

Injury Epidemiology: Fourth Edition

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Chapter 9. Research Designs and Data Analysis

The choice of study designs to investigate a given set of hypothesized causal factors is affected by numerous considerations. What is the unit of analysis (people, vehicles, environments)? In what population should the study be conducted? To what population of people, vehicles or environments will the results be generalized? What measurements of the factors are available or could be obtained? How reliable and valid are the measurements? How can the study isolate the effects of given factors independent of, or in combination with, other relevant factors? Can the data be collected without violating ethical guidelines? How much time will be needed to complete the study? How much will the study cost?

No single study will specify degree of effect of all the factors in a causal model. The goal of a prevention-oriented research project is to specify the extent to which injury or injury severity would be reduced by changing a given factor hypothesized to contribute to the injury or severity, other things being equal. A study design should be chosen that eliminates or minimizes the probability that factors other

than the changeable factor of interest somehow bias that estimate. See Appendix 9-1 for an example of elimination of alternative explanations.

Students of epidemiology are familiar with the general descriptive terms that are used to describe study designs, but they are noted here for readers unfamiliar with them. A cohort is a sample or population of units of analysis on which the researcher collects data continuously or periodically over a period of time. In a retrospective study, the researcher attempts to obtain data on a cohort accumulated in the past. In a prospective study, the data are gathered for a period of time after the fact of the generation of hypotheses and identification of the cohort to be studied.

CONTROLLED EXPERIMENTS. The most definitive results of research are produced by data gathered prospectively in controlled experiments where a modification is introduced in one set of whatever units of analysis, but not in one or more others. Any change in outcomes, such as injuries, are attributable to the introduced modification if the experimental and control groups were otherwise equal at the outset. That design requires that the researcher has control of one or more hypothesized causal factors, at least to the extent of being able to assign units of analysis (people, vehicles, environments) to experimental and control groups. The assignment is preferably randomized such that effects of other factors on injury or other relevant outcomes are random.

The controlled experiment is appealing not only because it maximizes the confidence that other factors are equalized by random assignment, it also illustrates that the causal factor in question is controllable, although control in an experiment does not necessarily imply that control is possible to the

same degree in the natural occurrence of the factor of interest.

If the experimental manipulation of a given variable has more than an extremely remote possibility of increasing injury, ethics dictate that the experiment should not be conducted (McGough and Wolf, 2001). For example, most researchers would not consider an experiment in which drivers in the experimental group would be given alcohol and then sent out to drive in traffic, although a few such studies have been conducted on environmentally benign driving ranges or roads without other traffic. Of course, vehicle crash tests can be done experimentally on instrumented crash dummies rather than human subjects. Controlled experiments are especially recommended to determine the efficacy of injury control efforts before they are widely distributed.

The effects of alcohol on various behaviors, including driving in environments simulated by motion pictures and other devices, have been studied by controlled experimental designs. These studies have specified the effects of alcohol on impairment of various behaviors -- reaction time, steering, etc. -- and on certain emotions (e.g., Loomis and West, 1958). There are suggestive correlations of self-reported alcohol use for emotional reason, including sensation seeking, in interviews (e.g, Cooper, et al., 1995). Apparently no experiment has yet been undertaken to disaggregate the effects of alcohol and emotions, separately and in combination, on behaviors highly predictive of injury.

Whether laboratory experiments can be generalized to the "real world" can always be questioned. Use of experimental and control groups stratified on other factors such as age, gender, and impulsiveness not only allow the researcher to test for effects of combinations of factors, but also addresses

the issue of generalization to segments of the population. Such more complicated experimental designs increase the numbers of persons (or other units of analysis) needed for statistical power, and associated costs of the research. A textbook on experimental designs should be consulted regarding varieties of designs for efficiency and statistical power (e.g., Lundquist, 1953).

CASE-CONTROL STUDIES. A study design that can approximate the conditions of a controlled experiment is the case-control design. A case may be an injured person, a vehicle that rolled over or a section of road where a vehicle hit a tree. The analogous controls would be persons not injured, vehicles that did not roll over, or sections of road that the vehicle traversed without hitting trees. The research question is the extent to which relevant individual, vehicle or environmental factors differ between cases and controls. The controls may be matched on certain factors (age, gender, time, place) or unmatched.

For example, the important role of alcohol in motor vehicle injuries was demonstrated by case-control studies (e.g., Haddon, et al., 1961). Alcohol was measured in fatally injured pedestrians, and in randomly selected persons at the same places, walking at the same time of day, same day of week, and moving in the same direction as the fatally injured. Therefore, these environmental factors were the same for the cases and controls and could not account for the large differences in alcohol found in the cases and controls. The same design was also used with drivers as the unit of analysis (McCarroll and Haddon, 1962).

One way of studying the alcohol issues mentioned in the previous chapter would be to replicate these case-control studies and measure hypothesized biological factors that

might contribute to alcohol use, other behaviors, or both jointly. Two major problems would be encountered in such a study. First, while measurement of alcohol in breath samples of controls may be allowed by sufficient numbers of persons selected as controls, requests for blood or other biological specimens might not be acceptable. Second, good evidence that trauma does not change the hypothesized biological factor is necessary before assuming that a difference between cases and controls is indicative of causation.

Selection of people engaged in the same activity at the same site, time of day, and day of week may not be possible for activities that occur at the case sites infrequently, such as use of "all terrain" vehicles or snowmobiles. A child injured in a home may have no siblings close enough in age to serve as controls within the household, although children in reasonable proximity in the same neighborhoods may serve as controls depending on the factors of interest. For example, children who were killed in a cluster of unsolved child homicides were compared to children from the same neighborhood regarding potential risk factors. Several factors indicative of greater exposure (time and specific hours away from home alone, running errands for money) were identified as placing the killed children at greater risk (Goodman, et al., 1988).

Within-household controls are obviously not appropriate if the hypothesized hazard is common to all members of the household. A study of risk of having a gun in a household, for example, used households in the surrounding neighborhood of those with a fatal shooting as controls, and statistically controlled for such factors as illicit drug use and a history of physical fights. The study documented that gun ownership increased the risk of homicide, given the same history of drug use and fighting (Kellerman, et al., 1993).

The selection of controls in case-control studies requires careful thought, and measurement of certain factors retrospectively can be quite problematic. In clinical situations, it is tempting to select controls from patients who have arrived at the same clinic or hospital for reasons other than injury. If the hypothesized causal factor contributes in some way to problems other than injury that lead people to seek medical care, however, the comparison of cases and controls will underestimate the contribution of that factor to injury. If the hypothesized causal factor were reduced by factors that also led to the seeking of medical care, the effect of that factor would be overestimated.

