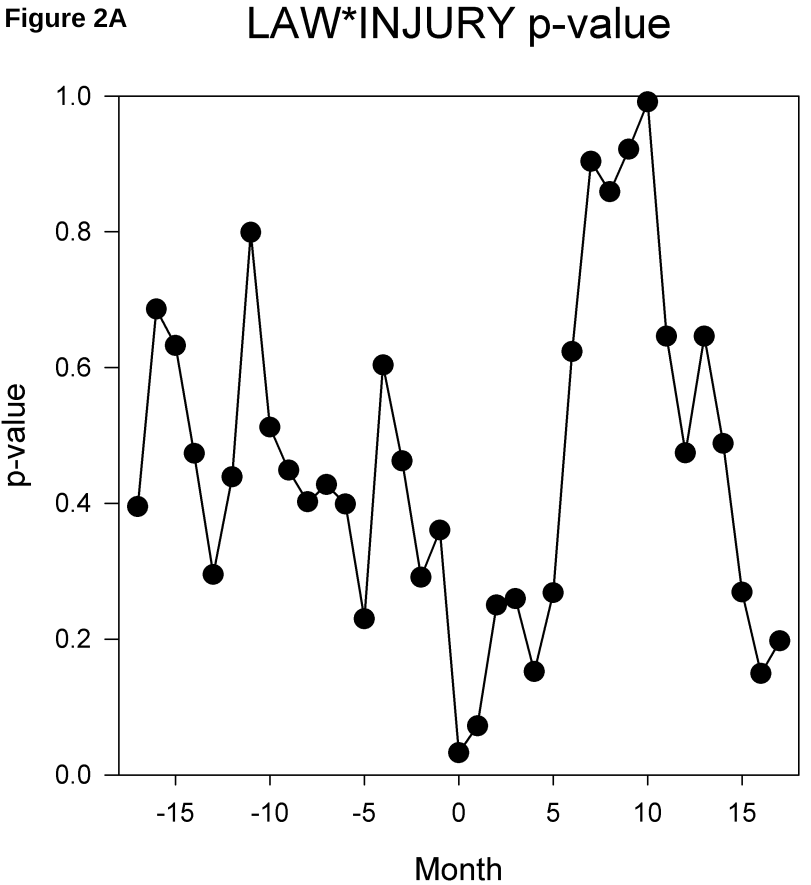
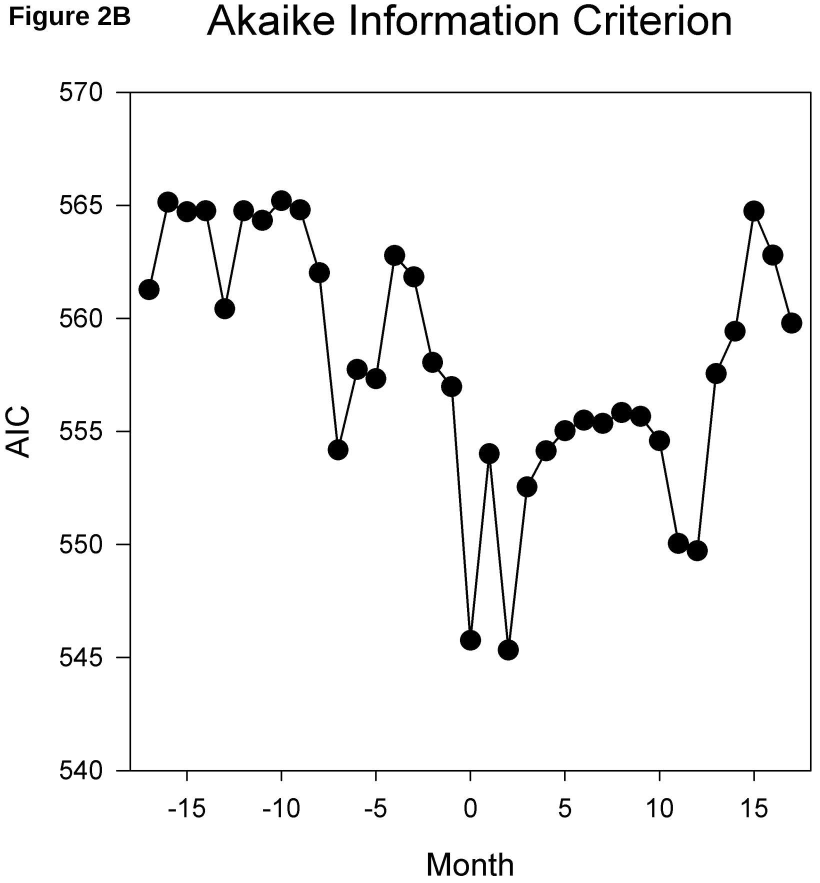
