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## Education Corner

# The epidemiologic principles underlying traffic safety study designs

June H Kim and Stephen J Mooney\*

Department of Epidemiology, Columbia University, New York, NY, USA

\*Corresponding author. Department of Epidemiology, Mailman School of Public Health, Columbia University, 722 W. 168th St, Room 729, New York, NY 10032, USA. E-mail: [sjm2186@cumc.columbia.edu](mailto:sjm2186@cumc.columbia.edu)

Accepted 26 May 2016

### Abstract

This article describes the epidemiological principles underlying four observational study designs commonly used to assess traffic safety: the case-control, case-crossover, culpability and quasi-induced exposure designs. We focus in particular on the specific challenges for preventing bias using each design. Whereas recruiting controls representative of the source population poses a special challenge in case-control traffic safety studies, case-crossover designs are prone to recall bias, and culpability and quasi-induced exposure studies can be undermined by difficulties assigning crash responsibility. Using causal diagrams and worked examples, we provide a simple way to teach traffic safety designs to epidemiologists and to encourage proper application of epidemiological principles among researchers designing traffic safety studies.

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### Key Messages

- Four observational study designs are often used to assess traffic safety risk factors, including two related designs unique to traffic safety: the culpability and quasi-induced exposure designs.
- These study designs differ in underlying assumptions and in how results should be interpreted.
- Careful consideration of the exposure of interest is important when selecting a traffic safety study design.

### Introduction

Observational studies are a necessary complement to laboratory-based experiments for assessing factors contributing to traffic safety.<sup>1</sup> However, observational studies have often failed to reach consensus regarding whether specific factors influence crash risk, including use of cannabis,<sup>2</sup> other drugs,<sup>3</sup> cellphones<sup>4</sup> or the influence of other

passengers.<sup>5</sup> These discrepancies can partially be attributed to design differences across the observational studies employed. A deeper grasp of these designs can help not only to synthesize findings across previous studies but also to develop more informative future studies. To that end, we review four of the most common observational study designs in traffic safety research, with particular emphasis on

potential sources of bias that may lead to conflicting results.

Because traffic crashes are rare and many exposures that raise individuals' crash risk factors (e.g. alcohol consumption) are transient, cohort traffic safety studies are impractical. Observational traffic safety studies therefore typically employ retrospective designs treating drivers who have been involved in crashes as cases. Researchers then select one of three comparison techniques resulting in four study design types: (i) in a case-control design, cases are compared with control subjects selected independently of the case's crash event; (ii) in a case-crossover design, each case is compared with herself or himself at another time point; and (iii) in a responsibility design, the subset of the cases deemed responsible for crashes is compared with the subset not responsible. There are two common forms of responsibility designs: in culpability designs, all responsible cases are compared with those not responsible. By contrast, in quasi-induced exposure designs, at most one responsible case in each crash is compared with the not-responsible cases involved in the same crash. Figure 1 is a taxonomy of these four study design types.

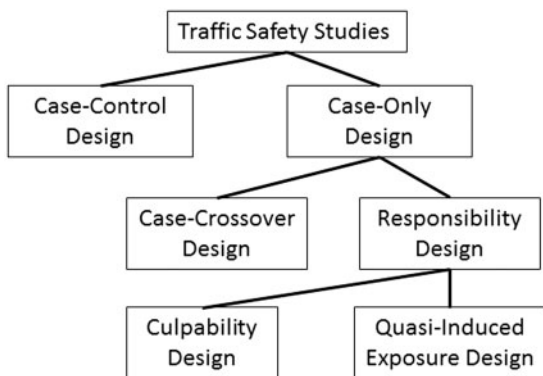


Figure 1. A taxonomy of observational study designs used to assess traffic safety.

### The case-control design

The source population for traffic safety designs is a dynamic cohort of adults driving in a defined geographical area over the course of the ascertainment period. An ideal cohort study would estimate the rate ratio as the crash rate in exposed drivers ( $a/t_1$  in Table 1) divided by the crash rate among a group of non-exposed drivers (i.e.  $c/t_0$  in Table 1).

