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our work

Celebrating the Clinical Research Nurse 2015

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Celebrating the Clinical Research Nurse 2015

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foreword

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 through 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*

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building team skillsets

The Clinical Research Nurse role within Primary Care: Helping research teams understand our skillset

Alice Mackie *Clinical Research Network*

West Midlands Clinical Research Network

BACKGROUND

The role of the Clinical Research Nurse within Primary Care is multi-faceted and ever changing. Primary Care Clinical Research Nurses are often under-represented and their responsibilities are often misunderstood.

AIM OF THE WORK

The aim of this work was to highlight the overall role of the Research Nurse within Primary Care and to underline the specific skills which research nurses employ and the responsibilities they undertake.

WHY WAS IT IMPORTANT?

The team attended numerous research training events and conferences, which focused largely on secondary care research and did not relate to large areas of our practice. As Clinical Research Nurses within Primary Care, we are proud of the work that we do and the challenges that we have faced as a team and wished to help the wider research teams we worked with to understand how we can support them.

WHAT WAS DONE?

To ensure a study pathway emerged that worked in practice, safeguarding patient safety and data integrity we worked closely with the West Midlands Clinical Research Network team to:

- Engage general practice and NHS secondary care colleagues
- Support research clinic set up and appointment systems
- Manage Clinical Research Nurse rotas to ensure all study activities were covered

The lead nurse worked closely with study teams to operationalise clinical research nurse activity for the studies, including:

- Study set-up – including feasibility and practicalities
- Study working instructions and supporting study documentation design
- Training the clinical research nurse team
- Advising on study research nurse interventions

WHAT WERE THE LESSONS LEARNT?

Due to the nature of primary care, our team is often dispersed. Developing this case study has given us time to come together and celebrate our achievements and learn more about the depths of our roles. It taught us that we use more skills than we often appreciate and gave us a greater awareness of our team skillset and our varied role within the many different research teams that we work with.

HOW HAS THIS WORK BEEN DISSEMINATED?

This work has been displayed at events celebrating the research nurse and the NIHR Clinical Research Network as well as within the Clinical Trials Unit in which we are based, therefore allowing a greater insight into our work for the extended research teams that we work amongst.

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challenges and solutions to recruiting into clinical trials

Research in the Emergency Department: Four challenges and solutions

Jason Pott *Lead ED Research Nurse*
Geoffrey Bellhouse *Research Nurse*
Imogen Skene *Research Nurse*

Barts NHS Trust

AIM OF THE WORK

To increase the number of Emergency Department (ED) patients taking part in NIHR portfolio trials.

WHEN WAS THE WORK UNDERTAKEN AND OVER WHAT PERIOD?

We applied in April 2012 for funding and appointed staff in November 2012. The new team structure was rolled out and evaluated at one year and after evaluating the impact funding has been maintained at this level.

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

A 09:00–17:00 model of research delivery was not effective in the ED setting as it only enabled 30% of the weekly attendance to be potentially recruited into clinical trials. Not all clinical environments have planned workloads so a range of strategies was needed to optimise research delivery and provide as many patients as possible with the opportunities to enter clinical trials.

WHAT WAS DONE?

We provided optimal recruitment cover in a 24hr specialty. The successful recruitment of patients into clinical trials in the emergency setting required a tailored approach to staffing and rotas. The three EDs of Barts Health are opened around the clock and have an annual census of approximately 350,000 people. We reviewed ED patient attendance data by hour of arrival.

We introduced a research rota cover from 08:00 till 00:30 Monday–Friday and 12:00 till 00:30 shift on Saturdays, which allowed the team to screen 70% of all ED patients for open clinical trials.

WHAT WERE THE OBSTACLES AND HOW WERE THEY OVERCOME?

Barts Health EDs are located in three London boroughs. Given the departments' geographic locations, the challenge of public transport and the tight times lines of emergency trials, we applied for and were given funds by the Local Clinical Research Network (now North East Thames CRN) for transport to move staff between the three sites which increased the potential for patient recruitment. The cross site model has been effective in providing more patients with the opportunity to enter into trials while keeping resource expenditure low.

CONSENT IN THE INCAPACITATED PATIENT

The nature of emergency medicine is that care episodes are unplanned and patients are often incapacitated. Patients are often unable to understand or retain information regarding medical trials. In this situation, the research nurses may consult a patient's relatives or use a Professional Legal Representative (PrLR). In Barts Health, senior ED nurses have assumed the responsibility of PrLR and have been trained in this role by the research team. This had helped to overcome the preclusion of patients lacking capacity from taking part in research.

WHAT WERE THE OUTCOMES?

Our primary outcome has been to ingrain research into the day to day business of working in the ED of Barts Health. Part of what made this a reality was sharing the research teams' work as a success for the whole department. The research team members are involved with the department's teaching rota, help to train staff and work with clinical staff to develop care pathways. All staff also spent some time working clinically within the departments. Each patient recruitment is celebrated and acknowledged through group emails, thanking staff who contributed.

