

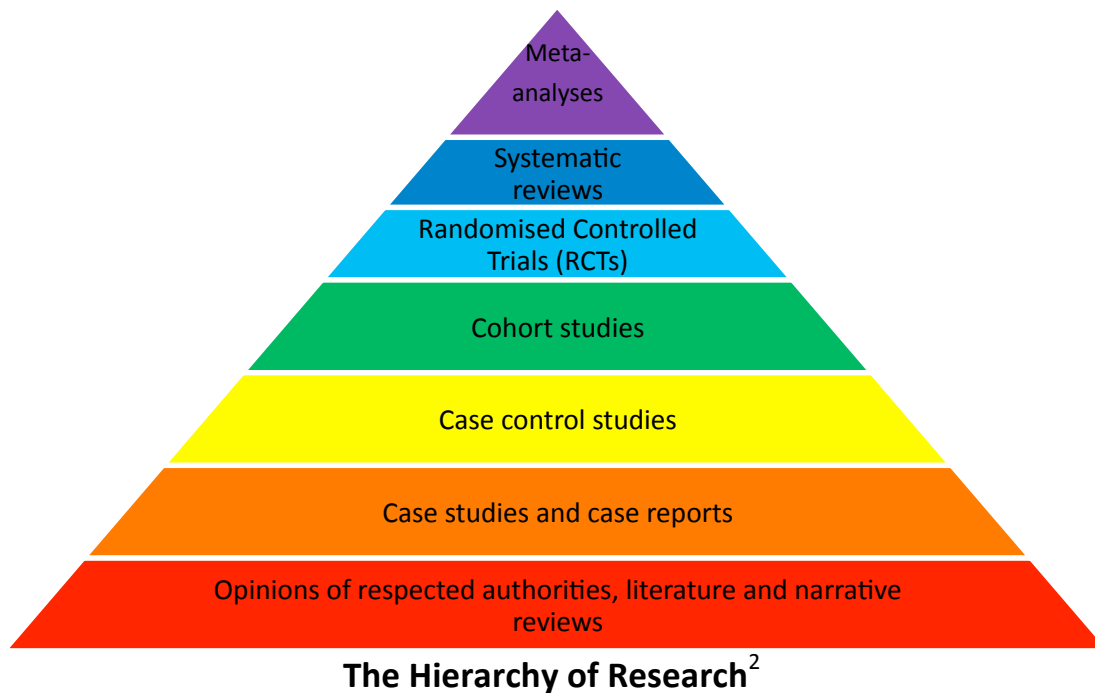
Quantitative Research Methods

INTRODUCTION

There are a variety of ways of exploring the world around us using research. Healthcare utilises a range of types of evidence to inform best practice and the direction of future research. Some types of research help us to understand disease, for example the distribution of disease, its causes and determinants and the populations involved. This information can help us direct other types of research to investigate ways of preventing and treating disease, how effective, cost-effective and safe treatments are. Another increasingly important area of enquiry in modern healthcare is patient experience; research in this area can help us to improve patient care and its access and find out what is meaningful to patients in the management of health issues.

Research methods can be viewed as being broadly composed of two different types, i.e. qualitative and quantitative. Quantitative research primarily focuses on numerical evaluation. In contrast, qualitative research involves the investigation of human experience and analysing words rather than numbers.¹ The different approaches of qualitative research will be described in a separate tutorial.

In addition, research methods exist which aim to summarise large quantities of information including literature reviews, narrative reviews, and systematic reviews. The strengths of some of the different approaches have been summarized by Sackett et al, 1996 in the Hierarchy of Research.²



QUANTITATIVE RESEARCH METHODS

Quantitative research aims to answer a specific research question; it is tangible and countable in nature and the designs are predetermined and structured, remaining consistent throughout the study making them potentially reproducible.³ They involve the researcher(s) either intervening in participants' healthcare in some way, for example, administering a treatment in order to test its effect; or observing participants without manipulating their behavior or course of treatment. There are lots of different types of interventional and observational studies; the study design is chosen based on how well it can answer the research question of interest while being ethical and cost-effective.

