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A scientific approach to your research

An appreciation of the principles of scientific enquiry and research methodology relevant to your discipline is expected for the award of a qualification, when studying at Master's or postgraduate level. This includes possessing a conceptual understanding that enables you to: critically evaluate current research and advanced scholarship, and to evaluate and critique relevant methodologies. It is also expected that you can use this knowledge to select and apply techniques applicable to your own research. You should be able to demonstrate an understanding of how established techniques of research and enquiry contribute to the development of a discipline and its application.

Many smaller projects (especially those undertaken in part fulfilment of requirements for an undergraduate or Master's degree) form part of a larger project or research programme. In these cases, many decisions may have already been made about the aims, design and methodology of the research. The project may already be under way. However, if this is the case, you should still be able to reflect on principles and practices of scientific enquiry and research methodology in relation to your study. When you come to write up your project you should be prepared to discuss these issues as they apply to your work.

A feature of research into healthcare, pharmacy practice and medicines use is that it has attracted researchers from a wide range of disciplines, including pharmacy, sociology, anthropology, psychology, medicine, education, history, epidemiology, demography, policy analysis and economics, among others. Researchers from these

disciplines have applied their own scholarship, perspectives and techniques, helping to create the broad and stimulating discipline of pharmacy practice research. Approaches and methods from all these disciplines are now applied by pharmacy practice researchers, who frequently collaborate with academics and practitioners with a wide range of backgrounds and interests. However, the ultimate goal of pharmacy practice research is to improve our understanding of professional practice and medicines use, to inform the development of pharmacy services to meet health and pharmaceutical care needs of patients and the public. Applied research, by its very nature, is often designed to achieve pragmatic rather than theoretical goals. Nevertheless, it is important to demonstrate how the work is underpinned by a scientific approach, which may, or may not, be germane to a particular discipline, and that the findings of the research are clear and dependable.

What is a scientific approach?

The question of the nature and principles of scientific enquiry is a huge subject area in itself, and one that has been addressed and contested from many standpoints. Thus, the goal here is to provide some insights into the way that researchers from different disciplines and perspectives may conceptualise, formulate and address research questions. This may enable you to step back and consider the underlying assumptions and perspectives that surround your own research questions.

Researchers from different disciplines have their own ways of viewing 'their world'. This is sometimes referred to as *ontology* (which has been defined as the study of being or existence). This world view influences the different approaches that a researcher may take to further understanding. This is sometimes referred to as *epistemology* (theory of human knowledge). These differing perspectives will, in turn, influence the questions that researchers would pose and the methods that they would use in their research.

For example, faced with an issue of mental health in a population, historians, anthropologists, epidemiologists, clinicians and

pharmacists bring their own viewpoints about the nature of mental health and illness. These perspectives would lead them to develop distinct research agendas to further their knowledge and understanding. Particular types and sources of data may be required. Thus, researchers from the different disciplines would then have their own methodological approaches, or research tools, that they would employ to answer these questions. Different ways of viewing phenomena are often complementary. Thus, in addressing many issues in pharmacy practice and health service research, a range of researchers from different disciplines and backgrounds may be involved.

Table 5.1 illustrates some of the differing viewpoints that may be adopted by researchers from different disciplines, together with examples of the sorts of research question that they may formulate and the methods that they may use.

In our learning we are embedded in the perspectives, approaches and methods that distinguish our discipline from other disciplines. In our research we often do not acknowledge the role of these perspectives as determinants in the research process. More often we take for granted our ontology and epistemology, and do not stop to reflect on wider or alternative perspectives and approaches. As a consequence, any scientific appraisal tends to focus exclusively on methodology and methods. For your own research, you may like to broaden this to reflect on the following:

- Your ‘world view’ and underlying perspectives and assumptions regarding the nature of your research topic and the type of knowledge that will further your understanding
- How these have led to the formulation of your research question (identification of research priorities)
- What has informed your choice of methods for your study (methodology).

Pharmacy practice and related research is most commonly executed as an applied discipline. However, it may be necessary to view any piece of research in the context of its discipline to appraise its scientific rigour: the conceptualisation of the research question, the methodological approach and the execution of the work itself.