Inclusion of the entire ED department has helped nurture a supportive and enthusiastic research environment. The research teams' presence within the departments has increased awareness of research trials in the ED and encouraged both nurses and doctors to identify potential trial participants.

WHAT WERE THE LESSONS LEARNT?

Team work is vital to successfully deliver a project such as this. Embedding a research team within complex clinical areas such as the ED is possible and enables research to be delivered.

HOW IS THIS APPLICABLE TO CLINICAL RESEARCH NURSING PRACTICE?

Research nurses need to assess and evaluate the service they provide.

HOW HAS THIS WORK BEEN DISSEMINATED?

This work has been shared at NIHR nursing conferences, online via Twitter and Linkedin and through conversations with ED researchers around the UK who have approached their CLRNs to duplicate parts of our model.

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creating skilled research nurses

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Transforming research nursing: One trust's journey

Paula Tacchi *Research Matron*

University Hospital Bristol NHS Foundation Trust

AIM OF THE WORK

Change and research are mutually inclusive; both lead to each other in a continuing spiral which we would hope describes progress, innovation and improvement in healthcare. As research nurses deliver much of the patient facing interactions, it is essential that the context in which they work empowers them to be an effective force for change.

WHEN WAS THE WORK UNDERTAKEN AND OVER WHAT PERIOD?

The work was undertaken in April 2013, with an aim 'to develop and sustain a highly motivated and skilled research nursing workforce who deliver all studies with efficiency and effectiveness to maximise the number of people participating in high quality research.'

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

It was important to establish where we were and where we wanted to be. We had discussions with research nurses to understand their challenges and needs which led to three main areas for focus:

- **Processes:** learning from each other
- **Organisation:** developing good structures
- **Effectiveness:** having appropriate support

WHAT WAS DONE AND WHAT WERE THE OUTCOMES?

The research matron worked with the senior research nurses to establish and share the best ways of working; ensure the right structures were in place eg team skill mix and standardised job descriptions; and develop good systems of support. This was also steered by a delivery group of research and clinical staff who represented the research nurses and their managers.

Processes Two main themes of work were undertaken which looked at the way in which teams functioned and their success in delivering studies. This was done in parallel with the results collated and analysed by the delivery group. The most efficient processes were shared across all teams.

'Sharing best practice' meetings – 13 questions about study delivery were asked of every research team ranging from their decision making processes (for taking on new studies) to engaging with clinical colleagues. Useful tools were collected from within and outside the trust and shared across all teams.

Analysis of team performance – delivery of studies to benchmarks; type of study undertaken; band of study. These objective measures enabled good practice to be identified and shared.

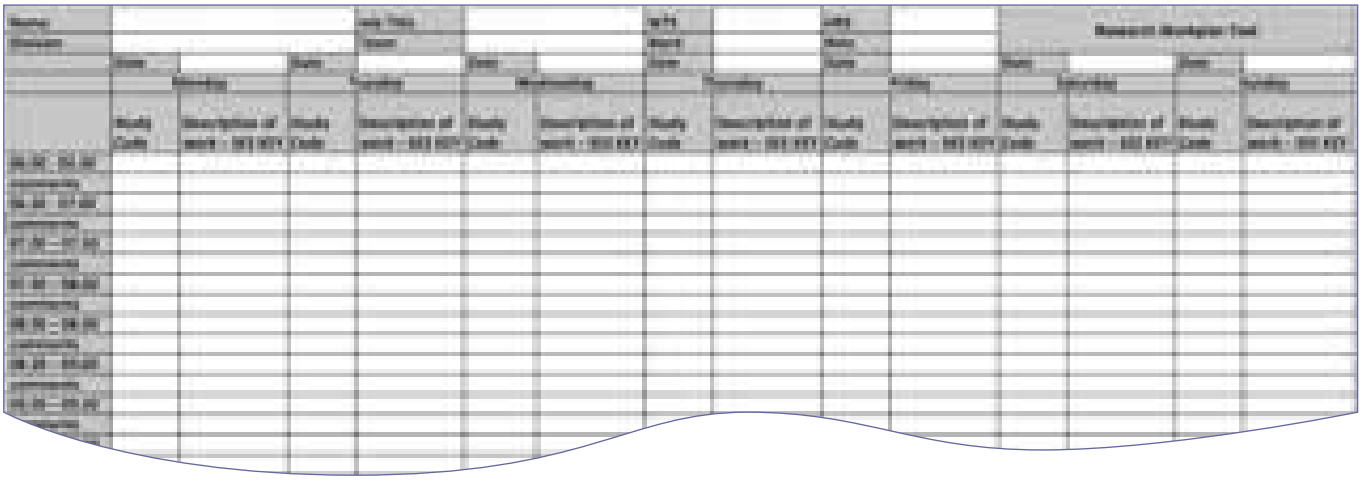
Organisation First we identified who was delivering research and what they were doing. All staff completed a 'Work Plan Tool' in which activity was selected from a detailed list of tasks every half an hour for four weeks. Analysis of this was used to strengthen skill mix and detail the workload of each team.

