



SHARPENS YOUR THINKING

Towards a framework of advanced nursing practice for the clinical research nurse in cancer care.

BIRD, J. and KIRSHBAUM, M.

Available from Sheffield Hallam University Research Archive (SHURA) at:

<http://shura.shu.ac.uk/303/>

This document is the author deposited version. You are advised to consult the publisher's version if you wish to cite from it.

Published version

BIRD, J. and KIRSHBAUM, M. (2006). Towards a framework of advanced nursing practice for the clinical research nurse in cancer care. *Clinical effectiveness in nursing*, 9 (3/4), 161-171.

Repository use policy

Copyright © and Moral Rights for the papers on this site are retained by the individual authors and/or other copyright owners. Users may download and/or print one copy of any article(s) in SHURA to facilitate their private study or for non-commercial research. You may not engage in further distribution of the material or use it for any profit-making activities or any commercial gain.

Towards a Framework of Advanced Nursing Practice for the Clinical Research Nurse in Cancer Care

Joanne Bird RN BMedSci

Marilyn Kirshbaum RN BSc MSc PhD

ABSTRACT

Background

The Nursing and Midwifery Council (NMC), the regulatory body in the UK, is in the process of opening a new part of the register for Advanced Nurse Practitioners. This presents a potential opportunity for clinical research nurses within cancer care.

Objectives

To explore the role of the clinical research nurse in cancer care whilst considering whether the role can be performed at a level that could be considered advanced practice. Consequently, a developmental model to enable the clinical research nurse to work towards an advanced level of practice is explored.

Method

A literature review of the clinical research role in cancer care and analysis of published frameworks of advancing practice in nursing.

Discussion

Advanced practice is not defined by the role but by the level of skill to which it is performed. There is scope within the role of the clinical research nurse to practice at a level beyond initial registration. A framework for development towards advanced practice within the cancer clinical research nurse role is suggested.

Conclusion

Advanced practice within clinical research nursing is possible and provides a further level of career development that may facilitate movement between research and

clinical practice. This could aid awareness, recruitment and retention of research staff within cancer care and other specialities.

Keywords: advanced practice, cancer care, research nurse, conceptual framework

Background

In the United Kingdom (UK) there is a noticeable momentum concerning advancing nursing practice that has been recognised by the central government and regulatory agencies. Recently, the Department of Health (DH) introduced the Agenda for Change (DH 2003) as a new pay structure applicable to the majority of National Health Service (NHS) employees to promote increased equity across the service. An attempt was made to reduce the number of titles used by health care professionals; this proved to be an unsettling experience for many nurses working in advanced clinical roles.

Within the profession, the Nursing and Midwifery Council (NMC 2005) proposed a framework aimed at providing a regulated level of practice beyond that of initial nurse registration to protect the public and provide a recognised standard. The framework provided grounds for speculation and debate surrounding which nurses may be permitted to use the title of 'Advanced Nurse Practitioner'.

Within cancer care, the clinical research nurse has a diverse and complex role, one which could be considered to involve a level of nursing practice beyond initial registration. The benefits or rationale of a research nurse registering as an advanced practitioner may not be apparent. It may only add another title, possibly 'Research Nurse Practitioner'. It would, however, if sufficiently acknowledged and understood, provide a more flexible career path for nurses working within clinical research; it could afford a level to work towards and extend existing careers in research, or facilitate movement into a more clinically focused post. A flexible career path through research and back to clinical practice may encourage more nurses to consider clinical research as a career option, encouraging recruitment and facilitating a greater appreciation of clinical research in general.

Aim and Objectives

The aim of this paper is to examine the role of the clinical research nurse in cancer care and the potential within this role to practice at an advanced level, which will hopefully provide some valuable clarity to nurses practicing in this specialty area.

Three main questions were posed.

1. What are the main elements of the clinical research nurse role within cancer care?
2. Can the role of the clinical research nurse be applied to models of advanced practice?
3. If the potential to practice at an advanced level exists within the role, how can the clinical research nurse develop towards becoming an advanced practitioner?

A model for this development is consequently explored.

Method

A literature review of the role of the clinical research nurse role and analysis of published frameworks of advance practice were utilised to explore the concept of advancing practice within the context of clinical research nursing in the UK and present a developmental model.

