A systematic review of methods used to assess mandatory bicycle helmet legislation in New Zealand

by Jake Olivier¹, Joanna JJ Wang^{1,2} and Raphael Grzebieta²

Abstract

Background: Mandatory helmet legislation (MHL) for cyclists became effective in New Zealand (NZ) on 1 January 1994. Assessments of the NZ MHL have led to conflicting conclusions regarding its effectiveness at reducing cycling head injury and risk of fatality. These studies also differ in their use of analytic approaches and data sources.

Objectives: The aim of this paper is to systematically review all studies that assess the NZ MHL in accordance with quality criteria for assessing population-based interventions.

Data Sources: A search of Medline, Scopus and Web of Science for peer-reviewed articles from 1994 to 9 September 2014 was conducted.

Study Selection: Documents were independently extracted by two reviewers and limited to original articles in peer-reviewed journals that assessed the NZ MHL in terms of cycling head injury.

Results: The results from three of the four included studies indicated a positive effect of MHL for increasing helmet wearing and reducing head injuries. However, the findings of these studies must be interpreted within the context of methodological limitations.

Conclusion: We believe more high quality evaluations are needed to provide evidence for an objective assessment of MHL in NZ.

Keywords

Bicycle helmet legislation, New Zealand, Systematic review, Quality criteria

Introduction

Helmet use was made mandatory in New Zealand (NZ) for cyclists of all ages on 1 January 1994. The law applies to on road cycling where a road is defined to include: a) a street; b) a motorway; c) a beach; d) a place to which the public have access; e) all bridges, culverts, ferries, and fords forming part of a road or street or motorway or a place

referred to in d); and f) all sites at which vehicles may be weighted for the purposes of the Act or any other enactment (New Zealand Land Transport (Road User) Rule 2004).

Although the impetus for helmet legislation is to reduce cycling head injury, there is no direct causal link. Instead, helmet legislation acts to increase helmet usage among cyclists and, given the hypothesised protective effect of helmets, should lead to a decrease in cycling head injury. A diagram of this hypothetical relationship is given in Figure 1.

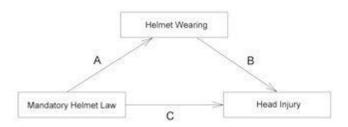


Figure 1. Diagram of the relationship between helmet legislation, helmet wearing and cycling head injury

Given the relationship between these variables, an assessment of helmet legislation can take on many forms. This can include assessing the association (A) between the law and helmet wearing, (B) between helmet wearing and head injury, or (C) between the law and head injury. The analysis of an intervention, such as analyses (A) and (C), is best analysed as an interrupted time series [24]. Because of the inter-relationship between these analyses, we believe a full assessment of the effects of helmet legislation to reduce head injury requires assessing all three associations.

Much of the literature assessing helmet legislation has focused on one type of analysis. Rodgers [18] assessed the effect of helmet legislation on the uptake of bicycle helmet use among children less than 16 years of age in US states. Povey, Frith and Graham [14] assessed the relationship between changes in helmet wearing and cycling head injury in NZ using data before and after helmet legislation. Cameron et al. [3] assessed changes in cycling head injury following helmet legislation in Victoria.

Helmet wearing has consistently been shown to be effective in case-control studies; however, there are conflicting results when assessed at a population level [1, 25, 20].

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Therefore, it is important to assess the quality of studies, as high quality evaluations are necessary to provide solid evidence supporting or opposing the intervention which, in turn, has profound implications for future decision-making by governments.

The aim of this paper is to perform a systematic review against quality criteria for peer-reviewed manuscripts assessing the effect of the NZ helmet law on cycling head injuries. We chose to focus on NZ due to the abundance of relevant data (over five years of pre-helmet law hospitalisation data and yearly helmet wearing estimates from 1986-2012). Also, none of the NZ studies met inclusion criteria of a Cochrane Review [9] and therefore none were assessed against quality criteria.

