

## **Quality Assessment Study Design Description Reference Sheet**

### Case Control Study

A study that compares patients who have a disease or outcome of interest (cases) with patients who do not have the disease or outcome (controls), and looks back retrospectively to compare how frequently the exposure to a risk factor is present in each group to determine the relationship between the risk factor and the disease. Study participants are enrolled based on disease status (i.e., case or control).

Case control studies are observational because no intervention is attempted and no attempt is made to alter the course of the disease. The goal is to retrospectively determine the exposure to the risk factor of interest from each of the two groups of individuals: cases and controls. These studies are designed to estimate odds.

Case control studies are also known as “retrospective studies” and “case-referent studies.”

### Case Report

A case report is a descriptive study of a single individual (case report) in which the possibility of an association between an observed effect and a specific exposure is based on a detailed clinical evaluation and history of the individual.

### Case Series

A case series is a descriptive study that follows a group of patients who all have the same diagnosis or who are all undergoing the same procedure/treatment over a certain period of time. Case series do not employ control groups. Results of case series can generate hypotheses that are useful in designing further studies, including randomized controlled trials. However, no causal inferences should be made from case series regarding the efficacy of the investigated treatment.

### Cohort Study

A study design that follows prospectively over time one or more populations (called cohorts) to determine which patient characteristics (risk factors) are associated with the development of a disease or outcome. As the study is conducted, the outcome from participants in each cohort is measured and relationships with specific risk factors are determined.

#### Prospective Cohort Study

In a cohort study, individuals exposed and not exposed (to suspected risk factors) are followed and compared to assess the extent to which each group experiences an outcome of interest -- often illness or death. Participants who are enrolled in the study do not have the outcome of interest at the enrolment date.

#### Retrospective Cohort Study

Most cohort studies are prospective; however, cohort studies that have reconstructed exposure data from historical records are referred to as retrospective cohort studies. In these studies, exposure and outcome data are followed up without actually following cases, which can result in considerable savings of time and money.

#### Randomized Controlled Trial

A study design that randomly assigns participants into a treatment/intervention group or a control group. As the study is conducted, the only expected difference between the treatment/intervention and control groups is the outcome variable being studied.

#### Before-After Design

A study design in which the dependent variable (such as a clinical outcome) is measured before and after an intervention in the same group of individuals. Comparison of outcome measures taken before and after the intervention is made to assess the effect of treatment.

#### Cross Sectional Study

Studies that conduct measurements on a group of subjects at one point in time. Cross-sectional studies look at both exposure and outcomes at one point in time and may be used to generate hypotheses for further investigation in prospective cohort studies or RCTs.

#### Crossover Trial

A two-period study design in which each participant serves as their own control. In the first period of the study, participants receive either the treatment or control. Then, after a “washout” period to minimize the effect of the first period, the participant switches to receiving the control or treatment, depending on which they received in the first period. Randomization is used to assign the order in which the treatment and control conditions are administered.

#### Time series

The defining feature of time series research designs is that each participant or sample is observed multiple times, and its performance is compared to its own prior performance. In other words, each participant or population serves as its own control.

#### Quasi-Experimental Study

A study design in which researchers manipulate an active independent variable but do not have

full control over the allocation or timing of the intervention. Quasi-Experimental designs are often used when it is not possible to conduct a true experiment with complete random assignment, as is often the case in policy or real-life settings.

#### Interrupted Time Series Design

Study design in which outcomes are measured repeatedly in a single group of participants both before and after a manipulation or a natural event.