

Health research in context, defining the research question and designing the study

In this first part of a series on practical issues in research from the point of view of the cardiac nurse, Maria Flynn, Sarah Watmough, Angie Wright and Kathryn Fry introduce the wider context of research in the NHS, and highlight the importance of a clearly defined research question

An understanding of theory and method is an essential starting point for any cardiac nurses interested in becoming involved in research and the *British Journal of Cardiac Nursing* recently published a series of articles providing an overview of methods, techniques and appraisal of health research (Holt, 2009; Delaney, 2009a, MacInnes 2009a, Astin and Long, 2009; Delaney, 2009b; Goodman and Gilchrist, 2009; Astin, 2009; MacInnes 2009b; Delaney, 2010). In the course of their daily work many cardiac nurses may contribute to health research projects through recruiting patients to studies or collecting data for clinical trials. They may also be aware of aspects of care for which there is little evidence to guide practice or there may be everyday nursing 'problems' which need to be investigated. For those nurses who have an understanding of method and wish to become more actively involved in the research process there are a range of practical issues that also need to be considered.

Maria Flynn is Senior Lecturer and Director of NIHR MRes Programme, School of Health Sciences, University of Liverpool, L69 3GB; **Sarah Watmough, Angie Wright and Kathryn Fry** are NIHR trainees, University of Liverpool

Email: m.flynn@liverpool.ac.uk

KEY WORDS

- ◆ NHS research
- ◆ National Institute of Health Research (NIHR)
- ◆ Research questions
- ◆ Study design.

Accepted for publication 28 June 2009

Before any study can be designed and executed it is important to think about such questions as how the research will contribute to the wider health research agenda; what is the appropriate study design to answer the research question; what expertise is needed on the research team; should patients or members of the public be involved in the research; how should ethical approval and research sponsorship be secured; how are participants going to be recruited to the study; how is the research going to be funded and how are the results to be disseminated.

Dealing with these practical issues can be daunting, even for the most enthusiastic researchers. However, these aspects of the health research process are important and necessary to ensure good research governance and high quality health research which safeguards the best interests of NHS patients, the public and researchers (Department of Health (DH), 2006).

The context of NHS research

NHS research is driven by the DH and although the new UK government may ultimately change the current health research strategy, there is a widespread recognition throughout the service that first-class research is central to the provision of the best quality care in the NHS.

The National Institute of Health Research (NIHR) has patients and the public at its core and it serves to coordinate and support health research activity in the NHS. The NIHR is made up of four components—the faculty, the infrastructure, programmes and systems. The faculty consists of key opinion leaders and experts in different health-related fields. It also includes experienced health and social care researchers and clinical investigators who work in NHS trusts and

UK universities. NIHR trainees are experienced NHS staff developing their research expertise through PhD or Masters of Research (MRes) studies.

The infrastructure for NHS research includes national and regional research networks as well as especially dedicated units which develop and test new health interventions, techniques and technologies. There are twenty five Comprehensive Local Research Networks (CLRNs), based throughout the regions, which support health research programmes and large multi-centre trials. NHS research activity is also served by several national networks, which synthesize and support clinical research related to specific disorders or conditions such as Cancer (CRUK), Dementias and Neurodegenerative diseases (DeNDRoN), Diabetes (DRN) and Stroke (SRN). At a more local level all NHS trusts have a designated director of research and development (R&D) and many also have R&D departments who are responsible for coordinating and monitoring trust research activity.

Throughout the country the clinical research infrastructure is supported by the UK Clinical Research Collaboration (UKCRC), which brings together funding councils, professional regulatory bodies, patient groups and researchers in the NHS and universities (UKCRC, 2010).

The NIHR research programmes coordinate the management of funded research in the NHS and also support research units and centres dedicated to different types of health research activity. The NIHR provides funding for research programmes and individual projects and has a series of competitions and calls for research proposals, which are open to research teams seeking financial support for their projects.

Through the clinical academic careers pathway the NIHR also supports the development of research capacity in the NHS by funding nurses, midwives and allied health professionals to further their research knowledge and skills. The NIHR systems include the national research ethics service and governance network, information systems and a research advice service (NIHR, 2010). For a nurse starting to think about becoming involved in research the NIHR website is an invaluable source of information about current and planned research activity in the NHS (www.nihr.ac.uk).

The range and scope of health research is vast and the DH monitors NHS research activity under the UKCRC health categories (Table 1) and different research activity codes (Table 2). An awareness of these classifications can be useful to cardiac nurses when starting to think about a potential research project, both to gain an understanding of where their study may 'fit' into the wider context of NHS health research and also to help guide their preliminary searching of the existing evidence in their field of interest.

