

FOURTH EDITION

ANN BOWLING

**RESEARCH
METHODS
IN HEALTH**

**Investigating health
and health services**

Research Methods in Health

Research Methods in Health: Investigating Health and Health Services

FOURTH EDITION

Ann Bowling



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Praise for this book

“This excellent text really is a must for anyone involved in health research. It is truly multidisciplinary in its scope, drawing on a breadth of relevant research from health economics, to epidemiology to psychology which is beyond the scope of most books on research methods. Yet in spite of the wealth of material included it is written and presented in an accessible way so that it will be an invaluable source for those with a background in either qualitative or quantitative research and from students to experienced researchers.”

Robert J. Edelman, Professor of Forensic and Clinical psychology, Roehampton University, UK

“Health service researchers - new and old - will be delighted by this new edition of a popular and useful text. There is new content but also updated material making this practically useful as a resource at any stage of the research trajectory. While health is the focus the book is hugely valuable to researchers in cognate areas, such as social care, education and housing. The book meets its own high standards in being easy to follow, well indexed and containing interesting examples of approaches. The limitations of different methods are also honestly reported. A ‘must have’ for the book shelf.”

Jill Manthorpe, Professor of Social Work, King’s College London, UK

“When first published in 1997, this volume was the first systematic overview of research methods used in the health field. In its updated 4th Edition it remains vital and, if anything, more important given the growing number of researchers and students investigating health issues and health services. It provides an impressively comprehensive overview of health research methods in which the wealth and variety of experience of the author shines through at every point. Qualitative, quantitative and mixed methods are appraised and explained with unpartisan authority and rigour, and the volume covers everything from multidisciplinary collaboration in health service evaluation through the Delphi technique of consensus development to the health economics needed to evaluate costing.”

Paul Stenner, Professor of Social Psychology, The Open University, UK

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Preface to the fourth edition

This book is more than a text on research methods. It is an introduction to the theoretical concepts, as well as the descriptive and analytic research methods, that are used by the main disciplines engaged in research on health and health services. In order to understand why the various research methods are used, it is important to be aware of the conceptual backgrounds and scientific philosophies of those involved in research and evaluation, in particular in demography, epidemiology, health economics, psychology and sociology.

The fourth edition, while essentially similar to the earlier editions, includes updated classic and more recent references, and additional reference to key methodological developments, including realistic evaluation, stepped wedge trials, Zelen's design in trials, critical appraisal and evidence-based health care. The book is aimed at students and researchers of health and health services, health professionals and the policy-makers who have the responsibility for applying research findings, and who need to know how to judge the soundness of that research. The idea for the book, and its structure, are grounded in my career as a researcher on health and health service issues, and the valuable experience this has provided in meeting the challenges of research on people and organisations in real-life settings.

The varying terminology used by members of different disciplines in relation to the same research methods is often confusing. This variation simply reflects the multidisciplinary nature of this whole area, and the specialised languages of each discipline. While no descriptor can be labelled as incorrect, the multitude of them, especially when not clearly defined, can easily lead to confusion. Therefore, I have tried to justify the terminology used where it differs from that in other disciplines. Towards the end of the book I have included a glossary which I hope will prove useful for readers coming across unfamiliar terms. Readers wishing to explore methodological topics in more depth are referred to Bowling and Ebrahim (2005).

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Investigating health services and health: the scope of research

'Would you tell me, please, which way I ought to go from here?', asked Alice.

'That depends a good deal on where you want to get to', said the cat.

Lewis Carroll (1865) *Alice's Adventures in Wonderland*

Introduction

Research is the systematic and rigorous process of enquiry which aims to describe phenomena and to develop and test explanatory concepts and theories. Ultimately it aims to contribute to a scientific body of knowledge. More specifically, in relation to the focus of this book, it aims to improve health, health outcomes and health services.

The book aims to provide an overview of the range of research methods that are used in investigations of health and health services. Ultimately the purpose is to guide the reader in choosing an appropriate research method and design in order to address a particular research question. However, it is not possible to place research methods in a hierarchy of excellence, as different research methods are appropriate for addressing different research questions.

