

NATIONAL COUNCIL FOR THE PROFESSIONAL DEVELOPMENT OF NURSING AND MIDWIFERY

# Report on the Role of the Nurse or Midwife in Medical-led Clinical Research





An Chomhairle Náisiúnta d'Fhorbairt Ghairmiúil an Altranais agus an Chnáimhseachais

**NOVEMBER 2008** 



# A Celebration of Life

By Catherine Barron

# Mission Statement of the National Council

The Council exists to promote and develop the professional role of nurses and midwives in order to ensure the delivery of quality nursing and midwifery care to patients/clients in a changing healthcare environment.

© National Council for the Professional Development of Nursing and Midwifery 2008

Published by

National Council for the Professional Development of Nursing and Midwifery 6-7 Manor Street Business Park, Manor Street, Dublin 7

t: 353 1 882 5300 f: 353 1 868 0366

e: admin@ncnm.ie

w: www.ncnm.ie

# Report on the Role of the Nurse or Midwife in Medical-led Clinical Research





An Chomhairle Náisiúnta d'Fhorbairt Ghairmiúil an Altranais agus an Chnáimhseachais

**NOVEMBER 2008** 

# REPORT ON THE ROLE OF THE NURSE OR MIDWIFE IN **MEDICAL-LED CLINICAL RESEARCH**

# Contents

Foreward	Foreward v			
Project Inti	roduction	1		
Project Rat	tionale and Structure	3		
Phase One	Phase One: The Literature			
Phase Two	: Summary Report of Site Visits	19		
Phase Thre	ee: The Consultation	23		
Report Dis	cussion and Recommendations	57		
References	5	61		
Apendices				
Appendix A: Site Visit Reports				
Appendix I	B: UK (NHS) Job Statements	75		
Appendix (	C: Organisational Charts for Clinical Research Facilities	83		
Appendix I	D: Consultation Phase Instruments	85		
List of Tab	les			
Table 1	Worldwide R&D spending 1980-2005	1		
Table 2	Summary of empirical papers with a focus on titles.	7		
Table 3	Summary of empirical studies on role	8		
Table 4	Nursing research careers: clinical research pathway	16		
Table 5	Clinical research sites visited	19		
Table 6	Titles of nurse-led projects conducted in Edinburgh CRF.	20		
Table 7	Length of time in research role	23		
Table 8 Educational attainment at role entry and currently		24		
Table 9 Examples of Masters by Research and PhD titles		24		
Table 10	Medical speciality areas	24		
List of Figu	ires			
Figure 1	Elements of the research process in which research active nurses and midwives are involved.	11		
Figure 2 UKCRC (2007) Clinical academic training path.				



# **Foreword**

The National Council for the Professional Development of Nursing and Midwifery is pleased to present this report. It provides a timely and excellent contribution to the governmental policy of promoting medical-led clinical research in the Irish health services which ultimately improves the range of services to patients allowing them access to 'cutting-edge' treatments for their conditions. In order to create the environment for such research to thrive, a key driver is ensuring the human resource capacity. Central to success is the role of the research nurse or midwife. In this project and for the first time, data have been collected and collated relating to nurses and midwives in what has been heretofore a 'hidden' research resource in Ireland. As investment in infrastructure causes the expansion of medical-led clinical research, there is opportunity for greater professional development for research nurses and midwives, as well as further opportunities for nurse- or midwife-led research, all of which, if appropiately harnessed, will benefit patient care as well as building research capacity within the professions. The Report recommendations address some of the key professional issues for the role as it currently exists. It will be widely disseminated to inform all key stakeholders and ensure nursing and midwifery's contribution to this particular arena.

I wish to acknowledge Mary Bell for reviewing the literature, all the clinical research nurses and midwives who participated in phase two and three of the project, our UK colleagues who generously gave their time and expertise in the site visits, and professional colleagues in the National Council for reviewing the final document. Special thanks goes to Sarah Condell, Research Development Officer for leading the project to completion and for writing the final project report.

Yvonne O'Shea Chief Executive Officer National Council for the Professional Development of Nursing and Midwifery.

As Chief Executive of the Health Research Board (HRB), I am delighted to be able to endorse this report. The potential for world-class clinical research in Ireland is immense and its development is a key strategic objective of the Health Research Board. A multi-million euro investment plan for clinical research will establish Clinical Research Facilities on hospital sites, will provide shared high-cost technology platforms, will support the development of clinical research skills and expertise and will provide funding for clinical research programmes. Such investment, however, is unproductive if other barriers exist to rolling out clinical research for the patients and clients of our health services. The Research Nurse or Midwife is recognised internationally as a key member of clinical research teams and has played a large part in the success of Irish clinical research to date, much of which the HRB has funded. Yet little is known about this particular group, their practice and the barriers they encounter. A changing infrastructural context does mean a transition for the role of the Research Nurse or Midwife. This report is, therefore, opportune in examining the role as it currently exists in Ireland and exploring what has happened internationally. It provides the key considerations for the future direction of the role, to allow the expansion of clinical research in Ireland and demonstrate nursing and midwifery's contribution to that aspect of health care.

Enda Connolly Chief Executive Health Research Board



# REPORT ON THE ROLE OF THE NURSE OR MIDWIFE IN MEDICAL-LED CLINICAL RESEARCH Project Introduction

# **Historical and Policy Context**

A short historical review shows that randomized controlled trials were first used in the 1920's and are considered to be the ultimate test for the evaluation of clinical outcomes (Sadler et al, 1999). As far back as 1937, President Roosevelt signed the National Cancer Institute (NCI) Act to promote cancer research (White-Hershey & Nevidjon, 1990). Finding new chemical agents and testing them on humans originated in 1955 when the American legislature charged the NCI along with the Food and Drug Administration (FDA) to serve as the review organization for clinical trials. During the past few decades investment in research and development (R&D) has continued to grow in the United States of America (US). Much, although by no means all of this, has focused on new treatments and therapies. Two billion dollars were invested in developing 1000 new drugs to market in 1980 while in 2005 over fifty billion dollars were spent developing 2,700 drugs (PhRMA, 2006).

Table 1: Worldwide R & D Spending 1980-2005 (PhRMA, 2006.)

Year	PhRMA Members	Total Industry
2005	\$39.4	\$51.3
2004	\$37.0	\$47.6
2000	\$26.0	Not available
1990	\$8.4	Not available
1980	\$2.0	Not available

The US has 79.8% share of the R&D expenditure in the pharmaceutical industry worldwide, whilst the United Kingdom (UK) has 5.3% and other Western Europe nations including Ireland has 6.1%. In addition the world medical devices market is growing at a rate of 6% per annum and represents 9% of Ireland's exports. Fifty per cent of these companies are engaged in R&D in Ireland (IMDA/IBEC, 2006). An Irish Universities Association conference has stated that the "pharmaceutical industry is the bedrock of our economy" (IUA & IBEC, 2005; p 14). From a policy perspective, the Irish government's Strategy for Science, Technology and Innovation (Department of Enterprise, Trade and Employment, 2006) highlights that Ireland's health research funding is low by international standards at less than 0.25% of overall expenditure. However the pharmaceutical and medical devices industries in Ireland have grown at a faster rate with a higher level of foreign direct investment than in other countries and are perceived to contribute to the national knowledge economy.

The government's goal is to build the R&D potential within the health service further by increasing funding for health research and increasing the numbers of researchers throughout the health research system (Forfás, 2006). Furthermore Forfás emphasizes that necessary structures and incentives should be put in place to make health research careers an attractive option.

Historically, with the exception of a small number of academic studies from different health disciplines, the major health research activity that occurred within the health service was medical-led clinical research. This was of mixed origin either academic or pharmaceutical and was dependent on enthusiastic committed individuals rather than policy initiated. Much of the activity was in clinical trials or funded through peer reviewed competitive processes. Nurses and midwives were directly employed by the Principal Investigator to co-ordinate and 'run' the clinical studies. There was no national picture or formal linkages of this activity and it must be assumed that such working arrangements continue to exist. The next phase of development saw the formation of special interest groups. For example, the All Ireland Cooperative Oncology Research Group was established in October 1996. With the establishment of the All-Ireland NCI Cancer Consortium in 1999, governmental funding directly supported clinical research in the area of cancer and a network of funded activity has grown.

At the commencement of the project on which this report is based, clinical research facilities consisted of a 7 year old purpose built centre of the Royal College of Surgeons in Ireland on the Beaumont Hospital site in Dublin, the 1 year old University College Dublin Mater clinical research centre and the 17 year old independent Shandon Clinic clinical research centre based in Cork. However, rapid expansion in infrastructure was in the planning phase. In 2006, the Wellcome Trust and the Health Research Board announced the funding of a clinical research facility on the site of St. James Hospital in Dublin. This facility will be under the auspices of a consortium from the Dublin Molecular Medicine Centre, the Royal College of Surgeons in Ireland, Trinity College Dublin and University College Dublin. This funding draws Ireland into a pre-existing Wellcome network with an established nursing manager group. Jackson & Butterworth (2007) have claimed that such facilities create a need for skilled



nurses and midwives for a diversity of roles including the operational management of such facilities. In 2007, agreement was reached between the HRB and the Health Service Executive to build a clinical research facility on the site of University College Hospital, Galway. Further exploration of a similar initiative is occurring for Cork. In addition, further networking of activity has commenced. This will be through the Irish Clinical Research Infrastructure Network (ICRIN) which was established in 2006 (www.icrin.ie) and allows entry to a larger European network (ECRIN) (www.ecrin.org).

# REPORT ON THE ROLE OF THE NURSE OR MIDWIFE IN **MEDICAL-LED CLINICAL RESEARCH** Project Rationale and Structure

Given the policy context and the investment in clinical research infrastructure there are major implications for nursing and midwifery. Traditionally in Ireland, nurses and midwives have held roles in clinical research that combined the tasks of trial coordination with patient recruitment, education, data collection and patient care. A growth in clinical trial activity to fulfill the current policy agenda will demand a growth in recruitment and retention of such nurses and midwives working in this arena. It also highlights the need to identify professional career development issues for these nurses and midwives. The potential to build research capacity from this arena for nurse- or midwifery-led research should also be explored. Elsewhere, calls (Tierney, 2007; McCormack, 2004) for greater collaboration between research nurses and nurse researchers have been made to optimize the common ground that exists and to support greater synergies between academic nursing and midwifery and clinical research nurses and midwives.

# This project has three main components:

- 1. A literature review of the international experience of nurses' and midwives' role in medical clinical trials.
- 2. A series of site visits to centres of excellence
- 3. A consultation with nurses and midwives currently in the role in Ireland



# **PHASE ONE** The Literature

# The Search for Literature

A comprehensive literature search was conducted between February and March 2007 with a focused update in October 2007. A number of databases were accessed using the keywords: clinical research nurse, clinical trials, research, and clinical nurse researcher, role of the clinical trial nurse and pharmaceutical companies and appropriate combinations of these terms. The following databases were accessed: CINAHL (from 1982), MEDLINE (from 1996), British Nursing Index (from 1994), Science Direct (from 1979), Cochrane Library, MIDIRS (from 1985), Google Scholar and Pub Med. In addition, a number of papers were found from citations in other papers or serendipitous discovery through attendance at conferences.

# The Literature Review

This review examines the literature relating to the role of the clinical research nurse or midwife with a focus on the numbers in this role, the variety of titles used, the diversity of the role, the educational qualifications, professional issues and career pathway. It should be noted that much of the literature is opinion based rather than empirical evidence and many of the authors were clinical research nurses themselves. In total, 107 papers were reviewed with 24 being empirically based. The latter dated from 1993 until 2007 (see Table 3): 10 were from the US, 8 from the UK, 2 Canadian, 2 European, 1 Australian and New Zealand and 1 multinational from US, Canada and Sweden. Approximately 55% of the authors were clinical research nurses themselves whilst the remainder were primarily academics. Descriptive quantitative analysis was used by 14 studies, 5 studies used a qualitative approach, a multi-method approach was used by 3, and 2 studies were conducted using documentary analysis. The sample sizes ranged from 6 up to 1,300 however 17 of 24 studies had a sample size of less than 100. There was also a variety of response rates ranging from 29% to 90%. The biggest challenge reported by those authors who did discuss their methodology was identifying a sample of these nurses. As such, differing sampling strategies were utilised: snowball sampling, accessing a sample via Principle Investigators, convenience sampling or, in a few studies, accessing known nurses via large multi center clinical trials were used. While factors of research design and response rates must be considered when reading the empirical findings, the literature does provide an indication of some trends with a commonality about these nurses and midwives which appear universal and irrefutable.

# The Numbers in the Role

The international literature reports an anecdotal, exponential increase in the numbers of nurses or midwives employed in research posts associated with pharmaceutical clinical trials (Kenkre & Chatfield, 2004). However, no national or international database exists as to the number of Clinical Research Nurses that exist worldwide. In March 2007, 8500 clinical research coordinators and 5.400 clinical research associates, many of whom were nurses were registered with the international Association for Clinical Research Professionals (accessed www.acrpnet.org on 13/3/07). One could easily surmise that there is likely to be additional Clinical Research Nurses worldwide not registered. In the past for the UK, the existence of this particular group of nurses and midwives whilst acknowledged (Tanner & Hale, 2002) was not calculated (Fyffe & Hanley, 2002). More recently, attempts have been made at quantification. For example, an estimated 600 plus nurses work as clinical research nurses in the NHS Trusts (UKCRC, 2006). However, the Scottish Research Nurse and Co-ordinators Network has over 200 members in Scotland alone (Tierney, 2007) which shows that this UKCRC figure is likely to be an underestimate. Such a lack of labour market intelligence presents a "barrier to effective integration of research into nursing career pathways..." (UKCRC, 2007. p19).

For Ireland, a definitive or official number of Clinical Research Nurses within the Irish context is unavailable. The figure of 124 Clinical Research Nurses was identified by the Irish Research Nurses Association (www.ncnm.ie/irna) on an all-Ireland basis when the association was active. Ten per cent (n=24) of Directors of Nursing or Midwifery in the Republic of Ireland reported Clinical Research Nurses employed in their services in 2004 (NCNM, 2006). A baseline survey by Irish Clinical Research Infrastucture Network (ICRIN) failed to establish the numbers of Clinical Research Nurses working outside of existing Irish clinical research facilities or centres. Such invisibility is hampered by lack of official recognition whereby no grade title exists (Department of Health and Children, 2002) for health service employers to use when maintaining records of this group. Other difficulties in quantification are likely to be similar to the Scottish experience of diversity of work settings; contract variability and geographical dispersion (Tierney, 2007) while the diversity in role titles adds further complexity. Whilst accuracy of quantification might pose difficulties at a national level, there have been attempts to quantify numbers at regional or organisational levels in the UK with some producing unpublished reports (Carrick-Sen, 2007; Walker, 2007, Simpson 2006) or such reviews being



referred to by others (Luker, 1999). The drive for many reviews appears to stem from the Medical and Healthcare Products Regulatory Authority inspections, a concern for risk aversion, and UK policy initiatives such as Modernising Nursing Careers (Department of Health (UK), 2006) and the NHS Knowledge and Skills Framework (Department of Health (UK), 2004).

In summary no national or international database exists as to the number of Clinical Research Nurses that exist worldwide while a definitive or official number of Clinical Research Nurses within the Irish context is unavailable. With increasing numbers of clinical research facilities being established in the Republic of Ireland more of these nurses and midwives will be required in the future; although this is an assumption considering the lack of baseline data on which to predict future workforce planning.

# **Variety of Role Titles**

The Report of the Baseline Survey of Research Activity in Irish Nursing and Midwifery in 2006 gives the title Clinical Research Nurse (CRN) or Clinical Research Midwife (CRM) to mean nurses or midwives involved in research for purposes other than nursing or midwifery and is distinct from the title Nurse or Midwife Researcher as recognized in the Commission on Nursing (Government of Ireland, 1998). It was difficult to find any literature specifically looking at Clinical Research Midwives. Three studies (Carrick-Sen, 2007; Simpson, 2006; Brown et al, 2002) did make reference but provided no further details or gave no indication of numbers. Furthermore, caution should be applied as others may have used the title nurse as incorporating midwives. However the literature regarding the Clinical Research Nurses' role shows a large number of job titles for this role. Table 2 presents seven studies demonstrating the huge variety of titles for the same or similar roles occurring internationally and over time.

# Empirical evidence on role titles

A total of 21 different job titles were reported from 49 respondents in a study conducted in Australia and New Zealand (Rickard, et al). Fifty one percent used Research Coordinator or Clinical Research Coordinator while 12% used the term 'Research Nurse'. Sub-titles such as Assistant, Fellow, Manager, Officer were used in a variety of ways. A combined title such as 'Quality Improvement/Clinical Trial Coordinator' was used by four respondents. A qualitative study was conducted by Hathaway in 2005. She interviewed 6 Clinical Research Nurses, five of whom all had different job titles and one who could not articulate a title having no job description and no named employer (Hathaway, 2005; p32). As shown in Table 2, Simpson found a variety of job titles for those with what she describes as a 'primary research remit' (Simpson, 2006; p8) while studies conducted by Carrick-Sen (2007) in the UK, Connolly et al (2004) and Xanthos et al (1998) in USA and Rico-Villademoros et al (2004) in Spain reflect similar trends.

One large survey (ACRP, 2003) of ACRP members' salaries was conducted with a North American focus. Of the 4,500 questionnaires, 1,309 were returned and used in the analysis. The job positions identified were given the following eight titles: Clinical Research Coordinator, Clinical Research Associate, Project Manager, Site Manager, Regulatory/Quality Assurance/ Site Data Manager/ Sponsor Data Manager and Trainer. These jobs ranged across settings including hospitals, universities, research organisations and industry. Many respondents showed by the educational qualifications that they held nursing degrees and other professional nursing certificates and yet the term nurse was not used in any of the titles.

#### Other literature on role titles

Findings from empirical evidence mirror similar observations made by other authors (Deave, 2005; Raja-Jones, 2002). In an early published paper, Mullin et al (1984) argued that one individual at each clinical centre is designated to ensure all study data are gathered completely and accurately. This individual can be referred to as the 'Clinic Coordinator', Data Coordinator', 'Research Nurse Coordinator' or 'Data Technician' but is regarded by all as the key person who "makes it all happen". Deave (2005) defines the Nurse Researcher as someone who is based in a university department and has research fellow status whereas a Research Nurse is a research coordinator or research assistant in medical research projects. However, whilst Deave (2005) differentiates between the titles Research Nurse and Nurse Researcher, these titles are sometimes used interchangeably. In Australia, Waller (2002) gives three definitions for the term 'Research Nurse'. These are a nurse who takes time off their regular work to undertake a higher degree; secondly it can be a nurse who compiles or analyses data someone else has collected or finally it can be a nurse that works on a particular project assisting the primary investigator collecting data from patients involved in drug trials. As such it appears that in the Australian context the title 'Research Nurse' covers all roles that incorporate research with no differentiation between nursing or any other type of research or audit. The latter role Waller (2002) acknowledges is comparable to the Clinical Trials Coordinator. The role of the Clinical Trials Coordinator has huge diversity in Australia but it appears that in the US and Europe, there are similarities. (Deave, 2005; Waller, 2003; Muellar, 2001; Xanthos et al, 1998; DiGuilio et al, 1996; Arrigo et al, 1994). Finally the UK's Royal College of Nursing, in an employment brief regarding clinical research nurses some ten years ago (RCN, 1998), listed ten different job titles for nurses working in clinical research. These are Clinical Research Nurse, Clinical Nurse Researcher, Study Site Co-ordinator, Clinical Trials Co-ordinator, Research Nurse, Research Co-ordinator, Research Manager, Senior Staff Nurse-Research, Research Sister/Charge Nurse, Clinical Nurse Specialist-Research.



In summary, the literature shows an evolving scenario as far as titles are concerned with no consensus internationally. This may reflect an increase in non-health professionals undertaking roles in clinical research such as Clinical Trials Coordinator, Study Site Coordinator or Data Manager thus confining nurses to a clinical nursing role within the research continuum. In addition, since nurses and midwives are holding positions that do not contain 'nurse' or 'midwife' in the title, they can be hidden from 'official' figures such as research findings. The variety of job titles throughout the world indicates a somewhat ambiguous but potentially multifaceted role that is not fully understood. According to a report in 2006 (Simpson, 2006) this situation leads to uncertainty around accountability and responsibility for staff.

Table 2: Summary of Empirical Papers with a focus on titles.

Authors	Year	Country	Titles found	Sample
Carrick-Sen	2007	UK	Used fixed title of research nurse or research midwife	N = 132
Rickard et al	2006	Aus & NZ	Found 21 different titles: research coordinator (51%, n=19), ICU research coordinator (n=6), research nurse (n=6), manager, officer, fellow, nurse and assistant used in a variety of ways, quality improvement/clinical trial coordinator (n=4), no formal title (n=1)	N = 49
Simpson	2006	Scotland	Those with a primary research remit (n=60) had the following job titles: research practitioner, clinical trials nurse, research assistant, research sister. Those with secondary research remit (n=56), their job title was nurse specialist or practitioner.	N = 116
Hathaway	2005	UK	Clinical research nurse, research nurse, clinical trials nurse, research sister and lead clinical research nurse	N = 6
Connolly et al	2004	USA	Clinical research nurse (36%), clinical research coordinator (34%), data manager (14%), other (16%)	N = 50
Rico-Villademoros et al	2004	Spain	Data managers (74.3%, n=26),clinical research coordinator (8.6%, n=3)	N = 37
Xanthos et al	1998	USA	Job titles varied across institutions	N = 41

# The Role

According to the literature there has been an evolution in the CRN's role over the last 20 years (Hill & McArthur, 2006, Raja-Jones, 2002; Audley & Harrison, 1995; McEvoy et al, 1991). Rickard et al (2006) in searching MEDLINE and CINAHL databases, observed that there was minimal discussion of clinical research roles in the 1970s, at least 10 papers published in the 1980s and more than 50 papers in the 1990s. The bulk of the empirical literature for this review examines the role of the Clinical Research Nurse in all its diversity. Twenty one studies were found: 12 were quantitative, 8 qualitative and one used mixed methodology. All were published between 1993 and 2007. They are presented in Table 3. It should be noted that 15 of these 21 studies had sample sizes less than 50 respondents. Fifteen studies were descriptive in nature or audits describing demographics, job titles, role tasks, educational background, and positive and negative aspects of the role. This section will discuss the diversity of the role as presented in the literature regarding job description, role competencies and challenges to the role.

# Job description

At the beginning of any clinical trial, a clinical protocol must be designed. The protocol document has to clearly define the scientific rationale, the ratio of potential risks to benefits, the safeguards that will be used to protect subjects from injury and information about the execution of the trial (Fishwick et al, 2002; DiGuilio et al, 1996; Molloy Hubbard, 1982). Any special requirements for nursing care and patient education must be incorporated into the design which should include the job description of the nurses or midwives employed.



Table 3: Summary of empirical studies on role

Author	Year	Country	Study type	Description	Sample & Response
Sale	2007	Canada	Qualitative phenomenology		
Easter et al	2006	USA	Qualitative - semi- structured interviews	To investigate how the researchers and subjects who participate in clinical trials understand the presence of care in research	N = 18 CRNs, 19 Pls, 45 patients (n=82)
Simpson	2006	UK	Quantitative - email questionnaire	To identify the research roles provided by nurses and midwives and to understand their professional development needs.	N = 116 nurses and midwives no response rate
Rickard et al	2006	Aus & NZ	Quantitative - email questionnaire	To ascertain demographics, education, employment history, job structure and role content	N = 49 research coordinators no response rate
Hill & MacArthur	2006	UK			
Study 1	2002		Quantitative - postal questionnaire	To identify and elicit information from research nurses with regard to important human resource issues	N= 72, response rate 66%
Study 2	2003		Mixed method - Questionnaire & focus groups	Used same group of research nurses as study 1 to explore experiences and knowledge	N = 50, response rate 48%
Wilkes & Beale	2005	Aus	Qualitative - To explore experienced nurse researchers' views on the appropriateness of nurse actions when conducting clinical research		N = 12
Deave	2005	UK	Qualitative - documentary analysis	documentary research is stated in employment	
Hathaway	2005	UK	Qualitative - ethnography		
Rico-Villademoros et al	2004	Spain	Quantitative - postal questionnaire	To ascertain the standard tasks performed by clinical research coordinators in oncology clinical trials	N = 37, no response rate
Ehrenberger & Lillington	2004	USA & Canada	Mixed method - questionnaire & focus groups	To identify the significant dimension of the role of CRN and to construct a reliable and valid survey instrument to reflect these dimensions	N = 40
ACRP	2003	USA	Quantitative - postal questionnaire	To collect comprehensive statistically accurate salary and benefits data for specific positions within the research industry.	N = 1,300, response rate 61%



Author	Year	Country	Study type	Description	Sample & Response
Brown et al	2002	UK	Mixed method - Questionnaire & telephone interview	To assess the role of lead R&D nurses	N = 34, response rate 65%
Grunfeld et al	2002	Canada	Qualitative – focus groups	To identify barriers and facilitators to the accrual of patient to cancer clinical trials by learning the views of 'CRAs' on the subject	N = 29
Wright et al	2002	Canada	Qualitative – focus groups	To explore the factors that influence the decision of patients with cancer regarding clinical trial entry, specifically from the 'CRA' perspective.	N = 13, 10 of which were nurses
Davis et al	2002	USA	Qualitative – focus groups	To ascertain the role of the study coordinator	N = 45, 68% of which were nurses
Muellar	2001	USA	Qualitative - semi- structured interviews	To ascertain the role, career and work experiences of nurse trial coordinators	N = 38
Cox	2000	UK	Qualitative – observation & semi-structured interviews	To build a picture of the environment in which clinical trials are offered and administered	N = 4 for observation N = 10 for interviews
Xanthos et al	1998	USA	Quantitative - postal questionnaire	postal by clinical research coordinators in	
Kellen et al	1994	USA & Canada	Quantitative - postal questionnaire	To determine attributes of coordinators and see if these affect outcome of clinical trials	N = 132, response rate 57%
Arrigo et al	1994	15 states in Europe	Quantitative - postal questionnaire	To document the involvement of nurses in clinical trials	N = 312, response rate 38.4%
Scott	1993	UK	Quantitative - questionnaire	Survey to ascertain role, training and professional development of study site coordinators	N = 170, no response rate
Ahern et al	1993	USA	Quantitative - questionnaire	To document the different activities for which the trial coordinator assumed responsibility	N = 21, no response rate

There is some evidence to imply that a significant number of CRNs have no job description. An Australian study (Rickard, et al, 2006) showed that 31% had no job description. Simpson (2006) suggested that the 12% of participants in her study with no job description may be due to a lack of line management to the nursing hierarchy. Where job descriptions exist, there is some evidence of incongruence between the job description and the actual job (Hathaway, 2005). Hathaway found that three CRNs commenced their jobs without a job description, wrote their own at a later stage and as a result the descriptions were a



reflection of how they saw their role and did not necessarily contain their employer's perspective. A UK study in 2003 found that seventy two percent of participants had a job description and only half of these stated that it was an accurate reflection of their duties (Hill & MacArthur, 2006). An earlier American survey found that the original job description for CRNs in the protocol did not reflect the wide variety of duties undertaken by them (Ahern et al, 1993). One half of the job descriptions expected the CRNs would be involved in clinical management, and nearly 50% of the CRNs time was actually spent on this activity. It was found that 30% of the CRNs time was spent on administration but only half the principle investigators assigned this function to the protocol job description. In addition, it was noted that no CRN was on the committee assembling the protocol document, implying that the importance of the CRN role is not fully appreciated at the planning stages. This has implications when selecting personnel for the job as there may be inappropriate criteria for employment (Ahern et al, 1993). Furthermore some studies have shown that where there were protocol job descriptions the CRN's role encompassed a greater number of activities than was stated (Xanthos et al, 1998). It should be noted here that despite the difference in years between some studies this issue has remained unchanged.

In 1998, an American survey of CRNs was conducted to delineate nurses' roles. The diversity of activities reported were categorized and compared to those cited in the protocol job description (Xanthos et al, 1998). None of those who drew up the protocol job description were CRNs. Eleven (48%) respondents received written job description of which five found it inadequate, brief and vague. Interestingly, 39% (n=9) developed their own job description. A broad spectrum of clinical and non clinical activities was categorized into a list of ten. Activities identified by CRNs differed from those stated on the protocol job description in areas of education, participant-focused activities, coordination and direct care provision.

In summary, an accurate protocol job description, could positively affect CRNs retention and productivity as expectations by nurses and employers would be more closely aligned. Furthermore there is a strong emphasis in the literature that including clinical research nurses/midwives in the protocol committee when developing the protocol can benefit all.

# **Role Competencies**

The literature describing the role of the CRN, groups the role competencies involved in a number of ways. This section will discuss the empirical and some anecdotal papers with regard to how the competencies involved are categorized. Empirical papers are all presented in Table 3.

In 1994 a survey of one hundred and twenty CRNs in fifteen European countries stated that the role was then perceived as an essential component of the clinical trials process (Arrigo et al, 1994). However in Europe nurses or midwives' level of participation in this field is not well documented and frequently not recognized. A discussion paper by DiGuilio et al (1996) outlines how the range of competencies can vary from standard tasks such as monitoring patients, completing forms, administrating drugs to full involvement with the study design, interpretation of results and implementation of the medical protocol. Arrigo et al (1994) found that the activities undertaken by nurses are mainly focused toward direct patient care with nurses rarely involved in protocol review and preparation (29.3%). Despite these studies being over ten years old the results are not dissimilar to more recent studies (Simpson, 2006; Rico-Villademoros et al , 2004).

An American study conducted ninety minute focus groups on 45 participants (Davis et al, 2002). Sixty eight per cent were nurses. They reported that one hundred and twenty eight activities were performed by CRNs. The researchers identified three fundamental roles from their data that pertains to CRNs; patient advocacy, subject advocacy and study advocacy. Patient advocacy is the CRN's primary responsibility and incorporates the tasks governing 'mothering' or 'caring'; subject advocacy is the role that protects the rights of the individual while study advocacy is the policeman of the protocol (Davis et al, 2002).

A Spanish survey grouped CRNs activities into five categories; administration, clinical, monitoring, data management and statistics and researcher-related activities (Rico-Villademoros, 2004). Of these five categories most of the CRN's time was spent on the monitoring activity. This includes competencies such as patient registration, recruitment follow up, and reporting serious adverse events etc. Furthermore, while Mueller (2001) found that nurses saw their role as part medical and part nursing, Hathaway from an ethnographic study asserts that their role is a combination of direct patient caregiver, a measure of educator, ethical advocator and office style administrator (Hathaway, 2005). This is similar to DiGuilio's division of the role in 1996 (DiGuilio et al, 1996). Hathaway (2005) asserts that the role is determined by the principal investigator of the research study which perhaps explains the different job titles and variation in roles.

Patient recruitment is one of the key competencies that a CRN must conduct (Simpson, 2006; Hathaway, 2005; Tattersall, 2002; Wright et al, 2002; Kellen, et al, 1994) and an area of frustration (Kellen et al, 1994). This is not surprising as the recruitment phase of a clinical trial is recognised as the most resource intensive with the highest need for personnel. In addition, there is the ongoing dissatisfaction with the task of completing voluminous amount of paper work (Roberts et al, 2006; Kellen et al, 1994). Wright et al (2002) highlights the fact that CRNs identified information transfer within the informed consent process as a major aspect of their specialized role and that full disclosure of information was an important predictor of recruitment success. Another study found that individuals are influenced and affected by the way in which the trial is offered and the environment in which their trial treatment is given (Cox, 2000). Similar findings were found by Grunfeld et al. (2002) but they stated that

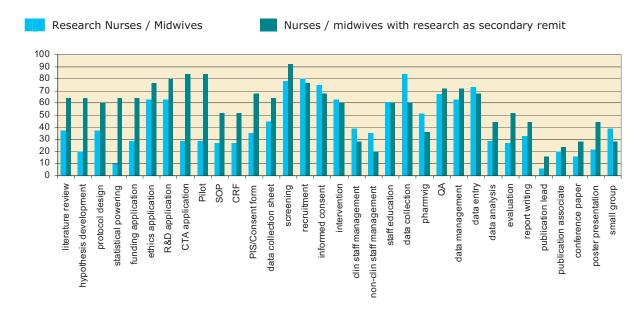


system factors had the greatest impact on the ability to accrue. Sale (2007) stresses that patients may not be aware of or prepared for what they were consenting to when enrolling in a trial. Somewhat alarmingly, Jenkins et al (1999) found the median duration of a consent interview was less than 15 minutes when conducted by doctors and that most patients signed the consent document at the first consultation when the clinical trial was discussed, thus showing minimal reflection on their decision. An opinion piece by Tattersall (2002) states that perhaps the appropriate training of CRNs who negotiate these consents merits a review. Since it appears from the literature that the CRN takes on quite a large ethical responsibility recruiting patients and yet are not usually part of the protocol committee such a review should centre on their level of training and support for this aspect of the role.

