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Primary care research nurses increase patient access to trials and help practices become research-active

Service evaluation provides reliable information to inform growth and change

Clinical research nurses need to adapt their methods in the face of challenges in primary care

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Primary care research

The National Institute for Health Research (NIHR) is the research arm of the NHS; its 15 local clinical research networks (CRNs) in England are the means by which research is delivered at local level – whether this implies working with researchers on their studies or enabling the recruitment of patients. Primary care is one of 30 specialties represented in the NIHR CRN and, in 2016, the NIHR celebrated the fact that one million people had actively participated in primary care research studies (NIHR, 2017). This was an impressive milestone.

As the nursing role in primary care has evolved, so has the position of nurses in primary care research. Long gone are the days when it was just the GP who would invite patients to take part in a study, inform them, obtain their consent and perform the clinical tasks required. Today, research in primary care is a collaboration between the study team, GP lead, GP practice and clinical research nurse. The nurse’s role is critical, as research delivery is predominantly nurse-led.

Lack of capacity

In the past, a practice nurse with an interest in research would be given training and funding to support a particular study. A small number of research-active practices funded nurses through the NIHR and these nurses were given protected time to work on a number of studies. However, that capacity was not available in the majority of practices, which were dealing with the many pressures facing primary care (such
Clinical Practice

Innovation

Box 1. Two examples of primary care clinical research studies

Since our team was established, we have worked on many studies from the Nuffield Department of Primary Care Health Sciences (NDPCHS) at Oxford University, including the Helicobacter Eradication Aspirin Trial (HEAT) and the Improved Novel Vaccine CombinaTion Influenza Study (INVICTUS).

HEAT was a randomised controlled trial investigating whether a one-week course of Helicobacter pylori eradication would reduce the incidence of gastric ulcer bleeds in patients taking aspirin. Hosted by Oxford University and led by professor Richard Hobbs, it closed at the end of October 2017. We supported 31 practices to take part in this study. Between all NIHR CRNs involved, 8,282 participants were recruited, of which 1,663 were recruited by CRN Thames Valley and South Midlands.

INVICTUS is a phase-IIb, randomised controlled, participant-blinded clinical trial. Its purpose is to examine whether a new flu vaccine combined with the existing seasonal flu vaccine will better protect older adults from flu-like illness and reduce the severity and duration of flu-like symptoms, compared with the existing flu vaccine alone. This study is being led by professor Chris Butler.

as the struggle to recruit and retain clinical staff). Lack of capacity was the predominant barrier to GP practices engaging in research. Today, despite a recruitment drive, the number of full-time-equivalent GPs is still falling (NHS Digital, 2017). To increase research activity in primary care, significant investment is required.

New service

The vision outlined by the CRN Thames Valley and South Midlands in its primary care team structure consultation (Woods, 2015) was to:

- Build a peripatetic clinical research nursing service to fill the gap between practice interest and practice involvement;
- Grow and embed research activity across the three CRN Thames Valley and South Midlands counties (Berkshire, Buckinghamshire and Oxfordshire).

In March 2016, I was appointed as the senior clinical research nurse with a remit to develop and manage this new primary care clinical research nursing service. Its main aims were to increase access for patients wishing to participate in research and support GP practices in becoming research-active. The first year, my focus was on building a sustainable and cost-effective service. We worked on four studies while three more were being set up.

Collaborations

We work collaboratively with the Nuffield Department of Primary Care Health Sciences (NDPCHS), clinical trials unit, Oxford University, to meet our common goal of conducting research in primary care. Since our team was established, we have worked on many of their studies and this collaboration is ongoing. Box 1 shows two examples. We also work with other academic centres and are always keen to form new collaborations.

We can now boast a portfolio comprising a variety of disease areas and types of research, from observational studies to large randomised controlled trials. The latest trend seems to be for studies that involve medication deduction. These studies explore the idea that patients might be able to safety reduce the number of medications that they are taking. This has been very well received by patients who are prescribed multiple medications.

Service evaluation

In 2017 I decided to explore the idea of an evaluation to quantify the impact of the service and assess its effectiveness, quality, safety and patient focus. We could see the impact and quality of the service, but needed evidence to demonstrate this. Investigation into what worked well and what did not, as well as gaining individual responses from the GPs, would provide valuable feedback. Pawson and Tilley (2004) explain how evaluators are encouraged to do more than just demonstrate effectiveness or produce evidence on the way something works or fails to work, further investigating what works for whom and how.

Evaluation is “a process that takes place before, during and after an activity. It includes looking at the content, the delivery process and impact of the activity. It is concerned with making an assessment, judging an activity or service against a set of criteria. Evaluation assesses the worth or value of something” (Research Council UK, 2011). That definition confirmed that service evaluation was exactly what I needed.