However, although the number of crashes is readily available within crash surveillance datasets, the denominator for these rates ( $t_1$  and  $t_0$  in Table 1) is not.<sup>6</sup> Without an estimate of exposure (i.e. the denominator), crash rates cannot be calculated. In some scenarios, group measures may be used as a proxy for individual exposure (e.g. using an aggregate measure of miles driven within subgroups), but such studies are prone to bias if the individuals who crash are not representative of the group.<sup>7</sup> Case-control studies approximate this denominator by sampling efficiently from the underlying cohort of drivers.<sup>8</sup> Epidemiological theory holds that the exposure odds ratio for a case-control study in a dynamic cohort may not approximate a prospective rate ratio unless: (i) eligible controls are representative of the underlying source population that gave rise to the cases; and (ii) both cases and controls are sampled independently of their exposure

For traffic safety studies, the source population shows substantial periodic fluctuation: it is larger during weekday rush hours, less late at night, etc. and these population fluctuations may be correlated with exposure status for some risk factors of considerable interest. For example, drivers may be less likely to have cellphone conversations while driving late at night when potential conversation partners are asleep. To account for this fluctuation in population at risk, case-control traffic safety studies typically attempt to sample controls under similar driving conditions (e.g. at the same location and time of the week) to those under which the cases arose<sup>9</sup> or restrict cases to those that match

Table 1. Idealized cohort and exposure distribution across study samples and different designs for a traffic safety study assessing the effects of cannabis use

|                                  | Idealized cohort  |         |               | Traditional case-control |                       | Case-crossover     | Responsibility (culpability or quasi-induced exposure) |                       |
|----------------------------------|-------------------|---------|---------------|--------------------------|-----------------------|--------------------|--|-----------------------|
|                                  | Total person-time | Crashed | Did not crash | Cases <sup>a</sup>       | Controls <sup>b</sup> | Cases <sup>c</sup> | Cases <sup>d</sup>                                     | Controls <sup>e</sup> |
| Exposed<br>Blood thc > 1 ng/ml   | $t_1$             | a       | b             | $a'$                     | $b'$                  | $a_a$              | $b_a$  | a                     |
| Unexposed<br>Blood thc ≤ 1 ng/ml | $t_0$             | c       | d             | $c'$                     | $d'$                  | $c_c$              | $d_c$  | $a_t$                 |

<sup>a</sup>Traditional cases, <sup>b</sup>Traditional controls, <sup>c</sup>Case-crossover designs compare exposure within person-time within cases, <sup>d</sup>Culpable cases, <sup>e</sup>Non-culpable cases.

**Table 2.** Example of selection bias in a case-control traffic safety study

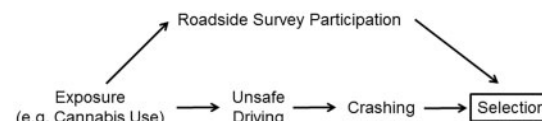
|   | All drivers | Did not crash | Selected controls           | Crashed |
|---|-------------|---------------|-----------------------------|---------|
| Exposed   |             |               |                             |         |
| Blood thc > 1 ng/ml   | 10000       | 9700          | 243                         | 300     |
| Unexposed   |             |               |                             |         |
| Blood thc <= 1 ng/ml  | 90000       | 88200         | 4410                        | 1800    |
| Total   | 100000      | 97900         | 4653                        | 2100    |
| Parameters: Pr (exposed) = 0.1; risk (unexposed) = 0.02; risk ratio (RR) (crash exposure) = 1.5; Pr (control exposed) = 0.025; Pr (control unexposed) = 0.05. |             |               | Prospective RR              | 1.50    |
|   |             |               | Prospective odds ratio (OR) | 1.52    |
|   |             |               | Case-control OR             | 3.03    |

the sampling frame of the controls.<sup>10</sup> In practice, control recruitment generally takes the form of roadside surveys where law enforcement and researchers set up a data collection site and randomly select vehicles to assess, inviting each vehicle's driver to participate in the survey.<sup>11</sup>

