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PostScript

RESEARCH LETTERS

Helmet laws and cycle use

Except for one study reporting decreased cycling by children aged 12–17 in Victoria, Australia, Macpherson *et al* stated: ''no other study about the relationship between legislation and exposure to cycling has been published''.[1] Macpherson's paper has already been cited several times as evidence that helmet laws do not discourage cycling, so it is important to examine the evidence.

In fact, several published studies of cycle use and helmet laws are cited and described in refereed journals. Some were attitude surveys. The equivalent of 64% of adult cyclists in Western Australia said they'd ride more except for the helmet law.[2 3] In New South Wales (NSW) 51% of schoolchildren owning bikes, who hadn't cycled in the past week, cited helmet restrictions, substantially more than other reasons, including safety (18%) and parents (20%).[4] Street surveys by cyclists' organisations in the Australian Capital Territory and Northern Territory found 28%–42% of cyclists would ride less/had ridden less because of helmet laws.[3]

Large scale roadside counts were also conducted. Pre-law surveys counted 6072 child cyclists in NSW,[3 5] 3121 cyclists (all ages) in Victoria;[3 6] and over 200 000 cyclist movements on two key routes in Western Australia.[3] Equivalent counts a year after enforced helmet laws showed declines of 36% (NSW), 36% (Victoria) and 20% (Western Australia).[3 5 6] Sunday recreational cycling in Western Australia (24 932 cyclists pre-law) dropped by 38%.[7] Increases in numbers wearing helmets, 1019 (NSW) and 297 (Victoria) were substantially less than declines in numbers counted (2215 and 1110).[3] These surveys were at the same time of year, in similar weather, and used the same sites and observation periods, so can be considered reliable indicators that enforced helmet laws discourage cycling. Reduced cycling activity is associated with increased injury rates per cyclist.[8] Australian data suggest injury rates per cyclist increased after helmet laws[3]; the consequences of reduced cycling because of enforced helmet laws should therefore be fully investigated.

Non-enforced laws may have a lot less impact. One state (Queensland), delayed enforcement for 18 months.[9] Helmet wearing increased initially, but 17 months after legislation, rates were little different from pre-law (primary schoolchildren 72%; secondary schoolchildren 21%, commuter cyclists 37%, recreational cyclists 22%, compared with 59%, 13%, 21%, and 22% pre-law).[9] Non-enforced laws can be widely flouted, conveying the undesirable message that road safety rules need not be taken seriously, perhaps encouraging dangerous riding and causing more injuries per cyclist than with no law. Enforcing laws unpopular with cyclists may require substantial effort. Queensland issued nearly 23 000 bicycle helmet offence notices annually, 6.7% of all traffic offence notices.[9] Per km, cyclists were three times more likely to receive a notice for not wearing a helmet than other road users for all other offences—speeding, drink-driving, failure to stop, give way, or obey other regulations. It is debatable whether this represents the best possible use of police road patrol time.

The Ontario law was not enforced[10] and the effect on helmet wearing rates was not reported.[1] The results should be interpreted with caution for three reasons. First, the study excluded 15–17 year olds, perhaps the most rebellious age group, despite Australian findings that teenagers were most affected by helmet laws (48% reduction for 12–17 year olds), then adults (29%) with the smallest effect on children under 12 (10%).[6] Indeed, in Ontario, only 16–17 year olds could be given direct penalties for non-wearing.[11]

Second, the annual sample size was much smaller than the Australian studies, only 1128 cyclists observed in 1999 (not 747 as reported,[1] for 112 hours of observation; A K Macpherson, personal communication).

Third, the Australian surveys reported weather conditions and used the same sites, time of year and observation periods, to ensure variation due to these factors was not confused with effects of the law. The Canadian study had 111 pre-selected sites, each recorded for one hour, but weather conditions were not reported[1] (though elsewhere 1999 was described as a particularly sunny summer; A K Macpherson, personal communication). Table 1 in the Macpherson *et al* paper shows that, in some years, some sites were recorded more than once.[1] Moreover, observations were not at the same time of day and day of the week each year (A K Macpherson, personal communication). Analysis of such data requires careful scrutiny of counts and helmet wearing rates to estimate and allow for differences in observation sites and times, as well as weather conditions, to avoid confusing them with year-to-year variation and the effects of the law. This does not appear to have been done.