Table 5.1 Disciplinary approaches to research: an example in mental health

Discipline	Viewpoint	Research questions	Methods
Anthropologist	Mental health/illness as part of life, viewed and managed in the context of beliefs and norms of a community	To identify relevant health beliefs from the perspective of the community; how mental health/illness is defined explained and/or managed in their natural contexts	Detailed observation and examination by a researcher who lives as a member of the community
Sociologist	Mental health/illness as a part or consequence of wider structures, operation of society and interaction of individuals within	How and why particular population groups may experience better or poorer mental health; factors in society that influence people's experiences of mental health and its management	Social surveys among populations and/or interviews with individuals, to gather information on experiences and views and possible associated factors
Psychologist	Mental health/illness as experienced by the individual	Impact on emotional well-being/self-concept. Decision-making about when to use medicines	Interviews and/or application of structured instruments to gain insights into the beliefs and perspectives of individuals

Epidemiologist/ pharmacoepi- demiologist	Patterns of mental health/illness in populations as defined by established measures (often clinical) in populations	The prevalence of mental health problems within a society, comparing different population groups, and identifying associated factors	Analysis of databases that include diagnostic information: patient notes, prescriptions dispensed
Economist	Cost and benefits to society and individuals as a consequence of health status; costs as central to decisions about the provision of healthcare	Costs to individuals, health services and/ or society of mental illness and its management	Cost analysis from the perspective of stakeholders; cost-effectiveness/ benefits of mental health programmes
Pharmacologist	Mental health/illness as altered physiological process	Development, and mechanisms of action, of chemotherapeutic agents on relevant cellular processes or neuronal and biochemical pathways	Examination of therapeutic and unwanted effects
Pharmacist	Mental health/illness viewed as altered physiological process modifiable by chemotherapeutic intervention	Use of pharmacotherapy in the management of mental health problems for individual patients	Which patients benefit from medication? Appropriateness/ choice of therapy for a patient; monitoring of outcomes

Reflexivity

Pharmacy practice and related research is eclectic. Researchers adopt and adapt methods from many disciplines that they deem will be the best way of answering a research question. However, they should not be oblivious to the underlying personal values or viewpoints that they bring. It is important to recognise that others may view any issue in a very different way and prioritise a different set of research questions. Thus, although researchers may view themselves as ‘objective’ investigators, they are, in fact, an important influence in the research process. This is often more apparent in qualitative research, where the researcher has a major role in directing and re-directing the research throughout the data collection and analysis (see Chapters 10 and 13). However, critical appraisal of the values and decisions of the researcher in conceptualising the research question, designing and executing the study, and interpreting the findings is referred to as reflexivity. Engaging in these reflexive activities requires scholarly thought and demonstrates an awareness of some of the difficulties of defining ‘objectivity’ or claiming a ‘scientific’ approach to research and the ‘knowledge’ generated.

In your study you may feel that it would be beneficial to reflect on the following:

- Your underlying viewpoints and preconceptions that you brought to the research, especially those that will have influenced your aims and objectives (as discussed above)
- The methods that you selected and decisions that you made to do things in particular ways (throughout the research)
- The effect that these might have had on your findings.

Methodology and methods

Methodology refers to the science or study of methods. It is about the choice and selection of particular methods to answer a research question. The scientific basis and rationale for selecting particular

methods (methodology) for any study should be discussed. This may explain, with reasons, your approach (e.g. quantitative or qualitative, study design), choice of methods (e.g. existing databases, interviews, observation) and details of study execution and procedures (e.g. populations and samples, instruments, data-processing decisions). This discussion of methodology can be distinguished from your methods, which is a description of what you actually did.

In your methodology you need to justify your approach and methods in terms of their scientific basis. Say why you have selected them, and highlight their strengths and weaknesses, perhaps comparing with alternatives. All methods have their advantages and disadvantages. You should show an awareness of potential difficulties and problems (e.g. regarding their validity or reliability) and any steps that you could take to address them. You have to argue that you have identified the most appropriate methods for achieving your objectives and show that you appreciate any compromises that stem from these choices, e.g. you may have to weigh up the value of a detailed study focusing on a small locality with a less comprehensive survey covering a larger geographical area.