The literature search

To identify literature pertaining to the role of the research nurse, a systematic search of the MEDLINE and CINAHL databases and the Internet via Google Scholar was conducted. The search terms 'research', 'nurse', 'clinical trial', 'study site' and 'co-ordinator' were initially combined in the search for relevant literature. Findings were then combined with the term 'cancer' to further narrow the literature search to only those articles that relate to oncology. Only literature regarding the UK was retrieved

in accordance with the objective of the search. In addition, only articles published during the period 2000 - 2005 have been accessed due to the considerable impact on service brought about by the publication of The Cancer Plan (Department of Health 2000), which recommended the formation of the National Cancer Research Network (NCRN) and recognised the importance of a dedicated cancer research workforce, to integrate research into cancer care. The final selection of eight articles was obtained from a total of 246 potentially relevant citations by excluding literature that did not directly relate to the role of the research nurse (or study site coordinator, as the two titles are often used interchangeably). NCRN, local Research and Development, Royal College of Nursing (RCN) and NMC policy and guidance articles were searched for relevance and incorporated into the investigation, even if published outside of the search period (e.g. RCN 1998). Textbooks relating to cancer nursing practice were also searched for applicable chapters and perspectives.

The literature retrieved as a result of the above search regarding the role of the research nurse was of variable quality and lacked empirical contributions. The majority of the articles consisted of expert opinion. One was a systematic literature review, one was a post-intervention role evaluation and the remaining being expert opinion supported by relevant literature. There was limited criticism of previous literature within the work retrieved, but this may be due to the searches of those works producing papers that were largely anecdotal or descriptive with no empirical evidence (Raja-Jones 2002). This would suggest that little of any further empirical evidence has been published within the last three years, although the results of a more thorough systematic review may have had slightly different conclusions. The current search strategy revealed that there was a significant amount of literature relating to the role of the nurse as a researcher, but for the most part they are not empirical. There was also an abundance of American literature concerning the

clinical research nurse; future work extending the analysis to include this body of work, would be valuable and may identify national and cultural differences.

Models of advanced practice specific to nursing were drawn from a previously unpublished systematic search of the nursing literature, which identified seven conceptual models and frameworks (Kirshbaum & Hempshall 2004) out of 84 retrieved articles published between 1994 and 2004 on the subject of the advanced clinical nurse. The models that seemed most appropriate and adaptable to the role of the research nurse were selected to address the aims of the current investigation.

The role of the clinical research nurse within cancer care

Common themes have emerged from the literature, which demonstrates a degree of congruency. For the purposes of synthesis the themes have been divided into: facets of the role of the clinical research nurse in cancer care (Box 1) and the knowledge and skills required for this role (Box 2). Some skills are not explicitly stated in all of the literature, but are essential for specific aspects of the role. For example, assessment skills are not noted in all of the papers, but are an integral requirement for the screening of potential trial participants.

Raja-Jones (2002) explored the role conflict between the clinical nurse specialist and clinical research nurse, and suggested that research can be considered a clinical speciality. The clinical nurse specialist role, along with the nurse practitioner role, is often referred to in the literature on advanced practice, however, the question remains concerning the place of the clinical research nurse in advanced practice.

The role of the research nurse as applied to frameworks of advanced practice

It appears that the concept of advanced practice stems from Benner's (2001) model of practice levels developed in 1981 that delineates the progression of the nurse from beginner to an expert practitioner. Hamric (2000) found that many subsequent

models used and adapted Benner's model. Benner suggested that experience is a requisite for expertise, where it is necessary to experience many clinical cases over time to acquire a sufficient evidence base for advanced clinical judgement. She subsequently proposed that early specialisation is therefore advantageous to attain increasing levels of expert practice, but also states that experience is more than the mere passage of time, suggesting that promotion should take place on the basis of skill rather than longevity. Specialisation is therefore not automatically an indication of advanced practice. Hamric (2000) supports this position stating that almost all nurses work in a specialised area with some roles considered specialist and some classed as involving advanced education, but not necessarily being advanced practice roles. If research nursing is considered a speciality it should be clear that it does not necessarily involve practicing at an 'advanced' level. However, it is proposed that the pathway to enable progression to a higher level of practice should be recognised.

There are a range of frameworks designed to encompass advanced practice. The application of one theory to a nursing role in order to declare that it is an advanced practice role is insufficient. Benner's work is the basis for many of these theories (e.g. Hamric, 2000), therefore any claim of advanced practice would be better supported if several frameworks were to demonstrate it. The amount of rigour with which an advanced practice framework is applied to a role description must also be considered. The work of Hamric (2000) may be valuable when discussing the clinical research nurse role in general, but it must be viewed within the context of the American, not British health system. There are variables such as the finance of care and the educational attainment of nurses that may affect the transference of the model.