For example, a team without administrative support was able to illustrate their need for an administrative role as 24% of the nurses' time had been spent on administrative tasks.

The work plan also enabled us to identify the amount of time spent on each study. This was a valuable resource when discussions were undertaken with Principal Investigators about available time.

See Table 1: Example of the Work Plan tool on next page.

TABLE 1: EXAMPLE OF THE WORK PLAN TOOL



The exercise identified a wide variation across all bands. As a result, job descriptions (JDs) were standardised to include core elements of the research role with the opportunity to add team or study specific detail. Each JD was linked with clinical non-research JD to enable flexible career choice. Line management was evaluated to see if it provided clinical, professional and research support.

Effectiveness Research and clinical support systems were implemented to ensure all staff groups received regular contact in relation to their clinical area of work and research role. A 'How to' guide was written for the line managers of research staff who did not have a research background. Research training analysis was undertaken to identify training needs and support local staff to deliver training when possible.

WHAT WERE THE LESSONS LEARNT?

The teams are more integrated with each other, best practice is shared, support is freely available and there is consistency across the trust. Research has a stronger presence.

HOW HAS THIS WORK BEEN DISSEMINATED?

This work has been shared across the trust as part of their Transformation Program. It was presented at the Celebrating Clinical Research Nurses – NIHR South of England Regional Meeting in Portsmouth, February 2014. The development and use of the 'Workplan Tool' is being written up for publication.

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improving patient experience

The Clinical Trial Patient Experience Questionnaire

Vicki Conroy *Senior Oncology Clinical Research Nurse*

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AIM OF WORK

Our team is responsible for all Malignant Haematology and Oncology trials within the Trust and we have an excellent reputation for recruitment to clinical trials. We have an expanding service, but up to this point we had not asked trial patients what their experience of being on a clinical trial was. Our aim was to improve the care and support we provide to patients. We wanted to evaluate what we were doing well and where we could improve. We identified forty haematology trial patients with an appointment between 17/06/2013 and 12/07/2013. They were asked to complete a questionnaire.

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

The Clinical Haematology department at the Manchester Royal Infirmary has undergone a rapid expansion within the last 5 years. In the past 12 months alone, there has been a 35% increase in Haematology outpatient referrals. We have an active clinical trials portfolio with plans to significantly expand. We have extended the Solid Tumour trials portfolio, and now cover trials in Upper and Lower GI, Dermatology, Hepatobiliary, Urology, Head and Neck, Gynaecology and Orthopaedics. With all these developments we wanted to ask patients about their clinical trial experience with the aim of improving their care/support during trials.

WHAT WAS DONE?

Forty haematology trial patients with appointments between 17/06/2013 and 12/07/2013 were asked to complete a questionnaire. The questionnaire was adapted from a template used by a local network cancer research team.

WHAT WERE THE OUTCOMES?

The questionnaire identified areas for improvement. All participants felt that being involved in a clinical trial was positive but communication with patients needed to be improved. This allowed the team to improve our communication with patients by:

- Giving patient cards. To ensure that patients were aware of what trial they were on, we wanted to produce cards which were small enough to fit in the wallet or purse, similar to business cards. We also wanted to put the contact details of the research team on it. These cards are now given to all newly recruited patients.
- Producing an information sheet for patients and their families explaining what clinical trials are and what the roles of the staff are
- Producing posters of the team in the outpatients departments so patients will know who to approach about clinical research
- Production of a diary which informs patients of the requirements of their trial
- Production of a telephone call log. As we are encouraging patients to phone us with any questions or problems, we wanted to ensure that these calls are documented properly. This book produces a carbon copy, and the original can be kept in the patients' notes, which ensures good clinical governance.

As we are also responsible for Solid Tumour Trials in the Trust, we intend to give this questionnaire out to patients on these trials, to establish what their experiences are. When all our changes are in place, we plan to re-introduce this questionnaire to the Haematology trial patients to assess how successful they were.

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improving patient experience

Introducing a research nurse led follow-up clinic for patients with prostate cancer

Roger Wheelwright *Senior Research Nurse – Oncology*

Poole Hospital NHS Foundation Trust

AIM OF THE WORK

A clinical research nurse led clinic was introduced in response to an increasing number of men with prostate cancer consenting to take part in clinical trials. This role would allow the clinical research nurse time to ensure that the trials were being managed to Good Clinical Practice/ International Conference on Harmonisation guidelines and that the patients are seen at the appropriate time points during the trial whilst enhancing the patient care pathway experience.

Patients reviewed in this clinic would have already have been randomised into a clinical trial, and had their initial appointment with the consultant, thus allowing the oncology consultant more time to see newly diagnosed patients, non-trial patients and patients with complex disease/treatments.

WHEN WAS THE WORK UNDERTAKEN AND OVER WHAT PERIOD?

The work commenced in April 2013 and is on-going.