Defining the research question

Many important studies that have informed nurses and nursing began as questions arising from everyday experience or as a practice 'problem' in need of a solution (Pearson 2000; Polit and Beck, 2006). However, not all professional questions or problems are researchable and they may need to be the subject of an audit or practice review rather than a research study (Bowling, 2009). It may also be the case that something that seems to need investigation has already been well researched, and the challenge then becomes one of critical appraisal, synthesis of evidence and implementation of change (Craig and Smythe, 2007).

Defining and articulating a research question is a creative process involving experience and knowledge of the field of inquiry, insight and intuition, analytical thinking and reflection, reading and discussion. It also involves the researchers' own values and beliefs and the way they construct knowledge and make sense of the world of nursing. In practical terms an important preliminary stage in the formulation of a research question has to involve a thorough and structured search of existing evidence, both to enhance understanding and to ensure that the proposed ques-

tion has not already been well researched. Polit and Beck (2006) also suggest that nurses should be mindful of the potential significance of the research to nursing knowledge and practice and in the context of the wider NHS it is also important that

the proposed study has the potential to enhance some aspect of the service.

There are also questions of researchability and feasibility to be addressed. Health research questions that present significant moral or ethical dilemmas are unlikely to

Table 1.
Summary of UKCRC health categories

Blood	Metabolic & Endocrine
Cancer	Musculoskeletal
Cardiovascular	Neurological
Congenital Disorders	Oral & Gastrointestinal
Ear	Renal & Urogenital
Eye	Reproductive Health & Childbirth
Infection	Respiratory
Inflammatory & Immune System	Skin
Injuries & Accidents	Stroke
Mental Health	Generic Health Relevance
	Other

Table 2.
Summary of UKCRC research activity codes

Underpinning Research: normal biological development and functioning; psychological and socioeconomic processes; chemical and physical sciences; methodologies and measurements; underpinning resources and infrastructure
Aetiology: biological and endogenous factors; factors relating to physical environment; psychological, social and economic factors; surveillance and distribution; research design and methodologies (aetiology); resources and infrastructure (aetiology)
Prevention of Disease & Conditions & Promotion of Well-being: primary prevention interventions to modify behaviours or promote well-being; interventions to alter physical and biological environmental risk; nutrition and chemoprevention; vaccines; resources and infrastructure (prevention)
Detection Screening & Diagnosis: discovery and pre-clinical testing of markers and technologies; evaluation of markers and technologies; influences and impact; population screening; resources and infrastructure (detection)
Development of Treatments and Therapeutic Interventions: pharmaceuticals; cellular and gene therapies; medical devices; surgery; radiotherapy; psychological and behavioural; physical; complementary; resources and infrastructure (development of treatments)
Evaluation of Treatments and Therapeutic Interventions: pharmaceuticals; cellular and gene therapies; medical devices; surgery; radiotherapy; psychological and behavioural; physical; complementary; resources and infrastructure (evaluation of treatments)
Management of Diseases and Conditions: individual care needs; end of life care; management and decision making; resources and infrastructure (disease management)
Health and Social Care Services Research: organisation and delivery of services; health and welfare economics; policy ethics and research governance; research design and methodologies; resources and infrastructure (health services)

be researchable and those where there is insufficient time, resource, cooperation or available subjects/participants may not be feasible.

In addition, all research has to be located within a body of theoretical knowledge, which will provide the framework for interpreting data and generating new knowledge or understandings. Refining and articulating a valid research question will take considerable time and effort and is not a linear process. A 'good' research question is one which is clear and unambiguous, specific, researchable, feasible, theoretical and relevant (Robson, 2002; Polit and Beck, 2006; Bowling, 2009).

To illustrate, if a nurse were interested in specialist professional education and cardiac nursing practice, a question that asked 'why do nurses take courses in coronary care?' might be relevant as broad field of enquiry, but would be too vague and unfocused to usefully frame a research study. In this example an exploration of the knowledge base and research evidence around such things as professional development and education, adult learning theories and advanced nursing practice would be important in refining and focusing the research question.