The goal of any clinical trial is the retention of the patient cohort. To achieve this, the CRN assists with activities directly and indirectly related to the study. For example, 86% of CRNs were found to attend funerals of former participants suggesting the depth of relationship developed between CRNs and research participants (Xanthos et al., 1998). Furthermore, Xanthos et al. (1998, p.44.) stresses that fostering such a "holistic approach may prevent the participants from feeling like experiments". Overall, this heightens the need for raising awareness of such hidden aspects of the role. The multi faceted activity of the coordination role highlights how CRNs maintain communication between numerous departments and clients to avoid duplication of services, promote cost efficiency, save time and energy expenditure. The direct care provider role involves direct nursing care and is dependent on clinical expertise while the education role implies that the CRN is the collector and disseminator of significant information to staff, patient and relatives and is seen as the continuously accessible resource to all (Xanthos et al, 1998).

In summary the literature suggests that the role profile of the CRN is quite complex, not well documented and frequently unrecognized. The range of competencies found varied from standard tasks such as monitoring patients, completing forms, administrating drugs to full involvement with the study design, interpretation of results and implementation of the medical protocol. Figure 1 which is adapted from Simpson (2006) shows the full range of competencies. Despite the suggestion that the role is now perceived as an essential component of the clinical trials process there is a need for raising awareness of many hidden aspects of the role. Furthermore, the perception of CRNs that the informed consent process is a major aspect of their specialized role is noteworthy while the literature suggests a review of appropriate training for CRNs.

Figure 1: Elements of the research process in which research active nurses and midwives are involved (Adapted from Simpson 2006: p17)



# Benefits and challenges to the role

Clinical research nurses have been referred to as invisible players whose job has been considered an assistant's position with little authority or autonomy (Davis et al, 2002). However they have many contributions to make. There is some evidence to suggest that CRNs improve subject recruitment numbers and subject retention while generally increasing study efficiency and data quality (Rico-Villademoros et al, 2004; Davis et al, 2002; Isaacman & Reynolds, 1996; O'Halloran et al, 1989). The CRN typically sees a project from commencement through to completion. "A continuous, holistic, caring approach fostered by nurses not only results in the successful management of a complex protocol but also humanizes the research process for the participants" (Xanthos et al, 1998. p46). However, there is evidence in the literature that nurses or midwives are not the sole



professionals employed in such research teams (Rico-Villademoros, et al, 2004; Davis et al, 2002; Kellen et al, 1994). Furthermore, there is a discussion on whether nurses or midwives are ideally suited to the position. Mueller & Mamo (2002) imply that nurses contribute positively to clinical trial coordination as they have the nursing related knowledge and skills coupled with their dedication to care work which makes them ideally suited to the demands of the role. It is suggested that only through the patient management role component that a real case of need for a CRN can be made as this makes the nursing management of the role an essential part of the role description (McCormack, 2004). Formalizing this role specifically for nurses is by specialty training but nurses need to empirically show that the skill and knowledge they bring to trial coordination are both quantitatively and qualitatively more beneficial than those from other occupational groups (Mueller, 2001). In the future, economic factors may dictate those employed in the role, as routine tasks that are now undertaken by CRNs may be transferred to less skilled and less expensive workers (Mueller, 2001).

A Spanish study in 2004 found that nurses and physicians in a clinical research team had greater involvement in clinical activities than those who did not have this background (Rico-Villademoros et al, 2004). 'Query resolution' was conducted by 100% as compared to 60.9% of those who lacked a clinical qualification. They argue that their results do not support the idea that nurses should assume the role of CRN but suggest that they are ideally suited to the 'sub investigator's role' that the authors perceive as a more advanced role. However Davis et al (2002) outline how nurses are mostly selected for the CRNs position because of their clinical experience and psychosocial skills but point out that many CRNs can have difficulties with protocols that deviate from the standard of care. Thus the issue of fluidity in role boundaries is highlighted across the research study continuum.

In summary the empirical literature indicates that nurses or midwives are not the sole professionals employed in the clinical research team. However there is some evidence to suggest that CRNs improve subject recruitment numbers and subject retention. In the future, nurses may need to empirically prove that the skill and knowledge they bring to trial coordination are both quantitatively and qualitatively more beneficial than those from other occupational groups. Additionally there is a suggestion that they are ideally suited to the 'sub investigator's role'; consequently the issue of fluidity in role boundaries is highlighted across the research study continuum.

# **Educational Qualifications**

This section will discuss the educational qualifications CRNs have on commencing their employment to clinical trials. The literature stresses that many nurses lacked experience and preparation for the multifaceted CRN's role (Hathaway, 2005; Mueller, 2001; Xanthos et al, 1998). Their prior educational experience varied. At the early stage of role development, it appears that this element was of minimal consideration. Arrigo et al (1994) reported that 74.2% had no university degree. In 2002 and 2005 a six month retrospective search and job analysis of job advertisements placed under the research section of the Nursing Times was undertaken by Deave (2005). This documentary analysis demonstrated that there was little or no research requirements for research nurses' posts suggesting no primary degree was required to apply for these posts. A comprehensive survey of members of the International Association of Clinical Research Professionals reported that 59.8% (277) of the Clinical Research coordinators and 80.5% (269) of the clinical research associates had a bachelor of science in nursing degree (ACRP, 2003). Other studies with smaller sample sizes report similar findings (Rico-Villadermoros et al, 2004; Davis et al, 2002; Xanthos et al, 1998). Increasingly, a number of CRNs have masters degrees or above ranging from 10-13% of respondents in some studies (Rickard et al, 2006; Muellar & Mamo, 2002). The UKCRC (2007) reports that of the 600 clinical research nurses working in five UK Welcome Trust Clinical Research facilities and their associated NHS Trusts, 70% had a first degree and 15% held a postgraduate degree. Fewer than one in ten nurses working in research in UK hospitals have a research degree (Association of UK University Hospitals, 2005 as cited by UKCRC, 2007).

One interesting finding was presented in the Australian study; a correlation between those CRNs who have a research degree with personal research activity. Overall, 81% of Clinical Research Nurses with partially or completed research degrees were undertaking their own research compared with 24% of CRNs without these qualifications (Rickards et al, 2006). In summary, there is evidence to suggest that CRNs' educational experience varies while there is little to no knowledge of research required prior to applying for this position. However for those who have a research degree it appears more likely that they will conduct their own nursing research.

# **Professional Issues**

A number of professional issues are highlighted in the literature and include the following; isolation, job dissatisfaction, role conflict, and lack of preparation for the role. Each of these is discussed in turn below.

#### Isolation

Many CRNs report to medical staff giving them a high degree of perceived autonomy while at the same time denying them contact with their nursing peers. In a Scottish study (Hill & MacArthur, 2006) 58% (n=29) of the respondents felt isolated in



their job while 43% were managed by doctors and 40% by directorate managers. The feeling of isolation is a recurring theme in the literature for this role (UKCRC 2007; Simpson, 2006; Ecklund, 1999). Kellen's et al (1994) survey found that 76% reported to the principle investigator. Roberts states that many CRNs work without direct support of colleagues and without clear guidelines of a job description and scope of an apparent career path (Roberts et al, 2006). One nurse described the situation very clearly: "ward nurses think we have a cushy nine to five job... I don't think you get an awful lot of sympathy" (Hill & MacArthur, 2006; p44). The lack of a job description or guidelines does not help. However Hathaway (2005) does not fully agree that CRNs feel isolated, unsupported and undervalued. Instead, feelings are of a mixed nature and dependent on the particular research team and the attitude of the principal investigator (Hathaway, 2005; Fishwick et al, 2002). In summary, the literature suggests that isolation may be context specific.

#### Job dissatisfaction

In an early exploratory study by Kellen et al (1994) to assess the characteristics of the CRN's role and to investigate whether these characteristics affect the clinical trial outcome, one hundred and thirty two questionnaires were returned, a response rate of 57%. The three main job dissatisfiers were patient recruitment (63%), dealing with patient deaths (34%) and physician unavailability (26%). Overall job satisfaction was mostly affected by frustration with patient recruitment.

#### Role conflict

As already stated, the literature suggests that CRNs have a wide but poorly defined role. It involves data collection but frequently needs a nurse to deliver care and treatment in a complex and isolated context which also demands awareness and implementation of ethical and professional responsibilities (Hill & McArthur, 2006). Balancing an individual patient's rights with the need to meet recruitment targets and to conduct good research that will benefit society as a whole can be fundamental to the CRN's role (Hill & MacArthur, 2006). Davis et al (2002) conducted focus group discussions with forty five participants. Analysis found that CRNs have a central position with complex relationships and much potential for conflict among the roles. As mentioned earlier three advocacies were identified from the groups; patient, subject and study advocacy. The difficulty is balancing these aspects of the role. For instance during the study's implementation via recruitment, screening and enrolment the CRN balances concerns for the patient, the subject and the study (Davis et al, 2002). There are times when one advocacy is more important than another and deciding which one to focus on requires skill, knowledge and experience.

Cox's (2000) study found that there was conflict between balancing the needs of the patient versus the wider needs of society. The ethical issue of care in research and how it is perceived by subjects and researchers was investigated in 2006 in the US (Easter et al, 2006). A striking finding was that the research participants saw researchers as providing better patient care than healthcare providers. Whilst this is particular to the US context of health care provision, the issue of a quality patient service may still be applicable considering the continuity of care that a CRN provides within the European type health systems. However Easter et al (2006) did not find a standard widespread pattern in which CRNs solely gave care leaving principle investigators to undertake the research. Finally the dominance of the focus of working ethically was found by Hathaway in her study in 2005.

In summary, CRNs have a broad but poorly defined role. The difficulty is balancing aspects of the role. Role conflict arises between balancing the needs of the patient versus the wider needs of society however there is evidence to confirm that CRNs' focus is to work ethically.

### Lack of preparation for the role.

The lack of preparation for the role is emphasized in the literature from an empirical viewpoint and anecdotally (Hathaway, 2005; Mueller, 2001; Xanthos et al, 1998; White-Hershey & Nevidjon, 1990). The transition from ward based nurse to CRN is a major leap (Hill & MacArthur, 2006; Ecklund, 1999; Chadwick, 1992; Johnson, 1986) and yet appears to be the main route of entry to the role. Hill & MacArthur (2006) found that only 50% had received staff induction while 44% had attended a job specific induction for their current post. A further 15 respondents who did not receive an induction said they would have found it useful. Arrigo et al's (1994) early survey found that 62% of nurses had no specialist knowledge in oncology and suggested that the lack of basic training in oncology and in clinical trials may impair nurses' understanding of the protocol, affect patient care and impact on the final results of the study. Seventy per cent of nurses indicated their interest in courses to acquire knowledge about clinical trials. There is a perceived deficiency in training needs (Roberts et al, 2006). Simpson (2006) found that training and education for research skills was ad hoc and commonly lacking prior to appointment to a research role. Only 20% of respondents in another study reported receiving training or education in research methods (Brown et al, 2002). Clinical research nurses have important training needs that need to be addressed (UKCRC, 2007). In addition, well trained and experienced CRNs can contribute significantly to the quality of the data collected (Rico-Villademoros, 2004) and benefit the patient. In the clinical research facilities in Edinburgh for example, what is most highly appreciated is on the job education and training and this provision is robust in this facility (Tierney, 2007).

In summary, the lack of preparation for the role is emphasised in the literature while specific job induction is ad hoc and not



provided to all new CRNs. Well trained and experienced CRNs can contribute significantly to the quality of the data collected.

# **Professional development**

A number of papers refer to 'professional development' but discuss it in relation to the lack of preparation for the role (Tierney, 2007; Hill & MacArthur, 2006). Simpson (2006) specifically asked if respondents had any professional development needs that they would like addressed. Advancement in research skills was the most common theme expressed followed by clinical skills and management skills. The Newcastle review reported that 7% of respondents identified continuing professional development would enhance their working life (Carrick-Sen, 2007). Furthermore, it was highlighted that the worst aspects of the job were the lack of training opportunities (Roberts, et al, 2006).

In summary, there is some evidence to suggest that professional development is lacking while the provision of these opportunities would positively support these nurses in their current roles.

# **Companion studies**

Randomized control trials offer unique opportunities to investigate questions relevant to nursing through the mechanism of companion studies also called parallel or ancillary studies (Dunbar-Jacob & Schron, 2002). A companion study is an investigation with scientific merit and objectives that are distinct from the primary objective of the overall trial (Meinhert, 1986 cited by Hill & Schron, 1992). Hill & MacArthur (2006) found five Clinical Research Nurses working on studies examining nursing practice which were undertaken alongside the clinical trial. However 52% (n=32) expressed an interest in conducting research looking at nursing practice and over half of that group felt it was possible in their position.

To advance nursing research there are four main areas of support needed; advice on preparing funding applications, support from the consultant, supervision from an experienced nurse or midwife and advice on preparing a research proposal. Anticipating companion studies during the protocol design phase will ensure such opportunities (Xanthos et al, 1998) but there is little evidence of such research perhaps due to a lack of nursing input to protocol design. Alternatively, the historical absence of specific nursing professional development for these nurses may also have contributed to a disempowerment of the nursing research aspect of the role (Muellar, 2001). Rickard et al (2006) claim that unless nurses have degree level education, they may not see the need to investigate nursing as is suggested by their findings where personal research activity was mainly conducted by CRNs who had a research degree. Rickard et al (2006) also found that personal research was strongly associated with the setting in which the clinical research was conducted. For instance, 100% of six paediatric Clinical Research Nurses undertook their own research compared to 30% and 25% from adults and a mixed unit respectively. Furthermore it was found that there was a trend to undertake personal research with increasing levels of CRN experience: 44% of Clinical Research Nurses with 4 or more years experience conducted their own research as compared to 22% with less than 1 year experience (Rickard et al, 2006). However Simpson found that the main barriers to conducting one's own research were lack of funding, time and opposition from the team (Simpson, 2006). Her report found that 31% of research nurses do their own research. Perhaps in the future nurses will have more opportunities to develop or be involved in companion studies answering nursing specific questions (Arrigo et al, 1994) such as those developed by Cox (1999; Cox et al, 2005).

In summary, there is little evidence of companion nursing research perhaps due to a lack of nursing input to the protocol design. However, unless nurses have degree level education, they may not see the need to investigate nursing. Nursing research was strongly associated with the setting in which the clinical research was conducted while a number of barriers were found including a lack of funding, time and opposition from the team.

#### Other issues

Additional issues were highlighted in the literature. These included employment issues such as concerns about length of contracts, employment grade and sources of funding for the post (Hill & MacArthur, 2006; Kellen et al, 1994). The lack of formal recognition of the CRN's input to clinical study outcomes is highlighted by a number of studies (Roberts et al, 2006; Mueller & Mamo, 2002). For example, CRNs non-identification in published accounts of the research. "Despite the fact that Clinical Research Nurses manage the completed projects that provide the hospital with excellent professional status, this often seems to go unrecognised by management." (Roberts et al, 2006. p.134.)

# **Career Pathways**

The literature so far has been reviewed to examine the role of the CRN and the competencies and professional issues involved. As has been highlighted, the lack of a job description, numerous job titles and the lack of recognition imply the lack of a structured career pathway for CRNs.

Nurses or midwives often become CRNs in an unplanned fashion and have no structured career pathway (UKCRC, 2006). There is anecdotal evidence to suggest that they hear about these jobs 'on the grapevine' or are approached personally by a



doctor who has worked with them (Mueller & Mamo, 2002). They are often selected because of 'hands on' skills, clinical expertise and psychosocial skills (Davis et al, 2002). Many CRNs sought out these positions or stayed in them as a result of their belief and experience with a form of status enhancement (Mueller and Mamo, 2002). Indeed "there is no singular pathway that leads nurses to careers as CRNs ... the decisions of nurses seemed to be informed by their interactions with other research professionals and by their complex calculations of personal and professional interests" (Mueller and Mamo, 2000; p54).

Once the nurse considers taking on the CRN role why do they go into it? The answer appears to lie in the pursuit of job satisfaction. Kellen et al's survey (1994) shows the elements pertaining to this. The challenge of doing research (85%), acquisition of new knowledge (84%), intellectual excitement (72%), autonomy in the role (77%), and patient contact (72%) were factors that attracted CRNs to the role. Results from the Australian study concur with that (Rickard et al, 2006). In addition the way in which CRNs do the job was most satisfying. They valued highly the ability to organize their own work routines and schedules. The respondents in the Australian study found seeing a project from commencement through to completion gave them respect, professional recognition and made them feel positive about their contribution. "It is possible that this non structured position attracts people who thrive on challenges and experimentations and equally take pride in their work" (Robert et al, 2006, p134). Mueller and Mamo (2000) noted that nurses follow a complicated pathway to trial coordination. They suggest that there are three sets of what they call career contingencies that are involved in the movement of nurses into these positions which are; local and personal (flexible hours allows for more family and leisure time), broader professional (mastery of new skills and knowledge) and social enhancement (working closely with physicians is perceived to give status enhancement). Finally the social contingency of being part of cutting edge medicine and the opportunity for continuity rather than episodic patient care services was very attractive to these nurses (Mueller & Mamo, 2002).

Job satisfaction, status enhancement and flexibility appear to be the primary reasons CRNs stay in the role (Hill & MacArthur, 2006; Rickard et al, 2006; Mueller and Mamo, 2002). Studies show a high level of job satisfaction. One study reported that 83% of respondent were extremely or very satisfied with the job (Rico-Villademoros, 2004). That nurses seek out these positions and remain in them for prolonged periods of time suggests that the benefits outweigh any drawbacks (Mueller & Mamo, 2002). It is the combination of research, management, clinical and education aspects that attracts nurses to the CRN role and why they perform their position well (Rickard et al, 2006).

This search found little or no evidence of a structured career pathway for CRNs in Europe (Kenkre & Foxcroft, 2001). It has been stressed however that the skills and knowledge experienced CRNs' possess should be valued and used to develop nursing research capacity (Tierney 2007; Hill & MacArthur, 2006; Simpson, 2006; McCormack 2004). "There are many opportunities for a 'nursing component' to be built into established research programmes that can enable a CRN to undertake doctoral study and advance a clinical nursing research career. These need to be maximised if the role is to advance and be a key player in clinical research" (McCormack, 2004: p29).

This literature review has shown that the international experience of the role of the CRN is complex, diverse and lacks recognition and structure. To advance as a distinct and recognised grade, CRNs should agree on a preferred title. Linked to that is the necessity of a clear pathway from a novice to an expert CRN (Rickard et al, 2006). The lack of a career structure was reflected in one study (Rickard et al, 2006) where salaries varied by Aus\$30,000 between respondents, reporting relationships varied and there was no differentiation in the job title as to the various levels of CRN therefore no opportunity for promotion. Earlier, the UK Royal College of Nursing (1998) suggest that nurses taking a research role should not be paid less than an E grade as the knowledge of research methodology is integral to the role. However, one recent report stated that the lack of job stability where many CRNs are on continuous temporary contracts overshadowed their ability to think about their career development (Simpson, 2006). A model contract is currently in development in the UK (UKCRC, 2007) which will enable career flexibility and address pension concerns for nurses wishing to combine clinical practice and research. In the absence of such, pragmatic solutions such as secondments are recommended (UKCRC, 2007).

Kenkre and Foxcroft (2001) claim that many nurses are currently applying for CRN posts in the UK because there is an evolving career structure (See table 4). Their paper shows a diagram of a career pathway for Clinical Research Nurse starting at an E grade and advancing up to I grade. With each grade is the corresponding level of education up to PhD or MBA level and salary. There are now a number of educational courses for CRNs in the UK which will enable them to gain academic recognition for the work they do (Kenkre & Foxcroft, 2001). Without a pathway there is no recognition and reward for developing their knowledge, skills and experience in this area. The UK grading as mentioned here has now transformed to a banding system and this project's site visits reports (See Appendix A) gives further details of the current situation. Whilst Kenkre and Foxcroft's (2001) work apply solely to CRNs, a more recent report from the UKCRC (2007) examines the situation for a broader role entitled clinical academic nurse which encompasses the current CRN. This pathway (see Figure 2) whilst showing an academic award trajectory, fails to link or integrate this with existing nursing roles although has the visionary end point of Senior Clinical Academic Nurse.



Table 4: Nursing research careers; clinical research pathway (Kenkre and Foxcroft, 2001:p42).

	Grade E	Grade F and G	Grade H	Grade I
Typical role	Identify and screen suitable patients for trials; carry out procedures and treatment interventions according to predetermined protocol. Undertake the practical organization of the trial, data collection, coding, entering data into computer and patient support.	F grade CRN does not work as an 'assistant' but has a degree of autonomy, often conducting concurrent studies. Liaises with sponsor companies and multi disciplinary research teams. Active role in maintaining ethical requirements, including ethics committee submissions, informed consent process and patient support. G grade CRN also has an educational and developmental role.  Leads the development of research projects and negotiates research funding; accountable for nursing and financial elements of research projects and negotiates research funding; accountable for nursing and financial elements of research projects and negotiates research funding; accountable for nursing and financial elements of research projects and negotiates research funding; accountable for nursing and financial elements of research projects and negotiates research funding; accountable for nursing and financial elements of research projects; responsible for submissions to research ethics committees and developing relations with sponsoring companies; advises specialists in the field on application of research; involved in the dissemination and publication of findings.		Provides strong leadership in research and development activity and works to bring together the right composition of research teams for research projects. Is involved in furthering the institutional research agenda locally, regionally and nationally; leads by example of research activity and publications
Experience	First experience in research capacity but has clinical experience at post-registration level within specialty. Works under close supervision.	rch capacity but concurrent research proto docui studies with minimal supervision to the specialty. Works standards required by proto docui supervision to the specialty.		Principle investigator; leads a research unit and conducts national and international studies; obtains funding to support staff contracts; a member of national committees; supervises post-graduate students.
Knowledge	Knowledge of good clinical practice, the health service, R& D departments and pharmaceutical industry partnership.	Knowledge of research design and methods and an understanding of the analytical process	Comprehensive knowledge enables appropriate costing of clinical trials. Has an understanding of the complexity of ethical issues for research staff involved in clinical research	Knowledge of the Good Clinical Practice: Consolidated Guideline(ICH 1997) for the management of clinical trials and the mechanisms for licensing of products
Training	Post-registration training in the clinical specialty. Good clinical research practice. IT skills.	Certificate in clinical research and specialist procedures required for each research project	Masters level training, including issues in ethics, law, drug development and management in clinical research	Doctoral level training or MBA to prepare for the development of nurse- led units
Skills	Numerate; can adhere to pre-determined protocols; IT skills; able to liaise with research staff and representatives of sponsor companies; good time- and project- management skills.	Good project management skills; protocol development, data analysis and writing for publication skills	Able to develop assess and direct research protocols; manages resources, including finances, equipment and staff members; maintains the overall standard of care for patients at all times	Able to lead, motivate and develop research teams, build research capacity and infrastructure, develop business plans and negotiate with professional colleagues for co-ordinated care in a nurse-led unit



	Grade E	Grade F and G	Grade H	Grade I
Desirable qualifications	UKCC registration	First degree; Certificate in clinical research	Masters degree	PhD or MBA

This leads to another debate found in the literature relating to career pathway and that is how does the CRN fits in with existing nursing roles? One review argues that there are many similarities in responsibility and autonomy between Clinical Research Nurse and the Clinical Nurse Specialist (Stephens-Lloyd, 2004). The point is put that the principle of managing medical clinical trials can be translated to evaluation of nursing interventions and techniques and therefore raises the question if CRNs are "the best placed nurses to embrace the nurse consultant posts of the future" with their clinical and research knowledge and educational skills (Stephens-Lloyd, 2004; p 26). Such debate appears to occur in countries where there is an absence of clear frameworks for specialist nursing roles such as CNS/CMS or ANP/AMP. The literature did not reveal any empirical work examining the CRN as a transitional role or any exploration of whether such nurses return to practice or other professional arenas on contract completion.

Bishop (2003) presents five case studies of nurses with successful careers in nursing research. All have similar outlooks. These include an openness to multidisciplinary care, a recognition of the importance of good mentorship and professional support, clear goals and an inner discipline to step outside the norm to achieve their goal (Bishop, 2003). Interestingly, each nurse got involved in research in different ways, some through the role of clinical research nurse. This points to valuing the CRN experience by linking it to other roles and allowing movement across career trajectories (Mueller and Mamo, 2000).

In summary, nurses and midwives become CRNs in an unplanned fashion and have no structured career pathway. Job satisfaction, status enhancement and flexibility appear to be the primary reasons CRNs stay in the role. Conversely, the lack of job stability where many CRNs are on continuous temporary contracts overshadows their ability to think about their career development. The CRN experience should be valued by linking it to other roles and allowing movement across career trajectories.

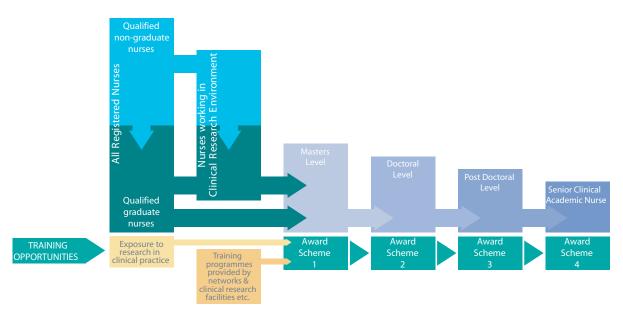


Figure 2: Adapted from UKCRC's (2007) Clinical Academic Training Path (p22)



# **Review Conclusion**

This review has examined the literature relating to the role of the clinical research nurse or midwife with a focus on the number of nurses in this role, the variety in titles used, the diversity of the role, educational qualifications, professional issues raised and career pathways. Furthermore it must be noted that most of the research reported here have sample sizes of less than 50 participants but again there is a commonality of strong trends that cannot be ignored. Despite the suggestion that the role is now perceived as an essential component of the clinical trials process there is a need for raising awareness of many hidden aspects of the role. The main conclusions are presented here.

- No national or international database exists as to the number of Clinical Research Nurses that exist worldwide while a
  definitive or official number of Clinical Research Nurses within the Irish context is unavailable. This has implications for
  workforce planning.
- The variety of job titles throughout the world indicates a somewhat ambiguous but potentially multifaceted role that is not fully understood and leads to uncertainty around accountability and responsibility for staff.
- An accurate protocol job description could positively affect CRN retention and productivity as expectations by nurses and employers would be more closely aligned. This may be achieved by the inclusion of CRNs when developing protocols or by standardizing job descriptions.
- The range of role competencies found vary from standard tasks such as monitoring patients, completing forms, administrating drugs to full involvement with the study design, interpretation of results and implementation of the medical protocol with CRNs having varying responsibilities across a sometimes multidisciplinary research continuum.
- Evidence suggests that CRNs' educational experience varied while there is little to no knowledge of research required prior to applying for this position. However for those who have a research degree, it is more likely that they will conduct their own nursing research.
- The lack of preparation for the role is emphasized in the literature while specific job induction is ad hoc and not provided to all new CRNs. Given that role conflict arises between balancing the needs of the patient versus the wider needs of society however there is evidence to strongly confirm that CRNs' focus is to work ethically. As such appropriate induction with ongoing training is a requirement.
- Nurses become CRNs in an unplanned fashion and have no structured career pathway at present. Job satisfaction, status enhancement and flexibility appear to be the primary reasons CRNs stay in the role. Dissatisfiers such as professional isolation may be context specific.
- The lack of job stability where many CRNs are on continuous temporary contracts overshadows their ability to think about their career development. The CRN experience could be valued by linking it to other roles and allowing movement across career trajectories.
- At the time of the review there was no literature pertaining to the role in Ireland

# PHASE TWO

# Summary Report of Site Visits

# Introduction

In phase two of the project a number of clinical research facility sites in the UK were visited (see Table 5). These visits were not confined soley to Wellcome Trust funded facility but were chosen in order to explore a range of clinical research activites and experiences. The visits were conducted by the project leader and in most cases accompanied by a clinical research nurse. Whilst a summary is offered here full reports of each site within the project timeframe are available in Appendix A. In addition the websites of other clinical research facilities such as Sheffield and Birmingham were searched for pertinent information.

Table 5: Clinical Research sites visited.

Date	Place	Funder	Visited by	Organisation
3/5/06 (pre-project)	Manchester	Wellcome	Mary McCarthy Kathleen MacLellan Sarah Condell Mary Day	DoHC NCNM NCNM DoHC
3/5/07	Dundee	Non-Wellcome	Sarah Condell	NCNM
24/5/07	Northern Ireland Cancer Clinical Trials Unit	Non-Wellcome	Sarah Condell Ailbhe Murray Anne Madigan	NCNM RCSI Mater
6/6/07	Newcastle	Non-Wellcome	Sarah Condell Ailbhe Murray	NCNM RCSI
7/6/07	Edinburgh	Wellcome	Sarah Condell Ailbhe Murray	NCNM RCSI
11/9/07	Southampton	Wellcome	Sarah Condell Yvonne Bailey Caroline Rooney	NCNM AMNCH OLHSC

# **Summary of site visit reports.**

# Career pathways

From the site visits there was no evidence of a career pathway to specialist posts within the Clinical Research Facilities (CRF). Instead, promotion occured across the nursing grades 5-7. Additional promotional routes were into facilities management or national network posts. Within the nurse role in the CRF there was differing involvement across the research continuum. For example, in the NI Cancer Clinical Trials Unit the nurses give the clinical care within the trial and work as part of a multidisciplinary team with a clinical trial practitioner preparing for trials through to ethical clearance and data managers inputting data. Elsewhere, some nurses undertook trial preparation and data inputting. Since the site visits were conducted in 2007 and under the auspices of the UK Agenda for Change, new national job profiles were published in 2008 (www.nhsemployers.org/pay-conditions/pay-conditions-1991.cfm). These are employment grades rather than professional grades. It shows progression from a Band 6 Clinical Researcher through Band 7 Clinical Researcher Specialist, and Band 8a Clinical Researcher Principal to Band 8bcd Clinical Researcher. (See appendix B for the job statements in relation to these grades). In most sites visited, nurse contracts were with the NHS and turnover was reported as low. Job descriptions were in place.

# Management

The site visits showed differing models of management of CRNs outside the CRF. In some cases such as Edinburgh, there was no formal relationship; others, such as Newcastle were evolving towards a single nurse with professional responsibility for CRNs regardless of the setting in which they practised. The latter model followed an organisational review (Carrick-Sen, 2007) and a



Medical and Healthcare Products Regulatory Authority inspection and was to ensure patient safety. In smaller organizations such as Dundee, a reluctance to deprive clinical areas of highly skilled clinical nurses has led to the development of some joint appointees between the clinical research centre and the hospital. The web-based search showed similar models. For example in Sheffield there is a Lead Nurse (R&D) who is responsible for the CRF and who is the Professional Lead for all Research Nurses working within Sheffield Teaching Hospitals NHS Foundation Trust. In Southampton there is a vision to develop a Clinical Research Institute which will incorporate all research activity and research nurses across the Trust. Appendix C shows some organizational charts and models, including internal research facilities structures and relationships with external key stakeholders. In summary, there was a trend towards ensuring research nurses had appropriate professional links in the absence of line management by a nurse.

#### Nurse-led research

Nursing-led research in CRFs varied. Edinburgh showed that 12 nurse-led studies had gone through the CRF. Interestingly these studies were not led by the nursing staff of the CRF itself but in most cases were led by clinical staff. Examples of the titles are provided in Table 6. In Newcastle, one nurse-led study on pain had been conducted through the CRF but examples of studies containing nursing or midwifery research elements or the potential for nursing or midwifery research were given such as promotion of sleep, development of nurse-led services, management of low risk antenatal care, obesity and pregnancy, long term management of non operative lower back pain, equality & dignity with sight and hearing impaired, falls in the elderly. Southampton reported some nurse and allied health professional-led research as well as complementary medicine. In 2007, Birmingham advertised for a Nurse MPhil/PhD opportunity. The position offered a post which would allow the post holder to undertake a part-time higher degree (0.5wte) as a combination with part-time (0.5 wte) nursing in the CRF. Again, the organisation charts show an inclusive relationship with nursing academics. For example, a Professor of Nursing sits on the Scientifc Advisory Board of the Southampton Advisary Board.