However, if either of the two key principles of control recruitment - source population representativeness and sampling independent of exposure status - fail to hold, then the resulting odds ratio will be a biased estimate of the true rate ratio. Suppose for example, that within a given geographical area over a given period of time, there were 100 000 drivers each contributing one 1-h driving trip. Among this population of drivers, 10% recently consumed cannabis, and those who had ingested cannabis were 50% more likely to crash compared with cannabis-free drivers and were twice as likely to refuse to participate in a roadside survey. Such a study would result in an observed odds ratio more than double the prospective rate ratio (Table 2).

The potential for selection bias in a case-control design, then, may depend greatly on whether drivers anticipate potential consequences for reporting exposure. For example, researchers employing case-control designs to assess collision risk associated with the presence of children in the car may expect relatively little selection bias, whereas researchers studying recent drug use face the daunting task of recruiting consenting drivers to serve as controls independent of their recent drug use. Figure 2 is a directed acyclic graph (DAG) representing the case-control design often employed in traffic studies. We emphasize that if exposed drivers opt to participate in the roadside survey at lower rates compared with unexposed drivers, both control recruitment principles are violated and the observed odds ratio is biased away from the null.

Some researchers using case-control designs have attempted to minimize this selection bias by sampling controls whose drug use would be less subject to concealment, such as using a sample of adults reporting to emergency



**Figure 2.** Collider-stratification (selection) bias in a case-control traffic safety study. The square around selection indicates that the study design implicitly conditions on meeting selection criteria.

rooms for non-traumatic reasons.<sup>12</sup> Conceptually, such a control selection procedure results in controls sampled independently of reported exposure status, equivalent to removing the arrow from exposure to survey participation in Figure 2. However this strategy can also be problematic, as these controls do not represent the source population (i.e. drivers) at the time the exposure was measured, which is the purpose of controls in a case-control study.<sup>8</sup> For example, if adults seeking emergency care for reasons other than trauma are disproportionately afflicted by previous morbidity, then their exposure to 'party drugs' such as ecstasy would likely understate that of the driving population, thereby biasing odds ratios away from the null.

### Case-crossover designs

Case-crossover designs avoid the potential for control selection to bias findings by allowing cases to serve as their own controls. By comparing each case's exposure status at the time of the crash to his or her exposure status at another time point,<sup>13-15</sup> the case-crossover design allows investigators to control for time-fixed potential confounding variables such as age and sex.<sup>1</sup> However, because exposure status must be measured retrospectively, this design is also vulnerable to reporting biases, especially for stigmatized exposures. For example, a subject who had recently been involved in a collision after consuming prescription opioids might be concerned that reporting consumption of prescription opioids at another time point might flag him or her as a problem user. The case-crossover design is thus

best suited for traffic safety studies investigating exposures that can be ascertained without self-report, such as driver cellphone use<sup>16</sup> or receiving a traffic citation.<sup>17</sup> The case-crossover design also cannot control for time-varying contextual factors. For example, if night-time drivers are less likely to use cell phones as well as more likely to crash compared with daytime drivers, cellphone use may be under-represented among time points in which the cases crashed (e.g. during the night) compared with time points in which they did not (e.g. during the day). This could result in the appearance of a null (or even protective) effect of cellphone use, even if cellphone use actually increases crash risk due to distracted driving.<sup>18</sup>

### Responsibility designs

Responsibility studies also bypass the control selection conundrum by focusing solely on cases. Instead of comparing cases with themselves at another period in time, however, drivers who crashed are classified as either responsible ( $a_a + c_c$ ) or non-responsible ( $b_a + d_c$ ). The exposure distribution among responsible drivers can then be compared with the exposure distribution among non-responsible drivers. Thus, these studies assess whether the exposure increases the risk of crash responsibility, rather than crash involvement, as the case-control and case-crossover designs do. In both culpability and quasi-induced exposure (QIE) studies, responsibility assignment can be based on police citations,<sup>19</sup> and blind ratings of crash responsibility can be based upon validated tools<sup>20,21</sup> or the presence/absence of driver-related factors as evidence for crash initiation or innocence.<sup>22,23</sup>

