NHS
National Institute for Health Research

The NIHR Research Design Service for the East Midlands

The NIHR Research Design Service for Yorkshire & the Humber

Introduction to the Research Process

Authors

Antony Arthur

Beverley Hancock

This Resource Pack is one of a series produced by The NIHR RDS for the East Midlands / The NIHR RDS for Yorkshire and the Humber. This series has been funded by The NIHR RDS EM / YH.

Reference as:
Arthur A. and Hancock B. Introduction to the Research Process. The NIHR RDS for the East Midlands / Yorkshire & the Humber, 2007.

Antony Arthur
School of Nursing
University of Nottingham Medical School
Queen's Medical Centre
Nottingham
NG7 2UH

Beverley Hancock
The Department of Primary Care & General Practice
The University of Birmingham
Edgbaston
B15 2TT
United Kingdom

Last updated: 2009

The NIHR RDS for the East Midlands
Division of Primary Care,
14th Floor, Tower building
University of Nottingham
University Park
Nottingham
NG7 2RD
Tel: 0115 823 0500

www.rds-eastmidlands.nihr.ac.uk
Leicester: enquiries-LNR@rds-eastmidlands.org.uk
Nottingham: enquiries-NDL@rds-eastmidlands.org.uk

The NIHR RDS for Yorkshire & the Humber
ScHARR
The University of Sheffield
Regent Court
30 Regent Street
Sheffield
S1 4DA
Tel: 0114 222 0828

www.rds-yh.nihr.ac.uk
Sheffield: rds-yh@sheffield.ac.uk
Leeds: rds-yh@leeds.ac.uk
York: rds-yh@york.ac.uk

Table of Contents

1. Introduction

The purpose of this pack is to introduce the reader to the main features of the research process. The type of information which informs decisions about how to undertake a research project is described and supported by examples from primary care and other health services research. The pack is intended for health care professionals with little or no previous research knowledge.

If a project is worth doing then it is probably worth convincing an interested organisation to fund it. There are no guaranteed ways of securing funding but there are steps you can take to maximise your chances of success. Applying for research funding might sound like the starting point of the research process but applicants need to demonstrate a clear idea of the entire process of a research project, right up until what will happen at the end of the process (for example modes of dissemination and practical implementation of results), in order to convince a funding body that their money will be spent wisely.

The pack is split into two sections. The first section 'Getting Started', takes the reader through a whistle stop tour of the research process and provides advice on how to get beyond a vague research idea to something that (with expert help, hard work and lots of enthusiasm) has the potential to generate new insights into health care issues and concerns. The second section, 'Getting Funded', looks at the context of research funding in the UK and encourages the reader to put their own research ideas to the acid test of a funding application.

As many of the terms used may be either new or used in a context unfamiliar to readers, a glossary of terms is provided at the back of the pack. We have tried to make the exercises of practical use to the reader. Some of the exercises test the reader's understanding of the concepts contained within the pack, while others give the reader the opportunity to work with their research ideas about their own areas of interest.

The other resource packs in this series provide more detail on specific aspects of the research process. The reader is pointed to specific resource packs at various points within this pack. The full list of packs produced by The NIHR RDS EM / YH can be found at:

http://www.trentrdsu.org.uk/resources_resource.html

LEARNING OBJECTIVES

After working through this pack, the reader should be able to:

1. List the main stages of the research process.
2. Recognise key differences between particular methodologies.
3. Identify appropriate funding sources where applications for funding may be targeted.
4. Recognise good and bad practice in writing a research proposal.

2. Getting started

Perhaps the first question to ask yourself is: why get involved in research? This is important because although the use of research is now considered an essential aspect of any practitioner's role, actively engaging in research takes up time and energy. It can also be frustrating and demoralising so should not be taken on lightly. Having said that, meeting the challenge of undertaking good research is immensely satisfying and both practically and intellectually rewarding.

Research can be thought of as a process of systematic and focussed investigation for the purpose of adding to the body of knowledge about a particular subject area. Contained within this definition are three key points:

1. The investigation is carried out systematically, therefore the investigation is planned.

2. Research is intended to add to the body of knowledge and in doing so assists our understanding about complex issues.

3. Research is a process, carried out in stages.

It is the last point that is particularly relevant when we think of the research process. Any general research methods text book will describe the process in a similar but not necessarily identical way. An essential quality of a good piece of research is originality, so by definition few projects go through these stages in exactly the same way or even in the same order. Indeed, some may question whether there is a 'generic' research process that can be applied to both quantitative and qualitative research. However, to make things easier, let's assume that there is. Figure 1 describes the main stages of what we describe as an 'idealised' research process.

