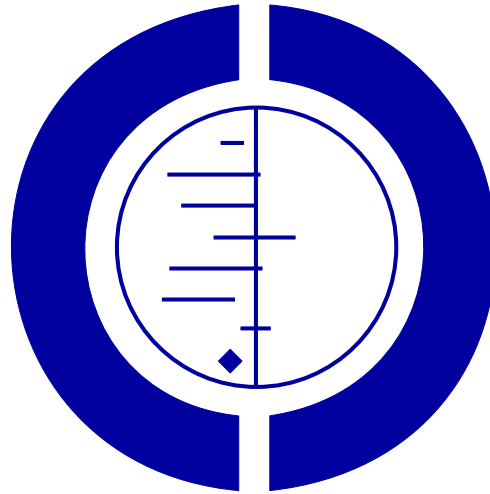


Bicycle helmet legislation for the uptake of helmet use and prevention of head injuries (Review)

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ABSTRACT

Background

Evidence exists to suggest that bicycle helmets may reduce the risk of head injuries to cyclists, however helmets are not uniformly worn by all bicycle users. Legislation has been enacted in some countries to mandate helmet use by cyclists, however the issue remains controversial with opponents arguing that this may inhibit people from bicycle riding and thus from gaining the associated health benefits, or that other countermeasures may have been responsible for decline in head injuries.

Objectives

To assess the effects of bicycle helmet legislation on bicycle-related head injuries and helmet use, and the occurrence of unintended adverse consequences.

Search strategy

We searched CENTRAL, the Cochrane Injuries Group's specialised register, MEDLINE, EMBASE, TRANSPORT and other specialist electronic databases, up to February 2006. In addition we searched government websites, handsearched selected journals and examined the reference lists of selected publications.

Selection criteria

We included studies that reported changes in either the number of head injuries, helmet use or bicycle use post- versus pre-legislation. Only studies that included a concurrent control group and which reported on the effect of legislation implemented at either the country, state or province wide level were included.

Data collection and analysis

Two authors independently extracted data and assessed methodological quality. The data were not appropriate for meta-analysis, thus the results of the included studies have been reviewed narratively.

Main results

Five studies, all from North America, met the inclusion criteria. For each of the studies, bicycle helmet legislation had been enacted for children only. Adults were used as controls in four of the studies, whilst jurisdictions with no helmet legislation were used as controls in the fifth. Three of the studies reported on changes in head injury rates and three reported on changes in helmet use. There were no included studies reporting change in bicycle use or other adverse consequences of legislation. In two studies, statistically significant decreases in head injuries were reported following the implementation of helmet legislation compared with controls, whilst one reported a non-statistically significant decline. Bicycle helmet use increased statistically significantly post-legislation in all three of the studies reporting on helmet use.

Authors' conclusions

Bicycle helmet legislation appears to be effective in increasing helmet use and decreasing head injury rates in the populations for which it is implemented. However, there are very few high quality evaluative studies that measure these outcomes, and none that reported data on an possible declines in bicycle use.

PLAIN LANGUAGE SUMMARY

To be added.

BACKGROUND

Bicycling is a very popular pastime and mode of transportation for children. However, bicycle-related injuries are common and frequently lead to hospitalisation. It is a global public health problem but one that particularly affects low-income countries, where road traffic injury rates are highest and where a high proportion of road users are cyclists.

Head injuries are a particularly serious consequence, accounting for 35 to 40% of paediatric hospitalisations and death resulting from bicycle-related trauma (Beaulne 1997; Durkin 1999). Furthermore, bicycle-related trauma has been reported among the most common causes of traumatic brain injury in many countries including Sweden (Peloso 2004), Taiwan (Tsai 2004) and the United States (Durkin 1999).

Bicycle helmets have been shown to be effective in preventing head, brain, and facial injuries to cyclists (Rivara 1998, Thompson 1996). A Cochrane systematic review reports that helmets reduce the risk of head injury by up to 88%, and reduce the risk of facial injury by 65% for cyclists of all ages (Thompson 2001).

However, despite the evidence of the efficacy of helmets in preventing serious injury, they are not universally used. Barriers to use include inhibitive costs, discomfort, lack of belief in the necessity, and an unpopular image of helmets among young cyclists (Finch 1996, Finoff 2001).

In order to overcome resistance to helmet usage, legislation has been implemented in various parts of the world, including Australia, New Zealand, the United States, and Canada. Jurisdictions differ in the population range affected by legislation. In Australia, for example, bicycle riders of all ages must wear a helmet. In Canada, however, most provincial legislation applies to children and adolescents only. Enforcement of legislation also differs across jurisdictions as priorities for policing vary between states and countries.