The distinction between the culpability and QIE designs lies in how drivers are sampled. In culpability studies, drivers are selected from a registry without regard to accident type (e.g. single-vehicle versus multi-vehicle), and responsibility is determined separately for each individual driver.<sup>20,21,24–27</sup> Drivers are typically rated as either responsible, contributory (i.e. sharing a degree of responsibility) or non-responsible. Contributory drivers are generally excluded entirely<sup>21</sup> or included among the responsible drivers.<sup>28</sup> Drivers involved in single-vehicle crashes are generally considered responsible for their crash, though the assumption that crash risk is equivalent between those involved in single-vehicle and multi-vehicle accidents may not be valid.<sup>29</sup>

By contrast, in QIE designs, drivers are sampled from crash sets; that is, pairs of drivers are selected from each multi-vehicle crash. QIE designs are usually limited to two-vehicle ‘clean’ crashes in which one driver each is deemed the responsible party and the other is deemed the non-responsible party. Two-vehicle crashes with concordant

pairs of drivers (e.g., both responsible or both non-responsible) are not informative and are therefore excluded.<sup>29</sup> QIE designs can also be extended to include multi-vehicle crashes, allowing for more than one non-responsible driver per crash.<sup>30</sup> In epidemiological terms, the QIE’s method of sampling pairs of drivers from the same crash is a form of matching which, by design, controls for factors that gave rise to the match (e.g. time of day, road conditions etc.) but also requires statistical analysis accounting for the matching, such as conditional logistic regression,<sup>31</sup> and precludes conventional investigation of the matched risk factors.<sup>32</sup>

Although the method of sampling differs, the key underlying assumption inherent in both QIE and culpability designs is the same: the odds of exposure among non-responsible drivers ( $b_a/d_c$ ) are assumed to represent the exposure odds in the underlying source population ( $t_1/t_0$ ). If this assumption is valid, then the odds ratio of a given exposure comparing responsible with non-responsible drivers estimates the relative increase in risk of crash responsibility associated with that exposure. Under the assumptions that responsibility represents a necessary component of a sufficient cause of a crash and that non-responsibility never represents a component cause,<sup>33</sup> the risk of crash responsibility estimates the risk of crash involvement. That is, if non-responsible drivers share no responsibility for the crashes they are in, then their involvement in the accident can be thought of as purely a product of being in the wrong place at the wrong time—i.e. random.<sup>34</sup> Under this assumption, which can be achieved only with a perfect measure of culpability, non-responsible drivers would accurately represent the exposure distribution in the source population that gave rise to the cases, and thus estimates of the risk ratio for crash responsibility

### Limitations of responsibility designs

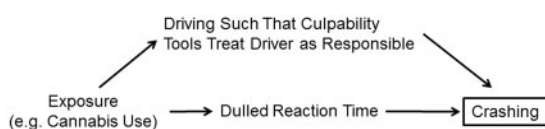
Unfortunately, assigning responsibility accurately can be problematic. Responsibility determined by police citation can induce bias if the non-responsible driver’s exposure (e.g. cannabis use) increases the probability of receiving a citation in situations where he/she is actually not responsible for the crash. Further, responsibility as determined by assessors is also problematic. Responsibility assessors have incomplete, often driver-reported, details about the crash circumstances, and need to imagine a counterfactual scenario in which one driver could have behaved differently. As no gold-standard measure is possible, it is hard to know if responsibility tools accurately conceptualize and capture the ideal counterfactual comparison needed to assess crash risk.<sup>34</sup> Because responsibility assessment classifies drivers’ outcome status, the validity of culpability and QIE designs

is contingent upon minimizing responsibility misclassification, particularly differential (exposure-dependent) misclassification. That is, the sensitivity and specificity of the responsibility measure must be consistent for all drivers, regardless of recent exposure status.