If the research question is descriptive, for example, 'What is the health status of population X?', then a cross-sectional survey of a sample of that population is required to provide population estimates. The survey method will also enable the answers to secondary questions to be estimated for that population (e.g. 'Are men more likely than women to report poor health status?') and certain (non-causal) types of hypotheses to be tested (e.g. 'Men will be X times more likely than women to report good health status'). If the research question is 'Do women have worse health outcomes than men following acute myocardial infarction (AMI)?', then a prospective, longitudinal survey of identified men and women who had suffered an AMI would be undertaken in order to be able to compare their health outcomes over time in the future.

If the research aims to find out information on a topic about which little is known, or is too complex or sensitive for the development of standardised instruments, then

qualitative methods (e.g. observational methods, in-depth interviews and/or focus groups) may be more appropriate (e.g. 'Is there quality of life on long-stay psychogeriatric wards?'; 'Are there dehumanising care practices in long-stay institutions?'; 'How do doctors prioritise their patient caseload?').

And if the research aims to investigate cause-and-effect issues, then an experimental design is, in theory, required (e.g. 'Do women aged 75+ have worse health outcomes than men aged 75+ following thrombolysis therapy for acute myocardial infarction?'; 'Do patients with osteoarthritis of the knee benefit from physiotherapy?'; 'Are specialists' outreach clinics held in general practitioners' surgeries as cost-effective as specialists' out-patient clinics in hospitals?'). While the double-blind, randomised controlled trial (RCT) is the true experimental design, and most appropriate for addressing these types of questions, there are also situations in which this method is unrealistic, impractical or inappropriate and other well-designed analytic (as opposed to descriptive) methods have to be employed instead (see Chapter 10). For some cause-and-effect questions, the RCT may be the most appropriate research design but it would be unethical to randomise people to interventions that are unacceptable, and the issue must therefore be addressed using other methods, such as a prospective, longitudinal survey of a population (e.g. 'Does drinking spirits increase the risk of heart disease?').

Finally, research methods should not be seen in isolation from each other. A triangulated or combined methodological approach to addressing different facets of a research issue, using different methods which complement each other, is increasingly recommended as a means of establishing the external validity of the research. In the same way in which prospective, longitudinal surveys can inform the results from RCTs, so qualitative research findings can enhance quantitative survey data by placing the latter into real social contexts and enhancing understanding of relevant social processes.

The importance of using triangulated research methods is enhanced by the multifaceted nature of health, and the multidisciplinary character of research on health and health services. This includes investigations by anthropologists, demographers, epidemiologists, health economists, health geographers, health policy analysts, health psychologists, historians, medical sociologists, statisticians and health professionals (clinicians, nurses, physiotherapists, and so on). Specialists in public health medicine play a key role in health services research, as they are equipped with a range of research skills, including epidemiology. In Britain and in some other countries, they also have responsibility for assessing needs for health services in specific geographical areas, and advising purchasers on effective health care. There is a close working relationship between researchers investigating health and health services and health professionals, particularly in relation to the development of measures of clinical outcomes and the appropriateness of health care interventions.

One consequence of this multidisciplinary activity is that a wide range of qualitative and quantitative, descriptive and analytical research methods is available. This diversity should enrich the approach to research design, although there has been a tendency in research on health services to focus mainly on the experimental method. All methods have their problems and limitations, and the over-reliance on any one method, at the expense of using multiple research methods, to investigate the phenomenon of interest can lead to 'a very limited tool box' (Pope and Mays 1993), sometimes with questionable validity (Webb *et al.* 1966), and consequently to a limited understanding of the phenomena of interest.

It is necessary at this point to distinguish between the terms *health research* and *health services research*.

Health research

Health research has been defined in relation to health generally. As well as having an emphasis on health services, it has an important role in informing the planning and operation of services aiming to achieve health (Hunter and Long 1993). As Davies (1991) observes:

“the process [of] obtaining systematic knowledge and technology . . . can be used for the improvement of the health of individual groups. It provides the basic information on the state of health and disease of the population; it aims to develop tools to prevent and cure illness and mitigate its effects, and it attempts to devise better approaches to health care for the individual and the community.”