The preliminary search and review of the existing evidence may reveal that when specialist trained nurses work with specific patient groups then overall patient satisfaction is increased. However, if there were no research at all that had been carried out in coronary care units, this would suggest that an exploratory study might be worthwhile. In this case the research question could be framed in terms of 'what is the patient experience of specialist nursing care in CCU?'. Alternatively, if the body of evidence showed that in units staffed by specialist trained nurses the patient length of stay was reduced, then an explanatory study might be indicated and the question could be articulated as 'what is the relationship between specialist nursing and patient length of stay in CCU?'.
At this point in defining the research question it is worthwhile to ask the 'so what' question. Considering the potential impact of the investigation will help the researcher to clarify whether the proposed study is relevant, if the emerging research question is clear and focused, whether the issue is researchable and feasible and also whether the results of the proposed study

would add to nursing knowledge and practice or the delivery of care in the NHS. The process of refining and clarifying the research question is essential in designing and delivering robust research and a 'good' research question and will guide the researcher to an appropriate study design and techniques for data collection.

Designing the study

Research study design is the process of turning ideas and questions into feasible projects (Bowling 2009). There are a wide range of methods and techniques that can be usefully applied to researching nursing problems (Polit and Beck, 2006) and new researchers can sometimes be overwhelmed with concerns about the 'best' method to employ. However, it is important to remember that the nature of the research question is of paramount importance.

If the research question is clear and focused, it will be possible to articulate the purpose of the study and it will then be apparent which research design would be most appropriate to meet the study aims. A clearly articulated research question will facilitate the clarification of study aims, help determine a necessary sample size, indicate feasible methods for collecting and analysing data, and help identify an appropriate theoretical framework in which to interpret the study findings.

In nursing and health research the purpose of studies can be broadly classified as descriptive, exploratory, evaluative or explanatory (Robson, 2002; Polit and Beck, 2006). Descriptive studies enable researchers to investigate and describe concepts, people or situations of interest to nurses and nursing. They can also be a useful starting point for generating further research questions. So for example, during the course of routine practice a nurse may observe that most patients participating in a cardiac rehabilitation programme are referred by the medical team. A descriptive study would enable the nurse to observe and classify the types, incidence and patterns of referrals to the rehabilitation service and may raise further questions about the referral process that are worthy of investigation.

Exploratory studies are useful for investigating novel or little understood phenomena or for assessing everyday situations or experiences in a new way. Exploratory studies can also generate questions for further

research. An illustration of this would be nurses working in a pre-operative cardiac surgery clinic who have a clear protocol to guide their practice and patient care, but who are also aware that they know very little about the experience and expectations of patients who are awaiting cardiac surgery. A preliminary search of existing evidence may show that there is a considerable body of research about the medical status of this patient group. The search and review may also reveal other research which has studied the pre-operative experiences of general surgical patients and also show that there is little or no evidence which is specific to pre-operative cardiac surgery patients. This may raise questions for cardiac nurses and cause them to wonder whether their patients' pre-operative experience is the same as those awaiting elective general surgery. If it were judged that an understanding of the patients' experience could enhance the care given to them, then it might be worthwhile to design an exploratory study to investigate the patients' perspective of something that is an everyday practice for cardiac nurses.

In the process of ongoing practice review and development it is often necessary to establish the value or assess the impact of an intervention, a treatment or an entire service, in which case an evaluation study can be used. Evaluation studies will differ depending on whether it is the processes or outcomes of the service that are being investigated. Although evaluation designs have some similarities with audit they are differentiated by being driven by a research question and a rigorous method of investigation. Like descriptive and exploratory study designs, evaluation studies can also generate questions for further research.

Studies with an explanatory purpose are those that seek to account for patterns, relationships and causes of the phenomenon under investigation and are necessary for the generation of new knowledge or to add understanding to an existing theory. An example of explanatory research can be found in those studies that have demonstrated the relationship between a specific human gene and a particular disease or disorder.

Similar to the stages in refining the research question, study design is not a linear process and it involves conceptualization of the whole research project and consideration of all the potential obstacles and pitfalls that may affect the study. When

designing the study it is necessary to maintain a clear focus on the aims and purpose of the research. This will determine who is going to be invited to participate and how this is going to be done. It will also indicate how many people need to be recruited to the study and whether there are sufficient resources to carry it out successfully.

At each stage of conceptualizing a research design an awareness of any potential problems that may arise makes it possible to evaluate alternative approaches. It is also important to consider what consequences any compromise in the study design may have for the results of the proposed study. If a statistician had calculated that it was necessary to recruit 200 new patients to a study in order to show statistical significance in findings, and there were only 100 new patients in the population of interest presenting in any given year, and it was only possible to secure research funding for 18 months, then the researcher would have to reconsider the overall project and make decisions about the proposed design. Would the study still provide valuable information even if statistical significance could not be demonstrated? How robust and applicable would the study findings be if only 100 patients could be recruited? Are there other funding bodies that may finance the study for a longer period of time? In making these types of decisions the advice and support of experts in the field and experienced health researchers is invaluable.