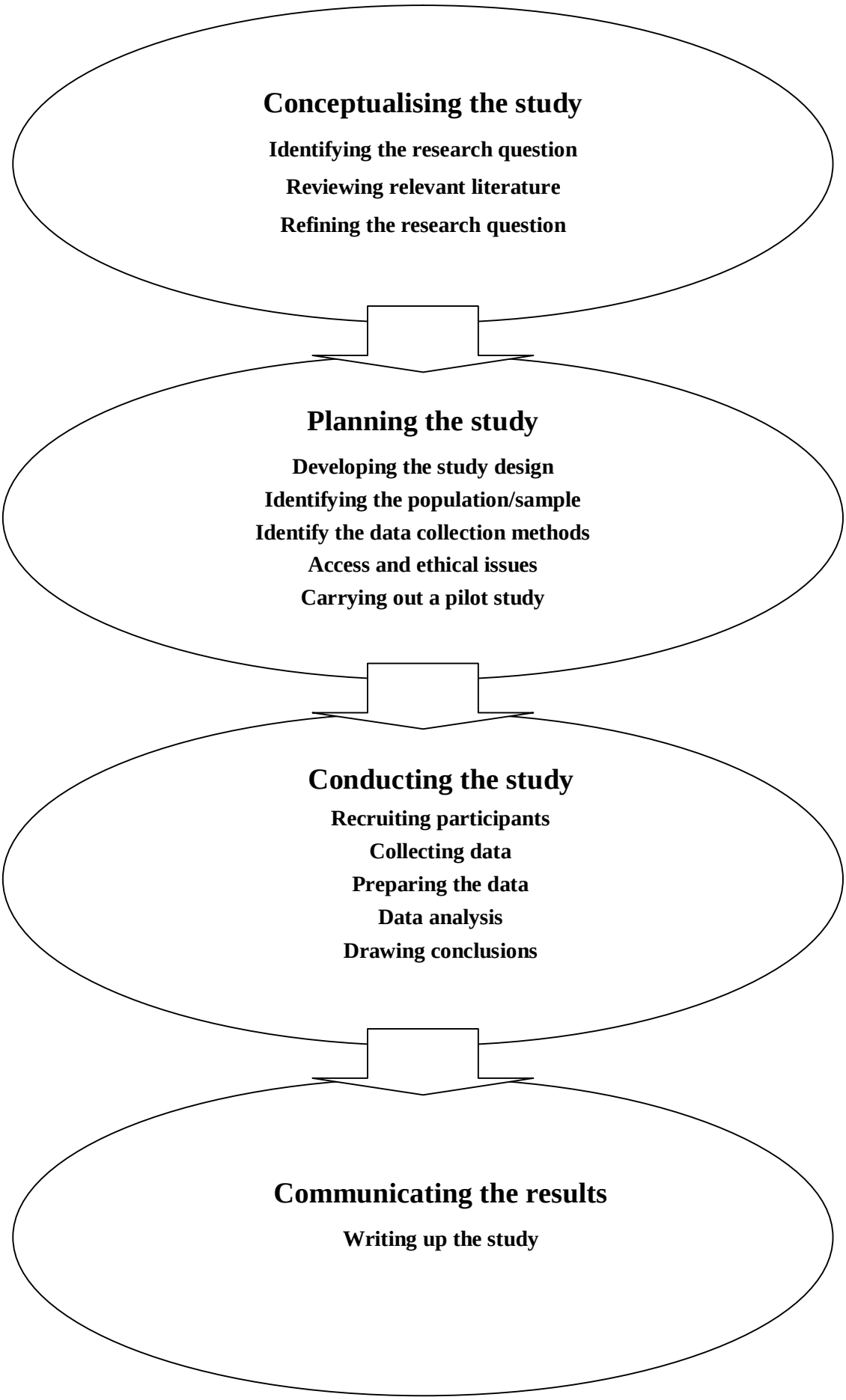

Figure 1: An 'idealised' research process

2.1 Conceptualising the study

Identifying the research question

If you have read this far, the chances are that you have already got some rough idea of a research project you might like to carry out. It may only be a hunch at this stage, or an area of interest that you would like to explore further. Ideas may come from a variety of sources: interesting patients, something you have read, conversations with others. Now is the time to brain storm.

Example

The subject of interest is depression in older people, more specifically non-pharmacological forms of treatment. It has been noticed that regular exercise seems to have a positive effect on other groups (for example patients following myocardial infarction) not only in terms of their physical health but also in terms of their mental health. This is the starting point, the research idea.....

Could physical exercise help older people with depression?

EXERCISE 1

Write down the subject area(s) that have been nagging away at you for a while. Think about why they interest you and what the trigger was that made you interested in them in the first place. You are probably worried that your ideas are vague. Elegant research projects start with vague ideas and to move forward from this starting point involves getting something, however embryonic, down on paper.

Reviewing relevant literature

You will have got together a few keywords by now which is enough to do a preliminary literature search. A good librarian can help you with this and let you know what literature databases are available, which are most suitable for your area of interest, and whether there is any cost involved in carrying out the search. For guidance in undertaking this you may wish to contact your local health sciences or hospital library.

Do not rely on computerised databases alone and if you are aware of a good paper on the subject, check through the references to see what else you may need to get hold of. Your first attempt at a database search may result in turning up one publication in the last ten years, or 2000 references per year. This is common and is an indication of the need to expand or refine your search rather than give up at the first hurdle.

Carrying out a literature search is not a trivial job but avoid the urge to track down every possible reference that is vaguely connected to your subject area. More recent articles are likely to summarise older work anyway. Allow yourself time to spend in a library to actually look at some of the references that you turn up. Some you will need photocopies of but photocopying is not a substitute for reading. When you get down to some selective but serious reading, certain themes should start to emerge from the literature, and the gaps in the literature should soon appear. Ultimately you are trying to establish what is already known about the specific subject area for your own idea. This provides a context

for your own research question. You are likely to turn up a range of papers that fall into one (but sometimes more than one) of the following categories.

1. Papers reporting original research (these take the classic format of introduction/background, methods, results, discussion).

2. Reviews of others work (these may be in the form of a highly systematic review to a more discursive analysis of others' work).

3. Opinion pieces (most journals have editorials where the writer is generally 'making a case' by drawing on research and other evidence).

4. Methodological papers (where particular research methods or research instruments are discussed, often by presenting data to illustrate particular points).

5. Policy documents (an understanding of the direction of relevant health policy and the associated policy debates will help you to think about your research idea from a wider perspective).

Example

In our earlier example, we were wondering if physical exercise may be of benefit to older people with depression. A number of keywords for this area of interest spring to mind: 'depression' 'older people' and 'exercise' are the most obvious. These are broad areas and most databases such as Medline, or BIDS, will allow you to restrict your search to papers where your keyword is the main focus.

EXERCISE 2

List the most relevant keywords to your own area of interest sketched out in Exercise 1. In the previous example the keywords fall neatly under three headings: the problem ('depression'), the population ('older people'), and the potential intervention or solution ('exercise'). If you have a number of keywords it may help to group them under these or other types of headings. Not only will this ensure that time spent searching databases is used wisely, but it will also start to order your research ideas into a more manageable form.

We have tried to give you an idea of how you could get started with your literature review. A good literature review takes time and skill. For more details you should see The NIHR RDS EM / YH Resource Packs: *How to search and critically evaluate Research literature.*

Refining the research question

Having a clear research question is essential for a successful project. The research question should guide the project from this point on. If it is too ambitious you may have to modify it, but you should never throw it out without something to replace it. Interest in carrying out a study of the effectiveness of health promotion clinics is to be at the idea stage rather than having a researchable question. A research question should include the area of interest (for example nurse lead health promotion clinics), the section of the population you might wish to investigate (for example patients attending a clinic aged between 20 and 65 years) and the specific issue you are seeking to address in the study (for example 'smoking cessation').

Example

Based on a literature review of (i) depression among older people; (ii) the effect of exercise on mental health; and (iii) exercise and older people; the following conclusions might be drawn:

- Standard therapy for treatment of depression among older people is drug treatment but many older people cannot comply with antidepressant medication because of side effects.
- In studies of younger adults there is evidence to suggest that aerobic and resistance (weight) training can help mildly depressed patients.
- Modified resistance training appears to be associated with a higher level of compliance than aerobic exercise and is safer for older people who are at risk of injury from falls.

From this summary of the literature, a research question can be posed:

Can weight training improve the quality of life in depressed older people?

This research question clearly begs other questions:

What is meant by weight training?

How is quality of life measured?

How do we define depressed older people?

These questions need to be addressed as the study is designed.

EXERCISE 3

The following titles are taken from recent publications and either take the form of a research question or address a research question:

Improving uptake of breast screening in multiethnic populations: a randomised controlled trial using practice reception staff to contact non-attenders. *(British Medical Journal).*

A descriptive study of the readability of patient information leaflets designed by nurses. *(Journal of Advanced Nursing).*

How common is medical training in palliative care? A postal survey of general practitioners. *(British Journal of General Practice).*

To get familiar with good research questions have a look at a recent journal that publishes papers reporting original research. Pick out three titles and identify the following components: outcomes (for example improved uptake in breast screening, readability of leaflets), interventions or potential causative agents (practice staff contacting non-attenders), populations (multiethnic populations, general practitioners), and study design (randomised controlled trial, postal survey).