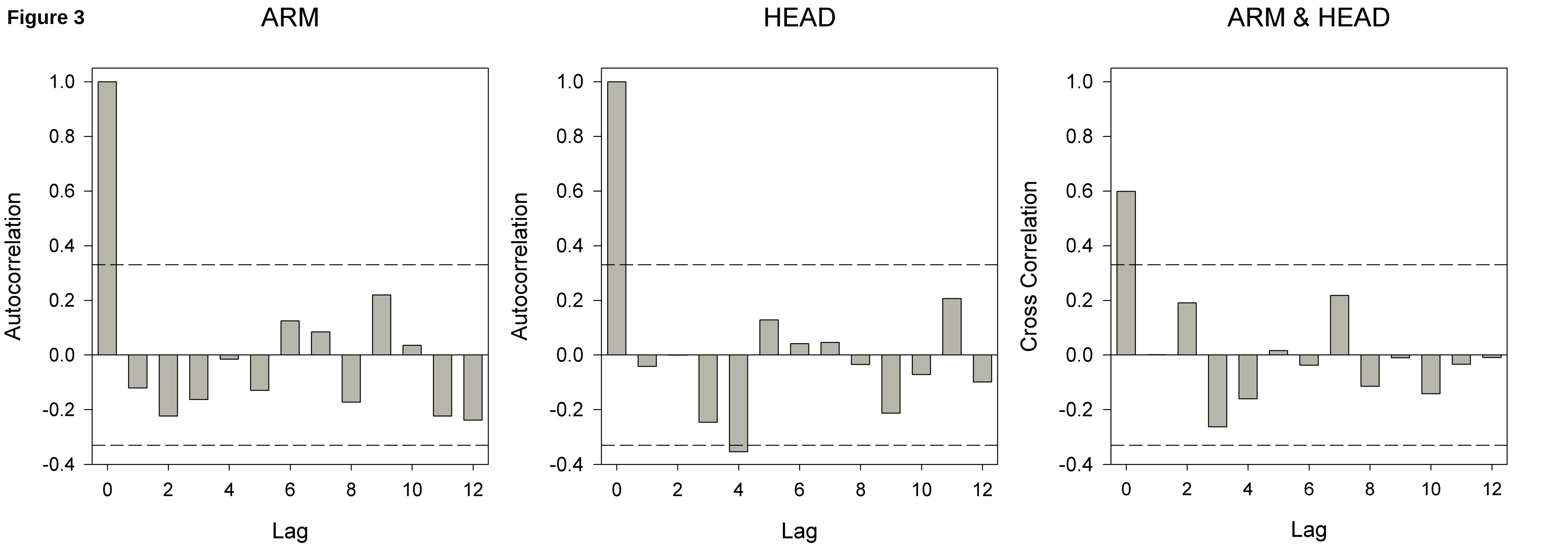