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

- Reduce the burden on oversubscribed clinics and meet demand upon service delivery, whilst increasing the uptake of patients being offered and entered into clinical trials.
- Reduce time patients had to wait to see a clinical member of the team.

WHAT WAS DONE?

The clinic set up ran parallel with oncology consultant's clinic, allowing immediate referral/discussion about a trial patient which the nurse had any concerns about. Appointment time slots were for 15 minutes, which would allow for history taking, review of blood results and the opportunity for the patient to ask any questions and raise any concerns that they may have.

WHAT WERE THE OUTCOMES?

What started as an logistical organisational problem has highlighted a concept that helps deliver high quality care which not only improves the patient's experience whilst they go along their care pathway, but enhances their overall satisfaction with the service they receive. Not only have we resolved some of the issues of over-booked clinics, we have also reduced patient clinic waiting times. Also of note, what came out of the patient satisfaction questionnaires was 'time'. Although they have the same allocated time to be seen in the clinical research nurse led-clinic as they receive with the oncology consultant, the majority expressed a sense of 'being given more time', although in reality it was the same. The clinics ensure continuity of care whilst offering holistic assessment and support for patients on long-term follow-up.

WHAT WERE THE LESSONS LEARNT?

The clinical research nurse-led approach was adopted to address a logistical organisational problem, which highlighted that the model helps deliver high quality care which not only improves the patient's experience whilst they go along their care pathway but enhances their overall satisfaction with the service they receive.

HOW IS THIS APPLICABLE TO CLINICAL RESEARCH NURSING PRACTICE?

The oncology research nurse led-clinic has increased professional responsibility and autonomy providing improved job satisfaction. This new approach provides a more team orientated approach to patient care in clinic with both the consultant and the nurse taking joint responsibility for caseloads, whilst overall responsibility remains with the consultant.

HOW HAS THIS WORK BEEN DISSEMINATED?

Work has been presented at national and international conferences with papers currently being written for publication.

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improving research experience

The visibility of stroke research: Changing a culture

Michael Keeling *Stroke Researcher*

York Teaching Hospital NHS Foundation Trust

AIM OF THE WORK

The visibility project follows on from a previous project entitled The 4 Ps of Research, which aimed to provide a patient centred research service offering patients the opportunity to participate in research throughout the care pathway. We aimed to raise awareness of stroke research by the use of posters along the stroke pathway, making research visible to patients, carers and staff, to improve engagement with stroke research and recruitment into research studies.

WHEN WAS THE WORK UNDERTAKEN AND OVER WHAT PERIOD?

The project coincided with the NIHR "Mystery Shopper" report which highlighted NHS shortcomings in promoting clinical research.

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

The report showed 91% of hospital trusts surveyed were not providing information to support patient choice and that patients and public were unable to find relevant information about clinical research. In May 2013 the NIHR launched the "OK-to-ask" campaign encouraging patients to ask about being involved in research. By making research more visible locally we felt that this would give patients the opportunity to ask about taking part.

WHAT WAS DONE?

We developed a project to provide visual materials by the way of posters placed at various points along the patient pathway to raise awareness amongst patients, carers and staff, to improve engagement with stroke research and recruitment into research studies. We created an image that was to link all aspects of our visibility work which was both eye catching and positive. The design and implementation for the material was decided with patient and staff involvement. We used the same format to link other forms of visibility, such as newsletters, posters, events and social media.

WHAT WERE THE OUTCOMES?

We have started a cultural change from the traditional format of the doctor or consultant approaching the patient about the possibility of research, to the patient now instigating the conversation.

The visibility project has enabled patients to feel empowered and more able to approach the doctor or member of staff and be an active participant in their own healthcare.

In the last ten months after the initial implementation of the project, we have had ten patients ask about how they might become involved in research in comparison to none in the six years prior.

This is a huge achievement and one which we will continue to improve on. We have shared our visibility work with other research teams within the trust and they have adapted it for their own local area and as a result they have had patients asking about research.

We are leading the development of research visibility within our local trust.

WHAT WERE THE LESSONS LEARNT?

- Research within an organisation is virtually invisible to service users and non-research staff
- How to make stroke research more visible by utilising the pathway and engaging more with patients and staff along the pathway
- The importance of engaging with patients with all aspects of our work, creating a patient centred service
- That being visible is a really good way to start a conversation about our role and research
- The importance of having a presence on social media to connect, learn, share and develop with professionals and members of the public

HOW IS THIS APPLICABLE TO CLINICAL RESEARCH NURSING PRACTICE?

Making stroke research more visible has enabled us to raise our profile within the organisation, and research nursing. We have engaged with more non research staff and started conversations about research. It has helped to empower patients, letting them know that research is going on in this area.

HOW HAS THIS WORK BEEN DISSEMINATED?

We shared our work locally through presenting to other research teams, and at patient groups, and further afield through the use of social media. The work has been entered into the Nursing Times Awards 2014 and was shortlisted as a finalist. We have presented at the NIHR National Research Nurse meeting and Local Research Nursing conferences within the UK and shared with the NIHR as part of ongoing continuous improvement.

