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**[Intervention Review]**

# Helmets for preventing head and facial injuries in bicyclists

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## ABSTRACT

### Background

Each year, in the United States, approximately 900 persons die from injuries due to bicycle crashes and over 500,000 persons are treated in emergency departments. Head injury is by far the greatest risk posed to bicyclists, comprising one-third of emergency department visits, two-thirds of hospital admissions, and three-fourths of deaths. Facial injuries to cyclists occur at a rate nearly identical to that of head injuries. Although it makes inherent sense that helmets would be protective against head injury, establishing the real-world effectiveness of helmets is important.

### Objectives

To determine whether bicycle helmets reduce head, brain and facial injury for bicyclists of all ages involved in a bicycle crash or fall.

### Search methods

We searched CENTRAL, MEDLINE, EMBASE, Sport, ERIC, NTIS, Expanded Academic Index, CINAHL, PsycINFO, Occupational Safety and Health, and Dissertations Abstracts. We checked reference lists of past reviews and review articles, studies from government agencies in the United States, Europe and Australia, and contacted colleagues from the International Society for Child and Adolescent Injury Prevention, World Injury Network, CDC-funded Injury Control and Research Centers, and staff in injury research agencies around the world. The searches were last updated in November 2006.

### Selection criteria

Controlled studies that evaluated the effect of helmet use in a population of bicyclists who had experienced a crash. We required studies to have complete outcome ascertainment, accurate exposure measurement, appropriate selection of the comparison group and elimination or control of factors such as selection bias, observation bias and confounding.

### Data collection and analysis

Two authors independently extracted data. Odds ratios with 95% confidence intervals were calculated for the protective effect of helmets for head and facial injuries. Study results are presented individually. Head and brain injury results were also summarized using meta-analysis techniques.

### Main results

We found no randomized controlled trials, but five well conducted case-control studies met our inclusion criteria. Helmets provide a 63 to 88% reduction in the risk of head, brain and severe brain injury for all ages of bicyclists. Helmets provide equal levels of protection for crashes involving motor vehicles (69%) and crashes from all other causes (68%). Injuries to the upper and mid facial areas are reduced 65%.

**Authors' conclusions**

Helmets reduce bicycle-related head and facial injuries for bicyclists of all ages involved in all types of crashes, including those involving motor vehicles. Our response to comments from critics are presented in the Feedback section.

## PLAIN LANGUAGE SUMMARY

### Wearing a helmet dramatically reduces the risk of head and facial injuries for bicyclists involved in a crash, even if it involves a motor vehicle

Cycling is a healthy and popular activity for people of all ages. Crashes involving bicyclists are, however, common and often involve motor vehicles. Head injuries are responsible for around three-quarters of deaths among bicyclists involved in crashes. Facial injuries are also common. The review found that wearing a helmet reduced the risk of head or brain injury by approximately two-thirds or more, regardless of whether the crash involved a motor vehicle. Injuries to the mid and upper face were also markedly reduced, although helmets did not prevent lower facial injuries.

# BACKGROUND

In the United States, there are 67 million bicyclists who ride approximately 15 billion hours per year (Rivara 1998; Rogers 1996). Each year, approximately 900 people die from injuries due to bicycle crashes and over 500,000 persons are treated in emergency departments (Baker 1993). While over 90% of deaths from bicycle-related injuries are caused by collisions with motor vehicles (MMWR 1995), these collisions cause less than 25% of non-fatal head injuries. Head injury is by far the greatest risk posed to bicyclists, comprising one-third of emergency department visits, two-thirds of hospital admissions, and three-quarters of deaths (Baker 1993; Bjornstig 1992; Ekman 1997; Friede 1985; Thompson 1989; Sacks 1991). Facial injuries to cyclists occur at a rate nearly identical to that of head injuries; 43 versus 45 per 100,000 population per year, respectively (Thompson 1990).

Although it makes inherent sense that helmets would be protective against head injury, establishing the real-world effectiveness of helmets is important. The magnitude of the protective effect is important for the promotion of helmet programs. Laboratory data (Snell Memorial Foundation, American National Standards Institute [ANSI], US Consumer Product Safety Commission [CPSC], Australian and European Standards) are not enough; real-world data are necessary to determine whether helmet use is effective in preventing head injuries. Prospective studies such as randomized controlled trials and cohort studies are unlikely to be feasible designs because of the relative rarity of the outcome event (that is, head injury).

Case-control studies are a good and efficient design for evaluating exposures, such as helmet use, that can not be easily manipulated and for outcomes that are uncommon, as is bicycle-related head injury. A well designed case-control study would look at a population of bicyclists who crashed (that is, who had the opportunity to sustain a head injury). In a case-control study, individuals (cases) with the outcome of interest (head injury from bicycling) are identified and are compared to a suitable control group without the outcome (crashing bicyclists without head injury). The cases and controls are then compared on the exposure of interest, helmet use. The odds ratio, which may be thought of as the ratio of risks, is then calculated to describe the odds of head injury in one group (for example, helmeted riders) compared to the odds of head injury in the unhelmeted riders. Multivariate analysis is used to take into account the various factors which could contribute to head injury (crash severity such as being hit by a car or high riding speed, falling on the street, age, gender, riding experience). Once these factors are taken into account for all riders, the effect of helmet use can be estimated.

# OBJECTIVES

- Evaluate the effectiveness of bicycle helmets in preventing head, brain and severe brain injuries in bicyclists who have crashed.
- Evaluate the effectiveness of bicycle helmets in motor vehicle crashes compared to other types of crashes.
- Evaluate the effectiveness of bicycle helmets in preventing facial injuries in bicyclists who have crashed.

# METHODS

## Criteria for considering studies for this review

### Types of studies

We searched for randomized and controlled studies that evaluated the protective effect of helmet use in bicyclists who had experienced a crash. Since we found no randomized controlled trials, this review includes only case-control studies.

In order to be included in this review, we required that studies ascertain cases prospectively and identify and validate all injuries from medical records. We also required determination of exposure (helmet use) at the time of the bicycle crash, appropriate selection of the control group and elimination or control of factors such as selection bias, observation bias and confounding. Studies selected had to have equal ascertainment of exposure for case and control groups. Additionally, controls should be selected from the same population from which the cases were derived.

### Types of participants

Bicyclists of all ages who had crashed or fallen while riding a bicycle.

### Types of interventions

Use of any type of bicycle helmet, including hard shell, thin shell or no shell helmets.

### Types of outcome measures

- Head injury, defined as injury to the scalp, skull or brain.
- Brain injury defined as loss of consciousness or some other evidence of brain injury or dysfunction as a result of trauma.
- Serious brain injury defined as injury which had an Abbreviated Injury Score (head AIS) of three or greater.
- Facial fracture or laceration.

## Search methods for identification of studies

The first step was to use known review articles, augmented by reviews found in MEDLINE, to create a core reference bibliography. Search results were regularly compared to the core bibliography to ensure key studies had been picked up. The searches were last updated in 2006.

The searches were not restricted by publication status, date, or language.

### Electronic searches

We searched the following databases;

- CENTRAL (*The Cochrane Library* issue 3, 2006)
- MEDLINE (1966 to 2006, September, week 3)
- EMBASE (1980 to 2006, September (week 39))
- Sport
- ERIC
- NTIS
- Expanded Academic Index
- CINAHL
- PsycINFO (1970 to 2006, August, week 4)
- Occupational Safety and Health

- Dissertation abstracts
- Web of Science (2005 to 2006, (searched October 3, 2006))
- Pubmed (searched October 3, 2006 (last 12 months))

Full search strategies for some of the electronic database searches are presented in Appendix 1.

Where full strategies are not listed, we used the keywords, 'accidents-traffic', 'accident-prevention', 'bicycling', and 'helmet' and all subheadings, adapted as appropriate to the specifications of each database.

#### Searching other resources

We searched the Internet, checked the reference lists of relevant studies and, where possible, contacted the first author of each included study to identify further potentially eligible articles. Experts in the field were contacted for additional leads to both published and unpublished reports.

### Data collection and analysis

#### Selection of studies

One author (a different person for different databases) scanned the titles and abstracts of reports identified by electronic searching to produce a list of possibly relevant reports. The results of the entire search were screened independently by two authors and articles evaluating the effectiveness of bicycle helmets using a controlled design were selected for full review. Disagreements were resolved by discussion.

#### Data extraction and management

We extracted data using a standardized form developed by researchers from the Injury Control and Research Centers in the United States. This form is available on request from the Cochrane Injuries Group.

#### Data synthesis

Summary odds ratio (OR) and 95% confidence interval (95% CI) were calculated using Stata (Greenland 1998; Stata 1999).

## RESULTS

### Description of studies

See the 'Characteristics of included studies' table for additional details.

Five case-control studies were found (Maimaris 1994; McDermott 1993; Thomas 1994; Thompson 1989; Thompson 1996). Data from the Thompson 1996 and Thompson 1996a reports are from one case-control study; likewise data from the Thompson 1989 and Thompson 1990 are from one case-control study. All five studies provided information on head injury, but only three (Thomas 1994; Thompson 1989; Thompson 1996) provided information on brain injury separately. Only one study (Thompson 1996) provided data on severe brain injury.

Three studies provided information on facial injury (McDermott 1993; Thompson 1990; Thompson 1996a).

One cohort study was excluded, because subjects were identified retrospectively by questionnaire and injuries were not validated from medical records (Dorsch 1987).

Updated searches have identified two further studies, both are currently awaiting assessment (Hansen 2003; Heng 2006).

### Risk of bias in included studies

See 'Characteristics of included studies' table for additional details.

#### Head injury studies

Thompson 1996
Large case-control study with 88% response rate. Prospective identification of cases and controls from medical records. Ascertainment of exposure (helmet use), demographic characteristics, riding experience and circumstances of the crash for cases and controls obtained by questionnaires. Information on all injuries was extracted from the medical records. Questionnaire report of helmet use at the time of the crash validated by medical record. Logistic regression analysis used to adjust for potential confounding by crash forces, age and sex.

Maimaris 1994
Prospective identification of cases and controls from the medical records. Ascertainment of helmet use, demographic characteristics and crash severity for cases and controls obtained by questionnaire. Injury information extracted from medical record. Multivariate analysis used to adjust for confounding factors. Head injuries in this study were defined as skull fractures and brain injuries. Soft tissue injuries (bruises, abrasions and lacerations of the scalp and forehead) were excluded.

Thomas 1994
Limited to children under 15 years old. Prospective case and control ascertainment. Ascertainment of helmet use, demographic characteristics and crash severity for cases and controls obtained by questionnaire. Injury information obtained from medical record review. Logistic regression used to evaluate effect of helmet use. Authors had a second control group of 65 children with facial injuries. This group should have been combined with the first control group to increase the sample size.