Without conclusive and scientifically sound evidence, the issue of helmet legislation remains controversial. Opponents of helmet legislation claim that people will use bicycles less if they are required to wear a helmet, and thus miss out on the health benefits and enjoy-

ment that may be derived from cycling. One study published subsequent to the enactment of legislation in Australia supports this hypothesis (Robinson 1996). Another argument against bicycle helmet legislation is that other potential safety initiatives (for example, separate bicycle paths and lower speed limits) may be passed over in favour of helmet legislation. Others adhere to the risk compensation theory, claiming that helmeted cyclists ride more dangerously than those without helmets, and hence put themselves at greater risk of injury (Hillman 1993; McCarthy 1993).

A systematic review of the highest level evidence is the first step to providing a clearer picture of the effectiveness of bicycle helmet legislation. If helmet legislation leads to a reduction in bicycle-related head injuries, the public health benefits could be substantial. The current review examined studies that have evaluated the effectiveness of bicycle helmet legislation for reducing head injuries in the whole population. The review also aimed to examine studies that evaluate changes in helmet use and additionally those assessing cycling participation to gauge possible deterrent effects of legislation, including reduced cycling.

OBJECTIVES

To assess the effects of bicycle helmet legislation on bicycle-related head injuries and helmet use, and the occurrence of unintended adverse consequences.

CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

Types of studies

We included the following study designs:

- cluster randomised controlled trials;
- interrupted time series analysis with a concurrent comparison group;
- controlled before-after study.

Types of participants

The whole population.

Types of intervention

Enactment of bicycle helmet legislation for either the whole population or for children only at a provincial, state, or country-wide level.

Types of outcome measures

- Head injuries (brain injuries, fractures, concussion, scalp lacerations and facial injuries) based on diagnosis given by a health professional and/or included in the medical chart.
- Helmet use (both self-reported and observed measures).
- Adverse effects of legislation (for example, reduced cycling participation).

SEARCH METHODS FOR IDENTIFICATION OF STUDIES

See: Cochrane Injuries Group methods used in reviews.

Electronic databases

We searched the following electronic databases:

- Cochrane Injuries Group's specialised register (to July 2005)
- CENTRAL (*The Cochrane Library*, issue 1, 2006)
- MEDLINE (to February 2006)
- EMBASE (to February 2006)
- TRANSPORT (to July 2005)
- CINAHL (to February 2006)
- National Research Register (issue 1, 2007)
- trials websites (to February 2006)
- ZETOC (a database of conference proceedings) (to February 2006)
- SPECTR (database of the Campbell collaboration) (to February 2006)
- HealthPromis (to February 2006)
- Bibliomap (EPPI-Centre database) (to February 2006)

The searches were based on the following terms, adapted as appropriate to the specifications of each database; (bicycle helmet) OR (pedal cycle helmet) AND (legislation OR law OR mandatory)

Other sources

We handsearched the journals *Injury Prevention*, *Accident Analysis and Prevention* and the *American Journal of Public Health* in addition to the reference lists of relevant studies.

In attempt to identify further unpublished studies we contacted colleagues from the International Society for Child and Adolescent Injury Prevention, World Injury Network, and CDC-funded Injury Control and Research Centers.

We also searched government web pages (in countries known to have helmet legislation including Australia, Canada, Finland, Iceland, New Zealand, Spain, Sweden, United States) to locate official reports.

The searches were not restricted by language or publication status.

METHODS OF THE REVIEW

Study identification & selection

Following the identification of possible studies for inclusion using the search strategy listed above, the two authors independently assessed the studies against the inclusion criteria. There were no disagreements between authors on study inclusion.

Data extraction

Data were extracted independently by two authors using a standardised data extraction form.

Assessment of methodological quality

We independently assessed methodological quality using the Downs and Black's instrument for non-randomised studies (Downs 1998). This instrument consists of a 27 item checklist which rates studies on the following key areas;

- reporting,
- external validity,
- internal validity,
- bias and confounding, and
- power.

We reported how each study performed in each area.

Data analysis

Data were available as measures of association linking either bicycle helmet legislation and changes in cycling related head injury rates, the proportion of head injuries amongst bicycle related injuries or helmet use.

