WABA
WASHINGTON AREA BICYCLIST ASSOCIATION

James G Titus
Board of Directors
6718 Glenn Dale Rd.
Glenn Dale, MD 20769
jtitus@risingsea.net

February 28. 2013

On behalf of the Washington Area Bicyclists Association and as an individual, I respectfully submit this request for correction of statements by the Centers for Disease Control (CDC) concerning the effectiveness of bicycle helmets. CDC exaggerates the effectiveness of bicycle helmets by stating that helmets reduce brain injuries by 88 percent (on the website) or 80 percent (as quoted by the *Washington Post*) without mentioning material caveats. CDC's statements about helmet effectiveness are misleading, by implying that effectiveness has been accurately estimated, when in fact it is very uncertain. Helmets can increase the risk of neck injuries, and no one has established that this side effect is less significant than the protective effect in circumstances when either the cyclist is traveling at a high rate of speed or the helmet is mounted improperly.

1 THE SPECIFIC RECOMMENDATIONS FOR CORRECTING THE INFORMATION

We seek correction of all statements on the CDC web site asserting that bicycle helmets reduce head injuries by 80% (or more), and any other statements that overstate the effectiveness of helmets as estimated by the combined weight of all published studies. Specifically, we seek

- Correction of the statement that "Wearing a bike helmet reduces the risk of brain injury by 88% and reduces the risk of injury to the face by 65%," which appears at http://www.cdc.gov/healthcommunication/toolstemplates/entertainmented/tips/headinjuries.html
- Clarification of the caveat on the FY2000 performance plan[1] to specifically state that the estimated helmet effectiveness of 80% no longer represents CDC's official estimate, and other clarifications needed to make it less likely that reporters will misinterpret out-of-date information offered for archival purposes, as what CDC says today. (See Ashley Halsey, *Washington Post*, February 7, 2013 ("The Centers for Disease Control and Prevention says helmet use reduces head injuries by 80 percent.")

2 THE SPECIFIC REASONS FOR BELIEVING THE INFORMATION DOES NOT COMPLY WITH OMB, HHS OR CDC GUIDELINES AND IS IN ERROR AND SUPPORTING DOCUMENTATION

The OMB, HHS, and CDC guidelines for information quality clearly require that information disseminated be objective, accurate, and unbiased.[2] "Objectivity is achieved by using reliable data sources and sound analytical techniques, and carefully reviewing information products prepared by qualified people using proven methods."[3] The estimate that helmets are 80% (or 88%) effective does not meet that requirement.

Several emails[4] to CDC seeking to learn the basis for the estimates have gone unanswered, so it is impossible for us to know whether CDC disseminates the inaccurate estimates because CDC has not been "using reliable data sources and sound analytical techniques"; it has not been "carefully reviewing information products"; the products were not "prepared by qualified people using proven methods"; or CDC simply continued to repeat the results of a single study conducted in 1989 even while more recent studies revealed the original study to be an outlier. But we can show that CDC misstates what is known about helmet effectiveness in four ways:

- The estimate of 88 percent is not even within the uncertainty range of the three meta-analyses of published case-control studies of helmet effectiveness.
- By stating that helmets reduce the risk by 88 percent, CDC implies that helmet effectiveness can be estimated to two significant digits, when in fact, it cannot be estimated to within one significant digit.
- Most case-control studies simply assert that the relative risk between wearing and not wearing a helmet, is equal to the odds ratio that the studies calculate; but assuming that the odds ratio equals relative risk always overstates the effect of safety equipment—sometimes significantly so.
- While less extensive than for head injuries, the available research suggests that increased neck injuries offset about half the reduction in head injuries from helmets.

2.1 The estimate of 88 percent is not even within the uncertainty range of the three meta-analyses of published case-control studies of helmet effectiveness.

Because CDC has not told us the basis for the estimates, we must assume that the estimates for head and brain injuries[5] came from a case-control study of injured cyclists in Seattle by Thompson et al. (1989)[6] [hereinafter "Thompson"]. That study includes the statement "we conclude that safety helmets reduce the risk of head injury by 85 percent and of brain injury by 88 percent."[7]

The Thompson study did not actually estimate 85 or 88 percent reductions in injuries. Rather they estimated the odds ratios to be 0.15 and 0.12 for head and brain injuries respectively, and mistakenly equated odds ratio with relative risk, in what turned out to be the most widely cited sentence of the study. The convention for case-control helmet studies is to estimate the odds ratio, which is defined as

$$\text{Odds} = \frac{H_{case}/E_{case}}{H_{control}/E_{control}}$$

where H signifies the number of people wearing helmets and E represents the number of people with exposed heads, for the case and control populations. The odds ratio is generally less than relative risk, but this distinction is often ignored; so many studies understate relative risk and overstate helmet effectiveness. See Section 2.3.