McDermott 1993
Large study with prospective identification of cases and controls. Ascertainment of helmet use, demographic characteristics and crash severity for cases and controls via questionnaire. Analysis limited to chi-square bivariate comparisons; multivariate analyses were not used. Relative proportion calculated by the authors is the same as the exposure odds ratio. Study authors excluded cyclists who died at the scene of crash or who were dead on arrival (DOA). Exposure to motor vehicles differed between cases and controls. If this difference had been evaluated statistically the results would have indicated an even greater protective effect of helmets.

Thompson 1989
First study to use case-control design to evaluate helmet effectiveness. Only study to use a population control group in addition to the emergency department controls. Multivariate analysis used to adjust for confounding by age, sex, education and income, crash severity and cycling experience.

**Facial injury studies**

Thompson 1996a
Restricted cases to serious injuries (lacerations and fractures) in order to minimize case ascertainment bias. Helmet effect evaluated for specific regions of the face, upper, middle and lower. Logistic regression analysis used to adjust for potential confounding by crash forces, age and sex.

Thompson 1990
Restricted cases to lacerations and fractures of the face. Evaluated helmet effect for upper and lower regions of the face using logistic regression to adjust for potential confounding by age, sex, education and income, accident severity and cycling experience.

McDermott 1993
Evaluated overall risk of facial injuries and did not evaluate separate regions of the face. The authors did not restrict facial injuries to serious injuries (lacerations and fractures) which would require treatment regardless of injuries to other portions of the body. This introduces ascertainment bias since people with minor facial injuries may be identified solely because bicyclists seek care for head injuries. Crude odds ratios presented. No adjustment for confounding by age, sex, crash severity.

## Effects of interventions

### Head injury studies

In all five case-control studies reviewed, there are consistent data indicating that wearing an industry-approved bicycle helmet significantly reduces the risk of head and brain injury during a crash or collision. The reduction in risk is somewhat dependent on whether the controls originate from the emergency department or the population at large. All studies found a large protective effect of helmets. One study was limited to children under 15 (Thomas 1994), the other four included bicyclists of all ages. Significant protective effect among helmet users for head injury compared to non-users was: adjusted OR 0.3 (95% CI 0.11 to 0.85) Maimaris 1994; adjusted OR 0.37 (95% CI 0.20 to 0.66) Thomas 1994; adjusted OR 0.31 (95% CI 0.26 to 0.37) Thompson 1996; crude OR 0.61 (95% CI 0.47 to 0.84) McDermott 1993; adjusted OR 0.26 (95% CI 0.14 to 0.49) Thompson 1989. The summary odds ratio for head injury was OR 0.31 (95% CI 0.26 to 0.37). This was calculated from the four studies that presented adjusted odds ratios (Maimaris 1994; Thomas 1994; Thompson 1989; Thompson 1996). The protective effect found for brain injury in studies using emergency department controls was: adjusted OR 0.19 (95% CI 0.06 to 0.57) Thompson 1989; adjusted OR 0.14 (95% CI 0.05 to 0.38) Thomas 1994; adjusted OR 0.35 (95% CI 0.25 to 0.48) Thompson 1996. Summary odds ratio for the three studies was OR 0.31 (95% CI 0.23 to 0.42). The protective effect of helmets found for severe brain injury was: adjusted OR 0.26 (95% CI 0.14 to 0.48) Thompson 1996. Results obtained using population based control groups were: head injury, adjusted OR 0.15 (95% CI 0.07 to 0.29) and brain injury, adjusted OR 0.12 (95% CI 0.04 to 0.40) Thompson 1989.

Protective effect among helmet users versus nonusers for cyclists involved in crashes with motor vehicles was: adjusted OR 0.31 (95% CI 0.20 to 0.48) and for cyclists who crashed for all other reasons, adjusted OR 0.32 (95% CI 0.20 to 0.39). Similar protection was found for brain and severe brain injuries and for cyclists of all ages (Thompson 1996).

### Facial injury studies

Three studies evaluated the protective effect of helmets for facial injuries (Thompson 1990; Thompson 1996a; McDermott 1993). The results from McDermott 1993 indicate a protective effect for facial injury, crude OR 0.64 (95% CI 0.49 to 0.84). Thompson 1990, did not find protection for the entire facial region, adjusted OR for serious facial injuries was 0.81, (95% CI 0.45 to 1.5). When facial injuries were analyzed by region (upper versus lower), a protective effect for helmet wearers was found for serious upper facial injuries , adjusted OR 0.27 (95% CI 0.10 to 0.80) comparing helmeted cyclists to non-helmet users. In the largest case-control study of helmet effectiveness, the authors were able to evaluate three regions of the face individually (Thompson 1996a). Helmet use significantly reduced risk of serious facial injury to upper and middle face regions by approximately 65% compared to non-users (upper face: adjusted OR 0.36 (95% CI 0.26 to 0.49); middle face: adjusted OR 0.35 (95% CI 0.24 to 0.50).

Overall, helmets decrease the risk of head and brain injury by 65% to 88% and facial injury to the upper and mid face by 65%. Helmets are effective for cyclists of all ages and provide protection for all types of crashes whether or not a motor vehicle is involved.

## DISCUSSION

Since we found no randomized controlled trials, we must estimate the effectiveness of bicycle helmets using observational studies. The results of five case-control studies from different countries have shown large protective effect of helmets. Case-control studies can suggest a causal mechanism; that is, helmets protect cyclists from head injury. Noncausal mechanisms (selection bias, observation bias, confounding and chance) were minimized in all studies by using a broad sample of bicyclists seeking treatment for bicycle injuries and by obtaining identical information from both cases and controls. Use of logistic regression to adjust for confounding can take into account any differential distribution of known risk factors between cases and controls and permits isolation of the effect of helmet use on head and brain injuries. The 95% confidence interval around the outcome effect indicates that the association is not due to chance. Internal validity of these studies is strengthened by: the correct time relationship (helmet worn at the time of crash), consistency of association among all participants, and a large protective effect. Study results can be generalized to other populations (external validity), since the association between head injury reduction and helmet use has biological plausibility.

Additional evidence of helmet effectiveness has been provided from time series studies in Australia, Europe and the US (Vulcan 1992; Carr 1995; Pitt 1994; Ekman 1997; Rivara 1998). These study results indicate that increased rates of helmet use resulting from multifaceted educational campaigns and/or legislation is linked to significant decreases in bicycle related head injuries. Several examples from Australia and the US illustrate the protective effect of bicycle helmets.

In Australia substantial gains in helmet use were achieved by educational campaigns followed by legislation. Helmet use in Melbourne increased from 36% in March 1990 (pre-law) to 83% in June 1992 (post-law). In the state of Victoria as a whole, helmet use increased from 31% pre-law to 75% one year later. The number of bicyclists admitted to the hospital with a head injury decreased by 40% in Victoria during the first four years after legislation (Carr 1995). A report by Newstead 1994 indicated the effects of helmet wearing legislation may have declined in the third year. However, the research team in Melbourne (Carr 1995) recognized that the criteria for admission to the hospitals had changed between year two and three allowing more people to be admitted to the hospital. The results were adjusted for case mix and the conclusion was that indeed the legislation had produced the expected drop in head injuries. Thomas and his group in Queensland, Australia, found a decline in brain injuries as a result of increased helmet use (Pitt 1994). Helmet use was 59% in 1991 versus 2.5% in 1986; head injuries decreased to 18 from 47 per 100,000 in 1986. Other bicycle injuries showed no change (Pitt 1994).

A time series study from the United States tracked observed helmet use and incidence of bicycle related head injuries over several years. Helmet use in Seattle, Washington, increased from 5.5% in 1987 to 40.2% in 1992 ($P < 0.0001$). Bicycle-related head injuries decreased by 66.6% in 5 to 9 year olds and 67.6% in 10 to 14 year old members of Seattle (WA) HMO ($P < 0.0001$) During the same time period helmet use in this group increased by 49.7% in 5 to 9 year olds and by 33.4 % in 10 to 14 year olds. Helmet use was highest for children riding with helmeted adults (94.7%) (Rivara 1994).

Some bicycling advocates have argued that helmeted cyclists may change their riding behavior influenced by a greater feeling of security and, thus take more risks and be more likely to crash (Hillman 1993). The converse argument has also been made that helmeted cyclists may ride more carefully and that these behaviors account for the reduction in head injury, not helmet use (Spaite 1991). We believe these arguments to be specious. The fundamental issue is whether or not when bicycle riders crash and hit their heads they are benefited by wearing a helmet. Cyclists would have to increase their risk taking four-fold to overcome the protective effect of helmets. This seems unlikely. There are no objective data to support this risk homeostasis theory, and now, five case-control studies have demonstrated the protective effect of helmets. In all five case-control studies reviewed, there are consistent data indicating that wearing an industry-approved bicycle helmet significantly reduces the risk of head or brain injury during a crash or collision. The size of the reduction in risk is somewhat dependent on whether the controls originate from the emergency department or the population at large. A population control group includes all bicyclists who experienced a crash and thus have the opportunity to experience a head injury, not just those who seek medical care. This group represents the exposure experience (helmet use) of the population at risk for head injury. One study (Thompson 1989) used both population and emergency department controls while the other four studies used emergency department controls. Use of population-based controls provides the best estimate of helmet effectiveness and allows the greatest generalizability. As long as proper attention is given to selection of study participants, studies of helmet effectiveness can be carried out using emergency department (ED) controls. ED controls are readily available, inexpensive and have experienced the same event as the cases. Helmets do not protect against other bodily injury, therefore we expect the ED controls with other injuries to approximate closely the exposure experience of the cycling population at risk for head injury. All five studies met these criteria.

In order to study facial injuries, cases should be limited to serious injuries (lacerations and fractures) that would result in an ED visit whether or not a head injury was also present. Examining facial injuries by location (upper versus lower face or upper, middle and lower face) make it possible to determine if a protective effect exists for any portion of the face. Studies that did this found a protective effect to the upper and mid face (Thompson 1990; Thompson 1996a). Overall, helmets decrease the risk of head and brain injury by 65% to 88% and facial injury to the upper and mid face by 65%.

This Cochrane review has been the subject of criticism, most notably in two unrefereed commentaries (Curnow 2003; Curnow 2005). In the first of these papers Curnow criticizes a meta-analysis (Attewell 2001), which found a strong protective effect among helmet users versus non-users for head, brain, facial and fatal injuries. Curnow claims that published studies fail to examine brain injury specifically, but lump it in with skull fractures. Four of the five articles included in our Cochrane review carefully define brain injury and exclude skull fractures from the definition. One article (Thompson 1996) was able to specifically examine serious brain injuries as those injuries with a head AIS score of three or greater. Curnow 2005 says our Cochrane review is based on "lack of scientific rigour" and restates arguments that he has previously directed at our review and the Attewell meta-analysis. His commentary contains factual errors and misinterpretations of the data. In contrast to Curnow's claims, the Thompson 1996 study found that all types of bicycle helmets (hard shell, soft shell and foam) provided substantial protection against head, brain and severe brain injuries for bicyclists involved in motor vehicle crashes and crashes due to other causes (Thompson 1996: Tables 3 and 4). In Curnow's Table 1 (Curnow 2005) he compares brain-injured cases to head injured cases without brain injury. He interprets the 1.06 odds ratio from this exercise as showing that helmets don't protect against brain injury. The correct interpretation is that the protective effect of helmets is similar for both head and brain injury. Cummings 2006 explains that many of Curnow's criticisms stem from misconceptions about the studies that have been done and about case-control studies in general. This paper provides a through discussion of case control study design particularly as it pertains to bicycle helmets. Hagel 2006 rebuts Curnow's arguments and points out the advantages that well conducted case-control studies have over ecologic study designs. In reply, Curnow 2006 continues the discussion and repeats arguments which have been addressed both in this review and the comments which follow at the end of the review.

