our work

Celebrating the Clinical Research Nurse 2014
Clinical Research Nurses are one of the most important professions in the NIHR – the research that they make happen underpins everything we do

In May 2013 I attended the first NIHR meeting to celebrate the work of Clinical Research Nurses and was inspired by the energy, enthusiasm, and excellence of everyone I met.

As part of that event, I was honoured to launch the booklet Our Voices, a collection of case studies about the role of clinical research nurses. Their stories highlighted the amazing diversity of the role, the adaptability of the individuals, and their commitment to delivering better care for patients through clinical research.

One of the purposes of the meeting was for clinical research nurses to share their experiences – of opportunities, of challenges, and of successes – through posters that were exhibited throughout the day. We want to bring those experiences to a wider audience through this booklet Our Work.

The case studies presented in this booklet address issues that are of central importance to the clinical research nurse including training and development; improving patient experience; patient recruitment; research management and delivery; and the care of patients participating in research.

Thank you to all those who agreed to have their poster published in Our Work.

I hope this collection will provide ideas and inspiration to all those who are interested in the role of the clinical research nurse - whether they are in an established post, have recently joined the profession, or are considering moving into this exciting and fulfilling career.

Dr Russell Hamilton CBE
Director of Research and Development
Department of Health

Their stories highlighted the amazing diversity of the role, the adaptability of the individuals, and their commitment to delivering better care for patients through clinical research
AIM OF THE WORK
In association with the North West Research Workforce Development & Education collaborative (NWRWD & E), the aim of this work was to introduce an induction framework for developing and supporting the current and future clinical research network workforce across the North West as part of a pan regional strategy. This is a continuous process commencing on induction to maximise individuals’ engagement from day one in their NIHR role.

WHY WAS IT IMPORTANT?
Key development programmes were identified as a minimum requirement within the first 3-6 months for staff commencing in a clinical research post i.e. Good Clinical Practice/Essential Skills Study Management/Valid Informed Consent to speciality specific training and mentoring/job shadowing constituting in a robust talent management programme. Local training is delivered by network and Trust based staff via the Train the Trainer approach therefore establishing a cohort of network facilitators for the local delivery of some of the programmes i.e. Essential Skills programme.

WHEN WAS THE WORK UNDERTAKEN AND OVER WHAT PERIOD?
The Induction Framework was initially proposed in 2011 and became part of the Delivering Education work stream in April 2012. This task and finish group, facilitated by the C & M CLRN Lead Nurse and Trust/Network representatives, planned and designed the Essential Skills study management programme, which is now facilitated by a cohort of research practitioners.

WHAT WAS THE ISSUE IT ADDRESSED AND WHY WAS IT IMPORTANT?
The diversity of experience of new staff joining a Clinical Research Network can result in a composition of staff that has a varied range of exposure to clinical research. The framework was seen as a way of overcoming the shortfall of suitably experienced trainers/facilitators and meeting the demand for research-skill training locally. Although many good induction programmes were in existence across research areas, there was a lack of consistency and collaboration which often resulted in duplication in many areas.

WHAT WERE THE OUTCOMES?
There is now a framework in place to ensure staff receive the information needed to perform well in their roles, as well as a solid foundation for their on-going professional learning establishing them on a research career pathway. This will result in bringing out the greatest potential of our research workforce by providing them with opportunities for training and career development, updating them in research nursing practices and constantly exposing them to the advances in the field of clinical research.

HOW HAS THIS WORK BEEN DISSEMINATED?
The work and training programmes of the NWRWD & E are widely established across the North West and are advertised on the NIHR Learner Management system (LMS).
AIM OF THE WORK
The project aims to assist research teams with the practical aspects of undertaking and managing research studies by providing access to a toolkit of resources and training materials to embed best practice across the Network.

WHEN WAS THE WORK UNDERTAKEN AND OVER WHAT PERIOD?
The work started in Autumn 2012 and is currently on-going.

WHAT WAS THE ISSUE IT ADDRESSED AND WHY WAS IT IMPORTANT?
The Study Management Project aims to provide researchers across the CRN with tools and resources to manage studies effectively to time and target in line with NIHR High Level Objectives.

WHAT WAS DONE?
A Subject Matter Expert (SME) was appointed to provide support and direction from a Local CRN study delivery and workforce perspective. The SME worked with the NIHR Clinical Research Network Coordinating Centre (NIHR CC) team one day a week for 3 months to help get the project off the ground. This involved contributing to the delivery of Network wide events to ensure the project received input from all parts of the CRN and beyond.

WHAT WERE THE OUTCOMES?
A study management framework has been defined and tools have been collected from across the CRN which will form the basis for tools and resources to be shared across the Network.

WHAT LESSONS WERE LEARNT?
This project has been successful to date thanks to the input of many contributors from across the CRN and the wider clinical research community. It has been encouraging to observe the willingness of others to share and contribute their ideas and methods of working as part of this project.
Initiatives to embed research activity alongside routine clinical care to improve the patient experience

Nathaniel Mills Lead Nurse
South Yorkshire Comprehensive Local Research Network

AIM OF THE WORK
To recruit a senior research nurse to meet the organisations and Comprehensive Local Research Network (CLRN) objectives with limited resource.

WHEN WAS THE WORK UNDERTAKEN AND OVER WHAT PERIOD?
The work was undertaken from June 2012 and is on-going.

WHAT WAS THE ISSUE IT ADDRESSED AND WHY WAS IT IMPORTANT?
To employ a senior nurse for the South Yorkshire CLRN to embed within the member organisation. In the past the senior nurse role had seen limited success and a new approach was needed to break down barriers and further increase research within the member organisation.