A secondary concern regarding responsibility measurement is that responsibility measured as ‘the absence of mitigating factors’ can result in a culpability definition that is synonymous with ‘culpable’ conditions (e.g. good weather, well-maintained roads).<sup>18</sup> This definition is problematic because these conditions influence driver behaviour, including choosing to drive, and that influence may itself be dependent on exposure status. For example, if cannabis consumption makes potential drivers less willing to drive under poor conditions (and thus less likely to crash and be included in the study), then cannabis exposure may prevent crashes under unsafe conditions but result in the appearance of elevated crash responsibility. However, QIE studies that match responsible and non-responsible drivers involved within the same crash<sup>22,28,35</sup> eliminate the potential for variations of these factors to influence estimates of exposure risk by design, because responsible and non-responsible drivers are matched on time of day, road conditions, weather and other measured and unmeasured environmental factors.

Because both QIE and culpability designs rely on the strong assumption that non-responsible drivers are a random subset of the driving population, it is vital that these studies assess this assumption’s validity.<sup>36</sup> For example, if cannabis use results in crashes where the driver is found non-responsible but the same driver may have avoided crashing had cannabis not been used (e.g. if cannabis use dulled reaction times and thus impaired defensive driving techniques), the result would be the selection bias outlined in Figure 3.

Studies have attempted to validate the representativeness assumption in a variety of ways. Whereas it is likely that non-responsible drivers are only representative of drivers prone to similar crash types (e.g. two-vehicle crashes),<sup>29</sup> this assumption can still be checked by comparing the exposure prevalence among non-responsible drivers with estimates obtained from external sources (e.g. drivers presenting at a hospital for non-traffic injuries). An alternative approach to validation is available internal to the



**Figure 3.** Collider-stratification (selection) bias in a culpability or quasi-induced exposure study. The square around crashing indicates that the study design implicitly conditions on crashing.

crash dataset. Assuming that responsible drivers ‘choose their innocent victims at random’, the distribution of characteristics other than the exposure (e.g. driver sex) among ‘chosen’ non-responsible victims should be similar across the same characteristics of the responsible driver.<sup>6</sup> That is, male responsible drivers should initiate accidents with the same proportion of male and female non-responsible drivers as female responsible drivers. Note, however, that this test may be flawed if the characteristics themselves cluster within the driving population. For example, in a racially segregated city, Black drivers may initiate more crashes with Black drivers whereas White drivers may initiate more crashes with White drivers, simply because residential segregation results in segregated driving patterns.

An alternative use for responsibility data blends the case-control design with the culpability design by restricting cases to culpable drivers.<sup>34</sup> For example, traditional case-control studies that have assessed both ‘all crashes’ versus ‘culpable-only crashes’ generally tend to find stronger associations among the latter.<sup>37–40</sup> In an alternative twist on this approach, cases can also be restricted to single-vehicle accidents on the assumption that drivers are always responsible for single-vehicle crashes.<sup>41,41</sup> The culpable-only case-control design is appealing because culpable cases are intuitively those most likely to have been affected by exposure, but it is subject to both selection bias due to difficulties in control recruitment and bias due to differential measurement error in the responsibility assessment. Culpable-only case-control designs thus represent a synthesis of both the benefits and drawbacks of case-control and case-only designs.

## Conclusions

The purpose of this article is to reconcile traffic safety study designs with modern epidemiological methods and principles and to clarify where case-only studies may be appropriate in the field of traffic safety. Figure 4 highlights the populations eligible for each study design type.