For example, a study of alcohol in emergency room patients compared those injured to those who appeared for illnesses (Wechsler, et al., 1969). Since we do not know the effect of the mix of illnesses seen in such clinics on alcohol use or the effect of alcohol use on seeking medical care for injury or illness, the extent of over- or underestimation of alcohol's effect on injury is uncertain from such a comparison. If alcohol contributes to the problem presented by the control patients or to the probability of seeking medical attention, the difference in alcohol measured between cases and controls could be less than if persons exposed to the circumstances of injury who had no reason to seek medical attention were chosen as controls. If the medical condition were such that the control patient would not have been engaged in activities similar to that of the injured person, the effect of aspects of those activities would be overestimated.

One study used people who died of other causes as controls to emphasize the over involvement of people in certain occupations in motor vehicle deaths (Loomis, 1991). Since the controls were just as dead as the cases, the

usefulness of such a study for preventing death is ephemeral. A study of violent behavior in the last year of life, as reported by relatives post mortem, compared people who committed suicide with "controls" who died in "accidents" (Connor, et al., 2001). Since violent behavior may be a risk factor for unintentional injury as well, the study likely underestimated the correlation.

A survey of people who were involved in motor vehicle crashes and a random sample of licensed drivers not involved in crashes was conducted as to frequency of use of cellular phones (Violanti and Marshall, 1996). No determination was made of whether the phone was in use when the driver crashed, much less cellular phone use at the same times and places. A later study more precisely specified phone use in proximity to the time of the crash from records of phone calls, suggested an increased risk of motor vehicle crashes related to phone use in cars (Redelmeier and Tibsliran, 1997).

The fundamental issue in selection of cases and controls is: What should be allowed to vary as the hypothesized cause, or causes in stratified samples, and what should be held constant? If the variables to be held constant can be other than randomly distributed between cases and controls, the purpose of the design is defeated. If the factor or factors treated as potential causes are not directly connected to injury or are unchangeable, the study is a waste of limited resources for research.

Collection of retrospective data on cases and controls also presents numerous problems. In assault cases, it may not be possible to identify the assailant or, if identified, the assailant may be non-cooperative or falsify information. If a person is injured in a neighborhood, controls that have knowledge of the injury may give misleading information

because of denial of personal vulnerability or other psychological factors. Even if data can be obtained by observation, such as by watching children engaging in the activity involved in the case, knowledge of the injury may have resulted in changes in participation in the activity or how they participate.

The human host or vector (assaulted person, driver) has been the unit of analysis in most case-control studies, to the neglect of factors that may be more subject to change for injury control. Case-control designs can also provide strong evidence regarding vehicle and environmental factors.

For example, advocates of the use of tractor-trailer trucks with more than one trailer argued that the risk was less because the crash rates per vehicle were similar, but fewer trucks were used because of more cargo per trip. A case-control study of trucks in crashes and trucks observed at the same time of day, on the same roads, moving in the same direction, revealed that two-trailer trucks were two to three times more likely to crash in the same environment, more than offsetting the advantage of carrying increased cargo (Stein and Jones, 1988).

In a study of environmental factors in motor vehicle crashes, the driver and vehicle can serve as their own controls. For example, the characteristics of crash sites where occupants of vehicles died striking fixed objects along the roadside were compared to sites one mile away in the direction from which the vehicle traveled. Since the driver and vehicle factors presumably did not change in a mile, those factors were virtually constant at the case and comparison sites. The substantial differences in road curvature and gradient of the road, coupled with no difference in number of potential objects along the road, indicated that environmental modifications would greatly

reduce the severity of fixed-object crashes on sections of roads with curves greater than 6 degrees on downhill grades greater than two percent (Wright and Robertson, 1976).

Subsequent research using this study design found excess involvement of similar road characteristics in off-road rollover fatalities (Zador, et al., 1987), vehicles running into water leading to occupant drowning (Wintemute, et al., 1990), and multiple vehicle crashes at other than intersections (Fulgham, et al., 1989). Since two vehicles were involved in the latter study, two control sites were studied for each case, one mile in the direction from which each vehicle traveled.

The power of case-control designs is sometimes poorly understood by those in a position to disseminate the results. For, example, federal road authorities ignore the specification of curvature and grade characteristics as road conditions that can be used to target sites for modification. The magazine "Public Roads" is a Federal Highway Administration publication that circulates to the officials who decide where, when, and how roads are to be built or modified. Articles on a decision-making system called the "Interactive Highway Safety Design Model" (Regan, 1994; Lum and Regan, 1995), contained no information on curvature and grade criteria established by the mentioned case-control studies. When the editor of Public Roads was informed of this in 1996, he refused to publish material on the issue.

RETROSPECTIVE COHORT STUDIES. Greater lag in time of data gathered retrospectively increases the problems in measurement. Occasionally one may be able to use extant records, such as school records, arrest records, motor vehicle records, and the like, to obtain direct or proxy measures of

certain variables. The most common source of data in retrospective studies is interview or questionnaire, but the steepness of the forget curve and the tendency for people to recreate their histories to foster a more favorable image severely limit the validity of recalled information. For example, in a study of people in motor vehicle crashes involving injury that was reported to police, persons involved were interviewed at different time periods following the incident. The percentage of interviewees who reported the injury declined from 97 percent in the first three months to 73 percent nine to twelve months after the crash (National Center for Health Statistics, 1972). More frequent but less severe injuries may be thought too trivial to mention or may be forgotten. Comparison of weekly fall reports among the elderly and recall at the end of the year indicated significant underreporting at year's end (Cummings, et al., 1988).

Where specific measures of variables worthy of study have been obtained in a cohort in the past, and it is possible to obtain data on subsequent injury, a retrospective cohort study may be less costly than a prospective study. For example, a cohort of children was studied at the time they were shedding their baby teeth. Concentration of lead in the teeth was measured as well as academic achievement, reaction times and several other aspects of psychomotor performance. Also teachers' behavioral ratings of various behaviors (distractible, hyperactive, and impulsive) that might increase risk of injury were obtained (Needleman, et al., 1979). Lead in bone was correlated to teacher and parent ratings of children's aggressiveness and other behaviors (Needleman, et al., 1996). If the subsequent clinical records of the children in these studies could be identified, the extent of the correlation of relevant factors to subsequent injuries

might be studied. Such a study would require tracing those that had moved, and reliability checks on reported clinical facilities used. A study of lead pollution among several cities found that aggravated assault rates rose and fell in strong correlation with lead pollution (Mielke and Zahran, 2012).