WHAT WAS DONE?
Working closely with the lead nurse who provided guidance for research within the member organisation, we split a traditional band seven role into 2 separate roles, one half of the role was an experienced member of the CLRN nursing team who was an expert in research delivery but had little management experience. The other half was a senior nurse from within that member organisation who knew the Trust inside out and could provide the relevant steer to engage with groups of staff who had not engaged with research in the past. Therefore the joint role began working together with the short term goals of engagement of the whole organisation, increasing the research visibility, bringing trust employed nurses line management and training and education needs in line with the nurses from the CLRN that were based at that member organisation.

WHAT WERE THE OUTCOMES?
The joint role has provided stability, an expert leadership approach in management and research delivery and engagement from Board level to clinical based staff. Matrons and specialist nurses involvement will help the Trust meet high targets of studies where specialist nurse involvement is imperative. The specialist nurses have begun to see research as a way of improving the lives of their patients rather than a higher workload. Due to this joint role, research and clinical based nurses are working together to share knowledge. Research nurses are imparting expertise in care pathways and the informed consent process.

WHAT LESSONS WERE LEARNT?
Logistic issues might have prevented this role ever happening. Dedication of the project by the member organisation and the CLRN has allowed it to develop and exceed expectations.

HOW IS THIS APPLICABLE TO CLINICAL RESEARCH NURSING PRACTICE?
This role is seen as a benchmark for future working across Yorkshire and will play a key role engaging fully with clinical staff.

HOW HAS THE WORK BEEN DISSEMINATED?
It has been discussed at various forums throughout the member organisations, displayed and discussed on clinical trials day and during the ‘OK to ask’ campaign about the accessibility of research nurses. It has also been highlighted as an area of good practice on the Yorkshire wide transition forum.

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**AIM OF THE WORK**
To seek the views of paediatric clients to allow reflection upon practice, demonstrate respect of their opinions and positively influence future study design.

**WHEN WAS THE WORK UNDERTAKEN AND OVER WHAT PERIOD?**
The NIHR Southampton Biomedical Research Unit (now Centre) in Nutrition Diet and Lifestyle conducted a longitudinal study of children with Crohn’s disease between December 2010 and April 2013. The children were recruited at diagnosis when acutely unwell. Families were asked to attend our research facility for seven visits over the course of one year for a significant number of interventions. The children and families were invited to complete a service evaluation questionnaire at the end of their respective study year.

**WHAT WAS THE ISSUE IT ADDRESSED AND WHY WAS IT IMPORTANT?**
How paediatric clients and their families felt about being approached to participate in research when acutely unwell and how they perceived the care received. Acknowledging participant perspective is important to ensure better quality care.

**WHAT WAS DONE?**
A family feedback questionnaire was designed that reviewed being approached at diagnosis, provision of information, study tasks and overall experience. Of the 19 children who successfully completed the study 17 children and their families completed a total of 36 questionnaires. Individual child and parent responses were considered important.

**WHAT WERE THE OUTCOMES?**
All respondents reported research participation as a positive experience. 100% felt able to ask questions and say no if they didn’t wish to participate in any parts of the study. 88% were satisfied with being approached at diagnosis and felt they fully understood the written study information. 73% acknowledged they were happy with all elements of the study and 100% felt appreciated and thanked.

Positive attributes of the research nurse identified included calmness, mutual respect, an approachable supportive knowledgeable listener, constancy of research staff throughout and the integration of research into clinical care.

Quotes from individuals:
- “I think the whole experience has made my child feel it is not an illness to hide from”
- “I am looking forward to being invited to join another research study”
- “I feel glad that I have taken a short time out of my life to benefit others”

**WHAT LESSONS WERE LEARNT?**
Acutely unwell children and families can have a positive experience of research participation. It recognised a need to support families as they transition out of an intense research programme. This evaluation has identified a group of families enthusiastic to engage and contribute to future translational research.

**HOW IS THIS APPLICABLE TO CLINICAL RESEARCH NURSING PRACTICE?**
There is a need to recognise families see, in the first instance, ‘a nurse’ and may not make a distinction between different roles and specialities. Evidence shows they value the provision of an effective interface between all those involved in their care.

**HOW HAS THIS WORK BEEN DISSEMINATED?**
This work has been shared at the paediatric research nurse forum and the poster is displayed in the department for all to read. Patient public experience and communication teams are involved to progress what has been learnt.

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Non-medical academic training programme: A nurse’s experience

Naomi Young  
Research Nurse  
Cambridge NIHR Clinical Research Facility

AIM OF THE PROGRAMME

The aim of the Clinical Non-Medical Training programme is to educate and facilitate a career pathway for clinicians looking to develop careers in academia whilst actively working on the front line.

WHAT WAS DONE?

A literature review was conducted asking ‘What are the experiences of patients participating in medium-high intensity clinical research?’ in order to provide a basis for research into how nurses can improve the experience of this emerging patient-group in line with the NICE Quality Standard for Patient Experience.

WHAT WAS THE OUTCOME?

The review showed that few studies have been undertaken in this area. The most significant theme emerging from the literature was ‘confusion’. Patients’ experiences fell into three categories; ‘avoidable problems’, ‘inevitable burdens’ and ‘compensations’.

The authors’ recommendations are that research professionals keep participants informed by clear and frequent communication, feedback results, involve participants, individualise care, plan ahead, follow-up, build positive relationships and show recognition of participants’ contribution. A key message was that with careful planning that takes the participant into consideration at every stage, problems can be avoided, burdens made easier to cope with and compensations enhanced.

HOW IS THIS APPLICABLE TO CLINICAL RESEARCH NURSING PRACTICE?

There is need for a conceptual model of the role of the research nurse and to develop one that identifies the nurse as the link between the medical and scientific domains and the patient. An increased understanding of the role in relation both to the patient and to other professionals has the potential to empower nurses to advocate for patients, for example by being involved at an early stage of study planning or facilitating patient and public involvement.

HOW WAS THIS WORK BEEN DISSEMINATED?

The work has been presented at the Cambridge Research Nurse Seminar and the NIHR Research Clinical Research Meeting, disseminated among my colleagues at the CRF and was presented at the UK CFR Conference 2013.