Now have a go at putting your own research question together. It should include some (though not necessarily all) of the components mentioned above.

2.2 Planning the study

Developing the study design

Once you've clarified your research question the next stage involves planning the study. Within this stage the first job is to think about study design. The type of design you are likely to use is going to be driven by your research question. You have to ask yourself a series of questions that start to unpack your overarching research question. These are likely to include:

- What is the nature of my research question?
- What sort of information am I likely to need?
- How easy is this information to get hold of?
- What resources are available?
- How will I analyse and make sense of the information I collect?

An early consideration that will need to be made is your methodological approach. Broadly speaking you have three choices here: taking a predominantly quantitative approach; taking a predominantly qualitative approach; or taking an approach that draws on both quantitative and qualitative methodologies. What follows in this section is a very brief look at how quantitative and qualitative approaches differ. This is a huge subject in itself and relates to philosophical assumptions about knowledge and science. Those who wish to investigate this in greater detail are advised to consult a general research text book where these ideas are explored in depth.

Measurement is at the heart of quantitative research approaches. Questions such as: how many people are affected by a certain condition? Is a particular disease more common among people with certain characteristics? Is one treatment measurably better than another?

Some research questions cannot be easily broken down into a set of variables, for example those addressing human behaviour: why people act the way they do or how they feel in certain circumstances. When exploring questions around people's subjective experiences of health and illness, or in situations where measurement is inappropriate or inadequate, a qualitative approach is likely to be more useful. Qualitative research questions tend to be more open and of the type: Why? In what way? What are the implications? In quantitative research questions are those where a numerical answer is required: How often? How many? To what extent?

Further features of quantitative and qualitative research are listed in Table 1.

Type of approach	Quantitative	Qualitative
Research question	Highly focussed: How much? To what extent?	Open and flexible: in what way….? What are the essential

		features…?
Sample	Large and representative of the population from which it is drawn.	Often small, occasionally purposefully selected.
Data collection tools	Clinical measurements, survey instruments.	In-depth interviews, focus groups, observational techniques.
Data	In the form of numerical values.	Typically in the form of text as a result of interviews transcribed verbatim or observational commentaries.
Analysis	Statistical	Thematic
Presentation of findings	In the form of graphs and tables	In the form of data extracts to illustrate themes

Table 1: Features of Quantitative and Qualitative research

Within quantitative and qualitative research methodologies there are a number of well established study designs. The research question not only drives the methodological approach but is likely to determine the type of study design.

Quantitative research designs

Intervention studies

Intervention studies are used to evaluate the effectiveness of an intervention. The classic intervention study is the randomised controlled trial where two treatments are compared against each other by randomly allocating individuals to either treatment. They are then followed up after a pre-specified amount of time and the two groups are compared according to an outcome measure to see how the treatments compare. In routine clinical practice, those who receive certain treatments differ from those not receiving them in ways that may affect their likelihood of improvement. The process of randomisation removes this self-selection bias in an attempt to 'isolate' the treatment effect. Further information on studies of this type is contained in The NIHR RDS EM / YH Resource Pack: *Experimental Design.*

Cross-sectional studies

A cross-sectional study usually takes the form of a survey where data are collected from a number of individuals about their health, opinions, beliefs, attitudes or behaviours with regard to a given topic. Individuals are selected to take part in a survey because they share certain characteristics and form some kind of population. Data may be collected by a variety of means including postal questionnaires, face to face interviews or telephone interviews. Examples of surveys in primary health care include investigations of patient satisfaction and lifestyle studies. The survey is one of the most frequently used research designs. Most people have been asked to take part in a survey at some time. More information on surveys can be found in The NIHR RDS EM / YH Resource Pack: *Surveys and Questionnaires.*

Cohort studies

While a cross-sectional study provides a snap shot, a cohort study is longitudinal. It follows a group of individuals over a period of time. Initially, and throughout the follow-up period, data are collected relating to 'exposures' (for example age, gender, smoking consumption). If, as and when an individual experiences the outcome of interest, (this could be something like the development of a particular disease or death), then this is recorded and analysis is carried out to see whether there is any association between the exposure and outcome. Cohort studies tend to require large samples and require long follow-up periods. Consequently they are expensive to undertake.

Case-control studies

In many ways a case-control study is the reverse of a cohort study. Case-control studies are usually retrospective and start from the point at which an individual has already experienced the outcome of interest and are therefore considered a 'case' (of diabetes say, or dementia). A group of controls are then selected and matched with the cases on certain characteristics (such as age or gender) and then compared in terms of the exposure of interest. Although considered methodologically inferior to cohort studies, case-control studies have a number of advantages in terms of time and cost and they are an efficient way of studying associations between exposures and rare diseases.

Qualitative research designs

Action Research

Action research is used to investigate the effects of small-scale interventions in real life situations that involve practitioners. It is often used when practitioners want to change their way of working, or introduce a new service and want to monitor that change concurrently. It is a problem solving approach that involves the team in a process of reflecting on their situation, identifying problems and possible responses, implementing the change and evaluating the effects. Action research is considered cyclical in nature because the team may go through the process of reflection, identification, intervention, and evaluation several times. An example of action research might be the introduction of a particular nurse-led primary health care service. Although included within qualitative research designs, the researcher often collects a combination of qualitative and quantitative data.

Ethnography

Ethnography is a form of qualitative research. It is used to investigate cultures and population subgroups and seeks to explore, describe and explain cultural behaviour. An example of this might be to explore help-seeking behaviour for mental health problems within a particular ethnic group. In primary health care, ethnography helps health care professionals to develop cultural awareness and adapt existing services to develop new approaches to meet patients' needs. As a form of qualitative research, ethnography requires the collection of in depth information through face-to-face contact with individuals over a period of time. Analysis of data concentrates on understanding and describing the situation from the perspective of the culture or subgroup under study.

Phenomenology

Phenomenology literally means the study of phenomena. It is a way of describing things that are part of the world in which we live: events, situations, experiences or concepts. Phenomenological research investigates individuals' lived experience of events. It asks questions like "what does it mean to the individual to be involved in this situation and what

effect does it have on that individual's life, their feelings and their behaviour?" One example of phenomenological research would be an investigation into the experience of caring for someone with senile dementia. The study would consider the meaning of caring in that context, the components of caring and the impact on carers' lives.

Grounded theory

This is a form of research that goes beyond collecting and analysing data to add to the existing body of knowledge. In grounded theory the emphasis is on developing new knowledge and new theories about the topic being investigated.

Ethnography, phenomenology and grounded theory are all research designs based on the collection of qualitative data. Further information can be found in The NIHR RDS EM / YH Resource Packs: *Introduction to Qualitative Research and Qualitative Data Analysis.*

EXERCISE 4

Listed below are examples of research questions. Consider each one and suggest the most appropriate research design.

A. How do patients view the range of services provided by their local health centre?

B. What factors are likely to influence the uptake of screening services among women aged 16 - 50 years?

C. To what extent are homeopathic treatments used by the Chinese population in one city in England?

D. What is the most effective and efficient method of providing counselling to treat depression in primary care: counselling by GPs or counselling by the Community Mental Health Team?