Table 1 shows the reported odds ratios (95% range) from published case-control studies during the last quarter century.[33] What stands out is that none of the ten studies conducted after 1991 found an odds ratio of head injuries as low as the Thompson (1989) study. Even the more in-depth study of Seattle by that same team in 1996 found the entire confidence range for the odds ratio of head injuries to be greater than the estimates from their 1989 study, on which the CDC website evidently relies.[34] And most studies by other authors in different cities have found helmets to be substantially less effective than the Thompson team found for Seattle.

Three meta-analyses have developed summary estimates by combining the results from all the published studies meeting specified criteria. The right three columns of Table 1 show which studies were included in each. The most thorough assessment by Attewell et al.[35] found the odds ratios for head, brain, and face injuries to be 0.4, 0.42, and 0.53, respectively. Ten years later, Elvik[36] updated the Attewell analysis by adding the results of newer study and employing newer techniques for meta-analysis. The newer studies alone brought the odds ratio up to 0.5 and 0.74 for head and face injuries, respectively. With the newer analytical techniques as well, the odds ratios are 0.58, 0.47, and 0.83 for head, brain, and face injuries, respectively.

A smaller meta-analysis was conducted by Thomas et al (2009).[37] Their summary estimate of helmet effectiveness worldwide was the same as their 1996 estimates for Seattle, partly because they only included results from two studies outside of Seattle.[38]

Table 1: Odds Ratio[8] of Injury With Helmets

Head Injuries (95% range)				Study included in meta-analysis?		
Case Control Studies				Atte-well	Thomp-son	Elvik
Lead Author	Year	Low	High			
Dorsch[9]	1987	0.12	0.47		✓	✓
Thompson[10]	1989	0.07	0.29	✓	✓	✓
Spaite[11]	1991	0	0.23		✓	✓
McDermott[12]	1993	0.47	0.79	[13]	✓	✓
Maimaris[14]	1994	0.11	0.83	✓	✓	✓
Thomas[15]	1994	0.32	0.84	✓	✓	✓
Finvers[16]	1996	0.11	0.90		✓	✓
Thompson[17]	1996	0.26	0.38	✓	✓	✓
Jacobson[18]	1998	0.20	0.70		✓	✓
Linn[19]	1998	0.49	0.83		✓	✓
Shafi[20]	1998	0.61	3.1[a]		✓	✓
Hansen (hard)[21]	2003	0.21	0.6			✓
Hansen (soft)[22]	2003	0.41	1.7[a]			✓
Heng[23]	2006	[24]				✓
Amoros[25]	2009	0.44	0.88			✓
Meta-Analyses of all Qualifying Studies						
Attewell[26]	2001	0.29	0.55			
Thompson[27]	2009	0.26	0.37			
Elvik[28]	2011	0.45	0.75			
Neck Injuries (meta-analyses only)						
Attewell[29]	2001	1.0	1.86			
Elvik[30]	2011	1	72			
Head & Neck Injuries (meta-analyses only)						
Attewell[31]	2001	0.50	0.59			
Elvik[32]	2011	0.74	0.98			

a. Greater than 1.0 signifies that people wearing helmets had higher rate of injuries.

2.2 By stating that helmets reduce the risk by 88 percent, CDC implies that helmet effectiveness can be estimated to two significant digits when in fact, it cannot be estimated to within one significant digit.

A quick glance at Table 1 shows that the odds ratio (and thus the estimated effectiveness) of bicycle helmets has an uncertainty on the order of tens of percent. And the studies summarized in that table rely on the convenient assumption that the various case-control studies are independent and unbiased so that uncertainty eventually declines with the square root of the number of studies undertaken. If the case-control studies have inherent (but unknown) bias or measurement error[39], or the goal is to inform people what the effectiveness is likely to be for them (rather than for the entire population[40]), then a better estimate of our uncertainty would be the range of results, without discounting the variance by the number of studies.