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informed consent

The great debate: Clinical Research Nurses taking consent on CTiMPS

Gail Woodburn *Lead Nurse Research and Innovation*

Central Manchester University Hospitals NHS Foundation Trust

AIM OF THE WORK

To develop procedures and processes to support Clinical Research Nurses (CRN) to take informed consent on clinical trials of a medicinal product (CTiMPs).

WHEN WAS THE WORK UNDERTAKEN AND OVER WHAT PERIOD?

The work started in June 2012 and is ongoing.

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

The following were identified as drivers for the project

- A desire to develop innovative new ways of working
- Development of Advanced Practitioner roles in research
- Introduction of performance management targets (recruitment / 70 day time to target)
- Informed consent is often taken by transient and sometimes junior doctors, with limited knowledge of study protocols and the possibility of practice variations.
- Implementation in other trusts – eg Sheffield/Darlington
- National focus for RCN and UKCRF network

WHAT WAS DONE?

An initial scoping exercise was conducted to ascertain if there was a need for non-medical staff, especially nurses, to take consent on CTiMPs. An overwhelming 79% of respondents said they thought there was. A small task and finish group was set up comprising of research nurses, PIs, manager and research governance leads to debate the issues faced in practice when implementing a new initiative like this. The details of how to implement this in practice were worked out with particular regard to research governance, maintaining Principal Investigator oversight and professional accountability requirements to ensure staff and patient safety was maintained at all times.

WHAT WERE THE OUTCOMES?

Development of a Standard Operation Procedure to support Clinical Research Nurses (CRN) to take informed consent on CTiMPs. This includes a clear assessment of need by the PI to ensure the role is delegated appropriately.

- Development of a training programme
- Development of a competency assessment framework
- Pilot undertaken – 10 nurses trained and 2 nurses currently undertaking the role

WHAT WERE THE LESSONS LEARNT?

- Must focus on new studies as need identified rather than try to apply generally or retrospectively
- Engage with PIs early to identify the need and include nurse consent at Site Specific Information stage
- Develop and apply the standard of general consent training and competence assessment across all disciplines
- Target specific CTiMP consent training when study identified
- Extend pilot to a rolling pilot to aid learning, taking specific applications case by case

HOW IS THIS APPLICABLE TO CLINICAL RESEARCH NURSING PRACTICE?

This is a fantastic opportunity to enhance the role of the Clinical Research Nurse placing greater emphasis on holistic patient centred care, involving timeliness, consistency and continuity of care for patients. It also enhances clinical research nursing's contribution to meeting NIHR performance targets, enabling increased recruitment to clinical trials as nurses can take consent when medical colleagues are not available, therefore potential recruits are not missed and recruitment targets more easily achieved.

HOW HAS THIS WORK BEEN DISSEMINATED?

Poster or oral presentations at:

- UKCRF network annual conference in July 2014
- NIHR annual Celebrating Clinical Research Nursing event in May 2014
- Scottish Research Nurse and Coordinators Network annual conference October 2013
- UK Forum for Trust/Health boards Research Leads (nursing) meeting July 2014

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network education

Developing good practice for clinical research nurses: The contribution of the UK Clinical Research Facility Network Education Group

Kornelia Hathaway *Education and Training Manager*

Caroline Saunders *Head of Clinical Operations*

NIHR/Wellcome Trust Clinical Research Facility, Cambridge

AIM OF THE WORK

The UK Clinical Research Facility (UKCRF) Network Education Group was formed in 2009 by clinical research education leads based in Clinical Research Facilities in the UK and Dublin. The group aims:

- to provide relevant, shared expertise such as educational guidance and suitable resources that build up clinical research knowledge and skills and to enhance professional development of staff both in CRFs and in other associated clinical research organisations
- to collaborate and liaise with other research organisations to ensure the work of the group is up-to-date, responsive and complementary to regional and national development in training and education

WHEN WAS THE WORK UNDERTAKEN AND OVER WHAT PERIOD?

Since its beginning in 2009 the group has developed and disseminated valuable education tools to support the development of good practice of clinical research nurses.

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

Clinical Research Nurses (CRNs) are fundamental to conducting clinical research studies in the NHS. Approximately 8,000 alone are currently working within an NIHR funded setting. Those new to working in a CRN role are required to develop considerable clinical research specific knowledge and skills to perform their roles competently and effectively. There was little structured guidance available on preparing and developing Clinical Research Nurses for their roles.

WHAT WAS DONE?

The group completed the following projects:

- **Induction Framework for Clinical Research Staff.** Clear, thematically arranged comprehensive guidance for mentors of staff new to working in a clinical research role. First issued in 2011. Now version 3 – July 2014
- **Emergency Scenario Training Guidance Document** aimed at clinical research staff who wish to set up and conduct such training. Now version 2 – July 2013
- Launched in July 2014: the **Competency Assessment Template** with introduction and guidance notes provides a user-friendly template designed to be populated with the components of a specified task for which a member of staff has to be assessed
- Contributed to web-based research education resource list hosted by 'Clinical Research Training for Scotland' – under review

WHAT WERE THE OUTCOMES?