Another Canadian survey found ''large variations in the number of cyclists per unit time, depending on the time of day, the day of the week, or the month''.[12] Perhaps all we should conclude is that the Ontario survey was relatively small, with substantial year-to-year variation, possibly related to year-to-year differences in sites, observations time or weather conditions, these differences swamping any effects of the non-enforced helmet law.

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Reply to Robinson

Our study suggested that the enactment of bicycle helmet legislation is not necessarily followed by a reduction in bicycling.[1] Robinson cites six observational studies from Australia published largely in reports that do not appear in the peer reviewed literature[2–7] contesting our conclusion. Establishing the association between helmet laws and cycling is important, not only in relation to ''the consequences of reduced cycling because of enforced helmet laws'', but also because of the possibly substantial effect of helmet laws (enforced and non-enforced) on helmet use rates and head injuries.

The evidence depicting an association between helmet laws and helmet use is strong. All 15 studies that examine this relationship report a positive association.[8–23] One study, conducted in Ontario, suggests that the legislative effect on helmet use was greatest among children living in low income areas.[8] Evidence related to the association between helmet laws and reductions in head injury rates is also consistent. All six studies that examine this relationship found a reduction in head injuries post-law.[11 16 19 21–24]

The results of our study on children's exposure to cycling demonstrated that helmet legislation is not necessarily followed by a reduction in bicycling. Robinson suggests that all one can conclude from our six years of observations is that the ''Ontario survey was relatively small, with substantial year-to-year variation, possibly related to year-to-year differences in sites, observation time or weather conditions, these differences swamping any effects of the non-enforced helmet law''. However, our observations were conducted at the same sites, at the same time of the year, and in similar weather conditions. Even if only data from the school observations are included (gathered at the same time of day and the same month each year), there was no reduction in the number of children bicycling to school post-legislation. Further, the helmet law was only "enforced" by the schools' insistence on children wearing helmets to comply with the law.

The population based impact of helmet laws remains in need of further study. Although evidence for the benefits of legislation is impressive, we agree that it is important to further assess the influence on bicycling. In particular, we believe that evidence is lacking in the following areas:

1. The effectiveness and effects of enforced *v* non-enforced laws.
2. The effectiveness of legislation related to children only *v* all ages.
3. The relationship between helmet laws and bicycling among children who have grown up with helmet laws.
4. Social and cultural differences in the reaction to helmet laws between communities and between countries.
5. The effect of other trends (for example, the popularity of in-line skating, skateboarding, and scooters) on the use of bicycles.
6. Characteristics (including bicycling frequency) of cyclists who may be deterred from riding by helmet laws.
7. The effectiveness of other countermeasures (for example, bicycle friendly environments) to increase bicycling.

Given the benefits of bicycling and the importance of head injuries as a public health problem, it is essential that public policy and legislation is guided by the best available evidence. We need to understand whether, as suggested in our study, bicycling increases after a law because of the positive publicity related to bicycling. If bicyclists in Australia or elsewhere are deterred from bicycling for substantial periods, we need to explore other measures to encourage them to continue. It would help to know which cyclists change their behaviour after the enactment of a helmet law, and if they reduce their bicycling, whether they adopt other forms of activity in place. Finally, the most effective way to enforce helmet laws has yet to be determined.

Given the evidence for the relationship between helmet laws and the reduction in head injuries, and the paucity of well designed studies, perhaps all we can conclude from the studies published to date is that more evidence is needed to resolve the debate.

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Bias when using dead controls to study handgun purchase as a risk factor for violent death

In a recent, excellent study that found handgun purchase to be a risk factor for violent death, Grassel and colleagues gave explanations for why their findings may have inaccurately characterized the impact of handgun purchase on violent death, leading to results that if anything underestimate the magnitude of the danger associated with buying a handgun.[1] "The healthy handgun purchaser effect", which we suggest is akin to the healthy worker effect, may be a source of bias as well. Bias from this source could produce results that either underestimate or overestimate the impact of a handgun purchase on violent death.When dead controls are used in a case-control study, the death rate due to the comparison cause(s) should be equal in the exposed and unexposed populations.[2–6] If this assumption is met, the odds ratio (OR) can be used as an estimate of the mortality density (or rate) ratio:

$$\mathrm{OR} \cong \frac{\mathrm{MDR}}{\mathrm{MDR}'} = \frac{\dfrac{a}{T_E} \Big/ \dfrac{c}{T_{\bar{E}}}}{\dfrac{b}{T_E} \Big/ \dfrac{d}{T_{\bar{E}}}}$$

where a and c are exposed and unexposed cases and b and d are exposed and unexposed controls, respectively, and T_E and $T_{\bar{E}}$ are the person-time contributed by exposed and unexposed subjects, respectively. We follow Morgenstern and use his notation,[6] but notation used by others is similar.[2 4 5] In the present context, the OR represents the rate of violent death in handgun purchasers versus non-purchasers (mortality density ratio, MDR) relative to the rate of non-violent death in handgun purchasers versus non-purchasers (MDR′).If MDR′ equals 1, which occurs if the exposed and unexposed populations do have equal rates of death from the comparison (non-violent) cause(s), the person-time denominators cancel out, the formula collapses to the familiar *ad/bc* (that is, the formula to calculate an OR from a 2 × 2 table), and the OR provides an unbiased estimate of MDR. However, if the exposed and unexposed populations do not have equal rates of death from the comparison (non-violent) cause(s), MDR′ may not equal 1. In this instance, the OR will provide a biased measure of the parameter being estimated (that is, MDR).Even though the authors excluded from the comparison group causes of death that had clear associations with the purchase of a handgun, bias could still exist if handgun purchasers were "healthier" or less healthy than non-purchasers. For instance, consider that heart disease was the most common cause of death in California in 1998, accounting for 31% of all deaths.[7] Therefore, a proportion of subjects who comprised the comparison group in this study could reasonably have been expected to die from heart disease. In addition, the rate of heart disease among Californian adults was 1.4 times higher for men than for women in 1998.[7 8] Consider this alongside the fact that males accounted for 91% of the adults who purchased handguns in California in 1998[9] and that fewer than 1% of adult Californians purchased a handgun in 1998.[8 9] Therefore, the gender distribution of adults in California who did not purchase a handgun, and who represent approximately 99% of the adult population in California, was approximately equal to the gender distribution in the state; that is, about 50% male and 50% female.[8] This information provides reasonable evidence to expect that the death rate in the comparison subjects (that is, those who died by non-violent causes) was higher in handgun purchasers than in non-handgun purchasers. That is, $b/T_E > d/T_{\bar{E}}$ and therefore MDR′ >1. If MDR′ was actually >1 in the study by Grassel and colleagues, the OR would provide an underestimate of the true impact of handgun purchase on violent death.

However, it is especially difficult to assess the direction and magnitude of this source of bias in the study by Grassel and colleagues because many causes of death were included in the comparison group, each of which may have occurred at different, and potentially offsetting, rates among handgun purchasers and non-purchasers. Moreover, even if the comparison group had been comprised solely of heart disease decedents, the result of our short example above does not mean that this source of bias would necessarily serve to underestimate the impact of handgun purchase on the risk of violent death. Numerous factors could lead to variation in the direction and magnitude of bias stemming from an $MDR' \neq 1$. For instance, if we consider victim age, the relative rate of heart disease mortality among young (age 20–24 years) Californians in 1998 was actually lower in males than in females (relative rate = 0.8).[7 8] If the true value of MDR′ was <1 in the study by Grassel and colleagues, the resulting OR would be an overestimate of the true impact of handgun purchase on violent death among this subgroup of young Californians. The magnitude of the bias would be equal to the reciprocal of MDR′.[5 6] For example, if MDR′ was found to be 0.8 and a logistic regression model including only the subset of 20–24 year old subjects yielded an OR of 3.0, the effect estimate that is adjusted for the bias we are concerned with is actually $MDR = 3.0 \times 0.8 = 2.4$. That is to say, the initial OR of 3.0 was an overestimate, being 1.25 times ($1/0.8 = 1.25$) larger than expected. Including age as a covariate would not specifically control for this source of bias, nor would it obviate the need to test effect modification by age.

The major challenge in all case-control studies, including those in which injury cases are the center piece, is to identify control subjects that will yield unbiased risk factor estimates.[4 5] This note illustrates one mechanism of bias that injury epidemiologists must be wary of when designing and interpreting case-control studies that incorporate dead control subjects.