A narrative approach was adopted to describe and synthesise the results due to the heterogeneity of the data and uniqueness of methodological design for each included study. The specific reason for this narrative approach included different population size and demographics between studies, different study durations and different levels of enforcement between study jurisdictions. These elements rendered the combination of data inappropriate.

DESCRIPTION OF STUDIES

We retrieved the full text of 25 potentially relevant studies, five of which met the inclusion criteria.

Most of the excluded studies were not eligible as they failed to use a concurrent control group in the analysis (Borglund 1999, Cameron 1994, Finch 1996, Foss 2000, Leblanc 2002, Liller 2003, Macpherson 2001, Ni 1997, Parkin 2003, Povey 1999, Robinson 1996, Scuffham 2000, Shafi 1998, Taylor 2002, Vulcan 1992). Other reasons for exclusion were lack of baseline (pre-legislation) data (Kanny 2001, Puder 1999, Macknin 1994, Rodgers 2002), and the lack of legislation implemented at a state or provincial level (Cote 1992, Nolen 2004).

The five included studies reported changes in head injury rates and/or helmet use in Canada (Hagel 2006; Macpherson 2002), and the USA (Gilchrist 2000; Ji 2006; Lee 2005).

Two of the included studies assessed the impact of helmet legislation on head injury (Lee 2005; Macpherson 2002), two studies reported on changes in helmet use (Gilchrist 2000; Hagel 2006) and one study reported on both head injuries and helmet use (Ji 2006). There were no included studies that assessed change in bicycle use or any other potential adverse effects of legislation.

Studies from the USA

Gilchrist 2000

This study examined the effects of a local police enforcement program on bicycle helmet use in children in a rural Georgia community. Bicycle helmet legislation was passed for the state of Georgia in July 1993, mandating helmet use for all cyclists under 16 years of age. An enforcement program coupled with a helmet giveaway and education program, was implemented in one rural community (population = 2400) during the summer of 1997. The enforcement program required police to impound bicycles of non-helmet wearers after one prior written warning had been issued. Approximately 580 children from kindergarten to grade seven received free helmets along with fitting instructions and safety education. Helmet use observations were made before distribution, several times during the five month program, and once two years later. Riders were classified as children if their age was estimated to be under 13 years, teens if 13 to 15 years and adults if older than 16. The adult population was used as a comparative control group.

Ji 2006

This study assessed the effects of the Californian state-wide helmet law in San Diego County. The law was enacted on January 1st, 1994 and required all cyclists aged 17 years and under to be helmeted. Violation of the law was punishable by a fine of up to \$US25. The study authors accessed data from the San Diego County Trauma Registry from 1992 until 1996. Injured youths aged 17 years comprised the intervention group and injured adults (18 years and over) acted as controls. The outcome measures were

serious injury, defined by anatomic region and abbreviated injury score (AIS) greater than three; and helmet use as reported by the injured cyclists. The head injury data reported in this study overlaps with those reported in Lee 2005.

Lee 2005

This study assessed the effects of the Californian helmet law throughout the entire state. The study authors obtained 10 years of patient discharge records from all public Californian hospitals from 1991 to 2000. This included three years of baseline data (1991 to 1993) and seven years of post-intervention data (1994 to 2000). Adults, who were not required by law to wear helmets whilst cycling, were used as a control group for comparison. Three types of injury were used as outcomes: traumatic brain injury, other head or facial injury and other (below neck) injury. All fatal cases were excluded. No data were available on actual helmet use at the time of injury, or on enforcement or compliance with the law.

Studies from Canada

Hagel 2006

This study measured the prevalence of bicycle helmets two years after the introduction of legislation mandating their use in cyclists under 18 years of age, in the province of Alberta. The legislation was introduced in 2002. The study authors compared bicycle helmet use observations conducted from July to August 2004 (two years post-legislation), to similar observations performed in 2000 (prior to legislation). Observations were made for both child and adult cyclists, with the age of the cyclist estimated into broad age groups (< six years, six to 12 years, 13 to 17 years, 18 to 54 years, > 54 years) The adult group (aged 18 years and over) was not subject to the legislation requirements and was therefore used as a comparative control group. In 2000, the observations were conducted in the two main cities of Edmonton and Calgary, and additional communities located within 50 km of these two centres. In 2004, the observations were made in Edmonton only.