The broader aspects of health research are described in Chapters 2, 3 and 4 (e.g. in relation to health needs and sociological and psychological aspects of health).

Health systems and health services research

There is no accepted definition of a health system, and it has been variously defined in terms of the structures used to deliver health care, the geographical boundaries of the latter, or the strategies used to attain population health (Nolte *et al.* 2005). Health systems research has thus been defined fairly broadly as: ‘ultimately concerned with improving the health of a community, by enhancing the efficiency and effectiveness of the health system as an integrated part of the overall process of socio-economic development’ (Varkevisser *et al.* 1991).

In Britain and the USA the general focus is on health services research, rather than on health systems research. Health services research is defined more narrowly in relation to the relationship between health service delivery and the health needs of the population: for example, as ‘the identification of the health care needs of communities and the study of the provision, effectiveness and use of health services’ (Medical Research Council, see Clarke and Kurinczuk 1992). While there is an overlap with health research, health services research needs to be translated into action to be of value and should ‘transcend the R (acquiring knowledge) and the D (translating that knowledge into action) divide’ (Hunter and Long 1993).

Each of these definitions emphasises the multidisciplinary nature of health research, health systems research and health services research. Health services research, for example, has been described as ‘a space within which disciplines can meet’ (Pope 1992), and as an area of applied research, rather than a discipline (Hunter and Long 1993).

Within these definitions, the topics covered in Chapters 1, 4 and 5, on evaluating health services, health needs and their assessment (the latter also comes within the definition of broader health research) and the costing of health services, are encompassed by health services research. Chapter 2, on social research on health, and Chapter 3, on quality of life, also fall within both health research and health services research. Not everyone would agree with these definitions and distinctions. For example,

some might categorise the assessment of needs as health research rather than health services research. What is important is not the distinctions and overlaps between these branches of research, but a respect for each discipline in relation to its contribution to a multidisciplinary body of knowledge about health and disease, health systems as a whole and health services.

Finally, it should be pointed out that research on health services is not insulated from the society within which it is placed. It is often responsive to current policy and political issues (see Cartwright 1992), and is thus dependent upon decisions taken by others in relation to research topics and research funding. While it is common for researchers to initiate new research ideas, much of the funding for this research comes from government bodies, who tend to prioritise research and development on a local or national basis. The research topics are rarely value-free. The research findings are also disseminated to members of a wide range of professional, voluntary and management groups. In relation to this multidisciplinary nature, the agenda for research and the consumers of the research findings, it contrasts starkly with the traditional biomedical model of research.

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Evaluating health services: multidisciplinary collaboration

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Introduction

Research on health and health services ranges from descriptive investigations of the experience of illness and people's perceptions of health and ill health (known as research on health, or health research) to evaluations of health services in relation to their appropriateness, effectiveness and costs (health services research). However, these two areas overlap and should not be rigidly divided, as it is essential to include the perspective of the lay person in health service evaluation and decision-making. Other related fields of investigation include audit, quality assurance and the assessment of needs for health services (usually defined in terms of the need for effective services), which come under

the umbrella of health research but also have a crucial link with health services research. Audit and quality assurance are not strictly research in the sense of contributing to a body of scientific knowledge and adherence to rigorous methods of conducting research (quantitative or qualitative). Instead they are concerned with monitoring in order to ensure that predefined standards of care are met. They are increasingly important activities with the emphasis on clinical governance in health care (Lugon and Secker-Walker 1999). They are described briefly below with the other main areas of research activity.

Health services research

It was explained in the introduction to Section I that health services research is concerned with the relationship between the provision, effectiveness and efficient use of health services and the health needs of the population. It is narrower than health research. More specifically, health services research aims to produce reliable and valid research data on which to base appropriate, effective, cost-effective, efficient and acceptable health services at the primary and secondary care levels. The phrase health technology assessment has been coined to describe the wider evaluation of health care interventions in terms of both their costs and their effectiveness.