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LETTER

The new traffic law and reduction of alcohol related fatal crashes in Japan

The National Police Agency reported in June 2003 that the number of fatal crashes caused by drunken drivers had decreased by 30% in the 12 month period after the change of the traffic law.[1] The number of alcohol related fatal crashes in the period from June 2001 to May 2002 and that in the same period of 2002–2003 were 1187 and 830, respectively. In addition, the number of drivers found guilty of driving under the influence of alcohol was reduced by 7% (from 218 377 to 202 985) during the same period.

In Japan, the Traffic Act was changed and the new law took effect in June 2002. The legal limit for alcohol concentration while driving was lowered and penalties became tougher under the new law. Moreover, it became much harsher on drivers who committed the most serious offenses.

Drunken drivers have been defined in Japan by the level of alcohol measured by breath test. The new act lowered the breath alcohol concentration at which it is illegal to drive a motor vehicle from 0.25 mg/l breath to 0.15 mg/l breath. Given the fact that in the United Kingdom the legal limit for drink-driving is 0.35 mg/l breath, which is equivalent of the legal limit of blood alcohol concentration (BAC) at 0.08%,[2] this limit of 0.15 mg/l breath seems stricter than other industrialized countries and actually requires ''zero tolerance''.

Motorists convicted of drinking and driving can be sentenced to up to three years in prison and fined up to Yen 500 000 (US$4250). They can have administrative penalties imposed, such as license suspension or revocation, and penalty points according to the range of alcohol concentration.

Lowering the legal limit is a proven effective countermeasure that will reduce alcohol related traffic fatalities, especially combined with more severe penalties and enhanced enforcement.[3] However, the extent to which these measures can reduce injuries is not known. It may vary between nations, since drivers' attitudes are influenced by many factors. Ten years ago, there was an Australian study that showed a remarkable effect—the proportion of drunk-drivers involved in accidents fell by one third in the year when the 0.08% BAC limit went into effect.[4]

To implement such a strong measure, public support is essential. Movements against drunk-driving have been rapidly developing in Japan since 1992, when two children were killed by a drunken driver on the Tohmei Super Express Way and the victims' parents started a petition. Thereafter, public awareness has been raised and most people support ''zero tolerance'' to drunk-driving.

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BOOK REVIEWS

Guide to Evaluating the Effectiveness of Strategies for Preventing Work Injuries: How to show whether an intervention really works.

Lynda S Robson, Harry S Shannon, Linda M Goldenhar, Andrew R Hale. United States Department of Health and Human Services, National Institute for Occupational Health and Safety, Centres for Disease Control. Cincinnati, Ohio, April 2001 (free at: www.cdc.gov/niosh).

The stated aim of the publication is to ''provide students, researchers and practitioners with the tools and concepts required to conduct systematic evaluations of injury prevention initiatives and safety programs''. This review contends that the authors have fulfilled their aim and commends the publication as an excellent, easily followed introduction to evaluation in the area of injury prevention.

Chapter 1 introduces effectiveness evaluation of safety interventions. Chapter 2 argues for planning right from the start, and covers models of evaluation, including qualitative and quantitative methods, choosing evaluation design, and practical tips. Chapter 3 deals with before and after design, including some of the threats to validity. Chapter 4 covers quasiexperimental and experimental design. Chapter 5 deals with study samples and who should be included in the intervention and evaluation process; chapter 6 with measuring outcomes; chapter 7 with qualitative methods; and chapter 8 with assessing whether the results are significant. Chapter 9 is a summary of recommended practices. There are three sets of appendices on models to assist in planning; examples of statistical analysis; and examples of reporting results.

There is a glossary and a bibliography. At the end of the document there is an evaluation form provided as a mechanism for getting feedback and improving the document.

In thinking critically about the publication, there are some areas where it could be clearer about defining relevant research and evaluation questions and making decisions from them about the mix of methods, but this is more of a quibble on an issue of concern to the reviewers, than a major problem.

The range and scope of the literature canvassed is good. While there could perhaps have been a wider discussion of qualitative methods, this would have made the book longer, to its detriment.

The use of Patton as the base for qualitative research is a good choice because he does not get caught up in the sniping so often seen when qualitative and quantitative meet. Patton has an excellent description of the role of sampling in qualitative research.

