Research in health care

CHRISTOPHER SILAGY

Research is often described as 'organised curiosity' that is coupled with systematic problem solving. The main purpose of research is to increase our level of knowledge and understanding of a subject. Research has always been an important and integral aspect of the health care system. It spans a wide spectrum of interests and endeavour, ranging from the molecular and genetic basis of disease through to broader community issues involving the structure and effectiveness of the health care system. For example, in the area of breast cancer researchers are involved in sorting out the intricacies of genetic profiles which may predispose women to the development of the disease; clinicians in a variety of disciplines are engaged in trials to try to find effective therapies; behavioural research scientists are concerned with examining the psychosocial implications of the disease; and health service researchers are examining the benefits of providing community-based mammography screening services. At all of these levels, research has helped to improve our understanding of both health and disease, and has frequently formed the basis for developing effective therapeutic interventions which can be offered to individuals or communities.

This chapter is concerned with describing the different types of research that are most frequently used in health care, particularly in clinical settings. Later chapters will deal with specific aspects of the research process where information technology has a particularly important role to play.

Classification of research

Health care research can be broadly defined into two categories: laboratory based and clinical.

Laboratory based research is usually concerned with trying to find explanations for how and why the human body is structured or functions in a particular way. Although a lot of laboratory based research involves complex
genetic, molecular, or physiological procedures, information technology is being used increasingly as part of such research. Sophisticated computer software is now available to assist in areas as diverse as gene mapping, prediction of pharmacokinetic effects with various drugs, and dissecting anatomical structures and pathways. Laboratory based research provides an important foundation for many developments in health care; however, it will not be described here in further detail.

Clinical research, which is the main focus of this chapter, can also be divided depending on the type of data or the study design.

**Type of data**

Researchers often distinguish between use of *quantitative* data and *qualitative* data. Quantitative data involves collection of data which is measurable and which can lend itself to analysis using various statistical methods. Most clinical and epidemiological research draws heavily on quantitative methods. Measurements of parameters can be compared between people with, or without, a particular disease as well as between people who receive, or do not receive, a particular therapy. Statistics are an integral part of quantitative research. However, this does not mean that every researcher must be an expert statistician. Various computer software packages are available to assist researchers manage large amounts of data and deal with complex mathematical calculations. As a result, the important issue for researchers who rely on quantitative methods is to have an understanding of the basic concepts of data management and statistics, a working knowledge of the various software programs available, and the ability to seek out expert advice as required.

Qualitative research is concerned more with meanings and processes than simply measurements. It allows an analysis of a broad range of topics (including symptoms, processes, decisions, and outcomes) using in-depth enquiry which elaborates on data in a descriptive rather than quantitative manner. Qualitative research seeks to understand human behaviour from the subject's own frame of reference. Frequently, this type of research has been confused with subjective enquiry. This is incorrect; qualitative research has its own unique methods of data collection and rigour. These include direct (or indirect) observation, interviews, focus groups, questionnaires, videotape or audiotape recordings and narratives. Analysis of qualitative data often involves trying to identify themes or recurring patterns in how people think or behave. Although this can be a very tedious task, specific computer software has recently been developed to assist.

**Study design**

It is usual to distinguish between *observational* and *experimental* designs (Table 28.1) In observational studies, nature is allowed to take its course and changes or differences in one characteristic are related to changes in another.
### Table 28.1 Classifying clinical research study design

<table>
<thead>
<tr>
<th>Observational</th>
<th>Experimental</th>
</tr>
</thead>
<tbody>
<tr>
<td>Descriptive</td>
<td>Random allocation</td>
</tr>
<tr>
<td>• Cross-sectional survey</td>
<td>• Randomised controlled trial</td>
</tr>
<tr>
<td>• Case series</td>
<td>• Non-random allocation</td>
</tr>
<tr>
<td>Analytical</td>
<td>• Quasi-randomised trial</td>
</tr>
<tr>
<td>• Cohort study</td>
<td></td>
</tr>
<tr>
<td>• Case-control study</td>
<td></td>
</tr>
</tbody>
</table>

Observational studies are usually further sub-divided into *descriptive* or *analytical*. One of the simplest forms of descriptive research is a case series, which provides an account of one or more patients with a particular condition, syndrome, or pattern of symptoms. Often a combination of quantitative and qualitative data are collected in the process. The case series is the equivalent to applying a spotlight or using a microscope.

