Introduction to Research Methods

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1. What is research?

n. a careful search: investigation: systematic investigation towards increasing the sum of knowledge (Chambers).

The term 'research' can be used to mean many things. At the end of many television programmes, someone is credited with research. This might mean finding a suitable location to represent the old country house in the library of which Poirrot reveals the identity of the murderer. In a well-known cat food commercial, viewers are assured that 'in tests, nine out ten owners said their cats preferred it'. If we assume these tests are genuine, someone must have done them and this is research. Where, when, and how they did it is anybody's guess. How about the statement that 'Incorporating a simple screening and treatment programme for subclinical vaginal infections into routine prenatal care early in the second trimester reduces the rate of spontaneous preterm deliveries by 50% in all weight categories'? This comes from the *British Medical Journal* (Kiss *et al.* 2004) and is the conclusion of a different kind of research: scientific research.

What makes this scientific research is that it is :

- ***Generalisable –*** we can apply the results to something other than the patients in the study (unlike the television research).
- ***Empirically verifiable, repeatable –*** we are told how, where and when it was done, so we could check that it had actually been done and repeat it to check that we got the same results (unlike the cat food commercial).
- ***Transparency of decision making –*** we know what was done and why.
- ***Builds on the work of others –*** the authors refer to earlier research which showed that infections are related to increased risk of preterm delivery and earlier attempts to intervene.
- ***Generates new ideas for testing –*** We can ask what features of the programme led to the effect, e.g. treatment of bacterial or fungal infections.

Scientific research follows the scientific method:

1. Start with an idea or theory.
2. Devise an investigation to test the theory.
3. Carry out the investigation.
4. If the results do not support the theory, think of a new theory.

2. Evidence-based practice

Why should we be interested in research?

In the past, decisions about methods of diagnosis and treatment were based on authority. The opinion of the eminent practitioner, based on experience and the earlier authority of others, was the main source of information. As health care became more scientific, experience became more formalised, in the form of controlled experiments and formal data collection, following the work of early pioneers such as Pierre-Charles-Alexandre Louis, Florence Nightingale, and John Snow and later innovators such as Richard Doll and Austin Bradford Hill. Now, practitioners are encouraged to use scientific data as the source of their decisions about methods of diagnosis and treatment. We are in the era of evidence-based medicine. This is a shift in the paradigm of health care in all its branches, from authority-based to evidence-based practice.

This evidence can be approached at various levels. The fundamental level is the paper reporting the results of an individual study. This is important for papers closely related to the practitioner's own activity. The next level is the review article, which puts together the evidence and opinion on a topic. Next is the meta-analysis, which combines all the available studies of a topic to give a single estimate of a treatment effect, etc. The Cochrane Collaboration is a world wide, UK initiated project to provide reviews and meta-analyses of all known treatments for all known conditions. It is named after a great UK pioneer of evidence-based medicine, Archie Cochrane. Cochrane Collaboration reviews are updated regularly and distributed in electronic form.

3. Types of health care research

Research is often divided into two broad categories: explanatory and pragmatic. By 'explanatory' we mean theoretical research to test hypotheses about health, disease, and those who are concerned with them. For example, we could ask 'Does air pollution affect health?'. Pragmatic research is applied or policy research. We are concerned with estimation rather than testing hypotheses. For example, a pragmatic question might be 'How many deaths (if any) each year are attributable to air pollution?' or 'Would reducing air pollution reduce the number of deaths?'.

4. Generating research questions

When we want to do some research, we usually start with a generalised, ill-focused question, for example 'Does air pollution affect health?'. As it stands we cannot design a research project to answer this, it is too general. We have to refine our question to a narrower, more specific question: a hypothesis to test or a quantity to estimate. For example, we might ask 'Was there an increase in deaths following an air pollution episode in London?' or 'Are daily rises and falls in air pollution accompanied by rises and falls in hospital admissions for asthma?' (The answers to both are 'yes', Anderson *et al.* 1995; 1996).

For another example, Richard Doll and Austin Bradford Hill started with the general question 'Why has the incidence of lung cancer increased?'. Their main theory was that the increase in air pollution from road traffic was responsible, but they thought that they should look at other ways in which pollutants might enter the lungs. Their research question became 'Do lung cancer patients have greater exposure to air pollution or cigarette smoke than do patients with other diseases?' (Doll and Hill 1950). As the main difference was in cigarette smoking, they developed another question: 'Is the proportion of smokers who develop lung cancer over five years greater than the proportion for non-smokers?' (Doll and Hill 1956). And so on.

5. Planning a research study

Research is not easy. After all, when you do research, you are doing something no-one else has done. It is essential to approach it in a systematic way. There are several things that must be decided:

1. Decide the research question and your aims and objectives
2. Is the answer already known? - literature review
3. Research team
4. Study population
5. Study design, sample size
6. Data collection --- what and how
7. Data analysis
8. Presentation

Having done this, these decisions should be incorporated into a protocol which describes what you intend to do and why. This should include a timetable so that you can check that the research is on track.

