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JOSEPHINE G PATERSON

The role of the clinical research nurse

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Abstract

With increased emphasis on clinical research within the NHS, it is vital that training and educational opportunities are available to enable clinical research nurses to progress in their careers. This article describes the work of the clinical research nurse and examines the advantages and disadvantages of the role. It discusses the history of clinical research nursing and those aspects and guidelines that have shaped the way the role has developed. The lack of a career pathway for nurses who decide to pursue a career in nursing research and/or medical research is considered, and suggestions are made regarding the future of clinical research nursing and education.

Authors

Claire Louise Gibbs
Critical care clinical research sister, St Mary's Hospital, Imperial College Healthcare NHS Trust, London.

Karen Lowton
Senior lecturer in ageing and health, Institute of Gerontology, King's College London.

Correspondence to: claire.gibbs@imperial.nhs.uk

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CLINICAL RESEARCH NURSING combines the more familiar nursing responsibilities of holistic patient care with the world of clinical research protocols, governance and management. The clinical research nurse (CRN) is 'employed principally to undertake research within the clinical environment' (UK Clinical Research Collaboration (UKCRC) 2007). This article considers what a CRN does, what rewards and challenges those working in the role can expect, and how far their educational needs are being supported.

Role definition

CRNs are registered nurses who usually possess at least 12 months' post-registration general nursing experience. They work as members of multidisciplinary study teams that can consist of physicians, pharmacists and staff from other disciplines who have a specific interest in the clinical study. The principal investigator is the person who takes overall responsibility for the conduct of the study; this is usually a physician, although the principal investigator can come from any health discipline, including nursing.

The research studies on which CRNs work are often therapy-related, for example clinical trials that aim to test the properties and effectiveness of a new drug or intervention. Such studies are interventional and usually, through a process of randomisation, compare new therapies or interventions against standard treatments; research teams and patients are deliberately not made aware of whether a patient has received the new therapy or standard treatment. Clinical trials are conducted in four phases:

- Phase I tests a new drug or treatment in a small group of healthy volunteers.

- Phase II expands the study to a larger group of volunteers and patients.
- Phase III studies are conducted with an even larger group of patients and are often randomised to confirm therapeutic effect.
- Phase IV consists of formal post-marketing surveillance studies, which may include other population groups and surveillance for interactions with other drugs.

CRNs may also manage observational studies in which inferences are drawn or hypotheses tested through non-interventional methods; here, events are often simply observed and described as they occur naturally. One example of an observational study involves the discreet but overt observation of contact between multidisciplinary staff and patients' relatives in the critical care unit to understand current practice and uncover similarities and differences in multidisciplinary team members' communication styles. In this way, helpful and unhelpful aspects of staff members' interactions with family members can be identified and staff members' awareness of these may be subsequently improved through education and training. In this type of study, the CRN's role would be to observe and document discussions, make note of body language and identify salient themes through analysis of the data.

The CRN's main responsibility is to co-ordinate day-to-day trial management and to ensure studies are conducted in line with relevant legislation, research protocols and guidelines. CRNs possess a high degree of autonomy and have a high level of patient contact, with their communication and practical skills being used constantly. The role of the CRN is vital, although the specific skills required can vary according to the type of study conducted. The most common skills and responsibilities include screening, recruitment and obtaining informed consent from patients and/or relatives; administration of the intervention being studied; monitoring participants and performing some laboratory work, collecting data and reporting any adverse events; and general management of the trial, including maintenance of study files and resolving data queries.

Essential aspects of an experienced CRN's role include communicating with study sponsors and training and supervising nursing, medical and new research team members. These CRNs also work on regulatory procedures, such as obtaining approval for a study from an appropriate NHS research ethics committee and gaining insight into the internationally agreed guidelines that govern the way in which clinical trials are conducted. As they are in an ideal position to instigate change from the frontline, more experienced CRNs may develop their own research questions, devise study protocols and conduct their own studies.