Methods

Potential studies were selected through searches on Medline, Scopus, and Web of Science on 9 September 2014. Google Scholar was not chosen due to its inability to search within titles and abstracts only. The search terms were "helmet" and "New Zealand" for articles published from 1994 onwards. The search terms were intentionally broad in scope in an effort to avoid omitting relevant studies. Articles were excluded if they were duplicates, were commentaries or did not assess the impact of the New Zealand bicycle helmet law.

Those studies meeting the selection criteria were then independently assessed against quality criteria (see Appendix) by two of the authors (JW and JO) in accordance with PRISMA guidelines [12]. Compliance with each criterion was either "Yes", "No", "Partial", "Unclear" or "Not applicable". The assessments are shown in Table A1. Disagreements regarding criteria were discussed and all disagreements were resolved.

Quality criteria were adapted from Downs and Black [5], Ramsay et al. [15] and Macpherson and Spinks [9]. The criteria fall under the broad categories of Study Design, Reporting, Internal Validity and Interrupted Time Series (ITS) Design. Detailed information regarding specifics of scoring is given below.

Study Design

The quality criteria for study design consist of assessing the three pairwise associations of helmet legislation, helmet wearing and head injury. This corresponds to relationships A, B and C in Figure 1. A "Yes" is given when there is a formal analysis of the association and "Partial" is given if there is only a description of the association.

Reporting

The quality criteria for reporting are assessed against whether the manuscript included the study hypothesis, main

outcomes and interventions, main findings, estimates of random variability, p-values and potential adverse impacts of the intervention.

Internal Validity

Both randomisation of pre- and post-intervention time periods and blinding are infeasible for population-level intervention studies. It has been argued that internal validity can be maintained by including cases and controls from the same population and over the same period of time [9]. A potential threat to internal validity is the reliability of compliance with the intervention. Therefore, a discussion of changes in the helmet wearing rate with the helmet law is required as a measure of compliance. Adjustment for confounding is also essential in an assessment to address potential biases. It is, however, unclear what type of adjustment would be sufficient or most appropriate to address potential confounding. Other issues related to internal validity include using appropriate statistical tests, and accurate and valid outcome measures.

(Interrupted) Time Series Design

Interrupted time series (ITS) designs broadly encompass analytic approaches to assess interventions using time series data. The criteria given have been adapted from Ramsay et al. [15]. Not every analysis will follow an ITS design, e.g. assessing changes in helmet wearing and head injury over time. In those instances, a study will be assessed in accordance with the quality criteria related to time series designs.

It is required the data cover at least 80% of the total number of participants in the study. For the assessment of helmet legislation using hospitalisation data, this translates to no more than 20% of the data that can be missing around the effective date of the law. Specific to ITS designs, the authors need to state a rational explanation for the shape of the intervention effect. This may come in the form of an abrupt or gradual change in the time series or whether the hypothesised effect is immediate or delayed.

Serial correlation often occurs in observations taken over time and p-values are underestimated for models that assume independence when serial correlation exists. It is therefore important for models to explicitly account for serial correlation (e.g. autoregressive integrated moving average (ARIMA) or structural time series models) or to check for residual correlation for models that do not (e.g. linear or generalised linear regression).

Other criteria in this area include justifying the number and level of data aggregation and using a concurrent comparison group.

Results

A flow chart for studies included for quality assessment is given in Figure 2 [12]. The three search engines identified 149 potential articles for inclusion of which 62 duplicate records were removed and 79 articles were excluded by a title and abstract search according to the selection criteria. These papers were excluded as they were unrelated to cycling (59%), did not focus on New Zealand (25%), did not assess helmet legislation (6%) or were commentaries (9%).

Of the eight remaining papers, two papers were cost-benefit analyses and did not directly assess changes in helmet wearing or head injury [7, 22]. Two papers were excluded as they were commentaries of other studies [16, 17].