Probably the most widely recognised type of descriptive research is a cross-sectional study. This type of research usually examines a particular subset (or sample) chosen from the community at a single point in time. It enables data to be obtained about the proportion of the sample with a particular characteristic(s). Cross-sectional studies often use survey methodology to collect the data. If such studies follow a group of people forward in time and are repeated at various intervals, they can be useful in monitoring whether changes in a characteristic are occurring over time. For example, what proportion of people who have just had a myocardial infarction will die in the next five years? The major limitation of descriptive research is that it does not enable associations or causal links to be established between various characteristics and outcomes.

Analytical studies can be subdivided into non-experimental or experimental. Case-control and cohort studies are examples of non-experimental analytical studies. In an analytical study the investigator is concerned with attempting to explain the relationship between a variable and a particular outcome. One way in which this can be done is a cohort study, which involves identifying a group of people and following them forward (prospectively) over time. By measuring whether people within the group who are exposed to the variable (say, cigarette smoking) are more likely to develop an outcome (such as lung cancer) it is possible to make inferences about the likely association between cigarette smoking and lung cancer.

In a case-control study, the investigator begins by identifying people with the outcome of interest (i.e. ‘cases’) and then identifies another group of people who are similar in most ways except that they do not have the outcome of interest (i.e. ‘controls’). After suitable cases and controls have been selected, exposure to the variable of interest is measured and compared in the two groups. The relationship between brain tumours and exposure to high tension power lines is an example. Firstly, a group of patients with brain tumour are identified. Secondly, a group of people with similar backgrounds, but no brain tumour, are selected as controls. Then the past and/or current exposure to
high power tension lines is compared in the two groups. The major difficulty with a case-control study is selection of the control group. Frequently, the group from which controls are chosen is not representative of the study base from which the cases arose.

Experimental studies are one of the strongest weapons available to a researcher who wishes to test a hypothesis. The main reason for choosing an experimental design is to minimise the chance of bias interfering with the effect of an intervention on a particular outcome. In an experimental design, individuals are allocated to either an intervention or control group and the effect of this on the outcome of interest can then be measured. A common example is evaluation of a new drug, where 50 patients may be allocated either to receive the new test drug or a standard drug.

Randomised controlled trials are often described as the gold standard of experimental design because they effectively eliminate the major sources of bias that are present with the various research designs described previously. Unfortunately, it is not always possible to use this design and various modifications are necessary, which are referred to as quasi-experimental studies.

**Uses of research in health care**

Research is potentially of limited value if it is ultimately not applied to produce desired changes in the health care system. No matter how much is known about the molecular basis of a particular disease and the effectiveness of a particular therapeutic agent, if the therapy is not offered or used appropriately then individuals may miss out on receiving health care of an appropriate quality.

The need to ensure that research is translated into action has become a major effort in its own right in a number of health care systems in recent years. Set in a context of contracting resources, health care providers are being increasingly encouraged to ensure that resources are used most effectively. This type of thinking is part of a paradigm shift in attitude emerging within the health care system. The role of evidence based practice is being valued more highly than unsystematic reports of clinical experience in influencing decision making. High quality clinical research needs to underpin clinical practice and policy decisions.

Clinical audit, which involves documenting what currently happens in clinical practice, comparing that against a pre-determined standard, and then instituting appropriate modifications to clinical practice has become a routine part of many health care settings. For clinical audit to be effective and efficient, there is a need to have satisfactory information systems available in order to facilitate the collection and monitoring of relevant data.

Outcomes research is concerned with determining the effect of a particular intervention or service on some measurable outcome. For example, the effect of a new treatment for stomach ulcers could be measured against a range of laboratory based outcomes (such as the level of acid secretion), investigational outcome (such as ulcer healing as detected by endoscopy), or clinical outcomes (such as symptom improvement). Incorporating measures of quality of life
and economic indices as part of the outcome assessment is important if the overall effects of an intervention are to be fully assessed.

**Stages in research**

Conducting a research project involves a number of discrete stages. Each needs to be considered in detail, and generally, the greater the effort that is put into the design phase, the more likely the project is to be successful. Listed below is an outline of the six main stages in undertaking a research project. In addition to these steps it is important to set a realistic timetable and budget for the project and to give due consideration to any ethical issues that may be relevant.

- Asking a research question
- Selecting appropriate methods
- Data collection
- Data management
- Data analysis
- Presentation and dissemination of results.