Readers are directed to the 'Feedback 1' section of the review, where comments from four critics and the authors' replies cover the major areas of controversy concerning the effectiveness of bicycle helmets.

# AUTHORS' CONCLUSIONS

## Implications for practice

The scientific evidence that bicycle helmets protect against head, brain, severe brain and facial injuries has been well established by five well designed case-control studies. Bicycle helmets of all types that meet various national and international standards provide substantial protection for cyclists of all ages who are involved in a bicycle crash. This protection extends to crashes from a variety of causes (such as falls and collisions with fixed and moving objects) and includes crashes involving motor vehicles. Helmet use reduces the risk of head injury by 85%, brain injury by 88% and severe brain injury by at least 75%. The protective effect of helmets for facial injury is 65% for the upper and mid facial regions. No protection is provided for the lower face and jaw. Bicycle riders of all ages should be encouraged to wear helmets. General bicycle helmets with chin protection should be developed.

### Implications for research

The studies presented here are conclusive in their findings with respect to helmet use and head and facial injury. However, important future research in bicycle helmet effectiveness might examine the protective effect of helmets with mouth and face guards. A randomized trial design could be used to compare facial injuries between cyclists randomized to receive standard bicycle helmets and those randomized to receive helmets with face guards.

## ACKNOWLEDGEMENTS

Matthew Patterson MPH.
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Chris Beahler MLS.

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## CHARACTERISTICS OF STUDIES

### Characteristics of included studies *[ordered by study ID]*

**Maimaris 1994**

| | |
|---|---|
| Methods | Case-control study. |
| Participants | Bicycle crashes resulting in emergency department visits to Addenbrooke's Hospital, Cambridge, UK in 1992 (n=1040).<br>Cases: those treated for head injury.<br>Controls: those treated for other injuries. |
| Interventions | Bicycle helmet use. |

**Maimaris 1994** *(Continued)*

| | |
|---|---|
| Outcomes | Head injuries among helmet users and non-users.<br>Head injury present if evidence of skull fracture or brain injury shown by CT, or loss of consciousness or post traumatic amnesia associated with important post-concussion symptoms.<br>Cause of crash stratified into motor vehicle, other bicycle, pedestrian, and fall categories. |
| Notes | Helmet use significantly reduces the risk of sustaining a head injury, regardless of type of bicycle accident.<br>8.1% head injury among non wearing helmet owners and 9.2% among non-owners; 3.5% head injury among helmet users.<br>Significantly higher proportion of children (16%) using helmets than adults (9%). |

**McDermott 1993**

| | |
|---|---|
| Methods | Case-control study. |
| Participants | Bicycle crashes seen in two Melbourne, Australia, hospitals, April-December 1987 and Sept-May, 1989 (n=1710).<br>Cases: those treated for head injury.<br>Controls: those treated for other injuries. |
| Interventions | Bicycle helmet use. |
| Outcomes | Fatalities, head and facial injuries. |
| Notes | Helmet use significantly protects against head and facial injury. Excluded cyclists who died at the scene or were DOA.<br>No significant differences in mortality rates between helmeted (approved or non approved) and non-helmeted bicyclists.<br>Protective effect of helmets does not appear to be due to cautious riding behavior by helmeted cyclists. This is based on observations that "collision of cyclists" head, face, or helmet with motor vehicles occurred slightly more often to helmeted casualities than to unhelmeted casualties (17.6% versus 14.5%). Helmeted casualties also had higher non-head ISS scores than unhelmeted casualties. |

**Thomas 1994**

| | |
|---|---|
| Methods | Case-control study. |
| Participants | Bicycle crashes among children <15 years seen in two Brisbane, Australia, hospitals between April 15, 1991., and June 30, 1992 (n=445).<br>Cases: those treated for head injury.<br>Controls set 1: those treated for other injuries.<br>Controls set 2: those treated for facial injuries only. |
| Interventions | Bicycle helmet use. |
| Outcomes | Head and brain injuries among helmet users and non-users.<br>Head injury (injury to skull, forehead, scalp, or loss of consciousness) assessed by clinician using standard Queensland injury surveillance prevention project form.<br>Brain injury-loss of consciousness or more serious brain injury. |
| Notes | Helmet use significantly reduces the risk of upper head injury and loss of consciousness in a bicycle crash. |

### Thompson 1989

| | |
|---|---|
| Methods | Case-control study, population based. |
| Participants | Bicycle crashes resulting in ED visit to one of five Seattle area hospitals, Dec 1986 through Nov 1987 (n=668).<br>Cases: those treated for head injuries.<br>Controls set 1: other ED patients treated for non-head bicycle injuries.<br>Controls set 2: population-based controls from local health maintenance organization. |
| Interventions | Bicycle helmet use. |
| Outcomes | Head, brain and serious brain injuries among helmet users and non-users. Head injury classified as any head injury including superficial contusions, abrasions, lacerations, skull fractures and brain injuries of all types. Brain injury, and severe brain injury classified using ICD-9 codes and AIS scores. Brain injuries included concussions or more serious injury. Severe brain injury restricted to AIS 3 or greater. |
| Notes | Helmet use protects against risk of head and brain injury by 85% and 88% respectively compared to those not wearing helmets.<br>Population-based control group provides the best estimate of helmet effect. |

### Thompson 1990

| | |
|---|---|
| Methods | Case-control study. |
| Participants | Bicycle-related injuries resulting in ED visit to one of five Seattle-area hospitals, December 1986 to November 1987 (n=531).<br>Cases: those treated for serious facial injuries, including those with concurrent head injuries.<br>Controls: those treated for injuries to other body areas. |
| Interventions | Bicycle helmet use |
| Outcomes | Type and location of facial injuries (upper, lower, or entire face) among helmet users and non-users. Serious facial injury defined as lacerations, fractures of the facial bones, and fractures of the teeth. |
| Notes | Current helmet designs have little or no protective effect on overall risk of facial injury, but do protect against serious upper facial injury. |

### Thompson 1996

| | |
|---|---|
| Methods | Case-control study. |
| Participants | Bicycle crashes resulting in emergency department (ED) visits to one of seven Seattle-area hospitals from March 1992 through August 1994. (Seattle, WA, USA) (n=3390).<br>Cases: head injured cyclists treated in ED, hospitalized, or who died at scene.<br>Controls: injured cyclists with injuries other than to head. |
| Interventions | Use of three types of bicycle helmets, classified as hard-shell, thin-shell, or no-shell. |
| Outcomes | Head, brain and serious brain injuries among helmet users and non-users. Head injury classified as any head injury including superficial contusions, abrasions, lacerations, skull fractures and brain injuries of all types. Brain injury, and severe brain injury classified using ICD-9 codes and AIS scores. Brain injuries included concussions or more serious injury. Severe brain injury restricted to AIS 3 or greater. |

**Thompson 1996** *(Continued)*

| | |
|---|---|
| Notes | Bicycle helmets are effective for all bicyclists regardless of age and regardless of motor vehicle involvement in the crash.<br>Protective effect of helmets found for head, brain and severe brain injuries.<br>No differences seen in protective effect among helmet types.<br>No evidence that children under 6 years need different helmet standards or different type of helmet. |

**Thompson 1996a**

| | |
|---|---|
| Methods | Case-control study. |
| Participants | Bicycle crashes resulting in emergency department (ED) visits to one of seven Seattle-area hospitals between March 1, 1992 through August 31, 1994 (n=3388).<br>Cases: cyclists with serious facial injuries.<br>Controls set 1: cyclists treated for non-facial and non-head injuries only.<br>Controls set 2: those treated for non-facial injuries only (that is, head injuries retained in this control group). |
| Interventions | Bicycle helmet use. |
| Outcomes | Serious facial injuries among helmet users and non-users.<br>Facial injury defined as any injury of the jaw, lips, cheeks, nose, ears (external), eyes (external), forehead, or mouth (intraoral). Cases restricted to fractures or lacerations of these areas.<br>Head injuries defined as superficial lacerations, abrasions, or contusions on the scalp, as well as skull fractures, concussions, cerebral contusions, serious lacerations, and all intracranial hemorrhages (excluding injuries to the forehead and ears).<br>Facial injuries stratified by region: upper, middle, and lower face. |
| Notes | Helmets protect against upper face and middle face injuries.<br>Use of two control groups thought to "bracket" the true effect of helmets on the risk of facial injury.<br>Elimination of all persons with head injuries from the first control group likely resulted in some overestimate of the protective effect of helmets on serious facial injury. Conversely, retaining persons with head injuries in the second control group likely resulted in an underestimate of the protective effect. |

## Characteristics of excluded studies *[ordered by study ID]*

| Study | Reason for exclusion |
|---|---|
| Acton 1996 | Study authors investigated the frequency of oral/maxillofacial injuries admitted to the hospital and found that helmets were not protective for facial injuries. Data were not analyzed as a case control study. Upper and lower portions of the face should have been examined separately in addition to evaluating injuries to the entire face. |
| Attewell 2001 | Study authors conducted a meta-analysis of 16 studies with individual injury and helmet use data published between 1987 to 1998. Outcome measures were head injury, brain injury, and facial injury as defined by the various studies as well as fatal injuries. Authors found a strong protective effect among helmet users versus non-users for head, brain, facial and fatal injuries. Results provide clear evidence of helmet benefits. Study excluded because this is a meta-analysis, not an original study. |
| Dorsch 1987 | This retrospective cohort study was the first attempt to evaluate helmet effectiveness. Authors found statistically significant association between helmet use and severity of head injury using multivariate analysis to adjust for age, sex and severity of crash. Study was excluded because ret- |

| Study | Reason for exclusion |
|---|---|
| | rospective design can produce recall bias and incomplete identification of injured cyclists. Injuries were not validated using the medical record. |
| Finvers 1996 | Study authors studied children ages 3 to 16 who were treated in the emergency room of a tertiary care children's hospital. They reported a strong protective effect of helmets for serious head injury. The protective effect of helmets was underestimated due to exclusion of ICU cases. The study was excluded because it was a tertiary care study and not population based. |
| Kelsch 1996 | This prospective study of 76 hospitalized cyclists examined head injury, brain injury and death in helmeted and unhelmeted cyclists. Authors concluded bicycle helmets reduced the incidence and severity of head injuries. Excluded because this was a case series of hospitalized cyclists, not a case control study. |
| Lastennet 2001 | Study authors conducted an international qualitative and systematic review using the criteria of the French Health Accreditation and Evaluation National Agency (ANAES) to evaluate the effectiveness of bicycle helmets in preventing head injury in children. Five studies met all selection and qualitative criteria. All studies found helmets effective in preventing head injury in children. Authors concluded helmets should be worn at all times. Study excluded because this is a meta-analysis, not an original study. |
| McIntosh 1998 | Case series study of helmeted cyclists limited to those who hit their helmets in a crash. Provides good information on helmet performance under crash conditions. Not a case-control study of helmet effectiveness. |
| Spaite 1991 | This study was excluded because the cases and controls represented a biased sample. The study was limited to patients treated at a trauma center for motor vehicle/bicycle collisions and does not represent the exposure experience of the population at risk for bicycle head injuries. |