Those in the public health community have traditionally assumed that most people making decisions need a single number, and that conveying the range of uncertainty will leave too many people with the impression that scientists don't know enough to justify action. But that view is changing, and the trend is increasingly toward a transparent communication of what is and what is not known—and a confidence range.

Regardless of whether the Thompson studies provided the best estimate of the nationwide effectiveness of bicycle helmets, it was always clear that there is a very wide confidence range. Failing to communicate that uncertainty is a form of bias, in which the public is asked to have more faith in a given estimate than even the original researchers have about their own results.

2.3 Most case-control studies simply assert that the relative risk between wearing and wearing a helmet, is equal to the odds ratio that the studies calculate; but relative risk is always greater than the odds ratio—sometimes significantly so.

The CDC website provides an estimate of the potential for helmets to reduce the risk of a head injury. Helmet effectiveness is simply one minus the relative risk. Defining **P**(case) as the probability of a head injury, and **P**(control) has the probability of not sustaining a head injury in an accident, we can define relative risk (*R)* as

$$R = \mathbf{P}(case|helmet)/\mathrm{P}(case|exposure)$$

where "helmet" means that the cyclist is wearing a helmet and "exposure" means she is not wearing a helmet. In a study based on random trials, we could estimate relative risk as

$$\hat{R} = \frac{H_{case}/(H_{control}+H_{case})}{E_{case}/(E_{control}+E_{casel})} = \frac{H_{case}/E_{case}}{(H_{control}+H_{case})/(E_{control}+E_{case})}$$

In the case-control studies, we do not directly measure either of these conditional probabilities. Instead, we have a case and a control group, which allows us to measure

$\hat{P}$(helmet|case) = H_{case}/N_{case} , $\hat{P}$(exposure|case) = 1 – $\hat{P}$(helmet|case) = E_{case}/N_{case}

$\hat{P}$(helmet|control) = $H_{control}/N_{control}$ $\hat{P}$(exposure|control) = 1 – $\hat{P}$(helmet|control) = $E_{control}/N_{control}$

where N = H + E, that is N is the total number of people in either the case or control group. These four estimators are the quantities needed to estimate the odds ratio:

$$Odds = \frac{H_{case}/E_{case}}{H_{control}/E_{control}}$$

Although **P**(*case|helmet)* is not the same as **P**(*helmet|case*) , Cornfield (1951)[41] pointed out that the odds ratio provides a good estimate of relative risk for rare diseases, which in this case would mean: provided that head injuries are extremely rare. (Notice that the numerators are the same in our equations defining *Odds* and $\hat{R}$, and that the denominators converge if H_{case} and E_{case} are very small.[42]) Other researchers have pointed out that although the odds ratio is not the same as relative risk, it is possible to design a case-control experiment to estimate relative risk as well.[43] Nevertheless, most of the case control studies on helmets are designed to estimate the odds ratio but not relative risk. Some authors are content to report the odds ratio, while others have made statements about the effectiveness of helmets as if the odds ratio was equal to the relative risk.

Given that the numerators are the same in the equations defining *Odds* and $\hat{R}$, one can express relative risk as a multiple of the odds ratio[44]:

$$\hat{R} = Odds\ \frac{H_{control}/(H_{control} + H_{case})}{E_{control}/(E_{control} + E_{case})}$$

The ratio must always be a greater than one if helmets are effective, because it is simply the ratio of the fraction of helmeted cyclists who do not get a head injury, to the fraction unhelmeted cyclists who do not get a head injury. That is, the practice of calculating the effectiveness of helmets as if the odds ratio was an estimate of relative risk, always understates relative risk and overstates the effectiveness of helmets.

Table 2: Comparing the Odds Ratio and Relative Risk of Head Injury With and Without Helmets

