A group of research nurses developed, piloted and rolled out a course to help set a baseline for the education of research nurses in England.

In this article...

- The need to improve and standardise nurse research education
- Development of a course to improve research skills
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Patients do better in hospitals that participate in clinical trials than in those that do not (Ozdemir et al, 2015; Majumdar et al, 2008). This means it is important to ensure patients are offered the opportunity to take part in research (Department of Health, 2013). It is also crucial that the quality of data from these often complex studies is valid and reliable.

To ensure clinical research takes place in all settings, there must be a trained and competent clinical research nurse (CRN) workforce able to deliver clinical trials; this requires a consistent and standardised approach to research nurse training. While research courses existed in 2013, there was no recognisable accreditation in clinical research nursing in the UK. To address this, a group of senior research nurses worked to develop, robustly pilot and roll out nationally a Fundamentals of Clinical Research Nursing course funded by the National Institute for Health Research (NIHR).

Background

The Department of Health plan (DH, 2011) and higher-level objectives of the NIHR aim to improve research performance through investment, by developing an infrastructure for research to take place. With that infrastructure in place, the research workforce must be supported by relevant training programmes to deliver the target number of recruited patients into clinical studies.

The need to translate research findings from early phase experiments to phase 3 and 4 studies requires a skilled research nurse workforce to ensure the quality of the research is appropriate. This would also help convince the pharmaceutical industry that the UK is the place to conduct clinical trials.

Clinical trials are increasingly becoming an expected treatment option for patients (DH, 2013), and more than 600,000 patients were enrolled on a clinical trial in 2014/15 (NIHR, 2015). In order to ensure optimum patient recruitment into clinical trials, the existing workforce – which includes approximately 10,000 CRNs in the UK – needs to be supported in developing the skills and knowledge required to recruit patients successfully, as well as to ensure ongoing consent and data-collection accuracy. Developing a standardised training course to support improved trial participation in the UK was urgently needed.

We sent a national survey to all comprehensive local research networks in 2011, asking about interest in a CRN course; this showed that the majority of respondents wanted a course to be made available to CRNs. A workshop, convened with NIHR support, showed there was consensus on...
the need and content for a standardised CRN course. While one of the authors, Emma Munro, was on a Florence Nightingale Foundation Travel Scholarship to the National Institute of Health (NIH) in the US in 2012, the institute offered its course as a template for adaptation to meet UK needs.

Following the NIH model, we pursued a unified approach with standardised components, enabling a more flexible workforce to meet the demands of clinical-trial delivery across all specialties and care settings. Thirteen expert research nurses from NHS organisations across the south and west of England worked together for six months in 2013 to develop a course. The NIHR supported four pilots that were held around the country and received excellent evaluations; they showed a clear positive impact on practice including on research efficiency, participant safety and the quality of research data once the course had been completed.

Course development

It was essential to develop a sustainable approach to training, so the course was written to enable delivery by any suitable CRN. The final pilot was delivered by a team of CRNs not involved in the course development, as this allowed them to evaluate the quality of the facilitator notes and therefore assess whether the course would withstand a “train the trainer” roll-out.

Research needs to be clinically embedded to achieve full impact, so it was important to develop a course that would also be suitable for nurses not involved directly in clinical research. This would enable them to better understand this evolving and growing field of practice.

Course content

Each session can be delivered as a stand-alone, and the complete course covers research principles and the whole patient journey in clinical research. It reflects the principles of Compassion in Practice (DH, 2012), which embraces the values central to all nursing practice with the patient at the focus of all that we do; putting the patient at the centre of all that we do; ensuring patients receive appropriate information and are able to give informed consent; recruiting participants into clinical research and retaining them for the study period; managing studies, data entry and documentation, and ensuring protocol integrity.

The sessions are designed to improve standards, and incorporate review and continuous improvement. The ultimate aim is to enable participants to develop expertise in delivering complex protocols, as well as ensuring robust quality systems and documentation.