The probability of longer term survival after severe injury has been studied using the Social Security Administration Master Death File (Shafi, et al. 2012). In the past, scientists have been able to query the file to obtain reported date of death. The validity of data in the file has been called into question by audits that find millions of deaths unreported and some people reported as dead who are still alive (<http://oig.ssa.gov/audits-and-investigations/audit-reports/all>). The Bipartisan Budget Act of 2013 denied access to the files of people in a position to correct errors, including scientists querying the file (http://quality-control.us/death_master_file.html).

PROSPECTIVE COHORT STUDIES. The likelihood of collecting reliable and valid data is much better when data are collected prospectively in a cohort of relevant units of analysis and the cohort is followed to measure the incidence and severity of the outcomes of interest. A major disadvantage of this design is that very large samples and a long period of data collection are required to obtain statistical power when the outcome is relatively rare.

For example, in the U.S. in 2012, the annual combined hospitalized and fatal injury rates from motor vehicles was about 64 per 100,000 people. If one could obtain data on hypothesized causes in a cohort of 100,000 people representative of the population, it would take nearly 16 years of data collection to obtain data on 1000 severe injury cases. Controlling statistically for several factors would

spread the cases very thinly among the various combinations of factors. The numbers of cases identified would be increased if less severe injuries were included but, as noted previously, the causes of less severe injuries are often different from causes of more severe injuries. In the case of motor vehicles, for example, the causes of low-speed crashes, which occur more often during the day in congested traffic, are often different from the causes of severe and fatal injuries which occur disproportionately at night, at higher speeds and in little or no traffic.

A prospective cohort design may be efficient for study of certain age groups with higher injury rates. For example, about one in five newly licensed 16-year old drivers will have a motor-vehicle crash resulting in injury or more than \$400 in property damage within two years. If reliable and valid data on the behavioral factors and abilities in Figure 8-1 could be obtained from 16-year olds in several high schools, and their licensure, vehicle use and crash experience measured in a subsequent two-year period, the data might provide better specification of the hypothesized paths in the model for that age group. In communities with a substantial dropout rate before age 16, however, the usefulness of the findings would be limited. Also, follow up of those students who leave home or whose families move would be difficult.

Prospective cohort studies of manageable size can be done if one has data on a hypothesized high risk factor. For example, what is the severe injury risk for people who used tranquilizers (benzodiazepines)? Using claims from a health insurance plan, researchers compared the injury claims for 4,554 persons less than 65 years old who had a pharmacy claim for tranquilizers during a nine month period, but not during the preceding three months, compared to a sample of

persons who did not have a claim for tranquilizer use and were unrelated to the users. Three nonusers were matched to each user by age, gender and calendar month when tranquilizer use began (Oster, et al, 1990).

One obvious question is whether any difference in injury rates is the result of factors that precipitated the perceived need for tranquilizers rather than the possible effect of the drugs. Also, the use of the drugs could at least partly be the result of post-injury anxiety. The researchers found that injury claims were substantially higher in the user group in the three months prior to prescription of the drug. Therefore, comparison of the rate of injury while the users were using the drug was controlled statistically for pre-use injury rate, as well as general care seeking and use of mental health services. The relative risk of hospitalization for injury to those who had no injury in the three months prior to receiving a prescription for the drug was higher than for the total study group (Oster, et al., 1990). Apparently, neither prior injury nor discretionary use of medical services totally accounted for the higher injury rates of tranquilizer users.

CROSS-SECTIONAL STUDIES. A cross-sectional study involves measurement of relevant variables in a sample of appropriate units of analysis during a specified time period. The effect of a given factor is estimated by the direction and degree of its correlation to the outcome of interest. The validity of the inference of causation depends on assumptions about the time order of the variables and the extent and pattern of co-variation among the factor of interest and other factors.

Suppose that a researcher obtained measures of some or all of the behavioral factors in causal model of motor vehicle injury in Figure 8-1 in a series of drivers hospitalized for

injury and correlated them to relevant circumstances of the injury. The data indicate that attention spans are shorter and impulsiveness is more frequent among drivers that ran off the road and hit fixed objects than in drivers that were struck from behind. Since the presence of sub-clinical brain injuries may be different in the two sets of drivers, and such injuries could affect attention spans or impulsiveness, the inference that these factors were present in the degree measured prior to the crashes would be questionable.

Cross-sectional studies also do not provide definitive evidence of causation when there is co-variation among hypothesized causal factors. If A is correlated to B, but X is also correlated to A and B, there are several possibilities. A could cause X which causes B. X could cause A which causes B. The three variables could be intertwined in a feedback system. Also, the correlation could be spurious. This occurs when X causes A and B independently, and there is no causal relationship between A and B. Again that is what epidemiologists call "confounding".

Some of these possibilities can be ruled out by reasonable assumptions about the time sequence of the factors, or whether the X factor can reasonably be expected to play a causal role. For example, when researchers examined the rollover rates of certain utility vehicles (Jeeps, Broncos, Blazers), they inferred from physics that the higher rollover rates of these vehicles relative to cars was the result of differences in stability -- the g force to overturn the vehicle -- calculated by the width between the center of the tires divided by twice the height of center of gravity (Snyder, et al., 1980). Road tests of the least stable vehicle, the Jeep CJ-5 driven by remote control, indicated that it would roll over in low-speed turns (Insurance Institute for Highway Safety, 1980). A critic of the research claimed that the higher

rollover rates of lower stability vehicles could have occurred because of differences in mileage, or use by higher risk drivers or in higher risk environments (Joksch, 1983).

Since the rollover rates of the least stable utility vehicles were 3-20 times those of cars, the argument that mileage could account for the difference was unreasonable. The least stable vehicles would have to have been driven more miles in a year than most vehicles are driven in their average ten years of use for their rates to be the result of more miles of use (Robertson and Kelley, 1989). Also, other risk factors would contribute to all types of crashes -- hitting a tree and a pole, hitting other vehicles -- yet the stability factor was strongly correlated to rollover rates, but hardly at all to non-rollover rates.

Since miles of use by particular drivers in particular environments was unknown, it was not possible to calculate rates of rollover and other types of crashes to use of the vehicles by particular drivers in particular environments. Using a mathematical model of the potential relationship of proportional mortality of higher and lower risk drivers and environments, however, it was possible to rule out other factors as an explanation of the correlation of stability and rollover.