E. How will the introduction of a weekly social worker clinic alter the existing services and workload of other team members?

So far we have looked at various study designs and methodological approaches that present a number of routes that a researcher may take to address their research question. Now comes the hard part. You will probably have already got a picture in your own mind of the kind of study you are hoping to carry out. The most important considerations in choosing an overall study design are that it should be feasible and appropriate to the subject of interest. If you are attempting to evaluate a new therapy or service and compare it with an existing therapy or service then a randomised controlled trial is probably your best bet. You are unlikely to better understand the organisational culture of particular parts of the health service with a quantitative approach and depending on the exact nature of your question you are likely to need a phenomenological or ethnographic study design. For looking at levels of disability, or prevalence of different types of attitude to certain health behaviours or health services, a cross sectional study is likely to be more appropriate. In order to understand links between exposures and diseases, and depending on time, money and the number of potential recruits to your study, a case-control or cohort study is probably the study design of choice. A good text book on health services research methods will cover the differences and relative advantages and disadvantages of each type of study design.

Identifying the population/sample

In any research the researcher has to identify the population under study. As with almost all decisions in the planning stage this is determined by the research question. The population is the group of interest and for whom the results will be applicable. The population needs to be defined in fairly formal and precise terms so that it is clear who falls within your definition and who falls outside of it. Populations are usually large which is why, for practical purposes, a study sample is taken in order to represent the population. Certain sampling strategies are associated with different methodological approaches and different study designs. In quantitative study designs, random sampling is considered the gold standard. When a proportion of the sample is selected randomly, this removes selection bias. However, this is only possible when we have a complete list of the population (known as the sampling frame). Qualitative study designs may be less concerned with drawing inferences about a population and may use approaches such as purposive sampling whereby potential participants are selected for their potential to yield the most relevant information for the study on the basis of known characteristics.

If your research question is well thought through, you should be able to clearly state your inclusion and exclusion criteria for the potential study. A suitable sampling frame will be needed and a decision made on whether to include all who satisfy the inclusion criteria or whether a sample should be taken. The size of the sample you will need to take will depend on a number of factors: time and resources available, prevalence of the condition you are studying, and likely response rate. If you want to undertake a Randomised Controlled Trial (RCT) you will need to carry out a sample size calculation and you are advised to consult a statistician for this. How you carry out a sample size calculation is one of the most frequently asked questions of statisticians working in health services research. It is a relatively simple procedure but if you get it wrong it will have the effect of carrying out a trial unnecessarily large, or one too small to be able to evaluate your intervention.

EXERCISE 5

Try and estimate how many eligible participants there are for your study. If you work in general practice and your subjects are going to include men and women aged between two specified ages, find out how many patients are registered who fall into this group. If you then want to look at a particular group with a particular condition (for example those with non-insulin dependent diabetes), using your knowledge of the prevalence of the condition, calculate how many potentially eligible patients there will be in your study. The same rules apply if you are researching a group of primary care workers. How many are there? Over what geographical area? If your subjects are new referrals to a clinic, look at past referral data to find out the weekly/monthly/annual number of new referrals.

Identify the data collection methods

The point of a sample is to collect data from sample members. Data is collected in a variety of ways depending on the research question, the study design, and the nature of your sample. The most commonly used methods of collecting information are questionnaires, interviews and through observation.

Questionnaires

Questionnaires comprise a written set of questions either completed by the respondent or completed by an interviewer as part of a formal, structured interview. Questionnaires, particularly self-completion questionnaires are considered a good way of getting a lot of

data relatively quickly and cheaply. There are drawbacks though, the amount of data you can expect to get from an individual participant is limited, complex questions requiring a certain level of explanation are unsuitable for self-completion questionnaires, and particular groups of the population (for example highly mobile sections of the population) are hard to reach using this method. Guidance on using questionnaires to collect data can be found in The NIHR RDS EM / YH Resource Pack: *Surveys and Questionnaires.*

Interviews

Interviews are usually held on a one-to-one basis, but some studies may use group interviews or focus groups. An interviewer administered questionnaire is a highly structured form of an interview. In qualitative research, interviews tend to have a far looser structure (often termed semi-structured or unstructured) with much greater flexibility. Data generated by these types of interviews is usually in the form of text. Guidance on using interviews to collect data can be found in The NIHR RDS EM / YH Resource Pack: *Using Interviews in a Research Project.*

Observation

Observation is a technique for collecting data through visual observation of events. It requires the nature of the data to be observable. Like the other two methods of collecting data, observation schedules can be highly structured or relatively unstructured, depending on the type of information required and the nature of the observed event.

The method of data collection chosen for a study should be appropriate for the type of information required. It would be time wasting to use unstructured interviews for essentially quantitative studies where information could be more efficiently collected through structured interviews or questionnaires. Conversely, self completed questionnaires are generally unsuited to qualitative research even when there is space for comments or for respondents to express ideas, the space is limited and requires respondents to have skills in articulation and literacy.

There are a range of established scales used to measure certain attributes (for example quality of life) and attitudes. You are likely to discover some of these in your review of the literature. Designing scales is a complex process and where there is a suitable established scale you should use it.

EXERCISE 6

It is probably a good point to start bringing some of your ideas together. From your research question decide how you are going to define your study group (in terms of age, sex, presence or absence of certain conditions, receiving or not receiving certain services etc.) and the concepts you are interested in. Even the most straightforward of concepts need definition. Take smoking for instance: do you include people who consider themselves ex-smokers? Those that smoke socially? People who smoke only cigars? Will you measure extent of smoking by average daily number of cigarettes? What if the number of cigarettes smoked in the week differs substantially from that smoked at the weekend?

Now try and sketch out your study design. If you are attempting a cross sectional survey you might want to start making a list of the sort of data you want to collect and the type of questions you are going to be asking. If your study is longitudinal it is probably easiest to do this in diagrammatic form, especially if different groups of participants take different pathways (as in an RCT or in a study where the first stage is cross sectional and a sub-sample of participants go on to a second stage).

Example

The research question:

Can weight training improve the quality of life in depressed older people?

is attempting to evaluate an intervention (weight training) and an RCT was considered the most appropriate study design.

Actually, this research question was posed in a study from the US and reported in the paper: Singh N Clements K, Fiatarone M, (1997) A randomized controlled trial of progressive resistance training in depressed elders. Journal of Gerontology 52A: M27-M35.

The problem of definition was addressed as follows:

Weight training: a supervised exercise training regimen of resistance training of the large muscle groups (chosen for their importance in functional activities). A session lasting approximately 45 minutes took place on three days a week for 10 weeks.

Quality of life: this was broken down into separate domains (depression, morale, and physical functioning) with previously validated instruments used to measure each domain.

Depressed older people: Subjects aged 60 years and over who fulfilled specified diagnostic criteria.