In exploring new roles, Read *et al.* (1999) found that clinical nurse specialists (CNSs) do not necessarily hold a first degree, whereas in the USA a masters degree for this level of practice is this the norm. This educational difference is likely to be resolved in the future as practitioners will increasingly be required to demonstrate Masters level thinking (Woods 1997, Castledine 2003, Department of Health 2004, Ball 2005).

Ball & Cox (2003, 2004) suggested the theory of legitimate influence which could be adapted to the role of the clinical research nurse, but as it was conceived with the critical care inpatient setting in mind. Further development of the theory is required to be able to generalise it. The basis of this theory is clinical credibility resulting from negotiation with other clinical groups, but based on the practitioner having clinical expertise. Demonstrating this is no easy task, but as knowledge of the disease and its management is required for the role of the clinical research nurse (James & Armitage 2002, Kenkre & Chatfield 2004, Cox *et al* 2005), it could be argued that this constitutes clinical credibility. The theory builds on the concept of advanced practice examining its purpose, the potential outcomes, and influences on these. The strategic activities and intervening conditions relate to the outcomes of the interventions made by a clinical research nurse, but there is an emphasis on restoring patients to health, which is not always associated with this role, at least not in early phase clinical trials for cancer where the patient is not guaranteed to benefit from treatment.

Two frameworks that appear to reflect the role of the clinical research nurse in the UK are those of McGee & Castledine (2003) and Atkins & Ersser (2000). McGee & Castledine (2003) suggest three key elements of advanced nursing practice: professional maturity, challenging professional boundaries and pioneering innovations; These are very broad elements that are open to interpretation. This allows application to a number of nursing roles, but one needs to ask: what is

considered to be expert practice, by whom and why? (McGee & Castledine 2003). The three elements are not merely competencies to be achieved, but together demonstrate a holistic view of the practitioner including the personal values and attributes that contribute to the role to achieve advanced practice. However, it is not stated that all components are equal. Woods (1997) supports the suggestion that all role components do not share equal significance or importance, expressing that the temptation to prepare an 'all-singing, all-dancing super nurse' should be resisted and tempered by the reality of clinical practice (p821).

When defining professional maturity it is suggested that the practitioner should have wide ranging experience in different settings and with diverse client groups. This contradicts Benner's (2001) suggestion that early specialisation is advantageous. Early specialisation may enable quicker progression towards specialist practice in a very narrow area but will not fully prepare the practitioner for situations outside of their sphere of knowledge. If placed in an unfamiliar environment, a practitioner who specialised earlier may take longer to progress to the level of expert again in comparison to someone with wider experience. Unfortunately the current career structure for nurses within the UK does not presently support this. In order to progress, nurses are normally advised to stay within a speciality or one that is related; movement between specialities is not encouraged. This often means that the experience gained in other specialities is not always given the value it deserves. It may be worth noting that the recent change to the NHS pay structure (DH 2003) has not addressed this issue.

The second element of advanced nursing as suggested by McGee & Castledine (2003) is that of challenging professional boundaries through collaborative working and leadership to enhance patient care. Corner (1997) notes that cancer nursing historically evolved from the role of the research nurse assisting clinical trials of

cancer treatments. The view that research nurses are frequently seen by colleagues as mere data collectors (Raja-Jones 2001, Kenkre & Chatfield 2004) is contestable in light of current practice. As the role of the clinical research nurse may not be understood by others including nurses and other healthcare disciplines, there is a need for self-promotion of the role. Within the conduct of a clinical trial, it is well documented that the research nurse can demonstrate collaborative team working and will often provide leadership (RCN 1998, Kenkre & Foxcroft 2001, Raja-Jones 2002, Richardson et al 2002, Kenkre & Chatfield 2004, Cox et al 2005).

The third element, pioneering innovations, is inherent in the role of the clinical research nurse where critical evaluation of each trial, assessment of every potential participant and collaborative working is required to ensure ethical practice (RCN 1998, Kenkre & Foxcroft 2001, Raja-Jones 2002, Richardson et al 2002, Kenkre & Chatfield 2004, Cox et al 2005).

Castledine (2003) also proposed specific criteria, roles and functions of advanced nurse practitioners, divided into seven categories that concur with the fifteen attributes of advanced nursing practice identified by Atkins and Ersser (2000). These can be applied to the elements of the clinical research nurses role (Box 1). The attributes identified by Atkins & Ersser (2000) form part of a model of education for advanced nursing practice that identifies opposing forces within advanced practice education. In an attempt to be all encompassing, they form an unnecessarily complicated framework, but these elements are concurrent with the role of the clinical research nurse.

The clinical research nurse role can therefore be applied to frameworks of advancing practice and it could be concluded from this that the research nurse is therefore an advanced practitioner. Another interpretation would be, that the research nurse role

and models of advanced practice can therefore be easily applied to each other due to the role of the research nurse being multi-faceted and models of advanced practice aiming to be applied to any area of nursing.