	Case		Control		% Injured		% head injuries	**Odds ratio**	**Quasi Relative Risk**
Lead Author	H	E	H	E	H	E			
Dorsch	62	61	60	14	51	81	62	**0.24**	**0.62**
Thompson[a]	17	218	103	330	14	40	35	**0.25**	**0.36**
Spaite	1	37	115	131	1	22	13	**0.03**	**0.04**
McDermott	90	468	276	876	25	35	33	**0.61**	**0.71**
Maimaris	4	100	110	828	4	11	10	**0.30**	**0.33**
Thomas	31	67	126	140	20	32	27	**0.51**	**0.61**
Finvers	4	72	92	531	4	12	11	**0.32**	**0.35**
Thompson[b]	222	535	1497	1137	13	32	22	**0.32**	**0.40**
Jacobson	18	38	97	76	16	33	24	**0.37**	**0.47**
Linn	101	467	226	668	31	41	39	**0.64**	**0.75**
Shafi	21	107	10	70	68	60	62	**1.37**	**1.12**

a = Thompson (1989), b = Thompson (1996).
Source: First 8 columns are from Attewell. See text for how relative risk is calculated. "Quasi relative risk" would be a valid estimate of relative risk if the study had been designed so that the proportion of people with head injuries and/or wearing helmets in the study reflected the proportions in the general population.

Table 2 provides some indication of the difference between the odds ratio and calculated relative risk, for the studies reviewed by Atwell. The two columns at the right show the odds ratio and relative risk, as calculated by the observations of *E* and *H* for the case and control populations. The table suggests that mistakenly treating the odds ratio is if it were relative risk, will generally overstate the effectiveness of helmets by more than 10 percent.

The table uses the term "quasi relative risk" as a reminder that the calculated relative risk is only a valid estimator in a random trial experiment, or if the study is otherwise designed so that (a) the fraction of cyclists who use helmets in the study matches the fraction of all cyclists involved in crashes who are wearing helmets and/or (b) the fraction of cyclists who get head injuries matches the actual experience in the population at large. Because that was generally not the case in the studies summarized in Table 2, the quasi relative risk calculations in Table 2 are shown merely to illustrate how the odds ratio *would* underestimate relative risk if the study *had been* designed to estimate relative risk.

2.4 While less extensive than for head injuries, the available research suggests that increased neck injuries offset about half the reduction in head injuries from helmets.

Most doctors and drug companies recognize an ethical duty to warn of side effects, even when those side effects are almost certainly less harmful than the medical condition being treated. Table 1 shows that the risk of increased neck injuries offsets approximately half the head injuries caused by helmets. Interestingly, the incidence of neck injuries is negatively correlated with head injuries, so that the variance of all head and neck injuries is less than the variance of either head or neck injuries alone.

So far, only four studies have quantified the risk of neck injuries from helmets, and this side effect is understood even less than the extent to which helmets reduce head injuries. An organization that wants to encourage the use of helmets might be inclined to avoid mentioning the side effect of neck injuries until they are better established. Such an approach would show bias, for two reasons. First, CDC was willing to broadcast estimates of the effectiveness of helmets based on only one study. Second, CDC is providing quantitative estimates of helmet effectiveness, and once an agency enters that arena, it has a duty to present all of the results from the body of research on which they rely, not merely those that support a particular policy.

3 THE SPECIFIC RECOMMENDATIONS FOR CORRECTING THE INFORMATION;

We recommend that CDC immediately delete phrases that quantify the risk reduction from bicycle helmets, at least temporarily. For example, the statement “Wearing a bike helmet reduces the risk of brain injury by 88% and reduces the risk of injury to the face by 65%” could be either deleted or changed to “Wearing a bike helmet reduces the risk of brain injury and injury to the face.” If the statement is not deleted, then two caveats should also be added, concerning neck injuries and the possibility that helmets improperly worn do not provide significant protection. So this particular sentence might read “Wearing a bike helmet reduces the risk of brain injury and the risk of injury to the face. A helmet can also increase the risk of neck injury, so wearing it correctly is important.”

On any html web page that might be misconstrued by careless readers as still presenting up-to-date-information on helmet effectiveness, the warning should be made more explicit and prominent that CDC has updated its view of bike helmet effectiveness. Until now, CDC might have reasonably assumed that the disclaimer was clear enough. But now that a reporter for *the Washington Post* overlook the caveats that the year-2000 plan does not necessarily represent current views of CDC, one can only conclude that a more obvious warning is necessary on that page and similar html pages. Most people recognize that when they open a pdf file, the contents represent the views of the author on the date the report was issued, but many people assume that an html page on a government web site represents the existing view of the government—and web pages tend to have so much superfluous or repetitive material around the margins that the eye often hones in on the normal looking text and ignores disclaimers that a web designer might believe to be palpable.