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The role of the Clinical Research Nurse: An empirical evaluation of the day-to-day activities of the Clinical Research Nurse in a district general hospital

Lisa Hyatt  Specialist Research Nurse
Emma Munro  Trust Lead Research Nurse
Portsmouth Hospital NHS Trust

AIM OF THE WORK
To establish the core elements of the daily role of the Clinical Research Nurse (CRN) in a district general hospital (DGH).

WHEN WAS THE WORK UNDERTAKEN AND OVER WHAT PERIOD?
Data was collected over one week in November 2010 and March 2013.

WHAT WAS THE ISSUE IT ADDRESSED AND WHY WAS IT IMPORTANT?
The role of the CRN has evolved over the last decade and there has been a shift away from being simply a data collector (Green, 2011), to a role that is varied, challenging and encompassing a wide range of professional skills (Spilsbury et al, 2008; Watmough et al, 2010; RCN, 2011). However, existing evidence to support the role of the CRN is largely descriptive and anecdotal. Locally, nursing colleagues and managers have little understanding of the role of the CRN and do not identify it as patient facing. Therefore, an empirical evaluation of the core activities of band 6 CRNs across several clinical specialties was performed.

WHAT WE DID?
A novel data collection tool was collaboratively designed to capture core elements of the CRN daily role. CRNs (n=24 in 2010; n=9 in 2013) used the tool to record the frequency of their daily activities. Data was then collated into categories and analysed.

WHAT WERE THE OUTCOMES?
It was identified that, locally, CRNs are actively involved in all stages of the clinical trial process. CRNs spent the largest proportion of time per week performing clinical trial activities that involved direct contact with a patient at both the 2010 and 2013 data collection points (44.09% and 52.82% respectively). These activities included identifying patient cohorts, screening, consent, trial assessments, data collection, follow-ups and patient education. CRNs also spent a good proportion of time performing lab and office based tasks directly related to study protocols (29.27% and 22.70% respectively) and general administrative tasks (20.47% and 20.33% respectively). It was also identified that CRNs see a greater number of patients per week than the number recruited into studies.

WHAT LESSONS WERE LEARNT?
This empirical evaluation provided vital data to begin to benchmark the local CRN role. The results provided confirmation that the CRN role is mainly patient-facing, therefore their potential impact on the patient journey is evident. However, further evaluation is required to establish the burden of screening and follow-up, and the average size of caseload per CRN.

HOW IS THIS APPLICABLE TO CLINICAL RESEARCH NURSING PRACTICE?
The results supported the anecdotal and descriptive evidence for the CRN role being varied and encompassing a wide range of skills. Empirical evidence to highlight the core elements of the CRN role will support the development of training and induction programmes for new staff, and raise awareness of the work undertaken by CRNs.

HOW HAS YOUR WORK BEEN DISSEMINATED?
The preliminary data was shared with local CRN colleagues and presented at the Celebrating Clinical Research Nurses meeting.

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Sue Beatty  Clinical Research Nurse
Rachel Franklin  Clinical Research Nurse
Sandie Wellman  CRUK Consultant Nurse
University of Oxford, Oxford University Hospitals

AIM OF THE WORK

The aim of the Oxford Research Network is to foster an open and constructive environment in which those working in research can share knowledge, experience and information. This group provides an opportunity to:

- Network in an open and constructive environment
- Provide access to local expertise
- Promote educational and support needs of its members
- Be part of a supportive and developmental environment
- Offer a point of access for others who want to engage with the clinical research community

WHEN WAS THE WORK UNDERTAKEN AND OVER WHAT PERIOD?

The current network was started in 2011 and is on-going.

WHAT WAS THE ISSUE IT ADDRESSED AND WHY WAS IT IMPORTANT?

The Oxford University Hospitals & University of Oxford Research Network Forum was established in 2011 and offers an opportunity for nurses, co-ordinators, data managers and others working in clinical research to get together at quarterly meetings. It provides a contact point for all those working in research across the Trust and University, especially those outside the established Networks.

WHAT WAS DONE?

The Oxford Research Network meets quarterly for 1 hour usually at lunchtime. The meetings are open to anyone working in clinical research across the Trust and University. The Network held its first conference in May 2012 with an attendance of over 150 delegates. Meetings take place across three different hospital sites and across the week to maximise access for all research staff.

The Network topics include:

- Medicines and Healthcare Products Regulatory Agency Inspection Feedback
- Delegation and Accountability in Clinical Research
- Patient Recruitment in Clinical Research
- Meet the Networks – speakers from the CRN, DRN and CLRN
- Public Involvement in Research
- A Day in the Life of… includes a variety of roles within research
- December meetings are a debate or ‘Question Time’ panel

WHAT WERE THE OUTCOMES?

- The meetings regularly attracts between 40 and 80 people across the research community
- The Committee email account provides useful network resource for members between meetings
- A Joint University and Trust meeting encouraged direct communication and sharing
- Facilitate speakers from both local and national initiatives

WHAT LESSONS WERE LEARNT?

Providing a forum gradually develops a resource for research teams that is based on peer support.

HOW IS THIS APPLICABLE TO CLINICAL RESEARCH NURSING PRACTICE?

It helps support the education and training needs of those working in research locally and provides the opportunity to share ideas and adopt examples of best practice.

HOW HAS THE WORK BEEN DISSEMINATED?

A network contact database and information about meetings are maintained and any information thought to be useful is distributed. The quarterly meetings are advertised through poster display and the Research and Development newsletter circulated via our Joint Trust/University Research office.

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BACKGROUND
The NIHR/Wellcome Trust Clinical Research Facility (CRF), Cambridge hosts both adult (n = 96) and paediatric studies (n = 30). All areas are multifunctional to accommodate both adults and children. The CRF is committed to ensuring the children have a positive experience of research within the facility. Children have different concerns and needs to an adult when coming into hospital; these were not being fully addressed and needed exploring further.