Design of the RCT: two volunteer databases were used and all those aged 60 years and over were sent a screening instrument for depression and those scoring over a specified score were contacted by phone to see if they (i) fulfilled the diagnostic criteria; (ii) were not ineligible on grounds of recent treatment with antidepressant medication, recent weight training exercise, or suffering from unstable diseases and (iii) agreed to take part in the study. These subjects were then invited to attend a local clinic for assessment and then randomised into either the intervention group (to undertake the 10 week resistance training) or the control group. Control subjects took part in an interactive health education programme to ensure that any improvement in outcomes in the intervention group was not the result of the increased social contact gained during the exercise. Outcomes were measured at the end of the ten week period.

Access and ethical issues

Carrying out research on human subjects throws up certain ethical issues. At the very least this involves issues of confidentiality and anonymity because participants are divulging information, often highly sensitive information, about themselves. However, there are other factors to consider. The relationship between researcher and participant can be complex, particularly in health services research where the participant may be a patient of the researcher or an employee of the researcher's organisation. This may result in participants feeling obligated to take part in research that they may feel uncomfortable with. There are particular ethical dilemmas in experimental research where treatments for individuals are determined by the study, however a full discussion of these issues are beyond the scope of this pack. Research on NHS patients and staff needs to be given formal clearance by an NHS research ethics committee and the relevant NHS organisation. The systems for obtaining this clearance can seem daunting. Help can be found in The NIHR RDS EM / YH Resource Pack: *Ethical Considerations in Research*. However, you are strongly advised to check that you are working with the most up-to-date information because these procedures have undergone extensive change in recent years and likely to continue to do so.

In trying to access the sample the researcher has to consider how this can practically be achieved and whose permission must be sought. Access may only be available through a third person or 'gatekeeper'. This might be a condition for approval given by an ethics committee or it may simply be the best way to access your sample. In which case the gatekeeper becomes central to the success of your study.

Carrying out a pilot study

Once the researcher is ready to undertake the study he/she should carry out a small pilot study to check that the methodology has been correctly thought through. The pilot is the study in miniature and is essentially a way of testing the water to iron out problems early on.

The pilot study enables the researcher to check the following:

- The accessibility of the sample group.
- The likely response rate.
- Whether or not the method of data collection can generate the depth, range and quality of information required.

If problems are detected at the pilot study stage the researcher has the opportunity to make revisions before undertaking the main study and therefore increasing the chance of the main study being a success.

2.3 Conducting the study

Recruiting participants

It is not at all uncommon for studies to fail because not enough participants could be recruited. The initial approach you make to potential participants is crucial in determining that you get an adequate proportion to actually take part in your study. Your method of approach will probably depend on the way you select your subjects. To recruit young people with asthma you might inform them of the study at an asthma clinic although it is important to be aware that this method would restrict your sample to those already receiving certain services. If you are interested in a particular age group, you may be able to take a random sample from a register of patients, in which case you would probably write to those selected, inviting them to take part. Piloting your method of approach is an important part of your pilot study, particularly if you think you might have trouble persuading people to take part. You should keep a logbook of who is approached, when, whether or not they agreed to take part and, where possible to determine, reasons for refusal.

EXERCISE 7

Think of three good reasons for people to take part in your study. Now think of possible reasons why people may refuse. Use this information to compose a letter inviting a potential participant to take part in your study.

Collecting data

Once the methodology has been thought through and the method of data collection has been piloted, the researcher reaches the stage of conducting the interviews, sending out the questionnaires or recording observations. For many researchers, this is the most exciting or enjoyable part of the research process. After months, maybe even years, of planning - developing the research idea, reviewing the literature, designing the research approach - the researcher starts to investigate the topic through the collection of original data.

The key to data collection is to be consistent, particularly once the pilot phase is over, so try and avoid carrying out interviews in different locations (for example home and surgery) or treating self-completed questionnaire data and interview data as if they were collected in the same way. Sometimes you have to be flexible and in these circumstances it is important to record the reasons for deviating from the study protocol.

Preparing the data

Once you have collected your data, you need to store it securely, and manage it in a way that will make it meaningful when you come to analyse it. There are various computer software packages which facilitate the transition from questionnaire to dataset but they still require human effort to input the information. Coding of questions should be clear and unambiguous and any decision about the most appropriate code must be made before data entry takes place. Researchers not entering their own data should bear in mind that another person undertaking this task is unlikely to be as obsessive and passionate about the overall project, therefore failure to ensure that data entry is a smooth procedure is likely to result in a loss of accuracy. Errors inevitably creep in at the data entry stage but there are certain things that you can do to spot these. In a quantitative dataset, look for

contradictory situations (for example cases where marital status is given as ‘single’ and source of social support is ‘spouse’, or cases where date of death falls before date of last consultation) and check for extreme values (for example people with a systolic or diastolic blood pressure that might make you suspect an incorrect value has been entered).

Data analysis

Whole books are devoted to this subject so this pack will only touch on the kind of activities that take place and hurdles encountered during this stage of the research process. The type of analysis carried out will be limited by the type of data collected. Abandon hope now of using qualitative techniques on self-completed questionnaires which only included closed questions, or using sophisticated statistical techniques on transcribed loosely structured interviews. As a general rule of thumb, start simple and build up. Describe the sample in terms of demographic characteristics (number of men and women, distribution across age groups etc). You are probably going to need to report this anyway when it comes to writing up but it will also help you familiarise yourself with the dataset. When you want to start looking at differences between groups (for example: is alcohol consumption higher in those living in rural rather than non-rural areas?) or identify predictors for certain events (for example: what factors are associated with falls among older people?) you may need the help of a statistician. A statistician will be able to tell you whether certain tests are appropriate for the data you are working with, whereas a statistical package will uncritically carry out whatever you ask of it.

For more information about techniques of data analysis you should consult The NIHR RDS EM / YH Resource Packs: *Using SPSS* and *Using Statistics in Research*.

Drawing conclusions

What a statistician will not provide is a clinical interpretation of the findings. This has to come from your understanding of the subject area and familiarity with the way the study was carried out. When the data have been analysed and a full set of results has been produced, the researcher reviews the results and considers them in the context of previous knowledge and the way in which the results were generated.

The research question needs to be re-visited. To what extent have the results addressed the question? At this stage, you need to be extremely critical in your thinking. Are there alternative explanations for the answer(s) that you arrived at? Could your results be an artefact of the way the study was designed and conducted? You need to then consider what the implications of your study and the results are for practice and future research. Can you legitimately make recommendations for practice based on your study findings? How feasible are these recommendations? Think too about the overall methodological limitations of your study (there will always be limitations of some kind). Can others learn from the mistakes you made? Can you make recommendations for future research in this area?

2.4 Communicating the results

Writing up

A good research paper or report will be a good read and carry some sort of message. If the research question was important in the first place then it should make no difference whether the message is positive or negative (for example a new and exciting intervention may have been found to be no more effective than the existing treatment or management). Ideally, a paper should be able to satisfy both the busy clinician who is

looking to see how the study's findings might affect his or her practice, and the academic who is likely to subject the methods section to closer scrutiny. One of the reasons why researchers find writing up the most difficult part of the research process is because they are trying to write for an audience who has not lived and breathed the entire project from beginning to end. A fine line needs to be negotiated between including all the relevant parts of the conduct and findings of the study, without becoming bogged down in superfluous detail or being highly selective and misleading.