Similarly, CDC should either delete substantial portions of the *Morbidity and Mortality Weekly Report* (MMWR) on “Injury Control Recommendations: Bicycle Helmets”[45] or retire that 18-year old publication and keep it on the website solely for archival purposes with an appropriate caveat.

These changes can be made rapidly at little expense. It is up to CDC to decide whether it wants to invest the resources to continue providing the public with quantitative information about the consequences of wearing a bike helmet. If so, we recommend that CDC try harder to stay reasonably up-to-date on the literature. A first step would to provide the complete references for quantitative estimates of helmet effectiveness on any html web page, so that people maintaining the web site and the public will realize how old the sources are for particular claims.

If CDC chooses to continue providing an estimate of helmet effectiveness, we suggest you provide an uncertainty range rather than a single number. That uncertainty range should encompass the entirety of the uncertainty ranges from the three published meta-analyses by Attewell et al., Thompson et al., and Elvik, for example, an odds ratio of 0.26 to 0.75 in the case of head injuries (see Table 1). Doing so would reflect greater uncertainty than any of the meta-analyses alone, but that is appropriate. The published analyses are all designed to estimate the mean population parameter. But cyclists want to know how effective the helmet is likely to be for them or their loved ones in their community, which is inherently more uncertain that the best estimate of the mean helmet effectiveness, which the published studies are designed to estimate. Given the side-effect of increased neck injuries, CDC should also present the range of odds ratios for head and neck injuries, which appears to be 0.5 to 0.98. Because relative risk will be greater than the odds ratio, CDC would have to decide whether to add some text to explain what the odds ratio implies about helmet effectiveness, or obtain additional information to derive the relative risk implied by the estimated odds ratio. Pretending that the odds ratio equals relative risk, however, is no longer acceptable. Perhaps the time has come for a new MMWR report on Bicycle Helmets.

4 HOW THE PERSON SUBMITTING THE COMPLAINT IS AFFECTED BY THE INFORMATION ERROR; AND

The Washington Area Bicyclists Association (WABA) conducts bicycle safety classes in the Washington area. A component of those classes includes providing the students with information related to helmets. We wish to convey accurate information.

WABA has 5000 members and more than 30,000 supporters in the Washington area, all of whom ride bicycles. Most use helmets most of the time, but might occasionally have to choose between riding without a helmet, or skipping a ride altogether because their helmet is misplaced, somewhere else, or needs to be replaced. The decision whether to ride under those circumstances involves a balancing of risks. A relative risk of 88% implies that the risk of injury without a helmet is 8 times as great as riding with a helmet, while a relative risk of 25% implies that such a ride is only 33% more risky. Many people might reasonably take the ride if the risk is only 33% greater, because the health benefits of cycling appear to offset the risk of an accident, and one might compensate for the extra risk by taking a shorter ride or riding more carefully. But those same people might choose not to ride that day if the risk without the helmet is 8 times as great. So our members need to know whether the relative risk is 88% or something closer to 25%.

As an individual, I personally face the same consequences. Moreover, I regularly shuttle back and forth on a bicycle worth less than $40 between the family cottage on Long Beach Island (New Jersey) and either the my sailboat or the ocean, both of which are approximately 1000 feet from the house, often towing a trailer with tools or beach equipment. I don't wear a helmet on these rides because I am not going to leave a bike helmet exposed to the sunlight on the beach or a dock for several hours just for a 1000-foot ride. I'm far more likely to get a neck injury body surfing or a head injury when the boom hits my head than on that short of a ride. Moreover, the minimal risk of injury on such a short is probably outweighed by the risk of damage to the helmet from sunlight and the resulting increased risk of head injury during the later portion of the helmet's 5-year life. Please realize that I am hyperconscious about safety to the point where I will run 200-lumen front and rear blinking lights in the day time, because I have observed that drivers make left turns or pull out of parking spaces in front of me when I don't run the lights. If I thought that the risk of a head injury was 8 times greater without a helmet, I would wear a helmet even for these 1000-foot rides. But as it stands, the CDC has no credibility with me on the subject of bike helmets, given its simple, glib, repetition of old studies without any evidence of a critical review.