Quantitative and qualitative research

In terms of research methodology, probably the most important distinction is that of quantitative and qualitative methods. Quantitative methods have a much longer history in research into aspects of healthcare and the use of medicines. Nevertheless, qualitative methods are now well established as well as being seen as essential for many research questions.

Researchers who come from health professions, including pharmacists, are generally more familiar with quantitative approaches to enquiry than qualitative approaches. Quantitative studies are those in which the researcher aims to quantify phenomena. They may be small or large, or local, national or international. In terms of design,

studies may be descriptive or experimental. Examples of quantitative studies may be:

- assessments of the *frequencies* of events
- establishing the *proportion* of people in a population/sample who hold particular views or attitudes
- *audits* of professional practice and use of medicines, requiring assessment against set criteria
- assessment of *rates* of adherence among particular populations
- the *timing, duration* and *resources* associated with activities
- a *comparison* of prescribing patterns and rates between hospitals
- examination of *associations between variables* in a dataset, e.g. number of medicines prescribed and reports of medication-related problems, or attitudes and population characteristics or experiences
- randomised controlled trials in which differences in outcomes between groups are *measured* and *compared*
- studies that involve the application of *statistical procedures*.

Qualitative studies are considered appropriate for ‘how?’ and ‘why?’ questions. They may be used to explore processes and patterns in people’s thoughts and behaviour and/or to examine the operation of services in the context of their particular settings or circumstances. For example, qualitative researchers may investigate how people see or interpret events or how they make sense of their experiences or the world around them.

They may also aim to identify the meanings that people attach to particular situations or explain their priorities and concerns. In these studies you are exploring the viewpoints of individuals in detail, usually with a small number of carefully selected samples. You are not trying to establish the numbers of people who think in a particular way or hold certain views, but may be trying to find out *why* they hold these views and *how* this affects their behaviour. For example, you may employ a qualitative approach to explore involvement in professional activities from pharmacists’ perspectives. This may examine how pharmacists make decisions about whether or not to engage in the activity, to identify beliefs, experiences or attitudes that influence their decisions, and/or to gain insights into constraining or facilitating factors in their practice setting that are important

determinants. Detailed qualitative work will not provide an overview of the extent of involvement, but may provide clues about possible reasons, problems and barriers from practitioners' points of view. The findings may inform further research, perhaps with a larger sample, to find out (or quantify) the extent to which these perspectives and problems are also experienced by other practitioners.

Thus, you can see how qualitative research, which is often exploratory, tries to explain people's thoughts or actions or other events in terms of their belief systems, experiences, situation or circumstances, and suggest why different situations may arise. Researchers aim to present the viewpoints of respondents as accurately and comprehensively as possible, leaving their own views and preconceptions behind. To achieve this, methods that provide opportunities for respondents to present and explain their individual thoughts, beliefs and behaviours are required. In contrast, in quantitative research the goal is to count events or behaviours, test a hypothesis and/or quantify relationships between variables or population groups. Predetermined structured instruments are commonly applied.

To gain an understanding of how and why people think and behave in particular ways, qualitative research is often undertaken in the *natural setting*, e.g. if you were interested in the sorts of problems people had when using their medicines at home, it might be helpful to visit them at home to collect the data. You could then examine in detail how they use their medicines in the context of their environment and home life, the types of problems that they experience, how and why these arise, and how they are managed.

Although health services research draws on quantitative and qualitative methods, often as part of the same research programme or project, combining these has not been without its controversies. Some researchers believe that combining quantitative and qualitative approaches (or methods or data) ignores the differing epistemological approaches that underpin the research. The distinction between quantitative and qualitative research is sometimes seen as reflecting, on the one hand, a positivist world view based on a belief that there is a true state of affairs that can be objectively measured, and, on the other, a context-specific social reality in which the qualitative

researcher is an actor. Purists may see quantitative and/or qualitative research as representing different paradigms: distinct ways of viewing the world with consequences for conceptualisation of problems, and methodologies for the gathering and interpretation of data.

Methodological approaches in quantitative and qualitative research

Many different approaches and methodologies are associated with both quantitative and qualitative research. It is not possible to provide comprehensive coverage here. But, to illustrate the diversity of approaches and methods that have been applied in pharmacy practice and medicines research, a few of the most common are outlined. There are many texts that you can turn to if you wish to explore either the broad subject area or particular approaches in more detail.