In total, four studies met selection criteria [14, 21, 13, 4]. A brief description of each study is given as follows:

Povey, Frith & Graham (1999)

The effect of changes in cycle helmet wearing on head injuries was assessed using hospitalisation data between 1990 and 1996, and separately for motor vehicle and non-motor vehicle crashes. Estimates of helmet wearing rates were obtained from national surveys conducted by the Land Transport Safety Authority. Injury data was obtained from the New Zealand Health Information Service and cases were identified by ICD-9-CM (1990-1994) and ICD-9-CM-A (1995-1996). Injury counts were aggregated by year. Non-motor vehicle injury data was further broken down into three age groups: primary school age (5-12 years), secondary school age (13-18 years) and adult (age 19 and above). The number of limb fractures provided a measure of exposure to the risk of cycling injuries and was used as a comparative control group.

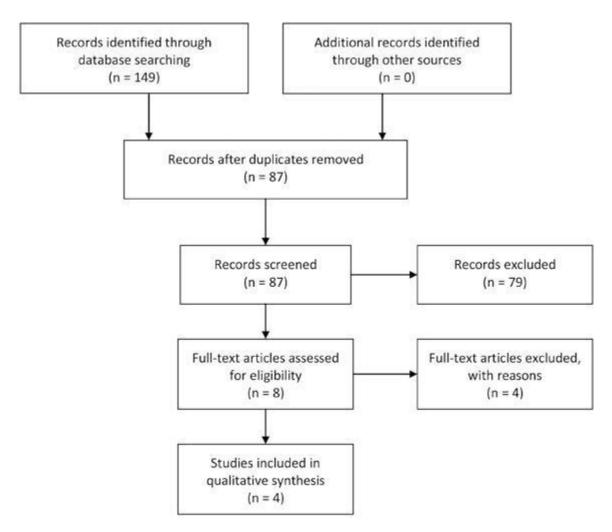


Figure 2: Flow diagram of selection of articles considered for inclusion

Scuffham et al. (2000)

The effect of changes in helmet wearing and the helmet law on serious head injury to cyclists was assessed for motor vehicle and non-motor vehicle crashes between 1988 and 1996. Hospitalisation data were obtained from the New Zealand Health Information Service. Injury data were aggregated into quarterly intervals centred on the months of the helmet surveys and intervening months. Age was categorised by primary school children (5-12 years), secondary school children (13-18) and adults (19+ years). Head injury data was disaggregated into fractures, intracranial injuries and lacerations defined by ICD-9-CM codes. A negative binomial regression model was used with head injury count as the outcome and the helmet wearing rate as an explanatory variable. All injured non-cyclists admitted to hospital were used as a comparison group. The number of cyclists admitted without a head injury was used as an offset.

Moyes (2007)

The impact of helmet law and safety campaigns was assessed on bicycle injuries in children in the Bay of Plenty. Data consisted of all bicycle injuries to children that presented at the Whakatane Hospital Emergency Department in the periods 1982-1986 and July 1998-December 2005. Comparisons were made on an average yearly rate per 100,000 population between the two time periods. There was no assessment of the association between helmet law and helmet wearing, or between helmet wearing and cycling head injury. No concurrent comparison group was used in the analysis.

Clarke (2012)

A review of publicly available data and analyses was performed to assess the impact of the NZ helmet law in terms of cycling activity levels, safety, health, law enforcement, accident compensation, and environmental and civil liberties issues. The exposure data came from the Land Transport Safety Authority and the ongoing New Zealand Household Travel Surveys. Fatality data was obtained from the Ministry of Transport and injury data was sourced from Tin Tin, Woodward and Ameratunga [23]. However, cycling head injuries were not presented in the study apart from other cycling injuries. There was no assessment of the association between the helmet law and helmet wearing, between helmet wearing and cycling head injury, or between the helmet law and cycling head injury. Pedestrian fatality numbers were used as a comparison group.

A more detailed discussion of these studies with regards to quality criteria follows.

