CLINICAL INVESTIGATION

Do clinical research networks work? The NIHR diabetes research network after 6 years

Clin. Invest. (2012) 2(10), 971–974

Eleanor Kennedy[1]
& David R Matthews*[1,2,3]

[1]Oxford Centre for Diabetes, Endocrinology & Metabolism, Churchill Hospital, Oxford, UK
[2]National Institute for Health Research Oxford Biomedical Research Centre, Oxford, UK
[3]Harris Manchester College, Mansfield Road, Oxford, OX1 3TD, UK
*Author for correspondence:
Tel.: +44 1865 271015
E-mail: david.matthews@ocdem.ox.ac.uk

Clinical research in the UK has been boosted over the past decade thanks to the creation of a number of dedicated clinical research networks. Each of these facilitates the conduct of trials from both the academic and commercial sectors. The National Institute for Health Research Diabetes Research Network has been established to facilitate research that will be of benefit to people with diabetes or those who are at risk of developing the condition. Since 2006, the network has helped to recruit over 200,000 patients into over 600 clinical trials and other well-designed studies. The challenge over the next few years will be to consolidate this progress and to work with the network's sister networks to drive forward new and innovative ways to encourage patients and members of the public to become involved in research; from participation in clinical trials to working with the networks to ensure that the patient voice is heard and that the trials that are run are pertinent and relevant to people living with the condition.

Keywords: clinical research network • diabetes • National Institute for Health Research

Clinical research is at the core of our progress in health and medical care. We know how to stop duodenal ulcers, how to prevent heart disease, how to treat hypertension and how to increase longevity in diabetes. The information is not generated in a library or by computers or even in research laboratories – the knowledge comes ultimately from the army of volunteers who give both their time and dedication to help future generations. This is an altruistic contribution to our society, and one that needs acknowledging, encouraging and facilitating.

Since clinical research is so fundamental to the improvement of healthcare, the Department of Health set up the National Institute for Health Research (NIHR) in 2006 to create a world-class research environment embedded within the UK NHS. The aim of the NIHR is to support outstanding individuals, working in state-of-the-art facilities and conducting leading edge research focused on the needs of patients and the public [101].

Accordingly, the NIHR Clinical Research Networks were established to provide essential infrastructure to high-quality clinical studies and other well-designed research across the pharmaceutical sector and the academic arena [102]. Six topic-specific Clinical Research Networks formed the first phase of network development and they addressed cancer; dementia and neurodegenerative diseases; diabetes; medicines for children; mental health; and stroke. Two subsequent networks were created – a primary care research network and a comprehensive clinical research network, covering all other disease areas [103,104].

The NIHR Diabetes Research Network

The NIHR Diabetes Research Network was awarded by competitive tender to an innovative consortium from Imperial College London and the Oxford Centre

FUTURE SCIENCE part of fsg

for Diabetes Endocrinology and Metabolism at the University of Oxford (Oxford, UK).

The primary goal of this network was, and remains, the overarching need to achieve benefits for people with diabetes, or at risk of developing diabetes, through excellence in clinical research. Its aim is to provide a world-class health service infrastructure, both to support clinical research in diabetes and to remove the barriers to its conduct [105]. With the direct patient care costs of diabetes in the NHS currently at £9.8 billion per annum and the indirect costs associated with diabetes estimated to be approximately £13.9 billion per annum, there is a very pressing need to ensure that the UK pioneers new treatments for a condition that, by 2035, is expected to increase to affect 6.25 million people in the population of the UK [1].

NIHR Diabetes Research Network Local Research Networks

In order to facilitate research in as many regions of England as possible, the network set up eight Local Research Networks to support the delivery and conduct of clinical diabetes research [2]:

- Eastern England – Cambridge University Hospitals NHS Foundation Trust;
- North East and Cumbria – Newcastle Upon Tyne Hospitals NHS Trust;
- North East London – St Bartholomew's and the London Hospital NHS Trust;
- North West – Salford Royal Hospitals NHS Trust;
- North West London – St Mary's Hospital NHS Trust;
- South East Midlands – University Hospitals of Leicester NHS Trust;
- South West Peninsula – Royal Devon and Exeter NHS Trust;
- Thames Valley – Oxford Radcliffe Hospitals NHS Trust.