Survey research has a wide application across many subject areas and is possibly the most common method in pharmacy practice research. Survey research is viewed as a quantitative approach in which data are collected from a sample of sufficient size and representativeness to enable generalisations to be made to a wider population. Data are usually collected using structured instruments that will have been selected and devised in line with the study objectives. Analysis will usually involve the application of appropriate statistical procedures. Survey data can also be collected in interviews with participants, by observation of activities or events in different practice settings. Other sources of survey data may be diverse, e.g. patients' notes, prescriptions dispensed, queries to a helpline. A *census* differs from a survey in that data are collected from the entire population rather than a sample.

Epidemiological research often relies on data in existing databases. It is a population-based approach in which statistical procedures are employed to examine patterns of disease, health needs, service uptake, prescribing, etc., according to predetermined objectives. *Pharmacoepidemiology* employs similar methods but with a more specific focus on issues related to the use of medicines.

Experimental studies, in particular *randomised controlled trials* (RCTs), are central to the development of an evidence base to guide the

provision and delivery of healthcare and the use of medicines. These employ experimental design (see Chapter 7) which is characterised by carefully controlled conditions and designed to ensure that all variables except those under study are equivalent in the experimental and control groups. These studies also apply tight eligibility criteria in the selection of participants. RCTs conducted and reported according to established guidelines, e.g. those of the CONSORT group (see www.consort-statement.org – accessed January 2010), are often seen as a gold standard in ‘objective’ research, generating dependable data distinguishing different treatment regimens as measured by specific outcomes.

However, the place of RCTs as a ‘gold standard’ is contested. The strictly controlled eligibility criteria, often narrow outcome measures, are believed to represent an artificial setting, i.e. one that does not necessarily take into account the different patient groups and environments in which any treatment or intervention may be applied. Thus, a study provides objective evidence in relation to a specific hypothesis (the effectiveness of an intervention when compared with a control or other course of action) that it was designed to test. However, the study findings may not be applicable to other patient groups, settings, circumstances, etc., that were outside the study criteria.

Experimental studies are sometimes seen as *reductionist* in that they are focused on a particular predetermined outcome measure. Some researchers see this as limitation of RCTs, arguing that a more *holistic* approach to the evaluation of an intervention has advantages. An example of this is *realistic evaluation*. A more holistic approach may include the gathering of contextual data relating to the operation and wider outcomes of an intervention, contextual factors that are pertinent to the outcomes in different settings and circumstances (which may have to be controlled or excluded in an RCT to enable valid statistical comparisons). There may also be factors that are important to the feasibility or success of a particular intervention that will not necessarily be identified by a tightly structured RCT.

A *reductionist* approach breaks down and examines a process or situation in terms of its different components, and studies each one

independently of the others or the wider context. In contrast a *holistic* approach assumes that ‘the whole is greater than the sum of the parts’ and endeavours to examine a process or event from different perspectives within the same project. Research in which a holistic approach is taken can be complex. To enable an examination from a range of perspectives, a number of different approaches and/or methods may be required. This is referred to as *triangulation* (see Chapter 7). Not uncommonly, both qualitative and quantitative methods may be employed.

A feature of holistic research is that it is generally concerned with an examination of behaviours, or events taking contextual factors into account. *Ethnography* refers to the study of individuals in their natural setting to characterise and provide potential explanations for particular events and behaviours. It is a qualitative methodology that aims to provide systematic and detailed evidence to explain phenomena in the light of structural and organisational factors, actions and interactions, personal experiences and views. A mixture of methods may be applied in an ethnographic study.

Phenomenology is a qualitative approach that focuses on meanings. It is concerned with individuals and how they see or interpret situations and events in the world around them. A phenomenological approach aims to examine events and actions from the perspective of the individuals under study: understand their interpretations of events and situations and how these lead to different beliefs, actions and behaviours. Thus, phenomenology is concerned with *interpretation*, and individuals’ *constructions of reality*. This can be contrasted with *positivism*, in that, instead of trying to explain events and situations in an ‘objective’ way, it assumes that behaviours and events are a consequence of an individual’s beliefs, ‘ways of seeing’, meanings that they attach to phenomena and ultimately their constructions of their own realities.

