

Clinical research nurse and nurse research roles are distinct but often confused with each other. Understanding both will help nurses pursue the right research career path

Clinical research nurse or nurse researcher?

In this article...

- › Outline of the clinical research nurse role
- › Details of the nurse researcher roles
- › Growth and future expectations for both roles

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This article gives an overview of two research-related roles that can form part of a nurse's career path: clinical research nurse and nurse researcher. It highlights the influences on both roles, and the skills and differences within them, as well as offering advice on how nurses can access either role.

Research is at the heart of evidence-based healthcare, and its importance in the NHS has recently increased. The Health and Social Care Act (2012) acknowledged the importance of research and pledged to embed it as a core function of the NHS.

Nurses' involvement in research has grown, and two distinct roles have emerged to enable them to forge a career in this area: clinical research nurse and nurse researcher. These roles are now recognised within the profession (Box 1).

The terms "clinical research nurse" and "nurse researcher" are often confused and used interchangeably (MacArthur et al, 2014; Johnson and Stevenson, 2010) but each role – and its requirements – varies considerably. Each role's skills and responsibilities are unique, and each can be a career path in its own right. Table 1 (p14) highlights the key differences.

Clinical research nurse Growth in the role

The clinical research nurse (CRN) role has become an established and increasingly

intrinsic part of many multidisciplinary teams. Roles and responsibilities have developed and nurses can now progress up the salary scale as their skills increase.

Much of the growth is the result of the development of the research network infrastructure across the country, which began with the establishment of the National Cancer Research Network in 2001. The publication of Best Research for Best Health (Department of Health, 2006) led to the setting-up of the National Institute of Health Research (NIHR) and further growth of the research networks system to cover all therapeutic areas.

Many organisations have a growing CRN workforce across numerous clinical areas. This growth has occurred in line with an increase in research activity across many organisations. In 2013-14 the NIHR Clinical Research Networks recruited more than 600,000 patients to studies. More than 3 million patients have been recruited since 2008 (*The Guardian*, 2014).

Role responsibilities and skills

As the CRN workforce has grown, the role has become multifaceted: CRNs take increasing responsibility across the whole research pathway, from setting up studies to closing them down and archiving all study-related documents. The role focuses around the coordination and management of clinical trials to ensure adherence to:

- » Study protocols and procedures;
- » Research governance requirements;
- » Patient safety.

Clinical trial studies often involve testing new drug treatments or devices (interventional studies), but can also include non-treatment studies (observational studies), such as those that may

5 key points

1 Research is a growing area for nursing careers

2 The roles of clinical research nurse and nurse researcher have both developed over recent years

3 Although the roles have similarities they both require unique skills and can each be a career path

4 The National Institute of Health Research has had a major impact on the development of both of these roles

5 Fully funded training schemes are available to help support nurses to develop as researchers



Nurses must ensure the safety of patients in research studies by observing symptoms

measure patient experience or quality of life related to a longstanding health condition.

It was recognised more than 30 years ago that the quality of clinical therapeutic studies improved when nurses were involved (Barnes, 1981). Since then, the role of the CRN has evolved with the influence from the pharmaceutical industry and the need for dedicated support in their drug development programmes.

Governance

An increase in research governance, legislation and guidelines now means that CRNs must ensure all studies within their team are fully compliant with requirements; as a result of this, training in these areas is an important initial requirement of the role. Although the degree of responsibility may vary, before any patients consent to a study, CRNs must ensure all necessary approvals have been obtained and the relevant correspondence is stored in the study site file.

Patient safety

Ensuring the safety of patients in research studies is a requirement for the in-depth collection and reporting of any symptoms they experience. "Adverse event reporting" involves recording all incidents that have occurred to a patient while involved in the study, whether related or not.

CRNs are generally patients' first point of contact, so it is important that patients and other staff involved in their care understand that during the study CRNs must be made aware of any new symptoms. They will be discussed with the principal investigator (PI) and an assessment of their severity will be made, along with a note of which of the research reporting criteria they fit. The CRN will often take the lead in reporting these to the study sponsor. When serious events occur, such as hospital admission or death, the study sponsor is informed within 24 hours of the research team being made aware of them.

Communication

Effective communication skills are vital for any CRN, particularly when gaining patients' informed consent to participate in a research study. Although the primary responsibility for obtaining consent lies with the PI, CRNs have a key role in the initial explanation to patients and relatives so they fully understand what is involved before deciding whether to take part.

If a study involves a new treatment, this explanation may often involve a complex discussion of the drug involved and any known or possible side-effects.

BOX 1. GLOSSARY OF TERMS

- **Principal investigator (PI)** The main researcher, often a doctor, responsible for a research study at a hospital.
- **National Institute of Health Research (NIHR)** Main Department of Health-funded body that is responsible for funding NHS research
- **Research governance** The process covering the required guidelines and legislation around the running of research studies
- **Study site file** The main file, which contains any document used within the study and information related to the conduct of the study
- **Adverse events** Any clinical symptoms experienced by the patient during the study, whether related to the trial or not
- **Study sponsor** Organisation responsible for the management of a research study

Study management

Leadership and organisational skills are also crucial for CRNs. Although the responsibility for a clinical trial remains with the PI, CRNs often play a key role in its overall coordination and management. This can include groups of studies that may be at various stages in the research process. Coordinating and managing trials involves:

- » Helping to identify potential study participants;
- » Helping to recruit patients to the study;
- » Coordinating all follow-up visits, along with any investigations required within these;
- » Collecting and reporting investigation results and patient data in a timely manner. Within this is a requirement to liaise with numerous clinical departments including pathology, imaging and outpatient areas.