I needed to find out whether the evaluation would require approval from a research ethics committee, and sought guidance from the Health regulatory Authority. The National Research Ethics Service guidance (NRES, 2013) indicates that the service evaluation is deemed by its design and conduct to judge current care, and thus does not require ethical approval.

Methodology

My first task was to make a plan to investigate the following:

- Are we having a positive impact on GP sites and their patients?
- Are we meeting the needs of our users?
- How are people responding to our service and where can we improve it?

Fig 1. Participants’ replies on overall experience (n=27)

Please rate your overall experience of working with the CRN clinical research nurse
The plan was to keep the questions short and straightforward to achieve as many responses as possible. Asking clear and concise questions is important when conducting an evaluation (Holmes et al, 2013), as gaining a good response rate is challenging.

A working group was formed to assist with finalising the evaluation questions and design. We considered different survey tools and selected Google Forms to deliver the questionnaire. Areas of consideration were pitch, delivery, timing, format and collection. Data collection and dissemination of the questionnaire were of paramount importance to ensure we would receive enough responses to obtain a true reflection of our service.

Seven questions – including free-text boxes – were developed. The questionnaire was embedded into an email, so that once people opened the email all they needed to do was to complete the questionnaire. To optimise the number of replies, we sent the emails out after the Easter break on 19 April 2017 and gave a deadline of 27 April 2017 for completing the questionnaire.

We established a list of practices (n=33) that we had supported in some way and sent the email directly to our contacts. The majority were the lead GPs for research with whom the research nurses had worked. In certain practices, the contact was the practice manager, as they had been more involved with research delivery. In total, we invited 33 practices to complete the survey.

Results
We received 27 responses before the deadline and were satisfied with the response rate, which we thought was enough to truly reflect our service. Among respondents:
- 70% said their overall experience of working with the clinical research nurse was excellent and 30% said it was good (Fig 1);
- 69% said they would recommend the service to other practices and 41% already had done so;
- 52% said they had seen a significant improvement for the practice and 44% said they had seen some improvement; one respondent said the practice had not benefited.

The results demonstrate that the service has been well received and that GPs and practice managers have had a positive experience. Some practice staff had already recommended us to other healthcare providers, which was good to hear.

Annaliese Owen, practice director at Key Medical Practice in Kidlington, told us: “We are new to research and have undertaken many studies simultaneously. This would have been impossible without the research nurses. They have all been well organised, very pleasant colleagues and we are enjoying having them in practice.”

“At first it can feel rather daunting exposing yourself during service evaluation”

Outcomes
Service evaluation provides evidence-based information that is credible, reliable and useful (World Health Organization, 2013). Demonstrating our quality has set a benchmark for continual growth and enriched the team, who can use the evaluation for their professional development. The evidence has been invaluable in enabling us to bring about change and secure funding for additional team members; as a result, our team has grown from four to six nurses. The evaluation has had other practical outcomes; for example, respondents had often asked us for advice on how to improve recruitment, so we are currently working on a ‘tips for recruitment’ resource. It has also highlighted the altruism of our research participants, without whom we would not progress.

Challenges and opportunities
The NIHR clinical research nursing strategy published in October 2017 encourages leadership and innovation (Hamer, 2017). With that strategy in mind, I wish to develop the service and my team. We want to deliver a dynamic, flexible service with impeccable professional standards. We are now a team of six nurses currently working on 18 studies. We will continue to build on existing collaborations, network to strengthen our position and explore new ways to increase recruitment.

I am currently exploring ways of increasing recruitment to opportunistic studies, which are inherently difficult to recruit to. The strategy involves approaching patients attending their GP practices ‘on the day’. We have been piloting a model that provides support for this type of recruitment strategy, and early indicators are that this has optimised recruitment.

The Nursing and Midwifery Council recently announced that more nurses are leaving the register than joining (NMC, 2017); this will exacerbate an already difficult situation. As GP practices shift to form federations, we need to be responsive in how we help them optimise recruitment to research studies. We need to keep evolving in our model design to meet the needs of an ever-changing NHS and respond to the many challenges faced by primary care services.

Conclusion
At first it can feel rather daunting exposing yourself during the process of service evaluation. However, it is vital to be transparent – and transparency can improve health quality and be a powerful catalyst for change (Feeley, 2016). Performing service evaluation is a positive step that generates tangible data to inform change.

The outcomes of our service evaluation have given us direction and scope for the future. They have inspired new ideas of ways to work and have reinforced our will to be more flexible and responsive in our approach. I would like to see service evaluation fully integrated into healthcare, and I would recommend undertaking a service evaluation to any team that wishes to gain insight into, and improve, their performance. NT

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