Macpherson 2002

This study examined Canada-wide hospital discharge data over a four year period, to examine the protective effect of legislation in provinces that had implemented bicycle helmet laws. Four provinces had enacted legislation on the following dates: Ontario, October 1995; New Brunswick, December 1995; British Columbia, September 1996; and Nova Scotia, July 1997. Data were collected for the fiscal years 1994 to 1998 from Canadian Institute of Health Information. All children aged between five and 19 years, hospitalised with injuries related to pedal cycle incidents were included. Children for whom discharge diagnosis data were missing or who died before being admitted to hospital were excluded. The study authors defined a head injury as any injury to the head, face or brain. Children residing in the provinces with bicycle helmet legislation comprised the intervention group, whilst children from the rest of Canada were controls. Hospitalisation rates from the provinces were combined irrespective of when the

helmet legislation was passed. The study authors maintain that this approach was adopted for methodological reasons and would confer a conservative estimate of the protective effect of helmet legislation.

METHODOLOGICAL QUALITY

The five key areas of methodological quality assessed by the Downs and Black Instrument are: reporting, external validity, bias (internal validity), confounding (internal validity), and power. The performance of the included studies in each of these areas is discussed below and presented in Table 01. Other methodological issues relevant to the topic are explored further in the discussion of the review.

Reporting

Reporting was adequate for all of the included studies. This included reporting of the study hypothesis, the main outcomes and interventions, estimates of random variability and the distributions of principal confounders. However, none of the studies attempted to report adverse impacts of bicycle helmet legislation.

External validity

This was also good for each of the included studies, with each study population representative of the general population.

Internal validity

According to the rating instrument, internal validity bias may have occurred because of an inability to apply blinding to either the study population or the study investigators. This was due to the nature of the intervention itself and it can be argued that these two methodological techniques are infeasible to implement in community-based research where the unit of intervention is the community itself. A further threat to the internal validity for three of the included studies (Ji 2006; Lee 2005; Macpherson 2002), however, was compliance with the legislation requirements. For these studies either no attempt was made to measure helmet use and hence compliance (Lee 2005; Macpherson 2002), or the proportion of participants for whom helmet use was unknown was high (Ji 2006). Other issues related to internal validity bias (appropriate statistical tests, valid outcome measures) were not problematic for any of the studies.

Bias and confounding

Confounding bias to internal validity was limited for each of the included studies despite none of the studies employing randomisation of intervention or allocation concealment. As with blinding, these methodological techniques are infeasible to apply for evaluation studies implemented at the community level. Nonetheless, internal validity was maintained by each of the studies by including cases and controls from the same populations and over the same period of time.

Statistical power

Power was adequate for each of the included studies.

RESULTS

Head injury

Ji 2006

In San Diego County, there were 1116 bicycle-related trauma patients admitted to hospital during the study period: 510 children and 606 adults. Of the admitted cases, 310 involved serious head injuries. Although downward trends were apparent in the post-legislation period, logistic regression analysing time trends of serious head injury found no statistically significant decrease in the proportion of head injuries post legislation compared with the pre-legislation period for either children ($P = 0.19$) or adults ($P = 0.4$).

Lee 2005

Between 1991 and 2000, there were 44,069 cases of non-fatal bicycle related injury events that required hospitalisation in the State of California. Aggregate data analysis revealed changes in the distribution of proportion of injury types for youth aged 17 years and younger ($P < 0.001$) but not for the adult comparison group ($P = 0.505$). The authors computed odds ratios (OR) to examine these changes further: proportions of traumatic brain injury among youth were found to have decreased after legislation (OR 0.82; 99% CI 0.76 to 0.89), while other head and facial injuries did not change (OR 1.08; 99% CI 0.90 to 1.23), and other (below neck) injuries increased (OR 1.09; 99% CI 1.05 to 1.13). The corresponding ORs for pre versus post legislation for the adult comparison group were: TBI (OR 1.01; 99% CI 0.93 to 1.10), other head injury (OR 1.05; 99% CI 0.91 to 1.22) and other (non-head) injury (OR 0.99; 99% CI 0.97 to 1.02). The authors therefore concluded that an 18.2% (99% CI 11.5 to 24.3) reduction occurred in the proportion of traumatic brain injury in youth cyclists during the post compared with the pre-legislation period. Additional statistical analysis was conducted to assess the effects of legislation on injuries in different age groups within the youth category. The greatest changes were in the younger age groups (zero to four and five to nine years) compared with youth aged 10 years and older. Teenagers aged 14 to 17 experienced a small decrease in the proportion of TBI and slight increase in proportion of other head injuries.