# Table 6: Titles of nurse-led projects conducted in Edinburgh CRF

Establishing professional and educational support for research nurses (Nursing)

Prevalence & Severity of Chronic Pain In Patients Undergoing An Elective Surgical Procedure - cross sectional observational cohort study (Nursing)

An audit of opioid use in patients with chronic non-malignant pain. (Nursing)

A randomised controlled trial comparing bladder infusion with standard catheter removal in the urology outpatient setting: A pilot study to examine voiding efficiency, patient satisfaction, time and cost effectiveness. (Nursing)

A double blind, cross over comparison between placebo and local anaesthetic wound catheters on postoperative pain and opiate use. (Nursing)

Are essential oils applied topically of more benefit than synthetic oils for stress reduction in the workplace? (Nursing)

A pilot study comparing basal bolus insulin therapy, carbohydrate counting and dose adjustment with traditional insulin regimes in patients with type 2 diabetes. (Nursing)

Assessing Hydration Status in Acute Stroke Patients. (Nursing)

An exploratory study into the quality of life measures among survivors of critical illness and prolonged mechanical ventilation at up to 6 months following discharge from the general intensive care unit. (Nursing)

Implementation and evaluation of a self-directed learning package for nurses caring for patients with colorectal cancer. (Nursing)

The social construction of fatherhood within the context of problem drug use: A qualitative study of service user and service provider accounts (Nursing)

Population based DNA sample collections from colorectal cancer patients, close relatives and matched controls (SOCCS) – (this was a large medically-led project but it facilitated a spin off nursing project leading to a PhD)



# **Networking**

The nurse managers of Wellcome Trust Research Facilities had formed a group and meet on a regular basis to share standard operating procedures, etc. An annual meeting/conference was also held for all clinical research staff. From website searching, it was ascertained that a UK Clinical Research Nurses Association (CRNA) has been in existence for 25 years with its current leadership based in London. The CRNA has a website, publishes a newsletter, and runs an annual two-day conference. There is a small annual fee for membership but numbers were not available from the website. In Scotland, there appeared to be much more networking effort. One ex-staff member of the Edinburgh Trust Clinical Research Facilities was responsible for establishing the Scottish Research Nurses and Coordinator's Network. This has a steering group of 4 representing the main geographic areas of clinical research activity in Scotland, 280 members across the whole country and offers a website, email alerts and annual conference. The website has shown 10,000 hits since established in 2005. The main content is information of the role, education and training and job opportunities. There was a small set-up grant from the R&D Office but the website is maintained by a committed individual and there is no fee for joining the association. From the sites that were visited little or no European networking was reported apart from European study specific meetings.



# PHASE THREE The Consultation

# **Methods**

The final phase of the project gave rise to particular difficulties. There is a total lack of employment metrics for the role with no Department of Health and Children employment grade, a mix of employers, and the lack of tenure giving rise to potentially transient employees. Such 'hiddeness' creates an inability to rigorously sample a group as there is no sampling frame. Nevertheless, this phase aimed to consult a group of nurses and midwives in the role of clinical research nurse. Others, such as CNSs and practice nurses whose primary role was clinical practice but who also conducted medical-led clinical research were not included in the consultation.

Snowball sampling was utilised. Faugier & Sargeant (1997) claim that such a sampling method is used on 'hard to reach' populations for reasons of invisibility or sensitivity and is dependant on the existence of an informal network. Streeton et al (2004) used snowball sampling to map research activity across a health authority area and were successful in finding pockets of 'hidden' researchers. For this project there were a number of strategies used as start points for the snowball sample. A letter of introduction was sent or emailed to all HRB funded hospital based principle investigators (n=64) in April 2007 which yielded 3 responses. An advertisement was posted in the NCNM Quarterly Review (circulation = 70,274) in August 2007 which yielded 2 responses. Directors of Nursing and Midwifery were informed at regional meetings in May and September 2007, giving an additional three contacts. The leadership of the inactive Irish Research Nurses Association also provided contacts. The researcher had two personal contacts through friends and work colleagues serendipitously garnered a further two contact names. Once the consultation commenced, 5 CRNs themselves provided further contacts. On follow-up not all contacts wished to participate, and not all contacts remained in post. Others were not utilised for a variety of reasons e.g. working in a disease area already well represented or not working within the Republic of Ireland. The final 'sample' was assessed for 'face validity' and judged on its representativeness to included research topics across settings, disease types and patient lifespan, the different employment models of nurses or midwife roles in the role and length of time in the role. The analysis consequently offers a 'tentative map' of the role from a broad range of experiences within the Irish context.

### The 'sample'.

Consultations were conducted with nurses and midwives whose primary role was in medical-led clinical research (n=41). Twenty one consultations were held over an eight month period. These took the form of 13 individual interviews and 8 group interviews. Within the group interviews, the number ranged from 2 to 7 but the majority (n=5) were of 3-4 participants. Twenty nine CRNs were Dublin based and eleven were from around the regions. In the main, the consultations were tape-recorded and transcribed. In the case of two consultations, the participants asked not to be taped and in a further two the environmental noise levels meant that tape recording would have been of limited value. In these four consultations, extensive notes were written. In the case of all data, potential identifiers were removed by the researcher for confidentiality purposes and participants given the opportunity to view and amend the notes or transcriptions to their wishes. A thematic analysis was then undertaken.

# Profile of consultation participants

Male and female CRNs participated. Thirty three of the participants were aged between 30 and 49 years. The participants were all experienced nurses and midwives, with 30 of them being more than 10 years in nursing and/or midwifery. Length of time in the specific role varied as per Table 7 below.

Table 7: Length of time in research role.

< 2yrs	2-5 yrs	5-10 yrs	10-15 yrs	15-20 yrs	Non-resp
16	11	9	1	3	1

Participants were asked about their formal educational attainment both at entry to the role and their current status which included being registered for an educational award. As the Table 8 below shows the profile showed trajectory toward higher degree status and this was reitereated in the interviews and the titles of Masters by Research (and PhD) supplied as per Table 9.

C22 And I mean the one thing that I would say... is that many of the nurses that have come in to positions here have gone on to do Masters in nursing or various different areas like primary care or ethics and law. So they have certainly developed their skills as researchers and I think this job has enabled them to do that and it is just something that we would like to try and develop further...



Table 8: Educational attainment at role entry and currently.

Education level at entry	Cert	Dip	HDip	Degree	MSc
(response n=41)	11	11	6	10	3
(response n=40)	6	8	6	8	12

Table 9: Examples of Masters by Research and PhD titles

Masters by Research	Colorectal Cancer- Patients experiences from Onset of Symptoms to Referral, Implications for Nurses in Primary Healthcare.
Masters by Research	Neutrophil Transcriptomic Responses in Uremic Patients (Pre & Post Initiation of Dialysis)
Masters by Research	Evaluation of Biologic Agents on the Health Related Quality of Life of Patients with Rheumatoid Arthritis
PhD	An investigation of possible mechanisms in the formation of venous leg ulcers and the use of neuromuscular electrical stimulation as a possible treatment modality.

# **Employment details**

Twenty eight participants worked full time, and thirteen worked part-time. Part-time hours varied between 12 to 36 hours. When asked to rate their equivalent salary scales, 6 reported being paid as a staff nurse, 4 as a CNM1, 25 as a CNM2, 4 as a CNM3 and 2 as 'other'. Such variance of salary scale was shown intra- and inter hospital sites. Twenty six reported having hospital contracts with 9 on university contracts and 2 reporting both hospital and university contracts. Three reported having a HRB contract and there was one non-responsednt. Only eight reported having a permanent contract, thirty two being on temporary or fixed term contracts. Eleven had no job description.

# Modes of working

Eighteen of the participants were solo nurses, with twenty three reporting work in a team of research nurses. These team sizes varied with some consisting of two members only. Others reported in interview that they work within a multidisciplinary team which included roles such as Principle Investigator, Research Registrar, Laboratory Scientists and Data Managers. Knowledge of other research nurses within their hospital setting was in most cases very limited and twenty four reported having no formal professional relationship to nursing or midwifery within their setting.

# **Settings and specialities**

One CRN role was based in primary care, the rest being hospital based. Forty reported conducting research with adults of which one included adolescents. Whilst the majority worked in cancer and haematology, the profile included those working in midwifery, paediatrics and mental health (Table 10). The focus on cancer and haematology reflects activity due to increased resourcing, but may also be a result of some sampling bias as these CRNs were more likely to work in teams and hence increase the snowballing effect.

Table 10: Medical speciality areas

Cancer	26	Respiratory	6
Haematolgy	18	Infectious diseases	5
Diabetes	8	Vascular	2
Cardiovascular	7	Renal	2
Gastrointestinal	7	Rheumatology	2
Obstetrics	2	Hepatology	1
Mental health	1	Neurology	1



# **Findings of the Consultation**

# Entering and exiting the role

The nurses' and midwives' descriptions of entry to the role appear to show a continuum of choice with one element of entry being 'falling into it' through to the element of 'seeking it out'. In 'falling into it', the nurses and midwives described entry to the role as a passive-type process rather than an active choice. Sometimes they were responding to an opportunity in the face of little or no alternative such as being unemployed or not being physically fit for full clinical practice.

# Falling into it

- C1 I wasn't attracted in I was unemployed at the time and I was doing agency in the hospital and the Director of Nursing at the time knew me and knew my employer, he was looking for a nurse - his nurse had left suddenly and she wanted to do him a favour so she gave him me. That's how it happened. I went down from agency that day... I'll never forget it. He liked me, I liked him and we got on and he said you will be fine and I will help you and I stayed in the job. So it was him that attracted me to the job ultimately because I could have left that day but he said could I come back to-morrow. So it was his manner of telling me I was great that got me there... and I thought maybe I'll try this.
- SC So it was not a planned entry into the role? No definitely not. But there was a plan to stay though.
- G15 Total default. Fell into absolutely, I was out of work, I had a bad injury, very frustrated, couldn't work, jobs would come up and I wasn't able to go into it and a lady in here was aware of that. She had contacted me about other jobs and the consultant here had gone to her to see if she could recommend anybody, she rang me and I thought well I'll put in a year, get through it and get out, and that was over five years ago.
- G12 I didn't really choose to go into it at all you know. I was working as a midwife and then about twenty years ago when I was returning to nursing after having my children I went back to do a 'back to nursing' course and at that point I was approached because one of the clinical departments were looking for a nurse to do some research so I accepted the position at that point and more or less fell into it.

# Getting some experience

Others described getting some experience in the role which then encouraged them to either continue or to seek a similar position later.

- G11 I sort of fell into it. I was on a surgical ward in the UK and there was a pain research job and I was lucky to get onto the pain team at the time.
- SC So you fell into it?
  - Yes I thought it would be a step into something else. I thought that I would leave it for a year and thought of going somewhere else and then I moved back to Ireland and I thought I'd definitely... I really disliked it in the UK - it was pain research and was very difficult. But here there was a position in a totally different specialty and it just suited me at the time. And then I ended up in that for nine years and I liked it and enjoyed that post... so that's where that happened and it wasn't a structured career path that I thought I love to do.
- G12 I was working in a specialist unit and a clinical trial came about and they were looking for a nurse to do that trial within my work place. So I did that and then I got a bit of a liking for it. That was how I got into it. So then once the study was over that was it. But then a position came up within the department for a research nurse and I applied and that's how I got into it.
- G16 Years ago I was doing... as part of my nursing experience in London, part of my role I also had responsibility for clinical trials. I had about 8 clinical trials going as well as a caseload of patients. I had clinical trials and really enjoyed it and I've been in the specialist area here for a few years and then I moved onto another specialist area, I was doing that for the previous 4 years and then this job just came up. And I was keen to get back to looking after patients because my last job, I had no patient contact at all and I got bored. I had experience in clinical trials and I was keen to come back into main specialist area again and...
- SC Get back to patients... Yeah, definitely get back to patients
- C41 I suppose without knowing anything about it, I thought it was going to be an area I would interested getting into and when I was doing my HDip I found a placement that I thought would be the area that would suit me... Yeah I got a placement and did a couple of days down there and now it only a couple of days but it was excellent. The nurse had a huge wealth of experience as well and she was passionate about what she did. It was kind of there anyhow, but that kind of rubbed off as well. So it kind of encouraged me to look at it again.



In 'seeking it out', the nurses and midwives described a more active process as a response to 'wanting a change' 'using my education' or 'having a role model'. Here entry to the role appeared to be a more active choice.

# Wanting a change

- SC What made you go in this direction?
- G13 I have no idea. I can be very honest. I was working in the hospital here and there was an ad that came up and I wanted to change where I was working
- G15 Part of the attraction was that I really, really wanted to leave my existing job, which was very pressured and was in an acute clinical environment but also I had done my masters at this stage, in my own time, at my own expense and I really felt I wanted to use it and get new experiences really. So it was a combination of things, leaving the existing job, the quality of life opportunity and also wanting the challenge... I sought it out really I was watching the advertisements in the paper opportunities and when I saw this advertised I applied for it... But I was actively seeking a research nurse post myself
- GI1 I've been in post for just over a year now but I was working in a unit as a sister and I found that just an awful lot of organisational skills. I was already working Monday to Friday but the workload was huge down there but being in a sister's post you are almost away from the clinical setting. It's all organisational and you are trying to organise people, organise the patients, the beds all the time
- GI3. A bit like the job I was in I was in it a long time and was looking for something different and looking for a change...

# Using my education

- GI1 and I was doing a course with my current colleague we were actually doing a higher diploma in a clinical specialty at the time so I saw the research nurse role as a way of actually expanding my education in that area.... So I just felt that the education got doing the higher diploma that the job gave me a chance to expand it in this situation and it was cutting edge stuff really.
- C17 ...you know with my third level education and my experience and then having done the small piece of research that I did for my academic course. I mean I applied and I did an interview and I really felt that I was taking a major leap but I did the interview and felt very comfortable with it.
- GI3 Because I had finished my nursing degree...and my plan was always to be a clinical nurse specialist in my area and that's what I was... and as such. So I had arrived supposedly at where I was going to be for the rest of my life and only to find it wasn't really what I thought it was going to be. And then I suppose from my prospective then I... the paperwork thing didn't worry me at all because I worked in research from a nursing prospective. I did nursing research for a year and a half in one of the universities.. So in some ways it reminds me this is different but it reminds me a lot of my work there.
- GI7 Well I was working in the day unit and I was doing my degree and I wanted to do something with my degree because I had worked very hard at it, put a lot of hours in it. I had an interest in research when I was doing the course, when I had do my own part of the research and I made enquiries and found out about the research here... and the fact of the hours I put in studying, I wanted promotion as well so I did as a result.
- C17 Well to be totally honest with you I studied I did the Bachelor of Science Degree in Nursing Management in one of the higher educational institutions and it was during the different modules that I came across research it was part of our it was one of our modules that we had to do. And I found that I really enjoyed the whole experience, researching a topic and writing up the findings for it and then when it came to doing the research proposal I did it on the role of clinical of nurses looking after people with a particular condition. That was my very first time to do a bit of research and I obtained funding for it. I just enjoyed the whole experience even though it was purely for a college assignment and then when I did my Masters in another institution I really enjoyed the research modules. So that's kind of what attracted initially and then I got my first research position almost three years ago in another hospital and a different study.

# Having a role model

- C22 Well I first came into contact with the role when I worked in Australia in a specialised unit and there was a research nurse there and just from talking to her about her job then when I came back to Ireland I went back into specialised unit. I just felt that the opportunities for promotion and development were not what I wanted. I wanted to develop professionally but not necessarily in that area. So I enquired about research. I liked the idea of a project being mine and having some guidance but being the director of the project if you like.
- GI7 I've been mainly working in Dublin and then I moved here. And it's not as easy. I would have been working as a clinical



nurse specialist in Dublin and I suppose when I was there I worked with my other colleague who had worked in clinical trials prior to that. And I felt that she had a good knowledge of when a patient who was coming to the end of treatment options for area that we were in and she would have to say "oh is there a trial" or "I think there is a trial". And she just seemed to have a greater knowledge which I wouldn't have had because I didn't work in clinical trials.

GI8 I had worked in the states and I was familiar with clinical trials from over there and they were just starting off here I suppose. And I was interested in developing the area here, that was number one.

... I suppose I would be the same. I worked in a cancer centre in the States and clinical trials were a big part of our daily routine, not just from a medical point of view but also from a patient care point of view. So I suppose when clinical trials came up, I suppose my understanding of it wouldn't have been always related to drugs, I would be more patient interested and that's why I went into the area. Also I suppose when I came to clinical trials first, I wanted to do more nursing research within the hospital, the psycho-social aspect of the disease, I had huge interest that I have and that would be area I feel that's overlooked and needs more stuff done on.

For one nurse, research had been a career aim from the outset of nurse training and two others had reached the stage of 'being at a crossroads' in their careers.

- G14 Research is something I wanted to do before my nurse training. But it was more going down university and doing biology that type of research. Then there was a national advertisement campaign for nurses and so I looked into combining it and becoming a research nurse. So before I did my training that was the original plan to become a research nurse. But I did my nurse training and my clinical specialty and never thought anything of it again. You kind of get into your own set ways and didn't look into it. Then I was moving to Ireland through a recruiting agency. So I was looking at the same clinical specialty area and they actually put it to me would I be interested in this role. So it got the bells ringing again. I did actually want to do that. And so I applied for it and it would have been something I was interested in originally and it went from there.
- GI8 I would have had over five years in clinical specialty experience. So I would have been in a day ward setting, so I suppose I saw it as a natural progression either I became a research nurse or maybe something a bit more specialised, kind of come off the floors a bit but with keeping patient contact. So that would have been the main reason why I would have done it.
- C35 I was kind of at a cross roads really in my career, I needed to, from a personal point of view I wanted, I felt I had reached saturation point in what I was doing, wanted a change but yet didn't really want to lose my area completely, just wanted to diversify from where I was and I was just very fortunate that this particular research post had started and the principal investigator contacted me and asked me if I would be interested

The entry to the role was not always accompanied by knowledge of what the role entailed. Some of the nurses and midwives actively sought information on the role in order to inform their decision. Within this group person-fit for the role did not show a pattern in that whilst some had experience in the clinical specialty in which the research was conducted, others did not. Likewise, some, but by no means all, had had research education.

# 'Being ignorant'

- GI3 I didn't really know what was involved in the role. I did come over and talk to our co-ordinator here and she told me what it involved. But still even doing the interview I didn't exactly know what was ahead of me. I didn't really know what research was and even when I left the department I was in they all thought - nursing research and qualitative and quantitative studies which isn't really what we were about at all.
- Gl2 None of us... Like when I started you didn't know what you were letting yourself in for. There is nothing out there in a similar view in learning about what you are going to be doing. There is no formal process of education, it's learn on the job, the hard way.
- C12 The opportunity arose and I went for it. I knew nothing about the role before I went into it and I had no clinical experience in the specialty.
- C29 I have to admit when I went into research I had a completely ignorant view of what it was. I actually thought it was stuck in an office all day with charts and computers and not seeing patients and I had no real rationale of what it was



# 'Finding out what it entailed'

- G12 Well I suppose I did make some enquiries before I applied for the position and it was an informed decision. I didn't just apply for the job not knowing what I was getting myself into.
- G12 Well I spoke to a research nurse and she was saying what the whole job was about and so I sort of knew what research was about before I got into it.
- G12 I was asked to set up a research unit in the specialty and I didn't really have any experience whatsoever. Twenty years ago there was absolutely nothing so I went to Belfast to a nurse in Belfast that was doing some similar research and I kind of just worked with her for a week or so and came back and tried to emulate what she had done.
- C22 I made a lot of enquiries. I contacted a lot of people who were involved in research.
- C41 ....as I got into the clinical specialty, I thought that it would be the kind of area I would like.
- SC And before you got that placement did you know anybody in the role or did you talk to anybody in the role?

  No because there was no research here prior to that. So other than academic research that I mentioned like, the only research I knew about was research theory paperwork research, sort of qualitative and quantitative, that would be done through the diploma course.
- G15 For myself, it was also, I'd worked in various different clinical areas within a disease area, I came back from abroad and worked here in this hospital for a year and then I wanted to get out and do something more routine in it, with more autonomy. I knew somebody who was in research and she gave me an outline of her job and then I came and spoke to somebody who manages a research centre and she knew of a consultant who was looking for a research nurse,
- G17 I made enquiries and found out about the research here. And the girl whose job I took over, I asked her what it entailed and everything so that's where I got an inkling of what it would be like.

The nurses and midwives who participated in the consultation were currently in the role of clinical research nurse or midwife. However, within the consultation, it became obvious that there was movement in and out of this role. Participants referred to those they had replaced, absences they had taken themselves for child rearing, and planning to leave the role in the near future. For the latter, this was sometimes a choice in order not to loose pension entitlements or an enforcement, due to no further funding for the study being available

- C18 I suppose it's great because the girls, our little group, our team is lovely... we just get on very, very well. We know we're very, very lucky but we also know that we all won't be staying here forever. We're enjoying it for now.
- GI3 It depends on the day of the week but I can't see myself leaving at the moment. I am only in it just over a year... There is a lot to learn and I need to give it a chance, but some days I feel very comfortable and others I am just out of my depth. But I just kind of feel that it needs time and patience and I am willing to give it a chance and at the moment being true to myself, I don't think I will leave at the moment. That's the way I feel anyway.
- GI6 I don't see myself doing it for 20 years... they say a research nurse lasts about 5 years, that's what they traditionally....

In addition, some movement was due to lack of role clarity or person suitability. There were contrasting views as to the potential the role offered within an overall career pathway with some holding positive views of 'stepping stones' and others viewing the role as a 'cul-de-sac' partly as it does not allow geographical movement.

- C9 Certainly some people the job wouldn't be for. Definitely, definitely not and I think a huge amount of that is to do with they just hear research and they think exactly back to what you did in college and they think that's what the job is and it couldn't be further removed from that really
- C1 The role acts as an alternative career path but is very different from the traditional role and is not for everyone. There is a need to explain the role more to other nurses.
- C23 At the moment I'm very happy and I want to stay put in research but maybe try a different part or area later. I don't want to go back to clinical practice, this is more rewarding and ward work is just not appreciated. I think others would be afraid of the short term nature of contracts but this type of job can be a stepping stone to other things.
- GIS I honestly don't know to be honest because I think also that it's very... there's only specific centres that do research so if you did want to move, down the line, there might not necessarily be a research post in that area so therefore...
- C18 I'm not from here and my family aren't here so even though I love it, I can't see myself being here for 10 years, 5 years even, not in an acting role when I see my colleagues the same age, the same year qualified, the same qualifications are all progressing nearly every year.
- G14 I would love to stay in yeah. I do like it...but definitely it is something that I would like to do long term. Will I be able to



stay in it? It's unlikely. The time will come when I will move back down the country and I don't think that's a facility then that would be available to me. I don't think they'll be planning for research any time soon in smaller places. Where will that leave me?

#### Initial attractions of the role

For this group of nurses and midwives, there were a number of initial attractions of the role. Regular hours was the most common reason cited and was viewed as a solution to exhaustion from shift work like night duty and the ease of combining regular hours with children and elder care commitments. Flexibility of hours was also cited. For most of these nurses and midwives the role was also perceived as a promotional opportunity.

- GI1 I was doing agency and there wasn't a huge amount going on and then I saw it and I just saw it as a promotional post really where there wasn't much going on in the hospital and the opportunity to develop something was there.
- GI1 Promotional post, so more money for not having to work at night and week-ends that was definitely it. And educational development as well.
- G17 So I moved here then and as I said it would be I was working as a staff nurse in another hospital and I saw this job advertised for clinical trials here and I suppose apart from the fact that I felt it was something I would like to work in, it's also a kind of promotional opportunity and regular hours.

However, this was not always the case and for others entry to the role was seen as a sideways or downgrading move.

- I was on the ward for six over six years before I went into this job so I had done the whole staff nurse, I had done CNM on the ward, I had done shift work and this came up...But I went for it and they offered me the CNM 1 position
- So it wasn't a promotion position No it was sideways for me at that stage and I said yeah absolutely sure we'll give it a go... So I went for it, got it, then a year later went for another interview and was upgraded to CNM 2
- C11 I'm employed by the consultant and whilst I took a job demotion for this role, I had the benefit of regular hours.
- GI5 ....why I say quality of life was that I actually opted to leave a permanent, pensionable post and also to take a drop in earnings to do a job that I felt I'd have more control in and that would suit me better

Other initial attractions included the autonomy and control of the workload, others' respect for the role and the opportunity of contributing to new developments.

#### 'Autonomy and Respect'

- G12 The autonomy of the role if you are into that. There is a huge difference and there is respect which you get in this job compared to what you would get on the wards.
- C23 I also liked the control you have over your work. You can use your own initiative and spread your case load but at the same time you can't be lax. It is up to yourself.
- C22 And just from my experience that I had in Australia from seeing how that position ran and the autonomy that that girl had and here relationship with nurses on the ward and with the medics on the ward. She was on her own but she was respected by both teams very much and her role was respected. She was able to develop her role in whatever way she wanted and I liked that idea. That's initially what attracted me to it.

#### 'Cutting edge'

- G11 So I just felt that the education got doing the higher diploma that the job gave me a chance to expand it in this situation and it was cutting edge stuff really.
- G12 In the clinical area that is one of the things that attracted me to it was that I have worked in the clinical speciality for such a lona time and you know I did see over the years the changes that were made and were brought about because of research (gives an example) and that's one of the things that would have attracted me to getting involved in research. I did see directly how it affected peoples' quality of life and that was a big thing for me.
- GI8 The other thing was I suppose, I felt it was cutting edge, you know people getting an opportunity and that to me....
- C18 ... but then there was the girls who were looking after the patients on the (drug name) trial at the time. So I always had an interest in it and then as the time went on as the (drug name) was licensed and that was kind of a major break through and I was like wow they were in that from the very, very beginning and it was their work that helped to bring this to life.

The role was also perceived as offering challenges and development opportunities. In addition, having a caseload allowing



patient contact was also an attraction and offset any negative aspects of the role such as the paperwork.

#### Challenge and opportunity

- C10 Also working on your own I think is strengthening and good and just to do something different I think its really good for you to challenge yourself you know. Challenging myself to see if I could do that.
- C11 Additionally, there was great variety in the work which included audit and establishing patient clinics.
- G18 Number two it was actually an opportunity that I could see that was going to help my career development, my own professional development.
- C22 I could see that there were opportunities for developing professionally in ways that I wouldn't get in the hospital. I would say that I would have thought that sometimes you might be stopped from doing things that you wanted to do as a nurse in a hospital. That there would be a lot of red tape to go through if you wanted to implement something or change something or do something that... people with more experience might get the opportunity because you are just younger or junior you might not be taken seriously. I just felt that in this environment it would be easier to take steps ahead than in the nursing environment....Yeah and I also saw there were opportunities once you got into it to develop other skills like management, organisation. I was aware at the time that once you became a research nurse you could potentially get into the pharmaceutical industry. And had that idea in mind although when I get into the job I realised that that wasn't for me. It was more actually I liked the research nursing aspect of it.

#### Patient contact versus paperwork

- GI8 A large quantity of your job, the time spent in the job is still dealing one to one with the patients, which is what I want.
- G18 ...one thing about being in clinical research is that you have continuity of care and you journey with the patient which is unique from start to finish and simply because you been with them for 10 years. I suppose I never thought of that when I worked in the area. But that's what I like
- C18 Initially when I started on the day ward at the time, it was actually a number of years ago now, there was a trial (drug name) going on and I just really liked what the girls did, you know, they kind of had their own patients. This is initially what attracted me to it knowing who they were, how they were diagnosed, what their actual diagnoses as opposed to just breast, colon, prostate.
- GI7 ...and I knew there was a lot of paperwork and everything but I didn't realise until I actually did the job, the amount of paperwork but what interested me was the fact of catching the information and you still had the patient contact because you still do the visits and the autonomy of the position.
- GI3 So I spoke to a research nurse about it and it sounded good. I know she told me that there was a lot of paperwork, a lot of paperwork that's what she kept saying to me. "Ok" I thought "I can do paperwork." And the hours appealed to me. So I went for it.

## Hearing about the job.

For these nurses and midwives, hearing about the job opportunity came in two different ways. 'Word of mouth' was common with either approaches being made to the individual by other research nurses, by medical consultants or less commonly by nurse managers or news of the post being passed around the hospital 'on the grapevine'.

- C12 I heard about the job by word of mouth and had an informal interview, actually more a casual discussion, with the Research Registrar and Consultant and ended up getting the job.
- SC So was the job advertised?
- C35 No it wasn't
- SC It was an actual contact from the principal investigator?
  - A contact yeah. It is a very specialised area and they had advertised for a similar role, the same post lets say, but not a research post and they had to advertise it at national level 3 or 4 times to get 1 person, before 1 person applied. So they knew that there weren't really the staff out there and that there would be no point in advertising initially.
- C22 ...somebody who was in the position who I knew... through a friend friends of mine knew her told my friend to tell me that there was a position coming up and to get my CV in. So I sent my CV in just on speck because it wasn't advertised but I heard it through the grapevine and I got called for the interview and that's how I got the job. So I was just lucky.
- SC Through contacts?
  It was through contacts yes.



- C23 The job wasn't advertised, it was really word of mouth and I was approached by the nurse who was leaving. There are two of us full time and whilst I've been here two years the other person has also changed
- GI5 Then I came and spoke to somebody who manages a research centre and she knew of a consultant who was looking for a research nurse, that's how I...
- SC. So it was word of mouth really It was word of mouth, yeah and I've got a few other people into research posts through research posts through word of mouth.

Internal or national advertisements were another means of hearing about posts.

- GI1 I just saw the job advertised and just went into it. I had experience in the area so I just went for it and used it as an opportunity. I was the same so.
- C17 It was advertised in the paper and it was because of my third level education and having done the research modules during my course that meant that I was confident enough to even apply for it because I had a good understanding what was involved in the role.
- G13 I was working in the hospital here and there was an ad that came up and I wanted to change where I was working. It was an internal advert and it was also in the national newspapers.

#### What the role entails.

Whilst described as 'the pivotal role' (GI2) within this consultation it was obvious that role diversity existed. There appeared to be a number of reasons for this including the type of data being collected, the length of time the role and/or the study had been established, and whether the role was solo or part of a nursing team. In addition, the presence of other research roles such as data managers in the team impacted on what individual research nurses did. Diversity was also the outcome when the origin of the studies differed. So generally there was more involvement in a greater number of types of activities when the studies were academic as opposed to pharmaceutical in origin. The exception here was the greater level of monitoring and audit for pharmaceutical trials. Often the role was summarised in terms of the patient journey and an outline of principled, role performance was described by one nurse.

- C29 I see my role as carrying out the research according to the way it should be done. My primary focus always is the safety and well being of my patients, that's my abiding principle, not paperwork, not rules/regulations, that each individual patient is well looked after, has a positive experience and their care is the primary goal. And I see myself as a facilitator to make sure that the study is done, co-ordinated, efficiently carried out, patients are look after, that I, my 'pharma' colleagues and whoever else is involved in the study will have worthwhile, substantive, accurate data on these patients with a view to disseminating it with a view to building other research upon it etc. That's the way I look at my role.
- C9 What I do is I look after all the patients who are enrolled on clinical trials. Basically all treatments are clinical trials. There are some of them open and some of them aren't open. So I look after all the ones that are open and all the patients that are on it... I look after them from the start until they finish their treatment.

Within the role the most common research activities were patient identification and recruitment, eligibility screening, interpreting for consent, performing an intervention or organising the monitoring and collecting of data as per the protocol and educating others about the trial. Patient information was described as 'the bedrock of it all'.

#### Common research activities

#### Patient identification and recruitment

- C17 ...and I was involved in getting the assessment tool that I am using for the particular condition. So currently at the moment I am piloting that assessment tool just to see how it is working. I also attend out-patient clinics here at the hospital once a week to recruit patients from the out-patient clinic because the Consultant there is very supportive of research so he is very helpful. He is working in collaboration with the principle investigator in finding people for us. So I meet with the people and I explain the purpose of the research to them and take their names and contact details from them. I am currently recruiting them for the study which is beginning properly next month. And we also ran an advertisement in some of the local newspapers so we have people also coming in for the study purely from what they have read about it in the paper. Because we have to get healthy controls to compare findings with so our healthy controls we get from our advertisement in the papers.
- C1 You then have to find your patient so you would have to go to other departments like the Out-patients Department,



depending on the trial. So you have a lot of standing around looking for that and then you get your patient on the chart and on paper would fit the criteria of the trial. So you would have to have a fair bit of knowledge of that. Then you go to your patient and you explain the whole procedure to them. Would they be interested? You know by their demeanour whether they want to hear you or not.