The above listed educational tools are utilised by education leads across the Clinical Research Facility Network and have been adapted locally by a range of other NHS research organisations.

WHAT WERE THE LESSONS LEARNT?

There is a widespread need for structured tools that enable mentors of CRNs to guide and develop their staff, to ensure such tools constitute guidance that can be adapted to local needs, and to conduct long-term educational collaborations with rigorous project planning/management.

HOW IS THIS APPLICABLE TO CLINICAL RESEARCH NURSING PRACTICE?

The tools set out clear guidance that mentors and education staff of CRNs are using to good effect for the induction of their new staff and for the preparation of CRNs in dealing with clinical emergencies.

HOW HAS THIS WORK BEEN DISSEMINATED?

This work was published in the Nursing Standard in 2014. It is also available via the UKCRF Network Portal (now the NIHR Hub). It has been shared in workshops at national research conferences and poster presentations at national and international clinical research nurse conferences.

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one-stop workshop

The development of a 'One-stop workshop' for researchers in an NHS organisation

Laura Braidford *Lead Research Associate*

Valeria Silvestre *Research Associate*

Chelsea and Westminster Hospital

AIM OF THE WORK

In supporting clinicians and healthcare workers to engage in and deliver research at Chelsea and Westminster Hospital, the Research and Development (R&D) support office and Research Associate Team (RA) recognised that generally there were common themes in relation to areas that required focus for education and training of these staff.

WHEN WAS THE WORK UNDERTAKEN AND OVER WHAT PERIOD?

The work started in 2012 to present day.

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

A 'one-stop' research workshop was set-up to cover areas of research pathway that were least understood, from the concept of a study to the completion of a study. 10 common areas were identified through examination of enquiries made to generic research email inbox, telephone calls and face to face enquiries.

WHAT WAS DONE?

The trust's Lead Research Nurse organised a one day workshop covering theoretical and practical aspects of the 10 common areas identified by:

- Identifying experts/leaders in each of the 10 areas to prepare and deliver a 30 minute session within the workshop (including Head of R&D, Industry Facilitation Officer, R&D Business Analyst, Senior Research Nurses, PPI Lead, Clinical Fellows, and a member of the Research Design Service)
- Advertising the workshop to all staff via electronic daily notice board, R&D webpages and in-house training brochure

WHAT WERE THE OUTCOMES?

Evaluation forms from twelve attendees during the last workshop session (4 February 2014) were considered for results. As demonstrated by the comments obtained from attendee feedbacks 92% (11) of participants would recommend this course to others whilst 8% (1) would not. Within the strength of the course free text answers from attendees said: "interesting course motivating you to get into research and ideas" and "very effective overview of the infrastructure to support research." The main weakness of the course was reported as: "unfortunately each session was very fast to include all the information required" and "assumes a basic knowledge."

WHAT WERE THE LESSONS LEARNT?

The one-stop workshop is demonstrated to be interesting, fit for purpose and practical by increasing awareness of research and related processes.

HOW IS THIS APPLICABLE TO CLINICAL RESEARCH NURSING PRACTICE?

This is a successful workshop that has now been run four times in the past 18 months by establishing itself as a useful programme for increasing confidence/competence in those who attended.

We recommend others to repeat our experience in their working setting.

HOW HAS THIS WORK BEEN DISSEMINATED?

The work was shared at the NIHR Clinical Research Nursing Meeting on 12 May 2014. It was also presented internally.

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outreach service

Clinical research nurse outreach service

Faye Forsyth *Clinical Research Nurse*

Cambridge Clinical Research Facility

AIM OF THE WORK

To establish a new clinical research nurse outreach support service for studies with unmet requirements in an acute hospital.

WHY WAS IT IMPORTANT?

The service was designed to help researchers by making it easier to facilitate research in areas where research infrastructure was lacking and to help improve recruitment rates in studies which were struggling to meet targets. The first study team supported by this service was struggling to recruit in the emergency department; over an 18 month period only 16 participants had been enrolled; with 8 months remaining a drastic new approach was required to bring them closer to meeting the target of 100 patients.

WHEN WAS THE WORK UNDERTAKEN AND OVER WHAT PERIOD?

The work was undertaken between January and August 2013. A mobile, flexible approach was adopted to make it easier to recruit participants to an observational research study into mild and moderate head injury running in the emergency department (ED). This was the first and most successful project undertaken by this new initiative. The service has gone on to support multiple studies in a range of settings including obtaining blood samples in outreach clinics, administering infusions of experimental medicines in theatres and establishing a satellite clinic for collecting skin biopsies.

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

The main difficulty faced by the first study supported by the outreach service was recruiting to time and target. With limited time of the recruitment window remaining, a fast and effective new approach was required to ensure the intended patient benefits of the research were realised. Subsequent support efforts have focused less on recruiting to time and target and more on delivering the flexibility study teams need to make the research more convenient for the participant.