INTERVENTIONAL STUDIES

CLINICAL TRIALS

A clinical trial has been defined as:

'a planned experiment designed to assess the efficacy of a treatment...by comparing the outcomes in a group of patients with those observed in a comparable group of patients receiving a control treatment' Meinert, 1986.⁴ An important advantage of clinical trials is their ability to establish causality.⁵

Randomised controlled trials

Randomised controlled trials (RCTs) are commonly described as the "gold standard" in clinical 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 active treatment intervention (e.g. osteopathic treatment) or another (e.g. taking non-steroidal anti-inflammatory medication) at random; these are known as trial arms. Another group of patients will be assigned to a similar treatment which will act as a control to see whether one treatment has more effect than another. In some cases the control treatment may have little or no action and is termed a placebo. In physical therapy trials true placebos are difficult to achieve.

Random allocation of patients to a particular arm of a RCT can be achieved using a number of different strategies; the randomisation process helps to control selection bias. Randomisation can take place in a variety of ways including the use of random number generation. Some differences between participants in trials arms are likely to exist irrespective of the randomization technique employed. To address this, strategies such as block (or restricted) or stratified randomisation can be used.

The randomisation process most frequently involves individuals, but occasionally it can involve groups or populations of people. In a cluster trial, groups of participants, rather than individuals are randomised to receive either the intervention or a control.⁶ This can be useful when investigating an educational intervention, for example.

A further strategy to help reduce bias in trials is the use of **blinding** or masking regimes to keep one or more of the people involved in the trial naïve to the intervention being given or investigate. Blinding/masking regimes 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 be classified according to:

Exploring different aspects of the interventions they evaluate	- Efficacy (explanatory) trials; - Effectiveness trials; - Phase I, II, III, or IV trials in clinical drug development; - Equivalence trials.
How patients receive the intervention under investigation	- Parallel trials; - Cross-over trials; - Factorial design trials.
The number of participants receiving an intervention	- Fixed to a calculated sample size;

- N-of-1 trials and mega trials;

Whether investigators and participants are aware of which type of intervention they are receiving

- Open trials;
- Blinded or masked trials.

Parallel and crossover designs are the most common types of RCT when participant exposure to an intervention is considered.

Parallel. This between participant comparison is the most common type of RCT; all participants are treated and followed up in parallel.

Cross-over. Each participant in this type of study will receive both treatments but in a different order. This within participant design means that patients essentially act as their own control.

Factorial trial design. Two or more interventions can be compared either in combination or individually by researchers.

Non-randomised controlled trial

Participants are allocated to an intervention or control arm but the allocation is not randomised.

Before/after comparison

This involves collecting data before and after a group of participants receive an intervention. Comparing paired data makes this a useful design, however, it is not suitable for investigating long-term effects or conditions that change over time.⁶

Feasibility studies are used to help determine whether further study is appropriate for an intervention and to help define parameters which are important for the design of the future main study.^{7,8} These types of studies do not look at the outcome of interest of the main study.⁸ An example of a feasibility study in osteopathic research is Kirk et al: The effect of osteopathy in the treatment of chronic low back pain - a feasibility study.⁹

Pilot study

A pilot study is a small version of a main study that tests various components of the proposed main study and checks that they all work together.⁸ Important goals of pilot studies include defining the optimum intervention, for example, frequency and duration; and providing parameters to enable more accurate estimation of sample size.⁵

For assistance on critically appraising the quality of RCTs, a number of resources can be found at <http://www.ncor.org.uk/learning-online/critical-appraisal/>, and a helpful tool developed by CASP can be found at <http://www.casp-uk.net/#!/casp-tools-checklists/c18f8>.

OBSERVATIONAL STUDIES

Observational studies are used for many reasons in healthcare research, for example, when experimentation is unethical, difficult to implement, unnecessary or when it is not appropriate to generalize.⁶ They can be useful in generating hypotheses and identifying rare conditions or rare adverse events associated with treatments.⁶ With all observational studies, it can be difficult to establish causality and to interpret the influences of confounding variables, when compared to randomised controlled trials.⁵ There are two basic types of observational studies: these are the case-control and the cohort study.