#### Patient consent and eligibility

- C18 The PI consents but I'm always with the patient, so there would always be 3 of us. There doesn't have to be, once it's the PI and the patient, well once the patient is you know capable of consenting for themselves but in my experience it's been the PI, myself and the patient... once you give the protocol, the patient information leaflet to the patient, you document patient information leaflet given on such and such a date, you could go through it with them... You just assess it patient by patient, day by day. Some people are happy to take if off and the older generation are inclined to say "oh if that's what the doctors wants then I'll...", but you say "go home and read it, if you don't want to read, get your daughter to read it, maybe bring it to your GP, get them to read it with you, get someone to pick out the important bits". I will encourage them to read it but I don't know if sometimes they always do. But then with some of the patient information leaflets, they have to go into every detail and they do and it scares scare the life out some of the patients. Whereas if they were getting those drugs off-trial they would not be that much information, they'd be getting the important bits that are on any of the websites the side-effects like diarrhoea, constipation. Here they go into things like you know, you could die from this, it has to be said but it scares the life out of them. We always get a phone call back about that one
- G12 I think that we have a huge role there which we are trying to push forward. To present to the patient in a simple everyday languatge without removing the seriousness of what they are consenting to, But we do have that ability because all through our training we are explaining things to patients.
- G16 Well we're involved in it but we don't actually take the consent. It has to be the principle investigator who signs the consent form but we will always be there and we would fully explain to the patients what's involved in giving consent and we would be involved in going through in minute details, going through the patient information leaflets, what's involved. Before we bring on a patient to a study we would have spent hours with them, on any study, talking them through it, what might happen and what mightn't happen and they'd go away and think about it, they'd come back with another question and then at the end of it they might say no. It's very time consuming but it's great, it's a nice part of it
- C1 (checking eligibility) You have to go through the whole medical condition of the patient with the patient, get them seen by the doctor they usually need bloods, urines. They may need x-rays, scopes a whole lot of tests that you have to organise. And you would have to organise the results of the tests and see that the results still fulfil the criteria and then at every step of the way you are making sure that the patient is still in line with what you are looking for...

These initial activities of recruitment and eligibility screening whilst critical activities within the research process can be a source of frustration within the role.

- GI3 Then you finally get a patient who seems to meet the criteria, you go to run all their tests and they are all looking ok and then the last one will come back and they would be out. And you have put so much time and effort into it. So again that's not something that's very job satisfying... I suppose in the beginning I was going "ah this is so frustrating" but now I am used to it. I know it just sounds terrible but you just get used to disappointment... and not take it all so to heart.
  - ...I do get frustrated sometimes at my outcomes in that all the input I put and then I have as we mentioned no patients recruited. That is quite difficult to get your head around but I have to say that is getting better. I know it might sound odd but I have learned to live with disappointment. That it is not actually a disappointment it's just the reality and it's life and you just have to get on with it.
- C22 For a variety of reasons patients won't fit in so recruitment is a very time consuming process and can be very frustrating... it is very hidden and there can be an awful lot of frustration around it because the expectation is "oh we have loads of those patients" but then when you come to look at them you actually don't have loads of these patients that meet this exact criteria. I have so much experience of this what I do is... In clinics I make sure that they (the investigators) are aware of the patients that I am looking at. I get them to review the chart with me. I keep a detailed log of why patients aren't fitting into the study and go over it with the investigator and then they can see why patients aren't coming into the study. Over the years I have found that the more they are aware of that, the better success you will have...

#### Co-ordination

C9 Liaison with a lot more people than – like pathology, histology, biochemistry, haematology even but primarily the



consultants.

C18 I suppose you are ordering the CT's, bloods, some of the bloods aren't actually the normal blood that we would take say off-trial. So you just have to make sure that they're ordered up and they're done and that you are actually checking the results and other technical tests like echo's, bone scans, chest X-rays that you're ordering up. Other things I suppose would be the research bloods where the pharmaco-genetics or bio-markers and then if they have consented to order those extra blood tests, you're getting it on the date that it's required as per the protocol.

#### Education about the study

- C29 I primarily look after and do education with the patients and families. So education sessions with the NCHD's, with new nurses, orientation, treatment study days. A huge element of it is education. A huge element of it.
- Whenever it gets the go ahead then through ethics the consultant or the principle investigator does an opening meeting and we all go to that. They do the talk then I start to arrange – I organise teaching sessions for the ward. Do the teaching sessions generally before we start recruiting patients.
- Gl2 Once a month I have a meeting with the clinical speciality team and I explain to them all the research we are doing... and the types of patients we are looking for, so that if I happen to miss somebody that they can come to me and say that this patient might be suitable.

#### Less common research activities

Less common activities were accessing project feasibility, guiding proposals through ethical governance, data entry and analysis. Protocol development and dissemination were exceptional activities.

#### **Feasibility**

- C29 I try and focus on is looking at what we're proposing to do, seeing is it valid, seeing is it tangible, can it be done basically i.e. can we recruit these patients, have we got the time to do it.
- You would read the ethics submissions you have to help put together to go through but really it is already done as such and you are just checking that things are in accordance with the Irish ways of doing things and in accordance with Irish Law. Because a lot of these would be coming from England and they would have terms like the NHS. So you are really only looking out for things like that as opposed to any issue within the trial. Initially when a drug company might come to you they would have a feasibility study - how many patients would you see with this - you do that with the doctor but you actually don't know how many patients of a certain condition he would see within a month so he is giving those answers and you are gleaning the information and holding it for future use as opposed to doing any... And then you would read the contract to make sure that the contracts are fine – there would be financial agreements and apart from the trials specifics, that is really it in all relation to a specific trial.
- C12 I would describe my role as planning, organising and implementing pre-designed studies. The planning involves looking at patient suitability for recruitment, the method of developing patient contact, examination of equipment and space required to conduct the study. I have been required to liase with personnel from main co-ordinating centres throughout Europe and to ensure the accurate transfer of data and blood samples. In the past I've done costing for studies and occasionally have detailed information for ethics approval applications.
- I would read it I read the protocol before it goes down. I make the changes. They make changes from England to Ireland. So I make the changes for data management, read it through and if there is anything that either A) we can't do or B) we don't do, I run it by the Consultants. Then the girls send it down to data management. Whenever it gets the go ahead then through ethics the consultant or the principle investigator does an opening meeting and we all go to that.

#### **Data Management**

C22 I think that adds to the satisfaction. Even though data management can be a bit of a pain, I think it is actually an important thing in learning about research because I think it enhances your understanding of the importance of collecting data properly and how it's entered. Then you have an appreciation of how it's analysed. If you are not involved in that you don't really understand why they are driving you mad to get this thing right... I know that some places do have data managers and the research nurses are purely seeing patients and documenting in the notes and someone else collects the data... nurses did not like that idea at all because they felt it took away from their project and their control over the project. But I understand why that works in other places because it increases the efficiency of the nurse in terms of seeing patients - but I think that overall for job satisfaction nurses get much more out of the job if they are in control from start to finish.



#### Protocol development or dissemination

- GI7 We wouldn't develop our own protocols, that normally comes from a lot of the pharmaceutical companies or the research network or university based. Putting them to ethics, the IMB, yes we would have been involved in that process and through our regulation department within the hospital and getting approved within the hospital prior to us actually commencing on the trial. So we would be involved in that side
- C12 In the current study I am examining the results and writing them up. This is not expected of me or particularly encouraged but having said that I am not being discouraged from doing so!
- GI2 I would also get involved in submissions to clinical meetings and all of that...
  - ... all the consultants, surgeons and disease experts from around Europe, she (another nurse) spoke to them last week... we do an awful lot of clincial speciality work. We will get involved in attending journal clubs, the microbiology meetings or whatever and presenting and we have clinical trials meetings in other places...

In addition to the research activities the nurse or midwife utilised their clinical practice skills and technical skills and it was the clinical practice skills that were perceived as the uniqueness that nurses or midwives brought to the role. Included in clinical practice skills are the pharmacy role that nurses undertake such as medication management, storage of drugs, and the preparation or reconstitution of drugs.

GI4 Yeah I mean there is definitely the need for research nurses...

See... perhaps a bit black and white, but... I have my clinical speciality skills and that obviously is part of the nursing but apart from being a nurse and having a licence to administer medication, I don't need to be a nurse to write into that (points to the computer), I don't need to be a nurse to answer my telephone, or organise a visit. So the nursing side of it, although then you can look into... you're taking blood pressure, you need to know what you're blood pressure means, that side of it. I think the job maybe be able to be done without being a registered nurse, apart from obviously the medication side of it, but a lot of the work isn't what you did the training for...

...what makes you unique as a nurse that you hold this position. Like you say, it's the clinical side of it...

#### **Technical skills**

- C17 As well as doing the assessments of people I will also be taking a number of bloods which will be used for genetic analysis and biomarkers in the blood samples. So the reason I have to go to the laboratory in that I will be centrifuging the blood samples for various specific part of the sample which I'll pipette and store in the freezer.... At least I have the experience but this study there is quite a number of different factors involved and different techniques and so I have to be very conscious of the different types of sample bottles and how they are labelled. So there is a bit more involved. But I am very experienced from my previous study...
- GI8 We have our own centrifuge in the laboratory and we would have had some training when we came to the site. But the other thing is that some of the trials, not now but in the past, they wanted ECG's which was another skill. In one study now which they want pre-post endurance and again there was special training done on that and that would be another extension of the role. So it's like when you're a research nurse you have multiple skills in different areas.
- C35 I had five years practice with the technology... I had the technique but it was just... up until then I had been just doing it as clinical practice whereas now the role is slightly different because it's research... it's certainly increased my knowledge because while I'm still doing the basic stuff I'm doing extra examinations as well like blood flow tests and that kind of thing. So I had to read up loads about that and find out loads of stuff about that so it really increased my knowledge initially that way and I mean really what I would consider the examinations that I do are still used clinically as well but just they have this extra component
- SC And that's an extra technological piece is it?
  - Yes exactly, mostly extra diagnostic studies or checking some extra things which we wouldn't normally check...The specialist area itself is like an extended role so I think it's good to think that some of tests wouldn't normally be done, like there is one in particular which is conducted under the research protocol and consultants in the hospital here don't do it, the specialists don't perform that particular exam. So it's good to think that the likes of myself are doing it.

Clinical skills were deemed to have further developed by some participants especially in the areas of patient assessment and documenting care. Computer skills were also enhanced by being in the role, although most participants described themselves as self taught in this area. Database development or biobanking were exceptional, as here there was minimal or no patient contact.

#### **Developing databases**

C23 The role centres around establishing a database. There is a lot of paperwork regarding putting together patient information, consenting the patients and then there is laboratory work which centres on dealing with blood samples. I



deal with anonomisation, data transfer from one system to another and laboratory processes and supplies. I have to do monthly and yearly audits on things like recruitment and sample numbers, freezer statistics. I feedback those to the Principle Investigator and sometimes other hospital staff. I have minimal patient contact – getting consent and the samples are done mainly by the hospital staff, although I can be called to do them. I do have to talk to some patients over the phone though about the project. It is still in the early days so I quess I've not seen the full job but what I do, I

- C10 Well what we are doing is we are trying to establish a national database for a particular disease and we are now the centre of excellence we have managed to get that since I look over... Basically I try and shape the day around getting files, you know. It depends on what I'm at really... I normally do the files in the morning, I go in and I figure out what files I need. It's basically accumulation of data. So find out from the system where they are on any one day and try and go and get them and then take all the information out of them. I do that for the first part of the morning and for the second part of the day then I would enter the data... So it's kind of organising all of the patients we ever had and putting them into a spreadsheet, finding out who was still a patient. I look for trends in the data and then feed them back to the Consultant. So for example I would notice that a lot of patients have a particular intervention too late and somebody who doesn't sit down and go through their notes wouldn't really pick that up. So that's important for the patient - to say listen they need to see someone maybe three months before they are seeing people which is helping the patient even though I am quite removed from them.
- C40 This nurse has held two different CRN jobs... In the academic studies, the role involved data collection and quality review and follow up. This area had no patient contact but focused on chart review and the patient involvement was missed.

A small number of nurses saw the role as changing over time and becoming more specialised rather than arbitariness of 'the handmaiden'. However, examples were given of pharmacy and data management wherein nurses undertake others' tasks in their absence. In addition, the way of working was changing due to technological advances such as increasing computerisation and the increasing professionalisation of nursing and midwifery.

- C11 I would call myself a research assistant. I mainly do the practical work for the study as the protocol development has already been done by the pharmacutical company or the research registrar. The work is very much study dependent and now is mainly academic studies, although there were drug trials early on in this role. The type of work I have done includes information retrieval from sources such as charts; patient tracking which involves contacting GPs to get information; interviewing patients using structured interviews, consenting patients for studies, and biometric measurements including bloods and measuring vital signs. I have also had some experience of preparing for ethics applications and have done poster presentations but again these things are study dependant. I'd call myself a "jack of all trades" really and do pretty much whatever is requested. But I realise that for those coming into the role now, things are probably different and I'm more the "old fashioned" type of research nurse. I guess I saw this as a job that suits rather than a career.
- C1 the only huge difference I see is one there was no computer when I worked there before and now it's all computerised and two we receive no letters where we used to receive a lot of letters and there is a huge amount of paperwork for something that's now computerised – the paperwork has quadrupled. There is an awful lot of administrative work and you have to read it.
- Gl2 The good thing now for me now is compared to 1990 which was years ago when in those days I had no scope of practice and I had no job description. Now I have a scope of practice so in actual fact I am accountable. I know myself what I should do. So that was a great safeguard, a great boundary when I got a scope of practice and a job description
- GI5 Within the research centre, there isn't a pharmacist on staff. So we frequently have to act as a pharmacist. So we just have to be very careful that we're fully covered for that. I had one trial where we would dubious but not only that, when we finally did get a medic to do back up pharmacist, to check it, the medic was dubious and that particular trial it never actually went ahead and we were so relived because there was so many things... you were saying "I don't think that's quite right" and you have to be terribly careful and we have to watch our own registration

Regardless of changes, the potential for role monotomy exists. Yet, some research nurses were happy with the role and not seeking any changes.

- GI5 ... unless there was more professional development and... you could develop the role a little bit then it does get quite... when you've done a few clinical trials, it's different medication but it's the same thing - starting it up and patients coming in and everything, it can get monotonous...
- C10 I really do have to organise my day. So I do that in certain ways but it can get a bit boring but I have days when I rotate my time and I try to keep it rolling along and interesting.



- C40 This nurse was personally satisified with the job although found the role a bit tedious. She also found that there was an under utilisation of her skills "It is like everything you still have to do the housework".
- C29 I find it can be a bit bureaucratic with paperwork at times and one of the frustrating aspects.... For instance if we were initiated or waiting to be initiated for a study, they'd ring you up and they want this and they want the same kind of things all the time and want it on headed paper and want this and that way and it can be a little bit tedious and bureaucratic the demands of paperwork and stuff at times.
- GI7 ...like I'm not particular interested in going up the ladder, I'm happy in the role I'm in and I would be happy to stay in that role.
- GI3 ... I kind of feel I have plenty to learn yet. So I am not hugely interested in going on and in an upwards direction if you know what I mean. At the moment it suits me in terms of, I live close by here and all the hours and all the rest of it. But it suits me. So I have no plans to leave or go anywhere...

Some of the nurses or midwives were team or facility managers. This appeared to be the only clear existing pathway for the role. Managing a facility includes study feasibility, staff recruitment or orientation and contributing to broader hospital processes such as ethics committees as well as maintaining an overview of all activity and leading on preparation for audit.

- C22 Well I suppose for myself personally my role has moved on from being a research nurse to a manager of a research centre so there is a lot of variety in my job now. My boss gets me involved in other aspects of the running of the centre and in other aspects of research outside of the centre where you can at all. So that has kept me very motivated...For example, I am on the ethics committee in the hospital. So my contribution is as a nurse and specifically as a research nurse who is used to how a patient should be approached for research consent and all that and also I am involved with another group and network. So I am involved in that aspect of... that safety aspect so that's outside. So that's all developing me I suppose. So my role has developed and that is what has kept me really interested
- GI7 I suppose that I would be manager of the unit. The role that that involves has kept me interested. Working with so many different individuals within the post, liaising and communicating with the different pharmaceutical companies, liaising with the research nurses, nurse managers, the investigators but plus also as well we have so many different protocols, what the protocols involve, what the primary and secondary outcome of the protocol is and I suppose we're involved from the very beginning of the trial and we're nearly there at the end of 1 or 2 trials and just what the final outcome is in relation to the drug for that protocol. So I suppose will it be positive or not. I suppose I really wouldn't have much patient contact now but I'm grand with that...
- SC So you do see this as a place that you're going to continue your career?

  Yeah I would, like I'm not particular interested in going up the ladder, I'm happy in the role I'm in and I would be happy to stay in that role.
- Gl8 I'm the line manager if you'd like to call it that. So I'm at CNM3 level. So the way we set up our systems here is that I would do all of the feasibility, all of the preliminary work that is attached to getting a trial up and running here. So what's involved in regularity submissions, site specific forms, all of that administrative work in terms of ethics and all of that included. And then once the trial is ready to go, the initiation meeting happens and from there on in, it is the nurses responsibility to manage all the trial activity.

Regardless of the variety of activities key elements in role performance were 'attention to detail' and negotiating with others. In 'addition to detail', the nurses and midwives described dealing with a large amount of paperwork to produce 'a controlled situation' which is subject to audit and external monitoring.

- C18 You've a lot more paperwork with a lot less patients... Every time you see a patient, it's your documentation and I have to say my documentation has improved 100% since I've gone into this job. You know everything is dated, signed, graded, toxicities are graded, like when I worked on the day ward, you just say, "well how are you? you're fine, great, any problems, no, fantastic" and you proceed on, you know to the best of your, if they mentioned something was wrong, whereas now you're like, "did you have diarrhoea, when did it start, when did it stop, how many stools per day did you have?" You really, really assessing the patient a lot better than what I did anyway in the day ward... Much more depth, but then I have a lot less patients...
- G11 Attention to detail is massive. Protocols are so detailed and they are so full of fine print and you can't miss a thing. Like one sentence could really, the interpretation of one sentence could have huge implications on a patient's care so that's really important.
- GI2 Everything is just so important. Cross your T's and dot your I's or you get the DCS (laughter). There's very little room for error.
- GI3 Another thing you have to be very pernickety and pedantic in everything you do. You have to be meticulous because there is no room for error as such. Everything has to be done exactly to protocol. You have to be meticulous in your work.



- GI6 A huge amount of the job is paperwork, too much of it, it is paperwork.
- SC And what sort of paperwork...?
  - ... a lot of preparation goes into getting approval for individual studies, keeping the risk management department and the ethics department in the hospital updated, keep current file updates. So keeping them updated on what's happening... Other paperwork, maintaining all the necessary documents for each patient, patient visits, completing all the case reports forms, that can be tedious, keeping all the site files and everything in order and making sure that all the necessary documents are where they're meant to be, a huge amount of filing...
  - And you see there's always loads of amendments to the protocols and consent forms and they all have to be sent through to management for approval and it's just...
  - A huge amount, it's hard to even explain it until you're actually in it, it's just a never ending stream of paperwork.
- C1 On top of that you would get, this is now relation to the trial, the company would be letting you know then about any adverse events that have occurred with this drug anywhere in the world. So you would have to read that and take that onboard, get it signed, fax it back to the company to show that you have received it.
- C18 So then when the monitor comes in, she's kind of like correcting your work which is actually the better the monitor, the better your work because she'll spot things that you are doing incorrectly and obviously you learn and you don't do it again. The monitor could be from the pharmaceutical company or a lot of studies are coming through the clinical speciality network, so it could be somebody from there.

Negotiating with others includes members of the research team, hospital staff, and external quality control personnel and often occurs within a context where research is perceived to be a low priority for the organisation. This leads to feelings of not being valued and can manifest itself in issues such as negotiating space for the work or perceptions of being ignored by management. When negotiating on behalf of an individual patient's journey, the skill of diplomacy is utilised to offset the impression of research as an additional burden.

- ...research nurses aren't recognised by the hospital. **C**1
- What do you mean?
  - In their physical space and their physical presence. You know I physically work in one department and there are a few rooms and there is a clinical room and I'll try and book patients into this clinical room but nursing admin said that research has no place there... I have been told to my face that you shouldn't be in that office, you shouldn't be there. My actual computer wasn't provided by the hospital it had to come from the research budget... And that does make you feel a little bit... you know get your back up.
- C11 One element that is frustrating is the lack of space. We've just moved from an office which we were sharing with an expanding team. It was really noisy and we had to 'hot desk'. Now we're here with no space to see patients and no windows in the room... I would like to see the hospital valuing research, to me it always seems to be "tagged on" and sometimes you're made to feel as if you're the lowest of the low.
- GI7 I think with management, they're not really keen or interested. They don't want to know what clinical trials are and that's just the impression that we get. You try to bring it a step forward. You put in it in memos to them, this is what we've done this year, we've brought so much in drug costs, from a financial aspect, in relation to education from IMB's audits, that this is the quality of care that's being provided, that this is what clinical trials is all about but you get no feedback...General management, this would at the top senior management meetings. Now I could be completely incorrect but this is just my opinion on it. So I think we've developed the service, we've done amazing things for the clinical speciality within the hospital, we've built our extension. We can take it to another level. We could bring in data managers, we could double the volume of staff within the department, we could quadruple the volume of protocols that are coming in but we're restrained from doing that because the thing is you need to have the support of your hospital behind you to do this.
- GI7 ... maybe a patient condition changes and you have to re-arrange their treatment and cancel things and change all different procedures... Because you're dealing with people at all different levels, from the patient to the staff that you're booking things through just you're trying to liaise with so many different people at all different levels. You definitely even if you had existing skills you definitely develop them.
- Somebody said that you become a beggar.
  - (laughs) Completely, completely, always getting favours!
  - You do and sometimes the trial unfortunately it's seen as an extra. If you want bloods done today and they're not the usual bloods then it's kind of seen as an extra. They see it as an addition, another job for them, and they don't have enough staff or resources. Or radiology. We need radiology to report scans in a certain way to the criteria of the trials. That's an extra and when they see you coming, "what do you need"? You know even the junior doctors when they're documenting about the patients, they have to document in a certain way and they're kind of "oh what is it now?"



- GI1 I hate that always feeling that you are asking for favours off people... You know when you are asking if you are asking other nurses to slot things in you always feel that you are on the back foot, you know. You are asking for charts or you are asking for anything to do with the research like it is way down there on the priority.

  You add to their workload, you know, which they may have a point sometimes...
- G14 ...our skills are developing. It is kind of "please, thank you very much...". There was a situation that arose where the patients needed CT scanning and CT scanning is an expensive commodity to be bringing patients in for. So we need to maximise the time that we have the CT scanner. Bring in three or four patients on that evening and you have the issue where the testing unit which needed to link in with it and are stating "we used to do three patients and four for you but now we will only do two". Ok that's a problem ...

We can't get to the CT scanner until 5pm so you are holding everybody after hours like two consecutive weeks because you won't do them... And we had to bring in the investigator into it and I suppose there is that constant kind of back rubbing situation a little bit.

We are improving a bit though. Again there was an issue of bloods a couple of weeks ago and I got a phone call here one evening at 6.20pm and had returned the next morning to a very irate lab attendant who in no uncertain terms said "we didn't have this with your predecessor he was a wonderful man and he had a phenomenal relationship with us". "Ok hold on a second, you know I am not here to be everybody's friend I have a role to fill I have a job to do". I set this up and apparently the bloods needed to be in by 2 o'clock and that was never passed on to us and because we see patients at 5pm we get the patients in at 4.30pm so the bloods aren't going to be there until 4.45pm... And that kind of thing... you are having to eat a little humble pie and you don't want to be too humble at the same time.

#### GI3 I think charm.

#### SC What do you mean by charm?

You have to be sort of extremely extra nice and very diplomatic and watch the way you word things. I feel anyway I have to phrase things very positively like "this is just going to take five minutes and as a result of you doing this such and such a thing..." You nearly have to tell them what the reward is. "I know you are busy now but can I meet you anywhere five minutes of your time wherever is convenient to you".

The majority of participants reported that the role was satisfying. Trips abroad to meetings are viewed by some as reward or perks. In addition, 'seeing results' and having 'a good PI' also enhanced job satisfaction.

- GI5 What I was really excited about was the odd trip abroad and now you have to work very hard at them, you're certainly not getting any coercion or freebies or anything like but it's still lovely, it's a lovely way of networking and everything and just like that, seeing what other people are doing, meeting people from other countries and hearing their experiences and so on and it is nice seeing the bigger picture. I must say I enjoy that side of it, I know some people don't. They dread going to a meeting, but I like it. I suppose because I never had it before.
- C23 I think there is more job satisfaction than ward work. It is all your own work and you get to see the results of your work at the end of the day.
- G12 Well I am satisfied by seeing results, I'm that sort of person. So you do get results and we have clinical trials that are coming to an end now and I can actually see the clinical results of the work that I have put in.
- C1 The only driver I had was actually my employer who is wonderful. He was so supportive of me and everything I did. If there was a course go for it... a sad reflection on nursing he was a medic that he was the first employer I had that called me by my name properly and encouraged me to move on and constantly said how great I was. Now how shallow is that? That you need to be told how great you are but we all like a little bit of praise occasionally. And so he was the first employer to do that for me. And I actually felt sad a nurse should have encouraged me before and a nurse didn't.

From the literature review autonomy was identified as a positive role feature, so participants were specifically asked about this. They often linked autonomy with job satisfaction and respect from others.

- G12 The autonomy of the role if you are into that. There is a huge difference and there is respect which you get in this job compared to what you would get on the wards.
- C22 And just from my experience that I had in Australia from seeing how that position ran and the autonomy that that girl had and her relationship with nurses on the ward and with the medics on the ward. She was on her own but she was respected by both teams very much and her role was respected. She was able to develop her role in whatever way she wanted and I liked that idea

The participants most frequently described autonomy of decisions that impact on their patterns of work and caseload, whilst still recognising that the work itself is externally controlled by working through protocols and with regulation monitoring.



- C10 I think it can be refreshing to be self sufficient and responsible as opposed to working in a team environment... For me it's joyful to go into work and be able to control your day.
- C22 I think a lot of the satisfaction that people get is the autonomy that they have and being allowed to make their own decisions and there are not being the barriers to doing that there would be in the hospital setting... Autonomy is very important in that that is the crux of getting and making sure that you get this job done, directing yourself, that's very important.
- C29 The autonomy I consider to be, is to be able to come in, in the morning, get on with your work, not have people looking over your shoulders, not have people questioning what you do, not have to time yourself in and time yourself out, to be treated as a professional...
- G16 Well even though your work is regulated you can sort out your own time schedule.
- GIS That you plan your own work load and you set your own appointments and you're not necessarily working to someone else's schedule. Now there's also the thing that you can be very, very busy, you can also be very quiet but you have control over it.
- Gl3 You are autonomous enough in your own way. Somebody does keep an eye on what you are doing but you are doing it yourself a lot of the time. I found that a big shock to my system
- GI8 Yeah but I think with autonomy, you actually get the higher level of satisfaction because you're more in control of your day and the day to day running of things. You can kind of give a pat on the back to yourself then because you know you feel that you have achieved something

However, autonomy over work patterns demands flexibility on the part of the individual nurse or midwife to respond to demands but this is offset by the flexibility confered from the role's autonomous nature. In addition, there was an adjustment to caseload as opposed to shift working.

- C35 It's great to have the autonomy and the little bit of flexibility within... how you structure your day and how you structure your hours, but that too can have it's disadvantages. I found if something crops up last minute, say like if you're ill or you need to take emergency annual leave or it's very difficult then because there isn't the backup.
- GI3 All our hours are officially 8am to 5.30pm but I would be flexible around my patients in that. A few times a year maybe ten to twelve I would need to be in for 6.15 in the morning to see patients on a Monday because I don't work Saturday and Sundays and I need to see them before they go to theatre and generally speaking they would be going first. This is one of my academic studies. So as such, our boss would be flexible in terms of if I start at 6am I go at 3pm. So that's how I work my hours. Now sometimes I do work over because patients are admitted late and you need really to have them consented the day before if you want to get samples from them next morning for all sorts of reasons. So then if they are waiting on beds or patients aren't discharged or whatever. So as such the hours are set but they are not. ...But every second week usually I have to come in one morning at 7am and finish at 3.30pm now. It doesn't always happen that I finish at 3.30pm because there's maybe nobody to take over and we have to wait to collect whatever I am waiting for in the hospital.
  - ...you go away on holidays and have nobody to cover for you. I suppose in some ways, maybe not saying we were spoiled but because there was somebody to hand over to but the reality is this job is different and that's a thing you have to accept.
- G12 I think you have to be enormously committed because I work alone and if there is a difficulty at 5 o'clock in the evening, we have stay to see it through and there is no one else you can pass over to.
- If you take a day off, the work is still there when you come back the next day... As nurses we are used to handover we are not used to the work being left for us. Somebody takes over from us.

Autonomy of clinical decision-making was far less certain.

- C12 Certainly I have autonomy regarding the workload, my hours but not so much around making decisions or anything like that. I suppose a lot depends on the medics you work with.
- C41 a nurse is autonomous in making clinical decisions about what, we tend to decide what's best for the patient at some level, but the final say goes to the team. We can only autonomously pass on what we feel is...
- GI7 ....what I find here where there's a few of us, that you have your autonomy to be in charge of your workload but you also have the team that you can consult. If you've a problem you can ask, you know you can get on the phone and contact someone else. So it's a bit of both...
- C40 Whilst the role is autonomous there are clear criterion that the CRN works towards eq. timelines, protocol criteria.



There is autonomy in patient care with regard to referral onto others...

Autonomy was also seen to demand responsibility and factors such as requiring guidance or unwillingness to shoulder responsibility were viewed as negatives to undertaking or staying in the role.

- C35 Not really, like the autonomy... it is exciting and it is empowering. It is great but that it does in itself have the additional responsibilities that come with it.
- G12 We are given autonomy. We are responsible at the end of the day. It's like a business. You have to sit down and you have to show how many you have recruited into this and this. The work has to be done. Clinical trials are regulated so well with ICHGCP. You have to do it correctly there is no getting away because you are given the autonomy and the respect you get on with the job and do it. Whereas nursing to be honest, I could not go back there.

  There is an awful lot of autonomy you just have to be able to take on the responsibility...and you are dealing with a lot more people of different levels so you do need to become better at been able to sort of have conversations and deal with them.
- C1 I love the autonomy and I love working alone but there are the negatives... Because when you are fully autonomous you are answerable and suddenly something happens and you would like maybe to throw it by somebody or pass it by somebody and see that they think.
- GI8 In terms of autonomy I think it is a great position to be in, you know that you're pretty much autonomous. You're totally responsible for a trial, practically. I know the PI is ultimately responsible but ultimately it is actually a lot of responsibility is left to the nurse...

  You're responsible... and it's good to feel responsible and it gives you confidence then... I don't mind autonomy because as we all know, I suppose you were saying begging, it's great when you can organise it and then by networking you can eradicate begging. You develop good relations and you've got good communication skills coming into the job.
- C22 I mean I think it is an issue in terms that it is actually positive and I think it is one of the major attractions to the job. And I think over the years what I have noticed is that people who don't like autonomy who like to be guided, who like to be told what to do... that they are not really suited to this type of work. Because they struggle with it and... they have skills in a different area. So it's actually a pre-requisite to the position is to be an autonomous person.

Isolation was a negative role feature identified from the literature and so the participants were specifically asked their opinion on this. Whilst many could see how isolation could be an issue, far fewer reported experiencing it themselves. This they put down to personality factors and team working.

- C18 I could see how it could be a lonely job, a job in isolation but I think it's more got to do with you as a person and you want to sit in the office everyday and not talk to anybody but I don't. I'd head off for coffee and I'd meet them
- GI7 I think like that it can be a very isolated role because you're very independent, you're by yourself...

  ...but I think it's up to you as an individual how you work around that. You can be very much by yourself or you can take the next step and move out there and link up with other individuals within the hospital that you're in.
- C11 I think that isolation depends on the individual and the types of studies you're involved in.

So I like autonomy, I suppose it depends on the personality that you are yourself

- C41 I suppose we have a team here, from that point of view, from a team point of view I wouldn't feel isolated at all.