Actively encouraging children to become involved with clinical research can help to ensure that they receive appropriate, safe and effective treatment and care in the future. We wanted the children to help us shape our research and their experience as participants.

AIM OF THE PROJECT
• To enhance the experience of young people at the Cambridge CRF (which caters for both adults and children)
• To inform the design of future local metabolic studies for children
• To generate promotional artwork
• To engage the media in promoting the work of the CRF and NIHR

A children’s survey was created to obtain views from participants, patients and siblings of our facilities and suggestions for improvement. This survey was completed over a two month period from October to December 2012, with ages ranging from 7 to 16 years. All were asked if they would like to be Non-Executive Members of our Children’s Board. A board meeting was held on 2 February 2013 where six board members listened to a short presentation of the findings from the children’s survey. They also had the opportunity to try out some of the equipment in our metabolic research area and completed tick lists on their experiences which has enabled the research team to adjust an adult research protocol to be paediatric focused. The day was covered by BBC TV, radio and the local newspaper.

THE RECOMMENDATIONS FROM THE CHILDREN’S BOARD INCLUDED:
• To produce child friendly information booklets for children attending the CRF
• To develop age specific virtual tours for children attending the CRF for a research visit which can be accessed via the internet
• To purchase further entertainment supplies for children of all ages
• To ensure all nursing staff caring for younger children are wearing colourful tabards

A short video was produced; brilliantly conveying the fun children had, this has been disseminated widely within the Trust. Three children’s information booklets, a children’s activity menu and a web page have been completed. All are currently being reviewed by the Children’s Non Executive Board members and the local young person’s group. A board member, Jamie Maw aged 14 has written articles about his experiences which have been published in the Clinical Local Research Network biannual newsletter.

Encouraging and involving children to feel part of the clinical research experience is essential for advancing child health. Delivering care tailored to the needs and concerns of children attending the (CRF) is our ultimate goal.

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The AIMS OF THE PROJECT

• Provide a patient centred Stroke Research Service
• Provide a strong visible presence for Stroke Research
• To widen opportunities to participate in Stroke Research
• Share a common language and understanding
• Create a problem solving tool
• Help achieve NIHR objectives and develop a culture of continuous improvement

PROJECT SUMMARY

The 4 P's of Research consists of:

PATIENT - Identify where the patient meets the pathway
PATHWAY - Know the patient pathway
PROTOCOL – Have a protocol for where the patient meets the pathway
PERSON – Have a researcher available at that point to offer the study

This tool empowers staff to learn about their organisation by thinking in terms of the patient's pathway, and considering important questions including:

• Is there a protocol at all parts of the pathway?
• Are there issues with implementing the protocol?
• Can we offer the patient a study within the appropriate time frame? And if not, why not?
• Who is the person able to influence change?

The objective is to provide a patient centred research service that mirrors the patient pathway, whilst meeting NIHR objectives.

A strong visible presence of Stroke Research across the patient pathway involving the use of posters and promotional material.

A strong visible presence of the results from previous studies.

A strong visible presence of the Stroke Research team in each of the hospitals.

Notice boards communicating key messages for staff, patients and relatives.

Visible information for staff in all clinical areas.

IMPACT AND OUTPUTS

Utilizing the 4 P's of Research we aim to meet NIHR set High Level Objectives, widen participation in research (opportunity to participate) and meet Time to Target (First Patient).

The 4 P's project has been extended and has now been implemented within other sites in Yorkshire.

We have created a video explaining the 4 P's application in York which is posted on YouTube.

Increased visibility of Stroke Research has improved awareness of Stroke Research for patients, relatives, public and all staff groups.

In summary, thinking in terms of the 4 P's, increasing the visibility of research in clinical areas and engaging with staff at all points along the care pathway is improving the research service to patients and making research part of clinical care.

See the 4 P's video http://bit.ly/1jobis5

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The 4 P’s of Research

Michael Keeling, Clive Nicholson and Mia Porteous

York Stroke Research Team

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Shifting up a gear: Active monitoring of 3C study recruitment in Norfolk and Waveney from January to April 2012

Sue Allen, Heather Leisham, Lynne Mather, Emma Rayfield, Barbara Stewart, Helen Macdonald  
Research Nurses

Primary Care Research Network (PCRN) East of England – previously hosted by Norfolk now S Norfolk CCG

AIM OF THE WORK
To describe and evaluate performance management and active monitoring of recruitment to the Cough Complications Cohort (3C) Study in Norfolk and Waveney by the Norfolk Primary Care Research Network (PCRN) research nurse team.

WHEN WAS THE WORK UNDERTAKEN AND OVER WHAT PERIOD?
The work was carried out for a trial period between January and April 2012.

WHAT WAS THE ISSUE IT ADDRESSED AND WHY WAS IT IMPORTANT?
Many general practices were slow to start recruitment to the 3C study and a significant number had failed to start recruitment at all. Competing demands and priorities of general practice meant that the 3C study sometimes slipped into the background. There was a risk that target recruitment numbers would not be reached.

WHAT WAS DONE?
A plan of active monitoring was developed that included a face to face PCRN training session that was offered to the clinicians involved in the 3C study at their practice. In addition, fortnightly telephone contact was made to an identified key individual within the practice team to ascertain latest recruitment numbers and offer support, advice and encouragement.

The monitoring team referred practices that required extra support to a practice employed Primary Care Research Network (PCRN) liaison nurse. The PCRN team also produced a monthly newsletter which contained helpful hints, anecdotes, news items and study updates. Information in graphical format showing current recruitment levels of all the participating practices, which nurtured the spirit of inter practice competition, was also included. A PCRN certificate of achievement was sent to the highest recruiting practice each month.

WHAT WERE THE OUTCOMES?
Recruitment improved dramatically during the 3 month period of active monitoring compared to the previous 6 months since the study had started. Local targets were exceeded and nationally, target recruitment was reached and the study closed to recruitment earlier than anticipated.