Health care research can be costly and you may need to seek funding for it. There is no point in doing this until the protocol is drawn up. You will almost certainly have to seek the approval of a research ethics committee and research governance approval from a trust R&D committee. This can be very, very time-consuming.

Having done all that, if you still have strength, you can do the research!

6. The health care literature

The ability to read the health care literature critically is the essential skill for evidence-based practice. The health care literature is the written repository of knowledge. It includes scientific journals such as the *Lancet*, books, conference proceedings, reports, etc. Some of these are produced in electronic form, most on paper.

The core of the health care literature is the journals. There is a large number of these. Some are general journals, such as the *Lancet* and the *British Medical Journal*, which are directed at all doctors and others interested in medicine. Others are specialized, such as the *British Journal of Obstetrics and Gynaecology*, and are directed at clinicians working in a particular field.

These journals contain a variety of articles. The main part of the journal is usually the research reports, the results of new research which are published so that others can learn from them, criticize them, and put what has been learned into practice. They are also published for other reasons of course, such as to enhance the reputation of the authors. Most journals carry correspondence arising from these research reports, letters of support or criticism. Journals also include reviews summarising current knowledge, opinion on the medical issues of the day, book reviews, educational articles for doctors, news, obituaries, job ads, etc. It is research reports with which we shall be concerned.

Inspection of the research reports in journals will show that you need two things to understand a paper. One is a knowledge of the topic being investigated, such as the disease which is being treated, the drugs which are being prescribed, the possible approaches to treatment, etc. The other is an understanding of the research methods being used, the difference between a

randomized controlled trial and a case-control study, what is a hazard ratio or a confidence interval, etc.

7. The structure of a paper

The scientific method is to start with an idea or theory which we want to test. We devise an investigation to test the theory. We carry out the investigation. If the results do not support the idea or theory we think of a new theory to explain them. We then test the new idea, and so on. The plan of an investigation may be summarised as follows:

1. Define the general hypothesis to be investigated
2. Define the specific objectives of the study
3. Design the study
4. Carry out study and collect data
5. Analyse data
6. Draw conclusions
7. Publish results

A standard medical scientific paper has the following layout:

1. Summary or Abstract
2. Introduction
3. Methods
4. Results
5. Discussion

The Summary gives an outline of the paper, what the problem is, what the design is, the main results, and the conclusions. The Introduction explains what the question is and why it is being asked. It usually gives a brief account of what others have done which leads up to this study. The Methods describes what was actually done, the type of study design used, the source of patients if any, the treatments given, the measurements taken, and the statistical methods used to analyse them. The Results tells us what was found. The Discussion gives the authors interpretation of their results, compares them with the results of other studies in the field, and draws conclusions.

The structure of the paper matches the plan of the investigation as follows:

Plan of investigation	**Layout of paper:**
1. Define the hypothesis	Introduction
2. Define the objectives	Introduction
3. Design the study	Methods
4. Carry out study and collect data	Methods
5. Analyse data	Results
6. Draw conclusions	Discussion
7. Publish results	Summary

I have put the Summary by publication, because that is the first thing that will be read. Only if the Summary tells the reader that this paper will be of interest to them will the rest of the paper be looked at. It is the Summary which is stored on Medline and produced when we do a literature search.

8. Critical reading

Medical papers are written by fallible human beings like me. Before publication, they are read by referees, usually two. These are experts in the field of the research who comment on the suitability of the paper for publication and suggest improvements to the paper. They are also fallible.

There may also be a statistical referee, who is an expert in research methods rather than in the research topic, and is yet another fallible human being. Despite the efforts of authors, their colleagues, referees, and editors, most papers have flaws. These may be in the study design, execution, or interpretation. They may be minor and not affect the conclusions at all, or they may lead the authors into serious error. The reader must beware and should not take any paper at face value. Research must be read critically.

There are good reasons for this. Medical research is largely done by practicing doctors, who also have to attend to the needs of their patients. (This is not the way research is done in other fields: agricultural research is not done by farmers, building research is not done by bricklayers, etc. In most fields research is done by professional researchers.) It also involves many different skills and ways of thinking, and it is impossible for most of us to master all of these.

The purpose of critical reading is to discover (a) if the methods used can produce useful information and (b) if the conclusions drawn by the authors follow from the results of the study. We shall be in a better position to do this later in the course.

9. How to learn about research methods

The best way to learn about research methods is to read research. Read research papers in your own field and in general health care research. A very good source is the *British Medical Journal*, which is free online every week. Read the Papers and Primary Care sections. Concentrate on the Methods and Results of papers. Ask yourself

- Why did they do this?
- Was it correct?
- What could they have done instead?
- Do the conclusions match the methods and results?

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