Towards a framework for advanced nursing practice within clinical research

In applying the role of the research nurse and examining different frameworks, it would seem that the elements or aspects of a role alone cannot depict advanced practice. Advanced practice is demonstrated by the level of skill with which these are performed, suggesting that there is a personal element to this. Masterson and Mitchell (2003) discuss personal competence and the limits of such models. Brykczynska (2002), however, states that the critical essence of advanced nursing practice in cancer care is the ability to acknowledge the “awesomeness of the human individual” and refers to this as a “wise nursing attitude” (p40). Most notably she states that if this interpersonal quality and virtue of humility in the face of wounded humanity is lacking, then no amount of courses and degrees in cancer nursing will make an advanced practitioner out of a cancer technician. This is similar to Benner’s (2001) concept of the helping role of the nurse. Benner described this as a challenge to nurses to own their own helping role and, in the same manner as Brykczynska, states that this unique contribution is not easily replicated, standardised or interpreted.

For the clinical research nurse to develop towards advanced practice, a framework for the clinical research nurse in cancer care is suggested (Figure 1 and Box 3). The helping and caring role is placed at the centre, with surrounding role aspects that would be performed at varying levels depending upon the area of interest that the practitioner wishes to develop to an expert/advanced level. The proposed framework (Box 3) suggests ways for personal advancement and given the requirements for qualifications and certification suggested in the Manual for Cancer Services (DH

2004), it could be construed that advanced practice is achieved when all qualifications are achieved, if this is at all possible. It is therefore important that the caring and helping role is central to practice. The framework is short in comparison to the NMC competencies for advanced practice and only suggests ways to develop role aspects to achieve the NMC competencies. The suggested framework does not expand on a definition of assessment as much as that of the NMC and separates the professional role aspects. It could be construed that assessment skills hold less value than professional skills, so for that reason, the fact that suggested role aspects can hold different value at different stages of a career, should be kept in mind.

This adapted model is still dependent on the concept of advanced or expert practice in each clinical area. The frameworks for advanced nursing practice considered for the purpose of this paper are littered with concepts such as expertise, mastery, credibility and competence which are all subject to interpretation. Instead of defining advanced practice, the concept has been divided into role elements, but who will decide if a person is practicing at an advanced level? The debate above could be weighted to suggest the role of the clinical research nurse exists as an advanced practitioner, but who would be able to confirm or contradict such a claim? Who could judge the personal aspect of the role and how? Only another advanced practitioner in the same field would have enough of an insight into the role to debate it, as by the very nature of the role. No one else would possess the particular experience, knowledge and skill as the individual advanced practitioner. In addition, the critical evaluation of the effectiveness of an individual in an advanced practice role would be difficult to assess and require valid and reliable measurement data that would be ideally collected before and after appointment to the post.

Discussion

The NMC (2006) has provided a definition of advanced practice listing what may be expected of 'highly skilled nurses' who will be able to use the title. This definition provides some information as to the expected role of an advanced practitioner, but specific competencies that are matched to the Key Skills Framework (Department of Health 2004) have also been made available. These competencies, whilst being more explicit, are comparable to the elements of advanced practice suggested by McGee & Castledine (2003) and Atkins & Ersser (2000). Guidance as to how competencies can be demonstrated is yet to be provided, but not all will be applicable to every role. Depending on how the competencies are applied in practice, some nurses practicing at an advanced level according to current available theories may not be permitted to use the title.

The Clinical Research Nurse within cancer care would be able to meet many of the competencies listed by the NMC, but not all. For example, the ability to prescribe would only be applicable to approved medications when used on their own, not within the context of unknown interactions with experimental, unlicensed drugs.

The Clinical Research Nurse role within cancer care can be applied to a number of frameworks for advanced practice, including the competency framework proposed by the NMC. This provides a higher level of practice for nurses to develop towards if they so wish. Kenkre *et al.* (2001) suggest four career pathways for the clinical research nurse: clinical research, support/management, academic or pharmaceutical. The practitioner may wish to develop research ability, managerial skills or evaluation and auditing skills to a higher level depending upon their chosen career path. Within cancer care nurses may also choose to proceed to specialised clinical positions.