Finally, the Maryland House of Delegates appears likely to pass a bill that would make Maryland the first state to require all adult cyclists to wear helmets. The sponsors appear to have been influence in part by the repeated assertion that helmets stop 85-88% of head injuries, which CDC and at least one other federal agency has continued to repeat. The Washington Post quoted the CDC web site just before the key committee held its hearing. Thus, a state law may be enacted based on misinformation disseminated by the CDC website. Such a law would place all of our members in legal jeopardy whenever they ride a bike in Maryland without a helmet, which as mentioned, may happen from time to time even with people who try to wear a helmet whenever possible. That law would make the bikeshare programs infeasible, leading some of our members who work in Maryland to drive when they might otherwise take mass transit and ride a bike the last mile or two. Another direct consequence of the misinformation is that our staff and volunteer advocates are spending inordinate time this year working to stop that bill, instead of spending such time with their family or doing volunteer work that benefits the community. As an individual, I have or expect to experience all of these consequences as well.

5 THE NAME, MAILING ADDRESS, TELEPHONE NUMBER, E-MAIL ADDRESS, AND ORGANIZATIONAL AFFILIATION, IF ANY, OF THE INDIVIDUAL MAKING THE COMPLAINT.

This request for correction is being submitted by James G. Titus as an individual, and on behalf of the Washington Area Bicyclists Association. My contact information is as follows:

James G. Titus,
6718 Glenn Dale Road,
Glenn Dale Maryland, 20769
Cell: 301-602-5421
Email: jtitus@risingsea.net

* * * * *

Thank you for the opportunity to provide our views on the need to correct this information on bicycle helmets. We know that you are dedicated to improving the health and safety of Americans, and so are we. Some people may think that exaggerating the benefits of safety equipment is an appropriate way to promote public safety, but we prefer accurate and up-to-date information, and we hope you agree.

Yours truly,

James G. Titus
Board of Directors

Notes and References

[1] Apparently Mr. Halsey obtained this statement after failing to observe the caveat at http://www.cdc.gov/program/performance/fy2000plan/2000xbicycle.htm

[2] See OMB, "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Republication." 67 *Federal Register* 8452-8460. The CDC Guidelines implementing the Data Quality incorporate by reference the standards of information quality set forth in the OMB Guidelines.

[3] HHS GUIDELINES FOR ENSURING AND MAXIMIZING THE QUALITY, OBJECTIVITY, UTILITY, AND INTEGRITY OF INFORMATION DISSEMINATED TO THE PUBLIC §I(D)(4)(d).

[4] See "Possible request for correction--Injury Prevention factoid (bicycle helmets)" Email from Jim Titus to InfoQuality@cdc.gov, sent February 21, 2013, and "Re: CDC-INFO: Inquiry [ref:_00DU0YCBU._500U06ewmg:ref]" Email from Jim Titus to cdcinfo sent February 18, 2013. An email sent February 14, 2013 through the CDCInfo website entitled "Misrepresentation of literature on bicycle helmet effectiveness" was acknowledged with an explanation stating "Your comments have been forwarded to the CDC's National Center for Injury Prevention and Control - Division of

Unintentional Injury Prevention (NCIPC / DUIP) for their information. They will contact you directly if they have any additional questions."

[5] We are not sure where CDC got its estimate for a 65% reduction in injuries to the face, because that paper did not estimate facial injuries. While Thompson et al. 1990 did estimate injuries to the face, the results in that paper were fairly equivocal.

[6] Thompson, R.S., Rivara, F.P., Thompson, D.C., 1989. A case-control study of the effectiveness of bicycle safety helmets. 320 *New England Journal of Medicine*, 1361–1367.

[7] Id. at 1365.

[8] All of the studies cited here report results based on the so-called odds ratio, rather than the relative risk. The odds ratio is a ratio of two ratios. It is based on the odds that someone having a head injury was wearing a helmet, compared with the odds that someone who did not have a head injury was wearing a helmet. The numerator of the odds ratio is calculated from a sample population of cyclists with head injuries as the ratio of people wearing helmets to people without helmets. The denominator is calculated from a separate sample population of people who did not have a head injury, as the number of people wearing helmets divided by the number not wearing helmets. Relative risk, by contrast, measures the probability that someone wearing a helmet will or will not get a head injury. Although the studies only calculate the odds ratio, they often present the results as if they had calculated relative risk. The studies generally do not calculate relative risk because to properly do so under Bayes Theorem, they would need to estimate the unconditional probability of either wearing a helmet or having a head injury when involved in an accident, neither of which can be estimated with the hospital data alone. This table includes all studies evaluated by Attewell et al. or Elvik, except for one study published in Norwegian.