Clinical research nurses will also become skilled in many new roles that, traditionally, may not have been associated with a nursing role. Within their study portfolio there may be a requirement to become competent in a particular skill related to the clinical area of the study; this can include skills such as skin biopsies for dermatology CRNs, or lung function tests for respiratory CRNs. All CRNs will become skilled and competent within their clinical area and so their knowledge level can often be likened to that of a nurse specialist.

Nurse researcher

Whereas the CRN role involves working on projects related to treatments and patient care, nursing research is based on the acquisition of new knowledge related to the progression of nursing. It has been defined as a "systematic inquiry designed to develop knowledge of importance to nurses, including nursing practice, nursing education and nursing administration" (Polit and Beck, 2006).

The role of the nurse researcher is generally part of an academic career path that allows nurses to undertake further education such as a master's degree or PhD. Like the CRN role, the nurse researcher role has undergone a period of development over recent years, which has allowed an increasing number of nurses to choose this as part of their career. However, unlike the CRN role, where initial entry requires advanced clinical skills and a desire to acquire the relevant research skills, the role of a nurse researcher requires a baseline knowledge of research methodologies.

The UK Clinical Research Collaboration (2007) examined the role of nurses as researchers and identified the barriers that prevented them from pursuing research careers. It determined that:

- » Most nurses involved in research were doing so as part of a CRN role, while working on clinical trials;
- » A major reason for the lack of nurses doing their own research was that few were sufficiently skilled to lead research programmes.

The UK CRC therefore recommended the establishment of a clinical academic training path to support further development of nurse researchers.

Clinical academic training pathway

Currently, most nurse researchers are lecturers who are leading research projects as part of their academic job, or carrying out a research study within their current clinical role as part of an academic qualification. The NIHR's aim is to create more clinical and academic careers in research for nurses. It has played a major part in helping to develop and fund the clinical academic training pathway, which gives nurses the opportunity to apply for fellowship grants to fund their academic studies at various levels. As an initial step, the pathway supports a master's degree in clinical research places for nurses, midwives, allied health professionals and pharmacists who work in the NHS, and currently allocates funding to 12 higher education institutions to provide this.



“I love my job and in five years’ time I would like to be in the same care home, continuing to care for older people”

Paul Phelue >p24

TABLE 1 CLINICAL RESEARCH NURSE AND NURSE RESEARCHER ROLES

Function	Clinical research nurse	Nurse researcher
Experience/knowledge	Previous experience not initially required when choosing this role	Required to have an initial knowledge and understanding of research methodologies
Research ideas	Carries out research related to other people’s ideas	Develops own research ideas
Leadership areas	May not lead on the getting required approvals but must ensure all in place before study starts	Generally leads on obtaining the required ethics and research and development (R&D) approvals
Data analysis	Not routinely involved in data analysis and reporting	Analyses results and reports findings
Working methods	Often works as part of a team	Often works independently
Location	Usually based within a hospital	Often based within a university department
Study areas	Studies are often treatment related	Studies answers an academic questions related to nursing
Number of studies	Coordinates the running of a group of studies	Generally focuses on one project
Patient care	Often directly involved with patient care pathway	No direct involvement with patient care

Funding covers applicants’ salary and course fees, and allows them to be seconded from their current role to provide dedicated time to develop these skills. Once they have completed the master’s degree, nurses can apply for PhD and post-doctoral fellowships to further develop their research training. Details are available on the NIHR website (Bit.ly/NIHR-TrainingProgs). This programme is proving successful; four members of the research nurse workforce at Guy’s and St Thomas’ Foundation Trust have been accepted to study for a 12-month master’s in research, while another has been accepted for a PhD.

Study management

Unlike CRNs, whose role is based around supporting other people’s research ideas, nurse researchers must be able to develop their own ideas into robust research questions and projects, based around a structured methodology. If they are undertaking a research degree they will have support in this from an academic supervisor.

As well as developing a research idea and question, nurse researchers must also complete any associated documents required for the running of the study. This may include:

- » Participant information sheets and consent forms;
- » Interview schedules;
- » Survey questionnaires;
- » Any other data collection tools.

This is one of the big differences between the two roles, as CRNs often have limited or no involvement with this side of a research project.

Nurse researchers must lead on all study activities, including identification

and consent of study subjects and all data collection. Following this, in-depth analysis of all data is required to identify the main study findings. This is a unique aspect of the role compared with that of CRNs; their role in studies is generally completed once all data collection is over, especially if their workload is based around clinical trials.

Governance

Like CRNs, nurse researchers must ensure all research governance requirements are met before the start of their research project. However, it will be their responsibility to lead on this, including completion and submission of all documents. As part of an academic pathway, ethics approval will need to be sought from their academic institution and then the main National Research Ethics Service if their project involves patients. Approval from the research and development department within the organisation where they plan to carry out their research may also need to be sought. Nurse researchers must be aware of all the requirements within this and make the necessary decisions as to what approvals are required.

Conclusion

Research is a growing area for nurses, who have the opportunity to develop their skills within two distinct roles. Those working as CRNs may often cross over into the role of nurse researcher as part of an academic programme of study. Awareness of NIHR-funded schemes is growing and in 2013/14 the institute awarded 12% of its academic training programmes across all of its awards to nurses. An aspirational goal has been set that by 2030, 1% of the qualified nursing and midwifery workforce will be

working in a clinical academic role (Association of UK University Hospitals, 2012). To help achieve this, nurses must continually be made aware of the research options available to them and provided with the necessary support to develop into the role of their choice. This will support the future change in nursing research to equip more nurses to lead on research projects related to the nursing profession. **NT**

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