Author's response to reviews

Title: Personal and trip characteristics associated with safety equipment use by injured adult bicyclists: A cross-sectional study

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Author's response to reviews: see over
**Reviewer's report**  **Title:** Personal and trip characteristics associated with safety equipment use by injured adult bicyclists: A cross-sectional study

**Version:** 1

**Date:** 10 July 2012

**Reviewer:** Brent Hagel

1. Page 4: Methods: Though the authors indicate that the "Methods of study conduct and reliability testing have been described...elsewhere." It would be useful to provide some indication of the reliability of these data in the present manuscript in order to assess the potential for misclassification bias in the effect estimates presented.

   *This is an error of copying from another manuscript. We did not do reliability testing of the variables in this aspect of the study (we did it for the route type classifications used in the main study analyses). We have removed the reference to reliability testing in the Methods.*

   Our method of considering the reliability of the variables (safety equipment and alcohol use) for this analysis was to compare our results to those of others (in the Discussion). The prevalences we found compared favorably to other more objective measures of safety equipment use.

2. Page 5: Methods: “Don’t know’ or ‘refused’ responses for all questions were grouped with the ‘no’ category.” I think the investigators need to be careful in assuming that all of these ambiguous responses represent absence of the characteristic. Did the authors examine the characteristics of the individuals with missing information to be sure that the covariate patterns were similar to the “no” category? Have the authors attempted any imputation approaches on these data? In any case, it would be useful to show in the tables the percentage of missing data for each predictor variable.

   The numbers with don’t know or refused responses were reported in full in the last paragraph on page 6. This must not have been easily noted, so the following has now also been added to the footnote of Table 2:

   - for lighting, 7 participants (1.01%) indicated they didn’t know,
   - for visible clothing, 56 (8.1%) indicated they didn’t know, and
   - for helmets, 2 indicated they didn’t know and 1 refused (0.44%).

   The approach we chose had two rationales:

   - To provide a conservative estimate of the prevalence of use. *(This rationale is now included in the text in the methods.)*
   - To group the unknowns with the category with the largest number of observations. This method of categorizing missing categorical data has been shown to provide the least attenuated (biased to the null) estimates of association. *(Dosemeci M, Stewart P.A. Recommendations for reducing the effects of exposure misclassification on relative risk estimates. Occup Hyg 1996;3:169-176)*
   - The exception to the latter rationale in our analyses was helmet use – where the two rationales conflicted in suggested classification. We chose to follow the first rationale. Since the unknown
numbers of helmet users was so small, no other analysis was likely to create a different result.

- The only safety equipment type with an important number of “don’t know” responses was visible clothing. We have now redone the analysis excluding these responses, an approach to missing data whose disadvantage is not bias, but power. The variables that were associated with visible clothing in this reanalysis were identical to those in the original analysis that included the “don’t know” responses with the “no” responses. The two analyses are shown below. We have not included the full results of the reanalysis in the paper, but have indicated that it was done and that there were no material differences in the results.

- Other than the missing data described above for the three safety equipment variables that were used as an outcome variable in one analysis each and as predictor variables in the other two analyses, the only predictor variable with missing values was income. The number reporting income is indicated in Table 1. In all analyses, income included a “don’t know or refused” category (see Table 5).

<table>
<thead>
<tr>
<th></th>
<th>Adjusted (&quot;Don’t know&quot; responses excluded)</th>
<th>Adjusted (&quot;Don’t know&quot; responses grouped with “no” responses)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Odds Ratio (95% Confidence Interval)</td>
<td>Odds Ratio (95% Confidence Interval)</td>
</tr>
<tr>
<td><strong>Trip weather type</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clear sky</td>
<td>1 (reference)</td>
<td>1 (reference)</td>
</tr>
<tr>
<td>Cloud cover</td>
<td>0.85 (0.55 – 1.30)</td>
<td>0.85 (0.56 – 1.29)</td>
</tr>
<tr>
<td>Fog, mist, rain or snow</td>
<td>0.31 (0.15 – 0.63)</td>
<td>0.33 (0.16 – 0.68)</td>
</tr>
<tr>
<td>Wind</td>
<td>0.75 (0.22 – 2.50)</td>
<td>0.85 (0.26 – 2.86)</td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>19 - 29</td>
<td>1 (reference)</td>
<td>1 (reference)</td>
</tr>
<tr>
<td>30 - 39</td>
<td>1.15 (0.75 – 1.79)</td>
<td>1.19 (0.78 – 1.83)</td>
</tr>
<tr>
<td>40 - 49</td>
<td>1.37 (0.84 – 2.22)</td>
<td>1.35 (0.84 – 2.16)</td>
</tr>
<tr>
<td>50 - 59</td>
<td><strong>1.86 (1.09 – 3.17)</strong></td>
<td><strong>1.85 (1.10 – 3.10)</strong></td>
</tr>
<tr>
<td>≥ 60</td>
<td>1.47 (0.76 – 2.85)</td>
<td>1.27 (0.68 – 2.38)</td>
</tr>
<tr>
<td><strong>Cycling frequency</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(trips per year)†</td>
<td><strong>1.17 (1.05 - 1.36)</strong></td>
<td><strong>1.17 (1.05 - 1.30)</strong></td>
</tr>
</tbody>
</table>