Box 1 gives an overview of the course content with the impact of each session, while Fig 1 shows the length of time course participants had been working in the field of research nursing; the figures are from 69 respondents participating in three pilots and represent a 98% response rate. Participants are encouraged to develop an action plan detailing ways their learning could change their practice, and to write a reflective piece three months after attending the
course to evaluate its impact. Evaluation forms indicated that all participants anticipated changing their practice as a result of attending.

Evaluation of pilot courses
Each pilot course is subject to robust evaluation and the course evolved throughout the pilot to address the issues being raised. These included giving participants more time to complete the multiple-choice test taken at the end of the course and reviewing the order of the sessions to balance their intensity. The evaluations were overwhelmingly positive and high scores were achieved for all sessions. Fig 2 shows the extent to which each session achieved its aims, while Fig 3 shows some of the changes in practice anticipated by participants, while the quotes below are a selection from the evaluation forms:

- Session review: “Topics covered were very relevant and provide a framework for future learning”;  
- General: “Should be mandatory training for all researchers”; “best ever course that I have attended”; and “a must for new research nurses”;  
- Facilitation: “Nurses teaching nurses is excellent”; and “good interaction – provoked good discussions”;  
- Personal: “I feel more empowered and courageous”; and “better equipped to go back and review some areas of practice”;  
- Course structure/organisation: “Timing was managed excellently – really difficult to do, very impressive”;  
- Facilitators: “Run by a lovely group of people who are passionate about what they do – this makes me want to do better than I do already”.

Conclusion
We developed the course because we wanted to ensure that competent CRNs help deliver the best possible care and treatment options for patients in clinical trials. To do this, they required a consistent and standardised approach to training. To ensure sustainability, we have trained research nurse leaders to deliver the course within their local research networks. These leaders have worked with their local facilitators and the course has already been delivered to hundreds of research nurses to date.

The Fundamentals of Clinical Research Nursing course sets a baseline standard that is transferable across all the research networks. The need for trained and competent CRNs is clear to those in the field, and the course needs to be shared with the wider nursing community and funders. Essential to the success of the pilot was to have a tenacious and passionate group of research nurses collaborating to develop a standardised course, which was robustly evaluated and designed for delivery around the country. All of this was achieved within 18 months.

The rapid progression from concept to reality has made the course accessible not only to those new to this field of healthcare, but also to refresh existing skills and knowledge, as well as ensuring that clinical research staff have access to learning and remain fit to practise. As the course roll-out progresses across England, research patients and researchers are supported by a consistent and competent research nurse workforce, resulting in improved options for patients.

Innovation

The Florence Nightingale Foundation funded the travel scholarship that led to the development of the course.

References

For more on this topic go online...
- The nurse’s changing role in clinical research
  Bit.ly/NTResearchRole

Fig 3. Participants’ Intentions to Change Practice

- "Be more assertive when I would like to raise a concern, give me a stronger ability to challenge practices"
- "Implement patient diaries for all trials to help keep accurate A&E’s and their treatment"
- "Have a recruitment plan in place to help anyone who covers in my absence"
- "Introduce/discuss skills passport with colleagues. Discuss introduction site file check with colleagues. Discuss introducing weekly research meetings with senior research nurse"
- "Will write down my recruitment strategy"
- "To change the way I document in medical notes"
- "To try and coordinate a research midwives network in the North. Teach at mandatory MW days. More advertising. Ideas for increasing recruitment"
- "Better documentation following consent. I intend to look at all protocols for neonatal studies to establish what type of research they are, and who can receive consent for the studies"
- "Learn to say ‘No’ the right way. Voice my concerns"
- "Check if our trust has an archiving SOP, ensure all participants get travel payment consistently for all visits"
- "Proactive in networking with colleagues"
- "Implement study review meetings"
- "Implement study review meetings"
- "Keep on top of site files, in particular version control. Review our procedure for taking blood"
- "More structured audit preparation"
- "Think more about protocols and type of research. Be more involved in feasibility studies"
- "Better and more documentation recording"
- "To do an abbreviations and research word meaning list. To do a pack for new staff. Look at possibilities for email and text reminders for patients"
- "Proactive in networking with colleagues"
- "Go by the action plan provided (very useful)"
- "Check my local site files and their treatment options for patients in clinical trials. To do this, they required a consistent and standardised approach to training.

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