Clinical research networks in diabetes: the evolving role of the research nurse

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Summary

The importance of evidence-based care for patients with diabetes is well established, and the evidence required to make decisions about patient care is generated through research and audit. The rigours of the research process and the need to enrol large numbers of patient volunteers in a timely manner has meant that most studies are now conducted at multiple sites. Research infrastructure is costly to implement, but is important for successful clinical research projects. By establishing permanent networks this infrastructure can be maintained and built upon.

Research nursing has evolved as a new but very important discipline within the nursing profession in recent years and it has been pivotal for the success of many studies. In this article we examine the potential for clinical research networks to facilitate high quality clinical research and in particular the development of the research nurse role.

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Key words

Clinical research networks; research nurse

Introduction

Collaboration between researchers is not a new concept. Clinical studies of any significant size can only be completed with input from a number of sites, because of difficulty in recruiting large numbers of volunteers and the resources required. Recent landmark studies in diabetes, such as the Diabetes Control and Complications Trial (DCCT)[1] and the UK Prospective Diabetes Study (UKPDS),[2] have relied on the participation of numerous collaborators to support data collection, and have demonstrated the potential for success with this kind of research organisation. These multicentre collaborations are often informal, involving like-minded colleagues who have a common interest and purpose, yet to sustain large projects they still require a management and organisation infrastructure.

Despite the time and money involved in establishing collaborations for multicentre studies, few of the infrastructures remain in place after the project has finished. Therefore, new studies often have to start by building new collaborative networks. It makes sense, therefore, to establish permanent networks that have the management and organisation permanently in place to take on large new studies. In theory, such networks should prove cost-effective and should offer efficiencies of scale that can be realised through rapid start-up and recruitment.

The National Institute of Health (NIH) based in the USA has funded a project to create a catalogue of networks, as part of a project designed to speed translation of medical discoveries into clinical practice.[3] They defined a network as having at least three independent entities (participating centres), having its own research mission and having leadership that develops or appraises research ideas. The Inventory and Evaluation of Clinical Research Networks (IECRN) database holds details of over 250 networks across the USA. Nearly 20% of the networks listed state that diabetes is an area of research for their network, reflecting the growing problem of diabetes in both developed and developing nations.[4] Similarly, the National Health Service (NHS) in the UK has set up a register of networks, although this encompasses all networks, not just those set up for research purposes.[5]

In July 2006, the IECRN published a report of their survey of 248 of the networks registered with them.[6] They identified a number of issues that were important

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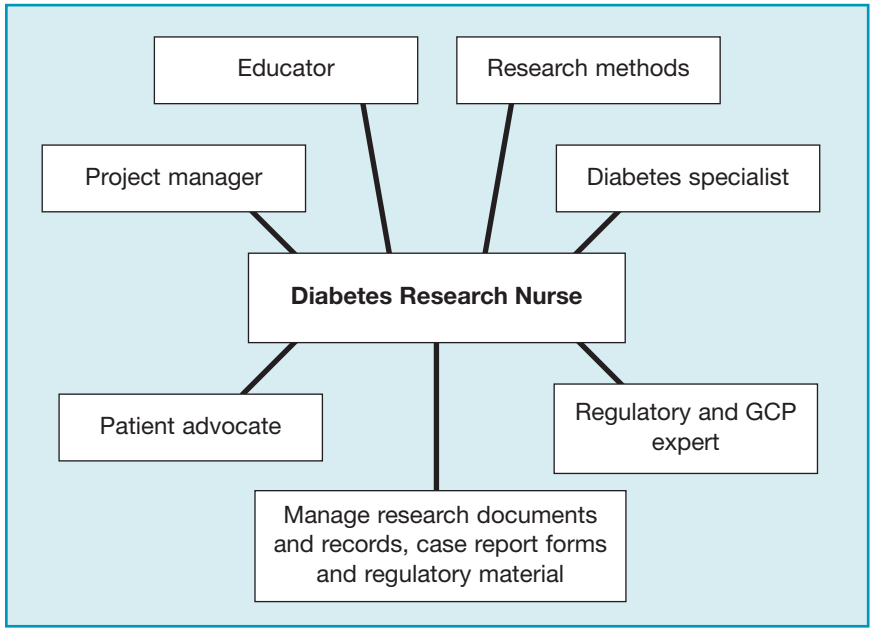

Figure 1. The many roles and responsibilities of the diabetes research nurse

for successful research networks, including:

- Training
- Support staff
- Commitment to maintain the infrastructure on a long-term basis.

The UK government has also recently recognised the benefits to be derived from a well-organised, high-quality research network, and has committed significant investment over a five-year period to establish permanent clinical research networks within the NHS.[7] The organisation of these networks will include a number of specialist networks set up to address major health issues, including medicines for children, cancer and diabetes.[8]

The research nurse: a new role in diabetes nursing

A critical function within the infrastructure of a clinical research network is that of the research nurse. This role was little recognised 10 years ago but in recent years has developed into its own nursing speciality.[9] Commercial research is prescriptive and limited by the need to satisfy rigid regulatory requirements, and while nurses have been pivotal in ensuring that projects achieve their timelines and goals, there are fewer opportunities for intellectual input. It is, however, through this route that many research nurses have developed their skills. The research nurse must be an expert in nursing and clinical care within a particular speciality, and in addition is also required to be a project manager and organiser, an expert in the methodologies and regulation governing clinical research, and a skilled communicator and recruiter (Figure 1). These skills now lend themselves to academic studies, where the research nurse can not only support research, but can be instrumental in originating and designing the study, taking a lead role in the project.