For observational studies it is helpful to be clear about the following commonly used terms:

Prevalence	Number of instances of a given disease/condition within a population at a given time
Incidence	Number of new events occurring in a population during a given time.

Cohort studies

Cohort studies are a powerful way to determine the incidence and natural history of a condition and can also be helpful in investigating potential causes of a condition.^{10,5} Participants (cohorts) are classified according to whether they have been exposed to something of interest; this could be smoking, physical activity or a certain type of diet. The participants are then followed up after a period of time to see if the exposure or characteristic of interest is related to a specified outcome(s). For example, to answer the question: What is the prevalence of atherosclerosis in smokers compared with non-smokers?

Retrospective and prospective studies

The feature that distinguishes a prospective study from a retrospective one is simply whether the particular outcome being investigated has occurred by the time an investigator initiates a study. In a prospective study, the researcher selects a sample from the population and then measures variables of interest. This approach allows the researcher greater control over measuring variables, meaning that they can be more complete and accurate.⁵ In rare outcomes, large populations must be studied in order to observe enough outcomes for the results to be meaningful, so in this respect, a prospective cohort study could be very expensive and inefficient.⁵

In a retrospective study the sample selection, baseline and follow-up measurements will have happened in the past, meaning that it can only be carried out if adequate data relating to your outcome or risk factor is available on a cohort that has been assembled for other purposes, for example in a previous study.⁵ In addition to the overall benefits of cohort studies, a retrospective cohort study can be more cost effective and less time consuming. The disadvantage is that there is far less control over sampling methods, the type and quality of data on the predictor variables and the accuracy and completeness of this data.⁵

Case-control studies

Participants (cases) are selected depending on whether or not they have a particular disease, and their previous exposure is then determined. Case control studies provide descriptive data on the characteristics of the cases but cannot estimate incidence or prevalence because cases are not sampled from the general population, however they can estimate the strength of association between predictor variables and the presence or absence of a disease.⁵ Case-control studies are more efficient than other designs when investigating diseases that are rare or have long latent periods between exposure and development of the diseases.⁵ There are a number of opportunities for bias but if well designed, they can be useful and less expensive than many other designs.⁵

A case-control study can be “nested” within a cohort study and this is referred to as a **nested case-control** design.⁵ It is a useful design to use for investigating predictor variables that are expensive to measure. Participants (cases) who develop the outcome of interest during the study are selected and assessed as well as a sample of participants without the outcome. The sample of controls can be matched by age and sex.⁵

A slightly different approach to this design is a **nested case-cohort**, which still involves comparing cases with controls but the controls are randomly selected from the cohort, meaning that they could also have the outcome of interest. The advantage of using this approach is that it can be more useful for estimating incidence and prevalence in that population and it means that the cohort sample can be used as a comparison group for more than one outcome.⁵

DESCRIPTIVE STUDIES

Case report

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 as the first step in communicating patient information and it can be suggestive of a clinical situation that may require further investigation. Case reports include a key number of features including:

- The background to this case and why you felt it was important;
- The history, examination, investigations and their findings;
- The treatment you delivered;
- What is the cause of this condition and the scientific explanation;
- What are the standard treatments for this condition;
- How did your treatment affect the outcome for the patient;
- What are your recommendations for future treatment for patients with the same diagnosis.

Case report guidelines for the International Journal of Osteopathic Medicine can be found at <http://www.elsevier.com/journals/international-journal-of-osteopathic-medicine/1746-0689/guide-for-authors>.

Further information on writing a case report can be found at http://student.bmj.com/student/view-article.html?id=sbmj.b5274&ga=w_ga_mpopular?ga=w_ga_mpopular and

http://www.ncor.org.uk/wp-content/uploads/2012/12/How_to_write_a_case_report.pdf.

Clinical Case series

Individual case reports can be developed to a case series. This type of surveillance of a number of patients with the same disease or symptoms can provide early pointers of trends warranting further in-depth investigation using different methodological approaches.