EXERCISE 8

Think ahead to the sort of paper you hope to write, once the research has been carried out. Obviously you will not have any results until the data is collected and analysed. However you should be able to anticipate the type of results you would like to present. Make a list of the titles of three tables you want to include (for example 'Response by age and sex', 'Baseline characteristics for intervention and control groups'). Use published papers of studies with a similar design to give you some ideas. The purpose of this activity is to reinforce the centrality of your research question throughout the process and to alert you to the kind of data you are going to need to collect.

If you have been carrying out the activities in this section then you have already started to write up your research by giving yourself a framework for the background, methods and results section. Just because writing up is at the end of the research process does not mean that you should only start writing once every other part of the process is complete. Writing should be ongoing throughout the project. That way it becomes a less daunting task.

For further help with the task of writing up, see The NIHR RDS EM / YH Resource Pack: *Presenting and Disseminating Research.*

Summary

This section has provided a brief overview of the research process. We have looked at the sequence of steps taken by researchers as they plan a research project, undertake the project and make sense of the findings. Depending on previous knowledge the pack may have acted as an introduction or as a reminder of the main elements of the research process. It is hoped that readers will feel encouraged to look at the other resource packs in The NIHR RDS EM / YH series although the selection of packs will depend on where further interests lie.

3. Getting funded

In section two, we described the research process and through some of the set exercises, we tried to get you to develop your own research idea(s). In this section we discuss research funding. If you now have a project in mind it is worth thinking about how much time and money the project is likely to cost. Obtaining research funding is a highly competitive process. However, working up your own application for research funding will help you see exactly where the strengths and weaknesses lie in your own planned study. There are two parts to this section. The first gives an overview of how research is funded in the UK. The second takes the reader through a generic application for funding and suggests how an applicant might approach a grant application. Before we move on, we have another exercise for you.

EXERCISE 9

Write down three good reasons why you think your project should be funded. Be authoritative and confident! If you have reached this point in the activities set so far, then you obviously believe that you have a potentially valuable project on your hands. Use your keywords, identified in Exercise 2 to think about potential sources of funding.

3.1 The context of research funding in the UK

Types of funding

Research funding varies in terms of source, size, purpose and the sort of strings that are attached to it. At this stage it is worth considering funding from two dimensions. Firstly, research can be purchaser (i.e. funding body) or provider (i.e. researcher) determined. Secondly, the investment of funds may be in the project itself or in the person carrying out the work. By taking these two dimensions together, it is possible to construct four broad categories of ways to secure funding for doing research (Figure 2).

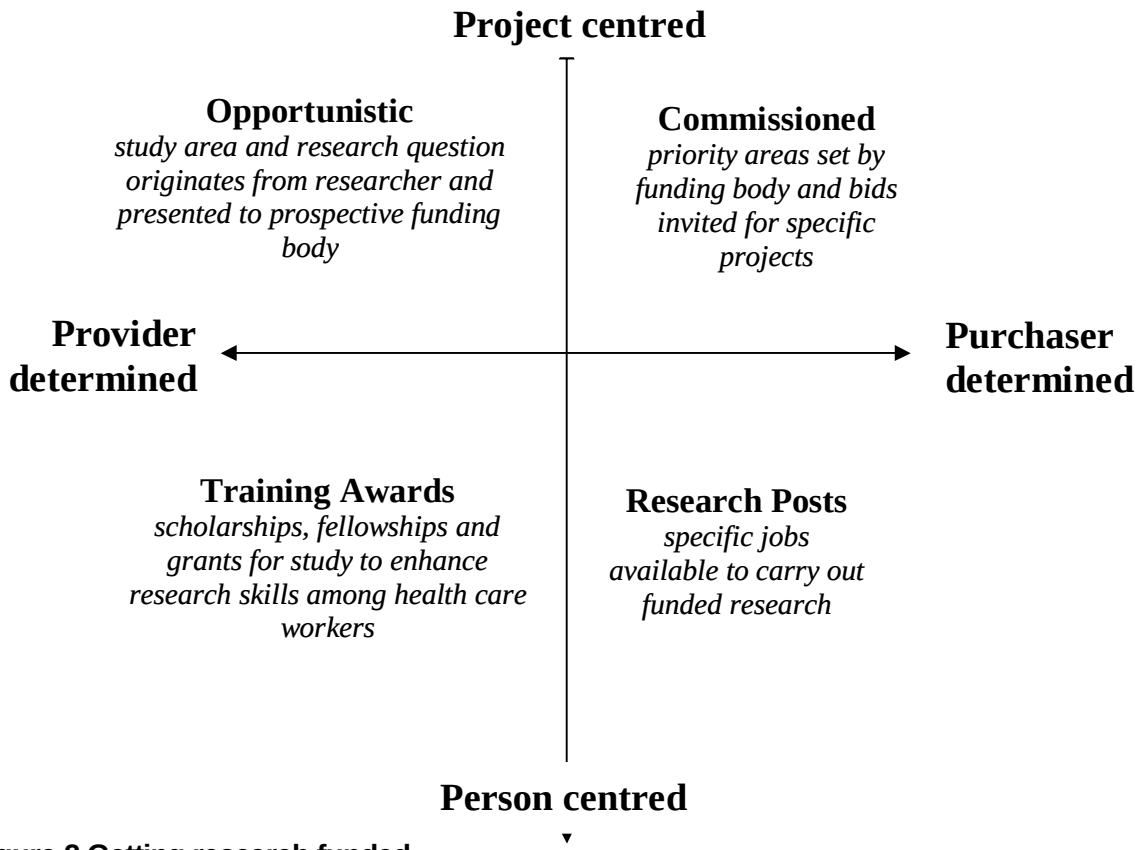

Figure 2 Getting research funded

Opportunistic funding is the type of research funding that those new to research are likely to be most familiar with. Research ideas are built up into a proposal, a suitable funding body is identified, and the funding body responds to the grant application. It is essentially provider determined and project centred.

Commissioned research is also project centred but the need is identified by the purchaser rather than the provider. In health services research the Department of Health commissions research based on NHS priority areas through the National Institute for Health Research (www.nihr.ac.uk). Calls for proposals appear periodically on the web, in the national press, and professional journals.

Research fellowships, scholarships and training awards are funds invested in the researcher (person centred) rather than the project. Grant making bodies will respond to a proposal for established or potential researchers to fund a piece of research to be carried out by the applicant, or for the applicant to undertake formal training in research skills. The

nature of the fellowship or training is likely to be put together by the applicant in the form of a proposal and as such is provider determined.

The fourth way to get paid to do research is to get yourself a research job. Once commissioned or opportunistic funding is obtained, grant holders are in the position to advertise for staff to carry out the research. Research posts are therefore determined by the grant holder (now in the role of purchaser) as funds have been awarded for a specific piece of work.