If stability were correlated to different use of the vehicles by low- and high-risk drivers or in low- and high-risk environments, the ratio of rollover crashes under low-risk conditions to those under high-risk conditions would be a function of the ratio of mileage in low- and high-risk conditions and, therefore, should be correlated to stability. Stated mathematically:

$$c \frac{L}{H} = \frac{RL}{RH} = b(S)$$

where L = low exposure to a risk factor

H = high exposure to a risk factor

c = constant ratio of risk from low- to high-risk factor

RL = fatal rollovers in low-risk-factor situations

RH = fatal rollovers in high-risk-factor situations

b = slope of the correlation

S = stability value for a given vehicle.

Using data from the Fatality Analysis Reporting System (FARS) for several years, RL/RH was not significantly correlated to vehicle stability for any of the major driver or environmental risk factors, except whether or not the vehicle rolled over on or off the road. The ratio of on-road to off-road rollovers was higher the less stable the vehicle. This suggests that the side force of turning contributed more often to those rollovers, since ramping or going over embankments would usually occur off the road (Robertson, 1989). This methodology was also employed in the study in Appendix 9-1.

Although data on every possible risk factor is not included in FARS, there are none excluded that could be correlated to stability, and exclusively to rollover crashes, strongly enough to render the strong correlation of stability and rollover as spurious. Furthermore, the correlation of stability and rollover has causal plausibility. It is predicted from well-known physics.

Where major variables are unmeasured or are inter-correlated without a clear indication of time sequence, a cross-sectional study cannot be definitive in specifying causal chains. One useful function of cross-sectional studies is to indicate maximum magnitude of a given correlation. If the correlation of a hypothesized causal factor and the type, severity, or risk of injury is weak or nonexistent in a cross-

sectional study, it is unlikely to be found a major factor in a study with a more powerful design unless the cross-sectional study includes invalid or biased measurement.

Using logical assumptions about the time sequence of variables in a causal model, it may be possible to analyze cross-sectional data in ways that enhance confidence in the degree of contribution of particular hypothesized causal chains. Social scientists have developed methods for such analyses of what they call causal paths using regression for quantitative variables (Blalock, 1964) and comparison of proportions and log linear techniques for categorical data (Hellevik, 1984). These models are highly sensitive to assumptions of direction of causation and variable specification, however.

An example of misuse of "causal path analysis" is an attempt to discredit the studies of vehicle stability and rollover using police reports from Michigan and Florida. Unable to find behavioral and environmental factors that explained the variance attributable to stability, the authors of the study included "single-vehicle accident" as a "cause" in the model (Donelson, et al., 1994). Since the majority of rollovers of lower stability vehicles occur when the vehicle rolls rather than slides to the side, collisions with other vehicles are less frequent than in non-rollovers. Also, "single-vehicle accident" does not mean that no other vehicle was involved. In some instances, the driver is making a sharp turn to avoid a collision with another vehicle. In multiple-vehicle crashes, it is not possible to specify which vehicle rolled in the Florida data. Therefore, the vehicles may have been misclassified as well.

Attribution of lack of collision with another vehicle as a cause of the rollover should have been obviously absurd to the authors and those who reviewed the paper prior to

publication. The lack of reference in the paper to any of the previous research on rollover should have been a signal of ethical lapse and bias as well.

ECOLOGICAL STUDIES. Frequently one can easily obtain data on injuries in geographical areas and correlate the rates to other characteristics of those geographical areas obtained from other sources. For example, one might correlate rates of specific types of injuries per population in states or counties to census data on incomes, housing characteristics, and other factors in those counties. The correlations obtained are called ecological correlations.

A major problem with causal inferences from ecological correlations is that the hypothesized causal factor, or the factors that are controlled statistically, may not have occurred in the same unit of analysis as the effect (Robinson, 1950). If motor vehicle occupant injuries were found higher in low income areas, that doesn't necessarily mean that persons with low income are any more likely to be the persons in severe crashes in those areas. The roads in low-income areas could be more hazardous because of lack of funds to maintain them, upgrade them, or remove hazards. They may be equally hazardous to all vehicle occupants irrespective of individual income.

The usefulness of such correlations depends on the interpretation. If the correlation were used as justification to modify the roads in the lower income areas, the injury rate may be reduced if the modifications chosen are effective. If the data are used to argue against action on the grounds that poverty is intractable, they are a hindrance to action.

Ecologic studies can be used to estimate the effects of changes in factors that affect a set of ecologic units as a whole, such as changes in laws among states or other legal

jurisdictions. In such studies, the researcher must be able to specify that the change in law or other factor applied to the particular units of analysis associated with the injuries for the results to be valid. As will be noted in Chapter 12, cross-sectional studies using ecological data have been especially misleading in that regard. Ecological studies are more convincing when a change in injury rates over time is shown to occur coincident with a change in law or other factor during a period in which other factors did not change appreciably.

The statistical technique called regression finds the line or curve that best describes the extent to which one factor predicts another. Regression coefficients indicate the increase (or decrease if minus) in a unit of the outcome variable per unit of the predictor variable. A correlation coefficient indicates how closely the data fit the line or curve, plus or minus one if the fit is perfect and zero if the relationship between the variables is random scatter.

Correlation of trends in aggregated data, such as injury rates and the economy, gives falsely high correlations. Year-to-year fluctuations in aggregated rates vary narrowly compared to the magnitude of the total rate above zero. The correlation is not based on the range of possible rates given combinations of driver, vehicle and environmental factors, but the marginal fluctuation of rates that vary narrowly with the economy not accounting for the base rate maintained by the presence of the other factors. A regression equation with greater disaggregation of these factors is discussed in Chapter 12.

MIXED DESIGNS. Many studies do not fit into a neat classification of study designs. The efficacy of a study design

is not whether it can be easily classified, but whether it reveals usable information without substantial bias. It is better to describe the study procedure and the efforts made to account for bias rather than state that the study followed some design classification that may not be totally accurate in its implication for the procedures followed (Cummings, et al., 1990).

DATA ANALYSIS. The types of variables involved and the study design substantially determine the statistical models appropriate to the analysis of data. Familiarity with the use and interpretation of various statistics appropriate to particular types of data and study designs is essential for data analysis and report preparation. Students and researchers in epidemiology should be familiar with statistical procedures (e.g., Armitage, 1971; Fleiss, 1981; Hellevik, 1984; Riegelman, 1981), and those who are not should consult a statistician in the design stage of a research project. The best statistician in the world cannot produce some magical statistical trick to rescue what the study design has ignored or biased. Here a few basic principles and comparisons of analytical methods are reviewed as a basis for consideration of issues that commonly arise.