Study design

None of the included studies formally assessed all of the three potential associations. Scuffham et al. [21] fully met two criteria and received a partial mark for a descriptive assessment of helmet legislation and changes in helmet wearing. On the other hand, Clarke [4] did not assess any of the possible associations.

Reporting

Reporting was in general adequate for all included studies, except for criterion six on providing estimates of the random variability in the outcome. Only one study [14] provided estimates of random variability for all the main outcomes.

Internal Validity

Two studies adjusted for exposure time [13, 4]. One study Clarke, [4] did not use any statistical tests and Moyes [13] used a t-test to compare two proportions. The use of the t-test is not justified for proportions although it gives similar results to the chi-square test for large sample sizes.

Adequate adjustment for confounding was also limited in these studies. Moyes [13] and Clarke [4] did not explicitly adjust for confounding while Povey, Frith and Graham [14] and Scuffham et al. [21] adjusted for confounding by comparing changes in head injuries with other injuries. Povey, Frith and Graham [14] used limb fractures to account for any variations in the level of cycling risk over time and possible changes to the cycling environment. On the other hand, Scuffham et al. [21] used injured non-cyclist admission counts to control for changes in the probability of being admitted to hospital with a head injury. However, it is unclear to what extent such strategies account for potential confounders, so these studies were given "Partial" marks against this criterion.

(Interrupted) Time Series Designs

The performance of the included studies was quite poor against this set of criteria. For two studies [13, 4], it was only evident from the publication they met one of seven quality criteria in this area. Povey, Frith and Graham [14] does not mention checking whether model assumptions were reasonable, therefore it is unclear whether the data was analysed using appropriate time series regression methods. None of the included studies state explicitly the anticipated effect of the intervention.

An overall score was given to each article by a weighted sum with "Yes" responses given a full mark and "Partial" responses a half mark. The highest mark, 16 for Scuffham et al. [21], was twice that of the lowest, eight for Clarke [4].

Discussion

A 2008 Cochrane Review considered the effect of mandatory helmet legislation [9]. Three New Zealand studies were considered [14, 21, 13] and none met inclusion criteria of the Cochrane Review. In our review of the New Zealand helmet law, we identified and included four studies that met our inclusion criteria.

The included studies differ in their methodological approaches in analysing data as well as the main findings. Three of the studies reported a significant protective effect of helmet legislation on bicycle related head injuries. In particular, Povey, Frith and Graham [14] estimated 24%, 32% and 28% reductions in head injuries in non-motor vehicle crashes for primary school, secondary school and adult age groups, respectively. For motor vehicle crashes, the estimated percentage reduction was 20% over all age groups. Scuffham et al. [21] concluded the helmet law led to a 19% reduction in head injury to cyclists over its first three years. Moyes [13] noted a substantial decrease in head injuries comparing two time periods twelve years apart, despite an overall increase in total injuries.

Clarke [4] concluded that following the helmet law, cycling usage reduced by 51% and cyclist's risk of injury increased. Furthermore, Clarke attributed 53 premature deaths per year to the New Zealand helmet law. This study met the fewest of the quality criteria and we have previously discussed the weaknesses of this study [26].

Our review found a discrepancy in the identification of injury in Povey, Frith and Graham [14] and Scuffham et al. [21]. When NZ converted from ICD9-CM to ICD9-CM-A, the primary diagnosis no longer represented the most serious condition. Therefore, Povey, Frith and Graham [14] examined all available diagnosis codes for the identification of head injury cases. However, Scuffham et al. [21] chose only the primary diagnosis for identifying head injuries. The authors examined the effect of using multiple diagnoses to identify head injuries and found the use of primary diagnosis only would have at most overestimated the effect of helmet wearing by 3.5%.