  Because we have a very mixed group of nurses and doctors and our PI is very dedicated and supportive as well.
- G12 And we are very much part of the team here. It's not the nurses in one section and the others.... We are at meetings with the scientists, with the consultants, with the research fellows, everybody.
  - ... This type of facility avoids the isolation syndrome
  - ... I think because we are a team it is not as isolating
- GI7 We would see ourselves as members of the team...
  - ... Yes we do and we attend the meetings for any patients that, we're there to contribute what the plan is for the patient, how they are getting on, so we contribute in conference with their social workers, everybody that's involved in that patient care, we are kind of incorporated into the team.
- C9 Isolation I can understand why that would be a problem. It's not for me at all because I am included in everything here now from meetings, ward meetings. I am a member of the team.
- C22 No, I have always worked within a team. When I started, there were two other research nurses. One of the girls was leaving and I took over her position so there was always another person for me to ask.
- GI6 I don't find there's isolation at all in this role.



- ...There's always somebody to ask or to go to and you're involved in the team meetings and the multi-disciplinary team and everything.
- ...Well I think first of all when I started, I felt a little bit isolated because I was here on my own and now that the research network has developed and there are a lot of different people you can link with.

'Solo' working brought the added burden of feeling responsible in scenarios of unavailability. Hence, one or two 'solo' workers did feel isolated.

- C35 It's great to have the autonomy and the little bit of flexibility within... how you structure your day and how you structure your hours, but that too can have it's disadvantages. I found if something crops up last minute, say like if you're ill or you need to take emergency annual leave or it's very difficult then because there isn't the backup. There's nobody else and you feel that quilt of "oh now I'm not there and there's nobody else that can do it". It is a responsibility and you worry then that something will happen, you know you've put off somebody's appointment and you worry that something will happen in the interim and worry about what's the right thing to do.
- C41 It is frightening to think if I went off sick in the morning there would be nobody left to pick up the pieces up... I suppose I'm lucky in the point of view that my direct line manager, my nurse manager is very aware of that. She actually spoke with the person in a similar position elsewhere and they discussed it at length and was... very, very aware of how isolated I am if something happened in the morning. And she had huge fear of maternity leave as well because there are no replacements
- GIS I suppose you're not replaceable. So if your sick today and you've people in the diary that you have to see, you have to solve that problem but you plan around that and you work with your colleagues and if it comes to it, you'll have a system in place where somebody can be contacted and cancelled if necessary and so on, but you're not replaceable.
- C10 I have got low days as in you think... it's hard to motivate your self all the time 24/7. Because really my position would be quite detached on an hourly basis. The consultant is there if I need her but I really do have to organise my day... It's not even a dissatisfy issue although sometimes it is because you don't have somebody to bounce ideas off or having someone sitting right beside you – your not a member of a team as such... In a sense it is quite isolating but I do enjoy that and you don't have the distraction of politics and you don't have the distractions which may sometimes pull back.
- C40 Both jobs consisted mainly of solo working hence a feeling of isolation. That being said there was a study manager for the academic study, who was reported to be an excellent role model and there were 3 monthly meetings.
- C1 ...you are very much alone which wouldn't suit everybody but that's also what I like.

There was also a sense of marginalisation and more specifically professional isolation from nursing itself.

- C35 And the isolation, yes possibly even though I do still work within the department and with other people, you know I'm not on my own in a little office somewhere... but I still find that I'm still separate to the staff, like they would have ward meetings and they would be discussing patients. So I still feel I'm separate even though I'm there with the group, I'm still separate to them.
- GI4 I'm not saying that somebody should be spoon feeding you, but we're not linked with the hospital... ...There's that isolation and not being in the loop of the hospital. I don't know why, but you've not got the nurses, you've not got somebody you can call on the next ward and say you've got some more experience can you come and give us a hand and I know there are nurses here that can help us with the research but there's not, but there's nobody else we can link in with
- C12 Yes I have felt isolated at times but more a sense of 'not belonging' to a particular group of nurses or to a particular clinic or ward. I have for the most part however, felt part of a team.
- Gl2 To be honest the only place that you feel isolated is from nursing management there is absolutely no management. ... They don't want to know anyway
  - ... No they don't actually and I don't know what the reason for that is.
  - ... I still feel that nursing should come on board and understand what we are doing.

A number of dissatisfactions were reported. The main issue was regarding employment uncertainty and a lack of a standardised approach to employment arrangements.

- C41 ... my substantive post is as a staff nurse in the clinical speciality but I'm on fixed term contract and come the end of this year my contract runs out officially unless we get further funding which we're obviously trying...
- C12 I have had to ask for every penny I got paid and actively seek increments and I really felt unable to negotiate an increase in grade because I lacked further acedemic qualifications.



- C18 Basically I'm seconded from the hospital, I'm in a temporary position. I'm acting CNM1, so to begin with it was great, you know CNM1 from staff nurse fantastic! However, a year on, you're still on the same salary, you're not going to up in money, you've no security for mortgages or that. I just see... you do compare yourself to your colleagues, a lot of them are going into permanent CNM2 positions whereas I'm still...
- C11 Another frustration is the employment conditions. I'm employed by the consultant and whilst I took a job demotion for this role, I had the benefit of regular hours. I was a bit naive though regarding pension entitlements and have lived with an element of job insecurity all along. There was always the threat though of a lack of funding. Initially, there was a lack of increments and whilst I'm now paid at the maximum of the grade, I do know that other research nurses have negotiated higher grades.
- C22 Well the only 'dissatisfier' is maybe the uncertainty... and I have to argue for every single person that's gets a job here to try and get them on a salary scale from the very beginning and I have to argue for a reasonable salary because the expectations are high and they expect nurses to be very educated when they come in. So salary scales and getting people onto salary scales and getting investigators to understand that they need to pay what is equivalent... in order to attract people and to get that quality of person in and to keep them because they are leaving permanent jobs in the hospital and all the benefits that go with that, possibly will never get back, and when they do get back maybe they are here for five years and go back on the same scale and it is not recognised they (the investigators) have to understand that it is a big step for people.
- G11 There is one thing for us, here we have no permanent contract. We are all on temporary contracts. We are on fixed term contracts but there is no obligation on the hospital once the contract finishes to re-employ us.
- GI4 I didn't realise either when I took the job, that it was going to be this temporary contact and when you look into it, no pension, no sick pay, there's nothing and so in the long run that's not very good for me.
- GI6 As well as being very hard on your pocket... And they just leaving acting for ever and a huge financial difference between, top of the CNM2 scale and the bottom
  ...In my situation because it was advertised as an acting CNM2, I am temporary to HRB but I'm permanent in the hospital. So I'm ok in that situation but it's never going to be resolved. I've to resign my post and then they have to decide where they can then put in a 2 year contract post and I have to take that post otherwise
- GIS ...most of the dissatisfaction would be in practical, financial terms... they would be the fact that you're loosing your permanency, you're loosing security,
- C1 I negotiate my contract annually but I have no hope of gaining a permanent contract very few of those exist. It would be nice at my age to get a permanent position as the lack of pension entitlements does disadvantage me.
- SC So how do you feel about that uncertainty?
  Well it's horrible really. I take it as a precious time and use it and I'm happy in it and am enjoying it and I just think it's not forever it's not permanent. I think once you accept that it's not well it does affect my pension my pension is on hold while I am doing this and that's a huge concern. So I couldn't stay in it too long for that reason. That's horrible really but it's important.

A second disatisfaction was the feeling of being unvalued in the research process which was reported by some but not all participants.

- C12 One disadvantage I see is that there is a lack of recognition and of general encouragement. Having said that, my boss has generally shown his verbal appreciation for the work that we have conducted. I suppose with hindsight, if I was prepared to work more hours, I might have considered doing some research of my own but then again, I have had limited time to give to something like that.
- G12 So the only thing I feel strange about is the fact that our names are not on the papers that are published. Like I would feel that we are actually doing like all the data collection and all the work the hard work and at the end of the day our names are not on the paper and that is an issue that I would have and something that I do think needs to change...

  ...Well that's not my experience. I have been included and I did work in a different institution than this one now and I was always included in all papers. You do value that.
- GIS I had a PhD student who was doing the main study to do with my trial and he acknowledge my contribution at the end of his, is it the viva, is what it's called? Yeah and I've been told my name will be on any publication he produces, that'll be about it really...
  - ...We just did one on a particular study looking at if you have the right trials, how you can recruit...Recruitment of patients yeah. That was a poster presentation and it's gone for publication. So yes, my name is on that because it would have been a trial I worked on, but standard no because even the academic ones, in your contract whoever is the one writing it and the 2 or 3 involved they won't even maybe allow the centre to have their name on it and these are written



very often in the paragraph of the contract that "can't be used for publication". I think some of them agree that among themselves at the early stages

### **Learning the role**

Most participants stated that they learnt the role 'on the job'. In a few cases, there was some handover from a previous postholder. Where facility managers or team leaders existed, some basic orientation was available. Those that were new to the role gave examples of 'trial and error' learning with varying levels of support from Principle Investigators. With regard to more formal learning the individual research nurse or midwife did take responsibility for their professional development and it appeared that some gave this more priority than others. Mandatory ICH GCP training had been undertaken by the majority of participants. In some cases, where clinical speciality networks or hospital research foundations exist there was fairly easy access to additional professional development activities. Some participants were undertaking a distance learning clinical research module. For others, gaining access to mandatory training that most clinical based nurses or midwives attend meant pretending to be hospital employees.

- You know you would make sure as well, this is the other problem because you wouldn't be employed by the hospital to try and get your manual handling and have all that because I would be keeping up with what the nurses have. I would want to keep that as well for myself, your cardiac support and that sort of thing. So I would do those and enrol myself in them. I would pretend that I worked for the hospital to get in on them because there isn't anything set up for that and I feel – you need it – you come across these things as well and you need to be up to date... From a professional development point of view I undertake the mandatory ICGP. I also attend anything of relevance so for example a series of seminars currently being organised by the hospital ethics committee.
- C41 ... I've done the HSE audit, on-line course. If there is an on-line course I do tend to pick those up because I can do them in my own time and they may not be fully accredited but they are for my development rather than the piece of paper...
- C12 I have attended research and speciality meetings... However this was all funded by drug companies and begging letters! These were informative and important as I got to meet other people involved in similar research. This was always done through my own initative but never encouraged, discouraged or financially helped from the department in which I worked!
- G12 Everything I have learned to date I learnt from the pharmaceutical industry not from nursing. The pharmaceutical industry is an education in itself when mastering clinical trials, quite honestly. ... You learn on the job. There is an obligation for the industry to ensure that you are proficient in what you are meant to do so part of their brief is to educate you.

Some learning occured through informal networking with other research nurses or midwives. However, in the absence of any other clinical speciality network or the existence of a clinical research facility, some participants saw the potential value of an active general network of research nurses.

- You build up your own network. I know some other research nurses in a research facility. I would speak to one or two of those. If it has to do with the trial I will speak to the doctor... But they actually don't really understand because they don't see the actual 'silly' side of it... like it might be something to do with paperwork - where do I get that paperwork? But it's nice talking it out with "the girls" because they have been there, they know what you are doing and they know what is troubling you and they also had problems as well that they come across... Because I've worked solo any networking is currently informal and study specific. I'd like to see a network for research nurses and there is a great need for some sort of an advice line, specifically for research nurses where you can talk through specific issues. Mind you, confidentiality clauses in pharma trials may limit the ability to seek advice from each other.
- C35 I have good support from the PI. He's good insofar as he's not over my shoulder. If I have an issue I know that I can go to him... and I feel that the (clinical speciality) research network have been supportive as well insofar as I know that if there are issues that I can contact them as well, which is good.
- SC And if there was a network for research nurses, do you think you would be happy enough to engage in that sort of
- C17 I would indeed. I can learn from the other nurses, I could contribute something to help them. And it could help us troubleshoot different areas of the job. I think it is important.
- C29 Like I think it's a good idea (a network) definitely. I think it was muted before and it was ongoing but I don't know what really happened it. I was asked to get involved and I didn't really have the time and in all honesty I'm one of these get on and deal with people. I don't like this 'wishy washy' talking and getting nowhere. I like something substantive, you know you come in, you can do it, you know it's going to have some benefits so that you move on. That's the way I kind of work and I don't like getting involved in these talking shops and stuff like that. I think if there's a need for it and it's



going to get some good work done and it's going to help regarding things like qualification, it's going to help regarding getting approved accredited course available for people to, getting formalised data available for people who are going to choose it as career pathway, getting things like proper salary scales and structures formalised for people working in it or act as a resource for people that want to go and recruit research nurses and know where they might be able to go and approach someone with a view to having a database of them of what area they are doing. Absolutely definitely, it's going to benefit in that regard, but at the same time I'd like to see that it's a useful tool, it's something that's done properly rather than just a get together and have a cup of tea/coffee and nothing comes of it, I'm not interested in that.

## Benefit of the role for patients

This group of nurses could clearly articulate the patient benefit of their practice. Benefits were divided into two categories. Firstly the general benefit of clinical trials for patients which included the standard of care available to trial patients being additional to the norm, the improvements that can pertain to an individual patient's disease status and the altruistic nature of volunteering for a research trial that can benefit others.

#### Enhanced standard of care for patient

- GI1 The standard of care is top class.
- C1 Extra opportunities for treatment outside the standard
- C12 In my opinion the patients who become involved in research benefit from much closer monitoring of their condition, especially when they are on clincal trials.
- G18 They do get more monitoring, yes. Other patients comment because they want maybe the consultant to come to them each time they come in and they wouldn't have that.
  - ... and research has shown in the past that patients that are in research trials do better because they're monitored more closely. Like scans are monitored, bloods are monitored, every single line in the chart because they have more one to one the whole way through and they do a lot better.
- G16 And on the monitoring basis they're seeing an additional person and more detailed in-depth about how are you, how was your symptoms. You know, that it is added extra patient care and then they get extra tests. Like we have a trial now and patients are coming back every 6 months for a physical exam so at least you don't have that when you're finished your treatment you're going back to your surgeon and you're seeing him every year, at least you have that extra benefit of someone seeing you and checking you...

#### Improvement in patient's condition

C22 and then some patients get very real medical benefits from being in the research. The medication works for them, they feel much better, they are absolutely delighted with themselves, their quality of life improves.

#### Making a contribution to advancing knowledge

- C1 Patients are excited to be part of research and placebo does not turn them off
- C22 I think patients get a huge amount from it. Certainly any patients that we have here, they enjoy being part of it. They enjoy their contributions and usually you know very early on you get a feeling from a patient whether they want to be involved or not. If they want to be involved, it purely altruistic for the most part. They are aware maybe that they won't get the active drug. They are probably hoping that they will get it. They want to help.
- C29 From the primary point of view, obviously the research that you are undertaking cause primarily you are undertaking clinical trials and research with a view to expanding knowledge about patients and medicines which is going to have a benefit for those patients and patients like them in the future.
- C23 The project has the potential to assist other researchers and certainly similiar studies in the UK have shown this. There has been no direct contribution to patient treatment yet but there can be in the long term.
- C29 And I find, in my experience that when we get the patients into the studies that they do thoroughly enjoy being in them. They find them very rewarding, they've got a sense of working toward doing something useful for themselves and for their fellow man and woman.
- SC Ok why have you got that sense, what tells you that?

  Because they feedback to me in regard that they do find it very fulfilling and when they get to the end of trials... For instance, a trial we worked on with 500 patients, when we go to the end of that study, when we actually approached patients to keep them on a database with a view to contacting for other studies, 95% wanted to stay on it



In some cases, the disadvantages for patients were also articulated.

G11 There are disadvantages for some patients. Oftentimes for patients who are travelling, you're asking them to drive further distance to come to this hospital because they can't get service such as this or can't be involved in clinical trials down the country. So oftentimes, you're talking about patients, certainly in our speciality that have you've got to balance up treatment with quality of living which includes extra travelling. You're adding burden. Certainly, that's a disadvantage from a patient's point of view. I do think that over all there are more advantages but there are certain drawbacks. Sometimes even things like blood tests can't be done in local hospitals because the studies require them to use the labs here and that can be a drawback for patients.

Secondly, the benefit of the research nurse role for patients was also clearly articulated. It included building relationships with patients that generally humanises the research process for the patient within the context of a busy service. This was frequently reported as a source of job satisfaction. Elements include providing a more individualised service, being available, being someone they can talk to and having time for the patient

#### Providing a personalised service

- C40 Specifically, the CRN role "shows a face behind the research and makes it more real for patients".
- G12 I think we are a resource for patients a enormous resource, in a huge conglomeration of staff, if they are in a situation where it is hard for them to know who to contact.
- GI3 You give them contact details... it's you they know to contact as a first port of call. For example if they have any problems, any worries, any queries and lot of phone calls made to the patient organising stuff and likewise they will be ringing you. They often use you as a sounding board and it's all part of it. It's the simple queries like "can I have a drink tomorrow" and as well as important... ringing that they have a rash or they are nauseated or not able to take the medication.
  - Sometimes they ring you about things that are not really anything to do with it all. They like somebody to talk to and they have your number.
- Gl2 They have the name of the nurse who they can ring instead of a secretary, they have an appointment given and they are seen on time, there is no queuing in clinics. Their bloods are followed up, you ring them with their results. It's a private service.

#### Being available

Whilst acting as a contact point is an important element of the role which is hugely beneficial for patients, those new to the role of research nurse may be naive in its operation, as shown here.

- GI4 It can be a little bit annoying but they'll be ringing you like at half past 5 and 8 o'clock in the morning and you're like "I'm off today". But they've got our mobile numbers which is perhaps our fault...
- SC Ok and what would they be ringing you about?

Changing appointments, we have a cough, should they see their GP, can we bring them in. The downside of it is that you say to them if you've a problem that you contact us, yes a problem relating to the study and I think we didn't make that clear enough initially and now they've a chest infection and they don't want to wait a few days to see your GP. Or they're just ringing... like their daughter's cousin has got a cough that was a bit similar to them, should they be tested, that doesn't need to ring me a half past five in the evening or on a Friday night!

And that's obviously our own fault because we were very, "here's my mobile number". Because we were so conscious that this was our responsibility because if there was a problem they needed to be able to contact us and we needed to be able to nip it in the bud.

They're comfortable ringing us.

They love it, like we've had texts or phone calls on a Saturday.

#### SC Having a contact. And do people ring you much?

C35 They do a bit, yeah a bit, again it's been a bit of a learning curve. Initially because I only work 2 days a week and because the research study was a bit of an issue in the department I just used to give patients my mobile. But then I kind of found they were ringing me on a Sunday morning and having pains (laughs). So now I just tend to say well I'm here on Mondays and Wednesdays and this is my number, but all very nice, I haven't had anybody pestering me or anything but.... It's just because of the initial, you tend to try and keep things straightforward and smooth and I just thought this would be a better way as opposed to ringing the department looking for me and whatever



#### Having time for the patient

C22 They like the personal attention and they like the fact that it's 10 o'clock, their appointment is 10 o'clock and they are seen at 10 o'clock. You are able to give them time for the duration of the visit and it is usually in or around that time, so their time isn't wasted... a lot of them like the social interaction a lot of them would tend to be older and they have the time.... Even also from the education point of view, the time that you have to spend with patients in talking to them about their illness or not about their lives or other little problems that they have and you can be just like a sounding board for them. I think they get a lot out of that there is probably in that a placebo effect the fact that a nurse is spending time with the patient.

#### Being someone they can talk to

- C17 Well I suppose my experience of working with patients and meeting with relatives, dealing with them through my working life. I think patients feel more at ease in talking to a nurse and they are quite at ease with the other members of the multi-disciplinary team but the nurse seems to be in my experience of research anyway, the nurse is the first point of contact between the patient and the research team. Patients are more inclined or their relatives to contact the nurse when they have any concerns about the person or even when they are looking for people about the research they will talk to the nurse, you know. That's just my own experience.
- GI2 I think a lot of them can talk to us.

The CRN role also offers continuity of care for patients. The nurses and midwives get to know their patients well and have a holistic view of the patient. They can advocate on their behalf and in some cases this includes expediating their access to other services.

#### **Continuity of care**

- C12 There is great continuity of care for them and they see the follow-up as someone being personally interested in them.
- G12 Providing a seamless service, being a constant person, being the pivotal person. I think they are our key roles.
- GI7 I think it's just, having that one person who knows that patient because you know all their history. You've gathered all their information, you coordinate all their bloods and scans and whatever and you could be just working on one patient for a couple of days, whereas if you're up in the wards you'd have... So there is more individualised care I think for the patient.

#### **Advocate**

- C18 You're their advocate... You build trust and they have great trust in you because they have met you from day one, you've been there the day they probably got their bad news, that either their disease has progressed or that they have the disease and that they need to go on a trial. And a lot of them who go into a doctor are scared, they've already told you that they want next week off (treatment) because it's the daughter's communion but yet they say "yes doctor, no doctor, yes doctor". So you're kind of going "but weren't you going to say that you wanted next week off for the communion", yeah, not a problem or whatever something can be done.
- GI5 As a patient advocate, what you would find is on the informed consent, you would then hear that there's social problems, you get the social worker. You then hear that there's something else at home. You get the dietician as suddenly she tells you that she's 2 stone lighter which you didn't know because she hadn't been weighed before surgery or whatever else. So I think as a nurse you will automatically, somebody comes in with terrible pain ok they are due their treatment, you'll get another team to see them...
- SC Being an advocate for the patient and standing up for the patient rights. How big an element is it in your role currently would you say?
- GI3 I think it is a very important role and I think... scientists I suppose tend to forget that the specimens are a part of people and we are all not walking specimens. So quite frankly I have no problem if the patient is needle phobic and I can't get blood. I am not going to go and brow beat a patient. I just don't ask a second time. It's the patient's right to refuse and that right is as important to protect as their right to say yes. I have to say my overall experience is very positive and Irish patients tend to be very keen, very keen. I think scientists tend to forget that people are part of... are connected to the samples or the body parts that they are willing to give away. Though these people are having parts of their bodies removed for whatever reason, disease or whatever and they are no good to them but they are still part of their body. And I would be hugely, hugely respectful of that... So yes, I do think sometimes people tend to forget that there is a patient behind it. No disrespect to scientists.
- GI2 But at the end of the day I think nurses are good at judging ethically and morally what is the right thing to do in



research, more so than doctors.

That's where our advocacy role comes in big time

Like I wouldn't be afraid to say to a Consultant "no we are not consenting that patient because of A, B, C, and D." ...from my experience some companies can ask patients to do things that are unreasonable and I think it's the nurse that protects them from all these things so I feel that my role is really looking after that.

#### Speeding them through the system

- GIS So I think as a nurse... you'll get another team to see them that day at the time, which they probably wouldn't get as the standard. They would get it but... those things are dealt with very expediently, when they're in on that visit. They're not coming back for 3 or 4 more visits.
- C22 They also, when they are involved in a study more often than not they have if they have other problems or you pick up on problems during the course of the trial, they get referred very quickly. You know things like that. They appreciate that and I think they just like....

Other benefits include education for patients which may focus on the research itself but can, in addition, include general health advice.

#### **Providing education**

- G12 They depend on us as well to explain in simple language what they have been approached with by the medical team. ...they actually trust you to explain to them what is this all about and what are the implications are and what are the risks. And you can use your role actually you know, to be very neutral you don't have to... I think that we have a huge role there which we are trying to push forward to present to the patient into a simple everyday language without removing the seriousness of what they are consenting to. But we do have that ability because all through our training we are explaining things to patients. So we do have that ability but the information overload is huge.
- C29 I find the patients find that in my job I put a focus on education and I kind of focus on being holistic with the patients. So I basically bring them in, I explain things. I find the patient will get better knowledge and insight into their conditions. You put a heavy emphasis on not just bringing them in and giving them drugs and letting them walk out the door. We put a heavy emphasis on health promotion with them, try to get them healthier, try to give them knowledge and information to make them healthier, to make more informed choices about their health. We would refer them onto smoking cessation, dieticians give them booklets and educational advice, other patient services, everything really. And when I get each individual patient in front of me, obviously they are on a study that we are doing, but at the same time I'm looking at them individually and say right what can I do to make this man or woman healthier? Do we need to just go through their tablets with them to make them take better, do we need to refer them to a dietician, do we need to inform them about the importance of lifestyle and we look at it very, very holistically.

## Contribution of the role to the professions of nursing and midwifery

Being asked what contribution the role of research nurse or midwife made to the professions, raised some of the tensions within the role including unclear boundaries and the relationship with the professions of nursing and midwifery and with medicine. Within group interviews this created the possibility for heated debate with colleagues holding differing standpoints on the uneasy position of the role. It was recognised that being linked to medicine enhanced the status of the role.

#### Contributing to nursing and midwifery

- C10 Probably not. I don't know how it would link into it's more of a medical focus isn't it really and a patient focus as opposed to nursing on the ground?
- GI5 Not the clinical trials aspect of it necessarily but the academic studies, possibly. It's depends, I mean for example, the one I mentioned previously, it may lead to a new product that actually helps the patient and ultimately then the nurses. But as regards contributing to the profession probably not, it would be to the patient care, it would just give a new
- GI1 I think probably that clinical trials are perceived as just being a medical thing and nothing to do with us nurses.
- G12 Contributes to nursing and midwifery? it's medical research at the end of the day. I think it contributes to patient care. I think we are more medically involved and people even find that if I say I'm working in research they think I am working in nursing research and I have to explain no medical research. We are not benefiting nursing. We are not doing any nursing research



It's medical. Like lets say, our director is talking about doing more qualitative research and quality of life and I think that will have an impact on the nursing but I think that we are doing at the moment is actually medical.

...all of our research here is consultant -led. The principle investigators are consultants.

- SC Even contributing to the nursing profession?
- GI2 I think we sort of walked away from that a little bit.
- C1 An additional satisfier is the prestige associated with the uniqueness of the knowledge within the role which gets recognition from other health professionals
- C18 People would say oh you're in research, ...friends even at the weekend colleagues of mine, "Oh you're in research, nursing research" and you're like "no it's actually not, you're facilitating medical research" and then a lot of them would say "God I'm not into it, it's just stats and I hated it in college" but it's actually not that kind of research.

Lack of role clarity and confusion regarding the research domains of nursing or medical research, means that the role is poorly understood by others, including nurses and midwives themselves. So one of the stated contributions to the professions is in selling the role to others.

- C29 I think you need good quality nurses in research to go and do the work basically ... as regards nursing and midwifery I think it's very important to have competent, experienced nurses in research posts, doing the work, looking at what we're doing, can it be done better, can we get better drugs, can we get better treatments, looking at patients experiences etc, etc and reporting on all those thing are highly important.
- C11 I think the role has shown both the public and the medical profession how competent nurses are.
- GI4 Yes it has because I think primarily nursing was seen as a hands on job and the academic side of nursing was left very much to the medics. I think it has brought nursing to the forefront and if it is improved upon and expanded, it will continue to do that and it will give the courage to people who have that academic ability, who have that interest in research to come forward and say, no it isn't just up to a principal investigator, we as the nurse have the same capabilities and interests and very often you see nurses a lot of the time with their patients see areas that would be very well met with research. So yeah I think it has.
- GI5 ... we certainly are interested in bringing new nurses in and I think we could have a role in educating those nurses, you know that's partly why I'm doing an e-learning module on clinical trials because it will re-enforce my own knowledge but also according as more junior nurses come in we'll be bringing them up to speed.

Being visible was also seen as an important part of selling the role. Such work has a background of those in the role perceiving themselves to be somewhat on the 'fringe' of the professions because they were not part of the overall nursing structure. However, ultimately they are still connected. So for example, during the consultation it was observed that a number of the nurses and midwives wore uniforms for their work. Two (C9 and C41) specifically mentioned this in terms of visibility and the role being conspicuous to ward staff. Others wore civiles but had the term nurse (or midwife) within their titles as per their work badges (C18) sometimes without the word research (C9). Such efforts to make the role visible were in the context of a lack of role familiarity on the part of nursing or other health professionals. In addition, some individuals worked in scenarios whereby there was less distance and greater integration with nursing structures or there was greater ward based activity.

- C9 ...initially I think when the jobs came in here as research nurses they certainly were not utilised properly. People weren't seen on wards by the patients or anything like that. I think a lot of people think now how did we work without them beforehand. Definitely I would think that they would think that we are a definite asset to the ward given the fact that apart from anything else we have so many more new patients now as well as everything else... I think a lot of people since I came into the job because I have been seen on the wards so much more and have been involved a lot more, they definitely value us. Whereas before this a lot of people were just like that's such a doss job "what exactly do you do?" and yet they had no interest in knowing what you did. They just thought we did nothing but it's not me...
- C41 My manager would be conscious that at CMN2 grade that you're visible. I suppose the difficulty with the uniform when I started first was that I was acting (in the role) in the beginning and it was very much from a negotiation point of view. There is a little bit of resistance there... if I were to stop wearing a uniform totally, whatever chance I have as an CMN2, I wouldn't have any chance if I didn't wear it or as a staff nurse. It was something we did discuss at the time because I had reluctance. I didn't want to make myself more visible but on hindsight you do need that visibility and that little element of power that you do get.
- SC And just for the tape I'm noting that you do call yourself a research nurse? Yeah, which does cause confusion because of the uniform system in the hospital.
- SC Do you think it's a lack of visibility of the role that you actually do, that other nurses don't understand it?
- C18 Oh yeah, absolutely. Here we all work in the clinical speciality so I'd say people do understand 80% of what you do.
  Where obviously I'm a nurse so a lot of my friends are nurses or midwives, ICU based and general medical and they



- have no idea what you do, and you explain and they're like "wow God that's really interesting" or some of them are like "God not for me", which is fine, because it's not for everybody, but definitely other people have no idea what you do.
- GI6 Sometimes maybe other nurses might perceive you, clinical trials and I think a lot of people wonder what we do and probably a lot of people think you might do nothing. And I suppose it depends on the nurse in question, they might look down on you a bit, like you're not a nurse specialist or...maybe. I wouldn't say I feel totally out of it but...
- SC A bit on the fringe Maybe yeah. An awful lot of what we're doing isn't nursing.
- C18 I think, in the past, there was "ah sure, do you do any work at all you're a research nurse, you paint you nails over in the office".
- SC And who would be saying that?
  - Nurses and medical as well I suppose because they would only see you when the patient is over so when the patient is gone they don't see you. So I think there definitely was a perception that you're painting your nails, drinking coffee in the office and you're saying "no, do you want to come back to the office and see actually that we're up to our eye in paperwork".
- GI3 If I have been around the hospital bringing charts back or getting charts... you could have a hundred and one things to do today and somebody meets you and goes "God you have a grand job, swanning around the hospital you know" and you think if you only knew and their perception is they probably think she is not stuck in the same ward all day she can go off and there she is having her cup of coffee at this time but that might be the only cup of coffee you are going to get for the whole day...

Some participants gave clear examples of how they had contributed to nursing and midwifery. This was usually in the context of their specific clinical speciality.

- C12 I am unsure as to whether the role of the research nurse has added to the overall nurse development. I quess it very much depends on the area in which one is working. I think perhaps most research nurses are expected to act as general assistants for the doctors in order for them to conduct the research which they are obliged to do as neccessity to further their qualifications! I have been involved in setting up a network for nurses in the clinical speciality in which I work – this was interesting especially seeing this organization going from strength to strength
- C11 I think the role has shown both the public and the medical profession how competent nurses are. But we've also given something back to nursing, as from our experience of being part of a UK network in the early days, we set up the equivalent in Ireland which has grown considerably. It has a much broader membership than just research nurses and encompasses all those nurses with an interest in the clinical speciality. This network holds an annual conference and is a great arena for professional development.

The potential and realisation for nursing and midwifery research to be developed within the role was articulated by a number of participants. Examples of relevant research questions were given which had been or could be addressed by nursing or midwifery research. In the main, it was thought that incorporating nursing or midwifery research into 'pharma' trials was problematic and this would be easier to achieve within academic studies. It was rightly pointed out that any 'piggy-backing' would need support from Principle Investigators. Others appeared less enthusiastic and argued for maintaining clear demarcations around medical-led clinical research and just being 'let do the job' they were employed for. There was clearly a lack of concensus on incorporating elements of nursing research into the role.

- C17 ... what I would like to do eventually if I can, is maybe to develop a research proposal and even go on and do a PhD thesis in collaboration with this piece of research. That I could develop another angle which will contribute to the overall study...Yeah I can see the potential angles that I could develop. Now the thing is that we will have to do some preparation work before I go and speak to some of the other people that would be supervising or supporting the study. Like, I would have to get their permission to go ahead and to submit it for funding say. But there are potential opportunities.
- GIS As part of the original academic studies I was involved with I was talking to patients and I realised I was filling out all these forms and every single patient I went to had a story to tell me about they ended up in hospital. I very quickly realised I'm discarding all this information. So we are encouraged in our job if we have an idea for an opportunity to go with it, so we're very supported in that. So I actually applied to a charity for a grant which we got and we've carried out a piece of research where we actually did an in-depth qualitative study, where we spoke to patients about their journey prior to diagnosis... and it was fascinating. Now we ended up interviewing a total of 14 patients and at that stage really we had a saturation of data so we stopped and we've submitted the report to the charity. But certainly for a nurse say in primary care setting for recognising symptoms that could have significance and we're hoping the charity will use it to inform health promotion strategies and so on.
- SC That particular study wasn't necessarily piggy backed onto one particular trial but it came from...?