The research knowledge acquired needs to be developed into action if the discipline is to be of value; hence the emphasis throughout industry and service organisations on 'research *and* development'. The focus is generally on:

- the relationships between the population's need and demand for health services, and the supply, use and acceptability of health services;
- the processes and structures, including the quality and efficiency, of health services;
- the appropriateness and effectiveness of health service interventions, in relation to effectiveness and cost-effectiveness, including patients' perceptions of outcome in relation to the effects on their health, health-related quality of life and their satisfaction with the outcome.

These areas of research are addressed in more detail in this chapter and in the other chapters included in Section I.

Health services research is distinct from audit and quality assurance, though they share the same concepts in relation to the evaluation of structure, process and outcome. Audit and quality assessment aim to monitor whether predefined and agreed standards have been met. Health services research has evaluation – rather than monitoring – as its aim. Health services research is also broader than traditional clinical research, which directly focuses on patients in relation to their treatment and care. Clinical research has traditionally focused on biochemical indicators, and more recently, and in selected specialties only, on the measurement of the broader quality of life of the patients. Health services research investigates the outcome of medical interventions from social, psychological, physical and economic perspectives. It has also been cogently argued that health services research should be concerned with the evaluation of the health sector in the broadest sense, and not limited to health services alone (Hunter and Long 1993).

Quality assessment and audit will be described next, followed by the concepts central to the latter and to health services research: the evaluation of the structure, process and outcome, including appropriateness, of health services.

The assessment of quality

The quality of care for the purposes of health care evaluation can be defined in relation to its effectiveness with regard to improving the patient's health status, and how well it meets professionals' and the public's standards about how the care should be provided (Donabedian 1980).

Approaches include performance indicators and assessment, and patient surveys. Systematic evaluations of quality follow Donabedian's (1980) or Maxwell's (1984) broader approaches. Donabedian focused on the measurement of *structure* (inputs and resources, such as staffing, buildings, funding); *process* (service delivery, organisation and use, including resources – e.g. rates of consultations and referrals, waiting times, admission and discharge procedures, prescribing practices); *output* (productivity and throughput, including discharge rates, access, effectiveness, equity); and *outcome* (death, disease, disability, discomfort, dissatisfaction). Maxwell described six dimensions of quality: *appropriateness*; *social acceptability* (patients' views, met expectations); *effectiveness* (consistent with desired effect); *relevance to need*; *equity*; and *accessibility* (siting, language, disability-friendly). Broader definitions are shown in Box 1.1.

Box 1.1 Modern definitions of quality of care

Higginson (1994) stated that quality of care needs to include humanity, as well as effectiveness, acceptability, equity, accessibility and efficiency. Building on work by Shaw (1989) and Black (1990), she defined quality of health care in broad terms:

- effectiveness (achieving the intended benefits in the population, under usual conditions of care);
- acceptability and humanity (to the consumer and provider);
- equity and accessibility (the provision and availability of services to everyone likely to benefit (in 'need'));
- efficiency (greatest benefit for least cost).

Higginson adds that patient empowerment might also be included, in order that they may increase their control over the services received, and each patient should be offered care that is appropriate.

Quality is clearly relevant to health services research. Quality assurance and medical and clinical audit are all initiatives to establish and maintain quality in health care, and also involve the evaluation of structure, process and outcome in relation to quality.

Audit

Audit is directed at the maintenance and achievement of quality in health care. Audit aims to improve patient outcome, to develop a more cost-effective use of resources and to have an educational function for health professionals. In theory, it should lead to change in clinical practice by encouraging a reflective culture of reviewing current practice, and by inducing changes which lead to better patient outcomes and satisfaction.

Suggested criteria for undertaking an audit include: the issue addressed should be a common, significant or serious problem; any changes following audit should be likely to benefit patients and to lead to greater effectiveness; the issue is relevant to professional practice or development; there is realistic potential for improvement; and the end result is likely to justify the investment of the time and effort involved (Clinical Resource and Audit Group 1994). Investigators of audit have reported that most audit has focused on process, rather than structure or outcomes (e.g. Packwood 1995).