WHAT LESSONS WERE LEARNT?
Regular communication between the PCRN and practices helps to build relationships, foster collaborative working and promote the concept of research as ‘core business’ of the NHS. Positive feedback about active monitoring was received from practices.

HOW IS THIS APPLICABLE TO CLINICAL RESEARCH NURSING PRACTICE?
Increased recruitment rates demonstrated that active monitoring had helped to keep awareness of the 3C study in the foreground during the 3 month trial period and so was continued until the end of recruitment in April 2013. In future, active study monitoring of appropriate studies by PCRN nurses will be introduced from the outset. Clinical research nursing skills and knowledge was important to provide this kind of practice support.

HOW HAS THE WORK DISSEMINATED?
This active monitoring model has been replicated in other PCRN geographical areas in the East of England. The work has been publicised in poster format and exhibited at a regional Clinical Local Research Network (CLRN) meeting and the Society of Academic Primary Care conference 2013.

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Barriers to recruitment: CRASH-ILR Cardio-Renal Arrhythmia study in Haemodialysis patients using Implantable Loop Recorders: A cardiology study

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Dr P Kalra Consultant Cardiologist
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WHAT WAS THE ISSUE?
End stage renal disease patients on haemodialysis have documented high risk of sudden cardiac death. They are at risk of pathophysiological abnormalities that have the potential to be arrhythmogenic. Identification of these treatable arrhythmias is lacking. Therefore, this study was clinically indicated.

WHAT WERE THE OUTCOMES?
Barriers to recruitment, compounded by cross site and cross specialty working, were identified and overcome as they arose by close multidisciplinary team liaisons.

It proved problematic recruiting unstable patients. To overcome this, Renal Consultants and Research Fellows began screening at satellite units where patients were more stable. Approached by their Consultants and Registrars aided participation. An amendment was submitted to relax the initial strict inclusion/exclusion criteria.

One partially sighted patient was unable to use home phone line to download information from device. The use of phone signal to download data was initiated. Demand increased with recruitment, so use of a Carelink Express box was identified. Multiple patients can now download on one box located in dialysis unit.

HOW IS THIS APPLICABLE TO CLINICAL RESEARCH NURSING PRACTICE?
Unknown to the cardiology team, patients were admitted to hospital, due to fistula complications. To overcome this communication barrier, a link nurse was identified in the dialysis unit. The link nurse informs of any admissions/deaths, and is able to carry out wound checks, post-implantation. An amendment was submitted to clarify what is termed a splenic artery embolisation (SAE).

HOW HAS THIS WORK BEEN DISSEMINATED?
The team constantly reviewed barriers to recruitment, highlighting the areas which needed to be addressed. The team is the first centre globally to successfully recruit to such a study after several sites in the US had failed.

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Supporting NHS Trusts across Clinical Local Research Network London (South) to recruit within Reproductive Health

C Singh¹; L Gerrie¹; A Briley¹; AM Murtagh²; A Shennan¹
¹Guy’s and St Thomas’ NHS Foundation Trust; ²London South CLRN

AIM OF THE WORK
Two new strategic posts within Reproductive Health and Childbirth (RH&C) to support four additional South London NHS Trusts in taking forward recruitment to Clinical Local Research Network (CLRN) Portfolio Studies.

BACKGROUND
London (South) CLRN Reproductive Health & Childbirth (RH&C) Speciality Group is involved in numerous clinical trials, both as local investigators and in collaboration with others, nationally and internationally. Guy’s & St Thomas’ NHS Foundation Trust is the largest recruiter within RH&C in London (South), with an 11 strong research midwifery team. In 2011, prior to recruitment of two strategic research posts, Guy’s & St Thomas’ recruited the majority of participants across London South to Reproductive Health (32.5%).

WHAT WAS THE ISSUE IT ADDRESSED AND WHY WAS IT IMPORTANT?
Initial funding from the CLRN was to recruit a Research Midwife band 7 to undertake CLRN portfolio studies in London South NHS sites and provided day-to-day support.

It became apparent that a more senior strategic post was required and a Modern Matron post was funded by the CLRN to:

- Facilitate the dissemination of CLRN portfolio studies
- Liaise with Principal Investigators and Research and Development departments, other staff
- Supporting sites-funding application and guidance on studies
- Provide midwifery resource
- Manage the delivery of women’s health research including recruitment activities across the network

The remit of these posts included supporting the research midwives and clinical researchers to promote excellence in women’s health research across the London (S) CLRN. Assisting the adoption, setting up and running of clinical research trials in hospitals across South London.

WHAT WAS DONE
Strategies were developed to:

- Building research and clinical relationships in a multi-faceted and multi-way approach
- Being on hand to advise ‘how to…..’
- Being responsive to site-to-site variations and requirements
- Encouragement of site and team working - five site visits in 5 days and 2.5 days site visits for the strategic staff
- Good ‘in-house’ publicity for research studies and research in general
- Making research accessible and enjoyable to all
- Locally – developing a research team through the CLRN funding, by providing multi-study staff cover

WHAT WERE THE OUTCOMES?
CLRN research portfolio studies have been set up in all four of the additional South London NHS Trusts.

One Trust is now recruiting to four studies, and has increased recruitment to studies by 13%.

One Trust now has 3% of the total recruits to RH&C where initially they had no CLRN Portfolio Studies.

HOW HAS THE WORK BEEN DISSEMINATED?
A CLRN London (South & North West) study day for midwives has been set up and has proved invaluable. This is now planned for biannually, and open to other research midwives providing a sustainable service across NHS Trusts, making research accessible to all.

ACKNOWLEDGEMENTS
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AIM OF THE WORK
The NHS constitution commits to notifying patients of their research opportunities, which means that all NHS staff (not just those directly involved in research) should understand their role in delivering this key objective. Improving staff research awareness is one way that the NIHR Clinical Research Network has tried to improve research culture in the NHS. The Dementias and Neurodegenerative Diseases Research Network (DeNDRoN) is now targeting staff in the early stages of their careers and is behind a new programme of learning for student mental health nurses.