Only in so far as we had access to the patients. So we had access of the patients through the academic study and when I spoke to the patients as part of that I informed them about the research. I actually didn't out carry out the patient interviews, another nurse did it, part of an MSc and I supported it... the only thing you have to be extremely careful is not to exploit the patient, that just because we've access and I know when we were planning our study we would have been encouraged maybe to do it on a bigger scale. We were very careful not to exploit the patient just because we had access to them

- C40 This nurse would personally like to expand the role to incorporate activity across the research continuum and include elements of nursing research. Currently, she is writing a reflective paper on the role of the nurse in RCTs as "it is important to get something for oneself out of it".
- C41 There could be more research from a nurse's perspective but it's not something that is focussed on, I suppose, from my point of view at the minute. From a research point of view we are looking at all the different things that we can. The CNS role obviously has a research element in it and we are trying to organise a little bit of research on the side of it, very much on a small scale and because of my role, I'm involved in that...
- SC You're going to be using a patient group anyway in relation to your masters thesis would that be right?
- GI5 Yeah why do patients want to come into clinical trials is what I'm going to be looking at. Yeah, I've done the literature review so far, so then we do the research next year.
- SC Do you see any scope for any nursing research on the back of the clinical trials or is that not a possibility?
- G11 At the moment we're in a difficult situation that we need to recruit patients to be funded so there's enough pressure on the nurses and if we don't get any funding for it. And it is so time consuming, research is time consuming that if we're to do our own practice research... I think it is outside our means and I don't know how our Principle Investigators would feel about us doing other research and whilst it would benefit our information it wouldn't necessarily benefit the unit or the funding.
- SC So there's an issue about selling it to non-nurses?
  - To non-nurses and I think it is as my colleague says within our own working remit which is obviously quite specifically clinical trials, the consultant's attitude wouldn't be supportive to be quite honest with you "sure what would you be wanting to do that for?" And I suppose they don't see it as scientific and theirs is scientific as they see it and even the outcome would have no bearing.... You could see the eyes going up and that's the reality. (laughs)
- C18 No, we're terrible. I think in Ireland, now I met a couple of nurses who they are really, they're go getters and they're into it and they have the time and one of my friends actually couldn't understand that I was doing medical research and not nursing research and we were on a night out last week, trying to convince me to do nursing research. Too much hard work, but it's definitely, I think it would be a great way to go but at the minute I think we all feel, we're busy enough and we're trying to get the work done and we're down staff as well with maternity leave and somebody who was covering is now going to a new job so I personally don't feel that I want to take on anything extra at the minute.
- SC Do you see any opportunity within the type of research that you do for some research of your own?
- C29 Yeah, like I often think... there's interesting perspectives and there's been work done say for instance on patient outcomes who have been involved in research and I think things like qualitative studies, looking at how patients find being involved in research, how it's benefited them, not so much focussing on the medical aspect, more focussing on the knowledge and the educational aspects and lifetime factors. But I certainly would like, not that I have the time, I would find an interesting study would be, I know there has been work done before, looking at patients outcomes in clinical trials compared to standard care... But I do think what would be interesting, for instance, a comparison of standard clinic patients and clinical trials patients and compare their knowledge about drugs, lifestyle advice, adherence etc, etc and I'm pretty sure you'd find a fairly substantial difference between the two of them.
- SC So plenty of research questions
  - Absolutely. Definitely and it's a question of doing them properly and having the time to do them basically. Like, in the ideal world, you would like to do these things but realistically, my job is to do what I'm paid to do and I have to focus on that and it's like everything in life you focus on what you have to do and if you have the times to do things you like to do, then great but if you don't then you just have to get on with it.
- GI2 Well I what I mean is like first of all nurses driving the research... Like I think that we should have principle investigators doing nursing research. So let's say I am the principle investigator and I would say what would I research?... ok let's say from a treatment point of view... I'm talking about qualitative research. Most nursing research is qualitative and very little quantitative so medical is quantitative, it's statistics it's numbers.
  - But I don't think that they will ever merge then. They are too different things.
  - That's what I am saying. Like it is separate. It's medical and it's nursing. I think we don't have enough. We don't have any nursing research.
  - But we should be looking at the opportunity to do nursing research in the job you have the opportunity to do it. I had the opportunity could you?



...And if that was available it may attract more nurses into the role because some people don't want just do this and this role – the medical. They want to do the work they were trained in.

Then it might amalgamate the medical and nursing but at the moment as it stands I see it as being only for the

With most clinical trials I would have always done a nursing questionnaire. I automatically put in some level or something that has a nursing focus.

As somebody said and it was a good way – that's what you're paid to do. You are paid to carry out a trial you are not really paid to do nursing research.

GI8 I think in terms of expanding the role that we really should be involved in more nursing clinical research. Nursing research, whether it's nursing clinical research or nursing general kind of research... and time is a factor, there isn't any allocated time and that's a factor with the consultants and it is also a factor for ourselves. If we're research nurses, why should we just confined to doing medical research, especially when we're well able and qualified to do our nursing research ourselves? And even more so when you read some of the protocols that are written by registrars or by medics, they leave a lot to be desired and you'd be tidying up a lot of them yourself. So I think ideally if there was more, if we had more time or if there was more people in the area then we could make time to focus on nursing research. Get some publications and start delivering some lectures and that over in the University. And I think that would further benefit and enhance the perception of the research nurse, certainly locally if you were beginning to be recognised nationally or internationally well that would certainly drive further to the nurses on the ground that there is something extraordinary happening here.

Acting as a resource was also seen as part of the research nurses' contribution to the professions. There were two elements here. One was as an educational resource regarding specific diseases and their treatments. This was mentioned by a number of participants as being currently in place. The second element was acting as a research resource and this was spoken more as a potential although in some cases it was an actualised activity.

#### **Educational**

- G11 Even in the information we're giving to the nurses, they are much more aware of research and some of the treatments we're giving – they are learning about them and their side effects before they are licensed. And then under the protocols they're learning how to clinically manage the treatment and then as soon as the treatment is licensed, they already know what to do and they are more vigilant. So it is training for them as well.
- GI6 Well it would in for educational purposes like. Each trial that we would have, patients coming on trail, we'd do an educational session with the girls in the wards. And everything has a trial, everything went through a trial stage so it's educational. I think it has extended the development for different treatments and different ways of giving treatment. ... Yeah but even for trials, even to know about your ethical and legal aspects, do you know that that would help in nursing as well.
- G11 Also we're teaching them things like... you know we were saying earlier on that you've to get so much information from your patient and you've to spend so much time compared to... Like we help them so much in their job but they don't see it and they can't see it. But we do so much of their day to day work in things like assessing their signs and symptoms. Like my colleague has been teaching them to use this booklet that we use all the time and how to use that well and how to assess patients well and grade properly. So it's giving them education tools out in the unit and they get lots of educational meetings through research.
- C10 Although the nurses are really happy to see this database up and running again and are happy to see that we are having a look at the data.
- SC In the team that you are kind of loosely based with are there clinical nurse specialists? And do they ever seek *information from you?* 
  - Oh there are. There would be about two or three of them. They haven't to date but I wouldn't be surprised if they did. It would be a good resource for them if any of them decide to do any work – it will be a good resource.
- SC How do you sell this job to nursing management?
- C9 Well you have to be seen that you are a resource to the ward. You have to be seen on the ward. There is no point in sitting up here in an office all day. You could learn plenty yourself that way but you are not going to teach anybody else anything. You have to be seen as a resource and an educator and an organiser.

#### Research

- GI8 And I think in all fairness we have and we endeavour to, or I certainly do to promote research awareness.
- C41 ...they'll ring up and say God I'm doing something on research... for themselves. And I am a valuable resource for



other people that they can say "she's a research nurse she might know about that". Usually because I've done the education and I would identify things quite quickly that other people wouldn't... Oh yeah absolutely and I'll always do that for them.

- SC So they do use you, do they? And this is for they're doing stuff for educational courses? Oh Yeah. Absolutely
- C22 But I think in terms of understanding research that's where it can benefit. I think that I would like to see down the line that as a research nurse that you could be a person that could advise a particular ward or whatever therapeutic... or say you are in cardiology if they are on a ward planning to do a research study you could actually help them in their project, help them to set it up, be an advisor, help them get their ethics proposals through. I think it could be beneficial in that way in the promotion of nursing research.
- SC Ok. As a research resource.
  - Yes. If we could evolve in that area as well in nursing research. And I mean the one thing that I would say about... well certainly here is that many of the nurses that have come in to positions here have gone on to do Masters in nursing or various different areas like primary care or ethics and law. So they have certainly developed their skills as researchers and I think this job has enabled them to do that and it is just something that we would like to try and develop further. And I think if we were able to develop that further that is definitely one area that we could link in with nursing in the hospital.
- GI7 Wave your magic wand and we could develop the potential. I mean I could definitely see the day where we support nursing research as well but I think, well I personally I haven't got my masters. So I wouldn't be conducting it but people who are at that level and who want to conduct nursing research I think yeah if we had the staffing levels and that we could have nursing research conducted within the hospital and especially in the area of our clinical speciality. I don't see why not. So again it's about making sure we have resources to do that

Whilst having the ability to articulate a contribution to nursing and midwifery, the place of the role within nursing and midwifery was perceived as marginalised and contributing to the sense of professional isolation. Nursing bodies working at policy level such as the regulatory and professional development agencies came in for criticism for failing to develop clear career pathways or offering professional guidance. This was a cause of concern for some but not all participants.

- G18 I would have to go on the line that I've gone on earlier, I think we've been forgotten about by the nursing community. SC And why do you think you've been forgotten?
  - Well because there isn't a defined pathway. There isn't any defined pathway, that would be the first thing. In every professional career you can see the pathway. There isn't, and research nurses have been around long enough now that there should be something here. You know that pathway should be well developed now at this stage... But I think in your broad development of nursing and midwifery, I don't know looking at the big... we don't seem to be counted. So I don't know how much of our role has impacted or contributed to the development
- G11 There is no career pathway for a research nurse, it is not really recognised by An Bord Altranais. There is no clinical research nurse speciality.
  - ...people will say it's not nursing because it's clinical trials. As does An Bord Altranais, they don't consider it at all.
- GI5 I'm actually doing a course right now that has nothing to do research at all, I'm doing a masters in something else with the view that if funding, I don't see actually funding will run out within my own area but it's just that being in the role now for 4½ years and An Bord Altranais hasn't yet recognised us. The movement is just a bit too slow for me. I'd rather it had been quicker because I know one of the research nurses, the manager down there was trying to get us be recognised by An Bord Altranais, but still...
  - ...It would be nice to be recognised as a CNS by the National Council but now how you'd prove that, I mean if you were a CNS within your own discipline really technically you'd just need a higher degree or a higher diploma. Now whether there could be an actual description of how do you qualify CNS. It doesn't necessarily mean that you'll be employed as a CNS in so far as there are so many varieties of contracts and all around. But that said that was the situation with nurse specialists when they started, there was stoma care nurses, staff nurses, CNMs, you know there were all kinds of grades. It would be nice to have actually regulations out if you were applying for a clinic nurse specialist in research, that's what you were...
  - ...Well we're just research nurses. I mean that isn't a formal recognition insofar as grades, for example.
- C22 ...you feel that perhaps the development isn't there unless you make it there. So you are not supported let's say, by peers. Yes, nursing peers... They don't appreciate the work that you do as a nurse and they often see it as a data collector for others. So that a little bit dissatisfying, in that there is no official career pathway and you are not really recognised by our own peers. And then the other dissatisfying thing would be that because you are not at the coal face of nursing it is difficult to be aware of what is happening on the ground... As a manager, I find that dissatisfying because I am not able to it is not easy for me to find out this information and tell the nurses that work here about it



because I find it difficult to get it - bar reading the INO magazine and An Bord Altranais. You know things like the nursing prescribing project would be relevant to us. So I only find that out on reading the magazines and that kind of thing. I mean one of the big things for us as research nurses is that we are giving unlicensed medications and there is I think about three lines in the scope of practice for nurses on the administration of unlicensed medications and I would love if there was more support and information for research nurses on that.

- GI5 Well there's nothing from An Bord Altranais at all, all we'll be told is well look in your Scope of Practice but there's only one paragraph that covers dispensing not-authorised medications and basically it puts the onus on the consultant...
- SC Do you think it's acknowledged by nursing and midwifery, the profession?
- C29 Not necessarily I don't think, but like I don't worry about that too much because I know that within the sphere of people that I work with and my colleagues in the hospital and my patients and the relatives I know that the work I do is appreciated and to me, I'm happy with that. I think within nursing and midwifery there's too much focus on things that they shouldn't be focusing on if you ask me and I'm not going to go into that and lack of focus on things that are far more important.

Although not explicitly sought within the consultation the existing relationship with the individual nursing or midwifery hierarchies were described by participants. Some relationships were formalised whilst the majority had no prescribed linkage to nurse management. In addition, the relationships with peers in their own organisations were referred to. In the main, all these relationships could be said to be distant, needing constant work, and somewhat ambivalent at times. Fear or a poor image of research was seen as a contributor. However, whilst individual research nurses and midwives had developed good working relationships with relevant managers and ward-based colleagues, others maintained the distance.

- C12 I know the nurse managers and have informal links with them. They know who I am and they do inform me about various presentations or whatever, but there is no formal type of relationship with them. Perhaps there should be.
- GI8 I'd be very dissatisfied with the nursing administration, you know that they don't acknowledge us as an integral part of the service, which is what we are. We're seen as, we're there, we're Health Research Board funded and even though we are under nursing admin, our chain of command is nursing, but I feel we are excluded in a lot of things... ...Certainly we're not entirely forgotten, I better take back some of my words, there's a particular group here now. And I suppose the coordinator, I'd be a good friend of hers and she'd have heard me moaning I suppose. And she has included me on the list of speakers every time there is anything, which is great. Because throughout that talk or certainly in any of talks that I've been giving here in the hospital to nurses I would always highlight research. I gave a talk here about 2 weeks ago, there was 8 nurses from the clinical speciality areas and I told them all about developments in infrastructure... I think what we have done here at a local level, this is to promote research and how is that going to be seen remains to be seen or has to be looked at.
- GI6 We answer to a nurse in the service, the nurse manager. We would be supposed to attend all the CNM2 meetings within the service. I don't go to them but we would be supposed to... we probably don't go enough but the quality meetings here within the services itself, a representative of all the groups of nurses within the centre. So I don't think we'd be intentionally left out of anything.
  - ...But they wouldn't be of any benefit to us... We haven't been intentionally left out but it's just not appropriate ...You just, I don't mean waste your time but you can go down there and like I kind of gave up going when I was in my last job. You go down there and listen to nurse managers arguing about the linen for like an hour, when I'm busy and I have nothing to do with linen. I'm not sayings that it's not a problem for people out on the wards because it obviously is...
- C41 I suppose from a nursing perspective, my manager... She would be very pro-active, an extremely pro-active manger compared to other managers and very much service-led. Which is great and she's a great support to me. She would very much acknowledge that she knows nothing about clinical trials at all. But at the same time whatever is needed to keep the service going she will do her best. Like we put in a bid for expansion... to go through the official channels to a get a part time, 0.5 wte but we get no response from these things. There's nothing you can do but at the same time she does drive it, whatever she does, she's quite strong whatever she puts her mind to....
- SC Brilliant support
  - Oh it's huge, it just wouldn't be as good without her.
- GI2 it's a terrible thing to say but no nursing rubbish would you agree? You miss out on that the nursing stuff that goes
- SC Are we talking nursing politics or the hierarchy...?
  - The hierarchy wanting to know where you are, when you are, how you are and what you are doing. ...That was one of the things that attracted me to this job - that I would be stepping away from nursing and the hierarchy.



- C1 And you need the nurses and they need you. And individually you are one of the girls. The girls will invite you for their nights out and we get on great with the girls... but it's the powers that be in administration the nursing administration that can make life difficult, which is a shame.
- G11 And you have to tread very carefully in certain areas. I think particularly with nurses, is probably that they tend to have this thing because you are not in the uniform that they don't need to do anything for us. You just have walked from here to there you know it is perceived I think by people generally from the unit or from the ward that you are not really doing anything.
- SC How's the relationship with the nurses on the ward per se?
- GI5 It takes a while to build up because you are an intruder and they are very busy. I'm often very surprised how tolerant they are of us. And I mean I've been in the opposite situation where I've somebody coming in trying to do research on my ward and I actually remembered how intrusive I found her but I think she wasn't that great. Even looking at it from my own perspective now I think she didn't deal very well with us. But I was very conscious that I mustn't make those mistakes. So I'll always introduce myself, you know and so on. I wouldn't ever approach a patient on the ward without finding out who is the nurse looking after them because I don't have the right to go and take bloods from their patient without them knowing and so on. Within the OPD's they're so, so busy, and we're trying to grab charts and we're trying to maybe take a patient that somebody else is looking for and so one. Diplomacy comes into it again and respect and so on, but also building up the rapport that they know you're there for a reason and also that you have the authority to be there. Because you are working for a consultant but if the consultant hasn't made that clear you're an intruder whereas if he has made that clear that he actually wants you to be doing this, it's a massive help. ...Thankfully I've found that it has been quite positive for the area that I work in but I did have to build it up at the start. For instance if I've going to do bloods on a patient, I'll say it to the nurse, do you need any bloods on this patient, I'll draw your bloods and then I'll do theirs as well. But it's two way thing because then if I need bloods out of hours and I need to get them ordered or whatever, they'll actually, a lot of them are helpful enough that they will make sure that the doctor does come and do the bloods and keeps them for me or something like that. So 9 to 5, if I'm willing to help them, like with a particular test if I'm going to do that test, I'll shove do an extra copy and put it in their notes too and different little things like that.
- C41 And there is a huge fear as well in clinical trials and in clinical research as a word doesn't bode well in most nurses' vocabulary... Just the way it's sold I suppose. Research has been sold very poorly anyhow. It's usually sold in an academic form and it's very hard to get past that... and it's sold very much on a monotone level with, it's qualitative, it's quantitative, this is the way it is, there is no deviation and research isn't like that but at the same time it also very much you have to know this for this exam and... I would have been the same... classroom research at some level does bore me as well. It's the theory side of it because lets say in classroom research it is the theory that is clung onto down the years, not so much as clinical research which is patient orientated at the end of the day.
- C9 Initially when I did research in college I avoided it like the plague... and I think a huge amount of that is to do with they just hear research and they think exactly back to what you did in college and they think that's what the job is and it couldn't be further removed from that really.... But I know... whenever I was in college, whoever was teaching me... it completely went over my head it really, really did this quantitative/qualitative debate, using these hypothesis and stuff like that. Way over my head it took me a long time to get my head around it.
- G11 You know, say students or even nurses when you say you are doing research they just their eyes just wash over because it seems to be the way it's taught in the colleges. It's all about the methodology of research, the theory of research. And they are just turned off by it... like it just goes on and on. It's really just a theory of what you do if you are doing research. They think it's really boring and they don't realise what it actually is and what it involves. Clinical trials. They kind of feel very sorry for people in research and it doesn't make it attractive for any students coming into it.

  ...I think it is probably one of the reasons why people don't apply for jobs in research. Once they see the word research they just switch off. They think it's what they learned when they are doing their degree but it's different completely.

Reasons for organisational relationship difficulties include the impact of the research on ward/departmental working, the loss of experienced staff to the role and elements of professional envy. Loss of autonomy was given as a potential outcome of having closer links, although this was not always seen in practice.

- C22 I would say if you asked research nurses ninety per cent of them would say that they do not want to be affiliated with nursing in the hospital because of the withdrawal of autonomy. I would say at the same time I think it is very important that we are kept in touch with what's happening by senior nursing in the hospital but it is very hard to make that link because we are not part of it.
- C35 The research study was a bit of an issue in the department... you tend to try and keep things straightforward and smooth...



One of things that I felt is the resistance of staff. That is an issue. I suppose because we are doing things slightly different to the way they've traditionally being done, there has been a lot of little vibes running around, like why are you doing it like that, we don't do that until later in the condition, that's not valid at this stage and there's no need for those additional test, if test A is normal, there is no need to progress to test B. And you kind of saying well this is the research policy and they're trying to identify if B is actually more accurate than A... It's mainly my colleagues really, yeah it is, it's mainly my colleagues that would have, we'd say like people that work within the department that would have always done it according to our policy, the hospital policy and now that policy is slightly different with the research study. And because there are additional examinations, the procedure itself would take longer so there is a little of bit of how much longer are you going to be, sure don't bother doing those, the first test is normal you know you don't need the additional information. Now things have improved. It was quite cold and frosty in the beginning but things have improved as they've got used to it. But that's one area I feel... the post just appeared and just started without much discussion at local level as to what the research was about and why they were doing the additional tests, you know the actual information behind why they had decided to carry out the research on this group of people and why they're doing these additional examinations. I feel that way if say somebody had come to speak to staff as a group initially it would have probably eased the transitional stage.

- SC So you think that within this particular hospital the issue of taking an experienced person from the ward to put them into a research role is contentious, is it?
- C9 Well, it has happened here they lost two. They lost me as CNM 1 off the ward and they lost another senior staff nurse. So with regards to the rest of the hospital I would say yes it's looked on with - yes they want experienced people to do the jobs but you are losing them off the floor.
- SC And do you think any of that was around envy of you in your role?
- C35 Well probably because I had been working as one of the girls in the department and then all of a sudden I had a different role and I suppose I was working that bit closer with the consultant and patients got to know me and would often ring up and ask specifically for me... It's just annoying, it's just a change stage. It is kind of, I was a bit surprised really because it was my colleagues, it nearly hurt more because it was my colleagues. If it was total strangers it wouldn't have bothered me as much, but it did because that sense of negativity was coming from colleagues that I had worked for a number of years, who I would have considered friends, but anyway...
- C23 The job can be quite isolating. There is a constant battle of trying to show others clincial practitioners and medics the importance of the study. There is an element of professional jealousy – I'm seen as having a nice job and no uniform and regular hours and there is no understanding of the amount of work that is involved.
- C11 I do remember feeling resented by other nurses when I started in the role but I don't think that happens now. It was recognised that where there was no formal relationship with nursing management it was inevitable that such a relationship would occur in the future as a response to a negative event.
- GI2 .... I kind of feel if we make a negligent act, if we conduct a negligent act nursing will have to come on board to deal with us and what we are. It's kind of a very nominal situation because in the clinic you are seeing patients, you are writing the charts but you have not got a line of authority or accountability up along on the nursing line. You are accountable really to your consultant and your team but I just feel that it's kind of a situation just waiting to happen where you might conduct a negligent act and then nursing will have to get on board...

#### **Limitations of the Consultation.**

This consulation was conducted with a 'sample' of research nurses and midwives identified through snowball sampling and interviewed either individually or in groups over an eight-month period. Whilst every effort was made to ensure face validity, such sampling may remained biased. Any reading or interpretation of the findings should be constrained with this knowledge. That being said, considering the contextual circumstances, such sampling was the only method available and so the findings as reported offer a tentative map to the current situation.



#### **Summary**

In summary, the findings of the consultation show:

The role of the research nurse or midwife is largely unknown.

The role of the research nurse or midwife is diverse depending on a number of factors such as role setting, mode of working, stage and origin of studies and the presence or absence of other research team members.

The research tasks within the role tend to cluster around the centre of the research continuum. The role itself is a good source of job satisfaction and most, but not all, roles contain a caseload of patients. The role includes nursing or midwifery clinical practice skills.

The contractual conditions of those in the role show large variance and can be a source of dissatisfaction.

Few enter the role in a planned fashion or with standardised entry criteria.

There appears to be movement in and out of the role but no real role progression beyond team management.

Professional development appears to be individually determined and negotiated and therefore lacks standardisation.

There appears to be a variety of practices and a lack of concensus as to engagement with nursing and midwifery.

There is potential to build nursing or midwifery research in parallel with medical-led clinical research.

# Report Discussion and Recommendations

#### **Discussion**

The purpose of this project was that the National Council would provide guidance in relation to career development for nurses and midwives in medical-led clinical research. The review of the literature, the site visit reports and the consultation have yielded valuable information providing insight into the role of such nurses and midwives. For the first time data have been collected and collated relating to Irish nurses and midwives in these roles.

As this consultation has shown the role of nurse or midwife assisting in medical-led clinical research exists within the Irish Health Services but is poorly understood. The role as it exists is hidden and diverse and lacks development, despite the best efforts of individuals to champion the role or progress their own individual professional develoment. The consultation phase has shown that a clear career development pathway does not exist in Ireland but needs to be constructed in order to recitify anomalies in the current situation. Without such a pathway, embedding medical-led clinical research into the health service will prove problematic due to recruitment and retention difficulties of these key personnel. This document therefore provides the background information and key considerations for progressing this career pathway and outlining the vision for the future of this role. This section outlines the key issues identified and considerations for progressing the career pathway

#### Title and role profile

The consultation was conducted with nurses and midwives whose main role was in medical-led clinical research. Throughout the project the title Research Nurse or Research Midwife was used by the project lead and the issue of title was not explored. That being said, some participants referred to themselves as clinical trial co-ordinators and there is the potential for a variety of role titles to be used, such as has happened internationally. Lack of clarity on title contributes to invisibility of the role and can lead to blurred role boundaries.

As it currently exists, role diversity occurs. This is dependent on a number of issues such as the type of data being collected, the length of time the role and/or the study had been established and whether the role was solo or part of a team of others including data managers or research nurses. Diversity was also an outcome of differing study origins. Regardless of the diversity, the participants described research activities similiar to those in the international literature and there appears to be a concentration of effort around the central activities of the research continuum. In addition, most, but not all, research nurses and midwives reported performing a clinical practice role which included elements such as patient assessment, medication management and advocacy. A role profile should be developed which outlines the competencies expected from a research nurse or midwife.

#### **Employment status**

There appears to be a number of reasons for the poor understanding of the role including small numbers, a lack of role visibility and a marginalised professional position. There is no employment grade, a mix of employment arrangements and due to lack of tenure a somewhat transitory workforce. Hence, there is no workforce data. So total numbers of this small workforce are unknown, as is movement in and out of the role. Such a lack of baseline data causes problems in predicting future workforce planning and produces a vacuum on career intelligence for the role. The NHS outlined employment grades introduced for such nurses. Consideration could be given to a similar process in Ireland. This would then show the presence of the role within the overall census of health service employment.

The presence of nursing and midwifery workforce planning at regional level has occured over approximately the last ten years but the disconnect between nurses and midwives in this particular research role and nursing management has meant that data on this group of nurses and midwives has not been captured. As an interim and in the absence of the creation of employment grade and considering the small numbers involved, workforce planners may be able to commence the task of gathering initial baseline data. Certainly, from the UK experience of clinical research regulation a personnel census of those employed in medical-led clinical research is a nessessary element of ensuring a quality environment for clinical research.

The lack of standarised employment practices with this group of nurses and midwives has lead to a range of scenarios with regard to employment terms and conditions. Some remain on temporary employment or fixed term contracts with an individual negotiation on salary scale on an annual basis, a prior lack of entitlements such as pension and the insecurity of the job being

1 The Protection of Employees (Fixed Term Workers) Act 2003 goes someway to improve the entitlements as employees.



dependant on continued funding. This scenario has led to some of those relatively new to the role intending to leave the role. In addition, should a nurse or midwife return to health service employment, there can be no recognition for the time spent in the role. Whilst movement through roles can be 'healthy', the failure to retain individuals with specific knowledge of clinical research can lead to a resource drain. Likewise, there was a reported perception of 'loss' of clinically experienced nurses or midwives to research nurse or midwife posts at organisational level. A better integration of medical-led clinical research into the health services and organisational appreciation of such research would go some way to counteracting notions of 'loss' and in practice, the site visit to Dundee showed a 'joint appointment' scenario as a means of managing this within a relatively small organisation.

Some research nurses and midwives have negotiated a secondment arrangement from nursing or midwifery positions, thus ensuring entitlements and job, if not role, security. Salary scales also varied both intra- and inter hospital sites. Such job uncertainty mitigates against any attempt to develop this area of nursing and midwifery as a career area. Considering the current investment being made to embed medical-led clinical research in the Irish health service through clinical research facilities this is an opportune time to prioritise a greater standardisation and regularisation of the contractual situation for this group of nurses and midwives. Initially this will occur through the establishment of the clinical research facilities but due consideration should be given to ensure best employment practices. A future vision may mean that all research nurses or midwives should be employed through clinical research facilities, regardless of whether they are sited in the facility for work. In other words, the clinical research facility may become an employing hub for research nurses and midwives throughout the service in a defined geographical area. This would ensure access to professional development opportunities and a professional reporting relationship to the senior nurse or midwife in the facility.

#### Job satisfaction

The role (minus the employment conditions) was a good source of job satisfaction. The research nurse or midwife's control over the working day and caseload was positive and gave a sense of independant, autonomous working. This perception existed even in the context of being part of a team and working within highly prescribed protocols and so not being autonomous clinical decision makers. The contribution to patient well-being was also highly valued. The participants reported responding to such job satisfaction by being flexible and responsive. Isolation, although experienced by some research nurses and midwives, appeared to be less of a role feature within the Irish context than internationally. For some of those that did work 'solo', clinical speciality networks existed thus circumventing some isolation issues. The presence of clinical speciality networks however can 'silo' research nurses or midwives within the speciality so that some of the broader issues for the role are not perceived as relevant to the individual.

Whilst intention to stay in the role was dependent on individual circumstances such as employment conditions and geographic availability of the role, entry to the role for this group appeared to be mainly unplanned. There was no standardisation with regard to criteria for entry to the role or for professional development beyond undertaking mandatory training once in the role. This leads to a central weakness in any argument for enhanced professional status. Although as the literature shows, even internationally, where the role fits within the profession remains uncertain. That being said, many, but not all, nurses and midwives were seeking and utilising opportunities for their own professional development needs. However, such efforts were not necessarily in a focused direction given the non-availability of specific educational opportunities. For many a career pathway was unimportant in the context of job insecurity. For those who did intend staying, there was no clear pathway beyond a direct management role. The establishment of clinical research facilities will give a very small number of additional promotional opportunities. Similarly, in the UK and with the exception of taking a managerial promotion, there is no professional career pathway for research nurses except into national network positions or to become investigators. The latter does seem to be the 'natural' direction for advancement since research activities are such a key element of the role. In the consultation one or two individuals intended to use the role experience to gain research knowledge and skills for their own academic purposes. So this pool of research nurses and midwives did contain potential investigators of the future. Protected time for nurses to conduct research is one of the recommendations of existing policy to enhance health research (Forfás, 2006) and would further foster this development.

#### **Preparation for role**

With some exceptions and unlike internationally, the research nurses in this consultation were not necessarily vastly experienced in the clinical speciality in which they were conducting the research prior to entering the role. Seeing a pattern in this was difficult because of the small numbers involved in the consultation but it did seem that those who worked solo or in small specialities were more likely to have practiced in the speciality prior to entry to the role. In one clinical facility, research across a range of clinical specialities was being conducted thus exposing the research nurses to clinical specialities where they had no clinical experience. Hence, in most scenarios, it is the research knowledge and skills that are valued rather than clinical knowledge and skills. That being said, there appeared to be no standardisation regarding criteria of entry to the role and entry appeared to be in an ad hoc manner.



There was a trajectory towards higher educational attainment with this group but it was difficult to ascribe cause and effect. However, this reflected the trend from the international literature. Specific professional development for research nurses and midwives was quite limited apart from the mandatory training in ICH GCP. A very small number were undertaking specific education in clinical research through an online module whilst one had travelled abroad for such education. With the advent of clinical research facilities it should be possible to widen the availability of specific education. Accessing professional development opportunities appeared to depend on the negotiation of the individual nurse or midwife and some gave this a higher priority than others. Should the clinical research facility become an employment hub for research nurses and midwives access to education and training and a record of professional development could be generated. In the meantime, there are a number of professional development educational resources widely available which research nurses and midwives could utilise.