Figure 2B



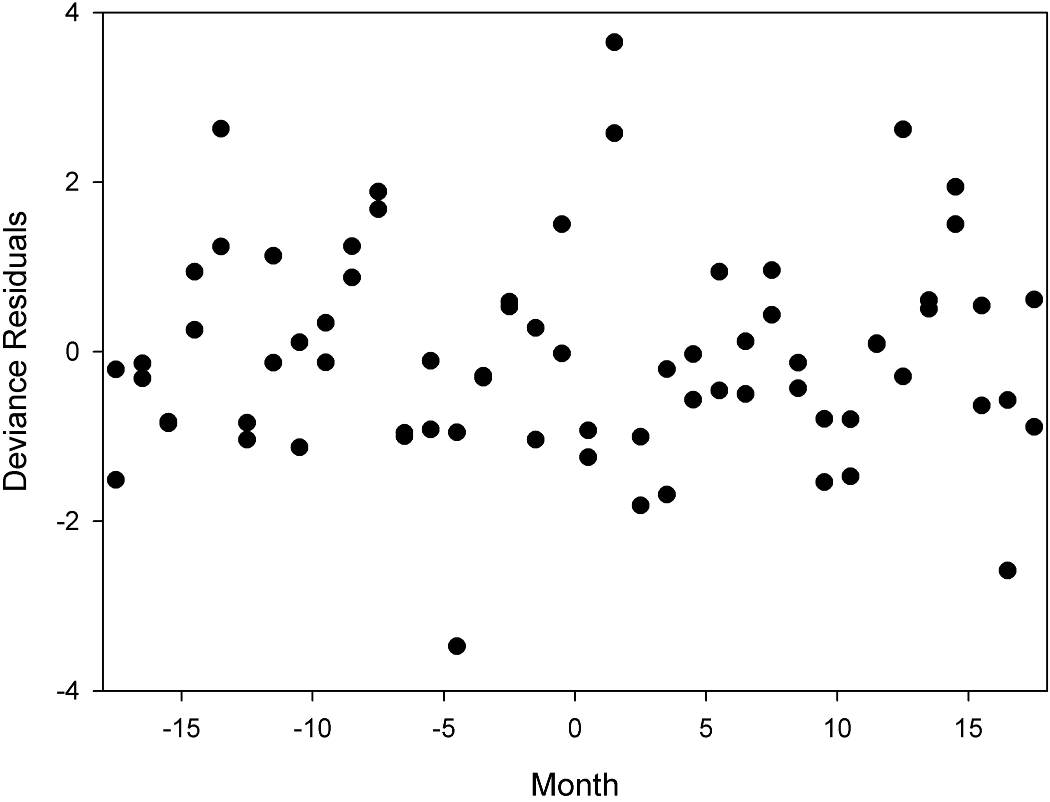
Akaike Information Criterion
570
565
560
555
550
545
540
AIC
-15
-10
-5
0
5
10
15
Month

Figure 3



ARM
HEAD
ARM & HEAD
Autocorrelation
Autocorrelation
Cross Correlation
1.0
0.8
0.6
0.4
0.2
0.0
-0.2
-0.4
0
2
4
6
8
10
12
Lag
Lag
Lag

Figure 4



Table(s)

Table 1: Comparison of untransformed negative binomial model estimates of cyclist head and arm injuries using the full and most parsimonious models.

	Original Analysis			Most Parsimonious Model		
Variable	**Estimate**	**95% CI**	**p-value**	**Estimate**	**95% CI**	**p-value**
TIME	-0.005	-0.019, 0.009	0.454	-0.007	-0.017, 0.003	0.157
INJURY	0.072	-0.128, 0.272	0.482	0.101	0.002, 0.200	0.045
LAW	-0.112	-0.318, 0.093	0.285	-0.124	-0.288, 0.040	0.138
TIME×LAW	0.015	-0.005, 0.034	0.137	0.020	0.005, 0.034	0.007
INJURY×LAW	**-0.322**	**-0.618, -0.027**	**0.033**	**-0.293**	**-0.439, -0.148**	**<0.001**
TIME×INJURY	-0.003	-0.022, 0.016	0.740			
TIME×INJURY×LAW	0.010	-0.018, 0.038	0.504			