WHAT WAS DONE?
Thames Valley DeNDRoN joined forces with local universities to educate trainee nurses about the importance of research in dementia, and across the NHS. In Oxfordshire mental health nursing students attend for either day visits or are allocated for a 4-6 week full time placement with the team. In Buckinghamshire, DeNDRoN collaborates with the University of Bedfordshire to provide a two-day programme which includes a one-day workshop, followed by a day placement. This programme is a mandatory part of their training for all second year student mental health nurses. Staff at Thames Valley DeNDRoN have studied for a qualification to mentor students and support their learning.

WHAT WERE THE OUTCOMES?
A workshop provides a real insight into the realities of research and includes everything from recruitment and Patient and Public Involvement (PPI) to good clinical practice and research governance. It aims to ‘demystify research’ and to explain what research nurses actually do on a day-to-day basis. It is important for today's students to have a clear understanding of research culture within the NHS. It is important that nurses and clinicians see us as researchers working alongside them.

Regular placements offered to students usually take place on wards or in community teams, but this project enables another view of nursing to be presented. Not every student will leave with a plan to pursue a career as a research nurse. The aim is that every trainee will go away more knowledgeable about research and how they can embed it within the area of clinical work they wish to pursue. The programme has forged excellent relationships with the associated universities and the team has benefited from the presence of students.

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Welcoming student nurses into Dementias and Neurodegenerative Diseases Research Network (DeNDRoN): Offering workshops and student placements to educate and inspire the next generation of nurses

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Educating and training a department to maximise patient recruitment

Polly Patterson  Research Associate  
Laura Braidford  Senior Research Associate  
Chelsea and Westminster Hospitals NHS Foundation Trust

AIM OF THE WORK
To maximise the number of women recruited to an obstetric study where eligible women could present at any time of day or night, often out of hours by training a department workforce.

WHEN WAS THE WORK UNDERTAKEN?
Chelsea and Westminster Hospital joined this study in September 2012 and were due to run it for just under a year.

WHAT WAS THE ISSUE?
This study needed to recruit very large numbers and with only one Research Associate (Midwife) recruiting meeting targets would have been impossible.

HOW WAS IT ADDRESSED?
In order to capture all eligible patients, a departmental workforce was trained to deliver safe and effective research. Prior to the study opening to recruitment, the Research Associate/Local coordinating midwife (LCM) organised and led a programme of training; targeting doctors, midwives and sonographers who may come into contact with eligible participants. This programme consisted of an overview of the study, training around informed consent and principles of Good Clinical Practice (GCP), as well as study specific clinical training.

WHAT WERE THE OUTCOMES?
At mid-point of the study (6 months) 475 women had been recruited as a result of the implementation of the departmental education and training programme. If the Principal Investigator and LCM were the only recruiters, it is estimated that only 104 women would have been recruited (22%) during that time.

WHAT LESSONS WERE LEARNT?
A structured education and training programme tailored to a department can maximise patient recruitment to a research study.

HOW IS THIS APPLICABLE TO CLINICAL RESEARCH NURSING PRACTICE?
Similar programmes of education and training could be replicated across a wide variety of specialties to ensure successful delivery of future research studies and amongst patients and the public.

HOW HAS THE WORK BEEN DISSEMINATED?
The benefits of such an approach extend further than recruitment as it is evident that the profile of research within Women and Children’s services in the Trust has been raised, generating interest amongst staff with and without research experience.
Advanced Research in Practice three day course for research nurses and practitioners

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Senior Research Nurse Managers, Lead Research Nurses and R&D Facilitators
Norfolk and Suffolk CLRN, Norfolk and Norwich University Hospitals NHS Trust, James Padget University Hospital NHS Trust and Ipswich Hospital NHS Trust

INTRODUCTION AND BACKGROUND
A workforce survey of research practitioners identified amongst other things the lack of training and career development opportunities for research practitioners. In response to this, locally delivered training was developed.

This course was designed for experienced research practitioners to develop their current knowledge and working practices. A three day course, commissioned by the Norfolk and Suffolk Clinical Local Research Network (CLRN) was run in 2011 and following review it was further developed and delivered in 2013. The course content was modelled to develop the core themes within the Research Nurse Competency Framework (2011) and in response to the ever changing landscape of the research agenda such as recruiting to time and target.

The course was facilitated by a variety of experienced research practitioners from varied backgrounds. It was held as a three day residential course with pre course preparation by each participant a requisite.

AIMS OF THE COURSE
• Contribute to the professional development of individuals by increasing and expanding their knowledge to plan, implement and conduct clinical research within current UK NHS governance and legislative research structures
• Provide each individual with opportunities to prepare presentations around assigned topics and to practice their presentation skills within small groups

WHAT WERE THE LEARNING OUTCOMES?
The learning outcomes were developed to enable individuals to extend and integrate their knowledge and application of clinical research to an advanced level. The outcomes were mapped against the Research Nurse Competency Framework (2011).

EVALUATION
The course was evaluated using the learning outcomes as a guide for feedback. The participants evaluated all aspects of the course including whether it met their personal learning objectives.

Most found the presentations challenging however, several suggested that it was an excellent opportunity to practice their individual presentation skills in a safe and supportive environment. Most respondents stated that the content and delivery of the course was well designed and related well to practice.

WHAT LESSONS WERE LEARNT?
The course content was ambitious with little time for reflection and consolidation. By mandating the preparation of the pre-course work it ensured that there was a commitment of each individual. The course gave opportunities to develop facilitation skills within the faculty.

In an emerging specialty, made up largely of nurses, research practitioners have previously not had the opportunities for continual professional development and this course is part of the way we have addressed this locally. By linking the learning outcomes to the Competency framework we have practically demonstrated how these are useful and effective to the individual practitioner and appraiser.