#### Relationship with nursing and midwifery management

From the consultation, there were a variety of relationships between research nurses or midwives and nursing or midwifery management of the setting where the clinical research was being conducted. This showed as a continuum from no relationship and complete separation to mutually, collegial and supportive relationships. There was also a variety of attitudes to nursing or midwifery management. Some reported negative attitudes which appeared to stem from previous exposure to a command and control type of management or a nurse management ignoring research nurses because of their 'unique' funding base. Others reported a formal if perceived as somewhat irrelevant relationship and still others reported a valued and supportive formal relationship with nurse managers. Overall, with a few exceptions, there was a sense of professional 'unease'. Whilst some negative attitudes may have their origin in historical events, others may stem from management's unfamiliarity with the role. Continued 'separateness' will not assist any change in negative attitudes and instead collegial relationships need to develop. Considering research nurses and midwives are registered professionals providing a patient service, within hospitals for the most part, consideration of a professional (rather than managerial) obligation to research nurses and midwives on the part of nursing and midwifery management is warrented. Certainly, in the UK there is a trend towards ensuring research nurses had appropriate professional links in the absence of line management by a nurse. Nevertheless, if not already in existence, a partnership approach between employers and nurse management is required if individuals are to be supported in professional development endeavours.

#### Lack of visibiltiy of role

Despite valient attempts by some, but not all participants, the role remains hidden and invisible. It therefore is an unknown to others including, in some cases those entering the role. If there is to be further development as a career area the role should be made more visible both to aspiring research nurses and midwives and to professional leaderships so that a degree of familiarity can develop. Whilst some support can be given, role visibility will only develop through the sustained efforts of research nurses and midwives themselves in showing others, including health services management and professional leadership, the patient services that they deliver and the contribution that they bring to nursing and midwifery.

There was a sense of professional marginalisation for these nurses and midwives with complaints by some of a 'lack of recognition' by An Bord Altranais (ABA) and the National Council for the Professional Development of Nursing and Midwifery (NCNM). It is not possible to ascribe cause or effect of any professional marginalisation to the 'separateness' from professional management, some of which is upheld by individual research nurses and midwives. That being said, there is a difficulty for 'fittedness' into any existing structures. Criteria for CNS posts and post holders are explicit from NCNM and most participants in the consultation would not necessarily fit all the necessary the criteria. The role cross-cuts ABA's divisions of the register. As such, research nurses and midwives are similiar to practice nurses. Whilst ABA Scope of Practice does give these nurses and midwives a professional framework for their practice, the regulation guidance on medication management was criticised as making minimal reference to some of the issues a research nurse or midwife might have to address.<sup>2</sup> Previous attempts to professionally organise through the Irish Research Nurses Association were unsustained. If research nurse and midwives are to become less professionally marginalised, then they need to make their role visible, concensusly engage with professional structures and work towards enhanced professionalistion through education and role development. This requires leadership and sustained effort on the part of research nurses and midwives. Reinvigoring the network with some support would be a vital first step, as would a concensus on professional development. Models do exist of somewhat similiar scenarios like the practice nurses who themselves, appear to have achieved greater professional advancement than research nurses. This has probably been achieved through professional organising and creating sustainable specific educational programmes at the required level. In addition, a professional relationship exists for practice nurses through the role of the regional Professional Development Coordinators' for Practice Nurses. Such a position might be established through either the clinical research facilities or through the specific supported network.

<sup>2</sup> However, guidance on issues that research nurses and midwives face could be addressed by submitting queries to the Scope of Practice column published in ABA's quarterly News publication.



#### **Building professional alliances**

Building professional alliances would be a key element for progressing the role. One importance alliance is that of nursing and midwifery academia. This is not only because of its role as accredited education provider but also such an alliance has the potential for reciprocal research relationships. Certainly, within both the site visits and consultation phases of the project the potential to build nurse- or midwife-led research was articulated and in some cases demonstrated. This included the conduction of nurse-led companion studies for Masters by Research or PhD by a few individuals.

#### Recommendations

- 1. The construction of a career pathway for nurses and midwives involved in medical-led research is recommended. This requires policy, employment and professional considerations. This is beyond the remit of the National Council as a single agency and requires multi-agency commitment. Such agencies could include policy makers, employers, professional regulators and other key stakeholders.
- 2. Considering the stage of development of the role in Ireland, an agreed title should be used.
- 3. Consideration should be given to the establishment of an employment grade. The employers through the newly developing clinical research facilities should commence standardisation and regularisation of the contractual situation for research nurses and midwives. In the interim the nursing and midwifery regional workforce planners should consider the inclusion of this particular group in their data capturing activities so that some baseline workforce planning intelligence can be gathered.
- 4. A role profile should be developed and disseminated to all key stakeholders to show what the role entails and its contribution as a patient service. All job descriptions should include professional responsibilities as a nurse or midwife. The competencies of the research nurse or midwife should be described. Such competencies should then be utilised in the delivery of specific educational programmes and should also guide the consideration of criteria for entry to the role.
- 5. Research nurses and midwives should have access to appropriate orientation to the role and education and training within the role. Clinical research facilities should play a key role here. In the interim, a resource pack should be developed outlining access to relevant professional development opportunities.
- 6. Where absent, professional relationships need to be fostered and built between research nurses or midwives and nursing or midwifery management. The establishment of a Practice Development Co-ordinator for Research Nurses or Midwives might be considered as a potential model.
- 7. Some clinical specialities already offer an optional clinical placement for post-graduate level students with research nursing and this should be considered by all educational establishments.
- 8. To avoid isolation and act as a resource of information in relation to research nursing and midwifery, a network of research nurses and midwives should be re-established with appropriate support.
- 9. Research nurses and midwives should be encouraged to build alliances with nursing and midwifery academia so that recipricol research relationships can emerge.

## References

- Association of Clinical Research Professionals (ACRP) 2003. August Member Compensation and Benefits Survey. Final Report. Accessed 13/3/07 www.acrpnet.org.
- Ahern J., Grove N., Strand T., Wesche J., Seibeck C., Brenneman A.T., & Tamborlane W.V. (1993) The Impact of the Trial Coordinator in the Diabetes Control and Complications Trial DCC. The Diabetes Educator. 9(6) 509-512.
- Arrigo C., Gall H., Delogne A., & Molin C. (1994) The Involvement of Nurses in Clinical Trials. Cancer Nursing. 17(5) 429-433.
- Audley T., & Harrison, M. (1995) Study site co-ordinators a 'job definition' challenge! Clinical Research Focus. 6(6)12-17.
- Bishop V. (2003) Introduction to careers in nursing research: Case studies and opportunities. In Nursing Research in context: Appreciation, application and development. (Freshwater D & Bishop V eds.) Basingstoke, Palgrove Macmillan. pp118-143.
- Brown N., Harris R., Hunt J., Kelly D., Kelley K., Pearce S., Plant H., Richardson A. & Sirzia J. (2002) An assessment of lead R & D nursing roles in acute trusts and an evaluation of their status within the NHS Research agenda. Nursing Times Research. 7(4) 274-286.
- Carrick-Sen D. (2007) Newcastle research nurse review. Newcastle hospitals NHS foundation trust and Newcastle University. Accessed 23/4/07 http://www.ncl.ac.uk/crc/rndocuments.php
- Chadwick L.R. (1992) Professional Nursing with a new focus: Staff Nurse to research coordinator. Journal of Neuroscience Nursing. 24(3) 170-172.
- Connolly NB., Schneider D & Hill, AM. (2004) Improving enrolment in cancer clinical trials. Oncology Nursing Forum. 31(3)610-614.
- Cox K. (1999) Researching research: Patients' experiences of participation in phase 1 and 11 anti-cancer drug trials. European Journal of Oncology Nursing. 3(3) 143-152.
- Cox K (2000) Setting the context for research: exploring the philosophy and environment of a cancer clinical trials unit. Journal of Advanced Nursing. 32(5) 1058-1065.
- Cox K., Wilson E., Arthur A., Elkan R., & Armstrong S. (2005). A randomized controlled trial of nurse-managed trial conclusion following early phase cancer trial participation. British Journal of Cancer. 93(1) 41-45.
- Davis AM., Hill SC., Grady C., Wilfond B S., & Henderson GE. (2002). The invisible hand in clinical research: the study coordinator's critical role in human subjects protection. Journal of Law, Medicine and Ethics. 30, 411-419,
- Deave T. (2005) Research nurse or nurse researcher: How much value is placed on research undertaken by nurses? Journal of Research in Nursing. 10(6) 649-657.
- Department of Health (UK) (2004). The NHS Knowledge and Skills Framework (NHS KSF) and the Development Review Process. London: Department of Health
- Department of Health (UK) (2006) Modernising Nursing Careers setting the direction. London, Department of Health.
- Department of Health & Children. (2001) Making Knowledge Work for Health. Government Publications: Dublin.
- Department of Enterprise, Trade & Employment. (2006) Strategy for Science, Technology and Innovation. Government Publications: Dublin.
- DiGuilio P., Arrigo C., Gall H., Molin C., Nieweg R., Strohbucker B. (1996) Expanding the role of the nurse in clinical trials: the nursing summaries. Cancer Nursing. 19(5) 343-347.
- Dunbar-Jacob J.& Schron E. (2002) Ancillary Studies in Clinical Trials. Nursing Research. 51(5) 336-338.
- Easter M., Henderson E., Davis AM., Churchill LR.& King MP. (2006) The many meanings of care in clinical research. Sociology of Health & Illness. 28(6) 695-712.
- Ecklund Dixie J. (1999) Establishing a Research Coordinator Network: the birth of an idea. Journal of Nursing Administration. 29(1) 20-25.
- Ehrenberger HE & Lillington, L. (2004) Development of a measure to delineate the clinical trials nursing role. Oncology Nursing Forum. 31(3) E64-E68.
- Faugier J & Sargeant M (1997) Sampling hard to reach populations. *Journal of Advanced Nursing* 26, 790-797.



- Fishwick K., Berridge J., Coffey M., Colussi A.M., Di Giulio P., Marinus A., Molin C. & Peters M. (2002) The EORTC Clinical Research Coordinators Group. *European Journal of Cancer.* 38,S54-S59.
- Forfás. (2006) Towards Better Health: Achieving a step change in health research in Ireland. Government Publications Office, Dublin.
- Fyffe T. & Hanley J. (2002) Scoping the nursing and midwifery research and development capacity in Scotland to inform the development of a future strategy. *Nursing Times Research* .7(4)255-262.
- Government of Ireland (1998) Report of the Commission on Nursing. Dublin: Stationary Office.
- Grunfeld E., Zitzelsberger L., Coristine M. & Aspelund F. (2002) Barriers and Facilitators to enrolment in Clinical Trials *Cancer* 95(7) 1577-1583
- Hathaway S.K. (2005) *An ethnographic exploration of the role of the registered nurse working as a CRN.* Unpublished Master of Science Thesis, University of Cambridge, Homerton College.
- Hill MN. & Schron EB (1992) Opportunities for nurse researcher in clinical trials. Nursing Research. 41(2)114-116.
- Hill G. & MacArthur J (2006) Professional issues associated with the role of the research nurse. Nursing Standard. 20(39) 41-47.
- IMDA/IBEC. (2006) Enhanced clinical trials. Infrastructure required to benefit public health. Accessed 23/4/07 http://www.ibec.ie/Sectors/IMDA/IMDADoclib4.nsf/9e4c0a18818ec03d80256d490033f2d3/6349217f329a93b58025723000401ec a/\$FILE/Clinical%20Trial\_v7.pdf
- Isaacman DJ & Reynolds EA. (1996) Effect of a research nurse on patient enrollment in a clinical study. *Pediatric Emergency Care.* 12, 340-342.
- IUA & IBEC. (2005) Careering towards the knowledge society. *Conference paper.* Accessed 23/4/07. http://www.iua.ie/publications/documents/publications/2006/CareeringTowardsAKnowledgeSociety.pdf.
- Jenkins VA., Fallowfield LJ., Souhaim A. & Santell M. (1999) How do doctors explain randomized clinical trials to their patients? *European Journal of Cancer.* 35(8) 1187-1193.
- Johnson JM. (1986) Clinical trials: New Responsibilities and Roles for Nurses. Nursing Outlook. 34(3) 149-153.
- Kellen JC., Schron EB., McBride R., Hale C. & Campion J. (1994) A Survey of clinical trial coordinators: Factors influencing job satisfaction and turnover. *Cardiovascular Nursing*. 3(4) 25-31.
- Kenkre JE. & Foxcroft DR. (2001) Career Pathways in research: Clinical Research. Nursing Standard. 16(5) 41-44.
- Kenkre JE. & Chatfield D. (2004) Study site coordinators/clinical research nurse. Clinical Research Focus. 15(8) 5-9.
- Luker K (1999) Guest Editorial: The dilemma concerning the nurse's role in a multidisciplinary research agenda. NT Research 4(2), 85-86.
- McCormack B. (2004) Clinical research nurses should be involved in nursing strategies of the future. Nursing Times Research. 9(1)28-29.
- McEvoy MD., Cannon L., & MacDemot ML. (1991) The professional role for nurses in clinical trials. *Seminars in Oncology Nursing.* 7(4) 268-274.
- Molloy Hubbard S. (1982) Cancer treatment research: the role of the nurse in clinical trials of cancer therapy. *Nursing Clinics of North America*. 17(4) 763-783.
- Mueller M-R., & Mamo L (2000) Changes in Medicine, changes in nursing: Career contingencies and the movement of nurses into clinical trial coordination. *Sociological Perspectives*. 43(4)43-57.
- Mueller, M-R. (2001) From delegation to specialization: nurses and clinical trial coordination. Nursing Inquiry. 8(3) 182-190.
- Mueller M-R., & Mamo L (2002) The nurse clinical trial coordinator: Benefits and drawbacks of the role. *Research and theory for nursing practice: An International Journal.* 16(1) 33-42.
- Mullin SM., Warwick S, Akers M., Beecher P., Helminger K., Moses B., Rigby PA., Taplin NE., Werner W.& Wettach R. (1984) An acute intervention trial: the research nurse coordinators role. *Controlled Clinical Trials*. 5. 141-156.
- NCNM (2006) Report on the Baseline Survey of Research Activity in Irish Nursing and Midwifery. Dublin: National Council for the Professional Development of Nursing and Midwifery.
- O'Halloran L J., Curl V R., Hagen L. & Sveningson L. (1989) A research nurse: enhancing participation in clinical trials. *Progress in Clinical and Biological Research*. 293, 355-360.
- Pharmaceutical Industry Profile (2006). PhRMA. Washington DC. Accessed 6/3/07 http://www.phrma.org/profiles\_&\_reports
- Raja-Jones H. (2002) Role boundaries research nurse or clinical nurse specialist? A literature review. Journal of Clinical Nursing. 11, 415-420.



- RCN. (December 1998) The clinical research nurse in NHS trusts and GP practices: Guidance for nurses and their employers. Employment brief 2 2/98. Accessed 28/03/07. http://www.manchester.ac.uk/rgn/rs/publ/clinresguides.htm
- Rickard CM., Roberts BL., Foote J., & McGrail MR. (2006) Intensive care research coordinators: who are they and what do they do? Dimensions of Critical Care Nursing. 25(5) 234-242.
- Rico-Villademoros F., Hernando T., Sanz JL., Lopez-Alonso A., Salamanca O., Caups C. & Rosell R.(2004)The role of the clinical research coordinator-data manager-in oncology clinical trials. BMC Medical Research Methodology. 4(6) 1-9.
- Roberts BL., Rickard CM., Foote J. & McGrail MR.(2006) The best and worst aspects of the ICU research coordinators role. Nursing in Critical Care. 11(3).128-135.
- Sadler GR., Lantz JM., Fullerton JT., & Dault Y (1999) Nurses' unique roles in randomized clinical trials. Journal of Professional Nursing. 15(2) 106-115.
- Sale J.E.M. (2007) What do primary care nurses and radiation therapists in a Canadian cancer centre think about clinical trials? Journal of Evaluation in Clinical Practice. 13, 186-191.
- Scott G. (1993) SSC Survey. Clinical Research Focus. 4(8)14-21.
- Simpson (2006) Research nurses/Midwives review. NHS Greater Glasgow and Clyde Acute services. Accessed 1/10/07. http://library.nhsgg.org.uk/mediaAssets/Nursing%20and%20Midwifery/RNRReview%20report.pdf
- Stephens-Lloyd A. (2004) The extended role of the clinical research nurse: building an evidence base for practice Nursing Times Research. 9(1) 18-25.
- Streeton R, Cooke M & Campbell J (2004) Researching the researchers: using a snowballing technique. Nurse Researcher 12 (1) 35-46
- Tanner J. & Hale C. (2002) Developing research capacity: identifying and quantifying nursing research activity in the NHS. Nursing Times Research. 7(3) 212-221.
- Tattersell M. (2002) Editorial: cancer clinical trial recruitment. *Cancer*. 9 5(7) 1397-1400.
- Tierney A. (2007) Capacity and capability for nursing and midwifery research in Scotland: report of a scoping exercise conducted towards end of 2006. Unpublished report: Scottish Executive.
- UKCRC (2006) Draft Report Developing the best research professionals. Accessed 21/1/07 http://ukcrc.org/publications/reports.aspx
- UKCRC (2007) Developing the best research professionals, Report of the UKCRC Subcommittee for Nurses in Clinical Research (Workforce). Accessed 31/10/07 http://www.ukcrc.org/PDF/Nurses\_report\_August\_07\_Web.pdf
- Walker A (2007) Audit of Research Nurses in Birmingham NHS Trust. Paper presented as part of symposium titled "Reality Check for Research Nurses" at RCN International Nursing Research Conference, Dundee 1-4 May 2007.
- Waller J. (2002) An insight into the role of the clinical trials coordinator. Australian Nursing Journal. 57, 1-2.
- Welcome Trust. (2007) Clinical Research Facilities. Accessed 23/4/2007 www.Welcome.ac.uk.
- Wilkes L., & Beale B. (2005) Role conflict: appropriateness of a nurse researchers actions in the clinical field. Nurse Researcher. 12(4), 57.
- White-Hershey D. & Nevidjon B. (1990) Fundamental for Oncology nurse/data managers-preparing for a new role. Oncology Nursing Forum. 17(3), 371.
- Wright J.R., Crooks D., Ellis P.M., Mings D. & Whelan T.J. (2002) Factors that influence the recruitment of patients to Phase 111 Studies in Oncology. 95(7) 1584-1591.
- Xanthos GJ., Carp D., & Geromanos Kl. (1998) Recognising nurses contributions to the clinical research process. Journal of the Association of Nurses in AIDS Care. 9(1) 39-48.



#### SELECTED BIBLIOGRAPHY

- Bird, J & Kirshbaum, M. (2005) Towards a framework of advanced nursing practice for the clinical research nurse in cancer care. *Clinical Effectiveness in Nursing.* 9, 161-171.
- Butterworth A., Jackson C., Brown E., Hessey E., Fergusson J & Orme M. (2005) Clinical academic careers for educators and researchers in nursing. *Journal of Research in Nursing*. 10(1) 85-97.
- Cameron C. (1997) The Clinical Research Unit: a nurse-led unit for patients undergoing early anti-cancer drug trials. *Journal of Cancer Nursing*. 1(1) 32-36
- Coulson S. & Phelan L. (2001) Clinical research in paediatric oncology and the role of the research nurse in the UK. *European Journal of Oncology Nursing*. 4(3) 154-161.
- Cox K. & Avis M. (1996) Psychosocial aspects of participation in early anti cancer drug trials: Report of a pilot study. *Cancer Nursing*. 19(3) 177-86.
- Dennis, KE. & Strickland, OL.(1987)The clinical nurse researcher: Institutionalizing the role. *International Journal of Nursing Studies*. 24(1) 25-33.
- Duncan F. & Haigh C. (2007) Editorial: the realities of a nurse led randomised control trial. Nurse Education in Practice. 7,1-3.
- Engelking, C. (1991) Facilitating Clinical Trials: The Expanding role of the nurse." Cancer. 67, 1793-97.
- Evans M., Ilsley J. & Webb D. (2007) Clinical Research training for Scotland. *Poster presented at RCN International Nursing Research Conference, Dundee,* 1-4 May.
- Fay M. (1992) The Role of nursing in Clinical Research Trials. *Gastroenterology Nursing*. 14(4)195-197.
- Freshwater D (2005) Researcher or Handmaiden. Journal of Research in Nursing. 10(6) 659-660.
- Jackson C & Butterworth T (2007) Every-one's business, no-one's responsibility; reporting clinical academic research activity by nurses in the United Kingdom. *Journal of Research in Nursing* 12 (3), 213-223.
- Kenkre JE & Foxcroft DR. (2001) Career Pathways in research: clinical practice. Nursing Standard. 16(4) 40-43.
- Kenkre JE & Foxcroft DR. (2001) Career Pathways in research: academic. Nursing Standard. 16(7) 40-44.
- Kenkre JE & Foxcroft DR. (2001) Career Pathways in research: pharmaceutical. Nursing Standard. 16(8) 36-39.
- Miles K. (2000) Establishing a research nurses' forum. Nursing Standard. 16(22) 31.
- Moore S., Corner J., Haviland J., Wells M., Salmon E., Normand C., Brada M., O'Brien M., and Smith I.. (2002) Nurse led follow up and conventional medical follow up in management of patients with lung cancer: randomised trial. *British Medical Journal*. 325, 1-5.
- McKinney, MM., Weiner, BJ. & Wang, V. (2006) Recruiting participants to cancer prevention clinical trials: lessons from successful community oncology networks. *Oncology Nursing Forum.* 33(5) 951-959.
- Ocker, B., & Pawlik Plank, D. (2000) The research nurse role in a clinic based oncology research setting. Cancer Nursing. 23(4) 286-292
- Pearson, M (2000) Making a difference through research: how nurses can turn the vision into reality. Nursing Times Research 5(2) 85-86.
- Pranulis, MF. (1997) Issues in clinical nursing research. Western Journal of Nursing Research. 19(1)130-136.
- Raybuck, J. (1997) The clinical nurse specialist as research coordinator in clinical drug trials. Clinical Nurse Specialist. 11(1)15-19.
- Rice, J. & Cheak, T.(2000)The role of nursing in hospital based clinical research. American Journal of Nursing. 100(6) 24E-24G
- Rickard CM. & Roberts BL. (2005) The role of the intensive care research coordinator in Australia. *Critical Care and Resuscitation*. 7(1) 50-52.
- Rosenzweig, MQ., Bender, CM. & Brufsy AM.(2005) The nurse as principal investigator in a pharmaceutically sponsored drug trial: considerations and challenges. *Oncology Nursing Forum.* 32(2) 293-299.
- Ruccione, KS., Hinds, PS., DeSwarte Wallace, J & Patterson Kelly, K.(2005) Creating a novel structure for nursing research in a cooperative clinical trials group: the children's oncology group experience. *Seminars in Oncology Nursing.* 21(2) supplement, 79-88.

# APPENDIX A Site Visit Reports

## **Dundee Clinical Research Centre (non-Wellcome Trust funded)**

Date of Meeting: 3rd May 2007

Visitor: Sarah Condell

Contact: Lesley Peebles, Clinical Research Manager (CRM) and Nurse

#### Research Profile of centre:

Mainly but not exclusively cardiovascular and cancer trials. Currently non-commercial studies are in the majority. No nursing research currently.

CRM has been in clinical research for >15 years and acts as support and mentor to others (eg. Children and Medicines CRN) within the Trust).

#### Number of nurses employed

2 F/T CRNs and 3 P/T in CRC (2 of the latter are 'joint appointments' with clinical service, so as not to drain service of experienced practitioners

~ 100 CRNs across NHS Trust and University.

#### Titles used

Clinical Research Nurses

#### Sample of Job Descriptions

All CRC CRNs work to job descriptions which include their professional responsibilities as nurses

#### Work management of the Nursing Resource.

All CRC staff work office hours currently and their allocation to studies is based on their previous clinical experience. Each CRN is teamed with other CRNs and has a mix of Liaison and Partner roles. Liaison is main contact with PI/Sponsor, partners support and cover leave etc.

Since establishment of CRC in 2005, there has been no turnover of staff. Generally, there is little turnover of CRNs across Trust/University with many remaining in research although moving posts at end of contract.

#### Relationships

With Nursing Service: Informal at present and based mainly at clinical level. One formal relationship is the representation of the CRM on the Shared Governance Research Council.

With Nursing Academy: Relationships developing with the opening of training programmes, inclusion in large conference organising etc.

#### **Role Tasks**

Involvement with...

protocol development - not a lot in CRC (but the Clinical Research Manager had done so in previous posts)

interpretation of results)

dissemination of findings} - not at moment in CRC

However, across Trust/Uni CRN roles, there are a few involved in the 2 latter issues – these are mainly CRNs who have/are completing higher degrees e.g health related Masters graduates.



#### **Employment Issues**

Eligibility criteria: clinical experience, and evidence of professional development. Having or working towards degree desirable but not essential.

Type of contract: can be university or Trust contracted. Mainly fixed term of 1 to 3 years.

Preparation for role: an induction programme is in development and GCP course essential (it is offered quarterly). On occasion, site visits to other centres are arranged.

Promotion opportunities: currently no promotional pathway

#### **Career Development**

Training: In house lunchtime topic seminars and occasional video linkage to Edinburgh fortnightly seminar and other CRF courses. Has small training budget from Chief Scientist Office. Avails of some pharma training if available. Training mostly unfunded and a little ad hoc. Uses annual network conference (SCRN) as a training opportunity.

Outside courses: None currently but there is potential to develop a Master programme. This might be one way of building links with the nursing academy.

Companion Studies: non-currently

#### Links

UK networking - mainly within Scotland

European networking – Not currently. There is some opportunity within study specific or annual multidisciplinary scientific meetings where nursing can hold own concurrent sessions.

#### Other comments:

This newly established CRC is undergoing another transition with the building of an onsite CRF as part of the medical school strategy. This is due to be ready to commission in autumn 2007 and will include an expansion of the nursing resource. It is envisaged that the CRF will act as a hub as not all clinical research will conducted within the new building. There will also be the opportunity to stream line processes across the Trust R&D directorate and the University.



## **Northern Ireland Cancer Clinical Trials Unit**

Date of Meeting: 24th May 2007

Visitors: Sarah Condell, Ailbhe Murray, Anne Madigan

Met: Ruth Boyd, Cancer Research UK Senior Nurse, Eileen Dillon, Clinical Research Nurse Co-ordinator Sally Campalani, Nursing Director

#### Research Profile:

45 ongoing and 33 pending, majority pharmaceutical rather than academic, all cancer.

#### Number of nurses employed

13.47 wtes (16 staff)

#### Titles used

Research Nurses

#### Sample of Job Descriptions $\sqrt{\phantom{a}}$

#### Work management of the Nursing Resource

3 teams – 4 x G grades in early trials (2.8 wtes), 6 oncology F grades (6.2 wtes) and 2 Haematology F grade (1.8 wtes). Each team has a team leader, a role which rotates every 6 months – see attached document on team leader responsibilities. For management purposes, there is also a clinical research nurse co-ordinator and a senior nurse and 1 E grade in UK collaborative trial of ovarian screening study.

The nurses give the clinical care within the trial and work as part of a multidisciplinary team with a clinical trial practitioner preparing for trials through to ethical clearance and data managers inputting data.

#### Turnover

Approximately 1 per year often for personal reasons but sometimes back into others arenas in the Cancer Directorate

#### Relationships

#### With Nursing Service:

Formal structures within the Directorate. The Nursing Director acts as a line manager for the CRUK Senior Nurse. CRNs attend all nursing groups and fora within the directorate and this level of representation is highly valued.

#### With Nursing Academy:

No formal relationship although the senior nurse does have honorary lecturer status with QUB.

#### **Role Tasks**

Involvement with...

protocol development – yes with protocols developed by own investigators, no with external trials

interpretation of results ]

dissemination of findings] no BUT inclusion as authors is supported by the Director of Clinical Trials Unit and so happens automatically.

Do have involvement in the multidisciplinary study review process.

#### **Employment Issues**

Eligibility criteria – depending on grade... minimum 2-3 years of clinical experience, evidence of post basic education/degree.

Type of contract – permanent to NHS Trust as posts are funded from core R&D funding, grant funding from Cancer Research UK and recently from other charitable research funds.



Preparation for role – Formal induction process x 2 weeks tailored to individual needs but based on UK Cancer Research Network.

Promotion opportunities – limited currently.

#### **Career Development**

Training – mandatory unit – see attached document

Some directorate training e.g infusional studies.

Outside courses – some staff undertaking QUB module, senior nurse undertaking postgraduate studies

Companion Studies – yes. MSc research study examining the adaptation of an assessment tool to the clinical trial environment. Involvement in national fatigue study by another nurse. Nurses act as initial patient contact (+/-) for other multidisciplinary researchers (pharmacy, physiotherapy).

#### Links

UK networking – yes within cancer

European networking - no



# **Newcastle Clinical Research Facility (non-Wellcome Trust funded) and Newcastle Clinical Research Centre**

Date of Meeting: 6th June 2007

Visitors: Sarah Condell & Ailbhe Cullen

Met: Dr. Debbie Carrick-Sen, Senior Nurse for Research

Also: Clinical director, Business Director, Operations Manager, Finance Manager, IT Manager, study site co-ordinators, nursing team leaders and other support staff.

#### **Research Profile:**

60% commercial: 40% academic. (20% diabetes, 20% immunology, 20% oncology, 10% stroke, 10% nutrition, 20% others). This CRF works 5-day week with office hours, although depending on studies can work Saturday mornings also.

One nurse-led study on pain has been conducted through the CRF and examples of studies containing nursing research elements were given.... Promotion of sleep, development of nurse-led services, repeat terminations of pregnancy, management of low risk antenatal care, obesity and pregnancy, long term management of non operative lower back pain, equality & dignity with sight and hearing impaired, falls in the elderly, being with patients - going back to basic's.

#### Number of nurses employed

18 within the CRF

#### Titles used

Head Nurse (band 7 – CNM2)

Senior Research Nurse (band 7)

Research Nurses (band 6+5 - CNM1 + S/N)

2 study co-ordinators positions have been created in the last 18 months, filled by nurses.

#### Sample of Job Descriptions

#### Work management of the Nursing Resource

Within the CRF there are teams with 6-10 nurses per team. Each team had a lead nurse. This was a designated position to develop managerial skills, other team members roles were clinical with some opportunities to develop advanced technical skills and some management experience.

Within the over-arching clinical research centre, all nurses are currently being formed into teams. This is mandatory if they meet the risk criteria for the Trust (employed on trust contract or working on acute trust property with patients of data.) to ensure working within research governance and to prevent critical incidents, a small number (two) of which have arisen with consequences for both the trust as sponsor, PI and nurse. One of these incidents resulted in a Medical and Healthcare Products Regulatory Authority reactive inspection.

#### Turnover

Due to the extensive restructure there has been a suboptimal turnover in terms of research nurses within the CRF, however this is now settling down. Turnover within research nurses not working within the CRF remains very low.

#### Relationships

#### With Nursing Service:

Following a review the structures of responsibility are evolving. A head of nursing and midwifery research is about to be appointed. This role holds 3 areas of responsibility – professional development and line manager for all clinical research nurses within the Trust (n=~120), education and training in research for all disciplines and lead in developing nursing and midwifery research. The latter includes supporting nurses and midwives undertaking and Masters and PhD studies within the Trust. This role is line managed by trust Director of Nursing and reports into the Director of the Clinical Research Centre/Trust R&D Clinical Director. (See diagram)

#### With Nursing Academy:

The CRF is currently an elective 6-8 week placement for student nurses/cadet nurses. There are plans for making this compulsory.



#### **Role Tasks**

Involvement with...

protocol development - input into 6 weekly Feasibility Meetings so some involvement for non-commercial studies

interpretation of results – depends on study – commercial usually no involvement, academic led research, usually PI of the study +/- statistical support from University Clinical Trails Unit dissemination of findings – Increasingly, recognition given to CRNs as authors on publications and opportunities to present at conferences

#### **Employment Issues**

Eligibility criteria - minimum of 2 years clinical experience at grade F in therapeutic area, research skills non-essential. We do appoint A4C band 5 but these are training roles with clear competencies and time scale (see attached JDs).

Type of contract – current move to ensure all contracts are permanent/open-ended and NHS based. Any existing university contracts tend to be open ended.

Preparation for role – There is an induction programme we use and we are developing a research resource pack for all areas including outreach, but won't be ready till beginning of next year.

Promotion opportunities – Some within the CRN role through management. Very likely to have a substantial change in the future with less band 7s and more band 5 training opportunities.

