Research nurses play a vital role in ensuring clinical studies run smoothly and that participants are safe.

The role of the research nurse

In this article...

- How research nurses help to increase clinical research activity
- Skills needed by research nurses and what the role involves

Keywords: Research nurse/Teamwork/ Patient advocacy/Patient safety

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Research support

In recognition of the benefits of promoting cooperation in research, the government established The National Cancer Research Network (NCRN) and the National Institute for Health Research (NIHR) to provide support and advice for anyone wishing to undertake clinical research. The NIHR has set up a portfolio of high-quality studies adopted by the institute. Recruitment into these studies is one way by which research teams are assessed and funding is awarded.

Within Bradford Teaching Hospitals the Bradford Institute for Health Research (BIHR) is led by an academic professor with a medical background. Shortly after the new consultant was appointed, he set about building a clinical research team for the specialty. Funding from the BIHR, NCRN and NIHR enabled us to recruit 1.3 whole-time equivalent (WTE) nurses to the maxillofacial research team. This core group of one consultant surgeon and 1.3 WTE research nurses worked with the rest of the head and neck cancer multidisciplinary team to increase our clinical trial activity; we have since received funding for another WTE research nurse and a research administrator. Our own CRUK funded multicentre trial will recruit a clinical trial coordinator and we are shortly to appoint a clinical research fellow.

The role of the research nurse

Coming into the world of clinical research from hands-on care provision involved a steep learning curve for the nurses. A solid foundation based on years of experience in nursing is vital to the role, but research is a vital aspect of the health service and essential to the provision of effective and safe health and social care (Royal College of Nursing, 2009; Department of Health, 2005). However, experience at Bradford Teaching Hospitals Foundation Trust has shown us that without dedicated research nursing staff it is difficult to succeed in clinical research. By developing a research team with nurses at its core we have substantially increased recruitment to clinical trials and obtained a phase 3 clinical trial grant from Cancer Research UK. This article discusses our experience of developing a new clinical research team and the role of its nurses.

Research in the maxillofacial unit

The trust’s maxillofacial unit plays a leading role in treating patients with head and neck cancers. Treatment for these cancers is often intensive and may involve major surgery, radiotherapy and chemotherapy. It can have a dramatic effect on patients’ quality of life and they often need support from a multidisciplinary team of health professionals. Research is essential to continue improving every aspect of their care, from earlier diagnosis to increased survival and from developing new treatments to helping patients with all their physical, social, psychological and emotional needs afterwards.

Until recently, the unit undertook little research activity. However, in 2006 a new consultant surgeon with an interest in clinical research was appointed, and the number of clinical trials has since increased, as has the number of patients recruited into trials. Within two years, four studies were opened and 120 patients enrolled. We now have five trials open and are hosting a new Cancer Research UK-funded multicentre trial.

Setting up and running a clinical trial is a complex process that takes time, planning and resources. All research involving humans is also strictly regulated to ensure participants’ safety and wellbeing.

Getting started in research is both exciting and challenging. One of the most valuable lessons we have learned is that teamwork is crucial. All members of our team have their own unique skills and expertise to contribute; this includes participants themselves, whose first-hand knowledge of being a patient can give researchers better insight into important issues to address that may be overlooked by clinicians. Collaboration with other researchers and experts is also important – several of the unit’s current projects are being run jointly with other hospitals and universities.

5 key points

1 Clinical research is vital for finding new treatments and improving patient care
2 Research nurses need a thorough understanding of the research process and terminology, and of the specialty under investigation
3 The nurses act as patients’ advocates, ensuring they are protected and supported throughout the research study
4 Research nurses need a wide range of skills including management and organisation, teaching and mentoring, communication and IT
5 Working with other researchers and the multidisciplinary team is crucial for successful research
it requires a range of additional skills and knowledge.

The research nurse’s job is complex, varied and interesting. Although the principal investigator (PI) has ultimate responsibility for any study, it is often research nurses who coordinate its day-to-day management. This means leadership and organisational skills and a flexible and adaptable approach are vital. Since the nurses may at times work alone, they also need to be able to prioritise and to make decisions. As Poston and Buescher (2010) explain, research nurses are at the fulcrum of clinical trials. They not only need a comprehensive understanding of the specialty in which they are working, but also an extensive knowledge of the research process and research-related legislation. In addition, they need a variety of computer-based skills, especially in the use of word processing, spreadsheets, database and presentation software, and the ability to undertake internet searches.

The many duties of a research nurse include preparing trial protocols and other trial-related documentation, submitting study proposals for regulatory approval, and coordinating the initiation, management and completion of the research.

Ensuring patients give fully informed consent before entering trials is a key part of the role. This involves screening for potential participants, ensuring patients are given all the information they need and that they fully understand the purpose of the study, any potential risks and benefits and what will happen to them if they agree to participate. It must also be made clear to patients that they do not have to participate and are free to withdraw at any time without it affecting their treatment or care. For this, nurses need an ability to give clear explanations, along with excellent communication and interpersonal skills.

Once patients are enrolled to a trial, the research nurse may be responsible for randomisation, and for collecting and recording data. Quality and reproducibility of data are two of the key principles of ethically sound research. All data must be accurate and complete for the results of the study to be valid, and research nurses often have responsibility for this aspect whether it be entering data or checking that all records are correct and up to date. This requires attention to detail, a meticulous approach and a high level of integrity.

Prompt reporting of adverse events is fundamental to patient protection and a responsibility of the research nurse. These may be any unfavourable change in health or suspected side-effect experienced by a participant, which does not necessarily have to have a causal relationship with the treatment they are receiving (European Medicines Agency, 2002).

In the event of a patient suffering any untoward occurrence such as significant disability, incapacity or death, any life-threatening event, hospitalisation or prolongation of hospital stay or any form of congenital abnormality, a serious adverse event must be declared within 24 hours of the researchers becoming aware of it. If there is any possibility of harm being done to participants as a result of being in a trial, it is essential to identify it quickly and take appropriate action, which may even mean closing the trial prematurely.

Finally, research nurses may also act as teachers, mentors and advisers to other health professionals, or to give presentations at conferences and other meetings.

**Patient protection**

Patient advocacy is one of the most important of the research nurse’s responsibilities. The International Conference Harmonisation Good Clinical Practice (ICH GCP) guide emphasises the protection, safety and wellbeing of trial participants must be a priority – no one taking part in clinical trials should be harmed. Anyone working in clinical research must, therefore, have up-to-date training in GCP (European Medicines Agency, 2002) and act according to the tenets of The Declaration of Helsinki’s Ethical Principles for Medical Research Involving Human Subjects (WMA, 2008). This stipulates that participants’ health and wellbeing must take precedence over all other interests. GCP training must be maintained on a two-yearly basis through a one-day course, or an online course with assessment.

**Conclusion**

From having a dearth of research, our unit has steadily built up an increasing portfolio of clinical trials. The key lesson learnt from building the portfolio has been the importance of teamwork, which is vital to the success of clinical research. Every member of the team has a significant part to play but research nurses are the lynchpin of our team. The role is extremely interesting, dynamic and challenging but demands a wide range of skills.