Macpherson 2002

Over the study period, there were 9769 paediatric admissions due to bicycle related injury throughout Canada. Discharge information was missing for 119 children so only 9650 were included in the analysis. Thirty-five percent ($n = 3246$) of cases sustained head injuries. Before legislation was implemented, the rates of head injuries in provinces were similar (18.27 and 18.35 per 100,000 respectively in provinces with and without legislation). Following the enactment of legislation, a 45% reduction in head injuries occurred in the intervention provinces (to 9.96 per 100,000) whilst a concurrent decline of 27% occurred in the control provinces (to

13.33 per 100,000). A Chi square test showed that the decline in the intervention provinces was significantly greater ($P < 0.001$) than that in the control provinces. At the same time, there were no significant differences in the change in other (non-head) injuries between provinces with and without legislation ($P = 0.11$).

Secondary analysis showed that the ratio of head injuries to other bicycle related injuries decreased significantly in both legislation and non-legislation provinces. The decrease in legislation provinces was 38% (ratio difference = 0.26; 95% CI 0.25 to 0.27) compared with 8% in the non-legislation provinces (ratio difference = 0.04; 95% CI 0.03 to 0.05).

Helmet use

Gilchrist 2000

Prior to the enforcement program, no cyclists wore helmets during 97 observations. Sixty-one of the cyclists initially observed were children. During the five months of the enforcement program police impounded 167 bicycles and 654 observations of cyclists were made. Forty-five percent of children (range 30 to 71%) wore helmets during 358 child observations. There were, however, no significant changes in adult usage among adult controls (from zero to 3%). Two years later post intervention, 54% of child cyclists (21/39) observed wore a helmet compared with 15% (2/13) teens and no (0/23) adults.

Hagel 2006

Pre-legislation, there were 699 observations of cyclist made. Twenty-eight percent (46/164) of child cyclists and 49% (234/474) of adult cyclists were helmeted during these observations. There were 271 observations made in the post-legislation period. During this time, 83% (34/41) of child and 48% (110/230) of adult cyclists were helmeted. The prevalence of helmet use amongst children increased significantly (Prevalence Ratio 2.96; 95% CI 2.22 to 3.94) and remained unchanged in the adult population. After adjusting for gender, age and average annual income, the increase in prevalence of helmet use amongst children was 3.69 (95% CI 2.65 to 5.14) compared with the pre-law period.

Ji 2006

Helmet use as reported by injured cyclists post injury increased significantly amongst children post-legislation (OR 1.84; 95% CI 1.48 to 2.28). There was a concurrent smaller trend amongst adult controls for increased helmet wearing (OR 1.17; 95% CI 1.00 to 1.38).

DISCUSSION

Principal findings

This review found positive evidence that bicycle helmet legislation both increases bicycle helmet use and reduces bicycle related head injuries. No evidence was found to either support or counter the possibility that legislation may lead to negative societal and health impacts such as reductions in cycling participation.

We identified and included five controlled evaluative studies that examined the effect of bicycle helmet legislation on bicycle related head injuries and helmet use. A large number of potential studies were excluded from the review, the majority for failing to include a concurrent control group.

All of the included studies were controlled time series analyses that were conducted in North America. The main findings of the review are discussed below.

Helmet laws and head injuries

There is a paucity of high quality evaluative studies assessing the effect of helmet legislation on bicycle related head injuries: only three were identified for this review. Two of the studies reported a significant protective effect of helmet legislation on bicycle related head injuries, whilst the third reported a non-significant decline in the proportion of head injuries compared with other bicycle related trauma.

Helmet use

The three studies included in this review found that helmet use increased significantly from between 45% and 84% with the introduction of helmet laws or, in the case of Gilchrist 2000, helmet law enforcement. This finding supports the results of a recently published systematic review on the same topic which used different criteria for including studies (Karkhaneh 2006).

Adverse effect of legislation (reduced cycling participation)

None of the included studies measured pre- and post-legislation cycling participation rates, hence no evidence was available to assess the adverse potential of helmet legislation.

Strengths and weaknesses of this systematic review

Strengths of this review are the high level of methodological rigour required for studies to be included. Comparison of the intervention group against a control is important for study validity mainly because it allows for the control of changes over time. Without a concurrent comparison group, it is impossible to determine the relative effect of the law compared with other environmental and legislative changes including changes in cycling rates, improved bicycle paths and lower vehicle speeding limits (Robinson 2001).

Limitations of the review are related to the small number of high quality studies that were identified for inclusion, meaning that there was either restricted or no evidence to provide sound scientific support for either side of the bicycle helmet legislation debate. Only three studies were available that reported on bicycle related head injuries, and none that reported on potential adverse effects of helmet legislation. There were, in addition, no studies that assessed bicycle helmet legislation for adult populations. Therefore, the results of this review can only be applied to paediatric populations, and are limited in their conclusive strength.