Recent history of clinical research nursing

Over the past decade government and national research bodies, such as the Department of Health (DH) and National Institute for Health Research, have encouraged suitably qualified nurses to consider clinical research nursing. The DH published *Making a Difference* in 1999, which aimed to strengthen training and education for nurses and establish new career pathways, and *Towards a Strategy for Nursing Research* (DH 2000), which recognised that as a significant part of the NHS workforce nurses should be encouraged to become actively involved in research. At the time these documents were written, however, the number of nurses with research skills and qualifications was unknown and recommendations of how many should be working in this capacity were not made. Interestingly, the number of CRNs working in the NHS is still not known.

In 2004, the UKCRC was formed with the aim of re-establishing the clinical research environment in the UK. The UKCRC is a national partnership of health-related research funding bodies, academic organisations, the NHS, regulatory bodies, the bioscience, healthcare and pharmaceutical industries, and patients. An initial aim of the partnership was to address the fact that conducting research was much more difficult than it needed to be, despite the NHS providing a perfect environment in which to conduct high-quality studies. One early recommendation of the UKCRC was to encourage trusts to employ CRNs to manage specific clinical research studies.

A research strategy, *Best Research for Best Health* (DH 2006), continued to promote the importance of clinical research and encouraged nurses to conduct this within a research team, although no career structure was developed and no funding was available. In 2007, the UKCRC recognised CRNs as integral to the success of NHS research and established career progression pathways for research nurses as a priority. As CRNs can undertake very different roles and often receive different levels of support for professional and career development (Raja-Jones 2002), the Royal College of Nursing devised a competency framework within the UKCRC's recommended career pathways

(UKCRC 2009); however, it was left to individual organisations to decide whether this framework was adopted.

The *Operating Framework for the NHS in England 2009/10* (DH 2008) emphasised the need for all providers of NHS care, including nurses, to increase their participation in research and set out to double the number of patients taking part in clinical research within five years. In the same year, the National Institute for Health Research began to fund education for those wishing to take part in clinical research by launching a clinical academic training pathway for nurses, midwives and allied health professionals.

Benefits of being a clinical research nurse

The role of a CRN is intellectually demanding, which encourages personal development and a desire for knowledge. CRNs possess many skills that are highly respected by fellow healthcare professionals (including medical staff) and develop skills associated with essential patient care. Performing laboratory techniques such as centrifugation (a process used to separate cells and plasma) alongside analytical skills such as quantitative and qualitative data analysis are additional competencies developed in the CRN role. CRNs work autonomously, take on managerial responsibilities – those in senior positions are often in charge of a financial budget – and collaborate closely with clinical and academic staff, as well as with study sponsors and pharmaceutical companies, all of which enhance the individual's communication capabilities.

As teaching is fundamental to the smooth running of research studies, public speaking and general teaching skills are developed and consolidated. CRNs help to develop cohesion between nursing, medicine and science. Specialist knowledge of research methodologies, and the provision of support and education for multidisciplinary staff, assist in closing the historical hierarchical gap between nursing and medicine. The ultimate reward for the CRN is the awareness that the research he or she is conducting is likely to have a positive benefit for patients both now and in the future.

Challenges associated with clinical research nursing

Although the CRN's role brings many rewards, some challenges remain. Nurses may enter the CRN role after years of clinical experience to find themselves running multiple studies early in their research careers, which can affect their self-confidence and lead them to question their decision to leave clinical care. Lack of job descriptions and inappropriate line management have also been described as issues for CRNs (Pitt 2011). Occasionally clinical colleagues from other disciplines appear not to understand the nature of the research. They may perceive the CRN's role as attempting to direct medical treatment and so undermine the treating physician's authority. This can lead to role conflict; for example, in wanting to alter a patient's planned care, the treating physician may go against an agreed research protocol (Hill and MacArthur 2006). In these situations, the CRN needs to be clear about his or her role and retain the essence of why the research is being undertaken, which is to enable better treatment for patients.

NHS trusts are beginning to recognise the need to structure research nursing careers to improve the safety and quality of research, but they also admit that provision of and access to training, education, management, support, supervision and career progression is not readily available (UKCRC 2007). Many CRNs are employed on fixed term contracts, leading to concerns about job security. Some trusts may not fund nurses' further study if they have little continuous service, therefore applications for funding and study time can be rejected.