[9] Attewell, R.G., Glase, K., McFadden, M., 2001. Bicycle helmet efficacy: a meta-analysis. Accident Analysis and Prevention 33, 345, 349 Table 3 (citing Dorsch, M.M., Woodward, A.J., Somers, R.L., 1987. Do bicycle safety helmets reduce severity of head injury in real crashes? Accident Analysis Prevention 19, 183–190).

[10] Thompson, R.S., Rivara, F.P., Thompson, D.C., 1989. A case-control study of the effectiveness of bicycle safety helmets. New England Journal Medicine 320, 1361–1367.

[11] Attewell at 349 (citing Spaite, D.W., Murphy, M., Criss, E.A., Valenzuela, T.D., Meislin, H.W., 1991. A prospective analysis of injury severity among helmeted and nonhelmeted bicyclists involved in collisions with motor vehicles. Journal Trauma 31, 1510–1516.)

[12] Id. (citing McDermott, F.T., Lane, J.C., Brazenor, G.A., Debney, E.A., 1993. The effectiveness of bicyclist helmets: a study of 1710 casualties. Journal Trauma 34, 834–845).

[13] The Thompson et al. meta-analysis treated this study as a qualifying study, and reported its results, but did not include the results in its summary odds ratio, apparently because the study reported a crude odds ratio but not an adjusted odds ratio. Of the five studies that Thompson et al. deemed worthy of consideration, this study had a far higher odds ratio than the others; so its exclusion lowered the summary odds ratio substantially.

[14] Attewell supra note 9 (citing Maimaris, C., Summers, C.L., Browning, C., Palmer, C.R., 1994. Injury patterns in cyclists attending an accident and emergency department: a comparison of helmet wearers and non-wearers. British Medical Journal 308, 1537–1540).

[15] Id. (citing Thomas, S., Acton, C., Nixon, J., Battistutta, D., Pitt, W.R., Clark, R., 1994. Effectiveness of bicycle helmets in preventing head injury in children: case control study. British Medical Journal 308, 173–176).

[16] Id. (citing Finvers, K.A., Strother, R.T., Mohtadi, N., 1996. The effect of bicycling helmets in preventing significant bicycle-related injuries in children. Clinical Journal Sport Medicine 6, 102–107).

[17] Id. (citing Thompson, D.C., Rivara, F.P., Thompson, R.S., 1996b. Effectiveness of bicycle safety helmets in preventing head injuries. A case control study. Journal American Medical Association 276, 1968–1973).

[18] Id. (citing Jacobson, G.A., Blizzard, L., Dwyer, T., 1998. Bicycle injuries: road trauma is not the only concern. Australian New Zealand Journal Public Health 22, 451–455).

[19] Id. (citing Linn, S., Smith, D., Sheps, S., 1998. Epidemiology of bicycle injury, head injury and helmet use among children in British Columbia: a five year descriptive study. Injury Prevention 4, 122–125).

[20] Id. (citing Shafi, S., Gilbert, J.C., Loghmanee, F., Allen, J.E., Caty, M.G., Glick, P.L., Carden, S., Azizkhan, R.G., 1998. Impact of bicycle helmet safety legislation on children admitted to a regional pediatric trauma center. Journal Pediatric Surgery 33, 317–321).

[21] Hansen, K.S., Engesæter, L.B., Viste, A., 2003. Protective effect of different types of bicycle helmets. Traffic Injury Prevention 4, 285–290. Considering only the data collected for hard shell helmets.

[22] Id. For soft shell helmets.

[23] Heng, K.W.J., Lee, A.H., Zhu, S., Tham, K.Y., Seow, E., 2006. Helmet use and bicycle-related trauma in patients presenting to an acute hospital in Singapore. Singapore Medical Journal 47, 367–372.

[24] Heng et al. stated in the text that the odds ratio for head injuries was 0.14, but that they were not reporting it in the table because it was not statistically significant.

[25] Amoros, E., Chiron, M., Ndiaye, A., Laumon, B., 2009. Cyclistes victimes d'accidents (CVA). Partie 2. Études cas-témoins. Effet du casque sur les blessures à la tête, à la face et au cou. In: Convention InVS J06-24 ,. INRETS, Lyon. Based on logit regression coefficients reported on page 21.