## APPENDICES

### Appendix 1. Search strategy

**CENTRAL issue 3, 2006**

#1 MeSH descriptor Accident Prevention explode all trees
#2 MeSH descriptor Accidents, Traffic explode all trees
#3 (injur* or fatal* or accident* or crash* or collision* or collide*)
#4 (#1 OR #2 OR #3)
#5 MeSH descriptor Bicycling explode all trees
#6 (bicycl* or cycle or cycling or cyclist*)
#7 (#5 OR #6)
#8 MeSH descriptor Head Protective Devices explode all trees
#9 helmet*
#10 (#8 OR #9)
#11 (#4 AND #7 AND #10)

**MEDLINE 1966-2006**

1. explode "Accidents-Traffic" / all SUBHEADINGS
2. explode "Accident-Prevention" / all SUBHEADINGS
3. explode "Bicycling" / all SUBHEADINGS
4. explode "Head-Protective-Devices" / all SUBHEADINGS
5. helmet* in ab,ti
6. bicycl* or cycling or cyclist* in ab,ti
7. injur* or fatal* or accident* or crash* or prevent* or collide* or collision* in ab,ti
8. 1 or 2 or 7

9. 3 or 6
10. 4 or 5
11. 8 and 9 and 10

**EMBASE 1980-2006**

1. exp accidents traffic/
2. exp accident prevention/
3. (injur$ or fatal$ or accident$ or crash$ or prevent$ or collide$ or collision$).ab,ti.
4. 1 or 2 or 3
5. exp bicycle/
6. (bicycl$ or cycle or cycling or cyclist$).mp. or cycle$.ab,ti. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]
7. 5 or 6
8. 4 and 7
9. helmet$.ab,ti.
10. exp Helmet/
11. 9 or 10
12. 8 and 11

**PSYCINFO 1970-2006**

1. explode "Motor-Traffic-Accidents" in MJ,MN
2. explode "Accident-Prevention" in MJ,MN
3. explode "Transportation-Accidents-+" in MJ,MN
4. injur* or fatal* or accident* or crash* or prevent* or collide* or collision*
5. bicycl* or cycle or cycling or cyclist*
6. helmet*
7. 1 OR 2 OR 3 OR 4
8. 5 AND 6 AND 7

**TRANSPORT to 2006**

1. bicycl*
2. cycle
3. cyclist*
4. cycling
5. bicycl* or cycle or cyclist* or cycling
6. helmet*
7. accident*
8. crash*
9. injur*
10. fatal*
11. accident* or crash* or injur* or fatal*
12. #5 and #6 and #11
13. (200506 or 200509 or 200512 or 200603 or 200606) in UD
14. #12 and #13

**Web of Science (searched October 3, 2006)**
TS=((injur* or fatal* or accident* or crash* or prevent* or collide* or collision*) and (helmet*) and (bicycl* or cycle or cycling or cyclist*)) AND TS=(random* or control* or trial* or comparison* or group* or study or studies)

**Pubmed (searched October 3, 2006 for last 12 months)**
(injur* OR fatal* OR accident* OR crash* OR prevent* OR collide* OR collision*) AND (helmet*) AND (bicycl* OR cycle OR cycling OR cyclist*) AND (random* OR control* OR trial* OR comparison* OR group* OR study OR studies)

## FEEDBACK

### Helmets for preventing head and facial injuries

#### Summary

Bill Curnow's comments are summarised below. Each comment has a number with a corresponding response from the reviewers in the reply section below.

1. The review requires, first, that there is a hypothesis to explain how helmet wearing and changes in head injury are linked by proximate cause and effect obeying scientific laws." Mr. Curnow suggests a biomechanical hypothesis is necessary.

2. Secondly he says "the hypothesis should be tested by experiment or, with human subjects, randomized controlled trial. The studies, however detailed their data or refined their statistical methods, are therefore mere empirical correlations between helmet wearing and head injury. They do not establish mechanisms of cause and effect applicable to other circumstances".

3. Axonal shear injuries are the only injuries that matter.

4. There is good reason to expect that helmet wearing may actually increase the risk of brain injury.

5. NHMRC report on football injuries of the head and neck. "The NHMRC's assessment was that helmets may possibly reduce scalp lacerations and other soft tissue injury, but may increase cerebral and non-cerebral injuries including diffuse brain injury".

6. The suggestion that helmets protect against injuries to the face including orbit/eye, nose and middle face is not plausible.

**Reply**

The authors appreciate this thoughtful critique of our review "Helmets for preventing head and facial injuries in bicyclists". Bill Curnow makes several points, which are answered below.

1. Answer: We disagree. We should like to point out that while a detailed proven biomechanical explanation for head injury in bicyclists is desirable, it is not a necessary pre-condition for proving that safety helmets work. An even older reference than Holburn 1943, makes this point (Snow 1855). John Snow's famous intervention of removing the handle from the Broad Street pump after seeing the clustering of cholera cases in this area of London in 1849 quelled a cholera epidemic. No one knew the bacterial agent or the pathophysiology of cholera at the time. We hypothesized that bicycle helmets would act to reduce head and brain injury, and this hypothesis is supported by the studies reviewed. There was substantial evidence from motorcycle helmets that this would be true.

2. Answer: We disagree. We would point out that RCTs are also empirical correlations between an intervention and an outcome and if properly executed can provide the highest level of causal inference. However, other designs, well conceived and executed to take into account potential confounders as our work was, (no one has raised a supportable claim of biases unaccounted for in our work) can provide a solid basis for causal inference. This is especially true when a number of other studies have replicated these results. The nature of causality is well discussed by J. Mark Elwood in his book, Causal Relationships in Medicine (Elwood 1988).
The case control studies reviewed provide evidence that helmeted bicycle riders who experience a crash are much less likely to have a head injury than unhelmeted riders crashing under the same circumstances. The background section of the review (second paragraph) and the discussion section (first paragraph) of the review explain how case control studies are an appropriate study design for evaluating helmet effectiveness in the absence of randomized controlled trials. We agree that RCT's would be ideal, but believe this is unlikely. High quality case control studies and other experimental and non-experimental study designs can provide solid inferences in the absence of randomized trials (Elwood 1988). The key question is-if you experience a bicycle crash and hit your head , will a helmet protect your head and brain? These studies all indicate that helmets protect the rider from brain injury, skull fractures and soft tissue injury. In the largest study (n=3390), the authors evaluated the risk of brain and severe brain injury separately and found a strong protective effect. This study also evaluated the protective effect of helmets among bicyclists involved in a motor vehicle crash as an example of a crash with high impact forces (Thompson 1996). Helmets are as protective , that is provide the same reduction of head and brain injury, regardless of why the crash occurred. In other words, the protection is the same for bike-motor vehicle crashes as for falls.

3. We disagree. We feel that concussions, subdural and epidural hematomas and parenchymal bleeding are serious injuries that result from linear or direct impact forces. Helmets reduce potential injury by linear or direct impact forces by dissipating energy using the foam and shell. Axonal shear injuries result from rapid deceleration or rapid rotation of the head. The magnitude of reduction of axonal shear injuries by bicycle and motorcycle helmets is difficult to measure. However, it is important to point out that significant head trauma occurs at forces below those which produce axonal shear injuries.

4. We disagree. Mr. Curnow is overstating the findings of the two studies quoted in his letter. There is an excellent and very thorough review of the biomechanics of head injury by Dr. Michael Henderson of NSW Australia (Henderson 1995). He concludes that "real world crash experience shows that none of these laboratory results are reproduced in the field to any measurable extent, in other words, in the real world rotational acceleration has not shown up as an important problem." Henderson also reviews a number of studies measuring bicycle helmet effectiveness including a study by Corner that found "bicycle helmets were reducing the severity of head injury, and this was particularly the case when injury resulted from collision with another vehicle." (see page 27) (Henderson 1995). Laboratory work by Dr. Voight Hodgson suggested that soft shell helmets might not slide on a surface as easily as hard-shell helmets, possibly increasing head rotation and leading to neck injuries (Hodgson 1990). The widespread use of helmets worldwide since 1990 has shown that these neck injuries did not occur. The largest case control study of helmet use was able to look at the protective effect of three helmet types, hard shell, soft shell and no shell (Thompson 1996). The protective effect of helmets is so large that the small differences that may occur between different types cannot be detected (Thompson 1996). Further analysis of this large group of cyclists indicated that wearing a helmet of any type was not associated with neck injuries (Rivara 1997). Studies of motorcycle helmets have also indicated no association with neck injury (Shankar 1993).

5. We disagree. The NHMRC report is not evidence based, but simply a statement of opinions. The Thompson, 1989 study is misquoted; this study found that the protective effect of helmets for brain injury was 88% (Thompson 1989). For several reasons observations based on sport helmet use can not be applied to bicycle helmets, which are designed to absorb energy of one crash event and then be replaced. Sport (football) helmets are equipped with resilient liners that are intended to recover their properties after an impact. As a result, much of the impact management that might be fitted into the same helmet volume is lost. Also the impact standards are much less demanding so that in impacts comparable to those applied to bicycle helmets, a football helmet would be overwhelmed.

6. We disagree. We developed and tested the hypothesis that helmets could provide protection for the forehead and mid-face after consulting with experienced engineers who were experts in helmet design and laboratory testing. We also hypothesized that there would be no effect on the jaw area. We found that helmets protect the forehead, and mid-face area, but they do not provide protection to the jaw and mouth. The proper method of analyzing facial injuries is explained in the Cochrane review (section on facial injuries). It is necessary to restrict the facial injuries to lacerations and fractures to avoid ascertainment bias and analyze these injuries by facial region (upper and lower, or upper, middle and lower face.) Please refer to our paper referenced in the review for a full discussion of methodology and additional references (Thompson and Nunn 1996).

Summary: The authors agree with an editorial by Leonard Evans which accompanied the Maimaris article in BMJ. "Discussions on whether to require cyclists to wear helmets would become more productive if everyone would accept that it is well established that helmets substantially reduce risk [of head injury] in a crash, and that passing laws making wearing them mandatory would substantially reduce casualties" (Evans 1994).