One consideration that is often ignored is the requirement of a given journal. Some journals require confidence intervals on estimates of percentages, rates, regression coefficients, rate ratios, and odds ratios, rather than probabilities (p values) that an estimate could be the result of chance fluctuation in samples. Deciding, before data analysis and writing the report, where the report will be submitted and checking out the requirements and style of the target publication can save time and trouble.

Another consideration is the potential use of the results. Table 9-1 presents several measures used in summarizing the correlation of categorical data with two categories of each variable, a simple two-by-two table (partly from Abramson, 1985). There are obviously more potential measures of association of numbers in the table than there are numbers in the table. The statistic(s) to be used depends on the potential uses of the data.

Table 9-1. Common Measures of Association of Categorical Data

	Injured	Not Injured	Total
Factor present	a	b	$a + b$
Factor absent	c	d	$c + d$
Total	$a + c$	$b + d$	$N = a + b + c + d$

$$\text{Sensitivity} = a/(a + c)$$

$$\text{Specificity} = d/(b + d)$$

$$\text{Odds ratio} = ad/bc$$

$$\text{Rate ratio} = [a/(a + b)]/[c/(c + d)]$$

Assuming a risk factor:

$$\text{Rate difference} = [a/(a + b)] - [c/(c + d)]$$

$$\text{Population excess risk} = [(a + c)/N] - [c/(c + d)]$$

$$\text{Attributable risk} = [a/(a + b) - c/(c + d)]/[a/(a + b)]$$

$$\text{Attributable fraction in population} = [(a + c)/N - c/(c + d)]/[(a + c)/N]$$

Assuming a protective factor:

$$\text{Excess risk if unprotected} = c/(c + d) - a/(a + b)$$

$$\text{Population excess risk} = (a + c)/N - a/(a + b)$$

$$\text{Preventable fraction of the unprotected} = [c/(c + d) - a/(a + b)]/[c/(c + d)]$$

$$\text{Prevented fraction in the population} = [c/(c + d) - (a + c)/N]/[c/(c + d)]$$

$$\text{Preventable fraction in the population} = [(a + c)/N - a/(a + b)]/[(a + c)/N]$$

If the results have potential for use in screening persons, vehicles or environments for some intervention to reduce injury, the issue of statistical significance is much less relevant than the sensitivity and specificity of the factor as a

basis for screening. Sensitivity is the proportion of persons injured that had the screening factor present prior to injury. Specificity is the proportion of persons not injured for whom the screening factor was absent. Assuming that the sample is not biased, if sensitivity is near 1.00, the factor will identify most of the people who would be injured. If specificity is near 1.00, the factor will not misidentify many people who would not be injured.

From the public health standpoint, it is desirable that sensitivity be high. From the economic standpoint, if the intervention costs money, it is desirable that specificity be high. Too many missed cases (false negatives) greatly dilute the potential effect of the countermeasure and too many cases included that would not be injured (false positives) makes the application of the countermeasure more expensive.

Notice in Table 9-1 that, if the factor is a necessary condition for injury, c would be zero and the odds ratio and rate ratio would each be infinite. The rate difference would be 1.00 only if the factor were a necessary and sufficient condition and could be small if the proportion injured of the population where the factor was present were small. The population excess risk would be even smaller if the latter were true. The attributable risk and attributable fraction in the population, however, would each be 1.00, indicating that all of the injuries could be eliminated by eliminating the risk factor. Yet the latter two statistics are seldom reported in analyses of injury data. If the researcher presents the data and the data are population based, however, they can be calculated.

The advantage of the odds ratio is that studies with different designs can be compared. Rate ratio, rate difference, population excess risk, attributable risk and

attributable fraction in the population are not comparable among studies unless the data are population based, or are adjusted for the sampling fraction if based on a sample.

The use of the statistics measuring effects of a protective factor (Table 9-1) assumes that the protection examined is randomly distributed in the population at risk. If those at higher or lower risk are more or less likely to use the protection, the statistics will vary depending on the proportion of the population using the protection. In chapters 10 and 11, the effects of differential use of seat belts by those at higher and lower risk of severe crashes and the estimates of seat belt effectiveness with and without belt use laws are discussed in that regard.

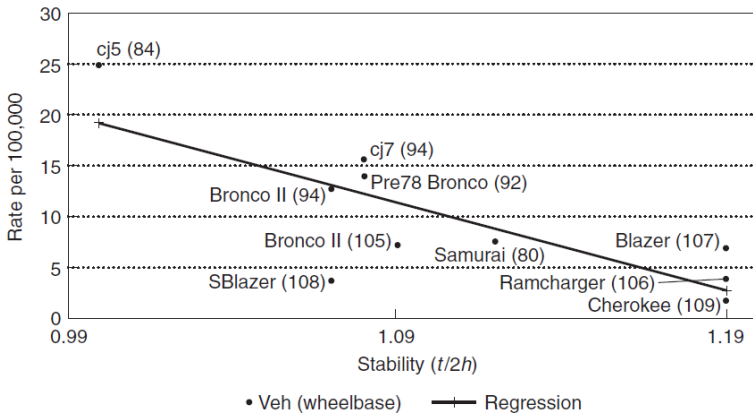


Figure 9-1. First-Harmful-Event Rollovers per 100,000 Vehicles in Use per Year.

In this and the previous chapters, mention was made of "regression" and percent of variation explained. Unfortunately, these statistical techniques are often left out of the introductory biostatistics course. The calculations are complicated but the concept is straightforward. Figure 9-1 shows a regression line fitted to the plot of fatal, first-harm rollover rates of popular utility vehicles in the 1980s as a

function of $t/2h$ (track width divided by twice the center of gravity height) .

The computer program that fits the line minimizes the deviations of each observation from the line and gives the result in the form of an equation, in this case:

$$\text{Rollover Rate} = 106 - 86 (t/2h)$$

If you know the $t/2h$ for a vehicle, you can put it in the equation and get the expected rollover rate. The scatter around the line occurs because of other factors. The number in parenthesis by each vehicle is the wheelbase, the distance from front to rear axle. Notice that the two vehicles substantially below the regression line (Bronco and SBlazer) have longer wheelbases than those near the line at that $t/2h$. In Chapter 12, an equation that includes $t/2h$, wheelbase and non-rollover for a larger sample of vehicles is discussed.

