The UK Diabetes Research Network—an opportunity and a challenge

D. R. Matthews, E. D. Kennedy, J. H. Darbyshire* and D. G. Johnston†

Oxford Centre for Diabetes, Endocrinology and Metabolism, The Churchill Hospital, Oxford, *MRC Clinical Trials Unit, London and †Imperial College, St Mary's Hospital, London, UK

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Abstract

The Department of Health has funded a national diabetes network to support clinical research. The network will facilitate recruitment into clinical trials and has been widely welcomed by clinicians. However, if the network is to reach its full potential, all those involved will need to advocate a change in attitude towards clinical trials and research, encouraging participation and contribution of data. Clinicians need to be willing to take a proactive view about research studies, and to encourage patients to adopt a positive and altruistic attitude towards trial participation. The future of trials and other important clinical research in the UK may depend on it.

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Abbreviations GP, general practitioner; MRC, Medical Research Council; NHS, National Health Service; QOF, Quality Outcome Framework; UKCRN, UK Clinical Research Network

Introduction

In July 2005, the Department of Health announced that an important component of the UK Clinical Research Network (UKCRN) would be the creation of a diabetes research network. A national network is being developed to support clinical research and to facilitate the conduct of randomized prospective trials and other well-designed studies. In addition to diabetes, UKCRN supports five other topic-specific clinical research networks in cancer, dementia and neurodegenerative diseases, medicines for children, mental health and stroke. A primary care network is also currently being established. The ultimate aim is to facilitate and to increase the quantity and quality of clinical research across the full spectrum of disease and clinical need. The UKCRN will sit within the larger, international arena of clinical research and particularly emphasize the need to collaborate with other existing or proposed networks in Europe.

The UKCRN and the Department of Health have recently announced the appointment of eight Local Research Networks to support the delivery and conduct of clinical diabetes research. The new networks span England and are based in the following regions:

- North East London (Barts and the London Hospital NHS Trust with Professors Graham Hitman and Gene Feder as clinical leads);
- South West Peninsula (Royal Devon and Exeter NHS trust with Professor Andrew Hattersley as clinical lead);
- North and East Cumbria (Newcastle Upon Tyne Hospitals NHS Trust with Professor Mark Walker as clinical lead);
- South East Midlands (University Hospitals of Leicester NHS Trust with Professor Melanie Davies and Dr Kamlesh Khunti as clinical leads);
- Eastern England (Cambridge University Hospitals NHS Foundation Trust with Professor Nick Wareham as clinical lead);
- North West London (St Mary's Hospital NHS Trust with Professor Robert Elkeles as clinical lead);
- North West (Salford Royal Hospitals NHS trust with Dr Martin Gibson as clinical lead);
- Thames Valley (Oxford Radcliffe Hospitals NHS trust with Dr Andrew Farmer as clinical lead).

The primary goal of this new diabetes initiative is to achieve benefits for people with diabetes, or at risk of developing diabetes, through excellence in clinical research. The creation of the diabetes network provides a unique opportunity to estimate current prevalence, to gain insights into the relative importance

Correspondence to: Professor D. R. Matthews, Chairman, Oxford Centre for Diabetes, Endocrinology and Metabolism, Churchill Hospital, Headington, Oxford OX3 7LJ, UK. E-mail: david.matthews@ocdem.ox.ac.uk

of established and novel risk factors and to determine new strategies for the treatment and prevention of diabetes. Its remit is to deliver high-quality clinical research for both the commercial and academic communities and to improve both the clinical research capacity and its coordination throughout the UK.

Involving more people affected by diabetes in research is not, however, a simple undertaking. In a climate where research and researchers are regularly scrutinized in the media, we need to be robust in our justification for clinical research and trial participation and the benefits these can bring in strengthening evidence-based medicine. For the network to succeed, it is vital that people with diabetes are provided with a variety of ways by which to become involved. Working closely with INVOLVE (formerly Consumers in the NHS), a national advisory group which aims to promote active public involvement in the NHS, we need to develop a network of volunteers willing to be a part of this initiative and a framework that encourages awareness, understanding and participation across a wide section of society.