The research nurse is the patients' advocate during the study. The enrolment of volunteers into research projects is well-known as a potential area for studies to fail to meet their targets, and diabetes is no exception.[10] It is the recognition of nursing skills that has put nurses in the vanguard of successful research projects. It is often the research nurse who is the best communicator with patient volunteers, who has the time to inform and the time to deal with patient concerns. It is often the nurse that the research volunteer will see and deal with on a regular basis throughout their study involvement. The research nurse is critical for developing a relationship of trust and professionalism with the research subject, and such is the importance of this role that study bereavement in research volunteers has now been recognised when studies have completed.[11]

Like so many research posts, however, the research nurse position is insecure and often subject to the vagaries of research grants or short-term income from clinical trials. The UK Diabetes Research Network goes some way to addressing this problem, with a commitment to five-year funding for a team of approximately 35 diabetes specialist research nurses, strategically located in centres of clinical research excellence around the UK.[12]

Research nursing: training and career development

As yet, there is little training available specifically for the research nurse, although many courses and programmes are available through commercial and academic institutes covering many of the topics relevant to research nursing, such as clinical trial methodology, regulation of clinical research and ethics. It is important that research teams are appropriately trained, not only to meet their obligations under European legislation and good clinical practice,[13] but more importantly for the sake of patient safety. The UK Diabetes Research

Network has recognised this lack of research nurse-focused training, and has organised training specifically designed to address these needs.[12] This will be further enhanced when a research nurse forum is established to guide new programmes of training and development for the network.

As research nursing develops as a career, it offers the opportunity for nurse professionals to develop their own programmes of research and expand their careers.[14] The IECRN network definition requires that the term 'clinical' be interpreted as 'health related to humans' and includes health communication, patient care and quality improvement. This illustrates that there is wide scope for nursing research to be carried out through effective and well-managed networks.

Research nurse representation on review committees

Recent years have seen the development of patient and public involvement in healthcare and in research, especially where supported through public funds. Lay persons have for many years been represented on ethics committees and charitable funding organisations, but public involvement is now widening to the extent that patient advocates are becoming not only a key part of the research review process, but are helping to set the direction of medical and clinical research. It is possible that this will lead to some refocusing away from basic science to patient-centred issues, and topics more directly relevant to care and to patient management.

Research nurses are likely to be best placed to lead this type of research and their experience will be essential in establishing the feasibility and practicality of all research projects.

Research nursing across Europe

The potential for research networks to stretch across national boundaries is important, especially within Europe. In 2004, the member states of the European Union (EU) were required to introduce legislation governing clinical trials with investigational medicinal products.[12] This created a homogenous regulatory environment and should smooth the system for implementing trials across Europe. Furthermore, the 25 member states of the EU have a joint population of approximately 460 million,[15] of which it is estimated that 25 million have diabetes, a number which is likely to double by 2025.[16] Therefore, the potential for recruiting patients into clinical trials is significant if appropriate research network infrastructures can be put in place. Organisations such as FEND,[17] the Alliance for European Diabetes Research (EURADIA)[16] and European Diabetes Nursing Research[18] are promoting pan-European networking, and promoting more high-quality research dedicated to diabetes in Europe. Since 1999 FEND has recognised the role of the nurse in research through its annual award for nursing research in diabetes. Furthermore, the European Medicines Agency[19] has been calling for a pan-European network for studies to investigate medicines for children, which would provide obvious possibilities for diabetes studies in the young.

Research projects often take several years to complete, during which time professional relationships are established. The formation of networks can overcome some of the issues of alienation and remoteness that individual centres might experience at the start of a project. Establishing contacts within a network is important for sharing ideas and best practice, and also acts as a motivator during meetings and conferences. Pan-European networks offer the opportunity to share experiences and differences in working practice, although these differences may need to be taken into account when considering the feasibility of multi-national research projects.

Finally, it is pertinent to recognise the importance of effective communications and information flow for successful projects. By establishing networks of research centres, successful systems and procedures can be carried from one project to the next, thereby avoiding constant repetition and additional cost because network staff become familiar with the operational aspects of their work.

Conclusion

The evolution of clinical research networks and the development of diabetes research nursing as a speciality (usually embedded within the role of the diabetes specialist nurse) offers great potential for successful research outcomes and fulfilling careers. The importance of the research nurse has already been established through landmark studies,[1,2] and this role will be pivotal to the future success of clinical research networks.

Networks that recognise the full range of skills required to deliver a successful research project will be able to address a wide range of issues relevant to patients and carers. Research nurses will be at the vanguard and appropriate training and recognition of their specialist skills is urgently needed.

Conflict of interest statement:
None.

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