Each of these subsidiary network centers has clinical and academic collaborations across an area that encompasses a wide variety of clinical services and patient populations, including primary, secondary and tertiary care. Their objective is to lead, support and promote research in both Type 1 and 2 diabetes with a focus on recruitment to national clinical trials and other well-designed studies. This leads to improved patient care, coordination and speed of research, and enhances the quality of research.

Progress

Since inception, the NIHR Diabetes Research Network has recruited more than 200,000 patients into a portfolio total of over 600 studies [106]. A major emphasis is placed on recruitment to time and to target. Currently, the network has an 82% success rate in this for industry-led studies and 88% for academic studies. The network has both a co-director and an industry and portfolio lead who specialize in working with the commercial sector to provide unique access to a broad range of centers in primary and secondary care settings, and unparalleled access to newly diagnosed patients with Type 1 diabetes. Additionally, contingent on a large number of different commercial trials that have been run through the network since 2005, the organization now has particular experience and expertise in cardiovascular outcome trials, monoclonal antibody studies and Type 2 diabetes studies in primary care settings.

With increasing emphasis on treating people with Type 2 diabetes in primary care, the network has made enormous strides in offering general practices and primary care professionals the opportunity for them and their patients to participate in high-quality research studies [3].

Involvement of patients

Clinical research is expensive and complex. By contrast with experiments in laboratories, the environment for clinical research is generally not controllable. Therefore, large numbers of patients need to be recruited to correct for the vagaries of chance in a free-living society. A typical trial involves clinicians asking patients to take one of two possible choices of drug – selected by randomization – and then coming to special research clinics at intervals for a check-up. This lays a particular burden on the patients, who may have to come to a clinic or be seen by a nurse more frequently than they might normally expect. On the other hand, there is a substantial gain to these volunteers who are likely to receive better continuity of care, get to know the healthcare team at a personal and friendly level and likely to have many checks on their health. The recorded responses to questions about being in trials are almost always enthusiastic [107].

One core function of the networks has to be 'making the case' for research to patients. Health centers, hospitals and clinicians need to encourage patients into feeling part of the drive for improvement – in a health-service that is fundamental to the wellbeing and prosperity of the nation, we need to espouse the idea that we have rights to medical care and responsibilities to contribute to its improvement through better processes, better drugs and safer and faster procedures. These all depend on the volunteer army.

Nor is it necessary for patients to experience research in its most obvious form – that of the randomized controlled trial. We should be asking patients to help with at least one of four ways of engaging with the research community:

- Allow researchers to access data in anonymized format for epidemiology and hypothesis generation, and sign up for the receipt of newsletters and opportunities in research;
- Fill out a questionnaire about experiences of the service and give us ideas of how the health service can be improved;
- Volunteer as a 'patient advocate' to put forward the patient perspective as someone affected by diabetes;
- Participate in one of the clinical trials or research studies adopted by the network.

One of the core objectives of the diabetes network has been to expand and enhance participation in research. This includes public outreach initiatives delivered to local communities, and staff speaking at events coordinated by patient support groups or partner organizations. For 2010–2011, the NIHR Diabetes Research Network recorded 24,348 individual points of contact between its staff and the public, helping to engage more people in recruitment and involvement activities. Patient advocates can also benefit from receiving training including 'research process' and 'critical analysis skills' sessions.

Involvement of pharmaceutical companies & academic researchers

The thinking behind the networks is hard-headed. Trials and medical research drive up standards, keep pharmaceutical companies engaged in centering medical research in the UK and drive down costs by the abandonment of processes and drugs that work less effectively. However, trials and studies are tough to run. It has been stated that there are three problems with most clinical trials – recruitment, recruitment and

Executive summary

Background
- Clinical research is fundamental to the development of new treatments. Trials involve an altruistic contribution by patients to the good of society and the networks are designed to enable more patients to participate and to deliver trials infrastructure available to both the pharmaceutical sector and the academic community.

The National Institute for Health Research: Diabetes Research Network
- Diabetes costs the NHS over £10 billion every year. There is a pressing need for new treatments and therapies. This research network has as its overarching goal the improvement of care and the delivery of optimal therapy to those with diabetes, by supporting recruitment into trials and studies within the context of a world-class health service infrastructure. This has been achieved through eight local area networks, now covering the whole of England and coordinated by an innovative consortium based in Imperial College London and in Oxford.

Progress
- The progress has been dramatic in terms of the totality of trials, studies and recruits. Over 600 trials in diabetes have been accepted into the portfolio and over 200,00 patients have been recruited.