There are two major obstacles to this undertaking. First, diabetes is essentially a 'quiet', low-profile condition. It affects all age groups, with Type 1 diabetes predominantly occurring in young people and Type 2 diabetes nowadays affecting people of all ages. Most people living with diabetes are cared for in primary care and many regard the condition as a private (and, sometimes, even a secret) matter. Patients move from the acute phase to self-management very quickly and, because the care received is predominantly general practitioner (GP) rather than secondary care based, the seriousness of the problem may remain unappreciated until the patient presents with one of the long-term tissue complications.

Second, the voice of people affected by diabetes often goes unheard in the clamour of other disease areas—for example, cancer, Alzheimer's and multiple sclerosis—where patients, carers and families are much more vocal. There are currently approximately 2 million people living with diabetes in the UK and perhaps more than a million others living with the condition who are unaware that they have diabetes [1]. As yet we have no cure for the disease and individuals are committed to a life which is regimented by diet, tablets and injections. With perhaps as much as 4% of the population therefore affected, why is their collective lobby much quieter or, perhaps, less active than that for human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS), for example, which affects a much smaller number of people but has a disproportionately louder voice? The quiescent phase of the condition can be comparatively long before the damaging complications of diabetes supervene, which means that diabetes is often regarded as less serious than, say, cancer where patients may be faced with the immediate prospect of a life-threatening condition and a rapid deterioration in their quality of life.

These features of diabetes are very different from some of the other topic-specific clinical research networks—in particular cancer—where much, if not all, of the care received is in secondary care. As a result, the numbers affected by any particular cancer can be more easily quantified and streamlined into the relevant clinical trial. Even with curable disease, cancer raises the threat of life-changing pathology, and specialists in secondary care treating cancer and those receiving therapy have a close relationship, albeit for a short period of time. It is consequently comparatively easy to identify and therefore recruit patients, if the optimal treatment is still not known, with appropriate informed consent, into a clinical cancer trial. Perhaps the leading exemplar of this is the MRC leukaemia trials. Since the mid-1960s, MRC leukaemia trials have become internationally acclaimed for their contribution to seminal advances in treatments for the disease. In the UK alone, recruitment has continued to increase with over 90% of children with leukaemia now treated within MRC trials. Such recruitment, for both adult and childhood leukaemia, has allowed these trials to be amongst the largest in the world [2]. Importantly, this success has led to fruitful collaborations with other groups and a continuing high level of patient awareness of the trials.

To build on this experience, it is important for the Diabetes Research Network to develop collaboration of individuals which will allow clinical researchers to conduct studies more rapidly and with a greater capacity to recruit. Studies may be sponsored by the pharmaceutical industry, developed by academic groups or derive from health-care-related issues, all addressing important questions about the management of diabetes. Both Scotland and Wales have achieved high-quality databases in diabetes using strategies based initially on clinical information rather than on research needs [3,4].

In Scotland, the DARTS database was possible because data from different sources including hospitals, GP surgeries and pharmacies could be linked by one unique patient identifying number. In Wales, the same result was achieved as an epiphenomenon of the retinopathy screening programme. In England, however, there is no unique patient identifier. GP practices use a variety of different databases and the promise of electronic patient records has yet to be fulfilled. Recent changes to the primary care environment precipitated by the Quality and Outcome Framework (QOF) payments through the National Service Framework standards mean that GPs are now more motivated to record all the details for patients with diabetes. Realistically, however, despite the ongoing Connecting for Health initiative, the seamless integration of all of these data into a coherent and usable format may still be some way off.

If public advocacy for clinical research in the diabetes network is to succeed, then the identification of the population with diabetes must be the first step. The network will be working closely with Diabetes UK as the major patient-based organization in the country. It is our goal to set up schemes aimed not just at identifying the individuals but also at encouraging and supporting their active involvement in the network. At this stage, the diabetes network is establishing a directory of those who have expressed an interest in participating in the network's activities. As the network expands and trials are adopted, this directory can be interrogated to identify possible mechanisms through which patients can support the network at a level with which they feel comfortable:

- *By wishing to be kept informed of the network's activities*. The diabetes network will guarantee to keep these individuals informed of network activity on a regular basis. This is likely to be through a newsletter mailed to interested parties and regular updates of the diabetes network website.
- *By participating in the information-gathering programme*. This will involve patients being asked to answer questionnaires or surveys occasionally circulated by the diabetes network.
- *By participating in clinical trials or research studies*. This level of involvement includes participation in trials and other clinical research studies. Patients at this level may also be signed up to Level 1 and 2, but Level 3 will mean willingness to participate in appropriate randomized trials and other studies. As the network expands there will be opportunities for detailed epidemiology.
- *By becoming a Patient Advocate*. The Patient Advocate is a person with diabetes, or a family member or carer of someone with diabetes who participates in one or more of the research network's committees or advisory groups. This may be a central committee, organized by the network's coordinating centre or in one connected to a local research network centre in the patient's region. Patient Advocates will play a vital role within the network by helping to set the research priorities, to develop the research studies and collaborations as well as the patient information literature and help to disseminate the results of research to a wider audience.

As diabetes is a life-long disorder, and as people's circumstances and opinions may change, appropriate exit mechanisms must be built in, such that patients may opt out at any stage without difficulty or explanation.

The roles fulfilled by these groups will naturally impact on the national ethical debate about patient rights, confidentiality and data protection, as well as the equally relevant and important issue of a person's responsibility to society. It is also of relevance that the ethical issues are very different when patients have volunteered to be contacted or for their data to be used for research than if they have not volunteered. The network is working closely with a variety of organizations to ensure that patient confidentiality issues are properly addressed and that data protection legislation is adhered to. However, turning the tide in the public's perception of research involvement must be promoted if this is to succeed. The current debate over animal usage in medical research is a deeply polarized one. Although animal experimentation continues, the numbers of animals used has halved in the last 30 years [5]. If this encouraging trend is to continue, society has to recognize the importance of human research participation.

Recent media coverage has highlighted both the good and the bad outcomes of clinical trial participation. At the same time, as new statin research yielded rapid and encouraging results about the possible reversal of atherosclerosis, another trial stopped as healthy volunteers suffered serious adverse effects of a new anti-inflammatory monoclonal antibody therapy. As the research environment changes, the network must remain sensitive to the barriers to participation and work with the different sectors of society to identify possible mechanisms to break these down.

The government's strong support for the creation of a UK-wide system of clinical research networks will do much to stem the flow of clinical research to other countries. While this is to be applauded, the difficult job of turning the concept into a reality remains, from a public advocacy angle, largely unaddressed. For the research community, this presents a particular challenge. We need to be willing to take a proactive view about research studies, and to encourage our patients towards active involvement in the development and prioritization of research, and towards trial participation which will improve the quality of trials from a patient perspective. The future of trials to develop new preventative and therapeutic interventions in the UK may depend on it, as may the ability to conduct the epidemiological and public health studies for which the UK has a strong tradition. This has been made possible because of the unique health-care system which has led to major breakthroughs in public health.

If you are interested in joining this debate or have ideas about patient involvement and trial participation, please contact Professor David Matthews (david.matthews@ocdem.ox.ac.uk)

Competing interests

None declared.

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References

1 Diabetes UK. *Diabetes: The Figures*. Fact sheet no. 2, 2000. Available from: http://www.diabetes.org.uk/infocentre/fact/fact2.htm (accessed 4 September 2006).
2 The Select Committee on Science and Technology, Medical Research Council. *MRC Leukaemia Trials: Achievements to Date*. 2000. Available from: http://www.publications.parliament.uk/pa/cm199900/cmselect/cmsctech/332/332ap14.htm (accessed 4 September 2006).
3 Morris AD, Boyle DI, MacAlpine R, Emslie-Smith A, Jung RT, Newton RW *et al*. The diabetes audit and research in Tayside Scotland (DARTS) study: electronic record linkage to create a diabetes register. DARTS/MEMO Collaboration. *Br Med J* 1997; **315**: 524–528.
4 Owens DR, Gibbons RL, Kohner E, Grimshaw GM, Greenwood R, Harding S. Diabetic retinopathy screening. *Diabet Med* 2000; **17**: 493–494.
5 Research Defence Society. *Numbers of Animals—How Much Animal Research is Done?* 2006. Available fromL http://www.rds-online.org.uk/pages/page.asp?i_ToolbarID=2&i_PageID=31 (accessed 4 September 2006).