To make these career pathways attainable research nurses need access to a wide variety of educational and developmental opportunities which will require a certain amount of investment by their employers. The publication of Best Health for Best Research (DH 2006) states an intention to attract, develop and retain research professionals. The adoption of a developmental model such as the one discussed in Box 3 could provide a career choice as a clinical research nurse with the potential to develop towards registration as an Advanced Nurse Practitioner. This may attract more nurses towards a research career and may retain those already working within clinical research. For those who decide not to stay within research, the registration could provide a pathway back into more clinically based practice while utilising and developing their research aptitude and skills within patient service and professional practice development sectors of the National Health Service.

Conclusion

The role of the clinical research nurse, specialising in the care of research participants is one that is vital and rewarding. It is expanding to meet the increasing needs of clinical research participants in the UK and the full extent and impact of the role on both patient care and research still requires thorough exploration. Examination of current models of advanced practice suggest that the role has the potential to be, but is not necessarily, advanced practice. There is no doubt that the role of advanced practitioner within clinical research would have implications for workforce development and education; this is a challenging and exciting prospect which has the potential to deliver positive rewards for both nurses and patients.

References

- Atkins S & Ersser S 2000 Education for advanced nursing practice: an evolving framework, *International Journal of Nursing Studies* 37:523-533
- Ball J 2005 NMC Consultation on a proposed framework for the standard for post-registration nursing. [online] London, Employment Research Ltd. <http://www.nmc-uk.org/aFrameisplay.aspx?DocumentID=1004>
- Ball C & Cox C 2003 Part one: Restoring patients to health – outcomes and indicators of advanced nursing practice in adult critical care, *International Journal of Nursing Practice* 9:356-367
- Ball C & Cox C 2004 Part two: The core components of legitimate influence and the conditions that constrain or facilitate advanced nursing practice in adult critical care, *International Journal of Nursing Practice* 10:10-20
- Benner P 2001 *From Novice to Expert: Excellence and power in clinical nursing practice*, Commemorative Edition, Upper Saddle River, Prentice-Hall Health
- Brykczynska G 2002 *The Critical Essence of Advanced Practice*. In: Clarke D, Flanagan J, Kendrick K 2002 *Advancing Nursing Practice in Cancer and Palliative Care*. Basingstoke, Palgrave Macmillan
- Castledine G 2003 *The Development of Advanced Nursing Practice in the UK*. In: McGee P, Castledine G *Advanced Nursing Practice*, 2nd edition. Oxford, Blackwell Publishing
- Corner J 1997 *Beyond survival rates and side effects: cancer nursing as therapy: the Robert Tiffany Lecture 9th International Conference on Cancer Nursing Brighton, UK, August 1996*, *Cancer Nursing* 20 (1):3-11
- Cox K, Avis M, Wilson E & Elkan R 2005 *An evaluation of the introduction of clinical trial officer roles into the cancer clinical trial setting in the UK*. *European Journal of Cancer Care*. 14:448-456
- Department of Health 2000 *The NHS Cancer Plan – Providing a patient centred service*. London, Department of Health
- Department of Health 2004 *Manual for Cancer Services*. London, Department of Health
- Department of Health 2003 *Agenda for Change*. London, Department of Health
- Department of Health 2006 *Best Research for Best Health: a new national health research strategy*. London, Department of Health.
- Hamric A 2000 *A Definition of Advanced Nursing Practice*. In: Hamric A, Spross J, Hanson C *Advanced Nursing Practice: An integrative approach*. 2nd edition. Philadelphia, W. B. Saunders.
- James N & Armitage F 2002 *The importance of clinical trials in Cancer Care*, *Cancer Nursing Practice* 1 (9):24-29

Kenkre J & Foxcroft D 2001 Career pathways in research: clinical research, Nursing Standard 16 (5):41-44

Kenkre J, Foxcroft D & McMahon A 2001 Research Career Pathways, Nursing Standard 16 (4):39

Kenkre J & Chatfield D, 2004 Study Site Co-coordinator/Clinical Research Nurse: A career for nurses in the pharmaceutical industry? CR Focus 15 (8): 5-9

Kirshbaum M & Hempshall P 2004 Prominent issues and conceptual perspectives within the literature on the Advanced Clinical Nurse: implications for promoting evidence-based practice, School of Nursing and Midwifery, University of Sheffield

Lenburg C 2000 Promoting Competence through self-reflection and portfolio development: the inside evaluator and the outside context, Tennessee Nurse. 63 (3): 11-20

Masterson A & Mitchell L 2003 Developing Competencies for Advanced Nursing Practice. In: McGee P, Castledine G Advanced Nursing Practice, 2nd edition. Oxford, Blackwell Publishing

McGee P & Castledine G 2003 A Definition of Advanced Practice for the UK. In: McGee P, Castledine G Advanced Nursing Practice, 2nd edition. Oxford, Blackwell Publishing