Main funding organisations

Within the NHS

Apart from the Department of Health, via the National Institute for Health Research mentioned above, individual trusts have research and development departments that occasional put out calls for local researchers to bid for research grants. You are advised to contact your local trust Research and Development Office to find out whether there are any schemes in your area and whether you would be eligible.

Research Councils

Two of the big research councils which fund health services research, are the Medical Research Council (MRC) and the Economic and Social Research Council (ESRC).

The Medical Research Council funds medical and related biological research. The main funding schemes are project grants, programme grants, studentships and fellowships.

The Economic and Social Research Council funds research in all areas relating to the understanding of social and economic change. Award types vary and include project grants, research centres, research programmes and fellowships.

Charities

Medical research charities and more general charities provide project grants, studentships and travel grants. Grants are only likely to be awarded on their relevance to the charity's particular area of interest. Charities vary greatly in terms of the level of financial support available.

Professional bodies

Depending on your professional background, it is worth contacting your professional body for details of funding schemes currently available.

Where to search

There are a number of websites dedicated to collating information on currently available funding opportunities. At the time of writing, for health services research the most comprehensive is available at http://www.rdfunding.org.uk

3.2 Putting together a grant application

With your research ideas sketched out in the activities in the first section, you should start to be able to put a first draft of a research proposal together. Most funding bodies will have their own application forms and guide for applicants. This should be read carefully and if you are unsure about any part of the application form or guidelines then you should contact the funding body. The front sheet will usually be a summary sheet asking for the

names of the applicant(s), the total funds sought, proposed starting date and duration of project and a short space for project title and summary.

The next section will ask you for details of the proposed investigation and most funding bodies will break this down under certain headings. A typical layout is given below and the kind of information you should be providing is described. Not all of the *dos* and *don'ts* will apply to your own research but as you are going through the different sections of the application form, start to sort your own notes under the same headings.

Aim(s) of the project

This should be a clear and succinct statement of the research question(s).

DO make it obvious that the study is setting out to discover something.

DO refer back to the aim(s) constantly in the other sections of the grant application.

DON'T state more than three aims. They should be memorable without the person reviewing your application needing to keep referring back.

Background to the project

This is a mini literature review. It is your chance to demonstrate the need for your study in terms of the importance of the issue and lack of evidence elsewhere.

DO keep it brief and refer to key literature.

DO demonstrate timeliness of proposed study.

DON'T attempt to show how widely read you are. The important thing is to keep the review focused.

DON'T rubbish other work in the field (it is impolite and you run the risk of insulting somebody who will be sent your application to review).

Study design

This may be, for example, a randomised controlled trial, cross-sectional survey, case-control or qualitative study. If there is more than one phase to the study (for example a cross-sectional survey followed by an RCT involving a sub-section of the survey sample), now is the time to identify these as Phase 1 and Phase 2 and consistently refer to them as such during the remainder of the application.

DO describe the design in broad terms.

DON'T go into too much detail on the actual methods to be employed - this comes later.

Methods

This part of the application will probably be the longest section. If the form does not do it for you, it may be useful to break it down into a series of subheadings yourself. The subheadings used here are: study population, sample size, approach and consent, assessment and interviews, analysis and time scale.

Study population

You need to be very explicit about who will be eligible for the study and who will not be. Try and think of all potential recruits to the study and how your eligibility criteria should be drawn. The study setting should be stated clearly (for example, hospital admissions, outpatients, general practice, community dwelling, nursing home residents) and the appropriateness for using such a sample should be justified.

DO state what type of sample you are taking (random, stratified-random, or non-random) and the sampling fraction(s) you intend to use.

DON'T be coy about the fact that you are not taking a random sample if it is inappropriate, impossible or unethical. If your sample is not random, there should be good reasons for this and you should state them confidently.

Sample size

You should state how many people you estimate to be included in the study and on what information you have based your estimate. This may be from audit information, previous research or pilot studies. Not using available information will give the impression that you are not as familiar as you should be with the literature and/or the service that you intend to study.

DO add in a factor for non-response and subjects dropping out of the study before the end point.

DON'T give a whole series of long hand calculations - the application is likely to go to a statistical referee who will check this.

Approach and consent

These are not just issues of concern to the local ethics committee, grant application referees will also want to know that this has been thought through in advance. Mode of approach (e.g. telephone, clinic staff, letter) and how informed consent will be obtained should be stated.

DO justify unorthodox modes of approach and demonstrate that you have considered their acceptability to potential participants.

DON'T underestimate the burden on staff not directly involved in the study. If you are relying on them to approach potential subjects, then you need to make this as easy as possible for them.

For RCTs…

There are certain details that will need to be explained if the proposed study is an RCT. The unit of randomisation (individual, household, clinic), the point of randomisation (directly following recruitment, following interview etc) and the method of randomisation (sealed envelopes, phoning back to a central point) are all decisions to be made prior to commencement of the study. The intervention(s) should be described and it should be made clear how the arms of the trial differ from each other.

DO consider using a pathway diagram to demonstrate how recruits will pass through the study. (This may apply to other complex study designs).

DON'T forget to mention who will be 'blind' in the trial (subject, assessor, clinician).

Assessment and Instruments

A reviewer is going to need to know where assessment will take place (in the subject's home, in hospital etc), by whom or what (a lay interviewer, clinical interviewer, postal questionnaire etc), how long the assessment is likely to take and whether any follow-up assessments are planned. The instruments used during the assessment will need to be stated and justified in terms of their suitability for the task. If the instruments have been validated in a similar population then you should cite this work. Be very specific about your main outcome measure(s), and again, demonstrate its suitability to fulfil the aim(s) of the study.

DO give reasons for using non-standard instruments

DON'T list instruments without stating what you intend to measure with them.

DON'T use abbreviations for measures without defining them.

Analysis

For certain types of study (for example, RCTs with two arms and one binary outcome measure), the analysis may be self-explanatory but for other study designs you should state the techniques you intend to use.

DO remember that the analytical methods should make sense in the light of the overall research question.

DON'T be overly technical; you can cite references to support the use of non-standard techniques.

Time scale

Think this through carefully. The parts of the research process that take time are usually those that are outside of the direct control of the researcher, including gaining permission to carry out research in clinical settings, recruiting research staff and arranging meetings with project advisors from different organisations. Allow sufficient time at the beginning of the study period for preparing assessment instruments and recruiting subjects, and allow time at the end for writing up.

DO consider using a diagram with project milestones clearly marked.

DO be realistic about what you (and others) can achieve.

DON'T organise the time scale in such a way that recruitment or posting questionnaires will occur around times of the year when many people are away (for example, just before Christmas and during summer holidays).

Resources and costing

This part will be picked over with a fine toothed comb by the grant making body and reviewers. Careful and accurate costing of the component parts of the project will give the impression that the applicant has a clear idea as to the resource needs of the proposed study. Depending on the size of the project you should use sub-headings where appropriate for staff, equipment, and other running costs. The research office of the relevant NHS Trust, should be able to assist with this.