Medical audit, clinical audit, quality assurance and clinical governance

Audit consists of reviewing and monitoring current practice, and evaluation (comparison of performance) against agreed predefined standards (Standing Committee on Postgraduate Medical Education 1989). It is divided into medical and clinical audit, and is related to quality assurance. These have become commonplace in the British National Health Service (NHS) and are now built into the structure of provider units (e.g. hospitals and, increasingly, general practice). These three concepts have been clarified by Higginson (1994) (see Box 1.2.):

Box 1.2 Study of three concepts in audit

- Medical audit is the systematic critical analysis of the quality of *medical care*, including a review of diagnosis, and the procedures used for diagnosis, clinical decisions about the treatment, use of resources and patient outcome (Secretaries of State for Health, Wales, Northern Ireland and Scotland 1989a). Examples of medical audit include analyses of avoidable deaths, and the assessment of medical decision-making, resources and procedures used in relation to patient outcome.
- Clinical audit is conducted by doctors (medical audit) *and* other health care professionals (e.g. nurses, physiotherapists, occupational and speech therapists), and is the systematic critical analysis of the quality of clinical care. It includes collecting information to review diagnosis and the procedures used for diagnosis, clinical decisions about the treatment, use of resources and patient outcome (Secretaries of State for Health, Wales, Northern Ireland and Scotland 1989a).
- Quality assurance is a clinical and management approach which involves the systematic monitoring and evaluation of predefined and agreed levels of service provision. Quality assurance is the definition of standards, the measurement of their achievement and the mechanisms employed to improve performance (Shaw 1989). Medical and clinical audit is usually one part of a quality assurance programme. Quality assurance usually implies a planned programme involving the whole of a particular health service.

Audit can be carried out internally by organisations, members of a discipline (peer review), individuals who systematically review their work or that of their teams, or external bodies (e.g. purchasers for contract monitoring, or professional bodies). Certain criteria need to be met for conducting successful audit, including: effective clinical leadership;

strategic direction (vision, strategy, objectives and planning); audit staff and support (e.g. high calibre, right skill mix, reward, staff development); basic structures and systems (e.g. business planning); training and education; understanding and involvement (e.g. communication, leadership and so on); and organisational environment (e.g. structure, relationships) (Walshe 1995).

The process of audit

The process of audit involves multiple methods, such as document searching and analysis (e.g. analysis of complaints files, random or systematic selection of nursing and medical records for routine reviews), analysis of routine data, clinical case reviews and presentations in team meetings (see Hopkins 1990, for a review). It can also include the collection of information by focus groups of patients or by questionnaire, for example, patient satisfaction, patient-assessed outcome (see Riordan and Mockler 1996, for an example of this in an audit of a psycho-geriatric assessment unit). While quantitative research methodology is most appropriate for audit, much can also be gained by supplementing this with qualitative methods such as observation (e.g. visits to wards and clinics to assess quality by observation). The design of audits should also aim to be scientifically and methodologically rigorous (Russell and Wilson 1992; Department of Health 1993b).

Clinical governance

Clinical governance is a framework through which health care organisations are accountable for the quality and standard of the health care they provide. This is implemented by having systems in place to ensure best practice based on evidence-based medicine; clinical audit (measuring practice against predefined standards); monitoring and minimising risk; having systems for protecting patient confidentiality; education and training to enable staff competencies; providing good working conditions; being responsive to patients' needs; encouraging, and listening to, their feedback; being open about information and having formalised complaints procedures; and by patient and public involvement in service planning.

Evaluation

Evaluation is the use of the scientific method, and the rigorous and systematic collection of research data, to assess the effectiveness of organisations, services and programmes (e.g. health service interventions) in achieving predefined objectives (Shaw 1980). Evaluation is central to health services research and audit. It is *more* than audit because it aims to record not only what changes occur, but also what led to those changes. Evaluation can be divided into two types: formative and summative. Formative evaluation involves the collection of data while the organisation or programme is active, with the aim of developing or improving it. Summative evaluation involves collecting data about the active (or terminated) organisation or programme with the aim of deciding whether it should be continued or repeated (a health promotion activity or screening programme) (Kemmer and Booth 1992).