Strengths and weaknesses of the included studies

The findings of the review must also be interpreted within the context of the methodological limitations of the included studies. The inability to measure actual helmet use, or missing information

helmet use information were the biggest limitations for the studies which evaluated changes in bicycle related head injury. The lack of helmet use data makes it difficult to clearly illustrate that lower head injury rates are the direct consequence of increased helmet use.

Other possible explanations for the decreases in the reported head injury rates or proportion of serious head injuries including changes in hospital admission procedures, reduced cycling exposure (for reduced head injury rates) or an increase in other bicycle related injuries (for reduced proportion of head injuries).

The inclusion of comparison control groups attempts to discount these other possible explanations, however the adequacy of the chosen controls may also be called into question. In particular, comparing adults with children may be problematic because admission procedures or cycling exposure may have changed for one age group but not the other, whilst comparisons between states or provinces may not take other local changes (e.g. changes to speeding laws, improved road conditions) into account

Arguments against helmet legislation

Opponents of bicycle helmet legislation have argued that decreasing trends in head injuries in jurisdictions with bicycle helmet legislation can be explained by lower numbers of people cycling. They argue that enforced helmets act as a deterrent to cycling, and the net overall effect on health is negative because of the reduction in the benefits of exercise and enjoyment. We attempted to address this concern in our review, however we found no studies meeting predetermined quality standards that directly measured cycling rates before and after the introduction of helmet legislation.

However comparisons between the pre and post legislation proportion of head injuries of total bicycle related injuries (as performed by both Lee and Macpherson) does allow for cycling exposure to be controlled.

Both of these studies reported significant declines in the proportion of head injuries compared with other bicycle related injuries.

Other arguments against helmet legislation are that other effective safety initiatives (for example, lower vehicle speeding limits and separate cycling paths) may be overlooked, or that cyclists may be less careful if wearing a helmet. This review was not able to explore these possibilities.

Enforcement

Many jurisdictions with helmet legislation impose monetary fines for non-compliance. Unfortunately, there was insufficient evidence available to determine the level at which legislation was enforced in four of the included studies. The study conducted in rural Georgia, however, clearly demonstrates the importance of police enforcement (Gilchrist 2000). Prior to the enforcement program, the existing helmet legislation had a negligible effect on actual helmet use with no children observed using a bicycle helmet

despite the pre-existing law. The positive effect of the enforcement program in which police were instructed to impound the bicycle of non-helmeted child cyclists was still discernible two years later, although it was not possible to distinguish the effects of the enforcement program with the concurrent helmet give-away program on helmet use.

Future Research

We believe that the results of this review highlight the necessity for further high quality evaluations of the impact of bicycle helmet legislation. Evaluations are required in order to strengthen the evidence base suggesting a protective effect of helmet legislation against head injuries and extend the evidence to the adult population. High quality evaluations are also needed to either support or dispute the argument that legislation may discourage cycling and hence negatively impact upon health by reducing physical activity participation increasing reliance on motor-vehicle use as an alternative transport mode.

High quality evaluations to provide the necessary evidence would include objective assessment of head injury rates both prior to and post the introduction of helmet legislation in both an intervention and control group. The ideal control group would be the same age cyclists in a neighbouring state or province where all other influential factors such as driving laws and other environmental initiatives would be kept as similar as possible. Accurate measurements of both cycling participation rates and actual helmet use would also be measured in both intervention and control groups so that the mechanism of effect could be clearly illustrated. Ideally, a time frame of several years would be used for both pre and post legislation periods so that the long term effect of helmet legislation could be evaluated, and to capture the effect of pre-legislation trends in head injury rates, cycling participation and helmet use.

AUTHORS' CONCLUSIONS

Implications for practice

The best available evidence, although limited in quantity and quality, suggests a protective effect of bicycle helmet legislation against head injury among cyclists.

It can be surmised with reasonable certainty that legislation increases bicycle helmet use, however enforcement is necessary to ensure compliance. The relationship between police enforcement of laws, helmet use and cycling rates is yet to be determined, although there is some evidence that legislation without enforcement may have a limited effect on helmet use.

No strong evidence yet exists to either suggest or discount an adverse effect of bicycle helmet legislation (for example, fewer cyclists).