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**Contributors**

Author of comments: Bill Curnow

### Helmets for preventing head and facial injuries

**Summary**

Dorothy Robinson's comments are summarised below. (Her comments may be seen in full on http://www.update-software.com/ccng/ccng.exe?SourceID=CD001855#Content153.) Each comment is numbered and has a corresponding response from the reviewers in the reply section.

1. This Review cannot be recommended as a valid interpretation of the existing published information on helmets.

2. The reason for studying helmet efficacy is to predict changes in injury rates when a population of cyclists all start to wear helmets. Helmets can only be considered effective if the increased helmet wearing actually reduces injuries.

3. It is well known that most case-control studies of bicycle helmets have found substantial differences between those who chose to wear helmets and those who do not.

4. Fundamental differences between populations choosing to wear or not wear helmets make it difficult for any case-control study to separate these effects. However, the differences relate not just to head injury rates, but also many other attributes of the two groups.

5. In contrast, a study comparing hospital admissions for all cyclists before and after a helmet law, compares the pre-law population of non-wearers with the same population of wearers post -law---this means there should be less difficulty adjusting for bias, making the results more reliable.

6. Two time series studies indicate helmets do not reduce head injuries. 1) "-- results of the first 3 years of post helmet law data in the State of Victoria, Cameron et al (1994) reported that results showed "the observed proportion of head injured cases to be no different from the downward trend predicted by the model using pre-law wearing rates" (Cameron 1994). " Another major time series analysis, (Scuffham & Langley 1997), not mentioned by this Review, observed a downward trend in the percentage of cyclists suffering head injuries 'present before, and independent of, helmet wearing'. After accounting for this trend, increased helmet wearing had 'little association with serious head injuries as a percentage of all serious injuries to cyclists'. Such trends are a confounding factor that the reviewed case-control studies appear not to have estimated or adjusted for. This leaves the results of such case-control studies open to question. After correctly adjusting for such trends, no published time series analysis has been able to show any noticeable decrease in head injury rates, despite the large increases in helmet wearing because of helmet laws or substantial promotion of helmets.

7. Such trends (Scuffham & Langley 1997) are a confounding factor which the reviewed case-control studies appear not to have estimated or adjusted for.

8. Dorothy Robinson: states that recommending or mandating that helmets be worn may change the circumstances, e.g., by making cyclists feel safer and take more risks. The act of recommending or mandating helmets may also discourage people from cycling. These factors cannot be considered in isolation from the effects of helmets. They are part of the package that comes with mandating or recommending helmets.

9. "For Seattle, Rivara et al. (1994) reported that an increase in helmet use among school age children from 5.5% in 1987 to 40.2% in 1992 was accompanied by a 66.6% decrease in bicycle related head injuries in 5 to 9 year olds and a 67.6% decrease in 10 to 14 year old members of a health maintenance organization. However, unless those wearing helmets are many times more likely to seek hospital treatment, a relatively small increase in helmet wearing (5.5% to 40%) cannot plausibly produce a two thirds reduction in head injuries."

10. "The 7 fold difference in helmet wearing rates between the community controls (21.1%) (Koepsell 1998) in this study and in cyclists of the same age group riding on Seattle streets (3%) (DiGuiseppi 1989) invalidates the conclusions of this study making it ineligible for inclusion in the Cochrane Review. Whilst use of emergency room controls gives a less biased result, helmet wearing in child cyclists requiring emergency room treatment was also higher than in the street survey, suggesting that, if case-control studies are to provide a valid estimate of the total effect of helmets (including any risk compensation), helmet wearing in the 'case' group of head injured cyclists should be compared not only to controls requiring emergency room treatment for other injuries, but to population wearing rates of non-injured cyclists, or controls chosen from street surveys of cyclists not involved in accidents.

11. "This Review appears to confuse odds ratios with the percentages of head injuries which might be prevented by helmets. This is a serious problem, potentially leading to significant errors of interpretation. The authors of this Review for the Cochrane Collaboration refer to the paper by Sacks et al., so obviously know of this misinterpretation of their results, but never appear to have attempted to correct it, or explained to the CDC why this is invalid. And they still continue to mislead other scientists by referring to odds ratios as percentage reductions in head injuries.

**Reply**

The authors appreciate the opportunity to respond to Dorothy Robinson's critique of our Cochrane review "Helmets for preventing head and facial injuries in bicyclists".

1. Authors reply: We disagree. The objective of the review was "To determine whether bicycle helmets reduce head, brain and facial injury for bicyclists of all ages involved in a fall". We followed the Cochrane methodology and evaluated the best available evidence. This came from case control studies. We think that a substantial portion of the disagreement can be resolved through a clear understanding of case control and ecological study designs that have been used to examine bicycle helmet effects. To achieve a common basis for discussion, a brief review of these designs and their applications follows. Case-control study: Cases are persons with the outcome of interest, and controls are drawn from the same population that produced the cases. The exposure of both groups is then compared. Information on critical co-variates is also collected. The unit of analysis is the individual. Case-control studies can be prospective or retrospective. This is also a type of observational study. Case-control design is especially useful when the outcome of interest is relatively rare, and/or when circumstances do not permit a randomized controlled trial. In the case of bicycle helmets, this design has been used to address the questions, "Do bicycle helmets work? Do they reduce the risk of head injuries in wearers who crash?" Ecologic study: The intervention of interest is applied across an entire population or group. The investigator has no control over the intervention. Outcomes are then measured in the group(s) that received the intervention and the group(s) that did not receive the intervention. The unit of analysis is the

group. These studies generally fall into two categories, ecological time studies and ecological group studies. The first category involves one group and the analysis measures outcomes before and after the intervention is applied. One could call this, simply, a before-and-after study or a time-trend study. The second type, the ecological group study involves comparing two or more groups concurrently. Both within-group changes and between-group changes are examined. For example, we might compare traffic-crash mortality before and after passage of a seat-belt law in State A, to the mortality data in State B, which had no such law during the entire period being examined. Ecological studies may be called many different things by different authors and research disciplines: time series studies, before and after studies, Pretest-Posttest studies, and others. Ecological studies may be used to address the question of the population effects of a given intervention. In the case of bicycle helmets this design has been used to examine the effects of laws or campaigns on bicycle helmet use and/or head injuries in bicyclists. This design poses a number of challenges: often there is no control group so secular trend may not be taken into account, if there are control groups or communities, variance across communities (clustering effect) (Murray 1997, Murray 1998, Koepsell 1998) is often not taken into account. This is like failing to adjust for co-variates in an individual level analysis. Any number of unanticipated factors (i.e. the head injury death of a prominent leader cycling without a helmet) in addition to the intervention of interest (a law or regulation requiring helmet use) can make isolation of intervention effects problematic. If hospital admission data are used the effect of the intervention on the total population disease burden will be underestimated. Hospital admission policies can change resulting in biased case ascertainment. Despite these and other limitations, repeated ecological studies that are well designed and well analyzed can help build the case for population effects of a given intervention. Our review was focused on the question best addressed by case-control studies, "Do helmets work?" In addition, we have summarized the ecological studies designed to assess the effects of helmet laws or regulation in the discussion section, but this was not the primary focus of the review. Our Cochrane review indicates that there is very solid evidence that bicycle helmets protect against head and brain injury.

2. Authors reply: We disagree. D.R. is mixing the issue of whether helmets are protective with the issue of overall population effects of helmet use. Five case control studies from three continents have provided scientific evidence that bicycle helmets reduce head and brain injury. These are clearly discussed in the review. The ecological studies of populations have also shown that increasing bicycle helmet use reduces head injuries in these populations.

3. Authors reply: We agree. Helmet wearing may differ by age, sex, personal characteristics of the cyclists such as race, and circumstances of the crash particularly involvement with motor vehicles and other measures of crash severity. This is why it is important to measure and adjust for these co-variates. Other researchers and we have done this in performing case control studies of helmet effectiveness.

4. Authors reply: We agree that it is difficult, but it can be done. Well designed and analyzed case-control studies can separate these effects. Four of the five case control studies did take these differences in to account using multivariate analyses (Maimaris 1994, Thompson 1989, Thompson 1996, Thomas 1994). Case control studies take these differences into account by collecting information on personal characteristics of the cyclists (demographics), crash severity (riding speed, reason for crash-i.e. motor vehicle involvement, fall or crash surface) and using this information in the logistic regression analysis. Proper statistical adjustment for factors that could contribute to head injury makes it possible to isolate the effect of helmet use on head injury. Logistic regression allows for comparison of helmeted and non-helmeted cyclists with other factors being equal. This approach also negates concerns about risk compensation since in the comparison one compares cyclists (helmeted vs. not helmeted) adjusted for crash forces and other factors. This approach results in a comparison of crashing cyclists who may be thought of as experiencing the same crash forces. Four of the five studies (Maimaris 1994, Thompson 1989, Thompson 1996, Thomas 1994) reviewed carried out this type of analysis and did take into account differences between cases and controls for a wide variety of factors including helmet use. McDermott collected co-variate information but used univariate chi-square analysis and calculated a relative proportion (McDermott 1993). His techniques do not permit adjustment for case and control differences that could contribute to head injury. All the case control studies included in the Cochrane Review found that helmets reduced head and brain injuries (Maimaris 1994, Thompson 1989, Thompson 1996, McDermott 1993). Remember, all of these cyclists had crashed (so riding behavior is beside the point), those with head injuries (the cases) were less likely to be helmet wearers than the cyclists with other injuries (controls). Please see the Cochrane review, 2nd paragraph of the background section and 1st and 5th paragraphs of the discussion section for a short explanation of case control methodology. Interested readers should also consult Mark Elwood's text (Elwood 1988) and James Schlesselman's text (Schlesselman 1982) for an excellent discussion of case control methods and the conclusions, which may be drawn from these methods.

5. Authors reply: This is seldom true. In the analysis of ecological before/after or time series studies it is necessary to account the change in hospital admission policies, other road initiatives, changes in cycling exposure which could decrease or increase over time as well as secular trend. The best studies of this type use a separate comparison group to permit measurement of secular trend (DiGuiseppi 1989). It is becoming increasingly clear that variance across groups must also be taken into account as described by Murray and others (Murray 1997, Murray 1998, Koepsell 1998). Additionally, to determine the full effect of helmet laws it is desirable to determine the total burden of injuries in the population, including those treated in primary care and emergency departments, not just hospital admissions and deaths.

