

## Research study designs: an appraisal for peer reviewers and science editors

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**Abstract** Research study designs systematise scholarly works. Inadequate knowledge of research designs and reviewers' comments that are not based on research reporting standards result in low quality publications. In this paper we present some medical research designs and discuss how peer reviewers and editors should comment to ensure the adherence to research reporting standards.

**Keywords** Research design; peer reviewer; editor.

### Introduction

Adherence to research reporting standards can increase the quality of scholarly publications, which should be based on thorough data collection and systematic analysis<sup>1</sup> within the frames of a chosen study design.<sup>2-7</sup> Peer review and editorial appraisal of research studies are aimed at facilitating quality control and providing the readership with the most accurate data, translating research hypotheses into practically applicable findings.<sup>8</sup>

Limited knowledge of research designs and how to comment on them based on research reporting standards results in substandard peer review.<sup>9</sup> Peer reviewers and editors must be familiar with different research designs and skilled to provide high-quality comments.

Learned associations can take the lead in educating authors, reviewers and editors by facilitating dissemination of information on research designs, ensuring integrity in research reporting, developing programmes on editing and standards of research reporting, and endorsing reporting guidelines.<sup>10</sup>

In this paper we examine some common research designs, focusing on medical studies but many are more widely applicable. We explore how peer reviewers and editors should comment and appraise them in order to ensure the adherence to research reporting standards.

### Cohort studies

This design investigates a particular cohort with a certain trait by observation over a certain period of time.<sup>11</sup> Disease-free patients are initially classified as either exposed or unexposed and outcomes are compared using relative risk.<sup>8</sup>

Cohort studies can be retrospective, prospective or bidirectional.<sup>7</sup> A retrospective cohort study investigates historical data to evaluate the effects of a particular variable.<sup>7</sup> A prospective cohort study clarifies the effects of a certain variable on a cohort over time.<sup>11</sup> A bidirectional cohort study combines both aspects.<sup>7</sup>

Cohort studies provide incidence data, help establish a time sequence for causality, eliminate recall bias and

investigate rare exposures to risk factors.<sup>8</sup> Unfortunately, this type of design is expensive, time-consuming, does not provide details of rare outcomes and usually requires large sample sizes.<sup>8</sup> Exposure to risk factors can also change with time.<sup>8</sup>

Peer reviewers must check inclusion and exclusion criteria and pay attention to follow-up methods.

### Case-control studies

Case-control design compares the group under investigation, eg patients with a disease, and controls.<sup>11</sup> It focuses on the assessment of exposures.<sup>8</sup> Through the analysis of specifically designed questionnaires and medical case notes, data on past and present medical history of patients are gathered, enabling cross referencing between patients and statistical analyses of trends. The rationale for inclusion and exclusion of cases and controls must be detailed.

Case-control studies are relatively inexpensive, suitable for generating new hypotheses and may be executed in a short period of time. Inherent limitations of this design are that it does not establish cause-effect relationships, does not assess the incidence and prevalence of risk factors, and is prone to selection bias.<sup>8</sup>

### Cross-sectional studies

Cross-sectional design assesses selected population at a given period of time and provides conclusions for the whole population. It allows one to describe associations between several factors and to determine their prevalence.<sup>8</sup> This research design is used to identify potential areas of interest.<sup>12</sup> It may identify a specific cause of the trend in a longitudinal study.

Cross-sectional studies are quick, relatively inexpensive and useful for formulating hypotheses. However, these studies do not test cause-effect relationships.

### Reviewing cohort, case-control and cross-sectional studies

Reviewers should ensure that the study design is mentioned in the title and abstract of the articles, and that objectives are specified. In the methods section, study location, dates and follow-ups must be checked. All outcomes, exposures, predictors, potential confounders and effect modifiers must be commented on. In the statistical analyses section, reviewers should pay attention to the corrections for confounders, methods used to examine subgroups and interactions, and how missing data are addressed.

The STROBE (STrengthening the Reporting of

Observational studies in Epidemiology) guidelines<sup>13</sup> can be used as a reference for reviewing cohort, case-control and cross-sectional studies.

### Quasi-experimental design

Quasi-experimental design is used mainly in the social sciences and psychology. It identifies general trends, where preselection and randomization of groups are difficult.<sup>14</sup> Groups are initially selected without prescreening and randomization.

Reviewers must ensure the clarity of the description of subject inclusion and exclusion criteria. Clear statements regarding the details of the interventions and how and when they were administered are needed.

The TREND (Transparent Reporting of Evaluations with Nonrandomised Designs) guidelines<sup>15</sup> can be used as a reference for appraisal of quasi-experimental studies.

### Randomised controlled trials

In a randomised controlled trial, subjects are randomly allocated to test one or more interventions.<sup>16</sup> There are controlled clinical trials and controlled field trials.<sup>2</sup> This design focuses on the effects of interventions on outcomes (eg disease recurrences, mortality rates).

Randomised controlled trials are relatively expensive and the generalization of conclusions to the whole population is not always appropriate.

The appraisal of articles on such trials must ensure that the title indicates the study design. There should be a clear description of the trial design (eg parallel, factorial), allocation ratio, eligibility criteria, interventions in each group, primary and secondary outcomes.

The CONSORT (CONsolidated Standards Of Reporting Trials) guidelines<sup>17</sup> are a useful guide.

### Meta-analysis

Meta-analysis is based on statistical techniques to merge and compare results across studies.<sup>8</sup> It identifies sources of disagreement across the pooled results, and may reveal publication, aggregation and study exclusion biases.<sup>18</sup>

Reviewers must ensure that the paper identifies the report as a meta-analysis. Clear explanations are required for the background, objectives, data sources, eligibility criteria, and interventions.

The PRISMA (Preferred Reporting Items for Systematic reviews and Meta-Analyses) guidelines<sup>19</sup> can be used to comment on meta-analyses.

### Qualitative design

Qualitative design is applied in case studies, interviews and surveys. It defines concepts of hypotheses for quantitative studies. Qualitative research is often non-linear.<sup>20</sup> It requires clear description of the enrolled subjects (eg gender, social status) and their relationships. Methodology should indicate subject selection and data collection setting.

The COREQ (CONsolidated criteria for REporting Qualitative research) guidelines<sup>21</sup> provide benchmarks for reviewing this type of design.

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