In summary, helmet legislation is just one of many interventions that may decrease head injuries to cyclists. It is most likely that a

similar approach must be taken as that adopted for motor vehicle safety, that is a variety of countermeasures are necessary to increase overall safety.

Implications for research

More high quality studies are needed to assess the impact on bicycle related head injuries, particularly in adult populations, and the potential for legislation to discourage cycling participation.

Funding should be made available by governments introducing helmet laws to ensure that methodologically sound evaluations of the protective effect and potential reductions in cycling are conducted.

POTENTIAL CONFLICT OF INTEREST

Alison Macpherson is an author of one of the included studies.

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External sources of support

- No sources of support supplied

Internal sources of support

- No sources of support supplied

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* Indicates the major publication for the study

T A B L E S

Characteristics of included studies

Study	Gilchrist 2000
Methods	Controlled before-and-after study.
Participants	Intervention: Child cyclists in one Rural Georgia community. Control: Adult cyclists living in the same community.
Interventions	Legislation requiring mandatory bicycle helmets for children, in combination with helmet give-away program, fitting instructions and safety education. Police enforced helmet use by impounding bicycles of non-helmet wearers after one written warning.
Outcomes	Observed bicycle helmet use.
Notes	
Allocation concealment	D – Not used

Study	Hagel 2006
Methods	Controlled before-and-after study.
Participants	Intervention: Child cyclists in Alberta, Canada. Control: Adult cyclists in Alberta, Canada.
Interventions	Legislation requiring mandatory bicycle helmets for all youth aged 17 years and under. Enacted 2004.

Outcomes	Observed bicycle helmet use.
Notes	
Allocation concealment	D – Not used

Study	Ji 2006
Methods	Case-controlled before-and-after study.
Participants	Intervention: Injured youth (Aged 17 years and under) hospitalised for bicycle related trauma in San Diego Country, California. Control: injured adults hospitalised for bicycle related trauma.
Interventions	Legislation requiring mandatory bicycle helmets for all youth aged 17 years and under. Enacted 1st January 1994.
Outcomes	Proportion of head injury. Reported bicycle helmet use.
Notes	
Allocation concealment	D – Not used

Study	Lee 2005
Methods	Case-controlled before-and-after study.
Participants	Intervention: Californian youth (aged 17 years and under) hospitalised for bicycle related trauma. Control: Californian adults hospitalised for bicycle related trauma.
Interventions	Legislation requiring mandatory bicycle helmets for all youth aged 17 years and under. Enacted January 1st 1994.
Outcomes	Three types of injury; - traumatic brain injury, - other head or facial injury, - other injury (below neck).
Notes	
Allocation concealment	D – Not used

Study	Macpherson 2002
Methods	Controlled before-and-after study.
Participants	Intervention: Children in four Canadian provinces (Ontario, New Brunswick, Nova Scotia, British Columbia). Control: Children in the remainder of the country (six provinces, three territories).
Interventions	Legislation requiring mandatory bicycle helmets for cyclists of various ages.
Outcomes	Rates of head injury requiring hospitalisation, obtained from the Canadian Institute of Health Information for fiscal years 1994 to 1998.
Notes	
Allocation concealment	D – Not used

Characteristics of excluded studies

Study	Reason for exclusion
Borglund 1999	No control community used as comparison.

Characteristics of excluded studies (Continued)

Cameron 1994	No control community used as comparison.
Cote 1992	Legislation was not implemented at state or provincial level.
Finch 1996	No control community used as comparison.
Foss 2000	No control community used as comparison.
Kanny 2001	No (pre-legislation) baseline data was available.
Leblanc 2002	No control community used as comparison.
Liller 2003	No control community used as comparison.
Macknin 1994	No (pre-legislation) baseline data were available.
Macpherson 2001	No control community used as comparison.
Ni 1997	No control community used as comparison.
Nolen 2004	Legislation was not implemented at state or provincial level.
Parkin 2003	No control community used as comparison.
Povey 1999	No control community used as comparison.
Puder 1999	No (pre-legislation) baseline data were available.
Robinson 1996	No control community used as comparison.
Rodgers 2002	No (pre-legislation) baseline data were available.
Scuffham 2000	No control community used as comparison.
Shafi 1998	No control community used as comparison.
Taylor 2002	No control community used as comparison.
Vulcan 1992	No control community used as comparison.