DO consult the grant making body's guide for this, as they may state specifically the kind of costs they are willing and unwilling to fund.

DON'T forget travel costs, photocopying, telephone costs, library charges and consultancy fees.

Likely benefits of the proposed research

This is extremely important. A beautifully designed study with no potential practical (either clinical or managerial) or theoretical gain is clearly not worth funding. State how the findings will affect decision making in delivering health services. Where possible, give an estimate of the numbers of service users or service providers who will be potentially affected by the health issue you are investigating.

DO make the connection between your study and current policy initiatives.

DO think about potential cost savings in terms of disease burden, economic, and hidden costs (for example burden on carers).

DON'T be shy at this point - you may be acting locally, but start to think nationally if not globally!

The ability of the applicant(s) to carry out the study

This part can be off putting for first time researchers as the implication is that the applicants should have a proven track record. This may be true for large projects to be carried out over a number of years by a team of dedicated researchers. However, for smaller projects the applicant should be able to demonstrate that the field of study is an area of their particular interest. This might be shown through the applicant's curriculum vitae in terms of professional rather than academic experience.

DO think about what is unique to your position for carrying out the proposed study.

DO contact experts in the field and ask if they would consider formal collaboration or acting as advisors to the study.

DON'T undersell your clinical experience and useful contacts.

Dissemination

The whole point of carrying out research into health care is to improve the way services are delivered. Therefore findings from the research have to be communicated to those who need to know. The most obvious way this is done is through publication in a suitable journal, but speaking at relevant conferences and feeding back findings to local service providers and subjects who helped with the project should also be considered.

DO try and be imaginative at this stage, publication in academic journals alone is probably not enough.

DON'T lose sight of local implications. You might want to organise a special workshop for these groups.

EXERCISE 10

The purpose of the exercise is to get you to think about how a reviewer, asked to review your grant application, may approach this task. What you should be getting a feel for is that good grant applications share certain characteristics. Try to judge your own application by using the following criteria:

- Is there a clear researchable question?
- Does the project appear well thought through?
- Is it an important area?
- Is the project timely?
- Are the findings likely to be generalisable?
- What is the potential value to the field of knowledge?
- What is the potential practical value?
- How appropriate is the overall study design?
- How suitable are the methods/measures to be used?

It is often hard to assess your own work so ask a colleague for their frank opinion of your proposal.

Summary

Give yourself time

The process of obtaining research funds takes longer than you think. Most grant making bodies will have deadlines for applications at certain times each year. Do not underestimate how long it will take to put your application together. Many of the hold-ups (for example waiting to meet people who will be able to grant you access to potential participants) will be out of your control. You should also get others to read your application through to check the main messages are getting across to the reader.

Know what's going on

You need to be aware of changes in health policy, nationally and locally. Read the news section of your professional journals and pay attention to health issues reported on national and local media. A research study does not exist in a vacuum but in the ever changing world of health service provision. When you write your application you need to show how your study fits in to the bigger picture.

Dealing with rejection

Putting together a decent application for funding involves a lot of hard work and if it is unsuccessful then this can be a major blow to the applicant. Try not to despair, or harbour resentment against the referees whose comments should have been returned with the application.

If the grant making body is prepared to consider a re-submitted proposal (amended along the lines of the reviewers' comments) then you have to consider whether this can be done. Generally, persistence pays off. Clearly the funding body is interested and if there are good reasons not to change certain aspects of the proposed study then justify this in the re-submission. It may be that the referees have misunderstood the proposed study in which case you need to improve the clarity of the application.

If the negative response was more final, then you might consider an alternative funding body. It is still worth taking on board the referees' comments. Referees are likely to be experts in the field and their insight should be valued. Another option is to consider applying for funds for a pilot study. If a smaller pilot study, rather than the definitive piece of research, is proposed, it will inevitably be seen as a less risky investment of funds by the grant making body.

Glossary

Case-control study	an observational epidemiologic study comparing a group of people with a disease (cases) with a group of people without the disease (controls) in terms of exposure to a risk factor. The groups should be similar in terms of certain characteristics (such as age and sex).
Cohort study	a prospective epidemiologic study which takes a defined population who experience different degrees of exposure to a risk factor and are observed over time to compare incidence rates across different exposure levels.
Cross-sectional survey	a study design that takes a 'snap shot' of the population at a particular moment in time. It is not longitudinal and subjects are not followed up.
Dissemination	the distribution of information relating to the study (particularly its' findings) to groups, agencies and organisations who are potentially affected by the findings.
Eligibility criteria	an agreed set of characteristics that patients or subjects need to satisfy before they can be included or sampled for inclusion into the study. These may include age range, gender, presentation to a certain service, receiving specific treatment, registration with a practice or a combination of factors.
Evaluation	a systematic investigation into the effectiveness of a service or intervention according to agreed objectives.
Exposure	a risk or protective factor shared by some or all of a study group. For example smoking, family history of heart disease, vitamin supplements.
Generalisability	the extent to which findings can be extended from the study sample to the wider population the sample represents.
Grant holder	one of the named applicants on a successful grant application responsible for carrying out the funded research.
Grant making body	an organisation or agency who award research grants.
Intervention	a therapeutic or preventative regimen offered to some or all of the subjects in a study, usually for the purposes of evaluation.
Interview	a method of data collection which may range from structured (where questions and permissible range of answers are pre-determined) to unstructured (where neither the questions, nor the form of answers are set out in advance).
Keywords	words or terms used to categorise and identify published research papers.

Outcome measure	a measure of an aspect of health considered to be potentially affected by an intervention that has taken place.
Piloting	the process of testing out any aspect of a study design.
Power	a statistical concept relating to the ability of a study to demonstrate a significant finding if an association actually exists. It is expressed as a percentage and is determined by a number of factors, but particularly sample size.
Prevalence	the number of cases of a certain condition in a specific population at a designated time.
Process measure	an indication of the level of service provision and uptake (for example number of patients attending health promotion clinics, or ratio of home visits to surgery visits).
Proposal	a plan of investigation including background of study, study protocol, and full costing.
Protocol	a detailed step by step plan to be followed during period of study.
Randomisation	the process by which subjects are assigned to groups (for example, experiment or control) to avoid investigator bias. The method is predetermined using tables of random numbers or computer generated random assignment.
Randomised Controlled Trial (RCT)	an experiment in which subjects are randomly allocated to groups (sometimes referred to as 'arms'). These groups are usually intervention (receiving a specific intervention) and control (not receiving the intervention). The two groups are then compared in terms of the outcome measure of the study.
Recruits	subjects who agree to take part in study. Usually used in the context of experimental research.
Referee	an expert reviewer of grant applications.
Response rate	the number of respondents who agree to participate in study divided by the number of respondents invited to participate and expressed as a percentage.
Sampling frame	a list of the sampling units used in the selection of the sample. Examples of sampling frames are local electoral roll and practice register.
Sample	is a group or subset of the chosen population. A sample can be selected by random or non-random methods. Findings from a representative sample can be generalised to the wider population.