NCRN (National Cancer Research Network) 2003 Informed Consent in Cancer Clinical Trials: The need for clarification of the role of the research nurse. London, NCRN

NMC (Nursing and Midwifery Council) 2004 The NMC code of professional conduct: standards for conduct, performance and ethics. London, NMC

NMC (Nursing and Midwifery Council) 2005 The Proposed framework for the standard for Post-registration nursing – February 2005. [online] London, NMC. <http://www.nmc> [Accessed 9th April 2006]

NMC (Nursing and Midwifery Council) 2006 The Proposed framework for the standard for Post-registration nursing: As at February 2006. [online] London, NMC. <http://www.nmc> [Accessed 9th April 2006]

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

Royal College of Nursing (RCN) 1998 Employment Brief 22/98. The clinical Research Nurse in NHS Trusts and GP Practices: Guidance for nurses and their employers. [online] Manchester, RCN. <http://www.man.ac.uk/rcn/clinresgrades.htm> [Accessed 22nd December 2005].

Read S, Lloyd Jones M, Collins K, McDonnell A & Jones R (1999) Exploring New Roles in Practice: Implications of Developments within Clinical Teams (ENRIP). Sheffield, University of Sheffield

Richardson A, Di Giulio P, & Waddell D 2002 Nursing research in cancer care. In: Kearney N, Richardson A, Di Giulio P Cancer Nursing Practice: A textbook for the specialist nurse. London, Churchill Livingstone

Woods L 1997 Conceptualizing advanced nursing practice: curriculum issues to consider in the educational preparation of advanced practice nurses, *Journal of Advanced Nursing* 25: 820-828

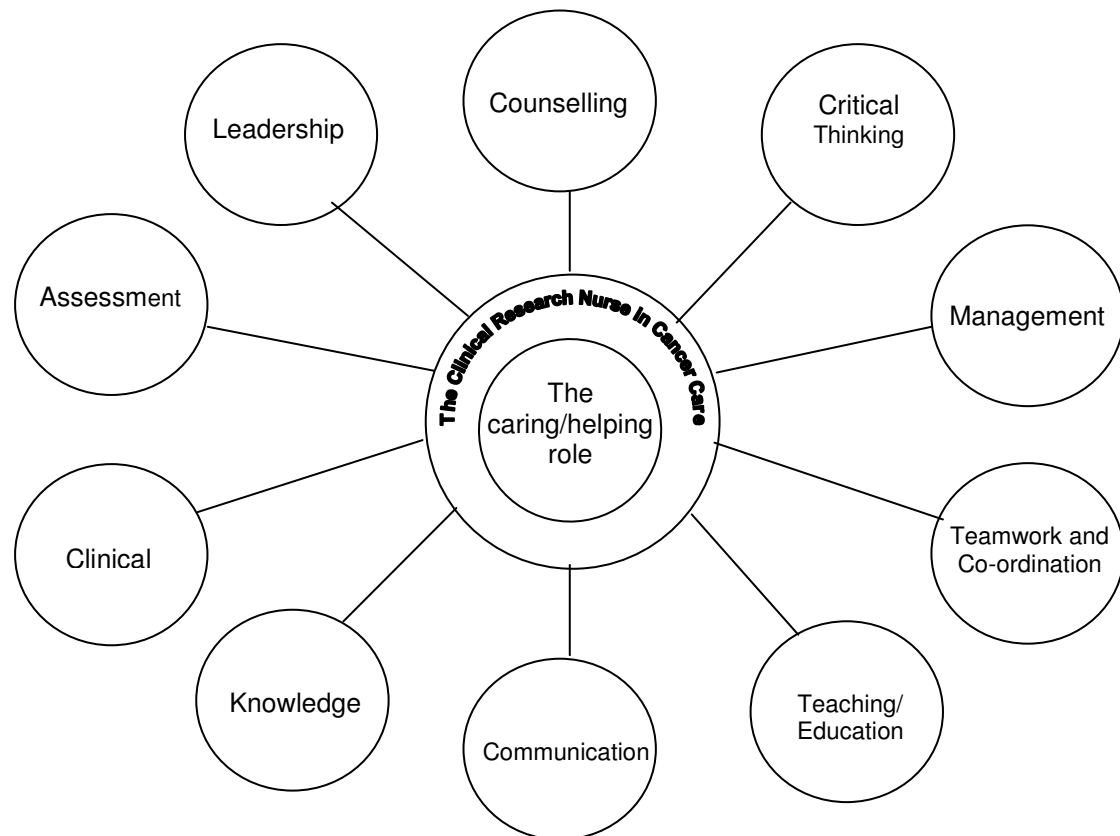
Box 1: Aspects of the Clinical Research Nurse Role