Wheelbase "explains" some of the variation not predicted by $t/2h$. Percent variation explained, called R square, is one minus the ratio of squared deviations from the line to the total squared deviations from the average of the predicted variable, in this case rollover rates. If all the data points were on the line, the variation explained would be $1 - 0 = 1$ or 100 percent. If the scatter is totally random, the line would have no slope and the variation explained would be $1 - 1 = 0$ or 0 percent.

Notice also in Figure 9-1 that the line will cross zero at $0 = 105 - 86(t/2h)$ or, solving for $t/2h$, $t/2h = 1.22$. Since passenger cars have $t/2h$ up to 1.62, it is obvious a straight-line regression will not fit the data if cars are included. In that case, a regression model that estimates two lines, one less than 1.2 and one at 1.2 or greater can be used (Robertson

and Maloney, 1997). There are also regression programs that fit curves rather than straight lines.

A variation on the concept of regression is logistic regression. The predicted outcome in a logistic regression is the logarithm of the odds of an outcome such as rollover. The equation that predicts back to the rate is not a straight line and is a little more complicated (Appendix 9-1), but the basic idea is to predict a particular outcome by knowing one or more risk factors. Other things being equal, if those "other things" have been adequately controlled, it is then possible to say how much difference changing the risk factor will make in the outcome.

META ANALYSIS. Statistical techniques are also available to examine various studies simultaneously to obtain a consensus estimate of the effect of a given factor or the effect of an intervention. Selection of studies for such analyses is problematic because studies that produce results that are not statistically significant are often not published (Bunn, et al., 2001). Also, many study reports do not include adequate detail on the results and how the data were obtained to weight the attributes and liabilities of including the study in a meta-analysis. A wide-ranging set of meta analyses of human, vehicle and environmental factors to reduce motor-vehicle injuries is available (Elvik and Vaa, 2004). The adequacy of each should be judged based on the quality of the research included.

Appendix 9-1. Vehicle Factors That Reduce Motor Vehicle Fatalities. Adapted from Robertson (2007).

Recent research suggests that a few currently available motor vehicle features would prevent the majority of mortality associated with motor vehicles, if adopted for all vehicles. Electronic stability control (ESC) automatically adjusts braking, throttle or suspension to reduce the likelihood of loss of control of the vehicle. It is estimated to reduce fatalities by about 42 percent (Farmer, 2006). Failure to obtain the highest ratings on 40-mile-per-hour offset crash tests (Farmer and Lund, 2006) is associated with excess deaths. Unnecessary weight contributes as much as 28 percent (Robertson, 2006). Static stability is the distance between the centers of the tires divided by twice the height of center of gravity ($T/2H$), a factor that increases risk of rollover when below 1.2 (Robertson, 1989). Since changing one or more of the vehicle attributes would likely prevent some of the deaths attributed to others, the percentages cited cannot be added to get a total estimate.

The purpose of this study is to estimate the effect of these and other vehicle factors (side impact crashworthiness, braking distance from 60 mph to 0, and 0-60 mph acceleration time), each adjusted for the effect of the others, in a comprehensive analysis of preventable motor vehicle mortality. I also analyzed the potential for confounding of results by environmental and behavioral factors.

METHODS. I selected passenger cars, minivans and “sport utility vehicles” (SUVs) sold from the beginning of the new 1999 model year (beginning in October, 1998) through September, 2005 for which data were available on the mentioned vehicle characteristics. I excluded pickup trucks

because their weights and other characteristics vary considerably within make-model designations. If a vehicle was redesigned during the study period, it was treated separately as a new model. In those cases where ESC was added in a given model year without other changes, the vehicle was designated as a new model.

I counted deaths during the years 2000-2005 for each vehicle make-model designation and obtained data on environmental and behavioral factors from the Fatality Analysis Reporting System that contains data on virtually every fatal crash in the U.S. To account for differential exposure, I estimated years of vehicle use by multiplying the monthly sales of a given make and model by years remaining during 2000-2005, discounted by subtracting the estimated percentage scrapped as the vehicles aged (Ward's, 2002-2004). One hundred fourteen make-models with more than 100,000 years of use each were selected for analysis. These vehicles were involved in 25,367 crash-related deaths to their occupants or bicyclists and pedestrians.

Data on ESC availability and crash test results by make and model were obtained from the website of the Insurance Institute for Highway Safety. Vehicle specifications and the results of the government's front and side crash tests were obtained from a vehicle information website (InternetAutoguide.com, 2007). Unfortunately, the site no longer provides crash test results but did at the time of the study. Because real-world crashes seldom involve the full front of the vehicle, the Insurance Institute for Highway Safety conducts frontal offset crash tests at 40 mph into a fixed barrier with a 40 percent overlap of the barrier and the driver side of the vehicle. It assigns qualitative ratings of "good", "acceptable", "marginal" and "poor" to various aspects of performance on its offset frontal crash tests. I

assigned weights of 1 (good) through 4 (poor) to the ratings of four life-threatening elements of the tests - structural integrity, forces on the heads and, separately, the chests of test dummies, and performance of seat belts and air bags. These were averaged as an index of frontal offset crashworthiness.

The U.S. government tests vehicles in full-frontal barrier crash tests at 35 miles per hour and collects data on head and chest injury criteria as well as other body sites. Since head and chest injuries are the most threatening to life, the injury criteria relevant to these injuries were considered in the analysis. The government also tests side crashworthiness by impacting the sides of vehicles with a 3015-pound barrier at 38.5 miles per hour, with "give" in the barrier to simulate the front of a vehicle striking the side of another. Injury criteria measured on driver and passenger test dummies were included in the analysis. Because about 70 percent of occupant deaths occur to drivers, I weighted the injury criteria as 0.7 times driver side plus 0.3 times passenger side when assessing all deaths. When assessing driver deaths, I used the driver side injury criteria. I obtained static stability data from U.S. government measurements (Walz, 2005) as well as the vehicle information website. I classified a vehicle as stable if T/2H was 1.2 or higher.

I obtained data on braking distance from 60 miles per hour to 0 and acceleration time from 0 to 60 miles per hour from the Consumer's Union road-test data (Consumer Reports, 2007). I analyzed the data using least-squares correlation and logistic regression.

RESULTS. Logistic regression estimates the odds of an event, in this case death, as a function of specific factors that are assumed to be not significantly correlated. Neither the

presence of electronic stability control nor crash test results correlated significantly to the other factors. Correlations that could bias the assessment of vehicle weight, engine power, size, static stability and braking are displayed in Table 1.