Robinson [16] was excluded from this review as it was a critique of Povey, Frith and Graham [14] and was not a direct assessment of the NZ helmet law. Robinson [16] argued the large increase in helmet wearing associated with the helmet law did not result in any obvious change in head injuries over and above existing trends; therefore, trends were the most likely cause for the observed reduction in head injury. Since it is a commentary of a study included in this review, it is perhaps relevant to assess Robinson [16] against quality criteria with the view to identify possible improvements over the original paper. Povey, Frith and Graham [14] did not fully meet quality criteria on eight

items and, in each instance, Robinson [16] received an identical or lower mark.

Because the focus of this paper was on cycling injury, two cost-benefit assessments of the helmet law were not included. These assessments are, in part, dependent on estimates of the effect helmet legislation has on cycling injury. Therefore, the quality of the assessment of helmet legislation on cycling injury directly affects the validity of these cost-benefit analyses.

There are methodological limitations of the included studies. Despite the abundance of the NZ data relevant to assessing the helmet law, which includes yearly estimates of helmet wearing from 1986 to 2012 [11], none of the studies assessed all three potential associations to obtain a complete picture of the inter-relationships between helmet legislation (the intervention), helmet wearing (direct consequence of the intervention) and head injury (target outcome of the intervention). To account for possible confounding factors such as changes in cycling exposure, some of the studies included a comparison control group. However, sound methodologies needed to evaluate the adequacy of any attempted adjustment for confounding are still lacking. Justification for choosing a particular comparison group over others remains qualitative.

The Wikipedia page on Bicycle Helmets in New Zealand [27] was also reviewed as the online encyclopaedia is often used as a resource by the media and general public. The Povey, Frith and Graham paper [14] is incorrectly referenced as a NZ Ministry of Transport technical report (it appeared in the peer-reviewed journal Accident Analysis and Prevention). The webpage makes no reference to Scuffham et al. [21] or Moyes [13].

The Wikipedia page lists other studies not included in our review as none are indexed by Medline, Scopus or Web of Science. These other studies include a press release for a Massey University cycling campaign [10, 19], commentaries from anti-helmet websites [6, 2], a submission to the NZ coroner [8], and an assessment of cycling injury in New Zealand but not an assessment of helmet legislation [23].

As with Macpherson and Spinks [9], limitations of our review are related to the small number of studies meeting the inclusion criteria. Only one of the included studies argued against helmet legislation. Other papers that provided arguments against the helmet law were excluded from this review as they are mainly commentaries and thus did not meet the inclusion criteria. Half of the included studies failed to use appropriate statistical tests to analyse data and thus there is little evidence to provide support for or against helmet legislation in New Zealand.

Conclusion

The results of this review show that more methodologically sound evaluations with rigorous statistical methods for data analysis are urgently needed to assess the impact of helmet legislation on cycling head injuries in New Zealand. In line with the Cochrane review [9], we believe the quality criteria listed in this review are necessary for a high quality evaluation of helmet legislation.

Acknowledgements

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Appendix

Quality criteria (Adapted from: Downs and Black, 1998; Ramsay et al., 2003; Macpherson and Spinks, 2008)

Study Design

- A. Was helmet legislation and helmet wearing association assessed?
- B. Was helmet wearing and cycling head injury association assessed?
- C. Was helmet legislation and cycling head injury association assessed?

Reporting

- 1. Is the hypothesis/aim/objective of the study clearly described?
- 2. Are the main outcomes to be measured clearly described in the Introduction or Methods section?
- 3. Are the characteristics of the patients included in the study clearly described?
- 4. Are the interventions of interest clearly described?
- 5. Are main findings of the study clearly described?
- 6. Does the study provide estimates of the random variability in the data for the main outcomes?
- 7. Have all important adverse events that may be a consequence of the intervention been reported?

8. Have actual probability values been reported for the main outcomes except where the probability value is less than 0.001?