Another small area of weakness is the lack of a discussion of the difference between statistical significance and practical significance. If the numbers are large enough (that is, if the power is high enough) even very small changes will reach the threshold of significance. Where mass data are being used this means that changes that seem to be small and meaningless in terms of output efficiency will be statistically significant and the findings publishable. On the other hand when dealing with small or minority groups even quite large differences will be seen as not reaching the threshold of statistical significance. The changes, however, may be of great practical significance even though they can't be published. Some discussion of the level at which the threshold of significance should be set for different types of decisions would have been of value. This has been extensively canvassed in the journal *Evaluation* over the years.

That said, we return to the starting point of the review, that the guide is an excellent tool to improve evidenced based decision making in injury prevention.

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A Schema for Evaluating Evidence on Public Health Interventions. Version 4.

Lucie Rychetnik, Michael Frommer. National Public Health Partnership*, Melbourne, June 2002 (free as pdf file from www.nphp.gov.au).

The work leading to this publication arose out of discussion in the leading Australian committee for allocating health related research funds†. The committee considered the difficulties that can arise when established methods for evaluating evidence based medicine are used to evaluate research on public health interventions. When workshops of experts considered these issues they concluded that established methods of evidence appraisal provide a useful starting point for evaluating evidence of all types of health interventions but recommended that the methods should be expanded or adapted to take account of the specific issues in public health.

From this came the development of a draft schema (stage one), resulting in a discussion document in May 2000, based on literature reviews and consultation with senior public health researchers and practitioners. Then came a series of trials (stage two), resulting in the development of the document under review.

The schema covers two stages of appraisal—firstly the appraisal of individual papers or reports to determine whether they provide credible and useful information about an intervention(s) and, secondly, the formulation of conclusions about the value of the available evidence. The process of reviewing published and other literature on public health interventions and of using these findings is seen to involve at least six steps. These are: identifying the purpose of the literature review and formulating the review question(s); finding and collating the studies to be reviewed; appraisal of each article or report; formulation of a statement on the body of evidence; publication of the review findings; and, application of the review findings to policy and practice.

Section 1 of the document deals with setting the scope of any review; section 2 considers the papers in any review; section 3 with describing the results from the papers; section 4 with interpretation of each article; section 5 with summarising the body of evidence. Appendix 1 discusses the hierarchy of study design and the levels of evidence. Appendix 2 has a series of supplementary guides on reviews, random control trials, observation studies, economic evaluation, and qualitative studies. Appendix 3 has a sample table for summarising all the papers reviewed. There is a short list of references, primarily of Australian work.

The critical issue in public health and in injury prevention is that Cochrane style methods of assessing evidence do not work well for population based interventions or in dealing with evidence developed outside the framework of the medical model‡. This leads to certain classes of literature and methods being excluded from the development of an overview of the evidence. This in turn leads to limitations on the interventions that are funded and evaluated, further diminishing the evidence base for the future. The document is seen as a "work in progress" intended to facilitate critical appraisal of evidence and the role of evidence in public health policy and practice. It will be interesting to see the degree to which this process addresses these problems.

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*The NPHP is a formal Australian structure for officers of the Commonwealth, States, and Territory governments to come together to develop a joint Australian intergovernmental agenda for public health.

The National Public Health Partnership Group (NPHPG) is a subcommittee of the Australian Health Ministers' Advisory Council (AHMAC). The council's role is to support the Australian Health Ministers' Conference (AHMC), by providing strategic advice on health issues and by acting as a forum for planning, information sharing, and innovation.

†National Health and Medical Research Council (NHMRC).

‡This formulation of the issue is from Jerry Moller.

CALENDAR

Lifesavers Conference: National Conference on Highway Safety Priorities

28–30 March 2004, San Diego, California. Details: www.lifesaversconference.org.

7th World Conference on Injury Prevention and Safety Promotion

6–9 June 2004, Vienna. The major objectives of the conference are strengthening violence and injury prevention as an aspect of national public health policy and programs; producing synergy of the combined efforts of various violence and injury prevention disciplines; exchanging the most recent experiences in research and practice; and facilitating participation of experts from low income countries. Further information from www.safety2004.info. Details of the nine associated meetings can be found at www.safety2004.info/associated_meetings.php.