HOW WAS THIS WORK DISSEMINATED?
This work has been disseminated through the Network and Research & Development newsletters across the eastern region as well as presented at conferences. A journal submission is being planned.
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Emergency scenario simulation training for Clinical Research Nurses

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AIM OF THE WORK
The management of the NIHR/Wellcome Trust Clinical Research Facility, Cambridge (Cambridge CRF) wished to implement the highest recommended standard of training to prepare its clinical staff for dealing effectively with emergency situations they might encounter with their clinical research participants.

The gold standard of such training had been set out by the Medicines and Healthcare products Regulatory Agency (MHRA) (Nov 2007) whereby it stipulated that clinical staff in Phase 1 accredited clinical trials centres would be required to undertake regularly emergency simulation training in addition to Immediate Life Support (ILS) training.

EMERGENCY SCENARIO SIMULATION TRAINING (ESST)
• Enhances participants’ safety
• Exposes staff to peri-arrest situations relevant to their work
• Builds confidence and competence in dealing with emergency scenarios in a safe and supportive environment

THE PROCESS
The Cambridge CRF is not a Phase 1 Clinical Trials Centre. Nevertheless, its management considered ESST to be the gold standard to aim for. Training was first established in 2010.

Weaknesses in staff knowledge relating to clinical emergency situations were identified and the CRF sought expert input for the ESST programme leading to a design that combines a carefully constructed formal training programme with relevant hands-on scenarios conducted in the Trust’s Simulation Centre. The result is a close collaboration between local CRF expertise, the Trust’s resuscitation trainers and clinical doctors working in the research field. All learners have to actively engage in several simulated scenarios. Each session is followed-up with a detailed evaluation. Improvements are identified, implemented and re-evaluated.

WHAT WERE THE OUTCOMES?
From 2010 to 2013 there have been 14 such training days with an attendance of 5-6 learners at each event. Every clinical nurse from the unit annually undertakes at least one full day ESST. Attendees consider the training programme as valuable learning experience. Course evaluations confirm that the training has improved staff confidence in dealing with clinical emergency situations. For 73%- 85% of the learners, the ESST was the only emergency situation they had encountered in the prior 12 months.

WHAT LESSONS WERE LEARNT?
The planning required is complex and time-consuming, but becomes easier over time. It is essential to draw on the expertise of the Trust resuscitation trainers. To address learners’ high pre-course anxiety a scripted simulation scenario has been filmed to demonstrate an example of what to expect. The debriefing following each ESST is a crucial part of the learning experience and to be truly beneficial, facilitating such debriefing requires skill and trainers are advised to undertake specific training for this.

THE APPLICATION
Formally arranged simulation training in a simulation centre has proven to be an effective way for clinical research staff to become more confident. The framework in place at the Cambridge CRF can be adapted elsewhere.

Ideally this training should be complemented with unannounced simulated scenarios happening at the actual place of work.

HOW HAS THE WORK BEEN DISSEMINATED?
The work was presented as a workshop at the UK Clinical Research Facility (UKCRF) Network annual meeting in July 2013.

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Developing professional practice for Clinical Research Nurses / Staff, locally and beyond: An example from the Cambridge Clinical Research Facility

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BACKGROUND
Clinical Research Nurses are responsible for providing safe, caring, ethically sound and scientifically robust practice for research participants and research teams.

Opened in 2001, the Cambridge Clinical Research Facility (CRF) now comprises the NIHR/Wellcome Trust CRF, NIHR Clinical Investigation Ward and the NIHR CRF Satellite unit and currently employs 37 nurses at 3 different locations, working on 256 current studies in a wide range of medical specialties.

In 2008 the Cambridge CRF management introduced the new concept of employing a clinical research educationalist, later followed by a part-time Clinical Research Development Nurse in 2012.

AIM OF THE WORK
To have dedicated professionals who oversee the complex tasks required to plan, implement, evaluate and ensure delivery of training and education for the predominantly nursing workforce. To have clinical research professionals with prior training and education experience who would successfully collaborate with the wider clinical research community - at local, regional and national level - to develop and establish educational projects that would benefit:

- Existing clinical research communities
- Staff new to working in a clinical research role
- Staff interested in taking on a clinical research role

WHAT WERE THE OUTCOMES FOR STAFF ON THE UNIT?
The following training and education outcomes (strategically planned and delivered in a timely fashion) are a direct result of the unit's research education staff:

- Comprehensive, individually tailored induction training
- In-house skills and research competency training
- Regular Emergency Scenario Simulation Training
- Comprehensive training of adult-trained nurses to care for paediatric research participants
- Unit away days and twice-monthly staff education seminars delivered by staff from the unit, research teams and external speakers
- Updates on relevant research information, guidelines, newsletters
- Sourcing and overseeing relevant education opportunities
- Academic development: PhD, NIHR Masters in Clinical Research, EM HIEC Internship
- Increasing number of nursing staff presenting at conferences

WHAT WERE THE OUTCOMES FOR THE WIDER HEALTHCARE FIELD?

- 2 x 12 month Research Nurse Rotation posts across 5 local research organisations
- ‘Research Skills for Clinicians’ course x 8 - for medical trainees in the Eastern Region
- Mandatory introduction (course) for non-medical staff new to working in a clinical research post in the NIHR Cambridge Biomedical Research Centre (BRC). Attendance: n=116 over 16 months
- Collaboration with the Hospital Trust and NIHR supported organisations on non-medical education and training provisions

DISCUSSION
Employing a clinical research educational team specifically to focus on the professional development of research staff has led to more consistency in staff training and to exceptionally high staff compliance with mandatory training as well as a high up-take of Higher Education qualifications.

The employment of the education team resulted in a range of beneficial education and training collaborations with other research organisations on the BRC campus and nationwide.