3. Page 5: Methods: The authors indicate that they used “backwards selection to construct multiple logistic regression models, starting by offering all variables of interest. Based on the Wald test for each variable, the variable with the highest p-value was removed and the model refit...until all variables in the model were statistically significant...” I have some comments related to this analytic approach:

a) My first comment relates to the number of variables entered into the different
regression models. A rule of thumb would be no more variables than the minimum of 10% of the least frequent outcome category (Harrell Jr. FE, Lee KL, Mark DB. Tutorial in biostatistics. Multivariable prognostic models: issues in developing models, evaluating assumptions and adequacy, and measuring and reducing errors. Statistics in Medicine. 1996;15:361-87). Based on the variables listed in tables 3-5, there were at least 37 indicator variables included in the full model for each outcome. However, there were only 135 individuals with at least one bike light turned on and so based on the rule, a maximum of 13 variables could be included in the full model. Can the authors address this issue?

Thank you for alerting us to an interesting paper. None of us, including the study statistician, Dr. Hui Shen, were aware of it. The Harrell paper addresses predictive modeling, and the specific section prescribing the variable limitation described above was related to training and test samples.

The purpose of our analysis was not quantitative estimation, but simply to examine associations and their broad directions. A classic regression text (Kleinbaum DG, Kupper LL, Nizam A, Muller KE. Regression Analysis and Multivariable Methods, 4th Edition, Duxbury Press. 2007) suggests at least 10 observations per variable, a test our analyses easily met.

b) Backward selection based on p-values likely results in overly narrow confidence limits and potentially biased estimates for the effects of interest. Can the authors present the unadjusted estimates, the fully adjusted estimates, and then the estimates based on the backward selection process? This would be helpful to the reader in determining how robust the associations are to the modeling strategy; though, I would argue the fully adjusted estimates would represent the gold standard as they are the least confounded (but again, the authors need to consider my comment on the frequency of the least frequent outcome category in determining the number of predictor variables considered).

We have added the results of the unadjusted analyses for the variables that were included in the final model in each of Tables 3 to 5. We did not report the full adjusted models with all variables regardless of associations or significance, for reasons similar to those described above – the potential to over-specify the model. The full models may be of interest to some readers. We have not included them in the tables, because it would make them cumbersome and much less readable, but we have offered to provide the full models to anyone who is interested.

We have listed in the methods section all variables that were offered, so that readers know which variables were not significantly associated with each of the safety equipment types. No variables were significant in the full model that were not significant in the final model and the directions and sizes of effect were the same for all variables that were in the final and full models, so there was no evidence of bias by excluding the non-significant variables.

4. Page 6: Results: The authors state that “Participants represented 93.1% of those confirmed to be eligible and 66.5% of those estimated to be eligible.” I am confused as to where the 66.5% figure is derived from? Can the authors comment on this and provide any information on the characteristics of those who were excluded either in the results section or speculate on their characteristics and how excluding them may have affected the results in the limitations section?

We agree that this must have been difficult to understand as it was. We have added wording in that section to try to clarify, including the following “There were 667 with unknown eligibility (543 not
contacted, 124 refusals).” We hope that this improves understanding without requiring the large figure we included in the main publication for this study.

We have outlined the main reasons for ineligibility. One group was not relevant because their injury event took place outside of the geographic area of the study. The other main ineligible group were tourists and others who lived outside the study cities and were excluded because they were less able to accurately describe their route (an important component of the main study). We do not have demographic information on these individuals or on those who were never contacted. We have discussed the demographics of the sample in the section on study limitations. It is very similar to the demographics of North American cyclists described elsewhere, with the exception of cycling frequency.

MINOR ESSENTIAL REVISIONS:

5. Page 7: Results: In referring to highly visible clothing, the authors state that “Older adults (#50 years of age) and those who were more frequent cyclists were more likely to wear such clothing.” However, in table 5, the 95% confidence interval for the 60+ age group includes the null value of 1.0 (95% CI: 0.68-2.38). Can the authors clarify?

We have changed the wording to highlight only the category that was statistically significant.

6. Page 8: Discussion: There is a grammar problem with the sentence beginning “A new development in this area is bike share systems...”.

We have changed the wording and hope it is now clearer.

DISCRETIONARY REVISIONS:

7. Page 11: Discussion: The authors could include references for the sentence “Our results compared favourably to studies using observations of cyclists in the field.”, unless they are only referring to the alcohol results presented later in the paragraph.

Good idea – done.

Level of interest: An article of importance in its field Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I was asked to be a collaborator on a Canadian Institutes of Health Research Strategic Teams in Applied Injury Research grant that Dr. Cusimano successfully obtained in 2009 to look at the issue of traumatic brain injury. However, we have not, as yet, had the opportunity to work together on any related research projects and I have not published with Dr. Cusimano.