The future

It is debateable whether more than a decade of reports and proposals that advocate the importance of clinical research nursing and training to support this career structure has led to improved access to opportunities and education for CRNs. Organisations in the UK are beginning to enable nurses' to obtain postgraduate qualifications such as a master's degree in research, which is one positive step towards the provision of education for CRNs with significant research nursing experience. However, a challenge for less experienced CRNs is developing a basic understanding of the different approaches, principles and methodologies of research studies. Obtaining this knowledge while running studies in full-time employment is challenging and the decision of where to start can be daunting.

Although CRNs need to take personal responsibility to search for funding for courses, changes and developments are gradually making access to education easier. Of the minimal number of qualifications available, few have been relevant for nurses new to the CRN role. With increased emphasis on clinical research in the NHS, it is

vital that training and educational opportunities are available to enable CRNs to progress in their careers. However, there are few courses in the UK that provide research methods training and academic recognition for research nurses who are new to the CRN role. It is hoped that in time more courses will be developed to enable more CRNs to take advantage of training while they work. As postgraduate qualifications are becoming more commonplace through postgraduate certificate, diploma and master's programmes, they should be considered as an integral aspect of the CRN career pathway.

One of the authors, Claire Louise Gibbs, was keen to embark on a postgraduate research methods course to improve her knowledge, skills and understanding of conducting health-related research and was able to undertake a Postgraduate Certificate in Research Methods for Social Science and Health at King's College London after securing a fully funded research scholarship from the Florence Nightingale Foundation.

Conclusion

The role of the CRN is diverse, rewarding and challenging. Managerial tasks and communication with participants, colleagues and study funders must be undertaken alongside the more familiar tasks of patient care and data collection. Assertiveness, determination and commitment are required to maintain high standards of clinical research, patient care and job satisfaction. Government and NHS trusts are beginning to realise the importance of such nursing roles; however, access to education, training and funding remains limited. Typical research contracts last for 12 months and a lack of continuous service with an NHS trust can lead to rejections for funding and study requests. The availability of funding and high-quality postgraduate education are two vital steps in increasing the competence of CRNs, new and experienced alike **NS**

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Further information on the Postgraduate Certificate in Research Methods for Social Science and Health at King's College London is available from http://tinyurl.com/7rcbbpf

References

Department of Health (1999) *Making a Difference: Strengthening the Nursing, Midwifery and Health Visiting Contribution to Health and Healthcare.* The Stationery Office, London.

Department of Health (2000) *Towards a Strategy for Nursing Research and Development: Proposals for Action.* The Stationery Office, London.

Department of Health (2006) *Best Research for Best Health: A New National Health Service Research Strategy.* The Stationery Office, London.

Department of Health (2008) *The Operating Framework for the NHS in England 2009/10.* The Stationery Office, London.

Hill G, MacArthur J (2006) Professional issues associated with the role of the research nurse. *Nursing Standard.* 20, 39, 41-47.

Pitt H (2011) *Maximising the Nursing Contribution to the UK Clinical Research Agenda.* http://tinyurl.com/78exakh (Last accessed: February 9 2012.)

Raja-Jones H (2002) Role boundaries: research nurse or clinical nurse specialist? A literature review. *Journal of Clinical Nursing.* 11, 4, 415-420.

UK Clinical Research Collaboration (2007) *Developing the Best Research Professionals. Qualified Graduate Nurses: Recommendations for Preparing and Supporting Clinical Academic Nurses of the Future. Report of the UKCRC Subcommittee for Nurses in Clinical Research (Workforce).* UKCRC, London. www.ukcrc.org/index.aspx?0=1514 (Last accessed: February 9 2012.)

UK Clinical Research Collaboration (2009) *Clinical Academic Careers for Nurses, Midwives and Allied Health Professionals.* UKCRC, London. http://tinyurl.com/ykusout (Last accessed: February 9 2012.)