A better understanding of the assumptions inherent in these designs, as well as their respective strengths and limitations, is necessary for a critical evaluation of the designs and findings of previous studies. Case-only methods, particularly responsibility designs, are sometimes considered inferior to traditional case-control designs.<sup>9</sup> However, a more nuanced examination of these designs reveals that they are merely subject to different sources of bias, wherein the strength of the bias is dependent on the exposure of interest. Different exposures may be most suited to different study designs (Table 3). Whereas the validity of case-control designs rests primarily on selecting controls independent of exposure status, the validity of case-

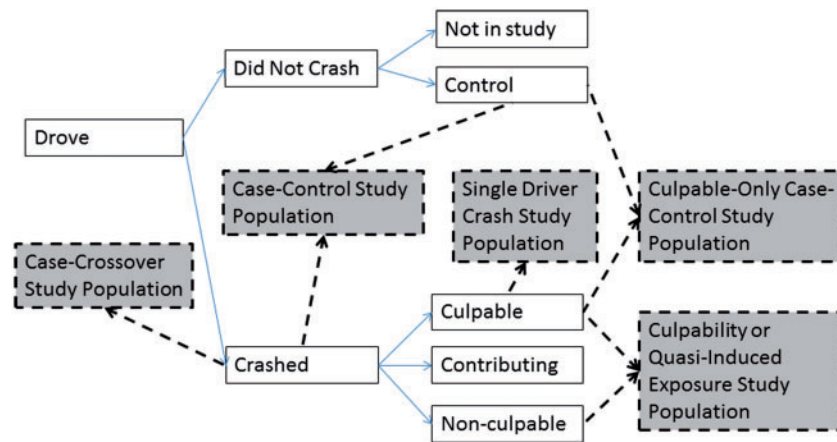


Figure 4. A taxonomy of drivers, highlighting the populations eligible for various study designs.

Table 3. Summary of traffic safety study designs

| Design                 | Cases                                  | Comparison group                                    | Assesses risk of                       | Key risk of bias  | Most suitable exposures   |
|------------------------|--|---|--|---|---|
| Case-control           | Drivers who crashed                    | Independently sampled controls                      | Crash involvement                      | Sampling controls independent of exposure                         | Exposures unlikely to cause refusal to participate (e.g. sleep history, chronic medical conditions)                     |
| Case-crossover         | Drivers who crashed                    | Cases themselves at another time point              | Crash involvement                      | Recall bias, contextual contributions to crash risk               | Administratively assessable exposures (e.g. cellphone use, previous citation)   |
| Culpability            | Drivers responsible for a crash        | Drivers involved in but not responsible for a crash | Crash responsibility                   | Responsibility assessment, contextual contributions to crash risk | Exposures assessable from biological samples that first responders are mandated to take (e.g. cannabis use, opioid use) |
| Quasi-induced exposure | Drivers responsible for a 2+ car crash | Drivers not responsible for the same 2+ car crash   | Crash responsibility in 2+ car crashes | Responsibility assessment   | Exposures assessable from biological samples that first responders are mandated to take (e.g. cannabis use, opioid use) |

crossover designs relies on valid exposure assessment at other time points and appropriate control for contextual risk factors. The validity of culpability and QIE methods is contingent upon minimizing responsibility misclassification, particularly differential (exposure-dependent) misclassification. In particular, QIE methods improve upon the culpability design by sampling within crash sets, thereby controlling by design for contextual factors such as

road lighting, time of day and weather conditions. Ultimately, evidence assembled from multiple studies employing different designs will be more informative than evidence obtained from any one design alone. No single observational study can ever be sufficient to answer a causal question.<sup>43</sup> Instead, consistency across a range of studies holding varying assumptions is necessary test the robustness of a causal hypothesis against potential

alternative explanations.<sup>44</sup> As traffic safety is increasingly recognized as a public health issue demanding rigorous study, it is critical that researchers understand the principles underlying traffic safety studies.

## Funding

This work was supported by: grants from the National Institute on Drug Abuse [grant number T32DA031099-01A1]; the National Center for Injury Prevention and Control of the Centers for Disease Control and Prevention [grant number 1R49CE002096]; and the Center for Injury Epidemiology and Prevention at Columbia. S.J.M. was partially supported by a fellowship provided by EHE International, Inc.

## Acknowledgements

The authors would like to thank Joanne Brady, Guohua Li, Andrew Rundle and Charles DiMaggio for their helpful comments on an earlier version of this work

**Conflict of interest:** None declared.

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