Assessment
Screening and recruitment of patients
Informed Consent Process
Clinical Care including giving of treatment and psychological care
Point of contact for patient for advice (including health promotion)
collection and processing of samples
Co-ordination of patient care including treatment, tests and follow-up
Advocate
Liaising with members of the MDT
Liaising with representatives of sponsoring company
Educator
Trial management
Ensure ethical conduct of trial including REC submissions
Data collection and management
Protocol writing
Autonomy
Financial responsibility
Staffing responsibility
Policy development
Maintenance of records
Data analysis, reporting and dissemination
Develop research potential and agenda at local, regional and national levels

Box 2: Knowledge and Skills required for the Clinical Research Nurse Role

Knowledge of the informed consent process
Knowledge of research protocols including experimental treatments and side effects
Knowledge of standard treatments including side effects
Understanding of the specific disease
Understanding of regulatory requirements within and outside employing institution.
Knowledge of research design, methodology and the analytical process
Organisational skills
Good communication skills
Critical Thought
Reliability and self-discipline
Ability to practically apply a research protocol within the pragmatic local requirements
Numerate with good IT skills
Management skills including those of time, finance, staff and project
Leadership skills
Teaching and Presentation skills
Clinical skills

Figure 1: A developmental model for the role of the clinical research nurse in cancer care



Each aspect is performed at least competently, but it is not necessary for all aspects to be performed at the expert/advanced level.

Adapted from Castledine (1996), Ersser (2000), Lenburg (2000), Atkins & Benner (2001), Brykczynska (2002).

Box 3: A developmental model for the role of the clinical research nurse in cancer care

Role Aspect	Role requirements	Development Possibilities
Assessment	Ability to perform holistic nursing assessment of the patient face to face or over the telephone and respond accordingly within the scope of practice.	Consider alternative assessment methods used by nurses and other healthcare professionals to improve practice and adopt an assessment that is refined and effective for the cancer research setting.
Clinical	These include close monitoring of patients during treatment and extended roles; venepuncture, IV cannulation, PICC line care, Hickman line care, administration of IV and cytotoxic therapies	Ensure safe working practice in compliance with the Scope of Professional Practice (NMC 2004) and Manual of Cancer Services (DH 2004) guidance regarding chemotherapy services.
Communication	Communicate effectively with patients and their families, other members of the multi-disciplinary team, representatives of sponsor companies.	Communication skills do not require accreditation in the way that is required of practical skills, but are of vital importance. Self-reflection and feedback from others can provide a measure of skill.
Counselling	Support patients through diagnosis, treatment and research. Respect spiritual beliefs and provide support through grief and loss.	Formal accreditation of these skills will be required by specialist practitioners in cancer care (DH 2004). Undertaking a formal course to reflect upon, expand and refine current skill would be advantageous.
Critical Thinking	Critically appraise and	Masters level thinking can be

	<p>evaluate care and research to enable effective, evidence-based practice. Critically consider research protocols to evaluate whether they are appropriate to the local situation and population</p>	<p>demonstrated through formal qualification, or undertaking nursing research. Critical thinking can be developed to doctoral level if desired. The evaluation of care can also be developed in the same way as assessment skills.</p>
Management	<p>Time, project and resource management are all required as part of the clinical research nurse role.</p>	<p>Managing more extensive projects with multiple sites and larger budgets would be a way to develop management skills. The management of personnel would also extend this skill or a management qualification could be undertaken.</p>
Leadership	<p>Leadership is demonstrated through the promotion of integrating research into practice when working with other professionals. It is also demonstrated through the dissemination of information via publication and the constant questioning and evaluation of current practice.</p>	<p>Leadership is closely linked to management and teamwork and is in essence the influence that can be exerted over professional thinking, policy and practice. Evidence based information is required to underpin this. Leadership is dependent upon personal qualities and may therefore be developed through the examination of personal values.</p>
Teamwork and co-ordination	<p>This is necessary for holistic patient care and safe, ethical conduction of clinical trials</p>	<p>Understanding the roles of other healthcare professionals can help working practice. Taking time to</p>