Involvement of patients
- Clinical research depends on volunteers – these volunteers need to be found and the experience of research has to be one of active engagement. There is a right to care within the NHS, but there is also a responsibility to help towards the therapies of tomorrow. Patients can help by allowing access to their records, by taking time to fill out questionnaires, volunteer as a 'patient advocate' or become involved closely by being a recruit into a trial.

Involvement of the pharmaceutical companies & academic researchers
- The three major problems of clinical research have been characterized as 'recruitment, recruitment and recruitment'. With this knowledge the trials networks were established with an explicit emphasis on helping the pharmaceutical industry and academics find volunteers who were willing and enthusiastic. Resource has followed the vision so that the core function of the network is to help the recruitment process.

Conclusion
- Networks have been a flagship accomplishment of the National Institute for Health Research. Thousands of patients have been recruited into trials. Academic researchers and pharmaceutical companies alike, have benefitted from this far-sighted programme.

Future perspective
- As the public becomes increasingly aware of the importance of clinical research, researchers need to make the pathway into research easier. The successful outcomes of clinical research and the potential benefits of participation need to be promoted to a much wider audience.

recruitment. So the core function of the network is to help this process. The resource is at the full disposal of the pharmaceutical industry accessed via the website [108]. There is a tendency to become bureaucratic but concentration on the deliverables is circumventing this. For example, ethical review and permission is essential in all trials, but once given should not be the subject of further enquiry and change by a grant-giving body or by a trust given the task of managing finance. The networks engage daily in the encouragement of trials into their portfolio, by the deployment of their nurses into the health centers, clinics and communities in order to find volunteers, and by helping with many detailed aspects of the delivery of high-quality studies.

Conclusion

Networks have been a flagship accomplishment of the NIHR. Thousands of patients have been recruited into trials. Academic researchers and pharmaceutical companies alike have benefited from this far-sighted program – it has been, and continues to be, a resounding success.

Future perspective

With such success, the NIHR Diabetes Research Network now faces the challenge of ensuring continued progress. With many patients and members of the public already enrolled into trials that are currently running through the network and many more who have volunteered and are awaiting a trial to join, the next test will be to find new ways of marketing the network. Increasing use of the internet and in particular of social networking sites means that the conventional, healthcare team-led way of recruiting people into studies is changing. And, as the public becomes increasingly aware of the importance of clinical research, researchers need to make the pathway into research easier. Additionally, the successful outcomes of clinical research and the potential benefits of participation need to be promoted to a much wider audience.

Financial & competing interests disclosure

DR Matthews is co-director and E Kennedy is a project manager of the Diabetes Research Network. The authors have no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed.

No writing assistance was utilized in the production of this manuscript.

References

1 Hex N, Bartlett C, Wright D, Taylor M, Varley D. Estimating the current and future costs of Type 1 and Type 2 diabetes in the UK, including direct health costs and indirect societal and productivity costs. *Diabet. Med.* 29(7), 855–862 (2012).

2 Matthews DR, Kennedy ED, Darbyshire JH, Johnston DG. The UK Diabetes Research Network – an opportunity and a challenge. *Diabet. Med.* 24(1), 7–9 (2007).

3 Kennedy ED, Chester P, Majeed A, Wallace P, Matthews DR. Networks offer new opportunities for diabetes research. *Prim. Care Diabetes* 4(1), 3–8 (2010).

Websites

101 UK NHS. National Institute for Health Research. www.nihr.ac.uk/Pages/default.aspx (Accessed 24 June 2012)

102 UK NHS. National Institute for Health Research – Clinical Research Network. www.crncc.nihr.ac.uk/homepage (Accessed 24 June 2012)

103 UK NHS. An overview of the Clinical Research Network and what it provides. www.crncc.nihr.ac.uk/about_us (Accessed 24 June 2012)

104 Guardian Healthcare Network. National Institute for Health Research clinical research zone. www.guardian.co.uk/healthcare-network-nihr-clinical-research-zone (Accessed 24 June 2012)

105 National Institute for Health Research Diabetes Research Network. www.ukdrn.org (Accessed 24 June 2012)

106 Clinical Research Network Study Portfolio. http://public.ukcrn.org.uk/search/ (Accessed 24 June 2012)

107 National Institute for Health Research Diabetes Research Networking. www.diabetesresearchnetworking.org (Accessed 24 June 2012)

108 The Diabetes Research Network – how we can help. www.ukdrn.org/industry/how-we-can-help.aspx (Accessed 24 June 2012)