APPLICATION
Larger clinical research organisations (> 25 employees) would benefit from employing a clinical research education professional to meet their staff’s complex professional development needs.

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AIM OF THE WORK
A method of nurse-led review / follow up for men diagnosed with localised prostate cancer and treated with Active Monitoring (AM) has been developed within the context of an RCT (comparing surgery, radiotherapy and AM). The primary aim of the ProtecT trial is to assess prostate cancer specific mortality at a median of 10 years follow up. A nurse-led approach to follow up has been adopted to maximise data completeness/quality and minimise attrition.

WHEN WAS THE WORK UNDERTAKEN AND OVER WHAT PERIOD?
Recruitment commenced in 1999 and ended in 2009. Follow up range is 3-13 years, dependent upon recruitment date. Primary analysis for the trial is due at the end of 2015.

WHAT WAS THE ISSUE IT ADDRESSED AND WHY WAS IT IMPORTANT?
Whilst radical treatments are available for men diagnosed with localised prostate cancer there is a risk of over-treatment. The aim of AM is to detect disease progression as early as possible, preferably while the tumour is still localised, but also to allow those whose disease remains stable to avoid intervention.

WHAT WAS DONE?
The ProtecT trial has developed a model for monitoring men utilising nurse-led review. This is detailed within the ethically approved protocol and is based on a ‘treatment pathway’. The treatment pathway defines routine tests, timelines and ‘triggers’ that action a decision to either continue monitoring, arrange further tests, refer back to the urologist or recommend a change of treatment. Development of AM has continued throughout the life-cycle of the trial utilising current evidence, patient feedback, audit, qualitative research methods and independent expert advice from the international trial steering committee.

WHAT WERE THE OUTCOMES?
The ProtecT trial will provide definitive evidence on treatment effectiveness, long-term quality of life and psychological impacts of AM when it reports in 2016. In the meantime, we have over a decade of experience in delivering a non-radical intervention to around 700 men in 9 clinical centres across the UK. Patients and clinicians have indicated that they trust nurses to deliver the treatment. Furthermore, having nurses available and easily contactable to arrange tests and discuss results is of primary importance and helps reduce anxiety.

WHAT LESSONS WERE LEARNT?
The nurse-led approach was adopted in order to enhance the quality of trial data. However, almost by default the trial has developed nurse-led clinics that seamlessly combine clinical and research components. The clinics have been well received by patients and attrition remains low.

How is this applicable to clinical research nursing practice?
Future research opportunities may be more amenable to research staff who additionally include clinical components … or clinicians could routinely combine research within their daily activity? Could this herald the end of the ‘us and them’ culture? Furthermore, researchers and patients involved in ProtecT are well placed to feedback to the Department of Health possible methods of delivering a similar non-radical intervention - Active Surveillance.

HOW HAS THIS WORK BEEN DISSEMINATED?
Papers on the experience and development of nurse-led AM clinics are currently being written for publication.

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AIM OF THE WORK
In an attempt to reduce barriers to research, further knowledge and evidence, supporting its necessity is required. The UK remains without a national framework for nursing research and the research nursing role is not perceived as an integral part of all Multi-disciplinary teams (MDTs). A mixed method exploration study composed of focus groups and questionnaires gained the MDTs understanding of the cardiac research nursing role by evaluating the service provided within an NHS Trust.

WHEN WAS THE WORK UNDERTAKEN AND OVER WHAT PERIOD?
Work commenced towards the end of 2010 and was completed by November 2011.

WHAT WAS THE ISSUE?
The aim was to enquire if the cardiac research nursing service was effective, in meeting standards and achieving goals, using inductive investigation to mould the new role. If the MDT members understood the necessity of the nursing role to assist innovation, it will influence the acceptance of change. Little evidence remains on the role of the research nurse and its apparent modest understanding of the role from MDT colleagues. Further research exploring the role of the research nurse and the position they play within service innovation, will clarify responsibilities amongst colleagues and hopefully reduce barriers within this area of the nursing profession.

WHAT WAS DONE?
A service evaluation study was performed, using mixed method exploration composed of focus groups and a questionnaire. A self-completed questionnaire was sent to all MDT members. Two tape-recorded focus group meetings were held. The setting was in the cardiology department of a district general hospital. The use of Lewin’s change management model (1951) and the Plan, Do, Study, Act (PDSA) cycle were used to focus implementation.

WHAT WERE THE OUTCOMES?
The MDT felt that including the research nurse in the team facilitated interdisciplinary collaboration, enhanced service development and helped deliver more equitable high quality patient care.

WHAT LESSONS WERE LEARNT?
The journey from planning, initiating and implementation of the project has enforced the researcher’s independent learning. As the researcher is the individual embarking on this new role within Cardiology it enhanced passion and motivation in the pursuit of generating new knowledge within this clinical speciality.

HOW IS THIS APPLICABLE TO CLINICAL RESEARCH NURSING PRACTICE?
A unique layer of significant additional components has been established highlighting the importance of communication within a team, relationships, transferable skills, experience and liaison amongst colleagues disseminating the purpose of research within the Local Trust. Clinical research has been recognised as a necessity to provide evidence based practise and increased quality of care provided to patients. Positive fundamentals have been established with the introduction of a cardiac research nurse, areas of improvement have been recognised facilitating the next cycle of the PDSA model for improvement.

HOW HAS YOUR WORK BEEN DISSEMINATED?
Locally several oral presentations of the findings have been undertaken in Cardiology and within several services including management, to broadcast the value of a research nurse role for united faculty innovation. Poster presentations have been accepted for forthcoming nursing conferences, targeting the inter-professional population. The researcher also intends to present this research project for online publishing to target a wider audience to add to the limited knowledge base surrounding this enquiry.

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our work

Celebrating the Clinical Research Nurse

For more information about clinical research nursing or to receive your copy of our monthly newsletter please contact the team at the NIHR Clinical Research Network at crncc.training@nihr.ac.uk

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