6. Authors reply: We disagree. We point out that the authors of both ecological studies she refers to have since published papers showing a positive population effect of bicycle helmet legislation (Carr 1995, Schuffman 2000). Statements 1) and 2) do reflect the published findings of these two studies (Cameron 1994, Schuffman 1997) and illustrate the difficulty involved in time series analyses, particularly the need for analyses to take confounding factors into account.
The Cameron reference quoted above (#1) was a presentation of work in progress. The published report of the three year results, (Newstad 1994), emphasized in the preface to the report that there were problems with the data analysis and that further work was being done. In the reanalysis and report of the four year results, Carr (1995) reported that the criteria for admission to the hospitals had changed between

year two and three (post law) allowing more people to be admitted to the hospital in years three and four. The time series analysis was adjusted for case mix and the conclusion of this report was that indeed the legislation had produced the expected drop in head injuries (Carr 1995). This information is presented in the 3rd paragraph of the discussion section of our review. This is a direct quote from the Carr report. "Multivariate time series analyses of the corrected number of bicyclist admissions to hospital in Victoria indicated admissions in the first four years of the helmet legislation were 40% below the number expected on the basis of pre-legislation trends. The inclusion of other road-safety-related factors in the modelling process suggested the reduction in bicyclist admissions was largely due to the helmet legislation. Analysis of the severity of head injuries for crash-involved bicyclists similarly indicated the severity of head injuries has declined after the introduction of the helmet wearing legislation" (Carr 1995). "It was concluded that the mandatory helmet wearing legislation has had a significant, positive effect on the number and severity of injuries amongst bicyclists, and that this effect has persisted for the four years since the introduction of the legislation." A second study from New Zealand by Scuffman et al was published in July, 2000. This group concluded that their helmet law had been an effective road safety intervention leading to a reduction in head injury to cyclists over its first three years. Their conclusion was that "the helmet law has been an effective road safety intervention that has lead to a 19% (90% CL: 14,23%) reduction in head injury to cyclists over its first three years" (Schuffman 2000). The authors consider this new study superior to their preliminary study which reported little effect of the New Zealand helmet law after one year (Thompson 1989). As noted in our Cochrane review, five ecological studies (Carr 1995, Vulcan 1992, Pitt 1994, Ekman 1997, Rivara 1994) indicate that increased rates of helmet use resulted from multifaceted educational campaigns and/or legislation were linked to significant decreases in bicycle related head injuries.

7. Authors reply: We disagree. In all the case control studies cases and controls were selected at the same time. Thus, there is no reason to adjust for secular trend. However, it is important to adjust for secular trend in time-series studies.

8. Authors reply: We disagree. As previously stated, the objective of our review was "To determine whether bicycle helmets reduce head, brain and facial injury for bicyclists of all ages involved in a fall". D.R. is suggesting that risk compensation and decrease in exposure to cycling must be considered . These are separate issues that may be evaluated in other reviews. As we pointed out in the discussion section (last paragraph) there are no objective data to support a risk homeostasis theory for bicycle helmet effectiveness. To quote from our review-"The fundamental issue is whether or not when bicycle riders crash and hit their heads they are benefited by wearing a helmet." Adjusting for crash severity enables us to address this question regardless of any increase or decrease in risk behavior by the cyclists. James Hedlund presented a comprehensive review of the risk compensation debate at the Fifth World Conference on Injury Prevention and Control. We recommend his lecture to all interested readers (Hedlund 2000). Whether wearing a helmet contributes to risk-taking behavior can be illuminated by looking at evidence from seat belt legislation for motor vehicles, and motorcycle helmet legislation. The evidence from laws requiring seat belt use in cars indicates that any change in risk taking by drivers is small and there is more likely to be a reduction in injury risk if wearing seat belts is mandatory (Evans 1991, Evans 1994). In the United States nearly all 50 states passed laws requiring motorcycle helmets in the mid 1960's. In 1976 almost half of the states repealed their laws. This provided an opportunity for a natural experiment. Fewer motorcyclists wore helmets following the repeal of motorcycle helmet laws resulting in a 25% increase in motorcycle deaths (Evans 1991, Evans 1994). This makes it unlikely that wearing helmets leads to any large increase in risk taking (Evans 1994).
There is insufficient information on changes in cycling patterns associated with helmet use. Unfortunately information on cycling exposure is not routinely available. The reported decrease in cycling in Australia following mandatory bicycle helmet laws was mainly among teenagers, while adult cycling actually increased. Total bicycle use in 1992 was greater than in 1987-88, before mandatory laws (Henderson 1996, Finch). Well designed population based studies are needed to answer the question, Is bicycle helmet legislation responsible for decreases in cycling?

9. Authors reply: We disagree. D.R. misinterpreted our report. In our report the reduction in head injuries were population based rates obtained from Group Health Cooperative of Puget Sound (GHC) in 1987 and 1992 (Rivara 1994). The helmet use figures she quotes were from yearly observations of helmet wearing in the general Seattle population. The latter observations were conducted in order to assess the effects of a multi-faceted helmet campaign. GHC was part of the community campaign and, in addition, promoted helmet wearing among their members. The purpose of our report was to show that while helmet wearing rates in the overall Seattle area population were increasing significantly from 5.5% to 40%, the head injury rates in cyclists from one part of that overall population were decreasing dramatically (Rivara 1994).

10. Authors reply: We disagree. Dorothy Robinson's comparison of our case control study's population control group to observed cyclists on the bike paths and streets of greater Seattle is not methodologically sound. The correct control group must have had the opportunity to become a case, which means the cyclist must have experienced a crash. Further more we disagree with Dorothy Robinson on the proper selection of a population control group. A population control group includes all bicyclists who experienced a crash and thus have the opportunity to experience a head injury, not just those who seek medical care. This group represents the exposure experience (helmet use) of the population at risk for head injury. Use of population-based controls provides the best estimate of helmet effectiveness and allows the greatest generalizability. (please read the fifth paragraph of the discussion section of the Cochrane Review). Even Dorothy Robinson concedes that our emergency department control group was valid. We point out that the adjusted protective odds ratio was 0.19 using this group in our original 1989 study (Thompson 1989).

11. Authors reply: We disagree. Dorothy Robinson's comments are incorrect. We have not given a misleading interpretation of the odds ratio. A detailed explanation of the odds ratio is provided in the next several paragraphs.
Robinson expresses concern that odds ratios from case-control studies of bicycle helmets were treated as if they were risk ratios. This concern is misplaced; odds ratios from case-control studies should be treated as if they were risk ratios when the study outcome is uncommon in the population from which the cases and controls were selected.

The example that Robinson gave is a hypothetical sample of 100 helmeted cyclists who crashed, among whom 20 sustained a head injury and 100 unhelmeted cyclists in similar crashes, among whom 40 sustained a head injury. If we had data of this kind we would analyze this as a cohort study and compute that the risk ratio for the risk of head injury among helmeted persons compared with those who were not helmeted: risk ratio (20/100)/(40/100) = 0.5. If we computed the odds ratio, as Robinson suggests, we would get (20/80)/(40/60) = .375. When the outcome is common, the odds ratio will be further from the null value of 1.0 than the risk ratio and will not correctly approximate the risk ratio.
We commonly resort to case-control methods when the outcome is rare. When the rare disease assumption is met, the odds ratio from a case-control study will closely approximate the risk ratio from a cohort study set in the same population. Imagine, for example, that one head injury occurred among every 1000 bicyclists who crashed without a helmet and further that helmets reduced the risk of head injury by 50% in a crash. In a hypothetical population of one million cyclists who crash, half were wearing helmets. In this population there will be, on average, 500 persons with head injury in the group without helmets and 250 among those who were helmeted. We could compute the correct risk ratio of 0.5 by comparing those who wore helmets with those who did not: risk ratio = (250/500000)/(500/500000) = 0.5. A cohort study which ascertained the exposures and outcomes of a million cyclists would be very expensive. In contrast, a case-control study would involve less work. We might ascertain all 750 people who had a head injury and determine that 500 were wearing helmets when they crashed. We would sample 750 crash victims from the 999,250 who did not have head injuries and determine, on average, that the proportion that were helmeted was .500125*750 = 375. In our study sample of 1500 cyclists we can no longer determine the risk ratio because of our sampling scheme. We can, however, compute that the relative odds of head injury among the helmeted compared with those not helmeted was (500/375)/(250/375) = 0.5. This estimate is the same as the risk ratio previously calculated.
The fact that case-control studies can use the odds ratio in the study sample to estimate a risk-ratio in the study population was first noted by Jerome Cornfield, in a paper published in 1951 (Cornfield 1951). A few years later Mantel and Haenszel extended this idea to stratified methods of analysis which are still in use (Mantel 1959). The use of case-control studies to estimate relative-risks has been described in many textbooks (Schlesselman 1982, Breslow 1980, Hennekens 1987, Kelsey 1996, MacMahon 1996, Rothman 1998). As an aside we note that case-control studies can estimate relative risks even if the rare disease assumption is not met, provided that an appropriate sampling scheme is used (Rothman 1998, Rodrigues 1990). Readers will note that while the controls in our hypothetical example were chosen at random, the controls in studies of bicycle helmets set in emergency departments were selected from among persons who had injuries other than head injuries. This control group should serve to estimate the prevalence of helmet wearing among all cyclists who crash as long as helmets do not offer protection against injury to body sites other than the head. A discussion of case-control studies set in emergency departments, including discussion of control selection for bicycle helmet studies, has been published elsewhere (Cummings 1998).

Overall Concluding Remarks. Recommending or mandating helmet use is based on solid scientific evidence. This is a first step in reducing bicycle related head injuries. Encouraging cycling, building a bicycle friendly infrastructure, and promoting safe cycling instruction are also important activities. These activities are not mutually exclusive. Promoting bicycle helmet use does not exclude other road safety approaches. There are many parts to bicycle injury prevention, helmet use is just one technique, one which has proven effective.

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Author of comments Dorothy Robinson

Authors responding : Diane C. Thompson, Robert S. Thompson, Frederick P. Rivara

### Helmets for preventing head and facial injuries

#### Summary

Each comment has a number with a corresponding response from the reviewers in the reply section below.

1. The authors of this Cochrane Review (Thompson, Rivara, Thompson, 2000) are well known as advocates for cycle helmet wearing, but we have a right to expect more care and scruples if they wish to persuade us that they are also dispassionate scientists. By reference to five case-control studies from around the world comparing the degree of trauma from head injury following a road crash among cyclists wearing and not wearing a safety helmet, they have concluded that bicycle riders of all ages should be encouraged to wear helmets.

I also conducted a broad-ranging review of evidence on this subject (Hillman 1993). It concurred with the obvious judgement, confirmed in hospital-based studies that, if cyclists fall off their bicycles, or are knocked off them in a collision with a motor vehicle, helmeted heads are very likely to be less seriously damaged. No one is denying that.

2. What is at issue, however, is whether the wearing of a helmet influences cyclists' behaviour, thereby affecting the likelihood of them being involved in such an incident in the first place.

3. The authors of the Review dismiss the contents of the report on my study in just two lines by employing the dubious tactic of misquoting me as stating that 'helmeted cyclists feel "invincible"' - a word I never used, yet they put it in quotation marks - 'and therefore ride in a more reckless manner'.

4. In fact, the wording of the relevant part of my text reads 'Cyclists are less likely to ride cautiously when wearing a helmet owing to their feeling of increased security. In this way, they consume some, if not all, of the benefit that would otherwise accrue from wearing a helmet.'