**Role of information technology in research**

With the growing complexity of health care research, there is an increasing role for information technology to be utilised at various stages of most research projects. The potential uses of information technology in this context are summarised as follows:

1. Research design
   - bibliographic management/literature searching
   - determining sample sizes
   - randomisation
2. Data collection
   - use of existing computer databases (e.g. for medical records)
   - design of data collection forms
   - multi-centre data collection systems
   - data coding systems
   - safety checks on data accuracy
3. Data analysis
   - software packages (both for quantitative and qualitative analyses)
4. Presentation and dissemination of results
   - report preparation (including use of graphics)
   - dissemination via on-line systems

In some areas, information technology has almost revolutionised the ability of the researcher to access and summarise data. For example, the availability of bibliographic databases provides researchers with the tools to catalogue
references from a variety of sources, to link these with large international online databases, and to search and organise these databases in an almost endless number of combinations. Tasks that previously required extensive statistical calculation, such as sample size estimates, or tedious manual manipulation, such as randomisation of subjects in a study, can now be undertaken in a few minutes with the aid of purpose written software. Furthermore, the variety of data management and statistical analysis software that is now available means that even a novice researcher can manage large data sets simply and effectively.

Some of the special purpose software packages that are available for health care research cover multiple stages of a project, such as from the design of a questionnaire, through to data entry, analysis and then writing up the final report and preparing graphics for slides. Despite the benefits that technology has brought to the mechanics of research, it is important to remember that the most crucial aspect of a research project, asking a good question, is still very much dependent on the critical faculties of the researcher.

One of the growing trends in health care research is towards large scale multi-centred studies which involve co-ordination of data collection from a number of sites. With the advent of small portable computers and the ease of networking, it is now possible to link many sites to a central data management site.

With the increased use of computerised patient record and data management systems in a variety of health care settings, it is now possible to access large databases which contain a variety of patient information. If patient identifying details are removed from these databases, it is possible to use the non-identifiable patient data for research purposes. The quality of data extracted from these large computer-based record systems is frequently superior to that contained in written medical records. One such system which is based in the UK, known as VAMP, has been used to study adverse effects of various drugs, and sentinel practice monitoring of infectious diseases. The advantage of these large practice based systems is that results of research can be fed back into the system to use for clinical audit.

One of the least exploited uses of information technology in a research context has been the dissemination of research findings. However, as the pressure grows on health care providers and policy makers to make greater use of available evidence in their decision-making processes, it will be necessary to have ready access to research findings. On-line systems, such as INTERNET, and disk based methods can be used to disseminate research findings. Several electronic based research journals have recently been developed, which allow their subscribers to access on-line research outputs as they become available. There is obviously an enormous potential for research disseminated in this way also to be regularly up-dated.

**Future applications of information technology in health care research**

As the knowledge and technical skill with information technology systems continues to develop, the possibility for introducing innovative developments
in health care research will continue to expand. The potential for developing
computer aided decision support systems that use large research databases as
their source of 'expert knowledge' is huge. Such systems can only help to
facilitate the linking of research and health care decision making. Technical
advances in storing data on Smart Cards has potential application as a method
of storing information about participants in research studies. Similarly, with
increased networking and linkage between a variety of different points within
the health care system, it may be possible to open up new avenues of research
that were previously logistically impossible.

FURTHER READING

Publications, Oxford

London


Sackett D R, Haynes B, Tugwell P 1984 Clinical epidemiology: a basic science for
clinical medicine. Little Brown, Boston

University Press, New York


Documents that help researchers access the literature include indices to and
abstracts of these published documents.

Health care information also consists of important, but more difficult to
access, informal literature. This includes unpublished, non-copyrighted reports,
databases from other studies and surveys, and patient care protocols or facts
relating to practice, education, research or management in health care.

Bibliographic and library information retrieval systems are important
research tools and also exist in both paper (books) and computer form.

Computer-based retrieval systems may be available on-line or stored on
CD-ROM or magnetic tape. They are extremely powerful tools because of their
ability to be updated rapidly and searched widely. Computer searches allow
many users to access the same tools and information from a variety of
geographic locations at virtually the same time. These resources may be local
in nature (local area networks or LANs) or may be extensive, commercial tools
and include use of the Internet (see also Ch. 10).

Electronic bibliographic retrieval systems enable researchers to identify
documents and the location of these publications. Some systems contain more
than just the citation and allow the user to access an abstract or even the
entire text of a document via their computer terminal or printer. These tools
vary according to the scope and content of these databases. The most common
uses are current citations to published journal articles, books and monographs.

Other common information retrieval systems are the technical systems, unpublished
theses, statistical materials, computer software packages and other media
forms.

Electronic databases vary in many ways. For example: citations, patient
in a given database may use a variety of codes, such as pathology, medicine.