ADDITIONAL TABLES

Table 01. Methodological quality of included studies

	Gilchrist 2000	Hagel 2006	Ji 2006	Lee 2005	Macpherson 2002
REPORTING Is the hypothesis/aim/objective of the study clearly described?	Yes	Yes	Yes	Yes	Yes
REPORTING Are the main outcomes to be measured clearly described in the Introduction or Methods section?	Yes	Yes	Yes	Yes	Yes
REPORTING Are the characteristics of the patients included in the study clearly described?	Yes	Yes	Yes	Yes	Yes
REPORTING Are the interventions of interest clearly described?	Yes	Yes	Yes	Yes	Yes
REPORTING Are the distributions of principal confounders in each group of subjects to be compared clearly described?	Yes	Yes	Yes	Yes	Yes
REPORTING	Yes	Yes	Yes	Yes	Yes

Table 01. Methodological quality of included studies (Continued)

	Gilchrist 2000	Hagel 2006	Ji 2006	Lee 2005	Macpherson 2002
Are the main findings of the study clearly described?					
REPORTING	Yes	Yes	Yes	Yes	Yes
Does the study provide estimates of the random variability in the data for the main outcomes?					
REPORTING	No	No	No	No	No
Have all important adverse events that may be a consequence of the intervention been reported?					
REPORTING	Yes	Yes	Yes	Yes	Yes
Have the characteristics of patients lost to follow-up been described?					
REPORTING	Yes	Yes	Yes	Yes	Yes
Have actual probability values been reported for the main outcomes except where the probability value is less than 0.001?					
EXTERNAL VALIDITY	Yes	Yes	Yes	Yes	Yes
Were the subjects asked to participate in the study representative of the entire populations from which they were recruited?					
EXTERNAL VALIDITY	Yes	Unclear	Yes	Unclear	Yes
Were those subjects who were prepared to participate representative of the entire population from which they recruited?					
EXTERNAL VALIDITY	Yes	Yes	Yes	Yes	Yes
Were the staff, places, and facilities where the patients were treated, representative of the treatment the majority of patients receive?					
INTERNAL VALIDITY	No	No	No	No	No
Was an attempt made to blind study subjects to the intervention they have received?					
INTERNAL VALIDITY	No	Yes	No	No	No
Was an attempt made to blind those measuring the main outcomes of the intervention?					
INTERNAL VALIDITY	Yes	No	Unclear	Yes	
If any of the results of the study were based on 'data dredging', was this made clear?					
INTERNAL VALIDITY	Yes	Yes	Yes	Yes	Yes
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 controls?					
INTERNAL VALIDITY	Yes	Yes	Yes	Yes	Yes
Were the statistical test used to assess the main outcomes appropriate?					

Table 01. Methodological quality of included studies (Continued)

	Gilchrist 2000	Hagel 2006	Ji 2006	Lee 2005	Macpherson 2002
INTERNAL VALIDITY Was the compliance with the intervention/s reliable?	Unclear	Unclear	Unclear	Unclear	Unclear
INTERNAL VALIDITY Were the main outcome measures used accurate (valid and reliable)?	Yes	Yes	Yes	Yes	Yes
INTERNAL VALIDITY Were the patients in different interventions groups (trials and cohorts studies) or were the cases and control (case-control studies) recruited from the same population?	Yes	Yes	Yes	Yes	Yes
INTERNAL VALIDITY Were the patients in different interventions groups (trials and cohorts studies) or were the cases and control (case-control studies) recruited over the same period of time?	Yes	Yes	Yes	Yes	Yes
INTERNAL VALIDITY Were the study subjects randomised to intervention groups?	No	No	No	No	No
INTERNAL VALIDITY Was the randomised intervention assignment concealed from both patients and health care staff until recruitment was complete and irrevocable?	No	No	No	No	No
INTERNAL VALIDITY Was there adequate adjustment for confounding in the analyses from which the main findings were drawn?	Yes	Yes	Yes	Yes	Yes
INTERNAL VALIDITY Were losses of patients to follow-up taken into account?	Yes	Yes	Yes	Yes	Yes

GRAPHS AND OTHER TABLES

This review has no analyses.

COVER SHEET

Title	Bicycle helmet legislation for the uptake of helmet use and prevention of head injuries
Authors	Macpherson A, Spinks A
Contribution of author(s)	The original concept and design of this review was initiated by Alison Macpherson. Both authors (Alison Macpherson and Anneliese Spinks) were responsible for searching for and locating potential studies, independently screening studies against inclusion criteria, extracting results, assessing methodological quality of the included studies and writing and editing the text of the review. Anneliese Spinks prepared the review for the Cochrane Database of Systematic Reviews using the RevMan software.
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