

Design strategies in quantitative research – an introduction

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Research design can be broadly divided into studies describing distribution of disease, its causes and the populations involved. Analytical studies, by comparison, focus on the determinants of disease. Each type of study design has its own unique strengths and limitations.

Descriptive studies

Descriptive studies look at particular features of the population with particular reference to:

- **The individual** including for example age, sex, occupation, marital status, ethnicity, smoking, exercise or consumption of particular foods.
- **Location** including for example variation in disease or health states within the same country, between countries and comparing rural and urban areas.
- **Time** including for example comparisons of current activity with episodes 5, 10, 15 years ago, etc .or looking at seasonal variations of symptoms or injuries.

They may consider:

- **Populations** using correlational studies
- **Individuals** using
 - case reports
 - case series
 - cross-sectional surveys

1. Correlational studies

These look at entire populations and attempt to compare the frequencies of disease states. This can involve looking at different groups at the same time, or looking at the same population at different points in time. The results of correlational studies can attempt to inform hypotheses concerning disease states; the hypotheses can then be tested using different research designs.

2. Case reports.

This is the most basic type of descriptive study related to individuals. It describes the medical history of a single patient by one or more clinicians; it is communicated in a narrative fashion. This is a useful way to communicate details about unusual patients. Writing a case report can be described the first step in communicating patient information and it can be suggestive of a clinical situation that may require further investigation. Case report guidelines for the *International Journal of Osteopathic Medicine* can be found at www.authors.elsevier.com/GuideForAuthors.html?PubID=7052458&dc=GFA.

Further information on writing a case report can be found at <http://careerfocus.bmjournals.com/cgi/content/full/327/7424/s153-a>.

3. Case series

This may be the natural sequel to a case report. A case series is comprised of information concerning a number of patients who experience a particular condition. Routine surveillance programmes often use accumulated case reports to suggest the emergence of beneficial treatment strategies, reactions to treatment, new diseases or epidemics.

4. Cross-sectional surveys

This type of study looks at the assessment of an individual and their health and any exposure they may have to a particular condition. Cross-sectional studies attempt to estimate the prevalence of a disease or the prevalence of an exposure to risk factors or both. It is important when considering surveys of this nature to distinguish between prevalence and incidence. Prevalence describes the overall proportion of a population that experience a disease; incidence describes the number of new cases of a disease each year.

Analytical studies

These may include:

- Observational studies
 - case-control studies
 - cohort studies (both retrospective and prospective)
- Intervention studies (clinical trials)

Analytical studies explicitly compare two factors that are suggestive of having a cause and effect relationship in healthcare. Two broad strategies are employed when undertaking analytical studies involving observation and intervention.

1. Observational studies

The natural course of events in a specified population is observed in this study design, as its name suggests. Information is recorded concerning who develops a particular disease state (e.g. disc injury) and who has been exposed or not exposed to a particular causative influence (e.g. bouts of heavy lifting). The two basic types of observational investigation are case-control and cohort studies; these will be considered in turn.

Case-control studies

In this type of study, patients with a particular condition or disease are identified and matched with a control group of patients who may have no disease or a different disease. Alternatively the control group may be composed of patients' relatives. Information concerning past medical history is recorded verbally from the patient or by examination of medical records.

A relationship between a past exposure to a particular causal disease agent is then explored from this information. Case control studies are fundamentally concerned with examining the aetiology of a disorder or what makes a particular patient group different. The proportions of affected individuals in a group are then examined. Case control studies are not concerned with studying therapeutic interventions in the management of a disease. They are particularly helpful when studying relatively rare disease states.

Cohort studies

Cohort studies are concerned with samples of people who share a common feature, e.g. age. Subjects in at least two (or more) groups are also classified on the basis of whether or not they are experiencing a particular disease state. They are then followed to discover what happens to them during a specified time frame in the future. Cohort studies can take a considerable period of time to conduct; the follow-up time in cohort studies is generally measured in years.

Subjects in cohort studies may or may not have a disease when the group is selected for monitoring; the cause of a disorder or disease is usually the main concern of this type of

study. The extended follow-up time is employed in the expectation that some of the subjects within the selected group will have developed the disease state under scrutiny. Cohort studies are most effectively used to study disease states that are relatively common in occurrence.

Cohort studies can be defined as retrospective or prospective but clarity must be used when employing these terms. Retrospective cohort studies refer to studies where a particular outcome being investigated has already occurred. In contrast, prospective studies refer to studies where particular outcomes will occur in the future.

2. Intervention studies

Randomised controlled trials (RCTs)

Randomised controlled trials are commonly described as the “gold standard” in medical research. Interventions concerned with treatment or prevention can be efficiently and objectively tested, but no information is provided about the context of a trial or the patients’ experience of treatment.

Participants in RCTs are assigned to one treatment intervention (e.g. osteopathic treatment) or another (e.g. taking non-steroidal anti-inflammatory medication) at random; this can be achieved using a number of different strategies. Interventions can be assigned to patients according to a variety of **blinding** or masking regimes which include:

- **Single blinding:** The patient does not know the type of treatment they are receiving.
- **Double blinding:** The patients and investigators do not know the type of treatment being received.
- **Triple blinding:** In this situation the patient, the investigator and the person responsible for analysing the data do not know the type of treatment being received. This ensures that the data analysis is as objective as possible and further reduces the influence of the placebo effect.

Randomised controlled trials can utilise a **placebo** intervention. A placebo is an inactive compound which looks, tastes and smells the same as the active compound in a pharmacological study. Placebo or sham interventions can also be used when researching complex interventions, e.g. acupuncture.

The patients in RCTs are followed for a designated period of time and specified outcomes are measured, e.g. changes in levels of pain or mobility to assess the level of effectiveness of the intervention.