Thus *positivism* (a belief in a ‘true’ state of affairs that can be objectively (scientifically) measured) and *constructionism* (including phenomenology) illustrate the diverse approaches of quantitative and qualitative research paradigms that are applied in research into

health and medicines. It should also be recognised that different terms, their meanings and definitions have also been, and remain, the subject of debate. Furthermore philosophy and methodology are evolving and not static fields. The philosophy of science, nature of scientific enquiry and what constitutes scientific knowledge are a huge subject matter beyond the scope of this text, and one that has engaged philosophers and scientists, and presented many schools of thought, over the centuries. You may wish to delve further.

Audit and research

Is audit research? Audit is a form of service evaluation. The goal of audit is to generate information that can be used to document and improve an organisation's processes and outcomes. It is seen as an indispensable activity for organisations involved in the provision of healthcare. That it is a tool designed for the specific purpose of service evaluation rather than intellectual pursuit leads to arguments about whether or not audit is a form of scientific enquiry or research on a conceptual and/or methodological level.

It is perhaps on a conceptual level that audit is distinguished from research. Audit does not generally draw on or aim to extend existing conceptual frameworks or theory. The knowledge generated will usually be of practical rather than theoretical application. It will also be particular to the local situation, rather than of wider relevance to other settings. Audit focuses on the documentation of current activity and achievements rather than questioning, developing and testing potential new approaches. A goal of audit is not to contribute to scholarship within a discipline or to provide new perspectives on an existing evidence base. However, audit requires a systematic approach to gathering data that is a valid and reliable reflection of the processes and outcomes of interest. To achieve this, sampling strategies and procedures, data collection, data analysis and interpretation have to be undertaken to a standard of methodological rigour similar to research.

Although many projects can clearly be categorised as either research or audit (service evaluation), in some situations the distinction is less

clear. An audit may provide background information at the planning stages of a research study. In some audits, although conducted locally, the findings may be argued to have wider relevance. Many research studies are confined to single sites. In some cases an audit or service evaluation may draw on an existing theoretical or explanatory framework, which will inform its design and execution.

Principles of validity and reliability

Whatever the methodological approach, questions of scientific rigour arise. The concepts of reliability and validity are pertinent to all studies. An understanding of these concepts enables you to achieve and demonstrate a scientific approach.

Potential threats to the reliability and validity of research arise in relation to all stages of the research process – sampling procedures, data collection, instruments and measures, data processing and analysis – and all types of study. They are discussed in different chapters of this book at the appropriate points. Throughout your project work you should apply critical thought to your methods and findings to ensure that you are realistic about the quality and integrity of the data. You need to feel confident of your interpretation of the findings and that you are not overstating any conclusions or the potential value of the work.

Reliability

Reliability refers to the extent to which procedures, measures and data are reproducible or internally consistent.

Problems of reliability may arise in relation to repeated measures on a piece of diagnostic equipment, uniformity between researchers in the collection of data, adherence of interviewers to an interview schedule, completeness in maintaining records of non-responders, care and attentiveness when observing events, consistency of questions in a questionnaire, agreement between researchers in the coding of data, etc. Problems of reliability can emerge at all stages in

research. In the development of research instruments, data collection procedures and data processing and analysis, potential problems with regard to the reliability of data must be identified and addressed. Poor reliability at any stage can undermine the value of the work and dependability of the study findings. It is important to keep an open mind and be alert to any concerns. Problems often cannot be ironed out completely, but it is important that you, as the researcher, identify difficulties. You are then in a position to take steps to address problems and/or assess their implications for the findings of the study.

Validity

Validity refers to the extent to which the findings of a study are a true reflection of phenomena under study. Do the instruments (e.g. questions in an interview, records maintained by an observer) actually measure what they are designed to measure?

All methods and studies present their own concerns with regard to validity. As with reliability, potential questions about validity can arise at all stages of the research process. It is essential for the ultimate value of the research that they be identified and addressed. Threats to validity that arise with different methods and at different stages of a project are highlighted in later chapters of this book.

