4. Study design: Present key elements of study design early in the paper.

**Example**

“We used a case-crossover design, a variation of a case-control design that is appropriate when a brief exposure (driver's phone use) causes a transient rise in the risk of a rare outcome (a crash). We compared a driver's use of a mobile phone at the estimated time of a crash with the same driver's use during another suitable time period. Because drivers are their own controls, the design controls for characteristics of the driver that may affect the risk of a crash but do not change over a short period of time. As it is important that risks during control periods and crash trips are similar, we compared phone activity during the hazard interval (time immediately before the crash) with phone activity during control intervals (equivalent times during which participants were driving but did not crash) in the previous week.”

**Explanation**

We advise presenting key elements of study design early in the methods section (or at the end of the introduction) so that readers can understand the basics of the study. For example, authors should indicate that the study was a cohort study, which followed people over a particular time period, and describe the group of persons that comprised the cohort and their exposure status. Similarly, if the investigation used a case-control design, the cases and controls and their source population should be described. If the study was a cross-sectional survey, the population and the point in time at which the cross-section was taken should be mentioned. When a study is a variant of the three main study types, there is an additional need for clarity. For instance, for a case-crossover study, one of the variants of the case-control design, a succinct description of the principles was given in the example above.

We recommend that authors refrain from simply calling a study ‘prospective’ or ‘retrospective’ because these terms are ill defined. One usage sees cohort and prospective as synonymous and reserves the word retrospective for case-control studies. A second usage distinguishes prospective and retrospective cohort studies according to the timing of data collection relative to when the idea for the study was developed.[31](http://journals.lww.com/epidem/Fulltext/2007/11000/Strengthening_the_Reporting_of_Observational.28.aspx#R31-28) A third usage distinguishes prospective and retrospective case-control studies depending on whether the data about the exposure of interest existed when cases were selected.[32](http://journals.lww.com/epidem/Fulltext/2007/11000/Strengthening_the_Reporting_of_Observational.28.aspx#R32-28) Some advise against using these terms, or adopting the alternatives ‘concurrent’ and ‘historical’ for describing cohort studies. In STROBE, we do not use the words prospective and retrospective, nor alternatives such as concurrent and historical. We recommend that, whenever authors use these words, they define what they mean. Most importantly, we recommend that authors describe exactly how and when data collection took place.

The first part of the methods section might also be the place to mention whether the report is one of several from a study. If a new report is in line with the original aims of the study, this is usually indicated by referring to an earlier publication and by briefly restating the salient features of the study. However, the aims of a study may also evolve over time. Researchers often use data for purposes for which they were not originally intended, including, for example, official vital statistics that were collected primarily for administrative purposes, items in questionnaires that originally were only included for completeness, or blood samples that were collected for another purpose. For example, the Physicians’ Health Study, a randomized controlled trial of aspirin and carotene, was later used to demonstrate that a point mutation in the factor V gene was associated with an increased risk of venous thrombosis but not of myocardial infarction or stroke. The secondary use of existing data is a creative part of observational research and does not necessarily make results less credible or less important. However, briefly restating the original aims might help readers understand the context of the research and possible limitations in the data.