Table 1 Least-squares correlation of selected vehicle factors

	Weight	Wheelbase	Turn distance	Braking distance	Horsepower	Acceleration distance	Static stability
Weight	1.00						
Wheelbase	0.64	1.00					
Turn distance	0.60	0.65	1.00				
Brake distance	0.20	0.17	0.06	1.00			
Horsepower	0.70	0.59	0.50	0.04	1.00		
Acceleration distance	-0.22	-0.19	-0.25	0.24	-0.50	1.00	
T/2H	-0.34	0.02	0.15	-0.18	-0.06	-0.14	1.00
Fuel economy	-0.76	-0.44	-0.39	-0.21	-0.65	0.10	0.47

Although excess weight and horsepower is adverse to other road users, size is related to lower risk because it gives occupants more room to decelerate in a crash (O'Neill, et al, 1974). The weight, horsepower and size variables (wheelbase and turn distance) are correlated to a degree that using more than one could bias the estimates. Because poor fuel economy is highly correlated with these variables, particularly weight and horsepower, and is an important consideration in vehicle purchases, it was chosen as an inverse proxy of weight-power. Braking distance, acceleration distance and static stability are sufficiently independent of one another and the other factors to be used in the regression analysis. The analysis also controlled for types of vehicle (minivan, SUV) because of their differential use compared to cars.

Preliminary analysis indicated that the head and chest injury criteria in the government's full frontal crash tests and braking distance are not significant factors in relation to odds of mortality, controlling for the other factors. These variables were dropped from the analysis. The logistic regression coefficients of the remaining factors and their 95 percent confidence intervals are presented in Table 2,

separately for deaths to all road users, driver deaths and deaths to pedestrians and bicyclists. Lower risk of all deaths is associated with the presence of ESC, particularly as standard equipment, good performance on the offset frontal and side crash tests, static stability of 1.2 or higher, and faster acceleration from 0 to 60 miles per hour. Drivers have lower risk of death when fuel economy is lower but the correlation reverses for all deaths – particularly pedestrian and bicyclist deaths. Vans and SUVs have lower overall death rates when the other factors are controlled.

Table 2 Logistic regression estimates of the preventive effects of vehicle factors

	All road users	Drivers	Pedestrians and bicyclists
	Coefficient (95% CI)	Coefficient (95% CI)	Coefficient (95% CI)
Intercept	0.2468	-1.7855	-2.9905
ESC standard	-0.5764 (-0.669 to -0.484)	-0.7806 (-0.943 to -0.618)	-0.4813 (-0.617 to -0.345)
ESC optional	-0.2551 (-0.297 to -0.213)	-0.3304 (-0.397 to -0.264)	-0.2014 (-0.270 to -0.133)
Front crash test	0.1329 (0.105 to 0.161)	0.3758 (0.339 to 0.413)	0.0928 (0.045 to 0.141)
Side crash test	0.0111 (0.010 to 0.012)	0.0090 (0.007 to 0.011)	0.0030 (0.001 to 0.005)
T/2H<1.2, else 1.2	-8.7614 (-9.559 to -7.964)	-8.258 (-9.532 to -6.985)	-6.0460 (-7.313 to -4.779)
Acceleration	0.0477 (0.034 to 0.062)	0.0687 (0.048 to 0.089)	0.0483 (0.024 to 0.073)
Fuel economy	-0.1100 (-0.114 to -0.106)	0.0036 (-0.002 to 0.009)	-0.0260 (-0.032 to -0.020)
Van	-0.3266 (-0.394 to -0.259)	-0.9167 (-1.034 to -0.799)	-0.3283 (-0.435 to -0.221)
SUV	-0.2994 (-0.369 to -0.230)	-0.5262 (-0.633 to -0.419)	-0.3548 (-0.465 to -0.244)

I calculated the reduction in deaths achievable by changing a given vehicle characteristic as other characteristics remained the same by substituting the value of a given variable in the regression equation for total deaths, applying the rate to the number of vehicles in use for each vehicle, subtracting the result from the actual total deaths, and summing the result across the vehicles. If all vehicles were equipped with ESC, the estimated death reduction would be 11,098, about 42 percent of the total. If all of the vehicles averaged one on the offset frontal crash test index, there would have been approximately 2211 fewer deaths, 8.6 percent of the total. If the vehicles that had injury criteria above average on the side crash tests were improved to the average, 4950 (19.4 percent) deaths would have been prevented. A static stability of 1.2 or higher among vehicles

with lower stability would have prevented 2737 deaths, 10.7 percent of the total deaths.

The effects of weight-power, reflected by fuel economy, and acceleration time were much less. If the weight and horsepower of all vehicles that had less than average fuel economy (28.4 miles per gallon) were changed to the average, the death reduction would be 492, 1.9 percent of the total. Achieving average acceleration time (9.4 seconds) for those with more would result in 495 fewer deaths, 1.9 percent of the total. The percentages add to an 85 percent potential reduction in deaths if all vehicles had the best of the mentioned characteristics.

For environmental or behavioral factors to confound these results, they would have to be correlated substantially with the vehicle factors. Since there are no data on the exposure to environmental and behavioral factors by make/model of vehicles, the potential for confounding must be assessed indirectly. If there were potential confounders among major known risk factors, they would be revealed by the correlation of ratios of lower to higher risk in the fatal crashes. Formally,

$$C(L/H) = RL/RH = b(\text{vehicle factor}), \text{ where}$$

L = low exposure to a risk factor

H = high exposure to a risk factor

c = constant ratio of risk from low- to high-risk factor

RL = fatal rollovers in low-risk-factor situations

RH = fatal rollovers in high-risk-factor situations

b = slope of the correlation.

Table 3 contains the correlations of the ratios of lower to higher risk environmental and behavioral factors relative to the vehicle characteristics and equipment. Almost all of the correlations are low and are not consistently in the direction of confounding. The two large correlations are opposite from what one would expect if there were confounding. Vehicles with poor scores in side crash tests are more involved in urban areas where risk of fatalities is lower than in rural areas but the specific risk of a side crash at an intersection is higher than in rural areas. The correlation does not suggest confounding but increases confidence in the specification of the effect of side crashworthiness. Drivers of vehicles equipped with ESC are somewhat less likely to have a valid driver's license, the opposite expected from confounding.