Rivara and the Thompsons appear to be intent on caricaturing the risk compensation hypothesis in order to dismiss it. Yet, the evidence that risk-taking behaviour is sensitive to the risk-taker's perception of safety and danger is now overwhelming - from trapeze artists with safety nets to drivers of cars fitted with ABS brakes (for readers new to this debate, an introduction to the evidence can be found in Wilde 1994; Adams 1995; Adams 1999). Yet, remarkably, Rivara and the Thompsons argue that the behaviour of cyclists is oblivious to changes in perceived risk.

5. The authors of the Review cite the fact there is no evidence that risk compensation applies to cyclists wearing or not wearing helmets. Given the evidence from other better-documented activities that behaviour is influenced by the perception of risk, the onus of proof surely lies on those who argue that cyclists are the unique exception to this rule.

#### Reply

The authors welcome the opportunity to respond to Mayer Hillman's comments on our Cochrane review "Helmets for preventing head and facial injuries in bicyclists"

1. Answer: We agree. Helmets protect the head and brain from injury. That is the issue our Cochrane review addresses.

2. Answer: We disagree. Bicyclists have crashed or fallen and sustained head, brain and other injuries for years before helmets were proposed as an effective intervention for head and brain injuries. The objective of our review was "to determine whether bicycle helmets reduce head, brain and facial injury for bicyclists of all ages involved in a bicycle crash or fall", and they do. (please read abstract)

3. Answer: We agree that our summary of Mayer Hillman's exact words could be misinterpreted. We regret any perturbation this may have caused. The last issue of the Cochrane review contains our revision. Our sentence summarising Hillman's views reads: "Some bicycling advocates have argued that helmeted cyclists will feel safe and, therefore, ride in a less cautious manner and be more subject to crashes."

4. Answer: We agree that this statement is in Mayer Hillman's Cycling and Health. However, we disagree with the statement. Our views of the role of risk compensation differ with those of Mayer Hillman. The conclusion of our systematic review indicated a strong protective effect of helmets, i.e. that bicycle helmets are effective. It was our opinion that changes in rider behaviour (cycling less cautiously or more cautiously) could not substantially change the protective effect of helmets or be the reason head and brain injuries were less likely in helmet wearers.

We disagree that the evidence supporting risk compensation is "overwhelming". This is a hotly debated issue. The closest analogy is to motorcycle helmet laws in the United States. Although there is general agreement that motorcycle helmets reduce head and brain injury when a crash occurs, many motorcyclists dislike helmets. Risk compensation theory would propose that a motorcyclist who prefers not to wear a helmet might drive more recklessly if legislation requires helmet use. Motorcyclists may also be considered vulnerable road users, since motorcycle crashes usually result in serious injury to the motorcyclists themselves and not to cars and other motor vehicle passengers. In the United States nearly all 50 states passed laws requiring motorcycle helmets in the mid 1960's. In 1976 almost half of the states repealed their laws. This provided an opportunity for a natural experiment. Fewer motorcyclists wore helmets following the repeal of motorcycle helmet laws resulting in a 25% to 40% increase in motorcycle deaths (Evans 1991; GAO 1991; Fleming 1992; Kraus 1994). This effect rules out the possibility that wearing helmets leads to any large increase in risk taking (Evans 1994).

5. Answer: We disagree. We did not argue that cyclists are a unique exception or that risk compensation does not exist. We said "cyclists would have to increase their risk taking four-fold to overcome the protective effect of helmets. This seems unlikely." (See the review, discussion section, paragraph 5). We are not convinced that Hillman's general "rule" for risk compensation will stand up to rigorous even handed scientific scrutiny. We suggest risk compensation is an appropriate area for systematic reviews.

Risk compensation behaviour has been widely debated in the literature. Mayer Hillman provides some references in his comment #4. We recommend that interested readers consult a comprehensive discussion of the risk compensation debate presented by James Hedlund at the Fifth World Conference on Injury Prevention and Control (Hedlund 2000). An extensive systematic review of automobile safety interventions by a non-federal national Task Force on Community Preventive Services has been sponsored by the Centers for Disease Control since 1996. The Task Force looked at both the benefits and the risk for any given intervention. The Task Force (MMWR 2000) found that child safety seats, seatbelts and alcohol laws all contributed to a substantial reduction in motor vehicle injuries and deaths. The Task Force recommended a number of community-wide information and enforcement campaigns for these areas. Based on results of systematic reviews, the Task Force makes recommendations on population-based interventions to promote health and prevent disease, injury, disability and premature death, and to reduce environmental hazards (MMWR 2001). Mayer Hillman cited the work of John Adams as supporting the general case for risk compensation. John Adams has long opposed seatbelt legislation based on risk composition theory (Adams 1995, 1999). The Task Force recommendations differ from John Adams' view.

The Adams essay published on the Cato Institute website, discusses risk compensation and seat belt legislation. The essay explains the theory of risk management and uncertainty but it is not a critical systematic review. Information on the United State experience with seatbelt legislation is omitted from the discussion. The reason is provided in reference number 3, "calls by Cato staff to the National Highway Traffic Safety Administration to obtain research results about how many lives have been saved through seat belt use were unsuccessful." However, this information is available to the public from the National Technical Information Service, Springfield, Virginia. It is also indexed in the Transportation Research Information Service (TRIS) database. Authors of a systematic review would obtain and evaluate all available research before arriving at a conclusion.

Readers may like to read more about risk compensation. The issue in debated in the journal Injury Prevention, Issue 7, 2001.

**Contributors**

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Authors responding: Diane C. Thompson, Robert S. Thompson, Frederick P. Rivara

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**Helmets for preventing head and facial injuries**

**Summary**

Each comment has a number with a corresponding response from the authors in the reply section below.

1. The quantitative aspects of this review seem reasonable to me.

2. The analysis and discussion are so badly flawed as to make the main practical conclusion "Bicycle riders of all ages should be encouraged to wear helmets" entirely mistaken. In fact, it seems likely that encouraging helmet use would have serious adverse consequences on the public health, without making any significant difference to the dangers of riding.

3. There are conceptual confusions in the review-Risk compensation
Quoting from the review: "Some bicycling advocates have argued that helmeted cyclists will feel safe and, therefore, ride in a less cautious manner and be more subject to crashes (Hillman 1993). The converse argument has also been made that helmeted cyclists may ride more carefully and that these behaviours account for the reduction in head injury, not helmet use (Spaite 1991). We believe these arguments to be specious."

These arguments are not specious, nor are they the converse of each other. They refer, first, to the fundamental practical reason why helmets may not be effective in reducing head injury rates, and, second, to the main scientific reason why case-control studies are not a valid way to estimate the effect of helmet use on injuries.

Firstly, people who find themselves compulsorily protected from a customary hazard may indeed slacken their vigilance - this idea is known as "risk compensation" and is well-evidenced at least as far as motor vehicle accidents are concerned (Adams 1995). Secondly, the people who voluntarily choose to take "safety" precautions such as wearing a helmet are likely to be more cautious in many other aspects of their activities on the roads. This means that comparisons of voluntary helmet-wearers with non-wearers are likely to show a lesser rate of injury among wearers.

4. Confusion with outcome measures
From the review: "The fundamental issue is whether or not when bicycle riders crash and hit their heads they are benefited by wearing a helmet." That is one relevant issue, and the review does competently confirm that indeed, this probably is the case.

5. Confusion with outcome measures -Not all injuries are identical
From the review: "Cyclists would have to increase their risk taking four-fold to overcome the protective effect of helmets. This seems unlikely."

If head injuries were the only threat to cyclists, and if all head injuries were of similar severity, this would be correct. However, as Gilbert and McCarthy describe; "Almost all cyclists' deaths in London are due to collision with motor vehicles, especially heavy goods vehicles" (Gilbert 1994). Precise analysis is lacking, but one may reasonably doubt if any practical helmet would help most of those severely injured by a motor vehicle. Therefore, only small changes in risk-taking would be needed to overcome any slight protective effect that helmets might have in saving lives.

6. Cycling is healthy and the review fails even to mention that helmets discourage cycling
The main relevance of cycling to health is probably mediated through its beneficial effect on cardiovascular risk factors. The BMA's report Cycling: Towards Health and Safety used actuarial data to determine the life years lost by cyclists killed in road crashes, which were then compared with the life years gained by people engaging in exercise programmes such as cycling several times a week. (Hillman 1992.) This suggested that cyclists who cover at least 40 kilometres each week may halve their risk of heart disease when compared with those who do not cycle.

7. I can find no reference in the review to the serious adverse effect of helmet use on the use of cycling, but, for example, in Australian states which have enacted laws compelling cyclists to wear helmets, Robinson points out "The deterrent effect on cycling was substantial. "

8. Failure to search or understand the literature. The authors say "There are no objective data to support this risk homeostasis theory"

This is straightforwardly wrong. The idea of risk compensation is well-evidenced, at least in the case of motor vehicle accidents. (Adams 1995)

9. I am not aware of any good-quality studies which have aimed to study its relevance to bike helmets, but "it seems extraordinary that a change in behaviour after the reduction in perceived risk would be invalid only in this instance." (Hillman 1997)

10. Inadequate analysis of time-trend data

From the review: "Additional evidence of helmet effectiveness has been provided from time series studies in Australia, Europe and the US (Vulcan 1992, Carr 1995, Pitt 1994, Ekman 1997, Rivara 1998). These study results indicate that increased rates of helmet use resulting from multifaceted educational campaigns and/or legislation is linked to significant decreases in bicycle related head injuries." Actually, it is rather difficult to get the stated results from the figures quoted. For example, W Robert Pitt and colleagues' graph, referenced by the review, (Pitt 1994) suggests an increase of non-head injuries due to cycle helmets.

11. I suggest that human behaviour is too confusing and complex for valid analysis in the face of insufficient numbers, inadequate information, inconstant underlying trends, and a poor scientific approach to data that are selectively quoted and potentially biased from the point of collection. Much of the published work on cycle helmets displays all of these problems. It is unfortunate that the Cochrane review dismisses or ignores the main issues. It is still more unfortunate that the reputation of the Cochrane Collaboration is then used to promote a damaging misunderstanding in a widely-respected popular scientific journal (Mullins 2000). It is greatly to the credit of New Scientist that they nevertheless come to a sensible conclusion (anonymous editorial 2000).

The main question for the Cochrane Collaboration is the issue of including non-randomised comparisons. Few issues are so conceptually complex as road safety measures, and few are so beset by simplistic preconceptions. This may therefore be a particularly interesting matter for methodological debate.

**Reply**

The authors welcome the opportunity to respond to Dr Richard Keatinge's comments on our Cochrane review "Helmets for preventing head and facial injuries in bicyclists".

Some of his points have been discussed in Comments 1 and 2. Please read our replies to Bill Curnow and Dorothy Robinson for a discussion of epidemiological methods, particularly case control methods.