Cross sectional (prevalence) studies

Cross-sectional studies have a similar structure to cohort studies except that the measurements are taken at one time point, with no follow-up.⁵ They describe the level or frequency of specific exposure, disease or other health related event in a defined population. They can sometimes be described as snapshots.¹⁰ Measurements of variables within a sample population are taken on a single occasion or within a short period of time¹². Since cross sectional studies only take measurements at one point in time, they are unable to establish the incidence of a disease, only the prevalence.⁵ Cross-sectional studies are useful because there is no need to wait for an outcome to occur, making them fast and inexpensive and there is no loss to follow-up.⁵ They can be used as a preliminary step for a cohort study by defining baseline demographic and clinical characteristics of a group.⁵ This study approach is not useful when trying to establish causality and they are impractical for investigating rare disease due to the large sample number needed to identify cases in the general population. However, this limitation can be addressed by carrying out the cross-sectional study on a group of diseased patients as opposed to the general population.⁵

REVIEWS OF EXISTING RESEARCH

Literature reviews are unable to answer anything that requires new evidence, however they can help to develop new ideas; justify and refine hypotheses; and help researchers to learn from and avoid failings of previous work.^{11,12,13} They can be broadly classified into three areas:

- Narrative review;
- Systematic review;
- Meta-analysis.

Literature searching can identify information from a variety of sources and such information can vary in a vast number of ways with conflicting data and biased interpretation. The conclusions of a narrative review are not sufficient to change health care practice.^{11,12} The best justifications for the delivery of health care practice come from a number of consistent results from studies identified systematically and evaluated on a consensus basis.¹⁴ The contradicting results from studies can often be explained by critically evaluating and assessing the worth of individual studies and valuing them in the context of other research

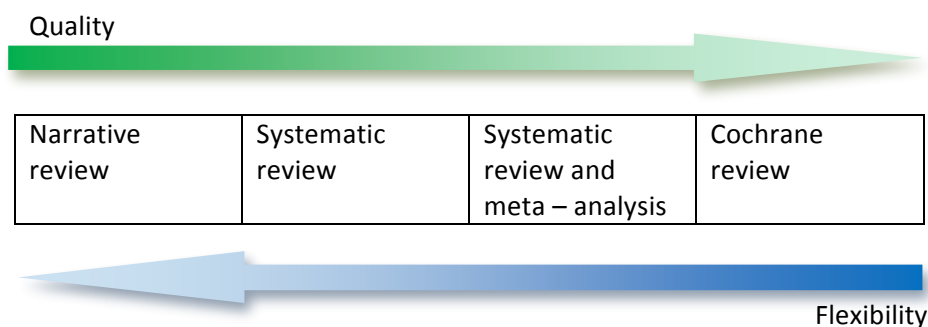
on the same topic.^{11,12} More information about critical appraisal is available on our website: <http://www.ncor.org.uk/learning-online/critical-appraisal/>.

Narrative reviews have existed in health care for many years but are often not systematic.¹⁴ They can lack focus in the research question, searching strategy and synthesis of literature so they can be difficult to repeat.¹¹ They can be prone to bias and their conclusions hard to verify.^{14,11} The purpose of a narrative review is to

- Place identified work in context when considering the research area of interest;
- Describe the relationship between the literature identified;
- Identify contradictions within the literature;
- Identify gaps in the literature and how these could be addressed.

Systematic reviews adopt a more schematic approach to answering research questions. They involve a clear search strategy, inclusion and exclusion criteria, and critical evaluation of studies by more than one researcher. The findings of the individual studies included in a review can be presented for easy analysis by clinicians. Their findings should be reported according to the PRISMA guidelines. **Cochrane reviews** are systematic reviews carried out by The Cochrane Collaboration using the predefined, rigorous and explicit methodology advocated by the Cochrane Group.¹⁵ The Cochrane Collaboration is a large international network of people who prepare, update and promote the accessibility of Cochrane reviews. Cochrane reviews are considered to be the highest quality and most rigorous systematic reviews.

When studies have been identified with sufficiently homogeneous population or interventions, their data can be pooled for **meta-analysis**. Pooled data can be analysed using a range of statistical approaches. This approach aims to try to give greater confidence in the conclusions of the review process.



SUMMARY

There are many different ways to answer a research question. Best practice in healthcare relies on a wide range of types of evidence so it is important to have an understanding of the differences and how the results of different studies can be interpreted for evidence-informed practice.

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