#### **Career Development**

Training – 6 weekly, 2 hourly open forum for research nurses and midwives. This consists of Trust Communication, National Initiatives and Nurse-led Research which is open to all. Monthly research seminars for 1 hour on a Friday lunchtime with a wide range of topics suitable for all disciplines including both nurse researchers and nurses doing clinical research

GCP is supplied and mandatory on a 3 yearly basis – this is bought in.

Workshops on consent and ethics submission – this is provided in-house.

Outside courses – link closely with education and seminar opportunities within Newcastle and Northumbria Universities.

Companion Studies – as above

#### Links

UK networking – yes. Twice yearly meetings with CRF national network for CRF managers. Visits from others especially in set-up phase.

European networking – not at the moment

Unique features:

Since opening in 2005 the CRF has evolved to become part of a networked clinical research centre. This superstructure incorporates other facilities called platforms eg. The Cancer CRF, Immunotherapy unit, clinical trials unit (university based support centre), MR centre, clinical aging research centre etc.



# **Edinburgh Clinical Research Facility (Western & Royal Infirmary sites) Wellcome Trust funded**

Date of Meeting: 7th June 2007

Visitors: Sarah Condell & Ailbhe Cullen

Met: Fiona McArdle, Clinical Research Manager

Sharon Cameron, clinical research nurse manager at Royal Hospital Site

Jane Ilsley, Education and Training Manager

Gordon Hill, previously clinical research nurse manager at Western Hospital site, now lecturer Napier University

#### Research Profile:

6% commercial, remaining academic across all clinical specialities, with more than 500 applications and 270 studies active at some point and 6,500 patient visits during 2006. Nurse-led research was a feature of this facility with 12 nurse-led studies through since 1998 – see attached list for titles. Much of the nurse-led studies were initiated by hospital staff and not CRF staff.

#### Number of nurses employed

20 wte

#### Titles used

Research Nurses

#### Sample of Job Descriptions

Yes – generic

#### Work management of the Nursing Resource:

One Band 7 on each site and then a mix of Band 5+6. Cross cover between sites occurs. A liaison nurse (usually a Band 6 or 7) is appointed to each study based on experience, current workload etc and a loose buddy system is also in place.

In addition, there are a number of national network posts employed thru the CRF in Diabetes, Stroke, Medicines for Children and Primary Care. These gave opportunity for promotion within the CRF. A background in the clinical specialty was seen as desirable but not essential for these roles. A component of these roles is to raise awareness and promote the use of the CRF.

Turnover: Low

#### Relationships

#### With Nursing Service:

There are good relationships with the Trust lead nurse for R&D (Julie MacArthur) and the Trust's Research Manager for Capacity and Capability Development (Janet Hanley). The former advices nurses and midwives on research and often guides them as appropriate to the CRF. This may explain the use of the CRF for nursing-led studies. The latter chairs a group specifically aimed at nurse, midwives and allied health professionals which the CRF Clinical Research Manager sits on.

#### With Nursing Academy:

There is good links with the nursing academy through the move of the CRNM to a lecturer position. In addition, a Chief Scientist Office Funded Consortium called the Centre for Integrated Health Research has the CRF Clinical Research Manager on its steering group.

An elective placement (3 wks) for student nurse education is offered and utilised. There have been some adjustments to try and optimise this for both individual students and CRF staff.

#### **Role Tasks**

Involvement with...

Protocol development. A little at times and usually with established user investigators.

A feasibility review is performed by the Band 7 and others with a focus on intensity, costings, feasibility etc.

Interpretation of results... Minimal



Dissemination of findings... Minimal

Authorship sometimes occurs but is more common for CRNs not attached to the CRF and employed directly by PI.

#### **Employment Issues**

Eligibility criteria – 3-4 year clinical experience (Band 5). Research skills not essential.

Type of contract – All nurses on NHS contracts, support staff usually university contracts. It is assumed that CRNs throughout the Trust however had a mix of contracts with  $\sim 100$  posts.

Preparation for role – 2 week induction with mentorship. Review of competencies on entry to role

Promotion opportunities – Limited to progress through to Band 7

#### **Career Development**

Training – Large in-house training schedule available but no academic accreditation (professional CPD points only). Video conferences fortnightly seminars to other centres. Is exploring on-line and web-streaming of E&T.

Outside courses – 3 nurses currently undertaking MSc.

Companion Studies - One nurse PhD as a companion study to a genetic study. (title)

#### Links

UK networking – yes across Wellcome and other sites. One ex-staff member responsible for establishing the Scottish Clinical Research Nurses Association. This has a steering group of 4 representing the main geographic areas of CR activity, 280 members across the whole country and offers a website, email alerts and annual conference. The website has shown 10,000 hits since established in 2005. The main content is information of the role, education and training and job opportunities. There was a small set-up grant from the R&D Office but is maintained by a committed individual and there is no fee. There is no national database of CRNs.

European networking – none.

#### **Unique Features:**

This CRF works across two sites at opposite ends of the city. A third site for paediatric research has just been established.

This CRF has made a concerted effort by all staff to produce conference posters as a means of highlighting its activities. The networks posts and the commitment of the Trust Lead Nurse for R&D have lead to good awareness of the CRF and the promotion of its service to nursing.



# Southampton Clinical Research Facility (Wellcome Trust funded)

Date of Meeting: 11th September 2007

Visitors: Sarah Condell, Yvonne Bailey, Caroline Rooney

Met: Jennifer Allison, Senior Nurse Manager (SNM) & member of Management Board and Scientific Advisory Board Carol Gough, Senior Research Sister

Rosemary King, Children's Research Sister

Robert Crouch, Consultant Nurse/Senior Lecturer & Scientific Advisory Board member

#### **Research Profile:**

Total of 352 studies with 170 active and of which 275 (78%) academic and 77(22%) NHS. Hepatology, dermatology, ophthalmology, paediatrics, respiratory, cancer care, sleep studies and rheumatology.

Some AHP and nurse-led research as well as complementary medicine.

#### Number of nurses employed

Core funding = 14.5 wte + 1 SNM4 wte from other funding.

#### Titles used:

Research nurses, research sister, senior healthcare assistants, specialist research nurses.

#### Sample of Job Descriptions $\sqrt{\phantom{a}}$

#### Work management of the Nursing Resource

Divided into three teams at Band 5, each with its own research sister at Band 6. One of the teams is paediatric specific. The specialist research nurses have clinical speciality or clinical research experience and are at Band 6. The respiratory research nurse co-ordinator, rheumatology research physiotherapist, senior research sister (and clinical trials and education co-ordinator) are Band 7. Cross cover occurs within teams and staff self roster for 24 hr studies but is the responsibility of the Senior Research Sister. Some outreach work occurs to wards, clinics, community volunteer and patient settings

#### Turnover

Low initially for first 5 years but has grown since. Vacancies occur for maternity leaves and many seek part-time work on return which to date has been facilitated.

#### Relationships

#### With Nursing Service:

The SNM has a nursing professional manager nominated by the Director of Nursing but line management is to the Director of the CRF. Service staff are formally involved in the CRF by representation on the Management Board and the Scientific Advisory Board (a Consultant Nurse). Formal Link Nurse Roles exist on all wards. WTCRF staff undertake required Link roles - eg Infection Control, Child Protection, Resuscitation, Fire, Manual Handling.

Representation in Trust wide groups also exists- Nursing and Midwifery Group (Senior Nurses, Divisional Heads of Nursing and Director of Nursing/Associate Directors) Nurse Practice Group, Clinical Governance- eg Risk Management, PPI, Education and Training Leads.

#### With Nursing Academy:

A professor of nursing sits on the SAB. The university does use the CRF as an optional clinical placement for degree students who nominate themselves. The CRF does presentations on its role functions for nurse education programmes.

#### **Role Tasks**

A New Projects Team consisting of the research sisters, the SNM, Operations Manager, laboratory manager and the Education leads review potential applications for feasibility. Informal advisory role in protocol feasibility/development by SNM, Senior Research Sister, no role in data management or interpretation of results.

Research Support Team provides help with Statistics, protocol development, applications to funders, Ethics and R&D.



Some dissemination on CRF nursing activity (Poster: Empowering children to be willing participants in healthcare research) and publications in nursing magazines. Frequent Oral and Poster Presentations at International and local Conferences. Development of annual WTCRF Conference (in collaboration with other WTCRFs)

Allison JL , King RM, Glasper EA Involving children in healthcare research. In: Glasper EA, Richardson J, Eds. A Textbook of Children's Nursing. Edinburgh: Elsivier, 2006: 222-241.

#### **Employment Issues**

All nurses on NHS contracts with the exception of the nurse educator. For Bands see above. Usually seek 2 years clinical experience for band 5 and 3 years for Band 6. Research skills not essential for Band 5 but desirable or clinical speciality experience for Band 6. Promotion opportunities – many options to Band 6, more limited progress through to Band 7. Preparation for role – induction with preceptorship. Example of documentation made available including competencies.

#### **Career Development**

In house training available.

Outside courses: One staff member with PhD and one about to commence Masters. Awaiting modular MRes which will include placement within CRF. Little demand from staff for outside courses currently, but encouraged to take up available funding

Some nurse and AHP led studies but mainly university or Trust based nurse led research. (example of titles). No companion studies- QoL studies have been undertaken by nurses along side medical studies.

#### Links

WT Clinical Research Facility Managers and staff, other CRF Managers/staff and some links by SNM to the US.

#### **Unique Features:**

Vision to develop Clinical Research Institute across Southampton which will incorporate all research activity and research nurses.

# **APPENDIX B**

# UK (NHS) Job statements

# **Profile Label: Clinical Researcher**

- **Job Statement** 1. Assesses/diagnoses/treats own caseload of patients/clients & maintain associated records.
  - 2. Undertake discrete research/audit projects, including development, design and implementation; disseminate research findings
  - 3. Contributes to the implementation of research findings into clinical practice and service development
  - 3. Participate in the education and training of health professionals on the application of research evidence on clinical practice

Factor	Relevant Job Information	JE Level	JE Score
1. Communication & Relationship Skills	Provide and receive complex or sensitive information; barriers to understanding Communicate complex information to patients regarding their condition & expected outcomes.	4a	32
2. Knowledge, Training & Experience	Specialist knowledge across a range of procedures underpinned by theory.  Professional, clinical knowledge acquired through degree supplemented by specialist training to post-graduate diploma level; knowledge of research methodologies	6	156
3. Analytical & Judgemental Skills	Complex facts or situations requiring analysis, interpretation, comparison of a range of options.  Analysis and interpretation of complex statistical /analytical/ research outcomes and queries; judgements regarding a range of clinical issues or complex patient conditions.	4	42
4. Planning & Organisational Skills	Plan and organise straightforward activities, some ongoing Plan and co-ordinate research activities,	2	15
5. Physical Skills	Developed physical skills; advanced sensory skills; manipulation of objects, people; narrow margin for error/ Highly developed physical skills, high degree of precision.  Use of clinical equipment or physical skills to assess and diagnose patients / Dexterity, co-ordination and sensory skills for assessment; manual assessment and treatment of patients, clients.	3(a)(b) - 4	27-42
6. Responsibility for Patient/Client Care	Provides clinical technical services/Develop programmes of care/care packages; provide specialist clinical technical services; provide specialist advice in relation to care.  Assesses, diagnoses and implements care packages; therapeutic or diagnostic procedures; provides specialised advice to patients, clients	4(b) 5 abc	22-30
7. Responsibility for Policy/Service Development	Implement policies and propose changes to practices, procedures for own area  Contribute to the implementation of research findings into clinical practice and service development	2	12



Factor	Relevant Job Information	JE Level	JE Score
8. Responsibility for Financial & Physical Resources	Personal duty of care in relation to equipment, resources/Authorised signatory, small payments.  Personal duty of care for equipment used/authorised signatory for small cash or financial payments	1-2d	5-12
9. Responsibility for Human Resources	Professional/clinical supervision; provide training in own discipline  Supervises work of less experienced staff; undertakes and provides training in clinical/ research/ audit skills and methods.	2(b) (c)	12
10. Responsibility for Information Resources	Occasional requirement to develop or create reports, documents  Use advanced software to create reports and analyse and manoeuvre data	2(b)	9
11. Responsibility for Research & Development	Regularly undertakes: R&D activity, clinical trials/ R&D activities as major job requirement  Regularly undertakes clinical audit or trials/ Frequently undertakes R&D activities	2(a)(b) – 3	12 – 21
12. Freedom to Act	Clearly defined occupational policies ;work is managed rather than supervised /Broad occupational policies  Work is managed not supervised, accountable for own professional actions, /Significant discretion to work independently ,	3-4	21-32
13. Physical Effort	Frequent light effort for t several short periods; Occasional light effort for several long periods/ Frequent moderate effort for several short periods.  Pushing or lifting equipment/ Moves, manoeuvres patients, equipment	2(a)(b)- 3(b)(c)	7-12
14. Mental Effort	Frequent concentration; work pattern predictable  Concentration for patient assessment treatment and research activities	2(a)	7
15. Emotional Effort	Occasional/ frequent distressing or emotional circumstances.  Patients with terminal illnesses, challenging behaviour, rare abnormalities	2(a)-3(a)	11-18
16. Working Conditions	Occasional/ frequent unpleasant conditions; occasional highly unpleasant conditions.  Odours, fleas, lice/ body fluids	2(a)-3(a) (b)	7-12
JE Score/Band		Band 6	397-464



# **Profile Label: Clinical Researcher Specialist**

Job Statement 1. Specialist for own area of work/clinical speciality

- 2. Acts as a source of advice and expertise within own speciality and as research specialist
- 3. Lead on research/audit projects, including development, design and implementations; may be the lead for own profession in multi disciplinary team research projects; advise and monitor research conducted by other health professionals; disseminate research findings
- 4. Lead changes to clinical practice and contribute to service development through integrating research findings into existing clinical practice

Factor	Relevant Job Information	JE Level	JE Score
1. Communication & Relationship Skills	Provide and receive complex information; barriers to understanding  Communicate difficult statistical or theoretical data, research findings both orally and in writing; communicate complex patient related information to a patient or other health professional	4(a) (b)	32
2. Knowledge, Training & Experience	Highly developed specialist knowledge, underpinned by theory and experience.  Specialist knowledge of research techniques, analysis and use of information; specialist knowledge of specific clinical conditions underpinned by degree and post-graduate level training, experience to masters level equivalent	7	196
3. Analytical & Judgemental Skills	Complex facts or situations requiring analysis, interpretation, comparison of a range of options.  Analysis and interpretation of statistical/ analytical/ research outcomes and queries; judgements regarding a range of clinical issues or complex patient conditions.	4	42
4. Planning & Organisational Skills	Plan and organise complex activities or programmes, requiring formulation, adjustment  Plan and co-ordinate multi-disciplinary activities, research programmes	3	27
5. Physical Skills	Developed physical skills; advanced sensory skills; manipulation of objects, people; narrow margin for error/ Highly developed physical skills, high degree of precision.  Use of clinical equipment; physical skills to assess and diagnose patients/ dexterity, co-ordination and sensory skills for assessment & treatment of patients, clients e.g. manipulation, suturing, intubation.	3(a)(b) - 4	27-42
6. Responsibility for Patient/Client Care	Develop programmes/ specialised programmes of care/care packages; specialist / highly specialist clinical technical services; provide specialised/ highly specialised advice in relation to care.  Assess, diagnose and implement care for patients, clients in a non specialist/specialist area; carry out specialist / highly specialist therapeutic or diagnostic procedures; provide specialist/ highly specialist advice to patients, clients	5(a) (b) (c)-6(a) (b) (c)	30 -39
7. Responsibility for Policy/Service Development	Implements policies and propose changes to practices, procedures for own area/Propose policy or service changes, impact beyond own area  Contribute to the implementation of research findings into clinical practice and service development / impacts on other areas, agencies.	2-3	12-21
8. Responsibility for Financial & Physical Resources	Personal duty of care in relation to equipment, resources/Authorised signatory, small payments.  Personal duty of care for equipment used/authorised signatory for small cash or financial payments	1-2d	5-12

Factor	Relevant Job Information	JE Level	JE Score
9. Responsibility for Human Resources	Professional/ clinical supervision; Provide/ Teach/ deliver training in own discipline/specialist training  Supervises work of less experienced staff; undertakes training in clinical/ research/audit skills & methods/undertakes specialist training in clinical or research methods.	2(b) c)- 3(c)	12-21
10. Responsibility for Information Resources	Occasional / Regular requirement to develop and create reports, documents  Use advanced software to create reports and analyse and manoeuvre data	2-3	9-16
11. Responsibility for Research & Development	R&D activities as major job requirement  R&D activities are a central part of work activity with dedicated time for their completion	3	21
12. Freedom to Act	Broad occupational policies  Works within codes of practice and guidelines, accountable for own professional action, lead practitioner	4	32
13. Physical Effort	Frequent light effort for several short periods; Occasional light effort for several long periods;  Pushing or lifting equipment	2(b)(c)	7
14. Mental Effort	Frequent concentration; work pattern predictable  Concentration for assessment of patients, treatment and research activities	2(a)	7
15. Emotional Effort	Occasional exposure to distressing or emotional circumstances.  Patients with terminal illnesses, challenging behaviour; pressures to complete research on time	2(a)	11
16. Working Conditions	Occasional unpleasant conditions Odours, fleas, lice	2(a)	7
JE Score/Band		Band 7	477-533



# **Profile Label: Clinical Researcher Principal**

**Job Statement** 1. Manage or co-ordinate research projects, including their development design and implementation

- 2. Provide expertise and guidance on Research and Development projects within the multi disciplinary team, across the organisation and in the wider health community; disseminate research findings & promote research culture.
- 3. Holds specialist caseload and leads changes to clinical practice and service using specialist expertise, by integrating research findings into existing clinical practice within own service
- 4. Participate in the education and training of own or other health professionals in area of specialism

Factor	Relevant Job Information	JE Level	JE Score
1. Communication & Relationship Skills	Provide and receive highly complex , sensitive or contentious information:cooperation required present complex information to large groups  Communicate difficult statistical or theoretical data both orally and in writing; communicate complex patient related information to a patient or other health professional/ presentations of research findings to large groups Disseminate research findings through a range of appropriate media	5 (a) (b)	45
2. Knowledge, Training & Experience	Highly developed specialist knowledge, underpinned by theory and practical experience.  Specialist knowledge of research techniques, analysis and use of information; specialist knowledge of specific clinical conditions underpinned by degree and post-graduate level training, experience to masters level equivalent	7	196
3. Analytical & Judgemental Skills	Complex facts or situations requiring analysis, interpretation, comparison of a range of options.  Analysis and interpretation of complex statistical/analytical/research outcomes and queries; judgements on a range of clinical issues or complex patient conditions.	4	42
4. Planning & Organisational Skills	Plan and organise complex activities or programmes, requiring formulation, adjustment  Plan and co-ordinate multi-disciplinary research activities/plans and coordinates research projects	3	27
5. Physical Skills	Developed physical skills; advanced sensory skills; manipulation of objects, people; narrow margin for error/Highly developed physical skills, high degree of precision.  Use of clinical equipment; physical skills to assess and diagnose patients/ dexterity, co-ordination and sensory skills for assessment & treatment of patients, clients e.g. manipulation, suturing, intubation.	3 (a) (b) -4	27-42
6. Responsibility for Patient/Client Care	Develops programmes of care/care packages; specialist programmes/care packages; provides specialist/highly specialised advice in relation to care; provides clinical/ technical services;/highly specialist services  Assesses, diagnoses and implements care for patients, clients in a specialist area; carries out specialist/highly specialist therapeutic or diagnostic procedures; provide specialist/ highly specialist advice to patients, clients or staff concerning care See comment re job statement. This point may be about providing advice/supervision to other staff rather than patient caseload	5 (a)(b)(c) - 6(a)(b) (c)(c)	30-39
7. Responsibility for Policy/Service Development	Propose policy or service changes, impact beyond own areas  Develops policy for speciality, impacts on other areas/agencies.	3	21

Factor	Relevant Job Information	JE Level	JE Score
8. Responsibility for Financial & Physical Resources	Authorised signatory large payments; Holds delegated budget  Authorised signatory for financial payments/manages delegated research budget	3(a)(d)	21
9. Responsibility for Human Resources	Day to day management; Teach/deliver specialist training  Day to day management of research team; undertakes specialist training in clinical or research methods.	3(a) (c)	21
10. Responsibility for Information Resources	Regular requirement to develop or create reports, documents.  Use advanced software to create reports and analyse and manoeuvre date	3(b)	16
11. Responsibility for Research & Development	Coordinate, implement R&D activities/Initiate and develop R&D activities  Coordinates research programmes/initiates research programmes	4-5	32-45
12. Freedom to Act	Broad occupational policies  Works within codes of practice and guidelines, accountable for own professional action, lead practitioner	4	32
13. Physical Effort	Frequent light effort for t several short periods/Occasional light effort for several long periods; Pushing or lifting equipment	2(b)(c)	7
14. Mental Effort	Frequent concentration; work pattern predictable  Concentration for assessment of patients/treatment and research activities	2(a)	7
15. Emotional Effort	Occasional distressing or emotional circumstances.  Patients with terminal illness, challenging behaviours, rare abnormalities/dealing with staff where changes to practice are indicated	2(a)	11
16. Working Conditions	Occasional unpleasant conditions Odours, fleas, lice	2(a)	7
JE Score/Band		Band 8a	542-579



## **Profile Label: Clinical Researcher**

- Job Statement 1. Manage external and internal research and development projects/programmes, ensuring quality of development, design and implementation
  - 2. Holds research budget/delegated budget responsibility, participate in obtaining funding for research and development within the organisation/service
  - 3. Act as a source of expertise and guidance on research and development projects/programmes across the organisation and the wider health & academic community; develop clinical practice and service, disseminate research findings & promote research culture.
  - 4. Work in partnership with academic institutions to develop education and training of own or other health professionals
  - 5. Acts as a source of advice and guidance to specialist clinicians directing change to patient care/may carry own specialist case load to inform research

Factor	Relevant Job Information	JE Level	JE Score
1. Communication & Relationship Skills	Provide and receive highly complex sensitive or contentious information; significant barriers to understanding; Presenting complex, sensitive or contentious information to a large group.  Communicate highly complex and contentious condition related information to patients or other health professionals/research staff/ presents research orally or published externally to national/international audiences	5(a)(b)	45
2. Knowledge, Training & Experience	Advanced theoretical and practical knowledge  Specialist knowledge of research techniques, analysis and use of information; plus advanced knowledge of specific clinical conditions underpinned by degree and post-graduate level research, study and experience to doctorate level equivalent	8 (a)	240
3. Analytical & Judgemental Skills	Highly complex facts or situations requiring analysis, interpretation, comparison of a range of options.  Analysis and interpretation of highly complex statistical, analytical, research outcomes; judgements regarding a range of clinical issues and/or highly complex patient conditions.	5	60
4. Planning & Organisational Skills	Plan and organise complex activities or programmes, requiring formulation, adjustment /Plan and organise broad range of complex activities; formulates, adjusts plans or strategies  Plan and co-ordinate significant multi-disciplinary research activities Plan and co-ordinate large scale research projects or programmes	3-4	27-42
5. Physical Skills	Developed physical skills; advanced sensory skills manipulation of objects, people; narrow margin for error/Highly developed physical skills, high degree of precision.  Use of clinical equipment, physical skills to assess and diagnose patients/dexterity, co-ordination and sensory skills for assessment & treatment of patients, clients e.g. manipulation, suturing, intubation.	3(a)-(b) - 4	27-42
6. Responsibility for Patient/Client Care	Develops programmes of care/care packages; specialist programmes/care packages; provides specialist/highly specialised advice in relation to care; provides clinical/ technical services;  Assess, diagnose and implements care for patients, clients in a specialist area; carries out specialist/highly specialist therapeutic or diagnostic procedures; provide specialist/ highly specialist advice to staff or patients, clients concerning care	5- (a) (b) (c) -6(a) (b) (c) (c)	30-39



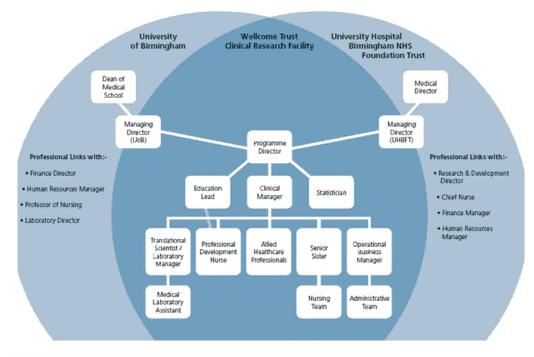
Factor	Relevant Job Information	JE Level	JE Score
7. Responsibility for Policy/Service Development	Propose policy or service changes, impact beyond own area.  Develops policy for speciality, impacts on other areas/agencies.	3	21
8. Responsibility for Financial & Physical Resources	Aurthorised signatory, small payments/ Holds delegated budget /Hold budget for a department, service  Manages delegated research budget/ Holds research budget.	3(d) - 4(a)	21-32
9. Responsibility for Human Resources	Day to day management; teach/deliver specialist training  Manage research team; delivers specialist training in clinical or research methods.	3(a) (c)	21
10. Responsibility for Information Resources	Regular requirement to develop or create reports, documents  Use advanced software to create reports; analyses and manipulates data	3	16
11. Responsibility for Research & Development	Co-ordinate, implement R&D activity as a job requirement/Initiate, develop R&D activities/ Initiate, develop R&D programmes, impact outside organisation.  Initiates research programmes/ impact across NHS and outside	4-5-6	32-45-60
12. Freedom to Act	Broad occupational policies/General policies, need to establish interpretation  Works within codes of practice and guidelines, accountable for own professional action, lead practitioner /Interprets national policies for specialist area	4-5	32-45
13. Physical Effort	Frequent light effort for several short periods/Occasional light effort for several long periods;  Pushing or lifting equipment	2(a)(b)	7
14. Mental Effort	Frequent concentration; work pattern predictable  Concentration for assessment of patients, treatments and for research activities	2(a)	7
15. Emotional Effort	Occasional exposure to distressing or emotional circumstances.  Patients with terminal illnesses, challenging behaviour, rare abnormalities;managing change; time/budgetary pressures for research activity	2(a)	11
16. Working Conditions	Occasional unpleasant conditions; Odours, fleas, lice	2(a)	7
JE Score/Band		Band 8bcd	604-695

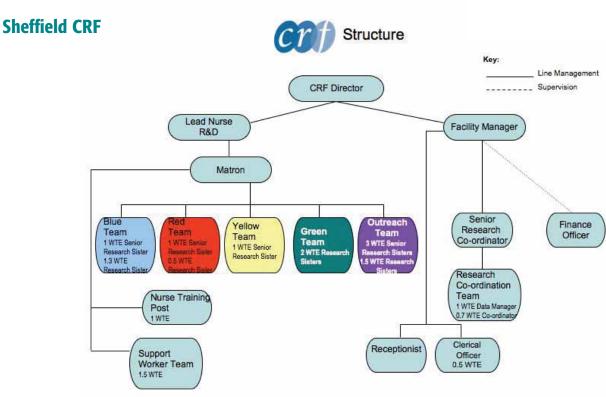
# **APPENDIX C**

# Organisational Charts for Clinical Research Facilities (CRFs)

# **Birmingham CRF**

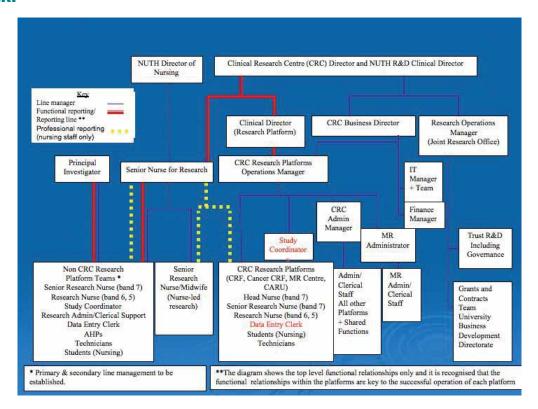
# Wellcome Trust Clinical Research Facility Organisational Chart



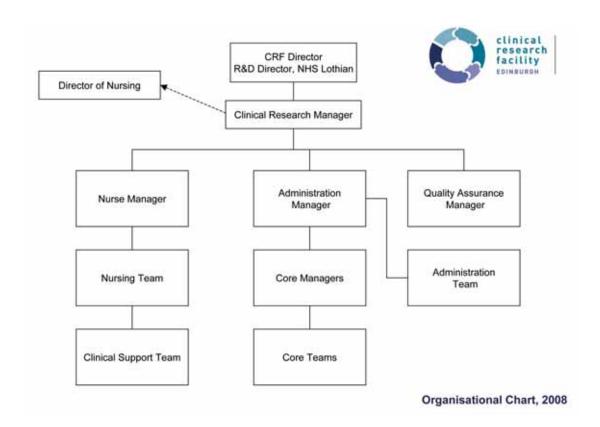




#### **Newcastle CRF**



# **Edinburgh CRF**



# **APPENDIX D**

# Consultation Phase Instruments

# **Nurses and Midwives working in Medical-led clinical trials**

**Project Consultation Phase: short biography.** (Office use only) Consultation Number:

Dear colleague
Many thanks for agreeing to participate in the consultation phase of this project. Before the formal interview/focus group, I'd appreciate if you would complete the following short anonymous questionnaire which focuses on some biographical details. It takes about 5 minutes to complete. This is so that I can compile a profile of participants for this phase of the project. Please indicate the information that best describes you own current situation using a highlighter. If you so wish, you may expand on some of these issues in the interview.
If you have any queries, please do not hesitate to ask.
Many thanks
Sarah Condell

Suran Conden
<b>Age:</b> 20-29. 30-39. 40-49, 50-59, 60+
<b>Number of years nursing:</b> 1-5 yrs, 5-10 yrs, 10-15 yrs, 15-20 yrs, 20+ yrs
Number of years in CRN role: <2yrs, 2-5 yrs, 5-10 yrs, 10-15 yrs, 15-20 yrs, 20+ yrs
I work in a team of clinical research nurses or single-handed as a clinical research nurse
I work full-time  or part-time  (approx hours per week =)
My salary is equivalent to the rate for $\square$ S/N, $\square$ CNM1, $\square$ CNM2, $\square$ CNM3,
other (specify)
My contract is with the hospital or university or other (specify)
My contract is permanent or temporary
I ☐ have/ ☐ have not a written job description
I $\square$ have/ $\square$ have not a formal professional relationship to nursing within the hospital.
My current educational level is:  Certificate,  Diploma,  Degree,  Masters,  PhD
My educational level at entry to the role was:   Certificate,   Diploma,   Degree,   Masters,   PhD
The research area I currently work with has $\  \  \  \  \  \  \  \  \  \  \  \  \ $
I work with $\ \square$ children and adolescence, or $\ \square$ adult or $\ \square$ across the lifespan
The disease areas I work with are $\square$ cancer, $\square$ haematology, $\square$ cardiovascular, $\square$ diabetes, $\square$ gastrointestinal, $\square$ hepatology, $\square$ respiratory, $\square$ vascular, $\square$ infectious disease obstetric/midwifery, $\square$ mental health,
other – please specify
I am keen to contact other nurses or midwives who work is this role.
Do you know of any such person who you think would be willing to talk to me.   No Yes
If yes, name and contact details



# **CRN project – interview schedule**

#### Dear colleague

Thank you for agreeing to participate in this consultation by interview or focus group. If you have no objection the proceedings will be audio-taped and when transcribed, I will send you a copy of the transcript for verification. All information will be treated confidentially. All identifiers will be removed or changed in the transcripts. If there is any content that you do not wish to be included in the analysis, this should be indicated at this verification stage. The transcripts will not be released as a whole, however quotes may be used in the final report. All transcripts will be destroyed once the report is published. If you decide not to be audiotaped, I will record notes and send these to you for verification instead. This schedule is a guide: should you wish to say anything additional, please do so.

If you have any queries, please ask. Again thank you for your time and interest.

Sarah Condell

What attracted you to clinical research initially?

Explanation of the current job – has this differed from other roles you've held in clinical research and how? Do you have formal involvement in protocol development, interpretation of results or dissemination of findings? What have been the skills development on the job?

Currently what is your level with satisfaction/dissatisfaction with role and why?

Do you see further scope for expansion of role – any likely drivers/barriers to that expansion?

What benefits does your role bring to the patients?

In your opinion, how has the role contributed to the development of nursing and midwifery?

What formal professional development have you undertaken, what informal professional development have you had, opportunities for training, own research?

From the literature review two issues emerge – Isolation and Autonomy. Have you any comments to make on either?

Anything not addressed in the above or in the biog sheet?

What would you like to see in a resource pack?





An Chomhairle Náisiúnta d'Fhorbairt Ghairmiúil an Altranais agus an Chnáimhseachais