It is also important for nurses to remember that not all good or interesting ideas will necessarily translate into worthwhile research projects and at some point in the process of articulating a research question or designing a study the proposed project may cease to be feasible. In this case the idea should be abandoned as a research enquiry and other solutions should be sought in the existing body of evidence or in trialling changes in practice.

Conclusions

In the modern NHS the generation and use of evidence is an important aspect of professional nursing practice. While many cardiac nurses may be aware of research, or have a role in clinical studies, there is still a need for research that addresses issues specific and relevant to the wide range of cardiac nursing practices. In order to make the transition from participation in medi-

cal or other research to the generation and ownership of ideas, cardiac nurses need to be equipped with research knowledge and skills. They also need to be aware of the practical aspects of designing and carrying out research in the wider context of the NHS research agenda.

The development and refinement of the research question can be a protracted process, but is fundamental to good research. It is important that research questions have the potential to inform cardiac nursing knowledge and practice and are also relevant to the NHS.

A clear research question will facilitate the process of designing an ethical and feasible study and it is necessary to maintain a focus on the aims and purpose of the inquiry. Although it is important to remember that not all ideas will translate into worthwhile research projects, clarity about whether the purpose of the study is to describe, explore, evaluate or explain will enable the researcher to determine a study design which is most appropriate to achieve the study aims.

Astin F (2009) A beginners guide to appraising a qualitative research paper. *British Journal of Cardiac Nursing* 4(11): 530–3

Astin F, Long AF (2009) Qualitative research: An overview. *British Journal of Cardiac Nursing* 4(8): 390–3

Bowling A (2009) *Research Methods in Health:*

Further reading: Sources of useful information

National Institute of Health Research – www.nihr.ac.uk

R&D Information (part of the NIHR and provides information about sources of funding and support for research projects) – www.rdinfo.org.uk

INVOLVE – (part of the NIHR and provides information and advice about patient and public involvement in health research) – www.involve.org.uk

UK Clinical Research Collaboration – www.ukcrc.org

Investigating Health and Health Services. Open University Press, London

Craig J, Smythe RL (2007) *The Evidence Based Practice Manual for Nurses*. Churchill Livingstone, Edinburgh

Delaney L (2009a) Descriptive statistics: Simply telling a story. *British Journal of Cardiac Nursing* 4(6): 283–9

Delaney L (2009b) Inferential analysis: Powerful storytelling. *British Journal of Cardiac Nursing* 4(9): 430–4.

Delaney L (2010) Hypothesis testing: To doubt or not to doubt. *British Journal of Cardiac Nursing* 5(2): 78–83

Department of Health (2006) *Best Research for Best Health: A New National Health Research Strategy*. DH, London

Goodman M, Gilchrist M (2009) Reading and critiquing randomised controlled trials. *British Journal of Cardiac Nursing* 4(10): 492–7

Holt J (2009) Qualitative research: an overview. *British Journal of Cardiac Nursing* 4(5): 234–6

MacInnes D (2009a) Understanding a systematic review. *British Journal of Cardiac Nursing* 4(7): 331–4

MacInnes J (2009b) Mixed methods studies: a guide to critical appraisal. *British Journal of Cardiac Nursing* 4(12): 588–91

National Institute of Health Research (2010) The National Institute for Health Research Systems <http://www.nihr.ac.uk/systems/Pages/default.aspx>. (accessed 28 June 2010).

Pearson M (2000) Making a difference through research: How nurses can turn the vision into reality. *NT Research* 5(2): 85–6

Polit DF, Beck CT (2006) *Essentials of Nursing Research: Methods, Appraisal and Utilisation*. Lippincott, Philadelphia.

Robson C (2002) *Real World Research*. 2nd edn. Blackwell, Oxford

UK Clinical Research Collaboration (2010) Research Infrastructure <http://www.ukcrc.org/infrastructure> (accessed 28 June 2010).

KEY POINTS

- ◆ Good quality health research is essential for the NHS and the NIHR supports health research through the infrastructure, programmes, systems and the faculty
- ◆ The quality of the research question is central to good health research
- ◆ Study design is directly related to the research question, the aims and purpose of the study and a clear focus on what the study is trying to achieve.
- ◆ When embarking on the development of a research idea the practical considerations in research planning and study design can be daunting, but are ultimately worthwhile in enhancing the evidence base for cardiac nursing practice

Copyright of British Journal of Cardiac Nursing is the property of Mark Allen Publishing Ltd and its content may not be copied or emailed to multiple sites or posted to a listserv without the copyright holder's express written permission. However, users may print, download, or email articles for individual use.