1. Answer: We agree.

2. Answer: We disagree. Dr Keatinge has already agreed the quantitative aspects of the review (the analysis) are reasonable. The results of five case control studies from three different countries have shown large protective effects of bicycle helmets. Wearing a helmet decreases the risk of head or brain injury among cyclists who fall or crash. Dr Keatinge disagrees with our overall conclusion that riders of all ages should be encouraged to wear helmets. He bases this on his opinion. We do not think there is valid scientific evidence to support the contention that encouraging helmet use has detrimental effects on public health.

3. Answer: We disagree. We stick by our prior statements. Furthermore, we think that the conceptual confusion is with Dr Keatinge, because he clearly did not understand that in our case control studies, we, in fact, controlled for crash severity by a number of measures such as involvement with motor vehicles, degree of damage to the bicycle, surface impact, etc. When this is done the focus is on comparing outcomes of cyclists with similar crash forces, which is the issue we addressed. The issue of risk compensation, while of interest to the scientific community, is irrelevant in this situation. It does not mean that risk compensation could not play a role in altering the risks of crashing in the first place. However, there is no evidence for this.

Contrary to Dr. Keatinge's opinion, case control studies which are well executed, can provide a solid basis for causal inference such as the protective effect of helmets on head injury. Please see our reply #2 to Bill Curnow.

Dr. Keatinge states that "risk compensation is well-evidenced at least as far as motor vehicle accidents are concerned "(Adams 1995). While this reference is widely quoted by the advocates of the risk compensation theory, there is ample evidence to the contrary. (NHTSA 1999, 1999a, MacKay 1945, MMWR 2001 in press). Whether wearing a helmet contributes to risk-taking behaviour can be illuminated by looking at evidence from seat belt legislation for motor vehicles, and motorcycle helmet legislation. The evidence from laws requiring seat belt use in cars indicates that any change in risk taking by drivers is small and there is more likely to be a reduction in injury risk if wearing seat belts is mandatory. (Evans 1991.) In the United States nearly all 50 states passed laws requiring motorcycle helmets in the mid 1960's. In 1976 almost half of the states repealed their laws. This provided an opportunity for a natural experiment. Fewer motorcyclists wore helmets following the repeal of motorcycle helmet laws resulting in a 25%to 40% increase in motorcycle deaths. (Evans 1991, GAO 1991, Fleming 1992, Kraus 1994). This effect rules out the possibility that wearing helmets leads to any large increase in risk taking. (Evans 1994).

As we pointed out in the discussion section (last paragraph) of our Cochrane Review, there are no objective data to support a risk compensation/homeostasis theory for bicycle helmet effectiveness. To quote from our review-"The fundamental issue is whether or not when bicycle riders crash and hit their heads they are benefited by wearing a helmet." Adjusting for crash severity enables us to address this question regardless of any increase or decrease in risk behaviour by the cyclists. Change in risk behaviour may contribute to the risk of crashing or falling. This is a different issue and has not been studied.

Risk compensation behaviour has been widely debated in the literature. We recommend that interested readers consult a comprehensive overview of the risk compensation debate presented by James Hedlund at the Fifth World Conference on Injury Prevention and Control (Hedlund 2000). See also author's reply to Dorothy Robinson's comments, (Comment 2, reply #8). An extensive systematic review of automobile safety interventions by a non-federal national Task Force on Community Preventive Services has been sponsored by the Centers for Disease Control since 1996. The Task Force found that child safety seats, seatbelts and alcohol laws all contributed to a substantial reduction in motor vehicle injuries and deaths. The Task Force recommended a number of community-wide information and enforcement campaigns for these areas. Based on results of systematic reviews, the Task Force makes recommendations on population-based interventions to promote health and prevent disease, injury, disability and premature death, and to reduce environmental hazards.

(MMWR 2001). These reviews took special care to examine both beneficial and adverse effects, such as would be produced through risk compensation. The Task Force conclusions contrast with views proposed by John Adams. (Adams, 1995, 1999)

Dr. Keatinge states that those who choose to wear helmets may be more cautious in other aspects of their behaviour. This means that they will have lesser injury rates than those who don't wear helmets. We disagree. When examining the issue of helmet effectiveness injury severity will depend on the crash forces and helmet use status. Helmeted cyclists have fewer or less severe head injuries than non-wearers due to the protection provided by helmets. As we pointed out above, when crash severity is taken into account, the issues raised about either increased risk taking or more cautious behaviour on the part of helmeted cyclists becomes a non-issue. We submit that any conceptual confusion on this issue is with Dr. Keatinge.

4. Answer: We agree.

5. Answer: We agree that not all injuries are identical. We disagree with his statement that helmets fail to protect cyclists from head injury in a motor vehicle crash. In our study in 1996, which had 3390 dead and injured cyclists identified from medical examiner records, emergency department and hospital records we had sufficient numbers to look at specific strata. One stratum was comprised of cyclists who were, in fact, in collisions involving motor vehicles. We found that the protective effect of helmets controlling for crash severity and other factors (age, gender, cycle speed, crash surface, motor vehicle involvement) was the same as individuals who crashed on their cycles, but did not impact motor vehicles. (Thompson 1996) The Gilbert and McCarthy studied included only cyclists who died in a motor vehicle/heavy goods "vehicles" collision. Their study is sound. Obviously motor vehicles are a hazard to cyclists. However many cyclists involved in a motor vehicle crash are not killed. In order to evaluate helmet effects, it is necessary to include cyclists treated in the emergency departments and hospitals as well as those who died. We think that while it is not unreasonable to suppose what Dr. Keatinge suggests, the scientific data indicate that he is wrong. There are numerous examples of cyclists hit by motor vehicles that had their helmets destroyed but were saved from head injuries. A recent example is Tour de France winner Lance Armstrong.

6. Answer. We agree that cycling is healthy, particularly if cyclists wear helmets to protect their brains in the event of a fall. There is no long-term evidence that helmets discourage cycling. This posited effect of helmets on decreasing cycling (Does helmet promotion or mandated use decrease cycling?) is an appropriate topic for research. This topic was not part of our review. The opinions expressed by Hillman in "Cycling and Health" do not scientifically prove discouraging cycling leads to increase rates of heart disease. Those who stop cycling could well take up other activities such as walking.

7. Answer We have replied to Dorothy Robinson's comments on this topic. Please see our replies (Comment 2, numbers 5, 6, and 7). We disagree with Dorothy Robinson's selective interpretation of the Australian data. In our review, we pointed out that the Australian and New Zealand experiences after passage of helmet legislation may have suggested some diminution in cycling initially. These reports were subsequently corrected for various factors, such as change in hospital admission policies (Australia) and a longer period of follow-up (New Zealand). The follow-up reports indicated no effects on actual cycling rates. This issue still remains an open question, but it is far from clear that helmet usage is associated with decreased cycling, given the presently available published data. In the meanwhile, we stick by our conclusion, which is that there are no published studies that can convincingly make the case that wearing bicycle helmets significantly decreases cycling behaviour.

8. Answer We disagree. Our literature search was extensive. The topic of our Cochrane Review was the effectiveness of bicycle helmets in preventing head and facial injury, not risk compensation. We feel that the proponents of risk compensation/homeostasis have shown that they select articles and anecdotal evidence that support their point of view . There are alternative explanations and selection biases that they do not mention. There are a number of studies in the traffic literature that point out problems or show data at odds with the RC/RH Theory. This is a varied literature and there hasn't been a systematic review. See our reply # 3 to Dr. Keatinge.

9. Answer. We agree that there are no quality studies supporting risk compensation behaviour among bicyclists. This is an appropriate area for a systematic review using pre-established criteria to judge the quality of the articles included in the review. Some well recognised groups using these methods are: The world-wide Cochrane Collaboration (hiru.mcmaster.ca/COCHRANE);Centre for Evidence-Based Medicine (CEBM) (http://www.cebm.jr2.ox.ac.uk; Agency for Health Research and Quality (AHRQ) Clinical Practice guidelines, http://www.text.nlm.nih.gov/fts/dbacess/ahcpr; the Canadian Preventive Services Task Force, US Community Preventive Services Task Force, and other groups

A well-conducted systematic review can take all the literature (peer reviewed, government reports and unpublished papers) and rate the study quality. Appropriately this gives more weight to better-designed and conducted studies. The evidence is then summarised across all the studies.

10. We disagree. Please see the discussion of time series studies in our reply to Dorothy Robinson, (Comment 2, replies #5 and #6). Note also that a new study from New Zealand reporting on the results of 3 years of helmet legislation found that "the helmet law has been an effective road safety intervention" (Scuffman 2000). Regarding the Pitt study, they found a reduction in head injuries following a sharp increase in helmet use. The authors concluded other bicycle injuries showed no change (Pitt 1994). Helmets offer protection to the head and face, but not to other portions of the body. An increase in non-head injuries could be interpreted to indicate more people were cycling.

11. Answer: We agree that human behaviour is complex. We disagree with Dr. Keatinge's criticism of our Cochrane Review. Well-conducted observational and non-experimental study designs can yield information of sufficient quality for action. Please see Causal Relations in

Medicine: A practical system for critical appraisal (Elwood 1988)(see also Comment 1, reply #2). He has offered no scientific evidence to support his opinion. Systematic reviews of the evidence for the effectiveness of a wide range of road safety measures would be an appropriate topic for several Cochrane Reviews. We invite him to undertake systematic review of a topic in this area.

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## WHAT'S NEW

| Date | Event | Description |
|---|---|---|
| 6 November 2008 | Amended | Typographical error corrected. |

## HISTORY

Protocol first published: Issue 4, 1999
Review first published: Issue 4, 1999

| Date | Event | Description |
|---|---|---|
| 31 July 2008 | Amended | Converted to new review format. |
| 17 January 2007 | New search has been performed | January 2007<br>An updated search for new studies was carried out in November 2006. One new study was found (Heng 2006) and is under review. The discussion section includes recent commentaries discussing this Cochrane review. |

## CONTRIBUTIONS OF AUTHORS

DCT wrote the protocol, performed searches, reviewed titles and abstracts, reviewed manuscripts of potential trials, extracted data, performed the analyses, and wrote drafts of the review.
FPR reviewed the protocol, reviewed titles and abstracts, reviewed manuscripts of potential trials, edited drafts of the review and provided statistical advice.
RST reviewed the protocol, reviewed manuscripts of potential trials, and edited drafts of the review.

## DECLARATIONS OF INTEREST

The authors are also authors of several of the papers included in the review. No other conflicts of interest are known.


## SOURCES OF SUPPORT

### Internal sources

- Harborview Injury Prevention & Research Center, University of Washington, USA.

### External sources

- Centers for Disease Control and Prevention, Atlanta Georgia, USA.


## INDEX TERMS

### Medical Subject Headings (MeSH)

*Head Protective Devices; Bicycling [*injuries]; Craniocerebral Trauma [*prevention & control]

### MeSH check words

Humans