WHAT WAS DONE?

The first study supported by this initiative involved extended hourly rounds of ED to screen for patients. During this time the outreach team built relationships with ED staff to raise awareness of the study and engaged in impromptu education sessions to promote the benefits of this research. If a suitable participant was identified, the team obtained informed consent and completed the extensive data collection. The outreach service substantially improved recruitment rates, an increase of 313% in the target group with mild head injury and 1200% for trauma controls in only eight months. Other outreach support efforts have enhanced convenience for participants, enabling the study to run in locations more convenient for the participant.

WHAT WERE THE OUTCOMES?

This initiative enabled study teams to conduct research in areas where infrastructure was not in place or fully supported. It helped to enhance study performance, ensuring results were delivered to time, target and to a high standard. It helped to engage with new patient groups and research staff. The service is mobile and is accessible to new clinical areas which helps to widen opportunities for staff to experience the research process and integrate research into standard patient care.

WHAT WERE THE LESSONS LEARNT?

Team work is essential for delivering results in research naïve areas. The team must be flexible with good nursing and research skills, great communication capabilities and a competitive spirit.

HOW IS THIS APPLICABLE TO CLINICAL RESEARCH NURSING PRACTICE?

There are implications for managing clinical research in the acute care environment. This initiative demonstrated the value of a clinical research nurse led outreach service in delivering results. Creating and managing outreach teams can enhance research capacity and capability within a trust.

HOW WAS THIS WORK DISSEMINATED?

This work has been disseminated through:

- UK Clinical Research Facility Conference, Birmingham, 2013 – Poster
- Celebrating Clinical Research Nurses: NIHR East of England Regional Meeting, 2014 – Poster and Presentation
- Celebrating Clinical Research Nurses, A Global Force for Change Event in London 2014 – Poster and Presentation
- UK Clinical Research Facility Conference, Sheffield 2014

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stroke research

Re-engaging the stroke research team

Tracey Dobson *Senior Research Nurse*

Lisa Hyatt *Senior Research Nurse*

Portsmouth Hospitals NHS Trust

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

Stroke research at Queen Alexandra Hospital in Portsmouth began in August 2010, with one clinical research nurse and 4 Principal Investigators (PI). Several changes within the team infrastructure resulted in a lack of individuals to drive research forward. The PIs were overwhelmed with clinical work and engagement with research waned. This resulted in several months of poor recruitment into open studies.

By August 2012 there were two specialist research nurses and 6 PIs working within the stroke service, but recruitment into studies remained low.

WHAT WAS DONE?

Communication A communication lead research nurse was identified for each study; they would be responsible for maintaining the Investigator Site File and streamlining communication between the study site and the trial co-ordinating centre. Both research nurses were aware of all of the protocols and on every delegation log.

Every stroke consultant is the PI for one study and all are on the delegation logs as co-investigator for the other studies, thus enabling cover at all times for recruitment of potential participants. One of the research nurses is also PI for two studies.

Meetings Bi-monthly meetings with the PIs and any other interested parties to discuss departmental research were organised. Research nurses also attend relevant departmental meetings such as the Quality and Governance, Stroke Strategy and bi-monthly meetings with the Chief of Service to embed research into the stroke service. Attendance at local, regional and national conferences has increased to gain knowledge of available studies through networking with other areas.

Visibility Daily attendance at the ward board round, where inpatients are discussed, to identify potential trial participants. Trial information had been added to the doctors' handover sheet so that information is readily available along with the research nurse contact details. Small credit card sized inclusion criteria cards were printed, one for each study, and put on rings for the consultants and nurse practitioners. A notice board was installed within the Acute Stroke Unit containing general information about research and photographs of the Research Nurses for ease of identification.

An educational session was organised for all professions within the stroke specific education days to talk about the role and process of research. A departmental research page is updated regularly, on the hospital intranet, as a resource for all staff, detailing current trials and with links to pertinent organisations and Government Departments.

The feasibility process was improved – Know Your Population – and previous screening logs were used for data analysis.

WHAT WAS THE OUTCOME?

These steps were implemented in October 2012 and there followed a slow but increasing recruitment resulting in an award from the South East Stroke Research Network for the most improved site in 2013/14 in March 2014.

WHAT WERE THE LESSONS LEARNT?

Looking at the issues surrounding poor recruitment has led to an increase in visibility of the research nurses in all areas of the stroke service including clinics, which in turn has led to an increase in recruitment. The research team is now more cohesive and engaged in research despite increasing clinical pressures.

The lessons learned from implementing these changes have been used in other research active clinical areas to enhance recruitment, and has again led to an increase in activity.

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training trust staff

Innovation in research education: The James Paget University Hospital (JPUH) Research Programme

Claire Gibbs *Senior Research Nurse*

Karen Reavell, Cheryl Phillips, Jane Woods, Helen Nutt, Allyson Davison, Lynn Everett, Celia Whitehouse, Basia Brown *Research Nurses*

James Paget University Hospital

AIM OF THE WORK

The purpose of the work is to provide the core Research and Development Team with a standardised education programme and to implement a defined and documented training package designed to meet the requirements of Medicines and Healthcare Products Regulatory Agency (MHRA) inspections.