[26] Attewell supra note 9.

[27] Thompson, D.C., Rivara, F., Thompson, R., 2009. Helmets for preventing head and facial injuries in bicyclists. Cochrane Review. The Cochrane Library (1), 2009.

[28] Elvik, R. 2001. "Publication bias and time-trend bias in meta-analysis of bicycle helmet efficacy: A re-analysis of Attewell, Glase and McFadden, 2001." Accident Analysis and Prevention. 43 (2011) 1245–1251.

[29] Elvik, citing results from Attewell, supra note **Error! Bookmark not defined.**.

[30] Elvik, R. 2001. "Publication bias and time-trend bias in meta-analysis of bicycle helmet efficacy: A re-analysis of Attewell, Glase and McFadden, 2001." Accident Analysis and Prevention. 43 (2011) 1245–1251.

[31] Elvik, citing results from Attewell, supra note **Error! Bookmark not defined.**.

[32] Elvik, R. 2001. "Publication bias and time-trend bias in meta-analysis of bicycle helmet efficacy: A re-analysis of Attewell, Glase and McFadden, 2001." Accident Analysis and Prevention. 43 (2011) 1245–1251.

[33] Many researchers report both the odds ratio as defined above, as well as one or more adjusted odds ratios that attempt to take into consideration difference between the case and control populations, so that the results do not attribute the all differences in the proportion of head injuries to helmets when it is reasonable to assume that other factors play a role as well.

[34] The Thompson team has backed away from the 85 and 88 percent effectiveness numbers (odds ratio of 0.15 and 0.12) in several respects. In their 2009 Cochrane review of case-control studies, they reported that the 95% confidence range for the adjusted odds ratio from the 1989 study was 0.14 to 0.49, with a best estimate of 0.26. Their 1996 best estimate was 0.31 with a range of 0.26 to 0.37. Similarly, the best estimate for brain injuries in their 1989 study was 0.19 with a range of 0.06 to 0.57, they said in 2009; and their 1996 revision was 0.35 with a range of 0.25 to 0.48. Thus, by 1996 the Thompson team had revised their estimates of helmet effectiveness to be substantially less than shown on the CDC website, and by 2009 Thompson et al. even viewed their 1989 study as showing less effectiveness than shown by the CDC's characterization of their 1989 study.

[35] Attewell supra note **Error! Bookmark not defined.**.

[36] Elvik, R. 2001. "Publication bias and time-trend bias in meta-analysis of bicycle helmet efficacy: A re-analysis of Attewell, Glase and McFadden, 2001." *Accident Analysis and Prevention*. 43 (2011) 1245–1251.

[37] Thompson, D.C., Rivara, F., Thompson, R., 2009. Helmets for preventing head and facial injuries in bicyclists. Cochrane Review. The Cochrane Library (1), 2009.

[38] The Thompson et al. meta-analysis treated this study as a qualifying study, and reported its results, but did not include the results in its summary odds ratio, apparently because the study reported a crude odds ratio but not an adjusted odds ratio. Of the five studies that Thompson et al. deemed worthy of consideration, this study had a far higher odds ratio than the others; so its exclusion lowered the summary odds ratio substantially.

[39] See e.g. Cochran, *Sampling Statistics* (chapter on measurement error showing that when there is measurement error, additional observations decrease the portion of the total variance dues to sampling error but not the portion dues to measurement error).

[40] Helmet effectiveness is likely to vary across people, due to differences if riding conditions, habits, and helmet variations. Additional data allows for an increasingly precise estimate of the mean effectiveness for the entire population, that is, the variance of the mean declines. But the population variance does not decline as the sample increases.

[41] Cornfield, J. 1951. "A method of estimating comparative rates from clinical data: Applications to cancer in the lung, breast, and cervix." 11 Journal of the National Cancer Institute 1269-75.

[42] Rodrigues, L. and B.R. Kirkwood. 1990. Case-control designs in the study of common diseases: Updates on the demise of the rare disease assumption and the choice of sampling scheme for controls." 19 *International Journal of Epidemiology* 205-213 at 206.

[43] See e.g. *id.*

[44] Cf. id. at 208, Table 1 (providing formulas for relative risk and odds ratio, with identical numerators).

[45] MMWR 44(16);325 (Apr 28, 1995) http://www.cdc.gov/mmwr/preview/mmwrhtml/00036941.htm