Internal validity

- 9. In trials and cohort studies, do the analyses adjust for different lengths of follow-up of patients, or in case-control studies, is the time period between the intervention and outcome the same for cases and control?
- 10. Were the statistical tests used to assess the main outcome appropriate?
- 11. Was compliance with the intervention/s reliable?
- 12. Were the main outcome measures used accurate (valid and reliable)?
- 13. Was there adequate adjustment for confounding in the analyses from which the main findings were drawn?

(Interrupted) time series design

- 14. Were there no more than 20% of data missing?
- 15. Was the shape of intervention determined a priori?
- 16. Was the number and level of aggregation of data points justified?
- 17. Were data analysed using appropriate time series methods?
- 18. Were model assumptions checked and verified?
- 19. Was a concurrent comparison group used?

Table A1. Methodological quality of included studies

Criteria	Povey et al. (1999)	Scuffham et al. (2000)	Moyes (2007)	Clarke (2012)	*Robinson (2001)
Study Design					
A	Partial	Partial	No	No	Partial
В	Yes	Yes	No	No	Partial
С	No	Yes	Yes	No	No
Reporting					
1	Yes	Yes	Yes	Yes	Yes
2	Yes	Yes	Yes	No	Yes
3	Yes	Yes	Yes	Yes	Yes
4	Yes	Yes	Partial	Yes	Yes
5	Yes	Yes	Yes	Yes	Yes
6	Yes	Partial	No	No	No
7	Yes	No	Yes	Yes	Partial
8	Partial	Yes	Partial	No	No

Criteria	Povey et al. (1999)	Scuffham et al. (2000)	Moyes (2007)	Clarke (2012)	*Robinson (2001)
Internal validity					
9	No	No	Yes	Yes	No
10	Yes	Yes	No	No	No
11	Yes	Yes	Unclear	No	Yes
12	Yes	Yes	Yes	Yes	Yes
13	Partial	Partial	No	No	No
ITS design					
14	Yes	Yes	No	No	No
15	NA	No	NA	NA	No
16	Yes	Yes	Partial	No	No
17	Unclear	Unclear	No	No	No
18	No	Partial	No	No	No
19	Yes	Yes	Partial	Yes	Yes
Overall Score	15.5	16	10	8	9.5

NA=Not Applicable; Overall score is weighted sum of yes (full) and partial (half) marks

An observational study of conflicts between cyclists and pedestrians in the city centre

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Abstract

City centres have large volumes of pedestrians and motorised traffic and increases in walking and cycling could potentially lead to more pedestrians and cyclists being injured. In this study, observers recorded cyclist characteristics, number of pedestrians within 1m and 5m radius and type of conflict (none, pedestrian, vehicle) for 1,971 cyclists in 2010 and 2,551 cyclists in 2012 at six locations in the Brisbane Central Business District. Only 1.7% of cyclists were involved in conflicts with a motor vehicle or pedestrian and no collisions were observed. Increased odds of a pedestrian-cyclist conflict was associated with: male riders, riders not wearing correctly fastened helmets, riding on the footpath, higher pedestrian density (within 1m but not within 5m), morning peak and 2-4 pm (compared with 4-6 pm), two-way roads, roads with more lanes, higher speed limits, and yellow marked bicycle symbols on the road.

Keywords

Active travel, Bike share, Traffic conflicts, Cyclist, Pedestrian, Public bicycle.

Introduction

Many jurisdictions around the world promote walking and cycling for health and transport reasons. Both walking and cycling are especially suited to short distance trips, and many trips in city centres are short trips. However, city centres have large volumes of pedestrians and motorised traffic and increases in walking and cycling could potentially lead to more pedestrians and cyclists being injured. Much previous research has focused on the high severity of injuries often incurred when motor vehicles collide with pedestrians and cyclists but there is increasing concern from pedestrians about the threats they perceive from cyclists. European studies [1, 2] have reported that elderly pedestrians consider cyclists riding on the footpath to be a hazard and a Japanese study [3] has shown that

^{*}Did not meet inclusion criteria, score is given as a comparison to Povey, Frith & Graham [14]