WHEN WAS THE WORK UNDERTAKEN AND OVER WHAT PERIOD?

A scoping exercise was carried out to confirm the programme content pertinent to both quality assurance and the needs of the team and to identify structures that were already in existence. (At the time the poster was written, the programme was being run for the first time). Ten sessions, each lasting one hour were delivered fortnightly. Attendance was compulsory and any session missed had to be undertaken within the two week period prior to the next scheduled session, at a time convenient to both the facilitator and the staff member. The programme was designed to cover topics which are relevant to both clinical and non-clinical research team members ie Clinical Nursing Team and the Research and Development Governance / Management Team. The course does not replace the ICH-Good Clinical Practice (GCP) course. All staff undertaking the James Paget University Hospital Research Programme will have previously undertaken ICH-GCP training.

WHAT WAS DONE?

Staff with six months experience were allocated a session to design, facilitate and evaluate with the support of the Senior Clinical Research Nurse (SCRN). All sessions were reviewed by the SCRN and Research and Development Manager and/or Band 7 Study Co-ordinator prior to being confirmed and agreed as ready for delivery.

WHAT WAS THE OUTCOME?

Verbal and written feedback was obtained following the delivery of each session and reviewed by the facilitator and SCRN. Suggestions for programme alterations were analysed and session content was changed where appropriate.

Delivery

- Group work
- Workshops
- Board game
- Scenarios
- PowerPoint / lecture
- Real-life situation examples

Programme Approval

The programme received approval from the JPUH Research Support and Governance Group, the Deputy Director of Nursing and the Trust Research Clinical Lead.

HOW IS THIS APPLICABLE TO CLINICAL RESEARCH NURSING PRACTICE?

The programme proved so successful that we now run four of the sessions on a monthly roll-out basis for all trust staff to attend, regardless of profession. The training has provided people with a much better understanding of the expectations required when they undertake a research study. This positive impact has also been shown in sponsors monitoring reports following study specific visits.

HOW HAS THIS WORK BEEN DISSEMINATED?

To date, this innovation has been disseminated at two conferences via poster presentation. We are currently in the process of writing an article for publication in a professional journal.

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working with families

Working with families to support and explain

Helen Richmond *Paediatric Research Nurse / Study Co-ordinator*

University of Oxford

AIM OF THE WORK

The study aimed to find out why babies and young children with Down syndrome (DS) have differences in blood production compared to babies without DS, and why about 1 in 100 young children with DS develop a specific DS leukaemia. The challenge was to engage families early, at a sensitive time, to recruit into the trial.

WHY WAS IT IMPORTANT?

DS leukaemia develops in pre-school children and can be highly curable with chemotherapy. The newborn period allows a unique window of opportunity for testing a population at risk for the presence of a transient biomarker (GATA1 mutation). This mutation, associated with DS leukaemia, becomes undetectable after the neonatal period and returns if leukaemia develops. We aim to monitor all participants until the children are five.

WHEN WAS THE WORK UNDERTAKEN AND OVER WHAT PERIOD?

The multi-site study began in 2006 and will recruit until spring 2016. In the first cohort of recruits (2006-2009), consent for sample analysis was not obtained at birth although samples were stored.

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

The urgent issues for the work were to:

- re-start the study operationally following a 9 month staffing gap
- apply for research ethics approval to seek consent to analyse samples at birth (which is more informative)
- engage with parents of new recruits to the study (300 additional recruits to date) and commence regular follow-up for the new cohort in both acute and community settings
- reconsent the initial cohort for retrospective analysis and a completion of study sample and data.

Identifying a population at risk is challenging ethically, logistically, technically and emotionally.

WHAT WAS DONE?

The starting point for me was to engage sensitively with parents who have just had a baby with DS. For the majority of families this is an unexpected diagnosis and family members face multiple challenges. I rely on the local collaborator in each site to introduce the study at an appropriate time. For most of the 18 geographically widespread recruiting hospitals, I am able to travel to meet new parents to support them and explain the study. I am able to explain how the result would enable monitoring of their child and/or extension of our knowledge.

WHAT WAS THE OUTCOME?

Setting up and adapting processes which I had first thought through in other nursing fields have enabled the execution of the multi-faceted aspects of the study. Revising the parent information sheet, developing partnerships with parents, negotiating working relationships with acute and community clinicians and their staff, NHS haematology laboratories and trusts have all helped to 'make it happen'. Thanks everyone!

WHAT WERE THE LESSONS LEARNT?

For the study process to succeed, it necessitates good practice, care, commitment, systematic organisation, perseverance (Keep Calm and Carry On!) and the motivation to do my best by the families. If I didn't know or realise these were all needed to start with, I know now!

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Celebrating the Clinical Research Nurse 2015

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

You can connect with our community on Twitter at #CRNurse.