Potential problems in validity arise, in particular, in relation to data collection and the development of instruments. In observation studies, it is recognised that people when being observed may purposely or inadvertently change their behaviour; data will not then be an accurate reflection of the true situation. In an interview respondents may be reluctant to discuss certain relevant issues or present a negative viewpoint, thus leading to biased information. In self-completion questionnaires respondents may tend to underestimate on some variables (e.g. their smoking habits) and overestimate on others.

Most studies require measurement of phenomena. Demonstration that any measure is a valid reflection of a variable of interest can be

difficult. Physiological measures are used in clinical medicine, but may or may not provide a reliable or valid indication of the severity of a condition or its impact.

Finding valid measures of some variables is not straightforward. Variables that are difficult to define will inevitably present problems for researchers, e.g. health inequalities are high on many governments' agendas. Thus, health service researchers will usually want to gather data that enable an examination of experiences of individuals of different socioeconomic status. To examine any associations between socioeconomic status and health or the use of medicines requires its measurement. Although socioeconomic status is a concept that is widely recognised, it is a complex construct that is difficult to define. Various approaches have been used as 'proxy' measures in survey research to measure socioeconomic status, including questions about occupation, education, income, other lifestyle factors and/or combinations of these. However, questions remain about the extent to which these measures are accurate (valid) reflections of what is generally recognised as socioeconomic status. Similar problems arise in the classification of people according to ethnicity: how can people be grouped in a way that is a valid reflection of their cultural identity?

Health status and health-related quality of life are important measures in much research. Measurement is complex. Individuals differ in their perceptions of their own health. In assessment of health-related quality of life, people's lives are compromised in different ways as a consequence of their health status, and each person may differ in the aspects of health that are most important to him or her. Conceptual, theoretical and practical problems in the measurement of these variables have engaged many researchers. As a consequence, there are many validated measures that can be employed.

Variables relating to the use of medicines can also be complex, e.g. a number of methods have been used to measure compliance with, or adherence to, medicine regimens. First, a conceptual issue may arise, which may influence the approach of the researcher. An assessment of 'compliance' might be a measure of the extent to which an

individual follows instructions. The concept of adherence recognises that the perspectives of individuals will influence their use of medicines. Thus, in studies of 'adherence' researchers often focus on patients' perspectives and measures reflect their role in decision-making with regard to their use of medicines. Thus, there is a range of measures of compliance/adherence that is commonly employed, each with its own strengths and limitations. These measures include records of refills from pharmacies, counting of doses remaining in a container, electronic devices to detect use of a product, physiological measures and self-reports. Other concepts or constructs employed by researchers into pharmacy and medicines that present difficulties include measures of potential severity of medicine-related problems, the quality of advice, self-efficacy in the management of illness and use of medicines.

In recent decades, measurement of complex variables in health service research has been an important focus of many methodologists. As a result, there are now many measures in the literature that have been developed and validated using rigorous approaches. In general, if you wish to measure a complex variable, it is better to look for, and adopt, an existing measure than attempt to devise your own.

Generalisability (external validity)

The generalisability (sometimes referred to as the external validity) is concerned with the extent to which the findings of a study can be applied to individuals beyond the sample. Many studies involve samples rather than a whole population. Studies are often focused on a single location or a small number of areas, but there may be a strong argument that the findings have wider relevance.

The most important issues that determine the generalisability of study findings are the sampling strategies, procedures and sizes, and response rates (e.g. surveys), and representativeness and completeness of data (e.g. databases). Assuming probability sampling procedures, comprehensiveness of databases and sampling frames, good response rates and validity of data, findings should be generalisable to the population from which the sample was drawn. In

addition to this, for many studies researchers may wish to address the issue of generalisability to populations beyond the sampling frame. There may be strong arguments for claiming that much wider generalisation is valid.

Conclusion

Your research project can provide an opportunity for you to engage in scholarship and be at the forefront of your discipline and/or to participate in the creation of new knowledge that will be relevant to professional practice and patient care. This work will require an appreciation of conceptual, theoretical and practical perspectives regarding the generation and interpretation of data within a discipline. Reflection on the scientific basis of your research question, methodology and methods will enhance your understanding of the research process.