Table 3 Correlation of vehicle characteristics, environmental and behavioral variables

	Front crash test	Static stability	ESC optional	ESC standard	Side crash test	Acceleration time	Fuel economy
Environment							
Urban/rural	0.035	0.292	0.081	-0.200	0.602	-0.180	0.206
Interstate/other	-0.159	0.178	0.285	0.300	-0.036	-0.291	-0.086
Onroad/off	-0.194	0.013	0.005	-0.030	-0.268	0.050	-0.227
3+ lanes/2 lanes	-0.160	0.189	0.033	0.386	-0.102	-0.121	-0.204
Speed limit<55/55+	-0.136	0.126	0.086	0.324	-0.092	-0.193	-0.128
Straight/curve	-0.174	0.240	0.159	0.319	-0.025	-0.254	-0.123
Level/grade	-0.160	0.044	-0.112	0.168	-0.064	-0.016	-0.232
Concrete/blacktop	-0.220	0.152	0.122	-0.032	0.101	-0.027	-0.141
Dry/wet	-0.141	0.062	0.193	-0.081	0.069	-0.003	-0.051
Daylight/other behavior	-0.132	0.001	0.073	0.228	0.001	-0.112	-0.193
Valid license/other	0.202	0.349	-0.371	-0.572	-0.209	-0.148	-0.206
No prior crash/1+	-0.046	0.050	0.133	0.199	0.100	0.149	-0.048
No prior suspension/1+	0.115	-0.034	-0.087	-0.007	-0.056	-0.074	-0.189
No prior driving while intoxicated/1+	0.002	0.040	0.089	0.150	0.102	0.103	-0.170
No prior speeding/1+	0.145	-0.020	-0.044	0.045	0.133	0.073	-0.248
No other conviction/1+	0.017	0.017	0.063	0.167	0.170	0.152	-0.215
No blood alcohol/.01+	0.046	-0.015	-0.042	0.147	0.126	0.097	-0.211
No illegal blood alcohol/1+	0.028	0.037	-0.024	0.101	0.133	0.115	-0.239
Age 25+ /<25	0.028	0.029	0.051	0.171	0.198	0.110	-0.173
Women/men	-0.043	0.056	0.181	0.294	0.296	0.234	-0.127

When the effect of each factor is corrected for the effect of the others, the estimated effect of electronic stability control is similar to the estimate from the cited research comparing vehicles of the same make-model before and after adoption of the technology. The effects of “good” scores on offset crash tests and power-weight reflected by fuel economy are

less than expected from previous research. Apparently, ESC would prevent some of the deaths formerly attributed to the other factors.

Electronic stability control is the most important innovation in reduction of vehicle-related mortality in decades, perhaps the single most effective innovation since the invention of seat belts. In contrast to seat belts which have to be worn to be effective, ESC works automatically. If all vehicle purchasers bought only vehicles with ESC and good offset frontal and side crash test ratings, deaths would be reduced by more than half after the older vehicles were scrapped. Although pickup trucks were not included for technical reasons, the results should apply to them as well. Pickups as a class have higher death rates than passenger cars, vans and SUVs. Few pickups on the market in the U.S. had ESC or did well on crash tests at the time of this study.

Although the effect of low static stability is less than in previous studies, apparently because ESC reduces some rollovers caused by instability, the effect of T/2H remains substantial. The installation of ESC does not totally negate the need to achieve a minimum static stability of 1.2 or higher.

A surprise in the results is the lack of effect of braking distance. Since ESC works by selectively applying brakes to wheels and could account for some of the same variance, a regression of the other factors and braking distance was done excluding vehicles with standard or optional ESC. No effect of braking distance was found among these vehicles either. The measurement of braking distance is somewhat subjective, dependent on the ability of the test driver to apply brakes fully while controlling the vehicle. It may not be possible to obtain an objective measure of braking distance that is applicable to drivers in panic situations.

While driver death rates are lower in vehicles with more weight power, their excess involvement in bicyclist and pedestrian deaths more than offsets the advantage to drivers and occupants in such vehicles. In addition, heavy vehicles are over involved in deaths to children backed over in home driveways, deaths that are not reported in FARS because they do not happen on public roads (Brisson, et al, 1988). They dump more carcinogenic polycyclic aromatic hydrocarbons and greenhouse gasses in the environment and deplete oil supplies. If vehicles have ESC and perform well on crash tests, there is little advantage in risk reduction to drivers who select a vehicle based on heavier weight and far more harm to others. Vehicles that are too small to protect occupants do poorly on crash tests and can be avoided on that basis.

The major threat to the validity of the conclusions of this study is the potential selectivity by risk conscious vehicle buyers who select vehicles based on crashworthiness tests and ESC. The lack of correlation of the major known behavioral risk factors with vehicle characteristics suggest that such selectivity did not occur to the extent that selectivity is manifested in well-known indicators of relative risks among drivers. Seat belt use is not included in the study because police and occupant reports of belt use in crashes have proved unreliable when crash recorder data are compared to reported belt use (Gabler, et al, 2004). Nonuse of belts is highly correlated to illegal alcohol concentrations among drivers (Foss, et al, 1994). The lack of correlation of alcohol and the vehicle characteristics studied here suggest that there is no systematic choice of less safe vehicles by higher risk drivers.

The significant correlation of reductions in pedestrian and bicyclist deaths with crash test results suggests some degree

of selectivity in buying vehicles that do well on crash tests by drivers less likely to hit other road users or drive in environments where there is less exposure to pedestrians and bicyclists. There is no reason to expect that front and side crashworthiness would reduce pedestrian and bicyclists deaths. Yet, when the regression results on other road users are used to estimate death reductions, pedestrian and bicyclists are 22.5 percent of the reduction in deaths attributed to good offset frontal crash tests and 9.4 percent attributed to better than average side protection. Even if 25 percent of the effects of each of the vehicle factors is attributable to selectivity, however, total deaths would have been 64 percent lower if each of the vehicles met the criteria mentioned on each factor.

This is a study of the effects of preventive measures, not causation. When such research is reported, vehicle manufacturers and others often comment that the main cause of vehicle crashes is behavior. The inference in such comments is that preventive efforts should be directed at the major causes. In fact, changing only necessary conditions for harmful results substantially prevents a variety of diseases and injuries (Chapter 7). ESC detects when the vehicle is nearing loss of control and adjusts throttle, braking and suspension accordingly. While changing vehicles does not preclude efforts to change behavior, the results of this study indicate that a substantial majority of vehicle-related deaths can be prevented by full adoption of changes in vehicle characteristics that are preventative, whatever the complex mix of factors that lead to serious crashes. By 2011, as more vehicles had ESC and did better on crash tests, several makes and models of vehicles experienced no occupant fatalities

<http://www.iihs.org/iihs/sr/statusreport/article/50/1/1>).

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