		<p>discuss or observe the role of others can enhance working practice through understanding and respect.</p>
<p>Knowledge and experience that facilitates autonomous practice</p>	<p>The disease and its standard management, any trial therapies and new innovations, research methodology and regulations, health and research policy and legislation, professional issues. Knowing ones individual limitations and recognising when to ask for guidance or assistance are essential</p>	<p>Knowledge can be extended through a variety of educational interventions but it is the synthesis and application of this knowledge within the context of experiential learning that denotes the level of practice.</p> <p>Requirements of specific courses (DH 2004) attempt to describe advanced practice. Undertaking education specific to cancer and its treatment or research methodology can enhance practice, but possibly the most valuable part of this is the interaction and exchange of ideas with other nurses wanting to advance practice.</p>
<p>Teaching/Education</p>	<p>Teaching of patients and other healthcare professionals is undertaken as part of the role, but currently no qualification is held.</p>	<p>Accreditation in teaching methods, evaluation of teaching sessions and reflective practice can enhance practice.</p>
<p>Helping/Caring role</p>	<p>This is the core of cancer nursing and undertaken by all nurses to some level.</p>	<p>This cannot be accredited but may be improved and developed through reflective practice.</p>

Adapted from Lenburg (2000), Brykczynska (2002), Castledine (1996), Atkins & Ersser (2000) Benner (2001) and NMC (2006)

Box 4: The role of the clinical research nurse literature matrix

Reference	Aim	Methods	Key findings	Comments
Raja-Jones, H. (2002)	To compare the role of the clinical research nurse to that of the clinical nurse specialist.	Systematic Literature Review. A search of CINAHL, MEDLINE and breast cancer web pages as well as inverse searching was performed. Articles, written in English, relating to nursing roles within oncology, breast cancer, research and nurse specialists were retrieved.	The roles are explored but a comparison could not be made due to evidence regarding the role of the research nurse being largely descriptive, anecdotal accounts.	A thorough and critical review of relevant literature. An interesting question that requires revisiting when the role of the research nurse is fully explored.
James, N. & Armitage, F. (2002)	To present an overview of clinical trials in cancer care and discuss the role of the research nurse in such trials.	Journal Article/ Expert Opinion	Mainly focuses on an overview of clinical trials but the main responsibilities of the research nurse in cancer care are listed.	Limitations of the literature used are not stated and it is descriptive rather than critical, but the authors are employed as research nurses.
Kenkre, J. & Chatfield,	Aims to explore opportunities for nurses	Journal Article/ Expert Opinion	It is widely accepted anecdotally that nurses are working as Study	Not presented as a systematic review although the criticism of a lack

D.(2004)	within clinical research		Site Coordinators but notes that there is very little up to date evidence regarding the role of the CRN and how long nurses stay in post.	of recent evidence suggests that some formal search has taken place. The target audience is associated with the pharmaceutical industry.
RCN (1998)	Identifies jobs and outlines job descriptions for CRNs. Explores education and careers for nurses in clinical research.	Employment guidance	Suggests appropriate clinical grades and salaries for research nurses.	Research based employment brief for nurses and negotiators. Explores the role of the research nurse in the context of ensuring fair pay and conditions. References from 1990's are not criticised and onlt half relate to the role of the CRN.
NCRN (2003)	To clarify the role of the research nurse with regard to informed consent	Briefing Note	Summarises the implications of current legislation, regulation and guidance, summarising that these conflict and does not provide a clear indication of what the	Applies to nurses working within cancer clinical trials in the UK. Discusses the current situation but does not provide guidance for future development or clarify the position of

			limitations of the nurse's role in informed consent should be.	nurses or their employers. Descriptive rather than critical.
Cox, A. et al. (2005)	To evaluate the introduction of Clinical Trial Officers into a regional cancer research network in order to increase recruitment.	Evaluation of the introduction of clinical Trial Officers through recruitment figures and semi-structured interviews with stakeholders and focus groups of post-holders	Clinical Trial Officers created an alternative method of staffing for cancer research networks. Recruitment to clinical trials increased.	Mix of rural and urban areas within one cancer research network in the UK. Short term evaluation of the intervention. A longer term evaluation considering recruitment and training costs and retention should be considered before further implementation.
Kenkre, J. & Foxcroft, D. (2001)	To inform readers of the knowledge required to conduct clinical trials to recognised standards and explore clinical research as a career pathway	Journal Article/ Expert Opinion	Suggests a career pathway in clinical research, outlining the role, experience, knowledge, training, skills and desirable qualifications for a clinical research nurse from grade E through to I.	Limitations of literature used not stated.

<p>Richardson, A. et al (2002)</p>	<p>To explore nursing research in cancer care. Nursing involvement in clinical trials is discussed as part of this.</p>	<p>Literature Review/Expert opinion</p>	<p>The research nurse role includes: Provision of direct care, administration of investigative therapy, observation of treatment-related side effects, patient advocacy , organisation of the study, staff education and data collection</p>	<p>Limitations of literature used not stated.</p>
--	---	---	--	---

